The effect of sagittal plane ankle-foot orthosis alignment on gait in children with cerebral palsy

Submitted by

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Abbreviations

AFO	Ankle foot orthosis
AFO-FC	AFO footwear combination
CP	Cerebral Palsy
GRF	Ground reaction force
HSD	Heel-sole differential
PiG	Plug-In-Gait
STA	Soft tissue artefact
SVA	Shank-to-vertical angle
$\theta_{AFO\ def}$	AFO deformation
$\theta_{ankle\ anat}$	Anatomical ankle movement
$\theta_{foot\ mov}$	Movement of the shoe on the AFO/foot
θ_{PiG}	Ankle kinematics according to the Plug-In-Gait model
$\theta_{tib\ mov}$	Tibial movement
3DGA	Three dimensional gait analysis

Summary

This thesis investigates the effect of ankle foot orthosis footwear combination (AFO-FC) sagittal plane alignment on gait in children with cerebral palsy (CP). Ankle foot orthoses are a common intervention used to manage deviations of ankle movement. Two types of AFOs were examined: solid or non-articulating AFOs and articulating AFOs with free dorsiflexion range of motion but blocked plantarflexion range of motion. The specific aspect of AFO-FC design investigated in this thesis is the sagittal plane alignment which is defined as the shank-to-vertical angle (SVA). This variable has been described theoretically as one stage of the AFO-FC 'tuning' process but little evidence exists which describes the effect of SVA, or any benefit arising from its optimisation.

A systematic review evaluating the level and quality of detail reported in AFO intervention studies in CP was conducted. The overall quality of the studies was found to be low, with few papers describing features of AFO-FC alignment. From this review, best practice reporting guidelines were generated to enable more consistent reporting in future investigations and to permit a transparent assessment of study quality.

An exploratory analysis of pilot data found evidence of two mechanisms by which changing AFO-FC alignment may affect gait, based on type of gait pattern. These results suggest that whether or not foot flat is achieved during stance phase may affect the specific biomechanical changes observed. These results and the methodological limitations of this pilot study informed the design of the major investigations of this thesis.

A study investigating the effect of systematic AFO-FC alignment changes in two types of AFO designs was conducted using three dimensional gait analysis (3DGA). This study revealed that knee moments were sensitive to AFO-FC alignment change in all children, but the degree of sensitivity varied. Solid AFOs were more sensitive to change than hinged AFOs, as were limbs conforming to the common pattern of knee kinematics. Changing the AFO-FC alignment produced systematic patterns of change in ankle, tibia and knee variables, which were more consistent in solid than hinged AFOs. Within the solid AFO group there was some evidence suggesting these changes were affected by type of knee kinematic pattern.

An optimum AFO-FC alignment could be identified according to the wedge size that best normalised knee kinematics, knee kinetics, tibial kinematics and ankle kinetics over mid-stance, for the majority of limbs. However, only two of the 27 limbs had perfect agreement across these variables on optimal wedge size while half had good agreement. An optimum wedge size was less apparent in terms of temporospatial parameters and subjective preference.

When the optimal SVA could be estimated it was found to vary according to gait pattern within the solid AFO group, but in the hinged AFO group was variable. Across both groups changes in knee kinematics tended to agree with changes in knee kinetics regardless of gait pattern. This suggests that changing the AFO-FC alignment does not permit normalisation across a range of variables, and that there must be a prioritisation of the most important variable to address. The best agreement between parameters was in the children wearing solid AFOs and who demonstrated good knee extension.

A new model based on *PlugInGait* (PiG) and static calibration was designed to overcome inaccuracies in the PiG model due to soft tissue artefact (STA) of the knee marker as well as measure the individual kinematics of the AFO, the tibia within the AFO, and the footwear. While discrepancies in the measurement of ankle kinematics was strongly related to knee kinematics and thus can be attributed to STA of the knee marker, the net effect on total ankle ROM was small (1.5°). At specific instances during the gait cycle there were larger discrepancies of up to 7°. The main cause of increased ankle ROM was flexion of the AFO (up to 13°) which increased with bodyweight but tibial movement was limited to approximately 4° and shoe movement to 3°.

This thesis presents the first investigation into the effect of systematic AFO-FC alignment change on gait in children with CP. It provides evidence that AFO-FC alignment can be manipulated to produce specific biomechanical effects but that some of these may be improvements to gait and others may be detrimental. The new approach for measuring AFO kinematics in 3DGA can be used in research and clinical settings to obtain a more accurate measurement of ankle kinematics as well as allow assessment of AFO stiffness, tibial movement and footwear movement. It is hoped that these outcomes can be used to improve gait and ultimately functional outcomes and quality of life in this, and in other populations.

Statement of authorship

Except where reference is made in the text of the thesis, this thesis contains no material published elsewhere or extracted in whole or in part from a thesis submitted for the award of any other degree or diploma. No other person's work had been used without due acknowledgement in the main text of the thesis. The thesis has not been submitted for the award of any degree or diploma in any other tertiary institution. All research procedures reported in the thesis were approved by the relevant ethics committees.

The systematic review presented in Chapter 3 of this thesis has been published in a peer-reviewed journal, Prosthetics and Orthotics International, and is attached as Appendix A.

The involvement of participants and the support and contribution of staff from NovitaTech and Novita Children's Services (Adelaide, SA), in addition to the funding support received from the Channel 7 Children's Research Foundation is acknowledged with regard to the pilot work re-analysed in Chapter 4 of this thesis. The original project was completed in 2007 and presented in report form to the relevant organisations in 2008. The work resulting from this re-analysis was presented as a poster at two international conferences in 2010 as part of the original research team. Ethics approval was obtained prior to this re-analysis in addition to written approval from the director of NovitaTech.

Chapter 8 of this thesis describes the development and testing of a new model to measure behaviour of the solid AFO in a 3DGA setting. This model was developed in collaboration with Dr Morgan Sangeux and Professor Richard Baker.

Signed: ____ Date: ________________

Publications and presentations

** Denotes work published during the time of the doctoral candidature but not arising from work related to this thesis*
***Denotes work arising from the re-analysis of pilot data presented in Chapter 4 of this thesis*

Publications

Ridgewell E, Dobson F, Bach TM, Baker R. (2010). A systematic review to determine best practice reporting guidelines for AFO interventions in studies involving children with CP. Prosthetics & Orthotics International, 34 (2) 129-145

Conference presentations

Ridgewell E, Dobson F, Bach TM, Baker R. (2010). A systematic review to determine best practice reporting guidelines for AFO interventions in studies involving children with CP. ISPO World Congress, Germany

* Graham E, Nguyen TC & Walker L. (2008). The relationship between AFO shank vertical angle and gait in children with cerebral palsy. Scientific Meeting of ISPO ANMS, Adelaide pg 26-27

* Gibson S, Graham E & Walker L. (2008). The effect of AFO shank vertical angle on functional outcomes in children with cerebral palsy, Annual Scientific Meeting of ISPO ANMS, Adelaide, pg 28-29

Posters

**Ridgewell E, Gibson S, Nguyen T, Walker L. (2010). The Biomechanical and Functional Effects of Ankle Foot Orthosis Shank-To-Vertical Angle in Children with Cerebral Palsy: A Pilot Study. ISPO World Congress, Germany and AusACPDM, New Zealand

Course proceedings

Ridgewell, E., James, J., and Dillon, M. (eds) (2010). Multi-disciplinary perspectives on the management of children and young adults with cerebral palsy. ISPO Advanced Instructional Course, 11-13th November 2010, Melbourne.

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Most importantly I would like to acknowledge and thank the children and their families who participated in these studies. Without their willingness to give of their time so generously this work would not be possible.

Finally, I dedicate this thesis to my wonderful husband Adam, whose love, support and encouragement never wavers. Thankyou.

In loving memory of my grandfather, Dr George Edward Doery (8.8.1922 – 18.9.2011) who was always a great believer in education. And who, for some strange reason, always thought I would make a good surgeon.

1 Introduction

1.1 Problem statement

Cerebral palsy (CP) is the most common physical disability in childhood (Reddihough & Collins, 2003) with an incidence of 2-2.5 per 1000 live births (Stanley, Blaire, & Alberman, 2000). While by definition CP is a static neurological lesion and a disorder of motor function, it is also recognized as a progressive musculoskeletal condition (Bache, Selber, & Graham, 2003; Graham, 2002; Rosenbaum *et al.*, 2007). Ankle-foot orthoses (AFOs; also known as splints or braces) are an external supportive device used to modify the structural and functional characteristics of neuro-muscular and skeletal systems (International Organisation for Standardisation, 1989). They are a common non-invasive management option for the musculoskeletal problems of the foot and ankle seen in children and adolescents with CP (Rodda & Graham, 2001). For example, the equinus foot position often seen in children with CP may be managed with the use of an AFO that prevents ankle plantarflexion. Thus the AFO provides direct control of the rotational movement of two body parts. Two common AFO designs used for children with CP are the solid AFO and hinged AFO with a plantarflexion stop. In addition to providing direct rotational control the AFO can also be used to alter the point of application and line of action of the ground-reaction-force (GRF). This can be achieved through the AFO design, for example, the movements the AFO permits, assists or resists; but also through the alignment of the AFO and the properties of the footwear. Thus the biomechanical effect of the orthosis reflects the AFO and footwear which has become known as the AFO footwear combination (AFO-FC).

There has recently been considerable interest in *tuning* the AFO-FC for children and adults with neurological disorders. *Tuning* is a complex procedure that involves modifying various aspects of the AFO-FC in order to optimise gait kinematics and kinetics (Owen, 2004c, 2005a; Owen, Bowers, & Meadows, 2004). Most often AFO-FC tuning focuses on reducing the excessive peak external knee extension moment and knee hyperextension often demonstrated by children with CP. The term AFO-FC has been limited to use with solid AFOs and has been used primarily with reference to the tuning procedure. Tuning has previously involved two-dimensional video vector gait laboratories where the GRF is projected onto a video of the patient walking and the position and orientation of this vector relative to the knee joint is assessed (eg. Owen, 2010; Stallard & Woollam, 2003). While there is some ambiguity within the literature regarding the precise goal of the tuning process, the majority of authors have focussed on the normalisation of knee kinetics during the mid to late periods of stance phase.

One of the principal biomechanical properties of the AFO-FC is its sagittal plane alignment, which is the angular relationship between the line of the shank and vertical, known as the Shank-to-Vertical-Angle (SVA). The SVA can be altered by adding material to the heel of the AFO within the footwear or by adding material to the sole of the footwear (the wedge angle), or by changing the AFO ankle angle. Tuning is considered to begin with the judicious choice of AFO ankle angle followed by an adjustment of the SVA to optimise the gait pattern in mid-stance and then modifying the profile of the heel and sole of the footwear to further optimise early and late stance.

The tuning process is commonplace in only a small number of facilities primarily in the United Kingdom, however the evidence supporting this process is largely anecdotal. The time and equipment required to perform tuning makes it a relatively expensive process. Those familiar with the tuning technique present anecdotal evidence to support its use and argue that it is essential for achieving optimal outcomes for children with CP (Anderson & Meadows, 1978; Meadows, Anderson, Duncan, & Sturrock, 1980; Owen, 2004c). However, very little is known about how AFO-FC tuning, or specifically, how altering AFO-FC alignment, can affect gait.

Within this limited body of work the methodological detail regarding the tuning process is often poorly described. The majority of studies do not describe the process in sufficient detail to enable the procedure to be replicated. While tuning algorithms (Owen, 2005a) have offered an explicit description of the process, most studies do not clearly describe the process for determining the final SVA, including the parameters at the heart of this optimisation process. This leads to difficulties in accurately interpreting the findings from an already limited body of literature.

Children with CP are known to present with a wide variety of gait patterns (Rodda & Graham, 2001; Sutherland & Davids, 1993; Winters, Gage, & Hicks, 1987). Within this body of literature there is little understanding of how tuning affects children with different gait patterns. There are suggestions from the literature that not all children are responsive to the AFO-FC tuning process (Butler, Farmer, Stewart, Jones, & Forward, 2007; Owen, 2004c). However the ambiguity regarding the tuning process and decision rules used to classify children according to success in the tuning process limit the generalisability of these findings. If indeed only children who have specific gait patterns can respond to the tuning process, it is essential that this sub-group is defined in order to identify who could benefit from this procedure.

While the majority of tuning literature has focussed on solid AFOs, applying the same principles of AFO-FC tuning to hinged AFOs may produce some similar effects. This type of AFO prevents plantarflexion beyond plantigrade and therefore modifying the SVA is likely to modify tibial kinematics and have subsequent effects on lower limb biomechanics. This AFO is a common prescription in children with CP but it is not known how altering SVA in this AFO design affects gait.

AFO-FC tuning is a complex three stage process whereby AFO ankle angle is chosen, SVA is optimised according to mid-stance kinematics and kinetics, and heel and sole profiles are modified to address early and terminal stance. The majority of studies in this area have examined the entire tuning process, have included multiple components of the tuning process, or have not reported which components were used. Therefore, little is known about the effect of the individual components of the tuning process. Optimising the SVA, or AFO-FC alignment is the focus of this thesis.

1.2 Research questions

The first five research questions were developed from a review of literature related to AFO-FC tuning and what is known about the effect of AFO-FC alignment change. These research questions were:

1. How well is AFO-FC alignment reported within the wider body of literature?
2. How does changing AFO-FC alignment affect gait?
3. Are all children responsive to AFO-FC alignment change?
4. What is the effect of AFO-FC alignment on the gait of children who wear solid and hinged AFOs?
5. Is there an optimal AFO-FC alignment?

A sixth research question was added to this thesis following observations of excessive ankle movement in the solid AFOs examined as part of the second study described in Chapter 4. This question was:

6. When ankle movement in a solid AFO is measured using three dimensional gait analysis (3DGA) does this accurately reflect anatomical ankle movement? Is there a way to measure movement of the anatomical ankle, the AFO, tibia and footwear?

1.3 Objectives

In response to the research questions the objectives of this thesis were:

1. To critically review the level and quality of detail reported in AFO intervention studies on children with CP, including AFO-FC alignment.
2. To understand the mechanisms by which changing AFO-FC alignment can affect gait.
3. To determine whether all children, or just a select group, are responsive to AFO-FC alignment changes.
4. To evaluate the effect of AFO-FC alignment on the gait of children and adolescents in solid and hinged AFOFCs.
5. To determine whether there is an optimal AFO-FC alignment for each individual limb
6. To develop a model that measured both anatomical ankle kinematics as well as AFO kinematics to first compare anatomical ankle kinematics to the output according to the *PlugInGait* model, and to allow an assessment of whether the AFO is flexing, or whether the tibia is moving within the AFO.

1.4 Synopsis

The overall structure and conceptual basis for this thesis is presented in the concept map shown in Figure 1.1. It shows that the review of literature in AFO-FC tuning alignment form the basis for the systematic review described in Chapter 3 and guides the formation of hypotheses and analytical approach of the pilot study described in Chapter 4. Limitations observed in the pilot study informed the design of the investigation into systematic alignment change described in Chapters 5 to 7, and resulted in the design of the final study of the thesis described in Chapter 8.

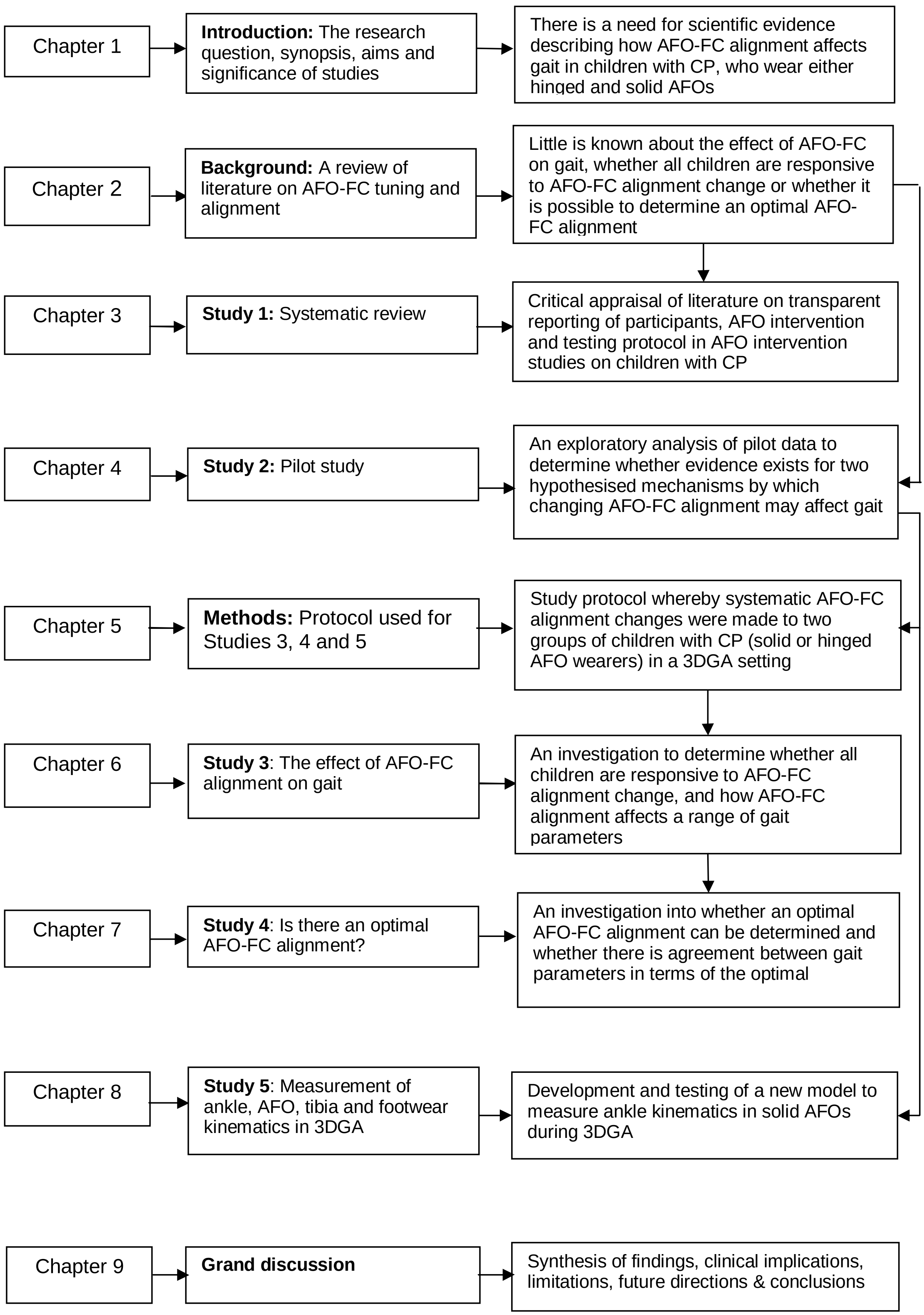


Figure 1.1 Concept map of thesis structure.

1.5 Overview of the thesis

An overview for each study included in this thesis is outlined below:

1.5.1 Study 1: A systematic review to determine best practice reporting guidelines for AFO interventions in studies involving children with CP

Chapter 3 presents a systematic review that investigated the quality and level of detail reported within the body of literature examining AFO interventions for children with CP. It had a specific focus on aspects of previous studies that relate to the research questions outlined above. These include the description of patient characteristics, orthotic interventions and test protocols. A rigorous systematic review methodology was employed to develop guidelines for future research in this area and these have formed the basis for the design of the clinical research studies comprising the rest of the thesis. This review has been published in *Prosthetics and Orthotics International*.

1.5.2 Study 2: Pilot study

Chapter 4 describes a re-analysis of pilot data collected by the candidate before enrolment for her PhD. The wedge angle of the AFO-FC of solid AFOs worn by six children with CP was modified systematically by the use of internal heel wedges. Three dimensional gait analysis (3DGA) was performed to measure the effect of AFO-FC alignment on gait. These results were analysed in order to validate two proposed mechanisms by which increasing AFO-FC alignment may affect gait. Mechanism 1 had been loosely described within the current literature which was thought to relate to achieving foot flat during mid-stance to produce the desired biomechanical changes due to direct incline of the tibia. Mechanism 2 was hypothesised to occur in limbs where foot flat is not achieved. These mechanisms were explored, defined and applied to the existing data. Limitations of the design of this study informed the hypotheses and design of the subsequent prospective studies 3 and 4. Observations of the extent of dorsiflexion occurring in the solid AFOs used in this study lead to the conduct of Study 5.

1.5.3 Study 3: The effect of AFO-FC alignment on gait

Chapters 5 and 6 describe a prospective experimental study to determine whether all children who wear solid and hinged AFOs are responsive to AFO-FC alignment change. The primary focus was on systematic changes in knee kinetics. A range of gait variables including joint kinematics and kinetics and segment kinematics at the level of the ankle, knee and hip and temporospatial parameters were also analysed. Gait patterns in the baseline AFO condition (without wedges) were investigated to assess the homogeneity of gait patterns between limbs within the solid and hinged groups separately and how responsiveness to alignment change was related to this.

1.5.4 Study 4: Is there an optimal AFO-FC alignment?

The broad conclusion of Study 3 was that systematic changes do occur which led to the question of whether it was possible to define an optimal wedge size for each child. Chapter 7 thus describes the results of a further analysis of the data collected as part of Study 3. This study investigates whether there is an optimal wedge size across a sub-set of gait parameters, and whether the optimal wedge size required to normalise knee kinetics is the same wedge size required to normalise knee kinematics, ankle kinetics and tibial projection angles. This was also compared to temporospatial variables and subjective preference.

1.5.5 Study 5: A new model to measure ankle, AFO, tibia and footwear kinematics in solid AFOs in three dimensional gait analysis

Chapter 8 reports the findings of a study describing the development and testing of a new model to measure ankle, AFO, tibia and footwear kinematics in three dimensional gait analysis (3DGA). This was in response to Research Question 6 which arose after observing significant ankle movement measured in solid AFOs using 3DGA in Study 2. There are several factors which may contribute to an output of significant ankle movement in a supposedly rigid device, but there is currently no method of assessing the contribution of error or other movement. Therefore the aim of developing this new model was to first compare anatomical ankle kinematics to *PlugInGait* (PiG) output to assess the error relating to soft tissue artefact of the knee marker, and to allow a measurement of AFO flexion, tibia movement within the AFO, and movement of the footwear on the AFO/foot complex as a measure of AFO performance. A new model was designed to isolate movement of the shank from the AFO, and movement of the shoe from an AFO/foot segment. This model allows quantification of movement of the limb, AFO and footwear which was previously unavailable and has implications for researchers and clinicians alike.

1.6 Significance of the research

Evidence based medicine has been defined as the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients (Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996). The practice of evidence based medicine involves integrating individual clinical expertise, which refers to the proficiency and judgment that individual clinicians acquire through clinical experience and practice; with the best available external clinical evidence, which refers to clinically relevant research into aspects such as the efficacy and safety of therapeutic, rehabilitative, and preventive regimens (Sackett, *et al.*, 1996).

In the field of lower limb orthotics much of our clinical practice with regard to the management of children (Bowers & Ross, 2009) and adults with neurological disorders (Bowers, 2007; International Society for Prosthetics and Orthotics, 2004) is not supported by a substantial body of high quality scientific evidence. Much literature has been published and although reviewers are now able to surmise that AFOs has a positive effect on passive and active ankle range of motion, gait kinetics and kinematics as well as functional activities related to mobility of children with CP, the quality of these studies remains low (Figueiredo, Ferreira, Maia Moreira, Kirkwood, & Fetters, 2008). In particular, the effect of AFOs on more proximal lower limb joints is less clear (Morris, Bowers, Ross, Stevens, & Phillips, 2011). In addition, AFO-FC tuning has been proposed as an essential component of orthotic management for children with CP as early as 1980, according to PhD work by Barry Meadows. While this work was never published and there remains very little substantive evidence as to its benefits, AFO-FC tuning is a procedure in use in several centres internationally, in some cases for the past eleven years (Owen, 2010). Thus when placing AFO-FC tuning in the context of evidence based medicine, individual clinical expertise may support this process but there is no opportunity to integrate this with clinical research. If indeed benefits are derived from this process they must be quantified so that more children have access to and may benefit from the process.

This thesis addresses a significant gap in the literature pertaining to AFO use in children with CP. It is not known how changing AFO-FC alignment, either by changing footwear, AFO ankle angle or by adding an internal or external heel wedge affects gait, even though clinicians must make e the decision to alter AFO ankle angle or add a heel wedge based on observable (kinematic) features of gait. It is not known how changing AFO-FC alignment affects gait in the context of the tuning process, where subsequent changes may then be made by altering the heel and sole profile of the footwear.

This research provides the first thorough evaluation of the effect of AFO-FC alignment in children with CP across a range of gait variables. It examines the two types of AFOs which are worn most commonly by children with CP within the state of Victoria, Australia, and potentially also nationally and internationally. By performing systematic changes to AFO-FC alignment valuable insight is gained into how altering this variable affects a range of gait related parameters. This research has application to both clinical and research settings.

The ability to assess the performance of the solid AFO in a 3DGA context provides invaluable insight into the efficacy of the device; that is the ability of the device to achieve the aims for which it was designed. In addition it provides users of 3DGA with improved ability to interpret the output of PiG, in terms of ankle kinematics. The ability to measure performance of the AFO and to test accuracy of the PiG output is essential in order to make informed clinical decisions regarding the efficacy of the device. It is hoped that this thesis, by improving our understanding of how AFO-FC alignment affects gait in this population and by providing a method for measuring solid AFO performance in 3DGA, moves the field of lower limb orthotics one step closer toward better implementing evidenced based practice.

2 Background

This chapter introduces the clinical presentation and classification of cerebral palsy (CP) and provides an overview of the biomechanics of the AFO and footwear combination (AFO-FC) before summarising the evidence base for AFO use in this population. The focus of this thesis was the effect of AFO-FC sagittal plane alignment, and as such this concept is defined and the theories underpinning responsiveness to AFO-FC alignment change and optimal alignment are introduced. A summary of the evidence base demonstrating the effect of AFO-FC alignment change is provided. This chapter concludes with the formulation of the broad research questions which were addressed in this thesis.

2.1 Cerebral palsy

2.1.1 Definition and incidence

Cerebral palsy refers to a group of disorders of the development of movement and posture, causing activity limitation, that are attributed to non-progressive disturbances that occurred in the developing fetal or infant brain (Rosenbaum*, et al.*, 2007). It is the most common physical disability in childhood (Reddihough & Collins, 2003) with an incidence of 2-2.5 per 1000 live births that has remained relatively stable over the past decades (Stanley*, et al.*, 2000). The term CP does not refer to a single entity, rather a heterogenous collection of clinical syndromes (Graham & Selber, 2003). For this reason the preferred or more appropriate term is the collective 'cerebral palsies' (Gorter *et al.*, 2004; Graham & Selber, 2003).

2.1.2 Clinical presentation and classification

The primary injury in CP is the static brain injury which results in an upper motor neuron lesion. This is considered to have a number of positive and negative features (Bache*, et al.*, 2003). The positive features include spasticity, hyper-reflexia and co-contraction; and the negative features include weakness, loss of selective muscle control and deficits in balance and coordination (Bache*, et al.*, 2003; Mayer & Esquenazi, 2003). These are often accompanied by disturbances of sensation, cognition, communication, perception, and/or behaviour, and/or by a seizure disorder (Bax, Goldstein, Rosenbaum, & Leviton, 2005). While by definition CP is a static neurological lesion and a disorder of motor function, it is also recognised as a progressive neuromuscular impairment as there is a tendency for the growth of the muscle-tendon units to fall behind the growth of the neighbouring long bone, which results in fixed contractures, secondary bony torsion and joint instability (Bache*, et al.*, 2003; Graham, 2002).

CP is generally classified according to both the nature of the dominant motor disorder: spastic (85%), dyskinetic (7%) or ataxic (5%) (Surveillance of Cerebral Palsy in Europe, 2002); and the topographical distribution (SCPE, 2000). Spastic CP is the most common motor disorder and is defined as hypertonia characterised by abnormal voluntary control, resistance to passive stretch and exaggerated reflexes (Stanley*, et al.*, 2000). Spastic CP is further classified as hemi-, di- and quadriplegia (and also mono- and triplegia) to describe the distribution for unilateral involvement, involvement of the lower limbs more than the upper limbs, and total body (four limb) involvement, respectively (SCPE, 2000). Ambulant children with spastic CP will generally have a consistent gait pattern, both stride to stride and day to day (Gage, 1993).

Dyskinetic (dystonia and choreo-athetosis) and ataxic CP are less common tone and/or movement abnormalities. In dystonic CP there is predominantly hypokinesia and hypertonia, whereas choreo-athetosis is dominated by hyperkinesia and hypotonia (Surveillance of Cerebral Palsy in Europe, 2002). Ataxic CP is characterised by a loss of orderly muscular co-ordination, so that movements are performed with abnormal force, rhythm and accuracy (Surveillance of Cerebral Palsy in Europe, 2002). These types of movement disorders are generally described as whole body movements and usually have high step-to-step variability (Gage, 1993). While there is often a dominant movement disorder, many children present with a mixed type (Rosenbaum*, et al.*, 2007) .

Classifying CP according to the type of motor disorder and topographical distribution primarily involves clinical description at the level of the impairment (Gorter*, et al.*, 2004). Equally important however are descriptions and classification of level of function achieved across this heterogenous group. Gross motor function in children with CP can be reliably and objectively classified using the Gross Motor Function Classification System (GMFCS) (Palisano *et al.*, 1997) (Figure 2.1). The focus of the GMFCS is self initiated movement, with particular emphasis on function in sitting and walking. Five levels are used with Level I describing the most independent motor function and Level V the least (refer to Figure 2.1). Five different age bands can be assessed: age 1 to 2, 2 to 4, 4 to 6, 6 to 12 years, and more recently 12 to 18 years (Palisano, Rosenbaum, Bartlett, & Livingston, 2008). The GMFCS has been shown to be reliable, stable over time and can validly predict motor function in this group of children (Wood & Rosenbaum, 2000).

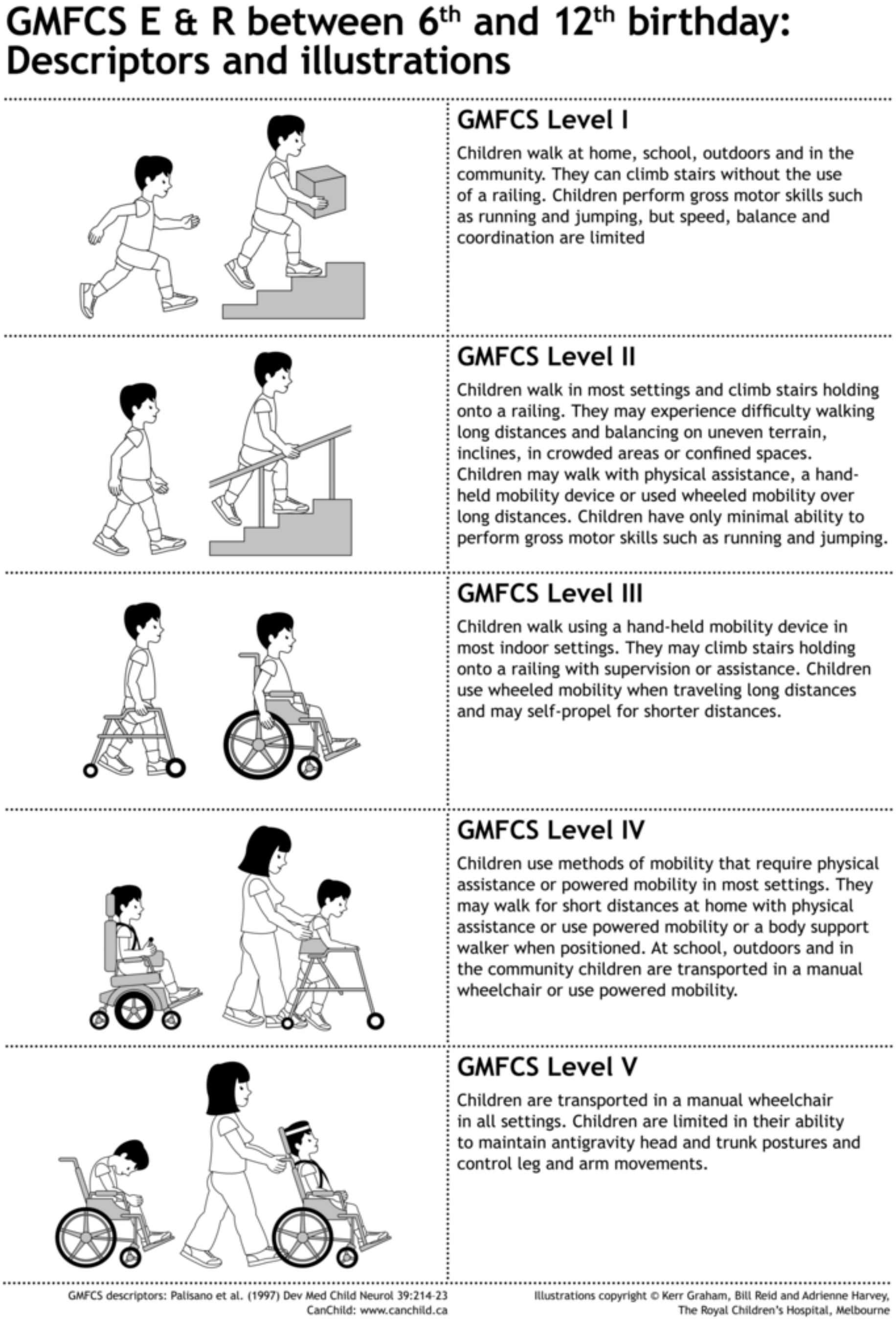


Figure 2.1 GMFCS for children in the 6-12 years age band © Kerr Graham, Bill Reid & Adrienne Harvey, reproduced with permission.

2.1.3 Gait patterns in cerebral palsy

Approximately two thirds of children with CP are able to walk independently, that is, without aids or assistance (Pharoah, Cooke, Johnson, King, & Mutch, 1998). This includes all children with hemiplegic CP, most with diplegic CP but rarely those with spastic quadriplegic CP (Graham & Selber, 2003). In the context of the GMFCS, all children at GMFCS Level I and II are able to walk independently over level ground, whereas children at Level III are dependent on aids, and those at Levels IV and V have limited or no functional walking.

While many children with CP are ambulant, the energy cost of walking has been shown to be greater than their typically developing peers, when assessed using either oxygen uptake or heart rate (Campbell & Ball, 1978; Duffy, Hill, Cosgrove, Carry, & Graham, 1996; Johnston, Moore, Quinn, & Smith, 2004; Rose, Gamble, Burgos, Medeiros, & Haskell, 1990; van den Hecke *et al.*, 2007). It has also been shown that the energy cost of walking increases with increasing severity of functional involvement (Johnston*, et al.*, 2004).

The combination of initial brain injury and consequent musculoskeletal deformities in children with CP results in a wide variety of gait deviations within this population. These gait abnormalities tend to be multiple, consisting of primary anomalies due to the damage to the central nervous system; secondary anomalies from abnormal bone/muscle growth; and tertiary abnormalities, or coping responses (Gage & Novacheck, 2001). These gait patterns often change over time as a result of musculoskeletal pathology, aging and as a result of intervention (Rodda & Graham, 2001).

Several classification systems have been developed to describe and classify the wide variety of gait deficits demonstrated in children with CP. These systems aim to enable homogenous sub-groups of similar patterns to be identified and thereby describe the complexities of spastic gait disorders in a manageable format (Rodda & Graham, 2001). The Winters, Gage and Hicks (WGH) (1987) classification system for spastic hemiplegic CP is one of the most cited gait classifications (Dobson, Morris, Baker, Wolfe, & Graham, 2006; McDowell, Kerr, Kelly, Salazar, & Cosgrove, 2008; Rodda & Graham, 2001). This system describes four gait patterns based on the sagittal plane kinematics of the ankle, knee, hip and pelvis (Figure 2.2).

In the most mild group, Group 1, the primary abnormality is at the ankle with increased plantarflexion during swing phase; in Group 2 this also occurs during stance phase; and is combined with restricted knee motion in Group 3; and then restricted motion at the hip in Group 4 (Winters*, et al.*, 1987). While this system is widely used, it has been suggested that that there may not be any patients who actually fit into WGH Group 3 (Dobson*, et al.*, 2006). Rodda and Graham (2001) provide a useful diagrammatic representation of the postural patterns seen in the WGH classification (Figure 2.3).

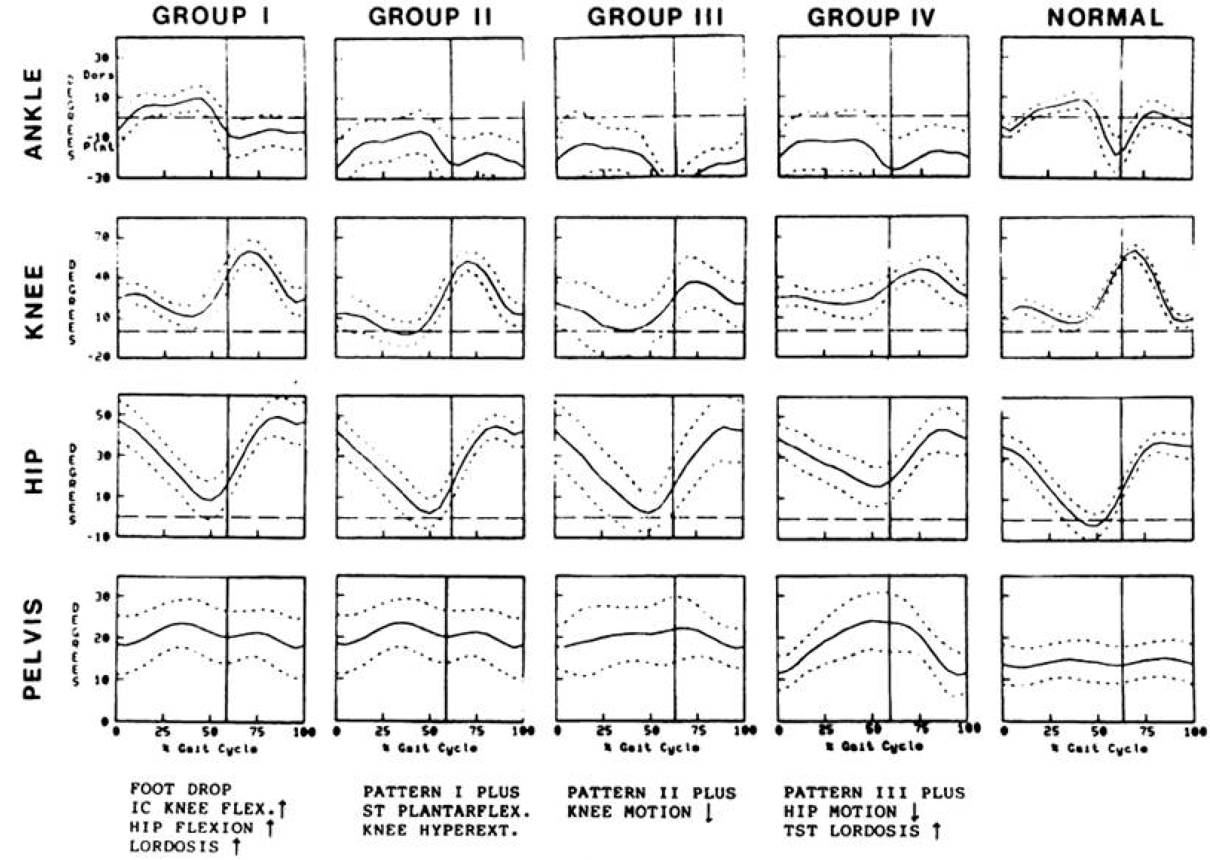


Figure 2.2 Kinematic patterns associated with the WGH classification (Winters*, et al.*, 1987).

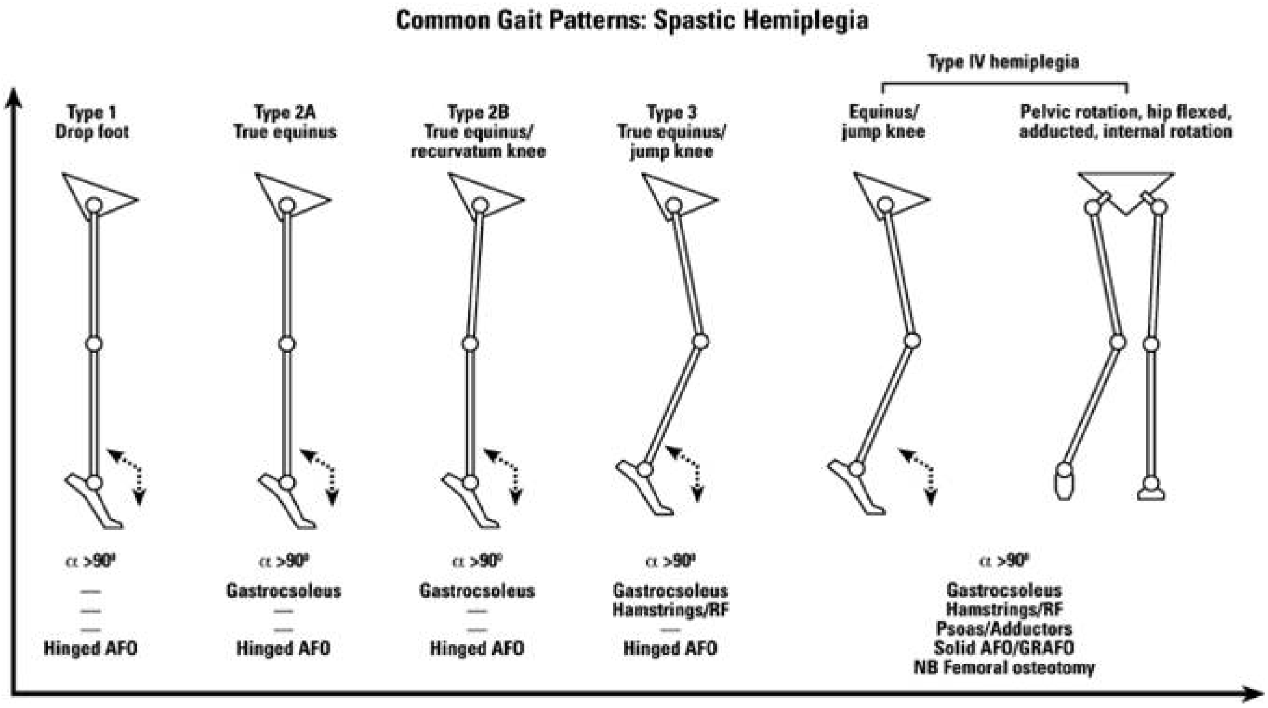


Figure 2.3 Postural patterns and management algorithms for spastic hemiplegic CP (Rodda & Graham, 2001).

The Sutherland and Davids classification (1993) is the most widely used classification system for diplegic CP, describing four common sagittal plane gait abnormalities of the knee; jump knee, crouch knee, stiff knee, and recurvatum knee. Jump knee is described as increased knee flexion in early stance phase with correction to normal or near normal extension in mid-late stance; crouch knee is characterised by increased knee flexion throughout stance phase; stiff knee gait presents with increased knee flexion throughout swing phase with variable motion in stance phase; and recurvatum knee presents with increased knee extension in mid to late stance phase (Sutherland & Davids, 1993).

The original patterns described by Sutherland and Davids (1993) have been more recently built upon in a classification by Rodda and colleagues (Rodda, Graham, Carons, Galae, & Wolfe, 2004). These authors provide both kinematic data and pictorial representations of four groups of kinematic patterns (Figure 2.4, Figure 2.5). Notable differences from the Sutherland and Davids (1993) classification are firstly that the classification by Rodda and colleagues (2004) does not consider 'stiff knee gait' as a single category, rather it is recognised as a feature of several different patterns. In addition, Rodda and colleagues (2004) utilise differences in ankle kinematics to distinguish between Groups II, III and IV, whereas the Sutherland and Davids (1993) classification focuses solely on knee kinematics.

A common feature of the gait patterns demonstrated by children with CP is an increased or decreased plantarflexion–knee extension couple (Gage, 1993). An excessive plantarflexion–knee extension couple is seen when excessive plantarflexion, which is often due to overactive triceps surae leads to an increased external knee extension moment. True equinus and jump knee gait in both the hemi- and diplegic population both demonstrate an excessive plantarflexion-knee extension couple. Other gait patterns demonstrate a reduced plantarflexion-knee extension couple. For example, the plantigrade and dorsiflexed ankle positions seen in apparent equinus and crouch gait result in the ground reaction force (GRF) vector moving from anterior to the knee to behind the knee (Gage, 1993). Thus while gait patterns are often described using kinematic patterns, there are also underlying differences in kinetic patterns.

Gait classifications are an essential tool in the research setting when such a heterogenous participant group is involved and when gait is considered a primary outcome. While the applicability of current gait classifications within the research setting has been questioned (Dobson, Morris, Baker, & Graham, 2007), homogenous groups or sub-groups must be considered to avoid masking the effect of an intervention because of the heterogeneity of the patient sample.

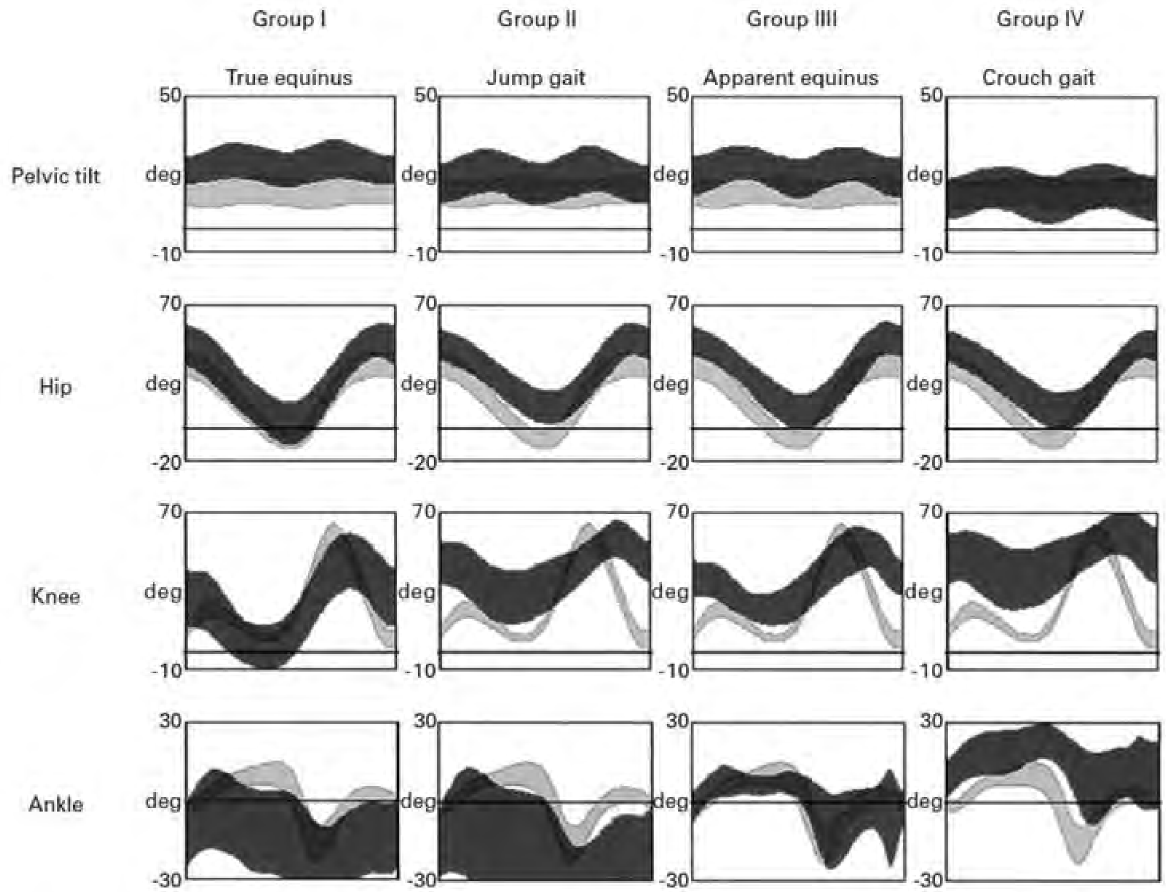


Figure 2.4 Sagittal plane kinematics for spastic diplegia (Rodda*, et al.*, 2004).

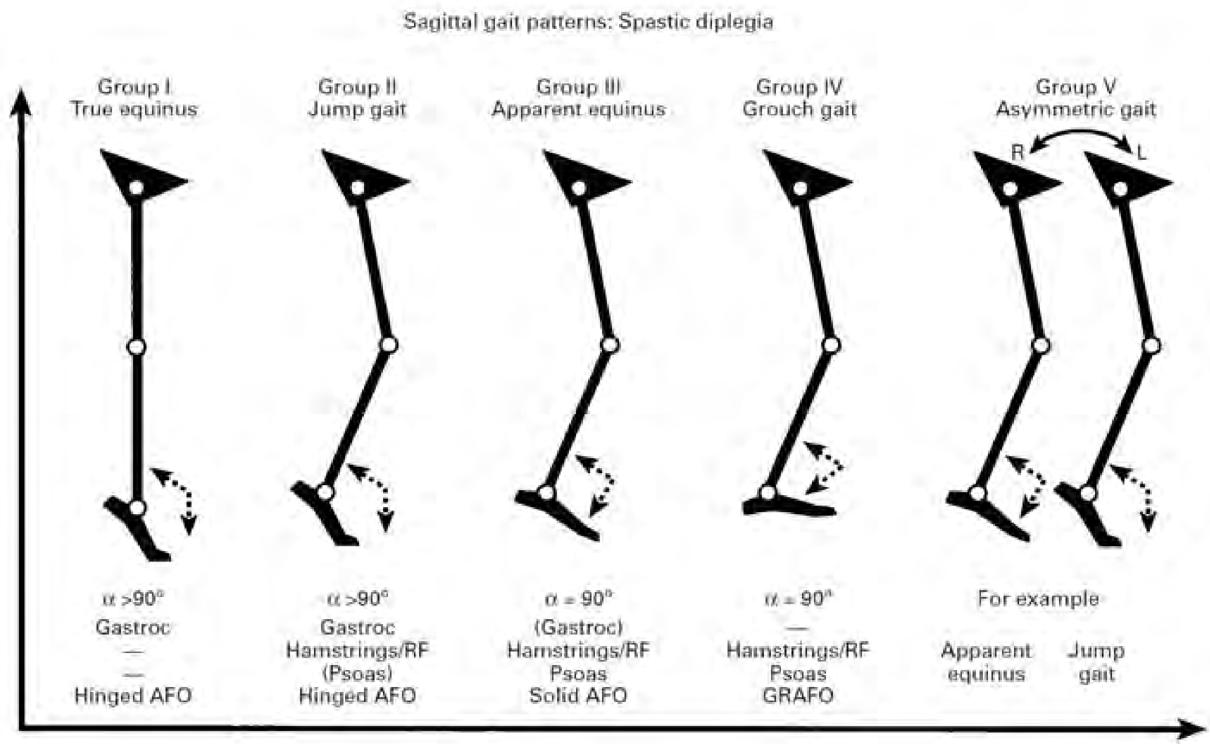


Figure 2.5 Diplegic postural patterns described by Rodda and colleagues (Rodda*, et al.*, 2004).

2.2 Ankle-foot orthoses

Ankle-foot orthoses (AFOs; also referred to as splints or braces) are a common conservative management option for children with CP. An orthosis is defined as 'an externally applied device used to modify the structural and functional characteristics of neuro-muscular and skeletal systems' (pg. 2, International Organisation for Standardisation, 1989). An AFO is a device 'that encompasses the ankle joint and the whole or part of the foot' (pg. 1, International Organisation for Standardisation, 1989).

AFOs are most commonly fabricated from high temperature thermoplastic or carbon fibre material, and are either prefabricated or custom-made over a positive model of the patient's limb. AFOs can be designed and constructed using a range of materials, trimlines and components in order to tailor the design toward meeting specific management goals. They are worn over socks and inside footwear. Appropriate footwear is considered an important determinant of the success of the AFO, which is reflected in the more common use of the term AFO footwear combination (AFO-FC) within this body of literature.

Two types of AFOs commonly used for children with CP are the solid AFO (synonymous with a rigid or static AFO), and the articulating AFO (Figure 2.6). Solid AFOs maintain the ankle in a fixed position and therefore do not incorporate an orthotic ankle joint. Trimlines are usually placed anterior to the malleoli in order to provide adequate stiffness to resist deformation of the plastic under loading. In most cases where a flexible foot deformity exists and adequate gastrocnemius length is available, the limb is positioned in as close to a neutral ankle, subtalar and forefoot alignment as possible. In the case of rigid deformities and contracture, these must be accommodated in the design of the AFO, specifically the choice of ankle and foot position. The solid AFO is one of the two AFO designs investigated in this thesis.

An articulating AFO incorporates an orthotic ankle joint located over the anatomical ankle joint, estimated by the apex of the medial and lateral malleoli. The design of an articulating AFO can be modified to allow free, assisted or resisted motion in either or both directions of dorsi- and plantarflexion, depending on the level of biomechanical control required. The most common design of articulating AFO used in children with CP allow unrestricted dorsiflexion but prevents plantarflexion with a mechanical stop, usually positioned at plantigrade. A pre-requisite for an articulating AFO permitting unrestricted dorsiflexion is generally gastrocnemius length which permits greater than 5° dorsiflexion, triplanar stability of the foot and absence of excessive spasticity in the gastrocnemius muscle (Bowers, 2007; Bowers & Ross, 2009; Owen, 2005b). This AFO design is the second design examined in this thesis, and is hereafter referred to as a hinged AFO.

AFOs are prescribed for patients with musculoskeletal or neuromuscular dysfunction to accomplish a wide range of goals. The International Society for Prosthetics and Orthotics has summarised these goal as preventing deformity, correcting deformity, promoting a base of support, facilitating training of skills, and improving the efficiency of movement, such as standing and walking (International Society for Prosthetics and Orthotics, 1995). The purpose for which the orthosis is prescribed informs the biomechanical principles to be applied in choosing the AFO design and guides the choice of appropriate outcomes in investigative studies. The following section provides terms and definitions relating to the characteristics of the AFO-FC before describing the biomechanics of the AFO and footwear in more detail.

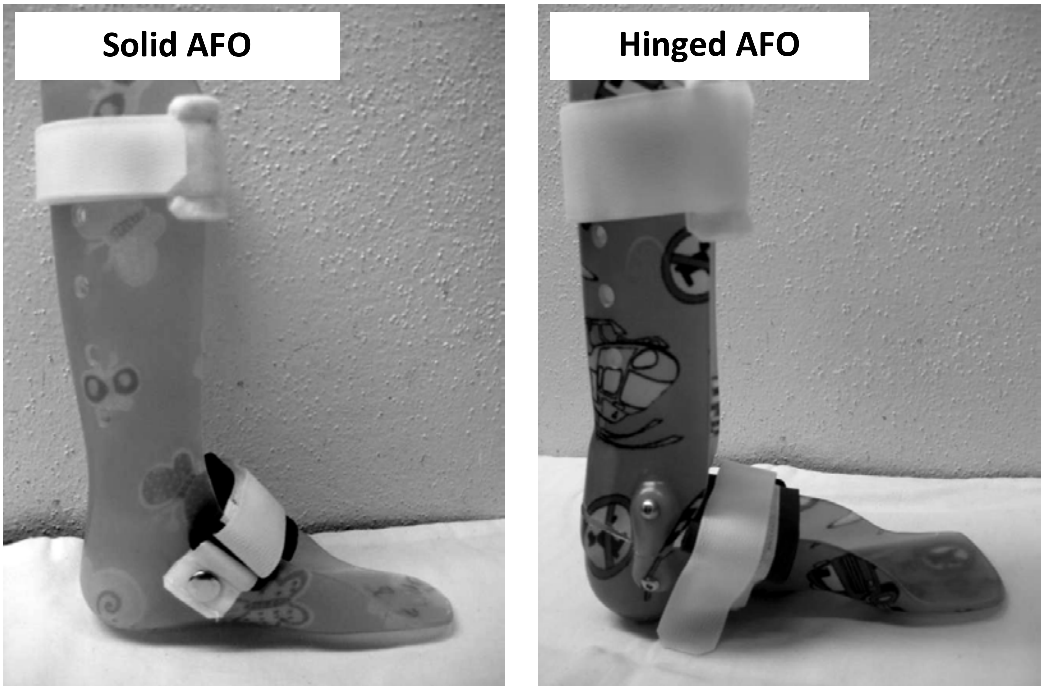


Figure 2.6 Examples of a solid and hinged AFO with a plantarflexion stop at plantigrade.

2.2.1 Terms and definitions

2.2.1.1 AFO-footwear combination (AFO-FC)

The AFO-FC refers to the combined unit of the footwear and the AFO. The alignment of the AFO-FC, as well as each individual component of the AFO-FC can be described independently. The alignment of the AFO is described by the AFO ankle angle (α), the alignment of the footwear is described by the heel-sole-differential (HSD) and resulting pitch (β), and the alignment of the final AFO-FC is described by the shank-to-vertical angle (SVA, θ) (Owen, 2004c; Owen*, et al.*, 2004) (refer to Figure 2.7). Use of the term AFO-FC has typically referred to solid AFOs.

2.2.1.2 AFO ankle angle

The AFO ankle angle (α) is the angle of the foot relative to the shank in the sagittal plane, while in the AFO. It is measured as the angle between the line of the fifth metatarsal and the line of the tibia defined as a line intersecting the centre of the knee joint (estimated as the lateral femoral epicondyle) and lateral malleolus (refer to Figure 2.7). The AFO ankle angle is selected prior to assessing the alignment of the AFO-FC, and is based upon clinical assessment of the musculotendinous length of gastrocnemius, dynamic characteristics of this muscle and tri-planar stability requirements of the foot (Bowers & Meadows, 2007; Bowers & Ross, 2009; Cusick, 1994; Meadows, Bowers, & Owen, 2008; Owen, 2005b). The AFO ankle angle is measured in degrees where a 90° angle is considered to be plantigrade (0°). Therefore, α is the angle from the plantigrade position into either dorsiflexion or plantarflexion.

2.2.1.3 Heel-sole differential & pitch

The heel-sole differential (HSD) refers to the measured difference between the thickness of the sole of the footwear at mid-heel and at the metatarsal heads, in addition to any material added to the AFO itself, measured in millimetres (Owen, 2004b). If the HSD is not equal to zero an angular offset (β) is produced (refer to Figure 2.7). This is referred to as the pitch of the footwear and is measured in degrees.

2.2.1.4 Shank-to-vertical angle

The shank-to-vertical angle (SVA) of the AFO-FC is measured in degrees and refers to the angle between the tibia and vertical, when the AFO is combined with the footwear and the foot is flat on the ground. The term SVA has been used to describe the static or bench alignment of the AFO-FC, as well as the dynamic alignment, for example a measure of tibial angle taken during stance phase. For the purpose of this thesis the term SVA will be used as a measure of static alignment of the AFO-FC, whereas any measure of tibial angle throughout stance will be referred to as a projection angle.

The SVA of an AFO-FC has been measured using landmarks of the lateral malleolus (LAT MAL in Figure 2.7) and lateral femoral epicondyle (KNEE in Figure 2.7)(Owen, 2004b) (refer to Figure 2.7), and has been measured using the line of the tibial crest relative to vertical (Jagadamma *et al.*, 2009; Jagadamma *et al.*, 2010). Some authors have suggested that using the tibial crest to measure SVA is the more accurate method especially in cases of excessive tibial torsion (Owen, 2004b) although this has not been quantified. In a hinged AFO the SVA is measured when the posterior opening of the plantarflexion stop is fully closed.

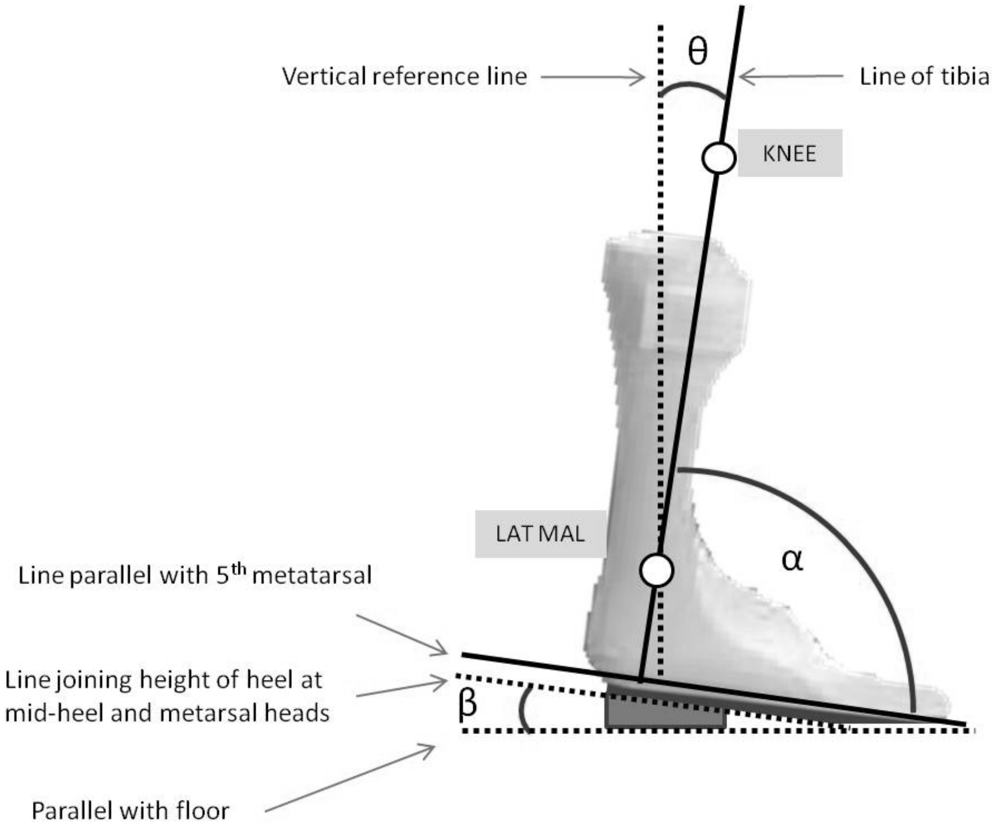


Figure 2.7 The SVA (θ) of the AFO-FC reflects the AFO ankle angle (α) and the pitch of the footwear (β).

When the shank is tilted anteriorly, the SVA is defined as a positive or inclined angle and a posterior tilt is referred to as negative or reclined SVA angle (Owen, 2004b). The net effect of the AFO ankle angle (α) and the pitch (β) produced by the HSD determines the SVA (θ). For example, a vertical SVA could be produced from a plantarflexed AFO comined with footwear with a positive pitch, or a plantigrade AFO combined with footwear with zero pitch, as demonstrated in Figure 2.8.

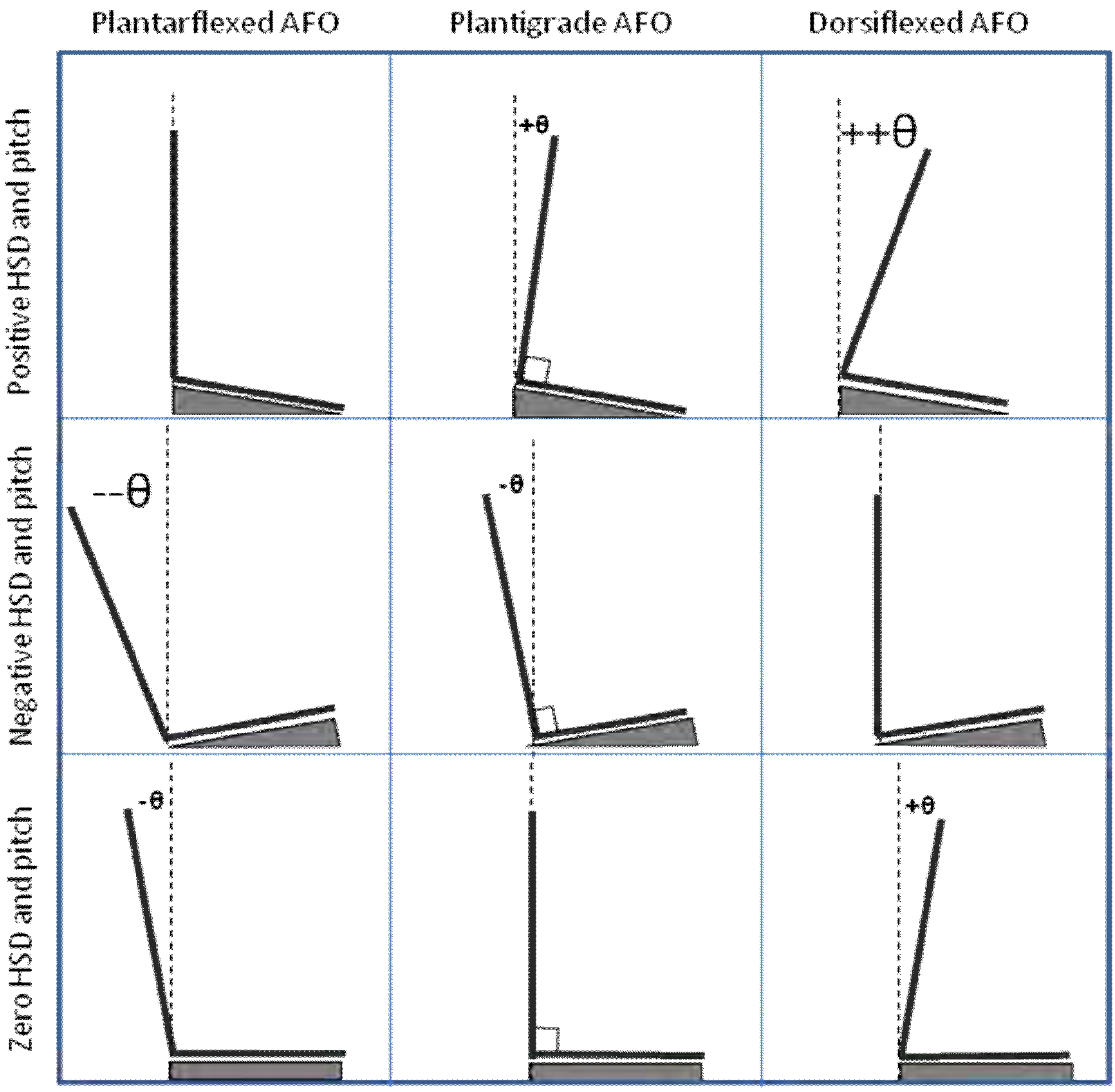


Figure 2.8 The SVA is a combination of AFO ankle angle and the HSD.

2.2.2 Biomechanics of AFOs

There are four ways in which an orthosis may modify the system of external forces and moments acting across a joint. This includes 1) restricting the rotational motion at the joint to modify joint moments; 2) restricting translational motion at the joint; 3) reducing the axial forces carried across a joint; and 4) modifying the point of application and line of action of the GRF (Bowker, 1993). In children with CP, AFOs are typically employed to achieve the first and last of these aims. The first method involves directly limiting the rotational motion at the ankle joint, and the last involves an indirect biomechanical influence over the GRF.

2.2.2.1 Controlling rotational movement

An AFO is an orthosis that directly encompasses the ankle joint and by virtue of variations in its design can prevent or assist different rotational movements at this joint. Control over rotational movements is achieved using a three point force application system. As previously described, one of the most common gait deviations demonstrated by children with spastic CP is an equinus foot position with the foot plantarflexed throughout swing phase and often also during the stance phase of gait (Goldstein & Harper, 2001; Rodda & Graham, 2001; Sutherland & Davids, 1993; Winters*, et al.*, 1987). This leads to an excessive PF-KE couple.

Both the solid and hinged AFO (with a plantarflexion stop) are designed to prevent excessive plantarflexion. The AFO must apply a corrective force to the posterior proximal calf (directed anteriorly; F1) and distal inferior toe plate (directed superiorly; F2) and a force directed posterior-inferiorly over the anterior ankle (F3), applied by the footwear and often also an ankle strap (refer to Figure 2.9). F3 is equal to the vector sum of reaction forces F1 and F2.

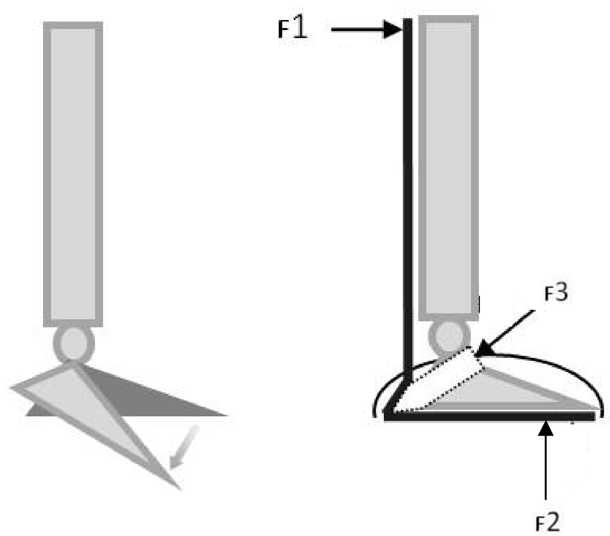


Figure 2.9 Diagram of forces applied to prevent plantarflexion.

Other gait patterns, such as crouch gait, demonstrate a reduced PF-KE couple, which results in excessive dorsiflexion (Rodda & Graham, 2001; Sutherland & Davids, 1993). Preventing excessive dorsiflexion requires the opposite force system to that described above, and therefore the design of the AFO is altered. Changes may be made to any design features including the location of trimlines, position of straps, the type of material used in AFO construction, the type of joints, and location of mechanical stop. While a solid AFO is an appropriate choice for preventing excessive dorsiflexion, a hinged AFO with free dorsiflexion is not appropriate. Rather a hinged AFO of the reverse design; that prevents dorsiflexion with a mechanical stop but permits unrestricted plantarflexion beyond plantigrade would achieve the required biomechanical aims (refer to Figure 2.10).

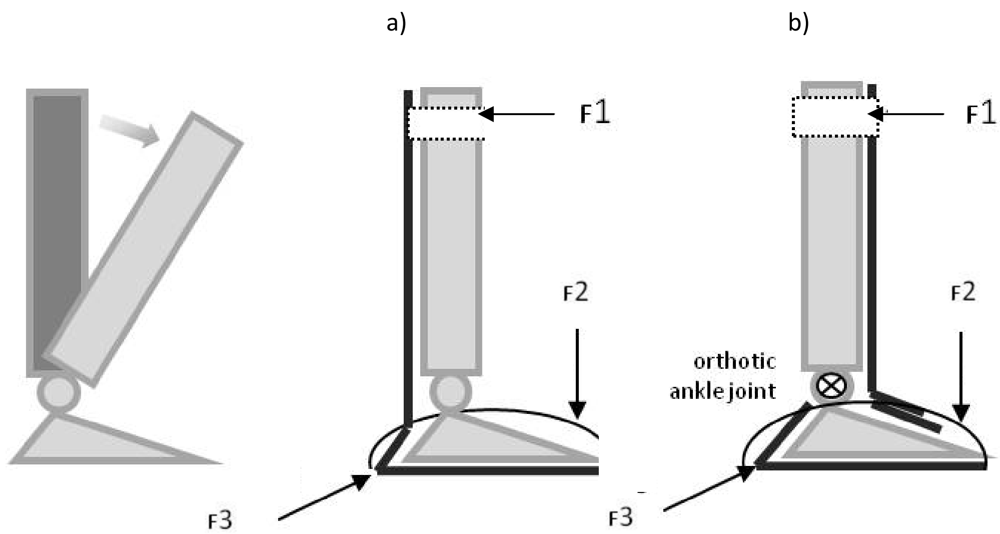


Figure 2.10 Diagram of forces applied to prevent dorsiflexion in a) a solid AFO; b) an articulated AFO with a dorsiflexion stop.

2.2.2.2 Modifying the GRF

The second way in which an AFO may modify the system of external forces around a joint is by modifying the point of application and line of action of the GRF (Bowker, 1993). The process of realigning the GRF at any particular joint involves changing the angular relationship either between the plantar surface of the foot and the floor or between the articulating segments at a more distal anatomical joint (Bowker, 1993). Figure 2.11 provides an example where an AFO restricts excessive plantarflexion thus controlling the rotational movement of the ankle. This improves the angular relationship between the two articulating segments (foot and shank) which also improves the angular relationship between the plantar surface of the foot and the floor. The foot can now achieve foot flat during mid-stance which moves the point of application of the GRF posteriorly along the foot.

An AFO can also indirectly influence the alignment of more proximal body segments (Bowker, 1993). For example in Figure 2.11 below, application of an AFO that restricts plantarflexion will reduce the PF-KE couple, and will therefore also reduce the excessive external knee extension moment and limit knee hyperextension. The line of action of the GRF is reoriented to produce smaller knee extension moments, and potentially also reduced hip flexion moments. AFOs can have both direct effects on the encompassed joint and indirect effects on adjacent joints. The name of the device reflects the joints encompassed by the orthosis, not the joints affected by the orthosis.

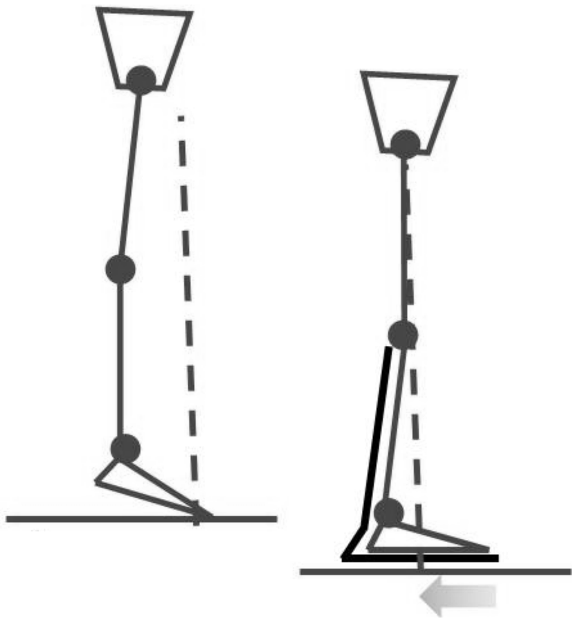


Figure 2.11 Example of the improved relationship between articulating segments as well as the angular relationship between the plantar surface of the foot and the ground.

2.2.3 Footwear

The increased use of the term "AFO footwear combination" within the wider body of literature acknowledges the importance of the footwear in achieving the desired orthotic outcomes. Changes to the design of the footwear have been purported to affect the GRF point of application and orientation throughout the gait cycle, primarily with reference to the process called 'tuning' (Owen, 2004a, 2005a). Tuning of the AFO-FC is a three step process of making adjustments to the SVA to alter GRF orientation during mid-stance, to the sole profile of the footwear to affect GRF orientation during terminal stance, and to the heel profile and properties of the footwear to affect GRF orientation during early stance (refer to Figure 2.12) (Owen, 2005a).

The modifications made to the footwear as part of the tuning procedure are thought to be essential in order to compensate for the limited ankle motion incurred in a solid AFO. In normal gait three ankle rockers have been described: ankle plantarflexion during loading response which is referred to as first rocker, ankle dorsiflexion during mid-stance which is referred to as second rocker and ankle plantarflexion at terminal stance which is referred to as third rocker (Perry, 1992). A solid AFO interferes with all three rockers because plantarflexion is prevented at heel contact and at late stance, with dorsiflexion prevented during mid-stance. The tuning process is suggested to address each of these restrictions by modifying the heel properties of the footwear, the SVA, and the sole profile of the footwear (Owen, 2004b). While this thesis focused on the first component of tuning, that is the effect of the SVA, an understanding of the potential effect of sole and heel modifications is required in order to interpret findings related to a change in SVA in the context of the entire tuning process.

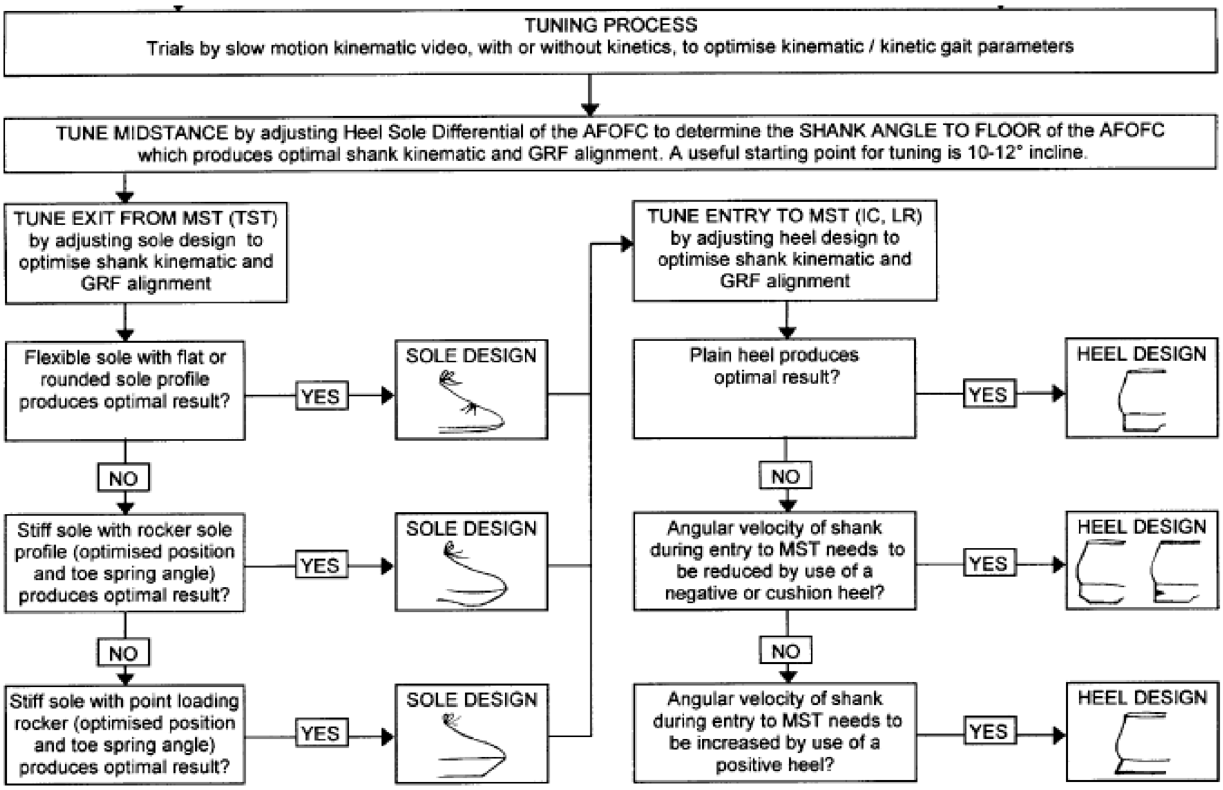


Figure 2.12 The sub-set of the algorithm proposed by Owen (2005a) which involves tuning the AFO-FC.

2.2.3.1 Sole profiles

Within the context of the tuning procedure, three types of sole profiles are used to tune the exit from stance phase (Owen, 2005a). These include a flexible sole; a stiff sole with a rocker sole profile; and a stiff sole with a point loading rocker (refer to Figure 2.12). A flexible sole is recommended when the patient is able to control tibial progression in terminal stance, whereas rocker soles or point loading rockers are recommended where tibial progression in terminal stance is uncontrolled (Owen, 2005a).

The purpose of the rocker sole has been described as allowing progression of the tibia over the stationary foot in the absence of ankle dorsiflexion, and to determine the site of the centre of pressure, that is the point of origin of the GRF (Hullin & Robb, 1991). Point loading rockers are said to enable better control over the timing of heel lift by delaying it until the point of application of the GRF reaches the point loading rocker (Owen, 2004a). This is said to facilitate achieving a GRF alignment posterior to the hip but anterior to the knee at terminal stance, and therefore production of hip extension moments (Owen*, et al.*, 2004).

Those with clinical experience in tuning AFO-FCs suggest that the sole profile of the AFO-FC is a critical component of the tuning process (eg. Owen, 2004a). A recent review has suggested that there is little evidence supporting the effectiveness of these modifications in modifying the kinematics or kinetics of gait (in the absence of an AFO) (Hutchins, Bowker, Geary, & Richards, 2009). There is some evidence of improvements in knee hyperextension in an adult with post-stroke hemiplegia (Jagadamma*, et al.*, 2010) and in two children with CP (Hullin, Robb, & Loudon, 1992) all of whom were wearing solid AFOs, though the rocker designs used in these studies are not well described.

There is also some evidence that rocker design can have a significant impact on kinetics, centre of pressure progression and tibia-to-floor angular velocity when the ankle is immobilised by a cast or AFO. Hullin and Robb (1991) examined 10 commercially available rockers on an able bodied subject wearing a below-knee cast and found that a rocker which allows rapid progression of the centre of pressure imposes a knee extension moment and tibial arrest, and a rocker which prevents centre of pressure progression causes a large knee flexion moment requiring excessive quandriceps activity and may result in a reduction in the second peak of the GRF (Hullin & Robb, 1991). Unfortunately the precise designs of the rockers tested are not described which makes it difficult to generalise their findings to specific rocker characteristics.

Owen recommends modifying the sole profile of the footwear as the second stage of the tuning process, after optimising the SVA (Owen, 2005a). While the precise effect of sole design on the biomechanics of gait is not known, it is apparent that there is potential to significantly affect kinematics, kinetics and COP progression. Changing the sole profile has the potential to induce these changes at any point where the foot is flat on the ground and therefore may influence mid-stance biomechanics as well as terminal stance. Thus, investigations into the effect of SVA on gait should take into account the potential for further modifications by modifying the sole profile of the footwear.

2.2.3.2 Heel profiles

Owen (2005b) describes three heel profiles that are used to tune the entry into mid-stance. These are 1) a plain heel; 2) a negative or cushioned heel; and 3) a positive heel (refer to Figure 2.12). Negative or cushioned heels are advocated for reducing an excessive angular velocity of the shank during early stance (Owen, 2005a; Weist, Waters, Bontrager, & Quigley, 1979) whereas a positive heel is suggested for when angular velocity of the shank needs to be increased (Owen, 2005a). Excessive angular velocity of the shank occurs at heel strike because the orthosis blocks plantarflexion causing the tibia to pivot anteriorly at the point of heel contact. Thus the orthosis imparts to the posterior tibia a knee flexing moment that must be resisted by quadriceps activation (Weist*, et al.*, 1979).

Little is known about the effect of heel profile on gait in pathological populations where ankle motion is limited. One study on nine able bodied adults wearing solid AFOs demonstrated that modifying the heel properties can effectively moderate the increased angular velocity of the shank that occurs due to an immobilised ankle. Negative or cushioned heels successfully reduced tibial advancement velocity compared with hard rubber heels (comparable to the plain heel) and led to increased stride length and therefore also increased walking velocity (Weist*, et al.*, 1979).

Thus in children who achieve heel strike, modifying the heel profile of the footwear as part of the tuning process is likely to induce positive changes to early stance phase, up until the foot achieves foot flat. Knee flexion moments may be reduced and stride length and walking velocity may be increased. It is possible that these changes produce carry-over effects to the remainder of the gait cycle however the tuning process has never been described as requiring a re-assessment of the SVA as the final step. The effect of AFO-FC alignment should therefore be considered in light of potential improvements to early stance gait characteristics that may be possible due to heel modifications.

2.2.3.3 AFO ankle angle

Selecting the correct AFO ankle angle is also considered to be part of the tuning process (Owen, 2005a). Owen (2005b) describes an algorithm for selecting the most appropriate AFO ankle angle based on a clinical assessment of gastrocnemius length, the ability to sustain the measured length without excessive pressure or discomfort and the risk of gastrocnemius or soleus length becoming shorter. An AFO ankle angle that does not accommodate the tri-jointed nature of the gastrocnemius muscle is thought to limit knee extension during gait and thus alter proximal kinematics and kinetics (Meadows*, et al.*, 2008; Owen, 2005b).

2.2.4 Evidence for the efficacy of AFOs

While there are a wide variety of applications for AFO use within the CP population, there is limited scientific evidence supporting their efficacy in achieving the stated goals. Several systematic reviews have been published in this area (Bowers & Ross, 2009; Figueiredo*, et al.*, 2008; Morris, 2002; Teplicky, Law, & Russell, 2002) but have drawn only limited conclusions about the effectiveness of AFOs. For example, one reviewer concludes that AFOs that prevent plantarflexion can prevent equinus deformity, and that this improves the temporospatial parameters (walking speed and stride length) of gait for most children, thereby also increasing gait efficiency (Morris, 2002).

However, when hemiplegic and diplegic children are considered as separate groups, the effect of AFOs on temporospatial parameters can be seen to vary according to unilateral or bilateral lower limb involvement. Hemiplegic children generally demonstrate increased walking velocity and decreased cadence whereas diplegic children generally demonstrate no significant changes in these two variables (Bowers & Ross, 2009). In all children step length, stride length and single support time are generally found to increase, but there is little evidence to suggest changes to double support (Bowers & Ross, 2009).

Power generation and absorption at the ankle is generally found to decrease when wearing an AFO, but kinematics at the ankle are generally improved (Bowers & Ross, 2009). Evidence for the effect of AFOs on more proximal joints, namely hip and knee kinematics and kinetics, are however largely inconclusive (Bowers & Ross, 2009). This is not due to a lack of studies which have examined these variables. Rather, methodological limitations make it difficult to synthesise findings across studies and impossible to perform meta-analyses. These studies have, by and large, examined the effect of a range of AFO designs on heterogenous groups of participants, and generally include only limited detail regarding the participants, protocol and apparatus in the trial reports (Bowers & Ross, 2009; Figueiredo*, et al.*, 2008; Morris, 2002; Ridgewell, Dobson, Bach, & Baker, 2010)

A recent review by Bowers and Ross (2009) also suggests that variations in the sagittal plane alignment of the AFO-FC, that is the SVA, used across these studies may contribute to the inconsistent effect on knee and hip kinematics and kinetics. There is an emerging body of evidence suggesting that changes to AFO alignment can affect lower limb kinetics and kinematics (eg. Butler*, et al.*, 2007; Jagadamma*, et al.*, 2009; Jagadamma, van der Linden, Coutts, Herman, & Yirrel, 2007). These studies suggest further, that each child has a unique optimal AFO alignment which minimises abnormal joint biomechanics (Owen, 2002). Bowers and Ross (2009) suggest that one of the reasons it is difficult to conclusively demonstrate the effectiveness of AFOs on the knee and hip in children with CP is because many studies do not report the alignment of the AFO-FC and have not conducted a tuning process to determine the most optimal alignment.

Modifying the SVA of the AFO-FC in order to optimise the performance of the device is one component of the tuning process. It is described as the first stage of tuning (Owen, 2005a), but is also the most common component referred to throughout other literature. Modifying the SVA of the AFO-FC is also arguably the simplest adjustment to execute. For example, an AFO can be fabricated to virtually any AFO ankle angle which will ultimately affect the SVA. Internal heel raises can be added which are a quick, simple and reversible solution. Permanent shoe modifications, though more time consuming, are possible in most clinical situations.

2.3 Tuning the AFO-FC

The influence of AFO-FC alignment was the focus of this thesis. The remainder of this chapter provides background information on the theory and evidence for aligning the SVA of the AFO-FCs of children with CP. Studies to date are critically reviewed and a second mechanism by which changing the SVA of the AFO-FC may affect the biomechanics of gait is proposed and is explored further in the subsequent chapter. The evidence base for the effect of AFO-FC alignment on gait in children with CP is critically reviewed and summarised. Hereafter the term tuning refers to modification of the SVA of the AFO-FC unless expressly described as involving heel and sole modifications. All joint moments are expressed as external moments unless otherwise stated.

Throughout the wider body of literature examining AFO interventions in children and adults with varying diagnoses, studies that report the AFO-FC alignment are rare. Owen (2004b) conducted a review of 310 publications investigating AFOs and casts for children and adults, from 1959-May 2004. This review revealed a lack of full and precise information about the majority of AFO-FCs described, as well as ambiguity in the terms used to describe the AFO-FC and its SVA (Owen, 2004b).

Among the papers that did report the AFO-FC alignment, it is apparent that many authors have specific preferences for a certain SVA or AFO ankle angle. For example Nuzzo (1983) recommends a 10° SVA in solid AFOs on the basis that it avoids any impairment to tibial progression. Hullin and colleagues (1992) also prefer a 10° dorsiflexed AFO to a plantigrade AFO, but do not report the design of the footwear thus making the SVA unknown. Other authors chose a specific alignment for each patient, including Rosenthal and colleagues (1975) who selected the AFO ankle angle for their participants by observing correction of genu recurvatum while their patients walked on an adjustable inclined walkway. Again, because the characteristics of the footwear were not reported, the final SVA is not known.

While a variety of AFO-FC alignments are used in the literature, there are also a variety of guidelines offered in orthotics textbooks. In *Paediatric Orthotics,* tuning is recommended but little detail is provided (Morris, 2007). In *Atlas of Orthoses and Assistive Devices* a 10-12° SVA is advocated as this is the shank incline achieved during mid-stance of normal gait, but it is also noted that optimal may be greater or less than normal in pathological situations (Meadows*, et al.*, 2008). Finally, in *Biomechanical Basis of Orthotic Management,* a dorsiflexed ankle angle is suggested possibly in combination with footwear incorporating heel wedges and/or rocker soles, to achieve a reduction in the knee extension moment (Condie & Meadows, 1993). Thus there is not only a lack of scientific evidence guiding clinicians as to how to align the AFO-FCs of children and adolescents with CP, but also a lack of a consistent clinical standard to form the basis of a sagittal plane AFO-FC alignment.

Some authors suggest that AFO-FC tuning leads to an improved biomechanical environment from which the patient can learn to manipulate the GRF while they walk and which encourages appropriate motor learning (Butler, Thompson, & Major, 1992). They suggest that the patient was “released from the need to actively attempt to control the GRF to the same extent, and was able to learn through this enforced situation” (Butler*, et al.*, 1992, p. 574). Other authors suggest improved long term outcomes such as a reduction in damage to the knee joint structures due to excessive extending moment (Butler*, et al.*, 1992) and fewer contractures which in turn minimises requirements for surgery (Owen, 2004b). Tuning is said to allow improved hip extension and hip extension moments thus permitting the child to undertake their own stretching therapy twice during each gait cycle, with increased hip flexion at terminal stance and increased hip extension at terminal swing (Owen, 2004b). Despite these claims, there is little evidence of the effect of tuning on gait, or on these longer term outcomes.

With only one exception (Desloovere *et al.*, 2006) the term 'tuning' has referred only to solid AFOs, which are the most common type of AFO prescribed in facilities that routinely conduct tuning protocols (Owen, 2005b). The intended function of the solid AFO is to prevent all movement of the ankle joint and therefore offer direct control over the ankle, but also indirect control over more proximal lower limb segments and joints (refer to Figure 2.11, p45). Thus the design of the solid AFO allows the greatest degree of control over manipulating the GRF vector and more proximal joints.

Only a limited body of research has been published which has reported experimental data from AFO-FC tuning. For the most part, the process has not been objectively described, decision rules guiding the choice of the final alignment often are not clear, and data describing the final outcome are often not reported. Two studies have reported the final SVA values of tuned AFO-FCs for children with CP. These were an average SVA of 11.86° (±2.05°, 7-16°) (Owen, 2002) and 10.8° (±1.8°) (Jagadamma*, et al.*, 2009). The study by Owen (2002) is a conference abstract reporting average tuned SVAs for the solid AFOs of children with CP, spina bifida and other conditions, according to patient diagnosis. While little detail is reported in the abstract this work is also described in the authors thesis (Owen, 2004b). These studies are discussed further in the subsequent sections.

AFO tuning is not performed in all clinical centres. In the candidate's experience, many clinicians opt for a plantigrade AFO ankle angle except in situations where a plantarflexion contracture must be accommodated. In combination with low pitched shoes this will produce a SVA between 0-5°. If the SVAs suggested in these studies are indicative of the most optimal AFO alignment then it is possible that one of the most common clinical AFO prescriptions are producing suboptimal outcomes.

2.3.1 Tuning Techniques

2.3.1.1 Force vector analysis

The majority of papers that report or describe AFO-FC tuning have used a two dimensional video vector system that superimposes a GRF vector over a video of the patient walking. Videos are usually taken in the sagittal and coronal planes (refer to Figure 2.13). This system permits immediate feedback, freeze frame, slow-motion and printing facilities and has been used in both paediatric studies (Butler*, et al.*, 2007; Butler*, et al.*, 1992; Meadows*, et al.*, 1980; Owen, 2004b; Stallard & Woollam, 2003) and in two case studies of adults with post-stroke hemiplegia (Bowers & Meadows, 2007) and acquired brain injury (Butler, Farmer, & Major, 1997). Tuning using force vector analysis involves modifying the characteristics of the AFO-FC in order to improve the sagittal plane moment arm of the GRF at the knee.

There are errors inherent in the use of force vector analysis to the extent that it assumes that changes in segment mass and accelerations are negligible. These errors have been quantified and found to be negligible for assessment of ankle moments and very small, particularly at mid-stance for assessment of knee moments (Boccardi, Pedotti, Rodano, & Santambrogio, 1981; Wells, 1981). As a clinical tool for assessing knee moments and as a way of explaining the effects of changing the point of application and line of application of the GRF, the force vector analysis is extremely useful.

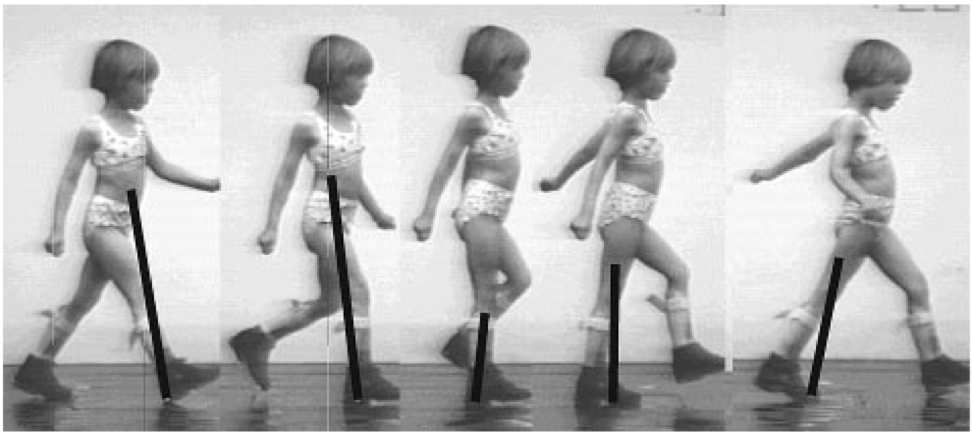


Figure 2.13 Example output of successive freeze-frame images taken from a two dimensional video vector generator (Stallard, 1987).

2.3.1.2 Three dimensional gait analysis

More recently, three dimensional gait analysis (3DGA) has been used to tune AFO-FCs of children with CP (Jagadamma*, et al.*, 2009), and one adult with post-stroke hemiplegia (Jagadamma*, et al.*, 2010). 3DGA is a form of quantitative gait analysis that seeks to understand the process of walking with measurable parameters collected through instrumentation. The sophisticated technology utilised in 3DGA overcomes many of the limitations of the force vector analysis approach including parallax and perspective error. Using 3DGA permits calculation of internal joint moments throughout stance phase whereas in studies using a video vector approach it is only possible to undertake a simple and more subjective analysis of the position of the GRF vector in the sagittal plane at various isolated instances. 3DGA also permits of measurement of the tri-planar motion deviations often demonstrated by children with CP.

2.3.2 Defining AFO-FC tuning

2.3.2.1 What parameter is optimised?

The body of literature that has reported or described AFO-FC tuning in both the paediatric and adult population is limited. Unfortunately, most studies report only limited detail about the goal of the tuning process. One of the most notable inconsistencies throughout the literature is the variable or parameter at the heart of the optimisation process. Some authors have considered the aim of tuning to be optimisation of the GRF moment arm to the knee in the sagittal plane (Butler*, et al.*, 1992; Owen, 2002) while others have also included reference to kinematic improvements (Bowers & Meadows, 2007; Butler*, et al.*, 2007; Jagadamma*, et al.*, 2009; Jagadamma*, et al.*, 2010; Meadows*, et al.*, 2008; Owen*, et al.*, 2004; Stallard & Woollam, 2003).

This disparity has two probable origins. The first of these may be an underlying assumption that a change in one variable always translates into changes in other variables. For example, some authors suggest that improvements in kinematics, namely shank kinematics, are key precursors to improvements in kinetics (Meadows*, et al.*, 2008; Owen, 2004c), and are therefore a necessary component of the tuning process. It is later argued however, that changes in knee kinetics are possible without changes in knee or shank kinematics.

The second possible cause may be confusion between the variables directly manipulated during the tuning process, and the variables assessed as outcome measures. For example, the current reasoning behind AFO-FC tuning suggests that increasing the HSD of the AFO-FC directly inclines the shank during stance phase. If the centre of pressure and line of action of the GRF remain the same, the result is a shift in the knee joint centre towards the GRF vector. This is a direct kinematic change that also reduces the moment arm of the GRF to the knee (refer to Figure 2.14), which is a kinetic outcome. While normalising the GRF moment arm to the knee may also normalise limb segment kinematics, recognising the difference between cause and response provides an important clarification in defining the goal of the tuning process.

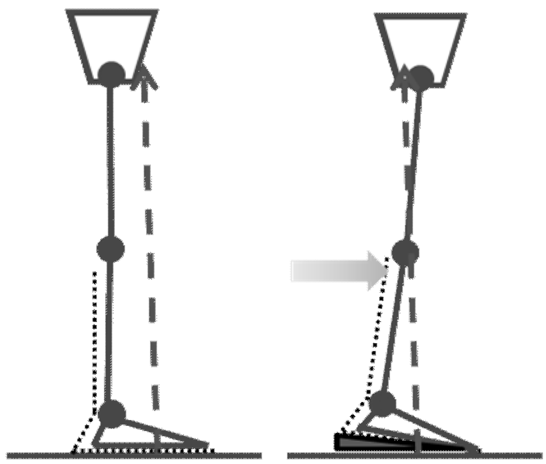


Figure 2.14 Increasing the HSD using a heel wedge increases the SVA and as a result, the distance from the knee joint to the GRF vector is reduced.

There is also disparity throughout the literature regarding the lower limb joints that are targeted during the tuning process. Most authors have focused solely on the knee (Butler*, et al.*, 1997; Butler*, et al.*, 2007; Butler & Nene, 1991; Butler*, et al.*, 1992; Jagadamma*, et al.*, 2010; Stallard & Woollam, 2003) while others recommend that AFO-FC tuning focus on the kinetics of both the hip and knee joint, simultaneously (Bowers & Meadows, 2007; Meadows*, et al.*, 2008; Owen, 2004c). One of these authors reports success in one post-stroke adult patient (Bowers & Meadows, 2007), however success in children with CP is likely to be limited at least initially, due to muscle weakness, contracture and/or spasticity limiting full hip and knee extension (Owen, 2004c).

While an increase in shank incline offers the potential to alter the moment arm of the GRF at the hip, the effect will be dependent upon the kinematics of the knee joint. For example, if shank incline occurs simultaneously with knee flexion, the moment arm of the GRF to the hip may remain unchanged (refer to Figure 2.15 a and b). If however, shank incline occurs with knee extension then the hip may move closer to the GRF vector thereby reducing the moment arm (Figure 2.15, c). Thus, changing shank incline will directly affect the GRF orientation to the knee, but the effect on the hip may be variable. In summary, AFO-FC tuning can be considered to focus primarily on kinetics at the knee, with a secondary effect on the hip.

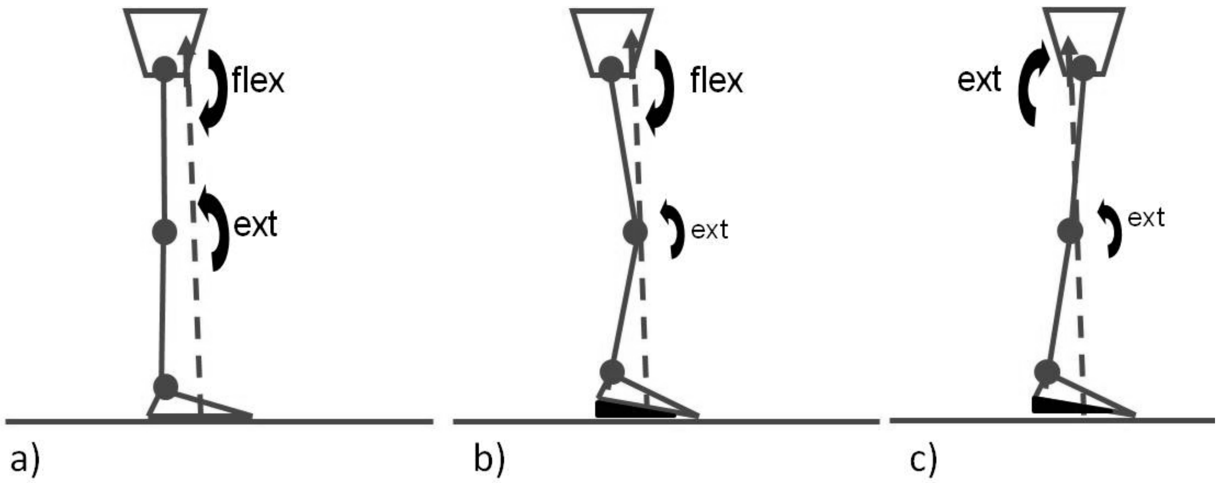


Figure 2.15 Diagram illustrating consistent reductions in knee extension moment due to increased shank incline, but a variable effect on the hip moment.

2.3.2.2 During which part of the gait cycle?

In Owen's definition of tuning, modifying the SVA is said to target GRF orientation during mid-stance (Owen, 2004b, 2004c). A variety of definitions for this period of the gait cycle exist within the literature, the most notable variants of these being a definition as a *phase* or a discreet *event*. Two common definitions that describe mid-stance as a phase or period of the gait cycle are 10-30% of the gait cycle (Perry, 1992) and the period between weight acceptance and push off (Winter, 1987). Discreet events consider mid-stance to be a temporal event (eg. 50% of stance phase); kinematic event (eg. when the medial malleoli of the swing limb passes the stationary limb); or kinetic characteristic (eg. when the GRF vector is vertical in the sagittal plane) (Gibson, Jeffery, & Bakheit, 2006).

Investigations using video vector analysis presumably required a discreet definition of mid-stance in order to assess moment arm of the GRF to the knee at a specific point in time in a reliable and repeatable way. Unfortunately this has not been reported beyond general terminology such as 'mid-stance' or 'middle of stance'. Authors have defined normal GRF orientation as simply that (Butler*, et al.*, 1992), or when the GRF vector is overlying the knee (Butler*, et al.*, 2007) or when the GRF vector is as close as possible to the centre of the knee joint (Jagadamma*, et al.*, 2009). No description was given of the point during the gait cycle that this was assessed. In addition, discreet definitions only have limited usefulness in the CP population as the gait deviations demonstrated by this group include a wide variety of temporal, kinematic and kinetic variations.

An alternative approach would be to focus on the specific characteristic of gait that is being modified during the tuning process, rather than the timing in the gait cycle. Several such characteristics have been described, including reducing the excessive external extension moment arm to the knee (Butler*, et al.*, 1997; Butler*, et al.*, 1992), and "when the GRF vector becomes briefly misplaced around mid-stance'' (Stallard & Woollam, 2003). Thus the focus here is the peak knee extension moment, regardless of the time at which it occurs. This is however, a gait characteristic which is excessive only in those children demonstrating an excessive PF-KE couple, thereby potentially limiting the population to whom this definition may be relevant.

Other authors who have used 3DGA to tune the AFO-FC of an adult with post-stroke hemiplegia have more recently overcome this limitation by defining the optimisation process as normalising joint kinematics and the moment arm of the GRF relative to the knee as far as possible, with the aim of correcting *any* abnormal joint moments created by pathological gait (Jagadamma*, et al.*, 2010). These authors are the first to clearly define the periods of stance phase of interest, using definitions largely in line with those proposed by Perry (1992), which are summarised in Figure 2.16. This definition considers the stance phase period of the gait cycle according to four sub-divisions: loading response (0-10% gait cycle), mid-stance (10-30% gait cycle), terminal stance (30-50%) gait cycle and pre-swing (50-60% gait cycle).

		Stride						
Periods		**Stance**				**Swing**		
Task		*Weight acceptance*	*Single limb support*		*Limb advancement*			
Support		**Double**	**Single**		**Double**	**Single**		
Phases		**Loading Response**	**Mid-stance**	**Terminal stance**	**Pre-Swing**	**Initial-Swing**	**Mid-swing**	**Terminal Swing**
Defining events	Initial contact	Foot flat	Heel rise	Contra-lateral initial contact	Toe off	Swing & stance limb in line	Vertical tibia swing limb	Initial contact
% Gait Cycle	0-2%	0-10%	10-30%	30-50%	50-60%	60-73%	73-87%	87-100%

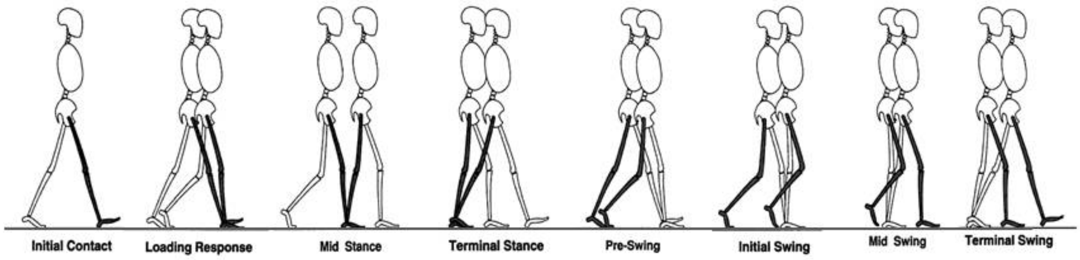


Figure 2.16 Divisions of the gait cycle reproduced from Perry (1992, p. 10).

In this study by Jagadamma and colleagues (2010) the authors focused on changing SVA to optimise knee kinetics over mid-stance (defined as 10-30% gait cycle), then used a rocker sole to optimise the period of terminal stance (defined as 30-50% gait cycle) to pre-swing (defined as 50-60% gait cycle). These authors found that increasing the SVA of the AFO-FC improved knee kinetics throughout mid-stance but also terminal stance. They suggested that adding a rocker sole further improved knee kinetics in terminal stance and pre-swing, though these changes were of a much smaller magnitude.

A recent paper by Owen (2010) also included reference to Perry's (1992) definition of the gait cycle. While this definition of mid-stance is in line with Perry's (1992), Owen refers to Perry's 'loading response' as early stance or entrance to stance, and Perry's 'terminal stance' and 'pre-swing', collectively as exit from stance phase. It can thus be inferred that in Owen's previous publications, her use of the term mid-stance was in line with that of Perry (1992). In addition, Owen (2010) states that the instant in the gait cycle assessed during 2D video vector tuning was the moment that the GRF was vertical, which occurred at the transition from mid- to terminal stance at 30% gait cycle. This highlights one of the discrepancies throughout the wider body of literature regarding the focus of tuning on either a phase or an instant in the gait cycle.

Regardless of how mid-stance is defined, it should be recognised that AFO-FC alignment will affect the orientation of the GRF to the knee, and possibly also the hip joints throughout all of stance phase. In addition to this, if 3DGA is used to measure the effect of AFO-FC alignment on gait, the point in the gait cycle at which this is measured does not need to be constrained to a specific temporal definition or gait characteristic. It remains helpful however to consider the focus of previous literature as this informs the research questions.

In summary, literature to date generally considers tuning by way of modifying the SVA to be focused on improving (that is, normalising) knee kinetics during mid-stance (10-30% gait cycle) and terminal stance (30-50% gait cycle), with a particular focus on the peak knee extending moment. The effect on hip kinetics remains of secondary concern.

2.3.2.3 What is successful and unsuccessful tuning?

While the goal of the tuning process has not been clearly described, there is also some ambiguity regarding how the final 'optimal' AFO-FC alignment was determined in each case. All proponents of the tuning process agree that the goal of the process is to achieve more normal kinetics. However, several authors have used the divisions 'successful' or 'unsuccessful' to define a patient's ability to respond to AFO-FC alignment change (Butler*, et al.*, 2007; Owen, 2004c). Such grouping requires *a-priori* decisions about minimum improvement required in a certain parameter in order to qualify as achieving 'closer to normal values'.

One study formed two groups of children based on their success in tuning, but did not report the decision rules used to determine success (Butler*, et al.*, 2007). They also did not report the baseline and tuned values of the variable considered in the tuning process, thereby making it difficult to consider this retrospectively. This makes it impossible to determine whether a child described as one who could have their AFO tuned successfully, achieved within normal values in this variable, or simply demonstrated some improvement regardless of the extent.

There is also no evidence to suggest that a single optimal AFO-FC alignment exists for each child, or whether there is a range of AFO-FC alignments that produce similar outcomes. The current tuning procedure described throughout the literature does not specify a process for determining which alignment is the final optimal alignment, beyond a statement of 'trial and error'. Such a process might be, for example, to continue making adjustments to the AFO-FC even after an optimal is determined, to ensure no further improvement can be made.

The recent case study by Jagadamma and colleagues (2010) described a method where this double-checking was not performed. One trial was captured in each condition with the data viewed and a decision made about the subsequent adjustment. This adjustment was stopped when the data came within one standard deviation of normal values. Such a method carries the assumption that a single AFO-FC alignment exists that will produce discernibly more normal knee kinetics than the surrounding alignments. This assumption is currently unfounded as no studies have sought to examine the effect of a range of AFO-FC alignments and thereby determine sensitivity to change.

It may therefore be helpful to consider children based on their *responsiveness* to a change in AFO-FC alignment, rather than success or failure in tuning. For example, in cases where changing AFO-FC alignment has no effect on knee kinetics a child could be categorised as unresponsive. A responsive child would therefore be one where changing the AFO-FC alignment elicited *a change* in knee kinetics, and this could be either an improvement or a deterioration in performance. In the first case this would indicate a sub-optimal baseline AFO-FC alignment, whereas the latter would indicate a more optimal baseline AFO-FC alignment as the change in AFO-FC alignment produced detrimental effects. The end result is therefore a two level classification which considers children firstly as responsive or unresponsive, and secondly assesses the direction of the response as an improvement or deterioration.

Examples in the literature support the idea of a positive or negative response to altered AFO-FC alignment. Stallard and Woollam (2003) reported results of a pilot transportable tuning program using the 2D video vector generator. While some children were documented to have improved knee kinetics using this method, others were reported to have had their orthotic set-up confirmed. This could reasonably be considered indicative of a baseline AFO-FC alignment that performed equally as well or better than any attempt at modification. Therefore, a child could be described as responsive to tuning, but due to an optimal baseline alignment, could derive no benefit from alignment adjustments. Responsiveness could therefore indicate the potential for altered knee kinetics, regardless of the baseline alignment.

The important differences between a two level classification system based on success, and one based on responsiveness can be demonstrated by examining further the results of the study that attempted to classify children into two groups according to whether or not their AFOs were tuned succesfully (Butler*, et al.*, 2007). Children whose AFOs were not tuned successfully were defined as those who demonstrated less or no change toward normal. This group likely included unresponsive children, responsive children who demonstrated detrimental effects, and responsive children who demonstrated positive effects but to a small degree. Therefore, the successful group would include only those children who were responsive and showed large improvements in their knee kinetics. Without considering baseline alignment, the categorisation proposed by Butler and colleagues (Butler*, et al.*, 2007) may not be able to identify all children who could potentially benefit from a tuning procedure.

The terms responsive and unresponsive are therefore useful to indicate whether a change in knee kinetics can be achieved as a result of AFO-FC alignment change. This categorisation is based simply on the presence of a change in knee kinetics rather than the direction of change or degree of normalisation that has occurred. This means it is not sensitive to differences in baseline patterns of knee kinetics. Subsequent to a categorisation of responsive or non-responsive an optimal AFO-FC alignment could be defined as the SVA producing the knee kinetic pattern closest to normal values. If responsive children can be predicted beforehand, clinical management of this group could be considerably improved.

2.3.2.4 Which children are responsive?

The study by Butler and colleagues (2007) is the only study that has attempted to determine the characteristics that define children whose AFO-FCs were tuned successfully, compared with those whose AFO-FCs were not tuned successfully. While the rationale by which children were classified into the two groups is questionable, the study described a child likely to have their AFO-FC tune successfully to have a barefoot gait pattern of knee flexion less than 20° in the first third of stance phase followed by knee extension of less than 10° knee flexion in the second third of stance phase (Butler*, et al.*, 2007). This represents a relatively extended gait pattern, such as true equinus which is demonstrated in both spastic hemi- and diplegic children (refer to Figure 2.3, Figure 2.5). These findings concur with the findings of Jagadamma and colleagues (2009) who reported successfully tuning the AFO-FCs of five children demonstrating knee hyperextension.

The criterion from Butler and colleague's (2007) study for children whose AFO-FCs did not tune successfully is therefore the opposite; a barefoot gait pattern with knee flexion greater than 20° in early stance, with persistent knee flexion greater than 10° during the second third of stance phase (Butler*, et al.*, 2007). This describes a relatively flexed gait pattern, findings that are in line with anecdotal evidence that tuning is less successful in the AFO-FCs of those who have more flexed gait patterns and increased proximal muscle tightness (Butler & Nene, 1991), dynamic tone and the inability to reach near full extension dynamically at the hip and knee joints (Owen, 2004c). These types of gait patterns (refer to Figure 2.3 and Figure 2.5) represent the more severe end of the CP spectrum (Rodda & Graham, 2001).

Given the supposition that extended gait patterns may be more responsive and flexed gait patterns less responsive to a change in SVA, an explanation for this division becomes apparent. If the child can achieve foot flat during stance phase, they demonstrate a relatively extended gait pattern. Any change to the HSD of the AFO-FC will therefore affect the kinematics of the shank, and subsequently the orientation of the knee joint to the GRF vector (Figure 2.17). This is referred to as Mechanism 1 and is further explored in Chapter 4. In comparison, if a child demonstrates hip and knee flexion during stance phase while wearing an AFO in a plantigrade position, the foot will be inclined with regard to the floor with the heel elevated. The foot is not flat on the ground and therefore any change to the HSD of the AFO-FC will have no direct effect on the kinematics of the shank (Figure 2.18). This is referred to as Mechanism 2.

When the work by Butler and colleagues (2007) is considered in this light, the finding that only the AFO-FCs worn by children demonstrating a more extended gait pattern tuned successfully is expected, as their definition of successful tuning required both kinematic and kinetic changes to the knee. Thus, according to this criteria, the AFO-FCs or children with foot flat gait pattern will tune successfully (i.e. be responsive to AFO-FC alignment changes) because kinematics of the shank will always be affected.

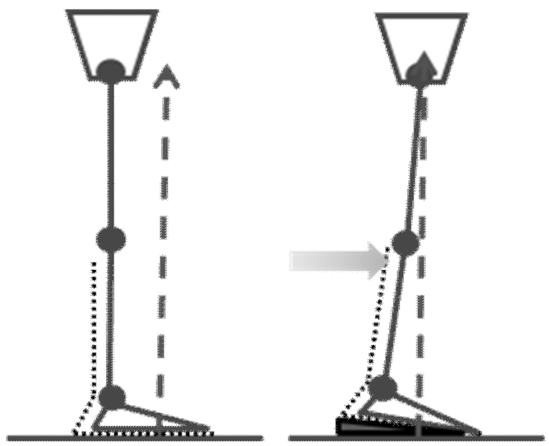


Figure 2.17 Mechanism 1: when the foot is flat on ground increased HSD results in shank inclination.

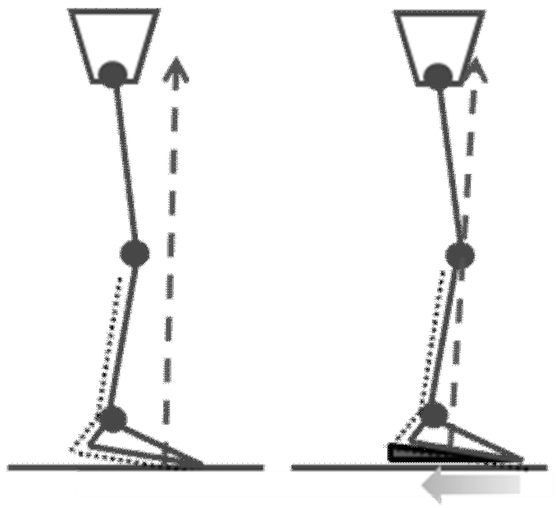


Figure 2.18 Mechanism 2: when the foot is inclined on ground increased HSD results in no change to shank inclination.

Many children with CP have flexed postural patterns and as such the question arises whether there are any benefits for this group of children. While the criteria from Butler and colleagues (2007) suggests that tuning was unsuccessful, Owen (2005) suggests attempting tuning even in children who have clinical predictors for lack of success, that is, hip and knee flexor tightness. She recommends increasing the HSD of the AFO-FC such that the sole of the shoe is brought to the floor, thus improving stability (Owen, 2004c). No studies have examined the effects of this wedging technique on gait, though Wesdock and Edge (2003) examined the effect of wedging on standing balance. Improvements in maximum standing time of an average 87 seconds was found to occur due to wedging the AFO-FCs in a sub-group of four children with CP, who could stand unaided for more than 15 seconds.

Wedging an AFO-FC in this manner may have two benefits. Firstly, the base of support over which the centre of mass must remain to maintain balance, is increased (Figure 2.19). This will shift the centre of pressure from its origin at the forefoot, posteriorly toward the centre of the foot (Figure 2.19). Figure 2.20 illustrates the corresponding shift of the position of the GRF vector posteriorly, which reduces the moment arms around the knee joint and the consequent external and internal joint moments. This allows the centre of mass (estimated as the level of the second sacral vertebrae) to shift posteriorly to remain within the base of support, which results in a more upright trunk posture.

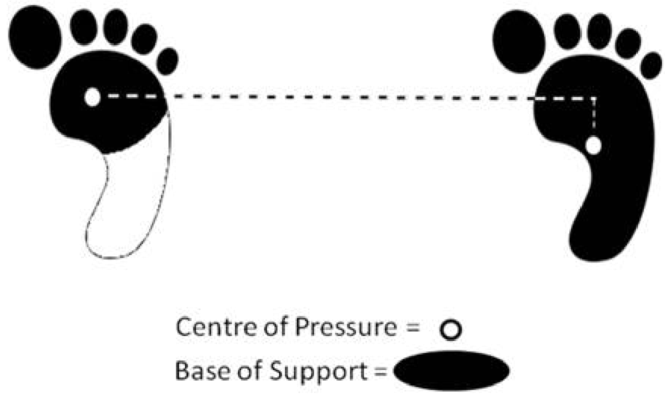


Figure 2.19 Increasing the HSD in a flexed limb increases the base of support thus shifting the centre of pressure posteriorly.

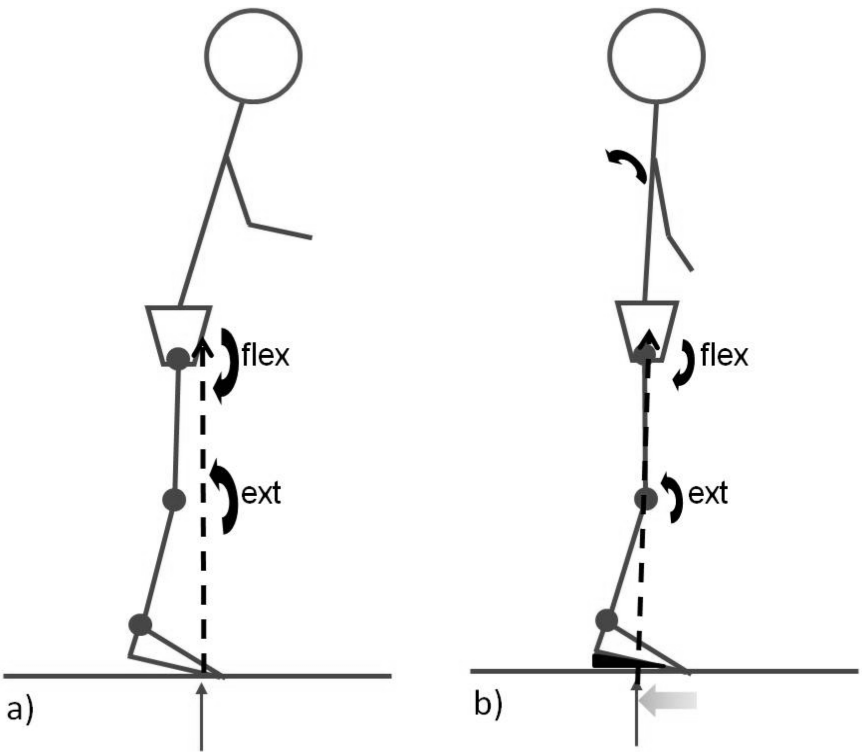


Figure 2.20 Increased HSD increases the base of support and shifts the centre of pressure posteriorly. Trunk lean, hip flexion moments and knee extension moments are reduced.

If this same theory is applied to the GRF orientation during the gait cycle, similar effects should result. A posterior shift in centre of pressure and hence of the GRF will alter knee kinetics with no changes to the shank kinematics. This mechanism could therefore normalise knee kinetics in children with a flexed gait pattern, while having no effect on knee or shank kinematics. This provides a second mechanism (refer to Figure 2.18) that is in contrast to the current theory (refer to Figure 2.17) where direct kinematic changes to shank inclination induces kinetic changes in children with an extended gait pattern.

No studies have investigated the effect of increased HSD on GRF alignment in children who walk with flexed gait patterns and therefore who do not achieve foot flat in their AFO-FC. If knee kinetics can be improved by increasing the HSD of the AFO-FC such children may also have the potential to benefit from an alignment procedure such as tuning. This idea not yet been recognised in current literature, and thus has potential to have a significant impact on our understanding of how AFO-FC alignment can affect gait in children with different gait patterns.

2.4 Evidence base for AFO-FC alignment

2.4.1 How does AFO-FC alignment affect gait?

Walking is an essential skill for functional mobility and as such is considered a component of the basic activities of daily living (James, 2008). Children with CP often walk with abnormal and more energy expensive gait patterns (Duffy*, et al.*, 1996; Johnston*, et al.*, 2004; Rose*, et al.*, 1990). The GRF vector is often at an abnormal position and orientation, and at greater distances from the lower limb joints (Hullin, Robb, & Loudon, 1996; Lin, Guo, Su, Chou, & Cherng, 2000). This produces large external moments that must be counteracted by equivalent internal muscle moments.

Although there is anecdotal evidence for the benefits of AFO-FC tuning (Anderson & Meadows, 1978; Bowers & Ross, 2009; Meadows*, et al.*, 1980; Owen, 2002), these are clinical observations that have not been rigorously tested. The following discussion outlines the available evidence describing the effect of AFO-FC alignment on knee kinetics and kinematics, hip kinetics and kinematics, temporospatial parameters and permanent motor learning. These data are summarised in Table 2.1 (p68).

This synthesis considers two methodological approaches that have been used to investigate the effect of AFO-FC alignment in children with CP. The first involves the previously described tuning process, whereby small trial-and-error adjustments are made to the AFO-FC alignment in an attempt to identify an optimal. The second method is to make systematic changes to the AFO-FC alignment in order to examine the effect of various alignments.

2.4.1.1 Knee kinetics

Knee kinetics have been the focus of the tuning procedure to date. In particular this has focussed on normalising any excessive external knee extension moment (Butler*, et al.*, 1997; Butler*, et al.*, 1992; Jagadamma*, et al.*, 2009; Stallard & Woollam, 2003). While two mechanisms have been identified by which changing the SVA of the AFO-FC is thought to affect body segments and GRF orientation, both will involve kinetic changes at the knee. Overall, the literature suggests that tuning an AFO-FC, will reduce and therefore normalise the peak knee extension moment in both adults and children (Bowers & Meadows, 2007; Butler*, et al.*, 1997; Butler*, et al.*, 2007; Butler*, et al.*, 1992; Jagadamma*, et al.*, 2009; Jagadamma*, et al.*, 2007). However several studies have noted that at the same time, this results in an increased peak knee flexion moment in early stance from 0.59 (±0.41) to 0.7 (±0.32) Nm/kg (Jagadamma*, et al.*, 2009). The only study to find no significant effect of SVA on knee kinetics attributed this to the range of SVAs tested being too small to induce a significant change on this variable. Two SVAs were tested which were 0° and 5-7° SVA (Fatone, Gard, & Malas, 2009). This study examined a group of adults with post-stroke hemiplegia and used articulated AFOs which may also been a contributor to the lack of change.

2.4.1.2 Knee kinematics

Despite several papers suggesting that the goal of the AFO-FC tuning process was to optimise knee kinematics (Bowers & Meadows, 2007; Butler*, et al.*, 2007; Meadows*, et al.*, 2008; Owen, 2004c; Stallard & Woollam, 2003), only a handful of studies reported changes to knee kinematics as a result of AFO-FC alignment change (Jagadamma*, et al.*, 2009; Jagadamma*, et al.*, 2007; Jagadamma*, et al.*, 2010; Reinthal & Hoy, 2005). These studies found reductions in peak knee extension angle in tuned AFO-FCs in children with CP as well as adults with post-stroke hemiplegia (Jagadamma*, et al.*, 2007; Jagadamma*, et al.*, 2010; Reinthal & Hoy, 2005). According to the two previously described mechanisms by which changing the SVA of the AFO-FC can affect gait, only Mechanism 1, involving children with a relatively extended gait pattern is expected to result in a change to the shank kinematics, and possibly also knee kinematics. In all of these examples the subjects demonstrated full knee extension.

It has been noted by several studies that in addition to reducing the amount of knee extension produced during mid-late stance, increased SVA also acts to increase knee flexion in early stance (Butler*, et al.*, 2007; Jagadamma*, et al.*, 2009; Jagadamma*, et al.*, 2007). This variable was quantified in only one case, and although increased by an average 6°, knee flexion was found not to be significantly different from the un-tuned condition (Jagadamma*, et al.*, 2009). The opinion of one author is however that any increase in early stance knee flexion is outweighed by the advantages of tuning (Butler*, et al.*, 2007).

2.4.1.3 Hip kinetics and kinematics

While several authors suggest that AFO-FC tuning should also be concerned with hip kinetics (Bowers & Meadows, 2007; Meadows*, et al.*, 2008; Owen, 2004b), only one case study investigating an adult with post-stroke hemiplegia, has specifically aimed to achieve more normal hip kinetics as a result of AFO-FC tuning (Bowers & Meadows, 2007). This report included photographs depicting the GRF vector superimposed on a video of the patient walking, indicating a re-orientation of the GRF vector from anterior to the hip joint to posterior, as well as increased contralateral step length. No quantitative data were reported.

2.4.1.4 Temporospatial parameters

Four studies have reported the effect of SVA on temporospatial parameters, one on children with CP (Jagadamma*, et al.*, 2009) and four on adults with post-stroke hemiplegia (Bowers & Meadows, 2007; Fatone*, et al.*, 2009; Lehmann, Condon, Price, & deLateur, 1987). Collectively, these studies suggest that in hemiplegic post-stroke adults an increased SVA is likely to increase walking velocity (Lehmann*, et al.*, 1987) and increase contralateral step length (Bowers & Meadows, 2007). Jagadamma and colleagues (2009) found similar effects in their hemiplegic CP subjects, with increased walking velocity (+0.06m/s) and increased cadence (+8 steps/min) in a tuned AFO-FC, whereas diplegic children showed a decrease in walking velocity (-0.06m/s); cadence (-12 steps/min) and stride length (-6cm). The authors suggest these differences may be due to diplegic children being less able to adjust to immediate changes in AFO alignment (Jagadamma*, et al.*, 2009). An alternate explanation may be that differences in gait patterns between the two groups affected the outcomes. If the two diplegic children demonstrated excessive knee flexion in early stance before hyperextending at the knee in mid-stance (eg jump knee gait), an increased SVA may have contributed to more detrimental effects during the first half of stance phase. The study by Fatone and colleages (2009) however found no significant differences in temporospatial parameters in their study of post-stroke adults, though this is likely due to the small magnitude of change in SVA.

2.4.1.5 Permanent motor learning

While the majority of research in this area has examined the immediate effect of AFO-FC alignment change on gait, several papers have suggested that permanent motor learning may occur as a result of improved GRF organisation in an ‘optimally aligned’ AFO-FC. These papers all described their subjects as demonstrating genu recurvatum though over a range of diagnoses including adults with acquired brain injury (Butler*, et al.*, 1997) and children with CP (Butler*, et al.*, 1992; Rosenthal*, et al.*, 1975). Improvements were seen in the barefoot gait pattern, specifically reduced (normalised) peak knee extension moment arms, after AFO wear. In all of these studies however, it is impossible to distinguish whether the results were due to simply wearing an AFO or to the effects of the tuning process. In the study by Butler and colleagues (1992) it is also impossible to separate the effects of balance training to that of the AFO.

One major limitation of much of this work is the lack of data describing gait in the baseline and tuned conditions. Several studies describe improvements in certain variables but report only a photograph with the GRF superimposed. In some cases this is because the study is published only in abstract form. Several other studies have however used 3DGA to either tune the AFO-FCs or provide a systematic assessment of the effect of SVA (Jagadamma*, et al.*, 2009; Jagadamma*, et al.*, 2007; Jagadamma*, et al.*, 2010). Unfortunately the protocol used to collect data in these papers has used only a single trial in each condition, which does not account for within subject variability.

The following table (Table 2.1) summarises the current available evidence investigating the effect of SVA on adults and children wearing solid and hinged AFOs.

Authors	**N; diagnosis; AFO type**	**Tuning technique; angles investigated**	**Findings (knee kinematics; knee kinetics; temporospatial and other)**
Case studies			
(Jagadamma, *et al.*, 2007)	N=1; child with CP demonstrating knee hyperextension; solid AFO *(abstract only)*	3DGA; systematic changes to SVA = 0, 10, 12, 13, 19, 22°	↑SVA = ↓peak KE angle and moment moment; ↑ KF at IC and peak KF angle
(Reinthal & Hoy, 2005)	N=1; child with CP with crouch gait; adjustable ankle solid AFO *(abstract only)*	3DGA; systematic changes to AFO ankle angle = 0, 5, 10, 15°	↑PF = ↓peak KF
(Jagadamma, *et al.*, 2010)	N=1; adult with post stroke hemiplegia; solid AFO	3DGA; tuned SVA & sole profile; T = 14° SVA	↓Tuned AFO-FC = ↓KE and ↑KF at initial contact
(Bowers & Meadows, 2007)	N=1; adult with post stroke hemiplegia; solid AFO	FVA; tuned SVA only	GRF alignment improved at hip and knee; improved temporospatial parameters. Video images only.
(Butler*, et al.*, 1997)	N=1; adult with acquired brain injury; solid AFO	FVA; tuned SVA only	Tuned AFO-FC = ↓peak KE moment
Studies of n>1			
(Jagadamma*, et al.*, 2009) & (Jagadamma *et al.*, 2008)	N= 5 children with CP; all hyperextend; solid AFOs	3DGA; tuned SVA only; T= 10.8° (1.8) SVA	Tuned AFO-FC = ↓peak KE moment and angle, ↑peak KF moment and angle, ↑KF at IC; improved temporospatial parameters in hemiplegic children, but not diplegic children
(Butler*, et al.*, 1992)	N=6 children with CP all hyperextend; solid AFOs	FVA; tuning component not stated; combined with targeted balance training to knees	Tuned AFO-FC = improved barefoot GRF orientation; Tuned AFO-FC = more upright trunk posture.
(Hullin*, et al.*, 1992)	N= 6; children with low-level myelomeningocele;	3DGA; tuned point loading rockers in	Point loading rocker = ↓knee hyperextension in sub-set of children where

Authors	N; diagnosis; AFO type	Tuning technique; angles investigated	Findings (knee kinematics; knee kinetics; temporospatial and other)
	solid AFOs	sub-set of participants	the AFO ankle angle was less dorsiflexed.
(Lehmann, *et al.*, 1987)	N=7; adults with post-stroke hemiplegia; double-stopped (solid) AFOs	3DGA; systematic changes to AFO ankle angle =5° DF vs 5° PF	Dorsiflexed AFO = ↑walking speed and KF moment.
(Fatone, *et al.*, 2009)	N=16; adults with post-stroke hemiplegia; hinged AFO with PF stop	3DGA; systematic change to AFO ankle = 0° vs 5-7°	No significant differences between conditions but large improvements compared to barefoot, especially for those with knee hyperextension.
Papers without gait data			
(Stallard & Woollam, 2003)	N=61; children with variety of pathologies; solid AFOs	FVA; tuned SVA	Reports outcomes of gait assessments, not results of tuning
(Owen, 2002)	N=74 children (112 limbs); children with neurological conditions (CP, spina bifida, other) *(abstract only)*	FVA; tuned SVA	For all children the SVA of the tuned AFO-FCs was mean SVA=11.36° (±2.08°, 7-15°). For children with CP (n=69), mean SVA =11.86°(±2.05°, 7-15°). For children with spina bifida (n=8), mean SVA=7.75° (±0.46°, 7-8°). For other children (n=35), mean SVA=11.28° (±1.41°, 8-14°).
(Owen, 2004a)	N=12; children with CP *(abstract only)*	FVA; tuned SVA and point loading rockers	Reports % foot length at which the point loading rockers were located
(Owen, 2005a)	N=0; *(abstract only)*	Tuning algorithm	A clinical algorithm for the design and tuning of AFO-FCs based on shank kinematics
(Owen, 2010)	Theoretical paper		
(Butler & Nene, 1991)	Theoretical paper		
(Butler, *et al.*, 2007)	N=21 children with CP; solid AFOs	FVG; tuned SVA only;	Retrospective review to determine baseline gait patterns of successful vs unsuccessful tuners
KF = knee flexion; KE = knee extension; FVA = force vector analysis; 3DGA = three dimensional gait analysis; PF = plantarflexion; DF = dorsiflexion			

Table 2.1 Summary of evidence describing the effect of AFO-FC alignment on gait in children and adults.

2.4.2 Implications for other AFO designs

The majority of research examining the effect of AFO-FC alignment has examined solid AFOs. Much of this literature has originated from the United Kingdom from facilities where solid AFOs are prescribed more commonly than other AFO designs (Owen, 2005a, 2005b). The types of AFOs prescribed for children with CP presenting with specific deficits are not however, consistent across facilities (Morris, Newdick, & Johnson, 2002). For example, at the Royal Children's Hospital, Melbourne, Australia, a hinged AFO is the AFO of choice provided there is adequate gastrocnemius muscle length, low spasticity, a stable foot and no excessive dorsiflexion during stance phase (Rodda & Graham, 2001).

The hinged AFO prevents plantarflexion beyond plantigrade, and therefore the inclination of the shank will reflect the SVA from heel contact until the point in the gait cycle at which dorsiflexion begins. After this point the tibia is unrestrained by the AFO and can rotate freely. Therefore, the SVA of a hinged AFO may influence the kinematics and kinetics of the lower limb in the earlier part of stance phase in a similar manner to solid AFOs, but will differ from the point the tibia begins to rotate around the foot. It is also possible that due to spasticity and contracture in the gastrocnemius muscle which is so often seen in children with CP, the range of dorsiflexion utilised in the hinged AFO will be limited. No studies have examined the effect of hinged AFO alignment changes on gait in children with CP.

2.5 Summary

This chapter has defined the individual components of the AFO and footwear combination that affect the SVA. It has been suggested that variety in the SVA of the AFO-FCs used in studies examining the efficacy of AFOs may contribute to the lack of conclusive evidence describing the effects of AFO-FCs on outcomes in children with CP. It is not known however, how well the wider body of orthotic literature with regard to children with CP report AFO-FC alignment, or how well it is considered.

The literature has been summarised to provide a critical review of the goal of the tuning process. The underlying theory describing how a change in AFO-FC alignment affects gait has been focused on a change in shank kinematics. This is thought to occur only when full contact is made with the foot to the floor. It is however proposed that this is only one of two distinct mechanisms by which an increase in HSD can affect GRF alignment to the lower limb joints. The second mechanism will occur when contact is made with the ground only with the forefoot. While no kinematic changes will occur as a result of increasing the HSD, the point of application of the GRF might shift posteriorly. On this basis it is hypothesised that tuning, or changing AFO-FC alignment will always affect the underlying kinetics and that this will only lead to a change in knee or shank kinematics when the foot is flat on the ground. It is not known whether patterns consistent with these two theoretical mechanisms actually exist.

While several authors have suggested that tuning is only effective in a sub-group of children, the ambiguity surrounding the definition of ‘successful’ calls this into question. A new method of categorising children based on responsiveness to alignment change has been proposed as a theoretical construct that accounts for differences in baseline SVA. In light of the above two mechanisms by which AFO-FC alignment change may affect gait, it is thus hypothesised that all children are responsive to AFO-FC alignment change.

There is also evidence to suggest that increasing the SVA of the AFO-FC will reduce peak external knee extension moment but will also increase peak knee flexion moment. In children with an extended gait pattern (full or excessive knee extension) there is some evidence to suggest that knee flexion angle in early stance will also increase, while knee extension angle in mid- to late stance will decrease. Very little is known however, about how parameters related to the hip, ankle and temporospatial parameters are affected by AFO-FC alignment. Overall, there is no evidence documenting the effect of AFO alignment change on a complete set of gait variables.

While solid AFOs have been the focus of tuning literature, hinged AFOs are a more common AFO design in the population of children with CP, in Melbourne, Australia. Changing the alignment in this AFO design is hypothesised to have similar effects to a solid AFO, although no studies have examined the effect of AFO-FC on hinged AFOs.

Therefore, an investigation into the effect of AFO-FC alignment on the gait of children with CP who wear either hinged or solid AFOs is warranted. This would examine whether all children were responsive to alignment change, and would provide a complete set of gait variables describing the effect of SVA on gait according to two AFO designs and across different gait patterns. If AFO-FC alignment can improve walking in these children, this provides grounding for implementation of AFO tuning procedures. This knowledge will also shed light onto interpreting the findings of past research.

2.6 Research Questions

The first five questions which will be addressed in this thesis are identified as follows:

1. How well is AFO-FC alignment reported within the wider body of literature?
2. How does changing AFO-FC alignment affect gait? Is there any evidence for the two mechanisms by which SVA can affect the biomechanics of walking?
3. Are all children responsive to AFO-FC alignment change?
4. What is the effect of systematic AFO-FC alignment change on the gait of children who wear solid and hinged AFOs?
5. Is there an optimal AFO-FC alignment?

3 A systematic review to determine best practice reporting guidelines for AFO interventions in studies involving children with CP

This chapter reports a systematic review that investigates the quality and level of detail reported about patient characteristics, the AFO intervention and testing protocol within the body of literature examining AFO intervention on children with cerebral palsy (CP). This includes an assessment of how well AFO-FC alignment and any associated tuning procedures have been reported, which was the first research question of this thesis. This review has been published in *Prosthetics and Orthotics International* and is included in Appendix A. This chapter provides an extended and enhanced version of the published review, providing discussion on the impact of these quality issues on the degree of confidence that can be had in the findings of these papers, and provides recommendations for improvements in future research in the form of best practice reporting guidelines. The outcomes of the review guide the focus of this thesis and the design of subsequent studies.

3.1 Introduction

Ankle-foot orthoses are a common non-invasive management option for children with CP. These devices are prescribed with a variety of aims including to improve walking, weight bearing, foot postures and musculoskeletal outcomes. However, the evidence supporting their effectiveness on a wide range of outcome measures within this population is limited. Reviewers have by and large, been unable to provide in-depth and meaningful conclusions describing the effect an AFO has on gait, apart from beneficial effects on temporospatial parameters and ankle kinematics (Bowers & Ross, 2009; Figueiredo*, et al.*, 2008; Morris, 2002).

Reviewers are not restricted in their ability to draw more significant conclusions due to lack of reviews or published research in this area. A significant body of literature has been published that has sought to quantify the effects of AFOs on children with CP. This includes two systematic reviews (Figueiredo*, et al.*, 2008; Morris, 2002) and one narrative review (Teplicky*, et al.*, 2002) published within the last eight years, with International Society for Prosthetics and Orthotics (ISPO) Consensus Conferences held on the topic in 1994 (International Society for Prosthetics and Orthotics, 1995) and more recently in 2008 (International Society for Prosthetics and Orthotics, 2009).

One factor that may restrict reviewers from drawing more substantial conclusions from this body of work is undoubtedly the heterogeneity of participants, interventions, testing protocols and outcome measures examined within this body of literature. This prevents any formal meta analyses and has been recognised as a characteristic limitation of this body of literature by several authors (Bowers & Ross, 2009; Figueiredo*, et al.*, 2008; Morris, 2002).

A second explanation relates to the quality of the studies included for review. Several reviewers have used Sackett's Levels of Evidence (Sackett, Straus, Richardson, Rosenberg, & Haynes, 2000) (refer to Figure 3.1) or other similar methods to assess evidence quality, and generally report this to be low for this body of research (Figueiredo*, et al.*, 2008; International Society for Prosthetics and Orthotics, 1995; Morris, 2002). These Levels of Evidence use an hierarchical approach to rank papers based on the elimination or minimisation of bias in research design (Sackett*, et al.*, 2000). The best type of evidence is considered to be a systematic review of randomised controlled trials (RCTs; Level 1a), followed by cohort studies, case controlled studies, case series and expert opinion as the lowest level of evidence (Level 5) (Sackett*, et al.*, 2000).

Level	Study design
1a	Systematic review (with homogeneity) of RCTs
1b	Individual RCT (with narrow confidence interval)
1c	All or none
2a	SR (with homogeneity) of cohort studies
2b	Individual cohort study (including low quality RCT; e.g., <80% follow-up)
2c	"Outcomes" Research; Ecological studies
3a	Systematic review (with homogeneity) of case-control studies
3b	Individual Case-Control Study
4	Case-series (and poor quality cohort and case-control studies§§)
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"

Figure 3.1 Sackett's Levels of Evidence (Sackett*, et al.*, 2000).

According to systems such as these, the quality of this body of work has not improved with the majority of papers ranked at Level 3 in 1994 (International Society for Prosthetics and Orthotics, 1995) and in 2006 (Figueiredo*, et al.*, 2008). As a result, reviewers recommend that this be addressed by conducting studies of higher ranking designs such as large scale RCTs (Morris, 2002) or one-group, interrupted time-series designs (single-subject design) (Bowers & Ross, 2009; Figueiredo*, et al.*, 2008; Morris, 2002).

The levels of evidence described by Sackett and colleagues (Sackett*, et al.*, 2000) is one example of a quality assessment system concerned largely with overall study design. An alternative quality assessment method is a checklist system that scores studies according to internal, external and statistical validity, thereby allowing them to be ranked by their score. One example is the PEDro scale for RCTs ("PEDro," 2008), which is presented below in Figure 3.2.

PEDro scale

1.	eligibility criteria were specified	no ❑ yes ❑ where:
2.	subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received)	no ❑ yes ❑ where:
3.	allocation was concealed	no ❑ yes ❑ where:
4.	the groups were similar at baseline regarding the most important prognostic indicators	no ❑ yes ❑ where:
5.	there was blinding of all subjects	no ❑ yes ❑ where:
6.	there was blinding of all therapists who administered the therapy	no ❑ yes ❑ where:
7.	there was blinding of all assessors who measured at least one key outcome	no ❑ yes ❑ where:
8.	measures of at least one key outcome were obtained from more than 85% of the subjects initially allocated to groups	no ❑ yes ❑ where:
9.	all subjects for whom outcome measures were available received the treatment or control condition as allocated or, where this was not the case, data for at least one key outcome was analysed by "intention to treat"	no ❑ yes ❑ where:
10.	the results of between-group statistical comparisons are reported for at least one key outcome	no ❑ yes ❑ where:
11.	the study provides both point measures and measures of variability for at least one key outcome	no ❑ yes ❑ where:

Figure 3.2 The PEDro scale ("PEDro," 2008).

The most recent systematic review of the effectiveness of AFOs on children with CP (Figueiredo*, et al.*, 2008) utilised the PEDro scale to assess study quality. Scores were out of a total of 10 because Item 1 was not scored. Scores were low, with two studies scoring 4/10, 17 scoring 3/10 and one study scoring 2/10. While the authors conclude that this is indicative of low quality evidence these results must be interpreted in light of the fact that four of the ten points on this scale focused on concealment of allocation and blinding (Items 3, 5-7) all of which are difficult if not impossible to apply in orthotic intervention studies. The PEDro scale is designed for RCTs but none of the included studies were RCTs. Scores could therefore be considered out of a total of six points rather than ten which highlights one of the limitations of using this checklist within this body of literature.

Quality assessment methods such as these, which focus on overall study design and aspects of internal, external and statistical validity, provide excellent insight when assessing these aspects of study quality. However, equally important is ensuring the quality by which the intervention itself is administered (Herbert & Bø, 2005). Assessing intervention quality acknowledges that the intervention may be administered differently across trials and that this may influence their effectiveness and may therefore be responsible for some of the variability in estimates of effects between trials (Herbert & Bø, 2005).

The effect of intervention quality is most problematic in complex health interventions, where the administration is likely to be different across different settings, and thus may be administered well or badly. Examples of complex multifaceted, interventions include physiotherapy programs, many surgical procedures, education programmes (Herbert & Bø, 2005) and arguably also studies of orthotic interventions. Methods of AFO prescription and choice of AFO design are often heavily influenced by the personal choice and experience of the staff, facility and geographical location and have been shown to vary between facilities (Morris*, et al.*, 2002).

Assessment of intervention quality relies on sufficient detail and transparency in trial reports (Herbert & Bø, 2005). Transparency refers to the level of detail and quality of the detail reported in the final publication or report. Within this specific body of literature reviewers have reported considerable variety in the depth and breadth of detail reported, particularly about the AFO intervention, the participants and testing protocol (Bowers & Ross, 2009; Desloovere*, et al.*, 2006; Figueiredo*, et al.*, 2008; Morris, 2002). Examples include the use of inconsistent terminology describing types of devices and in describing the ankle movements controlled by the AFO (Bowers & Ross, 2009; Desloovere*, et al.*, 2006; Morris, 2002); a lack of objective clinical measurement and assessment of the participant's functional status; and a lack of clear description of the parameters used to prescribe each type of device (Figueiredo*, et al.*, 2008).

Adequate transparency is necessary to determine the quality of the intervention and therefore the quality of the study. Only with good transparency can reviewers glean insightful and meaningful conclusions from a collective body of work. Reporting AFO-FC alignment is one example of information that is necessary in order to correctly interpret a study's findings. A review by Owen (2004b) suggests that the majority of studies investigating AFO-FCs and casts in children and adults with neurological disorders do not recognise or describe the AFO-FC alignment. There is however, a small body of evidence that suggests AFO-FC alignment may have a significant effect on sagittal plane knee kinematics and kinetics (Butler*, et al.*, 1992; Jagadamma*, et al.*, 2009; Jagadamma*, et al.*, 2007). Therefore, studies that have examined AFO-FCs with a variety of AFO-FC alignments, or which have not reported these alignments, may have confounding results. It is not known how well the studies that have examined AFO-FC on children with CP have reported these details. This information would help us better interpret the findings of previously conducted studies and would aid in the design of future investigations of the effectiveness of AFO-FCs on gait in children with CP.

Within this body of literature a wide variety of study designs, AFO designs, testing protocols and outcome measures have been applied on a population of children who are also inherently heterogeneous in their clinical presentation. This makes transparent reporting even more essential in communicating to the reader what was done, on whom, and why. Even if studies eliminate bias by virtue of study design, if the AFO intervention is not administered appropriately or is not described in sufficient detail to communicate this information clearly, the strength of the study's findings are compromised.

A lack of transparent reporting is not limited to this body of literature. Recent work described in the CONSORT statement (Boutron *et al.*, 2008), TREND statements (Des Jarlais, Lyles, Crepaz, Abbasi, & et al, 2004) and by the EQUATOR network (Altman, Simera, Hoey, Moher, & Schulz, 2008) emphasise that improved reporting transparency is necessary to improve the quality of health related research across all areas and study designs. These statements provide general guidelines for reporting of intervention detail in randomised and non-randomised trials, however there are currently no guidelines recommending the specific detail that should be reported in AFO intervention studies.

3.2 Aims

A systematic review of the literature investigating the effects of AFOs on children with CP was conducted to address two broad aims. The first was to assess the level of detail and quality of detail reported regarding the AFO interventions, the participants and testing protocol. This included assessment of how well studies reported sagittal plane AFO-FC alignment, and the procedures used to obtain this alignment, which was the first research question of this thesis. Secondly, it was anticipated that by focussing on examples of good practice within the literature, it would be possible to derive best practice guidelines for reporting of research in this area. It was hoped that use of these guidelines would improve the detail reported by future investigators and therefore improve the quality of this evidence-base.

3.3 Methods

3.3.1 Search Strategy

An electronic search of the literature was conducted in April 2009 using the following databases: MEDLINE (1966- April 2009), CINAHL (1982- April 2009), RECAL legacy database (1991-2009), EMBASE (1988-2009 week 18), AMED (1985- April 2009), INSPEC (1987- April 2009), ISI Web of Knowledge (sci-expanded, SSCI, A&HCI), Informit Databases (with the sub-selection of health, technology, science, engineering; 1998-2009), the Cochrane Database of Systematic Reviews (1991- April 2009) and the Physiotherapy Evidence Database (PEDro). Medline was also accessed using the internet (PubMed). Databases were searched from database inception with no a priori exclusions, restrictions or limits. Reference lists from the relevant identified papers were also searched manually.

A search using MESH terms and free text words was performed using the search terms related to "cerebral palsy", "child", "adolescent", "orthosis", "brace" and "AFO". Relevant truncation or wildcard symbols were used to retrieve all possible suffix variations of a root word. An example of the search strategy is listed below in Figure 3.3.

1) "cerebral pals$";

2) "child$" or "adolescen$";

3) "orthos$" or "orthot$" or "brace" or "AFO";

4) Combine 1 AND 2 AND 3.

Figure 3.3 Terms used in search of electronic databases.

3.3.2 Inclusion criteria

3.3.2.1 Participants

Studies were included if they examined children or adolescents (aged 6-18 years) who had a primary diagnosis of CP. Studies were excluded if they included participants with other diagnoses and did not present results separately for each diagnosis group.

3.3.2.2 Interventions

Papers were included in the review when they evaluated some aspect of AFO use in this group of children. An AFO was defined as an external supportive device that encompassed the ankle joint and the whole or part of the foot (International Organisation for Standardisation, 1989). This review limited inclusion to AFOs designed to control unwanted ankle movement from a biomechanical perspective and therefore included only AFO designs that extended to the proximal calf. Non-rigid AFOs such as elastic wrap or lace up ankle braces, Lycra garments and supramalleolar orthoses were excluded. Studies examining any of these devices in addition to other AFOs that matched the inclusion criteria were included. Devices referred to as dynamic ankle foot orthoses (DAFOs) were initially included and later excluded if further examination indicated that the devices were supramalleolar.

3.3.2.3 Outcome measures

To assess the effect of AFOs across the entire spectrum of outcome measures, studies examining any outcome measure or task were included. This included both ambulatory and non-ambulatory activities. Studies reporting any parameter including temporospatial, kinematic, kinetic, EMG, energy expenditure and any functional tasks were included.

3.3.2.4 Types of papers

Only full papers from peer reviewed journals were eligible for inclusion in the review. Papers in languages other than English were not included. Systematic reviews were excluded as were Level 4 and 5 studies such as case studies or opinion pieces (Sackett*, et al.*, 2000) as the focus of this review was experimental work. Non peer reviewed work such as theses and dissertations and any unpublished studies were not included to allow a reproducible search.

3.3.2.5 Evaluation methods

The title and abstract of each study identified from the search strategy was assessed by one reviewer (Emily Ridgewell) for inclusion or exclusion from the review. All papers that were initially discarded by the first reviewer were checked by the second reviewer (Fiona Dobson) to ensure no papers had been accidentally excluded. Any paper initially included but subsequently found not to meet the inclusion criteria was later excluded.

3.3.2.6 Data extraction and quality checklist

Data extraction refers to the process by which reviewers obtain information reported by the primary investigators (Khan, ter Riet, Kleijnen, Glanville, & Snowdon, 2001). Data extraction checklists have in the past been combined with quality checklists (eg. Dobson*, et al.*, 2007) that allow an assessment of the level of detail reported in a study. These checklists provide a useful tool for the systematic recording and reporting of specific data across a range of papers.

As no standardised or validated quality checklists were available for this type of review, a new data extraction and quality checklist was designed. Past literature reviews and studies in this area (Desloovere*, et al.*, 2006; Figueiredo*, et al.*, 2008; Morris, 2002; Teplicky*, et al.*, 2002) and in other areas of orthotic management (Bowers, 2007; Dillon, Fatone, & Hodge, 2007; Fatone, 2006), ISPO Consensus Conference documents (International Society for Prosthetics and Orthotics, 1995; Owen*, et al.*, 2004), and systematic review and checklist guidelines (Downs & Black, 1998; Khan*, et al.*, 2001; Oxman, 1994; "PEDro," 2008; Updated February 2008; Treatment Outcomes Committee, 2004; Wells *et al.*) were used to guide design.

The major themes for data extraction covered areas of general information including reviewer name and article identifiers; details regarding the type of study design, types and numbers of participants and interventions; and details regarding the participants, the AFOs and testing protocol (which were the primary focus of the quality assessment). Table 3.1 outlines the details obtained using this checklist.

Both reviewers piloted the data extraction and quality form independently on a sub-group of papers to check the form content and reliability. Inter-rater agreement was 81%. The draft checklist was subsequently altered to provide improved clarity and instruction. Following independent review of all papers by both reviewers, all non-consensus items were discussed until a consensus was reached. Each quality item had detailed pre-determined qualifiers to allow objective categorisation for each response. Any discrepancies were investigated using the original article to ascertain the correct response based on the objective a priori decision rules. Full consensus was reached on all items.

(item)		*(record details)*
Identifiers		
Authors, date, journal & reviewer initials		
General information		
Participant diagnoses Number of participants Intervention Control Study design Activity/outcome measures		
(item)	*(choose response)*	*(record details)*
Participant details		
Age	Complete/incomplete	Mean, SD, range
Diagnosis	Complete/incomplete	Topographic & type of movement disorder
Common deviation at ankle*	Clear/ambiguous/not stated/na	
Common deviation at knee*	Clear/ambiguous/not stated/na	
Common deviation at hip*	Clear/ambiguous/not stated/na	
Passive ankle (gastroc%) ROM	Individual/group/inclusion criteria/not stated	
Passive knee ROM	Individual/group/inclusion criteria/not stated	
Passive hip ROM	Individual/group/inclusion criteria/not stated	
AFO detail		
Orthotic aim	Clear/ambiguous/not stated/other	
Movements	Complete (all clear)/incomplete (some or all unclear)	Assisted, prevented and permitted
AFO ankle angle	Specified for individual/group/ambiguous/not stated/other	Ankle angle in AFO
Toe plate length	All clear/some clear/all ambiguous	Full length or 3/4
Materials	Complete/partial/not stated/na	Material & thickness
Manufacture	Custom made/prefabricated/not stated	
If prefab, is device name & supplier listed?	Yes/no	
Tuning	Complete/partial/not stated/na	Tuned? Details?
Shank-to-vertical angle	Complete/partial/not stated/na	Final value
Testing protocol		
Order of testing	Randomised/non randomised/not stated/na	
Acclimatisation	<1 day, 1-6days, 1-4weeks, >4 weeks/not stated/na	
Control condition	Barefoot/shoes/not stated	
Test condition	Clear/ambiguous/not stated	
** Deviation e.g. a pattern of movement occurring at each of these joints.* *% Ankle ROM (gastroc) =ankle ROM with knee extension* *na=not applicable*		

Table 3.1 Customised data extraction and quality checklist.

3.4 Results

3.4.1 Search yield

After removal of duplicates, the electronic search of selected databases identified 374 articles as having possible relevance to the use of AFOs in children with CP. Targeted searching revealed 55 articles that were all later discarded as duplicates. After applying the inclusion criteria, 41 full papers were included in the review.

3.4.2 Demographic and descriptive aspects

The total yield was published across 17 journals. More studies examined children with diplegic CP than hemiplegic CP with a total of 1201 children examined over a period of 38 years. The majority of articles were published after 1995.

Eleven different devices or device designs were examined. A barefoot condition was examined in 28 studies, a shod condition was examined in six studies, and one study included both barefoot and shod conditions (Desloovere*, et al.*, 2006). Eleven studies were retrospective with a prospective design in the remaining 30 studies. The majority of studies examined gait while walking on a level surface.

Table 3.2 presents the study details and demographics for the 41 paper yield. This includes participant diagnosis, number of participants, intervention, control, study design and primary activity/outcome examined.

Authors	Diagnosis	N=	Intervention	Control	Study design			Activity/Outcome
Rosenthal '75	Not stated	12	GRAFO	BF	retrospective	longitudinal	case control	Genu recurvatum
Simon '78	Hemiplegia & diplegia	15	SAFO	BF	prospective	cross sect	case control	Genu recurvatum
Sankey '89	Hemiplegia	29	SAFO	n/a	retrospective	cross sect	cohort/population	Surgery rates
Mossberg '90	Diplegia	18	AFOs on vs AFOs off	unknown	prospective	cross sect	case control	Level walking
Butler '92	Hemiplegia & diplegia	21	SAFO	BF	prospective	cross sect	cohort	Genu recurvatum
Ounpuu '96	Hemiplegia & diplegia	31	PLS	BF	retrospective	cross sect	case control	Level walking
Carlson'97	Diplegia	11	SAFO	shoes	prospective	cross sect	case control	Level walking
Hainsworth '97	Hemiplegia & diplegia	12	AFOs on vs AFOs off	BF	prospective	longitudinal	case control	AFO withdrawal
Radkta '97	Hemiplegia & diplegia	10	SAFO, short leg AFO+ TRF	BF	prospective	cross sect	case control	Level walking
Wilson '97	Diplegia	15	SAFO, HAFO	BF	prospective	cross sect	case control	Sit-stand
Abel '98	Diplegia	35	SAFO	BF	retrospective	cross sect	case control	Level walking
Brunner '98	Hemiplegia	14	SAFO, spring type AFO	BF	prospective	cross sect	case control	Level walking
Burtner '99	Diplegia	4	SAFO, carbon spiral AFO	unknown	prospective	cross sect	case control	Standing balance
Rethlefsen '99	Diplegia	21	SAFO, HAO	shoes	prospective	cross sect	case control	Level walking
Crenshaw '00	Diplegia	8	HAFO, HAFO+TRF	shoes	prospective	cross sect	case control	Level walking
Suzuki '00	Diplegia	6	HAFO	unknown	prospective	cross sect	case control	Level walking
Beals '01	Not stated	4	SAFO	BF	prospective	cross sect	case control	Trunk posture
Buckon '01	Hemiplegia	30	SAFO, HAFO, PLS	BF	prospective	cross sect	case control	Level walking
Maltais'01	Diplegia	10	HAFO	shoes	prospective	cross sect	case control	Level walking
Dursun '02	Hemiplegia & diplegia	24	Unknown	BF	prospective	cross sect	case control	Level walking
Kott '02	Mixed	28	orthoses on vs orthoses off	unknown	prospective	cross sect	case control	Obstacle course
Romkes '02	Hemiplegia	12	HAFO	BF	prospective	cross sect	case control	Level walking
Sienko-T. '02	Hemiplegia	19	SAFO, HAFO, PLS	BF	prospective	cross sect	case control	Stair climbing
Smiley '02	Diplegia	14	SAFO, HAFO, PLS	shoes	prospective	cross sect	case control	Level walking
Thompson '02	Hemiplegia	18	SAFO	BF	prospective	cross sect	case control	Level walking
White '02	Hemiplegia & diplegia	115	SAFO or HAFO	BF	retrospective	cross sect	case control	Level walking
Wesdock '03	Mixed	11	SAFO, wedged AFO	shoes	prospective	cross sect	case control	Standing balance
Buckon '04	Diplegia	16	SAFO, HAFO, PLS	BF	prospective	cross sect	case control	Level walking
Park '04	Diplegia	19	HAFO	BF	prospective	cross sect	case control	Sit-stand

Authors	Diagnosis	N=	Intervention	Control	Study design			Activity/Outcome
Lam '05	Diplegia	13	SAFO	BF	prospective	cross sect	case control	Level walking
Radtka '05	Diplegia	12	SAFO, HAFO	BF	prospective	cross sect	case control	Level walking
Desloovere '06	Hemiplegia	15	PLS, CFO	BF & shoes	prospective	cross sect	case control	Level walking
Romkes '06	Hemiplegia	10	HAFO	BF	prospective	cross sect	case control	Level walking
Balaban '07	Hemiplegia	11	HAFO	BF	prospective	cross sect	case control	Level walking
Butler '07	Mixed	6	SAFO	n/a	retrospective	cross sect	cohort	Group analysis*
Hayek '07	Hemiplegia & diplegia	56	community prescribed AFOs	BF	retrospective	cross sect	case control	Level walking
Lucareli '07	Diplegia	71	hinged GRAFO	BF	retrospective	cross sect	case control	Level walking
Westberry '07	Mixed	102	Unknown	BF	retrospective	cross sect	case control	Bony alignment
Brehm '08	Mixed	172	SAFO or PLS	BF	retrospective	cross sect	case control	Level walking
Van Gestel '08	Hemiplegia	36	PLS, CFO, orteams	BF	retrospective	cross sect	case control	Level walking
Smith '09	Diplegia	15	HAFO, dynamic AFO	BF	prospective	cross sect	case control	Level walking

HAFO = hinged AFO with plantarflexion stop, PLS = posterior leaf spring, GRAFO = ground reaction AFO, SAFO = solid AFO, CFO = carbon fibre orthosis, TRF = tone reducing features, BF = barefoot. Examined the gait patterns of children whose AFOs did and did not tune successfully*

Table 3.2 Demographic and descriptive aspects of all studies, in chronological order.

3.4.3 Quality assessment

Tables 3.3 & 3.4 present the results of the quality assessment of this systematic review. The following section provides a summary of these results according to the sections on participant details, AFO details and testing protocol.

3.4.3.1 Participant details

Topographical diagnosis (39/41) and participant age (36/41) were well reported. More studies provided information on passive ankle ROM (23/41) than knee (11/41) and hip ROM (10/41). Nineteen of the 41 studies made a clear attempt at describing a common pattern of abnormality or indication that was demonstrated by all participants, at the ankle, knee or hip joint. One study (Smith*, et al.*, 2009) clearly described a homogenous gait characteristic demonstrated by all participants. A homogenous mode of ankle movement was described most frequently (14/41), followed by knee movement (10/41) and three papers described a common pattern of hip movement.

3.4.3.2 AFO details

Seventeen studies clearly stated the orthotic aim of the AFO. A clear description of the type of AFO intervention was provided by most studies, as were clear descriptions of the movements prevented, assisted or permitted by the AFO (35/41). Sixteen studies clearly stated the AFO ankle angle. Nineteen studies gave clear descriptions of toe plate length for all devices tested. In some cases it was necessary to infer this information from photographs or diagrams. A full-length toe plate was used more often (18/41) than ¾-length toe plate (4/41). Two studies investigated both full length and ¾ toe plate lengths. Ten papers provided complete detail on both material type and thickness, and eight more papers provided partial information.
Five studies reported that the AFOs were tuned prior to testing. One study provided the final shank-to-vertical angle of the AFOs tested and two provided partial information. Custom made devices were most commonly tested (18/41). Three studies tested prefabricated devices with the name of the device and supplier provided by one study. The remaining twenty studies did not state whether the device was custom made or prefabricated.

3.4.3.3 Testing protocol

More studies used a randomised order of testing (16/41) than non-random (12/41). The remaining studies either did not report this information or the item was not applicable. Twenty studies tested devices unfamiliar to the participant. Across these studies the acclimatisation times ranged from less than one day (2/20), 1-4 weeks (4/20) or greater than four weeks (8/20). The remaining studies did not provide this information. Most studies clearly stated the control condition with barefoot being the most common (28/41), followed by shoes (6/41) and both barefoot and shoes (1/41). The test condition was clearly stated in most studies.

Item & Response	Number of studies	
Participant details		
Age		
Complete	36	(Abel, *et al.*, 1998; Balaban, *et al.*, 2007; Brehm, *et al.*, 2008; Brunner, *et al.*, 1998; Buckon, *et al.*, 2001; Buckon, *et al.*, 2004; Butler, *et al.*, 2007; Butler, *et al.*, 1992; Carlson, *et al.*, 1997; Crenshaw, *et al.*, 2000; Desloovere, *et al.*, 2006; Dursun, *et al.*, 2002; Hainsworth, *et al.*, 1997; Hayek, *et al.*, 2007; Kott & Held, 2002; Lam, *et al.*, 2005; Lucareli & Lima, 2007; Maltais, *et al.*, 2001; Mossberg, *et al.*, 1990; Ounpuu, *et al.*, 1996; Park, *et al.*, 2004; Radtka, *et al.*, 1997; Radtka, *et al.*, 2005; Rethlefsen, *et al.*, 1999; Romkes & Brunner, 2002; Romkes, *et al.*, 2006; Sienko-Thomas, *et al.*, 2002; Simon, *et al.*, 1978; Smiley, *et al.*, 2002; Smith, *et al.*, 2009; Suzuki, *et al.*, 2000; Thompson, *et al.*, 2002; Van Gestel, *et al.*, 2008; Wesdock & Edge, 2003; Westberry, *et al.*, 2007; White, *et al.*, 2002)
Diagnosis		
Complete	39	(Abel, *et al.*, 1998; Balaban, *et al.*, 2007; Brehm, *et al.*, 2008; Brunner, *et al.*, 1998; Buckon, *et al.*, 2001; Buckon, *et al.*, 2004; Burtner, *et al.*, 1999; Butler, *et al.*, 2007; Butler, *et al.*, 1992; Carlson, *et al.*, 1997; Crenshaw, *et al.*, 2000; Desloovere, *et al.*, 2006; Dursun, *et al.*, 2002; Hainsworth, *et al.*, 1997; Hayek, *et al.*, 2007; Kott & Held, 2002; Lam, *et al.*, 2005; Lucareli & Lima, 2007; Maltais, *et al.*, 2001; Mossberg, *et al.*, 1990; Ounpuu, *et al.*, 1996; Park, *et al.*, 2004; Radtka, *et al.*, 1997; Radtka, *et al.*, 2005; Romkes & Brunner, 2002; Romkes, *et al.*, 2006; Rosenbaum, *et al.*, 2007; Sankey, *et al.*, 1989; Sienko-Thomas, *et al.*, 2002; Simon, *et al.*, 1978; Smiley, *et al.*, 2002; Smith, *et al.*, 2009; Suzuki, *et al.*, 2000; Thompson, *et al.*, 2002; Van Gestel, *et al.*, 2008; Wesdock & Edge, 2003; Westberry, *et al.*, 2007; White, *et al.*, 2002; Wilson, *et al.*, 1997)
Common indication at joint		
Clear at ankle	14	(Abel, *et al.*, 1998; Balaban, *et al.*, 2007; Brunner, *et al.*, 1998; Butler, *et al.*, 1992; Dursun, *et al.*, 2002; Radtka, *et al.*, 1997; Radtka, *et al.*, 2005; Romkes & Brunner, 2002; Romkes, *et al.*, 2006; Simon, *et al.*, 1978; Smith, *et al.*, 2009; Thompson, *et al.*, 2002; Van Gestel, *et al.*, 2008; Wilson, *et al.*, 1997)
Clear at knee	10	(Brunner, *et al.*, 1998; Buckon, *et al.*, 2001; Butler, *et al.*, 2007; Butler, *et al.*, 1992; Lucareli & Lima, 2007; Simon, *et al.*, 1978; Smith, *et al.*, 2009; Thompson, *et al.*, 2002; Van Gestel, *et al.*, 2008; Wesdock & Edge, 2003)
Clear at hip	3	(Butler, *et al.*, 1992)
Passive ROM		
Ankle Complete	23	(Abel, *et al.*, 1998; Balaban, *et al.*, 2007; Buckon, *et al.*, 2001; Buckon, *et al.*, 2004; Burtner, *et al.*, 1999; Butler, *et al.*, 1997; Butler, *et al.*, 1992; Crenshaw, *et al.*, 2000; Dursun, *et al.*, 2002; Hainsworth, *et al.*, 1997; Lucareli & Lima, 2007; Park, *et al.*, 2004; Radtka, *et al.*, 1997; Radtka, *et al.*, 2005; Rethlefsen, *et al.*, 1999; Romkes & Brunner, 2002; Romkes, *et al.*, 2006; Smiley, *et al.*, 2002; Smith, *et al.*, 2009; Suzuki, *et al.*, 2000; Wesdock & Edge, 2003; White, *et al.*, 2002; Wilson, *et al.*, 1997)
Knee Complete	11	(Burtner, *et al.*, 1999; Butler, *et al.*, 2007; Butler, *et al.*, 1992; Lucareli & Lima, 2007; Park, *et al.*, 2004; Radtka, *et al.*, 1997; Radtka, *et al.*, 2005; Rethlefsen, *et al.*, 1999; Romkes & Brunner, 2002; Wesdock & Edge, 2003; Wilson, *et al.*, 1997)
Hip Complete	10	(Burtner, *et al.*, 1999; Butler, *et al.*, 2007; Butler, *et al.*, 1992; Lucareli & Lima, 2007; Park, *et al.*, 2004; Radtka, *et al.*, 1997; Radtka, *et al.*, 2005; Rethlefsen, *et al.*, 1999; Wesdock & Edge, 2003; Wilson, *et al.*, 1997)
AFO details		
Orthotic aim		
Clear	17	(Abel, *et al.*, 1998; Beals, 2001; Brunner, *et al.*, 1998; Buckon, *et al.*, 2004; Carlson, *et al.*, 1997; Desloovere, *et al.*, 2006; Dursun, *et al.*, 2002; Lucareli & Lima, 2007; Ounpuu, *et al.*, 1996; Radtka, *et al.*, 1997; Radtka, *et al.*, 2005; Rosenthal, *et al.*, 1975; Simon, *et al.*, 1978; Suzuki, *et al.*, 2000; Van Gestel, *et al.*, 2008; Wesdock & Edge, 2003; Wilson, *et al.*, 1997)
Movements		
Complete	35	(Abel, *et al.*, 1998; Balaban, *et al.*, 2007; Beals, 2001; Brehm, *et al.*, 2008; Brunner, *et al.*, 1998; Buckon, *et al.*, 2001; Buckon, *et al.*, 2004; Burtner, *et al.*, 1999; Butler, *et al.*, 2007; Butler, *et al.*, 1992; Carlson, *et al.*, 1997; Crenshaw, *et al.*, 2000; Desloovere, *et al.*, 2006; Hainsworth, *et al.*, 1997; Lam, *et al.*, 2005; Lucareli & Lima, 2007; Maltais, *et al.*, 2001; Ounpuu, *et al.*, 1996; Park, *et al.*, 2004; Radtka, *et al.*, 2005; Rethlefsen, *et al.*, 1999; Romkes & Brunner, 2002; Romkes, *et al.*, 2006; Rosenthal, *et al.*, 1975; Sankey, *et al.*, 1989; Sienko-Thomas, *et al.*, 2002; Simon, *et al.*, 1978; Smiley, *et al.*, 2002; Smith, *et*

Item & Response	Number of studies	
		al., 2009; Suzuki, *et al.*, 2000; Thompson, *et al.*, 2002; Van Gestel, *et al.*, 2008; Wesdock & Edge, 2003; White, *et al.*, 2002; Wilson, *et al.*, 1997)
AFO ankle angle		
Clear	16	(Balaban, *et al.*, 2007; Beals, 2001; Buckon, *et al.*, 2001; Buckon, *et al.*, 2004; Crenshaw, *et al.*, 2000; Hainsworth, *et al.*, 1997; Lam, *et al.*, 2005; Maltais, *et al.*, 2001; Park, *et al.*, 2004; Radtka, *et al.*, 2005; Romkes, *et al.*, 2006; Sienko-Thomas, *et al.*, 2002; Smith, *et al.*, 2009; Suzuki, *et al.*, 2000; Wesdock & Edge, 2003; Wilson, *et al.*, 1997)
Toe plate length		
Full length	16	(Buckon, *et al.*, 2001; Buckon, *et al.*, 2004; Crenshaw, *et al.*, 2000; Desloovere, *et al.*, 2006; Lam, *et al.*, 2005; Ounpuu, *et al.*, 1996; Park, *et al.*, 2004; Radtka, *et al.*, 1997; Radtka, *et al.*, 2005; Romkes & Brunner, 2002; Romkes, *et al.*, 2006; Smith, *et al.*, 2009; Suzuki, *et al.*, 2000; Van Gestel, *et al.*, 2008; Wilson, *et al.*, 1997)
Different lengths (clear or ambiguous)	4	(Sankey, *et al.*, 1989; Smiley, *et al.*, 2002; Thompson, *et al.*, 2002; White, *et al.*, 2002)
Material & thickness		
Complete	10	(Buckon, *et al.*, 2001; Buckon, *et al.*, 2004; Lam, *et al.*, 2005; Radtka, *et al.*, 1997; Radtka, *et al.*, 2005; Smiley, *et al.*, 2002; Smith, *et al.*, 2009; Thompson, *et al.*, 2002; White, *et al.*, 2002; Wilson, *et al.*, 1997)
Partial	8	(Abel, *et al.*, 1998; Brunner, *et al.*, 1998; Burtner, *et al.*, 1999; Crenshaw, *et al.*, 2000; Park, *et al.*, 2004; Rosenthal, *et al.*, 1975; Suzuki, *et al.*, 2000; Van Gestel, *et al.*, 2008)
Manufacture		
Custom	18	(Balaban, *et al.*, 2007; Brehm, *et al.*, 2008; Brunner, *et al.*, 1998; Buckon, *et al.*, 2001; Buckon, *et al.*, 2004; Crenshaw, *et al.*, 2000; Desloovere, *et al.*, 2006; Lam, *et al.*, 2005; Ounpuu, *et al.*, 1996; Radtka, *et al.*, 1997; Radtka, *et al.*, 2005; Rethlefsen, *et al.*, 1999; Rosenthal, *et al.*, 1975; Sienko-Thomas, *et al.*, 2002; Smiley, *et al.*, 2002; Smith, *et al.*, 2009; Thompson, *et al.*, 2002; Wilson, *et al.*, 1997)
Prefab. no detail	2	(Burtner, *et al.*, 1999; Van Gestel, *et al.*, 2008)
Prefab. with detail	1	(Suzuki, *et al.*, 2000)
Tuning		
Tuned	5	(Butler, *et al.*, 2007; Butler, *et al.*, 1992; Desloovere, *et al.*, 2006; Rosenthal, *et al.*, 1975; Van Gestel, *et al.*, 2008)
Shank-to-vertical angle		
Clear/ambiguous	5	(Desloovere, *et al.*, 2006; Lam, *et al.*, 2005; Romkes, *et al.*, 2006; Rosenthal, *et al.*, 1975; Van Gestel, *et al.*, 2008)
Testing protocol		
Order of testing		
Randomised	16	(Balaban, *et al.*, 2007; Buckon, *et al.*, 2001; Buckon, *et al.*, 2004; Carlson, *et al.*, 1997; Desloovere, *et al.*, 2006; Kott & Held, 2002; Lam, *et al.*, 2005; Maltais, *et al.*, 2001; Mossberg, *et al.*, 1990; Park, *et al.*, 2004; Radtka, *et al.*, 2005; Rethlefsen, *et al.*, 1999; Sienko-Thomas, *et al.*, 2002; Smith, *et al.*, 2009; Wesdock & Edge, 2003; Wilson, *et al.*, 1997)
Non randomised	12	(Abel, *et al.*, 1998; Beals, 2001; Brehm, *et al.*, 2008; Brunner, *et al.*, 1998; Hayek, *et al.*, 2007; Ounpuu, *et al.*, 1996; Radtka, *et al.*, 1997; Simon, *et al.*, 1978; Thompson, *et al.*, 2002; Van Gestel, *et al.*, 2008; Westberry, *et al.*, 2007; White, *et al.*, 2002)
Not applicable	3	(Butler, *et al.*, 2007; Hainsworth, *et al.*, 1997; Rosenthal, *et al.*, 1975)
Acclimatisation		
<1 day	2	(Smiley, *et al.*, 2002; Wilson, *et al.*, 1997)
1-4 weeks	4	(Butler, *et al.*, 1992; Hainsworth, *et al.*, 1997; Romkes & Brunner, 2002; Wesdock & Edge, 2003)
>4 weeks	8	(Buckon, *et al.*, 2001; Buckon, *et al.*, 2004; Carlson, *et al.*, 1997; Crenshaw, *et al.*, 2000; Radtka, *et al.*, 1997; Radtka, *et al.*, 2005; Sienko-Thomas, *et al.*, 2002; Smith, *et al.*, 2009)
Not applicable	21	(Abel, *et al.*, 1998; Balaban, *et al.*, 2007; Beals, 2001; Brehm, *et al.*, 2008; Butler, *et al.*, 2007; Dursun, *et al.*, 2002; Hayek, *et al.*, 2007; Kott & Held, 2002; Lucareli & Lima, 2007; Maltais, *et al.*, 2001; Mossberg, *et al.*, 1990; Ounpuu, *et al.*, 1996; Park, *et al.*, 2004; Romkes, *et al.*, 2006; Rosenthal, *et al.*, 1975; Sankey, *et al.*, 1989; Simon, *et al.*, 1978; Thompson, *et al.*, 2002; Van Gestel, *et al.*, 2008; Westberry, *et al.*, 2007; White, *et al.*, 2002)

Item & Response	**Number of studies**	
Control condition		
Barefoot	28	(Abel*, et al.*, 1998; Balaban*, et al.*, 2007; Beals, 2001; Brehm*, et al.*, 2008; Brunner*, et al.*, 1998; Butler*, et al.*, 1992; Dursun*, et al.*, 2002; Hainsworth*, et al.*, 1997; Hayek*, et al.*, 2007; Lam*, et al.*, 2005; Lucareli & Lima, 2007; Ounpuu*, et al.*, 1996; Park*, et al.*, 2004; Radtka*, et al.*, 1997; Radtka*, et al.*, 2005; Romkes & Brunner, 2002; Romkes*, et al.*, 2006; Rosenthal*, et al.*, 1975; Sienko-Thomas*, et al.*, 2002; Simon*, et al.*, 1978; Smith*, et al.*, 2009; Thompson*, et al.*, 2002; Van Gestel*, et al.*, 2008; Westberry*, et al.*, 2007; White*, et al.*, 2002; Wilson*, et al.*, 1997)
Shoes	6	(Carlson*, et al.*, 1997; Crenshaw*, et al.*, 2000; Maltais*, et al.*, 2001; Rethlefsen*, et al.*, 1999; Smiley*, et al.*, 2002; Wesdock & Edge, 2003)
Barefoot & shoes	1	(Desloovere*, et al.*, 2006)
Not applicable	2	(Butler*, et al.*, 2007; Sankey*, et al.*, 1989)
Test condition		
Clear	35	(Abel*, et al.*, 1998; Balaban*, et al.*, 2007; Beals, 2001; Brehm*, et al.*, 2008; Brunner*, et al.*, 1998; Buckon*, et al.*, 2001; Buckon*, et al.*, 2004; Burtner*, et al.*, 1999; Butler*, et al.*, 2007; Butler*, et al.*, 1992; Carlson*, et al.*, 1997; Crenshaw*, et al.*, 2000; Desloovere*, et al.*, 2006; Lam*, et al.*, 2005; Lucareli & Lima, 2007; Maltais*, et al.*, 2001; Mossberg*, et al.*, 1990; Ounpuu*, et al.*, 1996; Park*, et al.*, 2004; Radtka*, et al.*, 1997; Radtka*, et al.*, 2005; Rethlefsen*, et al.*, 1999; Romkes & Brunner, 2002; Romkes*, et al.*, 2006; Rosenthal*, et al.*, 1975; Sackett*, et al.*, 2000; Sankey*, et al.*, 1989; Sienko-Thomas*, et al.*, 2002; Simon*, et al.*, 1978; Smiley*, et al.*, 2002; Smith*, et al.*, 2009; Suzuki*, et al.*, 2000; Thompson*, et al.*, 2002; Van Gestel*, et al.*, 2008; Wesdock & Edge, 2003; Wilson*, et al.*, 1997)
All unlisted papers were categorised as either ambiguous or not stated		

Table 3.3 Summary of responses to each quality item where the outcome was clear.

	Participant details				AFO details						Testing protocol		
Authors	Age	Diagnosis	Common attribute	Passive ROMs	Orthotic aim	AFO move-ment	AFO ankle angle	Toe plate length	Materials	Alignment	Prefab or custom?	Randomised testing order?	Acclimati-sation time
Rosenthal ’75	-	-	K	-	clear	complete	ambiguous	-	ambiguous	T? SVA?	custom	n/a	n/a
Simon ’78	complete	complete	A, K	H	clear	complete	ambiguous	-	-	-	?custom	no	n/a
Sankey ’89	-	complete	-	-	-	complete	ambiguous	FL & ¾	-	-	?custom	-	n/a
Mossberg ’90	complete	complete	-	-	-	-	-	-	-	-	-	yes	n/a
Butler ’92	complete	complete	A, K	A, K, H	clear	complete	-	-	-	T?	-	n/a	1-4 wks
Ounpuu ’96	complete	complete	-	-	clear	complete	-	full length	-	-	custom	no	n/a
Carlson ’97	complete	complete	ambiguous	-	clear	complete	-	-	-	-	-	yes	>4wks
Hainsworth ’97	complete	complete	-	A	-	complete	complete	-	-	-	-	n/a	1-4wks
Radkta ’97	complete	complete	A	A, K, H	clear	-	-	full length	complete	-	custom	no	>4wks
Wilson ’97	complete	complete	A	A, K, H	clear	complete	complete	full length	complete	-	custom	yes	<1 day
Abel ’98	complete	complete	A	A	clear	complete	ambiguous	-	ambiguous	-	-	no	n/a
Brunner ’98	complete	complete	A, K?	-	clear	complete	-	-	ambiguous	-	custom	no	-
Burtner ’99	-	complete	-	A, K, H	ambiguous	complete	-	-	ambiguous	-	X prefab	-	-
Rethlefsen ’99	complete	complete	-	A, K, H	ambiguous	complete	?	-	-	-	custom	yes	-
Crenshaw ’00	complete	complete	-	A	-	complete	complete	full length	ambiguous	-	custom	-	>4wks
Suzuki ’00	complete	complete	-	A	clear	complete	complete	full length	ambiguous	-	X̣ prefab	-	-
Beals ’01	-	-	ambiguous	-	clear	complete	complete	-	-	-	-	no	n/a
Buckon ’01	complete	complete	K*	A	-	complete	complete	full length	complete	-	custom	yes	>4wks
Maltais ’01	complete	complete	-	-	-	complete	complete	-	-	-	-	yes	n/a
Dursun ’02	complete	complete	A	A	clear	-	-	-	-	-	-	-	n/a
Kott ’02	complete	complete	-	-	-	-	-	-	-	-	-	yes	n/a
Romkes ’02	complete	complete	A	A, K	-	complete	-	full length	-	-	-	-	1-4wks
Sienoko-T. ’02	complete	complete	-	-	-	complete	complete	-	-	-	custom	yes	>4wks
Smiley ’02	complete	complete	ambiguous	A	-	complete	-	¾ & ?	complete	-	custom	-	<1day
Thompson ’02	complete	complete	A, K	-	other	complete	ambiguous	¾?	complete	-	custom	no	n/a
White ’02	complete	complete	-	A	-	complete	-	FL & ¾	complete	-	X custom	no	n/a
Wesdock ’03	complete	complete	K	A, K, H	clear	complete	complete	-	-	-	-	yes	1-4 wks
Buckon ’04	complete	complete	-	A	-	complete	complete	full length	complete	-	custom	yes	>4wks
Park ’04	complete	complete	-	A, K, H	-	complete	complete	full length	ambiguous	-	-	yes	n/a

	Participant details				AFO details						Testing protocol		
Lam ’05	complete	complete	ambiguous	-	ambiguous	complete	complete	full length	complete	SVA?	custom	yes	?
Radtka ’05	complete	complete	A	A, K, H	clear	complete	complete	full length	complete	-	custom	yes	>4wks
Desloovere ’06	complete	complete	-	-	clear	complete	-	full length	-	T? SVA?	custom	yes	-
Balaban ’07	complete	complete	A	A	ambiguous	complete	complete	full length	-	-	custom	yes	n/a
Butler ’07	complete	complete	K	A, K, H	other	complete	-	-	-	T?	-	-	n/a
Hayek ’07	complete	complete	-	-	-	-	-	-	-	-	-	no	n/a
Romkes ’06	complete	complete	A, K	A	-	complete	complete	full length	-	SVA	-	probably not	n/a
Lucareli ’07	complete	complete	K	A, K, H	clear	complete	-	-	-	-	X custom	probably not	n/a
Westberry ’07	complete	complete	-	-	-	-	-	-	-	-	-	no	n/a
Brehm ’08	complete	complete	-	-	-	complete	-	-	-	-	custom	no	n/a
Van Gestel ’08	complete	complete	A, K	-	clear	complete	-	full length	ambiguous	T?SVA?	X prefab	no	n/a
Smith ’09	complete	complete	A, K, H	A	other	complete	complete	full length	complete	-	custom	yes	>4wks

*- =incomplete or not stated, A=ankle, K=knee, H=hip; *=by analysis; ankle ROM=gastroc ROM; x= details incomplete; FL=full length; T= tuned; SVA = shank-to-vertical angle*

Table 3.4 Results of data extraction and quality outcomes for all studies.

3.5 Discussion

The aim of this review was to conduct a systematic assessment of study quality with a focus on the details reported about the participants, AFO intervention, and testing protocol. This addressed the first research question of this thesis, which was to determine how well AFO-FC alignment was reported within the wider body of literature. This review identified 41 full papers that examined the effect of AFO use on a diverse range of outcome measures in children with CP. In line with the conclusions of previous reviewers (Figueiredo*, et al.*, 2008; Morris, 2002) there was considerable variety in the level and quality of detail reported. In many cases the lack of detail reported in these studies prevented assessment of intervention quality, and made it difficult to determine the confidence that can be had in the findings. Poor transparency further reduces the potential for future meta analyses to summarise results across studies in search of more substantial evidence of treatment effectiveness.

Within this body of literature there were however, sufficient examples of good quality interventions to enable best practice guidelines for future studies to be derived. These are discussed in full below and the recommendations for reporting of detail for AFO intervention studies are summarised in Table 3.5.

3.5.1 Participant details

A clear description of the clinical characteristics of a participant sample is necessary to enable the reader to generalise the study's findings to a similar population. This is particularly relevant in children with CP because of their diverse physical presentation. While almost all studies in this review reported age and diagnosis of their participant sample, several clinical measurements or descriptors that provide additional information regarding the participant sample, such as joint ROMs, muscle lengths and spasticity, were reported less often and in a variety of ways.

Gastrocnemius length is one clinical measure that often guides the choice of AFO design and AFO ankle angle. Therefore, in addition to helping provide a clear clinical picture of the participants, measures of gastrocnemius length can also be used to confirm the appropriate choice of AFO design and AFO ankle angle. Gastrocnemius length was considered to be synonymous with ankle ROM measured with the knee extended. While approximately half of the studies (23/41; Table 3.4) reported gastrocnemius length, this was done in a variety of ways including as group means, individual measurements and minimum/maximum values included within the exclusion or inclusion criteria. However, reporting only group mean values prevents an assessment of appropriate AFO ankle angle for each participant.

Sample homogeneity	
Orthotic aim	Report sample homogeneity with regard to indication for orthotic treatment.
Age	State range (years).
Diagnosis	Specify movement disorder, topographical distribution and GMFCS level.
Gait pattern	Focus on one particular gait pattern or sub-divide into different gait patterns. Describe using published gait classification systems or specify ankle, knee and hip posture in relevant planes.
AFO details	
Suitability	State orthotic aim and suitability of orthoses for the physical characteristics of the participants.
Movements	Describe the movements assisted, prevented, permitted by the AFO.
AFO ankle angle	Report the angle of the ankle in the AFO.
Materials	Report material type and thickness.
Trimlines	Report trimlines (including toe plate length and flexibility).
Tuning	Report whether AFOs were tuned, and the tuning procedure (what was done, the decision parameters used).
Shank-to-vertical angle	Report final shank-to-vertical angle of AFO and footwear combination.
Mechanical properties	If possible, quantify the mechanical properties of the AFO (stiffness and neutral position at the ankle and metatarsophalangeal joints)
Manufacture	Describe the manufacture as custom (same or different moulds?) or prefab (device name, supplier).
Testing protocol (specific to studies investigating AFOs)	
Control	Clearly state the control condition. Note that comparisons with barefoot may over estimate the effect of the orthosis by including a contribution from the shoe.
Order of testing	State the order of testing. Use a randomised order or provide a return to baseline measurement wherever possible.
Acclimatisation	State acclimatisation time.

Table 3.5 Best practicing reporting guidelines derived from this review.

In many cases where authors have attempted to provide this information, they have done so with the use of ambiguous terminology. Several studies stated that participants had ‘no fixed contractures’ but did not specify the muscles or joints that this concerns. In one case, this statement contradicted the reported values of gastrocnemius length, which indicated that contractures were actually present within the sample (Romkes, Hell, & Brunner, 2006). Personal communication with these authors (J. Romkes, personal communication, September 16 2008) confirmed that ‘no fixed contractures’ referred to ankle ROM with the knee flexed, and therefore soleus muscle length rather than gastrocnemius muscle length. This suggests that some authors may not appreciate the effect that two joint muscles such as gastrocnemius can have on the knee joint or foot position, in a patient with an AFO.

Measurements of knee and hip ROM may not directly guide AFO prescription, but they are useful clinical descriptors of the participant sample. While knee ROM was reported in 11/41 studies, and hip ROM was reported in 10/41 (Table 3.4) studies there was variety in the type of measurement used. For example at the knee, descriptions included 'no fixed contracture', specific limits to the size of contractures, as well as measures of hamstring length according to popliteal angle (Butler, Farmer, Stewart, Jones, & Forward, 2007; Rethlefsen, Kay, Dennis, Forstein, & Tolo, 1999; Wilson, Haideri, Song, & Telford, 1997) passive hyperextension (Butler, Thompson, & Major, 1992), and straight leg raise (Radtka et al., 1997; Radtka, Skinner, & Johanson, 2005). Such inconsistency makes it difficult to identify and compare similar patient groups.

While these clinical measurements may help inform the reader of the characteristics of the group, undoubtedly the most important information to be reported is whether or not the group is homogenous in their requirements for the same type of AFO. In children with CP, the majority of AFOs are prescribed to address specific gait related deficits. Each AFO design offers different control over the foot/ankle and over more proximal lower limb joints. Therefore each participant within a sample must demonstrate the same requirement for that AFO which requires both a homogenous group as well as a clear definition of the orthotic goal.

Approximately half of the studies in this review made a clear attempt at describing a deviation (such as gait pattern) that was common to all participants within the sample. However, most of these described solely the position of the ankle joint with only six papers providing descriptions of both ankle and knee movement (Butler*, et al.*, 1992; Romkes*, et al.*, 2006; Simon*, et al.*, 1978; Smith*, et al.*, 2009; Thompson*, et al.*, 2002; Van Gestel*, et al.*, 2008). Four of these used the Winters, Gage and Hicks classification system (Winters*, et al.*, 1987) for hemiplegic CP to describe the types of gait patterns within the sample group (Romkes*, et al.*, 2006; Smith*, et al.*, 2009; Thompson*, et al.*, 2002; Van Gestel*, et al.*, 2008) and two described a genu recurvatum type gait pattern (Butler*, et al.*, 1992; Simon*, et al.*, 1978). Only one study examined a group of participants who demonstrated a single clearly defined gait pattern (Smith*, et al.*, 2009).

An alternative to including participants who have only one type of gait pattern is to analyse sub-groups of similar patterns. One study analysed their results according to gait pattern type (Thompson et al., 2002), finding that the effect of the AFO was different on each type of gait pattern. Similarly, Abel and colleagues (Abel*, et al.*, 1998) found that children who had one of two common indications responded differently to the same type of AFO. Buckon and colleagues (Buckon*, et al.*, 2001) have attempted to address this issue of patient homogeneity with regard to gait pattern, by dividing the group into three subgroups according to the position of the knee during the stance phase during barefoot walking. While the AFO affected each group in a different way, this subgroup analysis was only performed on knee kinematics.

There is therefore, some evidence to suggest that the effect of an AFO on gait varies for different types of gait patterns. Use of non-homogenous groups may mask the true effect of the device. While including a single gait pattern type or analysing by sub-groups are ideal scenarios, it is acknowledged that there are practical limitations of defining such sample groups, which include the small sample sizes which are inherent in these investigations. It is also noted that variations in gait patterns lie upon a continuum and therefore there will always be instances where gait does not conform to identified patterns (Dobson*, et al.*, 2007). Despite this, it is imperative that future work consider participant homogeneity as a priority with regard to the types of AFOs tested.

3.5.2 AFO details

Descriptions of the AFO intervention should enable the device to be replicated and the results verified by an alternate research team. Clearly reporting the design of the AFO is essential as differences between AFO designs have been shown to produce differences in outcomes in temporospatial parameters (Brunner*, et al.*, 1998; Buckon*, et al.*, 2004; Rethlefsen*, et al.*, 1999), ankle kinematics (Buckon*, et al.*, 2001; Buckon*, et al.*, 2004; Desloovere*, et al.*, 2006; Radtka*, et al.*, 2005; Rethlefsen*, et al.*, 1999; Smiley*, et al.*, 2002) and knee kinematics (Buckon*, et al.*, 2001) in straight line walking, as well as stair ascent and descent (Sienko-Thomas*, et al.*, 2002).

Most studies in this review clearly reported the movements controlled by the AFO. There are several good examples of studies which have provided excellent descriptions of the physical characteristics of the AFO interventions (Buckon*, et al.*, 2001; Buckon*, et al.*, 2004; Lam*, et al.*, 2005; Radtka*, et al.*, 2005; Smith*, et al.*, 2009; Wilson*, et al.*, 1997). Such descriptions do not, however, account for the differences in mechanical properties arising from small variations in AFO design, such as trimline position and choice of materials that may contribute to altered mechanical properties (e.g. Bregman *et al.*, 2009; Major, Hewart, & Macdonald, 2004; Sumiya, Suzuki, & Kasahara, 1996). A new method of measuring the stiffness and neutral angle around the ankle and metatarsophalangeal joints has recently been described and demonstrated as reliable and clinically applicable (Bregman*, et al.*, 2009). Including such objective measurements in future clinical and research practice when they become available will improve our ability to compare AFO interventions. In the interim these small variations in design of the AFO-FCs should be reported.

The alignment of the AFO alone, (rather than the AFO footwear combination), is described by the AFO ankle angle, the choice of which is based on clinical measures such as passive and dynamic gastrocnemius muscle length and tri-planar stability of the foot. Severe spasticity or contracture of this bi-articular muscle must be accommodated by the AFO ankle angle to avoid limiting maximum knee extension or compromising the tri-planar stability of the foot (Bowers & Ross, 2009; Cusick, 1994; Meadows*, et al.*, 2008; Small, 1994). Reporting passive gastrocnemius length in addition to the AFO ankle angle is important because it permits the appropriate choice of AFO ankle angle to be confirmed.

It could be argued that reporting the evidence for the choice of AFO ankle angle (e.g. passive gastrocnemius length) is unnecessary. However there were two studies (Romkes*, et al.*, 2006; Wesdock & Edge, 2003) in which reported data suggested that the choice of AFO ankle angle did not consider passive gastrocnemius length. Similarly, three studies evaluated the effect of free dorsiflexion AFOs on children who either did have, or may have had limited gastrocnemius length (Brunner*, et al.*, 1998; Romkes & Brunner, 2002; Romkes*, et al.*, 2006). Interestingly, one study explicitly stated that if participants had 0° of available passive dorsiflexion range with full knee extension, this made them eligible for an AFO with free dorsiflexion (Brehm*, et al.*, 2008; Smith*, et al.*, 2009). However, in such cases the ankle may dorsiflex under the load of body weight by using muscle length gained by pronation of the foot or knee flexion (Bowers & Ross, 2009; Cusick, 1994; Small, 1994). On this basis a free dorsiflexion AFO is contraindicated in the case of limited dorsiflexion range (Bowers & Ross, 2009; Cusick, 1994; Owen, 2005b). Similar discrepancies between passive joint ranges of motion and choice of AFO have been identified in the stroke literature (Bowers, 2007). Given that many studies in this review did not report these two variables (gastrocnemius length and AFO ankle angle), there may be several cases where the type of AFO was contraindicated.

It may therefore be beneficial for future work to demonstrate that the choice of AFO ankle angle and AFO design considered restrictions in physical muscle length by clearly stating the relevant details. Alternatively, an explicit statement that gastrocnemius contractures were accommodated by the choice of an AFO ankle angle that did not exceed maximum passive dorsiflexion ROM with the knee extended, could be considered sufficient, with a similar statement regarding a minimum 5° passive dorsiflexion ROM at the ankle with knee extension, for unrestricted dorsiflexion ROM AFO designs. The use of ambiguous statements such as ‘no fixed contractures’, to describe muscle lengths or joint ROMs should be avoided unless the specific muscles and joints to which this refers are also reported.

When the AFO is combined with footwear, the AFO ankle angle may no longer describe the alignment of the device relative to vertical if there is a difference in height between the heel and forefoot of the footwear (heel-sole differential). In order to overcome this limitation, the alignment of the AFO-FC is described by the SVA. Differences in footwear heel-sole differential and therefore SVA angle which have been modified as part of a tuning process have been reported to induce changes such as decreased peak knee extension angle and peak external knee extension moment in stance phase (Butler*, et al.*, 1997; Butler*, et al.*, 2007; Butler*, et al.*, 1992; Jagadamma*, et al.*, 2009; Jagadamma*, et al.*, 2007).

One study (Romkes*, et al.*, 2006) reported the final SVA of the AFO-FC used, which was a standardised alignment for all participants. Five papers reported fine tuning the AFO-FCs to an individual's requirements (Butler*, et al.*, 2007; Butler*, et al.*, 1992; Desloovere*, et al.*, 2006; Rosenthal*, et al.*, 1975; Van Gestel*, et al.*, 2008) however the descriptions of the tuning process were not sufficient to allow reproduction, and the final AFO-FC alignment was not reported. While the concept of tuning is not new, it has only recently become more widely recognised, which may explain why only a few papers within this review reported tuning of the AFO-FC.

Where AFO-FC alignment is not reported, it is not possible to consider whether the alignment was appropriate and therefore retrospectively assess the implications of that choice of alignment. In the one study where AFO-FC alignment was reported it will be possible to consider retrospectively the effect of that alignment of the device has on gait, and therefore on the results of the study. While those studies that reported tuning procedures may have attempted to ensure that the orthoses were optimally aligned, not reporting the final alignments and ambiguous descriptions of the procedure make it impossible to replicate the studies.

Assessing the quality of the AFO intervention involves a range of aspects including assessing whether the AFO ankle angle was appropriate, reporting AFO design and construction details, and the suitability of prescription to the gait deficit. In order to allow readers to assess quality of the intervention in their critical review of published work, future work would benefit from descriptions of the movements prevented, assisted and permitted by the AFO, toe plate length and flexibility, trim-line position, materials and method of manufacture, AFO ankle angle, shank-to-vertical angle of the combined AFO and footwear, type of footwear worn and details of any tuning process undertaken. Testing of mechanical stiffness of the AFO and the combined AFO and footwear would further enhance objectivity. Transparent reporting permits replication of the study and makes it possible to understand how the variations in AFO design may affect intervention outcomes.

3.5.3 Testing protocol

The majority of studies clearly described the control condition used in the investigation. More studies used barefoot (28/41) rather than a shod comparison (6/41), with one study including both barefoot and shod conditions (Desloovere*, et al.*, 2006). These authors found that footwear alone could have either a negative or positive effect on gait (Desloovere*, et al.*, 2006), thereby confirming findings from the stroke literature (Churchill, Halligan, & Wade, 2003). In order to avoid attributing the effects of footwear to that of the AFO, future work should consider including both of these control conditions wherever possible.

A randomised order of testing is desirable as it eliminates bias resulting from the order of testing. This is particularly important in orthotic research as there are usually two or more conditions being compared over repeated trials of tasks such as walking. Use of a non-randomised order of testing introduces the risk of fatigue in the tasks performed last. Fifteen studies eliminated potential confounding series effects by randomising the testing order. Eight studies did not report the order of testing and 11 reported using a non-randomised order of testing. While a non-randomised order of testing is often unavoidable in cases of retrospective analysis, a randomised order of testing should be used wherever possible, and in any event, the order of testing should be reported.

It is thought that acclimatisation time to an unfamiliar device permits the novel nature of the device to be incorporated into the movement pattern thereby ensuring that the effects of the device accurately represent daily use. All but two studies in this review reported the acclimatisation period, with the majority permitting more than one week and two studies permitting less than one day (Smiley*, et al.*, 2002; Wilson*, et al.*, 1997). While there is no evidence recommending the required length of acclimatisation time to an unfamiliar orthotic device, this should be considered in all study designs and at the very least should be reported.

Several studies in this review did not clearly describe the type of AFO that was tested. Instead, they used descriptions such as "AFO-on" and "AFO-off" (Hainsworth*, et al.*, 1997; Kott & Held, 2002; Mossberg*, et al.*, 1990; Westberry*, et al.*, 2007), and the effect of "community prescribed" (Hayek*, et al.*, 2007) and "clinically prescribed AFOs" (White*, et al.*, 2002). Thus the aim of these studies can be considered to be investigations into the effect of AFO prescription practices within each particular clinical catchment. Unfortunately none of these studies reported the prescription algorithms or decision processes used during in their clinics which would provide information regarding which type of devices were provided for which types of participants. This limits the applicability of these findings to other clinical settings.

3.5.4 Future directions

Previous reviewers have suggested that the quality of this body of literature could be improved by focusing on the execution of large scale RCTs (Morris, 2002) or on alternate study designs which overcome some of the difficulties of RCTs, for example cross-over and one-group interrupted time-series (single subject) designs (Figueiredo*, et al.*, 2008). If however these studies are conducted but the same essential information is under-reported, ranking the quality of these papers based on the type of study design is largely inconsequential. Use of the reporting guidelines presented in Table 3.5 will enable more consistent reporting and permit a transparent assessment of study quality thereby improving the potential to combine results of several smaller studies using meta analyses.

These reporting guidelines are in line with suggestions arising from the recent International Society for Prosthetics and Orthotics (ISPO) consensus conferences on the orthotic management of CP (Bowers & Ross, 2009) and stroke (International Society for Prosthetics and Orthotics, 2004). While certain elements may be more relevant in CP research due to the heterogeneity seen particularly in gait patterns, the principles on which these guidelines are based may be equally applicable to other populations.

This review has identified several avenues of research that could benefit from focussed attention. For example, should the control comparison for AFO research be barefoot or a shod condition? What is the minimum acclimatisation required for a person to become familiar with a new device? Do small differences in AFO trimlines, stiffness and alignment have a significant effect on the effectiveness of the device? Answering these questions might facilitate comparison across studies already published.

3.5.5 Limitations

This review focussed on an assessment of reporting detail and transparency regarding the participants, AFO intervention and testing protocol. An analysis of appropriate choice of outcome measures was not included as this requires decisions about what research questions are most important. Considering the type of outcome measures employed in each study is, without doubt, essential to future meta analyses as these are only possible between studies that have examined the same outcome measures.

This review did not rank or assign quality scores to studies; rather it focussed on examples of best practice with regard to different aspects of intervention quality specific to research into the effects of AFOs for children with CP. To apply a weighted score to this data, a formal process would need to be undertaken to assign importance to different items according to consensus. Ratings of methodological quality are important in systematic reviews in which the objective is to assess the evidence for interventions but this was not the purpose of this review as no assessment of treatment effectiveness was undertaken.

Issues relating to effect size, power or choice of statistical analysis were not included in this review as they are well described in general literature on research methodology. Instead, this review focussed on methodological limitations relating specifically to lower limb orthotic management of children with CP. Other items such as reporting of GMFCS level, spasticity, previous surgery and previous injections of Botolinum-Toxin A could also have been assessed.

3.6 Conclusion

Assessing the quality of individual studies and the ability to utilise studies in quantitative research synthesis requires transparent reporting. While there was considerable variety in level and quality of detail provided by the studies included in this review, there were sufficient good examples of reporting detail and intervention quality. This enabled the generation of guidelines for reporting of detail in future AFO intervention studies. These guidelines should also direct the design of future investigations in this area which will improve the synthesis of quantitative research and therefore the quality of this evidence-base.

4 Pilot study: How does AFO-FC alignment affect gait?

This chapter describes a pilot study designed to address the second research question of this thesis, which was to determine whether there was any evidence for the two hypothesised mechanisms by which changing AFO-FC alignment can affect gait. This exploratory analysis examined data from four children with CP (after exclusion of two participants) to consider how increasing the heel-sole differential (HSD) of the footwear affects the biomechanics of the lower limbs. This study identified several methodological limitations that were addressed in the design of the subsequent investigation and also resulted in an additional research question for the thesis.

4.1 Introduction

Chapter 2 of this thesis proposed two mechanisms by which altering the alignment of an AFO-FC by increasing the HSD, may affect gait. In both cases it was hypothesised that increased HSD will reduce the peak external knee extension moment. However each mechanism is thought to achieve this in different ways, according to whether or not the foot achieves full contact with the floor during stance phase. In Mechanism 1 the foot is flat on the floor and an increase in HSD increases tibial incline and moves the knee joint closer to the ground reaction force (GRF) vector, thus reducing the peak knee extension moment, peak knee extension angle and increasing tibial incline (refer to Figure 4.1). This is thought to occur in limbs demonstrating full knee extension.

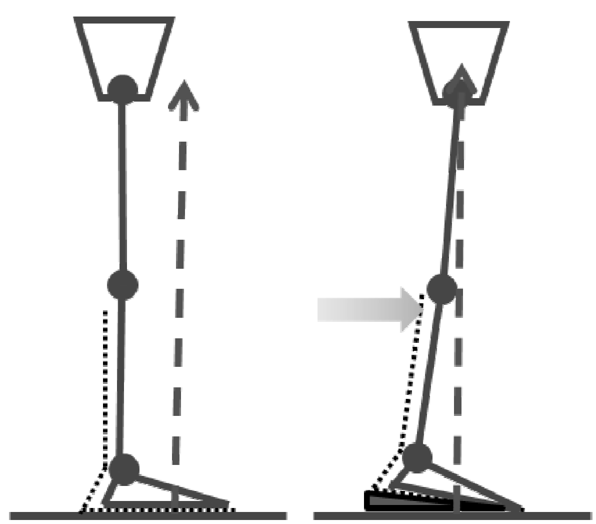


Figure 4.1 Mechanism 1: when the foot is flat on ground increased HSD results in shank inclination which moves the knee joint closer to the GRF vector thus reducing the external knee extension moment.

In Mechanism 2, the foot is inclined with respect to the floor and an increase in HSD will not affect tibial incline and knee kinematics (refer to Figure 4.2). Rather, the increase in HSD will act to shift the centre of pressure posteriorly and thus shift the GRF line of action closer to the knee and ankle joints, thereby reducing peak knee extension moment and reducing the first peak external dorsiflexion moment.

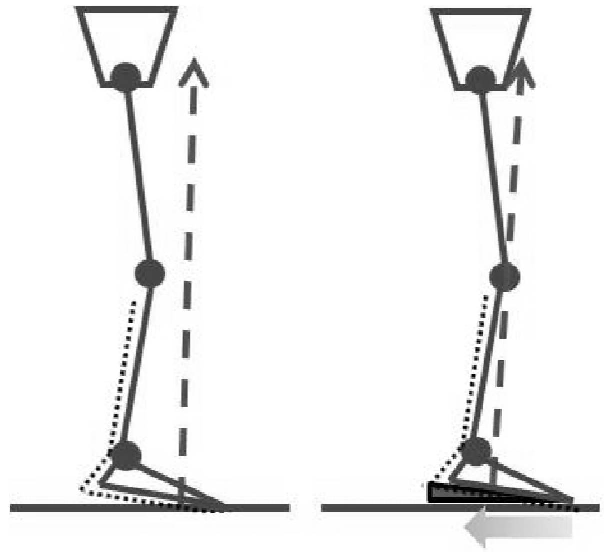


Figure 4.2 Mechanism 2: when the foot is inclined on the ground an increased HSD results in no change to shank inclination. Rather, the point of application of the GRF vector will shift posteriorly thereby reducing the external knee extension moment.

There is some evidence within the literature that supports these hypotheses. For example, children who demonstrated knee hyperextension, which occurs in conjunction with a foot-flat gait pattern, demonstrated reduced peak knee extension angle and moment as a result of increased HSD (Butler*, et al.*, 1992; Jagadamma*, et al.*, 2009). Other authors have suggested that children demonstrating relatively good knee extension are those who will tune successfully (Butler*, et al.*, 2007; Owen, 2004c). These suggestions support the theory of Mechanism 1.

With regard to Mechanism 2, it has been suggested that children with more flexed gait patterns are less likely to tune successfully, but that tuning should still be attempted as increasing the HSD leads to increased contact of the sole with the ground, which is said to lead to benefits such as increased stability (Butler*, et al.*, 2007; Owen, 2004c). This implies an effect similar to Mechanism 2 described above, where kinematic changes are not anticipated but some improvements may still be seen due to a posterior shift in the origin of the GRF vector. While there is some evidence in support of these two mechanisms, they have not yet been explored with a full set of quantitative gait data.

The aim of the study described in this chapter was to explore the 3DGA data from a previous pilot study in order to determine whether evidence existed for either or both of these mechanisms and thereby address the second research question, 'How does AFO-FC alignment affect gait?' If the biomechanics of walking can be influenced by modifying the AFO-FC alignment then it may be possible to improve walking for children with CP. From this other benefits may result such as improved functional outcomes and walking capacity.

These data were originally collected throughout 2007 during the candidate's employment as an orthotist at NovitaTech (the technology division of Novita Children's Services, Adelaide, South Australia). The project was supported by a grant from the Channel 7 Children's Research Foundation, on which the candidate was chief investigator. Ethics approval was obtained for re-analysis of this data as described below, and the support and contribution of the participants, NovitaTech, Novita Children's Services and the Channel 7 Children's Research Foundation are acknowledged.

Six ambulant children with CP took part in this investigation whereby the alignment of their AFO-FCs were systematically manipulated to reflect 5° incremental increases in SVA up to a maximum of 15°, with data collected in a 3DGA laboratory. Data from two children were excluded after an analysis of data quality. The original project focussed specifically on identifying the most optimal SVA in terms of sagittal plane knee and hip kinematics and kinetics, temporospatial data and subjective feedback. This project was conducted during 2007 and 2008 (Gibson, Graham, & Walker, 2008; Graham, 2008) and a final report (Graham, Nguyen, & Walker, 2008) submitted to the organisation under which the project was conducted (NovitaTech, Adelaide, South Australia) and the relevant funding body (the Channel 7 Children's Research Foundation Inc.).

For inclusion in this thesis these original raw data were re-processed and re-analysed according to a different set of aims and objectives. A thorough assessment of data quality was performed which is described in detail in the following methods section. This resulted in the exclusion of data from two participants. The data was then processed using an additional model (*Projections Model,* Appendix C) to calculate sagittal plane segment kinematics (femur, tibia and foot projection angles) as well as standard joint kinematics and kinetics provided by the model *PlugInGait* (Vicon, Oxford Metrics, Oxford, UK). The results were explored to further consider the evidence for the proposed mechanisms by which increasing HSD of the AFO-FC of solid AFOs is thought to affect gait.

4.1.1 Aim & hypothesis

The aim of this re-analysis was to investigate whether evidence exists for either or both of the mechanisms proposed in Chapter 2. It was hypothesised that in both mechanisms, and therefore all limbs, increased HSD would result in a reduction in peak external knee extension moment. It was also hypothesised that for each Mechanism it would be possible to distinguish the responses outlined in Table 4.1, and that these would occur in limbs with the corresponding gait pattern.

Variable	**Mechanism 1**	**Mechanism 2**
Peak knee extension moment	↓	↓
Peak knee extension angle	↓	No change
Tibial incline (projection angle)	↑	No change
First peak dorsiflexion moment	No change	↓
Gait pattern		
Baseline knee kinematic pattern	Full knee extension	Limited knee extension
Baseline foot position	Achieves foot flat	Foot inclined on ground

Table 4.1 Hypothesised response and corresponding baseline gait patterns according to Mechanism 1 and Mechanism 2.

4.2 Method

The original study received ethical committee approval from the Human Ethics Review Committee of the Children, Women and Youth Health Service (CWYHS), Adelaide, South Australia. Written informed consent was obtained from the parents or guardians of all children. Re-analysis of this data was approved by NovitaTech (Adelaide, SA), the CWYHS Human Ethics Review Committee (REC1870/9/09) and La Trobe University Health Sciences Faculty Human Ethics Committee (FHEC09/074), Melbourne, Australia.

4.2.1 Participants

Participants were recruited through the NovitaTech Orthotics Department and Physiotherapy staff at Novita Children's Services Inc. The details of the six participants are presented in Table 4.2. Eligibility criteria for participation in the project included age six to 18 years, primary diagnosis of spastic CP (either diplegia or hemiplegia), currently wearing solid AFOs, and level I or II on the Gross Motor Functional Classification Scale (GMFCS) (Palisano*, et al.*, 1997).

		Participant						
		Excluded						
		1	***2***	**3**	**4**	**5**	**6**	**Average**
Age (years)		*9.5*	*6.08*	9.6	11.92	9.92	12.25	9.88
Sex		*Male*	*Female*	Female	Female	Female	Male	
Height (cm)		*134*	*116.5*	126	144.5	141	150	135.33
Weight (kg)		*53.4*	*23.7*	29	43.6	31.8	52.6	39.17
Diagnosis		*hemi*	*hemi*	di	di	Di	hemi	
AFO side		*right*	*right*	bilateral	Bilateral	bilateral	left	
Dorsiflexion with knee extension (°) #								
R1	**Right**	*0*	*-25*	-15	-5	-20	-	
	Left	-	-	-20	0	-35	-5	
R2	**Right**	*7*	*-5*	0	7	-10	-	
	Left	-	-	0	10	0	5	
Popliteal angle (°)								
R1	**Right**	*20*	*20*	90	75	90	-	
	Left	-	-	90	75	90	85	
R2	**Right**	*0*	*0*	30	40	40	-	
	Left	-	-	35	35	30	35	
AFO ankle angle (°) #								
Right		*0*	*-5*	0	0	-10	-	
Left		-	-	0	0	0	0	

Table 4.2 Participant characteristics and AFO details. R1=Dynamic range of motion, R2=passive range of motion. # Negative values indicate PF, hemi=hemiplegic, di=diplegic. Joint ranges of motion were recorded by the physiotherapist researcher.

4.2.2 Apparatus

4.2.2.1 AFO design

All participants were provided with new custom made solid AFOs, fabricated by a qualified orthotist (ER). The AFOs had full length toe plates extending distally past the toes and on the mediolateral border of the foot, distal to the metatarsal heads. Proximal trimlines were 2-2.5cm below the fibula head with trimlines anterior to both malleoli and straps across the anterior ankle and the proximal tibia. AFOs were made from 4mm polypropylene homopolymer. No reinforcements were applied at the level of the ankle. The stiffness of the toe plate was not altered by adding reinforcements or by reducing the thickness of the plastic.

The choice of AFO ankle angle was determined on an individual basis, depending upon passive gastrocnemius length. If gastrocnemius length limited maximum dorsiflexion to an angle less than plantigrade with the knee in extension, the AFO was made in the equivalent plantarflexed angle. If gastrocnemius length permitted dorsiflexion beyond plantigrade, the AFO was made with ankle in a plantigrade position. The position of the hind and mid foot was maintained in the position closest to neutral.

4.2.2.2 Measurement of the AFO ankle angle and SVA

The AFO ankle angle was measured as the angle between the shank of the lower limb and fifth metatarsal when the participant was wearing the AFO. A plantigrade position (90°) was recorded as 0°. Passive dorsiflexion range of motion with the knee extended was measured using the same landmarks, but while the participant was barefoot and was positioned in supine. The line of the shank was considered to be a line joining the knee joint centre (represented by the lateral femoral epicondyle) and lateral malleolus. A hand-held goniometer was used to measure these angles.

For the testing procedure, the SVA of the AFO-FC was altered by adding wedges of high density EVA foam inside the shoe beneath the heel of the AFO. If a leg length discrepancy existed it was equalised by placing internal shoe raises inside the shoe of the shorter leg. Measurement of the desired or target SVA (0°, 5°, 10°, 15°) was considered as the angle between the line of the shank and vertical, as previously defined in Chapter 2. A modified long armed goniometer, aligned parallel to the line of progression of the foot, was used for all measurements which were conducted by the same investigator (ER) (refer to Figure 4.3). The goniometer provided the vertical reference line as well as a moveable arm to align with the shank. The SVA was measured in degrees with a positive angle denoting anterior inclination. This was performed with the participant seated while wearing the AFO and footwear to ensure that the sole of the foot was flat on the ground with even pressure between the heel and sole of the shoe.

Figure 4.3 Modified long arm goniometer used to measure SVA. The axis was positioned over the lateral maleolus, the stationary arm was therefore aligned vertically and the mobile arm was positioned in line with the lateral femoral epicondyle. This design provides a stable base on which to mount the goniometer for measurement.

Additional joint ranges of motion were measured and recorded by the physiotherapist researcher (see Table 4.2). This included both passive and dynamic measures of joint range of motion (ROM) at the ankle and knee on the affected sides. Ankle ROM was measured with full knee extension. Popliteal angle was measured in supine with the hip flexed to 90° and the knee extended to maximum range. The popliteal angle was the angle between the line of the shank and femur.

All children wore their own shoes throughout the study and during all gait analyses. At least one week of wearing-in time occurred between AFO supply and gait analysis. The AFO was combined with footwear without any deliberate change to the alignment. As participants wore solid AFOs prior to participation in the study it was anticipated that one week adjustment time would be adequate.

4.2.3 Data collection

Participants attended the South Australian Movement Analysis Centre at the Repatriation General Hospital (Daw Park, Adelaide) for one data collection session. Three dimensional kinematic and kinetic data were collected using an eight camera Vicon Mx3 Motion Analysis System (Vicon, Oxford Metrics, Oxford, UK) with four AMTI force plates (AMTI OR6 series, AMTI, Watertown, MA, USA). Vicon Nexus and Polygon software (Vicon, Oxford Metrics, Oxford, UK) were used for the capturing and processing of all data.

Participants were asked to walk laps of the 10m walkway at a self-selected pace while barefoot, in their AFO and footwear, and in 5° incremental increases in the SVA up to a maximum of 15°. In all participants with one exception, the baseline condition produced a SVA of 5°. This was the SVA that represented the combination of the AFO ankle angle and the participants chosen footwear and was therefore also the SVA that the participants had worn in the previous week. In these participants there were four test conditions (barefoot, and SVA of 5°, 10° and 15°). In the remaining participant (Subject 6) the baseline SVA was 0° due to the participant wearing shoes with a zero degree pitch. This resulted in five test conditions for this participant (barefoot, and a SVA of 0 °, 5°, 10° and 15°) (Table 4.2). The same order of testing was used for all participants in order to gain subjective feedback on the different AFO-FC alignments (not reported in the current re-analysis).

Measurements of height, weight, leg lengths and width at ankles and knees were taken for appropriate anthropometric scaling. Fifteen retro-reflective markers were placed on various bony landmarks of the lower limbs for three-dimensional kinematic data capture based on the Newington Marker Set (Davis, Õunpuu, Tyburski, & Gage, 1991). Markers were placed over the anterior superior iliac spines, posterior superior iliac spines, lateral femoral epicondyles, malleoli, calcanei and second metatarsal, along with thigh and tibial wands. Hypo-allergenic double sided adhesive tape was used to attach markers to the skin, AFO or footwear as required. Markers were taped over to ensure they were secure throughout all testing. To capture data in the AFO conditions the markers over the lateral tibia, malleoli, calcanei and forefoot were removed and replaced. The same investigator applied all markers. Several practice laps were performed in each condition prior to data collections. Six trials containing a clean force plate strike were collected for each affected limb.

4.2.4 Data analysis

4.2.4.1 Quality assessment

The original C3D files were reconstructed, labelled and checked for clean force-plate strikes and correct labelling of events using Vicon Nexus software (Vicon, Oxford Metrics, Oxford UK). Several trials were discarded on the basis of compromised force-plate strikes. The remaining trials were processed using two BodyLanguage models. The dynamic gait model provided standard joint kinematics and kinetics according to the *PlugInGait* model (Vicon, Oxford Metrics, Oxford UK), as in the original study. The angle of the limb segments with reference to the laboratory were calculated using the model *Projections* (Appendix C). During the static trial the foot segment was defined using the foot-flat setting. Therefore, in this study foot projections could be more accurately described as shoe projections. While this angle remained constant across conditions, use of the foot-flat setting resulted in an output showing increased dorsiflexion with each increase in SVA.

These data were further examined for adequate quality using Polygon software (Vicon, Oxford Metrics, Oxford UK). Polygon is an integrated tool for visualisation and analysing captured and modelled 3-dimensional data. It provides a single environment in which users can animate data and graph kinematic and kinetic analyses. A report was designed that enabled simultaneous viewing of both the reconstructed markers and skeleton, and the kinematic and kinetic data. These data included sagittal, coronal and transverse plane kinematics of the pelvis, hip, knee and ankle; kinetics of the hip, knee and ankle; and projection angles of the pelvis, femur, tibia and foot. These data were presented individually for each trial and for all trials in each condition. Trials were then averaged and presented graphically to include the standard deviation which permitted an assessment of within-subject variability. This report was used as a template from which data from each participant could be viewed.

Examining individual data in this way enabled any unusual data to be identified, investigated, and if necessary, discarded. In Participant 1 there were errors in the force plate calibration matrix that were unable to be rectified post data collection that resulted in this data set being discarded. The data from Participant 2 was discarded due to behavioural issues during data collection that resulted in an inconsistent gait pattern which was reflected in large standard deviations. Any trial where a force-plate strike was compromised was also discarded. At the end of this process each of the remaining four participants had between one and six trials containing kinetic data for all conditions (see Table 4.3). Due to the limited data set it was decided to include all available trials in this analysis.

	Participant 3			Participant 4			Participant 5			Participant 6		
	AFO	AFO1	AFO2	AFO	AFO1	AFO2	AFO	AFO1	AFO2	AFO	AFO1	AFO2
Left	2	2	3	4	3	3	1	2	4	5	4	6
Right	2	3	3	4	2	2	2	2	3	4	3	3

Table 4.3 Number of acceptable kinetic trials per condition for the four participants included in the analysis.

4.2.5 Evidence of Mechanisms

These data were examined to determine whether evidence existed for either or both of the mechanisms described in Chapter 2. The hypothesised patterns of change and corresponding gait patterns are listed in Table 4.1 (p102).

To identify these patterns, a series of key graphs were produced for the affected limbs for each participant. These included the average traces of each condition across the following sagittal plane variables: joint kinematics and kinetics at the hip, knee and ankle; and projection angles (the angle of these segments relative to the laboratory reference frame) of the femur, shank and foot. Normal data for able-bodied children (Hugh Williamson Gait Laboratory, Royal Children's Hospital, Melbourne) were included for illustrative purposes.

These key graphs were explored to identify patterns and trends indicative of Mechanism 1 and 2 by considering changes in the dependent variables illustrated below in Figure 4.4. These variables were tabulated and the responses according to Mechanism 1 and 2 were colour coded to enable quantitative comparison across conditions.

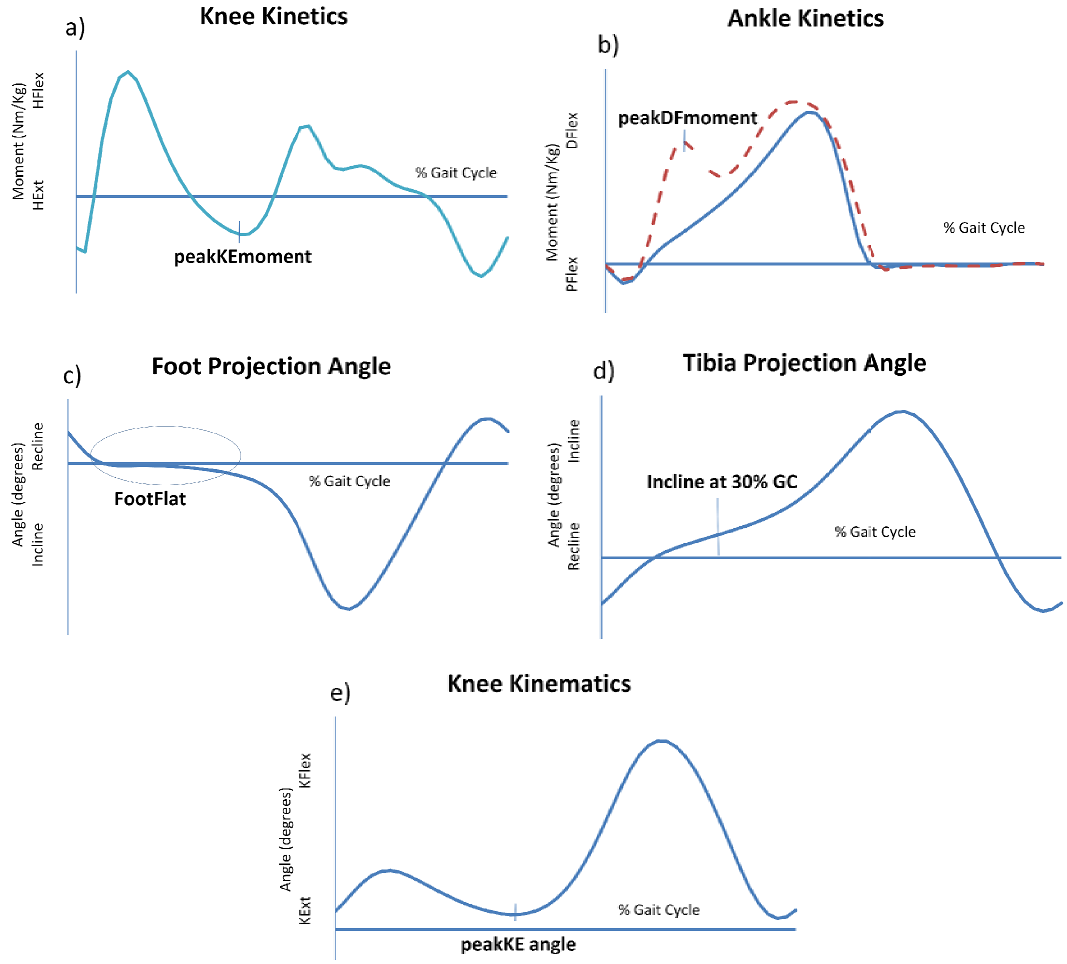


Figure 4.4 Key outcome variables: a) peak knee extension moment; b) first peak dorsiflexion moment in the common double-bump pattern; c) foot flat during mid-stance; d) tibial incline at 30% GC; e) peak knee extension angle. Data sourced from the Normal database maintained by the Hugh Williamson Gait Laboratory, The Royal Children's Hospital, Melbourne, Australia. All moments are external joint moments.

4.3 Results

4.3.1 Evidence of Mechanisms

The summary below describes the evidence that was found to relate to each mechanism, as well as other changes that were observed. Table 4.4 presents the changes in the variables of interest and codes these according to Mechanism type. In this table and the following series of Key Graphs (Figure 4.5-Figure 4.11), all of which present average traces, all changes are colour coded to indicate evidence of Mechanism 1 or Mechanism 2. Characteristics relating to the type of gait pattern (peak knee extension and foot incline) are also highlighted on each set of key graphs.

4.3.2 Summary

4.3.2.1 Mechanism 1

Mechanism 1 was demonstrated fully in two participants Participant 3LR (Figure 4.5, Figure 4.6) and Participant 6 (Figure 4.11). Peak knee extension moment was reduced systematically toward normal values with each increase in HSD. However, increasing the HSD also acted to increase knee flexion moments in early stance and away from normal values, in Participant 3.

Systematic increases in tibial incline and peak knee extension angle were also seen with 1increased HSD. It was also observed that knee flexion in early stance increased with each increase in HSD. The only improvement in kinematics as a result of increased HSD was peak knee extension in Participant 3R. All other changes produced detrimental effects (considered as changes away from normal values).

Consistent with the underlying theory, there were no consistent reductions to dorsiflexion moment. These participants demonstrated near full knee extension and achieved foot flat during mid- stance, indicating a relatively extended gait pattern, which is thought to enable these kinematic changes to take place.

At the hip, increased HSD resulted in increased peak hip extension on the left side in Participant 3 with reduced peak hip flexion on the right. Hip moments were however affected similarly on both limbs, with reductions in peak hip flexion and hip extension moments with increased HSD. These changes improved the hip flexion moments, whereas the changes seen in the peak hip extension moment produced a more abnormal pattern. There were no changes to hip kinematics or kinetics in Participant 6.

4.3.2.2 Mechanism 2

Mechanism 2 was demonstrated fully in both limbs of one participant, Participant 5 (Figure 4.9, Figure 4.10). Peak knee extension moment was reduced sequentially with each increase in HSD.

No systematic changes were seen in tibial incline or knee kinematics. Considerable improvements were seen in the reduction of the peak dorsiflexion moment, toward normal values. In line with this, a flexed knee posture was demonstrated throughout the entire gait cycle with limited knee extension (maximum knee extension of 27.3° and 36.6° flexion on the left and right respectively). As a result in both limbs the foot projection angles were inclined throughout stance phase.

At the hip, similar findings were seen as in Participant 3; increased HSD resulted in increased hip flexion on the left, but increased hip extension on the right. In both limbs the peak hip flexion moment was reduced with increased HSD which was an improvement toward normal values, though there was little change in peak hip extension moment.

4.3.2.3 Mixed

One participant demonstrated evidence of both mechanisms (Subject 4, Figure 4.7 & Figure 4.8). Peak knee extension moment reduced systematically with increased HSD, though the differences in magnitude (approximately 0.2Nm/kg total change) were smaller than those seen in the participants demonstrating evidence of a single mechanism (0.4-0.6 Nm/kg total change). This participant also demonstrated increased peak knee flexion moment in early stance with increased HSD. This was a deterioration as the changes were away from normal values.

While there were systematic increases to tibial incline, peak knee extension and peak knee flexion in early stance, these were smaller in magnitude than those limbs demonstrating only evidence of Mechanism 1, but also of shorter duration, with changes seen between 0-40% of the gait cycle, rather than from 10% of the gait cycle.

In addition to systematic changes to kinematics, evidence of Mechanism 2 was demonstrated in the considerable reductions in the early peak dorsiflexion moment in both limbs of Participant 4, to almost normal values. This participant did not demonstrate full knee extension (10° knee flexion in the baseline condition) and also demonstrated an inclined foot in baseline, which improved with each increase in HSD on the right more so than the left. There were no changes to either hip kinematics or kinetics with increased HSD.

	AFO Average (SD)	AFO1 Average (SD)	AFO2 Average (SD)	Normal Average (SD)
Participant 3L	**5°**	**10°**	**15°**	
Peak DF moment (Nm/kg)	**1.4 (0.15)**	**1.1 (0.26)**	**1.5 (0.26)**	None; 0.30 (.23) at 20%GC
Tibial incline (°)	**11.9 (1.7)**	**18.1 (5.0)**	**22.8 (1.9)**	11.0 (3.1)
Peak KE angle (°)	**4.9 (3.4)**	**11.6 (5.7)**	**20.1 (2.2)**	5.2 (5.7)
Peak KE Moment (Nm/Kg)	**-0.78 (0.20)**	**-0.43 (0.05)**	**-0.25 (.09)**	-0.16 (0.18)
Foot incline (flat or inclined)	**Flat**			
Baseline peak KE	**<5 °**			
Participant 3R	**5°**	**10°**	**15°**	
Peak DF moment (Nm/kg)	**1.7 (0.27)**	**1.9 (0.18)**	**1.6 (0.10)**	
Tibial incline (°)	**12.3 (5.2)**	**19.5 (2.9)**	**21.2 (3.2)**	
Peak KE angle (°)	**-4.3 (4.3)**	**2.9 (4.2)**	**6.2 (2.9)**	
Peak KE Moment (Nm/Kg)	**-0.92 (0.02)**	**-0.64 (0.03)**	**-0.39 (0.08)**	
Foot incline (flat or inclined)	**Flat**			
Baseline peak KE	**<5 °**			
Participant 4L	**5°**	**10°**	**15°**	
Peak DF moment (Nm/kg)	**0.77 (0.09)**	**0.58 (0.28)**	**0.43 (0.09)**	
Tibial incline (°)	**16.2 (1.9)**	**16.7 (1.4)**	**20.6 (1.7)**	
Peak KE angle (°)	**11.4 (1.2)**	**12.3 (1.5)**	**19.4 (2.4)**	
Peak KE Moment (Nm/Kg)	**-0.19 (-0.08)**	**-0.18 (0.10)**	**0.005 (0.08)**	
Foot incline (flat or inclined)	**Flat**			
Baseline peak KE	**>5 °**			
Participant 4R	**5°**	**10°**	**15°**	
Peak DF moment (Nm/kg)	**1.3 (0.16)**	**0.83 (0.18)**	**0.56 (0.004)**	
Tibial incline (°)	**20.4 (1.1)**	**21.3 (2.2)**	**23.7 (0.7)**	
Peak KE angle (°)	**13.6 (0.7)**	**16.9 (2.1)**	**20.9 (2.8)**	
Peak KE Moment (Nm/Kg)	**-0.27 (0.05)**	**-0.20 (0.12)**	**-0.06 (0.04)**	
Foot incline (flat or inclined)	**Flat**			
Baseline peak KE	**>5 °**			
Participant 5L	**5°**	**10°**	**15°**	
Peak DF moment (Nm/kg)	**0.97 (-)***	**0.89 (0.007)**	**0.74 (0.028)**	
Tibial incline (°)	**27.3 (2.7)**	**24.9 (2.2)**	**24.9 (6.1)**	
Peak KE angle (°)	**27.3 (2.4)**	**24.6 (3.4)**	**28.9 (8.1)**	
Peak KE Moment (Nm/Kg)	**-0.59 (-)***	**-0.22 (0.19)**	**0.10 (0.07)**	
Foot incline (flat or inclined)	**Inclined**			
Baseline peak KE	**>5 °**			
Participant 5R	**5°**	**10°**	**15°**	
Peak DF moment (Nm/kg)	**1.7 (0.06)**	**1.5 (0.16)**	**1.14 (0.087)**	
Tibial incline (°)	**25.0 (3.4)**	**25.5 (3.2)**	**23.8 (2.7)**	
Peak KE angle (°)	**36.6 (3.47)**	**31.1 (4.2)**	**37.9 (5.7)**	
Peak KE Moment (Nm/Kg)	**-0.59 (0.045)**	**-0.45 (0.01)**	**-0.15 (0.22)**	
Foot incline (flat or inclined)	**Inclined**			**AFO3**
Baseline peak KE	**>5 °**			**Average (SD)**
Participant 6	**0°**	**5°**	**10°**	**15°**
Peak DF moment (Nm/kg)	**1.57 (0.082)**	**1.41 (0.38)**	**1.47 (0.15)**	**1.42 (0.39)**
Tibial incline (°)	**16.6 (2.4)**	**16.5 (3.1)**	**23.4 (1.5)**	**28.2 (2.3)**
Peak KE angle (°)	**5.12 (3.0)**	**9.01 (3.3)**	**17.2 (3.5)**	**21.9 (3.5)**
Peak KE Moment (Nm/Kg)	**-0.68 (0.19)**	**-0.53 (0.12)**	**-0.43 (0.10)**	**-0.29 (0.098)**
Foot incline (flat or inclined)	**Flat**			
Baseline peak KE	**5 °**			

*Green indicates a change predicted by both mechanisms (ie. reduced peak KE moment); Red indicates patterns associated with Mechanism 1; Blue indicates patterns associated with Mechanism 2; Black indicates no change. * indicates only 1 trial with kinetic data therefore no standard deviation. DF= dorsiflexion, KE = knee extension, KF = knee flexion, tibial incline = tibial projection angle at 30% gait cycle. All peak KE angles are angles of knee flexion*

Table 4.4 Evidence of mechanisms across key dependent variables.

Key Graphs: Participant 3L (Mechanism 1)

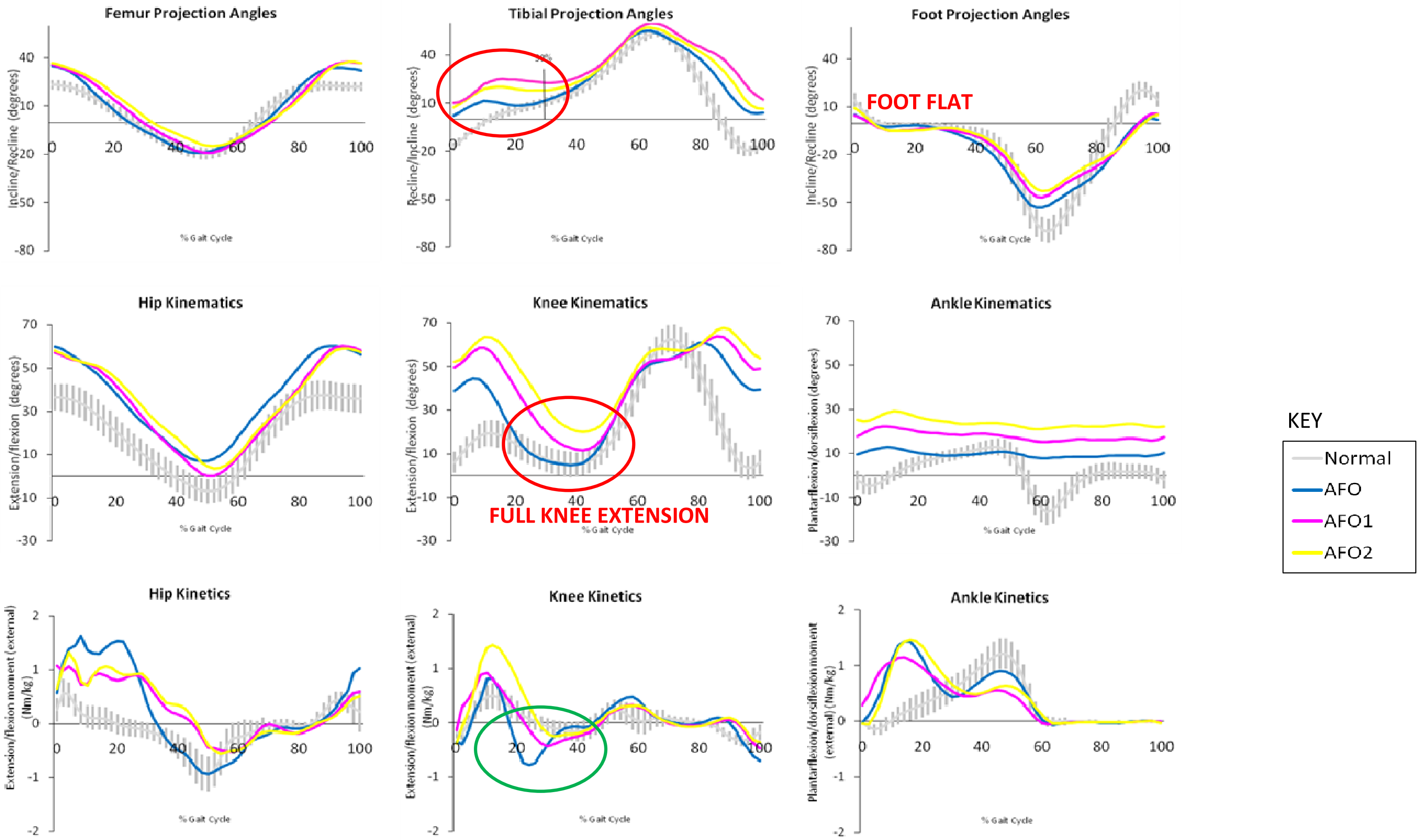


Figure 4.5 Key Graphs for Participant 3L.

Key Graphs: Participant 3R (Mechanism 1)

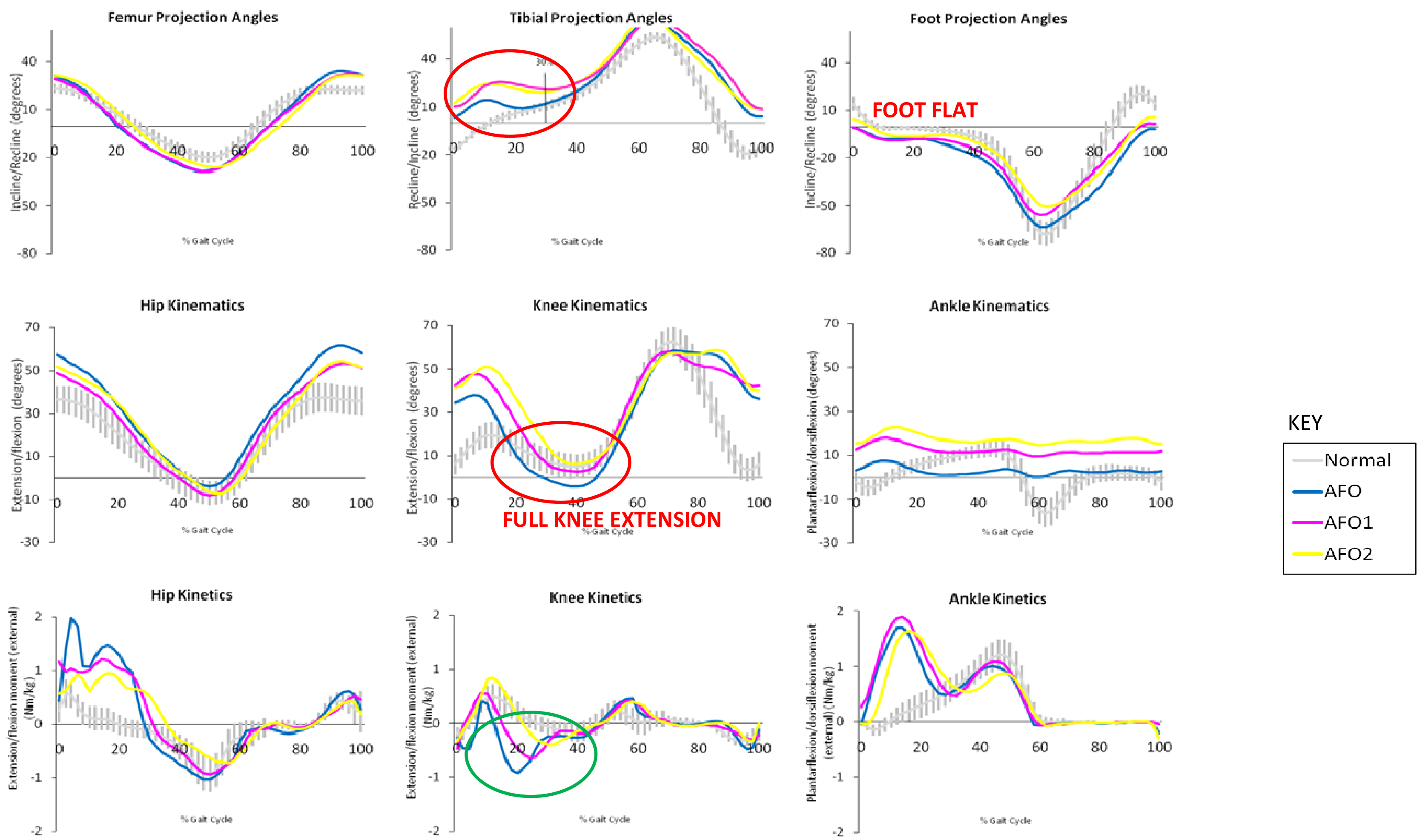


Figure 4.6 Key Graphs for Participant 3R.

Key Graphs: Participant 4L (Mixed)

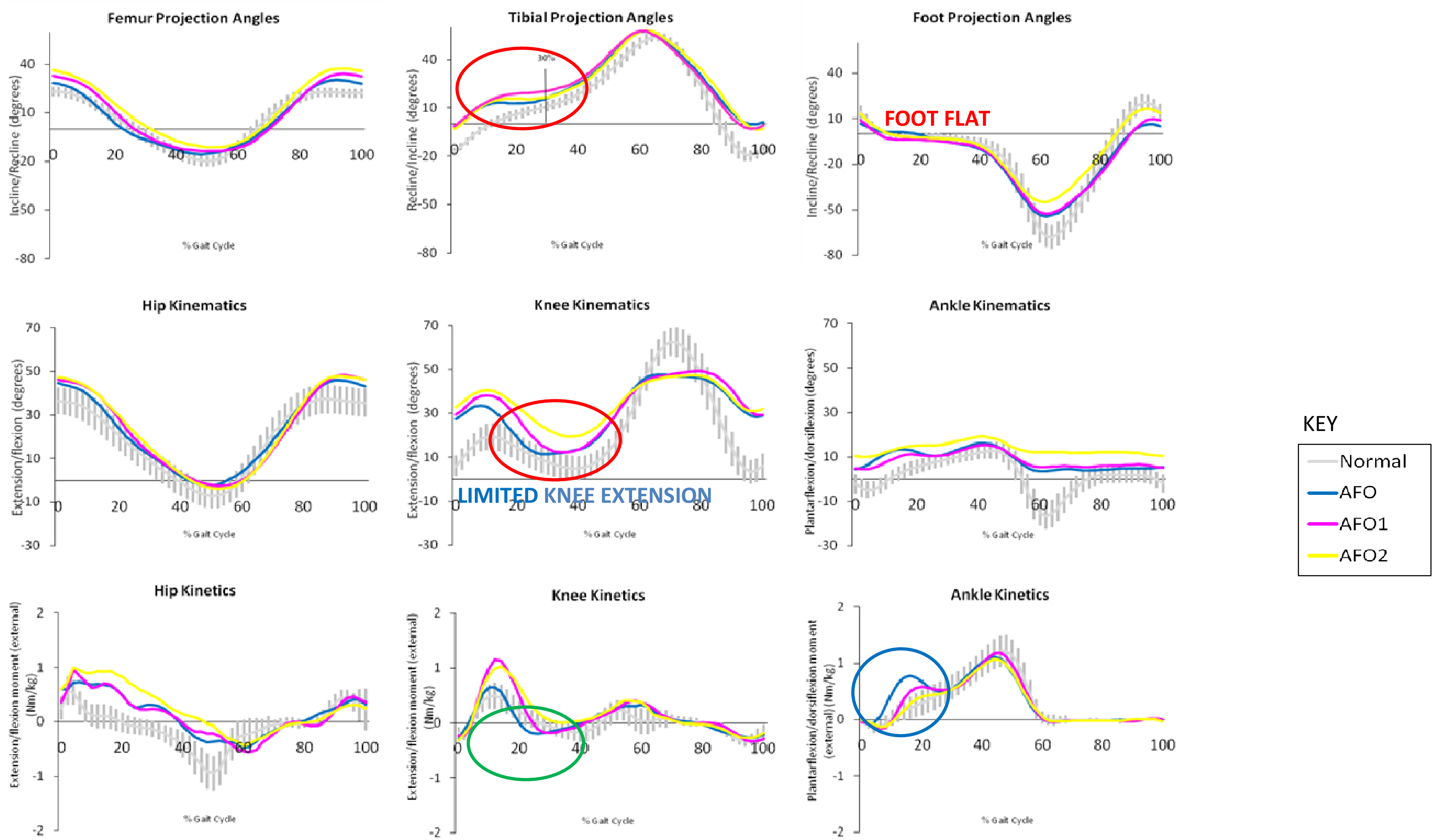


Figure 4.7 Key Graphs for Participant 4L.

Key Graphs: Participant 4R (Mixed)

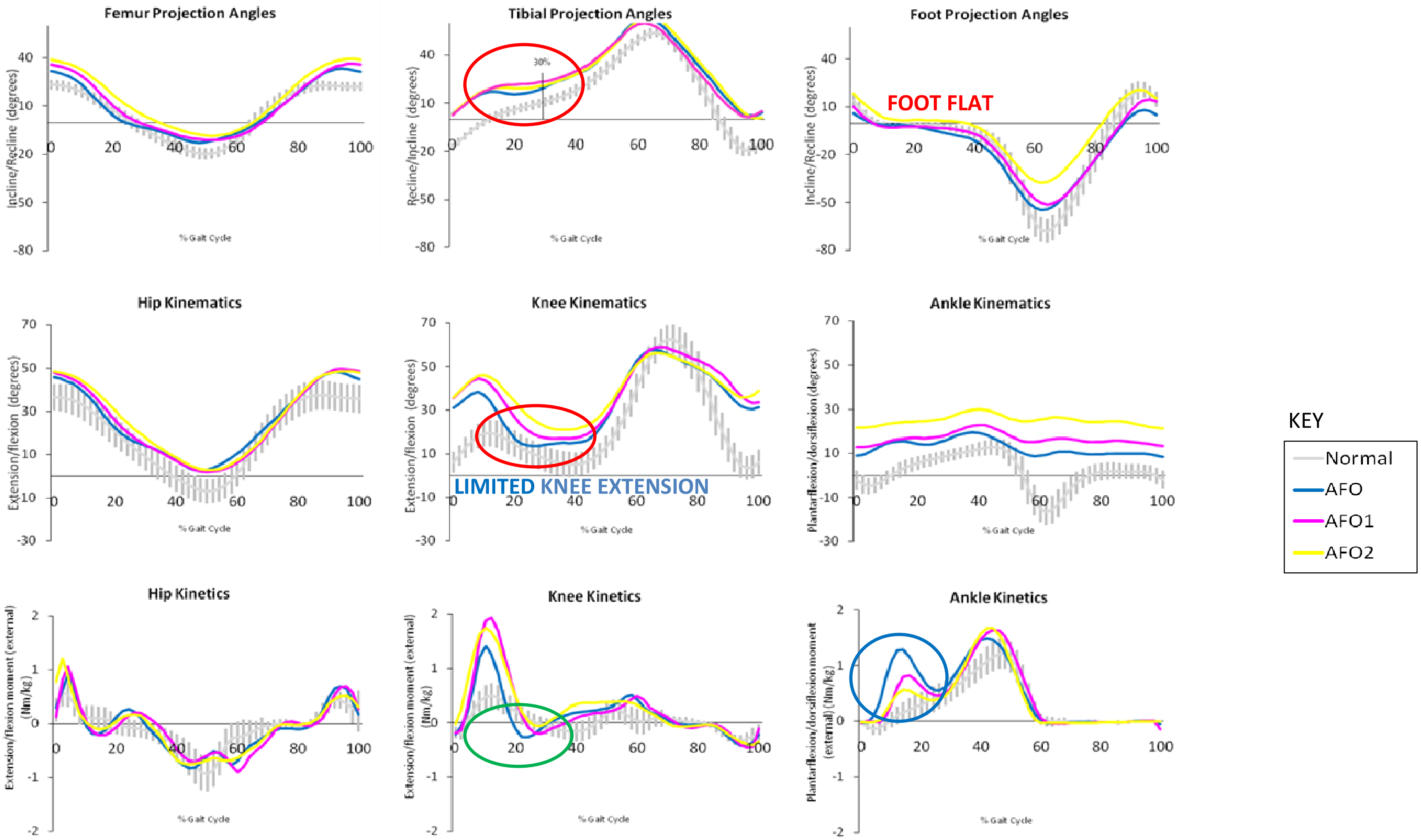


Figure 4.8 Key Graphs for Participant 4R.

Key Graphs: Participant 5L (Mechanism 2)

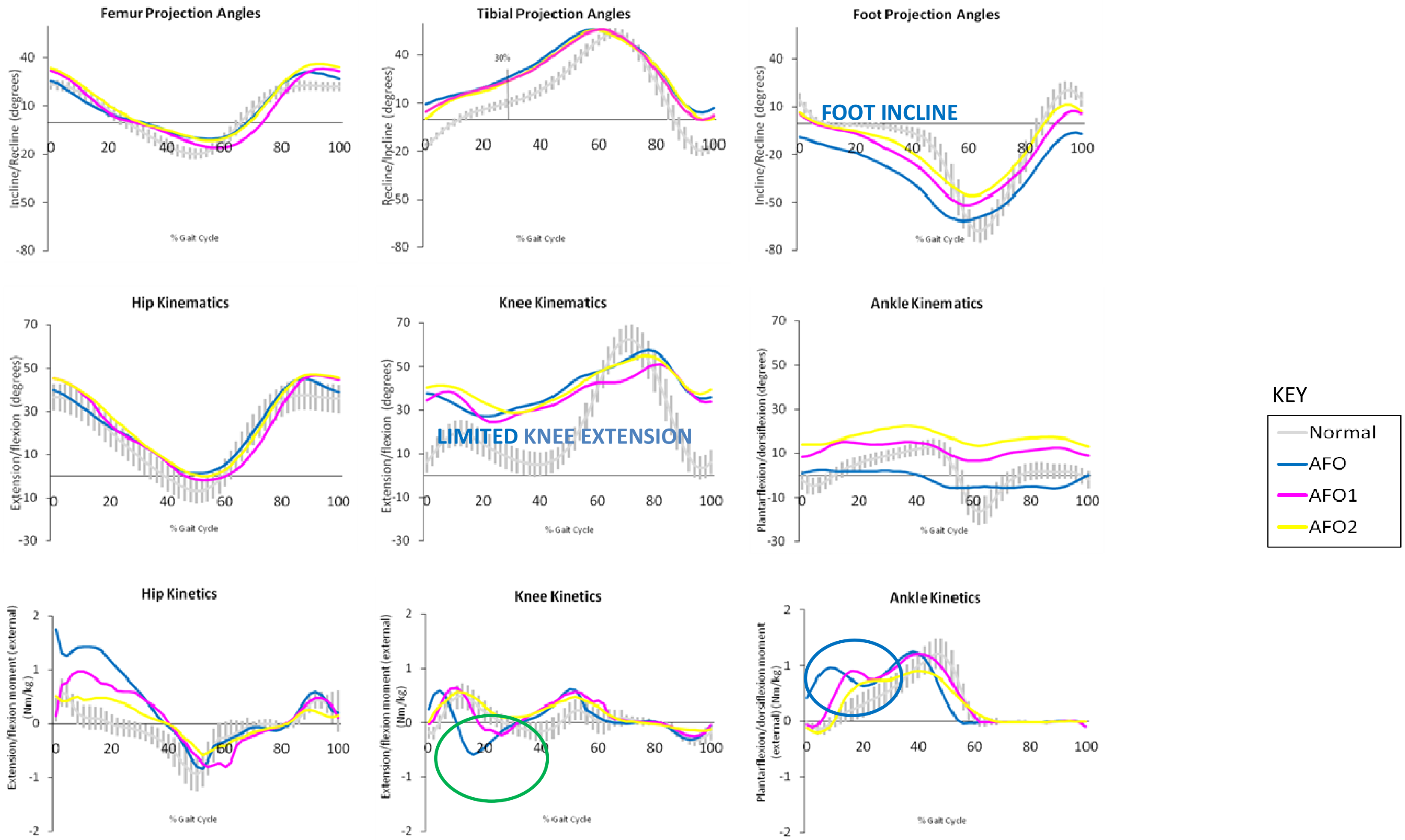


Figure 4.9 Key Graphs for Participant 5L.

Key Graphs: Participant 5R (Mechanism 2)

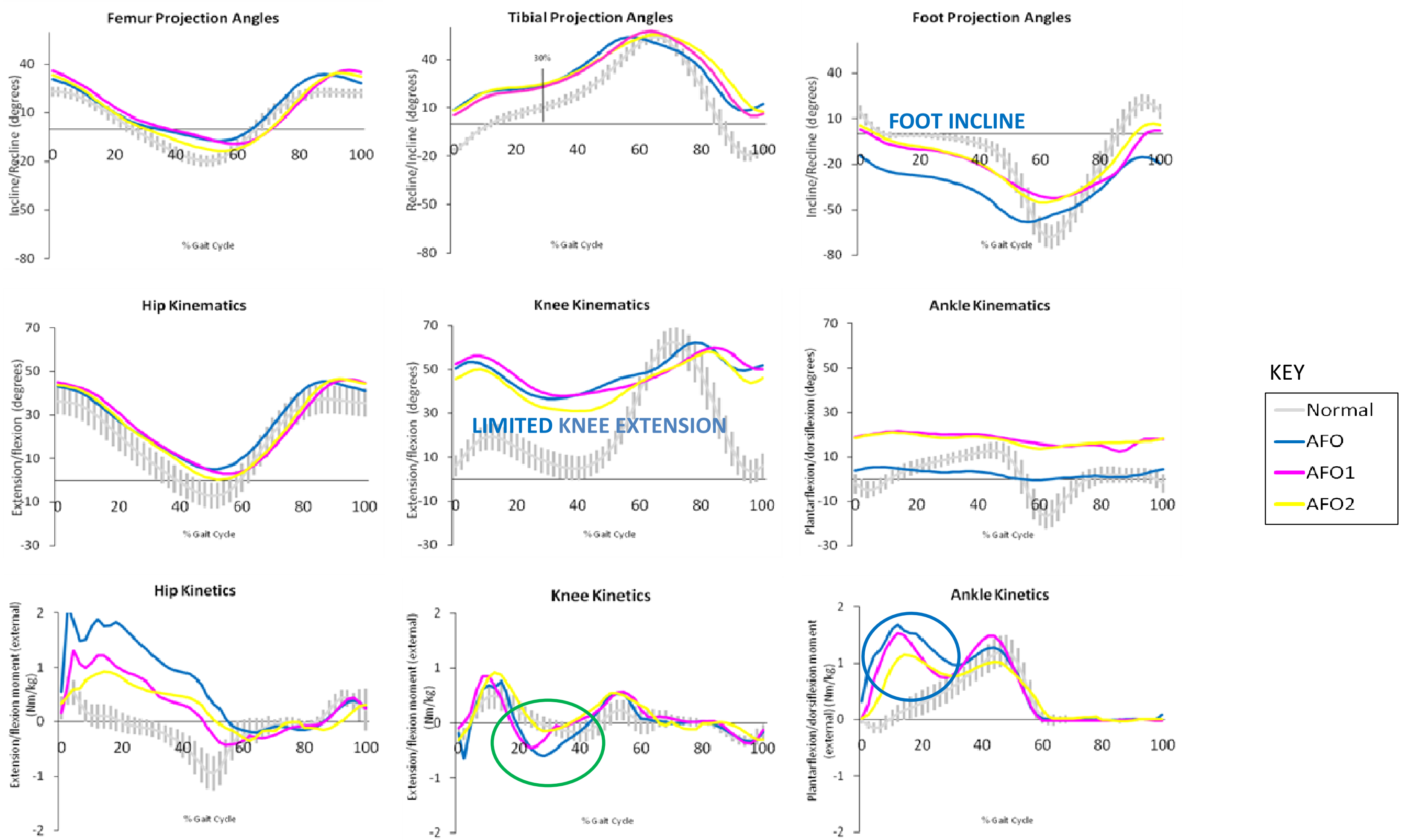


Figure 4.10 Key Graphs for Participant 5R.

Key Graphs: Participant 6 (Mechanism 1)

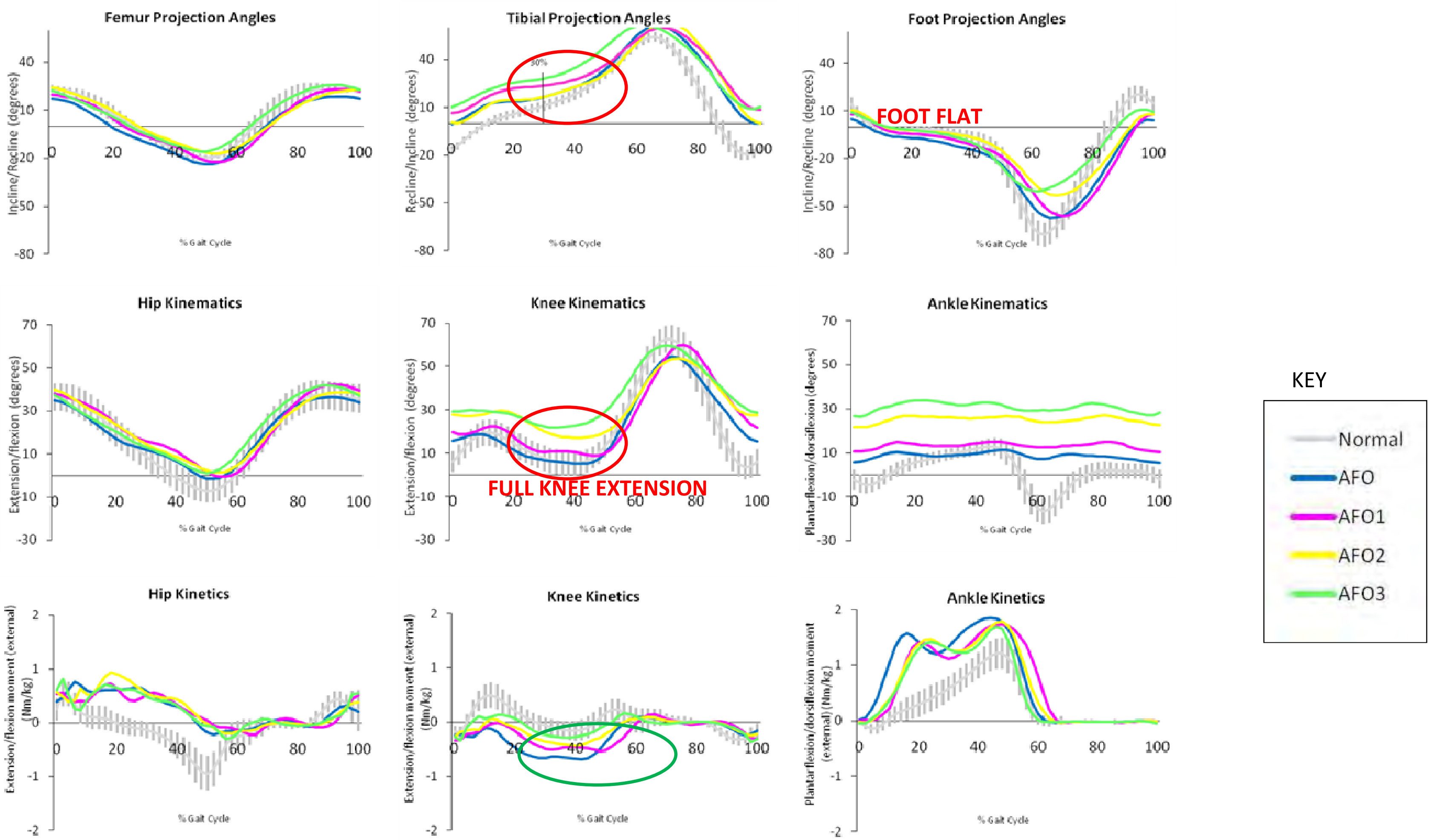


Figure 4.11 Key Graphs for Participant 6.

4.4 Discussion

This analysis examined the effects of a systematic change in AFO-FC SVA on the gait of four children with CP, all of whom wore solid AFOs to address the second research question of this thesis was 'How does AFO-FC alignment affect gait?' In line with the literature, (Butler*, et al.*, 1997; Butler*, et al.*, 2007; Butler*, et al.*, 1992; Jagadamma*, et al.*, 2009; Jagadamma*, et al.*, 2007) all children demonstrated reductions in peak external knee extension moment with increased SVA and in some cases the largest SVAs also produced external knee flexion moments (Participant 4L, 5L). Evidence was also found for the two proposed mechanisms by which changing the SVA of the AFO-FC could affect lower limb biomechanics. While the hypothesis was supported, the presence of 'mixed' type of response was not anticipated.

The most normal peak knee extension moments in this study were produced by a SVA of 10-15°. These findings are in line with the two studies that have reported tuned SVA alignment for children with CP, which were 11.36° (range 7-15°) (Owen, 2002) and 10.8° (±1.8°) (Jagadamma*, et al.*, 2009). However in the study by Owen (2002) modifications were also made to the heel and sole profiles of the footwear which makes direct comparisons more difficult.

This analysis identified that increasing the SVA had some positive and some negative effects depending on the variable examined and the time in the gait cycle. In particular, the limbs of all children who demonstrated evidence of Mechanism 1 also demonstrated increased knee flexion angles and moments in early stance with increased HSD, away from normal values. Similar results have been reported by other authors (Butler*, et al.*, 2007; Jagadamma*, et al.*, 2009) who considered this inconsequential compared with the supposed benefits of more normal knee kinetics at mid-stance (Butler*, et al.*, 2007). The changes in knee flexion angles and moments in early stance are however considered undesirable and energy expensive as the large external flexion moment must be opposed by a large internal extension moment which is produced by contraction of the quadriceps.

Because the full tuning process as described by Owen (Owen, 2004c, 2005a; Owen*, et al.*, 2004) involves two subsequent steps, heel and sole modification, it is possible that these and any other undesirable effects in early and late stance phase could be ameliorated by modifications to the heel and sole profile of the footwear. If it is not possible to perform a complete three stage tuning process, then the choice of SVA must be made on an individual basis, taking into account the desirable and undesirable changes in both kinematic and kinetic variables. While this thesis examines AFO-FC alignment in isolation in order to understand the first component of this complex procedure, there is a clear need to investigate the effect of heel and sole profiles on gait in future studies.

A mixed response was demonstrated in one participant (Participant 4) who demonstrated systematic kinematic changes as well as systematic reductions in peak dorsiflexion moment. Full knee extension was not achieved (maximum knee extension was 10° knee flexion) but the foot appeared flat on the ground, at least for a short period in early stance, in the baseline condition. It is probable that both responses are present because while the foot is flat on the ground, weight is unevenly distributed between the heel and forefoot, favouring the latter. Thus increasing the HSD provided more time for the foot to be flat on the ground and provided more even weight distribution.

4.4.1 Limitations and future directions

The small number of participants included in this pilot analysis is one of the major limitations of the work. Children with CP are an inherently heterogeneous population particularly with regard to gait pattern. A small sample size makes it difficult to generalise the results to the wider population and provides impetus for a study using a larger sample size.

Another important limitation of this study design was the non-randomised order of testing. This was done in order to facilitate subjective feedback from the participants, which was an aim of the original study and not reported here. Because the smaller SVAs were administered before the largest, the changes observed may have been affected by series effects. For example, increased knee flexion during early stance phase in conditions of larger SVAs may have been in part due to fatigue rather than simply due to the AFO-FC alignment. Future investigations involving repeated measures design should certainly provide a randomised order of testing to eliminate the possibility of series effects influencing the results.

A second limitation relates to measurement error arising from use of a hand-held goniometer to measure SVA. Reliability of goniometric measurement of ankle dorsi- and plantarflexion has been widely questioned (Elveru, Rothstein, & Lamb, 1988; Evans & Scutter, 2006; Lundgren *et al.*, 2008; Martin & McPoil, 2005; Van Gheluwe, Kirby, Roosen, & Phillips, 2002; Wright & Feinstein, 1992). Use of this technique to measure SVA in patients wearing AFOs may create additional error because the AFO may disguise the apex of the anatomical lateral malleoli and the tibia may move within the AFO. Goniometric measurement was used to determine the height of the internal heel wedge required to produce the required SVA. It was intended that SVA would increase in 5° increments however the changes to ankle kinematic data suggest that these increments were not consistent. This problem is also evident in a case study examining the effect of SVA on one child with CP (Jagadamma*, et al.*, 2007). Wedge size increased from 4°, 8°, 12° and 20° while the SVA was measured as 12°, 13°, 19° and 22°. The use of internal heel wedges to alter SVA may also compromise the fit of the AFO within the shoe, particularly in larger SVAs and cause increased movement between the shoe and AFO during walking.

An alternative method of inducing systematic SVA changes would be to use external wedges attached to the sole of footwear (Jagadamma*, et al.*, 2009). Footwear in a range of sizes could be prepared with a set of wedges that have been fabricated according to specific measurements to produce the desired SVA. This approach does not require individual measurement of SVA but calculation of the heel height of the wedge relative to foot length needed to produce the required SVA. This approach would have the further advantage that the fit of the footwear would not be compromised. This approach was used in the study reported in Chapter 5.

Of primary concern when prescribing a solid AFO is that the AFO is designed and fabricated in a way which prevents any movement of the ankle during walking, primarily in the sagittal plane. The results of this study suggest however that there was up to 12.5° sagittal plane ankle movement (Participant 4L). These results were similar to those reported in the wider body of literature, which report between 8-16° ankle ROM (Abel*, et al.*, 1998; Brunner*, et al.*, 1998; Buckon*, et al.*, 2001; Buckon*, et al.*, 2004; Carlson*, et al.*, 1997; Lam*, et al.*, 2005; Thompson*, et al.*, 2002). This movement has often been attributed to insufficient rigidity of the SAFO which allows plastic deformation and buckling at the ankle with loading (Buckon*, et al.*, 2001; Buckon*, et al.*, 2004; Carlson*, et al.*, 1997; Thompson*, et al.*, 2002).

There are however several other factors that may have contributed to the measured ankle range of motion. For instance, if the tibia moves in an anterior posterior direction relative to the orthosis, would be measured as a change in ankle angle though it reflects anatomical ankle movement rather than deformation of the AFO. As a result of these observations, a sixth and final research question was added to this thesis which asks, 'When ankle movement in a solid AFO is measured using 3DGA, does this accurately reflect anatomical ankle movement? Is there a way to measure movement of the anatomical ankle, the AFO, tibia and footwear?' This concept is addressed in the project reported in Chapter 8 which describes a new model developed to assess both the actual and the apparent ankle kinematics.

4.5 Conclusion

Biomechanical changes supporting both Mechanisms 1 and 2 were demonstrated within this pilot data, along with an additional mixed response. While some positive changes or improvements were seen in peak knee extension angle and moment, other kinematic and kinetic changes demonstrated according to Mechanism 1 were detrimental effects, that is, changes away from normal. The aim of orthotic intervention in this participant group is to improve gait and as such further investigation of the effect of SVA is warranted.

5 Methods

This chapter describes the method used for the studies reported in Chapters 6-8 in which systematic alignment changes were made to the AFO-FCs of children with spastic hemi- and diplegia who wore either solid or hinged AFOs, and the effect of these changes measured using 3DGA. The subsequent Chapters 6-8 address the third, fourth, fifth and sixth research questions of this thesis. Chapter 5 describes the participants, apparatus, data collection protocol and data processing that apply to all of these studies. Data processing and analysis particular to each of the subsequent studies is reported within the relevant chapter.

5.1 Introduction

The systematic review described in Chapter 3 resulted in the formation of best practice reporting guidelines for AFO interventions in studies involving children with CP. These were considered under the three broad areas of sample homogeneity, AFO details and the testing protocol. The method described in this chapter demonstrates the implementation of these guidelines in the design of the subsequent investigations.

The guidelines suggest that ensuring sample homogeneity in children with CP is essential in AFO intervention studies, particularly with regard to gait pattern. In these studies it was not considered feasible to limit the inclusion criteria to a specific type of gait pattern due to the potential small numbers of eligible participants. Instead the results were analysed according to homogenous sub-groups of similar types of gait patterns. Sub-groups were formed on the basis of similar patterns of knee kinematics in the baseline AFO condition. The aim of the current study was to investigate the effect of variations in AFO design (i.e. the SVA) and not the effect of the AFO intervention. Therefore the baseline AFO gait pattern was considered to provide the most relevant information. Published gait classifications could not be applied to the baseline AFO data because ankle movement, which is a defining feature for most classification systems, was constrained by the AFO which was worn for all conditions. The different gait patterns found within this group are however clearly described which enables comparison with other literature.

The guidelines also suggest that across participants there should be a common indication for orthotic treatment, and that the type of AFO should be suitable for each participant in order to achieve the same orthotic management goal. In these studies a common indication, orthotic goal or suitability of type of AFO to each patient was not considered to be critical to the investigation, as the purpose of the study was not to examine effect of the orthosis or to compare orthoses. Rather, the purpose was to determine how changing one feature of the AFO-FC (the sagittal plane alignment), affected gait, regardless of the rationale for AFO prescription. Further work could investigate the effect of AFO-FC alignment according to the original prescription goal.

The second area addressed by the reporting guidelines focussed on details describing the AFO intervention. Details describing the two types of interventions were clearly described and the individual variations recorded (refer to Appendix D). No methods were available for quantifying AFO stiffness, but in Chapter 8 a new method for measuring AFO flexion in a dynamic context was developed. The focus of the thesis was one area identified by the review as necessitating further research.

The final area addressed by the reporting guidelines focussed on the testing protocol, particularly on use of a control condition, a randomised order of testing and an acclimatisation time. Although barefoot data was collected in this study, this was not used as a control comparison. Instead, each patient had four test conditions which represented four AFO alignments. A randomised order of testing was used for all orthotic conditions according to a counterbalanced Latin square design. Acclimatisation time was provided but limited to approximately five minutes per condition due to an already lengthy testing time.

The protocol described in this chapter utilised 3DGA to collect data relating to a range of gait parameters. Historically, AFO tuning has been performed using two dimensional video vector analysis (Bowers & Meadows, 2007; Butler*, et al.*, 2007; Butler*, et al.*, 1992; Owen, 2002). While there are errors inherent in the use of force vector analysis these are negligible for assessment of ankle moments and very small, particularly at mid-stance for assessment of knee moments (Boccardi*, et al.*, 1981; Wells, 1981). More recently however, 3DGA has been used to tune AFO-FCs of children with CP (Jagadamma*, et al.*, 2009), and one adult with post-stroke hemiplegia (Jagadamma*, et al.*, 2010). As a clinical tool for assessing knee moments and as a way of explaining the effects of changing the point of application and line of application of the GRF, the force vector analysis is extremely useful. The sophisticated technology utilised in 3DGA overcomes many of the limitations of the video vector approach including parallax and perspective error. Using 3DGA permits calculation of joint moments throughout stance phase whereas in studies using a video vector approach it is only possible to undertake a simple and more subjective analysis of the position of the GRF vector in the sagittal plane at various isolated instances.

Chapters 6 and 7 of this thesis describe the results of a study designed to examine the effects of different AFO-FC alignments on two groups of children with CP who were wearing either hinged or solid AFOs, using 3DGA. Methodological limitations of the pilot study described in Chapter 4 informed the design of this study. Because the process of AFO-FC has not been clearly described a tuning process was not conducted. Instead, systematic changes were made to the AFO-FC alignment by attaching external heel wedges in line with the protocol described by Jagadamma and colleagues (2009). This avoided the need to measure SVA using hand held goniometry and maintained the fit and function of footwear as wedges could be pre-fabricated according to different size footwear to produce a range of systematic alignment changes.

5.2 Participants

5.2.1 Ethical approval

Ethical approval for these studies was granted through the La Trobe University Faculty of Health Sciences Ethics Committee (FHEC09/209) and the Royal Children's Hospital Human Research Ethics Committee (29106D) (Appendix B).

5.2.2 Recruitment

Participants were recruited through two paediatric Orthotic departments in Melbourne, Victoria: the Royal Children's Hospital Prosthetic and Orthotic Unit (Parkville, Victoria), and Orthotic Innovations (Surrey Hills, Victoria).

Three recruitment methods were employed. Advertisements were posted to clinic room walls allowing interested families to request an information sheet. If clinicians were consulting with a potential participant they could provide the family with an information sheet directly. Finally, a mail-out of invitation letters was performed after using two cross-checking methods. Permission was obtained to cross-check records from the Orthotic department at the Royal Children's Hospital, which identified all children supplied with solid or hinged AFOs within the past 12 months, against the Victorian Cerebral Palsy Register. This eliminated from the mail-out, all children with diagnoses other than CP. Permission was also obtained to conduct a search of the Hugh Williamson Gait Laboratory patient database at the Royal Children's Hospital to identify children with the appropriate diagnosis, GMFCS level and type of orthosis. The purpose of this second search was to identify children who had their orthoses supplied by Orthotic Innovations, rather than through the Orthotic department at the Royal Children's Hospital. Included in the mail-out was a reply slip, which if returned, permitted the researcher to contact them, confirm their eligibility and, if appropriate, to arrange a testing time.

5.2.3 Inclusion and exclusion criteria

Included in this study were children aged 6-18 years of age, with a primary diagnosis of spastic diplegic or hemiplegic cerebral palsy, a Gross Motor Function Classification System (GMFCS) level of 1 or 2 and who were currently wearing either solid or hinged AFOs (with a posterior stop). Children were excluded if they had lower limb orthopaedic surgery within the past six months.

5.2.4 Participant details

Details of all participants in this study are presented in Table 5.1 . Details of medical history including past surgeries, as well as AFO details are included in Appendix D. A total of twenty children participated. This included eight females and 12 males; eight with diplegic CP and 12 with hemiplegic CP (11 right sided, one left sided). All children with hemiplegia wore a hinged AFO on their affected side and six of the eight children with diplegia wore bilateral solid AFOs. One child wore bilateral hinged AFOs and the other wore one solid and one hinged AFO. The average patient weight was 37.13 (±14.47) kg, the average height was 143.57 (±17.46) cm, and the average age was 10.9 (±3.7) years.

Data from all children except one (HAHA) were included in the studies described in Chapter 6-7. Data from HAHA were excluded from these analyses due to an insufficient number of successful trials in all conditions. All children who wore solid AFOs participated in the study described in Chapter 8.

	Age Yrs.Months	Sex M/F	Dx	AFO side	AFO type	Height (cm)	Weight (kg)	Preferred SVA [#]	Limb	AFO Ankle Angle (°)	Gastroc		Soleus		Hamstrings		KF contrac.
											R2	R1	R2	R1	R2	R1	
ACBE	13.1	F	Hemi	R	Hinged	155.4	38.2	0>5>15=10	L								
									R	0	not measured ^						
ALBR	7.2	F	Hemi	L	Hinged	132.7	26.3	None	L	0	15	-10	15	0	45	62	0
									R								
CHJE	9.8	F	Hemi	R	Hinged	125	23.8	0=5>10>15	L								
									R	0	25	5	35	20	30	35	0
DEFO	11.8	M	Hemi	R	Hinged	155	34.9	10>5>0>15	L								
									R	-5	4	-2	9	0	60	55	0
DEHA	13.2	F	Di	B	Solid	149.8	68.7	10> 0, 5 & 15	L	3	0	-10	12	-5	50	64	0
									R	0	5	-15	15	0	55	57	0
HAGO	7.0	F	Hemi	R	Hinged	112.5	17.4	10=15>5>0	L								
									R	0	10	-10	20	0	10	28	0
HAHA [%]	6.0	F	Di	B	Solid	111.2	19.2	None	L	0	0	-5	5	-2	22	40	0
									R	0	0	-5	5	0	20	40	0
JABU	18.0	M	Di	B	Solid	174.5	59	5=15>10>0	L	0	0	0	12	5	45	55	0
									R	0	0	0	0	0	60	70	0
JANI	11.0	M	Hemi	R	Hinged	134.3	30.1	10>5>0=15	L								
									R	0 [$]	-10	-10	-20	-30	60	65	-5
JOBA	8.2	M	Hemi	R	Hinged	136.5	38.1	0>5=10>15	L								
									R	0	5	-5	11	0	45	53	0
JODA	12.8	M	Di	B	Solid	138.3	27.3	5=10>0 & 15	L	0	5	-10	11	5	48	55	0
									R	0	-2	-15	5	-11	52	62	0
JORI	12.9	M	Di	B	Hinged	164.5	44	10>5>0>15	L	0	0	-5	5	-5	60	70	0
									R	0	0	-10	0	-15	50	65	0

	Age Yrs. Months	Sex M/F	Dx	AFO side	AFO type	Height (cm)	Weight (kg)	Preferred SVA [#]	Limb	AFO Ankle Angle (°)	Gastroc		Soleus		Hamstrings		KF contrac.
											R2	R1	R2	R1	R2	R1	
JOTH	1.1	M	Di	B	Solid	140.5	34.8	10> 5 & 15	L	0	0	0	23	0	60	60	0
									R	0	3	-10	20	8	50	65	0
LIEM	14.4	M	Hemi	R	Hinged	169.7	59.3	5>0>10>15	L								
									R	0	5	0	0	-5	45	67	0
LIKE	9.5	M	Hemi	R	Hinged	130.5	25.5	15>10>5>0	L								
									R	0	0	-10	0	-20	46	50	0
LIRI *	10.1	M	Di	L	Solid	136	26.9	0=5>10 & 15	L	0	5	-3	20	0	60	73	0
				R	Hinged				R	0	5	-5	25	0	45	55	0
MAHO	13.1	M	Di	B	Solid	154	43.5	0>5>10 & 15	L	0	2	-7	10	8	56	55	0
									R	0	2	-4	12	5	50	56	0
ROHI	14.5	M	Hemi	R	Hinged	163.2	56.6	0=5>10>15	L								
									R	0	5	2	12	5	40	45	0
TACA	13.3	F	Hemi	R	Hinged	148	42.5	0 and 5	L								
									R	0	6	0	25	12	30	40	0
TIIR	11.9	F	Hemi	R	Hinged	139.8	26.5	10>0, 5 & 15	L								
									R	0	10	-4	21	9	52	55	0
Summary	10.9 (3.7)	12M:8F	12H: 8D	11R:1L: 8B	13H:7S: 1both	143.57 (17.46)	37.13 (14.47)										

Gastroc = maximum dorsiflexion with the knee extended and foot in most neutral alignment; Soleus = maximum dorsiflexion with the knee flexed and foot in most neutral alignment; Hamstrings = popliteal angle; Dynamic = R1, Passive = R2; negative values = PF or knee hyperextension, positive values = dorsiflexion or knee flexion, KF = knee flexion

[%] HAHA excluded from alignment study due to insufficient kinetic trials, but included in ankle kinematics study

* LIRI has one solid AFO and one hinged AFO with each AFO included in the respective group

[#] Greater than (>) used to denote favourite or order of favourites

[$] AFO ankle angle at 10° plantarflexion, wedged to plantigrade

^ clinical measures not taken due to behavioural issues

Table 5.1 Details of all participants

5.3 Apparatus

5.3.1 Footwear

Participants wore their own AFOs throughout testing along with modified footwear supplied for this project. Six pairs of Dunlop Volley (sport) shoes of a range of sizes were modified by reducing the heel height to obtain a zero degree pitch. A tri-square (Polysteel; Empire) incorporating a spirit level was used to ensure a zero degree pitch. The tri-square was positioned within each shoe with the corner approximating the centre of the heel, in line with the centre of the shoe as illustrated below in Figure 5.1. Downward pressure was applied, and material removed from the heel of the shoe until a zero degree pitch was produced, as indicated by the spirit level.

Figure 5.1 Footwear was modified to a zero pitch by using a spirit level incorporated into a set square.

5.3.2 Wedges

For each pair of shoes a set of sole attachments were fabricated by the candidate out of 250kg/m3 Polyethylene Foam (Metro Foam Products, Silverwater, NSW). There were four pairs of attachments for each pair of shoes which were fabricated to the shape of each shoe. This included one pair of flat attachments (10mm thick) and three pairs of wedges at 5°, 10° and 15°. Hereafter a sole attachment is referred to as a wedge despite the flat attachments having a 0° pitch.

To produce the correct wedge angle (θ) the heel height (*h*) was calculated with reference to the length of the shoe (*s*), such that:

$$h = \sin\vartheta \times s$$

Equation 5-1

Shoe length and heel height were used to calculate wedge length (*w*) (illustrated in Figure 5.2), such that:

$$h^2 + w^2 = s^2$$

$$w^2 = s^2 - h^2$$

$$w = \sqrt{(s^2 - h^2)}$$

Equation 5-2

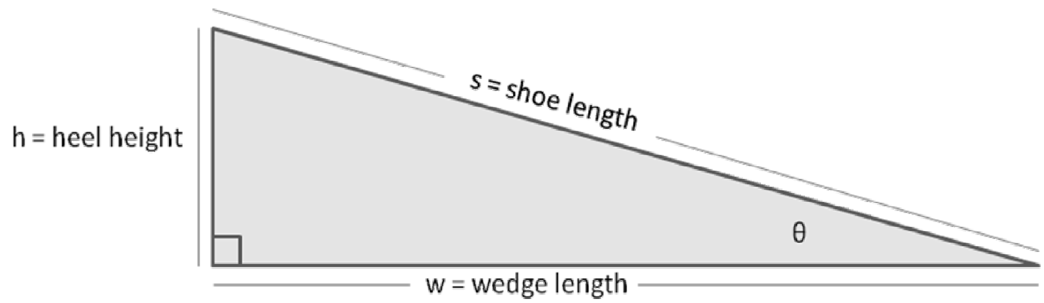


Figure 5.2 Definition of wedge dimensions.

Dimensions of the wedges are presented in Table 5.2. An electronic calliper with increments to the micro millimetre was used to guide fabrication of each wedge. All wedges were modified to include a heel rocker that extended 10mm vertically and 10mm anteriorly (see Figure 5.3). The flat wedges were also modified to include a toe rocker. During testing, all wedges were secured to the footwear using 5.5cm adhesive elasticised bandaged (Elastoplast). The same size footwear with bilateral wedges were used on both limbs regardless of whether AFOs were worn uni- or bilaterally. In the interests of clarity wedge size will hereafter be referred to as flat, small, medium and large, rather than by the size in degrees.

Size	Shoe length (cm)	Angle (degrees)	Heel height (cm)	Wedge length (cm)
		5	1.87	20.91
12	21.5	10	3.73	19.03
		15	5.56	15.40
		5	2.02	22.65
1	23.2	10	4.03	20.93
		15	6.00	17.70
		5	2.18	24.49
3	25.0	10	4.34	22.91
		15	6.47	20.00
		5	2.31	26.02
5	26.5	10	4.60	24.54
		15	6.86	21.85
		5	2.40	27.04
7	27.5	10	4.78	25.62
		15	7.12	23.05
		5	2.57	29.07
9	29.5	10	5.12	27.75
		15	7.64	25.40

Table 5.2 Dimensions of sole attachments; 0°=flat, 5°=small, 10°=medium and 15°=large.

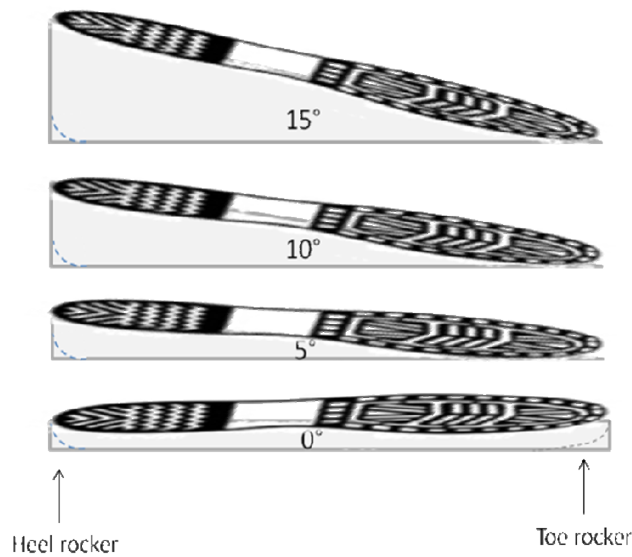


Figure 5.3 Diagram of wedges showing the heel and toe rockers; 0°=flat, 5°=small, 10°=medium and 15°=large.

5.3.3 3-Dimensional Gait Analysis

Data were collected using 3-dimensional gait analysis (3DGA) at the movement laboratory at La Trobe University (Bundoora, Victoria) and at the Hugh Williamson Gait Laboratory at the Royal Children's Hospital (Parkville, Victoria). Details of these two laboratories are presented in Table 5.3.

In both laboratories data collection was carried out along a straight walkway through the centre of the lab. Data was collected using Vicon Mx3 Motion Analysis Systems (Vicon, Oxford Metrics, Oxford, UK). Infrared cameras were used to capture kinematic data. Force platforms embedded in the floor of both laboratories, all of which were 400mm x 600mm in size, were used to capture kinetic data. The cameras and force plates were linked to Vicon computer software, Nexus (Vicon, Oxford Metrics, Oxford, UK) via a networked video processor that sampled video data at a rate of 100Hz and analogue data at a rate of 1000Hz. The video and analogue data were merged and reconstructed in Nexus. The capture volume was calibrated prior to data collection using standard protocols recommended by Oxford Metrics.

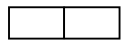
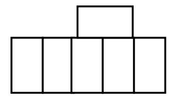
	La Trobe University	**Hugh Williamson Gait Lab**
Walkway length	12m	12m
Infrared cameras	10	10
Force platforms	2 (Kistler 9281B; Kistler Instruments AF, Winterthur, Switzerland; AMTI Accugait, AMTI, Watertown, MA, USA)	6 (AMTI OR6 series, AMTI, Watertown, MA, USA)
Force platform orientation		
Nexus version	1.5	1.5
Calibration wand	5 marker T frame	5 marker T frame
Calibration frame	5 marker T frame	RCH frame
Marker size	14mm	14mm
Wand marker size	25mm on 70mm wands	25mm on 60mm wands

Table 5.3 Details of the laboratories at La Trobe University and the Hugh Williamson Gait Laboratory.

5.3.4 Marker set

A modified marker set was used for the 3DGA. This marker set was based on the marker set described by Davids and colleagues (Davids, Ounpuu, Tyburski, & Gage, 1991) incorporating markers over the anterior superior iliac spines, posterior superior iliac spines, lateral femoral epicondyles, malleoli, calcanei and second metatarsal, along with thigh and tibial wands, as required by the PiG model. Two additional tibial markers placed on the anterior tibia and posterior calf were included for the study described in Chapter 8. Additional markers on the anterior and lateral thigh were included as per standard protocol for 3DGA at the Royal Children's Hospital. The full marker set is illustrated in Figure 5.4 and Table 5.4. Hypo-allergenic double sided adhesive tape was used to attach markers to the skin, AFO or footwear as required. These were taped over to ensure they were secure throughout all testing.

The following measurements were collected from all participants to input into the PiG model as recommended in Vicon Nexus:

- Height (mm)
- Mass (kg)
- Distance between right and left ASIS (mm)
- Perpendicular distance between greater trochanter and anterior superior iliac spine (when hip extended and neutrally rotated with the participant in supine) (mm)
- Knee width (mm)
- Ankle width (mm)
- Leg length (mm)

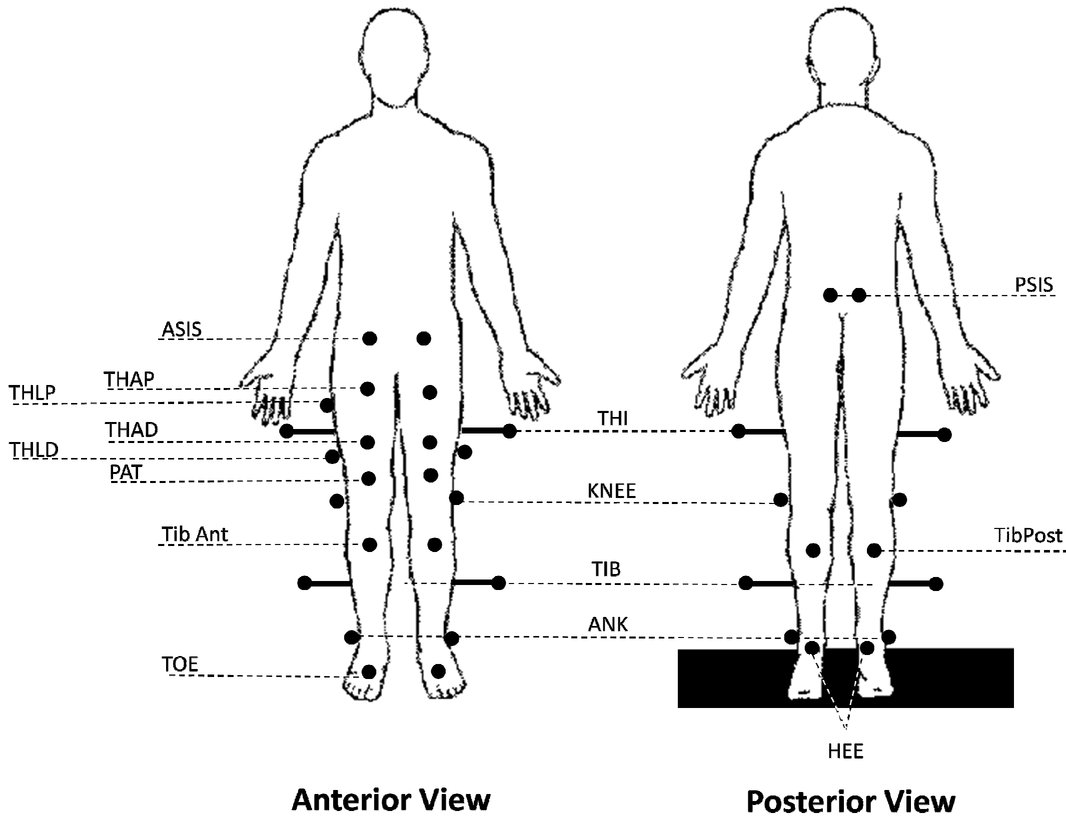


Figure 5.4 Diagram of full marker set.

Marker	Location
L/R PSIS	Posterior Superior Iliac Spine
L/R ASIS	Anterior Superior Iliac Spine
L/R THI	Lateral thigh (wand)
L/R THAP	Thigh, anterior proximal
L/R THAD	Thigh, anterior distal
L/R PAT	Thigh, patella (just proximal)
R THLP	Thigh, lateral proximal
L/R THLD	Thigh, lateral distal
L/R KNEE	Medial and lateral femoral epicondyles
L/R TIB	Lateral tibia (wand)
L/R TibPost	Posterior tibia
L/R TibAnt	Anterior tibia
L/R ANK	*Lateral malleoli*
L/R HEE	*Calcaneus*
L/R MED	*Medial malleoli*
L/R TOE	*Forefoot, in line with 2nd metatarsal*

Table 5.4 Location of all markers used in the 3DGA.

5.4 Protocol

Each participant attended a single testing session at one facility. This session involved a clinical assessment and 3DGA.

5.4.1 Clinical Assessment

Written informed consent was provided by all parents/guardians. A clinical assessment of lower limb ROM was performed by the candidate. This included passive and dynamic length of gastrocnemius and soleus, passive and dynamic hamstrings length according to the popliteal angle, measurement of any fixed contracture at the knee, according to maximum knee extension angle. No tools were used in the measurement of muscle length to standardised the applied toruqe. A standard long arm goniometer, metal callipers and a tape measure were used to perform these measurements, as well as the anthropometric measurements required for 3DGA. Details describing the construction and design of the AFOs were recorded and are listed in Appendix D.

5.4.2 3-Dimensional Gait Analysis

5.4.2.1 Order of testing

Five conditions were tested:

- Barefoot
- AFO and footwear with flat soles (0°)
- AFO and footwear with the small wedges (5°)
- AFO and footwear with medium wedges (10°)
- AFO and footwear with large wedges (15°)

Because all markers below the level of the knee had to be removed in order to don the AFO and footwear, and then replaced by attaching onto the AFO and footwear, data were captured in barefoot first to ensure that there were no changes to marker placement between the subsequent AFO conditions. Data were captured for the four AFO conditions in a counterbalanced order according to a Balanced Latin Square design to control for practice, fatigue, order and sequence effects.

A barefoot condition was collected as it was anticipated this data may be useful in classifying children according to their response to AFO-FC alignment change. This data was not however used in the subsequent analyses.

5.4.2.1.1 Balanced Latin Square design

The balanced Latin Square design is one method of incomplete counterbalancing that attempts to overcome the limitations of true counterbalancing – specifically that 24 combinations are required to ensure each of four conditions appears in every possible order. It was considered unlikely that exactly 24 participants would be recruited for this project. The Balanced Latin Square produces a choice of four orders of testing whereby each condition follows and precedes another an equal number of times, despite every order combination not being present (see Table 5.5).

To randomly allocate the counterbalanced order to participants, the first of every four participants selected an order from an envelope. This choice was then removed and the second and third participants chose accordingly. Every fourth participant did not choose an order as there was only one remaining. This process was repeated every four participants.

Order of conditions				
1	flat	small	large	medium
2	small	medium	flat	large
3	medium	large	small	flat
4	large	flat	medium	small

Table 5.5 Balanced Latin Square providing four possible testing orders for the four conditions.

5.4.2.2 Data collection

5.4.2.2.1 Barefoot

For the barefoot condition, a standing static calibration was performed using Knee Alignment Devices (KADs) (Motion Lab Systems Inc, Louisiana, USA) to define the knee joint axis. Knee markers (KNEE) placed over the lateral femoral epicondyles replaced the KADs for all remaining static and dynamic trials. The heel (HEE) and toe (TOE) markers were aligned parallel to the floor (in the sagittal plane) and to the long axis of the foot (second ray, in the transverse plane). All subject measurements were entered into the Nexus software and were designated as the 'barefoot' subject for each participant.

5.4.2.2.2 AFO conditions

Before selecting the order of conditions, all markers on the calf and foot were removed, and the AFO(s) and footwear donned. All removed markers were replaced with the participant in a seated position with even weight distributed between the heel and forefoot of the shoe, ensuring the heel and toe markers were aligned parallel to the floor and to the long axis of the foot. The same investigator applied all markers. A new subject was created in Nexus by copying the 'barefoot' subject. Ankle width in the AFO was measured and entered into the 'AFO' subject.

The participant selected their order of testing and the wedges for the first condition were donned. Footwear was not removed; the wedges were placed in line with the sole of the shoe and secured by wrapping with elastic adhesive bandage. A static capture was performed in standing with the thigh rotation offsets from the ‘barefoot’ subject applied. Prior to dynamic capture the participant performed several practice laps of the walkway.

All dynamic trials were captured at a comfortable walking pace selected by the participant, with sufficient repetitions to achieve five clean force plate strikes for each affected limb. The participant was also asked to consider whether they had a preference for any of the different wedges.

5.4.2.2.3 Subjective preference

During the dynamic trials of each condition participants were asked to think about which wedge size they preferred. At the end of data collection they were asked to nominate their favourite wedge size. These results are presented in Chapter 7.

5.4.3 Data Processing

Five trials with clean force plate strikes were selected for each condition for each participant. All data were processed using the *PlugInGait* model (Vicon, Oxford Metrics, Oxford UK) to calculate joint kinematics and kinetics. A specially developed model was used to calculate kinematics of the individual limbs segments relative to the orientation of the laboratory (*Projections model,* Appendix C). These data were imported into Polygon for a preliminary assessment of data quality. Data were then exported to Microsoft EXCEL for averaging within condition and limb, and for calculation of relevant variables. Subsequent analyses are described in Chapters 6-8.

6 The effect of AFO-FC alignment on gait

This chapter describes a study to address the third and fourth research questions of this thesis, which were 'Are all children responsive to AFO-FC alignment change?' and 'What is the effect of AFO-FC alignment on gait in children wearing solid and hinged AFOs?' The concept of responsiveness to AFO-FC alignment change is first described and subsequently defined according to changes in knee moment over three portions of the gait cycle. Differences in results according to these three analyses were investigated before describing the effect of AFO-FC alignment on a suite of gait parameters in children with CP wearing two types of AFO designs. The following chapter builds on these results by considering the concept of an optimal AFO-FC alignment.

6.1 Introduction

Responsiveness to a change in AFO-FC alignment was first introduced in Chapter 2, where it was broadly defined as a change in knee moment over mid-stance as a result of increasing the HSD. The direction of the desired change was not specified, thus distinguishing the concept of responsiveness from the terms successful and unsuccessful tuning. On the basis of theoretical work describing the tuning process (Owen, 2005a) this definition focuses on the period of mid-stance (10-30% gait cycle) as defined by Perry (1992). Changing AFO-FC alignment may however also affect features of terminal stance such as peak knee extension angle and peak knee extension moment (Butler*, et al.*, 1992; Jagadamma*, et al.*, 2009). Adding further complexity is that the technique as described by Owen (2004b) involves making measurements at a particular instant in the gait cycle. This instant has more recently been defined as the point when the GRF is vertical, which occurs at the transition from mid- to terminal stance, at 30% gait cycle (Owen, 2010). There is therefore, disagreement between the theory, evidence and technique of AFO-FC tuning regarding the period or instant in the gait cycle that is the focus of this process.

The principal aim of tuning is to affect the position and direction of the ground reaction force (GRF) with respect to the knee joint centre. Because knee moment is essentially a measure of this, if tuning is effective we would expect to see systematic changes to knee moment with systematic changes to the heel-sole-differential (HSD). Therefore, in order to address the third research question of this thesis 'Are all children responsive to AFO-FC alignment change?' responsiveness was defined as a significant systematic change in knee moment as a result of systematic change to HSD. This definition was applied over three portions of the gait cycle: mid-stance (10-30% gait cycle), all of stance phase and at a single point in the gait cycle (30%).

The results of these three analyses were compared to determine whether the period of the gait cycle used in the analyses affected the outcome. On the basis of the systematic patterns of change demonstrated in the pilot data as well as evidence within the literature, it was hypothesised that changes occurring over all of stance phase would be more consistent than those seen over mid-stance; whereas using only a single point in the gait cycle might produce more inconsistent changes.

The aim of AFO-FC tuning is to normalise gait, which is commonly assumed to result in improved mobility and reduced energy expenditure. This assumption is largely unfounded with little scientific evidence describing the effect of AFO-FC tuning and the subsequent benefits. Therefore, the second research question examined in this investigation was ‘What is the effect of AFO-FC alignment on gait?’ Subsidiary research questions also examined whether there were differences according to type of gait pattern and type of AFO. The systematic review described in Chapter 3 highlighted the importance of addressing sample heterogeneity in children with CP, particularly with regard to gait patterns. Several gait classification systems exist for children with CP which in general, divide children into groups based primarily on a combination of barefoot ankle and knee kinematic patterns. Barefoot gait classification was not used in this thesis as the investigation focused on the effect of variations to the AFO intervention rather than the effect of the intervention itself. Participants also had ankle movements constrained by AFOs and as a result, assessment of baseline gait patterns focused on common patterns of knee kinematics in the baseline (flat wedge) condition. If limbs demonstrated knee kinematic patterns with natural groupings these data could be averaged and considered a homogenous sub-group.

Based on the pilot data and the limited evidence in the literature, it was hypothesised that systematic changes to knee moment would be evident in all limbs, regardless of baseline gait pattern. Specifically, peak knee flexion moment would increase and peak knee extension moment would decrease systematically as wedge size increased. With regard to the remaining parameters, it was hypothesised that the type of changes seen would vary according to type of gait pattern.

In gait patterns demonstrating relatively good knee extension throughout stance phase, it was anticipated that as a result of increased HSD, peak knee flexion angle during early stance would increase, peak knee extension angle would decrease and tibial projection angle would increase. These changes are in line with Mechanism 1 as described in Chapter 2. In gait patterns that demonstrated less knee extension there would also be reduced first dorsiflexion peak (Mixed Mechanism); and in gait patterns demonstrating increased knee flexion throughout stance phase, there would be no kinematic changes while the same changes would occur to knee kinetics and ankle kinetics (Mechanism 2).

Throughout the investigation reported in this chapter and subsequently in Chapter 7, the results were analysed separately according to the type of AFO. The majority of research examining the effect of AFO-FC alignment, or AFO-FC tuning has examined solid AFOs. While this literature originates from facilities where solid AFOs are prescribed more commonly than other AFO designs (Owen, 2005a, 2005b), the solid AFO is also the only design that allows control over the shank due to the restrictions on both dorsiflexion and plantarflexion.

At the Royal Children's Hospital, Melbourne, Australia, a hinged AFO is often preferred to a solid AFO provided there is adequate gastrocnemius muscle length, low spasticity, a stable foot and no excessive dorsiflexion during stance phase (Rodda & Graham, 2001). The hinged AFO prevents plantarflexion beyond plantigrade, and therefore the inclination of the shank will reflect the SVA from heel contact until the point in the gait cycle at which dorsiflexion begins. After this point the tibia is unrestrained by the AFO and can rotate freely. Therefore, the SVA of a hinged AFO may influence the kinematics and kinetics of the lower limb in the earlier part of stance phase in a similar manner to solid AFOs, but may differ from the point the tibia begins to rotate around the foot. It is also possible that due to spasticity and contracture in the gastrocnemius muscle which is so often seen in children with CP, the range of dorsiflexion utilised in the hinged AFO may be limited, which may result in similar effects of SVA on both orthosis designs. No studies have yet examined the effect of AFO-FC alignment on the gait of children with CP wearing hinged AFOs. The final aim of this investigation was therefore to determine whether changing AFO-FC alignment in both solid and hinged AFOs produces similar results.

6.1.1 Aims and hypotheses

The aims of this investigation were to determine:

1. Whether all children are responsive to AFO-FC alignment change as determined by change in knee moment over mid-stance, and to determine the sensitivity of different indices of responsiveness by comparing the assessment of knee moment over mid-stance to all of stance phase and at a single point in the gait cycle
2. What the effect of AFO-FC alignment was on gait parameters
3. Whether any changes observed relate to underlying gait patterns
4. Whether hinged and solid AFOs produced similar results

The hypotheses for each of these aims were that:

1. All limbs would show a systematic effect on knee moment with systematic changes in SVA across mid-stance.
2. Using the stance phase analysis would result in a similar outcome to the mid-stance analysis, but using a single point in this calculation would result in less systematic results.
3. Increasing SVA would result in reduced peak knee extension moment and increased peak knee flexion moment in all limbs.
4. In fully extended gait patterns, peak knee flexion angle and tibial projection angle would increase and peak knee extension angle would reduce systematically, with increased SVA. In more flexed gait patterns, these same changes would occur along with a reduction in first peak dorsiflexion moment. In severely flexed gait patterns no changes to kinematic variables would be evident, but changes would occur in the first peak dorsiflexion moment.

6.2 Methods

6.2.1 Participants, apparatus and procedures

Participants, apparatus and procedures for this investigation are described in Chapter 5.

6.2.2 Data analysis

6.2.2.1 Sub-groups according to knee kinematic pattern

It was hypothesised that the effect of AFO-FC alignment on a range of gait parameters would depend on the baseline gait pattern, specifically, the pattern of knee kinematics. Sub-groups of limbs with similar knee kinematic patterns were determined based on natural groupings observed within the sample in the flat wedge condition. Limbs demonstrating this pattern of knee kinematics were considered part of the 'common' sub-group, and a group average was calculated. Limbs not demonstrating this common pattern were considered 'variant' limbs, but no group average was calculated because of the variability of the data. Sagittal plane joint kinematics and joint kinetics for the hip, knee and ankle; and segment kinematics (projection angles) for the femur, tibia and foot, were also examined to determine the variability within each group across these parameters.

6.2.2.2 Responsiveness to AFO-FC alignment change

To determine whether all children are responsive to AFO-FC alignment change, the effect of AFO-FC alignment on knee moment over the period of mid-stance was examined. The root mean square (RMS) difference between the average knee moment in the baseline (flat) condition and each of the small, medium and large wedge conditions was calculated for each limb, over the period 10-30% gait cycle which is the period defined as mid-stance by Perry (1992). The RMS difference yields a single positive value which represents the average difference between curves. It was anticipated that increasing wedge size would cause systematic changes to the underlying knee kinetics which would be represented by increasing RMS difference between the small, medium and large wedges compared to the flat wedge. To determine whether the number of limbs considered to be responsive was affected by the period or instant of stance phase used in the RMS difference calculation, the RMS difference was also calculated across a larger period of the gait cycle (all of stance phase), and the absolute difference in knee moment was calculated at a single point, 30% gait cycle.

The length of stance phase may vary between trials within and between different conditions, for every participant. In order to perform an RMS difference calculation on these data, an average stance phase length must be generated for each condition within each participant. The 'condition' average was calculated by averaging the stance phase length across trials within each condition, for each participant. Because the RMS difference compares two conditions, the average stance phase length of each of these conditions were then averaged to calculate the 'total' stance phase length for each RMS difference calculation.

6.2.2.2.1 Statistical analysis

The following statistical calculations were performed in Excel to describe the relationship and significance of the RMS values to the corresponding change in wedge size, for each limb. The LINEST function was used to calculate the gradient (Nm/kg/degree) of a line of best fit for these data as well as calculation of the standard error of the gradient (spread of data points around the regression), the Fischer F-statistic and the coefficient of determination (r^2). The LINEST function is a complete linear least squares curve fitting routine that produces uncertainty estimates for the fit values. The F-distribution function (FDIST) was used to calculate the level of significance (p) for the gradient of the line of best fit based on the F-statistic. Limbs which demonstrated a gradient with a probability value $p<0.05$ were considered to be responsive to AFO-FC alignment change. The coefficient of determination (r^2) describes the proportion of variance in common between the two variables. An r^2 value closer to 1.00 indicates a stronger relationship between RMS difference (representing change in knee moment) and wedge size.

The same statistical calculations were performed for each limb across these three analyses (mid-stance, all of stance phase and single point). The number of limbs considered to be responsive using each of these methods was calculated and summary statistics (average and standard deviation) generated for the RMS difference values, gradient and standard error according to each group (type of AFO) and sub-group (type of gait pattern). Both limbs from the diplegic children were included in the analysis.

In order to test whether these three analyses produced similar results in terms of responsiveness, the LINEST function was again used to calculate a line of best fit and coefficient of determination on the individual gradients calculated using the mid-stance and stance phase analyses, and the mid-stance and single point analyses. From the coefficient of determination (r^2) the correlation coefficient (r) was calculated. Because gradient is essentially a measure of sensitivity to AFO-FC alignment change a larger correlation coefficient (r) (indicating strength of relationship) and thus also a larger coefficient of determination (r^2) (indicating variability explained by the relationship) provides an indication of whether the different analysis techniques provide essentially the same or different outcomes.

6.2.2.3 The effect of AFO-FC alignment on gait

6.2.2.3.1 Parameter selection

It was hypothesised that knee kinetics would demonstrate systematic change across all limbs as a result of increased wedge size, whereby peak knee flexion moment would increase and peak knee extension moment would decrease. It was also hypothesised that peak knee flexion and knee extension angle, the first and second peak dorsiflexion moment and tibial projection angle would change systematically in particular subsets of limbs, based on the pattern of knee kinematics. This group of variables were called the 'probable response variables'. Changes to hip kinematics, kinetics and femur projections, peak knee flexion angle in swing and temporospatial variables were also examined though a systematic effect of AFO alignment on these variables was not hypothesized. This group of variables were called the 'possible response variables'.

Therefore, variables included in this analysis were peak knee flexion moment in early stance, peak knee extension moment, peak knee flexion angle in early stance, peak knee extension angle, tibial incline in early stance, peak tibial incline, first dorsiflexion moment, second dorsiflexion moment (Figure 6.1); as well as hip flexion at initial contact, peak hip extension angle, peak hip flexion moment, peak hip extension moment, recline of femur at initial contact and peak femur incline (Figure 6.2Figure 6.1). All variables were in the sagittal plane. All kinetic data refers to external joint moments. Average walking velocity, cadence and stride length were also calculated for each patient.

All variables with one exception (tibial projection angles) were either peak values or a measure obtained at a specific point in the cycle, e.g. initial contact. The following definitions were used to calculate the probable response variables according to one normalised gait cycle: peak knee flexion moment (maximum 0-40%); peak knee extension moment (minimum 10-60%); peak knee flexion angle (maximum 0-40%); peak knee extension angle (minimum 10-60%); 1st peak dorsiflexion moment (maximum 0-30%); 2nd peak dorsiflexion moment (maximum 0-100%); peak tibial incline (maximum 0-100%). Tibial incline in early stance is not characterised by a peak value nor do consistent patterns of change occur at a single point of the gait cycle. Therefore, changes in this variable were illustrated by calculating the average difference between the flat (baseline) condition and the small, medium and large wedges across 10-30% gait cycle, as this is the period where these changes were observed to occur most consistently. This calculation provides a single positive or negative value representing average difference but does not account for the variety of patterns of changes seen across individuals. The following definitions were used to calculate each possible response variable according to one normalised gait cycle: hip flexion at initial contact (angle at 0%); peak hip extension angle (minimum 0-100%); peak hip flexion moment (maximum 0-100%); peak hip extension moment (minimum 0-100%); recline of femur at initial contact (angle at 0%); peak femur incline (maximum 0-100%) and peak knee flexion in swing (maximum 50-100%). Data depicting the changes in each individual limb are listed in Appendix E.

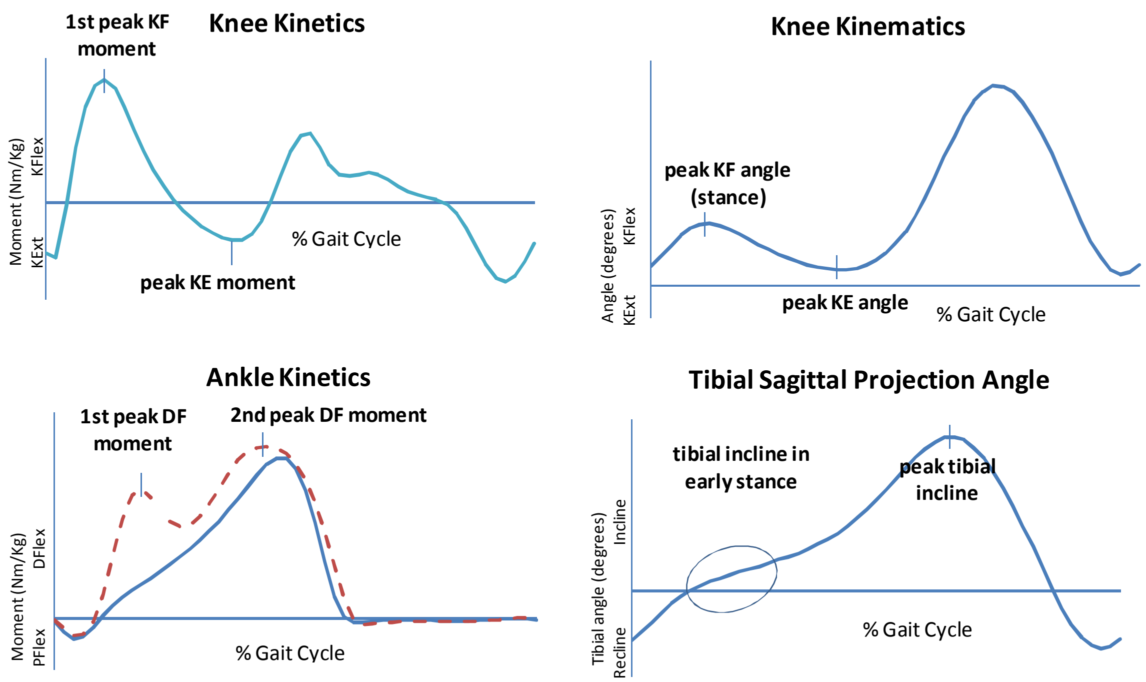


Figure 6.1 Probable response variables (hypothesised to demonstrate systematic changes across all limbs or a sub-set of limbs).

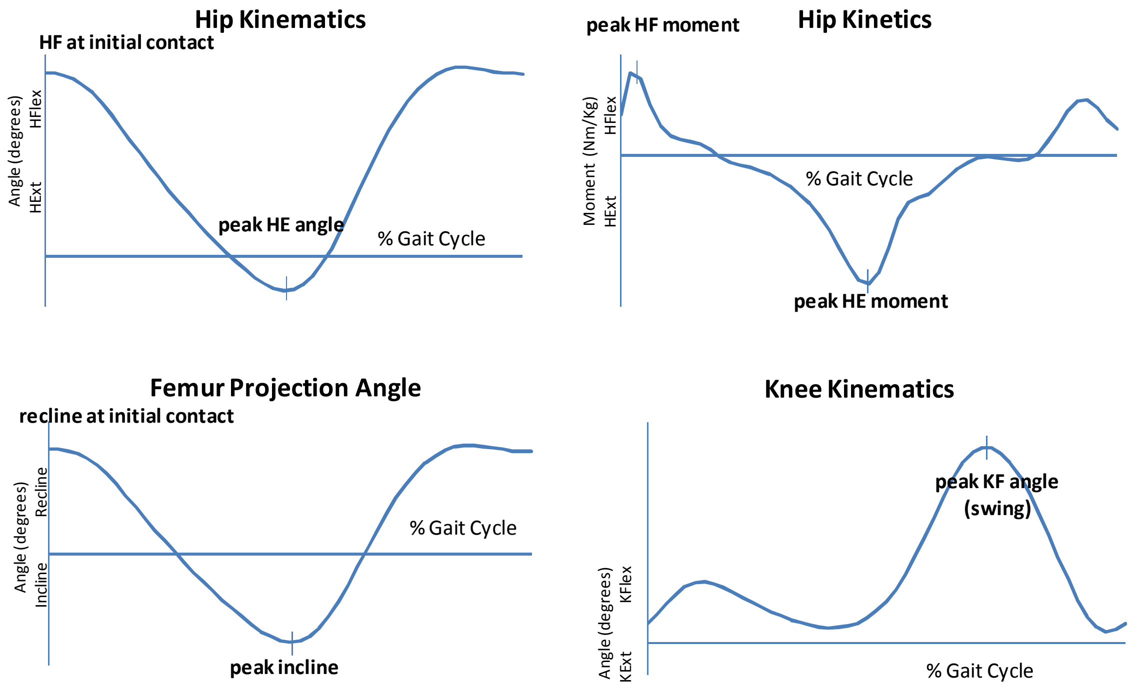


Figure 6.2 Possible response variables (hypothesised to demonstrate non-systematic changes with wedge size). All kinetic variables refer to external joint moments.

6.2.2.3.2 Statistical analysis

To determine whether increasing wedge size produced systematic change across all of the variables of interest, the change (Δ) in each variable from the baseline (flat) condition was calculated for each limb. Positive change indicate a positive value such as peak knee flexion moment getting larger with increased wedge size, or a negative value such as peak knee extension moment getting smaller; whereas a negative change indicate a positive value getting smaller or a negative value getting larger. Systematic change was defined as a sequence whereby each difference was either consistently larger or smaller than the one preceding it, thus resulting in a trend away from baseline.

The common sub-groups of both the hinged and solid AFO group showed consistent systematic changes and therefore these data were combined to calculate a group average. Statistical analyses were performed on this data for the hinged and solid AFO group separately. Tests of normality were conducted on all data using the Shapiro – Wilks test of normality, which is appropriate for samples of $n<50$ where a result of $p<0.05$ indicates significantly non-normal data. As 25/28 data sets relating to the probable response variables were found not to have significantly non-normal distribution, parametric tests were used to analyse the data. The results of the normality tests are listed in Appendix F.

A one way repeated measures analysis of variance (ANOVA) was performed on the group of seven probable response variables, separately for the solid and hinged AFO group. Bonferroni corrections for multiple comparisons were applied resulting in a significance level of $\alpha=(0.05/7) = 0.0071$. If a significant main effect of wedge size was found, post hoc tests (least significant difference) were conducted to determine significance of pairwise comparisons. Bonferroni corrections were applied according to six pairwise comparisons resulting in a significance level of $\alpha= (0.05/6) = 0.0083$. A one way repeated measures ANOVA with the same Bonferroni corrections was also performed on the possible response variables.

Finally, a two way repeated measures ANOVA (effect of wedge size and group) was performed on all variables for the combined group to determine whether the hinged and solid AFO groups had significantly differently responses to the change in AFO alignment. The same Bonferroni corrections were applied according to the previous analysis. Results were presented for the main effect of group and wedge size, as well as the wedge*group interaction. Post-hoc testing on significant interaction effects were conducted using independent samples t-tests, $p<0.05$ (no Bonferroni correction).

6.3 Results

6.3.1 Participants

While 20 children were included in this study, data from only 19 were used in this analysis and the analysis described in Chapter 7. Data from one participant (HAHA) was excluded due to an insufficient number of trials across all four AFO-FC conditions. This resulted in the solid AFO group comprising 11 limbs belonging to six children, and the hinged AFO group comprising 15 limbs belonging to 14 children, with one child (LIRI) contributing one limb to each group. Participant details are listed in Table 5.1 of Chapter 5.

6.3.2 Sub-groups according to knee kinematic pattern

6.3.2.1 a) Solid AFOs

Figure 6.3 presents the average traces for joint kinematics, joint kinetics and segment kinematic patterns for the ankle, knee and hip for the limbs in the solid AFO group for the baseline (flat) condition. Based on patterns distinguishable in knee kinematics, seven limbs were classified as 'common' (grey) as they all demonstrated similar knee kinematics. Four limbs were distinctly different (black). Two of these demonstrated a flexed pattern throughout the entire gait cycle (JABU-L-R; solid black) while two (DEHA-L-R; black dots) demonstrated excessive knee flexion in early stance, full knee extension and limited knee flexion in swing. Because of the differences in patterns demonstrated in these limbs, for the remainder of this analysis they were considered as individuals that were part of the 'variant' group.

The common group demonstrated relatively consistent patterns across all other variables, however two limbs (MAHO-L-R) demonstrated a lack of hip extension moment throughout late stance and increased knee flexion moments in early stance. The variant limbs (JABU and DEHA) both demonstrated increased peak knee flexion moment in early stance, minimal or no external knee extension moments in mid-late stance and increased tibial angle in early stance. Hip flexion angle and peak femur recline angle at initial contact was increased in DEHA but not JABU. All limbs demonstrated a double bump ankle kinetic pattern though in the variant limbs these were more severe. The variant limbs also produced the most dorsiflexion in the solid AFOs.

6.3.2.2 b) Hinged AFOs

Figure 6.4 presents the average traces for joint kinematic, kinetic and segment kinematic patterns for the baseline (flat) condition for all limbs in the hinged AFO group. The majority of limbs (13) demonstrated full or near full knee extension in late stance and were classified as 'common', with the remaining two limbs considered to be 'variants' as one demonstrated considerably more extension than the others (JOBA; black dash) and one limb (JANI; solid black) demonstrated a distinctly flexed pattern.

The common group demonstrated reasonable consistency across other variables although some limbs demonstrated increased knee flexion moment and some larger knee extension moments. One limb had limited knee flexion in swing (TIIR) and one limb demonstrated increased hip extension angle (HAGO). The flexed limb in the variant group (JANI) demonstrated increased hip flexion, increased hip flexion moment and decreased hip extension moment, a diminished second dorsiflexion moment peak, a more inclined femur and tibia but a less inclined foot position. The extended limb in the variant group (JOBA) demonstrated reduced peak knee flexion moment, increased peak knee extension moment, reduced femur recline at initial contact and increased peak incline, decreased tibial projection angle, no first dorsiflexion peak and reduced ankle dorsiflexion. The majority of limbs demonstrated excessive dorsiflexion.

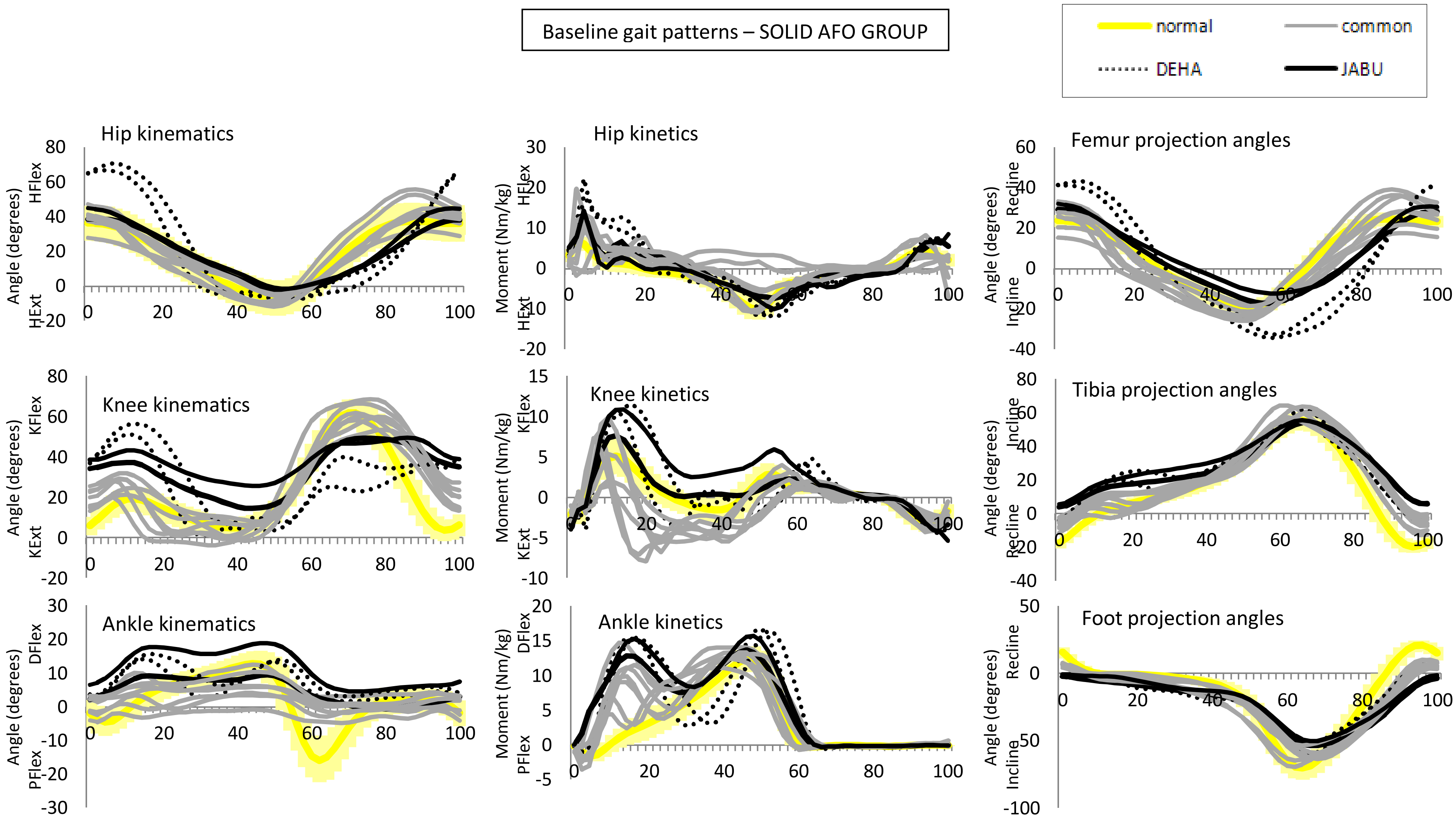


Figure 6.3 Average joint kinematics, kinetics and segment kinematics across the gait cycle for the baseline (flat) condition for each limb in the solid AFO group. Grey = common group; black = variant limbs; yellow = average ± 1SD for able bodied children (normal data provided by the Hugh Williamson Gait Laboratory, The Royal Children's Hospital, Melbourne, Australia).

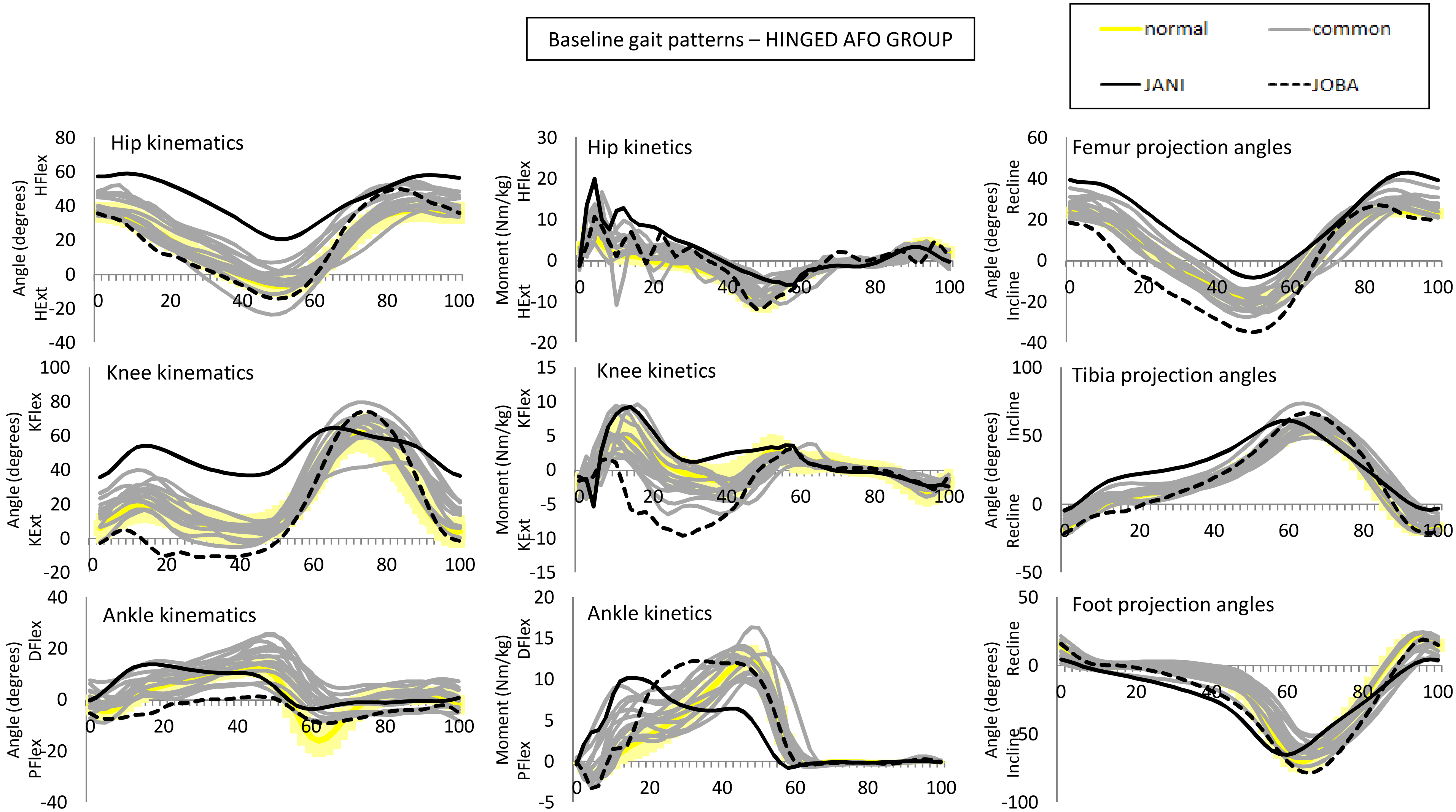


Figure 6.4 Average joint kinematics, kinetics and segment kinematics across the gait cycle for the baseline (flat) condition for each limb in the hinged AFO group. Grey =common group; black = variant limbs; yellow = average ±1SD for able bodied children (normal data provided by the Hugh Williamson Gait Laboratory, The Royal Children's Hospital, Melbourne, Australia).

6.3.3 Responsiveness to AFO-FC alignment change

Figure 6.5 presents the RMS difference in knee moment over mid-stance and over all of stance phase, and difference in knee moment at 30% gait cycle for all limbs in the solid and hinged AFO groups. The RMS values, coefficients of determination (r^2), gradient and significance level are presented in Table 6.1 and Table 6.2.

6.3.3.1 RMS difference over mid-stance

Using the RMS difference calculation over mid-stance, all limbs but one in each group demonstrated systematic increases in RMS difference in knee kinetics, whereby each increase in wedge size resulted in corresponding increase in RMS difference. In the solid AFO group, DEHA-L demonstrated small changes overall with the medium wedge producing smaller change than the small wedge. In the hinged AFO group, LIKE demonstrated systematic change in the small and medium wedges, but not in the large wedge. Coefficient of determination (r^2) values were close to 1.00 for the majority of limbs, with smaller values for the two limbs which did not demonstrate systematic change. All limbs that demonstrated a systematic increase in RMS difference with wedge size also had statistically significant correlations ($p<0.05$), and therefore 10/11 limbs in the solid AFO group and 14/15 in the hinged AFO group were classified as responsive by this criteria.

The size of change in knee moment varied across limbs within and between these two groups. The solid AFO group showed larger differences and greater variability than the hinged AFO group. This was reflected in the larger average and range of gradients in the solid AFO group (average 0.60, range 0.15-0.91 Nm/kg/degree), compared to the hinged group (average 0.41, range 0.31-0.61 Nm/kg/degree). In the solid AFO group, the common sub-group (average gradient 0.73 Nm/kg/degree) were more responsive than the variants (0.38 Nm/kg/degree). In the hinged AFO group the variant limb with a more extended pattern (JOBA; gradient 0.53 Nm/kg/degree) and the common sub-group (average gradient of 0.41 Nm/kg/degree) were slightly more responsive than the variant limb with a more flexed pattern (JANI; gradient of 0.31Nm/kg/degree).

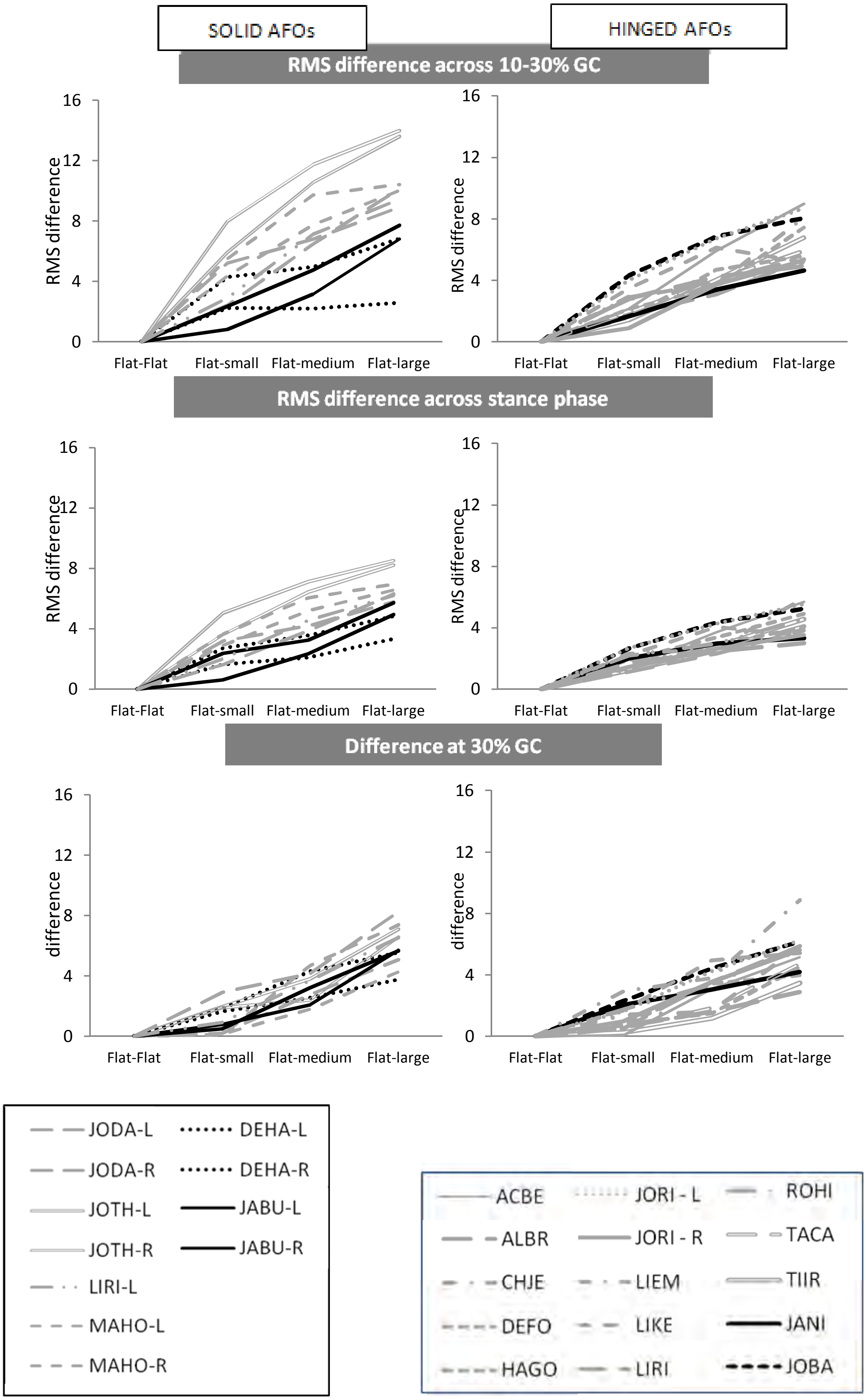


Figure 6.5 RMS difference between the baseline (flat) condition and the small (5°), medium (10°), and large wedge (15°) across 10-30% GC and all of stance phase, and difference at 30% GC for the solid and hinged AFO groups. A point 'zero' is included for comparative purposes. Grey = common group; black = variant limbs.

RMS difference in knee moments – solid AFOs

Sub-group	Limb	RMS dif. Mid-stance			r^2	G	SE	*p*	RMS dif. Stance phase			r^2	G	SE	*p*	Difference at 30% GC			r^2	G	SE	*P*
		Flat-small	Flat-med	Flat-Large					Flat-small	Flat-med	Flat-Large					Flat-small	Flat-med	Flat-Large				
Common	JODA-L	5.20	6.81	8.91	0.93	0.57	0.11	**0.038**	3.19	4.20	5.80	0.94	0.37	0.06	**0.029**	2.90	4.15	8.25	0.96	0.52	0.07	**0.020**
	JODA-R	2.40	6.46	10.14	0.99	0.69	0.05	**0.005**	1.62	3.87	6.31	0.90	0.42	0.03	**0.004**	0.18	2.75	5.06	0.91	0.36	0.08	**0.044**
	JOTH-L	5.93	10.5	13.59	0.98	0.91	0.09	**0.010**	3.62	6.43	8.22	0.98	0.55	0.06	**0.011**	1.94	3.81	7.08	0.98	0.46	0.05	**0.010**
	JOTH-R	7.95	11.7	13.98	0.92	0.91	0.18	**0.038**	5.03	7.11	8.52	0.91	0.55	0.12	**0.041**	1.87	2.41	6.57	0.89	0.41	0.10	0.057
	LIRI-L	2.88	7.11	9.44	0.99	0.65	0.05	**0.006**	2.01	4.54	6.21	0.99	0.42	0.02	**0.003**	0.92	3.70	6.53	0.96	0.45	0.07	**0.021**
	MAHO-L	4.35	7.72	10.01	0.98	0.67	0.07	**0.009**	2.90	5.20	6.56	0.98	0.44	0.05	**0.012**	0.12	1.80	4.26	0.88	0.29	0.07	0.061
	MAHO-R	5.48	9.72	10.42	0.91	0.71	0.15	**0.044**	3.65	6.04	6.96	0.94	0.47	0.09	**0.033**	0.11	4.69	7.40	0.91	0.54	0.12	**0.048**
Sub-group average (SD)		4.88 (1.89)	8.58 (2.07)	10.93 (2.02)	0.96 (0.03)	0.73 (0.1)	0.1 (0.05)	0.02 (0.02)	3.15 (1.1)	5.34 (1.22)	6.94 (1.0)	0.95 (0.04)	0.46 (0.07)	0.06 (0.03)	0.02 (0.02)	1.15 (1.1)	3.33 (1.0)	6.45 (1.4)	0.93 (0.04)	0.43 (0.1)	0.08 (0.02)	0.04 (0.02)
Variant	DEHA-L	2.23	2.21	2.57	0.71	0.15	0.07	0.159	1.63	2.08	3.34	0.96	0.21	0.03	**0.021**	1.63	2.56	3.76	0.99	0.24	0.02	**0.006**
	DEHA-R	4.28	4.97	6.81	0.90	0.42	0.10	**0.054**	2.71	3.55	4.84	0.94	0.31	0.06	**0.031**	1.84	4.30	5.54	0.99	0.38	0.03	**0.007**
	JABU-L	2.33	4.75	7.72	1.00	0.51	0.02	**0.002**	2.37	3.26	5.73	0.97	0.36	0.04	**0.014**	0.48	3.21	5.64	0.94	0.39	0.07	**0.031**
	JABU-R	0.81	3.16	6.79	0.93	0.45	0.09	**0.036**	0.62	2.34	4.93	0.93	0.33	0.06	**0.034**	0.78	2.08	5.69	0.89	0.37	0.09	0.059
Sub-group average (SD)		2.41 (1.43)	3.77 (1.32)	5.97 (2.31)	0.88 (0.12)	0.38 (0.16)	0.07 (0.04)	0.06 (0.07)	1.83 (0.9)	2.81 (0.71)	4.71 (1.0)	0.95 (0.02)	0.30 (0.07)	0.05 (0.02)	0.03 (0.01)	1.18 (0.66)	3.04 (0.96)	5.16 (0.93)	0.95 (0.05)	0.35 (0.07)	0.05 (0.03)	0.03 (0.02)
Average (SD)		3.99 (2.08)	6.83 (3.00)	9.13 (3.21)	0.93 (0.08)	0.60 (0.22)	0.09 (0.05)	0.04 (0.04)	2.67 (1.2)	4.42 (1.64)	6.13 (1.5)	0.95 (0.03)	0.40 (0.1)	0.06 (0.03)	0.02 (0.01)	1.16 (0.93)	3.22 (0.97)	5.98 (1.35)	0.94 (0.09)	0.40 (0.09)	0.07 (0.03)	0.03 (0.02)

Table 6.1 RMS difference in knee kinetics across mid-stance and all of stance phase and difference at 30% gait cycle, along with coefficient of determination (r^2), G=gradient (Nm/kg/degree), standard error (SE) of gradient, and significance (p) values for all limbs in the solid AFO group. Data significant at a p<0.05 is highlighted in bold.

RMS difference in knee moments – hinged AFOs

Subgroup	Limb	RMS dif. midstance			r^2	G	SE	*p*	RMS dif. stance phase			r^2	G	SE	*p*	Difference at 30% GC			r^2	G	SE	*p*
		Flat-small	Flat-med	Flat-large					Flat-small	Flat-med	Flat-large					Flat-small	Flat-med	Flat-large				
Common	ACBE	2.16	5.90	8.97	0.99	0.61	0.04	**0.005**	1.43	3.69	5.70	0.99	0.39	0.02	**0.004**	0.06	3.08	5.14	0.91	0.37	0.08	**0.048**
	ALBR	1.78	3.10	5.36	0.99	0.35	0.02	**0.005**	1.14	2.31	3.82	1.00	0.25	0.01	**0.002**	0.50	3.52	5.86	0.94	0.41	0.07	**0.031**
	CHJE	2.87	3.80	5.08	0.94	0.32	0.06	**0.033**	1.79	2.59	3.97	0.98	0.25	0.03	**0.010**	1.38	1.61	5.89	0.82	0.36	0.12	0.093
	DEFO	2.12	3.58	7.44	0.96	0.48	0.07	**0.021**	1.92	3.38	4.92	1.00	0.32	0.01	**0.002**	0.68	3.44	3.98	0.92	0.06	0.04	**0.040**
	HAGO	1.59	4.67	5.57	0.96	0.40	0.06	**0.020**	1.35	2.93	4.00	0.99	0.27	0.01	**0.003**	0.79	1.48	4.50	0.87	0.28	0.08	0.069
	JORI - L	4.01	6.71	8.66	0.97	0.47	0.04	**0.013**	2.66	4.28	5.53	0.97	0.36	0.05	**0.015**	1.60	4.24	6.26	0.99	0.43	0.03	**0.004**
	JORI - R	0.88	3.71	5.30	0.97	0.37	0.05	**0.018**	1.45	2.62	3.54	0.99	0.24	0.02	**0.005**	0.96	3.53	5.60	0.97	0.39	0.05	**0.014**
	LIEM	2.94	3.76	8.07	0.94	0.50	0.09	**0.031**	2.30	2.59	5.92	0.91	0.36	0.08	**0.044**	2.92	3.78	8.88	0.92	0.55	0.11	**0.040**
	LIKE	3.46	6.11	5.17	0.76	0.36	0.14	0.129	2.23	4.05	3.51	0.78	0.25	0.09	0.116	1.69	4.94	5.41	0.94	0.39	0.07	**0.033**
	LIRI-R	2.80	4.22	4.92	0.92	0.31	0.07	**0.040**	1.69	2.47	3.02	0.93	0.20	0.04	**0.034**	0.64	1.58	2.88	0.98	0.19	0.02	**0.012**
	ROHI	2.76	3.99	5.46	0.96	0.35	0.05	**0.018**	2.18	2.95	4.58	0.97	0.29	0.04	**0.015**	1.73	3.39	5.84	0.99	0.38	0.03	**0.005**
	TACA	1.92	4.00	5.92	1.00	0.40	0.00	**0.000**	1.20	2.49	4.08	1.00	0.27	0.01	**0.002**	0.54	1.83	4.69	0.90	0.31	0.07	0.054
	TIIR	1.42	4.00	6.75	0.98	0.46	0.04	**0.009**	1.24	2.81	4.56	0.99	0.31	0.02	**0.003**	0.25	1.17	3.47	0.86	0.23	0.07	0.075
Sub-group average (SD)		2.36 (0.87)	4.43 (1.11)	6.36 (1.45)	0.95 (0.06)	0.41 (0.09)	0.06 (0.03)	0.03 (0.03)	1.74 (2.33)	3.01 (3.66)	4.40 (4.3)	0.96 (0.06)	0.29 (0.06)	0.03 (0.03)	0.02 (0.03)	1.06 (0.8)	2.89 (1.2)	5.26 (1.5)	0.92 (0.05)	0.35 (0.12)	0.06 (0.03)	0.04 (0.03)
Variant	JANI	1.67	3.40	4.64	1.00	0.31	0.02	**0.002**	2.01	2.96	3.34	0.90	0.22	0.05	0.052	2.06	3.03	4.18	0.97	0.27	0.03	**0.015**
	JOBA	4.32	6.84	8.07	0.94	0.53	0.10	**0.032**	2.65	4.35	5.25	0.95	0.35	0.06	**0.024**	2.31	4.42	6.16	1.00	0.41	0.02	**0.002**
Sub-group average (SD)		3.00 (1.87)	5.12 (2.43)	6.36 (2.43)	0.97 (0.04)	0.42 (0.16)	0.06 (0.06)	0.02 (0.02)	2.33 (0.45)	3.66 (0.98)	4.30 (1.4)	0.93 (0.04)	0.29 (0.09)	0.06 (0.01)	0.04 (0.02)	2.19 (0.2)	3.73 (1.0)	5.17 (1.4)	0.98 (0.02)	0.34 (0.1)	0.03 (0.10)	0.03 (0.01)
Group average		2.45 (0.98)	4.52 (1.24)	6.36 (1.49)	0.95 (0.06)	0.41 (0.09)	0.06 (0.03)	0.03 (0.03)	1.82 (0.51)	3.10 (0.69)	4.38 (0.91)	0.96 (0.06)	0.29 (0.09)	0.04 (0.03)	0.02 (0.03)	1.21 (0.83)	3.00 (1.1)	5.25 (1.43)	0.93 (0.05)	0.33 (0.1)	0.06 (0.03)	0.04 (0.03)

Table 6.2 RMS difference in knee kinetics across mid-stance and all of stance phase, and difference at 30% gait cycle, along with coefficient of determination (r^2), gradient (Nm/kg/degree), standard error (SE) of gradient, and significance (p) values for all limbs in the solid AFO group. Data significant at a p<0.05 is highlighted in bold.

6.3.3.2 RMS difference over stance phase

When the RMS difference was calculated over all of stance phase, there were similar systematic increases in both the solid and hinged AFO groups, although the values were smaller and more consistent across conditions and limbs compared to the mid-stance analysis (refer to Figure 6.5). In the solid AFO group the average gradient was reduced to 0.40Nm/kg/degree, with a smaller range of 0.21-0.55 Nm/kg/degree, and in the hinged group the average was reduced to 0.29Nm/kg/degree, also with a smaller range 0.20-0.39 Nm/kg/degree (refer to Table 6.1 and Table 6.2). In the solid AFO group the common sub-group was still more responsive than the variant limbs, and in the hinged AFO group the extended variant limb (JOBA) was more responsive than the majority of the common subgroup, which were more responsive than the flexed variant limb (JANI). All limbs in the solid AFO group and 13/15 limbs in the hinged AFO group demonstrated significant results and were thus classified as responsive by this criteria. The two non-responsive limbs were LIKE, which did not demonstrate systematic change, and JANI, the flexed variant limb. LIKE was also classified as non-responsive according to the mid-stance analysis, whereas JANI was classified as responsive.

6.3.3.3 Difference at 30% gait cycle

When difference in knee moment was calculated at a single point at 30% of the gait cycle, there was a loss of sensitivity to change between the flat and small wedge in many limbs. In the solid AFO group the overall effect was to produce more consistent changes of smaller value whereas in the hinged group the effect was the opposite with more variable changes of large values, compared to the stance phase calculation. In both AFO groups there was little difference in responsiveness based on gait pattern. Only 9/11 limbs in the solid AFO group and 11/15 limbs in the hinged AFO group were statistically significant and therefore classified as responsive by this criteria.

6.3.3.4 Relationship between analyses

Scatterplots of the gradients produced by the mid-stance analysis compared to the stance phase and single point analyses are presented in Figure 6.6, along with the gradient and coefficient of determination of the regression. The correlation coefficient (r) and coefficient of determination (r^2) of these relationships are presented in Table 6.3.

The results revealed a strong positive relationship and therefore good agreement between data calculated using the mid-stance and stance phase analyses for both the solid and hinged AFO groups. High coefficient of determination (r^2) values suggest that 98% and 78% of variability within the data set is explained by this relationship, for the solid and hinged groups respectively. However when the mid-stance analysis is compared to the single point analysis, there is only a weak (r=0.58) to no relationship (r=0.18) between the data for the solid and hinged AFO groups respectively, suggesting poor agreement between these two methods of calculating responsiveness.

	Mid-stance vs stance phase		Mid-stance vs 30% gait cycle	
	r	r^2	R	r^2
solid	0.99	0.98	0.53	0.28
hinged	0.88	0.78	0.18	0.03

Table 6.3 Correlation coefficient (r) and coefficient of determination (r^2) for the solid and hinged AFO groups for the comparisons of the mid-stance analysis with the stance phase and single point analysis.

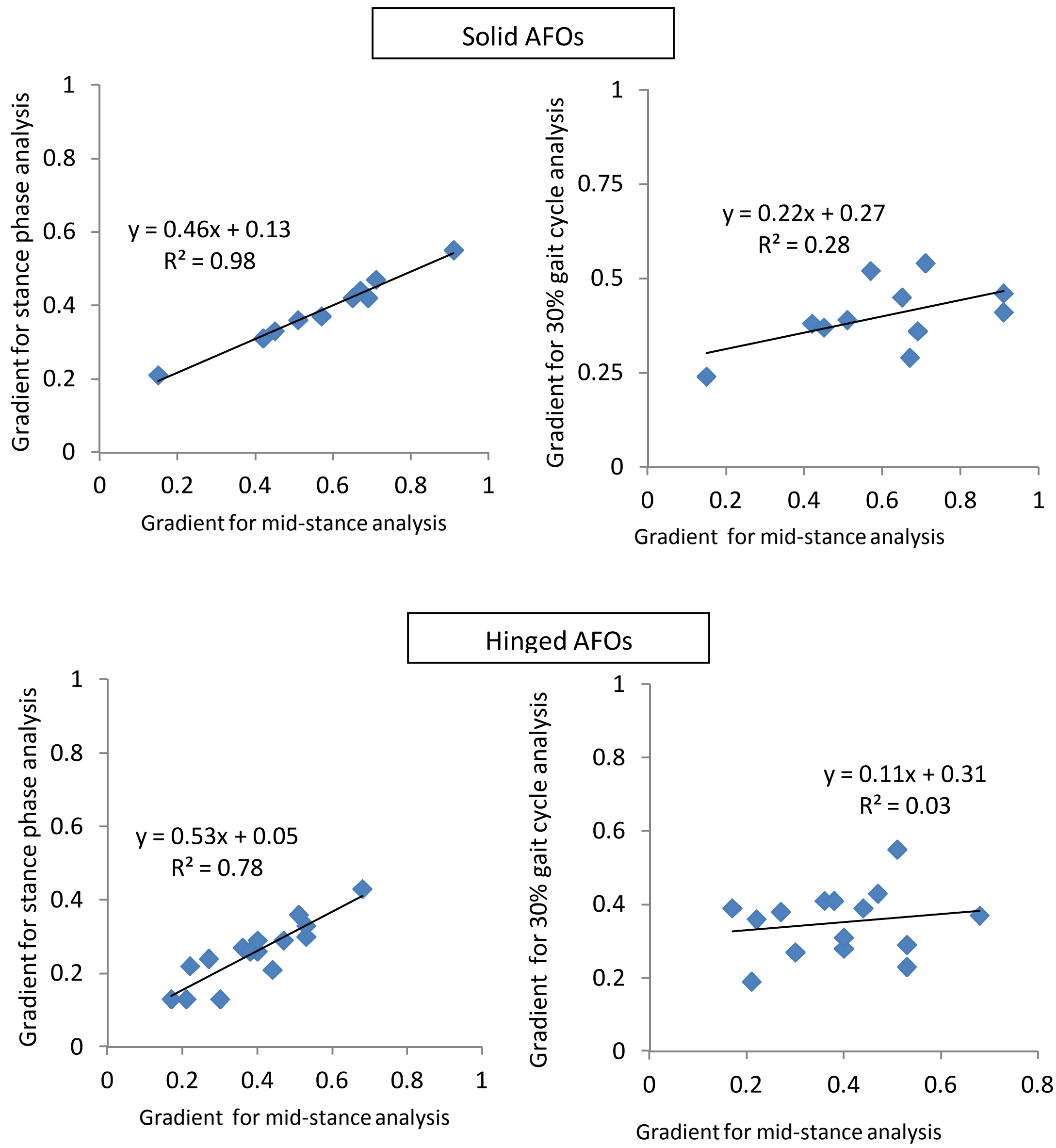


Figure 6.6 Scatterplot and line of best fit for gradient according to the mid-stance and stance phase analysis, and the mid-stance and 30% gait cycle analysis, including the coefficient of determination (r^2) and gradient.

6.3.4 Effect of AFO-FC alignment on gait

The following section summarises the effect of increasing wedge size on a range of gait parameters within the solid and the hinged AFO groups. Within each AFO group the analysis is divided into 'individual' results and 'sub-group' results. The individual results comprise the change in each of the probable response variables and possible response variables, which represent gait characteristics occurring over the entire gait cycle, between the flat and small, medium and large wedges for all limbs as well as the temporospatial results presented as absolute values. A summary table presenting the overall effect of wedge size on inducing systematic alignment changes concludes each individual section. This is followed by the average traces and parameters for the common sub-groups. The individual gait traces demonstrating the change due to each wedge size across all parameters are listed in Appendix E.

6.3.4.1 Solid AFOs

The change in each gait parameter between the flat, small, medium and large wedges for all limbs in the solid AFO group is presented in Figure 6.7, with the temporospatial results presented in Figure 6.8. In these figures, a value of zero indicates that the wedges induced no change in this parameter when compared to the baseline (zero degree SVA) condition. For a positive variable, for example peak (external) knee flexion moment, an increase in the difference between each condition and baseline indicates a larger knee flexion moment. For a negative value, for example peak (external) knee extension moment, an increase in the difference between each condition indicates a reduction in knee extension moment. The systematic changes observed in all parameters are summarised in Table 6.4.

Increasing wedge size tended to increase peak knee flexion moment and decrease peak knee extension moment across the majority of limbs. However, a plateau effect was seen in peak knee flexion moment in several limbs, all of which demonstrated substantially greater peak knee flexion moment compared to normal values, in early stance in the baseline condition. Increased wedge size resulted in increased peak knee flexion angle and decreased peak knee extension angle in stance across most limbs. However in one of the variant limbs, peak knee flexion reduced with increased wedge size. Tibial projection angle tended to increase in limbs in the common sub-group, but tended to decrease in the variant limbs, but these results, as measured by the average difference over 10-30% gait cycle, were not systematic. Peak tibial projection angle decreased across most limbs but systematically in only a handful. The first peak dorsiflexion moment was reduced in all limbs in the variant sub-group and some limbs in the common group. The second dorsiflexion moment peak was reduced systematically across all limbs, but by a smaller amount. The effect of wedge size on hip kinematics and kinetics and femur projection angles was variable, as was the effect on temporospatial variables (Figure 6.8).

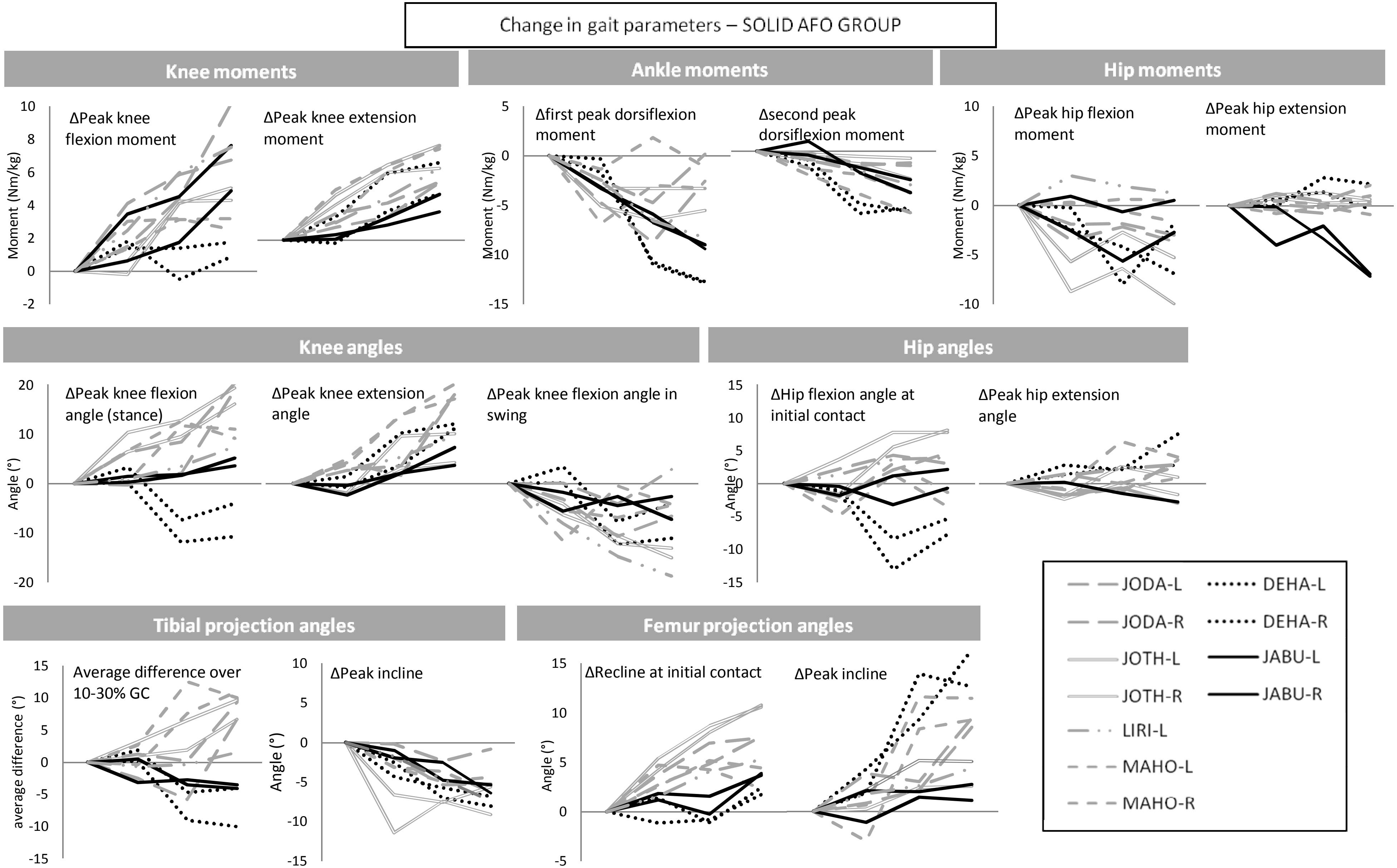


Figure 6.7 Change (Δ) in variables between the flat wedge and the small, medium and large wedges for all limbs in the solid AFO group. Grey = common sub-group; black = variant limbs.

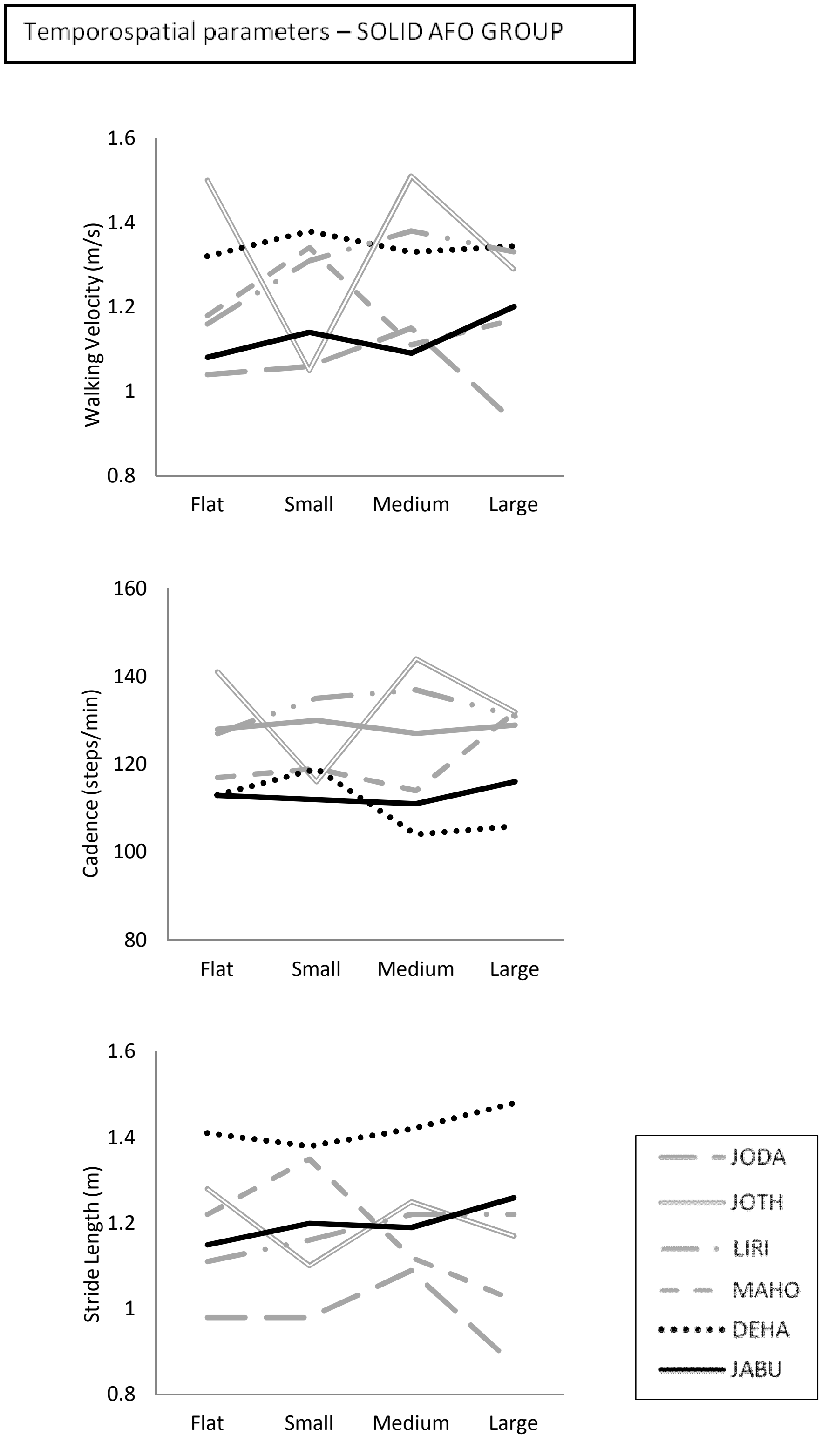


Figure 6.8 Individual average walking velocity, cadence and stride length across conditions for the solid AFO group.

<table>
<tr><th colspan="5">SUMMARY TABLE – SOLID AFOs</th></tr>
<tr><th colspan="2" rowspan="2">Variable</th><th colspan="2">Number demonstrating systematic changes</th><th rowspan="2">Additional information</th></tr>
<tr><th>Common n=7 limbs</th><th>Variant n=4 limbs</th></tr>
<tr><td rowspan="8">Probable response variables</td><td>Peak knee flexion moment</td><td>↑6*</td><td>↑3#</td><td>*# In 3 (*) and 1(#) of these limbs there was a plateau effect with no further increase after the small or medium wedges
* In the remaining limb there were systematic changes only in the medium and large wedges</td></tr>
<tr><td>Peak knee extension moment</td><td>↓7</td><td>↓4#</td><td>#The changes were systematic only after the small wedge</td></tr>
<tr><td>Peak knee flexion angle (stance)</td><td>↑6*</td><td>↑2#</td><td>*In the remaining limb the large wedge produced slightly smaller angles than the medium wedge.
#The remaining limbs produced reduced angles but were not systematic</td></tr>
<tr><td>Peak knee extension angle</td><td>↓5*</td><td>↓1#</td><td>*#In the two (*) and three (#) remaining limbs the changes were systematic after the small wedge</td></tr>
<tr><td>Tibial projection angle RMS difference 10-30% GC</td><td>↑2*</td><td>↓0#</td><td>*In the remaining limbs there were non-systematic increases
#In the four remaining limbs there were non-systematic reductions</td></tr>
<tr><td>Peak tibial projection angle</td><td>↓2</td><td>↓4</td><td></td></tr>
<tr><td>first peak dorsiflexion moment</td><td>↓2*</td><td>↓4</td><td>*In one of these limbs this first peak was completely eliminated by the medium wedge</td></tr>
<tr><td>second peak dorsiflexion moment</td><td>↓7</td><td>↓3#</td><td># In the one remaining limb the small wedge caused an increase before systematically reducing</td></tr>
<tr><td rowspan="11">Possible response variables</td><td>Peak knee flexion angle (swing)</td><td>↓3</td><td>↓1</td><td></td></tr>
<tr><td>Hip flexion angle at initial contact</td><td>↑2</td><td>↓0#</td><td>#Three other limbs demonstrated non-systematic reductions</td></tr>
<tr><td>Peak hip extension angle</td><td>↓1*</td><td>↓1#</td><td>*#Other limbs demonstrated non-systematic increases</td></tr>
<tr><td>Peak hip flexion moment</td><td>↓1</td><td>↓1</td><td></td></tr>
<tr><td>Peak hip extension moment</td><td>Variable</td><td>Variable</td><td></td></tr>
<tr><td>Femur recline at initial contact</td><td>↑5</td><td>0</td><td></td></tr>
<tr><td>Peak femur incline</td><td>↓4</td><td>↓1</td><td></td></tr>
<tr><td></td><td>n=4 children</td><td>n=2 children</td><td></td></tr>
<tr><td>Walking velocity</td><td>Variable</td><td>Variable</td><td>The variant limbs demonstrate less change than the common limbs</td></tr>
<tr><td>Cadence</td><td>Variable</td><td>Variable</td><td></td></tr>
<tr><td>Stride length</td><td>Variable*</td><td>Variable#</td><td>The variant limbs demonstrate less change than the common limbs, with a trend toward increasing stride length with increased wedge size</td></tr>
</table>

Table 6.4 Summary of systematic changes seen across the common and variant sub-groups of the solid AFO group.

6.3.4.2 *Average 'common' solid AFO sub-group*

Figure 6.9 presents the average traces for each condition across all parameters for the common solid AFO sub-group. The average peak values are reported in Table 6.5 and presented in Figure 6.10. On average, increasing wedge size by 5° resulted in increased peak knee flexion moment by approximately 2Nm/kg, and resulted in decreased peak knee extension moment by approximately the same amount. Every 5° increase in wedge size increased peak knee flexion in stance by approximately 4-5°, whereas peak knee extension angle was increased by an average of 3° in small wedges, and 7° in large wedges. The total reduction in knee flexion angle in swing was approximately 8°, in peak tibial incline was approximately 5°, in first dorsiflexion moment by approximately 4-5 Nm/kg and in second dorsiflexion moment by 2-3 Nm/kg. Peak hip flexion moment reduced by approximately 3Nm/kg whereas peak hip extension moment was largely unaffected. Both femur recline at initial contact and peak recline were increased and decreased respectively, by approximately 7° over the total range of wedge sizes, whereas hip flexion angle at initial contact and peak hip extension angle were increased and decreased respectively by approximately 4° in total.

Shapiro-Wilks tests of normality revealed all parameters with one exception were normally distributed (listed in Appendix F). The one-way repeated measure ANOVA revealed a significant effect of condition (wedge size) in all of the probable response variables; peak knee flexion moment [F(3, 18)=21.015,p=0.000], peak knee extension moment [F(3, 18)=66.080, p=0.000], peak knee flexion angle [F(3, 18)=21.382, p=0.000], peak knee extension angle [F(3, 180=21.533, p=0.000], peak tibial projection angle [F(3, 18)=12.713, p=0.000], first peak dorsiflexion moment [F(3, 18)=6.985, p=0.003] and second peak dorsiflexion moment F(3, 18=15.192, p=0.000], at an adjusted α level of 0.0071. Post hoc tests identified significant differences between a number of wedges across these variables at the adjusted post-hoc α level of 0.0083. Five of these were significant for 5° changes in wedge size with the remainder significant for 10° and 15° level wedge size changes.

A one-way repeated measures ANOVA was also conducted on the possible response variables, using the same Bonferroni corrections for multiple comparisons. Significant main effects were found in two of seven gait parameters; femur recline at initial contact [F(3, 18)=28.004, p=0.000] and peak femur incline [F(3, 18)=12.597, p=0.000]. Post hoc tests revealed significant pairwise comparisons for changes in wedge size of 5°, 10° and 15° for femur recline at initial contact, and for changes in wedge size of 10° and 15° for peak femur incline. No significant main effects were found in the temporospatial parameters. Any data that violated Mauchly's test of sphericity were analysed using the Greenhouse-Geisser correction. These data are presented in Table 6.5 and Figure 6.10.

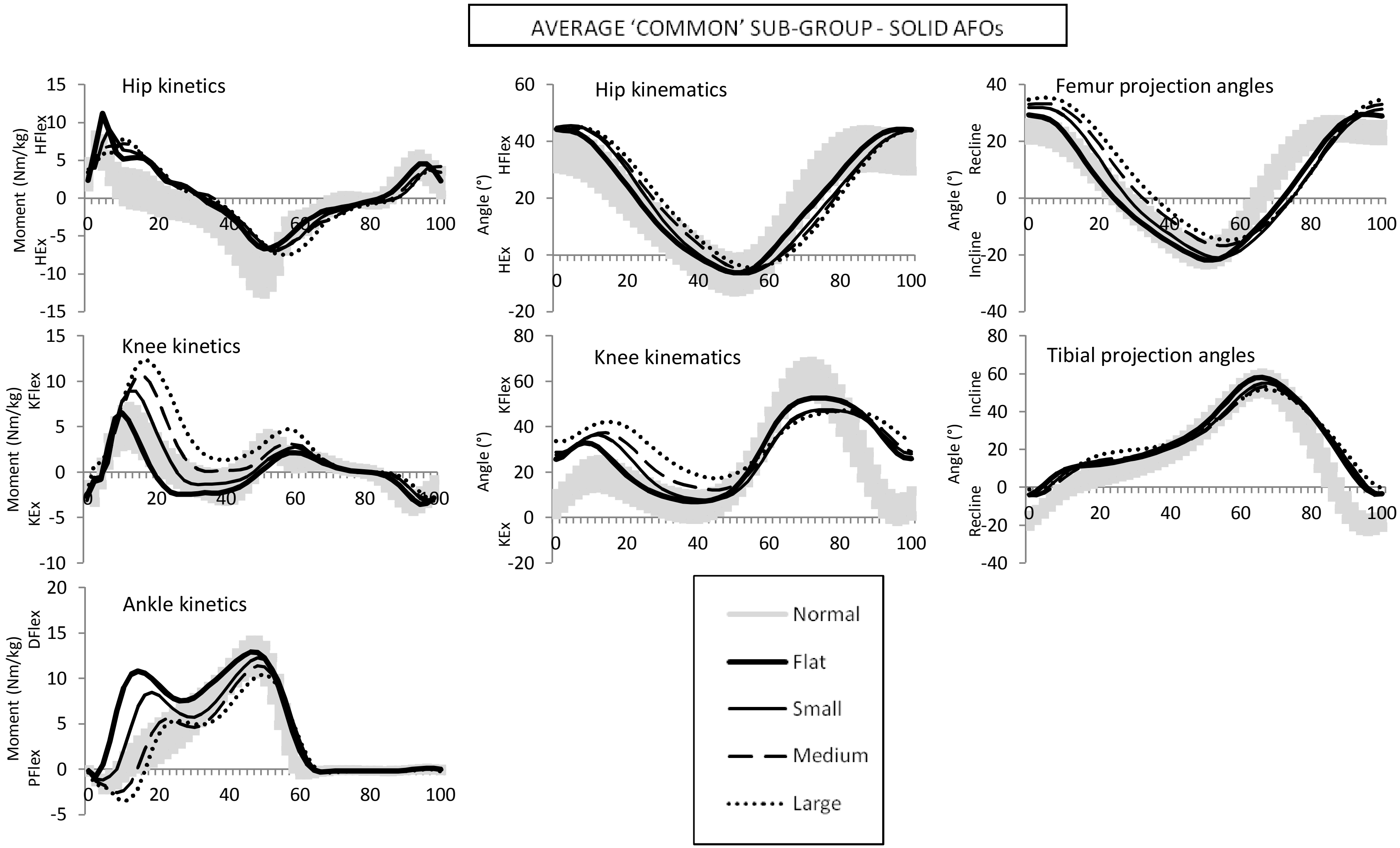


Figure 6.9 Average gait traces for each condition for the common solid AFO sub-group. Grey band indicates average ±1SD normal values for able bodied children.

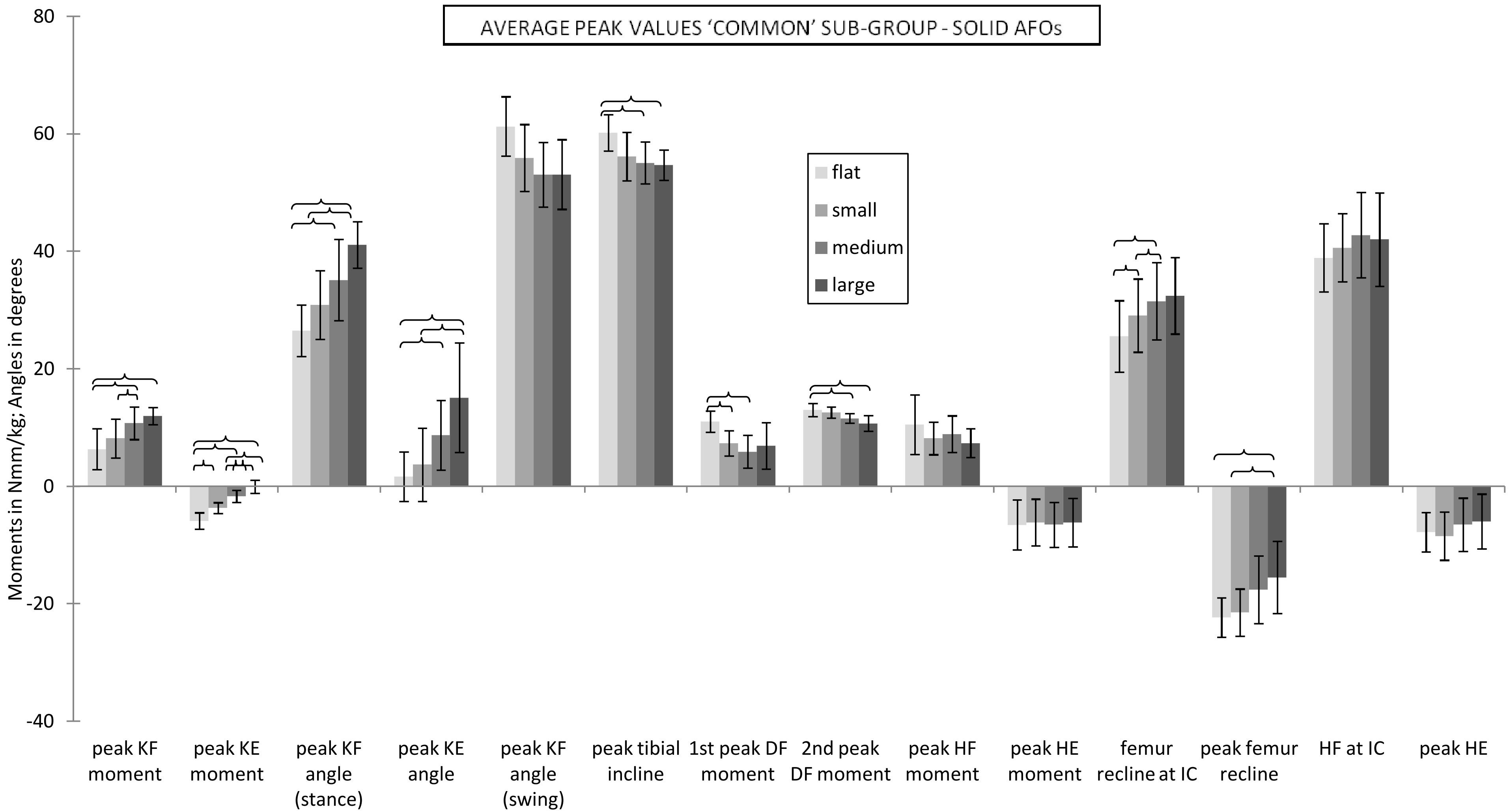


Figure 6.10 Average values ± 1SD for each condition for the common solid AFO sub-group. Moments are measured in Nmm/kg with positive values reflecting external flexion moments and negative values external extension moments; joint kinematics are measured in degrees with positive values reflecting flexion and negative values reflecting extension; projection angles are measured in degrees with positive values reflecting incline and negative values reflecting recline. Differences significant at a p<0.0083 level are indicated in brackets.

STATISTICAL RESULTS FOR THE AVERAGE 'COMMON' SUB-GROUP - SOLID AFOs

'Common' solid AFO sub-group	**Average**				**Standard Deviation**				**One way repeated measures ANOVA (Bonferroni correction, p<0.0071)**			**Post hoc tests (Bonferroni correction, p<0.0083)**					
	flat	**small**	**med**	**large**	**flat**	**small**	**med**	**large**	**DF**	**F**	**sig**	**flat-small (5)**	**flat-med (10)**	**flat-large (15)**	**small-med (5)**	**small-large (10)**	**med-large (5)**
peak knee flexion moment	6.33	8.16	10.74	11.97	3.48	3.29	2.78	1.44	3, 18	21.015	**0.000**	0.017	**0.000**	**0.001**	**0.003**	0.014	0.177
peak knee extension moment	-5.9	-3.69	-1.71	-0.09	1.41	0.91	1.03	1.12	3, 18	66.080	**0.000**	**0.002**	**0.000**	**0.000**	**0.002**	**0.000**	**0.001**
peak knee flexion angle (stance)	26.47	30.88	35.13	41.1	4.41	5.85	6.92	3.95	3, 18	21.382	**0.000**	0.028	**0.002**	**0.000**	0.016	**0.002**	0.065
peak knee extension angle	1.67	3.68	8.69	15.09	4.2	6.23	5.95	9.34	3, 18	21.533	**0.000**	0.105	**0.009**	**0.001**	0.038	**0.000**	0.032
peak tibial incline	60.2	56.17	55.06	54.65	3.1	4.13	3.57	2.59	3, 18	12.713	**0.000**	0.032	**0.000**	**0.001**	0.282	0.195	0.600
first peak dorsiflexion moment	11.01	7.32	5.89	6.91	1.83	2.12	2.79	3.97	3, 18	6.985	**0.003**	**0.001**	**0.010**	0.017	0.287	0.758	0.455
second peak dorsiflexion moment	12.98	12.58	11.56	10.71	1.11	0.95	0.81	1.33	3, 18	15.192	**0.000**	0.202	**0.000**	0.**002**	0.023	0.018	0.030
peak knee flexion angle (swing)	61.26	55.90	53.04	53.09	5.07	5.70	5.51	5.93	10.490, 1.748	6.528	0.017						
peak hip flexion moment	10.51	8.16	8.90	7.36	5.06	2.77	3.11	2.45	6.718, 1.12	3.580	0.100						
peak hip extension moment	-6.56	-6.15	-6.55	-6.15	4.24	3.98	3.84	4.14	3, 18	1.730	0.197						
femur recline at initial contact	25.51	29.06	31.51	32.44	6.09	6.23	6.56	6.52	3, 18	28.004	**0.000**	**0.000**	**0.000**	**0.001**	**0.003**	0.022	0.211
peak femur incline	-22.30	-21.50	-17.60	-15.50	3.32	4.00	5.76	6.14	3, 18	12.597	**0.000**	0.298	0.011	**0.001**	0.070	**0.006**	0.095
hip flexion angle at initial contact	38.87	40.62	42.77	42.01	5.80	5.78	7.26	7.96	3, 18	3.556	0.035						
peak hip extension angle	-7.80	-8.49	-6.54	-5.99	3.37	4.09	4.54	4.67	3, 18	3.789	0.029						
Walking velocity (m/s)	1.22	1.19	1.29	1.18	0.20	0.16	0.19	0.18	3, 18	0.422	0.742						
Cadence (steps/min)	128	125	131	131	9.84	8.98	13.03	1.41	3, 18	0.438	0.732						
Stride length (cm)	1.15	1.15	1.17	1.07	0.13	0.15	0.08	0.16	3, 18	0.775	0.537						

Table 6.5 Average and standard deviations of values for parameters of interest for the common solid AFO sub-group. Moments are expressed in Nm/kg, angles in degrees. Significant main effects at p<0.0071 indicated in bold (and post-hoc tests only conducted on these), significant pairwise comparisons at p<0.0083 indicated in bold.

6.3.4.3 Hinged AFOs

The change in each gait parameter between the flat, small, medium and large wedges for all limbs in the hinged AFO group is presented in Figure 6.11 with the temporospatial results presented in Figure 6.12. The systematic changes observed in gait variables are summarised in Table 6.6.

Increasing wedge size tended to increase peak knee flexion moment and angle and decrease peak knee extension moment and angle, although the systematic effects were more consistent on peak knee extension moment and angle. The effect on tibial projection angles was variable. The first and second peak dorsiflexion moments were reduced in approximately half of the limbs. The effect of wedge size on hip kinematics and kinetics was variable, however more than half of the limbs demonstrated changes to femur recline at initial contact and peak femur incline. Peak knee flexion during swing was also reduced in many limbs.

The effect of wedge size on cadence, walking velocity and stride length (Figure 6.12) in the hinged AFO group showed a variety of responses across the group.

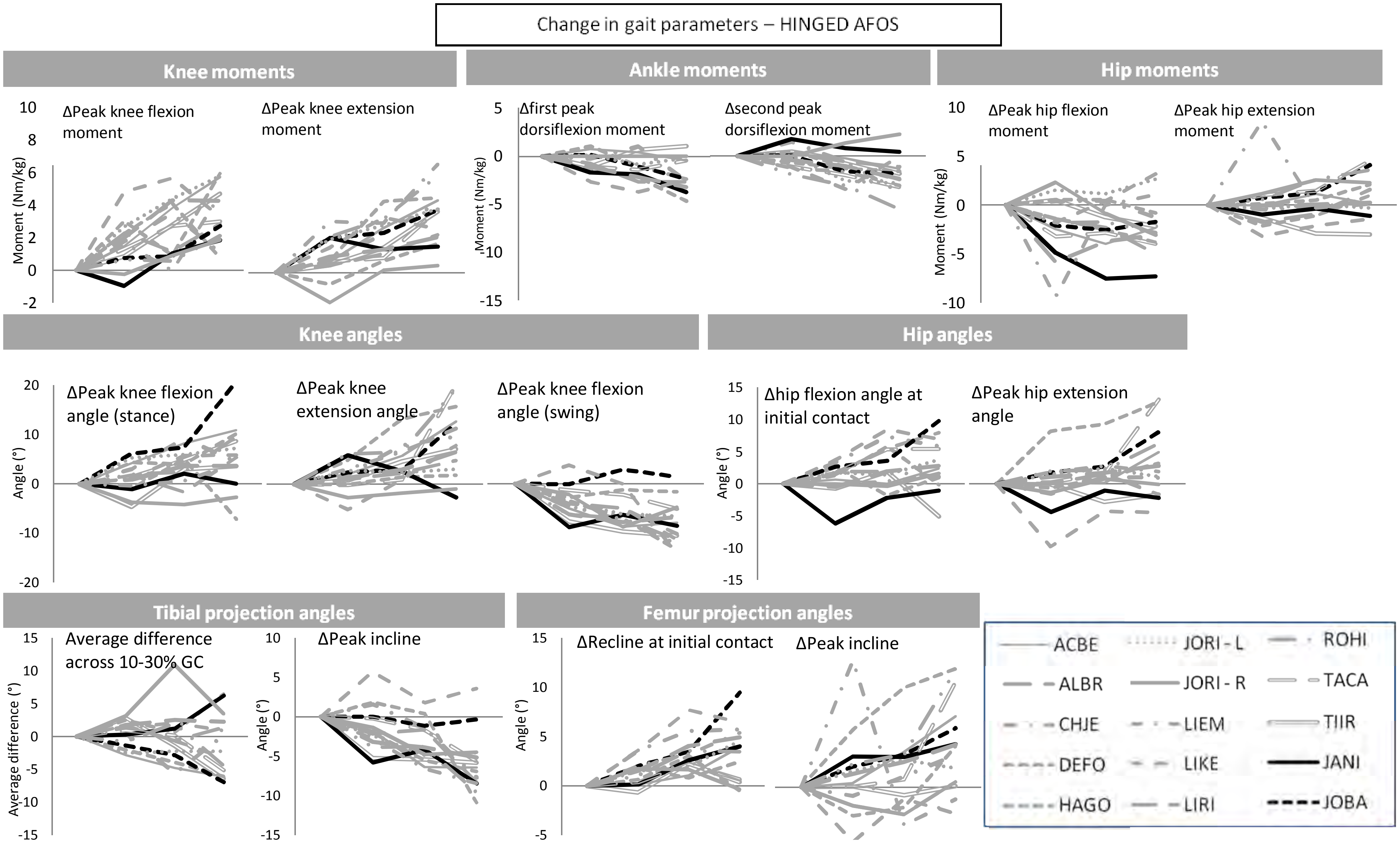


Figure 6.11 Change (Δ) in variables between the flat wedge and the small, medium and large wedges for all limbs in the hinged AFO group; and RMS difference over stance phase for tibial projection angles. Grey = common sub-group; black = variant limbs.

Temporospatial parameters – HINGED AFOS

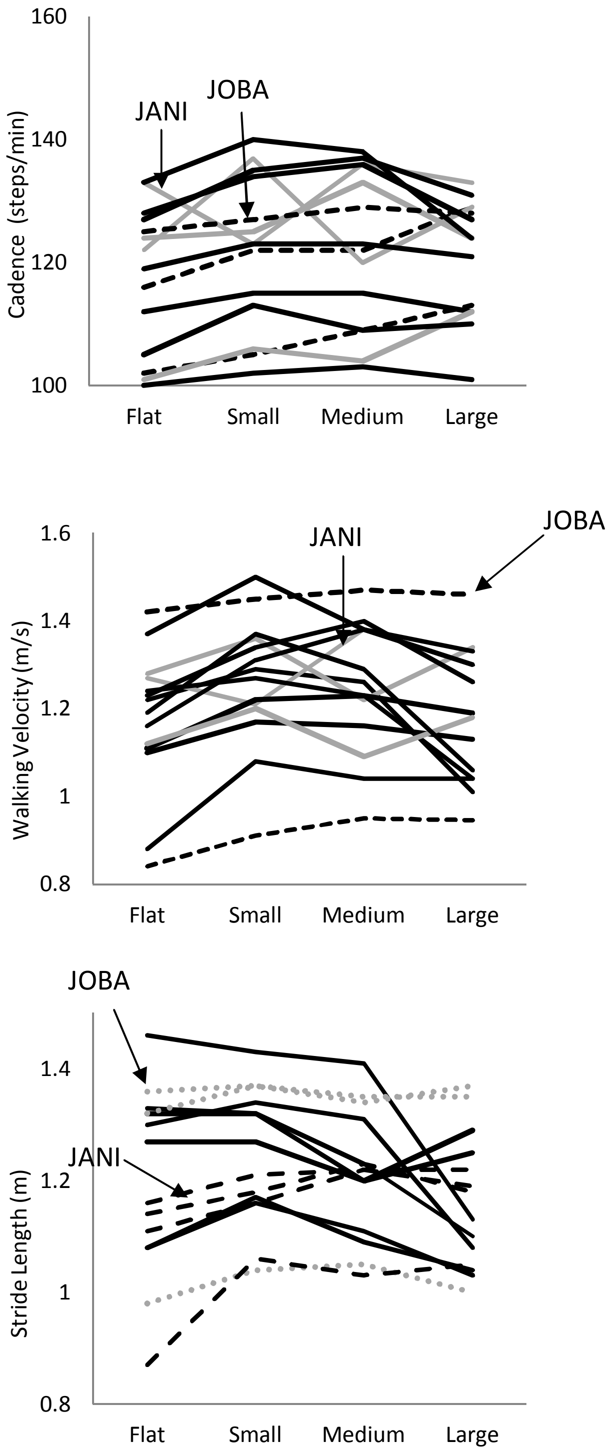


Figure 6.12 Individual average cadence, walking velocity and stride length across conditions for the hinged AFO group. NOTE – LIRI is included in both the solid and hinged AFO group as one limb had a solid AFO and one limb had a hinged AFO. Results belonging to the two variant limbs are indicated.

SUMMARY TABLE – HINGED AFOS				
Variable		Number demonstrating systematic changes		Additional information
		Common n=13 limbs	Variant n=2 limbs	
Probable response variables	Peak knee flexion moment	↑5	↑1#	#JOBA. JANI demonstrated systematic changes in the medium and large wedges
	Peak knee extension moment	↓10*	↓1#	*Two other limbs demonstrated systematic changes in the medium and large wedges #JOBA
	Peak knee flexion angle (stance)	↑8	↑1#	#JOBA.
	Peak knee extension angle	↓10	↓1#	#JOBA.
	Tibial projection angle RMS difference 10-30% GC	↑2, ↓2	↓1	#JOBA.
	Peak tibial projection angle	↓3	0	In many other limbs there were reductions but these were not systematic
	first peak dorsiflexion moment	↓7	↓1	
	second peak dorsiflexion moment	↓7	0	
Possible response variables	Peak knee flexion angle (swing)	↓9	0	
	Hip flexion angle at initial contact	↑3*	0	*Several other limbs demonstrated partial systematic changes
	Peak hip extension angle	↓1*	↓1#	*#Other limbs demonstrated non-systematic increases
	Peak hip flexion moment	↓3	↓2	
	Peak hip extension moment	↑1,↓4	↓1	
	Femur recline at initial contact	↑8	↑2	
	Peak femur incline	↓7	↓2	
		n=12 children	**n=2 children**	
	Walking velocity	Variable	Variable	The variant limbs demonstrate less change than the common limbs
	Cadence	Variable	Variable	
	Stride length	Variable*	Variable#	The variant limbs demonstrate less change than the common limbs, with a trend toward increasing stride length with increased wedge size

Table 6.6 Summary of systematic changes seen across the common and variant sub-groups of the hinged AFO group.

6.3.4.4 Average 'common' hinged AFO sub-group

Figure 6.13 presents the average traces in each condition across these variables for the common hinged AFO subgroup. Average gait parameters are presented in Table 6.7 and in Figure 6.14.

On average, increasing wedge size by 5° increased peak knee flexion moment by approximately 2Nm/kg which was similar to the solid AFO group, but the reductions in peak knee extension moment were smaller, with approximately 1Nm/kg per 5° increase in wedge size. The changes to knee kinematics were smaller than the solid AFO group with every 5° increase in wedge size increasing peak knee flexion in stance by approximately 1-2° and reducing peak knee extension angle by between 1-3°. Similar to the solid AFO group, the total reduction in knee flexion angle in swing was approximately 8° with peak tibial incline reduced by approximately 5°. The first and second dorsiflexion moment were reduced by approximately 3Nm/kg. Changes to hip moments, hip angles and femur projection angles were smaller than the solid AFO group with peak hip flexion moment reduced by approximately 3Nm/kg whereas peak hip extension moment was largely unaffected. Both femur recline at initial contact and peak recline were increased and decreased respectively, by approximately 4-5° whereas hip flexion angle at initial contact and peak hip extension angle were increased and decreased respectively by approximately 3°.

The one-way repeated measures ANOVA revealed a significant effect of condition (wedge size) in all probable response variables: peak knee flexion moment [$F(3,36)=17.477$, $p=0.000$)], peak knee extension moment [$F(3, 16)=13.266$, $p=0.000$], peak knee flexion angle in swing [$F(3,36)=7.896$, $p=0.000$], peak knee extension angle [$F(2.296,27.551)=39.126$, $p=0.000$], peak tibial incline [$F(3, 36)=20.313$, $p=0.000$], first peak dorsiflexion moment [$F(1.86, 22.32)=15.845$,$p=0.000$) and second peak dorsiflexion moment [$F(3,36)=21.376$), $p=0.000$], at an adjusted α level of 0.0071. Mauchly's test of sphericity was violated in two variables (reported in Appendix F) and so data were analysed using the Greenhouse-Geiser correction and are indicated above by fractional degrees of freedom. Post hoc tests identified significant differences between nine pairs at wedge sizes of 5° as well as several at wedge sizes of 10° and 15°, at an adjusted α level of $p<0.0083$.

The one-way repeated measures ANOVA on the possible response variables revealed four significant main effects: peak knee flexion angle in swing [$F(1.777, 21.326)=18.252$, $p=0.000$], femur recline at initial contact [$F(3,36)=24.675$, $p=000$], peak femur incline [$F(1.847, 22.159)=9.832$, $p=0.001$] and hip flexion angle at initial contact [$F(2.181, 26.178)=5.875$, $p=0.007$]. Again, where Mauchly's test of sphericity was violated a Greenhouse-Geiser correction was used and these particular tests are indicated by fractional degrees of freedom. Post hoc tests revealed significant pairwise comparisons across 5°, 10° and 15° wedge sizes. Temporospatial results revealed no significant main effects.

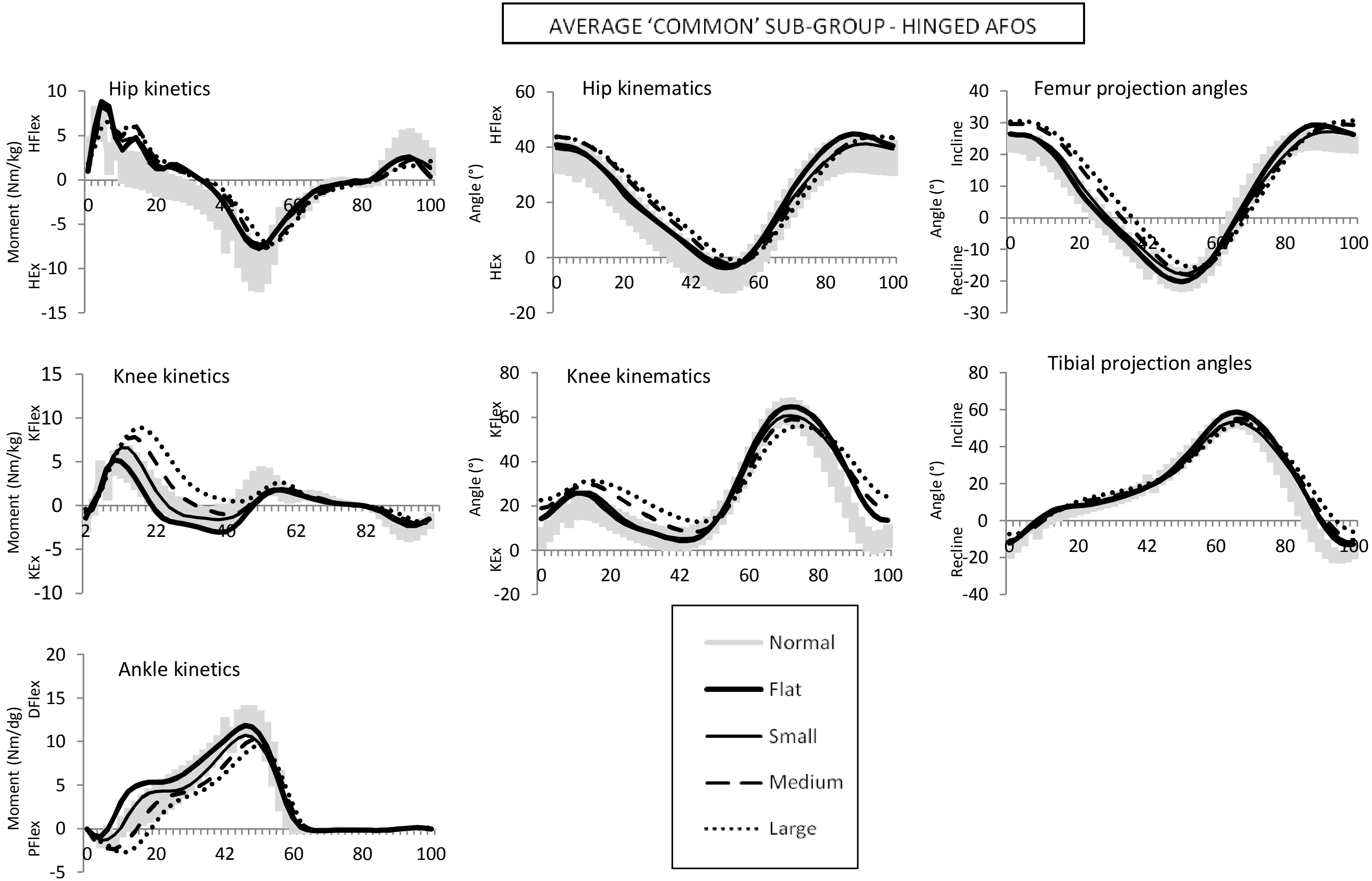


Figure 6.13 Average gait traces for each condition for the common hinged AFO sub-group. Grey band indicates average ±1SD normal values for able bodied children.

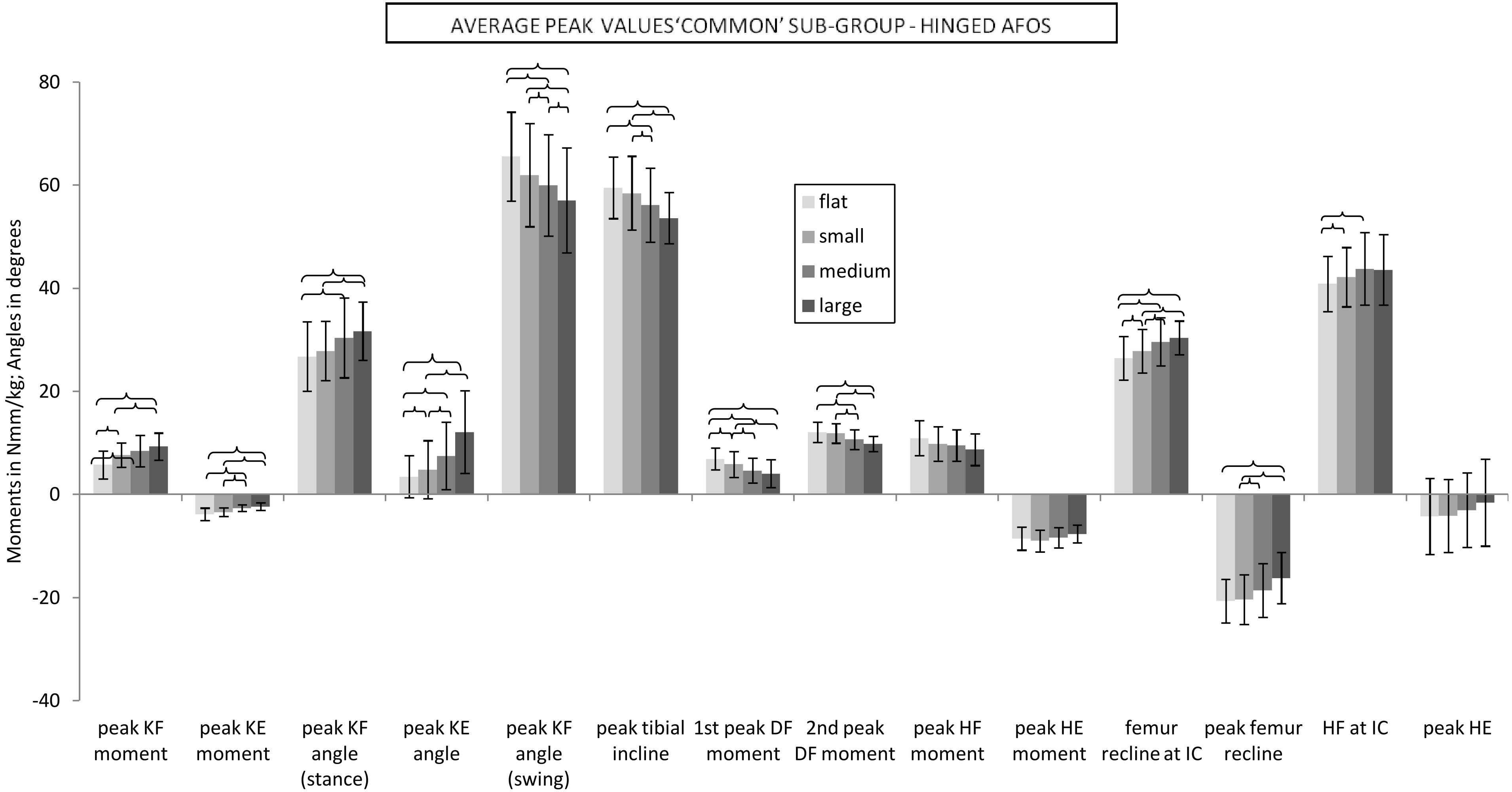


Figure 6.14 Average values ± 1SD for each condition for the common hinged AFO sub-group. Moments are measured in Nmm/kg with positive values reflecting external flexion moments and negative values external extension moments; joint kinematics are measured in degrees with positive values reflecting flexion and negative values reflecting extension; projection angles are measured in degrees with positive values reflecting incline and negative values reflecting recline. Differences significant at a p<0.0083 level are indicated in brackets.

STATISTICAL RESULTS FOR THE AVERAGE 'COMMON' SUB-GROUP - HINGED AFOs

'Common' hinged AFO sub-group	**Average**				**Standard Deviation**				**One way repeated measures ANOVA (Bonferroni correction, p<0.0071)**			**Post hoc tests (Bonferroni correction, p<0.0083)**					
	flat	**small**	**med**	**large**	**flat**	**small**	**med**	**large**	**DF**	**F**	**sig**	**flat-small (5)**	**flat-med (10)**	**flat-large (15)**	**small-med (5)**	**small-large (10)**	**med-large (5)**
peak knee flexion moment	5.73	7.35	8.17	9.10	2.89	2.60	3.27	2.79	3, 36	17.477	**0.000**	**.000**	**.000**	**.000**	.089	.009	.237
peak knee extension moment	-4.30	-3.78	-2.95	-2.57	1.87	1.33	1.31	1.13	3, 36	13.266	**0.000**	.104	**.001**	**.002**	**.001**	**.001**	.237
peak knee flexion angle (stance)	27.16	28.45	30.91	32.81	11.25	9.67	11.04	8.06	3, 36	7.896	**0.000**	.207	**.004**	**.005**	.015	**.004**	.379
peak knee extension angle	4.67	5.80	8.43	12.82	10.12	9.77	10.81	9.97	2.23, 27.56	39.126	**0.000**	**.001**	**.000**	**.000**	**.000**	**.000**	**.001**
peak tibial incline	60.11	58.80	56.82	54.41	5.87	7.05	7.12	5.67	3, 36	20.313	**0.000**	.204	**.001**	**.000**	**.000**	**.000**	.026
first peak dorsiflexion moment	7.47	6.29	4.93	4.43	2.49	2.63	2.42	2.74	1.86, 22.32	15.845	**0.000**	**.002**	**.000**	**.000**	**.001**	**.007**	.247
second peak dorsiflexion moment	11.98	11.65	10.69	9.93	1.90	1.96	2.05	2.01	3, 36	21.376	**0.000**	.349	**.000**	**.000**	**.000**	**.000**	.065
peak knee flexion angle (swing)	66.10	62.41	61.03	58.25	8.31	9.97	10.18	10.63	1.777, 21,326	18.252	**0.000**	0.151	**0.002**	**0.000**	**0.002**	**0.000**	**0.006**
peak hip flexion moment	11.52	10.07	9.59	9.00	3.92	3.39	2.95	3.03	2.012, 24.149	5.649	0.010						
peak hip extension moment	-8.60	-9.00	-8.40	-7.63	2.35	2.12	1.99	1.61	1.959, 23.502	3.898	0.035						
femur recline at initial contact	26.76	28.12	29.93	31.11	5.62	5.36	5.78	4.58	3, 36	24.675	**0.000**	**0.002**	**0.000**	**0.000**	**0.001**	**0.000**	0.195
peak femur incline	-20.78	-20.21	-18.58	-16.26	6.35	6.85	6.94	6.58	1.847, 22.159	9.832	**0.001**	0.726	0.035	**0.005**	**0.001**	**0.001**	0.035
hip flexion angle at initial contact	41.62	42.52	44.25	44.55	6.74	5.92	7.28	7.14	2.181, 26.178	5.857	**0.007**	**0.005**	**0.007**	0.015	0.054	0.098	0.802
peak hip extension angle	-3.27	-3.34	-2.11	-0.57	9.84	8.84	9.26	9.55	1.938, 23.258	3.707	0.041						
Walking velocity (m/s)	1.15	1.25	1.22	1.15	0.15	0.15	0.14	0.13	1.870, 20.565	6.386	0.008						
Cadence (steps/min)	116	121	121	119	11.58	13.29	12.99	9.53	2.018, 22.194	4.597	0.021						
Stride length (cm)	1.19	1.24	1.20	1.14	0.17	0.12	0.12	0.11	1.541, 16.952	3.546	0.062						

Table 6.7 Average and standard deviations of values for parameters of interest for the common hinged AFO subgroup. Moments are expressed in Nm/kg, angles in degrees. Significant main effects at p<0.0071 indicated in bold, significant pairwise comparisons at p<0.0083 indicated in bold.

6.3.4.5 *Between group differences*

The two-way repeated measures ANOVA revealed a significant effect of condition (wedge size) for the combined group for all variables with one exception; peak hip extension moment (refer to Table 6.8) at an adjusted α level of 0.0071. No variables had a significant effect of group. Mauchly's test of sphericity was violated in seven variables (data reported in Appendix F) and so data were analysed using the Greenhouse-Geiser correction or Huynh-Feldt adjustment and are indicated in Table 6.8 by fractional degrees of freedom.

A significant Wedge*Group interaction was found in only two variables; peak knee extension moment [$F(3,54)=29.299$, $p=0.000$] and peak knee flexion angle during stance phase [$F=(3,54)=7.573$, $p=0.000$]. Independent samples t-test were conducted to determine whether the groups were significantly different at each wedge size. There was a significant difference between groups for peak knee extension moment in the flat [$t(18)=3.50$, $p=0.003$], medium [$t(18)=-2.496$, $p=0.023$] and large wedges [$t(18)=-5.489$, $p=0.000$], and peak knee flexion angle in the large wedge size only [$t(18) =-3.13$, $p=0.001$]. Average data for these two variables is presented in Figure 6.15.

Variable	Average				Standard Deviation				Two-way repeated measures ANOVA (p<0.0071)								
									Effect of Wedge			Effect of Group			Wedge * Group interaction		
	flat	Small	Med	large	flat	small	med	large	DF	F	Sig	DF	F	Sig	DF	F	Sig
Peak knee flexion moment	5.97	7.83	9.25	10.24	2.92	2.65	3.10	2.58	3, 54	39.952	**0.000**	1, 18	1.658	0.214	3, 54	3.167	0.032
Peak knee extension moment	-4.55	-3.51	-2.30	-1.56	1.60	0.83	0.88	1.39	3, 54	87.728	**0.000**	1, 18	0.342	0.566	3, 54	29.299	**0.000**
Peak knee flexion angle	26.67	28.92	32.04	34.98	5.91	5.81	7.64	6.80	3, 54	33.133	**0.000**	1, 18	2.647	0.121	3, 54	7.573	**0.000**
Peak knee extension angle	2.84	4.42	7.91	13.16	4.12	5.71	6.20	8.37	1.415, 37.165	40.445	**0.000**	1,18	0.130	0.910	1.415, 37.165	2.028	0.145
Peak tibial angle	59.75	57.64	55.75	53.98	5.08	6.26	6.10	4.22	3, 54	26.772	**0.000**	1, 18	0.026	0.874	3, 54	2.663	0.057
1st dorsiflexion moment	8.35	6.36	5.08	5.03	2.82	2.43	2.55	3.41	2.734, 49.203	20.419	**0.000**	1, 18	5.717	0.028	2.734, 49.203	3.094	0.039
2nd dorsiflexion moment	12.40	12.11	10.97	10.13	1.75	1.64	1.66	1.47	2.03, 36.543	31.962	**0.000**	1, 18	1.527	0.232	2.03, 36.543	0.049	0.954
Peak knee flexion swing	64.05	59.84	57.54	55.65	7.71	9.08	9.08	8.97	3, 54	29.762	**0.000**	1, 18	1.921	0.183	3, 54	1.123	0.336
Peak hip flexion moment	10.79	9.23	9.28	8.24	3.93	3.17	3.00	2.88	2.025, 36.444	9.092	**0.001**	1, 18	0.504	0.487	2.025, 36.444	0.633	0.539
Peak hip extension moment	-7.86	-8.00	-7.75	-7.14	3.13	3.13	2.81	2.80	2.535, 45.636	2.405	0.089	1, 18	2.512	0.130	2.535, 45.636	1.941	0.145
Femur recline at initial contact	26.10	28.26	30.28	31.12	4.81	4.88	5.30	4.59	2.02, 36.366	56.09	**0.000**	1, 18	0.221	0.644	2.02, 36.366	4.418	0.019
Peak femur incline	-21.25	-20.77	-18.25	-15.97	3.93	4.47	5.30	5.27	3, 54	22.192	**0.000**	1, 18	0.016	0.900	3, 54	1.405	0.251
Hip flexion at initial contact	40.16	41.63	43.43	43.02	5.45	5.66	6.94	7.08	2.168, 39.032	9.177	**0.000**	1, 18	0.278	0.605	2.168, 39.032	0.152	0.875
Peak hip extension	-5.50	-5.67	-4.27	-3.11	6.42	6.42	6.51	7.53	3, 54	5.578	**0.002**	1, 18	1.754	0.202	3, 54	0.254	0.858

Table 6.8 Results of the two-way repeated measures ANOVA for the combined solid and hinged AFO groups. Significant effects are highlighted in bold (p<0.0071).

Post-hoc analysis on significant interaction effects										
Variable	**Wedge size**	**Levene's Test for Equality of Variances**		**t-test for Equality of Means**						
		F	**Sig**	**T**	**df**	**Sig. (2-tailed)**	**Mean Difference**	**Std. Error Difference**	**95% Confidence Interval of the Difference**	
									Lower	**Upper**
Peak knee extension moment	flat	0.771	0.392	3.500	18	**0.003**	2.08	0.60	0.83	3.33
	small	0.036	0.851	0.722	18	0.480	0.29	0.40	-0.55	1.12
	med	2.659	0.120	-2.496	18	**0.023**	-0.91	0.37	-1.68	-0.14
	large	0.833	0.374	-5.489	18	**0.000**	-2.26	0.41	-3.12	-1.39
Peak knee flexion angle (stance)	flat	0.813	0.379	0.103	18	0.919	0.29	2.84	-5.68	6.27
	small	0.011	0.919	-1.117	18	0.279	-3.02	2.70	-8.70	2.66
	med	0.044	0.836	-1.359	18	0.191	-4.76	3.50	-12.12	2.60
	large	1.283	0.272	-3.913	18	**0.001**	-9.41	2.41	-14.47	-4.36

Table 6.9 Results of independent samples t-tests (post hoc analysis on significant interaction effects). Significant results are highlighted in bold text.

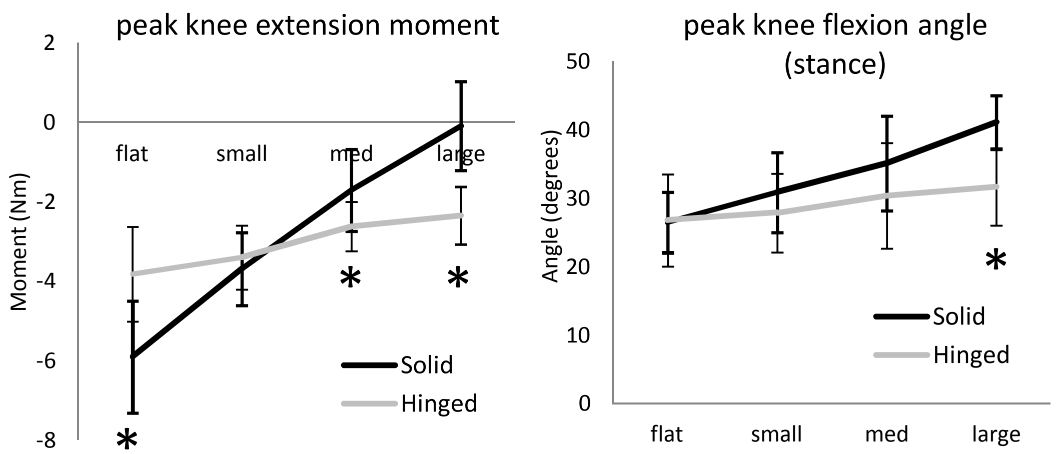


Figure 6.15 Average and standard deviations for peak knee extension moment and peak knee flexion angle during stance for all limbs in the solid AFO group and the hinged AFO group. Significant differences at p<0.05 are indicated with an asterix.

6.4 Discussion

6.4.1 Are all children responsive to AFO-FC alignment change?

The first aim of this analysis was to determine whether all children were responsive to AFO-FC alignment change according to changes occurring in knee moments over mid-stance. It was hypothesised that all limbs across both groups would be responsive when considering changes over mid-stance. This study found that when responsiveness was assessed using the mid-stance analysis, all limbs in both groups showed evidence of sensitivity to AFO-FC alignment change. In 24 out of 26 limbs (11 solid AFOs, 15 hinged AFOs) there was statistically significant correlation between wedge angle and knee moment.

While all limbs were sensitive to AFO-FC alignment change, some limbs were more sensitive than others, as measured by larger RMS differences and regression gradients. On the whole, knee moments in the solid AFO wearers were more sensitive than hinged AFO wearers, with larger average gradient of 0.6Nm/kg/degree compared with 0.41Nm/kg/degree. No other investigations have examined responsiveness to AFO-FC alignment change in these two AFO designs. Only one study has investigated the effect of AFO alignment (by changing the AFO ankle angle) on hinged AFOs which investigated adults with post-stroke hemiplegia (Fatone*, et al.*, 2009). While the question of responsiveness was not addressed in that study, the lack of significant changes to knee moments was attributed to the smaller range (0-7°) of AFO-FC alignments examined.

Across the mid-stance and stance phase analyses there were also some differences in sensitivity to AFO-FC alignment according to type of gait pattern. The most sensitive limbs were the common sub-groups and the variant limb of the hinged AFO group that demonstrated knee hyperextension. The least sensitive limbs were those with increased knee flexion during stance phase. This is in line with the findings of Butler and colleagues (2007) who suggested that children who could be successfully tuned, though not well defined, had limbs demonstrating less than 20° knee flexion followed by knee extension of less than 10°. Similarly Owen (2004c) suggested that tuning is more successful in those with more extended gait patterns.

According to these authors (Butler*, et al.*, 2007; Owen, 2004c) the four variant limbs in the solid AFO group would not be classified as successful tuners. However, these four limbs were all found to be responsive according to the stance phase analysis, with three of the four also responsive over the mid-stance analysis. Because the changes observed were an increase in peak knee flexion moment and a reduction in peak knee extension moment, changes for these limbs were largely away from normal values. The difference in classification of these limbs according to these methods reflects the differences between use of the term successful, which implies an improvement, and the term responsive which implies some change, either improvement or deterioration.

A subsidiary aim of this investigation was to determine whether the portion of the gait cycle included in the RMS analysis affected the number of limbs that were responsive. It was hypothesised that the results for mid-stance would be similar to all of stance phase, but that using a single point in the gait cycle would result in less systematic changes. The high correlation between the gradients of the mid-stance and stance phase analyses suggests that the two measures are closely related. In both instances, 25/27 limbs demonstrated statistically significant changes. When the difference calculation was performed on knee moment data from a single point in the gait cycle, there was reduced sensitivity to change across the majority of limbs. Importantly, there was also a loss of sensitivity to change induced by the small wedge. Fewer limbs were observed to change in a statistically significant manner, which supported the hypothesis. When the gradients of the regression between mid-stance and the single point analysis were compared, they drop to $r^2=0.22$ and $r^2=0.11$ for the solid and hinged AFO groups respectively, suggesting the two measures are not closely related. This probably indicates that error variability in the single point analysis is high because it is based on a single point whereas the mid-stance and stance phase analyses based on averages over a longer time are more stable.

Data was examined at 30% gait cycle because Owen (2010) suggested that this is the exact point in the gait cycle that children are tuned to using two dimensional video vector generators. Assuming stance phase length is 60%, this is equivalent to 50% of stance phase and thus is the 'middle' of stance phase. It is also the instant that the period of mid-stance according to Perry (1992) meets the period of terminal stance. The lack of agreement between the single point analysis and the mid-stance analysis suggests that there may be other changes occurring during mid-stance (and possibly also over all of stance phase) that change more consistently across limbs than the changes seen at 30% gait cycle. Alternatively, these differences may be because the single point measurement is more susceptible to error.

6.4.2 The effect of AFO-FC alignment on gait

The second aim of this analysis was to determine the effect of AFO-FC alignment on gait. It was hypothesised that peak knee flexion moment would increase systematically in all limbs and peak knee extension moment would decrease systematically in all limbs, but that the changes to knee kinematics, tibial projection angles and ankle moments would vary according to type of gait pattern. It was also hypothesised that hinged AFOs would behave similarly to solid AFOs for all variables during the early-mid stance phase.

6.4.2.1 Probable response variables

6.4.2.1.1 Knee moment

The results indicate that across all limbs the general effect of increasing wedge size was to systematically increase peak knee flexion moment and decrease peak knee extension moment (make less negative or became a knee flexion moment). The common sub-groups of both the solid and hinged AFO groups were also significantly affected by wedge size. This pattern was evident in all limbs in the solid AFO group, with some minor variations to the systematic effect. In several limbs, all of which demonstrated large knee flexion moments in early stance in their baseline knee kinematic pattern, a plateau effect in the peak knee flexion moment was observed where no further changes were induced after peak knee flexion moment reached approximately 12.5Nm/kg, This suggests an upper limit or tolerance to increases in peak knee flexion moment.

Because all limbs did not change systematically, the hypothesis was not supported. While this may be due to the narrow definition of systematic changes adopted for this analysis, the overall findings and significant effects demonstrated in the common sub-groups do support findings from previous literature, that changing an AFO-FC to increase the SVA will reduce peak knee extension moment in both adults and children (Bowers & Meadows, 2007; Butler*, et al.*, 1997; Butler*, et al.*, 2007; Butler*, et al.*, 1992; Jagadamma*, et al.*, 2009; Jagadamma*, et al.*, 2007) as well as increase peak knee flexion moment in early stance (Jagadamma*, et al.*, 2009; Jagadamma*, et al.*, 2010).

6.4.2.1.2 Type of gait pattern

While it was hypothesised that all limbs (across both AFO groups) would demonstrate systematic changes to knee kinetics, it was anticipated that the effect on other gait variables relating to the knee and ankle would be different according to type of gait pattern. For example, it was thought that the common sub-groups and the variant limb demonstrating knee hyperextension in the hinged AFO group would demonstrate kinematic changes to the knee and tibia but would have smaller, if any changes to ankle kinetic patterns (Mechanism 1, refer to Chapter 4); whereas, the variant limbs that demonstrate more knee flexion throughout stance phase would demonstrate smaller kinematic changes but larger ankle kinetic changes (Mixed response); and any very flexed limbs would demonstrate no kinematic changes but only changes to ankle kinetics (Mechanism 1).

Results of this study suggest that all limbs demonstrated some degree of change across all of these variables, which varied in terms of the size of change and how systematic these changes were. Therefore the hypothesis was not supported. However, within the solid AFO group there was some evidence of different patterns of change according to type of gait pattern. For example, the common sub-group demonstrated larger systematic increases in knee flexion angle whereas the variant limbs demonstrated smaller increases in knee flexion angle (JABU) or even reductions (DEHA). In terms of tibial incline the common sub-group showed increased incline but the variants demonstrated small reductions in tibial incline. In terms of ankle kinetics, the common sub-group had a variable response while the variant limbs had very clear, systematic reductions in the first dorsiflexion peak moment. Thus on this basis the majority of limbs in the solid AFO group could be considered to demonstrate a Mixed response that involves both Mechanism 1 and 2 changes, but to varying degrees.

The lack of a pure Mechanism 2 response may be because the degree of knee flexion demonstrated throughout stance phase in these limbs was too small. For a Mechanism 2 response to occur, knee flexion and the resulting foot incline must be large enough such that adding a heel wedge improves contact of the foot with the floor but does not result in total contact, thus having no effect on tibial or knee kinematics. In the pilot data presented in Chapter 4, the two limbs that demonstrated evidence of pure Mechanism 2 also demonstrated persistent knee flexion of greater than 30° throughout stance phase. In the present study, both limbs (JABU-L-R) in the solid AFO group with persistent knee flexion throughout the gait cycle were flexed less than 30°. In the hinged AFO group the one limb (JANI) with persistent knee flexion was greater than 30°, but the effect on knee kinetics was not systematic, which is in line with the results of the hinged group on the whole. This is likely to be a reflection of the inclusion criteria limiting participants to GMFCS levels I and II.

The sub-groups considered in this analysis were formed on the basis of similar patterns of knee kinematics in the baseline (flat wedge) condition. Therefore when considering whether limbs conform to Mechanisms 1, 2 or a Mixed mechanism, the variable of interest is the minimum knee flexion angle achieved during stance phase. An alternate measurement could be to assess the angle of the foot to the ground (foot projection angle) at the point of initial contact. If initial contact occurs at the heel, the foot projection angle will be positive (inclined), and at some point thereafter the foot must achieve foot flat and kinematic changes can be induced.

All children in both groups had positive foot projection angles at initial contact in the baseline AFO condition (Figure 6.3) although two of the limbs with more flexed gait patterns (DEHA-L-R) were borderline, within approximately 2°. If the group included limbs with more severely flexed gait patterns, negative foot projection angles would be seen at initial contact which would indicate initial contact made with the forefoot. Assessing foot projection angles at initial contact is potentially a useful measure which could be employed in any 3DGA study where these events are of interest.

6.4.2.1.3 Knee kinematics

Peak knee flexion angle was increased and peak knee extension angle was decreased in all limbs in the solid AFO common sub-group, with a handful of limbs demonstrating a small increase in peak knee extension angle with the first 5° change, before systematic reductions in the medium and large wedges. This suggests that an alignment change of more than 5° might be required to produce discernible changes to these variables in some limbs. This is in line with suggestions by Fatone and colleagues (2009) who induced an alignment change of approximately 5-7° in a group of post-stroke adults and suggested it may have been too small a change to effect any systematic results.

The average data for both common sub-groups also demonstrated a significant main effect of wedge size on both peak knee flexion and knee extension angle. Only a handful of other studies have reported changes in knee kinematics as a result of AFO-FC alignment change. These found reductions in peak knee extension angle in tuned AFO-FCs in children with CP as well as adults with post-stroke hemiplegia (Jagadamma*, et al.*, 2009; Jagadamma*, et al.*, 2007; Jagadamma*, et al.*, 2010; Reinthal & Hoy, 2005). In addition, increased SVA has also been found to increase peak knee flexion angle in early stance (Butler*, et al.*, 2007; Jagadamma*, et al.*, 2009; Jagadamma*, et al.*, 2007). This variable was quantified in only one case, and although increased by an average 6°, was found not to be significantly different from the un-tuned condition (Jagadamma*, et al.*, 2009). The opinion of one author was however that the increase in early stance knee flexion was outweighed by the advantages of the tuning (Butler*, et al.*, 2007).

6.4.2.1.4 Tibial angle

Despite the measure of tibial kinematics essentially being a measure of SVA in a dynamic context, this was the first study to measure the effect of AFO-FC alignment on this variable. The results suggest that increasing wedge size causes tibial angle to increase in limbs demonstrating greater knee extension and to reduce in limbs demonstrating less knee extension, though the exact patterns of change vary between limbs. This is in line with suggestions that one of the aims of tuning is to correct abnormal shank kinematics throughout stance phase (Owen, 2004c; Owen*, et al.*, 2004). However, the increases in tibial projection angle did not tend to have a normalising effect, which is discussed further in Chapter 7.

The reduction in tibial projection angle in all variant limbs in the solid AFO group, and the reduction in peak knee flexion angle in two of these limbs, were not anticipated. These changes occurred simultaneously with a plateau effect in peak knee flexion moment on one limb and a non-systematic reduction in peak knee flexion moment on the contralateral limb. This patient demonstrated a knee kinematic pattern with increased knee flexion angle in early stance (Figure 6.3). Therefore, these reductions in peak knee flexion angle and in tibial projection angles could be a result of increased stability resulting from the wedges producing a posterior shift in the origin of the GRF.

6.4.2.1.5 Ankle moments

A large first dorsiflexion moment peak was seen in limbs across both groups, though more consistently in the solid AFO group (refer to Figure 6.3 and Figure 6.4). This is an abnormal gait characteristic that has been well described as a barefoot gait pattern in children with CP (Gage, 1994; Lin*, et al.*, 2000; Õunpuu, Davis, & DeLuca, 1996). Increasing wedge size systematically reduced this peak in all four variant limbs of the solid AFO group, and in three of the limbs in the common sub-group (JOTH-L-R, LIRI). Thus in combination with the changes to knee and tibial kinematics, these three limbs demonstrated a Mixed Response as described in the pilot data (Chapter 4), where it was proposed that even though the foot may be flat, the centre of pressure is shifted posteriorly due to the addition of material under the heel. Four limbs however did not demonstrate these changes (MAHO-L-R, JODA-L-R) despite having an increased first dorsiflexion moment.

Across both groups the second peak dorsiflexion moment also tended to be reduced with increased wedge size. While these changes were smaller than the reductions seen in the first dorsiflexion peak, this is probably also a consequence of a posterior shift in centre of pressure. This reduction was often a change away from normal values. When considering tuning as a three stage process, modifications to the sole profile are suggested to affect gait characteristics at terminal stance. The reduced second peak dorsiflexion moment could be one factor addressed with the use of rocker soles as these focus primarily on controlling the progression of the point of application of the GRF along the sole of the foot. No other studies have examined the effect of AFO-FC alignment change on ankle moments.

6.4.2.2 Possible response variables

It was hypothesised that increasing wedge size would not have a systematic effect on hip kinematics or kinetics, femur projection angles or knee flexion angles in swing. The results support this hypothesis as the individual results reveal a lack of consistent, systematic changes across all limbs. This can be attributed to the knee having a modulating effect on any changes induced by modifying the AFO-FC alignment. It has been suggested that AFO-FC tuning should address hip kinetics as well as knee kinetics (Bowers & Meadows, 2007; Meadows*, et al.*, 2008) and that femur kinematics should be considered as well as tibial kinematics (Owen, 2010). However, prior to this study there has been no attempt to measure the effect of AFO-FC alignment on these variables in children with CP.

There was however, a trend in many of the limbs in both groups toward increased hip flexion and increased femur recline angle at initial contact with increased wedge size. This resulted in a significant main effect in some of these variables for the common sub-group in both the solid and hinged AFO groups. Increased wedge size may provide improved stability of the stance limb throughout stance phase which gives time for increased hip flexion and femur recline before initial contact occurs.

No systematic changes were seen in the temporospatial parameters which also supported the hypothesis. These results are in line with the only study to measure the effect of a tuned solid AFO-FC (which resulted in an increased SVA of approximately 5.6°) on walking velocity, cadence and stride length in five children with CP, where no significant effects were found (Jagadamma*, et al.*, 2009). Results for the hinged AFO were less variable than the solid AFO group. If the solid AFO group (n=6 children) had a greater number of data points, as compared to the hinged AFO group (n=14 children), similar consistency may have been evident. In addition, most of the children in the hinged group were affected unilaterally, which may allow them to either compensate or have more freedom to react to the biomechanical changes induced on the affected side. Finally, while the effect of increasing wedge size included increasing peak knee flexion during early stance, in some limbs this also acted to increase knee flexion at initial contact (refer to individual data in Appendix E). This may have shortened stride length as much as the small increases in hip flexion at initial contact increased stride length.

6.4.2.3 Summary

Knee moments changed approximately linearly with increased wedge size in 25 out of 27 patients. Within the common sub-groups the probable response parameters all showed statistically significant evidence of response but detailed analysis suggested quite variable responses within groups. Possible response variables showed less evidence of statistically significant change and were even more variable.

6.4.2.4 Type of AFO design

A secondary research question addressed in this study was whether the effect of AFO-FC alignment on these gait parameters was the same between the hinged and solid AFO groups. The hinged AFO group demonstrated similar patterns of change as the solid AFO group across the probable response variables, but these changes were less consistent and less systematic. Despite this, both groups demonstrated significant main effects across all probable response variables and most possible response variables. The increased sensitivity of the solid AFO group is demonstrated in the between-group analysis. There were significant differences between the groups in peak knee extension moment and peak knee flexion angle that arise largely from differences in the slope of change in these variables. Children wearing solid AFOs demonstrate a greater slope than those wearing hinged AFOs, which suggest increased responsiveness, and also "tunability" of solid AFOs than hinged AFOs. Therefore if "tunability" is a prerequisite of AFO design, solid AFOs may be the preferred design.

As a result of the analysis to determine whether all children were responsive to AFO-FC alignment change it was found that the hinged AFO group were on the whole, less sensitive to AFO-FC alignment change but also were less consistent in the changes observed. The individual analysis lends support to this conclusion as the changes in knee moments demonstrated by the hinged AFO group were smaller than the solid AFO group, and were much less consistent. However in contrast to this, the analysis examining responsiveness in terms of RMS difference in knee moment concluded that almost all limbs were significantly responsive, according to the mid-stance and stance phase calculations, respectively.

These contradictory findings are due to the nature of the RMS difference calculation. The RMS difference will show an increase in value regardless of whether systematic changes were seen in *both* peak knee flexion and knee extension moment, *either* peak knee flexion or knee extension moment, or whether there were *partial* systematic changes, such as increased peak knee flexion moment between the two smallest wedges and increased peak knee extension moment between the two largest wedges. Seven limbs in the hinged AFO group demonstrated systematic changes in *either* peak knee flexion or peak knee extension, and four demonstrated *partial* changes (see Appendix E for individual results). This is one limitation of using the RMS difference between curves to demonstrate systematic change, and therefore to measure responsiveness.

It was anticipated that the results for the solid and hinged AFO groups may be similar during early to mid stance on the basis that from initial contact until the point that dorsiflexion begins, a hinged AFO would behave similarly to a solid AFO. Similarly during terminal stance the AFO is likely to be in a plantigrade position due to the push-off phase. It was also anticipated that any dorsiflexion range of movement would be small due to limitations such as spasticity and contracture of the gastrocnemius muscle which are commonly seen in children with CP. This was found not to be the case, with excessive and early dorsiflexion demonstrated in all but three limbs (refer to Figure 6.4). Thus the child is able to use the ankle to modulate any alignment changes and as a consequence the biomechanical changes do not demonstrate the same systematic kinematic and kinetic changes as the solid AFO group. No other studies have investigated the effect of AFO-FC alignment on a group of solid and hinged AFO wearers. Neither has any other study investigated the effect of AFO-FC alignment on a full range of gait parameters.

6.4.3 Limitations

Responsiveness to AFO-FC alignment change was considered in terms of systematic changes in RMS difference between knee moments for the flat wedge condition and the small, medium and large wedges. As previously noted, use of the RMS difference in this context is limited in that it cannot distinguish between full or partial systematic changes across peak variables. Therefore an analysis of change in peak variables of interest, as performed in the subsequent analysis in this study, is required to supplement this first assessment.

While use of statistical measures including the gradient, standard error and p value according to the line of best fit provide an objective measure to consider the degree of responsiveness, it has some limitations. Use of a threshold α level of 0.05 results in some limbs being considered responsive while others which may have a p value only fractionally larger are considered non-responsive. These limbs also appear to be sensitive to AFO-FC alignment change, and therefore the p value should be considered in light of the gradient and standard error when considering a classification of responsiveness.

In this analysis an attempt was made to capture the changes in tibial projection angle in early stance using two variables; average difference over 10-30% of the gait cycle and peak tibial angle. These measurements are however limited in their ability to demonstrate and describe the variety and complexity of changes occurring to tibial kinematics. For example, within the solid AFO group there was a great deal of variety in the baseline patterns of tibial movement and the changes induced in tibial projection angle. Some limbs demonstrated an isolated period of increased tibial incline in early stance; other limbs demonstrated periods where the tibia demonstrated an unusual period of recline which tended to be reduced with increased wedge size; and still other limbs demonstrated change in tibial incline over most of stance phase (refer to Appendix E). In addition, within the hinged group the average difference in tibial angle between 10-30% gait cycle increased sequentially but this did not reflect the exact changes seen within individuals. These changes could only be described rather than objectively measured. Because the process of tuning involves changing the SVA, which is essentially a static measure of tibial projection angle, alternative methods of measuring change in tibial kinematics could be investigated. Tibial velocity, that is change in angle per unit time, could also be investigated.

The distribution of hemiplegic and diplegic children across the two AFO groups was not even. The solid AFO group comprised entirely of diplegic children whereas the majority of children in the hinged AFO group were hemiplegic. This distribution is indicative of the gait patterns demonstrated by each diagnosis group, for example orthotic management for diplegic children often requires restriction to dorsiflexion and therefore a solid AFO, whereas hemiplegic children often require restriction of plantarflexion only and hence a hinged AFO. The intact limb of the hemiplegic children may be able to compensate for some of the biomechanical changes induced on the affected side. Therefore the less systematic results demonstrated by the hinged AFO group may reflect the unilateral nature of the impairment rather than the type of AFO. If the solid AFO group included hemiplegic children the results may have been less systematic.

The sample sizes in both the solid and hinged AFO groups in this study were small. For this reason, data from both limbs of bilaterally affected participants were included. Because within-subject variability is likely to be smaller than between-subject variability this may have increased the likelihood of finding significant results.

The knee kinematic pattern used for gait classification was the gait pattern in the AFO with the flat wedge. Because the aim of the investigation was to investigate the effect of variations in AFO design rather than the effect of the AFO intervention this approach was considered to provide the most relevant information. Using a barefoot gait classification may have provided additional information but is not likely to affect the overall conclusions.

However, if any participants wore an AFO with an ankle angle that had not taken into account gastrocemius contracture, the baseline pattern of knee kinematics may have been affected due to a reduction in peak knee extension angle. It is evident from the measurements of AFO ankle angle and participant dorsiflexion ROM (recorded in Table 5.1) that two participants had AFOs that may not have accommodated for contractures of the gastrocnemius muscle. In these participants the AFO ankle angle was 3° and 2° (DEHA–L and JODA-R respectively) more dorsiflexed than the available passive dorsiflexion range. These discrepancies are however very small and may be attributed to measurement error.

One participant (JANI-R) had a plantarflexion contracture of 10° but wore a hinged AFO. While the AFO ankle angle accommodated for this contracture, a hinged AFO with free dorsiflexion range of motion is arguably an inappropriate prescription because ankle dorsiflexion can only occur at the expense of either or both knee extension or pronation. This highlights another limitation of the current study, that appropriate AFO prescription and AFO ankle angle were not considered either as part of the eligibility criteria, or by supplying participants with new AFOs at the study outset. This decision was due to the predicted difficulties in recruiting sufficient numbers of participants, which might be hampered due to the additional commitments required to provide a new AFO. The advantage of this decision is however that the AFOs in this study are a fair representation of those supplied clinically.

Despite these limitations, analysing the results according to sub-group of similar types of gait patterns provides greater confidence that the results seen in the common sub-group of the solid AFO group can be more widely generalised. For example, the average traces for this group demonstrated the same patterns of change seen across the individual limbs. The type of gait pattern in this sub-group is similar to those examined in several other studies on AFO-FC tuning. The study by Jagadamma and colleagues (2009) included only children who demonstrated hyperextension (<0° flexion) of the knee during mid to late stance; Butler and colleagues (1992) examined participants all who demonstrated excessive knee extension moments during mid to late stance; and in Butler and colleagues other work (Butler*, et al.*, 2007) the group of children found to tune successfully all demonstrated knee extension of <10° flexion during mid to late stance. It can therefore be concluded with confidence that in children demonstrating this type of gait pattern, systematic changes to these particular biomechanical variables can be induced by altering the AFO-FC alignment.

6.5 Conclusion

When responsiveness to AFO-FC alignment change is measured using the RMS difference in knee moment across mid-stance and all of stance phase, all limbs were found to be sensitive to AFO-FC alignment change. However, the number of limbs demonstrating statistically significant changes did change slightly, depending on the portion of stance phase used in the analysis. Solid AFOs were more sensitive to AFO-FC alignment change than hinged AFOs, as were limbs conforming to the common knee kinematic pattern. Using a single point of stance phase at 30% of the gait cycle to measure responsiveness resulted in a loss of sensitivity to change to the first 5° wedge in many limbs. Changing AFO-FC alignment tended to have a systematic effect on gait variables relating to the knee and ankle which were more consistent in the solid AFO group than the hinged AFO group. Within the solid AFO group there was some evidence suggesting that the strength of changes across these variables varied according to different types of gait patterns. In limbs that were relatively extended, peak knee flexion moment and angle tended to increase and peak knee extension moment and angle tended to decrease, with increased tibial projection angle and reduced ankle moments. In more flexed limbs the same changes occurred in knee and ankle kinetics but changes to knee kinematics and tibia projection angles were more varied. Hip kinematics, kinetics, femur projection angles, peak knee flexion in swing, walking velocity, cadence and stride length did not change systematically across either group.

7 Is there an optimum AFO-FC alignment?

The results of Chapter 6 provide evidence that changing AFO-FC alignment induces systematic changes in a range of gait parameters, particularly at the knee level and below. While these changes have now been quantified and described, it is not known which of these changes, if any, produce the best gait pattern overall. This chapter addresses the fifth research question of this thesis which was 'Is there an optimal AFO-FC alignment?' This was examined by first attempting to define an optimal wedge size or range of wedge sizes that produce the most normal result for each variable in each limb. Subsequent to this an analysis was conducted to determine whether there was agreement between parameters in terms of the best wedge size.

7.1 Introduction

Chapter 6 addressed the third and fourth research questions which were 'Are all children responsive to AFO-FC alignment change?' and 'What is the effect of AFO-FC alignment on gait?' Separate common patterns of knee kinematics were observed for the majority of children wearing either solid or hinged AFOs. There was strong evidence of changes in knee moment which were proportional to increased wedge angle for all children across both groups. There was also strong evidence for systematic changes in a range of other variables particularly amongst children wearing solid AFOs who demonstrated the common gait pattern.

The most consistent changes were seen in the effect of wedge size on knee kinetics. Peak knee flexion moment tended to increase and peak knee extension moment tended to decrease with increased wedge size. Therefore, depending on the baseline pattern of knee kinetics there was one wedge condition that produced the most normal peak knee flexion moment, which may or may not have been the same wedge size that produced the most normal peak knee extension moment. This apparent conflict in optimum wedge size may occur within one parameter (for example, peak knee flexion moment and peak knee extension moment) but also across parameters (knee kinetics and knee kinematics). Therefore, while Chapter 6 demonstrated that increasing wedge size resulted in systematic and predictable changes to certain gait parameters, it is not known which of these changes, if any, produce the best gait pattern overall.

Tuning is a process that focuses on the optimisation of gait. To enable comparison of these results to the tuning process it is therefore necessary to identify the wedge angle that gives the 'best' gait pattern for an individual child. While not explicitly defined in the wider body of literature, 'optimisation' is thought to be synonymous with 'normalisation' - that is, achieving a gait pattern closest to normal values for able bodied children. This is thought to lead to functional benefits such as improved mobility and reduced energy expenditure. In order to determine which gait pattern is the most normal, a sub-set of gait parameters must be defined on which to focus the analysis.

Chapter 6 examined the effect of systematic changes to AFO-FC alignment on a suite of sagittal plane gait parameters at the level of the hip, knee and ankle. The results suggest that the parameters distal to and including the knee joint are those producing the most consistent patterns of change. More specifically, knee kinematics, knee kinetics, tibial kinematics and ankle kinetics were the four parameters seen to produce the most consistent change.

Three of these four variables also feature as the focus of the tuning process within the wider body of literature. The focus of tuning has largely been on knee kinetics (Butler*, et al.*, 1992; Owen, 2002) but some authors have also focussed on normalising knee kinematics (Bowers & Meadows, 2007; Butler*, et al.*, 2007; Jagadamma*, et al.*, 2009; Jagadamma*, et al.*, 2010; Meadows*, et al.*, 2008; Owen*, et al.*, 2004; Stallard & Woollam, 2003). One author in particular emphasises the importance of improving abnormal shank kinematics via the tuning process (Owen, 2004c; Owen, 2010; Owen*, et al.*, 2004). Ankle moments have not previously been considered, but were identified as possible indicators of one of two theoretical responses by which increasing wedge size may affect the biomechanics of gait (refer to Chapter 2).

The investigation reported in this chapter will focus on the sub-set of four biomechanical variables that were seen to change most consistently as a result of changing AFO-FC alignment. The pattern, magnitude and direction (increase or decrease) of change has been described but it remains unknown how or whether these changes produce a more normal, or abnormal gait pattern. Because knee kinetics have been the focus of the literature, the wedge size normalising this variable will be prioritised, and as such used as the comparison for the optimal wedge size according to the remaining three variables.

Throughout the body of literature the period of the gait cycle that is addressed by tuning has not been clearly described. As a result, the analysis presented in Chapter 6 examined whether the period of the gait cycle in which changes to knee kinetics were examined, affected the results. Three analyses were conducted: responsiveness over Perry's (1992) definition of mid-stance, over the entire stance phase, and at a single point of the gait cycle (30% gait cycle). The classification of responsiveness was similar for the mid-stance and stance phase analyses (but more consistent for the mid-stance analysis) whereas the results for the single point analysis were variable.

Although tuning using a video vector generator requires a single point during the gait cycle to be assessed, it is clear that the tuning process involves modifying the SVA, the heel profile and sole profile, to affect three periods of stance phase: mid-stance, early and terminal stance respectively (eg. Owen, 2004b, 2004c; Owen*, et al.*, 2004). In order to generalise the findings of the present study to the tuning literature, and in light of the inconsistent results found in the single point analysis conducted in Chapter 6, this investigation will focus on the changes occurring over Perry's (1992) definition of mid-stance, that is 10-30% gait cycle. Therefore, for the purpose of this investigation the best or optimum wedge size is defined as one producing the most normal knee kinetics, knee kinematics, tibial kinematics and ankle moment, as compared to normal values for able bodied children, across the period of 10-30% gait cycle.

7.1.1 Aims and hypotheses

The aim of this study was to determine whether there was an optimum AFO-FC alignment. More specifically the aims were to determine:

- Whether an optimum wedge size could be identified for each limb within each parameter, and whether there was agreement in the optimum wedge size across the biomechanical parameters that produce systematic change;
- Whether this agreement between biomechanical parameters concurred with an optimum wedge size in terms of temporospatial variables and subjective preference;
- Whether these findings related to the underlying gait pattern or type of AFO.

Based on the systematic patterns of change demonstrated in Chapter 6, it was hypothesised that:

- An optimum wedge size would be identifiable for each of these four biomechanical parameters for each limb. Optimum wedge size would be less clear for the temporospatial parameters.
- In the majority of limbs there would not be complete agreement of optimum wedge size across the four biomechanical parameters, the temporospatial parameters and subjective preference
- The solid AFO group would have better agreement than the hinged AFO group, and within the solid AFO group, and limbs within this group demonstrating the common gait pattern would have better agreement across variables.

7.2 Data analysis

In the context of this thesis, the optimum AFO-FC alignment was considered to be the wedge size which produced the most normal pattern of knee kinetics, knee kinematics, tibial projection angles and ankle kinetics across the period of mid-stance as defined by Perry (1992). To determine which wedge size produced the most optimum outcome, the RMS difference between the average knee moment, knee angle, tibial projection angle and ankle moment for each condition in each limb was compared to normal values for able bodied children. Normal data was obtained from the database maintained by the Hugh Williamson Gait Laboratory at the Royal Children's Hospital (Melbourne, Australia). The smallest RMS difference represented the condition producing the closest to normal results over mid-stance, and therefore the optimum wedge size for that parameter.

7.2.1 Identification of optimum

The effect of wedge size with regard to normal vales was considered for the four biomechanical parameters seen to change consistently in Chapter 6. The aim of this analysis was to determine whether an optimum alignment could be identified for each the limbs within each of these parameters, as well as in cadence, walking velocity and stride length. To determine whether an optimum alignment existed, three possible trends were defined. These trends were considered to be 1) a clear optimum, 2) an ambiguous optimum and 3) no optimum.

The presence of a clear optimum was considered on three levels:

- *U-shaped curve (U)* – where the small or medium wedge clearly produced the lowest or the highest value.
- *Increasing trend (IT)* – where the flat wedge clearly produced lowest value. This would suggest that the flat wedge was optimum within the range tested but that a negative wedge might produce even better results.
- *Decreasing trend (DT*) – where the large wedge clearly produced the lowest value. This would suggest that the large wedge was optimum within the range tested but that an larger wedge might produce better results.

The presence of an *ambiguous optimum was* considered to be where two paired values were clearly lower than the others but were similar to each other. This included patterns similar to the U, IT or DT described above, but where the minimum value was too close to its neighbour to meet the minimum difference (described below).

The presence of *no clear optimum* was considered to be where the minimum value is one of three or more values that are similar and therefore do not meet the minimum difference; or when there is no clear pattern.

Figure 7.1 presents example data for each of these trends.

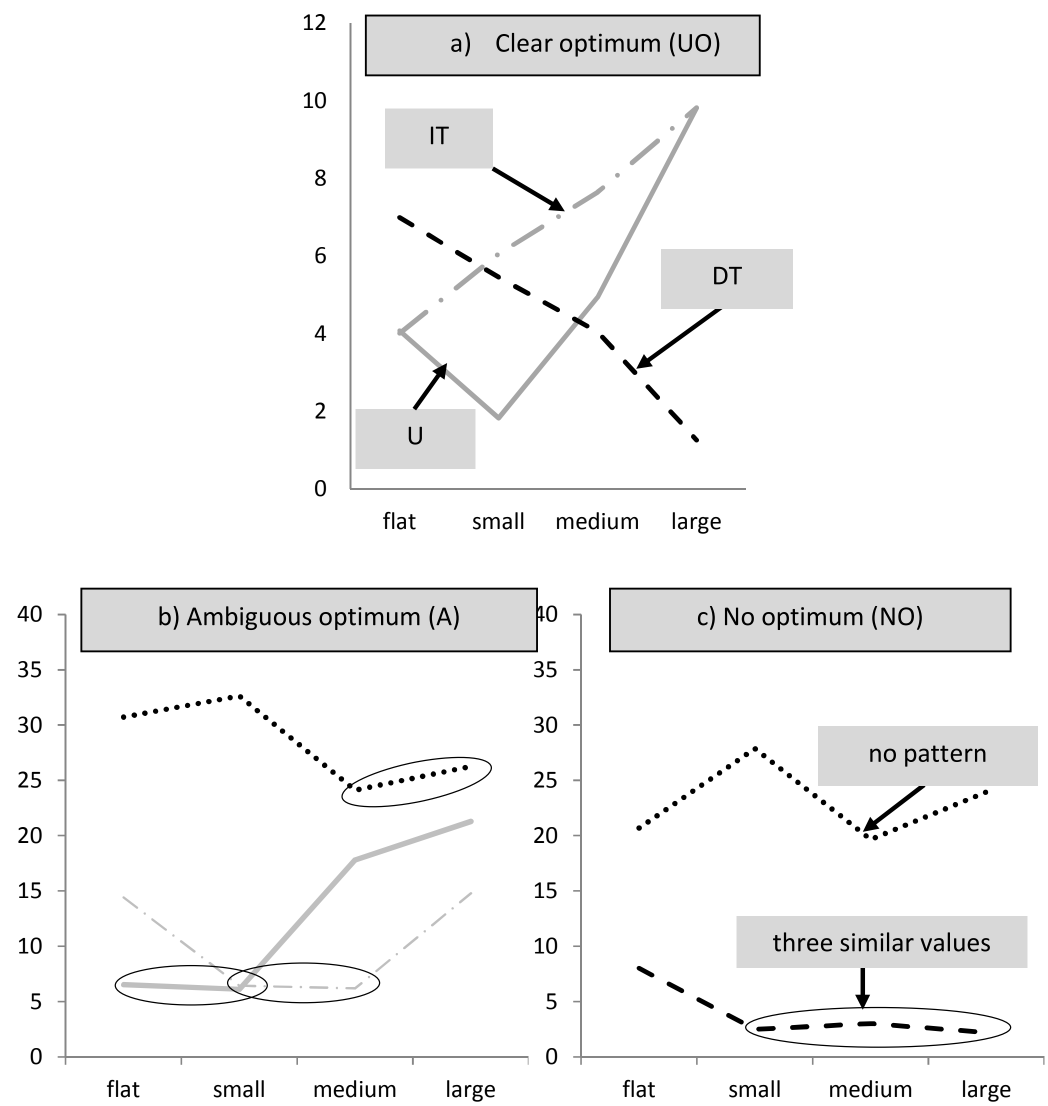


Figure 7.1 Example data demonstrating a a) clear optimum in a U shape (U), an increasing trend (IT) and a decreasing trend (DT); b) an ambiguous optimum (A); and c) no optimum (NO).

7.2.1.1 Minimum difference

A minimum difference was defined that provided an objective measure to distinguish between a clear and an ambiguous optimum. When two values were considered sufficiently different, that is, had a difference greater than the minimum difference, this would result in classification of a clear trend with a single wedge size identified as optimum. If two values were not sufficiently different (i.e. the difference between values was smaller than the minimum difference) this would result in classification of an ambiguous optimum (A) where optimum spanned two wedge sizes, or no optimum (NO) where the optimum spanned three or more wedges.

The minimum difference was based on an error range of 10% of the total range in RMS difference across conditions in each parameter for each individual limb (refer to Equation 7-1). This error range was applied to each value and if the two values were within this error range no true differences were considered to exist and the trend could be considered as an ambiguous optimum (A)(refer to Equation 7-2).

For example in JOTH-L (refer to Table 7.1, page 196) the knee angle RMS difference for the small and medium wedges suggested that the optimum knee angle occurred in the medium wedge (6.18), which was similar to, but smaller than, the value for the small wedge (6.43).

The error margin for these values was determined by calculating 10% of the total RMS range for this variable in this limb:

$$10\%\ total\ RMS\ range = 0.1 \times (\text{Max RMS} - \text{Min RMS})$$

$$10\%\ total\ RMS\ range\ (\text{JOTH} - \text{L}) = 0.1 \times (14.77 - 6.18) = 0.86$$

Equation 7-1

This error margin was used to determine whether the difference in RMS values was significant. In the following example, the difference between the two RMS values was smaller than the 10% error range and therefore considered not truly different. The resulting trend was described as an ambiguous optimum rather than an unambiguous optimum with a U-shaped trend.

$$RMS\ difference\ small\ (6.43) - RMS\ difference\ medium\ (6.18) < 10\%\ error\ (0.86)$$

Equation 7-2

7.2.2 Agreement between parameters

The second section of this analysis focused on identifying an individual optimum wedge size for each variable and determining the extent of agreement between the four biomechanical parameters, as well as with temporospatial parameters and subjective preference.

To determine the level of agreement between biomechanical variables the relationship between pairs of variables was investigated for each individual limb by calculating the Pearson's Product Moment Correlation using the CORREL funtion in Excel. The average of the correlation coefficient (r) were calculated using a Fisher-z transform for each group and sub-group and for each indiviudal limb. A correlation of 0.00 - 0.25 indicates little to no relationship; those from 0.25 - 0.50 suggest a fair degree of relationship; values of 0.50 – 0.75 are moderate to good; and values above 0.75 are considered good to excellent (Portney & Watkins, 2000).

The optimum wedge size determined for each parameter within each limb in the first part of this analysis was then compared across parameters. Because the primary focus of the tuning procedure has been optimisation of knee kinetics, the optimum wedge size for knee kinetics was identified and recorded first. The optimum wedge size for each of the remaining variables was subsequently identified and a score calculated to represent the number of variables in agreement with the choice according to knee kinetics.

'Perfect' agreement was considered to be a score of 3/3 whereby the optimum wedge size according to knee kinematics, tibial kinematics and ankle moment was the same as the optimum wedge size for knee kinetics. 'Good' agreement was defined as a range of optimum wedge size spanning only two wedge sizes (i.e. 5°), for example between flat and small, small and medium, or medium and large. When either perfect or good agreement was achieved, both the optimum wedge size and the optimum SVA could be calculated within a 5° range.

The fastest cadence, fastest walking velocity and longest stride length were also presented in this table, according to the results described in Chapter 6. These data are presented as absolute values rather than RMS difference to normal where the optimum wedge size was considered to be the wedge size producing the fastest cadence, fastest walking velocity and longest stride length. Because the largest value was considered the optimum rather than the smallest value, an an inverted U-shaped curve (n) was used to describe these data. The patient's preferred wedge size was also presented and a comparison drawn across the four biomechanical parameters, the temporospatial results and subjective preference.

7.3 Results

7.3.1 Participants

As in Chapter 6, data from only 19 of the 20 children included in this study were used in this analysis. Data from one participant (HAHA) was excluded due to an insufficient number of trials across all four AFO-FC conditions. The solid AFO group comprised 11 limbs belonging to six children, the hinged AFO group comprised 15 limbs belonging to 14 children, and one child (LIRI) contributed one limb to each group. Participant details are listed in Chapter 5.

7.3.2 Is there an optimum AFO-FC alignment?

7.3.2.1 Solid AFOs

7.3.2.1.1 Biomechanical variables

Figure 7.2 illustrates the changes induced in four biomechanical variables as a result of increasing the wedge size in 5° intervals, according to RMS difference calculated over mid-stance. A value closer to zero represents the change that most closely represents normal values for able bodied children. Across three variables (knee kinetics, knee kinematics and ankle kinetics), the changes were either increasing or U-shaped trends, whereas for tibial projection angles a range of trends were evident including increasing, decreasing or U-shaped.

Table 7.1 presents the RMS values, the trend that best describes the presence or absence of an optimum wedge size, and if identified also highlights the optimum wedge size for each variable within each limb. The majority of limbs (8/13 limbs) had a clear optimum for knee kinetics and ankle kinetics while less than half (5/11 limbs) had a clear optimum for tibial projection angles and only 2/11 limbs had a clear optimum for knee kinematics. The remaining limbs had an ambiguous optimum except for a select few limbs that demonstrated no optimum.

Different patterns were evident when limbs were considered according to sub-group. In the common sub-group, the trend for knee kinetics were almost all a clear U-shape (refer to Table 7.1), knee kinematics had a tendency toward an increasing trend and most of the changes in ankle kinetics and tibial projection angles were a variety of U-shaped and linear trends. In contrast, the limbs in the variant sub-group demonstrated increasing trends in knee kinetics, increasing trends or no patterns in knee kinematics, U-shaped trends in ankle kinetics and decreasing trends in tibial projection angles.

The optimum wedge size occurred most commonly in the flat and small wedges for knee kinetics and knee kinematics, whereas in tibial projections and ankle moments the optimum wedge size tended to vary according to sub-group. The common sub-group had optimum wedge size in the smaller wedges for both variables whereas the variant group tended to have optimum wedge size in the larger variables.

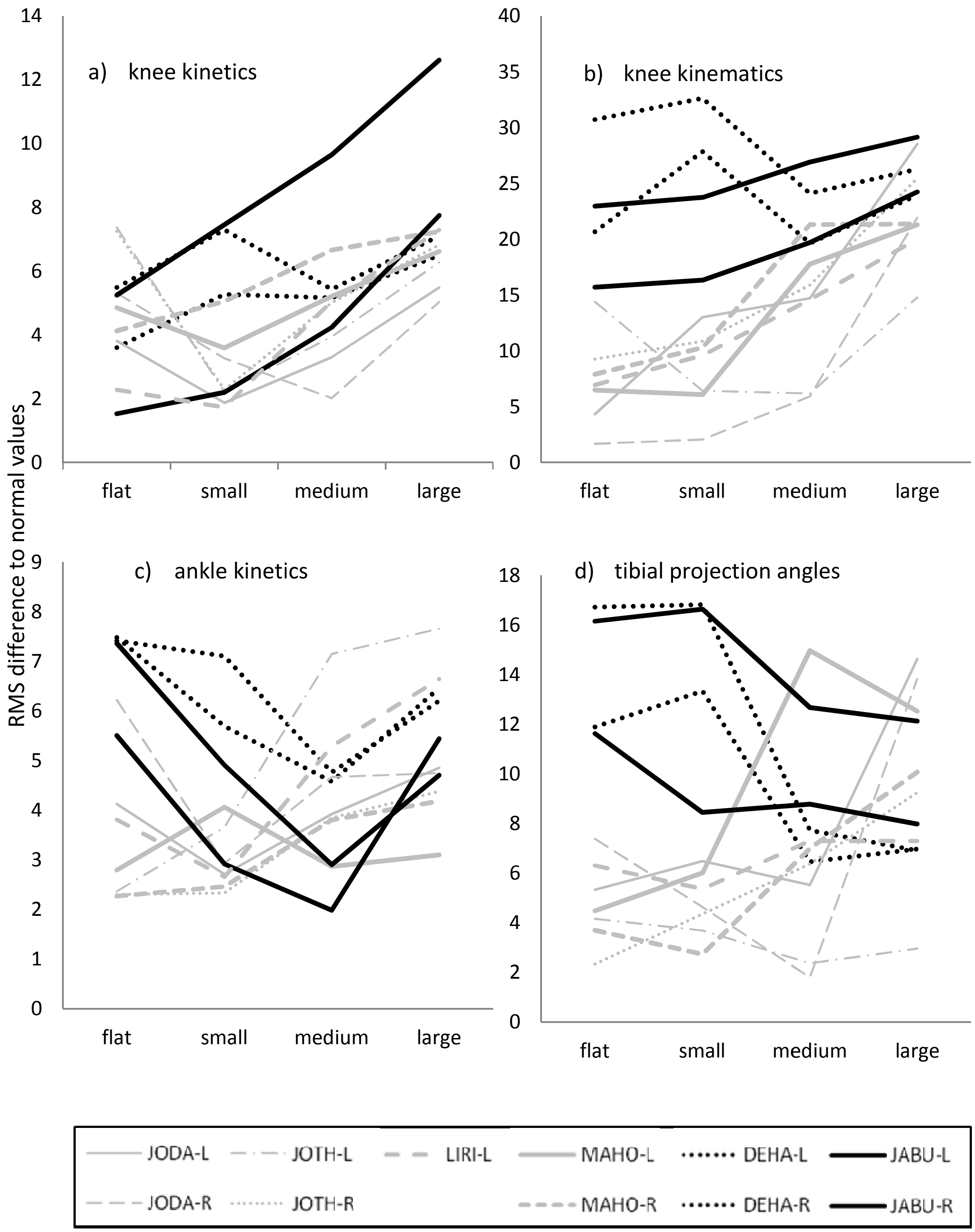


Figure 7.2 RMS difference to normal values for able bodied children for a) knee kinetics, b) knee kinematics, c) ankle kinetics and d) tibial projection angles for the solid AFO group.

	Parameter	Sub-group	Limb	RMS difference to normal: flat	small	medium	large	Trend
Solid AFO Group	Knee kinetics	Common	JODA-L	3.81	1.87	3.31	5.48	U
			JODA-R	5.31	3.27	2.01	5.03	U
			JOTH-L	7.37	2.22	3.95	6.28	U
			JOTH-R	7.25	2.28	5.01	6.83	U
			LIRI-L	2.29	1.73	5.06	7.29	A
			MAHO-L	4.86	3.6	5.22	6.61	U
			MAHO-R	4.13	5.05	6.66	7.24	IT
		Variant	JABU-L	5.25	7.45	9.65	12.61	IT
			JABU-R	1.53	2.2	4.24	7.74	A
			DEHA-L	5.49	7.29	5.43	7.1	NO
			DEHA-R	3.6	5.27	5.16	6.5	IT
	Knee angles	Common	JODA-L	4.32	13.02	14.7	28.51	IT
			JODA-R	1.68	2.06	5.92	21.93	A
			JOTH-L	14.39	6.43	6.18	14.77	A
			JOTH-R	9.27	10.88	15.91	25.43	A
			LIRI-L	6.95	9.6	14.59	20.03	IT
			MAHO-L	6.51	6.1	17.8	21.29	A
			MAHO-R	7.9	10.29	21.32	21.37	A
		Variant	JABU-L	22.97	23.75	26.92	29.14	A
			JABU-R	15.7	16.33	19.71	24.22	A
			DEHA-L	30.72	32.63	24.1	26.27	NO
			DEHA-R	20.68	27.85	19.66	23.95	NO
	Ankle kinetics	Common	JODA-L	4.12	2.71	3.92	4.86	U
			JODA-R	6.22	2.93	4.67	4.75	U
			JOTH-L	2.37	3.66	7.15	7.66	IT
			JOTH-R	2.3	2.33	3.84	4.38	A
			LIRI-L	3.81	2.65	5.29	6.64	U
			MAHO-L	2.79	4.06	2.86	3.1	NO
			MAHO-R	2.27	2.46	3.8	4.19	A
		Variant	JABU-L	7.36	4.91	2.9	4.71	U
			JABU-R	5.5	2.92	1.98	5.44	U
			DEHA-L	7.48	5.69	4.57	6.46	U
			DEHA-R	7.41	7.11	4.76	6.2	U
	Tibial Projection Angles	Common	JODA-L	5.33	6.48	5.52	14.63	NO
			JODA-R	7.38	4.64	1.79	13.83	U
			JOTH-L	4.16	3.69	2.36	2.96	U
			JOTH-R	2.34	4.36	6.38	9.25	IT
			LIRI-L	6.31	5.36	7.3	7.3	U
			MAHO-L	4.49	6.01	14.97	12.52	A
			MAHO-R	3.7	2.73	7	10.08	A
		Variant	JABU-L	16.15	16.64	12.67	12.13	A
			JABU-R	11.62	8.44	8.78	7.99	DT
			DEHA-L	16.72	16.82	7.73	6.9	A
			DEHA-R	11.89	13.34	6.46	6.98	NO

Table 7.1 RMS difference to normal, optimum wedge size and trend for all limbs and conditions across the four biomechanical parameters in the solid AFO group. Data not reaching the minimum difference is highlighted in grey. A = ambiguous, IT = clear increasing trend, DT = clear decreasing trend, U = clear U-shaped trend, NO = no optimum. If an optimum wedge size was identified, these cells are highlighted.

7.3.2.1.2 Temporospatial parameters

Table 7.2 presents the absolute values for cadence, walking velocity and stride length across the four conditions, along with the identified trend, and if applicable, the optimal wedge size. Only two children demonstrated clear trends in terms of cadence, and only three each in terms of walking velocity and stride length. All of the remaining children, with one exception, demonstrated no clear optima (refer to Table 7.5). When an optimum wedge was identified, it occurred across the small, medium and large wedges, but never the flat wedge (refer to Table 7.2). These data are summarised in Table 7.5.

	Parameter	Sub-group	Limb	Absolute Value Flat	Small	Medium	Large	Trend
Solid AFOs	Cadence (steps/min)	Common	JODA	128	130	127	129	NO
			JOTH	141	116	144	132	NO
			LIRI	127	135	137	131	U
			MAHO	117	119	114	132	NO
		Variant	DEHA	113	119	104	106	U
			JABU	113	112	111	116	NO
	Walking Velocity (m/s)	Common	JODA	1.04	1.06	1.15	0.93	U
			JOTH	1.5	1.05	1.51	1.29	NO
			LIRI	1.16	1.31	1.38	1.33	U
			MAHO	1.18	1.34	1.11	1.17	NO
		Variant	DEHA	1.32	1.38	1.33	1.34	U
			JABU	1.08	1.14	1.09	1.2	NO
	Stride length (m)	Common	JODA	0.98	0.98	1.09	0.87	U
			JOTH	1.28	1.1	1.25	1.17	NO
			LIRI	1.11	1.16	1.22	1.22	A
			MAHO	1.22	1.35	1.12	1.02	U
		Variant	DEHA	1.41	1.38	1.42	1.48	NO
			JABU	1.15	1.2	1.19	1.26	IT

Table 7.2 Average cadence, walking velocity and stride length (absolute values) for all limbs and conditions, and classification of optimum for the solid AFO group. Data not reaching the minimum difference is highlighted in grey. A = ambiguous, IT = clear increasing trend, DT = clear decreasing trend, U = clear U-shape trend, NO = no optimum. If an optimum wedge size was identified, these cells are highlighted.

7.3.2.2 Hinged AFOs

7.3.2.2.1 Biomechanical variables

Figure 7.2 illustrates the changes induced in four biomechanical variables as a result of increasing the wedge size in 5° intervals, according to RMS difference calculated over mid-stance. A value closer to zero represents the change that most closely represents normal values for able bodied children. In terms of knee kinetics and knee kinematics, the trends were either increasing or U-shaped with the exception of one variant limb demonstrating a decreasing trend. The trends observed in ankle kinetics and tibial projection angle were varied.

Table 7.3 presents the RMS values, the trend that best describes the presence or absence of an optimum wedge size, and if identifiable, highlights the optimum wedge size for each variable within each limb. In the hinged AFO group the trends observed across knee kinetics, knee kinematics and ankle kinetics were clear in approximately half of the limbs whereas only five limbs had a clear optima in terms of tibial projection angles. For knee kinetics and knee kinematics between two and three limbs had no clear optima, whereas for ankle kinetics and tibial projection angles six and eight limbs respectively had no clear optima.

When limbs were considered according to sub-group, different patterns were evident though these were less clear than in the solid AFO group. Most notably, the two variant limbs demonstrated opposing patterns of normalisation in knee kinetics and kinematics, whereby large wedge size improved knee kinetics and kinematics in one limb (JOBA) but worsened knee kinetics and kinematics in the other limb (JANI). However, in terms of ankle kinetics and tibial kinematics, these two limbs behaved similarly, with more normal ankle kinetics and tibial projection angles in larger wedge sizes.

Limbs across both sub-groups demonstrated optimum values across all wedge sizes, with the exception of one of the variant limbs for whom an optimal wedge size was identified in only one of the four variables.

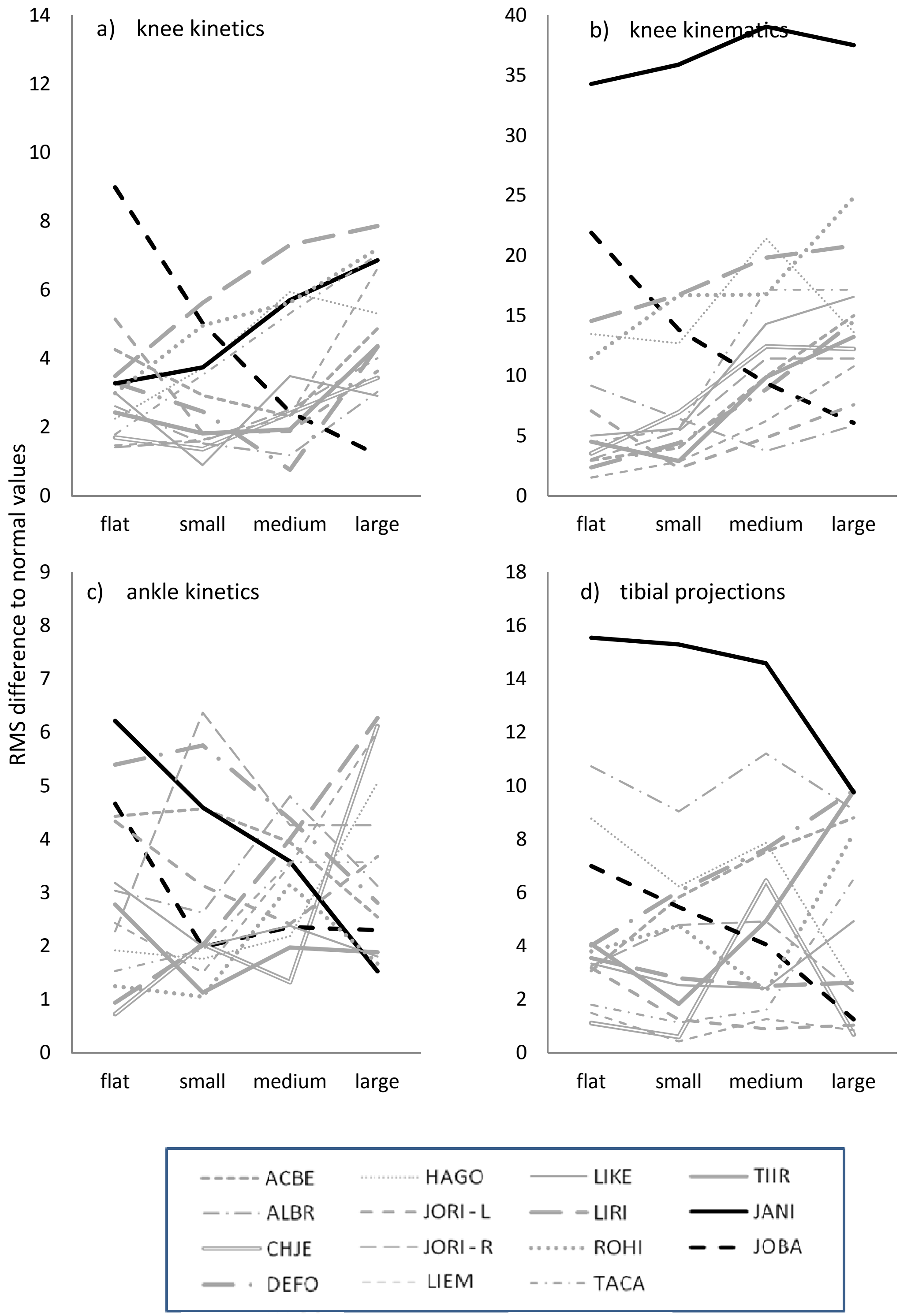


Figure 7.3 RMS difference to normal values for able bodied children for a) knee kinetics, b) knee kinematics, c) ankle kinetics and d) tibial projections, for the hinged AFO group.

Group	Parameter	Sub-group	Limb	RMS difference to normal				Trend
				Flat	Small	Medium	Large	
Hinged AFO group	Knee kinetics	Common	ACBE	4.25	2.93	2.31	4.87	U
			ALBR	2.61	1.53	1.18	3.02	A
			CHJE	1.70	1.36	2.41	3.43	A
			DEFO	3.29	2.45	0.75	4.33	U
			HAGO	2.25	3.72	5.94	5.30	IT
			JORI - L	5.14	1.82	1.88	3.62	A
			JORI - R	1.41	1.59	2.52	4.01	A
			LIEM	1.47	1.62	2.32	6.61	NO
			LIKE	3.00	0.89	3.48	2.91	NO
			LIRI	3.48	5.62	7.30	7.85	IT
			ROHI	2.99	4.96	5.63	7.19	IT
			TACA	1.79	3.52	5.31	7.02	IT
			TIIR	2.42	1.82	1.93	4.35	A
		Variant	JANI	3.27	3.73	5.70	6.85	A
			JOBA	8.98	5.03	2.43	1.18	A
	Knee kinematics	Common	ACBE	2.94	3.99	9.89	14.97	A
			ALBR	9.14	6.41	3.72	5.84	U
			CHJE	3.51	6.94	12.41	12.22	IT
			DEFO	2.35	4.39	8.84	14.50	A
			HAGO	13.44	12.68	21.40	13.62	NO
			JORI - L	7.06	2.28	4.83	7.56	U
			JORI - R	3.04	5.37	11.42	11.42	IT
			LIEM	1.52	2.82	6.21	10.76	A
			LIKE	4.99	5.58	14.30	16.55	A
			LIRI	14.54	16.73	19.81	20.81	IT
			ROHI	11.48	16.68	16.73	24.83	IT
			TACA	4.42	5.61	17.14	17.14	NO
			TIIR	4.50	2.89	9.86	13.21	A
		Variant	JANI	34.26	35.87	39.03	37.49	NO
			JOBA	21.89	13.81	9.37	6.07	DT
	Ankle kinetics	Common	ACBE	4.43	4.57	3.94	2.54	DT
			ALBR	3.03	2.62	4.80	3.12	A
			CHJE	0.72	2.03	1.32	6.12	IT
			DEFO	5.39	5.75	4.38	2.81	DT
			HAGO	1.91	1.75	2.18	5.05	NO
			JORI - L	4.33	3.13	2.41	3.67	U
			JORI - R	2.27	6.36	4.26	4.26	NO
			LIEM	2.42	1.50	3.51	6.01	U
			LIKE	3.17	1.99	2.38	1.80	NO
			LIRI	0.94	2.01	4.00	6.27	IT
			ROHI	1.24	1.05	3.15	1.66	NO
			TACA	1.53	1.92	3.56	3.56	NO
			TIIR	2.77	1.13	1.97	1.88	U
		Variant	JANI	6.21	4.59	3.58	1.52	DT
			JOBA	4.66	1.98	2.35	2.29	NO
	Tibial Projections	Common	ACBE	3.07	5.82	7.53	8.80	IT
			ALBR	10.73	9.03	11.19	9.10	NO
			CHJE	1.11	0.59	6.45	0.68	NO
			DEFO	4.00	6.05	7.64	9.81	IT
			HAGO	8.77	6.22	7.87	2.51	NO
			JORI - L	3.18	1.23	0.89	1.03	NO
			JORI - R	3.25	4.78	4.91	2.28	NO
			LIEM	1.48	0.42	1.26	0.84	NO
			LIKE	3.34	2.52	2.41	4.92	A
			LIRI	3.54	2.79	2.50	2.61	A
			ROHI	3.78	4.76	2.29	8.22	U
			TACA	1.79	1.13	1.59	6.50	NO
			TIIR	4.07	1.82	4.94	9.79	U
		Variant	JANI	15.54	15.28	14.58	9.75	NO
			JOBA	6.99	5.44	4.04	1.25	DT

Table 7.3 RMS difference to normal values for all limbs, conditions and parameters and classification of optimum for the hinged AFO group. Data not reaching the minimum significant difference highlighted in grey. A = ambiguous, IT = unambiguous increasing trend, DT = unambiguous decreasing trend, U = unambiguous U-shaped trend, NO = no optimum. If an optimum wedge size was identified, these cells are highlighted.

7.3.2.2.2 Temporospatial variables

Table 7.4 presents the absolute values for the three temporospatial variables, along with the identified trend and if applicable, the optimal wedge size. More than half of the children demonstrated clear trends in terms of cadence and walking velocity with an optima ranging between the small to large wedges. Almost half of the children demonstrated no clear trends in terms of stride length but when an optimum was identified it also included the flat wedge.

	Parameter	Sub-group	Limb	Absolute Value Flat	Small	Medium	Large	Trend
AFOs	Cadence (steps/min)	Common	ACBE	116	122	122	129	IT
			ALBR	128	134	136	127	U
			CHJE	124	125	133	124	U
			DEFO	122	137	120	129	NO
			HAGO	133	140	138	124	A
			JORI	105	113	109	110	U
			LIEM	100	102	103	101	U
			LIKE	119	123	123	121	A
			LIRI	127	135	137	131	U
			ROHI	101	106	104	112	IT
			TACA	112	115	115	112	A
			TIIR	102	105	109	113	IT
		Variant	JANI	133	123	136	133	NO
			JOBA	125	127	129	128	U
	walking velocity (m/s)	Common	ACBE	1.28	1.36	1.22	1.34	NO
			ALBR	1.23	1.34	1.40	1.26	U
			CHJE	1.11	1.22	1.23	1.19	A
			DEFO	1.37	1.50	1.38	1.30	U
			HAGO	1.19	1.37	1.29	1.06	U
			JORI	1.12	1.20	1.09	1.18	NO
			LIEM	1.10	1.17	1.16	1.13	A
			LIKE	0.88	1.08	1.04	1.04	U
			LIRI	1.16	1.31	1.38	1.33	U
			ROHI	1.24	1.27	1.23	1.04	U
			TACA	1.22	1.29	1.26	1.01	U
			TIIR	0.84	0.91	0.95	0.95	A
		Variant	JANI	1.27	1.21	1.38	1.30	NO
			JOBA	1.42	1.45	1.47	1.46	U
	Stride length (m)	Common	ACBE	1.32	1.32	1.20	1.25	NO
			ALBR	1.16	1.21	1.22	1.19	A
			CHJE	1.08	1.17	1.09	1.04	U
			DEFO	1.33	1.32	1.23	1.10	A
			HAGO	1.08	1.16	1.11	1.03	U
			JORI	1.27	1.27	1.20	1.29	NO
			LIEM	1.32	1.37	1.35	1.35	U
			LIKE	0.87	1.06	1.03	1.05	NO
			LIRI	1.11	1.16	1.22	1.22	A
			ROHI	1.46	1.43	1.41	1.13	NO
			TACA	1.30	1.34	1.31	1.08	NO
			TIIR	0.98	1.04	1.05	1.00	A
		Variant	JANI	1.14	1.18	1.23	1.18	U
			JOBA	1.36	1.37	1.34	1.37	NO

Table 7.4 Average cadence, walking velocity and stride length (absolute values) for all limbs and conditions, and classification of optimum for the hinged AFO group. Data not reaching the minimum significant difference highlighted in grey. A = ambiguous, IT = clear increasing trend, DT = clear decreasing trend, U = clear U-shaped trend, NO = no optimum. If an optimum wedge size was identified, these cells are highlighted.

7.3.2.3 Summary of trend type

Overall, a clear optimum was identified across the biomechanical variables more often in the solid AFO group than the hinged AFO group. The solid AFO group was less ambiguous in terms of knee kinetics but more ambiguous in terms of knee kinematics, when compared to the hinged AFO group. The effect of wedge size on ankle kinematics was more consistent in the solid AFO group, as was the effect on tibial projection angles. The hinged AFO group had a greater number of limbs demonstrating no clear optimal across all biomechanical variables. Limbs within the hinged AFO group did however demonstrate an optimum wedge size (either clear or ambiguous) in terms of temporospatial parameters, more often than the solid AFO group. Table 7.5 presents summary data describing the number of limbs within each group demonstrating each type of trend according to each variable.

Group	Parameter	Unambiguous optimum			A	NO
		U	IT	DT		
Solid AFOs (n=11 limbs; 6 participants)	Knee kinetics	5	3	0	2	1
	Knee kinematics	0	2	0	7	2
	Ankle kinetics	7	1	0	2	1
	Tibial projection angles	3	1	1	4	2
	Cadence	2	0	0	0	4
	Walking velocity	3	0	0	0	3
	Stride length	2	1	0	1	2
Hinged AFOs (n=15 limbs; 14 participants)	Knee kinetics	2	4	0	7	2
	Knee kinematics	2	4	1	5	3
	Ankle kinetics	3	2	3	1	6
	Tibial projection angles	2	2	1	2	8
	Cadence	6	3	0	3	2
	Walking velocity	8	0	0	3	3
	Stride length	4	0	0	4	6

Table 7.5 Summary data describing the number of limbs conforming to each type of trend for the solid and hinged AFO groups. A = ambiguous, IT = clear increasing trend, DT = clear decreasing trend, U = clear U-shaped trend (biomechanical parameters); NO = no optimum.

7.3.3 Is there agreement between parameters?

7.3.3.1 Solid AFOs

7.3.3.1.1 Correlation between biomechanical variables

To determine how the four biomechanical variables change with respect to each other, and thus establish the relationship between variables, the Pearson's Product Moment Correlation was performed between pairs of variables within each participant. Table 7.6 and Figure 7.4 present the correlation coefficient (r) for each pair of biomechanical variables for each participant within the solid AFO group, according to the common or variant sub-groups.

These results suggest that on average there is good agreement between the changes observed in knee kinetics with those observed in knee kinematics with a group average correlation coefficient of r=0.82. Limbs within both sub-groups demonstrated fair to strong positive relationships between variables.

Across the entire group the average correlation coefficient of r=0.33 indicates a lack of association between the changes seen in knee kinetics and tibial projection angle. However there were marked differences in the strength and direction of the relationship according to subgroup. The common sub-group demonstrated a moderate to good positive relationship (average r=0.66) whereas the variant sub-group demonstrated a moderate to good negative relationship (r=-0.60), thus resulting in a weak group average.

On average there was a fair to moderate positive relationship between changes in knee kinematics and changes in tibial projection angle (average r=0.67). However, two limbs in the variant sub-group demonstrated moderate to strong negative relationship (r=-0.66 and -0.95).

The direction and strength of relationship of ankle moment with both knee moment and knee kinematics varied across limbs within each sub-group. All limbs except two (in the common sub-group) demonstrated fair to strong positive relationships between ankle moment and tibial projection angle.

Two limbs in particular (MAHO-R and LIRI-L) had very strong agreement across all variables, with an average r=0.97 and r=0.92 respectively. Five other limbs (MAHO-L, JOTH-L, DEHA-R, JABU-L-R) had inconsistent agreement across parameters with some strong and some weak positive relationships, and some strong and some weak negative relationships.

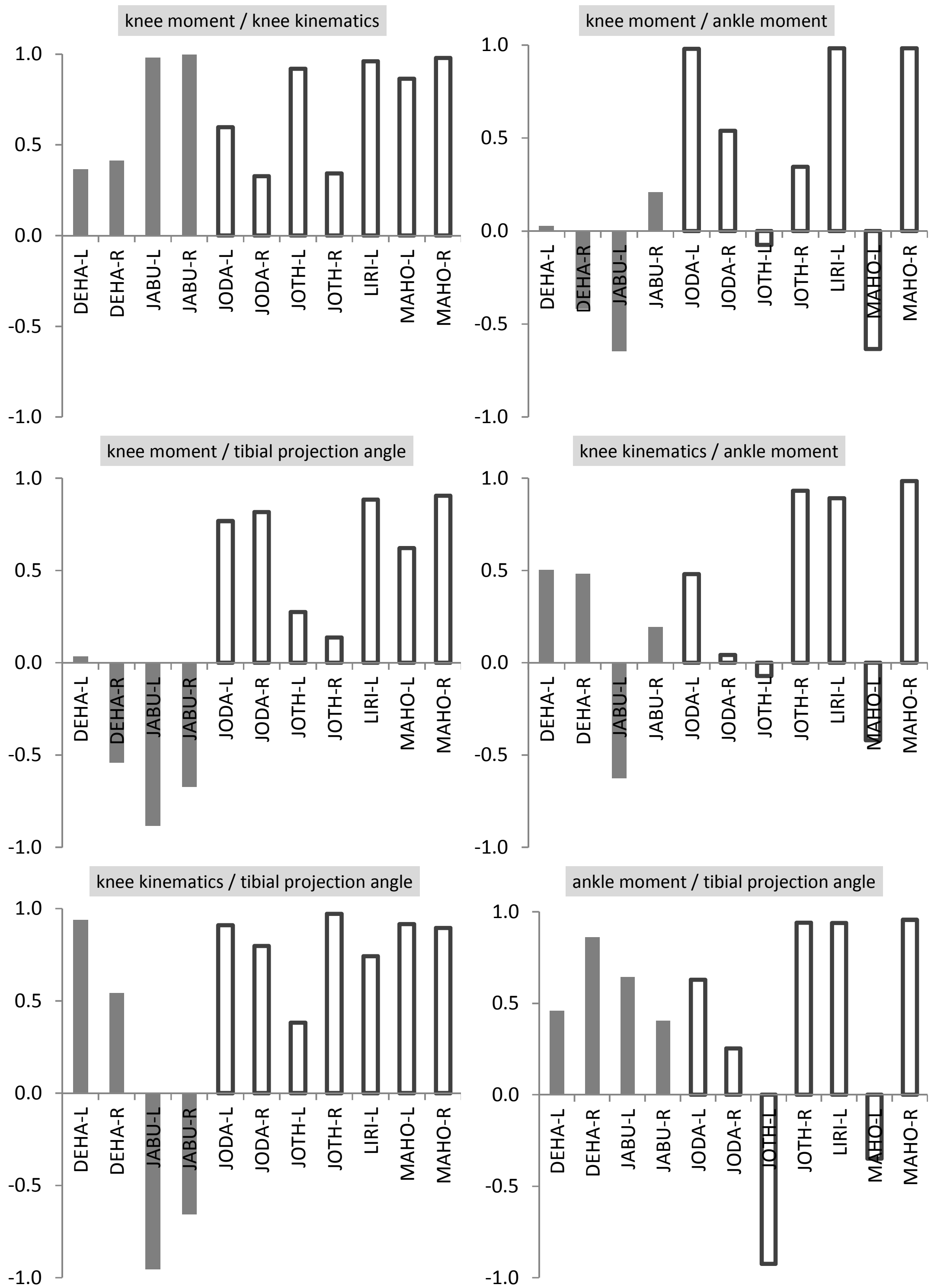


Figure 7.4 Correlation between pairs of biomechanical variables within each participant in the solid AFO group. Variant limbs in grey.

	knee moment / knee kinematics	knee moment / tibial projection angle	knee kinematics / tibial projection angle	knee moment / ankle moment	knee kinematics / ankle moment	ankle moment / tibial projection angle	Ave.
JODA-L	0.60	0.77	0.91	0.98	0.48	0.63	0.81
JODA-R	0.33	0.82	0.80	0.54	0.04	0.25	0.52
JOTH-L	0.92	0.28	0.38	-0.07	-0.07	-0.92	-0.17
JOTH-R	0.34	0.14	0.97	0.34	0.93	0.94	0.78
LIRI-L	0.96	0.88	0.74	0.98	0.89	0.94	0.92
MAHO-L	0.87	0.62	0.92	-0.64	-0.42	-0.35	0.33
MAHO-R	0.98	0.90	0.90	0.98	0.99	0.96	0.97
Ave.	0.68	0.66	0.86	0.66	0.48	0.40	0.74
DEHA-L	0.37	0.03	0.94	0.03	0.50	0.46	0.49
DEHA-R	0.41	-0.54	0.54	-0.42	0.48	0.86	0.29
JABU-L	0.98	-0.88	-0.95	-0.65	-0.62	0.64	-0.27
JABU-R	1.00	-0.67	-0.66	0.21	0.19	0.40	0.30
Ave.	0.89	-0.60	-0.07	-0.24	0.13	0.63	0.22
Group Ave.	**0.82**	**0.33**	**0.67**	**0.51**	**0.51**	**0.57**	**0.59**

Table 7.6 Correlation coefficient (r) values for pairs of biomechanical variables within each participant in the solid AFO group. Variant limbs in dark grey.

7.3.3.1.2 Agreement across all parameters

Table 7.7 presents the optimum wedge size across all variables; the score of agreement for biomechanical variables; the range of optimum wedge size, and for the sub-set of limbs where the range is 5° or less, the corresponding range of SVAs are reported. The optimum wedge size as nominated by knee kinetics occurred in the flat and small wedges in the majority of limbs, with only one limb having optimum in medium wedge and no limbs in the large wedge. Appendix G presents individual participant data depicting the RMS values for the four biomechanical parameters, and indicates the optimal wedge size according to knee kinetics, for both groups.

Only one limb achieved a perfect score of 3/3 for agreement across the four biomechanical variables, with four limbs each achieving 2/3 and 1/3, and one limb each achieving complete disagreement (a score of 0/3) and no clearly defined optimum. Six limbs had good agreement where the optimum wedge size was defined within a 5° range. The corresponding optimum SVA ranged from 0° to 10°.

An optimum wedge size for temporospatial variables was identified in only half of the possible conditions. When identified these were either the small, medium or large wedges and never the flat wedge. Patient preference varied between the flat, medium and small wedges but was never the large wedge. There was little agreement within temporospatial parameters, or between these and subjective preference, and the biomechanical parameters.

Sub-group	Participant and limb	**Knee kinetics**	Knee kinematics	Ankle kinetics	Tibial kinematics	**Score**[#]	Range of optimum[%] (°)	Optimum wedge size (°)	Fastest cadence	Fastest walking velocity	Longest stride length	Preferred wedge size
Common	JODA-L	**Small**	Flat	Small	NO	**1/3**	5	0-5	NO	Medium	Medium	Small
	JODA-R	**Medium**	Flat/small	Small	Medium	**1/3**	5	5-10				
	JOTH-L	**Small**	Small/medium	Small	Medium	**2/3**	5	5-10	NO	NO	NO	Medium
	JOTH-R	**Small**	Flat/small	Flat/small	Flat	**2/3**	5	0-5				
	LIRI-L^	**Flat/small**	Large	Small	Small	**2/3**	10		Medium	Medium	Medium/ large	Flat
	MAHO-L	**Small**	Flat/small	NO	Flat/small	**2/3**	5	0-5	NO	NO	Small	Flat
	MAHO-R	**Flat**	Flat/small	Flat/small	Flat/small	**3/3**	0	0				
Variant	DEHA-L*	**NO**	NO	Medium	Medium/large	**N/A**	N/A		Small	Small	NO	Medium
	DEHA-R	**Flat**	NO	Medium	NO	**0/3**	10					
	JABU-L	**Flat**	Flat/small	Medium	Medium/large	**1/3**	10		NO	NO	Large	Small
	JABU-R	**Flat/small**	Flat/small	Medium	Large	**1/3**	10					

Table 7.7 Optimum wedge size according to each variable for the solid AFO group. Score indicates the number of variables in agreement with knee kinetics. Limbs with agreement outside of 5° and therefore where optimum wedge size cannot be approximated are in grey. *DEHA-L AFO ankle angle is 3° DF. ^ Temporospatial results and favourite wedge size for LIRI also presented in the hinged AFO group. # N/A indicates no score because no clear optimum in terms of knee kinetics. % N/A indicates no range of optimum because no optimum wedge size was identified for knee kinetics. NO = no clear optimum.

7.3.3.2 Hinged AFOs

7.3.3.2.1 Correlation between biomechanical variables

Table 7.6 and Figure 7.4 present the correlation coefficient (r) for each pair of biomechanical variables for each participant within the hinged AFO group, according to the common and variant sub-groups. All limbs had a positive correlation between knee kinematics and knee kinetics, with an average of r=0.85. For all remaining variable pairs the direction and strength of the relationship varied substantially across limbs.

The best agreement across all pairs of variables (JOBA, r= 0.91) was demonstrated in the relatively extended limb within the variant sub-group. Two additional limbs had, on average, very good agreement (TACA, r=0.88; and JORI-L, r=0.77) with the remainder demonstrating a range of association across variable pairs in terms of both strength and direction of agreement.

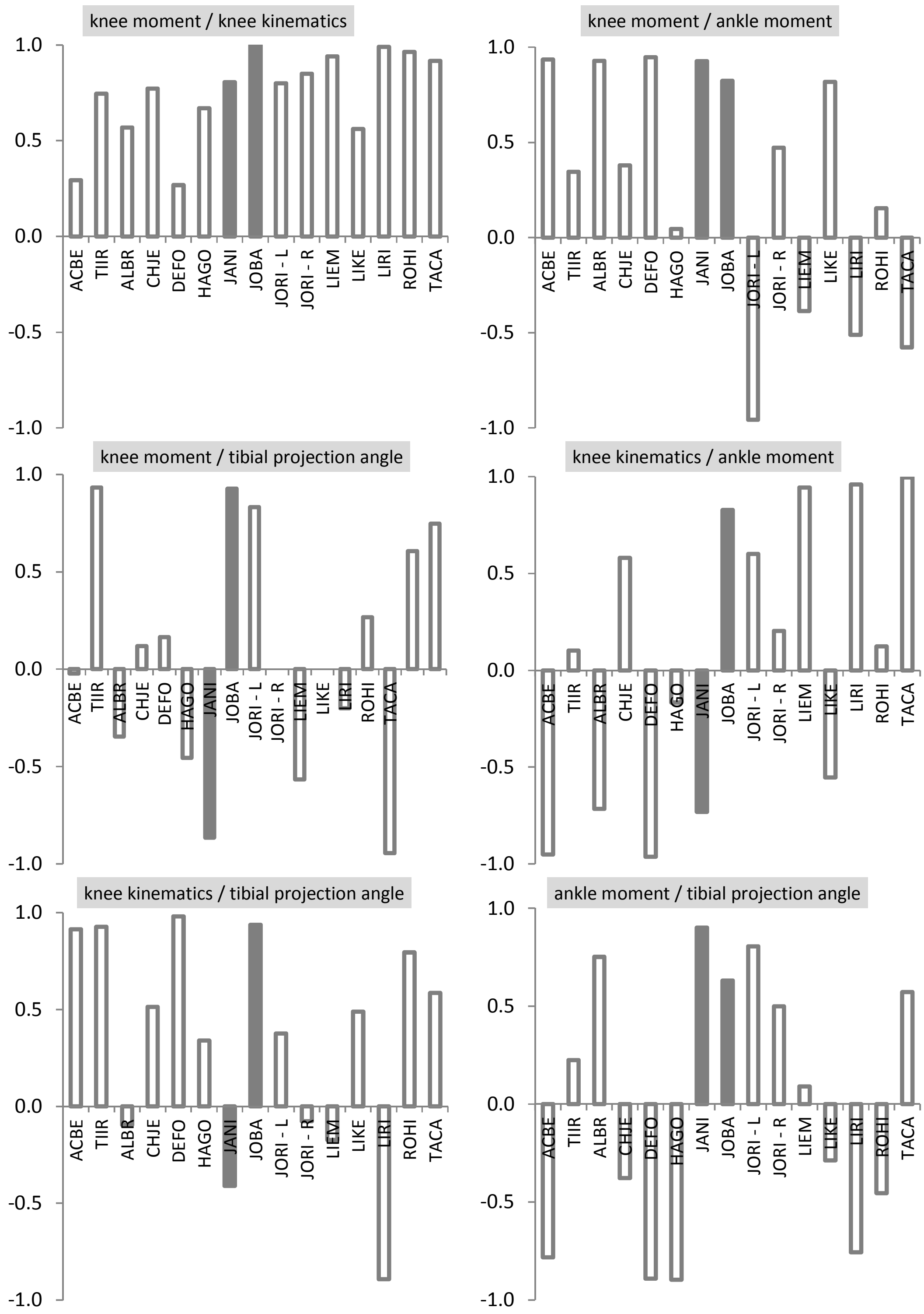


Figure 7.5 Correlation between pairs of biomechanical variables within each participant in the hinged AFO group. Variant limbs in grey.

	knee moment / knee kinematics	knee moment / tibial projection angle	knee kinematics / tibial projection angle	knee moment / ankle moment	knee kinematics / ankle moment	ankle moment / tibial projection angle	Ave.
ACBE	0.29	-0.02	0.91	-0.58	-0.95	-0.78	-0.28
TIIR	0.74	0.93	0.93	0.15	0.10	0.23	0.66
ALBR	0.57	-0.35	-0.10	-0.51	-0.72	0.75	-0.05
CHJE	0.77	0.12	0.51	0.82	0.58	-0.38	0.48
DEFO	0.27	0.16	0.98	-0.39	-0.96	-0.89	-0.17
HAGO	0.67	-0.46	0.34	0.47	-0.17	-0.90	-0.08
JORI - L	0.80	0.83	0.38	0.93	0.60	0.81	0.77
JORI - R	0.85	-0.57	-0.08	0.05	0.20	0.50	0.22
LIEM	0.94	-0.20	-0.17	0.95	0.94	0.09	0.68
LIKE	0.56	0.27	0.49	0.38	-0.55	-0.29	0.15
LIRI	0.99	-0.94	-0.89	0.93	0.96	-0.76	0.34
ROHI	0.96	0.61	0.79	0.35	0.12	-0.45	0.55
TACA	0.92	0.75	0.59	0.93	1.00	0.57	0.88
Ave.	0.82	0.12	0.51	0.54	0.20	-0.19	0.39
JANI	0.81	-0.86	-0.41	-0.96	-0.73	0.90	-0.32
JOBA	1.00	0.93	0.94	0.82	0.83	0.63	0.91
Ave	0.99	0.93	0.94	0.82	0.83	0.63	0.53
Ave.	0.85	0.13	0.52	0.44	0.19	-0.02	0.41

Table 7.8 Correlation coefficient (r) values for pairs of biomechanical variables within each participant in the hinged AFO group. Variant limbs in dark grey.

7.3.3.2.2 Agreement across all parameters

Table 7.9 presents the optimum wedge size across all variables; the score of agreement across biomechanical variables; the range of optimum wedge size, and for the sub-set of limbs where the range is 5° or less, the corresponding range of SVAs are reported. The optimum wedge size as nominated by knee kinetics was most commonly the flat wedge (7/15 limbs) and was only the large wedge in one limb, but this was not a clear optimum.

Only one limb achieved a perfect score of 3/3 for agreement across the four biomechanical variables, with seven limbs achieving 2/3, one limb achieving 1/3 and five limbs achieving complte disagreement (score of 0/3). In eight limbs there was 'good' agreement where the optimum wedge range could be defined within 5°. The corresponding optimum SVA ranged between 0° and 15°.

The optimum wedge size in terms of temporospatial variables varied across wedges although was never the flat wedge. Subjective preference varied across all wedge sizes. There was little apparent agreement within temporospatial parameters, or between these and subjective preference, and the biomechanical parameters.

Sub-group	Limb	**Knee kinetics**	Knee kinematics	Ankle kinetics	Tibial kinematics	**Score #**	Range of optima	Optimum SVA (°)	Fastest cadence	Fastest walking velocity	Longest stride length	Preferred wedge size
Common	ACBE	**Medium**	Flat	Large	Flat	**0/3**	15		Large	NO	NO	Flat
	ALBR	**Small/mediu**	Medium	Small	NO	**2/3**	5	5-10	Medium	Medium	Small/mediu	Couldn't tell
	CHJE	**Flat/small**	Flat	Flat	NO	**2/3**	5	0-5	Medium	Small/mediu	Small	Flat
	DEFO	**Medium**	Flat	Large	Flat	**0/3**	15		NO	Small	Flat/small	Medium
	HAGO	**Flat**	NO	NO	NO	**0/3**	N/A		Small/mediu	Small	Small	Medium/larg
	JORI-L	**Small/mediu**	Small	Medium	NO	**2/3**	5	5-10	Small	NO	Flat/small	Medium
	JORI -	**Flat/small**	Flat	Flat	NO	**2/3**	5	0-5				
	LIEM	**None**	Flat/small	Small	NO	**N/A**	5	0-5	Medium	Small/mediu	Medium/larg	Small
	LIKE	**Small**	Flat/small	NO	Small/mediu	**2/3**	5	0-5	Small/mediu	Small	NO	Large
	LIRI-RA	**Flat**	Flat	Flat	Medium/large	**2/3**	15		Medium	Medium	Medium/large	Flat
	ROHI	**Flat**	Flat	NO	Medium	**1/3**	10	0	Large	Small	NO	Flat
	TACA	**Flat**	NO	NO	NO	**0/3**	N/A		Small/mediu	Small	NO	Flat/small
	TIIR	**Small/mediu**	Small	Small	Small	**3/3**	0	5	Large	Medium/larg	Small/mediu	Medium
Variant	JANI	**Flat/small**	NO	Large	NO	**0/3**	10		NO	NO	Medium	Medium
	JOBA	**Medium/large**	Large	NO	Large	**2/3**	5	10-15	Medium	Medium	NO	Flat

Table 7.9 Optimum wedge size according to each variable in the hinged AFO group. Score indicates the number of variables in agreement with knee kinetics. Limbs with agreement outside of 5° and where SVA cannot be approximated are in grey. * DEFO AFO ankle angle is -3° PF. ^ Results for LIRI also presented in solid AFO group. # N/A indicates no score because no clear optimum in terms of knee kinetics. % N/A indicates no range of optimum because only one optimum wedge size was identified. NO = no clear optimum.

7.4 Discussion

This investigation addressed two research questions: 'Is there an optimum AFO-FC alignment?' and 'Is there agreement on optimum wedge size across biomechanical parameters, temporospatial variables and subjective preference?' The following discussion addresses these in turn before commenting on limitations of the work and future directions.

7.4.1 Is there an optimum AFO-FC alignment?

The first research question addressed in this investigation was 'Is there an optimum AFO-FC alignment?' For the purpose of this analysis the optimum AFO-FC alignment was indicated by the wedge size that produced the most normal pattern of knee kinetics, knee kinematics, tibial projection angle and ankle kinetics over mid-stance. It was hypothesised that an optimum wedge size would be identified across the biomechanical parameters in most limbs and that the solid AFO group would have an optimum wedge size identified more often than the hinged AFO group, particularly in the limbs demonstrating the common pattern of knee kinematics.

The results suggest that an optimum alignment could in fact be identified for individual biomechanical parameters in the majority of limbs. While this supported the hypothesis there were several instances across a range of the parameters where there was no clear optimum. These occurred over a range of parameters and limbs within both AFO groups and sub-groups. Broadly speaking however, the solid AFO group had more clear optima in the biomechanical variables than the hinged AFO group, and within both groups the limbs with fewer clear optima were the variant limbs in the solid AFO group and the flexed variant limb in the hinged AFO group.

The focus of the tuning procedure has largely been directed toward optimisation of gait. Despite this, no studies have explicitly reported the normalising effect of modifying AFO-FC alignment on the gait patterns of children with cerebral palsy. Given previous suggestions that children who will tune successfully are those with more extended gait patterns (Butler*, et al.*, 2007; Owen, 2004c; Owen*, et al.*, 2004), it is not surprising to find that it is these children who more often than not, have one particular wedge size that produces the most normal biomechanical pattern. Given the results of Chapter 6, it is also not surprising that the normalising effect of solid AFOs is considerably more consistent than hinged AFOs, in light of the differences in AFO design.

The tuning procedure is described as a trial and error process whereby small changes are made to the design of the AFO-FC in order to optimise its performance (Owen, 2004c; Owen, 2010; Owen*, et al.*, 2004). This description assumes that each subsequent change in design (eg a change in SVA) produces a discernable change in the outcome (most commonly knee kinetics but also often knee kinematics), such that an AFO-FC alignment producing the best gait pattern can be identified. The present study is the first to quantify the normalisation effect of AFO-FC alignment across a range of biomechanical variables in an attempt to provide substantiative evidence either in support of, or against these assumptions. The results suggest that certainly for the solid AFO group, discernable and systematic changes are produced in these four biomechanical variables which, when compared to normal values result in most cases, in a clear optimum.

Optimum wedge size can be translated into optimum SVA simply by adding or subtracting any dorsiflexion or plantarflexion inherent in the AFO ankle angle. Of the limbs which had agreement on optimum wedge size across biomechanical variables within a range of 5°, the wedge size produces the equivalent SVA because all AFOs had a plantigrade ankle angle. Results of the present study suggest that the optimum SVA in the solid AFO group was most frequently the 5° SVA (common sub-group) or 0° (variant limbs). These results do not agree with the only other studies that have reported the final SVA of AFO-FCs after having undergone a tuning procedure. These studies are in general agreement with each other with an average SVA of 11.86° (SD 2.05°) (Owen, 2002) and 10.8° (SD 1.8°) (Jagadamma*, et al.*, 2009), but report markedly larger SVAs than the present study.

This disagreement is likely to be a reflection of the gait patterns of the children included in each study. The study by Jagadamma and colleagues (2009) examined five children who demonstrated knee hyperextension (<0° knee flexion during stance phase). These children would have all demonstrated more knee hyperextension and greater peak knee extension moments than the children in the solid AFO common sub-group. The results of the present study suggest that greater degrees of knee extension result in larger optimum SVAs and as such these differences in gait pattern are likely to account for the larger SVA.

The average SVA values reported by Owen (2002) are the result of tuning the AFO-FC using a combination of modifications to the SVA, heel and sole profiles of the footwear. After selection of an appropriate AFO ankle angle, modifying the SVA is said to be the first stage of tuning, which is followed by changes to the heel and then sole. Verbal communication with this author suggests however that after modifying the heel and sole properties of the footwear, the final stage of tuning is to make a final assessment and adjustment of the SVA as necessary (personal communication with E. Owen, 2010). This process suggests that changing the heel and sole profile may also affect mid-stance biomechanics and may explain why the final SVAs identified by the present study differ from the study by Owen (2002). In addition, in the study by Owen (2002), knee kinetics were assessed at a specific point of the gait cycle (30% gait cycle) which, based on the results of Chapter 6, would result in a different outcome compared to measurements based on the mid-stance phase or all of stance phase.

Four biomechanical variables were examined in this investigation. Optimising knee kinetics over mid-stance is one of the primary aims of AFO-FC tuning (Butler*, et al.*, 1992; Owen, 2002). This study found that within the solid AFO group, knee kinetics was one of the two variables (the other being ankle moment) with the most consistent identification of an optimum wedge size. This lends support to the idea that children who wear solid AFOs will have a particular AFO-FC alignment that produces the most normal knee kinetic pattern during this period of the gait cycle. The optimal wedge size will however vary according to AFO type and sub-group.

While tuning has primarily focussed on the effect on knee moment, there are numerous other references regarding tuning to normalise knee kinematics (Bowers & Meadows, 2007; Butler*, et al.*, 2007; Jagadamma*, et al.*, 2009; Jagadamma*, et al.*, 2010; Meadows*, et al.*, 2008; Owen*, et al.*, 2004; Stallard & Woollam, 2003). This study found that all limbs in the solid AFO group (except for two of the limbs in the variant sub-group) had a specific wedge size or small range of wedge sizes that produced the most normal knee kinematics. In the majority of cases these were the flat and small wedges which suggests that the best knee kinematics over mid-stance can, in general, be achieved with a SVA of 0-5°

Another variable suggested to be at the heart of the tuning process is normalisation of shank kinematics (Owen, 2004c; Owen, 2010; Owen*, et al.*, 2004). The present study found that an optimum wedge size for tibial projection angle, which is essentially a dynamic measurement of SVA, could also be identified in the majority of limbs. When identified, this optimum wedge varied across the entire 15° range tested. This means that in any limb where the optimum was either the flat or large wedge, the true optimum may remain outside the tested range and as such is unknown. The reference to optimisation of knee kinetics, knee kinematics and tibial projection angle in the wider body of literature lend importance to the issue of whether these variables all normalise at the same wedge size. This is discussed further in the subsequent section.

Ankle kinetics were included in this analysis because of the systematic changes demonstrated in Chapter 6. They have not featured either as an outcome variable or as part of the tuning procedure in any other literature. Ankle kinetics were first examined on the basis of hypothesised mechanisms by which different patterns of response may occur as a result of differences in baseline gait pattern (refer to Chapter 2). In particular it was thought that limbs with more flexed gait patterns would demonstrate systematic reductions in ankle moment. The results of the present study support this suggestion as all limbs demonstrating a more flexed pattern (four limbs in the variant solid AFO sub-group and one variant limb in the hinged AFO group) demonstrated a clear optimum wedge size in the medium wedge and large wedge, respectively. Several other limbs with the common gait pattern also demonstrated an optimum wedge size in terms of ankle moment that were most clear in the solid AFO group. Therefore, these limbs could be considered as demonstrating a “mixed response” as seen in the pilot data presented in Chapter 4.

7.4.2 Is there agreement between parameters?

The second question addressed in this investigation was whether there was agreement on optimum wedge size across biomechanical parameters, as well as temporospatial variables and subjective preference. It was hypothesised that there would not be complete agreement across these parameters in the majority of limbs but that the solid AFO group would demonstrate better agreement than the hinged AFO group, and within the solid AFO group, the limbs demonstrating the common gait pattern would have better agreement than the variant limbs.

The results of the present study support these hypotheses as there were only two limbs across the entire sample for which perfect agreement on the optimum wedge size was obtained for the four biomechanical variables. However, if good agreement is considered to be a 5° range in optimum wedge size, more than half of the limbs in both the solid AFO group (6/11) and hinged AFO group (8/15) had good agreement. In the solid AFO group, all of these limbs were part of the common sub-group. In the hinged AFO group, these limbs were either in the common sub-group or was the variant limb demonstrating an extended gait pattern. This suggests that in the solid AFO group, limbs with good knee extension in mid- to late stance have better agreement in normalisation of these four biomechanical parameters than those with increased knee flexion.

The variant limbs in the solid AFO group demonstrated the worst agreement across variables with no clear optimum in knee kinetics in one limb, and scores of 0/3 or 1/3 for the remaining three limbs. The optimum SVA spanned 10° in these three limbs which resulted from disagreement in optimum wedge size for knee kinetics (flat wedge), compared to ankle kinetics and tibial kinematics (medium and large wedges). It is therefore difficult to select a wedge size that produces the best gait pattern overall in this sub-group without first prioritising one variable and in doing so accepting detrimental effects in other variables. It is also possible that changes to the heel and sole profiles could counter these effects.

Many of the proponents of the AFO-FC tuning process emphasise the importance of optimising both the kinetics and kinematics of gait (Bowers & Meadows, 2007; Butler*, et al.*, 2007; Jagadamma*, et al.*, 2009; Jagadamma*, et al.*, 2010; Meadows*, et al.*, 2008; Owen*, et al.*, 2004; Stallard & Woollam, 2003). Both tibial kinematics and knee kinematics have been identified as relevant kinematic variables that should be optimised as part of this process. This assumes that by changing AFO-FC alignment, normalisation will occur simultaneously across variables.

The results of this study do not support this contention, with only two limbs within each group having perfect agreement across the four biomechanical variables. The correlations between pairs of variables provide further insight into this disagreement. These data suggest that only a handful of limbs will have good agreement across all four biomechanical parameters. For children wearing either solid or hinged AFOs, knee kinetics and knee kinematics tend to normalise at similar wedge sizes and if considered together will, in most, but not all cases produce relatively good agreement, regardless of type of gait pattern. This is encouraging given the focus on these two variables throughout the literature.

However, if tibial projection angles are considered with regard to knee kinetics and kinematics, a distinction was seen within the solid AFO group with regard to the type of gait pattern. Limbs demonstrating the common pattern of knee kinematics will have good agreement, whereas in limbs demonstrating increased knee flexion (followed by either persistent knee flexion or knee extension) will have disagreement in terms of the normalising effect. If tibial projection angles are considered with knee kinematics, all limbs had good agreement except for the two variant limbs with persistent knee flexion. There was no consistent relationship within the hinged AFO group. Thus consideration of tibial angles adds complexity specifically to the optimisation of limbs who demonstrate increased knee flexion during early stance.

These variant limbs demonstrating increased knee flexion in early stance, either persisting or demonstrating good knee extension, demonstrate a gait pattern considered by some to be less likely to tune successfully (Butler*, et al.*, 2007; Owen, 2004c; Owen*, et al.*, 2004). Given the lack of agreement between knee kinetics and kinematics with tibial projection angles, it is probable that these authors considered tibial kinematics in their definition of unsuccessful tuning. Owen (2010) suggests that normalisation of shank kinematics is the precursor to normalised joint kinetics, which in light of the results of the present study may not be possible for these children.

Agreement across temporospatial parameters was variable in the solid AFO group with approximately half of these limbs demonstrating no clear optimum. When an optimum wedge size was identified there was however reasonable consistency within each individual participant. This is to be expected as changes in one of these variables, such as increased walking velocity must result from changes in at least one of the other variables, that is faster or longer steps. While the hinged AFO group had more limbs demonstrating clear trends, there was less agreement across variables within each participant.

Some limitations apply to the temporospatial results on the basis of the method used to determine optimum wedge size. Optimum was considered to be the largest value for all three variables, however some children with CP tend to decrease stride length when cadence increases (Brunner*, et al.*, 1998; Buckon*, et al.*, 2001; Buckon*, et al.*, 2004; Hayek*, et al.*, 2007; Radtka*, et al.*, 1997; Romkes*, et al.*, 2006). If this was the case we would expect to see opposing trends in these variables and ultimately disagreement in optimum wedge size.

The only study to report changes in temporospatial variables from a tuned to a non-tuned AFO-FC in children with CP examined five children demonstrating knee hyperextension and found no significant effect on walking velocity, cadence or stride length (Jagadamma*, et al.*, 2009). When children were considered on the basis of hemi- or diplegia, tuning the AFO-FC resulted in decreased walking velocity, cadence and stride length in two diplegic children but increased walking velocity and cadence in the three hemiplegic children (Jagadamma*, et al.*, 2009). All of the children in the solid AFO group of the present study had diplegic CP, which may account for the lack of consistent trends in response to wedge size.

This analysis also recorded the participant's subjective preference during data collection. Participants were asked to consider which, if any of the four wedges was their favourite. While the majority of children did identify a preferred wedge, several found it difficult because the wedges were administered in a randomised order. Two participants, one from each group, couldn't identify an optimum. There was variable agreement with preferred wedge size across the temporospatial and biomechanical variables. Thus subjective opinion of the patient as taken during the laboratory setting where systematic changes are made in a randomised order may not be a reliable indication of their preferred wedge size.

7.4.3 Limitations

This investigation employed a methodology whereby systematic alignment changes were made to the AFO-FC, and therefore cannot be likened to the trial and error tuning process. Because of this, these results must be considered in light of the potential changes that could be made to the gait pattern with the use of modifications to the heel and sole profiles of the footwear. Theoretically these components of the tuning process could affect these variables and thus lead to further improvements or deterioration in different parameters. A lack of solid evidence demonstrating the effect of heel and sole modifications on gait means that the potential effect of these components of the tuning process on the results of this study cannot be hypothesised.

In addition, using the RMS difference between curves across mid-stance does not allow one variable, such as peak knee extension moment, to be prioritised and also cannot distinguish between changes occurring across the duration of stance phase. In this analysis knee kinetics were prioritised and knee kinematics, tibial projection angles and ankle kinetics were given equal weighting on the basis of systematic changes seen in Chapter 6. Variables above knee level were not included because they did not present the same consistent changes, and the added complexity was not considered warranted.

Both groups in this study were of small sample size with n=6 participants (with 11 limbs) in the solid AFO group, and n=14 participants (with 15 limbs) in the hinged AFO group, with one participant included in both groups. Within each group the majority of limbs demonstrated a common knee kinematic pattern with good knee extension in mid-late stance in the baseline condition. In the solid AFO group this sub-group of limbs responded consistently to AFO-FC alignment change and showed good agreement across optimisation of biomechanical variables within 5°. As such these results can be generalised well with the wider population.

The sub-group analysis in this study and in Chapter 6 was based on recognisable patterns of knee kinematics occurring naturally within the data. Published gait classifications could not be applied in this situation as sub-groups were considered based on the baseline condition in the AFO and not a barefoot condition. In addition, ankle movement was constrained which eliminates the defining feature of jump knee gait, crouch gait and apparent equinus (Rodda & Graham, 2001). To use the descriptive terms of previous authors, the flexed limb in the hinged group (JANI) and JABU in the solid group could instead be described as exhibiting stiff knee gait (Rodda & Graham, 2001; Sutherland & Davids, 1993; Winters*, et al.*, 1987), while DEHA demonstrates a variation of true equinus (Rodda*, et al.*, 2004). Regardless of this, only three limbs demonstrated variations on the mild pattern and as such any differences relating to this are readily distinguished throughout the analysis despite being grouped together.

Ankle moment was included in this analysis on the basis of theoretical work presented in Chapter 2, pilot work of Chapter 4 and the results of Chapter 6. This variable was given equal weighting in calculating scores of agreement across variables. If this variable was removed from the analysis this will most likely change the degree of agreement across biomechanical variables. Thus the scores calculated in the present investigation should be considered in light of the relative importance placed on each of these four parameters.

7.4.4 Future directions

Further analysis could be conducted using gait summary measures to consider change over a range of parameters, levels and planes. For example, the Movement Analysis Profile which generates a Gait Profile Score (Baker *et al.*, 2009), and the Gait Deviation Index (Schwartz & Rozumalski, 2008) are two summary measures of overall gait pathology that have been used in children with CP. However both of these measures use only kinematic data and have not been validated for kinetic data. Alternatively, particular gait parameters considered important in the management of particular gait patterns could be prioritised, and a sub-set of parameters of primary concern could be included.

7.5 Conclusion

This study found that an optimum AFO-FC alignment could be identified according to the wedge size that best normalised knee kinematics, knee kinetics, tibial kinematics and ankle kinetics over mid-stance, for the majority of limbs. An optimum wedge size was however less apparent in terms of temporospatial parameters and subjective preference. Only one limb each from the solid and hinged AFO groups had perfect agreement in optimum wedge size across the four biomechanical variables, with approximately half from each group having good agreement. From these data an optimal SVA could be estimated and was found to vary according to gait pattern within the solid AFO group, but in the hinged AFO group was quite variable. Across both groups changes in knee kinematics tended to agree with changes in knee kinetics regardless of gait pattern. In the solid AFO group considering changes to tibial projection angle resulted in poor agreement particularly in limbs demonstrating increased knee flexion in early stance. Overall this suggests that changing the AFO-FC alignment does not permit normalisation across a range of variables, and that there must be a prioritisation of the most important variable to normalise.

8 A new model to measure movement of the ankle, AFO and footwear in solid AFOs using 3DGA

This chapter describes the development and testing of a new model to measure AFO, tibial and footwear movement in solid AFOs using 3-dimensional gait analysis (3DGA). This study addresses the sixth and final research question of this thesis which was, 'When ankle movement in a solid AFO is measured using 3DGA, does this accurately reflect anatomical ankle movement?' The first aim of this investigation was to compare ankle kinematics provided by the PluginGait (PiG) model (Vicon, Oxford, UK) to anatomical ankle kinematics that were calculated as the angle between the tibia relative to the foot. The second aim of this investigation was to determine the extent of AFO deformation, tibial movement within the AFO and movement of the footwear on the AFO. The outcomes of this study provide a novel approach for measuring AFO performance in both clinical and research settings and in doing so improve our understanding of how solid AFOs behave under dynamic conditions. This model also allows a more accurate measurement of ankle kinematics which will help clinicians and researcher make better informed decisions regarding the success of interventions.

8.1 Introduction

Solid AFOs are prescribed for adults and children with neurological conditions for the purpose of eliminating all motion at the ankle joint. The effect of this device on gait has been assessed in both the clinical and research setting using 3DGA. Despite the purported rigidity of the solid AFO, several studies investigating the effect of solid AFOs on children with cerebral palsy (CP) have reported a considerable range of ankle movement between 8-16° of dorsi- and plantarflexion (Abel*, et al.*, 1998; Brunner*, et al.*, 1998; Buckon*, et al.*, 2001; Buckon*, et al.*, 2004; Carlson*, et al.*, 1997; Lam*, et al.*, 2005; Thompson*, et al.*, 2002). This movement has often been attributed to insufficient rigidity of the AFO which deforms under loading and buckles at the ankle (Buckon*, et al.*, 2001; Buckon*, et al.*, 2004; Carlson*, et al.*, 1997; Thompson*, et al.*, 2002).

There are however other factors that may contribute to an output of significant ankle movement (θ_{PiG}) when using a lower limb kinematic model (see Figure 8.1). First, this ankle movement will include errors caused by soft tissue artefact (STA) of the knee marker which influences calculation of ankle kinematics. Second, while the real component of this movement is often thought to reflect AFO deformation ($\theta_{AFO\ def}$), it is actually a true measurement of anatomical ankle movement ($\theta_{ankle\ anat}$) (see Figure 8.2). In some cases AFO deformation will be the same as the anatomical ankle movement, but in others, some movement will occur between the tibia and AFO ($\theta_{tib\ mov}$). Because of the marker configuration used in most lower limb biomechanical models, the model is unable to distinguish between AFO deformation and anatomical ankle movement.

While there is likely to be some movement between the tibia and AFO, there is also likely to be some movement between the footwear and AFO($\theta_{shoe\ mov}$). While this is not going to affect the PiG output of ankle kinematics (described in detail below), the ability to measure the movement between the footwear and limb and thereby quantify the intimacy of the fit of the footwear, has both research and clinical utility.

The following discussion first addresses how the PiG modelling software may be affected by STA of the knee marker movement, movement of the tibia within the AFO and movement of the shoe on the AFO/foot. Secondly, the relationship between the individual segments, namely the tibia, AFO and footwear is examined. Finally, a new model based on the PiG marker set and static calibration is proposed that allows calculation of the effect of STA of the knee marker on ankle kinematics, as well as measurement of anatomical ankle movement, AFO kinematics and movement of the footwear.

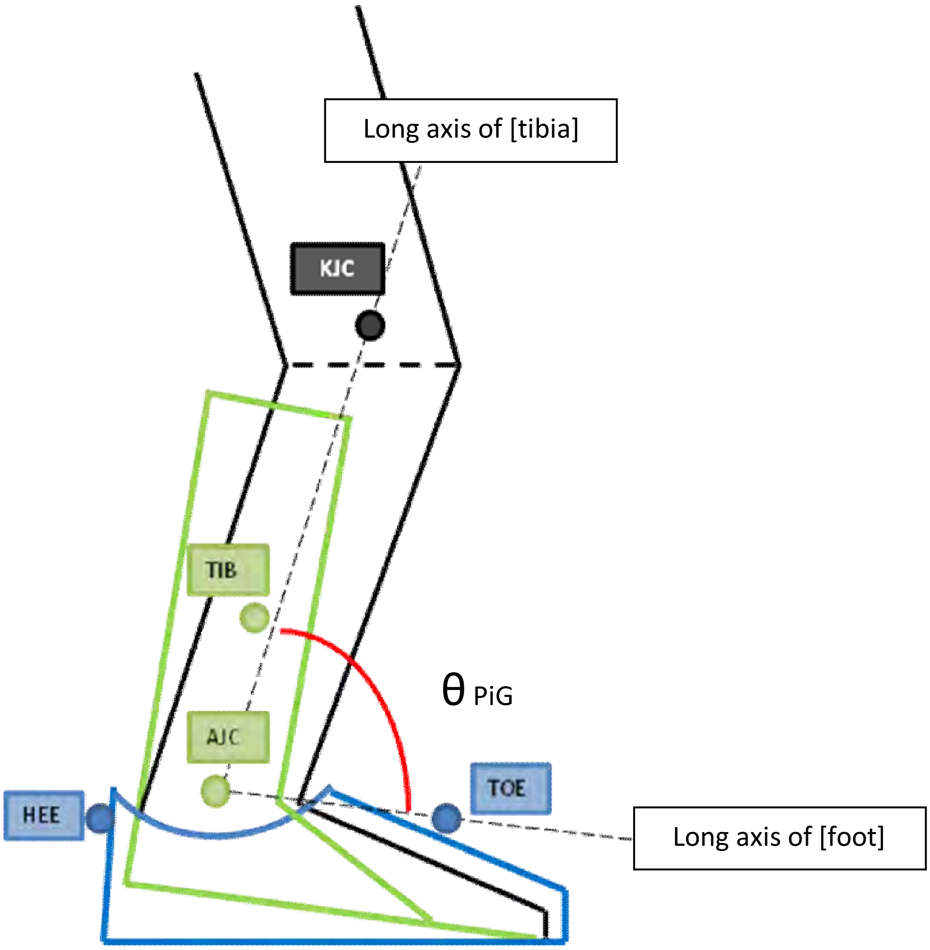


Figure 8.1 Concept diagram showing the long axis of the two limb segments used in the PiG calculation of ankle kinematics.

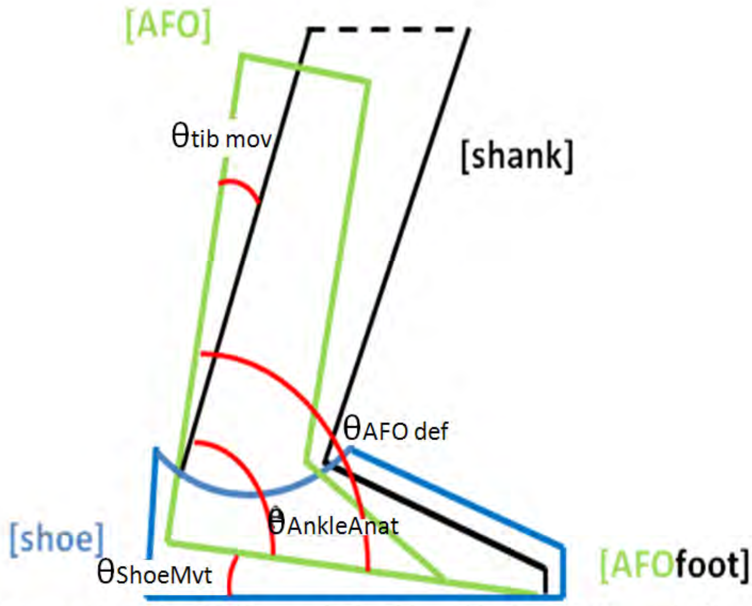


Figure 8.2 Concept diagram of movement of the AFO ($\theta_{AFO\ def}$), the tibia within the AFO ($\theta_{tib\ mov}$), the anatomical ankle ($\theta_{ankle\ anat}$) and the AFO foot piece within the footwear ($\theta_{shoe\ mov}$).

8.1.1 Plug-In-Gait

3DGA or instrumented gait analysis is considered the gold standard assessme nt method for measuring complex movements such as human walking. 3DGA involves measuring the movement of retroflective markers (indicated in text using uppercase) that have been attached to the skin over specific anatomical landmarks. As the subject moves within the laboratory, the system records the position of these markers within this laboratory based global co-ordinate system.

For the movement of these markers to provide useful information, they must also be 'mapped' to represent the underlying bones and joints. To map these markers a model is applied which uses the markers to define each body segment with an origin and three orthogonal axes, which are often based on how the model defines joint centres. This creates a local co-ordinate system for each segment. Segments are indicated in text using [square brackets].

The model also describes how segments are linked together and allows calculation of kinematic angles, moments and power quantities. PlugInGait (PiG) is a commonly used model provided by VICON (Vicon, Oxford, UK) modelling software. The PiG lower limb kinematic model uses the kinematic model described by Davis and colleagues (Davids*, et al.*, 1991) which has been one of the most commonly used models in gait analysis. Although the code for this is not published, several people have created very similar models in programming languages such as BodyLanguage (which forms the basis for VICON's BodyBuilder software), as well as programming languages for other 3DGA systems. While modelling in this investigation uses either PiG or BodyLanguage models written specifically for this project, the conclusions are not restricted to this specific model and analysis system.

8.1.2 Definition of a rigid-body segment

In 3DGA the body is defined as a series of linked rigid body segments. To define a rigid body segment a minimum of three points, or markers are required. Each point is expressed as co-ordinates relative to a particular frame of reference. Points can be global, in the co-ordinate system of the laboratory, or local, in the co-ordinate system of a segment.

To define a segment, one point is nominated as the segment origin, and two lines are defined that together uniquely describe the segment rotation according to three orthogonal axes (see Figure 8.3). One of these directions is taken as a principal direction and is used to directly define the direction of the first segment axis. The second direction is subordinate to the first, and is used with the first direction to define a plane. The third axis of the segment is taken to be perpendicular to this plane, with the second axis perpendicular to both the first and third axes. Thus rotation of a segment is represented by the orientation of its three axes, pointing in mutually perpendicular directions from the segment origin.

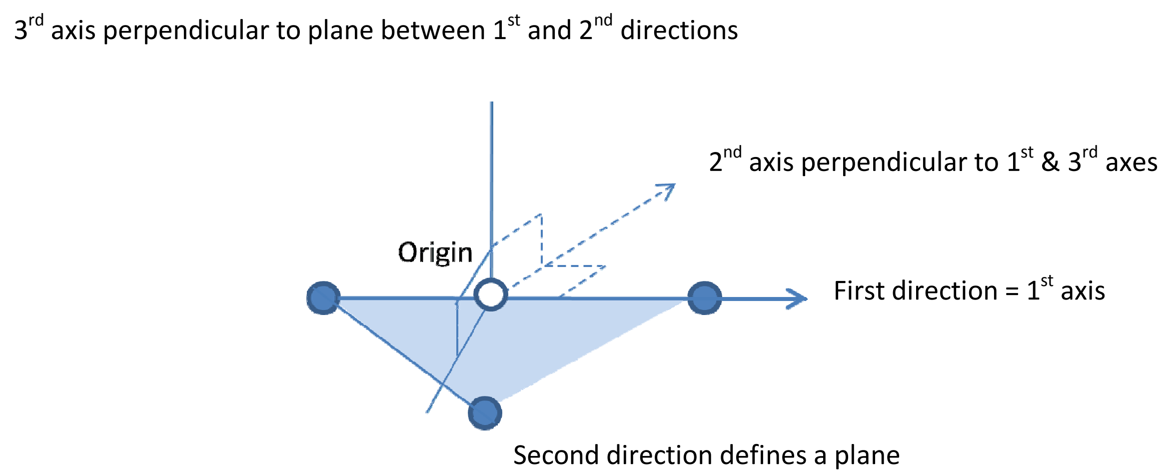


Figure 8.3 Definition of orthogonal axes for a rigid body segment.

8.1.3 Definition of the joint centre

Joint kinematics describe rotations of one segment relative to another, around a single point defined as the joint centre. A joint centre is most commonly designated as the origin of one of the segments. In PiG the knee and ankle joint centre are defined analogously with reference to three points. One of these points is a previously calculated joint centre from a proximal segment, a second is a real marker located at some known perpendicular distance (joint centre offset) from the required joint centre, and the third marker defines the plane. For example, PiG defines the knee joint centre (KJC) such that the KJC is at the offset distance (half width of knee) from the knee marker (KNEE), in a direction perpendicular to the line from the hip joint centre to the KJC, with the plane defined by the offset to the thigh marker (Figure 8.4).

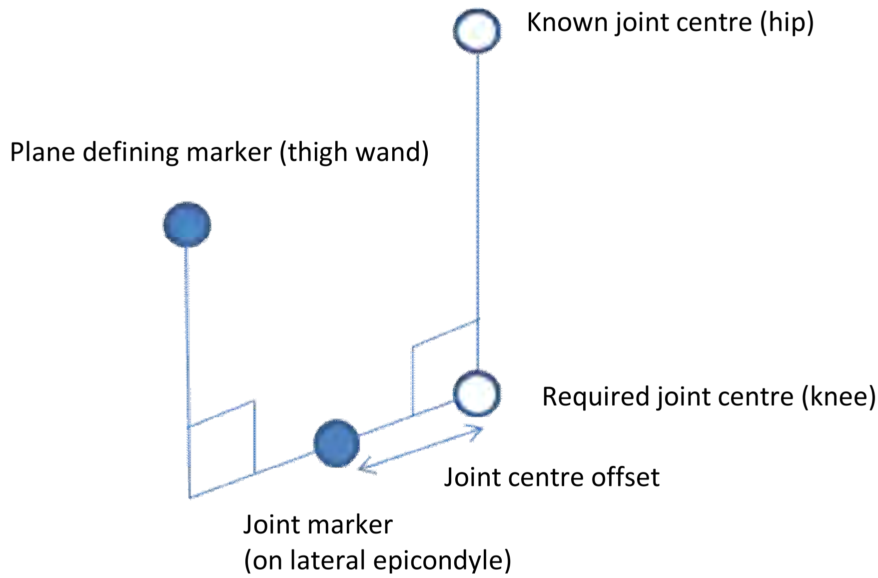


Figure 8.4 Definition of joint centre in PiG.

8.1.4 Soft Tissue Artefact of the knee marker

An inherent limitation in 3DGA is that rigid body segments are defined using markers attached to the skin. There will, therefore, be some degree of soft tissue movement that displaces the marker relative to the underlying bone thus leading to error in calculation of virtual points such as the joint centre. Soft tissue artefact (STA) refers to error in estimation of anatomical joint centres due to movement of the skin on which the marker is placed. While in some cases this can be minimized by choice of marker location, this is not possible in all cases.

In PiG, STA of the KNEE marker may lead to error in the output of ankle kinematics. As previously described, PiG uses the KNEE marker to define the knee joint centre (KJC), such that the KJC is at the offset distance (half width of knee) from the KNEE, in a direction perpendicular to the line from the hip joint centre to the KJC, with the plane defined by the offset to the thigh marker. The KNEE marker is known to move anteriorly with knee extension and posteriorly with knee flexion which will thus translate the KJC anteriorly and posteriorly (Akbarshahi *et al.*, 2010; Cappozzo, Catani, Leardini, Benedetti, & Della Croce, 1996). If the foot is fixed, STA of the KNEE marker will result in measured incline and recline of the [tibia] and of relative dorsiflexion and plantarflexion of the ankle.

STA of the KNEE marker is therefore likely to exaggerate plantarflexion during periods of increased knee flexion such as swing phase, and also stance phase in the case of crouch gait. Because PiG is a hierarchical model whereby proximal joint centres are defined first and then used to define distal joint centres, the knee joint centre will also be affected by STA associated with more proximal markers, particularly the thigh wand. These however will have a less predictable and generally smaller effect on the measured plantarflexion angle.

8.1.5 Calculation of the ankle joint centre

Using the PiG model to measure ankle kinematics in patients who wear an AFO may also result in error in the calculation of the modelled ankle joint centre (AJC). If, for example, there is any movement of the anatomical ankle within the AFO on which the ankle marker is mounted then the real AJC will move with respect to the markers and therefore the modelled AJC. This can be described as a direct source of error. There are also indirect sources of error. If the ankle remains securely within the AFO but the tibia moves within the AFO ($\theta_{tib\ mov}$) (Figure 8.2), this will also affect calculation of the modelled AJC, in a manner similar to STA of the knee marker. Of course this will only occur if the tibial wand is placed on the AFO and not on the skin.

PiG calculates the AJC using half the width in from the ankle (ANK) marker (ankle offset) in the plane of the ANK, tibial marker (TIB) and KJC (see Figure 8.5). If the tibial segment, defined as [tibia], moves anteriorly within the AFO, the KJC will also move anteriorly with respect to the TIB marker which is on the AFO, resulting in apparent external rotation (θ) of the modelled [tibia]. Given the AJC lies in the plane of the ANK, TIB and KJC, the modelled AJC will be displaced anteriorly due to the rotational effect. In the case of STA of the knee marker, where the marker moves posteriorly with increased knee flexion, the opposite effect would occur.

Because PiG calculates ankle kinematics using the angle between the [tibia] and line between the toe marker (TOE) and AJC (minus the static plantarflexion offset calculated as the angle between the TOE-AJC line and heel (HEE) marker-TOE line), any anterior displacement of the AJC would lead to exaggerated plantarflexion or dorsiflexion, and any posterior displacement would lead to reduced plantarflexion and dorsiflexion. This assumes however, that while the tibia moves within the AFO the ankle and foot are held securely within the AFO.

While slight anterior and posterior displacement of the AJC is likely to occur due to these two factors, the size of this change is likely to be so small it is considered negligible. The implications of this however are that any modelling involving the tibial segment should avoid the use of the AJC as the PiG tibial origin (TIO).

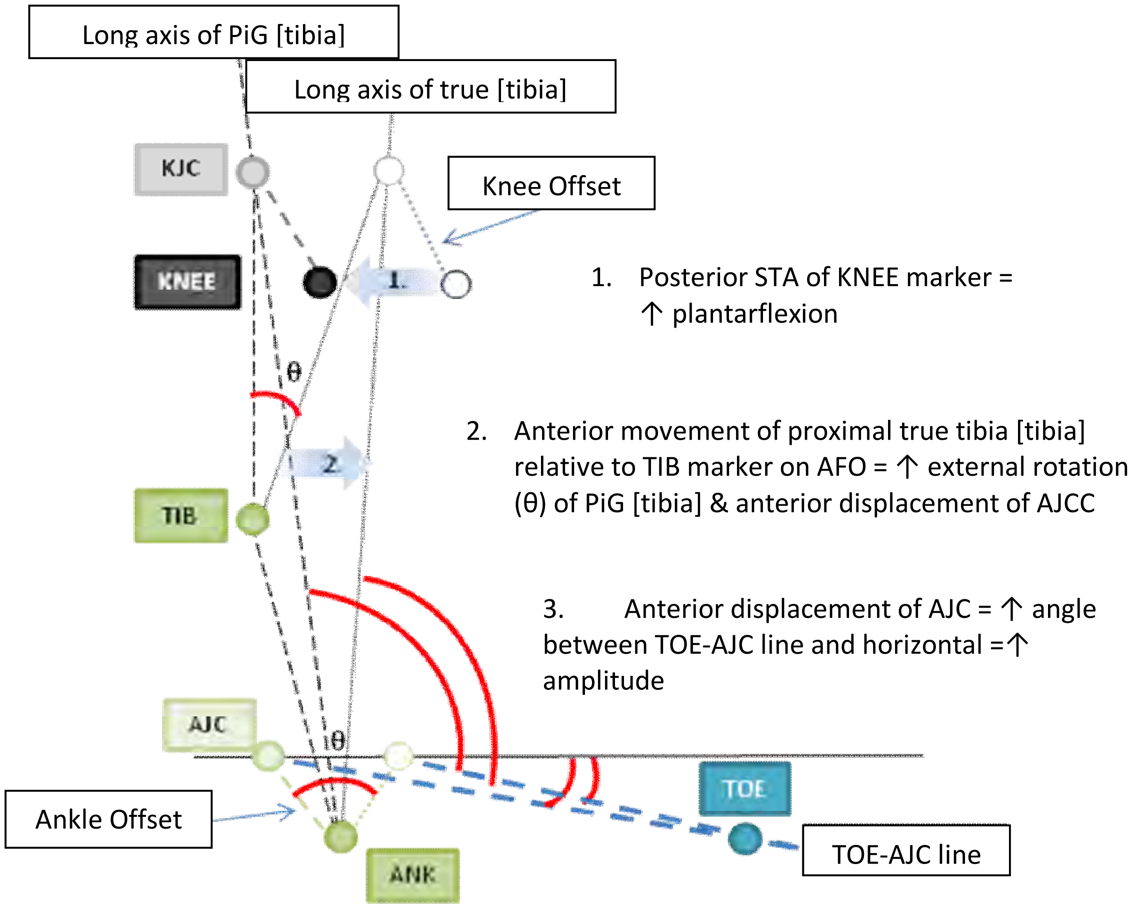


Figure 8.5 PiG segment definitions. This figure illustrates how STA of the KNEE marker and anterior tibial movement within the AFO can affect ankle kinematics.

8.1.6 Movement of the AFO and shoe

In both the clinical and research settings, the AFO and the footwear are considered to move as a single unit. While it is likely that the AFO will move with respect to the shoe, specifically at the heel counte $(\theta_{shoe\ mov})$, this will not affect PiG output of ankle kinematics. PiG calculates a plantarflexion offset during the static trial which is the angle between the TOE-AJC line and the HEE-TOE line. This offset is applied to every calculation of the TOE-AJC line in the dynamic trial. Because PiG uses the TOE-AJC line to calculate ankle kinematics, and not the HEE-TOE line, any movement of the AFO relative to the footwear will not influence the output of ankle kinematics.

Despite this, the ability to assess t he integrity of the foot and shoe complex remains important. The footwear worn with an AFO is considered integral in achieving the desired effects of the orthosis. Not only does an ill-fitting shoe pose a safety risk, but it also limits accurate observation of gait cycle events such as true heel contact and foot flat. It is also difficult to examine the effectiveness of shoe modifications if the intimacy of the foot and footwear cannot first be confirmed.

8.1.7 Calculation of AFO kinematics

Therefore, we would expect PiG's estimates of ankle angle to be a reasonable estimate of the anatomical ankle angle with a tendency to overestimate plantarflexion during periods of increased knee flexion due to STA of the knee marker (Equation 8-1). This should be affected very little by anterior displacement of the AJC due to excessive tibial movement or posterior displacement due to STA of the KNEE marker, and not at all by movement of the AFO within the shoe. If there is no tibial movement, anatomical ankle movement will also represent AFO kinematics ($\theta_{AFO\ def}$)(see Figure 8.2 and Equation 8-2). If however there is some tibial movement, the PiG output will not allow for separation of AFO deformation from anatomical ankle kinematics. This is because the KNEE marker defines the long axis of the tibia which pivots with respect to the ANK marker (see Figure 8.1). Thus while clinicians and researchers are able to reasonably assess anatomical ankle kinematics within an AFO, they are unable to assess AFO performance; that is, whether the AFO is rigid enough to prevent deformation under load and whether the tibia is well restrained within the AFO.

Therefore if;

θ_{PiG} is the angle between the PiG [tibia] and [foot];

$\theta_{ankle\ anat}$ is the angle between the [shank] and [AFOfoot], reflecting anatomical ankle movement;

$\theta_{AFO\ def}$ is the angle between the [AFO] and [AFOfoot], reflecting deformation of the AFO;

$\theta_{tib\ mov}$ is the angle between the [shank] and [AFO], reflecting movement of the tibia within the AFO;

$\theta_{shoe\ mov}$ is the angle between the [shoe] and [AFOfoot]; reflecting movement of the AFO within the shoe;

θ_{STA} is an estimate of the angular error introduced by movement of the KNEE marker over the bone;

Therefore we could expect that:

$$\theta_{PiG} = \theta_{ankle\ anat} + \theta_{STA}$$

Equation 8-1

$$\theta_{ankle\ anat} = \theta_{AFO\ def} + \theta_{tib\ mov}$$

Equation 8-2

And therefore, that:

$$\theta_{PiG} = \theta_{AFO\,def} + \theta_{tib\,mov} + \theta_{STA}$$

Equation 8-3

Measurement of $\theta_{shoe\,mov}$ is considered to be independent of the above variables.

8.1.8 Summary of problem & solution

PiG is used in clinical and research settings to measure gait kinetics and kinematics of patients wearing an AFO footwear combination. In these settings ankle kinematics is often of interest as it is thought to allow an assessment of AFO performance. The PiG calculation of ankle kinematics is however subject to error from STA of the KNEE marker and does not allow assessment of the performance of the AFO, specifically whether there is tibial movement within the AFO, AFO deformation or movement of the AFO within the footwear. A new model based on PiG marker set and static calibration was developed to calculate anatomical ankle movement ($\theta_{ankle\,anat}$) and compare this with PiG (θ_{PiG}) to obtain a measure of how STA of the knee marker affects ankle kinematics. This model also allows calculation of the AFO kinematics ($\theta_{AFO\,def}$) separately from movement of the tibia ($\theta_{tib\,mov}$), and movement of the AFO within the footwear ($\theta_{shoe\,mov}$). This model has utility in both the clinical and research settings to provide more accurate kinematics of both the anatomical ankle and the AFO.

8.1.9 Aims and hypotheses

The aims of this study were:

1. To determine how much anatomical ankle movement occurs within the AFO, and to compare this with PiG;
2. To determine what is happening in the AFO footwear combination, specifically:
    a. Kinematics of the AFO compared with movement of the tibia within the AFO;
    b. and movement of the AFOfoot within the shoe;

Based on these aims it was hypothesised that:

1. There will be some degree of anatomical ankle movement in all AFOs, which will reflect a combination of tibial movement and AFO flexion;
2. The PiG output will overestimate total ankle ROM compared to the output for anatomical ankle movement;
3. There will be some degree of movement of the footwear on the AFO/foot piece;

8.2 Method

8.2.1 Participants

This data was collected as part of the investigation described in Chapter 5. The participants included in this study were all those wearing solid AFOs. The participants are described in Table 5.1. A total of 13 limbs belonging to seven children were examined in this study.

8.2.2 Data collection

Participants underwent a 3DGA in barefoot and in four AFO conditions where four wedges were attached to the sole of the footwear thus inducing four shank-to-vertical (SVA) angles. The data reported here was that from the baseline (flat) condition. Thus the final SVA of the AFO and footwear combination reflects the AFO ankle angles that are recorded in Table 5.1.

8.2.3 Markers

A modified marker set was used for the 3DGA which is described in full in Table 5.4 and Figure 5.4 of Chapter 5. For the purposes of this study two additional tibial markers (TibANT; TibPOST) were added to the standard marker set. Figure 8.6 shows the placement of these markers on the limb, AFO and footwear. The KNEE and TibANT markers were on the skin, the TibPOST, TIB and ANK and MED markers were on the AFO and the HEE and TOE markers were on the shoe. The HEE-TOE line was parallel to the ground with the foot flat on the ground.

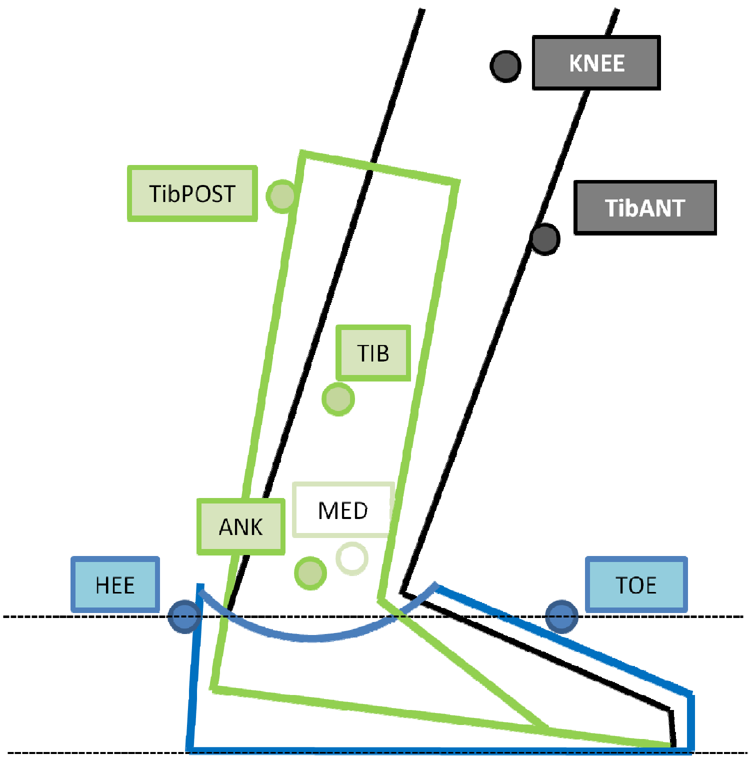


Figure 8.6 Location of the lower limb markers on the skin, AFO and shoe.

8.2.4 Data processing

All data was processed using Vicon Nexus software as described previously in Chapter 5, with the addition of the static and dynamic models described below on all static and dynamic trials respectively. Additional dynamic trials containing kinematic data but no kinetic data were included in this analysis. The new models described below were developed in collaboration with Dr Morgan Sangeux and Professor Richard Baker. The BodyBuilder code for the model is listed in Appendix G.

8.2.4.1 Definition of [AFO] and [shank] segments

In order to separate movement of the anatomical tibia and the AFO, two independent segments needed to be defined. The anatomical tibia [shank] is based on ANK, MED and TibAnt markers and the AFO [AFO] segment on the ANK, MED and TibPost markers. Both segments used the AJC as the origin, where AJC = mid-point between ANK and MED markers. Both segments were also defined with the same second defining line (ANK-MED). The first defining line and the primary axis of the [shank] was the AJC-TibAnt line, whereas the [AFO] used the AJC-TibPost line. From each of these segments the local co-ordinate position of the knee joint centre (FEO), relative to each segment, was calculated for each frame of the static trial, averaged across all frames and stored as an offset parameter (FEOAfo, FEOShank) for use in the dynamic model (refer to Figure 8.7). In the dynamic model the respective new knee joint centres (FEOAFO, FEOShank) were applied to the definition of each segment such that the first defining line and therefore the primary axis was from AJC-FEOAfo or AJC-FEOShank, respectively. Thus the two segments [AFO] and [Shank] had the same origin and second direction, but had a primary axes that moved independently of each other (see Figure 8.11).

8.2.4.2 Definition of [AFOfoot] and [shoe] segments

In order to calculate $\theta_{shoe\ mov}$, the [shoe] and the [AFO foot] segments also needed to be defined independently. For the purposes of this investigation, the anatomical foot was considered to be held securely within the AFO foot piece, which was therefore considered as a single segment, referred to as [AFOfoot]. The TOE marker was considered to represent the TOE of both the [shoe] and [AFOfoot] segments. Both segments were defined with the same origin (AJC) and the same second defining line (ANK-MED) as both the tibial segments. The [shoe] was defined with a primary axis of the HEE-TOE, but the [AFOfoot] was defined with a primary axis of TOE-AJC (see Figure 8.7). The local position of the HEE marker relative to the [AFOfoot] segment was calculated, and averaged across all frames. The new heel marker (HeeAFO) was stored as a parameter for use in the dynamic model. Here it was applied to the definition of the [AFOfoot] segment in the primary axis, thus [AFOfoot] and [shoe] have unique primary axes but have the same origin and second direction line (see Figure 8.8 & Figure 8.11).

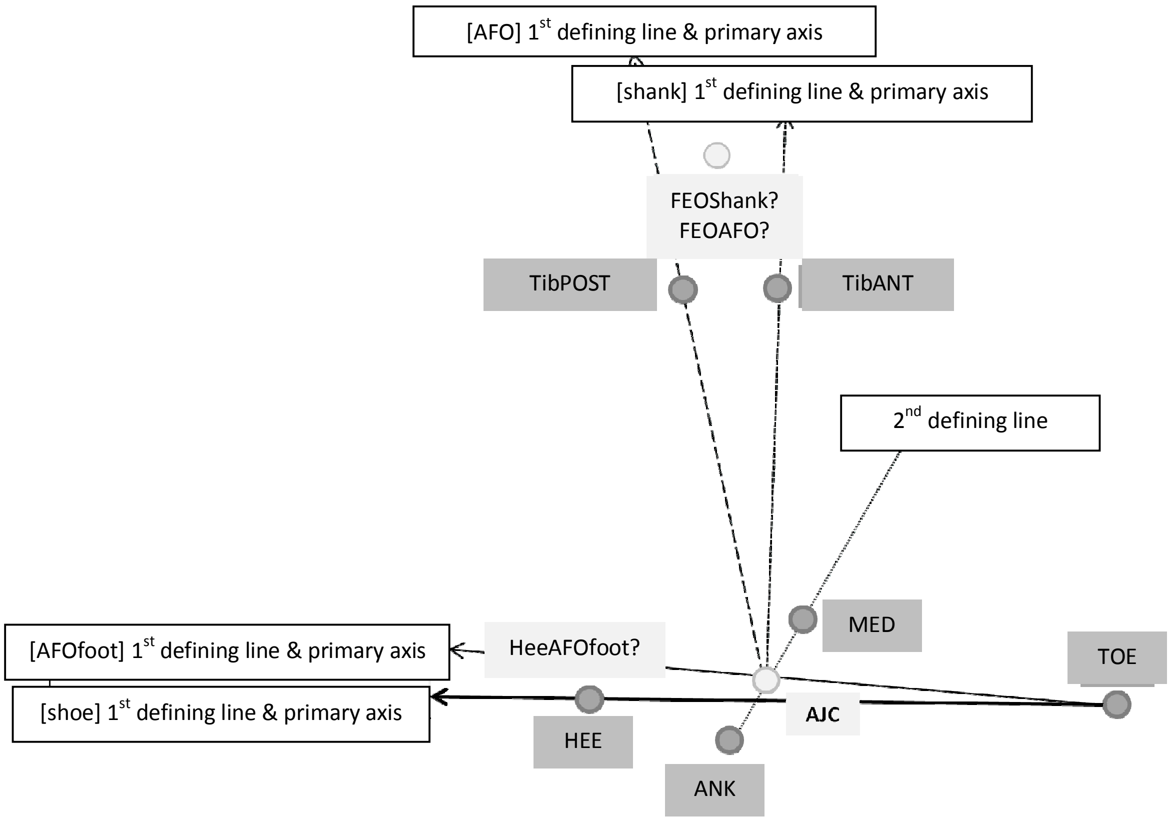


Figure 8.7 Static model segment definitions, used to calculate the local position of FEO relative to the [Shank] and [AFO] and the local position of the HEE marker relative to the [AFOfoot].

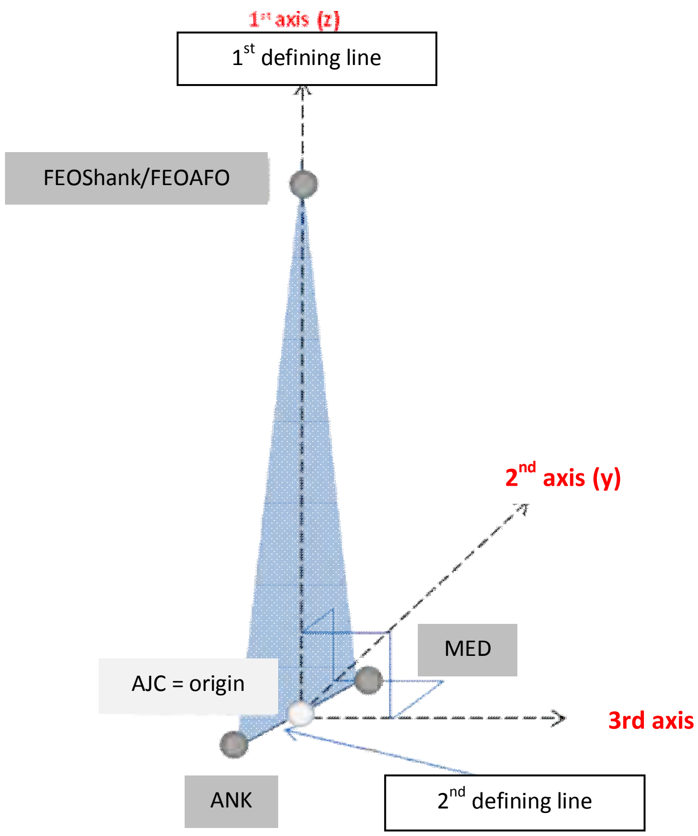


Figure 8.8. Definition and axes of the [AFO] and [Shank] segments.

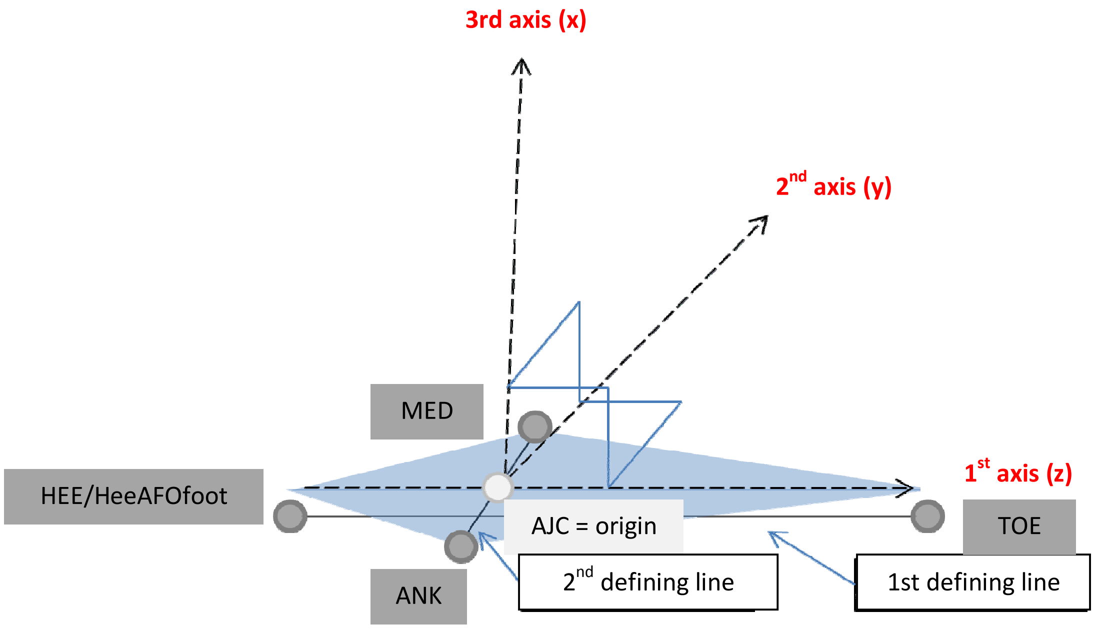


Figure 8.9 Definition of [AFOfoot] and [Shoe] segments

8.2.4.3 *Angle decomposition*

The dynamic model also calculated the four sagittal plane rotations of interest; $\theta_{ankle\ anat}$, $\theta_{AFO\ def}$, $\theta_{tib\ mov}$ and $\theta_{shoe\ mov}$ (refer to Figure 8.10 and Figure 8.11). The following segment pairs were used in these calculations. The first segment was nominated as the parent segment, and as such the rotations are expressed as movement of the child segment relative to the parent segment:

Angle	Parent Segments	Child Segment
$\theta_{ankle\ anat}$	*Shank*	*AFOfoot*
$\theta_{AFO\ def}$	*AFO*	*AFOfoot*
$\theta_{tib\ mov}$	*AFO*	*Shank*
$\theta_{shoe\ mov}$	*Shoe*	*AFOfoot*

Figure 8.10 Segments used to calculate the four angles of interest.

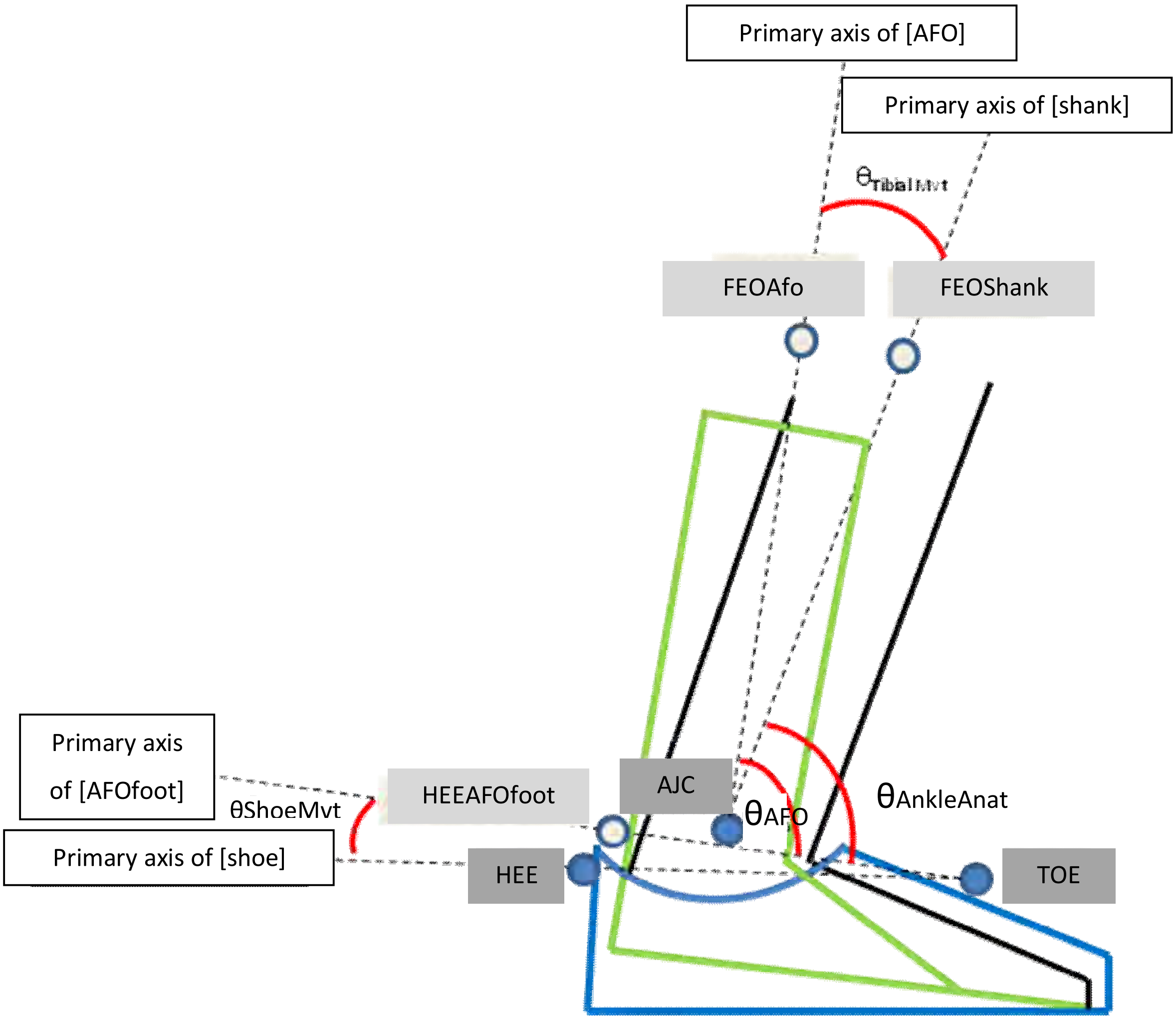


Figure 8.11 Diagrammatic representation of the four calculated rotations. The new HeeAFOfoot, FEOAfo and FEOShank are incorporated into the segment definitions.

All trials were exported to the software Polygon Authoring Tool (Vicon, Oxford Metrics, Oxford UK) for assessment of data quality. All data were normalized to 100% of the gait cycle. All data were then exported to Microsoft Office Excel (Microsoft Corporation, USA) and the relevant parameters extracted for analysis.

8.2.5 Analysis

8.2.5.1 Parameters

The following parameters were extracted directly from the processed data:

- $\theta_{ankle\ anat}$
- $\theta_{AFO\ def}$
- $\theta_{tib\ mov}$
- $\theta_{shoe\ mov}$
- θ_{PiG} (ankle kinematics)
- Knee kinematics
- Ankle moments

The average of each parameter was calculated by averaging the individual trials across the gait cycle. For three of these parameter ($\theta_{ankle\ anat}$, $\theta_{AFO\ def}$ and $\theta_{tib\ mov}$) a 'corrected' value was also calculated which expressed this data with reference to the unloaded position of swing phase. For these variables the average angle between 74-84% gait cycle was calculated, then subtracted from every frame. These data were considered as change (Δ) in the variable with reference to the unloaded position, thus giving three additional parameters:

- $\Delta\theta_{ankle\ anat}$
- $\Delta\theta_{AFO\ def}$
- $\Delta\theta_{tib\ mov}$

8.2.5.2 Comparison of ankle kinematics according to θankle anat and θPiG

The first aim of the study was to determine how much anatomical ankle movement occurred within the AFO and to compare this to the PiG calculation. The total range of movement (ROM) at the ankle of $\theta_{ankle\ anat}$ and θ_{PiG} across the gait cycle was calculated by identifying the maximum and minimum values across the averaged trial. The resulting differences between these two methods of measuring ankle kinematics were referred to as STA Error. The average STA Error over the gait cycle was calculated by averaging the absolute STA Error across all frames. To investigate the relationship between STA Error and knee kinematics, these parameters were compared on a scatter plot and a line of best fit plotted for the dataset of each limb. Pearson's Product Moment Correlation Coefficient (r) was calculated using the CORREL function in EXCEL. The correlation coefficient (r) provides a measure of strength of relationship between the two variables. The square of r provides the coefficient of determination (r^2) which represents the percent of variation of one variable explained by the second variable. The average of the correlation coefficient (r) were calculated using a Fisher-z transform.

8.2.5.3 Comparison of AFO, tibial and footwear movements

Before examining the AFO and tibial movement, accuracy of the model in defining the appropriate segments and angles was confirmed by correlating the sum of $\theta_{AFO\ def}$ and $\theta_{tib\ mov}$ with $\theta_{ankle\ anat}$. The correlation coefficient (r) was calculated to determine the strength and direction of the relationship between these variables, and the coefficient of determination (r^2) was calculated to determine the variability within the data explained by this relationship. A strong positive correlation was anticipated along with a coefficient of determination (r^2) close to 1.00, thus representing accurate modelling. The average of the correlation coefficient (r) were calculated using a Fisher-z transform.

To examine the kinematics of the AFO compared with the tibia, and to examine the extent of shoe movement, the total range of movement (ROM) for each of these variables was calculated by subtracting minimum values from maximum values. For each limb, three variables ($\theta_{AFO\ def}$, $\theta_{ankle\ anat}$ and ankle moment) were plotted over the gait cycle. The difference between $\theta_{AFO\ def}$ and $\theta_{ankle\ anat}$ is representative of $\theta_{tib\ mov}$ (refer to Equation 8-2).

8.2.5.3.1 Relationship between AFO and tibial movement with ankle moment and body mass

Finally, scatter plots were examined to investigate the strength of relationships between both $\theta_{AFO\ def}$ and $\theta_{tib\ mov}$ with absolute ankle moment, and with patient body mass (kg). For each dataset, a line of best fit was plotted and the LINEST function used to calculate the coefficient of determination (r^2) and the F-statistic. The F-Dist function was used to determine the level of significance of the F-statistic, where $p<0.05$ was considered statistically significant.

8.3 Results

8.3.1 Total ankle ROM

The average total ROM at the ankle according to PiG (θ_{PiG}) was 9.7° (SD 4.3°, range 5.1-20.8°), compared with $\theta_{ankle\ anat}$ of 8.2° (SD 4.2°, range 3.8-15.0°). The total ankle ROM for each limb, according to θ_{PiG} and $\theta_{ankle\ anat}$ are illustrated below in Figure 8.12. For the majority of limbs (θ_{PiG}) provided a large estimate of ankle ROM and for three limbs, the differences were quite large (JABU-L; HAHA-L, -R). For three limbs (DEHA-L, -R; MAHO-R) $\theta_{ankle\ anat}$ was larger. Refer to Table 8.2 for a summary of total ankle ROM.

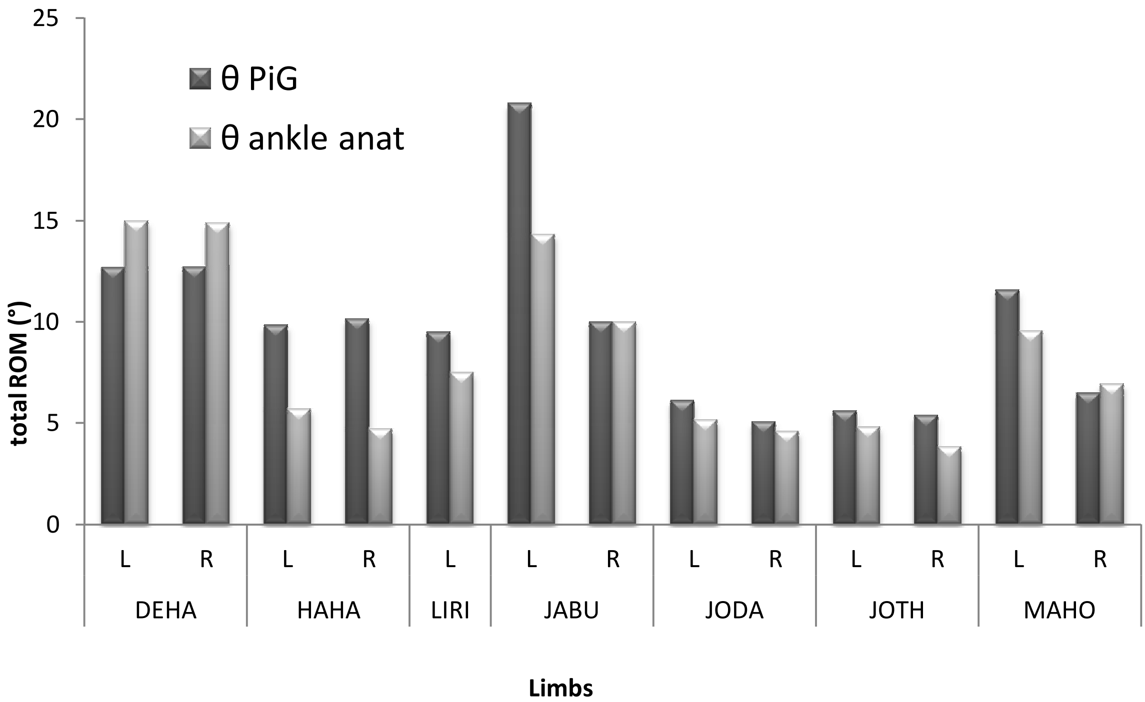


Figure 8.12 Total ROM at the ankle according to θ_{PiG} and $\theta_{ankle\ anat}$.

8.3.2 STA Error

8.3.2.1 STA Error across the gait cycle

Figure 8.13 presents STA Error across the gait cycle for all limbs. The average error across all limbs was 1.3° (SD 1.5°, range 0.2-6.7°). One limb had very large positive STA Error (JABU-L), and one limb had a very large negative STA Error (HAHA-R).

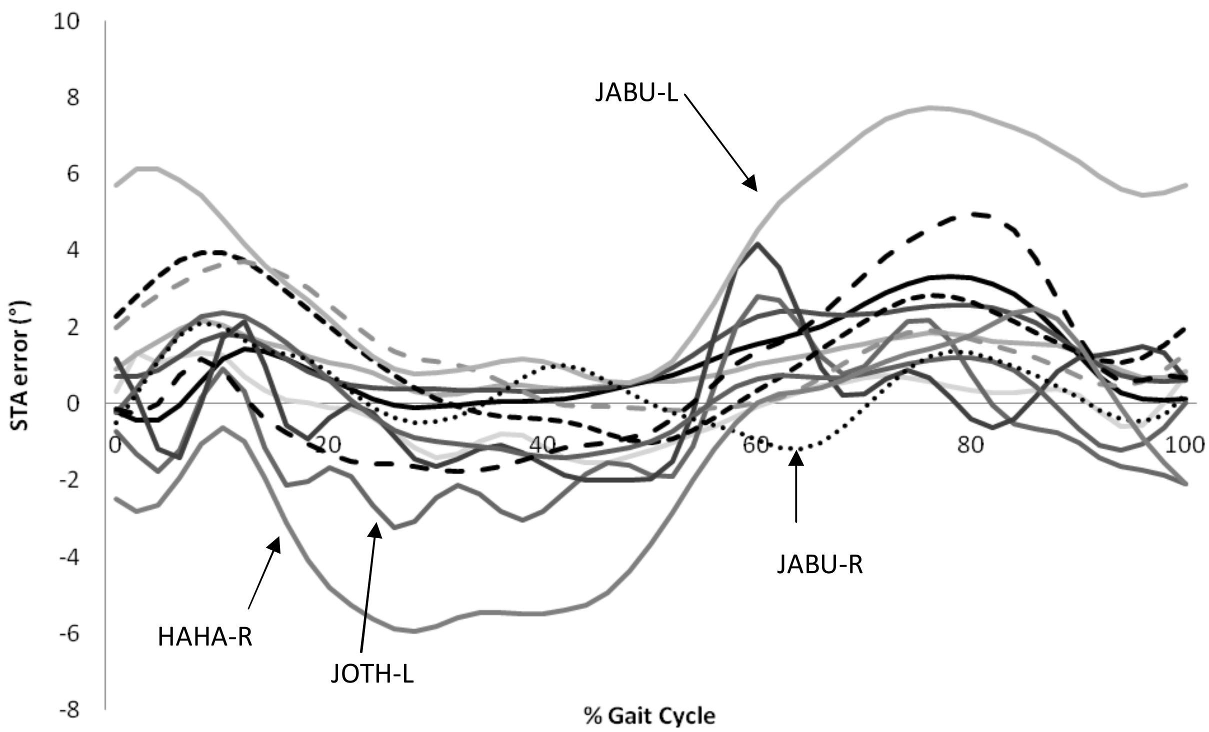


Figure 8.13 STA error across the gait cycle for all limbs.

8.3.2.2 Correlation of STA Error with knee kinematics

A scatter plot of STA Error and knee kinematics with a line of best fit revealed a strong positive trend across the majority of limbs, with an average correlation of r=0.75. One limb (JABU-R) demonstrated only a weak correlation (r=0.14) (Table 8.2). The average coefficient of determination (r^2) values was 0.61, indicating that on average, 61% of the variability in STA Error was accounted for by knee kinematics. There was however, a wide range of r^2 values, from 0.02 (JABU-R) to 0.88.

Figure 8.14 presents example data of a scatterplot of STA Error with knee kinematics and line of best fit from four participants. These data comprise the four limbs identified in Figure 8.13: the strongest correlation associated with positive STA Error (JABU-L; r =0.94), the weakest correlation (JABU-R; r = 0.14), the strongest correlation associated with the largest negative STA Error (HAHA-R; r = 0.84) and data representative of the average correlation (JOTH-L; r =0.79).

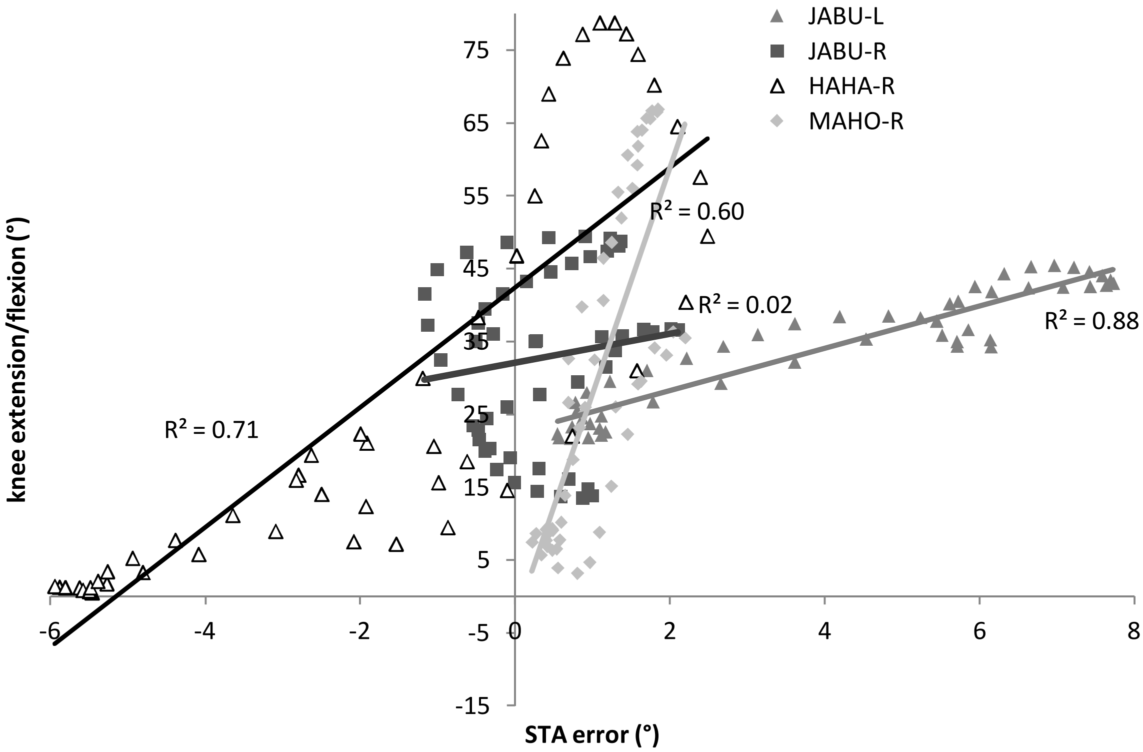


Figure 8.14 Example scatter plot and line of best fit of STA Error against knee kinematics for four limbs (JABU-L, JABU-R, HAHA-R and MAHO-R).

8.3.3 Kinematics of the AFO, tibia and footwear

8.3.3.1 Modelling correlation

Scatter plots (Figure 8.15) for $\theta_{ankle\ anat}$ and the sum of $\theta_{AFO\ def}$ and $\theta_{tib\ mov}$ revealed a strong positive relationship across all limbs. As anticipated, the coefficient of determination (r^2) and slope of the regression lines were close to 1.00 for all limbs, with the intercept close to 0, which confirmed correct mathematical modelling (refer to Table 8.1).

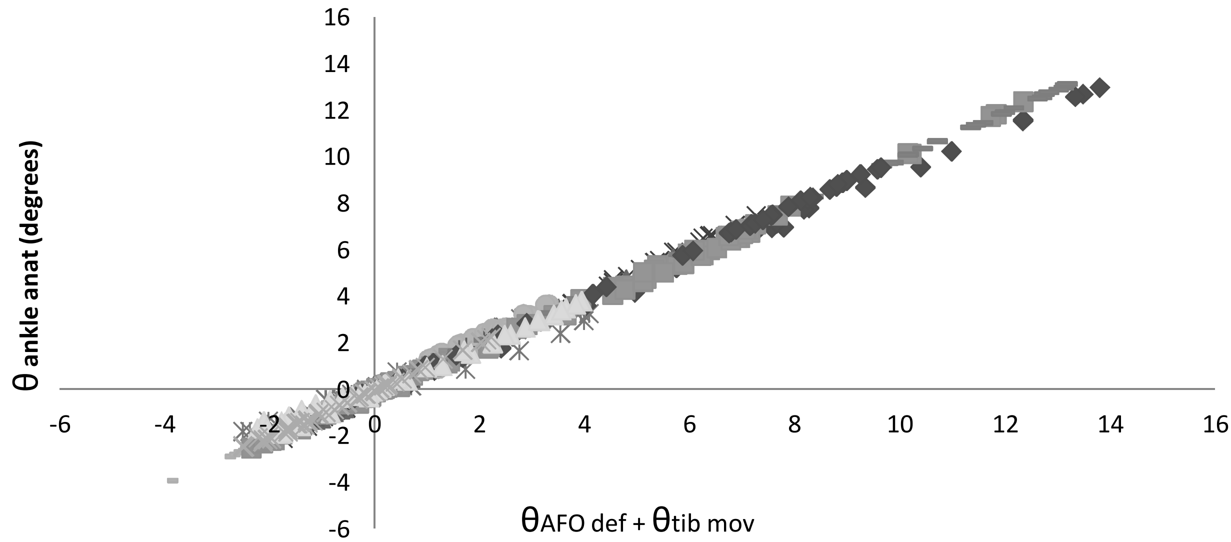


Figure 8.15 Scatter plot of $\theta_{ankle\ anat}$ against the sum of $\theta_{AFO\ def}$ and $\theta_{tib\ mov}$ for all limbs.

Participant	Side	Correlation coefficient (r)	Coefficient of determination (r^2)	Slope	Y-intercept
MAHO	L	1.00	1.00	1.04	-0.07
	R	1.00	1.00	1.01	-0.06
JODA	L	0.98	0.96	0.86	0.12
	R	0.99	0.99	1.08	0.05
JOTH	L	1.00	1.00	1.00	0.01
	R	1.00	1.00	1.11	-0.04
DEHA	L	1.00	1.00	0.95	-0.13
	R	1.00	1.00	1.01	-0.13
LIRI	L	1.00	1.00	0.95	-0.04
JABU	L	1.00	1.00	0.99	0.02
	R	1.00	1.00	0.99	0.02
HAHA	L	0.99	0.99	0.92	0.09
	R	1.00	1.00	1.01	0.00
Average		1.00	0.99	0.99	-0.01
Max		1.00	1.00	1.11	0.12
Min		0.98	0.96	0.86	-0.13

Table 8.1 Correlation coefficient, coefficient of determination, slope and intercept of the regression line representing the accuracy of the new model, for each participant.

8.3.3.2 Total ROM of the AFO, tibia and footwear

The group average total ROM of the tibia within the AFO ($\theta_{tib\ mov}$) was 2.8° (SD 0.9°, range 1.5-4.1°). The group average total ROM of the AFO ($\theta_{AFO\ def}$) was 6.0° (SD 4.3°, range 1.2-12.7°). The group average total ROM of the shoe on the AFOfoot ($\theta_{shoe\ mov}$) was 1.8° (SD 0.8°, range 0.7-3.3°). In 8/13 limbs the degree of AFO deformation was larger than the degree of tibial movement, in one limb the degree of AFO deformation and tibial movement were similar (LIRI-L) and in the remaining 4/13 limbs the degree of tibial movement exceeded that of AFO deformation. Figure 8.16 illustrates the total ROM of the tibia, AFO and shoe movement for each limb. These values are also listed in Table 8.2.

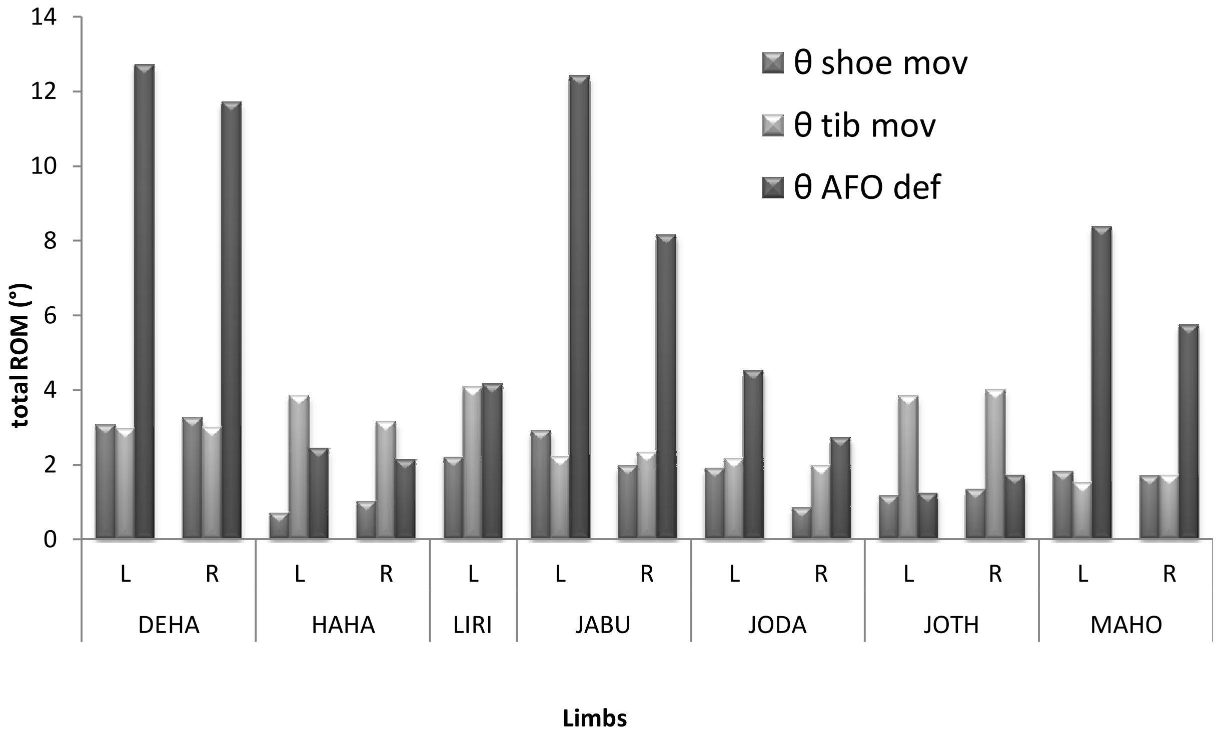


Figure 8.16 Total ROM of $\theta_{shoe\ mov}$, $\theta_{tib\ mov}$ and $\theta_{AFO\ def}$.

Total ROM									STA Error & Knee Kinematics	
Participant	**Side**	θ_{PiG} ***(ankle angles)***	$\theta_{ankle\ anat}$	***STA Error = Difference in total ROM***	***Ave. STA Error across gait cycle***	$\theta_{AFO\ def}$	$\theta_{tib\ mov}$	$\theta_{shoe\ mov}$	***Correlation (r)***	***Coefficient of determination (r^2)***
DEHA	L	12.7	15.0	-2.3	2.0	12.7	3.0	3.1	0.86	0.74
	R	12.7	14.9	-2.2	2.3	11.7	3.0	3.3	0.89	0.79
HAHA	L	9.8	5.7	4.1	0.2	2.4	3.8	0.7	0.93	0.86
	R	10.2	4.7	5.4	2.5	2.1	3.2	1.0	0.84	0.71
LIRI	L	9.5	7.5	2.0	0.3	4.2	4.1	2.2	0.62	0.38
JABU	L	20.8	14.3	6.5	5.7	12.4	2.2	2.9	0.94	0.88
	R	10.0	10.0	0.0	0.5	8.1	2.3	2.0	0.14	0.02
JODA	L	6.1	5.1	1.0	0.2	4.5	2.2	1.9	0.92	0.85
	R	5.1	4.6	0.5	0.7	2.7	2.0	0.8	0.93	0.86
JOTH	L	5.6	4.8	0.8	0.7	1.2	3.8	1.1	0.79	0.62
	R	5.4	3.8	1.5	1.2	1.7	4.0	1.3	0.50	0.25
MAHO	L	11.6	9.6	2.0	0.3	8.4	1.5	1.8	0.64	0.41
	R	6.5	6.9	-0.5	0.9	5.7	1.7	1.7	0.77	0.59
Ave.		9.7	8.2	1.5	1.3	6.0	2.8	1.8	0.75	0.61
SD		4.3	4.1	2.6	1.5	4.2	0.9	0.8	n/a	n/a
Min		5.1	3.8	-2.3	0.2	1.2	1.5	0.7	0.14	0.02
Max		20.8	15.0	6.5	5.7	12.7	4.1	3.3	0.94	0.88

Table 8.2 Total ROM of θ_{PiG}, $\theta_{ankle\ anat}$, $\theta_{AFO\ def}$, $\theta_{tib\ mov}$ and $\theta_{shoe\ mov}$ for all limbs, along with STA Error, average STA Error, the correlation coefficient (r) and coefficient of determination (r^2) between STA Error and knee kinematics.

8.3.3.3 AFO deformation and tibial movement across the gait cycle

All limbs demonstrated some AFO deformation and some tibial movement (the difference between anatomical ankle movement and AFO deformation). Before examining the relationship between these variables and ankle moment and body weight, the pattern of movement across the gait cycle was examined for each individual limb. Figure 8.17-Figure 8.18 below present $\Delta\theta_{ankle\ anat}$ and $\Delta\ \theta_{AFO\ def}$ for the limbs according to whether total ROM of AFO deformation was > or < tibial movement, with normalised ankle moment plotted on the secondary vertical axis. In the limbs demonstrating AFO deformation>tibial movement the pattern of ankle moment tended to coincide with the pattern of AFO deformation.

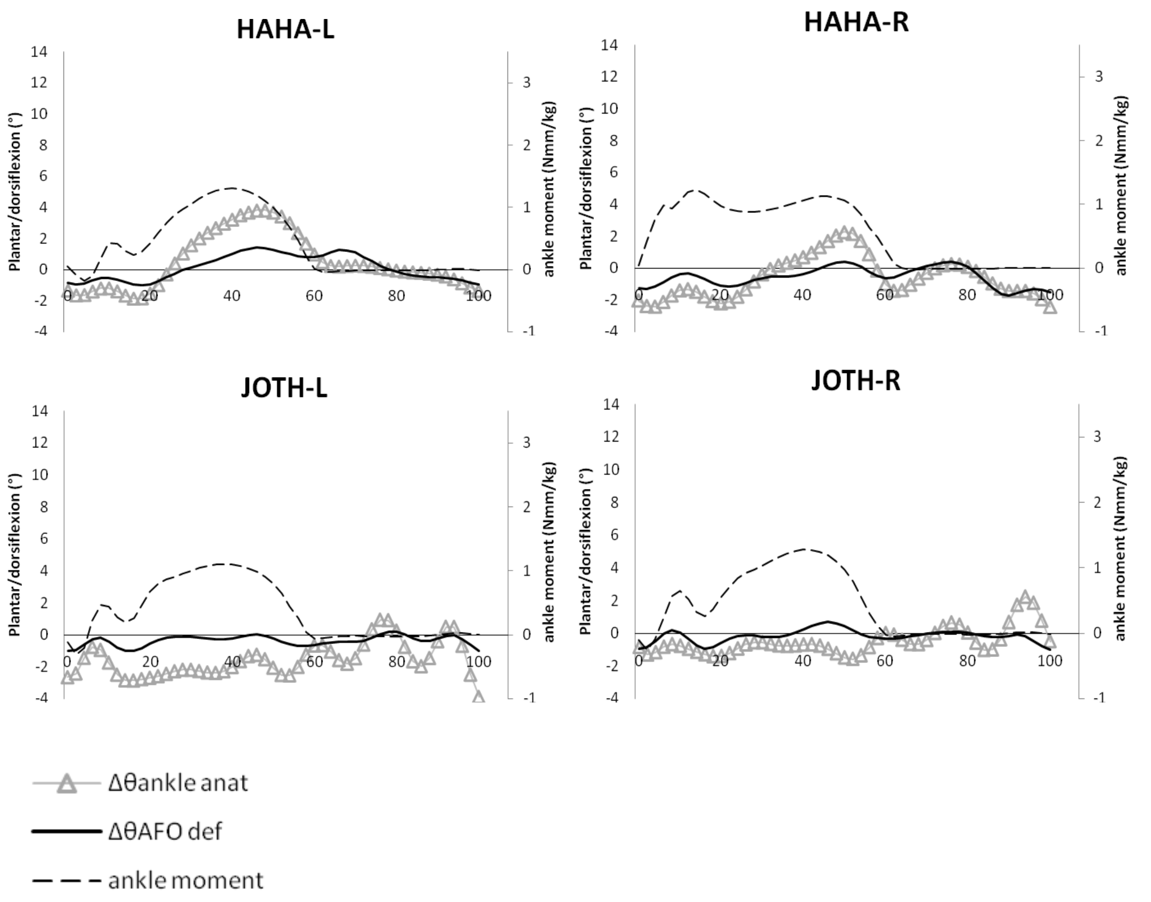


Figure 8.17 $\Delta\theta_{ankle\ anat}$, $\Delta\theta_{AFO\ def}$ and ankle moment for the four limbs demonstrating tibial movement > AFO deformation

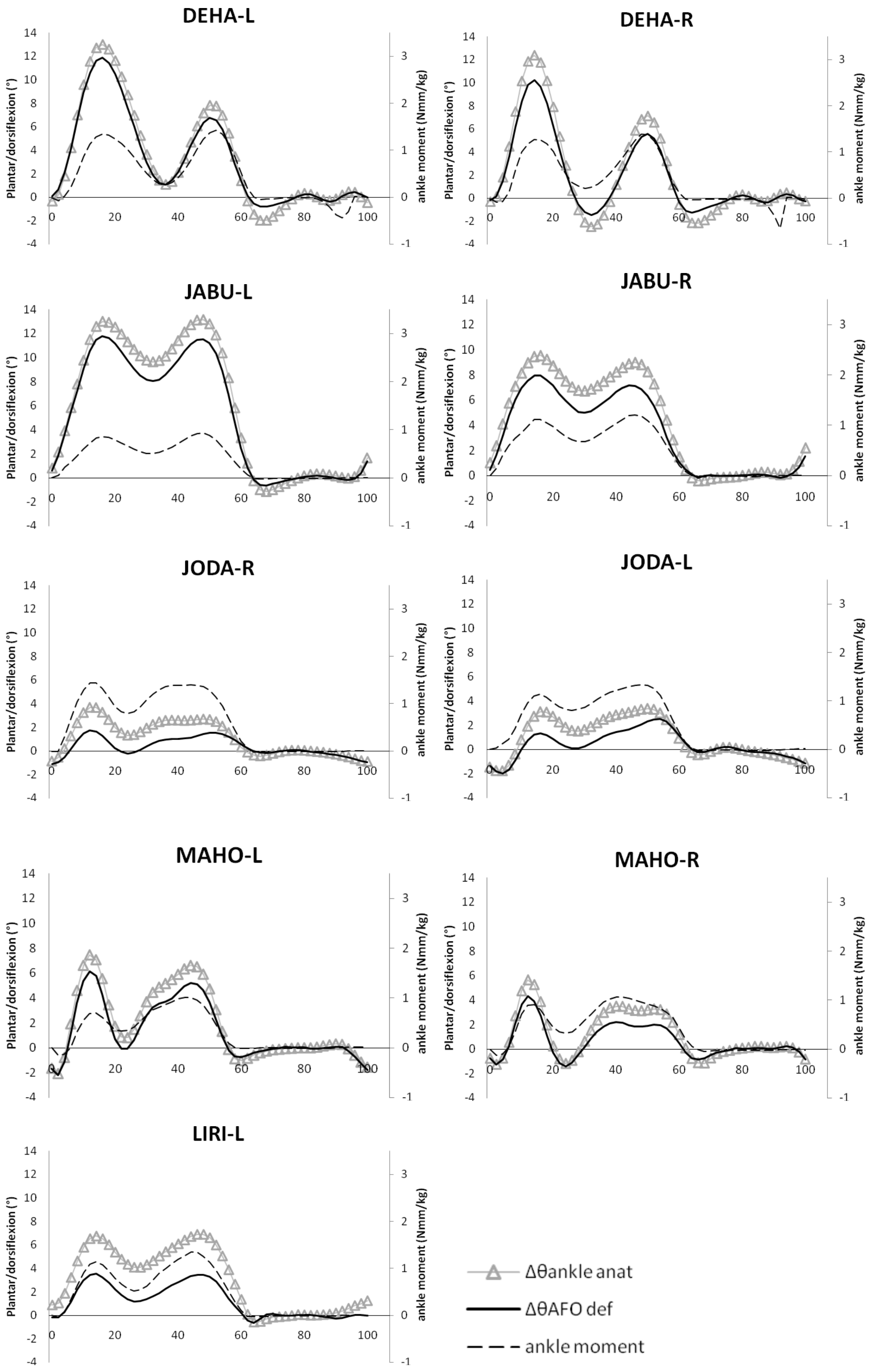


Figure 8.18 $\Delta\theta_{ankle\ anat}$, $\Delta\theta_{AFO\ def}$ and ankle moment for the nine limbs demonstrating AFO deformation > tibial movement.

8.3.3.4 Correlation between AFO deformation and ankle moment

A scatter plot of $\Delta\theta_{AFO\ def}$ and ankle moment with a line of best fit plotted for each of the 13 data sets (Figure 8.19). This revealed moderate to strong positive trends in most limbs with an average correlation coefficient of r=0.85. The weakest correlations were seen in limbs demonstrating little AFO deformation (JOTH-L, -R; HAHA-L, -R). This is probably due to a range attenuation effect resulting in clustering at the bottom of the scale. Table 8.3 presents the correlation coefficients (r) values for each limb.

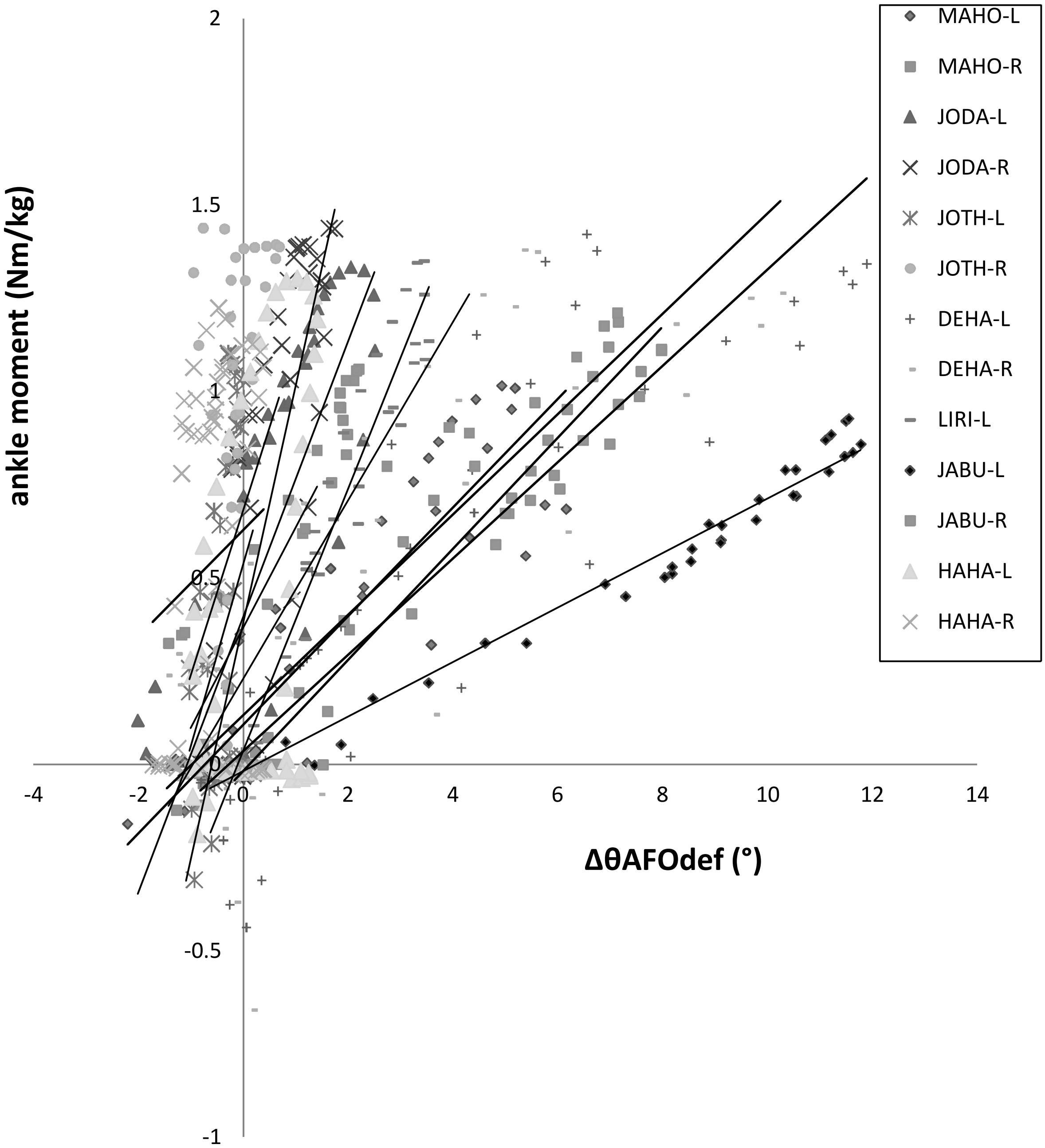


Figure 8.19 Scatter plot of ankle moment and degrees of $\Delta\theta_{AFO\ def}$ for all limbs.

8.3.3.5 Correlation between tibial movement and ankle moment

A scatter plot of $\Delta\theta_{tib\ mov}$ and ankle moment revealed strong positive trends in the majority of limbs (Figure 8.20) with an average correlation coefficient of r=0.81. There were three exceptions: two limbs demonstrated a negative trend (JOTH-L, -R, r=-0.57 bilaterally), most likely due to the excessive and prolonged knee extension demonstrated throughout stance phase, and one limb demonstrated a weak positive trend (HAHA-R, r=0.26). Table 8.3 presents the correlation coefficient (r) values for each limb.

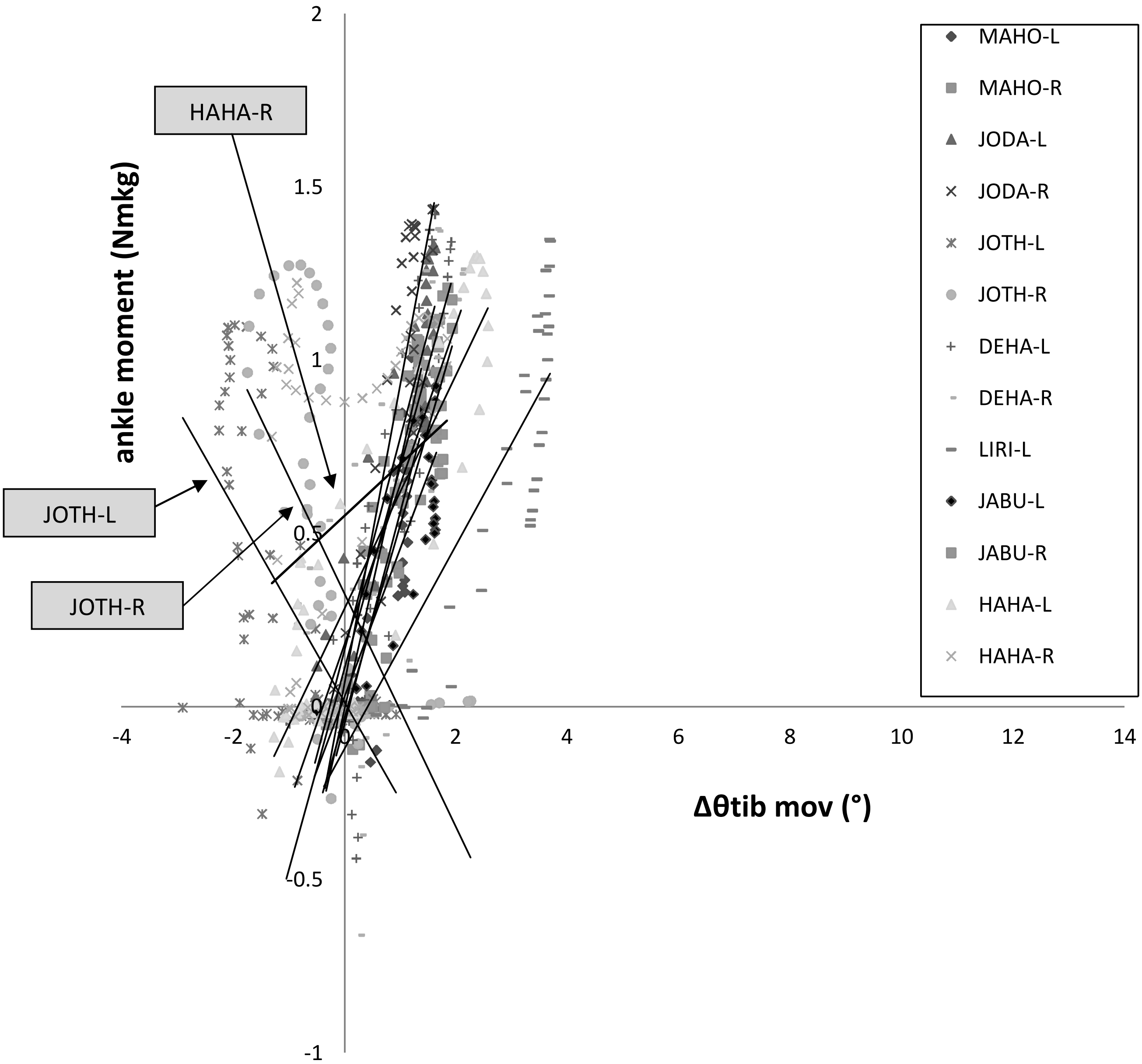


Figure 8.20 Scatter plot and line of best fit between ankle moment and $\Delta\theta_{tib\ mov}$ for all limbs.

Participant	Side	Body mass *(kg)*	Correlation (r)		Coefficient of determination (r^2)	
			$\theta_{\Delta AFO\ def}$ ***& ankle moment***	$\theta_{\Delta tib\ mov}$ ***& ankle moment***	$\theta_{\Delta AFO\ def}$ ***& ankle moment***	$\theta_{\Delta tib\ mov}$ ***& ankle moment***
DEHA	L	68.7	0.89	0.87	0.79	0.76
	R		0.83	0.76	0.69	0.58
HAHA	L	19.2	0.45	0.88	0.20	0.77
	R		0.17	0.26	0.03	0.07
LIRI	L	26.9	0.98	0.92	0.96	0.85
JABU	L	59.0	0.99	0.91	0.98	0.83
	R		0.98	0.94	0.96	0.88
JODA	L	27.3	0.77	0.94	0.59	0.88
	R		0.82	0.97	0.67	0.94
JOTH	L	34.8	0.33	-0.57	0.11	0.32
	R		0.50	-0.57	0.25	0.32
MAHO	L	43.5	0.91	0.88	0.83	0.77
	R		0.79	0.96	0.62	0.92
	Ave.	39.9	0.85	0.85	0.59	0.68
	SD	18.2	n/a	n/a	n/a	n/a
	Min	19.2	0.19	0.19	0.03	0.07
	Max	68.7	0.99	0.99	0.98	0.94

Table 8.3 Patient mass (kg), correlation coefficient (r) and coefficient of determination (r^2) of $\theta_{\Delta AFO\ def}$ and $\theta_{\Delta tib\ mov}$ with ankle moment.

8.3.3.6 Correlation of AFO deformation & tibial movement against body weight

A scatter plot of body mass (kg) and $\theta_{AFO\ def}$ revealed a very strong positive trend which was confirmed with a correlation coefficient of r= 0.90 (Figure 8.21). The coefficient of determination (r^2) revealed that 81% of variation in AFO deformation could be explained by body mass (kg). This correlation was statistically significant (F=47.59, p=0.00003). A scatter plot for patient weight and $\theta_{tib\ mov}$ did not reveal any trends with a correlation of r=0.16 (Figure 8.22), which was not statistically significant (F=1.27, p=0.33).

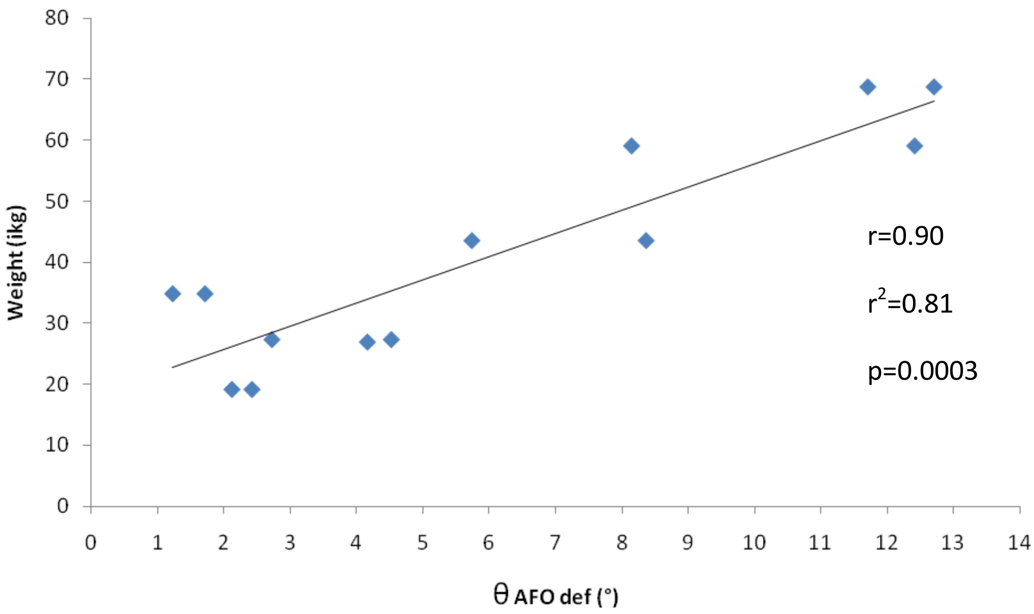


Figure 8.21 Scatter plot and line of best fit between $\theta_{AFO\ def}$ and body mass (kg)

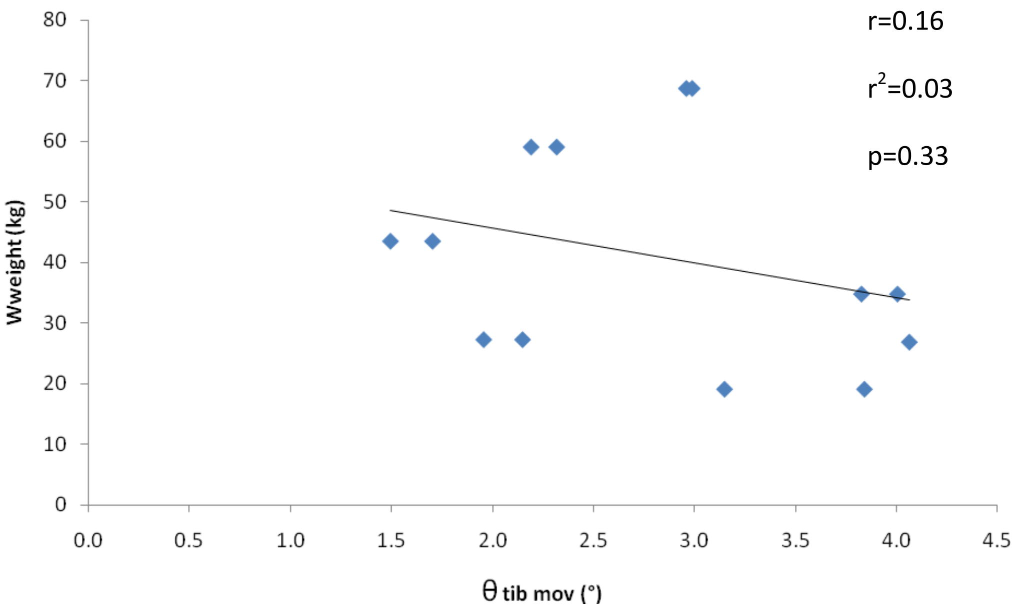


Figure 8.22 Scatter plot and line of best fit between $\theta_{tib\ mov}$ and body mass (kg).

8.4 Discussion

8.4.1 Accuracy of the PiG model

The first aim of this investigation was to determine how much anatomical ankle movement was occurring at the ankle and to compare this to the PiG output of ankle kinematics. The average ROM at the ankle according to PiG was 9.68°, which is in line with other studies reporting an average ROM at the ankle in solid AFOs of between 8 and 16° (Abel*, et al.*, 1998; Brunner*, et al.*, 1998; Buckon*, et al.*, 2001; Buckon*, et al.*, 2004; Lam*, et al.*, 2005; Thompson*, et al.*, 2002). These studies examined a mixture of hemiplegic and diplegic patients and all used Vicon Clinical Manager which used the same lower limb kinematic model as PiG.

The total ROM as measured by θ_{PiG} overestimated the total ROM as measured by $\theta_{ankle\ anat}$ by an average of 1.45° (SD 2.64) with an average STA Error across the gait cycle of 1.3°. These values were smaller than expected as it was anticipated that the PiG model would produce a larger total ankle ROM by artificially increasing plantarflexion during periods of knee flexion while leaving all other parts of the gait cycle unaffected. However, as all AFOs in this study deformed to some degree, PiG also acted to reduce this peak dorsiflexion, which reduced the net effect on total ROM. Figure 8.23 demonstrates the reduced peak dorsiflexion calculated by PiG during periods of increased knee flexion where the AFOs were under load, and the reduced dorsiflexion during periods of increased knee flexion where the AFO was not under load, resulting in minimal overall change to total ROM.

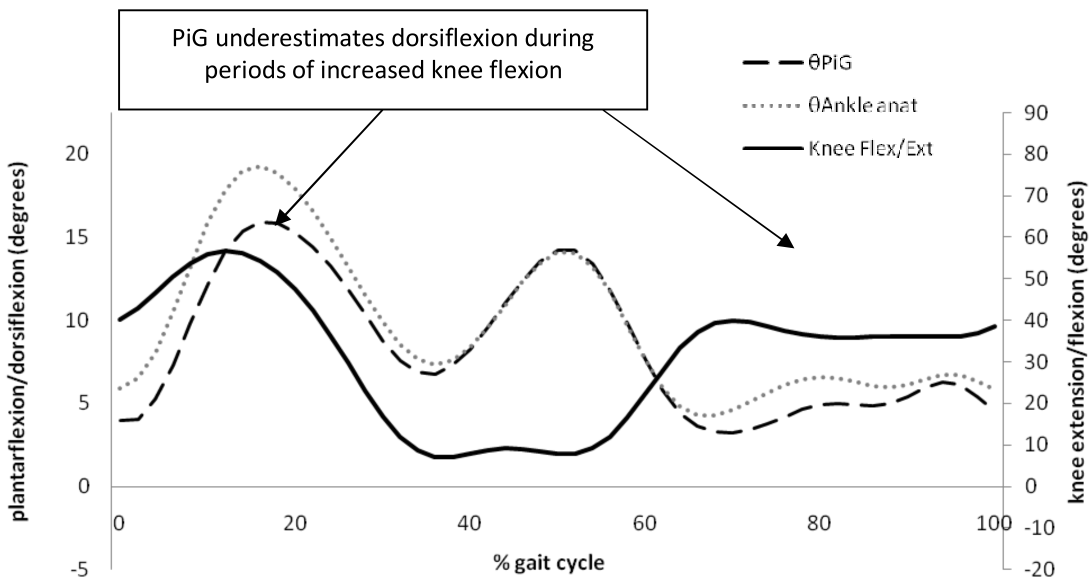


Figure 8.23 Example data (DEHA-L) where PiG reduces peak dorsiflexion during early stance phase and increases plantarflexion during swing phase, resulting in little change in overall total ROM.

There was however some variability within the sample. Three limbs (HAHA-L, -R; JABU-L) all exhibited larger differences in total ROM between θ_{PiG} and $\theta_{ankle\ anat}$ (that is, STA Error) of between 4.1-6.5°. In two of these limbs (HAHA-L, -R) the STA error was seen in the form of exaggerated dorsiflexion during periods of full knee extension as well as reduced dorsiflexion during times of knee flexion (see example in Figure 8.24). This was thought to be related to a static trial captured with the knee in relative flexion so that when the knee is further extended, STA of the knee marker results in overestimated dorsiflexion, which would result in a small negative average STA Error (refer to Table 8.3). This was found however, not to be the case and as such these results are unexpected.

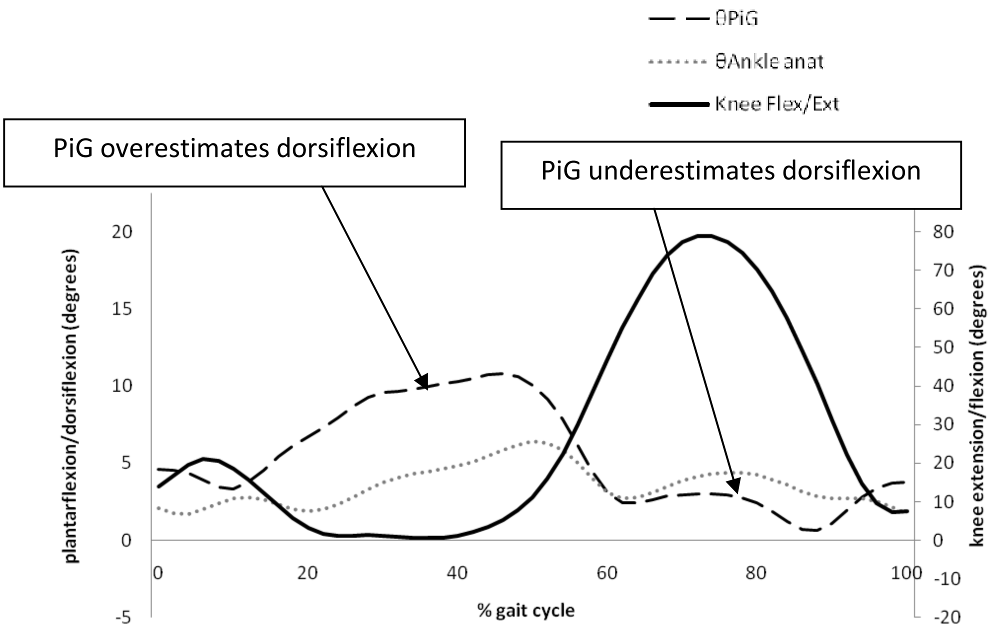


Figure 8.24 Example data (HAHA-R) where STA error has lead to overestimated dorsiflexion at times of increased knee extension in addition to reduced dorsiflexion at times of increased knee flexion during swing phase.

Thus while there was generally a strong correlation between STA Error and knee flexion angle the main effect was that as knee flexion increased there were positive STA Errors whereby the ankle angle was reduced (made more plantarflexed) and in some cases there may also have been negative STA Error whereby the ankle angle was increased during periods of knee extension (see notation on Figure 8.13 and Figure 8.14). Overall, PiG gave a reasonable estimate of total anatomical ankle ROM in solid AFOs.

8.4.2 Movement of the tibia

The second aim of this analysis was to quantify the movement of the AFO, tibia and footwear. Across the group, tibial movement was minimal (average of 2.8°) and was relatively consistent across limbs, never exceeding 4.1°. All but three limbs demonstrated a strong positive relationship between tibial movement and ankle moment where approximately 82% of variability in tibial movement could be explained by ankle moment. In the remaining three limbs, two demonstrated a negative relationship (JOTH-L-R) and one demonstrated a weak positive relationship (HAHA-R). The negative relationship is probably due to a period of excessive and prolonged knee extension throughout stance phase, thrusting the tibia posteriorly into the AFO. The limb demonstrating a weak correlation may reflect the individual pattern of ankle moment where increased dorsiflexion moment in early stance had little effect on tibial movement (refer to Figure 8.17).

While in general, tibial movement correlated strongly with ankle moment, there was no strong relationship between tibial movement and participant body mass (kg). This suggests that while the pattern of tibial movement generally follows the pattern of ankle kinetics, the calf strap will limit movement to approximately 4° regardless of patient weight. Thus in interpreting ankle kinematics in 3DGA clinicians can have confidence that less than 4° of the reported total ankle ROM can be attributed to tibial movement within the orthosis. Orthotists and researchers interested in further pursing causes of increased ankle ROM could therefore focus on other causes such as AFO deformation.

8.4.3 Movement of the AFO

On average, deformation of the AFO provided the largest contribution to anatomical ankle movement (average 6.0°). The extent to which the AFO deformed was highly variable, ranging from an approximately rigid AFO (1.2° total ROM) to an AFO flexing 12.7°. All limbs except those with the smallest AFO deformation (HAHA-L-R, JOTH-L-R) demonstrated a moderate to strong positive relationship between normalised ankle moment (Nm/kg) and AFO deformation. Within this sub-set of limbs 79% of variability in AFO deformation can be explained by normalised ankle moment. The four limbs demonstrating weak correlations are probably due to a range attenuation effect causing clustering of data at the low end of AFO deformation.

The limbs with the greatest amount of AFO flexion were also those participants with the greatest body mass (kg). Because body weight is proportional to ankle moment, a very strong relationship between body mass (kg) and AFO deformation is not surprising. This relationship may explain the apparent pair-wise relationship between the limbs of each child (refer to Figure 8.16) which suggests that the main cause of variability between limbs may be related to characteristics of the individual, such as their body weight, or may be the result of similar design and manufacture of the orthoses.

In a clinical setting, orthotists alter specific features of the AFO to suit each individual patient. This includes changing the material type, material thickness, including reinforcements around the ankle region and modifying the trimline position around the ankle, all of which have been shown to increase AFO stiffness (Bregman*, et al.*, 2009; Major*, et al.*, 2004). All AFOs in this study were prescribed and supplied by clinical facilities. While no AFOs included reinforcements around the ankle region, it is probable that clinicians did alter other design features of the AFO to ensure the AFO was appropriately rigid for each patient.

The strong positive relationship between body mass and AFO deformation found in this study suggests however, that any attempts to alter AFO design and thereby provide an AFO that would withstand the forces applied by body weight, were largely unsuccessful. Variations in body mass explains 81% of variation in AFO deformation, and therefore the remaining 19% can be attributed to other factors such as changes in AFO design. Given the heaviest patient (70kg) is more than three times the weight of the lightest patient (20kg), but design features of the AFO such as thickness of the plastic or radius of curvature of the trimlines around the ankle were not increased in the same proportion, these findings seem logical. Some changes in trim lines and material thickness are impractical, and manufacture must depend on the use of alternative materials (such as carbon fibre) or reinforcements around the ankle.

8.4.4 Movement of the footwear

This study found the degree of movement of the shoe on the AFO foot piece to be very small, across a range of 0.7-3.3°. These values may be smaller than those seen clinically as the footwear worn for this study were secured by wrapping with elastic adhesive bandages to keep the sole attachment in place. Footwear was supplied for this study (Dunlop Volleys) which had a flexible rubber sole likely to flex with the AFO and thus reduce the degree of footwear movement. While this limits the generalisability of these specific results, the findings demonstrate the ability to measure the movement of footwear in any 3DGA application and therefore confirm the integrity of the AFO and footwear combination.

8.4.5 Limitations

One limitation of this study was the small number of participants (n=7) contributing a total of 13 limbs. While it is suggested that attempts to match AFO design to participant weight in order to prevent AFO flexion were largely unsuccessful, it is important to note that the four limbs demonstrating the greatest AFO flexion belong to only two children and thus only two instances where the AFO failed to withstand body weight. Although small, this number is sufficient to demonstrate the utility of this model in providing more detailed information about the accuracy of PiG in calculating ankle kinematics, and the performance of the solid AFO and footwear in a 3DGA context.

It is important to take into account measurement accuracy in 3DGA when considering the implications of small movement quantities. Intra-assessor and intra-session reliability are two significant sources of error in 3DGA (McGinley, Baker, Wolfe, & Morris, 2009), but in this context will have little bearing on these findings given data was collected by a single assessor on one occasion. Equipment error, namely marker-location accuracy, is another potential error source. One method for measuring marker-location accuracy within a 3DGA system is the Standard Assessment of Motion System Accuracy (SAMSA) device (Piazza *et al.*, 2007). Recent tests with the SAMSA device at the Laboratory at the Royal Children's Hospital (Melbourne) indicate that marker-location accuracy is within 1mm. While these tests have not been conducted at the laboratory at La Trobe University, large differences in marker location error are unlikely. A measurement error of 1mm at the ANK marker would translate into only 0.2° angular error, given a 30cm tibial length. Thus measurement error makes a negligible contribution to the movement errors that have been described in this study.

It could be argued that a solid AFO that is 100% rigid is in fact undesirable, and that some movement of the ankle within the AFO, from either AFO deformation or tibial movement is acceptable, and in some cases, necessary. Any deliberate variation on the solid AFO design is of course acceptable, but should always be accompanied by a specific prescription goal against which to assess its performance (Ridgewell*, et al.*, 2010). A more appropriate name for such a device could be a semi-rigid AFO, which is really a relative of the posterior leaf spring AFO. Regardless of the specific purpose of the device, the ability to measure device performance accurately and interpret the findings correctly is paramount.

8.4.6 Future directions

The results of this study suggest that in this sample of 13 solid AFOs, any attempt by clinicians to match AFO design to body weight to prevent AFO deformation were largely unsuccessful. This has important implications for both clinicians and researchers. For researchers interested in determining the efficacy of a device or comparing two orthoses it is important to be able to assess that the device in question is meeting its design goals. Similarly, for clinicians it is important to confirm that the AFO that has been supplied is one that meets its prescription goal. The new model developed and tested in this study provides a useful tool to confirm the performance of the device in both research and clinical settings.

One pressing area of further research to be identified from this study is to determine how variations of design features of the AFO affect performance of the solid AFO in a dynamic context, that is, AFO deformation. Findings from such a study have the potential to lead to the development of AFO design protocols to help clinicians prescribe and supply AFOs that will resist flexion, appropriate to body weight. In addition, this new approach could be used to complement the data obtained from static AFO stiffness testing by providing a functional assessment of AFO stiffnes (Kobayashi, Leung, & Hutchins, 2011).

This model has utility in any 3DGA setting in any population wearing solid AFOs. It allows improved interpretation of the output of ankle kinematics with regard to potential errors that may affect ankle kinematic output, and sheds light on how much of this movement reflects AFO deformation and how much reflects tibial movement within the AFO. Given that 3DGA is so often used to evaluate a range of clinical interventions including surgery, physiotherapy, medical management (eg botox) and orthoses, this model provides a tool that will help clinicians to make better informed decisions regarding their treatment regimes.

This model provides the first tool to measure movement of the footwear on the limb in a 3DGA context. This model could also be applied in patients not wearing AFOs to examine factors such as footwear movement in relation to type of footwear and the relationship of footwear fit and falling in at-risk populations.

8.5 Conclusion

This study has described a new model based on PiG and static calibration designed to overcome inaccuracies in the PiG model due to STA of the knee marker as well as measure the individual kinematics of the AFO, the tibia within the AFO, and the footwear. It was found that overall PiG provided a good estimation of ankle kinematics though across the gait cycle discrepancies up to 7° were observed. In this sample of children, the main cause of increased ankle ROM was flexion of the AFO (up to 13°) which increased with bodyweight. Tibial movement was limited to approximately 4° and shoe movement to 3°. Researchers and clinicians using 3DGA to measure ankle kinematics in patients wearing solid AFOs would benefit from using this model to obtain a more accurate measurement of ankle kinematics in solid AFOs, and a measure of the degree of AFO flexion, tibia movement and footwear movement. This will assist in clinical decision making in order to improve management, fit and function of orthoses and footwear.

9 Grand Discussion

The aim of this thesis was to determine the effect of sagittal plane AFO-FC alignment on the gait of children with CP, in two types of AFO designs. The current chapter integrates the series of studies that were designed to achieve this goal. These studies involved a review of literature and of the theoretical rationale for AFO-FC tuning, a systematic review of reporting transparency in the wider body of AFO literature in this population, exploratory pilot work and a prospective experimental study involving two groups of children wearing either hinged or solid AFOs. The final investigation of this thesis tested the utility of a new model for calculating movement of the AFO, tibia and footwear in solid AFOs in three dimensional gait analysis (3DGA). This final chapter provides an overview of answers to each of the research questions before discussing the limitations of this research and the scientific, clinical and research implications of these findings. Future avenues of research will be presented, followed by the overall conclusions of the thesis.

9.1 Overview of findings

9.1.1 How well is AFO-FC alignment reported in the wider body of literature?

The first research question was to determine how well AFO-FC alignment was reported in the wider body of literature. This was addressed in the systematic review described in Chapter 3. Subsidiary research questions were to determine how well details describing the participant sample, AFO-FC intervention and testing protocol were reported. The review revealed that very few studies that investigated the effectiveness of AFOs on children with CP provided full details of the alignment of the AFO-FC. Many studies did not ensure a homogenous sample in terms of underlying gait pattern and did not describe the AFO-FC intervention in sufficient detail to allow replication. This review identified several avenues of research that warrant focussed attention and lead to the publication of guidelines for the reporting of details in AFO intervention studies on children with CP. These guidelines have formed the basis for the design of the experimental studies in this thesis.

9.1.2 How does AFO-FC alignment affect gait?

The second research question was to determine how AFO-FC alignment affects gait. Based on a review of the literature outlined in Chapter 2, two mechanisms were hypothesised by which increasing the heel-sole-differential (HSD) of the footwear and thus increasing the shank-to-vertical angle (SVA), were thought to induce biomechanical changes in the lower limbs. Mechanism 1 was thought to occur in limbs that achieve a clear foot flat during stance phase, whereby increasing the HSD results in increased tibial incline, increased peak knee flexion and decreased peak knee extension, thus leading to reduced peak knee extension moment. Mechanism 2 was thought to occur in limbs not achieving foot flat where increasing the HSD increases the area of contact of the foot with the ground, shifting the centre of pressure posteriorly thus reducing peak knee extension moment. Exploratory analysis of pilot data in Chapter 4 provided preliminary evidence that these different mechanisms may occur either in isolation or as part of a mixed response. However, results of the prospective experimental study described in Chapters 6-7, suggested that all limbs demonstrated a mixed response although the strength of the different mechanisms within each response varied.

The results of this pilot study highlighted several methodological limitations which were addressed in the design of the subsequent investigation of this thesis. These included inaccuracies in using a hand-held goniometer to measure changes in SVA as well as the limitations of using internal heel wedges to induce SVA changes due to compromised fit and function of the footwear. In addition, a sixth research question was identified that related to large sagittal plane ankle movement measured in the solid AFOs. As a result an investigation into the measurement of ankle and AFO kinematics in 3DGA was conducted and is reported in Chapter 8. All data relating to the subsequent investigations were captured using the method described in Chapter 5.

9.1.3 Are all children responsive to AFO-FC alignment change?

The third research question was to determine whether all children were responsive to AFO-FC alignment change. The first stage of the analysis included an assessment of homogeneity with regard to gait pattern, a recommendation arising from the systematic review. Separate common patterns of knee kinematics were observed for the majority of children wearing either solid or hinged AFOs. The results suggest that all limbs were sensitive to AFO-FC alignment when measured in terms of effect on knee moment over mid-stance, as well as over all of stance phase. Formal tests confirmed statistically significant linear correlations between the change in knee moment as a result of each wedge size, in 25 of the 27 limbs. On the whole, children wearing solid AFOs were more responsive to alignment changes than children wearing hinged AFOs. Furthermore, limbs demonstrating the common knee kinematic pattern were more responsive than those with variant gait patterns.

A subsidiary research question asked whether the method of determining differences from the baseline response affected the measured responsiveness. Three methods were compared: one which measured differences over the mid-stance period as defined by Perry (1992) of 10% to 30% stance phase (referred to as the mid-stance analysis), one which measured differences over the whole of stance phase (referred to as the stance phase analysis), and one which measured differences at 30% of the gait cycle (referred to as the single point analysis). The results suggested that the mid-stance analysis was twice as sensitive to change in knee moments to the stance phase analysis, and several times more sensitive than the single point analysis. In addition, using only a single point of the gait cycle in this analysis resulted in a loss of sensitivity to change between the baseline and the smallest wedge.

9.1.4 What is the effect of systematic AFO-FC alignment change on gait?

The fourth research question focussed on the effect of systematic AFO-FC alignment change on a range of gait parameters in children wearing two types of AFO designs. There was strong evidence for systematic changes in a range of variables relating to the knee, tibia and ankle, particularly amongst children wearing solid AFOs who demonstrated the common gait pattern. While similar patterns were seen in the hinged AFO group these were not as consistent or systematic. Variables related to the hip and femur, and temporospatial variables did not demonstrate systematic changes across the different limbs.

9.1.5 Is there an optimum AFO-FC alignment?

The fifth research question focussed on whether it was possible to determine an optimal wedge size that produced the best results over a range of variables. An optimum wedge size was identified in the majority of parameters across the majority of limbs but was more clearly defined in the solid AFO group, particularly in limbs demonstrating the common knee kinematic pattern. If knee kinetics were considered in isolation, the optimum wedge size was most commonly 5° in the common sub-group and 0° in the variant limbs of the solid AFO group, compared with between 0-10° for the hinged AFO group.

Agreement in optimal wedge size across variables was poor, with only one limb in each group in complete agreement across the biomechanical parameters, with only half of each group having good agreement. Within the solid AFO group these limbs were all part of the common sub-group. There was no clear optimal across temporospatial variables or subjective preference. The optimum SVA for the limbs with good agreement ranged between 0-10° in the solid AFO group and 0-15° in the hinged AFO group.

9.1.6 How does the Plug-in-Gait output of ankle kinematics compare to anatomical ankle kinematics? Can movement of the anatomical ankle, the AFO, tibia and footwear be measured?

The final research question was to determine how much anatomical ankle movement occurs within the AFO and to compare this with the Plug-In-Gait (PiG) calculation of ankle kinematics. Movement of the AFO, tibia and footwear were measured to determine their contribution to the output of ankle kinematics. The results suggested that overall, PiG provides a reasonable estimate of anatomical ankle kinematics despite the effects of soft tissue artefact (STA) of the knee marker. Ankle movement in the solid AFO was primarily a reflection of AFO flexion rather than tibial movement within the AFO. Movement of the footwear on the AFO/foot in this study was very small. AFO flexion correlated very strongly with ankle moment and patient weight, suggesting that the variability in AFO flexion is related more to the patient than to variability between AFOs.

9.2 Limitations of research

The limitations of the individual studies were discussed in detail within the relevant chapters. The main themes to emerge regarding the limitations as a whole relate to sample size and bias, variety in AFO design and manufacture, and generalising the findings to the wider body of literature on AFO-FC tuning.

9.2.1 Sample size and bias

The sample size recruited for the prospective experimental study of this thesis was small, with n= 7 children in the solid AFO group and n=13 children in the hinged AFO group (with one child with a limb in each group). This sample is therefore unlikely to be representative of the wider population of children with CP as the heterogeneity in baseline gait patterns did not cover the spectrum of gait disorders seen in this population (Rodda*, et al.*, 2004; Sutherland & Davids, 1993; Winters*, et al.*, 1987). However, because inclusion in the study was limited to children with spastic hemiplegia or diplegia who were GMFCS level I or II, the types of gait patterns that would be expected within the hemiplegic group are Winters, Gage and Hicks (Winters*, et al.*, 1987) Group II (ankle equinus throughout stance) and Group IV (involvement of hip and knee) (Dobson*, et al.*, 2007). These types of gait patterns concur with the common and variant sub-groups found in the current study. The majority of limbs demonstrated similar patterns of knee kinematics with only six limbs across the two groups demonstrating significant variations. Within this common sub-group the results were found to be consistent which means these results can be well generalised. There were comparatively few limbs in the variant sub-groups, which demonstrated a wide variety of patterns of baseline knee kinematics. This limits the extent that the results specific to this group can be generalised.

The recruitment method was from a sample of convenience, either through invitation from a clinician or from advertisements posted on waiting room walls. The recruitment process was year-long and conducted through both a private and a public paediatric orthotic facility, from which the majority of children in the state of Victoria received their orthotic management. Despite this strategy, the sample size was small. The major factor limiting involvement in the project was likely related to the three hour time commitment to complete the testing session. Participation in this project required time off school and for most families, significant travel time. As such the sample was probably biased toward more motivated families and potentially higher functioning children.

Many of the children in this study had medical histories including a range of surgical interventions such as muscle and tendon transfers, tendon lengthenings and rotation osteotomies (listed in Appendix D). These interventions are known to affect the kinematics and kinetics of gait (eg. Bell, Ounpuu, DeLuca, & Romness, 2002; Wren, Rethlefsen, & Kay, 2005) and thus affect the types of gait patterns demonstrated within this sample. If this study were repeated in an area with different protocols for managing spasticity as well as musculoskeletal disorders associated with CP it is likely that the types of gait patterns found within the sample would vary, as would the results.

The participants in this study demonstrated variable degrees of spasticity in their lower limb muscle groups, as indicated by a difference in joint ROM according to passive and dynamic measures. Heterogeneity in spasticity, along with other factors such as bony deviations and muscle contracture, are characteristics of this population and may account for some of the between subject variability in the results. Of the biomechanical changes observed in this thesis, the least systematic were in variables distal to the knee joint. While this may be attributed to the modulating effect of the knee joint, it might also be due to spastic hamstrings or gastrocnemius muscles limiting knee movement. Had the sample contained children with less spasticity the biomechanical effect of changing SVA might have been more systematic at the hip and femur.

9.2.2 Variety in AFO design and manufacture

For involvement in this study participants wore their own AFOs, and as such there was variety in terms of the details of AFO design. All AFOs used in this study were similar in terms of general type of design; they were all made of polypropylene homopolymer which extended proximally up the calf to just below the fibular head and had a full length toe plate with a calf strap and ankle strap of either a wrap-around or turnback design. The most notable variation was seen in the medio-lateral trimlines at the forefoot, which were positioned at a variety of locations from the metatarsal heads to the distal toe plate. While the thickness of plastic was measured, it was clear that there were inconsistencies in the thickness of the plastic if measured at different locations on the AFO, and when measured at the same location. Therefore rigidity at the ankle in solid AFOs and rigidity at the forefoot in both types of AFOs was not controlled. The results of Chapter 8 demonstrated that some of the solid AFOs deformed considerably, particularly in those children who were heavier and demonstrated more flexed gait patterns. Similar effects may occur at the forefoot which has the potential to contribute to inconsistent patterns of change in terminal stance.

Examining the effect of AFO-FC alignment on the participants' own AFOs has however, some advantages. These AFOs represent those supplied clinically and therefore accurately depict the changes that could be induced in real clinical settings, where there will be a variety of ankle and forefoot rigidity in the AFO. If AFOs had been supplied for each limb for the purpose of this study, it could not be guaranteed that these would also have been entirely rigid at the ankle. In addition, a choice of standard forefoot trimline would have been required which may not have been the most appropriate option for each individual. Supplying new AFOs would also require two additional visits for participants, which likely would have made recruitment more difficult.

9.2.3 Generalisation to the tuning process

One limitation of these investigations into AFO-FC alignment is the difficulty in generalising these findings to the majority of tuning literature. In this thesis the effect of AFO-FC alignment was considered as the sole independent variable and was implemented by using systematic alignment changes rather than a trial and error approach to optimisation. The results of these studies must therefore be considered in light of the potential effect of heel and sole modifications on these same variables. If future investigations find that modifying heel and sole profiles of footwear can address some of the negative changes seen in early and terminal stance, the results of this study can be reinterpreted in light of these subsequent changes.

For example, the EVA wedges used in this study had a rounded heel profile similar to runners/sneakers which are commonly worn by children who wear AFOs. This type of heel profile might allow for a smoother transition from heel contact to foot flat by maintaining the point of application of the GRF vector at the heel before allowing it to progress along the foot. Had a square heel profile been used a faster transition from heel contact to foot flat might result which would increase tibial velocity and peak knee flexion in early stance. It is possible that there may also be flow-on effects to the rest of the gait cycle. Further work should be conducted to investigate how changing sole profile affects gait biomechanics.

Difficulties also arise in translating the systematic patterns of change reported in Chapter 6, to the question of optimal alignment addressed in Chapter 7. While the published literature is not clear with regard to how optimal alignment was determined during the tuning process, focus has primarily been on optimising knee kinetics. This analysis assessed knee kinetics over the period of mid-stance rather than addressing a specific parameter, such as peak knee extension moment, or a specific instant in the gait cycle, such as at 30% gait cycle. This method averages the knee moment over the period of mid-stance (10%-30%) in contrast to the method described by others which takes the knee moment at a single point in time.

9.3 Implications of research

The following section discusses the scientific, clinical and research implications of this research in terms of the contribution of this work to the current body of literature, and how these findings affect clinical and research practice. This focuses on a sub-set of the most important findings of the research which relate to the reporting guidelines published as part of the systematic review, results of the experimental study investigating the effect of AFO-FC alignment and implications of the new model to measure ankle, AFO and footwear movement in 3DGA.

9.3.1 AFO-FC alignment is under reported and potentially underappreciated within the wider body of literature

The body of literature supporting the efficacy of AFO use in children with CP has been described as having poor quality (Figueiredo*, et al.*, 2008; International Society for Prosthetics and Orthotics, 1995; Morris, 2002). Many reviewers have recommended that studies of stronger methodological designs, such as RCTs, are needed to improve the evidence base for AFO use in children with CP (Figueiredo*, et al.*, 2008; Morris, 2002). However equally important is improving the reporting transparency in these studies, which is essential to allow an assessment of intervention quality (Herbert & Bø, 2005).

The systematic review described in Chapter 3 highlighted many of the issues noted by other authors such as heterogeneity in participants and AFO designs, as well as poor reporting transparency (Bowers, 2007; Bowers & Ross, 2009; Figueiredo*, et al.*, 2008; International Society for Prosthetics and Orthotics, 2004; Morris, 2002), but did so using a systematic and repeatable methodology. The review found that very few studies reported sufficient information about the AFO intervention to allow the device to be replicated. Only one study (Romkes*, et al.*, 2006) reported the final SVA of the AFO-FC used in their study, which was a standardised alignment for all participants. Five papers reported fine tuning the AFOs to an individual's requirements (Butler*, et al.*, 2007; Butler*, et al.*, 1992; Desloovere*, et al.*, 2006; Rosenthal*, et al.*, 1975; Van Gestel*, et al.*, 2008) however the descriptions of the tuning process were not sufficient to allow reproduction, and the final AFO-FC alignment was not reported. These results support the findings of Owen (Owen, 2004b) who conducted a review in 2004 and found that only handful of papers investigating AFOs and casts in children and adults reported the AFO-FC alignment.

In response to this, the remaining studies in this thesis have provided a comprehensive assessment of how AFO-FC alignment affects the biomechanics of gait. It is now evident that all limbs are sensitive to AFO-FC alignment change, with 25/27 demonstrating statistically significant changes, and that changing AFO-FC alignment results in systematic changes to gait. In light of this new understanding, the results of the studies that have reported AFO-FC alignment can be reinterpreted to gain improved understanding of the effect of the AFO-FC. For example, a study using a standard SVA of 0° is likely to produce reduced peak knee flexion moment and angle and increased peak knee extension moment and angle in comparison to a study that has used a SVA of 10°. In the latter example, if the barefoot gait was a typical equinus pattern with good knee extension, we would also expect to see larger changes from a barefoot comparison.

In studies that investigate the ability of an AFO to normalise gait, use of a standard alignment across all AFOs is likely to produce inconsistent results because of the variety in baseline gait patterns.

The systematic review resulted in the formation of guidelines for the reporting of details in AFO intervention studies in children with CP. These guidelines encourage both consumers and producers of this literature to consider pertinent issues in the design, execution, reporting and interpretation of AFO intervention studies in this and other populations. These guidelines have utility in the design of new research projects and in the critical review of previously published work. The findings of this thesis provide additional insight into the effect of AFO-FCs on gait in children with CP which makes a considerable contribution to the evidence base for orthosis use in this population.

9.3.2 When examining the effect of AFO-FC alignment the type of gait pattern matters

A second major theme to emerge from the systematic review was the importance of ensuring participant homogeneity with regard to gait pattern. Children with CP form an inherently heterogeneous population, particularly in terms of gait pattern. It is therefore essential that a homogenous group or sub-group of children are examined within each sample, and also that the resulting orthotic goal is consistent across all limbs. This is essential in AFO intervention studies because the type of AFO affects different gait patterns in different ways (Abel*, et al.*, 1998; Buckon*, et al.*, 2001; Thompson*, et al.*, 2002). If a study is comparing the efficacy of different AFO designs, each AFO must also be appropriate to the participant’s particular requirements, which must be similar for all participants.

The systematic review described in Chapter 3 found that the majority of studies did not report a consistent orthotic goal and only a handful of studies attempted to assess and describe sample heterogeneity or ensure that samples were homogenous with regard to their need for an AFO (Abel*, et al.*, 1998; Buckon*, et al.*, 2001; Butler*, et al.*, 1992; Romkes*, et al.*, 2006; Simon*, et al.*, 1978; Smith*, et al.*, 2009; Thompson*, et al.*, 2002; Van Gestel*, et al.*, 2008). This lead to the issue of sample heterogeneity featuring in the reporting guidelines arising from the systematic review.

On the basis of these recommendations, the experimental work of this thesis focussed on assessing the effect of AFO-FC alignment on sub-groups with homogenous gait patterns. The results suggested that differences in underlying gait pattern resulted in different patterns of response to AFO-FC alignment, and influenced how well a range of parameters optimise with regard to the optimal wedge size, particularly within the solid AFO group. These results lend support to the importance of addressing sample heterogeneity and describing the features of the AFO design.

9.3.3 All limbs are sensitive to changes in AFO-FC alignment

Previous literature has suggested that not all children are able to tune successfully (Butler*, et al.*, 2007; Owen, 2004c). The terms 'successful' and 'unsuccessful' tuners have been used but have not been clearly defined regarding the variables measured and the direction of change. There is therefore some ambiguity surrounding which children these are. If this research is relevant to only a small body of children then it is important to define this population.

According to some authors, successful tuners are those with less than 20° knee flexion in early stance followed by 10° or less of knee flexion in mid-to-late stance (Butler*, et al.*, 2007; Owen, 2004c) or those with more severely flexed postures (Butler*, et al.*, 2007; Owen, 2004c). This type of gait pattern is similar to the gait pattern described for the theoretical response 'Mechanism 1' which was described in Chapter 2 and explored in the pilot data of Chapter 4. This type of gait pattern can also be likened to the common pattern of knee kinematics demonstrated by the majority of limbs in this study.

All limbs in this study appeared to be sensitive to AFO-FC alignment change and 25 out of 27 demonstrated a statistically significant correlation between wedge angle and knee moment. This suggests that response to wedge angle is more common than suggested by Butler and colleagues (Butler*, et al.*, 2007) or Owen (Owen, 2004c).This thesis adopted the terminology of responsive and non-responsive instead of using the terms successful and unsuccessful tuners. These terms imply that a change occurred but do not specify whether the change resulted in an improvement or were detrimental. Therefore, while all limbs in this study demonstrated sensitivity to AFO-FC alignment change, and the majority demonstrated a significant response, the direction of the change was not identified. It is possible that many of the "unsuccessful" tuners described by Butler and colleagues (2007) and by Owen (2004b) started with an optimal alignment and changed with tuning to a less satisfactory gait pattern.

The degree of sensitivity of knee moments to AFO-FC alignment varied according to type of gait pattern. Type of gait pattern also affected the patterns of response seen across other variables and the agreement of optimal wedge size across these parameters. The common sub-group was more sensitive, demonstrated the most consistent changes across variables and had the best agreement across parameters in terms of optimal wedge size. The variant limbs were less sensitive, demonstrated more varied patterns of change across parameters but in terms of agreement in optimal wedge size were poorest.

These results suggest that previous authors (Butler, *et al.*, 2007; Owen, 2004c) considered successful tuners to be those who demonstrated improvements in the parameter of interest, but others may have been sensitive to tuning without improving from the starting alignment and therefore labelled as “unsuccessful”. This judgment may have been based primarily on knee moments but may also have included changes in knee kinematics. The present work therefore provides an important distinction between the concepts of successful tuning and responsiveness to AFO-FC alignment change. It has clarified the findings of previous work and provided valuable insight into how AFO-FC alignment affects children with different gait patterns, and the type of children who might benefit from an AFO-FC tuning procedure.

9.3.4 AFO-FC alignment has a significant effect on gait

Despite anecdotal evidence suggesting benefits as a result of the AFO-FC tuning process (Anderson & Meadows, 1978; Bowers & Meadows, 2007; Meadows, *et al.*, 1980; Owen, 2002), there is little scientific evidence in the published literature that different AFO-FC alignments do affect gait in children with CP. This study is the first to provide a thorough examination of the effect of AFO-FC alignment on a suite of gait parameters in children with CP who wear solid or hinged AFOs.

Overall, similar patterns of change in gait parameters distal to and including the knee were seen in all limbs, although these were more consistent and systematic in the solid AFO group. The exact patterns of change did vary somewhat according to gait pattern. In limbs demonstrating the common knee kinematic pattern the types of changes observed support those described in the related literature: reduced peak knee extension moment (Bowers & Meadows, 2007; Butler, *et al.*, 1997; Butler, *et al.*, 2007; Butler, *et al.*, 1992; Jagadamma, *et al.*, 2009; Jagadamma, *et al.*, 2007) and peak knee extension angle (Jagadamma, *et al.*, 2007; Jagadamma, *et al.*, 2010; Reinthal & Hoy, 2005); and increased peak knee flexion moment (Fatone, *et al.*, 2009; Jagadamma, *et al.*, 2009) and peak knee flexion angle (Butler, *et al.*, 2007; Jagadamma, *et al.*, 2009; Jagadamma, *et al.*, 2007). By and large these studies examined children demonstrating knee hyperextension or excessive knee extension moment which are similar to patterns of knee kinematics and kinetics demonstrated in the common sub-group.

This sub-group of limbs also demonstrated increases to tibial projection angles with increased wedge size. No other studies have measured the effect of AFO-FC alignment on tibial angle despite much of the theoretical work focussing on the importance of optimising tibial kinematics on the presumption that this would cause other biomechanical parameters to optimise (Meadows, *et al.*, 2008; Owen, 2004c; Owen, 2010; Owen, *et al.*, 2004). While tibial angle increased, the exact changes were highly variable in terms of pattern and size of change across individual limbs. There is much scope for future work to consider the effect of AFO-FC alignment on tibial projection angles as well as other measures such as tibial angular velocity.

This investigation was also the first study to measure the effect of AFO-FC alignment on ankle moments. It was hypothesised that ankle moments would reduce with increased wedge size particularly in gait patterns where the foot is inclined on the floor resulting in uneven weight bearing between the heel and toe. Reductions in ankle moment with increased wedge size were seen across the majority of limbs, but were strongest in the solid AFO variant sub-group. This is thought to relate to a posterior shift in centre of pressure due to increased contact of the foot with the ground. This may lend support to the suggestion that tuning should still be attempted in children who have previously been considered to be unsuccessful tuners, because increasing the HSD of AFO-FC such that the sole of the shoe is brought to the floor may improve stability (Owen, 2004c).

This was also the first study to measure the effect of AFO-FC alignment on variables such as hip moments, angles and femur projection angles. While there have been suggestions that AFO-FC tuning should also focus on modifying hip moments (Bowers & Meadows, 2007; Meadows*, et al.*, 2008; Owen, 2004b), this study did not find systematic effects of AFO-FC alignment on these variables. This is thought to be due to the modulating effect of the knee joint. There were however a number of significant main effects in these variables in the hinged AFO sub-group with the common gait pattern.

Limbs in the solid AFO variant sub-group demonstrated similar patterns of changes to knee kinetics as the common sub-group, but these changes were often smaller in magnitude. These limbs would be considered by previous authors (Butler*, et al.*, 2007; Owen, 2004c) to be unsuccessful tuners. Only one case study has examined the effect of AFO-FC alignment on a child with a flexed gait pattern. This study changed the AFO ankle angle on a child with crouch gait and only limited biomechanical data was presented (Reinthal & Hoy, 2005). One study (Wesdock & Edge, 2003) has examined the effect of wedges on standing balance in a group of children all demonstrating a flexed or crouch posture in standing. Increases in balance time with the wedges were seen only in the sub-group who could stand for more than 15 seconds unaided (Wesdock & Edge, 2003). These improvements in standing time may be due to the same changes described as part of Mechanism 2: an anterior shift in the centre of pressure as a result of improved base of support.

9.3.5 AFO-FC alignment affects terminal stance as well as mid-stance

Modifying AFO-FC alignment is the first stage of the tuning process. It is said to address mid-stance, whereas modifying heel and sole profiles address early stance and terminal stance respectively. These results suggest however that modifying AFO-FC alignment induces changes in terminal stance as well as mid-stance. For instance, peak knee extension angle and moment occur in terminal stance, and were systematically reduced with increased wedge size.

This finding was also evident in the results examining responsiveness to AFO-FC alignment change. Change in knee moment was considered over the period of mid-stance (10-30% gait cycle), over all of stance phase and at a single point in the gait cycle (30% gait cycle). While the mid-stance analysis was more sensitive to change than the stance phase analysis, the stance phase analysis was more consistent across conditions and limbs, that is, had less variability. The RMS values were also smaller on average. This suggests that either there may have been some consistent changes occurring in either early or terminal stance that were otherwise missed by the mid-stance analysis, or that there were fewer changes occurring during this time, thus reducing the average value.

It is therefore likely that peak knee variables such as knee extension moment and angle, as well as other gait features occurring in terminal stance, can be further modified by changing sole profiles. One case study has demonstrated that while increasing the SVA can reduce knee hyperextension, modifying the sole profile of the footwear resulted in further reductions (Jagadamma*, et al.*, 2010). Further research is required to verify this.

9.3.6 All biomechanical parameters do not optimise simultaneously

The focus of the tuning procedure is often described as to optimise or normalise gait (Butler*, et al.*, 2007; Jagadamma*, et al.*, 2009; Jagadamma*, et al.*, 2010; Owen, 2010). Unfortunately the definition of optimal or normal gait has been somewhat ambiguous, and a lack of data demonstrating the changes to gait after tuning an AFO-FC make it difficult to assess this retrospectively. In this thesis the most normal or optimised gait pattern was considered to be the one demonstrating closest to normal values. The four biomechanical parameters that were found to change systematically with increased wedge size were used in this analysis.

Optimising knee kinetics is at the heart of the tuning procedure. If knee kinetics is considered in isolation, the wedge size that best normalises knee kinetics varies according to gait pattern and AFO type. In the solid AFO common sub-group, the knee kinetic pattern was optimal most commonly in the 0° wedge, whereas in the variant limbs it was 5°. In the hinged group the optimum wedge size for knee kinetics was more variable. However, if the optimum wedge angle for knee kinetics is compared to the optimum wedge size for knee kinematics, ankle kinetics and tibial projection angles, only two limbs of a total 27 had complete agreement for a particular wedge size and only half had good agreement, defined as agreement spanning 5°.

These results suggest that variables will not all optimise for the same wedge size to give a better gait pattern overall. In fact it appears that one particular variable needs to be prioritised, and sub-optimal patterns for other variables accepted. This has important ramifications for much of the theoretical work on tuning that suggests that the optimising one variable, for example tibial kinematics, results in optimisation of a range of other variables (Meadows*, et al.*, 2008; Owen, 2010). It is also possible that these results may be altered by changing the heel or sole profile of the footwear, or may be affected by forefoot AFO variability.

In summary, this work represents the first investigation of the effect of AFO-FC alignment on gait in children with CP. Many of the findings support previous literature but further understanding is gained for how changing AFO-FC alignment affects children with different gait patterns and in different types of AFOs. In particular this work highlights some limitations of previous theoretical and experimental work in this area. These results have a range of implications for clinicians, researchers, policy makers and families of children with CP which are discussed in more detail in the subsequent section.

9.3.7 AFO flexion is the most significant contributor to excessive ankle ROM in solid AFOs

The utility of the new model for measuring anatomical ankle kinematics, AFO kinematics, tibial and shoe movement was demonstrated on the solid AFO group in the final investigation of this thesis. This is the first study to measure and quantify movement of the AFO, tibia and footwear during 3DGA and as a result provides the scientific community with a valuable tool for measuring the performance of solid AFOs and footwear in 3DGA.

The large degree of AFO flexion demonstrated in the pilot study was of concern because solid AFOs are designed and prescribed with the aim of eliminating all movement at the ankle. This degree of ankle movement in a solid AFO was however found to be common within the wider literature with 8-16° of ankle ROM reported in the solid AFOs of several studies on children with CP (Abel*, et al.*, 1998; Brunner*, et al.*, 1998; Buckon*, et al.*, 2001; Buckon*, et al.*, 2004; Carlson*, et al.*, 1997; Lam*, et al.*, 2005; Thompson*, et al.*, 2002). This study found an average of 10° total ankle movement which is similar to previous studies.

This research found that the primary contributor to this excessive ankle ROM was in fact AFO flexion, with much smaller contributions from STA of the knee marker and from tibial movement within the AFO. This provides support to anecdotal suggestions in the literature that the large degree of ankle movement was due to flexion of the AFO itself (Buckon*, et al.*, 2001; Buckon*, et al.*, 2004; Carlson*, et al.*, 1997; Thompson*, et al.*, 2002). This is likened to the description to 'frogmouth' (Clarke & Lunsford, 1978; Lehmann, DeLateur, & Price, 1992), which is when the plastic anterior to the ankle, both medially and laterally, bulges outwards, allowing the AFO to dorsiflex. AFO flexion was found to have a very strong correlation with ankle moment and with patient weight. There was also a strong pairwise relationship between limbs belonging to the same patients which suggests that the main factor contributing to the degree of AFO flexion is individual patient factors including weight or gait pattern, or a similar manufacture AFO design.

The findings from this study may help clinicians and researchers to better interpret the results of previous research. In light of these results we can expect that in any investigation of solid AFOs there will be increased ankle range of movement in the heavier patients which may also reduce the effectiveness of the device in controlling more proximal lower limb joints. For instance, in the study described in Chapters 6-7, the solid AFO variant limbs belonged to the heaviest patients. In these limbs, increasing wedge size resulted in some reductions in tibial projection angle and in peak knee flexion angle which were unexpected results. This was originally attributed to increased stability due to increased base of support, however in light of these findings it is possible that these results are due to reduced AFO flexion. Indeed, ankle moment, which is correlated strongly with AFO flexion, was also reduced.

9.3.8 Implications for clinical researchers

The reporting guidelines generated from the systematic review guide are a useful tool for clinical researchers as they provide a framework for the design and execution of AFO intervention studies that better consider important issues specific to this area. These guidelines encourage clear reporting and thoughtful assessment of orthotic goal and sample homogeneity, which, if followed, have the potential to improve the quality of the evidence base in this area.

The studies in this thesis have clearly described the effect of AFO-FC alignment on a range of gait parameters in two groups of children with CP, wearing two types of AFO designs. In light of these findings, researchers can now fully appreciate the effect of AFO-FC alignment on gait when designing and executing AFO intervention studies. For example, if a study uses AFO-FCs with a standard SVA, the normalising effect of the device on different biomechanical parameters will vary according to baseline patterns of kinetics and kinematics. If the SVA is chosen by a process of optimisation, this must be done in accordance with a specific, clearly defined and clinically relevant variable and with the effect of such optimisation reported. Improvements in variables of interest may be made at the cost of detrimental effects on some other variables.

The new model for measuring ankle, AFO, tibia and footwear kinematics in 3DGA provides information about the behaviour of the AFO-FC that was previously not available using the standard PiG model in 3DGA. This model provides a method of measuring ankle kinematics that is not influenced by tibial movement within the AFO or by STA of the knee marker. Only two additional markers are required to be able to assess the integrity of the fit of the footwear, the rigidity of the AFO and how well the tibia is restrained in the AFO. As such this model has utility in any research project investigating the effect of an AFO or a variant of AFO design.

9.3.9 Implications for clinicians

These studies tell us that AFO-FC alignment is important for all children wearing solid and hinged AFOs. It is now apparent that a certain subset of systematic biomechanical changes can be induced by altering AFO-FC alignment. Depending on the type of gait pattern, the exact changes will vary, but all of these systematic changes will occur at the knee level and below. While the focus of changing AFO-FC alignment in the context of AFO-FC tuning is to affect mid-stance, changes will also be seen in early and terminal stance. It is however unlikely that modifying the SVA alone can lead to optimisation over a range of biomechanical gait parameters.

This information has direct clinical relevance to those involved in the orthotic management of children with CP at a clinical level. Orthotists can now appreciate that the combined effect of the footwear and AFO on AFO-FC alignment is an important consideration because it does have a significant effect on gait. If changes are made to the AFO-FC alignment, changes will occur across stance phase, across anatomical joints, and across variables. Many of these changes are subtle and cannot be assessed using observational gait analysis.

In a clinical 3DGA setting, changes to AFO-FC alignment can be made based on the results of a baseline gait analysis. The findings from this study describe how gait will change, and by approximately how much when 5° incremental changes are made to the SVA. The choice of AFO-FC alignment can be modified based on this information, and a quantitative assessment of these changes performed to confirm the results. This information therefore provides clinicians with a valuable tool to alter and potentially improve gait in children with CP.

The model to measure AFO, tibial and footwear kinematics in solid AFOs in a 3DGA context has direct implications for orthotists. In clinical settings that routinely use 3DGA, a gait analysis has the potential to provide information about the patients gait in barefoot and with any assistive devices or orthoses, as well as how well the AFO is providing rigidity at the ankle. Direct feedback can be provided to orthotists about the rigidity of the device that allows them take action to increase the rigidity of the device if necessary.

This model also provides an alternative measurement of ankle kinematics from that offered by Plug-In-Gait. This measurement is not affected by STA of the knee marker. While the total ankle ROM reported in this study according to these two measurements was similar, there were more substantial variations at different points of the gait cycle. Use of this model in a routine clinical 3DGA setting would provide clinicians with a more accurate measure of anatomical ankle kinematics which should permit a more accurate assessment of the effectiveness of health related interventions related to the ankle.

9.3.10 Implications for children, families and policy makers

Further investigation is required to determine the effect of heel and sole profiles on gait, and to combine this with the findings of this study to more fully understand the complex three stage process of AFO-FC tuning. If, after further investigations the tuning process is proven to lead to better outcomes in children with CP, introducing these practices to routine clinical management will have implications for both patients and families, as well as for policy makers.

In facilities that already use this process routinely, all children are supplied with two pairs of leather boots incorporating an EVA sole. This permits permanent changes to be made to the heel and sole profile of the footwear which are worn on a full-time basis with their orthoses. In Australia, shoes are not provided as part of orthotic treatment, rather footwear is chosen by the family, often in conjunction with advice from their orthotist.

If families retain the ability to choose and provide footwear for their child, providing consistent and appropriate footwear modifications is likely to lead to logistical difficulties in ensuring the sole is suitable for modification, as well as providing the same modifications to all pairs of shoes simultaneously. If specific footwear was provided for the purpose of ensuring appropriate footwear for these modifications, this would add significant cost to the process and by imposing restrictions on the choice of footwear may exacerbate some of the issues surrounding concerns with cosmesis that are already demonstrated by children with foot and ankle problems (Morris, Liabo, Wright, & Fitzpatrick, 2007). One avenue of future research could therefore focus on the design of a range of footwear that meets certain cosmetic requirements but also provides facility to alter the properties of the footwear as required.

Another consideration relates to the time and resources required to implement a tuning procedure. An AFO-FC tuning process will require 2D or 3DGA system which raises issues such as initial cost and physical space requirements. The cost of these motion capture systems have reduced significantly and are now less dependent on technical support. For example, a 6 camera system can now be purchased for US$6000 (http://www.naturalpoint.com/optitrack/products/motion-capture/). There are ongoing costs associated with the time required to tune each child that must also be considered. While it is relatively feasible for even small orthotic facilities to purchase and use these motion capture systems, substantial evidence demonstrating the benefit from AFO-FC tuning remains essential. In the interim, investigations into each component of the process are essential not only in working toward such a goal but also to provide insight for clinicians into the effect of their interventions.

9.4 Future avenues of research

9.4.1 What is the effect of heel and sole modifications on gait?

There are many avenues of research in this area that have been identified throughout this thesis. First and foremost there is a clear need to determine the effect of heel and sole modifications on gait in children with CP. Similar protocols to those used in this thesis could be employed to investigate the effect of different types of heel profiles and different types of sole designs to provide the full complement of information required to understand the AFO-FC tuning process. Once the effects of these interventions are known, the effect of the combined three stage tuning process can be investigated.

9.4.2 What is the effect of AFO-FC alignment on other domains of the ICF?

The experimental study in this thesis focussed on the effect of AFO-FC alignment on biomechanical variables during straight line level walking in a laboratory setting. Measurement of gait can be considered part of the 'body functions' domain of the framework outlined by the International Classification of Functioning, Disability and Health (ICF) (World Health Organisation, 2001). Future work should consider other domains of the ICF, which include body structures, activities and participation. There are suggestions that tuning might provide active stretching to muscles (Owen*, et al.*, 2004) or permanent motor learning (Butler*, et al.*, 1997; Butler*, et al.*, 1992) which both relate to changes in body structures, however neither of these suggestions are supported by scientific evidence. No studies have yet examined whether AFO-FC alignment or the AFO-FC tuning process have any effect on other activities such as balance, or on outcomes related to participation and quality of life.

9.4.3 What is the effect of AFO-FC alignment on other populations?

While this thesis focussed on children with CP, similar protocols could be applied to other populations, such as adults with post stroke hemiplegia or children with spina bifida to determine the effect of AFO-FC alignment on gait. It is likely that the systematic changes observed in children with CP will be similar to other populations who also wear solid AFOs but this should be verified by additional investigations.

9.4.4 How does AFO rigidity vary across different clinical settings?

The model for measuring kinematics of the AFO, tibia and footwear in 3DGA could be applied to any population wearing solid AFOs to assess how well these devices are performing. Comparisons could be made across different pathological populations, across different AFO designs, across different clinicians, facilities or geographical locations. The results of this thesis suggest that a significant factor in the degree of AFO flexion is simply the weight of the patient, rather than inherent variation across different AFOs. Various design and material changes can be used to stiffen the device. These include use of different materials (carbon fibre instead of plastic), more anterior trimlines at the ankle, reinforcements around the ankle and use of an ankle strap to provide tension in the mediolateral direction. Studies utilising mechanical testing provide some evidence that modifying these design features affects the stiffness of the device (eg. Bregman*, et al.*, 2009; Major*, et al.*, 2004; Sumiya*, et al.*, 1996). These variables have not been investigated in a dynamic setting which may produce different results due to factors such as rotational and translational forces occurring in other planes. Future research could examine the effect of these variables on the rigidity of the AFO, or could focus on the type of strap design that best restrains the tibia. Based on these findings new protocols for the choice of material and/or thickness of solid AFOs could be implemented that would help orthotists provide AFOs which are sufficiently rigid to withstand body weight.

9.4.5 What is the effect of poor fitting footwear?

Similar avenues of research could be pursued with regard to the movement of footwear on the AFO footpiece. While the results of this thesis suggest that footwear movement was limited to an average of 2° (SD 1°, range 1-3°) this is probably an underestimation of total ROM because the footwear was wrapped with elastic adhesive bandage to secure the external wedges to the shoe. Footwear is arguably more likely to move on an AFO than on a bare limb because of the limitations of ankle movement and the smooth plastic around the heel. If movement of footwear can be quantified, for example in the stroke population, there is potential for larger scope projects to examine the relationship between the fit of footwear and falling in at-risk populations.

9.5 Overall conclusions

The aim of the thesis was to investigate the effect of AFO-FC sagittal plane alignment on the gait of children with CP. This aim has been fulfilled with the main conclusions from the investigations in this thesis listed below:

- The degree to which AFO-FC alignment was reported and thus appreciated in the wider body of literature was found to be poor. Sample homogeneity and reporting AFO detail were also not well addressed. Best practice reporting guidelines were generated which if used, will enable more consistent reporting and permit a transparent assessment of study quality thereby improving the potential to combine results of several smaller studies using meta-analyses.

- All limbs were found to be responsive to AFO-FC alignment change according to change in knee moment over mid-stance. Solid AFOs were more sensitive to a change in AFO-FC alignment than hinged AFOs, as were limbs conforming to the common knee kinematic pattern.

- Changing AFO-FC alignment was found to produce systematic changes in a range of gait variables distal to and including the knee joint. Within the solid AFO group there was evidence suggesting that the strength of changes across these variables varied according to different types of gait patterns. In limbs that were relatively extended (the common knee kinematic pattern), peak knee flexion moment and angle tended to increase and peak knee extension moment and angle tended to decrease, with increased tibial projection angle and reduced ankle moments. In more flexed limbs the same changes occurred in knee and ankle kinetics but changes to knee kinematics and tibia projection angles were more varied. These same patterns of change were observed in the hinged AFO group but were less consistent than the solid AFO group. Hip kinematics, kinetics, femur projection angles, peak knee flexion in swing, walking velocity, cadence and stride length did not change systematically across either group.

- An optimum AFO-FC alignment could be identified according to the wedge size that best normalised knee kinematics, knee kinetics, tibial kinematics and ankle kinetics over mid-stance, for the majority of limbs. However, only two of the 27 limbs had perfect agreement across these variables on optimal wedge size while half had good agreement. An optimum wedge size was less apparent in terms of temporospatial parameters and subjective preference.

- When the optimal SVA could be estimated it was found to vary according to gait pattern within the solid AFO group, but in the hinged AFO group was variable. Across both groups changes in knee kinematics tended to agree with changes in knee kinetics regardless of gait pattern. This suggests that changing the AFO-FC alignment does not permit normalisation across a range of variables, and that there must be a prioritisation of the most important variable to address.

- A new model based on *PlugInGait* (PiG) and static calibration was designed to overcome inaccuracies in the PiG model due to STA of the knee marker as well as measure the individual kinematics of the AFO, the tibia within the AFO, and the footwear. While discrepancies in the measurement of ankle kinematics was strongly related to knee kinematics and thus can be attributed to STA of the knee marker, the net effect on total ankle ROM was small (1.5°). At specific instances during the gait cycle there were larger discrepancies of up to 7°. The main cause of increased ankle ROM was flexion of the AFO (up to 13°) which increased with bodyweight but tibial movement was limited to approximately 4° and shoe movement to 3°.

This thesis presents the first investigation into the effect of systematic AFO-FC alignment change on gait in children with CP. The biomechanical changes that can be induced by variations in AFO-FC sagittal plane alignment have been described across two types of AFO designs and according to gait pattern. This work addresses a significant gap in the body of literature as it provides evidence that AFO-FC alignment can be manipulated to produce specific biomechanical effects but that some of these may be improvements to gait and others may be detrimental.

The new approach for measuring AFO kinematics in 3DGA can be used in research and clinical settings to obtain a more accurate measurement of ankle kinematics as well as measure AFO flexion, tibial and footwear movement. This approach improves our understanding of the accuracy of 3DGA and of how solid AFOs behave in a dynamic context. It may be applied in a variety of clinical and research settings to guide decision making regarding the efficacy of interventions. It is hoped that the knowledge gained from this work can be used to improve gait and ultimately functional outcomes and quality of life in this, and in other populations.

Appendices

Appendix A: Systematic review publication

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informa
healthcare

A systematic review to determine best practice reporting guidelines for AFO interventions in studies involving children with cerebral palsy

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Abstract
Studies which have examined the effects of ankle-foot orthoses (AFOs) on children with cerebral palsy (CP) often report insufficient detail about the participants, devices and testing protocols. The aim of this systematic review was to evaluate the level and quality of detail reported about these factors in order to generate best practice guidelines for reporting of future studies. A systematic search of the literature was conducted to identify studies which examined any outcome measure relating to AFO use in children with CP. A customized checklist was developed for data extraction and quality assessment. There was substantial variability in the level and quality of detail reported across the 41-paper yield. Many papers reported insufficient detail to allow synthesis of outcomes across studies. The findings of this review have been used to generate guidelines for best practice of reporting for AFO intervention studies. It is important to ensure homogeneity of gait pattern in a subject sample or to subdivide a sample to investigate the possibility that heterogeneity affected results. It is also important to describe the orthosis in sufficient detail that the device can be accurately replicated because differences in designs have been shown to affect outcomes. These guidelines will help researchers provide more systematic and detailed reports and thereby permit future reviewers to more accurately assess both the reporting and quality of orthotic interventions, and will facilitate synthesis of literature to enhance the evidence base.

Keywords: *Ankle-foot orthosis; cerebral palsy; systematic review; reporting guidelines*

Introduction

Cerebral palsy (CP) describes a group of permanent disorders of the development of movement and posture, causing activity limitation.[1] The resulting lower limb muscle imbalances, deformities and gait abnormalities are often managed by ankle-foot orthoses (AFOs). The evidence-base for the use of AFOs in children with CP has been repeatedly described as low quality.[2–4] These conclusions and recommendations for improvement are

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largely based on general methodological construct and minimising study bias, which were assessed using tools such as Sackett's Level of Evidence[5] or the PEDro scale.[6]

Writing recently in the *British Medical Journal*, however, Herbert and Bo have argued that equally important in ensuring high quality research is the quality of the intervention itself.[7] This conclusion is also implicit in the recent publication in the *Annals of Internal Medicine* of an extension of the CONSORT statement to trials of non-pharmocologic treatment,[8] and is evident in the work done by the Equator Network (http://www.equator-network.org).

Whether or not the AFO intervention has been administered in a way which is reliable, valid and clinically relevant, will affect the confidence that can be had in the study's findings and the degree to which the results are considered generalizable. Assessment of intervention quality relies on sufficient detail and transparency in trial reports.[7] Several authors have noted variable depth and breadth of detail provided by studies within the body of orthotic literature.[2,3,9] While there are general guidelines for reporting of intervention detail in randomized and non-randomized trials (e.g., the CONSORT statement,[8,10,11] and the TREND statement[12]), there are currently no guidelines recommending the specific detail that should be reported in AFO intervention studies.

This is thus the first review to focus specifically on the level and quality of detail reported by AFO intervention studies on children with CP, about the participant samples, AFO interventions and testing protocol. It was anticipated that by focussing on examples of good practice within the literature, it would be possible to derive best practice guidelines for reporting of research in this area. These guidelines will improve the detail reported by future work and thereby the quality of this evidence-base.

Methods

Search strategy

An electronic search of the literature was conducted by one reviewer (ER) in April 2009 using the following databases: MEDLINE (1966–April 2009), CINAHL (1982– April 2009), RECAL legacy database (1991–2009), EMBASE (1988–2009 week 17), AMED (1985–April 2009), INSPEC (1987–April 2009), ISI Web of Knowledge (sci-expanded, SSCI, A&HCI), Informit Databases (with the sub-selection of health, technology, science, engineering; 1998–2009), the Cochrane Database of Systematic Reviews (1991–April 2009) and the Physiotherapy Evidence Database (PEDro). Medline was also accessed using the internet (PubMed). Databases were searched from database inception with no *a priori* exclusions, restrictions or limits. Reference lists from the relevant identified papers were also searched manually.

A search using MESH terms and free text words was performed using the search terms related to "cerebral palsy", "child", "adolescent", "orthosis", "brace" and "AFO". Relevant truncation or wildcard symbols were used to retrieve all possible suffix variations of a root word. An example of the search strategy: (1) "cerebral pals$"; (2) "child$" or "adolescen$"; (3) "orthos$" or "orthot$" or "brace" or "AFO"; (4) Combine 1 AND 2 AND 3.

Inclusion criteria

Studies were included if they evaluated any outcome measure relating to AFO use in children or adolescents (aged 6–18 years) who had a primary diagnosis of CP. Only full papers from peer reviewed journals which were published in English were eligible for inclusion. As only experimental work was of interest, systematic reviews were excluded as were Level IV and V studies (case studies or opinion pieces).[5]

An AFO is defined as an external supportive device which encompasses the ankle joint and the whole or part of the foot.[13] This review limited inclusion to AFOs designed to control unwanted ankle movement by use of physical application of force through a three point pressure system. Therefore, studies of non-rigid AFOs such as elastic wrap or lace up ankle braces, Lycra garments and supramalleolar orthoses were excluded. Studies which examined any of these devices in addition to other AFOs which matched the inclusion criteria were included. Because the term "dynamic ankle foot orthosis (DAFO)" is used ambiguously, devices so named were initially included and later excluded if further examination indicated that the devices were supramalleolar orthoses.

Data extraction and quality assessment

The title and abstract of each study identified from the search was assessed by one reviewer (E. Ridgewell) for inclusion or exclusion from the review. All papers that were initially discarded were checked by the second reviewer (F. Dobson) to ensure no papers had been accidentally excluded. Any paper initially included which upon full reading did not meet the inclusion criteria, was later excluded.

A customized quality checklist was used to conduct a systematic assessment of evidence quality. As no standardized or validated quality checklists were available for this type of review, a new checklist was designed which combined data extraction and quality assessment (Table I). Past literature reviews and studies in this area[2,3,9,14] and in other areas of orthotic management,[15–17] ISPO consensus conference documents,[4,18] systematic review and checklist guidelines[6,19–24] as well as examples of customized quality checklists previously used in other systematic reviews,[25–27] were used to guide design.
There were three major themes to the checklist:

(1) *Participant details*. This included reporting of topographical diagnosis, age, ankle, hip and knee passive joint range of motion (ROM) and the description of a common abnormality/indication within the group regarding a pattern of ankle, knee and hip movement.
(2) *AFO details*. This included reporting of the orthotic aim, descriptions of movements permitted, prevented and assisted, AFO ankle angle, toe plate length, material type and thickness, AFO tuning, final AFO shank-to-vertical angle and whether the AFOs were described as custom made or prefabricated. The AFO shank-to-vertical angle is the angle between the lower leg and vertical while standing in the AFO. It is measured as the angle between the vertical and a line joining the knee joint centre and lateral malleolus in the sagittal plane.[28]
(3) *Testing protocol*. This included reporting of the control and test conditions, and details regarding randomization and acclimatization.

Both reviewers (E. Ridgewell; F. Dobson) piloted the data extraction and quality assessment form independently on a sub-group of papers to check the form content and reliability. Inter-rater agreement on full consensus items was 81%. The draft checklist was altered accordingly to provide improved clarity and instruction. Following independent review of all papers by both reviewers all non-consensus items were discussed until a consensus was reached. Any discrepancies were investigated using the original article to ascertain the

Table I. Customized data extraction and quality checklist.

(Item)	(Choose response)	(Record details)
Participant details		
Age	Complete/incomplete	Mean, SD, range
Diagnosis	Complete/incomplete	Topographic
Common deviation at ankle?	Clear/ambiguous/not stated/na	
Common deviation at knee?	Clear/ambiguous/not stated/na	
Common deviation at hip?	Clear/ambiguous/not stated/na	
Passive ankle (gastroc) ROM	Individual/group/inclusion criteria/not stated	
Passive knee ROM	Individual/group/inclusion criteria/not stated	
Passive hip ROM	Individual/group/inclusion criteria/not stated	
AFO detail		
Orthotic aim	Clear/ambiguous/not stated/other	
Movements	Complete (all clear)/incomplete (some or all unclear)	Assisted, prevented and permitted
AFO ankle angle	Specified for individual/group/ambiguous/ not stated/other	Ankle angle in AFO
Toe plate length	All clear/some clear/all ambiguous	Full length or $\frac{3}{4}$
Materials	Complete/partial/not stated/na	Material and thickness
Manufacture	Custom made/prefabricated/not stated	
If prefab, is device name & supplier listed?	Yes/no	
Tuning	Complete/partial/not stated/na	Tuned? Details?
Shank-to-vertical angle	Complete/partial/not stated/na	Final value
Testing protocol		
Order of testing	Randomized/non-randomized/not stated/na	
Acclimatization	<1 day, 1–6 days, 1–4 weeks, >4 weeks/not stated/na	
Control condition	Barefoot/shoes/not stated	
Test condition	Clear/ambiguous/not stated	

Note: Each quality item had detailed pre-determined qualifiers to allow objective categorization for each response.

correct response based on the objective *a priori* decision rules. Full consensus was reached on all items.

Results

The electronic search of selected databases identified 374 articles as having possible relevance to the use of AFOs in children with CP. Targeted searching of relevant on-line journals revealed 55 articles which were all later discarded as duplicates. After applying the inclusion criteria, 41 full papers were included in the review.

Demographics

Table II outlines the study details and demographics including participant diagnosis, number of participants, intervention, control, study design and primary activity/outcome examined. The total yield was published across 17 journals. A total of 1201 children with CP were examined over a period of 38 years with the majority of articles published after 1995. Eleven different devices or device designs were examined. The majority of studies examined gait while walking on a level surface. More studies examined diplegic children than hemiplegic children.

Table II. Demographic and descriptive aspects of all studies.

Authors	Diagnosis	*n* =	Intervention	Control	Study design			Activity/outcome
Rosenthal et al. 1975[55]	Not stated	12	GRAFO	BF	retrospective	longitudinal	case control	Genu recurvatum
Simon et al. 1978[38]	Hemiplegia & diplegia	15	SAFO	BF	prospective	cross sect	case control	Genu recurvatum
Sankey et al. 1989[63]	Hemiplegia	29	SAFO	n/a	retrospective	cross sect	cohort/population	Surgery rates
Mossberg et al. 1990[64]	Diplegia	18	AFOs on vs. AFOs off	unknown	prospective	cross sect	case control	Level walking
Butler et al. 1992[36]	Hemiplegia & diplegia	21	SAFO	BF	prospective	cross sect	case control	Genu recurvatum
Ounpuu et al. 1996[65]	Hemiplegia & diplegia	31	PLS	BF	retrospective	cross sect	case control	Level walking
Carlson et al. 1997[66]	Diplegia	11	SAFO	shoes	prospective	cross sect	case control	Level walking
Hainsworth et al. 1997[67]	Hemiplegia & diplegia	12	AFOs on vs. AFOs off	BF	prospective	longitudinal	case control	AFO withdrawal
Radkta et al. 1997[68]	Hemiplegia & diplegia	10	SAFO, short leg AFO+ TRF	BF	prospective	cross sect	case control	Level walking
Wilson et al. 1997[57]	Diplegia	15	SAFO, HAFO	BF	prospective	cross sect	case control	Sit-stand
Abel et al. 1998[30]	Diplegia	35	SAFO	BF	retrospective	cross sect	case control	Level walking
Brunner et al. 1998[40]	Hemiplegia	14	SAFO, spring type AFO	BF	prospective	cross sect	case control	Level walking
Burtner et al. 1999[69]	Diplegia	4	SAFO, carbon spiral AFO	unknown	prospective	cross sect	case control	Standing balance
Rethlefsen et al. 1999[42]	Diplegia	21	SAFO, HAO	shoes	prospective	cross sect	case control	Level walking
Crenshaw et al. 2000[70]	Diplegia	8	HAFO, HAFO + TRF	shoes	prospective	cross sect	case control	Level walking
Suzuki et al. 2000[71]	Diplegia	6	HAFO	unknown	prospective	cross sect	case control	Level walking
Beals 2001[72]	Not stated	4	SAFO	BF	prospective	cross sect	case control	Trunk posture
Buckon et al. 2001[31]	Hemiplegia	30	SAFO, HAFO, PLS	BF	prospective	cross sect	case control	Level walking
Maltais et al. 2001[73]	Diplegia	10	HAFO	shoes	prospective	cross sect	case control	Level walking
Dursun et al. 2002[74]	Hemiplegia & diplegia	24	Unknown	BF	prospective	cross sect	case control	Level walking
Kott & Held 2002[75]	Mixed	28	orthoses on vs. orthoses off	unknown	prospective	cross sect	case control	Obstacle course
Romkes & Brunner 2002[50]	Hemiplegia	12	HAFO	BF	prospective	cross sect	case control	Level walking
Sienko-Thomas et al. 2002[45]	Hemiplegia	19	SAFO, HAFO, PLS	BF	prospective	cross sect	case control	Stair climbing
Smiley et al. 2002[44]	Diplegia	14	SAFO, HAFO, PLS	shoes	prospective	cross sect	case control	Level walking
Thompson et al. 2002[32]	Hemiplegia	18	SAFO	BF	prospective	cross sect	case control	Level walking
White et al. 2002[76]	Hemiplegia & diplegia	115	SAFO or HAFO*	BF	retrospective	cross sect	case control	Level walking
Wesdock & Edge 2003[49]	Mixed	11	SAFO, wedged AFO	shoes	prospective	cross sect	case control	Standing balance
Buckon et al. 2004[41]	Diplegia	16	SAFO, HAFO, PLS	BF	prospective	cross sect	case control	Level walking
Park et al. 2004[77]	Diplegia	19	HAFO	BF	prospective	cross sect	case control	Sit-stand

(*continued*)

Table II. (*Continued*).

Authors	Diagnosis	n=	Intervention	Control	Study design			Activity/outcome
Lam et al. 2005[56]	Diplegia	13	SAFO	BF	prospective	cross sect	case control	Level walking
Radtka et al. 2005[43]	Diplegia	12	SAFO, HAFO	BF	prospective	cross sect	case control	Level walking
Desloovere et al. 2006[9]	Hemiplegia	15	PLS, CFO	BF & shoes	prospective	cross sect	case control	Level walking
Romkes et al. 2006[37]	Hemiplegia	10	HAFO	BF	prospective	cross sect	case control	Level walking
Balaban et al. 2007[78]	Hemiplegia	11	HAFO	BF	prospective	cross sect	case control	Level walking
Butler et al. 2007[54]	Mixed	6	SAFO	n/a	retrospective	cross sect	cohort	Group analysis
Hayek et al. 2007[79]	Hemiplegia & diplegia	56	community prescribed AFOs	BF	retrospective	cross sect	case control	Level walking
Lucareli & Lima 2007[35]	Diplegia	71	hinged GRAFO	BF	retrospective	cross sect	case control	Level walking
Westberry et al. 2007[80]	Mixed	102	Unknown	BF	retrospective	cross sect	case control	Bony alignment
Brehm et al. 2008[81]	Mixed	172	SAFO or PLS	BF	retrospective	cross sect	case control	Level walking
Smith et al. 2009[29]	Diplegia	15	HAFO, dynamic AFO	BF	prospective	cross sect	case control	Level walking
Van Gestel et al. 2008[39]	Hemiplegia	36	PLS, CFO, orteams	BF	retrospective	cross sect	case control	Level walking

HAFO, hinged AFO with plantarflexion stop; PLS, posterior leaf spring; GRAFO, ground reaction AFO; SAFO, solid AFO; CFO, carbon fibre orthosis; TRF, tone reducing features; BF, barefoot.

Participant details

Table III provides a summary of the data extraction and quality outcomes across all studies. Table IV provides an overview of the responses of all studies to each item on the data extraction and quality assessment checklist.

Topographical diagnosis and participant age were well reported. More studies provided information on passive ankle ROM (23/41) than knee (11/41) and hip ROM (10/41). Nineteen of the 41 studies made a clear attempt at describing a common pattern of abnormality or indication that was demonstrated by all participants. One study[29] clearly described a homogenous gait characteristic demonstrated by all participants. A homogenous mode of ankle movement was described most frequently (14/41), followed by knee movement (10/41) and three papers described a common pattern of hip movement.

AFO detail

Seventeen studies clearly stated the aim of the AFO intervention. A clear description of the type of AFO intervention was provided by most studies (35/41), as were clear descriptions of the movements prevented, assisted or permitted by the AFO. Sixteen studies clearly stated the AFO ankle angle. Nineteen studies gave clear descriptions of toe plate length for all devices tested. In some cases it was necessary to infer this information from photographs or diagrams. A full-length toe plate was used more often (18/41) than $\frac{3}{4}$-length toe plate (4/41). Ten papers provided complete detail on both material type and thickness, and eight more papers provided partial information.

Five studies reported that the AFOs were tuned prior to testing. One study provided the final shank-to-vertical angle of the AFOs tested and two provided partial information. Custom made devices were most commonly tested (18/41). Three studies tested prefabricated devices with the name of the device and supplier provided by one study. The remaining 20 studies did not state whether the device was custom made or prefabricated.

Testing protocol

More studies used a randomized order of testing (16/41) than non-random (12/41). The remaining studies either did not report this information or the item was not applicable. Twenty studies tested unfamiliar devices. Across these studies the acclimatization times ranged from less than one day (2/20), 1–4 weeks (4/20) or greater than four weeks (8/20). Most studies clearly stated the control condition with barefoot being the most common (28/41), followed by shoes (6/41) and both barefoot and shoes (1/41). The test condition was clearly stated in most studies.

Discussion

This review identified 41 full papers which examined the effect of AFO use on a diverse range of outcome measures in children with CP. In line with the conclusions of previous reviewers,[2,3] there was considerable variety in the level and quality of detail reported. In many cases this limits any assessment of intervention quality and the impact this may have on confidence in the findings. This variability also reduces the potential for meta-analyses to summarize results across studies to provide more substantial evidence of treatment practices. Incomplete reporting of data further reduces the potential to combine results across studies.

Table III. Results of data extraction and quality outcomes for all studies.

Participant details					AFO details						Testing protocol		
Authors	Age	Diagnosis	Common attribute	Passive ROMs	Orthotic aim	AFO movement	AFO ankle angle	Toe plate length	Materials	Alignment	Prefab or custom?	Randomized testing order?	Acclimatization time
Rosenthal et al. 1975[55]	–	–	K	–	clear	complete	ambiguous	–	ambiguous	T?SVA?	custom	n/a	n/a
Simon et al. 1978[38]	complete	complete	A, K	H	clear	complete	ambiguous	–	–	–	?custom	no	n/a
Sankey et al. 1989[63]	–	complete	–	–	–	complete	ambiguous	FL & $\frac{3}{4}$	–	–	?custom	–	n/a
Mossberg et al. 1990[64]	complete	complete	–	–	–	–	–	–	–	–	–	yes	n/a
Butler et al. 1992[36]	complete	complete	A, K	A, K, H	clear	complete	–	–	–	T?	–	n/a	1–4 wks
Ounpuu et al. 1996[65]	complete	complete	–	–	clear	complete	–	full length	–	–	custom	no	n/a
Carlson et al. 1997[66]	complete	complete	ambiguous	–	clear	complete	–	–	–	–	–	yes	> 4 wks
Hainsworth et al. 1997[67]	complete	complete	–	A	–	complete	complete	–	–	–	–	n/a	1–4wks
Radkta et al. 1997[68]	complete	complete	A	A, K, H	clear	–	–	full length	complete	–	custom	no	> 4wks
Wilson et al. 1997[57]	complete	complete	A	A, K, H	clear	complete	complete	full length	complete	–	custom	yes	< 1 day
Abel et al. 1998[30]	complete	complete	A	A	clear	complete	ambiguous	–	ambiguous	–	–	no	n/a
Brunner et al. 1998[40]	complete	complete	A, K?	–	clear	complete	–	–	ambiguous	–	custom	no	–
Burtner et al. 1999[69]	–	complete	–	A, K, H	ambiguous	complete	–	–	ambiguous	–	X prefab	–	–
Rethlefsen et al. 1999[42]	complete	complete	–	A, K, H	ambiguous	complete	?	–	–	–	custom	yes	–
Crenshaw et al. 2000[70]	complete	complete	–	A	–	complete	complete	full length	ambiguous	–	custom	–	> 4wks
Suzuki et al. 2000[71]	complete	complete	–	A	clear	complete	complete	full length	ambiguous	–	prefab	–	–
Beals 2001[72]	–	–	ambiguous	–	clear	complete	complete	–	–	–	–	no	n/a
Buckon et al. 2001[31]	complete	complete	K*	A	–	complete	complete	full length	complete	–	custom	yes	> 4wks
Maltais et al. 2001[73]	complete	complete	–	–	–	complete	complete	–	–	–	–	yes	n/a
Dursun et al. 2002[74]	complete	complete	A	A	clear	–	–	–	–	–	–	–	n/a
Kott & Held 2002[75]	complete	complete	–	–	–	–	–	–	–	–	–	yes	n/a
Romkes & Brunner 2002[50]	complete	complete	A	A, K	–	complete	–	full length	–	–	–	–	1–4wks
Sienoko-Thomas et al. 2002[45]	complete	complete	–	–	–	complete	complete	–	–	–	custom	yes	> 4wks
Smiley et al. 2002[44]	complete	complete	ambiguous	A	–	complete	–	$\frac{3}{4}$ & ?	complete	–	custom	–	< 1day
Thompson et al. 2002[32]	complete	complete	A, K	–	other	complete	ambiguous	$\frac{3}{4}$?	complete	–	custom	no	n/a
White et al. 2002[76]	complete	complete	–	A	–	complete	–	FL & $\frac{3}{4}$	complete	–	?custom	no	n/a
Wesdock & Edge 2003[49]	complete	complete	K	A, K, H	clear	complete	complete	–	–	–	–	yes	1–4 wks
Buckon et al. 2004[41]	complete	complete	–	A	–	complete	complete	full length	complete	–	custom	yes	> 4wks
Park et al. 2004[77]	complete	complete	–	A, K, H	–	complete	complete	full length	ambiguous	–	–	yes	n/a
Lam et al. 2005[56]	complete	complete	ambiguous	–	ambiguous	complete	complete	full length	complete	SVA?	custom	yes	?
Radtka et al. 2005[43]	complete	complete	A	A, K, H	clear	complete	complete	full length	complete	–	custom	yes	> 4wks
Desloovere et al. 2006[9]	complete	complete	–	–	clear	complete	–	full length	–	T?SVA?	custom	yes	–

(*continued*)

Table III. (*Continued*).

Participant details					AFO details						Testing protocol		
Authors	Age	Diagnosis	Common attribute	Passive ROMs	Orthotic aim	AFO movement	AFO ankle angle	Toe plate length	Materials	Alignment	Prefab or custom?	Randomized testing order?	Acclimatization time
Balaban et al. 2007[78]	complete	complete	A	A	ambiguous	complete	complete	full length	–	–	custom	yes	n/a
Butler et al. 2007[54]	complete	complete	K	A, K, H	other	complete	–	–	–	T?	–	–	n/a
Hayek et al. 2007[79]	complete	complete	–	–	–	–	–	–	–	–	–	no	n/a
Romkes et al. 2006[37]	complete	complete	A, K	A	–	complete	complete	full length	–	SVA	–	probably not	n/a
Lucareli & Lima 2007[35]	complete	complete	K	A, K, H	clear	complete	–	–	–	–	?custom	probably not	n/a
Westberry et al. 2007[80]	complete	complete	–	–	–	–	–	–	–	–	–	no	n/a
Brehm et al. 2008[81]	complete	complete	–	–	–	complete	–	–	–	–	custom	no	n/a
Van Gestel et al. 2008[39]	complete	complete	A, K	–	clear	complete	–	full length	ambiguous	T?SVA?	X prefab	no	n/a
Smith et al. 2009[29]	complete	complete	A, K, H	A	other	complete	complete	full length	complete	–	custom	yes	> 4wks

–, incomplete or not stated; A, ankle, K, knee, H, hip; *by sub-group analysis; ROM at ankle refers to gastroc ROM; x, details incomplete; FL, full length; T, tuned; SVA, shank-to-vertical angle.

Table IV. Summary of responses to each quality item.

Item	Response	Number of studies	
Participant details			
Age	Complete	36	9,29–32,35–45,49,50,54,56,64–68,70,71,73–81
Diagnosis	Complete	39	1,9,29–32,35–41,43–45,49,50,54,56,57,63–71,73–81
Common indication at ankle	Clear	14	29,30,32,36–40,43,50,57,68,74,78
Common indication at knee	Clear	10	29,31,32,35,36,38–40,49,54
Common indication at hip	Clear/ambiguous	3	36,56,64
Passive ankle ROM (gastroc)	Complete	23	29–31,35–37,41–44,49,50,54,57,67–71,74,76–78
Knee ROM	Complete	11	35,36,42,43,49,50,54,57,68,69,77
Hip ROM	Complete	10	35,36,42,43,49,54,57,68,69,77
AFO detail			
Orthotic aim	Clear	17	9,30,35,36,38–40,43,49,55,57,65,66,68,71,72,74
	Other	3	29,32,54
Movements	Complete	35	9,29–32,35–45,49,50,54–57,63,65–67,69–73,76–78,81
AFO ankle angle	Clear	16	29,31,37,41,43,45,49,56,57,67,70–73,77,78
Toe plate length	Full length	16	9,29,31,37,39,41,43,50,56,57,65,68,70,71,77
	Different lengths (clear or ambiguous)	4	32,44,63,76
Material & thickness	Complete	10	29,31,32,41,43,44,56,57,68,76
	Partial	8	30,39,40,55,69–71,77
Manufacture	Custom	18	9,29,31,32,40–45,55–57,65,68,70,78,81
	Prefab. without detail	2	39,69
	Prefab. with detail	1	71
Tuning	Tuned	5	9,36,39,54,55
Shank-to-vertical angle	Clear/ambiguous	5	9,37,39,55,56
Testing protocol			
Order of testing	Randomized	16	9,29,31,41–43,45,49,56,57,64,66,73,75,77,78
	Non randomized	12	30,32,38–40,65,68,72,76,79–81
	Not applicable	3	54,55,67
Acclimatization	< 1 day	2	44,57
	1–4 weeks	4	36,49,50,67
	> 4 weeks	8	29,31,41,43,45,66,68,70
	Not applicable	21	30,32,35,37–39,54,55,63–65,72–81
Control condition	Barefoot	28	29,30,32,35–40,43,45,50,55–57,65,67,68,72,74,76–81
	Shoes	6	42,44,49,66,70,73
	Barefoot & shoes	1	9
	Not applicable	2	54,63
Test condition	Clear	35	5,9,29–32,35–45,49,50,54–57,63–66,68–73,77,78,81

All unlisted papers were categorized as either ambiguous or not stated.

There were, however, sufficient examples of good quality interventions to enable best practice guidelines for future studies to be derived. These are discussed in full below and the recommendations for reporting of detail for AFO intervention studies are summarized in Table V.

Participant details

In a number of studies in which participants were subdivided according to gait pattern, differences in outcomes between the sub-divisions were observed. Abel and

Table V. Best practice guidelines for reporting AFO intervention studies.

Sample homogeneity	
Orthotic aim	Report sample homogeneity with regard to indication for orthotic treatment.
Age	State range (years).
Diagnosis	Specify movement disorder, topographical distribution and GMFCS level.
Gait pattern	Focus on one particular gait pattern or sub-divide into different gait patterns. Describe using published gait classification systems or specify ankle, knee and hip posture in relevant planes.
AFO details	
Suitability	State orthotic aim and suitability of orthoses for the physical characteristics of the participants.
Movements	Describe the movements assisted, prevented, permitted by the AFO.
AFO ankle angle	Report the angle of the ankle in the AFO.
Materials	Report material type and thickness.
Trimlines	Report trimlines (including toe plate length and flexibility).
Tuning	Report whether AFOs were tuned, and the tuning procedure (what was done, the decision parameters used).
Shank-to-vertical angle	Report final shank-to-vertical angle of AFO and footwear combination.
Mechanical properties	If possible, quantify the mechanical properties of the AFO (stiffness and neutral position at the ankle and metatarsophalangeal joints)
Manufacture	Describe the manufacture as custom (same or different moulds?) or prefab (device name, supplier).
Testing protocol (specific to studies investigating AFOs)	
Control	Clearly state the control condition. Note that comparisons with barefoot may over estimate the effect of the orthosis by including a contribution from the shoe.
Order of testing	State the order of testing. Use a randomized order or provide a return to baseline measurement wherever possible.
Acclimatization	State acclimatization time.

colleagues[30] found differences in the effect of a solid AFO on the gait of children with either equinus or plano-valgus feet.[30] Buckon and colleagues[31] found that normalization of knee motion was dependent upon the position of the knee during stance while barefoot, as well as the type of AFO. Thompson and colleagues[32] observed that responses varied in hemiplegic children with different Winters, Gage and Hicks (WGH)[33] gait classifications. Significant changes were found for the groups with Type I and Type II gait patterns, but not Type III.

Given these differences in outcomes according to the type of AFO tested and underlying gait pathology, it is clear that studies should focus on participant groups which exhibit some degree of homogeneity with regard to gait pattern, or should sub-divide groups to investigate the possibility that heterogeneity affected the results. At a minimum, this sub-division could include participant age, nature of the movement disorder, topographical distribution and GMFCS[34] level, but ideally would include a description according to a gait classification system. In a study of the effects of AFOs, it could be argued that homogeneity in the orthotic aim, the basis of which is largely dependent on gait pattern, is equally important.

There are good examples of studies which focused either on participants with a particular gait pattern[29,30] or sub-divided participants on the basis of gait pattern.[31,32,35] Several other studies ensured homogeneity by describing knee and ankle posture either with[29,36,37,39] or without[38] reference to published gait classification systems.

AFO details

Clearly reporting the design of the AFO is essential as differences between AFO designs have been shown to produce difference in outcomes in temporospatial parameters,[40–42] ankle kinematics[9,31,41–44] and knee kinematics[31] in straight line walking, as well as stair ascent and descent.[45] No studies have examined the effect of different AFO toe-plate lengths on children with CP, however one study of post-stroke adults[46] found differences in stance phase dorsiflexion as a result of toe-plate length. Variation in the material properties used in construction of the AFO may also influence the flexibility of so called "rigid" devices at the ankle and metatarsophalangeal joints.[47]

The alignment of the AFO alone is described by the AFO ankle angle, the choice of which is based on clinical measures such as passive and dynamic gastrocnemius muscle length and tri-planar stability of the foot. Severe spasticity or contracture of this bi-articular muscle must be accommodated in the AFO ankle angle to avoid limiting maximum knee extension or compromising the tri-planar stability of the foot.[48]

Reporting passive gastrocnemius length in addition to the AFO ankle angle permits the appropriate choice of ankle angle to be confirmed. It could be argued that reporting the evidence for the choice of AFO ankle angle (e.g., passive gastrocnemius length) is unnecessary. However, there were two studies[37,49] in which reported data suggested that the choice of AFO ankle angle did not consider passive gastrocnemius length. Similarly, three studies which evaluated the effects of free dorsiflexion AFOs on children who had or may have had limited gastrocnemius length.[37,40,50] In such cases, dorsiflexion of the ankle will only occur at the expense of knee extension or compromised foot position. Similar findings have been identified in the stroke literature,[17] which suggests that reporting this information may be a reasonable proposition.

When the AFO is combined with footwear, the AFO ankle angle may no longer describe the alignment of the device relative to vertical if there is a difference in height between the heel and forefoot of the footwear (heel-sole differential). In order to overcome this limitation, the alignment of the AFO and footwear is described by the shank-to-vertical angle. Differences in footwear heel-sole differential and therefore shank-to-vertical angle have been demonstrated to affect the alignment of the ground reaction force during quiet standing[52], with suggestions that SVA can be modified to improve GRF orientation during walking.[17,28,36,48,53,54] One study[37] reported the final shank-to-vertical angle of the AFO and footwear used, which was a standardized alignment for all participants. There is however some evidence suggesting that AFOs require individual adjustment, or tuning of the shank-to-vertical angle in order to obtain optimal function.[53] While the concept of tuning is not new, it has only recently become more widely recognized which may explain why only five papers[9,36,39,54,55] reported tuning of the AFO interventions.

Most studies in this review clearly reported the movements controlled by the AFO. There are several good examples of studies which have provided excellent descriptions of the physical characteristics of the AFO interventions.[29,31,41,43,56,57] Such descriptions do not, however, account for the differences in mechanical properties arising from small variations in AFO design, such as trimline position and choice of materials e.g.[58–60] A new method of measuring the stiffness and neutral angle around the ankle and metatarsophalangeal joints has recently been described and demonstrated as reliable and clinically applicable.[58] Including such objective measurements in future clinical and research practice will improve our ability to compare AFO interventions.

To enable the quality of the AFO intervention to be more accurately assessed, future work should describe the movements prevented, assisted and permitted by the AFO, toe plate length and flexibility, trim-line position, materials and method of manufacture, AFO ankle angle, shank-to-vertical angle of the combined AFO and footwear, type of footwear worn and details of any tuning process undertaken. Testing of mechanical stiffness of the AFO and the combined AFO and footwear would further enhance objectivity. Transparent reporting permits replication of the study, and makes it possible to understand the variables that may affect intervention outcomes.

Testing protocol

All studies with the exception of one used either barefoot or shoes as the control comparison. This study[9] included both barefoot and shod conditions and found that shoes alone could have either a negative or positive effect on gait, thereby confirming findings from the stroke literature.[61] Future work should consider including both of these control conditions wherever possible to avoid attributing the effects of footwear to the AFO.

A randomized order of testing is desirable as it eliminates bias resulting from the order of testing.[21] This is particularly important in orthotic research as there are usually two or more conditions being compared over repeated trials of tasks such as walking. Use of a non-randomized order of testing introduces the risk of fatigue in the tasks performed last. Several studies used a non-randomized order of testing, which is often unavoidable in cases of retrospective analysis. Fifteen studies eliminated potential confounding series effects by randomising the testing order. A randomized order of testing should be used wherever possible, and in any event, the order of testing should be reported.

Acclimatization time to an unfamiliar device permits the novel nature of the device to be incorporated into the movement pattern thereby ensuring that the effects of the device accurately represent daily use. Many papers examined devices other than the device already worn by the participant. Most testing protocols permitted more than one week of acclimatization time. Only two studies permitted less than one day.[44,57]

Future research

Previous reviewers have suggested that the quality of this body of literature could be improved by focussing on the execution of large scale RCTs[2] or on alternate study designs which overcome some of the difficulties of RCTs, for example cross-over and one-group interrupted time-series (single subject) designs.[3] However, equally important is a more systematic and detailed approach to reporting the participant sample, the AFO intervention and testing protocol. Use of the reporting guidelines presented in Table V will enable consistent reporting and will also permit a transparent assessment of study quality thereby improving the potential to combine results of several smaller studies using meta-analyses.

This review has identified several avenues of research which could benefit from focussed attention. For example, what is the most appropriate control condition for comparison with an AFO intervention? What is the minimum acclimatization required for an unfamiliar device? Do small differences in AFO design, stiffness and alignment have a significant effect on AFO effectiveness? Answering these questions might facilitate comparison across studies already published.

These reporting guidelines are in line with suggestions arising from the recent International Society for Prosthetics and Orthotics (ISPO) consensus conferences on the orthotic management of on CP[62] and stroke.[18] The principles on which these guidelines are based may also be applied to AFO research on other populations. However, certain elements may be more relevant in CP research due to the heterogeneity seen particularly in gait patterns.

Limitations

This review focused on an assessment of reporting detail and transparency regarding the participants, AFO intervention and testing protocol. An analysis of appropriate choice of outcome measures was not included as this requires decisions about which research questions are most important. Considering the type of outcome measures employed in each study is, without doubt, essential to future metanalyses as these are only possible between studies which have examined the same outcome measures.

This review did not rank or assign quality scores to studies; rather it focussed on examples of best practice with regard to different aspects of intervention quality specific to research into the effects of AFOs for children with CP. Issues relating to effect size, power or choice of statistical analysis are well described in general literature on research methodology.

Conclusion

Assessing the quality of individual studies and using studies in quantitative research synthesis requires transparent reporting.[12] While there was considerable variety in level and quality of detail provided by these studies, there were sufficient good examples of reporting detail and intervention quality. This enabled the generation of guidelines for reporting of detail in AFO intervention studies. These guidelines should also direct the design of future investigations in this area which will improve the synthesis of quantitative research and therefore the quality of this evidence-base.

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Appendix B: Ethical Approval

The **Royal Children's Hospital** Melbourne

RCH HUMAN RESEARCH ETHICS COMMITTEE APPROVAL

HREC REF. No:	**29106 D**
PROJECT TITLE:	Can AFO alignment be optimised to improve walking in children and adolescents with cerebral palsy?
DOCUMENTS APPROVED:	Reply Slip v1 dated 23 July 2010 Cover Letter v2 dated 23 July 2010 P/GIS & Consent Form v6 dated 23 July 2010 PIS & Consent Form v6 dated 23 July 2010
PRINCIPAL INVESTIGATOR:	Morgan Sangeux
DATE OF MODIFICATION APPROVAL:	**04 August 2010**
DURATION:	13 months
DATE OF APPROVAL EXPIRY:	**29 September 2011**

SIGNED: 6/8/10
COMMITTEE REPRESENTATIVE

COMMENTS:

APPROVED SUBJECT TO THE FOLLOWING CONDITIONS:

ALL PROJECTS

1. Must comply with the Investigator's Responsibilities in Research available at http://www.rch.org.au/emplibrary/ethics/Investigators_Responsibilities_in_Research.pdf
2. Any proposed change in the protocol or approved documents or the addition of documents (including flyers, brochures, advertising material etc) must be submitted to the Human Research Ethics Committee (HREC) for approval prior to implementation.
3. The Principal Investigator must notify Ethics & Research of:
   - Any serious adverse effects of the study on participants and steps taken to deal with them.
   - Any unforeseen events (e.g. protocol violations or complaints).
   - Investigators withdrawing from or joining the project.
4. A progress report must be submitted annually and at the conclusion of the project.
5. RCH HREC approval must remain current for the entire duration of the project. If the project is not completed in the allocated time a renewal request must be submitted to the Ethics & Research Department. Investigators undertaking projects without current HREC approval risk their indemnity, funding and publication rights.

CLINICAL TRIALS

6. Must comply with Good Clinical Practice (GCP) available at http://www.tga.gov.au/docs/pdf/euguide/ich/ich13595.pdf
7. Must report all internal (occurring in RCH participants) Serious Adverse Events (SAE) to the sponsor and the RCH HREC within 72 hours of occurrence.
8. Must report all Suspected Unexpected Serious Adverse Reactions (SUSARS) to the Therapeutic Goods Administration (TGA) (for sponsored studies the sponsor may take this responsibility).

La Trobe University
Faculty of Health Sciences
MEMORANDUM

TO: Assoc Prof Tim Bach
Assoc Prof Richard Baker
Prof H Graham

National Centre for Prosthetics & Orthotics

SUBJECT: *Reference:* **FHEC09/209**

Student or Other Investigator: Emily Ridgewell

Title: **Can AFO Alignment be optimised to improve walking in children and adolescents with cerebral palsy**

DATE: 25 August, 2010

The Faculty Human Ethics Committee's (FHEC) reviewers have considered and approved the modification to the above project. You may now proceed.

Please note that the Informed Consent forms need to be retained for a minimum of 5 years. Please ensure that each participant retains a copy of the Informed Consent form. Researchers are also required to retain a copy of all Informed Consent forms separately from the data. The data must be retained until participants are 25 years old (as per external HEC requirements).

Please note that any modification to the project must be submitted in writing to FHEC for approval. You are required to provide an annual report (where applicable) and/or a final report on completion of the project. A copy of the progress/final report can be downloaded from the following website: http://www.latrobe.edu.au/rgso/forms-resources/forms/ethic-prog-final.rtf

Please return the completed form to The Secretary, FHEC, Faculty of Health Sciences Office, La Trobe University, Victoria 3086.

If you have a student/s involved in this project, a copy of this memorandum is enclosed for you to forward to the student(s) concerned.

Neil McDonald
Secretary
Faculty Human Ethics Committee
Faculty of Health Sciences

Appendix C: Projections model

This model was written by Professor Richard Baker

```
{* This model is for quality assurance purposes and calculates the projections of the segment axes onto the principal planes of the lab axis system. The angles should thus be those recorded on the sagittal and coronal plane video if the effects of parallax are accounted for.*}

OptionalPoints(PelO,PelL,PelA,LFeO,LFeP,LFeA,RFeO,RFeP,RFeA)
OptionalPoints(LTiO,LTiP,LTiA,RTiO,RTiP,RTiA,LFoO,LFoP,RFoO,RFoP)

{* Some angles depend on which way the subject is walking.*}
If PelA(1) > PelO(1)
  Progress    = 1
else
  Progress    = -1
endif

{* Pelvic angles  *}
LPelvisLat          = PelL-PelO
LPelvisAnt      = PelA-PelO
LPelvisSagAngle  = -Progress*atan(LPelvisAnt(3)/LPelvisAnt(1))
LPelvisCorAngle  = Progress*atan(LPelvisLat(3)/LPelvisLat(2))
LPelvisTraAngle  = atan(LPelvisLat(1)/LPelvisLat(2))

LPelvisProjections = <LPelvisSagAngle,LPelvisCorAngle,LPelvisTraAngle>
output(LPelvisProjections)

RPelvisLat          = PelO-PelL
RPelvisAnt      = PelA-PelO
RPelvisSagAngle  = -Progress*atan(RPelvisAnt(3)/RPelvisAnt(1))
RPelvisCorAngle  = -Progress*atan(RPelvisLat(3)/RPelvisLat(2))
RPelvisTraAngle  = -atan(LPelvisLat(1)/LPelvisLat(2))

RPelvisProjections = <RPelvisSagAngle,RPelvisCorAngle,RPelvisTraAngle>
output(RPelvisProjections)

{* Femur angles*}
LFemurUp          = LFeP-LFeO
LFemurAnt         = LFeA-LFeO
LFemurSagAngle  = -Progress*atan(LFemurUp(1)/LFemurUp(3))
LFemurCorAngle  =  Progress*atan(LFemurUp(2)/LFemurUp(3))
LFemurTraAngle  = -atan(LFemurAnt(2)/LFemurAnt(1))

LFemurProjections = <LFemurSagAngle,LFemurCorAngle,LFemurTraAngle>
output(LFemurProjections)

RFemurUp          = RFeP-RFeO
RFemurAnt         = RFeA-RFeO
RFemurSagAngle  = -Progress*atan(RFemurUp(1)/RFemurUp(3))
RFemurCorAngle  = -Progress*atan(RFemurUp(2)/RFemurUp(3))
RFemurTraAngle  =  atan(RFemurAnt(2)/RFemurAnt(1))

RFemurProjections = <RFemurSagAngle,RFemurCorAngle,RFemurTraAngle>
```

```
output(RFemurProjections)

{* Tibia angles*}
LTibiaUp         = LTiP-LTiO
LTibiaAnt        = LTiA-LTiO
LTibiaSagAngle  = Progress*atan(LTibiaUp(1)/LTibiaUp(3))
LTibiaCorAngle  =  Progress*atan(LTibiaUp(2)/LTibiaUp(3))
LTibiaTraAngle  = -atan(LTibiaAnt(2)/LTibiaAnt(1))

LTibiaProjections = <LTibiaSagAngle,LTibiaCorAngle,LTibiaTraAngle>
output(LTibiaProjections)

RTibiaUp         = RTiP-RTiO
RTibiaAnt        = RTiA-RTiO
RTibiaSagAngle  = Progress*atan(RTibiaUp(1)/RTibiaUp(3))
RTibiaCorAngle  = -Progress*atan(RTibiaUp(2)/RTibiaUp(3))
RTibiaTraAngle  =  atan(RFemurAnt(2)/RFemurAnt(1))

RTibiaProjections = <RTibiaSagAngle,RTibiaCorAngle,RTibiaTraAngle>
output(RTibiaProjections)

{* Foot angles*}
LFootUp          = LFoO-LFoP
LFootSagAngle  = Progress*atan(LFootUp(3)/LFootUp(1))
LFootTraAngle  = -atan(LFootUp(2)/LFootUp(1))
LFootProjections = <LFootSagAngle,0,LFootTraAngle>
output(LFootProjections)

RFootUp          = RFoO-RFoP
RFootSagAngle  = Progress*atan(RFootUp(3)/RFootUp(1))
RFootTraAngle  = atan(RFootUp(2)/RFootUp(1))
RFootProjections = <RFootSagAngle,0,RFootTraAngle>
output(RFootProjections)
```

Appendix D: Participant and AFO details

Participant details

		Medical history as provided by parents/guardians
Solid	**DEHA**	past botox to calves and hamstrings, calf lengthenings
	HAHA	past botox to calves and hamstrings, no surgery
	JABU	past botox; numerous lengthenings/transfers to calves, adductors, hamstrings; no osteotomies
	JODA	past botox, no surgery
	JOTH	past botox, metal plates 2007-2009, calves lengthened, adductors released
	LIRI	past botox; L femoral osteotomy; L hamstrings lengthening, adductors and calf
	MAHO	past botox; bilateral femoral osteotomies, hamstring release, psoas, calves
Hinged	**ACBE**	past botox; R strayer (2004) and osteotomy
	ALBR	Nil
	CHJE	Nil
	DEFO	past botox to calves, no surgery
	HAGO	botox 1 week ago, VP shunt, epilepsy
	JANI	botox to calves and adductors several times; muscle lengtheninings
	JOBA	past botox to calves, no surgery
	JORI	surgery 1 yr ago - tendon releases, no femoral osteotomoies
	LIEM	past botox; femoral osteotomy; calf and adductor lengthenings
	LIKE	past botox, no surgery
	LIRI	past botox; femoral osteotomy; hamstrings, adductors and calf lengthenings
	ROHI	past botox, no surgery
	TACA	2ya SPLAT, 3ya tendon lengthening, nil botox
	TIIR	Possible botox; current 8 plates, adductors and hip plates, R hip remodelling

AFO details

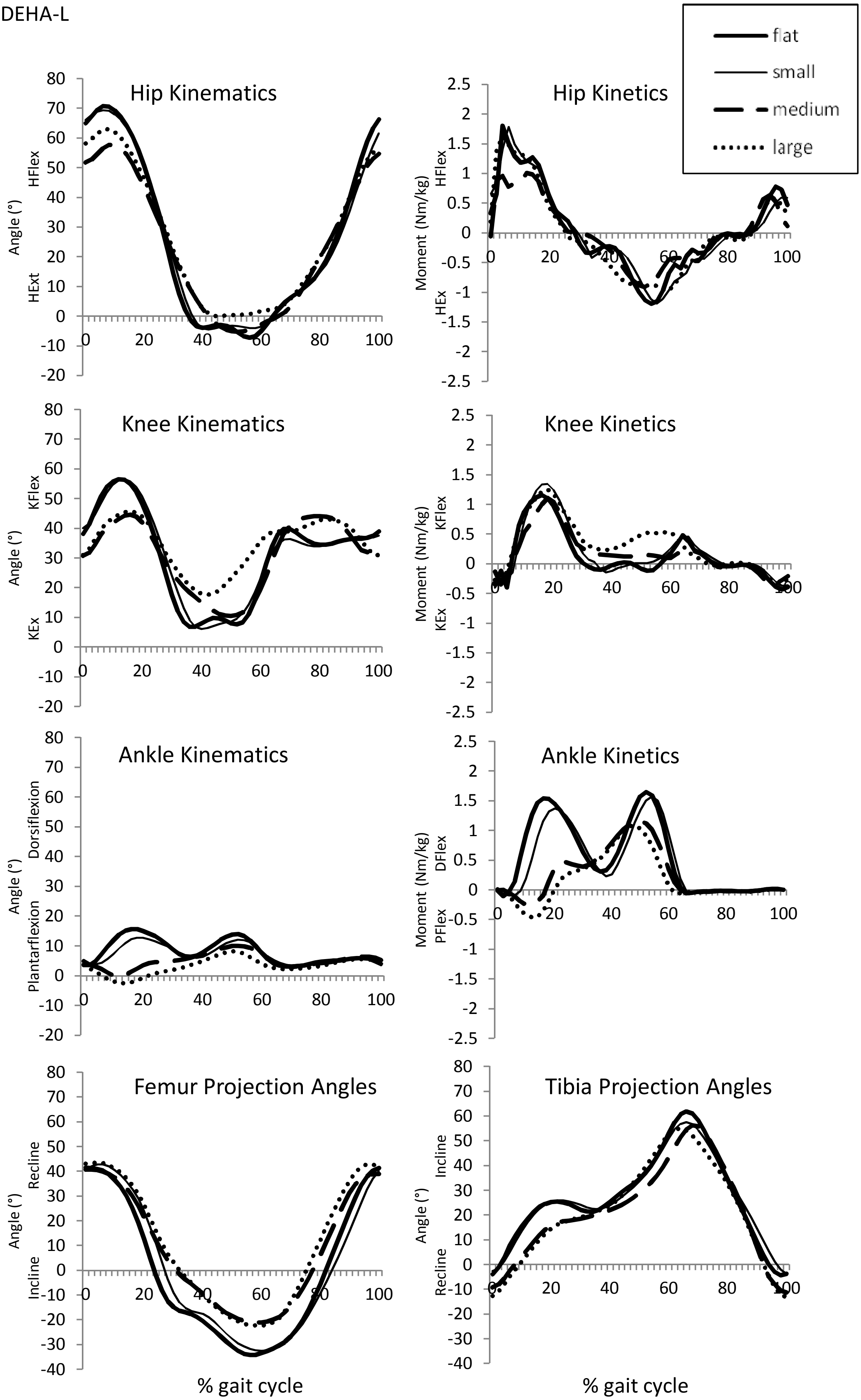
		Material	Thickness (to nearest 0.5mm)	Proximal calf strap	Ankle strap	Trimline position (relative to met heads#)
Solid	**MAHO**	PP	5	Turnback	Turnback	Distal
	JODA	PP	4	Wrap	Turnback	Distal
	JOTH	PP	4.5	Turnback	Turnback	Distal
	DEHA	PP	5	Turnback	Turnback	Distal
	LIRI	PP	4	Wrap	Turnback	Distal
	JABU	PP*	5	Turnback	Turnback	Distal
	HAHA	PP	4	Turnback	Turnback	Distal
Hinged	All hinged AFOs extended proximally on the calf between 2-4cm distal to the fibular head, extended beyond the toes (full length toe plate) and all had a calf and an ankle strap though of varying designs. All AFOs were manufactured either from copolymer or homopolymer polypropylene and utilised Tamarack joints of a variety of sizes. All had medial and lateral footpiece trimlines that extended to, or distal to the metatarsal heads. Details of material type and thickness, strap design and trimline position were not recorded for hinged AFOs as these variables would not affect AFO stiffness.					

*Reinforced around ankle using corrugations. #All distal trimlines on the footpiece extended past the metatarsal heads but to varying degrees. PP = polypropylene homopolymer

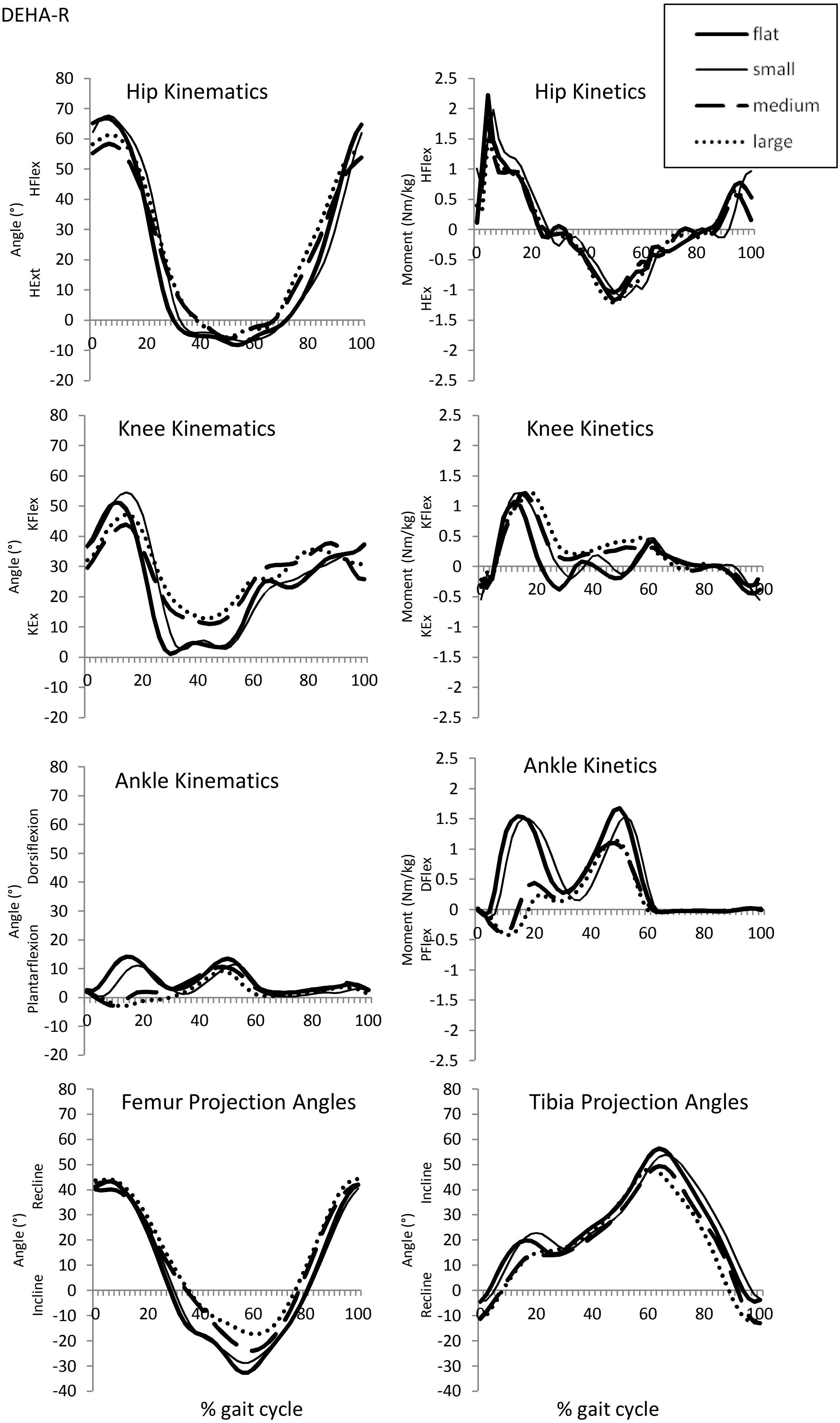
Appendix E: Individual participant results for Chapter 6

Solid AFOs

DEHA-L



DEHA-R



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Tibia Projection Angles
Angle (°)
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% gait cycle
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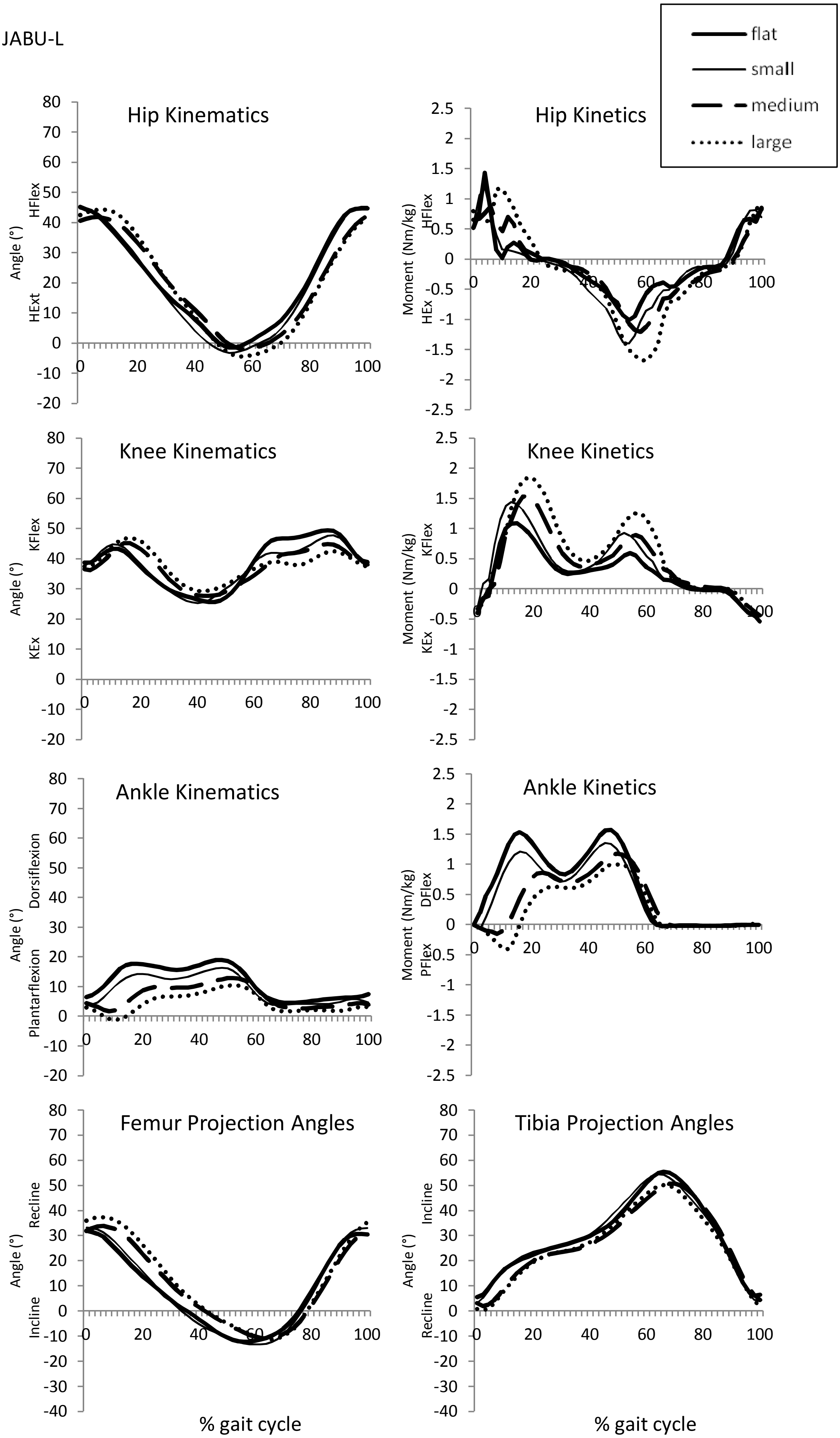
JABU-L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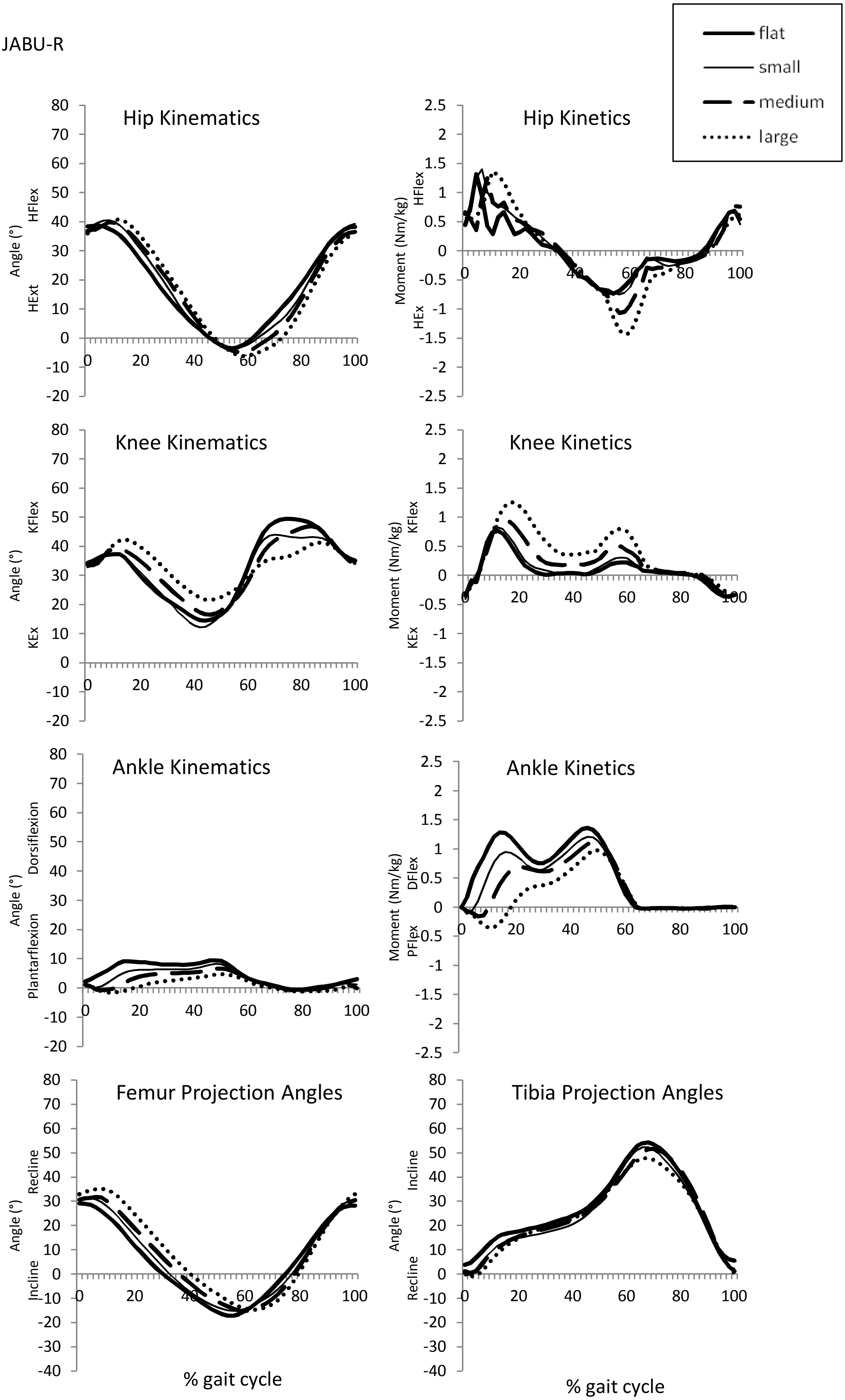
JABU-R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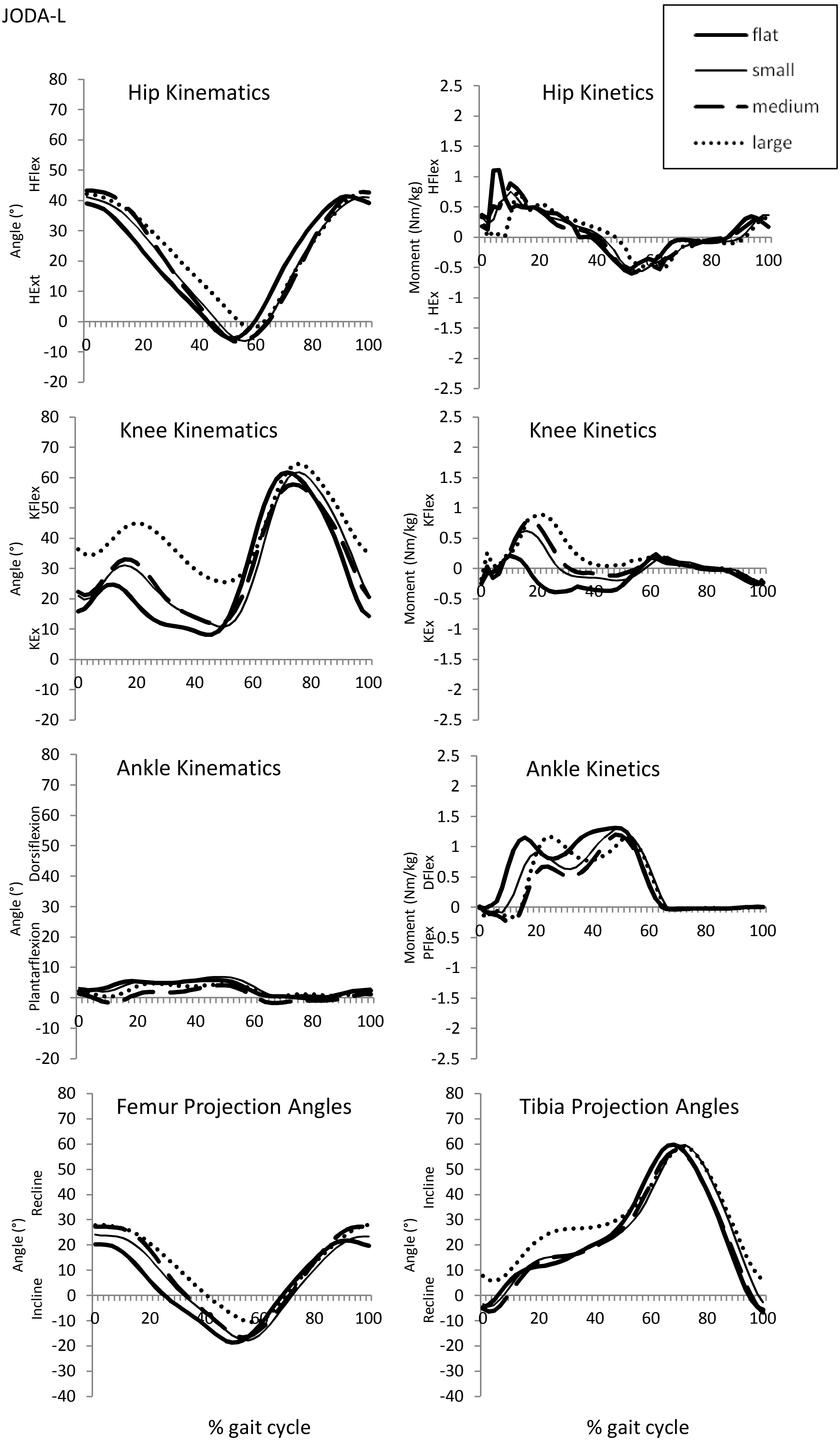
JODA-L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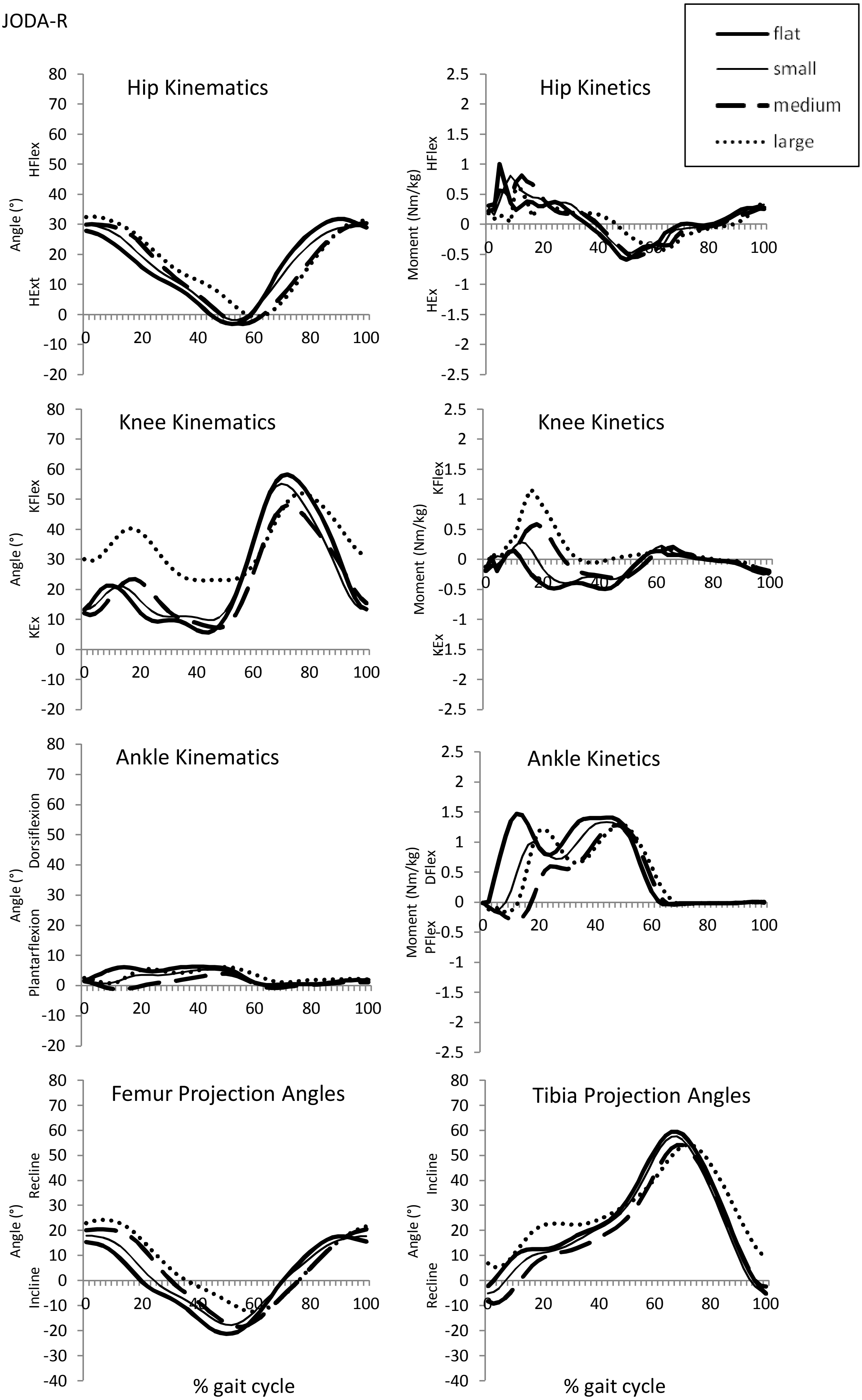
JODA-R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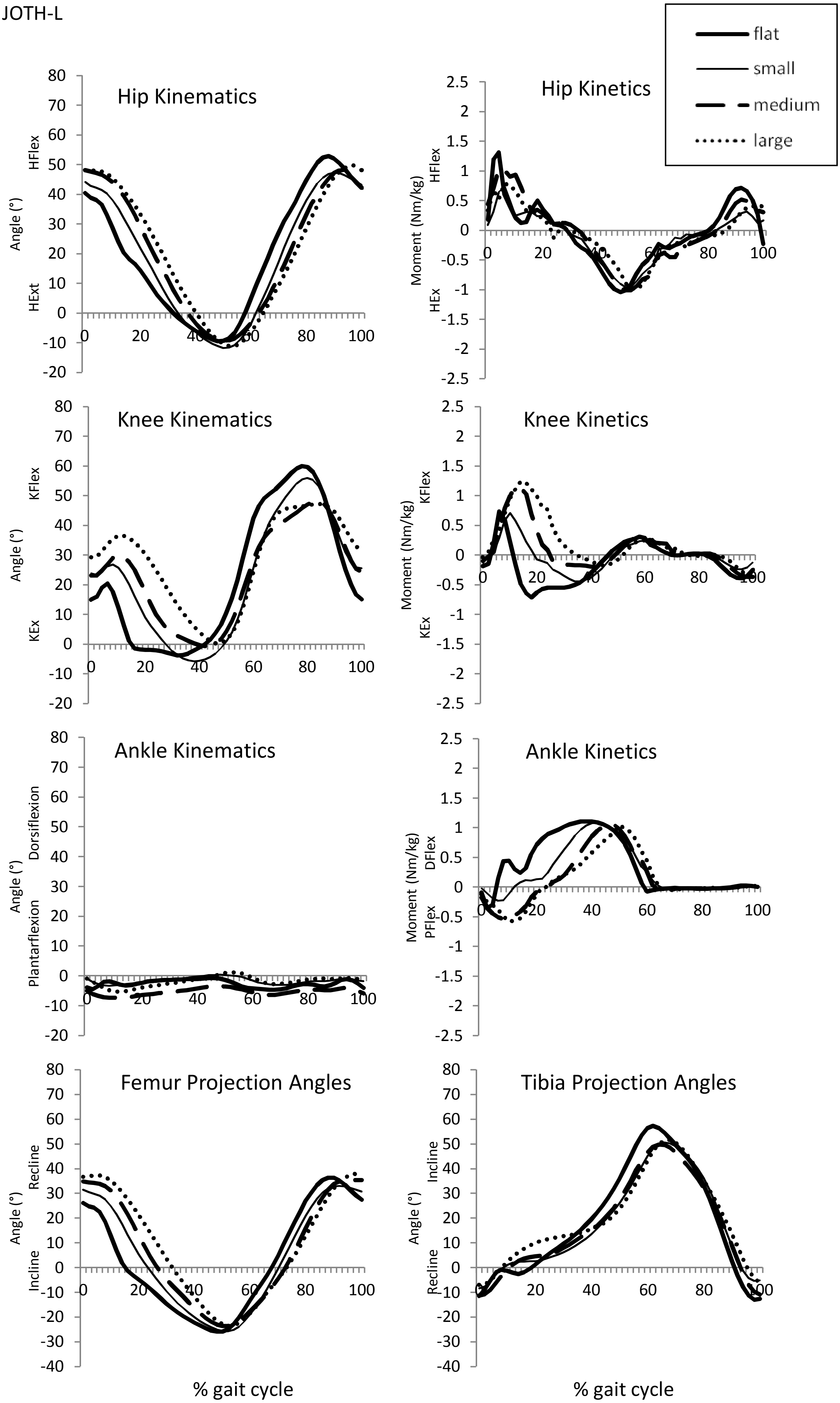
JOTH-L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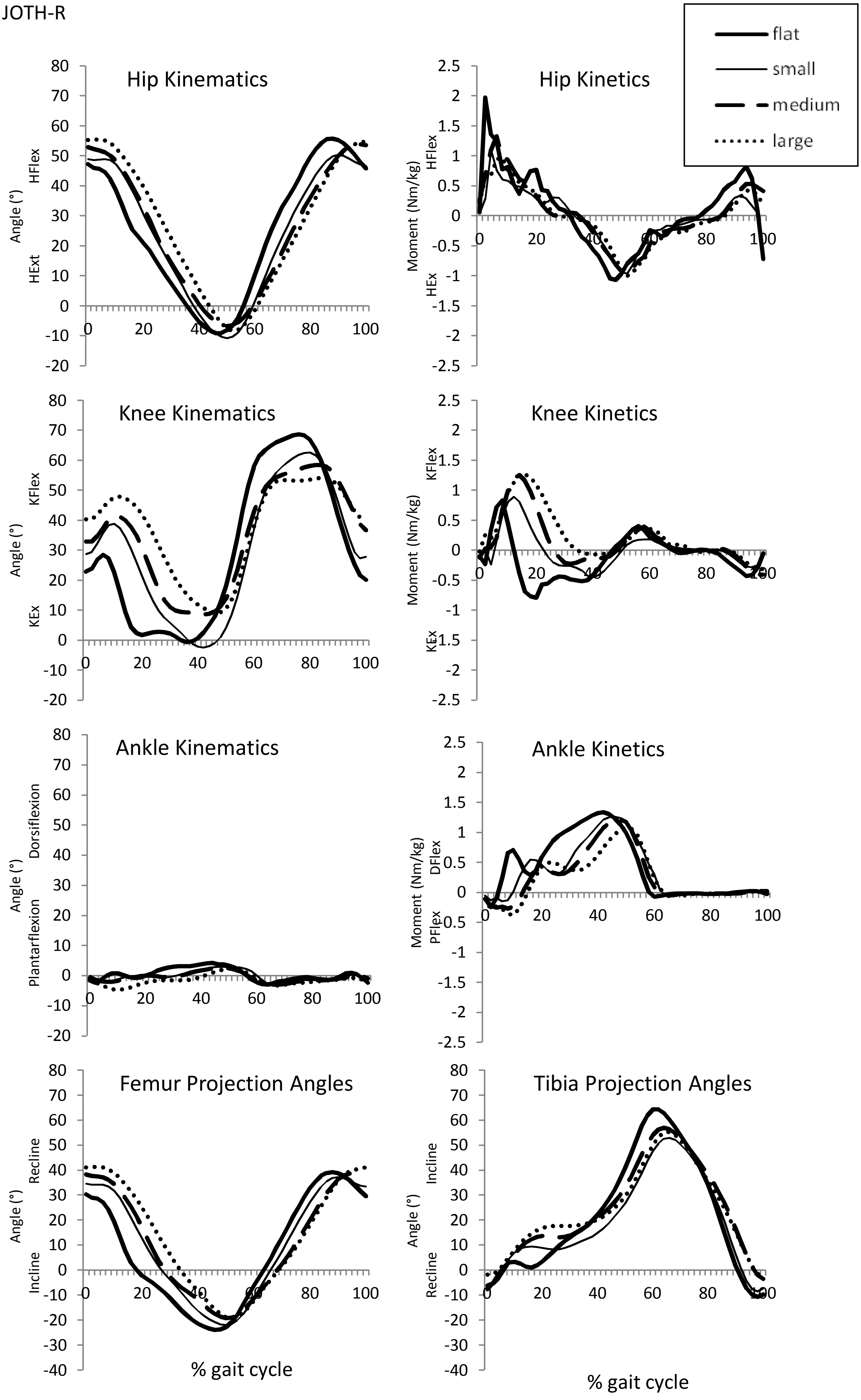
JOTH-R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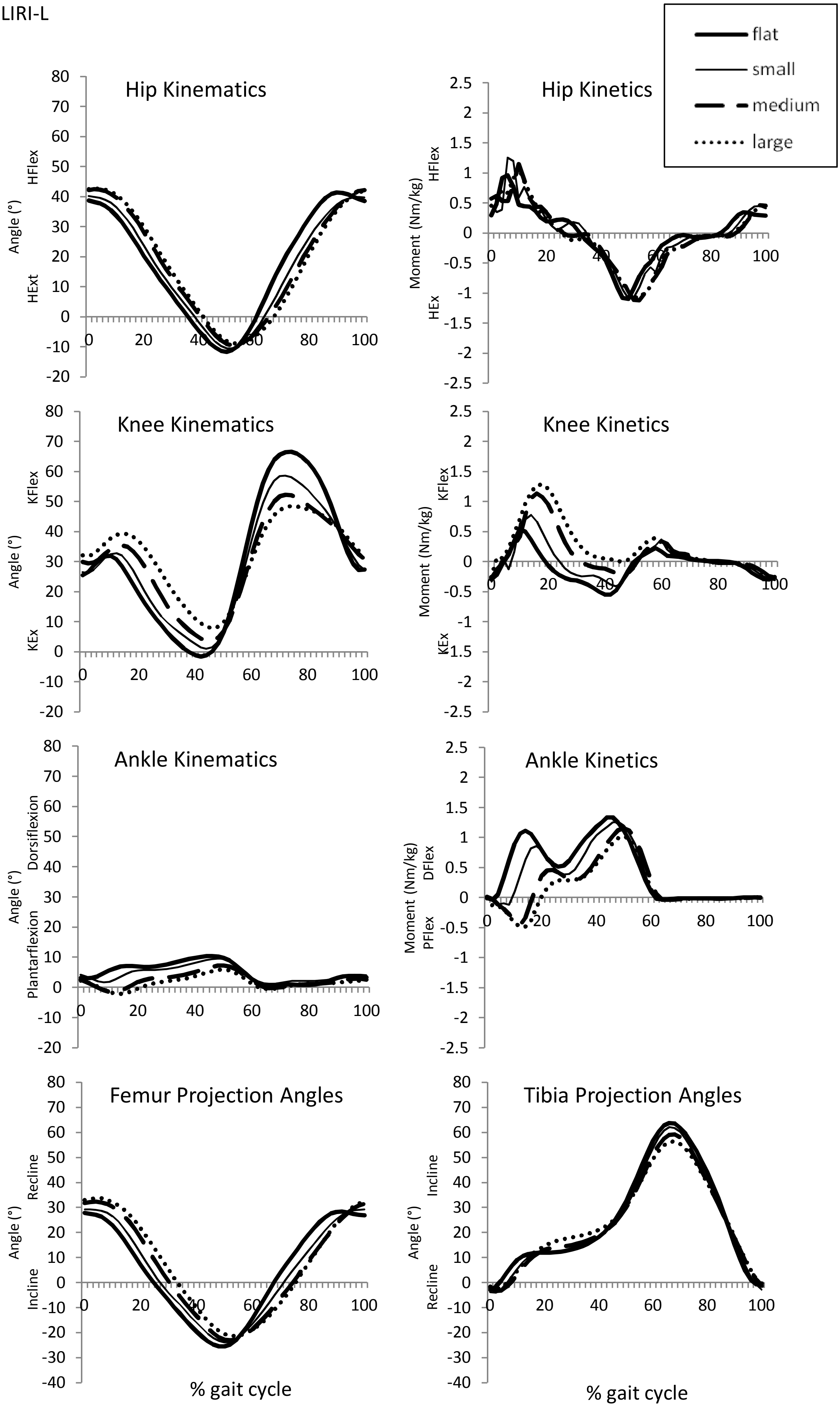
LIRI-L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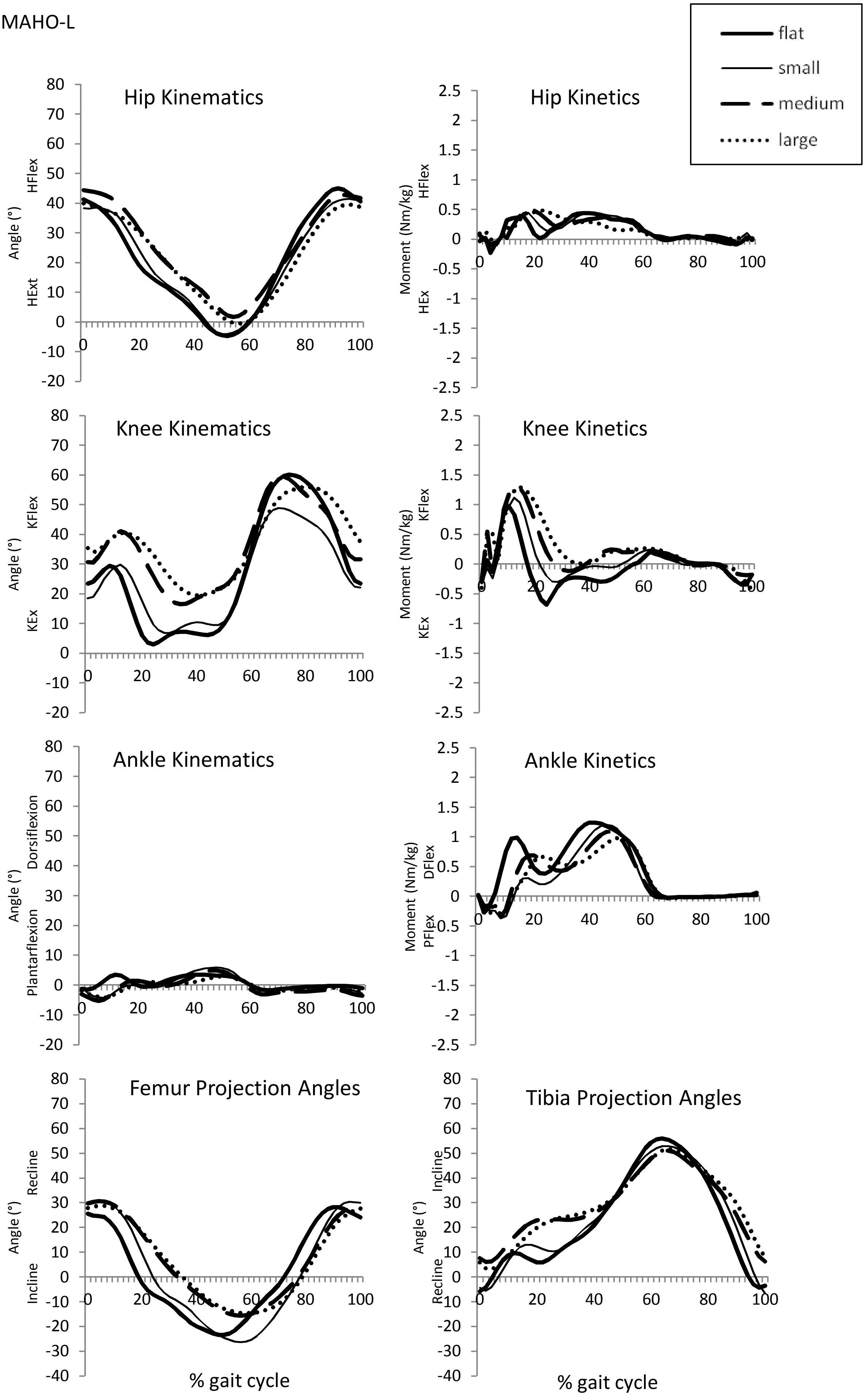
MAHO-L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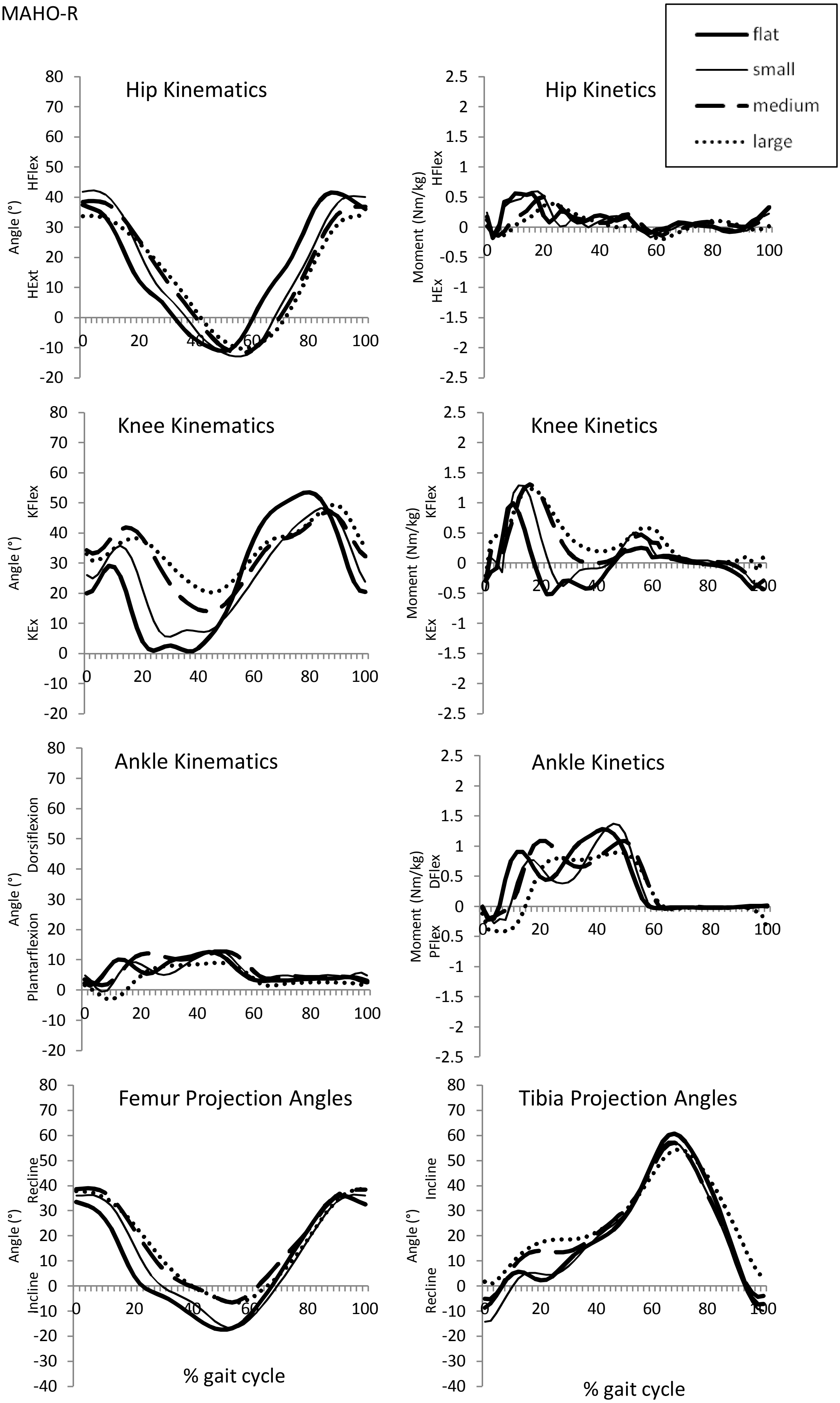
MAHO-R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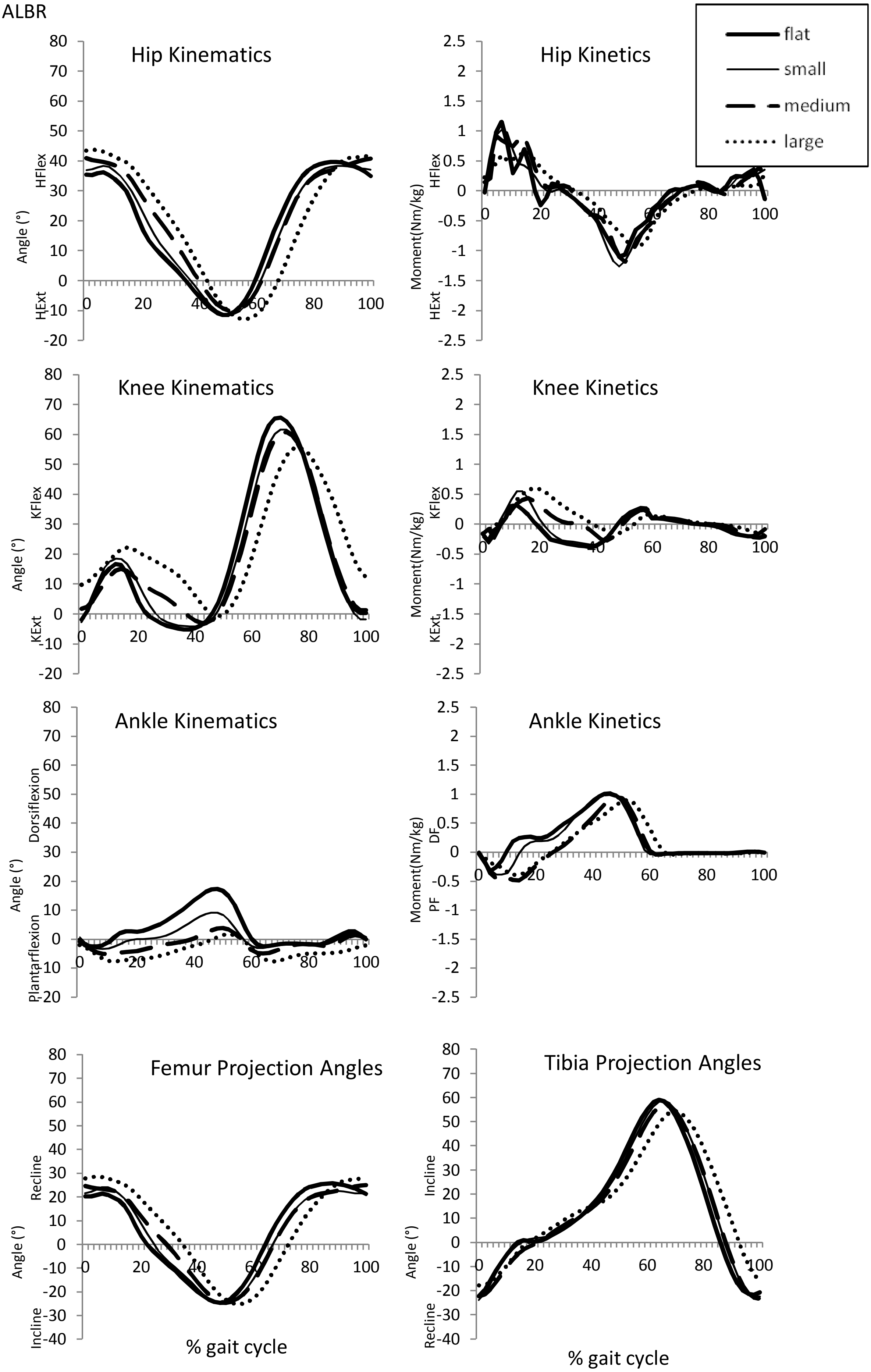
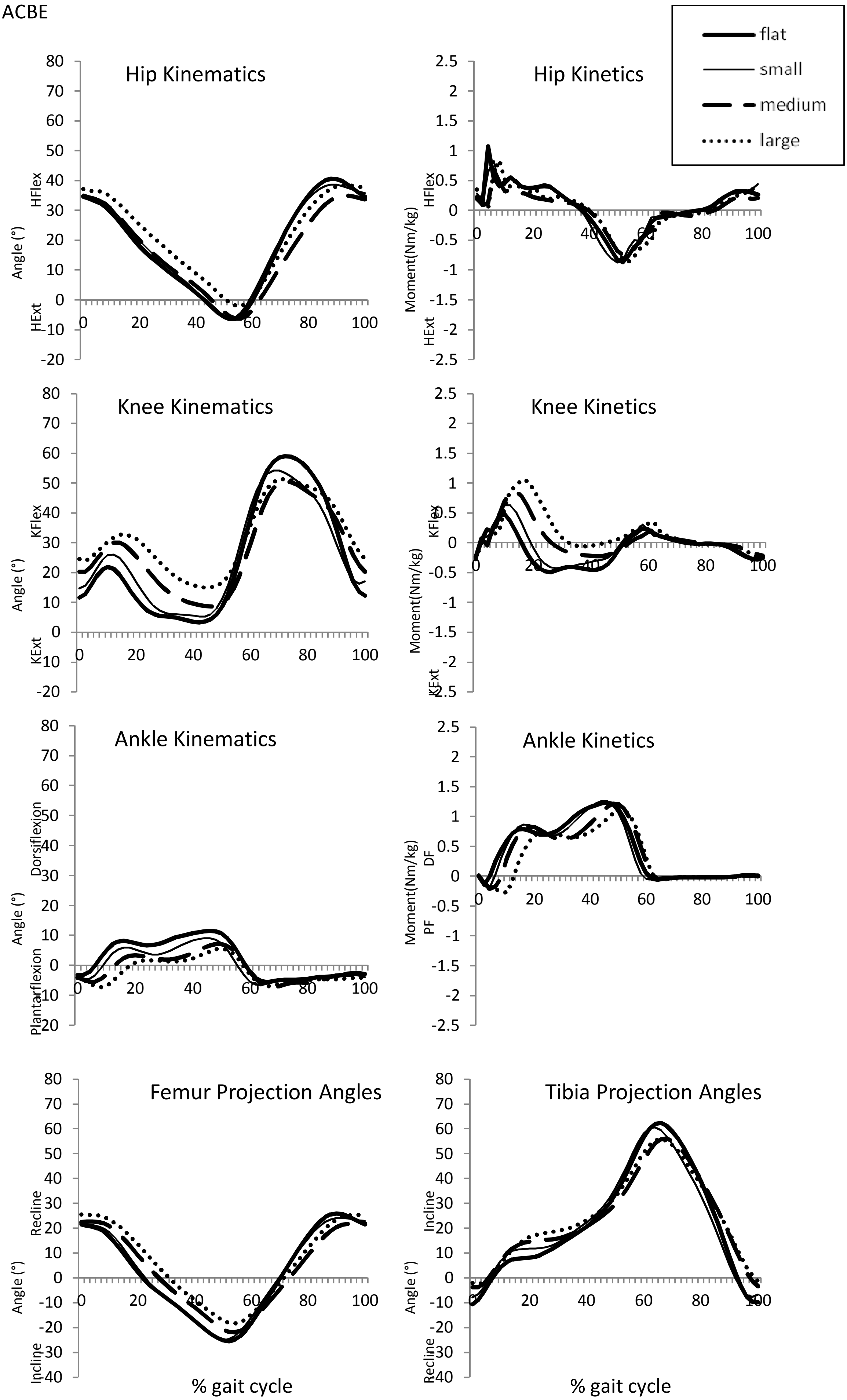
Hinged AFOs

ALBR



ACBE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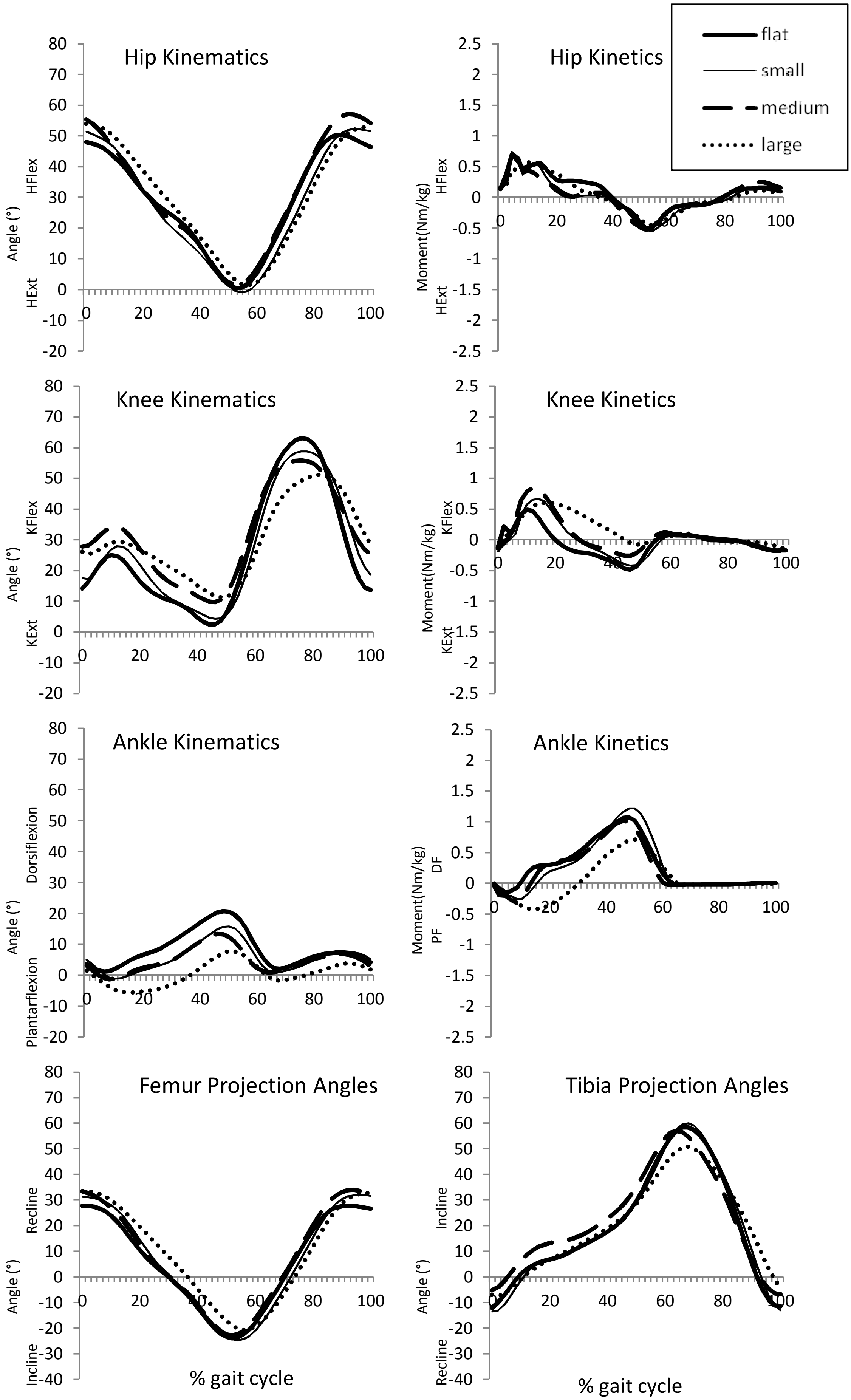
% gait cycle

CHJE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Hip Kinematics
Angle (°)
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Hip Kinetics
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Knee Kinematics
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Knee Kinetics
Moment(Nm/kg)
KFlex
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Ankle Kinematics
Angle (°)
Dorsiflexion
Plantarflexion
Ankle Kinetics
Moment(Nm/kg)
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Femur Projection Angles
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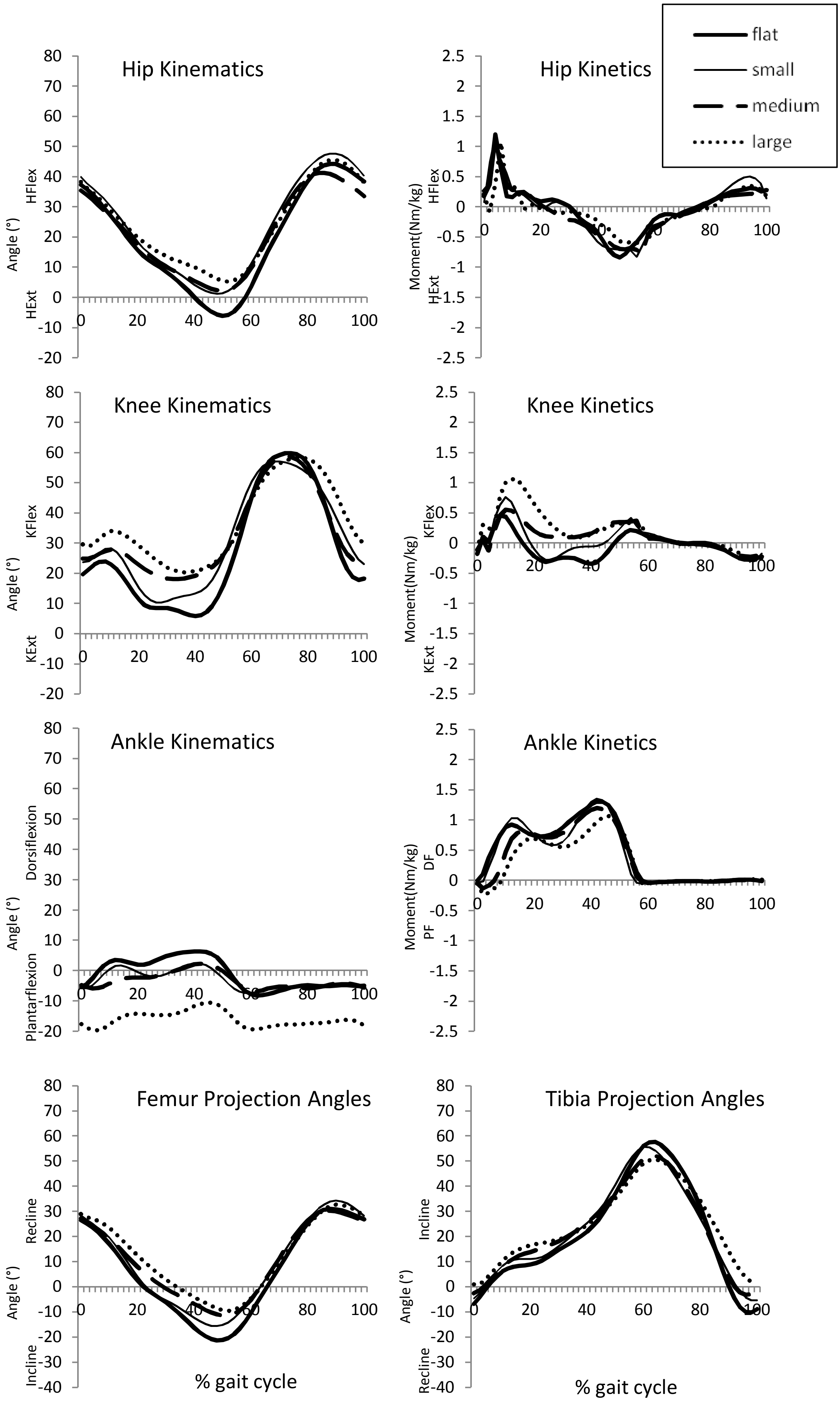
Incline
% gait cycle
Tibia Projection Angles
Angle (°)
Incline
Recline
% gait cycle

DEFO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Knee Kinetics
Moment(Nm/kg)
KFlex
KExt
Ankle Kinematics
Angle (°)
Dorsiflexion
Plantarflexion
Ankle Kinetics
Moment(Nm/kg)
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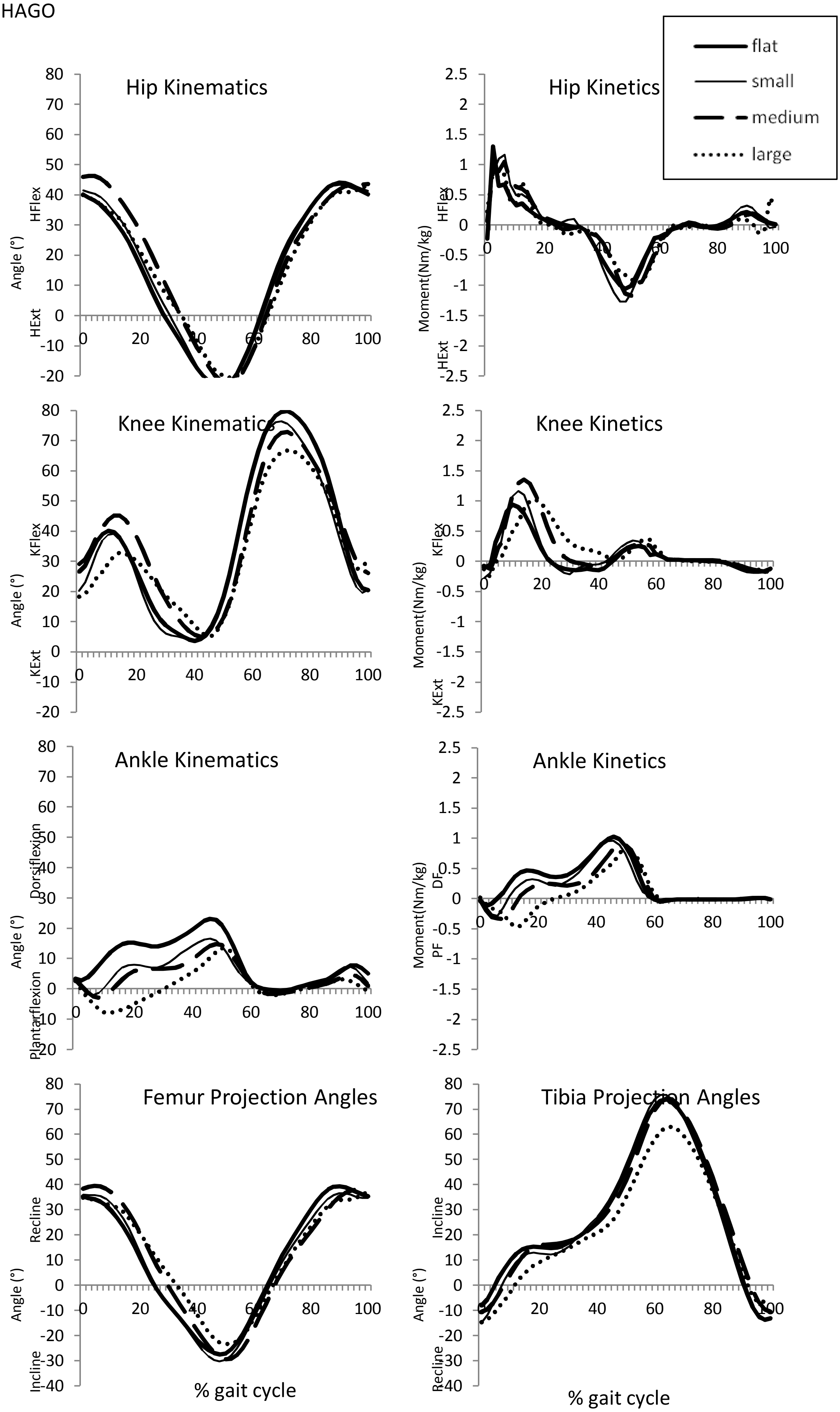
Femur Projection Angles
Angle (°)
Recline
Incline
% gait cycle
Tibia Projection Angles
Angle (°)
Incline
Recline
% gait cycle

HAGO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Ankle Kinematics
Dorsiflexion
Plantarflexion
Ankle Kinetics
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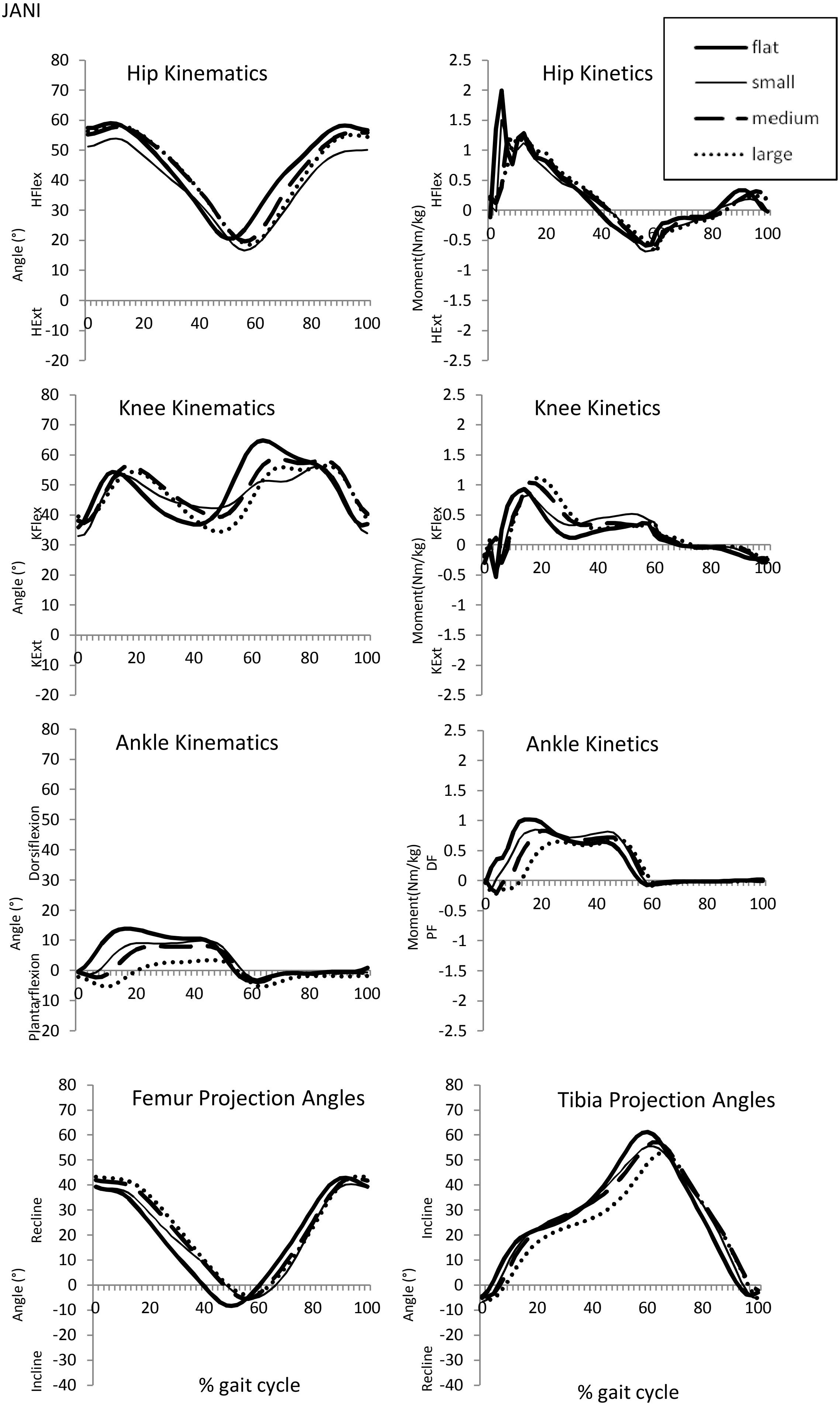
Femur Projection Angles
Recline
Incline
Tibia Projection Angles
% gait cycle
% gait cycle

JANI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Knee Kinetics
Moment(Nm/kg)
KFlex
KExt
Ankle Kinematics
Angle (°)
Dorsiflexion
Plantarflexion
Ankle Kinetics
Moment(Nm/kg)
DF
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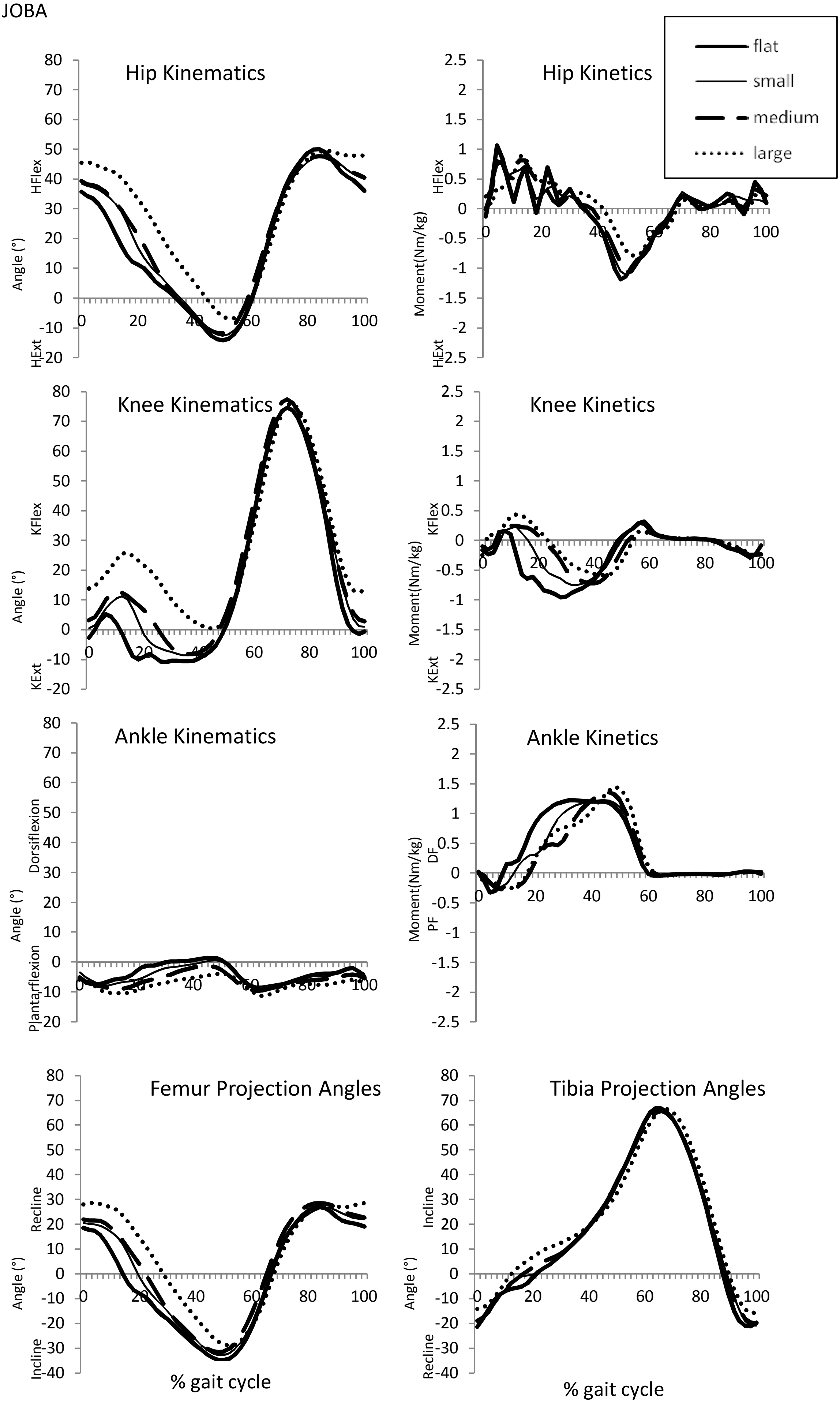
Femur Projection Angles
Angle (°)
Recline
Incline
% gait cycle
Tibia Projection Angles
Angle (°)
Incline
Recline
% gait cycle

JOBA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Femur Projection Angles
Tibia Projection Angles
Angle (°)
Moment(Nm/kg)
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KFlex
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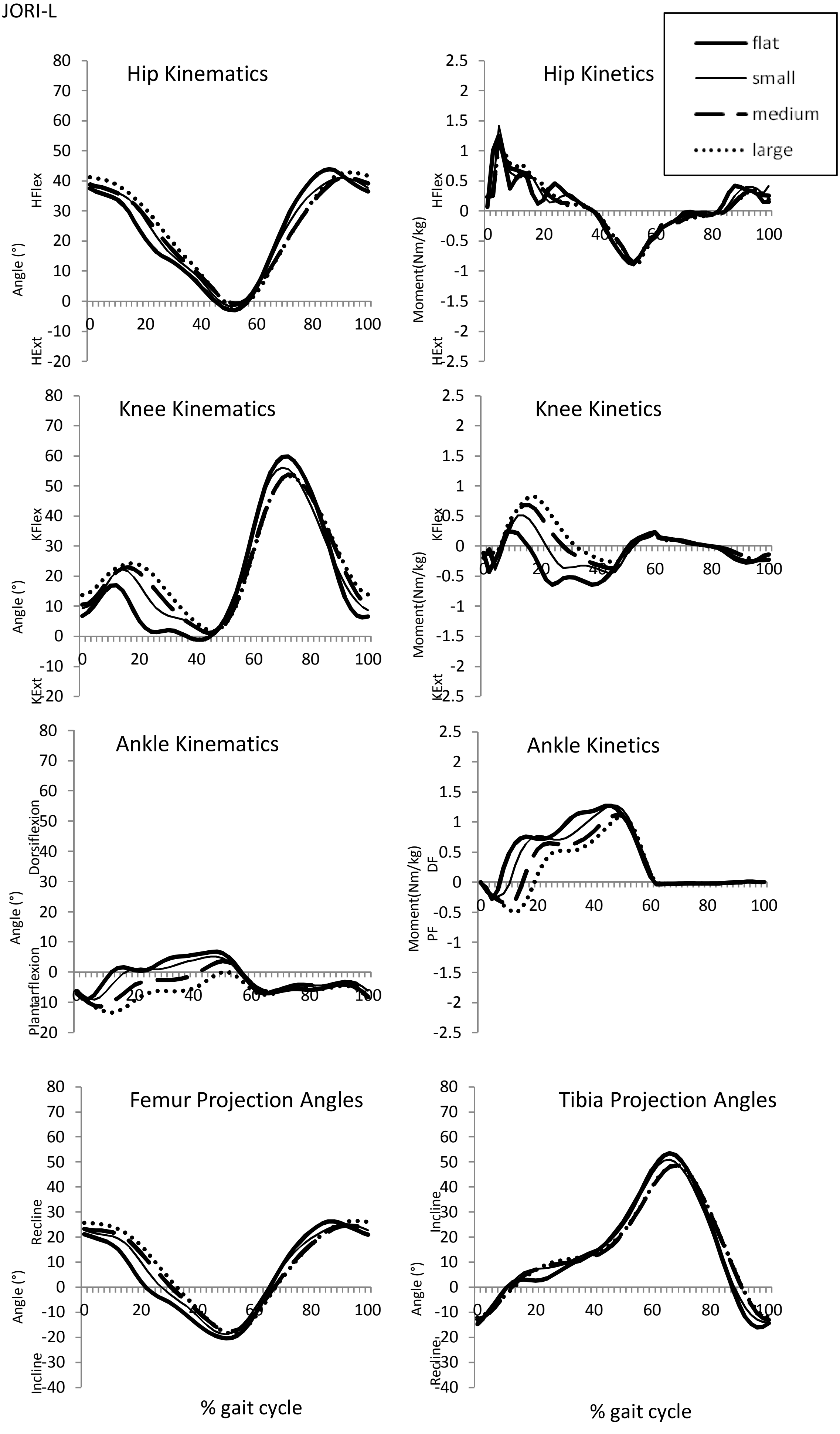
Dorsiflexion
Plantarflexion
DF
PF
Recline
Incline
% gait cycle

JORI-L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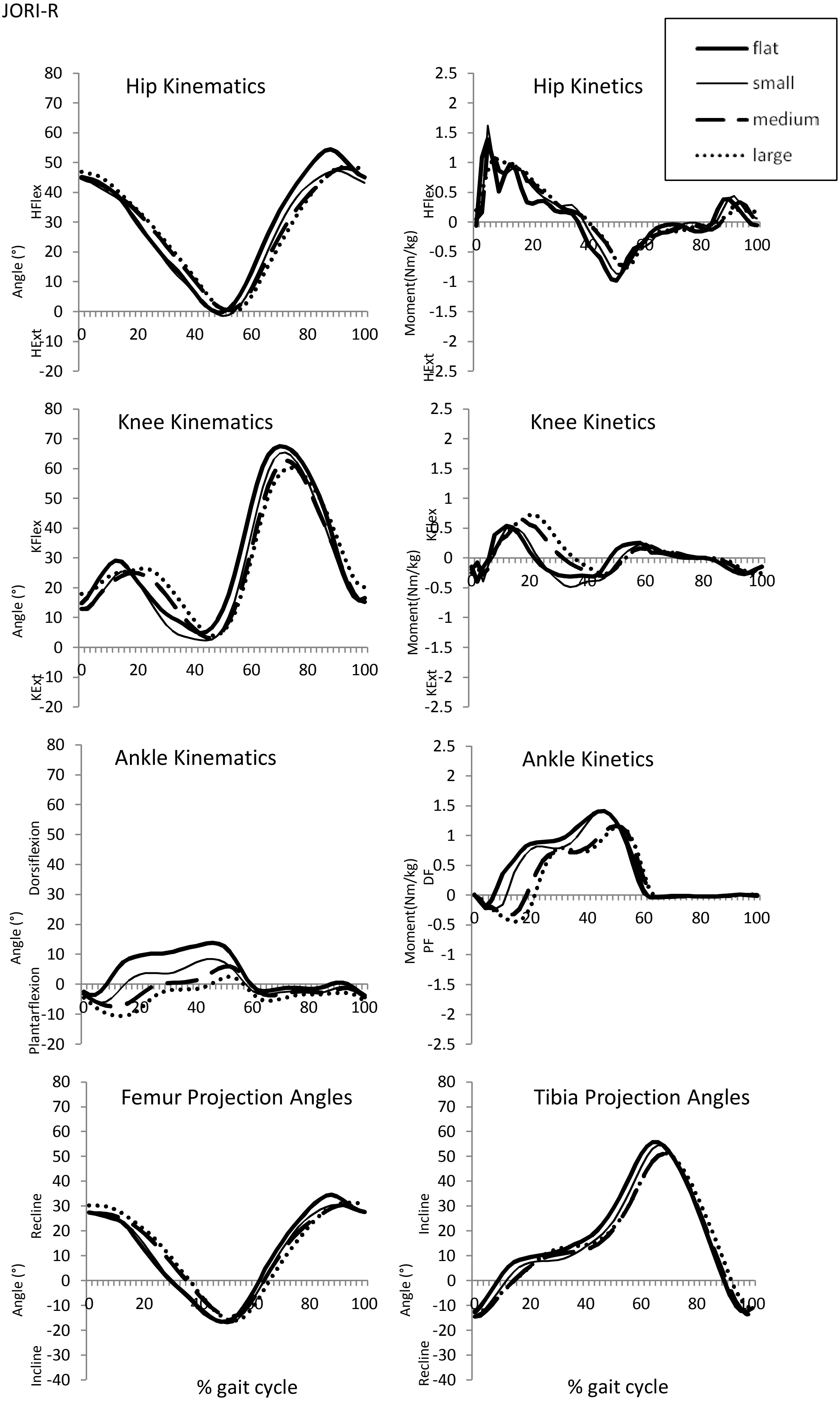
Knee Kinetics
Moment(Nm/kg)
KFlex
KExt
Ankle Kinematics
Angle (°)
Dorsiflexion
Plantarflexion
Ankle Kinetics
Moment(Nm/kg)
DF
PF
Femur Projection Angles
Angle (°)
Recline
Incline
% gait cycle
Tibia Projection Angles
Angle (°)
Incline
Recline
% gait cycle

JORI-R



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Hip Kinematics
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Knee Kinematics
Knee Kinetics
Ankle Kinematics
Ankle Kinetics
Femur Projection Angles
Tibia Projection Angles
Angle (°)
Moment(Nm/kg)
HFlex
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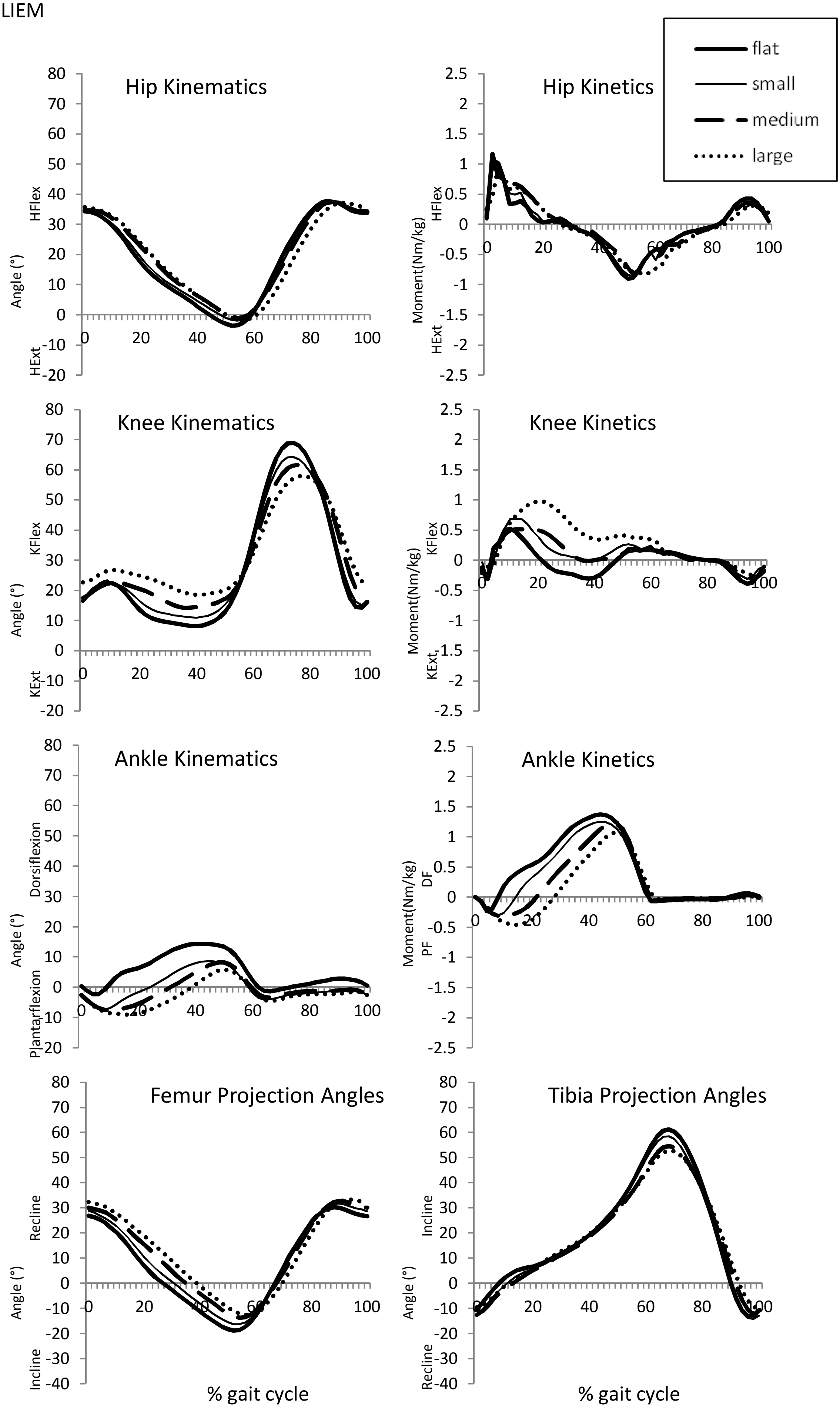
KFlex
KExt
Dorsiflexion
Plantarflexion
DF
PF
Recline
Incline
% gait cycle

LIEM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Angle (°)
Knee Kinetics
KFlex
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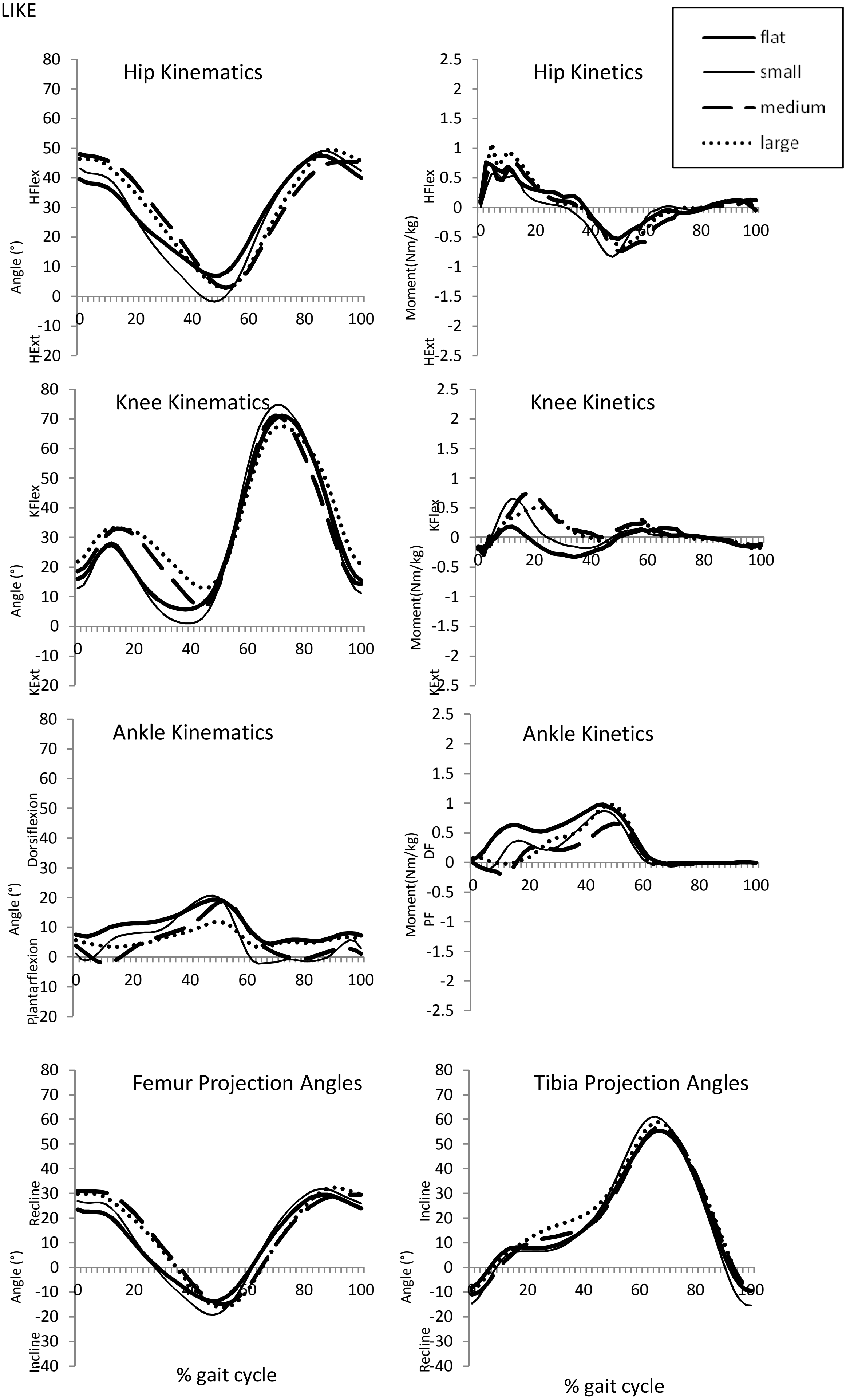
Moment(Nm/kg)
Ankle Kinematics
Dorsiflexion
Plantarflexion
Angle (°)
Ankle Kinetics
DF
PF
Moment(Nm/kg)
Femur Projection Angles
Recline
Incline
Angle (°)
% gait cycle
Tibia Projection Angles
Incline
Recline
Angle (°)
% gait cycle

LIKE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Ankle Kinematics
Dorsiflexion
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Plantarflexion
Ankle Kinetics
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Moment(Nm/kg)
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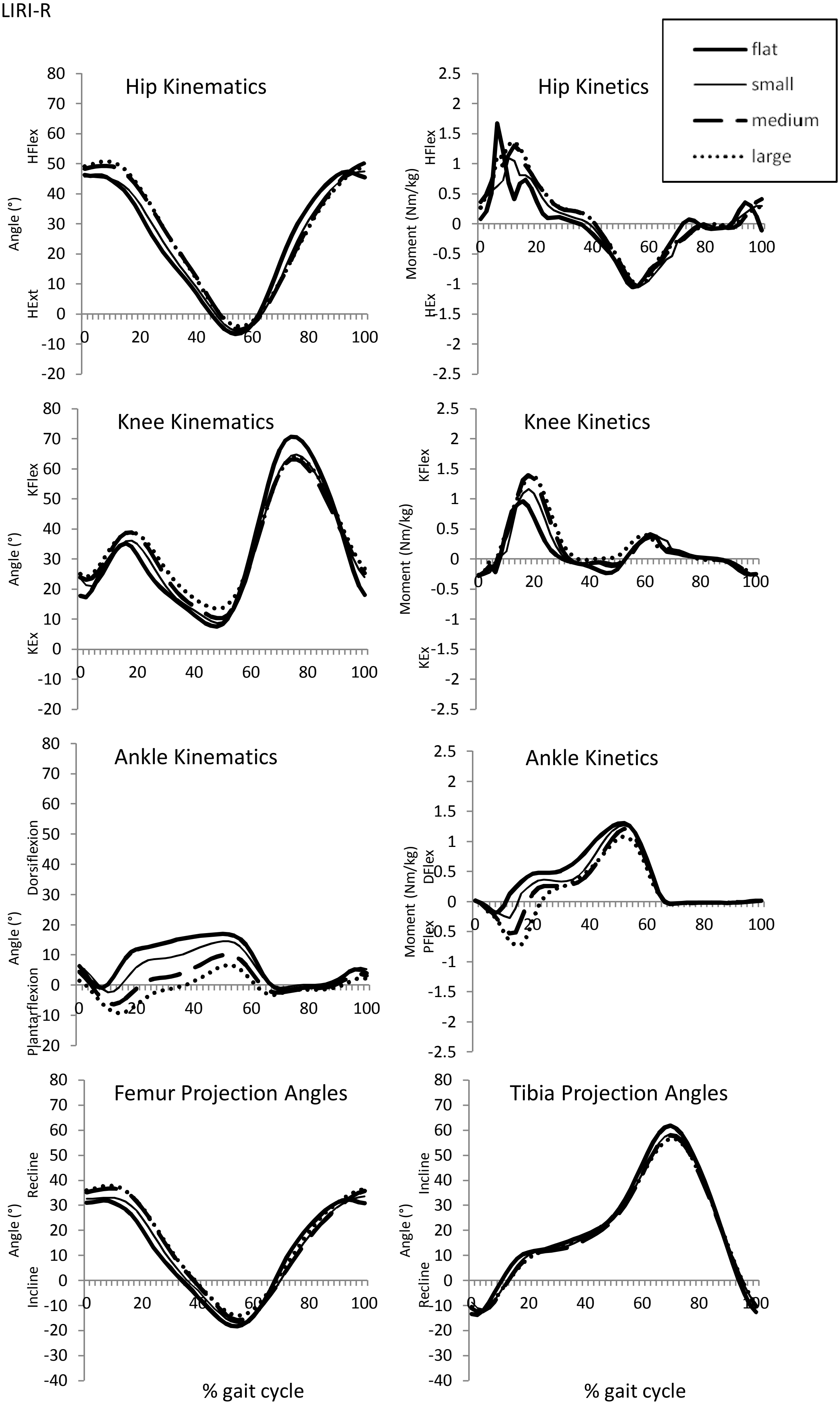
Femur Projection Angles
Recline
Angle (°)
Incline
% gait cycle
Tibia Projection Angles
Incline
Angle (°)
Recline
% gait cycle

LIRI-R



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Hip Kinematics
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Hip Kinetics
Moment (Nm/kg)
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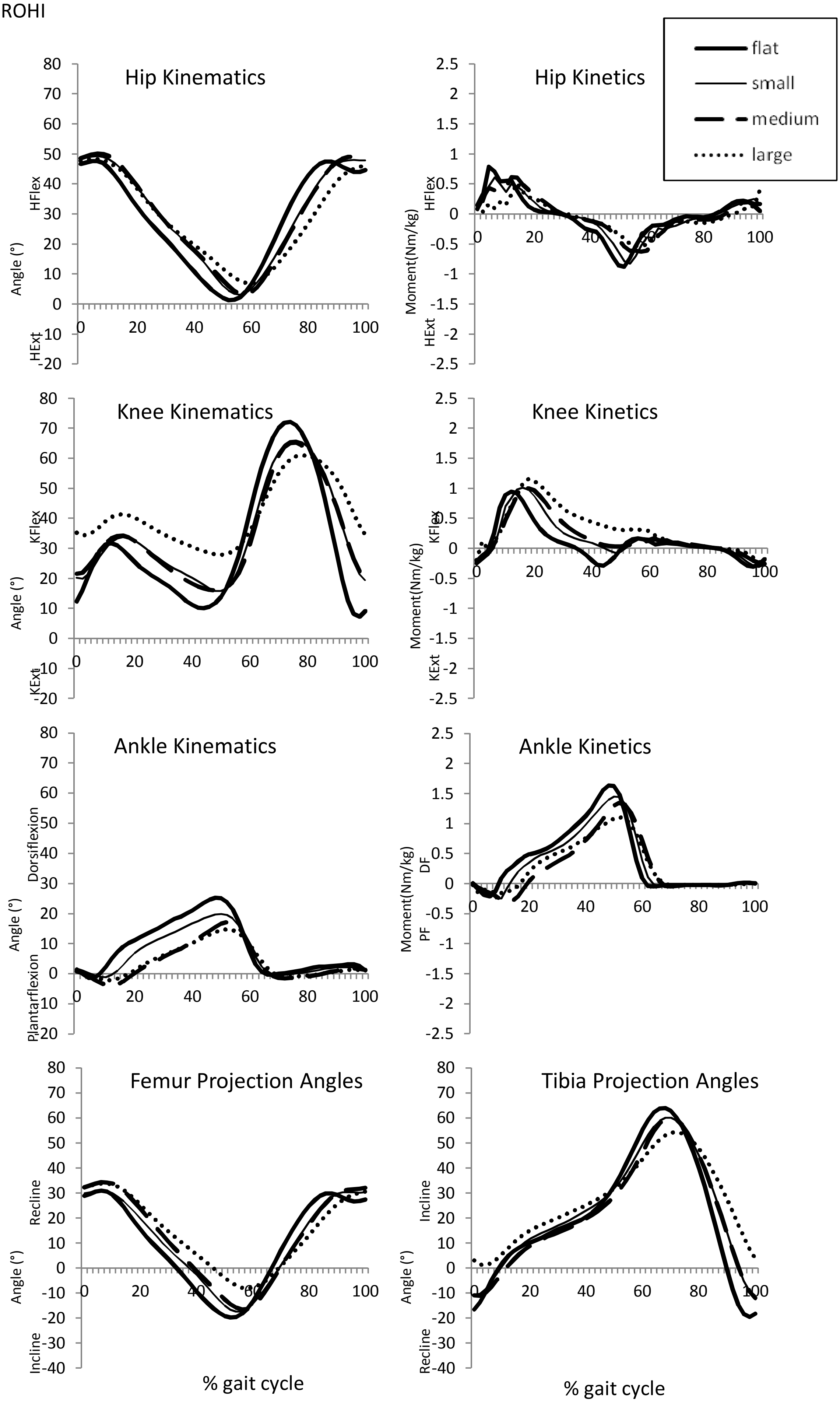
Angle (°)
KFlex
KEx
Knee Kinetics
Moment (Nm/kg)
KFlex
KEx
Ankle Kinematics
Angle (°)
Dorsiflexion
Plantarflexion
Ankle Kinetics
Moment (Nm/kg)
DFlex
PFlex
Femur Projection Angles
Angle (°)
Recline
Incline
% gait cycle
Tibia Projection Angles
Angle (°)
Incline
Recline
% gait cycle

ROHI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Hip Kinematics
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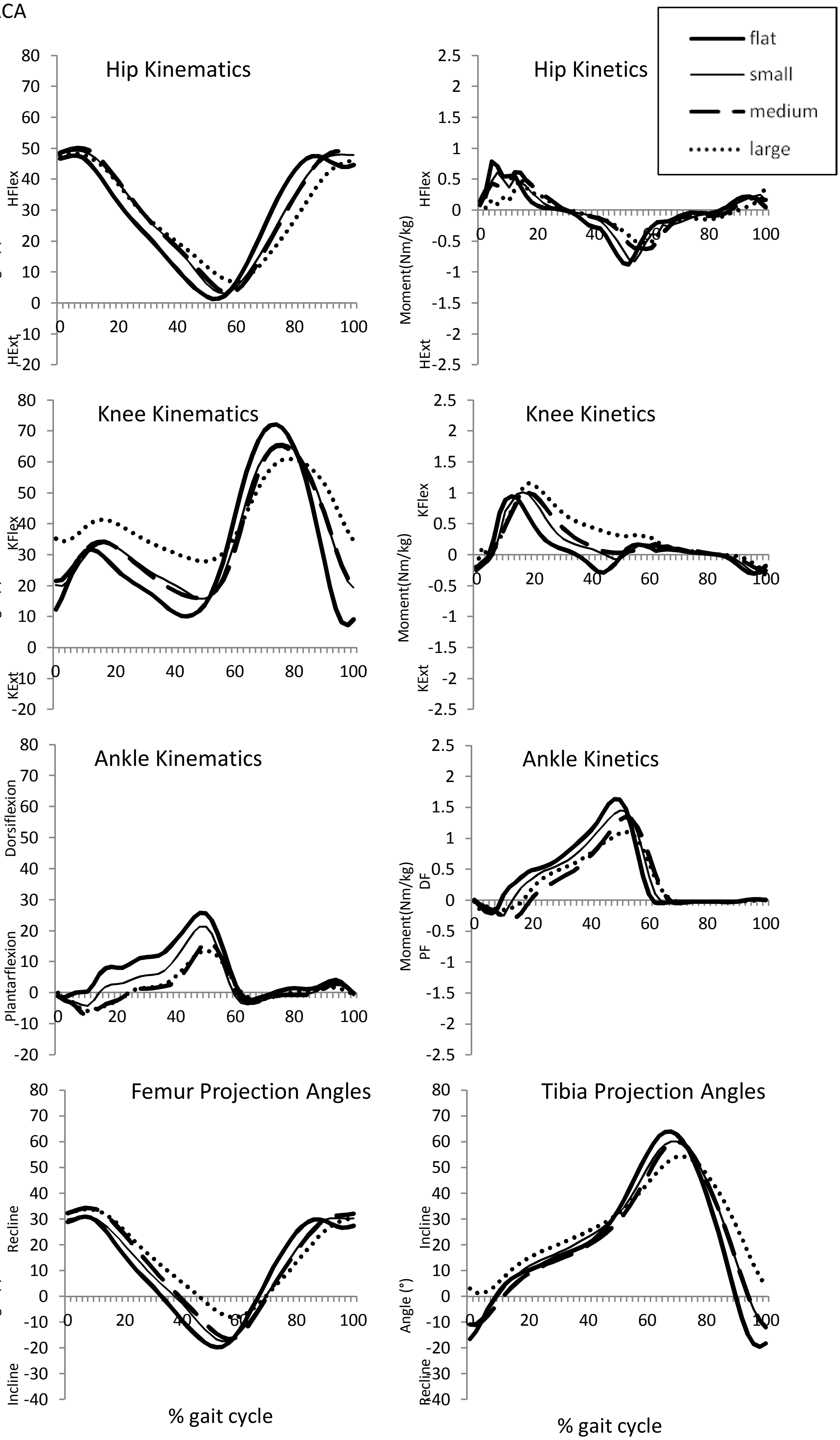
Ankle Kinematics
Ankle Kinetics
Femur Projection Angles
Tibia Projection Angles
Angle (°)
HFlex
HExt
Moment(Nm/kg)
KFlex
KExt
Dorsiflexion
Plantarflexion
DF
PF
Recline
Incline
% gait cycle

TACA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Hip Kinematics
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Angle (°)
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Moment(Nm/kg)
Knee Kinematics
KFlex
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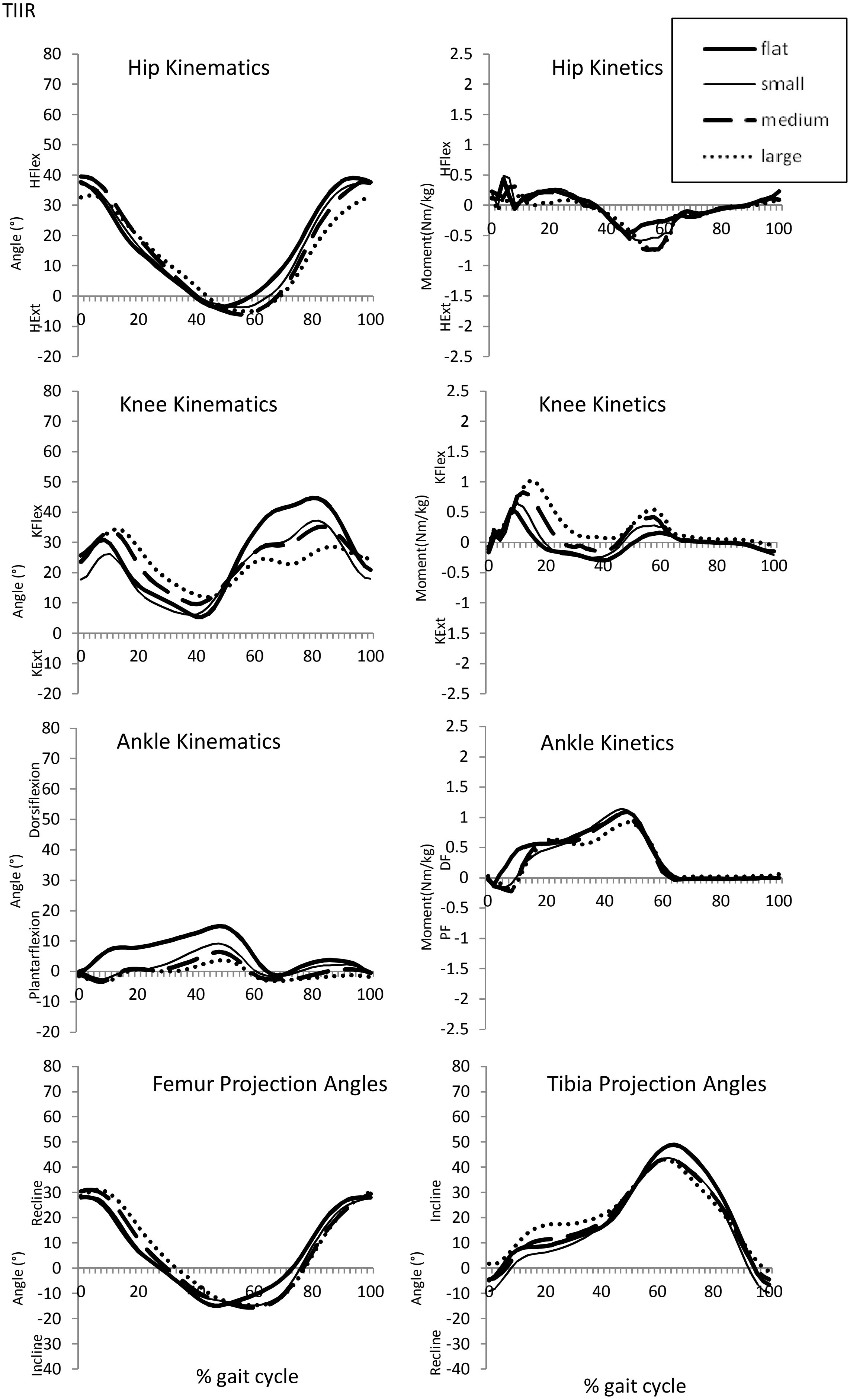
Angle (°)
Knee Kinetics
KFlex
KExt
Moment(Nm/kg)
Ankle Kinematics
Dorsiflexion
Plantarflexion
Angle (°)
Ankle Kinetics
DF
PF
Moment(Nm/kg)
Femur Projection Angles
Recline
Incline
Angle (°)
% gait cycle
Tibia Projection Angles
Incline
Recline
Angle (°)
% gait cycle

TIIR



Hip Kinematics
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Knee Kinematics
Knee Kinetics
Ankle Kinematics
Ankle Kinetics
Femur Projection Angles
Tibia Projection Angles
Angle (°)
Moment(Nm/kg)
HFlex
HExt
KFlex
KExt
Dorsiflexion
Plantarflexion
DF
PF
Recline
Incline
% gait cycle

Appendix F: Tests of normality and sphericity

Test of normality

Results of the tests of normality for variables considered in the average common subgroups for solid and hinged AFOs for the variables hypothesised to change, found four variables that had a significantly non-normal distribution (indicated in bold):

Probable response variables

Test of normality (Shapiro-Wilks) (p<0.05=not normally distributed)		
	Solid n=7	**Hinged n=13**
F_peakKFmoment	0.28	0.10
F_peakKEmoment	0.79	0.92
F_peakKFanglestance	0.36	0.96
F_peakKEangle	0.89	0.29
F_peaktibialincline	0.67	0.51
F_1stpeakDFmoment	0.16	0.18
F_2ndpeakDFmoment	0.73	0.20
S_peakKFmoment	0.98	**0.03**
S_peakKEmoment	0.16	0.45
S_peakKFangleS_tance	0.98	0.57
S_peakKEangle	0.61	0.29
S_peaktibialincline	0.65	0.07
S_1stpeakDFmoment	0.89	0.18
S_2ndpeakDFmoment	0.67	0.38
M_peakKFmoment	0.09	0.41
M_peakKEmoment	0.78	0.89
M_peakKFanglestance	0.33	0.96
M_peakKEangle	0.96	0.23
M_peaktibialincline	0.31	0.16
M_1stpeakDFmoment	0.79	0.26
M_2ndpeakDFmoment	0.62	0.45
L_peakKFmoment	**0.01**	0.56
L_peakKEmoment	0.83	0.31
L_peakKFanglestance	0.40	0.82
L_peakKEangle	0.42	**0.01**
L_peaktibialincline	0.61	0.97
L_1stpeakDFmoment	0.53	0.54
L_2ndpeakDFmoment	0.86	**0.03**

Results of the tests of normality for variables considered in the average common subgroups for the variables hypothesised not to change, found three variables to have a significantly non-normal distribution (indicated in bold):

Possible response variables

Test of normality (Shapiro-Wilks) (p<0.05=not normally distributed)		
	Solid n=7	**Hinged n=13**
F_peakKFangleswing	0.82	0.12
F_peakHFmoment	0.62	0.79
F_peakHEmoment	0.18	**0.03**
F_femurreclineatIC	0.85	0.73
F_peakfemurrecline	0.42	0.89
F_HFatIC	0.35	0.08
F_peakHE	0.36	0.10
S_peakKFangleS_wing	0.38	0.98
S_peakHFmoment	0.70	0.92
S_peakHEmoment	0.33	0.20
S_femurreclineatIC	0.55	0.63
S_peakfemurrecline	0.20	0.09
S_HFatIC	0.66	0.52
S_peakHE	0.40	**0.00**
M_peakKFangleswing	0.12	0.90
M_peakHFmoment	0.63	0.37
M_peakHEmoment	0.46	0.39
M_femurreclineatIC	0.64	0.97
M_peakfemurrecline	0.31	0.30
M_HFatIC	0.88	0.37
M_peakHE	0.56	**0.01**
L_peakKFangleswing	0.28	0.91
L_peakHFmoment	0.84	0.45
L_peakHEmoment	0.24	0.90
L_femurreclineatIC	0.76	0.85
L_peakfemurrecline	0.85	0.97
L_HFatIC	0.71	0.80
L_peakHE	0.08	0.55
F_cadence	0.746	0.325
S_cadence	0.514	0.394
M_cadence	0.874	0.208
L_cadence	0.161	0.242
F_walkingvelocity	0.338	0.185
S_walkingvelocity	0.086	0.698
M_walkingvelocity	0.452	0.559
L_walkingvelocity	0.404	0.402
F_stridelength	0.804	0.684
S_stridelength	0.885	0.698
M_stridelength	0.433	0.708
L_stridelength	0.653	0.461

Mauchly's test of sphericity

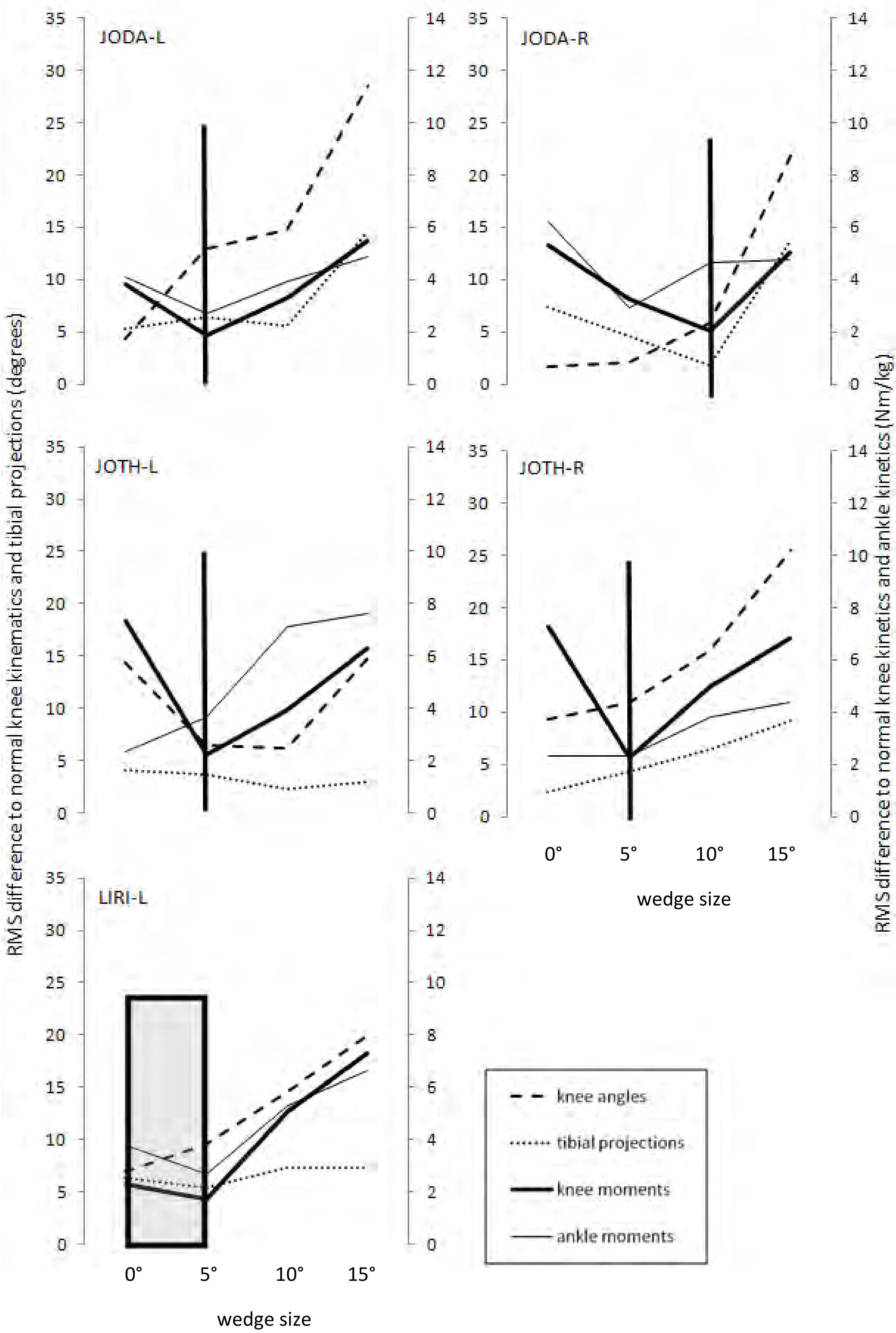
Mauchly's test of sphericity was performed on all data as part of the one-way and two-way ANOVAs. In the one-way ANOVAs, two variables in the solid AFO group and eight in the hinged AFO group failed this test (indicated in bold) and as such a Greenhouse-Geisser correction was used according to the epsilon values (ε) values. In the two-way ANOVA, seven variables failed this test, of which two were corrected using the Huynh-Feldt correction (indicated by asterix).

Mauchly's test of Sphericity (p<0.05 = sphericity not assumed)		
One-way ANOVA		
Probable response variables		
	Solid (n=7)	**Hinged (n=13)**
peakKFmoment	0.227	0.254
peakKEmoment	0.303	0.082
peakKFanglestance	0.507	0.201
peakKEangle	0.220	**0.034**
peaktibialincline	0.350	0.995
1stpeakDFmoment	0.556	**0.039**
2ndpeakDFmoment	0.079	0.155
Possible response variables		
	Solid (n=7)	**Hinged (n=13)**
peakKFangleswing	**0.020**	**0.032**
peakHFmoment	**0.000**	**0.037**
peakHEmoment	0.223	**0.039**
femurreclineatIC	0.058	0.126
peakfemurincline	0.266	**0.017**
HFangleIC	0.273	**0.041**
peakHEangle	0.606	**0.026**
cadence	0.677	**0.016**
walkingvelocity	0.745	**0.048**
stridelength	0.918	**0.004**
Two-way ANOVA		
Peak KF moment	0.119	
Peak KE moment	0.088	
Peak KF angle	0.054	
Peak KE angle	0.110	
Peak tibial angle	0.069	
1st DF moment	**0.024***	
2nd DF moment	**0.045**	
Peak KF swing	**0.017**	
Peak HF moment	**0.000**	
Peak HE moment	**0.014***	
Femur recline at IC	**0.012**	
Peak femur incline	0.229	
Hip flexion at IC	**0.046**	
Peak hip extension	0.178	

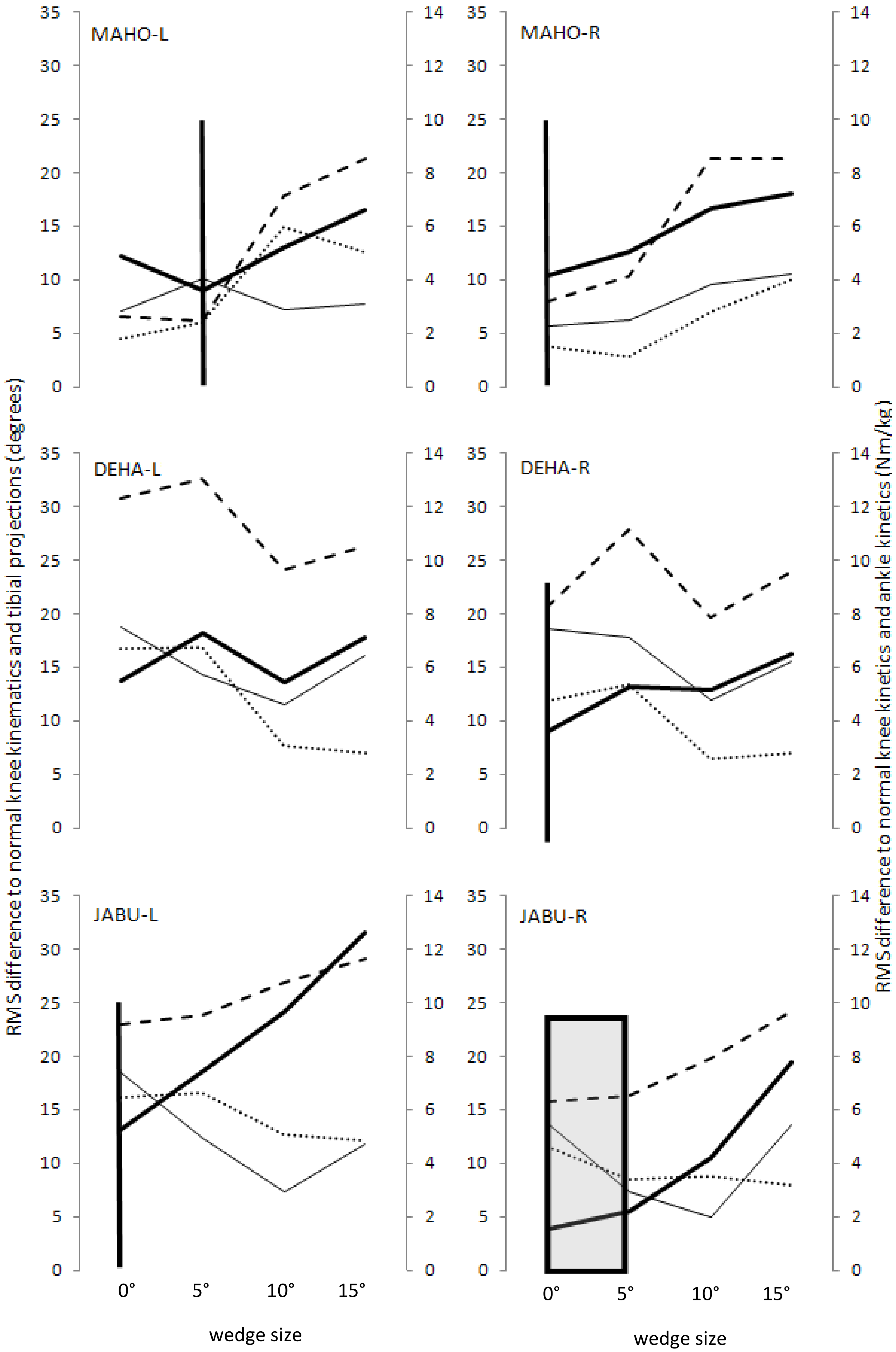
Appendix G: Individual participant results for Chapter 7

The following graphs present the RMS (root mean square) difference to normal for knee kinematics, tibial kinematics, knee kinetics and ankle kinematics across the four wedge sizes. The optimal wedge size according to knee kinetics is indicated by a vertical line. Where the optimal wedge size spans two conditions this is indicated by a rectangle.

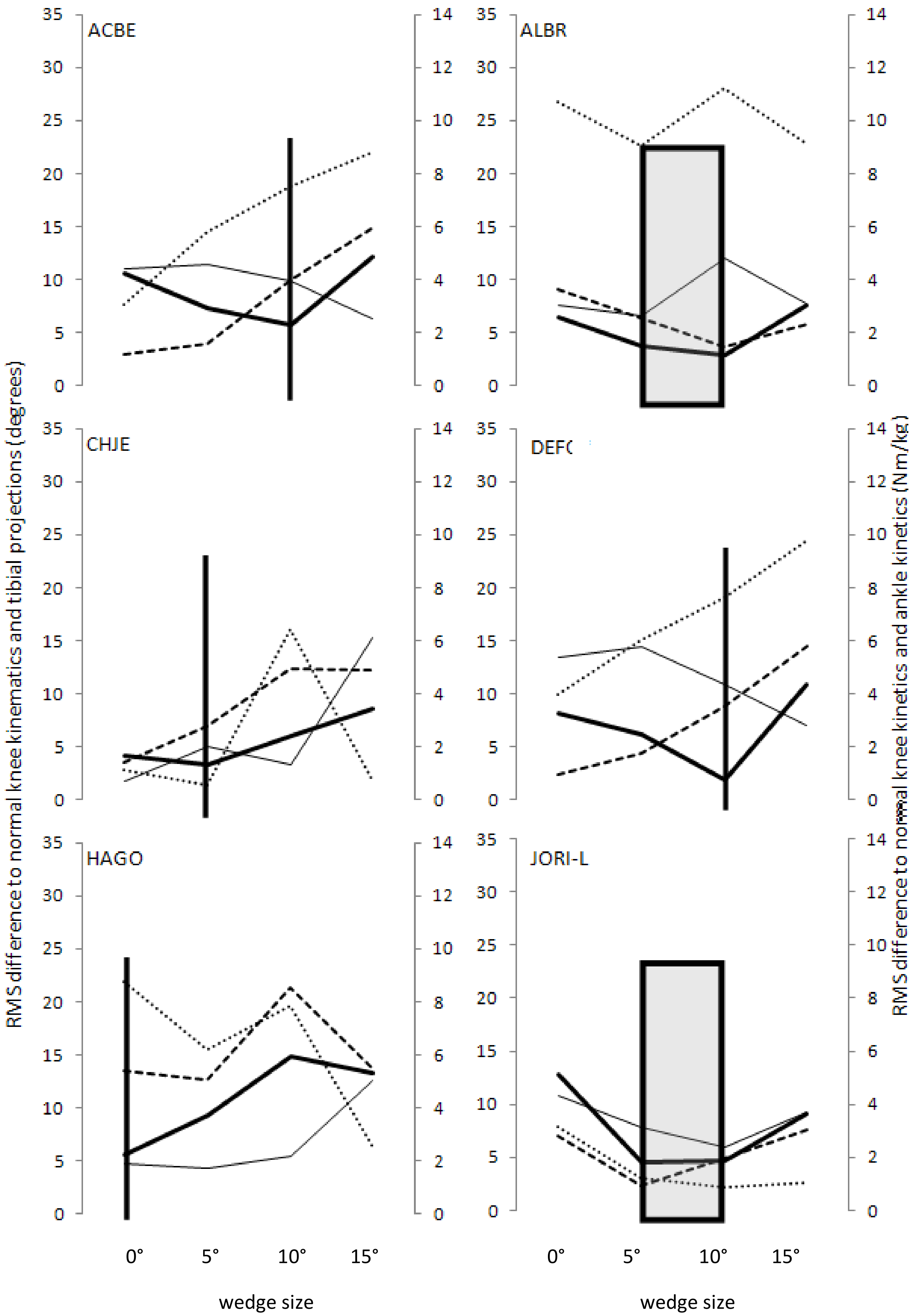
Solid AFOs



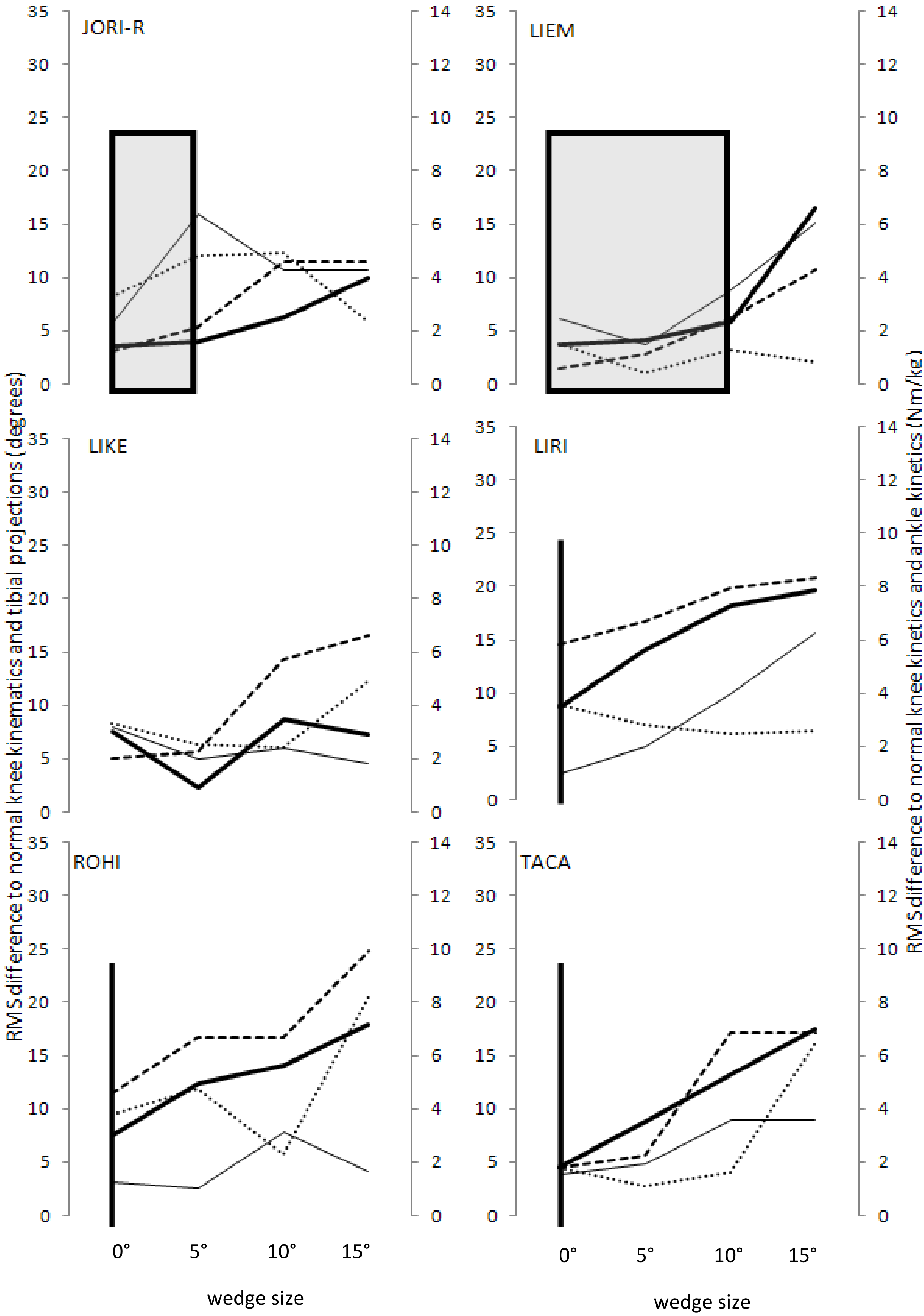
JODA-L
JODA-R
JOTH-L
JOTH-R
LIRI-L
RMS difference to normal knee kinematics and tibial projections (degrees)
RMS difference to normal knee kinetics and ankle kinetics (Nm/kg)
35
30
25
20
15
10
5
0
14
12
10
8
6
4
2
0
0°
5°
10°
15°
wedge size
knee angles
tibial projections
knee moments
ankle moments


MAHO-L
MAHO-R
DEHA-L
DEHA-R
JABU-L
JABU-R
RMS difference to normal knee kinematics and tibial projections (degrees)
RMS difference to normal knee kinetics and ankle kinetics (Nm/kg)
0 5 10 15 20 25 30 35
0 2 4 6 8 10 12 14
0° 5° 10° 15°
wedge size

Hinged AFOs



ACBE
ALBR
CHJE
DEFC
HAGO
JORI-L
RMS difference to normal knee kinematics and tibial projections (degrees)
RMS difference to normal knee kinetics and ankle kinetics (Nm/kg)
0°
5°
10°
15°
wedge size


JORI-R
LIEM
LIKE
LIRI
ROHI
TACA
35
30
25
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15
10
5
0
14
12
10
8
6
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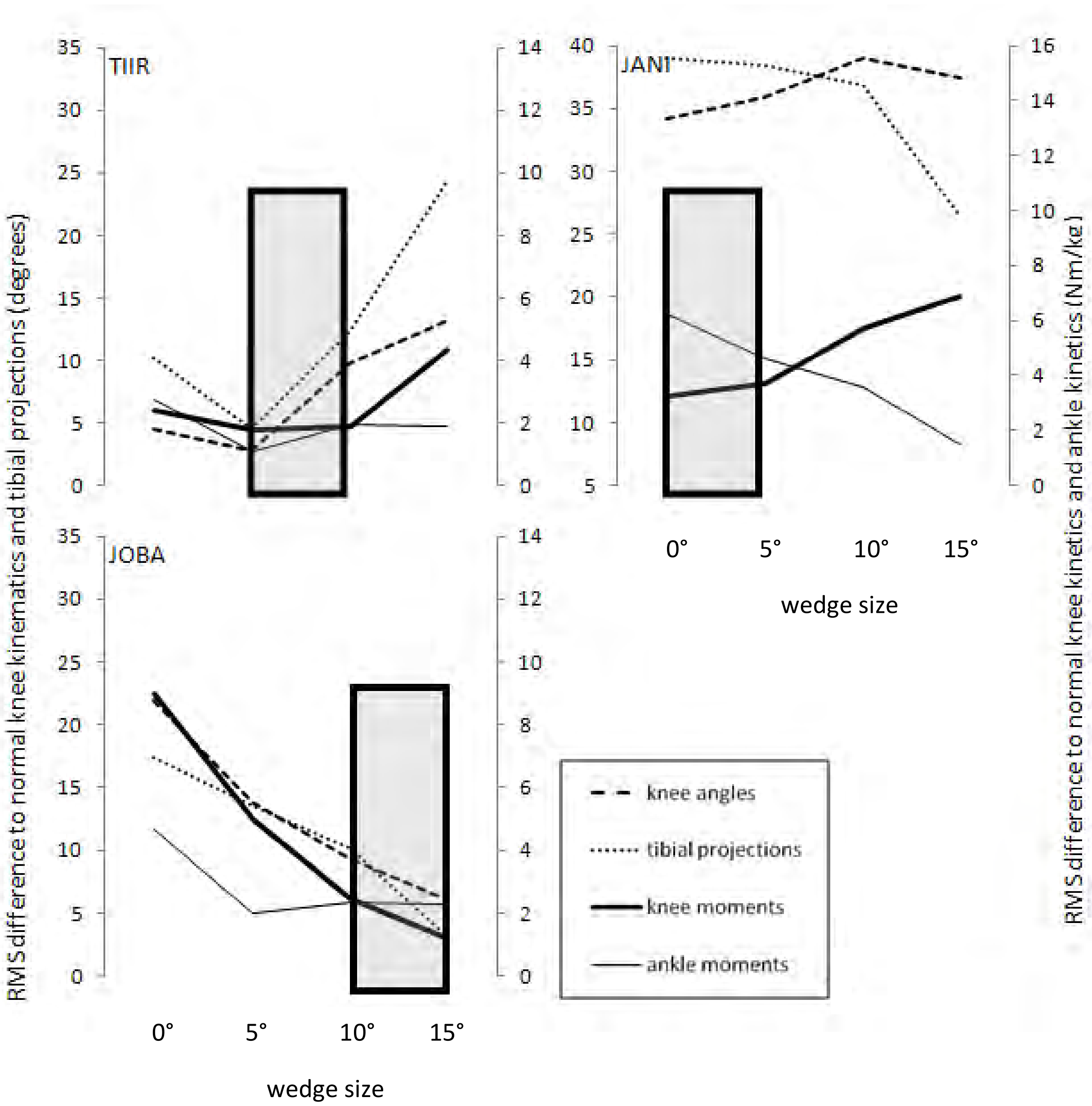
RMS difference to normal knee kinematics and tibial projections (degrees)
RMS difference to normal knee kinetics and ankle kinetics (Nm/kg)
0°
5°
10°
15°
wedge size


TIIR
JANI
JOBA
35
30
25
20
15
10
5
0
14
12
10
8
6
4
2
0
40
16
0°
5°
10°
15°
wedge size
knee angles
tibial projections
knee moments
ankle moments
RMS difference to normal knee kinematics and tibial projections (degrees)
RMS difference to normal knee kinetics and ankle kinetics (Nm/kg)

Appendix H: A new model to measure AFO, tibial and footwear kinematics in 3DGA

This model was developed in collaboration with Dr Morgan Sangeux and Professor Richard Baker. Bodylanguage script is shown for the left side only.

Static Model

AJC = (LANK+LMED)/2
LShank = [AJC, LTIBant-AJC, LANK-LMED, zxy]
LFEOShank = LFEO / LShank
%LFEOShank = average(LFEOShank)
param(%LFEOShank)

LAFO = [AJC, LTIBpost-AJC, LANK-LMED, zxy]
LFEOAfo = LFEO / LAFO
%LFEOAfo = average(LFEOAfo)
param(%LFEOAfo)

Dynamic Model

AJC = (LANK+LMED)/2
LShank = [LAJC, LTIBant-LAJC, LANK-LMED, zxy]
LFEOShank = %LFEOShank * LShank
LShank= [LAJC, LFEOShank-LAJC, LANK-LMED, zxy]

LAFO = [LAJC, LTIBpost- LAJC, LANK-LMED, zxy]
LFEOAfo = %LFEOAfo * LAFO
LAFO = [LAJC, LFEOAfo- LAJC, LANK-LMED, zxy]

LShoe = [LAJC, LTOE-LHEE, LANK-LMED, zxy]
LAFOfoot = [LAJC, LTOE-LAJC, LANK-LMED, zxy]
LHeeAFO = LHEE / LAFOfoot
%LHeeAFO = average(LHeeAFO)
param(%LHeeAFO)

LAFOfoot = [LAJC, LTOE-LAJC, LANK-LMED, zxy]
LHeeAFO = %LHeeAFO *LAFOfoot
LAFOfoot = [LAJC, LTOE-LHeeAFO-LTOE, LANK-LMED, zxy]

LShoe = [LAJC, LTOE-LHEE, LANK-LMED, zxy]

Angle decomposition

LAnkleAFO=-<LAFO,LAFOfoot,yxz>
LAnkleAFO=<-1(LAnkleAFO)-90,-3(LAnkleAFO),-2(LAnkleAFO)>

AnkleAnat=-<LShank,LAFOfoot,yxz>
LAnkleAnat=<-1(LAnkleAnat)-90,-3(LAnkleAnat),-2(LAnkleAnat)>

LFootMvt=-<LShoe,LAFOfoot,yxz>
LFootMvt=<-1(LFootMvt),-3(LFootMvt),-2(LFootMvt)>

LTibialMvt=-<LAFO,LShank,yxz>
LTibialMvt=<1(LTibialMvt),-3(LTibialMvt),-2(LTibialMvt)>

output(LFootMvt,LAnkleAFO,LTibialMvt,LAnkleAnat

References

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