THE BIOMECHANICAL OPTIMISATION (TUNING) OF THE ANKLE FOOT ORTHOSIS - FOOTWEAR COMBINATION (AFO-FC) OF CHILDREN WITH CEREBRAL PALSY - THE EFFECTS ON SAGITTAL GAIT CHARACTERISTICS, MUSCLE AND JOINT CHARACTERISTICS AND QUALITY OF LIFE.

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ABSTRACT

The current study aimed to investigate influences of rigid Ankle Foot Orthoses (AFOs) on gait in children with Cerebral Palsy (CP), immediate effects of tuning of AFO-FC (AFO-Footwear Combination) on gait of children with CP, short-term effects of tuning of AFO-FC on gait, muscle and joint characteristics and quality of life in children with CP, and the feasibility of conducting a larger trial.

The study included 11 healthy children and 8 children with CP. Outcome measurements included sagittal plane kinematics and kinetics derived using 3D motion analysis, Gait Deviation Index (GDI), physical examination, and quality of life using the PedsQL™ questionnaire.

Data from healthy children demonstrated influences of shoes on gait parameters and the role of the ankle joint in adapting to various wedges and rockers during gait.

When studying children with CP, beneficial effects of rigid AFO-FC on gait parameters were evident; these were thought to relate to the appropriateness of the AFO-FC and familiarisation with the prescription. Immediate effects of tuning varied according to gait patterns previously demonstrated with non-tuned AFO-FC; benefits to knee kinematics and kinetics were largely seen in legs with extended knee gait, followed by jump knee gait, and with poorest responses in legs with crouch knee gait.

Short-term effects of tuning were evident when comparing measurements taken before and after two-to-four months of wearing the tuned AFO-FC. Barefoot walking demonstrated significantly improved walking speed. Stride-length improved when comparing tuned AFO-FC at baseline with the tuned AFO-FC following the intervention period. No short-term changes were seen in PedsQL™ scores, muscle and joint characteristics, and GDI. Feasibility issues were also identified.

It was concluded from this exploratory trial that tuning of AFO-FC improved gait for children with CP, although initial gait pattern affected the amount of benefit. This was evident immediately after tuning and some parameters improved further after short-term intervention. A randomised controlled trial is required; power analysis indicates the need for a larger sample of 18 in each group to detect change in GDI with a medium effect size and at a power of 0.8 and $p < 0.05$.

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CHAPTER 1 INTRODUCTION

Cerebral Palsy (CP) is a group of disorders associated with developmental brain injuries that occur during foetal development, birth or shortly after birth. The incidence is reported as 1.5 to 4.4 per 1000 live births, and longitudinal epidemiological studies from several countries have reported increased prevalence over time (Liu et al. 1999; Wichers et al. 2001; Winter et al. 2002; Cans et al. 2002). CP is a motor disorder often with associated impairments such as sensory, cognitive, communication and/or behaviour, and/or seizures (Bax et al. 2005). The primary problem is motor impairment, indicating problems with movement, co-ordination and balance. Symptoms such as spasticity and weakness or paralysis are very common among children with CP.

Although CP is a non-progressive neurological condition, skeletal growth during childhood often compounds the primary problem; abnormal development of bone and muscle characteristics is caused by abnormal forces acting on these structures. For this reason, in addition to surgical and therapeutic interventions, orthoses play an important role in the management of the child with CP. Approximately two thirds of children with CP will achieve some walking ability. However, their walking patterns differ from those of healthy children (Pharaoh et al 1998). For the ambulatory child with CP, the rigid Ankle Foot Orthosis (AFO) is probably the most commonly prescribed type of orthosis for the management of gait impairments. Rigid AFOs maintain the ankle in an optimal position and maintain stretch on the triceps surae muscle. It has been suggested that rigid AFOs are capable of improving the efficiency of gait and preventing deformities (Condie and Meadows 1993). A review by Morris (2002) concluded that preventing plantar-flexion improved gait efficiency by improving stability in the stance phase (Miller, 1999), clearance during swing (Ounpuu et al. 1996), step length and walking speed (Abel et al. 1998), and oxygen consumption (Maltais et al. 2002).

There have been several studies on the effects of rigid AFOs on the gait of children with CP. However, ambiguity exists regarding their efficacy. While some studies found impacts on temporal and spatial parameters and kinematics of proximal joints with the use of AFOs (Brunner, Meier and Ruepp 1998; Abel et al. 1998), others found changes only in temporal and spatial parameters and ankle joint kinematics (Carlson et al. 1997, Radtka, Skinner and Johanson 2005). Another study did not find any changes except at the ankle joint (Smiley et al. 2002). The ambiguity can be attributed to many factors. Firstly, there is a lack of uniformity in several aspects of study design, such as patient population and sample size (Balaban et al. 2007), and time given to get accustomed to AFOs. Secondly, there is a lack of comparison between different diagnostic groups and/or gait patterns.The only two studies that made direct comparisons between hemiplegia and diplegia produced conflicting results (White et al. 2002; Radtka et al. 1997). Finally, none of the above mentioned studies considered biomechanical optimisation of AFOs, which has been suggested to have a vital role in optimising the use of AFOs for children with CP (Meadows 1984; Owen 2004b).

Even though biomechanical optimisation or "tuning" of AFOs was suggested decades ago (Cook and Cozzens 1976; Wiest et al. 1979; Nuzzo 1980; Meadows 1984), there still exists a lack of evidence and consensus regarding tuning of AFOs. Although there have been only a few studies on the effects of tuning, all of them invariably reported positive results (Butler, Thompson and Major 1992; Stallard and Woollam 2003; Butler et al. 2007). Tuning involves modifying the alignment of the AFO – footwear combination using aids such as wedges, heels, and rockers to optimise gait. Some authors emphasised the use of wedges to optimise the alignment of the ground reaction force (GRF) in relation to the knee joint in sagittal plane during mid-stance (Butler and Nene 1991). The use of rockers and heels has also been suggested to optimise mid/terminal stance, and initial stance, respectively (Hullin, Robb and Loudon 1992; Owen 2004b). While a few studies have reported the effects of tuning using wedges on gait (Butler, Thompson and Major 1992; Stallard and Woollam 2003; Butler et al. 2007), evidence regarding the effects of heels and rockers is empirical at best. Some authors and clinicians have also emphasised the importance of the angle of the ankle in the AFO and its influence on activity of the triceps soleus muscle (Owen 2004b). This also lacks evidence.

Furthermore, while pre existing rotational deformities of joints are taken into consideration while casting AFOs and tuning, the tuning procedure involves modification of GRF in sagittal plane.

Considering the various aspects involved, it can be assumed that tuning has evolved as a complex intervention over years. As such it can be investigated using the Medical Research Council (MRC) framework for developing and evaluating complex interventions for improving health (Medical Research Council 2000). This defines a complex intervention as including a number of aspects that contribute to its effectiveness, making it difficult to identify any single element as key. The MRC framework highlights the importance of the Randomised Controlled Trial (RCT) as a study design in clinical research, as its experimental nature enables comparison of different conditions, with random allocation of participants to experimental and control groups (Portney and Watkins 2000). However, the framework also identifies difficulties associated with the evaluation of a complex intervention and suggests a staged approach, including modelling of the potential efficacy of different elements of the intervention (Medical Research Council 2000). The current level of evidence in tuning requires investigation into the effects of components of tuning (Phase I or modelling stage) and exploration of the feasibility (Phase II or exploratory trial stage) of conducting a definitive RCT. Furthermore, at this stage emphasis should be on sagittal plane gait parameters.

To summarise, there is ambiguity in the literature regarding effects of rigid AFOs on the gait of children with CP, which may be attributed to a lack of uniformity in study design, lack of comparisons between diagnostic classifications and/or gait patterns, and a lack of biomechanical optimisation (tuning) of AFOs. While tuning is reported to be effective in optimising AFO interventions, there is lack of both evidence and consensus regarding tuning methods. Considering the complexity of tuning as an intervention, it is important to identify the specific components of tuning and investigate their effects, as well as to explore the feasibility of conducting an RCT.

Therefore, the overall aims of the current study are:

1) examine the ambiguity in the literature relating to AFO intervention and identify possible reasons;
2) investigate the influence of rigid AFOs on the sagittal plane gait parameters of children with CP
3) explore the effects of components of tuning on the sagittal plane gait parameters of children with CP;
4) investigate the immediate effects of tuning on the sagittal plane gait parameters of children with CP;
5) investigate the feasibility of tuning as a meaningful clinical intervention that might be implemented within a clinical trial;
6) investigate the short-term effects of tuning on the gait, muscle tone and strength, passive range of motion and quality of life of children with CP

In order to address these general aims, a literature review was conducted and different experiments were designed. Based on the literature review, experiments to address the validity and reliability of measurements, and experiments to address the general aims 2 to 5 were designed. The individual experiments and their objectives are stated below.

Study aims:

1. Pre trial 1 – Precision and accuracy of the 3D motion analysis system:
   a) To estimate the precision of VICON 3D motion analysis systems used in the project in relation to calculation of distances
   b) To estimate the precision of VICON 3D motion analysis systems used in the project in relation to calculation of angles
2. Pre trial 2 – Precision and accuracy of the force plates:
   a) To estimate the precision and accuracy of the AMTI force plates used in the project in relation to measurement of vertical forces
3. Pre trial 3 – Accuracy and reliability of gait analysis – comparison of three marker sets:
   a) To compare the accuracy of three marker methods in measuring knee kinematics, in order to identify the marker method to be used in the project

b) To investigate the inter and intra-rater reliability of the chosen marker set

4. Pre trial 4 – Reliability of mid-stance identification using kinematics definition
    b) To investigate the intra-rater and inter-rater reliability of the method of mid-stance identification used in the current project (kinematic method)
    c) To compare the kinematic method with the traditional method of mid-stance identification (temporal method)
5. Main study 1 – Effects of shoes, rockers and wedges on the gait of healthy children
    a) To generate reference data for the gait of healthy children, enabling comparisons
    b) To investigate the role of shoes in the gait of healthy children
    c) To investigate the influences of rockers and wedges on the gait of healthy children
6. Main study 2 – Effects of non-tuned AFO-FC and immediate effects of Tuned AFO-FC on the gait of children with CP
    a) To investigate the effects of rigid AFO-FC (non-tuned) compared to barefoot on temporal-spatial parameters, lower limb kinematics and joint moments, shank to vertical angle (SVA) and Gait Deviation Index (GDI) in children with CP
    b) To investigate the effects of tuned AFO-FC compared to non-tuned AFO-FC on temporal-spatial parameters, lower limb kinematics and joint moments, SVA and Gait Deviation Index (GDI) in children with CP
7. Main study 3 - Effects of wedges and PLRs on the gait of children with CP
    a) To investigate the effects of increasing sizes of wedges on temporal-spatial parameters, lower limb kinematics and joint moments, and SVA in children with CP
    b) To investigate the effects of increasing sizes of PLRs on temporal-spatial parameters, lower limb kinematics and joint moments, vertical forces and SVA in children with CP

8. Main study 4 – Feasibility study on the short-term effects of tuning of AFO-FC for children with CP
    a) To investigate the short-term effects of tuning of AFO-FC on temporal-spatial parameters, lower limb kinematics and joint moments, SVA, Gait Deviation Index (GDI), muscle tone, muscle power, joint range of motion and quality of life in children with CP
    b) To investigate the feasibility of conducting a larger trial looking into short-term effects of AFO-FC for children with CP

CHAPTER 2 CEREBRAL PALSY: AN OVERVIEW

2.1 Introduction

The term ‘Cerebral Palsy’ (CP) has always been used to define a broad range of clinical conditions. There have been attempts to explain this broad term based on aetiology, impairments, and presentation. This chapter attempts to provide an overview of various definitions and classifications that have been used and are presently in use, prevalence, aetiology, impairments, management, and prognosis of CP.

2.2 Definition and classification of CP

CP has been defined and redefined in the last two centuries, due to the complexity associated with the term. William John Little addressed the deformities and contractures associated with perinatal injuries in his lecture in 1843 (Little 1843). The first and most frequently used definition was put forward only in 1957 by a group called the ‘Little Club’ which defined CP as: “a permanent but not unchanging disorder of movement and posture appearing in the early years of life and due to a non-progressive disorder of the brain, the result of interference during its development” (Mac Keith and Polani 1959, cited in Morris 2007, p.5). Later in 1964 another group redefined CP as “a disorder of movement and posture due to a defect or lesion of the immature brain” (Bax 1964, p.295). They also stated that any disorder of short duration, caused by sheer intellectual deficit, or any progressive condition, should be excluded from CP.

Another definition was put forward after three international meetings on the epidemiology of CP in 1987, 1989 and 1990. In the third meeting, a new definition was put forward: “an umbrella term covering a group of non-progressive, but often changing, motor impairment syndromes secondary to lesions or anomalies of the brain arising in the early stages of its development” (Mutch et al. 1992, p.549). The research group ‘Surveillance of Cerebral Palsy in Europe’ (Cans 2000) did not attempt to amass a new definition, but suggested that any definition should consider five important factors regarding CP, namely: it is an umbrella term; permanent but not unchanging in nature; a disorder of movement and/or posture and of motor function; caused by a non-progressive interference, lesion or abnormality; and the causative damage is in the developing brain. It is clear that the SCPE (Cans 2000) more or less agreed to the definition put forward by Mutch et al (1992).

In an international meeting in 2004 a new definition was put forward which, apart from the already suggested criteria, took into consideration activity limitation and other impairments. The definition was as follows;

> Cerebral Palsy describes 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. The motor disorders of Cerebral Palsy are often accompanied by disturbances of sensation, cognition, communication, perception, and/or behaviour, and/or by a seizure disorder. (Bax et al. 2005, p. 572)

The definition was commented on by several authors in Carr et al. (2005); while the addition of 'activity limitation' was considered more inclusive by Carr, Stevens found the term inappropriate and suggested the use of 'impaired function' as a replacement. Blair and Love criticised the definition as incomplete, through not annotating satisfactorily the term "non-progressive" and not addressing the age limit for onset and lower limit of severity appropriately Carr et al. (2005). The definition was later modified by stating the nature of the 'group of disorders' as permanent, and also by adding secondary musculoskeletal problems to the list of possible associated problems (Rosenbaum et al. 2007). The attempts to redefine CP are encouraging. It is clear that the process is expected to continue, but while the definition is becoming more complicated, it is also becoming more inclusive.

Similar to definitions, classifications of CP have also been controversial. The first known classification was by Little in 1862, and since then various classifications and approaches to classifications have been used. Three common approaches to classification addressed the nature of the motor problem, topography, and aetiology.

Motor disorders are often identified as spastic, dyskinetic–choreo athetoid, dystonic and ataxic, to describe different presentations. All the classifications have identified spasticity as an important feature, but earlier authors used the term rigidity (Little 1862). The presence of involuntary movements was also identified (Little 1862; Ingram 1955). Some classifications included atonia as a type of disorder (MacKeith and Polani 1959, cited in Morris 2007; Minear 1956), and this is no longer incorporated.

Variation is also present in topographical classifications, which focus on which limbs are affected. While this approach seems straightforward, disagreements existed in the distributions identified and terminology used to explain the types. While the common types identified were diplegia, hemiplegia and quadriplegia, types such as monoplegia, triplegia and double/bilateral hemiplegia were also included by some authors (Minear 1956; Ingram 1955). The lack of consensus in the definition of terms between the classifications was criticised, diplegia being probably the most controversial (Colver and Sethumadhavan 2003). A classification by Hagberg, Hagberg, and Olow (1976) was used in a reliability study looking at agreement between clinicians in the classification of CP; this concluded that education would be beneficial (Blair and Stanley 1985). More recently the SCPE has suggested the use of a new classification system in which only the terms bilateral and unilateral are used instead of more traditional terms (Cans 2000). This approach was supported at the International Workshop on the Definition and Classification of CP in 2004, where consideration of the trunk and oropharynx was also advocated. While workshop participants recommended that the terms quadriplegia and diplegia were not to be used, they found the SCPE classification unclear in identifying the possibility of opposite side involvement in unilateral, and asymmetry in bilateral CP (Rosenbaum et al. 2007).

Not many classifications of CP have considered aetiological factors or causal pathways. The advent of modern diagnostic systems like Magnetic Resonance Imaging has increased the possibilities of early identification of underlying pathology. The International Workshop on the Definition and Classification of CP recommended the use of neuroimaging findings and cause in categorising children with CP (Rosenbaum et al. 2007).

To summarise, the literature demonstrates a lack of consensus regarding classification of CP. When it comes to treatment of gait problems, clinicians tend to make use of classifications that are based solely on gait patterns. A mixture of topographical and gait classifications are also used and these vary across treatment centres.

2.3 Prevalence of CP

Epidemiological studies on CP are abundant. While several epidemiological studies have been conducted in developed countries, fewer relate to lower income countries. European countries have taken more effort in recording and publishing prevalence data relating to CP. The SCPE has formed a register for CP that incorporates data from eight countries (Cans 2000; Cans et al. 2002). While the prevalence of CP is more or less similar between developed countries, findings are more variable in developing countries. Table 2.1 gives the rate of CP per 1,000 births according to the latest data available. It should be noted that none of the studies have included data from the whole country/continent where the study was conducted, and that the year given indicates the birth year of children in the study, rather than the publication date.

It can be seen from the Table 2.1 that the prevalence of CP in developed countries ranged only from 1.7 to 2.6. When only the last decade is considered, the range is even less (1.9 to 2.6). This is not the case for developing countries, where prevalence ranges from 2.0 to 4.4. A particularly high prevalence is demonstrated in Turkey. This may be due to problems with obstetric and neonatal care, but the authors also pointed out the increased percentage (49%) of CP of unknown aetiology (Serdaroglu et al. 2006).

Table 2.1 Prevalence of CP in various countries

Area of the study	Year	Prevalence /1000 live births	Reference
England	1967 – 1984	1.7	Pharoah et al. (1990)
Northern Ireland	1994 – 1997	2.2	Dolk, Parkes and Hill (2006)
UK (five centres)	1986 – 1996	2	Surman et al. (2006)
West Sweden	1995 – 1998	1.92	Himmelmann et al. (2005)
Norway	1996 – 1998	2.1	Andersen et al. (2008)
Denmark	1987 – 1990	2.4	Topp, Uldall and Greisen (2001)
Atlanta, US	1986 – 1991	2	Winter et al. (2002)
South Sweden	1994 – 1997	2.6	Westbom, Hagglund and Nordmark (2007)
Netherlands	1986 – 1988	2.44	Wichers et al. (2001)
Europe (eight centres)	1980 – 1990	2.08	Cans et al. (2002)
Turkey	1980 – 1996	4.4	Serdaroglu et al. (2006)
Hong Kong	1994 – 1997	2.6	Yam et al. (2006)
China	1997	2	Liu et al. (1999)
Malta	1986 – 1990	2.4	Sciberras and Spencer (1999)

N.B. Decimal places for prevalence estimates are as stated by study authors.

Longitudinal studies have recognised varying trends in the prevalence of CP. Table 2.2 includes studies, or series of studies, that demonstrate trends in the prevalence of CP in different places. No specific pattern can be seen. While the majority of studies show a marked increase in prevalence over time (Cans et al. 2002; Liu et al. 1999; Wichers et al. 2001; Winter et al. 2002), some do not demonstrate any significant change (Dolk, Parkes, and Hill 2006; Sciberras and Spencer 1999) and one study shows a marked decrease (Meberg and Broch 1995). The series of Swedish studies spanning over four decades shows an interesting trend. While prevalence increased from 1.9 to 2.49 during the period 1959 to 1986, it then decreased to 1.92 by 1998 (Hagberg et al. 2001; Hagberg et al. 1996; Himmelmann et al. 2005). Prevalence increased in the majority of studies, which is probably due to improved neonatal care, resulting in lower infant mortality and a greater number of survivors demonstrating CP. The variability in data from longitudinal studies may be due to factors such as geographical differences and availability of obstetric and neonatal care. Differences in the study design might also have had an effect; for example, several studies did not consider CP with postneonatal origin (Cans et al. 2002; Dolk, Parkes and Hill 2006; Westbom, Hagglund, and Nordmark 2007; Wichers et al. 2001; Winter et al. 2002) and one study did not consider CP with either neonatal or postneonatal origin (Topp, Uldall, and Greisen 2001).

Table 2.2 Changes in prevalence of CP over time

Area of the study	Year	Change in prevalence/ 1000 live births	Reference
Northern Ireland	1981 – 1997	2.3 to 2.2	Dolk, Parkes and Hill (2006)
UK (five centres)	1976 - 1996	1.9 to 2	Surman et al. (2006)
West Sweden	1959 – 1986	1.9 to 2.49	Hagberg et al. (1996)
	1987 - 1998	2.49 to 1.92	Hagberg et al. (2001)
	1959 – 1998	1.9 to 1.92	Himmelmann et al. (2005)
Norway	1970 – 1989	2.8 to 2	Meberg and Broch (1995)
Atlanta, US	1975 – 1991	1.7 to 2	Winter et al. (2002)
Netherlands	1977 – 1988	0.77 to 2.44	Wichers et al. (2001)
Europe (eight centres)	1976 – 1989	1.5 to 2.08	Cans et al. (2002)
China	1990 – 1997	1 to 2	Liu et al. (1999)
Malta	1981 – 1990	2.4 to 2.4	Sciberras and Spencer (1999)

N.B. Decimal places for prevalence estimates are as stated by study authors.

2.4 Aetiology of CP

The aetiology of CP has been widely studied to aid in prevention of its occurrence. Aetiological factors are commonly grouped according to the timing of the insult: antenatal, perinatal, neonatal and postnatal (Stanley 1994). Postnatal can also be referred to as postneonatal. The common Central Nervous System (CNS) pathologies which result in Cerebral Palsies are haemorrhage, hypoxia and ischaemia in the CNS (Koman, Smith, and Shilt 2004). Gestational age is identified to have a high correlation with prevalence of CP, and a high association between spastic diplegia and prematurity has also been reported (Thorngren-Jerneck and Herbst 2006). A population-based study has found the prevalence of CP to have increased in preterm live births over the time period from 1993 to 2002 (Vincer et al. 2006).

Traditionally perinatal causes were considered the prime culprit in causing CP. However, a population-based study has maintained that there is a lack of association between perinatal causes and CP in term born children (Badawi et al. 2005).This was contradicted by another population-based study which found greater association between perinatal/neonatal causes and CP (Hagberg et al. 2001). However, Hagberg and colleagues (2001) also found that of the 37 children with birth asphyxia, one third had prenatal predisposing factors. Another study found that newborn encephalopathy (perinatal risk) has various prenatal causes associated to it (Badawi et al. 1998). Prenatal causes have the potential to either cause CP on their own, or to make the foetus vulnerable to perinatal asphyxia (Stanley 1994). The various identified prenatal causes include multiple pregnancy and teratogenic factors such as infections, drug administration during pregnancy, maternal trauma, intrauterine growth retardation (IUGR) resulting in low birth weight, pre-eclampsia, and placental abnormalities (Jacobsson and Hagberg 2004; Stanley 1994; Thorngren-Jerneck and Herbst 2006).

Several studies have looked into associations between peri/neonatal factors and CP. Common peri/neonatal factors are: instrumental delivery, neonatal jaundice, placental abnormalities, neonatal seizures, maternal pyrexia, infections, and maternal diabetes. In a Swedish population-based study, it was found that peri/neonatal causes had strong associations with gestational age. (Hagberg et al. 2001). Another study reported associations between CP and factors such as maternal diabetes, abruptio placentae, low birth weight, pre-eclampsia, multiple pregnancy, breech presentation at vaginal delivery, emergency caeserian delivery and instrument assisted delivery (Thorngren-Jerneck and Herbst 2006).

Postnatal or postneonatal causes refer to factors leading to CP where it occurs four weeks or more after birth, with an upper limit that varies from two to ten years (Blair and Stanley 1982; Stanley, Blair, and Alberman 2000). Reviewing several studies in both developing and developed countires, Stanley, Blair and Alberman (2000) identified several postneonatal causes of CP. The most common were infections, head injury and cerebrovascular accidents. Other reasons such as convulsions, suffocation, and near drowning were also identified. The SCPE studied seven different centres and identified that 7.7% of all CP cases were of postneonatal origin, with an age of onset of less than 25 months (Cans et al. 2004). A population-based study in Sweden found that 2.9% of children with CP had postneonatal causes (Hagberg et al. 2001). A collaborative network of CP registers in the UK recorded that 8% of children with CP born in the period between 1960 and 1997 demonstrated postneonatal origin (Surman et al. 2006). Another study in the UK included children with ages of onset up to five years and reported that 18% of the total number demonstrated postneonatal origin (Pharoah, Cooke, and Rosenbloom 1989).

In a review of literature relating to incidence, impairments and risk factors relating to CP, Odding and colleagues identified low birth weight, intrauterine infections and multiple pregnancy as the most vital risks associated with incidence (Odding, Roebroeck, and Stam 2006). However, while the authors conducted an extensive review of literature and identified several pre and peri/neonatal factors, there was obvious lack of information about postneonatal factors. Furthermore, three important papers on postneonatal were not included in the review (Blair and Stanley 1982; Cans et al. 2004; Pharoah, Cooke and Rosenbloom 1989). While there is an abundance of literature relating to aetiology, there is a lack of agreement regarding the possible causes and associations between different causes and risks of developing CP. Variations in study design and geographical differences can be held responsible for the lack of agreement.

2.5 Impairments associated with CP

Children with CP tend to have several associated impairments which further complicate their condition. Intellectual deficit is the most common, and is normally categorised using Intelligence Quotient (IQ). Impairment can vary from learning disability to severe mental retardation. Nordmark et al. (2001) reported that 65.2% of children with CP had some intellectual deficit, supported by Wichers et al. (2005) who reported an incidence of 65.4%. However, Andersen et al. (2008) reported a smaller prevalence of mental retardation (31%), similar to findings reported by the SCPE (31%) (Cans et al. 2002).

Epilepsy is the next most prevalent impairment associated with CP. Prevalence of epilepsy among children with CP ranged from 18.9% to 38% (Nordmark et al. 2001; Cans et al. 2002; Wichers et al. 2005; Andersen et al. 2008; Carlsson, Hagberg, and Olsson 2003). It is been noted that the frequency of epileptic attacks generally decreases after the age of 16 (Odding, Roebroeck and Stam 2006).

Studies contain different findings regarding the prevalence of visual impairment. Nordmark et al. (2001) reported that 22.2% of children with CP had visual impairment, while Wichers et al. (2005) reported 33.9% to have mild or severe visual impairment. Cans et al. (2002) and Andersen et al. (2008) reported contrasting prevalences of severe visual impairments, 11.1% and 4%, respectively. Hearing and speech impairments also occur with CP. Andersen et al. (2008) found that while 4% of their CP population had severe hearing impairment, 28% presented with speech problems.

2.6 Management of CP

A wide range of management opportunities are available for CP; some are evidence-based, while others are clinically common but the evidence is inconclusive. The most frequently available treatment options include therapeutic interventions, modalities and devices, pharmacological and surgical strategies. The availability of such a wide a range of treatment options across the globe makes choices difficult, and most frequently a combination of strategies is employed. Although there is an abundance of literature available on management options for CP, a detailed account is beyond the scope of this section. Due to the central issue of gait impairment, this section aims to provide a brief overview of the available management options of gait problems.

2.6.1 Physical and functional interventions used in the management of CP

Traditionally physiotherapy and occupational therapy have been extensively involved in the rehabilitation of CP. While extensive research has been carried out into the effectiveness of these therapies, evidence remains inconclusive (Koman, Smith and Shilt 2004; Kunz et al. 2006; Ronan and Gold 2007). Kunz et al. (2006) reviewed relevant literature and stated that RCTs in the area of physiotherapy for CP are complicated, and that the low prevalence and high variability of the condition makes it difficult to manage and interpret research. Another possible factor contributing to the difficulty is that physiotherapy and occupational therapy form routine treatment for children, making the inclusion of an untreated control group unethical. In order to address this, several studies have instead compared different intensities of therapy (Bower et al. 2001; Christiansen and Lange 2008; Tsorlakis et al. 2004).

When comparing the effects of intense versus intermittent physiotherapy on children with CP, no differences were found in motor function (Bower et al. 2001). Similar findings were reported by Christiansen and Lange (2008) in another study which compared intermittent and continuous physiotherapy. The authors found no significant difference between the groups. While there is a lack of conclusive evidence regarding the effects of physiotherapy and other therapy options on children with CP, it is believed that physiotherapy plays a vital role in conjunction with orthopaedic surgery and oral/intramuscular or surgical spasticity treatment (Albright, Peacock, and Krach 2004; Christianson and Murr 2004).

A variety of therapy options exist, such as neurodevelopmental therapy, Vojta therapy, conductive education, hyperbaric oxygenation, acupuncture, and acupressure (Ronan and Gold 2007). Neurodevelopmental therapy (NDT), otherwise known as Bobath therapy, is probably the most common treatment option followed by paediatric physiotherapists (Barry 2001). While no RCTs are available in the area, one study compared two groups of children who received NDT intermittently and intensively (Tsorlakis et al. 2004). The authors reported significant improvements in the gross motor function, measured using Gross Motor Function Measure (GMFM), of children who received intensive NDT, in comparison to those who received intermittent treatment.

2.6.2 Devices used in the management of CP

There are several devices and modalities used to help children walk better, including electrical stimulation devices, splints, casts and orthoses. Electrical stimulation for children with CP is not as extensively researched as for adults. Three types of electrical stimulation were proposed:

1) electrical stimulation at a low intensity for long periods, earlier known as therapeutic electrical stimulation and later as threshold electrical stimulation (TES) (Dali et al. 2002; Sommerfelt, Markestad, and Berg 2001);

2) electrical stimulation applied to produce muscle contractions for shorter durations (van der Linden et al. 2003); and

3) electrical stimulation to assist functional activity, known as Functional Electric Stimulation (FES) .

Dali et al. (2002) investigated the effect of TES in a double-blinded RCT and found no significant differences in muscle bulk, range of motion (ROM), or tone. Similarly, Sommerfelt and colleagues (2001) carried out a randomised, controlled, crossover study and reported no benefits from the electrical stimulation. However, FES was found to have some benefits in children with CP (van der Linden et al. 2008). In an RCT, the authors reported significant improvement in gait kinematics through use of FES on the ankle dorsiflexors (orthotic effect), although the differences were not significant over time (therapeutic effect). However, the non-significant long term results were not conclusive owing to the small sample size. The effect of short periods of electrical stimulation to produce muscle contraction has also been investigated (Hazlewood et al. 1994; van der Linden et al. 2003). In a randomised, matched, control design, Hazlewood et al. (1994) investigated the effect of stimulation of the dorsiflexors; van der Linden et al. (2003) used a similar design to investigate the effects of stimulating the gluteus maximus muscle. While the former study reported increased ankle ROM and dorsiflexor strength, the latter did not find any significant differences.

Among orthotic devices, the Ankle Foot Orthosis (AFO) is most commonly used to aid gait (Koman, Smith and Shilt 2004). Although several types of AFOs are available nowadays, conventional rigid AFOs are commonly used. The effects of AFOs on the gait of children with CP are explained in Chapter 6 (page 56).

2.6.3 Pharmacological management of CP

Pharmacological interventions are also commonly used to manage spasticity associated with CP. While a wide spectrum of antispastic agents is available, not all are ideal for paediatric use. While all the agents are capable of reducing tone, their mode of action differs and so do related side effects (Gormley, Krach, and Murr 2004; Ronan and Gold 2007). Another option for reducing spasticity is the use of neurolytic blocks, which have the merit of local administration, thus preventing any generalised effect (Ubhi et al. 2000). Phenols and botulinum toxin A are the most common neurolytic blocking agents, of which botulinum toxin A is the drug of choice due to negative side effects of phenol use (Gormley, Krach and Murr 2004). Botulinum A is injected into the muscle, which then produces a temporary reversible paralysis. A comprehensive rehabilitation plan along with botulinum toxin A injection is considered the ideal management strategy (Scholtes et al. 2006a; Scholtes et al. 2007).

In an RCT, Scholtes et al. (2006a) investigated the effect of botulinum toxin A combined with comprehensive rehabilitation. The results showed that botulinum toxin significantly improved motor function even after 24 weeks. Another study investigated the effects of botulinum toxin A, combined with comprehensive rehabilitation, on gait pattern, muscle length and spasticity of children with spastic CP (Scholtes et al. 2007). After six weeks there was a significant improvement in parameters such as knee extension during mid-stance and terminal swing, gait score (Edinburgh Visual Gait Analysis Interval Testing scale), tone and length of hamstrings and gastrocnemius, and tone of soleus. While the improvement in all parameters disappeared after 24 months, muscle length was maintained.

2.6.4 Surgical management of CP

The surgical management of CP involves procedures to reduce spasticity and orthopaedic procedures to correct contractures and/or deformities. The surgical reduction of spasticity involves either intrathecal infusion of baclofen (ITB) or selective dorsal rhizotomy (SDR). Intrathecal infusion of baclofen involves the implantation of a baclofen pump so that an adequate amount of the drug is delivered to the cerebrospinal fluid (CSF) (Koman, Smith and Shilt 2004). ITB is indicated for children with moderate to severe spasticity or dystonia and is only preferred after unsuccessful oral medication. Associated complications are catheter problems, infections, and leakage (Albright, Peacock and Krach 2004). An RCT which studied the effects of the baclofen pump reported significant reductions in muscle tone and pain, and better ease of care in the experimental group compared with the control group (Hoving et al. 2007).

SDR involves the transection of dorsal rootlets arising from the spinal cord. The rootlets are selected according to which muscle groups require treatment for spasticity (Albright, Peacock and Krach 2004). Rhizotomy may lead to temporary muscle weakness, necessitating physiotherapy and use of orthotics post-surgically (Koman, Smith and Shilt 2004). Effects of SDR on CP have been investigated through several well designed studies (McLaughlin et al. 1998; Steinbok et al. 1997; Wright et al. 1998). Three RCTs compared SDR combined with physiotherapy with physiotherapy only. While Steinbok et al. (1997) and Wright et al. (1998) found significantly greater improvements in motor function with the use of SDR combined with physiotherapy than with physiotherapy alone, McLaughlin et al. (1998) did not find any significant differences in motor function. All three studies found significant reductions in spasticity with the use of SDR. A meta-analysis of the three RCTs concluded that motor function and spasticity reduction was significantly different (McLaughlin et al. 2002). A multivariate analysis also revealed a relationship between percentage of rootlets transacted and improvement in motor function. A retrospective study compared the outcomes of SDR and orthopaedic surgery (Schwartz et al. 2004). The authors found that while both surgery and rhizotomy guided by preoperative gait analysis were significantly beneficial for children with CP, the children who received both interventions had a significantly lower rate of soft tissue surgeries when compared with children who received only orthopaedic surgery.

Orthopaedic surgical management of CP includes a variety of surgical procedures such as transecting a tendon (tenotomy), lengthening of the muscle tendon, aponeurosis recession, transfer of a tendon, fusing a peripheral joint (arthrodesis), transecting a bone (osteotomy), myotendinous lengthening, and multiple spinal fusions. It is beyond the scope of this chapter to discuss all of the procedures. One, or a combination, of these procedures is used in management of CP, and no RCTs have yet attempted to identify an optimum combination of surgeries (Koman, Smith and Shilt 2004). For ambulatory children with CP, the most commonly practised procedures are: tendon lengthening surgeries, recession of the aponeurosis to relieve tightness, and osteotomies to correct skeletal deformities (predominantly rotational).

The two muscle groups which require lengthening are hamstrings and triceps surae. Studies have shown that hamstrings need not be short even in crouch even though they are clinically tight, and it was reported that the length of the muscle unit can be more during gait than static examination (Hoffinger, Rab, and Abou-Ghaida 1993). The mechanism of crouch is described in Section 5.3.1.1. (page 44) The use of SDR reduces the requirement for soft tissue release at the knee (Schwartz et al. 2004). Both these factors have led to decreased use of hamstring lengthening procedures (Novacheck 2004).

Tightness of the Tendo Achilles (TA) and resultant equinus is the most common deformity seen in children with CP (Wren, Rethlefsen, and Kay 2005). As SDR is not found to have any merit over soft tissue release around the ankle joint (Schwartz et al. 2004), lengthening surgeries of triceps surae are still widely performed. The procedures capable of releasing tightness of triceps surae are lengthening of the TA, lengthening of gastrocnemius muscle, recession of the fascia of soleus or gastrocnemius or both. Since lengthening of the TA weakens the soleus muscle and reduces power generation at the ankle, it is not the preferred procedure (Novacheck 2004). Unwarranted lengthening of soleus can result in crouch gait with excessive dorsi-flexion at the ankle (Sutherland and Cooper 1978). Therefore, lengthening of gastrocnemius at the muscle belly, or recession of gastrocnemius fascia with or without recession of soleus fascia is preferred. Orthopaedic surgery is believed to have long term effects on the gait of children with CP. A retrospective study investigated the effects of calf lengthening surgeries with a mean follow-up period of 6.9 years (Borton et al. 2001). While 42% of the total sample maintained a good calf lengths, 22.6% developed recurrent equinus and 36% developed calcaneus deformity. However, it is worth noting that lengthening of the TA was conducted in 71% of the sample, and recession of the gastrocnemial fascia in the rest. This would have left the soleus muscle weak in the majority of children.

Traditionally, conservative treatment approaches were tried first, followed by invasive procedures. Nowadays, instead of choosing one ideal treatment for CP, a comprehensive management plan involving more than one treatment option is preferred (Gormley, Krach and Murr 2004). However, the heterogeneity of the condition and combination of treatments makes any research with children with CP difficult to manage.

2.7 Prognosis of CP as a long-term condition

For ambulatory children with CP the concerns of prognosis normally relate to ambulatory capacity and mortality. Studies have looked into life expectancy and influencing factors. In a study which investigated the life expectancy of persons with CP born between 1958 and 1994 (Blair et al. 2001), the mortality rate was reported to be 6.23 deaths per 1,000 person-years. The strongest predictor of mortality was mental retardation and only 50% of children with an IQ of under 20 reached adulthood, whereas 76% of children with IQs of between 20 and 34 reached adulthood. The authors noted that it was CP that resulted in mortality in the majority of cases. 59% of deaths were accounted for by respiratory infections as the immediate cause. Another study looked at variation in life expectancy over the period from 1983 to 2002, and reported that life expectancy has improved in people with severe CP and who require gastrostomy feeding. They found only a very small difference in less severe group of CP (Strauss et al. 2007). It was also reported that life expectancy was lower in adults who have lost their mobility (Strauss et al. 2004). Associated impairments also compound the risk of mortality. A study which investigated the regional variations of life expectancy in people with CP in the UK reported that mortality was directly proportional to the number of impairments (Hemming et al. 2005). It was reported that 60% of people with four impairments did not survive to the age of 20.

Although CP is predominantly childhood pathology, deterioration continues into adulthood. Bottos et al. (2001) reported that 30.5% of people with CP who had one or other method of ambulation had lost the ability by adulthood. Of those who were independent walkers, 44.8% had lost the ability and all those who maintained the ability to walk demonstrated deterioration in their performance (Bottos et al. 2001). A study of Californians found that children with the ability to walk and climb stairs without difficulty at the age of ten had only 23% chance of decline, whereas those who walked with difficulty and used wheelchairs had 36% chance of losing the ability. It was also reported that those who were able to walk and climb stairs without difficulty at the age of 25 had only 23% chance of deterioration (Day et al. 2007).

2.8 Relevance to the project

- The incidence of CP has increased in the last three decades owing to better neonatal care, which emphasises the need for research into the rehabilitation of children with CP.
- There is a lack of consensus regarding the classification of CP. However, since this project emphasises gait in CP, classifications based on gait pattern are considered and traditionally used terms to explain CP are used wherever required.
- The long lasting effects of various treatments are important when deciding the inclusion/exclusion criteria for any research study. For example, children who have undergone any orthopaedic surgery or surgical reduction of spasticity may require exclusion owing to the long lasting effects. Transient effects of botulinum toxin A are also considered, and any child who has had botulinum injection in the last six months may also require exclusion.
- Use of comprehensive rehabilitation programmes is preferred nowadays, which makes managing research into CP difficult. This must be recognised when recruiting children into a research study, as some of the treatment options may relate to exclusion criteria.

CHAPTER 3 NORMAL GAIT: KINEMATICS AND KINETICS

3.1 Introduction

Normal human gait can be defined as "a method of locomotion involving the use of the two legs, alternately to provide both support and locomotion" (Whittle 2001, p. 42). Analysis of human locomotion involves several aspects - temporal and spatial parameters, joint kinematics and kinetics, and muscle activity. The advent of computerised motion analysis systems, force platforms and electromyographs has made the assessment of human locomotion less cumbersome. Gait being a complex activity, it is much easier to analyse one cycle at a time. One gait cycle of a limb normally extends from the point when the heel of the reference limb touches the ground, to the same happening again (Olney 2005). Furthermore, categorising one gait cycle into phases, sub-phases and events makes it easier to analyse normal and abnormal gait.

3.2 Phases, sub-phases and events of the gait cycle

There have been various classifications explaining the phases, sub-phases and events occurring during a complete gait cycle. The most commonly used classification systems are those developed by Olney (2005; the 'traditional'), Trew (2005; the 'international terminology'), Perry (1992 - derived from the Rancho Los Amigos (RLA) medical centre classification), Whittle (2001), and Sutherland (Sutherland, Kaufman, and Moitoza 1994). All the classifications agree on the division of gait cycle into two phases, namely the stance and swing phases. The stance phase forms 60% of the gait cycle and occurs when the reference limb is contact with the ground. The swing phase occurs when the reference limb is not contact with the ground (swinging), which forms the remaining 40% of the gait cycle. There are also periods when both limbs are in contact with the ground, known as double support.

The phases are further categorised to sub-phases, which are periods in the gait cycle spanning two points in the gait cycle, and events: specific points in the gait cycle which are considered to be relevant. The sub-phases and events described by various authors are compared in Tables 3.1 and 3.2.

Table 3.1 Sub-phases of the gait cycle as defined by major classification systems

Traditional (Olney 2005)	Perry (Perry 1992)	Whittle (Whittle 2001)	Sutherland (Sutherland, Kaufman, and Moitoza 1994)
Heel strike	Initial contact	Initial contact	Initial double support
	Loading response	Loading response	
Mid-stance	Mid-stance	Mid-stance	Single limb stance
Push off	Terminal stance	Terminal stance	Second double support
	Pre-swing	Pre-swing	
Acceleration	Initial swing	Initial swing	Initial swing
Mid-swing	Mid-swing	Mid-swing	Mid-swing
Deceleration	Terminal swing	Terminal swing	Terminal swing

It can be seen from Table 3.1 that Whittle (2001) has adopted the RLA/Perry classification of sub-phases. However, the classification by Perry (1992) did not include any events (table 3.2). In the current study the sub-phases suggested by Perry (1992) and Whittle (2002) were used. Among the events given in Table 3.2, those included by Whittle (2002) are used more clinically. However, Whittle failed to include an event equivalent to the mid-stance event in the traditional classification when the body weight is directly over the supporting extremity. Mid-stance as an event has been considered vital for tuning (Owen 2004b; Butler and Nene 1991) and is considered important in the context of the current study aims. Therefore, all the events considered by Whittle (2001) and mid-stance (Olney 2005) are referred to in the current study.

Table 3.2 Events of the gait cycle as defined in the major classification systems

Traditional (Olney 2005)	Perry (Perry 1992)	Whittle (Whittle 2001)	Sutherland (Sutherland, Kaufman, and Moitoza 1994)
Heel strike	Nil	Initial contact	Foot strike
Foot flat		Opposite toe-off	Opposite toe-off
Mid-stance		Heel raise	Reversal of fore-aft force
Heel-off		Opposite initial contact	Opposite foot strike
Toe-off		Toe-off	Toe-off
		Feet adjacent	Foot clearance
		Tibia vertical	Tibia vertical

From the tables, the events and sub-phases which can be used to explain the complete gait cycle are listed below.

Events (Whittle 2001; Olney 2005):

1. Initial contact: the point when heel of the referred limb strikes the ground.
2. Opposite toe-off: the point when the contra-lateral foot leaves the ground.
3. Mid-stance: the point when body weight is directly over the supporting lower extremity
4. Heel rise: the instant when the heel of the referred limb leaves the ground.
5. Opposite initial contact: the instant when the heel of the contra-lateral limb touches the ground.
6. Toe-off: the point when the foot of the referred limb leaves the ground.
7. Feet adjacent: the point when the swinging limb passes the standing limb leaving both the limbs side by side.
8. Tibia vertical: the time when the tibia of the swinging limb becomes perpendicular to the ground.

Sub-phases (Perry 1992):

1. Loading response: this phase begins at initial contact and ends when the opposite limb leaves the ground (opposite toe-off) at about 10% of gait cycle
2. Mid-stance phase: mid-stance begins when the other foot leaves the ground (10% of the gait cycle (GC)) and extends until the body weight is directly over the fore-foot or when the heel of the supporting limb raises from the ground (30% of GC)
3. Terminal stance: this phase extends from the heel rise of the supporting limb (30% of GC) until the contralateral limb touches the ground (50% of GC).
4. Pre-swing: this phase begins with initial contact (50% of GC) of the opposite limb and extends up to toe-off (60% of GC) of the referred limb.
5. Initial swing: Idefined as the period which begins with toe-off (60% of GC) and ends when both the feet are adjacent to each other (73% of GC) (feet adjacent or foot clearance).

6. Mid-swing: this phase starts with feet adjacent (73% of GC) and ends at the point when the tibia is vertical to the ground (87% of GC)
7. Terminal swing: this begins with a vertical tibia (87% of GC) and ends when the heel strikes the ground (100% of GC).

While the above classification looks more or less complete, incongruity exists in the timing of events. According to Perry (1992) and Whittle (2001), the mid-stance phase ends at 30% of the gait cycle when the body weight is aligned over the fore-foot and terminal stance phase begins at 30% of the gait cycle when the heel raises. However, according to the traditional classification, the mid-stance event happens at 30% of the gait cycle when the body weight is directly over the reference limb and terminal stance phase begins with the heel-off event which is at 40% of the gait cycle. When using computerised three-dimensional motion analysis, or video vector analysis (commonly used for tuning of AFO-FCs), an observable point in time is required to identify mid-stance rather than estimating events using a percentage of the gait cycle. Hence the traditional classification system is most appropriate in this context.

Owen (2004b) suggested using the point during the gait cycle when the opposite limb crosses the reference limb as mid-stance for the purpose of tuning. However, the author did not address the reliability of using the method. Gibson, Jeffrey and Bakheit (2006) compared three definitions of mid-stance and two definitions of mid-swing developed though expert consensus. The definitions of mid-stance were named as "temporal mid-stance: 50 per cent of the time interval from initial stance to toe-off", "kinematic mid-stance: when the medial malleolus of the swing phase limb passes that of the stance phase limb in the direction of progression" and "kinetic mid-stance: when the ground reaction force is vertical in the sagittal plane" (Gibson, Jeffrey and Bakheit 2006, p. 626). Among the three definitions, the kinematic definition of mid-stance is in line with that used by Owen (2004b). Gibson, Jeffrey and Bakheit (2006) made comparisons using data from thirty healthy children. The timing of the mid-stance event was identified as a percentage of the gait cycle according to all definitions, and the strength of associations between the results were calculated using Pearson's correlation coefficient. The authors reported moderate correlations between temporal and kinematic definitions of mid-stance (r = 0.5 for right leg and 0.3 for left leg), temporal and kinematic definitions of mid-swing (r = 0.3 for left leg), and kinetic and kinematic definitions of mid-stance (r = 0.4 for left leg). While the authors deemed temporal mid-stance as having similar accuracy as other definitions, the strength of associations were only moderate. The authors also did not attempt to address inter- and intra-rater reliability of mid-stance definitions.

Of the recordable gait variables, temporal and spatial parameters are among the most commonly used and meaningful. They are considered clinically significant and thus have been investigated in various studies (Kadaba, Ramakrishnan, and Wootten 1990; Murray, Drought, and Kory 1964; Oberg, Karsznia, and Oberg 1993). While there are several temporal and spatial parameters, it is important to identify the most relevant to the type of investigation being conducted.

3.3 Temporal and spatial parameters of gait

Commonly recorded temporal factors include stance time, single support time, double support time, swing time, stride time, step time, cadence and speed. The spatial factors are stride-length, step length, step width and degree of toe out. Only three variables are of interest in the present study, and these will be discussed in this section.

Cadence is the total number of steps taken in a unit of time; the unit being either seconds or minutes. The mean (SD) for healthy children (age range 7 to 15) has been reported to be 131.8 (7.4) steps/minute (Steinwender et al. 2000).

Walking speed is the rate of forward motion of the body and is commonly measured in metres per second. The mean (SD) for healthy children (age range 7 to 15) has been reported to be 133.3 (10.4) m/s (Steinwender et al. 2000).

Stride-length is the distance between two successive events by the same limb; for example, the distance between two successive heel strikes of the right leg equates to the stride-length of the right leg. The mean (SD) for healthy children (age range 7 to 15) has been reported to be 21.8 (7.3) (Steinwender et al. 2000).

Walking speed, cadence and stride-length are found to have correlations with function in children with CP, of which cadence and walking speed demonstrate the highest correlations (Damiano and Abel 1996). Hence these parameters become relevant for the current study. From the definitions it can be deduced that walking speed can be calculated from stride-length and cadence. While healthy individuals are capable of increasing the walking speed by increasing both stride-length and cadence, this might not be the case with the neurologically impaired. Damiano and Abel (1996) demonstrated that children with diplegia used the strategy of increasing cadence to walk faster, while the healthy controls increased both stride-length and cadence.

While normative values are roughly the same as those given above, there is variability in the reported literature. This variability is commonly linked to the influence of environment on the walking pattern of participants (Kirtley 2006). Furthermore, the gait pattern develops with age, which makes the generalisation of normative values difficult. The change of gait with age is a vital consideration for any research involving children. One issue is the influence of maturation on gait – erroneous assumptions might be made if the effects of an intervention are investigated in a patient group of children whose gait is still developing. Secondly, parameters like stride-length are dependent on leg length (Sutherland, Kaufman and Moitoza 1994), which would also influence velocity and cadence. Hence any investigation carried out over time in growing children is vulnerable to the erroneous assumptions. Sutherland and colleagues (1994) studied paediatric gait extensively and reported the ages where their sample achieved maturation. According to the authors, children achieved the walking speed of a mature gait at the age of four which was the same for stride-length. However, cadence did not stabilise until the age of five.

The ideal method of removing the influences of changing body dimensions on gait, is the normalisation of gait parameters to make them dimensionless quantities (Hof 1996; Stansfield et al. 2003; Sutherland 1996; van der Linden et al. 2002).

Some examples of normalised parameters are by van der Linden et al. (2002) and Stansfield et al. (2003); relevant equations are presented below:

$$\text{Normalised stride-length} = \frac{\text{stride-length}}{l}$$

$$\text{Normalised walking speed} = \frac{\text{Walking speed}}{\sqrt{(g \times l)}}$$

$$\text{Normalised cadence} = \frac{\text{cadence}}{\sqrt{(g / l)}}$$

Where g is gravitational constant (9.8 m/s^2) and l is limb length.

In addition to temporal and spatial parameters, joint kinematics and kinetics are two other gait variables of interest in the current study.

3.4 Kinematics and kinetics of gait

Kinematics observes and describes patterns of movement disregarding the cause (Robertson 1997), including joint motion, displacement, velocity and acceleration of body segments. One way of explaining human gait is through explaining the joint motion in all three planes. There have been studies using varied equipment ranging from still photography to three dimensional motion analysis, providing a plethora of information on joint motion (Sutherland 2001; Sutherland 2002). Although there may be individual differences in joint angles, the curve obtained by plotting joint angle against time will be more or less identical in shape for healthy individuals. However, in children, when comparing non-normal gait with that of healthy participants, it is important to use data from individuals belonging to the same age group.

Kinetics describes the factors resulting in movement and principally looks at the forces involved (Robertson 1997). Kinetic analysis of gait generally addresses joint moments and powers. During the gait cycle the body applies force to the ground, while the ground also applies force back to the body; the latter is most frequently studied (Olney 2005). The force applied by the ground has a magnitude as well as direction, and is termed Ground Reaction Vector (GRF). It has three components: vertical, anteroposterior (fore-aft) and mediolateral. When a force is capable of producing a rotational movement, it is measured as a moment or torque (Meglan and Todd 1994). Moments can be internal or external. Internal moments are generated by muscles, ligaments, joint friction and structural limitations, whereas external moments are forces produced by the GRF acting on the joints. Power generated or absorbed can be calculated from moments acting on a joint and the angular velocity of the joint. Together, kinetics and kinematics provide information which increases understanding of the causes of certain gait pathologies (Ounpuu, Davis, and DeLuca 1996).

There are several methods and varied equipment available nowadays to record all parameters related to gait. Modern day gait analysis most commonly involve the use of self contained computerised systems, capable of collecting all gait data at once through individual items of equipment.

3.5 Relevance to the project

- Kinematic definition of mid-stance is considered relevant for tuning. However the reliability of the definition has to be ascertained.
- The age at which maturation of gait is achieved must be taken into consideration when deciding on inclusion criteria of participants in the current study.
- Temporal and spatial parameters should be normalised for differences in body dimensions wherever relevant.
- Healthy reference data should be collected from healthy children belonging to the same age group as participants with CP.

CHAPTER 4 GAIT ANALYSIS: BACKGROUND AND CRITIQUE

4.1 Introduction

Gait analysis involves quantitative measurement, description and assessment of all mechanical aspects of human locomotion (Cappozzo 1984; Gage, DeLuca, and Renshaw 1995) Information is gathered about the movement of the body's centre of mass and forces involved, and both energy expenditure and muscle work involved are estimated (Cappozzo et al. 2005). Although clinical gait analysis is a relatively young field, it enables clinicians to objectively assess human locomotion which provides information on pathologies of human gait. This is not possible through physical examination (Gage, DeLuca and Renshaw 1995). Gait analysis has been used by clinicians to evaluate interventions, as well as to develop understanding of normal and pathological gait (Chester, Biden and Tingley 2005).

Although researchers agree that modern gait analysis started with the work of Inman and Eberhart in the 1950s (Bontrager 1998; Chester, Biden, and Tingley 2005), the history of gait analysis documents efforts as early as 1680 when Borelli studied human locomotion using Galileo's scientific method (Cappozzo 1984). A change from the static method to dynamic started in 1870s when Marey in Paris and Muybridge in California performed kinematic studies using still cameras, followed by the use of cine photography (Whittle 1996). Modern gait analysis started with the work by Inman and Eberhart, which later developed into a clinically useful tool through the efforts of Sutherland and Perry (Bontrager 1998). Development of precise three dimensional motion analysis systems linked to computers became established in the 1970s, which led to a more accurate understanding of gait parameters. Modern gait analysis systems are also capable of calculating joint moments and joint powers from kinematic and kinetic data, using engineering mathematics (Whittle 1996).

The most commonly used methods for motion analysis nowadays are optoelectronic motion analysis systems and electrogoniometers (Bontrager 1998). Most of the motion analysis laboratories have several items of equipment: optoelectronic systems track external markers placed on the patient to enable motion capture, force plates measure patient–interaction forces, and electromyography equipment measures muscle activity (Davis 1997). Various types of gait instrumentation are capable of either measuring one or all aspects of gait.

4.2 Optoelectronic systems in gait assessment

Optoelectronic systems make use of optoelectronic video cameras that track and measure two-dimensional (2D) or three-dimensional (3D) coordinates of markers attached to the participant's skin (Davis 1997). The 3D optoelectronic system involves at least two cameras configured around a calibrated measurement volume which records 2D coordinates of the body markers. These data, along with calibration data, allow the reconstruction of 3D coordinates of each marker (Davis 1997). This reconstruction of 3D coordinates is made possible by combining the 2D view from each of the cameras (Bontrager 1998). This results in calculation of joint angles in the correct plane (Cappozzo et al. 2005). Capture makes use of light produced by, or reflected by, markers to analyse movement. The sampling frequency of the cameras (the number of frames captured per second) varies from 50 Hz to 200 Hz for most systems (Whittle 2001).

Markers can be active where light-emitting diodes are being used, or passive where they are covered with retro-reflective tape (Perry 1992). In the case of active marker systems, each marker has its own power pack, which enables it to transmit infrared rays to the cameras. In passive marker systems the strobe is located in the camera, and transmits infrared radiation which is reflected and captured by the cameras. The retro-reflective markers can be of various sizes depending on the application; human movement analysis makes use of markers from 25 mm spheres to 3 mm hemispheres (VICON system manual 2002). Both the marker systems have advantages and disadvantages. The active marker system is restricted due to the attached wires and power pack, whereas reflective markers are devoid of them. However, the active marker system does enable automated identification of markers, which is not the case with passive markers (Ladin 1995)

Each marker should be visible to at least two cameras (Everett 2005). The number of markers relative to a single body segment is also important. One marker per segment allows the system to record displacement, while two markers enable calculation of velocity and acceleration. Three or more markers on the segment allow the system to measure angles at the joints (Everett 2005). While three markers are required to define a body segment, it is not necessary to have three surface markers, as virtual markers can be created by the system.

Since the cameras do not provide a video image, instead tracking marker position to evaluate the kinematics of underlying bony structures, marker positioning is critical. Various biomechanical models have been developed with different marker placement protocols, but the majority of laboratories use one that is based on either of two conventional models, namely the Helen Hayes marker set (Kadaba, Ramakrishnan and Wootten 1990), or the Cleveland Clinic marker set developed by Kevin Campbell (Sutherland 2002).

Although bony segments are connected by joints with six degrees of freedom, and the soft tissues around the bony segments can be considered deformable, most authors support classical mechanics in which the body segments are considered to be rigid, non-deformable bodies (Cappozzo et al. 2005). It is also common to assume that markers positioned on the skin represent the underlying bony landmarks and can be tracked to approximate the bones (Soutas-Little 1998). So in principle, analysis of the movement of body segments is uncomplicated when using classical mechanics, although the errors associated with soft tissue deformability have been shown to influence the results of gait analysis (Cappozzo et al. 2005).

In brief, the cameras detect the positions of markers, and the 2D data are converted to 3D data using direct linear transformation. The body segments and joint centres are then defined through modelling using markers (real or virtual) and anthropometric measurements. Joint kinematics are estimated by calculating the relative movements of body segments around the joint centres. The methodology followed in motion analysis is fairly standard, with specific modifications related to the models used. The methodology is further discussed in Section 10.2 (page 118).

4.3 Force measurement platforms

In order to measure kinetics relating to gait, one needs to identify the forces acting on the moving body. In order to accomplish this force platforms are used which measure the Ground Reaction Forces (GRF) acting on the feet, while the kinematic data are being acquired by the 3D motion analysis system. The force data provide very important information when pooled with kinematic data (Whittle 1996). Kinetic analysis is not only restricted to the measurement of forces, as joint moments and joint power are equally important. Force platforms are sensitive to both direction and magnitude of forces, thus detecting forces in three directions: vertical (directed upwards), anteroposterior or fore-aft shear force, and mediolateral shear force. The vertical force opposes gravitational force, whereas shear forces counteract the anteroposterior and mediolateral accelerations of the body. The point where the GRF acts on the body is termed 'Centre of Pressure' (COP) and during the stance phase it moves from posterior to anterior of the foot (Meglan and Todd 1994).

Force platforms are embedded in a walkway and have an instrument centre below the floor. The forces and moments relative to this instrument centre are determined. Data are usually sampled at 1000 Hz (Soutas-Little 1998). Force platforms are normally connected to the optoelectronic system and the same software processes both sets of data. Three-dimensional joint moments are normally calculated using a mathematical model termed inverse dynamics. This model considers each body segment to be a separate entity and the calculation of forces and moments are conducted in an order from distal to proximal. The inverse dynamics model requires incorporation of force data, inertia data and motion data. Estimation of joint moments is further explained in Section 10.2 (page 118).

4.4 Variability of stereo photogrammetric data

Increasing use of gait analysis in clinical practice and research places a huge demand on the clinician as clinical interpretation of data requires knowledge of reliability of measurements. (Kadaba et al. 1989) Various studies have been carried out and sources of errors identified, which can be broadly grouped into anatomical landmark misplacement, soft tissue artefacts and instrumental errors (Chiari et al. 2005; Della Croce et al. 1997; Della Croce et al. 2005). Della Croce et al (1997) stated that errors associated with anatomical landmark displacement are the greatest source of error when compared to the other two. This is contradicted by Cappozzo et al. (1996) who identified soft tissue artefacts as the greatest source of error. This is supported by Leardini et al. (2005) in a systematic review.

4.4.1 Anatomical landmark misplacement

Inaccuracy in estimating anatomical landmarks (AL) can significantly influence the calculation of joint centres and thereby result in erroneous estimation of joint kinetics and kinematics (Della Croce et al. 2005; Stagni et al. 2000). The ALs can be either subcutaneous (palpable) or internal (non palpable) (Stagni et al. 2000).

The mislocation of subcutaneous ALs can be attributed to the palpation procedure used, the presence of soft tissue covering the ALs, and non-pointy nature of ALs (Della Croce et al. 2005). There have been various studies looking at precision in locating surface ALs (Della Croce et al. 1997; Piazza and Cavanagh 2000; Rabuffetti et al. 2002).

Della Croce et al. (1997) conducted a study on two healthy participants to examine the intra- and inter-rater repeatability of AL identification. Skin cluster markers were placed on two healthy participants by an experienced gait laboratory physiotherapist six times, according to a predetermined protocol. A stick with two markers was used to carry out an anatomic calibration all six times. This was based on the calibrated anatomical systems technique (CAST) protocol proposed by Cappozzo et al. (1995), according to which static capture was conducted with the stick pointing towards each anatomical landmark. Inter-rater repeatability was checked by repeating the same procedure with six other physiotherapists. The results demonstrated greater intra-rater repeatability than inter-rater. Joint angle errors were predominantly above 10°, which questions the reliability of joint angle calculation. They also found that out all body segments, the foot segment is most difficult to calculate.

Piazza and Cavanagh (2000) investigated the possibility of “cross-talk” with erroneous identification of anatomical land marks. Cross-talk was defined as the movement around one axis being interpreted as movement around another axis. Instead of using human participants, the authors used two devices, which functioned in a similar manner to the knee joint. One device simulated the flexion-extension movement, while the other simulated screw home rotation along with flexion-extension movement. The authors introduced error in locating the axis which resulted in cross-talk, that is, screw home motion was recorded when there was no actual screw home motion possible. The authors concluded that kinematic cross-talk is capable of creating false measurement of screw home motion in the knee where it isn’t actually present (Piazza and Cavanagh 2000). Rabuffetti et al. (2002) compared the precision and accuracy of AL identification by three participants with that of three experts. While self-marking was not deemed to be a reliable method, both intra- and inter-rater precision of the experts were good. Among the landmarks, the greater trochanter was least precise.

In a review by Della Croce et al (2005), the authors concluded that the precision of AL identification significantly influences the reliability of gait data. They also emphasised that repeatability can be ensured by including a greater number of ALs for defining the anatomical frame, and by improving the AL identification method by using imaging techniques or/and by including a greater number of ALs in the protocol.

4.4.2 Soft tissue artefacts in motion analysis

Current practice in motion analysis only employs skin markers. Various other techniques exist, such as roentenography, bone pins, and fixators, but all present limitations such as invasiveness and exposure to radiation. It has not yet been possible to measure the movement of skin markers in relation to the underlying skeleton, which comprises the primary concern associated with motion analysis (Andriacchi and Alexander 2000). There have been various studies looking into soft tissue artefacts, using alternatives to the skin marker system, such as example external fixators, bone pins and fluoroscopy (Cappozzo et al. 1996; Reinschmidt et al. 1997; Stagni et al. 2005).

Cappozzo et al (1996) investigated inaccuracies due to skin movement over the underlying bone. All the participants had been treated for femur or tibia fracture fixed with an external fixation device. Markers were attached to the skin on the ALs and to the fixator, and hence were indirectly attached to the bone. In order to limit bias due to the abnormal condition of patients' musculature, data were collected on four able-bodied participants, simultaneously collecting data with digital fluoroscopic system. The outline of femur and tibia were superimposed on relevant frames to determine the movement of markers with respect to corresponding bones. The study revealed the level of artefacts of various markers. During hip flexion of 60°, the greater trochanter marker showed an artefact with a magnitude of 30 mm. A 45 degree external rotation of hip produced an artefact of 30 mm in the antero-posterior direction. The lateral condyle marker moved backwards up to 40 mm when the knee was flexed to 120°. The tibial marker moved up to 25 mm during flexion of 110° and the lateral malleolus markers moved up 15 mm in all directions.

Reinschmidt et al. (1997) studied the errors caused by skin movement artefacts during rotation of knee and ankle joint complex in three participants. They made use of intra-cortical pins, with triads of reflective markers which were inserted into the lateral femoral condyle, lateral tibial condyle and posterior aspect of the calcaneum. An additional six markers were stuck onto the thigh and shank and three were stuck to the shoes. The Root Mean Square difference (RMS Diff.) between skin and marker based rotations were calculated. Out of five participants, results were available only for three; data showed significant variability in frontal and transverse plane motion of the knee. The RMS Diff. for frontal plane motion of the knee ranged from 2.1° to 2.8°. For transverse plane motion of knee it was 2.1 to 4.2 and for sagittal plane motion it was 1.5 to 1.7. In the case of the ankle joint motion the RMS Diff. for the frontal plane ranged from 2.9 to 4.4, for transverse plane motion it was 2.0 to 4.3, and for sagittal plane motion it was 3.1 to 4.4. The authors concluded that soft tissue artefacts are a significant source of error and at the knee joint; they affect the transverse and frontal plane motion to such an extent that they may exceed the actual range of motion. In the case of the ankle joint complex, rotations are generally over-estimated when using external markers. The authors have also reported the possibility of some errors which might have occurred because of the smaller size of calibration volume.

In a systematic review, Leardini et al. (2005) identified soft tissue artefacts as the most significant error in motion analysis and concluded that they should be addressed in motion analysis protocols used to determine in vivo human movements. The authors considered knowledge of this artefact important as far as clinicians are concerned, as it can significantly affect clinical judgement (Leardini et al. 2005).

4.4.3 Instrumental errors in motion analysis

Errors associated with stereophotogrammetry can significantly influence the human movement analysis. While there are errors associated with misplacement of anatomical landmarks and movement of soft tissue in relation to the underlying bony landmarks, motion analysis can be further complicated by inaccurate reconstruction of the marker positions by the system (Chiari et al. 2005). The errors can be systematic or random. Systematic error is produced by optic distortion or non-linearities which neither the calibration procedure, nor the model, could address. Random error can be attributed to the digitization process itself, which converts the co-ordinates into their numerical values (Cappozzo 1991). In their systematic review, Chiari et al. (2005) concluded that instrumental errors are handled using different techniques, depending on the stage at which the error arises. Optical distortion and associated error can be dealt through different camera calibration procedures, random errors can be managed through filtering and smoothing methods, and software packages can be used to handle missing markers (Chiari et al. 2005).

Richards (1999) compared seven commercially available systems for their ability to measure distances between two markers rotating in the volume, and movement of a marker when on its own and when in close proximity to a second marker. The authors reported that of the seven systems, five had RMS errors of less than 2 mm with moving markers and less than one mm with stationary markers. VICON 370 produced an RMS error of 0.6 mm for stationary markers and 1.3 mm for moving markers. It was also reported that all systems encountered difficulty in discriminating markers that were close to each other than one cm. The RMS error in measuring the angle ranged from 1.4° to 4.3°, of which VICON 370 was the lowest. The results demonstrated that the commercially available systems were similar in relation to instrumental errors (Richards 1999).

Ehara et al. (1995) compared eight commercially available systems for accuracy and time taken for processing. Data were captured for each system when a participant walked a known distance while holding a rod vertically that had two markers attached 900 mm apart. The distance between the markers, and processing time were compared. The mean absolute error for measuring distance ranged from 0.9 to 6.3 mm. The VICON 370 produced a mean absolute error of 2.3 mm. The processing time ranged from five seconds to 42 minutes, with 35 seconds for the VICON 370 (Ehara et al. 1995). Using a similar protocol, Ehara et al (1997) compared 11 commercially available systems for accuracy and time taken for processing. The protocol was the same as the previous study except that the authors measured the distance between markers in all three planes of movement. The mean absolute error for all planes ranged from 0.53 to 18.42 mm, with 0.94 mm for VICON 370. Processing times ranged from ten seconds to 28 minutes, with a 15 second processing time for the VICON 370.

It can be seen that the accuracy of commercially available systems is variable, and the VICON 370 demonstrated good accuracy in all three studies. However, it may be necessary to periodically estimate the accuracy of system through field testing.

4.5 Relevance to the project

- A strict protocol should be followed when placing markers on anatomical land marks to reduce misplacement error.
- Comparison should be conducted between different marker sets to identify the one with lowest ‘kinematic cross talk’.

- Regular calibration should be carried out and accuracy and precision of the motion analysis system should be investigated to address instrumental errors.

CHAPTER 5 GAIT IN CHILDREN WITH CEREBRAL PALSY: PATHOLOGICAL MECHANISMS AND PATTERNS

5.1 Introduction

Cerebral Palsy (CP) primarily affects movement and posture, often substantially influencing ambulation. About two thirds of children with CP achieve some degree of walking ability, although this typically deviates from the normal pattern of gait (Pharoah et al. 1998). Children with CP have a multitude of structural and functional abnormalities that result in abnormal gait. It is too complex to identify all of them through standard physical examination or visual observation of gait. Therefore, clinical gait analysis is commonly required to provide the clinician with more precise information on pathologies underlying gait abnormalities (DeLuca 1991; Gage 1994). The advent of computerised 3D motion analysis has led to a surge in research relating to gait in CP

Gait pathology associated with CP has been documented well. While several authors attempted to classify gait patterns (Hullin, Robb, and Loudon 1996; O'Byrne, Jenkinson, and O'Brien 1998; Rodda et al. 2004; Sutherland and Davids 1993), others have investigated specific patterns and underlying pathologies (Arnold et al. 2005; Kerrigan, Deming, and Holden 1996; Steinwender et al. 2001; Thompson et al. 2001). Still others have investigated gait in CP with reference to the treatment employed (Goldberg et al. 2006; Kay et al. 2002; Wren, Do, and Kay 2004). This literature review draws upon the most current evidence from leaders in the field of gait. The chapter is structured to address pathological mechanisms underlying gait deviations of CP, existing classifications based on gait, patterns and underlying pathologies relevant to this project, and finally, the role of gait analysis in the rehabilitation of children with CP and associated issues.

5.2 Pathological mechanisms of gait abnormalities in children with CP

Perry (1992) suggested four attributes of normal gait which are generally affected by gait pathologies: first, stability during stance phase; second, sufficient clearance of the swinging foot during swing phase; third, appropriate prepositioning of the swinging foot for the next heel strike; and fourth, adequate step length. Gage (1991) added energy conservation as another attribute. In children with CP, gait abnormalities can be caused by various factors, such as contracture or deformity, muscle weakness, loss of selective control of the muscles, abnormal muscle tone (usually spasticity), reappearance of primitive reflexes, and impaired balance reactions (Gage 1991; Gage 1994; Gage and Schwartz 2004; Perry 1992).

These features occur as a direct result of damage to the central nervous system and are referred to as ‘primary effects’. These place abnormal loads of force on the bones and joints, adversely affecting musculoskeletal structures, leading to ‘secondary effects’. Gait abnormalities caused by primary and secondary effects may lead to compensatory movements, commonly referred to as ‘tertiary effects’ (Gage and Schwartz 2004). Gait abnormalities in CP present as a mixture of primary, secondary and tertiary effects.

5.3 Gait patterns in children with CP

The clinical presentation of CP varies, making it complex for clinicians to perform pre- and post-treatment assessments effectively. Although there are many treatment strategies available for children with CP, their success depends on the accuracy of the diagnosis (Gage 1994). Several efforts have been made to classify CP based on gait patterns. These aim to help clinicians by assisting them in classifying the patient into a pre-defined gait pattern, instead of elucidating the gait in detail (O'Byrne, Jenkinson and O'Brien 1998).

A literature search identified 18 studies which classified gait in CP based on patterns recognised either qualitatively or quantitatively. Qualitative recognition of gait pattern involves visual assessment of kinematic, kinetic and/or EMG data (Hullin, Robb and Loudon 1996; Lin et al. 2000; Rodda et al. 2004; Simon et al. 1978; Stebbins et al. 2007; Sutherland and Davids 1993; Winters, Gage, and Hicks 1987). In one study the author used slow motion pictures and freeze frames to recognise the patterns qualitatively (Yokochi 2001). Quantitative recognition of data has been carried out using statistical methods for pattern recognition. Methods have included cluster analysis techniques (Kienast et al. 1999; O'Byrne, Jenkinson and O'Brien

1998; O'Malley et al. 1997; Wong, Simon, and Olshen 1983) and Hidden Markov Models (Carollo, He, and Debrunner 2004). While most quantitative studies have attempted to identify clusters based on distinct characteristics of one or combinations of gait parameters, two studies grouped their sample into patterns which were defined *a priori* (Carollo, He and Debrunner 2004; Stout et al. 1995). Most of the authors included either spastic hemiplegia or diplegia in their classification, whereas some included both, and only one study included spastic quadriplegia (Wong, Simon and Olshen 1983).

A gait classification system should allow the groups to be distinguishable from one another based on defined characteristics (Dobson et al. 2007). Although gait in CP has distinct features, the symptoms overlap, making grouping difficult (Toro, Nester, and Farren 2007). The literature has demonstrated that authors are able to identify distinct features to classify the gait of CP. However, there has been a lack of standardisation in methods employed and classification. While classifications based on qualitative methods are less scientific and prone to subjectivity (O'Malley et al. 1997), quantitative classifications do not seem relevant for clinicians (Rodda et al. 2004). In a recent review Dobson et al. (2007) concluded that none of the studies conducted to date were robust enough to completely address gait deviations in CP.

Although the availability of enormous quantity of literature is helpful to any clinician or researcher dealing with CP, the lack of consensus creates perplexity. It is beyond the scope of this chapter to critically evaluate all the studies to draw definite conclusions; instead, patterns relevant to the current study are identified. Discussion of similarities between different classifications is emphasised, while care is taken to describe the key differences. Patterns are discussed in relation to the sagittal plane only, as this plane reflects most movements occurring during gait, and the current study intends to address the influence of tuning of the AFO-FC in the sagittal plane only.

5.3.1 Flexed knee gait patterns

Flexed knee gait can be seen with varying degrees of severity; some authors prefer to name any gait with excessive knee flexion as crouch (Wren, Rethlefsen and Kay 2005), whereas others have attempted to classify it further according to the degree of severity and involvement of other joints. In this chapter flexed knee patterns are grouped as crouch gait, jump knee gait, and other flexed knee patterns.

5.3.1.1 Crouch knee gait pattern

Crouch gait is probably the only pattern explained by most authors addressing diplegia (Lin et al. 2000; Rodda et al. 2004; Sutherland and Davids 1993). As the name indicates, crouch gait involves excessive knee flexion. It is considered to be the most complicated and severe of the gait patterns. None of the classifications of hemiplegic gait used the term crouch, instead reporting a pattern of flexion of the hip, knee and ankle (Hullin, Robb and Loudon 1996).

There have been controversies regarding joint kinematics in crouch gait. Sutherland and Davids (1993) and Rodda et al. (2004) reported excessive knee and hip flexion with ankle dorsi-flexion throughout the stance phase. In contrast, Huk et al. (1987) and Bleck (1987) reported that crouch (hip and knee flexion) can be associated with ankle equinus as well. However, Sutherland and Davids (1993) failed to mention whether their study included participants with surgically lengthened Tendo Achilles (TA), predisposing them to dorsi-flexion. Rodda et al. (2004) included TA lengthening as an exclusion criterion, but also recognised another pattern where hip and knee were excessively flexed with no dorsi-flexion in the ankle. This pattern was similar to the crouch with equinus as explained by Huk et al. (1987) and Bleck (1987).

In crouch the Ground Reaction Force (GRF) lies posterior to the knee joint during the stance phase creating a flexion moment at the knee. This leaves the plantar-flexion-knee extension couple incompetent (Rodda et al. 2004). There is also a high flexion moment at the hip. In the crouch pattern with dorsi-flexion there is a high ankle dorsi-flexion moment (Lin et al. 2000). The vertical GRF as plotted by Lin et al. (2000) showed a lack of trough between the first and second peaks, which represents a lack of effective weight transfer. Decreased knee extension in late swing reduces the stride-length, thus reducing gait velocity (Rodda et al. 2004).

The causes of crouch gait have been well investigated, and are mostly attributed to hamstrings contracture (Rodda et al. 2004; Sutherland and Davids 1993). Weakness of the calf muscles is also a major cause of crouch gait with dorsi-flexion (Rodda et al. 2004). This can be due to inappropriate lengthening of triceps surae, leaving the muscle weak and pulling the patient into a crouch posture (Sutherland and Cooper 1978). The possible mechanism in this case is that the weak soleus permits the tibia to move forwards rapidly, thus orienting the GRF posterior to the knee joint (Gage 1991). As the femur and trunk progresses less quickly, knee flexion is produced, and as the trunk fails to advance past the knee, stride-length reduces (Perry 1975).

The common explanation of short hamstrings in crouch was challenged by Hoffinger, Rab and Abou-Ghaida (1993). They suggested that although the hamstrings are clinically tight in crouch, they need not be always be short. It was reported that the length of the muscle unit can be greater during gait than during static examination, due to the position of the hip. Because the hamstrings span two joints, its length relative to the joint position is determined by the perpendicular distance between the joint centre and the point of muscle attachment (lever arm). During normal gait this lever arm is three times greater at the hip than at the knee, but hip flexion contracture demands further lengthening of the hamstrings (Hoffinger, Rab and Abou-Ghaida 1993). Gage and Schwartz (2004) have explained that in crouch the lever arm is greater at the knee than at the hip. Hence the hamstrings becomes a stronger knee flexor than the hip extensors, which in turn initiates a cycle. Rectus femoris is recruited to resist knee flexion, which, being a hip flexor as well, attempts to flex the hip joint, placing more demand on the hamstrings. This increases the crouch further. Electromyographic data shows that there is prolongation of activity in the hamstrings and quadriceps during stance phase (Sutherland and Davids 1993).

5.3.1.2 Jump knee gait pattern

As the name indicates, this pattern resembles a jumping movement during gait. This pattern was not recognised by studies which only involved hemiplegia (Hullin, Robb and Loudon 1996; Winters, Gage and Hicks 1987). Studies that only recruited patients with diplegia, and used qualitative recognition, noted this pattern (Lin et al. 2000; Rodda et al. 2004; Sutherland and Davids 1993). O'Byrne, Jenkinson and O'Brien (1998) identified two groups similar to jump knee pattern, named drop foot pattern, and ankle double bump pattern; the difference between the two was predominantly in the range through which the hip and knee joints moved.

In jump knee pattern there is increased knee flexion during initial contact, followed by knee extension (ranging from normal to near normal). Hip flexion is increased throughout the gait cycle, particularly during initial stance, followed by varying degrees of extension at mid to late stance (Lin et al. 2000; Rodda et al. 2004; Sutherland and Davids 1993). The pelvis either moves through normal range, or is tilted anteriorly (Rodda et al. 2004). Various possibilities were observed for ankle movement. Sutherland and Davids (1993) reported near normal ankle dorsi-flexion until late stance, with reduced plantar-flexion during toe-off; this was contradicted by later studies. Lin et al. (2000) noted that although there was dorsi-flexion during initial stance, it then changed to equinus during late stance. In contrast, Rodda et al. (2004) reported equinus throughout the gait cycle.

Looking at the kinetics of jump knee gait, Lin et al. (2000) found that the GRF vector is constantly directed posterior to the knee joint, thus generating a knee flexion moment which is high during initial contact and the loading response. This rapidly decreases during mid-stance and then reaches the second peak during the opposite heel strike. The moments at the hip joint follow a different pattern; at initial contact, the hip has a flexion moment that approaches normal, which then rapidly changes to a high extension moment by terminal stance. At the ankle joint a high dorsiflexion moment is seen at initial stance, which then decreases and eventually increases at terminal stance (Lin et al. 2000). This pattern was similar to that found by O’Byrne, Jenkinson and O’Brien (1998). Lin et al. (2000) also noted that the vertical force curve had a deep trough at mid-stance, indicating effective transfer of body weight.

Jump knee gait pattern may be associated with contractures in hamstrings, hip flexors and adductors, and weakness of quadriceps (Sutherland and Davids 1993). According to Lin et al (2000), triceps surae contracts eccentrically during initial stance, allowing slight dorsi-flexion, followed by a concentric contraction, to generate a premature plantar-flexion during the late second rocker. During mid-stance the quadriceps also shows some concentric activity, thus producing effective weight transfer. The third rocker is characterised by a second contraction of the triceps surae, thus generating push-off force. This was contradicted by Sutherland and Davids (1993), who did not identify the second contraction of triceps surae.

5.3.1.3 Other flexed knee patterns

Some authors have used the term crouch to explain any gait with flexed knee (Toro, Nester and Farren 2007; Wren, Rethlefsen and Kay 2005), while others have specifically noted patterns with flexed knee that is less pronounced than in crouch gait, discussed in this section (Hullin, Robb and Loudon 1996; O'Byrne, Jenkinson and O'Brien 1998).

Out of two patterns described by Hullin, Robb and Louden (1996), the first was termed ‘knee flexion and hip extension’. In this pattern, the knee remains flexed and the ankle plantar-flexed throughout the stance phase. Progression is brought about by the use of hip extension and early heel lift. The authors identified tightness of gastrocnemius as the primary pathology, preventing the knee from extending, and the ankle from dorsi-flexing. The second pattern, termed ‘persistent hip and knee flexion,’ or ‘triple flexion’ has fixed hip, knee and ankle. Here, propulsion is carried out by early heel lift while the trunk moves over the fixed limb. In this pattern, all three joints are locked by the short hip flexors and the tight plantar flexors. While this pattern seems similar to the crouch gait with equinus, it is difficult to make an assumption because the authors failed to give a detailed account of range of motion of the lower limb joints. This study provides a good account of biomechanical reasoning of the patterns identified, however the lack of information makes it difficult to compare their pattern with those identified by other authors. Thus ambiguity exists in whether their classification is applicable to any other group than hemiplegia (Hullin, Robb and Louden 1996).

Of the two patterns observed by O’Byrne, Jenkinson and O’Brien (1998), the first one, termed ‘stiff crouch with toe walking’, resembles crouch gait with equinus pattern. Although the peak knee flexion in this pattern is high in comparison to crouch with dorsi-flexion, it cannot be compared to the crouch with equinus pattern, as no range of motion was reported by the authors (Bleck 1987; Huk et al. 1987). Similarly, the second pattern, ‘mobile crouch gait’, demonstrated resemblances to crouch gait with equinus pattern, except that the knee and hip joints showed good range. The ankle showed a good range as well, but was predominantly in plantar-flexion except during mid-stance, where the body weight produced mild dorsi-flexion.

5.3.2 Recurvatum knee pattern

This pattern is characterised by hyper-extension of the knee joint during stance phase and can be seen with or without dorsi-flexion (Hullin, Robb and Loudon 1996). Patterns with hyper-extension were identified in children with hemiplegia (Hullin, Robb and Loudon 1996; Simon et al. 1978; Winters, Gage and Hicks 1987) and diplegia (Huk et al. 1987; Lin et al. 2000; O'Byrne, Jenkinson and O'Brien 1998; Sutherland and Davids 1993). Rodda et al (2004) did not recognise any pattern with hyper-extension in their sample; instead a pattern with ankle plantar-flexion and normal knee extension was observed. The authors explained that this was the result of excluding children who had undergone any lengthening surgeries, whereas Sutherland and Davids (1993) did not have such an exclusion criterion. In contrast, Lin et al. (2000), Huk et al. (1987) and O’Byrne, Jenkinson and O’Brien (1998) excluded children who had undergone lengthening surgeries and still noted patterns with knee recurvatum. This disparity could be an effect of the age group of the sample. A longitudinal study reported that in patients with diplegia, a knee extension pattern is only seen at a very young age, with later development of a flexed knee gait.

(Yokochi 2001). All the authors who reported recurvatum gait in diplegia, failed to provide the age range of their sample sizes. Hence, although there is a possibility that age factor influenced the results of these studies, exact conclusions cannot be made.

Of the two knee recurvatum patterns, the one without ankle dorsi-flexion is more commonly seen and was identified in several classifications (Hullin, Robb and Loudon 1996; Lin et al. 2000; Simon et al. 1978; Sutherland and Davids 1993; Winters, Gage and Hicks 1987). In this group knee flexion is reduced during the initial stance, which further decreases to reach hyper-extension during mid or late stance. It then reverses to reach peak flexion during swing. The ankle joint is plantar flexed at initial stance, with loss of dorsi-flexion during mid-stance, leading to plantar-flexion again during terminal stance (Sutherland and Davids 1993). Hip joint excursion and lumbar lordosis are increased throughout the gait cycle (Winters, Gage and Hicks 1987).

Simon et al. (1978) suggested that the large knee extension moment created by the anterior translation of the GRF prevents the ankle from dorsi-flexing, producing hyper-extension. This was contradicted by Hullin, Robb and Louden (1996), who found the presence of knee hyper-extension even with dorsi-flexion; they found that tightness of the soleus prevented progression of the tibia over the stable foot. This led the femur and the trunk to move over a relatively stationary tibia, thus producing hyper-extension. In this pattern the tibia can be either stationary, or moving in a reverse direction during the stance phase (Connolly et al. 1999; Simon et al. 1978).

A knee hyper-extension pattern with dorsi-flexion was identified by Huk et al. (1987) and Hullin, Robb and Louden (1996). In this pattern the knee starts extending at early mid-stance and the ankle progressively dorsi-flexes until pre-swing. Tibial progression is not arrested, but movement of the femur over the tibia is more rapid than the tibia over the foot. There are two possible mechanisms, the first being the effect of spastic quadriceps, which prevents knee flexion at initial contact. The hip extensors are then recruited to push the body over the fixed knee and the weak gastrocnemius is unable to prevent the knee from hyperextending. The second mechanism is an action to compensate for weak quadriceps, incapable of resisting the flexion moment during initial stance. In order to prevent the knee from buckling into flexion, the hip extensor activity brings in knee stability through hyper-extension of the knee (Hullin, Robb and Loudon 1996).

In both types of recurvatum knee gait, the GRF is oriented posteriorly at initial contact, then moving forward rapidly, creating a high knee extensor moment (Hullin, Robb and Loudon 1996; Simon et al. 1978). Lin et al. (2000) found that the vertical GRF graph was characterised by a loss in mid-stance trough, which symbolises less effective transfer of the body weight. Hyper-extension of the knee joint decreases walking velocity by limiting stride-length (Sutherland and Davids 1993), and is often associated with anterior lean of the trunk (Ounpuu 2004).

5.3.3 Stiff knee gait pattern

Stiff knee gait is primarily a swing phase abnormality and hence may coincide with other stance phase abnormalities. Not many authors have recognised this pattern. Sutherland and Davids (1993) included stiff knee gait as one of the patterns in their classification, whereas Rodda et al. (2004) recognised the pattern, but excluded it without providing a reason. Stiff knee gait is characterised by a lack of knee flexion during the swing phase, with variable range during stance. Peak flexion in swing might be delayed as well (Sutherland and Davids 1993). While Sutherland and Davids failed to state a criterion for stiff knee gait, Rodda et al. (2004) considered that it was evident only where knees demonstrated less than 30° excursion.

The prime patho-mechanism of stiff knee gait is thought to be increased activity of the knee extensors during swing phase (Goldberg et al. 2006; Sutherland and Davids 1993). This is predominantly seen in mid-swing when rectus femoris is constantly active (Gage 1991). In some cases, reduced knee flexion during pre-swing decreases the knee flexion moment, which may be further complicated by a lack of push-off due to the inadequate activity of gastrocnemius. This demands compensatory hip flexion during swing, for which rectus femoris is recruited. Hamstrings also become active with the aim of flexing the knee. The lack of selective muscle control results in antagonistic actions of both the muscles, i.e. rectus femoris resisting knee flexion and hamstrings resisting hip extension. This results in reduced knee and hip flexion during swing phase (Gage 2004). Stiff knee gait pattern may produce compensatory movements such as circumduction, vaulting of the contra-lateral limb, and/or pelvic tilt (Sutherland and Davids 1993).

Apart from the patterns explained above, a group with minimal gait disturbance was identified among both children with hemiplegia (Hullin, Robb and Loudon 1996; Winters, Gage and Hicks 1987) and diplegia (Rodda et al. 2004). In children with hemiplegia with minimal gait disturbance, the only abnormality was the presence of drop-foot in swing phase (Hullin, Robb and Loudon 1996; Winters, Gage and Hicks 1987). In contrast, in children with diplegia, the mild group was characterised by only transverse plane abnormalities like in-toeing (Rodda et al. 2004).

It can be seen that although other joints are considered wherever relevant, most classifications predominantly focus on knee joint patterns. It is pertinent to discuss some specific abnormalities in the sagittal plane associated with other joints, which may be relevant to this project.

5.3.4 Specific patterns associated with other joints

5.3.4.1 Ankle double bump pattern.

This pattern is named after the shape of a specific time series plot showing sagittal plane kinematics and or moments. In the kinematic double bump pattern, there is an initial dorsi-flexion, followed by sudden plantar-flexion during mid-stance which is then followed by dorsi-flexion during terminal stance. Similarly, in the kinetic double bump pattern there is an initial peak of dorsi-flexion moments during mid-stance, which is followed by a second peak during terminal stance (Ounpuu 2004). This pattern is generally associated with spasticity, and/or clonus of the plantar flexor muscles, and lack of dorsi-flexion of the ankle during initial contact (Ounpuu 2004; Pierce 1997).

5.3.4.2 Pelvic single bump and double bump patterns

Both these patterns are kinematic patterns. The pelvic single bump pattern is mostly seen in children with hemiplegia, and is characterised by increased anterior pelvic tilt, which reaches a peak during pre-swing. This is generally associated with decreased hip motion (Ounpuu 2004). The pelvic double bump pattern is mostly seen in children with diplegia, and is characterised by two peaks of increased anterior pelvic tilt - once during stance, and once during swing (Ounpuu 2004).

5.4 Gait analysis applied to CP:

Gait analysis has been acknowledged to be an effective tool for identifying gait pathologies associated with CP. The relevance of gait analysis in the rehabilitation of CP has always been controversial. While proponents advocate the value of gait analysis as an assessment tool (DeLuca 1991; Gage 1994), critics find it expensive and clinically not very useful (Watts 1994). Studies have looked into variability of gait data (Noonan et al. 2003; Steinwender et al. 2000; Stott et al. 2005), variability in the interpretation of the data (Skaggs et al. 2000; Steinwender et al. 2000) and the influence of gait analysis on treatment decisions (Cook et al. 2003; DeLuca et al. 1997; Kay et al. 2000).

Steinwender et al. (2000) investigated within–day and between–day repeatability of laboratory-based gait data. Kinematic data, kinetic data and temporal and spatial parameters were compared between normal children and children with CP. In general, the results of normal children were more repeatable than those of children with CP. However, between–day repeatability of the kinetic data was better in children with CP. For both groups, repeatability of kinetic data was better than that of kinematic data. When discussing the lack of repeatability of the kinematic data in children with CP, the authors associated it with the presence of contractures and noted a lack of consistency in the placement of certain markers. This corroborates the findings of Kadaba et al. (1989) which portrayed marker placement error as the major source of variability in gait analysis. The lack of ability of the children with CP to adapt their muscles was considered to be the reason for better repeatability of their individual joint kinetic data. However, normal children showed less variations when the total moment was compared, thus supporting the argument (Steinwender et al. 2000).

One study found significant kinematic variability between 12 Shriners motion analysis laboratories in the USA, and significant variation between clinicians (Gorton, Hebert, and Goode 2001). The systematic error between sites was less than 1°, hence the variability was attributed to differences in marker placement among the clinicians. The authors suggested that variability can be reduced by using a standardised protocol. However, the results from this study point out definite flaws in the motion analysis systems currently in use. Noonan et al. (2003) reported considerable inter-observer variability in gait analysis data from children with CP. The data were collected from 11 patients in four different centres. Apart from comparing the gait data, resulting treatment recommendations were also compared. Considerable variability in the gait data between the centres was reported and of the 11 patients, only two had similarity in the treatment recommendations. Although the variability across the laboratories was questioned for its significance (Gage 2003), it raises concerns. The differences in treatment recommendations may be due to dissimilarities in treatment principles followed by different institutions. A comparison between clinicians from the same institute would have given a better picture.

Skaggs et al. (2000) also reported variability in the interpretation of gait data across different institutions. In this study the gait data of seven patients were evaluated by 12 clinicians from six institutions. There was only slight to moderate agreement between the clinicians about the most commonly diagnosed conditions, and agreement related more to soft tissue problems than to bony problems. Of the surgical recommendations, only hamstring lengthening showed significant agreement (kappa = 0.64). While the authors attributed the variability of interpretation among the institutions to differences in treatment principles, no attempt was made to investigate the variability between the clinicians of the same institution.

Gait analysis supposedly influences treatment decisions made for the children with CP. DeLuca et al. (1997) compared the surgical recommendations made from clinical examination and gait observation to recommendations made from gait analysis data. Surgical recommendations were given for 91 patients based on clinical examination and gait observation. This was followed by a second round of decision-making after including data from gait analysis. This altered the recommendations for 52% of participants. While the results show the importance of gait analysis in decision-making, there were some limitations in the study. All the clinicians included were experts in gait analysis, and the time gap between the two reviews was inadequate, creating a bias in the investigators. The investigators were also not blinded. Kay et al. (2000) reported similar results, with alteration of the surgical decision made in 89% of their sample after including gait analysis data. Of the 273 surgical procedures recommended, 39% were not carried out. Similarly Cook et al. (2003) reported alteration of surgical recommendations in 40% of the total sample. This study reported good agreement in recommendations for bone surgery, whereas the agreement for soft tissue operations was poor.

In a study which investigated the effectiveness of gait analysis in children with CP (Chang et al. 2006), the authors compared two groups, one with children whose management conformed to the gait analysis recommendations, and the other with children whose management did not. The authors defined the outcome criteria according to the surgical procedure recommended and the criteria were purely based on kinematics. The outcome was categorised into positive, negative and no change. The first group was found to have more positive outcomes (44%) than the second group (26%). The authors concluded that the children with CP whose management followed the recommendations of gait analysis experienced positive outcomes 3.8 times more often than those whose management did not. The outcomes selected in the study are questionable, as no measures of functional ability were included; only kinematic variables which would specifically be influenced by the surgical procedure were compared. The influence of gait analysis on the recommendations was also not considered. Whether the recommendations would have been any different if they were made purely based on clinical examination was not investigated.

None of the studies explored the influence of gait analysis on any treatment for CP other than surgery. While it is obvious from the literature that variability exists in gait analysis of children with CP, more controlled trials are required to establish the degree of variability involved. Errors relating to the rater can be improved by standardisation of the protocol and training. Technological development will probably address the technical errors associated with gait analysis.

5.5 Relevance to the project

- Several gait patterns and gait pathologies in children with CP were identified that are relevant to the current study.
- Although other joints are considered wherever relevant, most classifications based on gait patterns predominantly focus on knee joint patterns.
- Marker placement error is considered important and must be considered in the current study, preferably by ensuring that the same person marks all the participants and follows a standard protocol.
- The variability of gait analysis data must be considered, especially where all the data are not collected in a single session.

CHAPTER 6 CRITIQUE OF ANKLE FOOT ORTHOSES (AFO) INTERVENTION FOR CHILDREN WITH CEREBRAL PALSY

6.1 Introduction

Orthoses are commonly used either to correct or prevent structural abnormalities and/or to improve function in children with Cerebral Palsy (CP) (Morris 2002b). Investigating the variation of orthotic prescription in NHS health services in two districts of the UK, Morris, Newdick and Johnson (2002) found that over half of the samples were prescribed at least one orthosis over a period of nine months. The number prescribed could be greater, as the average time over which children outgrow their orthoses is ten months (Supan and Hovorka 1995). It was also noted that rigid AFOs were most commonly prescribed, after footwear. A health survey found that 54% of children with CP had some kind of orthosis in the US (Knutson and Clark 1991). Furthermore, about 53,000 AFOs per year were prescribed in the US to correct or prevent equinus (Parker, Naumann and Cleghorn 1994).

Condie and Meadows (1993) identified various pathologies that indicate the need for intervention in the form of AFOs, such as: muscle weakness (specifically ankle plantar and dorsi flexors, and knee extensors), equinus due to spasticity or tightness of the ankle plantar flexors, equinovarus, and valgus. In CP, AFOs are capable of influencing both swing phase and stance phase abnormalities (Condie and Meadows 1993; Davids, Rowan, and Davis 2007).

This chapter delineates the use of AFOs in children with CP. While different types of AFOs are considered, the emphasis is on rigid AFOs, as these are considered to be tunable and used in the current project. A brief introduction to various AFOs is included followed by a discussion of the effects of AFOs on gait in children with CP.

6.2 Current AFO devices in the management of CP

While orthoses are still a preferred treatment for equinus in children with CP, the prescription and design of AFOs varies (Morris 2002a). Although this project only involves rigid AFOs, it is pertinent to briefly mention the other orthoses commonly used in CP. These include supramaleolar orthoses (SMO), posterior leaf spring orthoses (PLSO), articulating AFO (hinged), and floor reaction ankle foot orthoses (FRAFO) (Gage and Quanbeck 2004).

The SMO extends upwards to just above the ankle joint and predominantly influences stance phase. PLSOs extend up to the proximal third of the calf muscles. Their posterior shell narrows, which allows mid-stance dorsi-flexion to occur while plantar-flexion, is still controlled in the swing phase. They also have a spring-like action, which supposedly facilitates the third rocker and push-off. The hinged AFO extends to the proximal calf and has tibial and foot segments. These two portions are connected by a hinge made of plastic or metal, which normally blocks plantar-flexion, but allows dorsi-flexion. The FRAFO has an anterior trim line which covers the anterior part and extends up the proximal third of the tibia. It locks the ankle joint and resists dorsi-flexion during mid-stance (Davids, Rowan and Davis 2007; Gage and Quanbeck 2004).

Although new designs of AFOs allow customisation as required by the patient, there are some limitations. With increasing complexity, the cost increases, as do the time and expertise required. In upper motor neuron disorders like CP the abnormal forces are high, and hence an inflexible AFO is required, such as one made of polypropylene (Condie and Meadows 1993; Davids, Rowan and Davis 2007) . While several studies have compared the effects of different orthoses on the gait of children with CP, literature search did not reveal any RCTs in the area of rigid AFO intervention. Most research addresses the immediate effects of orthoses, failing to address potential long-term impacts that may be affected both by the intervention and skeletal growth (Morris 2002a)

6.3 Influences of rigid AFOs on gait parameters of children with CP

As mentioned in the last section, research in the area of orthotic intervention is not robust and contradictions exist in findings relating to the effects of AFOs on the gait of children with CP. These contradictions can be attributed to the lack of consistency in study designs, sample characteristics, and conditions compared. CP is a disorder with varying presentation, making variability in the studies inevitable and necessitating care when interpreting the results. The studies which investigated the effect of AFOs on gait and function of CP are discussed in this section. While acknowledging the variability amongst the studies, attempts are made to identify trends and draw conclusions. Some authors have compared effects of rigid AFOs to the barefoot condition on the gait of children with CP (Abel et al. 1998; Thompson et al. 2002); others have compared the effects of rigid AFOs with other types of AFO (Brunner, Meier, and Ruepp 1998; Buckon et al. 2001; Carlson et al. 1997; Lam et al. 2005; Radtka et al. 1997; Radtka, Skinner, and Johanson 2005; Rethlefsen et al. 1999; Smiley et al. 2002). Variables investigated have included temporal and spatial parameters, joint kinematics and kinetics, energy expenditure, and muscle length and activity. Of the studies discussed here, those by Carlson et al. (1997), Rethlefson et al. (1999), and Smiley et al. (2002) used the shod condition as a baseline, whereas all the others used the barefoot condition.

Comparing the effects of rigid AFOs, SMOs and shoe-alone conditions, Carlson et al. (1997) collected kinetic and kinematic data from 11 participants with spastic diplegia using motion analysis. The authors followed an A-B-A-C cross-over design, in which the participants wore shoes without orthoses for the first month, followed by a randomly assigned orthosis in the second month. In the third month no shoes without orthoses were worn, with the alternative orthosis worn in the fourth month. Data were collected at the end of each month, allowing the authors to obtain data for two baselines and two orthoses. There were significant differences for stride-length, cadence and velocity between the first baseline and the orthoses. However, since the changes were not significant when the second baseline was compared to the orthotic conditions, the authors concluded that there was no difference. The authors also reported that when comparing the rigid AFO with the barefoot condition, the former led to increases in dorsi-flexion at initial contact, maximum dorsi-flexion during stance, and dorsi-flexion moments during terminal stance. They also found decreases in sagittal excursion of the ankle joint, and plantar flexor power generation during pre-swing. There were no significant changes in the kinematics of proximal joints.

Similar findings resulted when Rethlefson et al. (1999) compared the effects of rigid AFOs, hinged AFOs and shoes alone on gait patterns of children with CP. The authors followed a prospective design, where trials with three different conditions were carried out on the same day. In order to allow the children to accommodate to the different conditions, they alternated between conditions every three days for four to six weeks leading up to data collection using 3D motion analysis. The authors found that there were no significant differences in the temporal and spatial parameters between any of the conditions. The authors demonstrated that when comparing rigid AFOs with shoes alone, the former increased dorsi-flexion at initial contact and maximum ankle dorsi-flexion during stance, and decreased sagittal excursion of the ankle joint. It was also reported that peak knee flexion during the loading response reduced with rigid AFOs, but the authors acknowledged the lack of generalisability of the knee data, since the selection criteria had prevented the inclusion of children with any tendency to crouch in the study. Among the kinetics investigated, while rigid AFOs significantly increased plantar flexion moments during terminal stance, the plantar flexor power generation was less at pre-swing (Rethlefsen et al. 1999).

Smiley et al. (2002) compared the effects of rigid, hinged, PLS orthoses, and shoes alone, on gait and energy expenditure in children with spastic diplegia. In their prospective study, all trials with the three types of AFO and with shoes were carried out on the same day. The authors calculated an energy efficiency index from resting heart rate, heart rate recorded during a six-minute walk test, and walking speed. They found no significant differences in the temporal and spatial parameters with the use of rigid AFOs. Among the kinematics, dorsi-flexion at initial contact and peak ankle dorsi-flexion during stance increased, and sagittal excursion of ankle joint reduced with rigid AFOs compared to the shoes alone. There was no significant change in the kinematics of proximal joints. No significant difference was found in energy expenditure.

While the findings of the three studies discussed above demonstrate influences of shoes on gait in CP, no attempt was made to compare AFOs with barefoot gait. It is also worth noting that the children involved had mild degrees of impairment. Rethlefson et al. (1999) and Smiley et al. (2002) only included children who had 5° of passive dorsi-flexion in their study, which is a sign of milder involvement and is considered to be a primary indication for using a hinged AFO (Gage and Quanbeck 2004). Carlson et al. (1997) had no such inclusion criteria, but stated that their sample included only children with mild involvement. Thompson et al. (2002) found that among ambulatory children with hemiplegia, the more severe the impairment is, the greater their improvement in temporal and spatial parameters. While the methodology employed by Carlson et al. (1997) was powerful, the authors did not identify the possibility of children retaining effects until the point of the second baseline measurement. This may explain the lack of difference between stride-length measurements between the second baseline and with orthosis use. Interestingly, the authors found a significant difference between the two baselines, attributed to the children gaining confidence in the laboratory. In their design, Rethlefson and colleagues (1999) ensured that children could become accustomed to different orthoses; Smiley et al. (2002) failed to do so, which would have affected their results.

All the studies which compared barefoot data with AFOs found significant differences in at least one of the temporal and spatial parameters. While Abel et al. (1998), Buckon et al. (2004), Lam et al. (2005) and Radtka, Skinner and Johanson (2005) included only children with diplegia as their sample, Brunner, Meier and Ruepp (1998), Buckon et al. (2001) and Thompson et al. (2002) included children with hemiplegia. Dursun, Dursun and Alican (2002), White et al. (2002), and Radtka et al. (1997) included both groups in their studies.

Abel et al. (1998) investigated the effect of rigid AFOs on the gait of children with spastic diplegia, using a sample size of 35. The authors used a retrospective assessment of gait data collected while children walked barefoot and wearing AFOs on the same day. The children were prescribed orthoses to control either equinus, or pes planovalgus and crouch. The authors reported that there were significant increases in stride-length, velocity and single support time with the rigid AFOs in comparison to barefoot. Significant increases in ankle dorsi-flexion at initial contact, and excursion of, knee, hip and pelvis in the sagittal plane were found with rigid AFOs when compared with barefoot. The authors also reported significant decreases in power generation during pre-swing (Abel et al. 1998).

Lam et al. (2005) compared the effects of rigid AFOs and dynamic AFOs (DAFO) on the gait of children with diplegia. They evaluated the kinetics, kinematics and EMG data of 12 children. The data was collected on the same day while the children walked barefoot, with rigid AFOs and with DAFOs. Of the temporal and spatial parameters, only stride-length differed significantly between barefoot and the orthoses. Among the kinematics, the authors reported increased ankle dorsi-flexion at initial contact, peak ankle dorsi-flexion, and knee flexion at initial contact, and found decreased ankle excursion in the sagittal plane with rigid AFOs compared to barefoot. Among the kinetics, significant increases in dorsi-flexion moments during terminal stance were reported with rigid AFOs compared to barefoot. No significant differences in power parameters were reported, whereas the median frequency of EMG signals from calf muscles decreased with the use of rigid AFOs compared to barefoot.

Radtka, Skinner and Johanson (2005) compared the gait of children with diplegia between barefoot, rigid AFOs and hinged AFOs. The authors used a repeated design where children used rigid AFOs and hinged AFOs for a month each, separated by two weeks of no orthoses. All the children stopped using AFOs for two weeks before the study, at which point barefoot data were recorded. Motion analysis with force plates was used to record kinematics and forces. EMG data were recorded to investigate the timing of muscle contractions. It was found that both orthoses increased stride-length, but no significant changes were seen in cadence and velocity. Increased dorsi-flexion at initial contact and peak dorsi-flexion moments during stance were reported, but power generation during pre-swing decreased. No differences were noted in muscle contraction timings, or in proximal joint kinematics.

Buckon et al. (2004) investigated the effects of rigid AFOs, hinged AFOs and PLSOs on gait, energy expenditure, and functional skills in 16 children with diplegia. The authors reported increased stride-length and decreased cadence with the use of a rigid AFO compared with barefoot. While none of the proximal joint kinematics yielded any significant differences, dorsi-flexion during initial contact, and peak dorsi-flexion during stance and swing increased with rigid AFOs compared with barefoot. The range of ankle motion in the sagittal plane decreased with rigid AFOs compared to barefoot. Among kinetics, plantar-flexion moments during initial stance and dorsi-flexion moments during terminal stance increased, and peak ankle power generation during stance decreased with the use of rigid AFO compared to barefoot. The energy cost also decreased with the use of rigid AFO compared to barefoot.

When comparing the parameters common to all four studies with children with diplegia, Abel et al. (1998) found the most significant changes. This may be due to the fact that the authors specifically investigated the effect of rigid AFOs and included participants who were clinically prescribed the device. Radtka, Skinner and Johanson (2005) only included children who had passive ankle dorsi-flexion of 5° and who had milder degrees of impairment. While Lam et al. (2005) and Buckon et al. (2004) did not have any such inclusion criteria, they did not mention whether the participants had been prescribed, or had been using either of the two orthoses previously. The participants were also not given the opportunity to become accustomed to the orthoses in the study by Lam et al. (2005), which would have affected their results. None of the authors attempted to biomechanically optimise the AFOs.

The three studies which investigated the effects of AFOs on the gait of children with hemiplegia found that there were significant differences in temporal and spatial and parameters with the use of AFOs (Brunner, Meier and Ruepp 1998; Buckon et al 2001; Thompson et al. 2002).

Brunner, Meier and Ruepp (1998) compared three different conditions in a sample of 14 children with hemiplegia: barefoot, rigid AFO and spring AFO. The same AFO was adapted differently to make rigid as well as spring AFOs, enabling the spring AFO to allow dorsi-flexion while it and the rigid version both controlled plantar-flexion. With AFO use there were significant increases in gait velocity, stride-length, step length and single support time, and significant decreases in cadence and double support time. When comparing AFOs with barefoot, the authors also reported increased peak dorsi-flexion, hip excursion in the sagittal plane, hip abduction, the second peak of vertical force, decreased ankle joint and knee joint excursion in the sagittal plane, maximal knee extension, and hip adduction. The pelvic obliquity was more normalised with rigid AFOs compared to barefoot.

Thompson et al. (2002) primarily aimed their study at investigating the effects of rigid AFOs on hamstring length in 18 children with hemiplegia. They also reported temporal and spatial parameters and knee kinematics. A comparison was made between barefoot and rigid AFOs. The authors reported statistically significant increases in velocity and step length with AFO use, as well as a significant decrease in cadence. They also reported increased ankle dorsi-flexion at initial contact, and maximum ankle dorsi-flexion during stance, and decreased peak knee extension during stance and knee flexion during initial contact, when comparing AFOs with barefoot. With further comparison based on type of hemiplegia, the authors suggested that AFOs normalised knee kinematics in all groups. It was also reported that hamstring length improved with the use of rigid AFOs.

Buckon et al. (2001) investigated the effects of rigid AFOs, hinged AFOs, and PLSOs on gait, energy expenditure, and functional skills in 30 children with hemiplegia. The authors reported increased stride-length and decreased cadence with the use of rigid AFOs compared to barefoot, whereas walking speed remained the same. Other changes with rigid AFOs compared to barefoot included increased ankle dorsi-flexion at initial contact and peak dorsi-flexion during stance, and decreased ankle power generation in stance. Knee kinematics were analysed by grouping the children based on their peak knee extension during stance phase. When comparing rigid AFOs with barefoot, children with peak knee extension during stance of less than 10° (of flexion), had increased peak knee extension and decreased peak knee flexion during initial contact. However, with groups of children who had knee hyper-extension and a peak knee extension of more than 10° (of flexion), variables did not alter significantly with rigid AFOs.

Sample characteristics were well explained by Thompson et al. (2002) who included only children who were using rigid AFOs. In contrast, while Buckon et al. (2001) included only children who were using or who were prescribed AFOs, it was not clear which type of AFOs had been used or prescribed. Brunner, Meier and Ruepp (1998) failed to mention whether the participants were prescribed or using either of the two orthoses being compared. Walking speed data collected by Thompson et al. (2002) appeared not to be comparable with that of any other study discussed here. They reported a walking speed of 2.2 m per second in barefoot and 2.4 m per second with the AFO, which is double the walking speed of normal children.

Three studies compared barefoot to AFOs, and included all types of CP (Dursun, Dursun, and Alican 2002; Radtka et al. 1997; White et al. 2002). Radtka et al. (1997) compared three conditions – barefoot, rigid AFO and dynamic AFO (DAFO). The authors used a repeated design where ten children used rigid AFOs and DAFOs for a month each, separated by two weeks of no orthoses. The timing of muscle contractions, joint motion and temporal and spatial parameters were compared. The authors reported a significant increase in stride-length and decrease in cadence with the orthoses in comparison to the barefoot. There was no significant increase in velocity. Other changes included increased ankle dorsi-flexion during initial contact and mid-stance. There were no significant changes in proximal joint kinematics or timing of muscle contractions with AFOs. They also did not find any difference between children with hemiplegia and diplegia in any of the parameters compared.

Dursun, Dursun and Alican (2002) investigated the effects of AFOs on the gait of 24 children with CP with dynamic equinus gait, using video recordings. They statistically analysed temporal and spatial parameters and Clinical Gait Assessment Scores (CGAS). The authors found significant improvements in velocity, stride-length and CGAS score with AFOs in comparison to barefoot.

In a retrospective study, White and colleagues (2002) assessed the effect of clinically prescribed orthoses on temporal and spatial parameters of gait in children with CP. They included 115 children with CP classified using the Gross Motor Function Classification System (GMFCS) into groups I, II and III. Of those included, 29 children used rigid AFOs and 86 used hinged AFOs. The authors reported statistically significant improvements in velocity, stride-length, step length and percentage single limb stance when the children used orthoses in comparison to barefoot. Similar results were found when rigid AFOs and hinged AFOs were analysed individually. The authors also compared the temporal and spatial data normalised to age-specific percentages of healthy children, producing similar results. An interesting observation was reported by the authors, in which they found that the increase in walking speed was greater in children with hemiplegia compared to diplegia. However, the groups were not compared statistically.

The only parameter which showed similar results in the above three studies was stride-length. While Dursun and colleagues (2002) and White et al. (2002) found similar results for velocity, Radtka et al. (1997) did not find any difference. There are three possible reasons. Firstly, Radtka et al (1997) only included children who had passive ankle dorsi-flexion of 5°. Secondly, their sample size was much smaller when compared with the other two studies. The authors carried out a power analysis which revealed effect sizes of under 0.38, and power of less than 0.45 for all the non-significant variables. This leaves the possibility of a type II error. Finally, White et al. (2002) and Dursun, Dursun and Alican (2002) compared the effects of using AFOs which were clinically prescribed to the children, which was not the case for Radtka et al. (1997). While White et al. (2002) made sure that the children were accustomed to the orthoses, Dursun and colleagues (2002) did not. Dursun, Dursun and Alican (2002) also failed to mention the type of AFO used. The comparison between hemiplegia and diplegia by White et al. (2002) produced observations that contradicted those of Radtka et al. (1997). However, the study designs were different. White et al. (2002) did not statistically compare the difference between diplegia and hemiplegia, and included both types of AFOs in the comparison.

A summary of the changes in temporal and spatial parameter is given in Table 6.1 and kinetics of all lower limb joints and kinematics of proximal joints is given in Table 6.2. It can be seen that most of the studies reported significant differences in at least one parameter. However, the findings were inconsistent.

Table 6.1 Summary of differences in temporal and spatial parameters with the use of AFOs compared to barefoot/shod from the literature

Study	Comparison condition	Patient population (sample size)	Difference with AFO compared to barefoot/shod		
			Walking speed (m/s)	Stride-length (m)	Cadence (steps/minute)
Carlson et al. 1997	Shod	Diplegia (11)	0.13	0.11*	-2.2
Rethlefsen et al. 1999	Shod	All CP (21)	0.01	0.0	-3
Smiley et al. 2002	Shod	Diplegia (14)	0.06	0.03	5
Abel et al. 1998	Barefoot	Diplegia (35)	0.1*	0.1*	-2.3
Buckon et al. 2004	Barefoot	Diplegia (16)	0.05	0.11*	-18*
Lam et al. 2005	Barefoot	Diplegia (13)	0.01	0.05*	-7.1*
Radtka, Skinner and Johanson 2005	Barefoot	Diplegia (12)	0.04	0.08*	-7.4
Brunner, Meier and Ruepp 1998	Barefoot	Hemiplegia (14)	0.05*	0.12*	-6.9*
Buckon et al. 2001	Barefoot	Hemiplegia (30)	0.04	0.13*	-10*
Thompson et al. 2002	Barefoot	Hemiplegia (18)	0.2*	0.11*	-3
Radtka et al. 1997	Barefoot	All CP (10)	0.02	0.1*	-14.6*
White et al. 2002	Barefoot	All CP (115)	0.11*	0.13*	-3
Dursun, Dursun and Alican 2002	Barefoot	All CP (24)	0.05*	0.02*	-1.2

NB: *statistically significant difference

Table 6.2 Summary of the differences in kinetics of all lower limb joints and kinematics of proximal joints with the use of AFOs compared to barefoot/shod from the literature.

Study	Comparison condition	Patient population (sample size)	Kinetics and proximal joint kinematics
Carlson et al. 1997	Shod	Diplegia (11)	↑ dorsi-flexion moments during terminal stance ↓ plantar flexor power generation during pre-swing
Rethlefsen et al. 1999	Shod	All CP (21)	↑ dorsi-flexion moments during terminal stance ↓ plantar flexor power generation during pre-swing ↑ peak knee flexion during loading response
Smiley et al. 2002	Shod	Diplegia (14)	no significant difference
Abel et al. 1998	Barefoot	Diplegia (35)	↑ dorsi-flexion moments during terminal stance ↓ plantar flexor power generation during pre-swing
Buckon et al. 2004	Barefoot	Diplegia (16)	↑ knee, hip and pelvic ROM ↑ peak plantar-flexion moments during initial stance ↓peak ankle power generation
Lam et al. 2005	Barefoot	Diplegia (13)	↑ knee flexion at initial contact ↑ dorsi-flexion moments during terminal stance
Radtka, Skinner and Johanson 2005	Barefoot	Diplegia (12)	↑ dorsi-flexion moments during terminal stance ↓ plantar flexor power generation during pre-swing
Brunner, Meier & Ruepp 1998	Barefoot	Hemiplegia (14)	↑ total knee excursion, hip ROM, hip abduction ↓ peak knee extension, knee ROM, hip adduction more normal pelvic obliquity
Thompson et al. 2002	Barefoot	Hemiplegia (18)	↓knee flexion during initial contact ↓peak knee extension during stance
Buckon et al. 2001	Barefoot	Hemiplegia (30)	↓peak ankle power generation ↓knee flexion during initial contact for one sub group of sample
Radtka et al. 1997	Barefoot	All CP (10)	no significant difference

NB: ↑ - increased, ↓ - decreased, ROM- range of motion

The variability in study findings can be attributed to several factors. Firstly, study design differed. Most of the studies compared the effects of different types of AFO on the gait of children with CP, selecting AFO type without reference to the specific AFO that was clinically indicated, prescribed to, or being used by the child. Only four of the studies evaluated the effectiveness of the AFOs which had been clinically prescribed to, or were being used by the child (Abel et al. 1998; Dursun, Dursun and Alican 2002; Thompson et al. 2002; White et al. 2002). The studies also demonstrated a lack of consistency in the outcomes of statistical analyses. For example, while White et al. (2002) found a difference of 0.11m/s in walking velocity statistically significant, Carlson et al. (1998) did not find a difference of 0.13 m/s to be significant, possibly due to differences in sample size. White et al. (2002) used a sample size of 115, whereas Carlson et al. (1998) had only 11 participants. Another study with a sample size of 35 also found a difference of 0.10 m/s statistically significant, supporting this argument. Despite having small sample sizes, none of the studies except that of Radtka et al. (1997) attempted power analysis. Radtka et al. (1997) found effect sizes of less than 0.38 and power of less than 0.45 for all the non-significant variables in their study. This demonstrates the possibility of a type II error. The authors did not attempt statistical analysis separately for diplegics and hemiplegics, as a two-way ANOVA did not reveal any interaction between diagnosis and intervention; however, there was a difference of 0.12 m/s in the velocity in children with diplegia. This probably strengthens the possibility of a type II error and is applicable to all the studies with smaller sample sizes. A further issue relating to study design is the time given for children to become accustomed to the prescription. While most of the studies provided time for this, Lam et al. (2005) and Smiley et al. (2002) did not take it into consideration and Brunner, Meier and Ruepp (1998) failed to mention whether children had been given adequate time to get accustomed.

Another factor likely to have increased variability in study findings was the lack of group-wise comparisons. Comparisons were not made based on diagnosis or gait patterns in most of the studies. Due to differences in study design, it is difficult to directly compare data from studies that included children with hemiplegia, with that of studies that included children with diplegia. The two studies which included all children with CP and made comparisons between hemiplegia and diplegia produced conflicting results (Radtka et al. 1997; White et al. 2002). Two other studies by Buckon et al. (2001) and Bucken et al. (2004) used the same design and included children with hemiplegia and diplegia, respectively. The differences in temporal and spatial parameters with rigid AFOs compared to barefoot were similar between the studies, whereas in children with hemiplegia there was difference in knee kinematics in a sub-group. It was also noticeable that only two studies carried out comparisons based on gait patterns (Buckon et al. 2001; Thompson et al. 2002). According to Thompson et al. (2002), AFOs can normalise proximal joint motion by reducing the flexion of the hyperflexed joints and extension of the hyperextended joints, so mean values of joint flexion/extension and a statistical analysis based on such mean values might not detect clinically significant changes in such a diverse group. More research using specific sample groups is required.

Another factor which may have influenced the findings of the previous literature is angle of ankle in AFO. All the studies used rigid AFOs casted in plantigrade. It has been recommended that casting the AFOs at an angle to accommodate the tightness of gastrocnemius is important for children with CP (Bowers and Ross 2009) and adults with stroke (NHS Quality improvement 2009).

Finally, none of the studies considered biomechanical optimisation (tuning) of AFOs for children with CP. Several authors have stated the effect of biomechanically aligned orthoses on proximal joints (Butler and Nene 1991; Meadows 1984; Owen 2004b). Although there are only a few studies which have investigated the effect of biomechanically optimised AFOs, they all indicated the potential of tuning in improving the gait of children with CP, suggesting the need for further research (Butler, Farmer, and Major 1997; Butler, Thompson, and Major 1992; Butler and Nene 1991; Stallard and Woollam 2003).

6.4 Relevance to the project

- Variability exists in the literature regarding effects of AFO intervention.
- Influences of AFOs on proximal joint kinematics and kinetics were not evident from the literature. However, the effects might be different for children with different gait patterns.
- Most of the literature on AFO intervention did not consider biomechanical optimisation of AFOs.

CHAPTER 7 TUNING OF ANKLE FOOT ORTHOSES – FOOTWEAR COMBINATION (AFO-FC): THEORY AND EVIDENCE BASE

7.1 Introduction

Chapter 6 revealed varying findings regarding the effects of rigid AFOs on the gait of children with CP. One of the reasons identified for the variability is that none of the studies attempted biomechanical optimisaiton of AFOs. Interestingly, the potential of biomechanical optimisation (tuning) was identified early on (Cook and Cozzens 1976; Meadows 1984; Nuzzo 1986; Wiest et al. 1979). In his PhD thesis, Meadows (1984) emphasised the effect of 'tuning' of the 'ankle foot orthoses footwear complex' (AFO-FC) on the gait of children with CP. Cook and Cozzens (1976) identified the role of heel height of shoes in the biomechanical optimisation of AFOs; this was further investigated by Meadows (1984), who also reported the effects of tuning on kinematics and kinetics of proximal joints and the Ground Reaction Force (GRF). Although there have been only a very few studies on the effects of tuning of AFO-FC, all reported positive influences (Butler, Farmer and Major 1997; Butler, Thompson and Major 1992; Stallard and Woollam 2003). Stallard and Woollam (2003) recognised that tuning of the AFO-FC using motion analysis is vital and should be the part of routine clinical processes.

Tuning predominantly involves modifying shoes to optimise the kinetics and kinematics of gait. The parameters which are commonly modified include height of the heel, type and design of the heel, and type of the rocker at the metatarsal heads (Butler and Nene 1991; Hullin, Robb, and Loudon 1992; Meadows 1984; Owen 2004b). The modification of these parameters is carried out to optimise alignment of the GRF during various stages of the gait cycle. Initially some authors emphasised the use of wedges to modify the height of the heel to optimise the GRF in relation to the knee joint during mid-stance (Butler and Nene 1991). The use of different types and designs of heels and rockers to optimise initial stance and mid/terminal stance has also been suggested (Hullin, Robb and Loudon 1992; Owen 2004b). Among the different components of tuning, the emphasis has been on use of wedges (Butler and

Nene 1991). While a few studies reported the effects of tuning using wedges on gait (Butler, Thompson and Major 1992; Stallard and Woollam 2003; Butler et al. 2007), the evidence regarding the effects of heels and rockers is mostly empirical and has been less frequently investigated. Nevertheless, tuning has evolved from being an intervention with one component (wedges) to a complex intervention with several components.

Butler, Thompson and Major (1992) stated that properly aligned AFOs can passively maintain the forces acting on the knee joint, thus relieving the child from the effort of maintaining knee alignment. This helps motor learning to occur. In contrast, non-tuned AFOs will not provide this environment that facilitates motor learning. Stallard and Woollam (2003) hypothesised that tuning influences the knee joint by controlling ankle joint kinematics. Butler, Thompson and Major (1992) stated that appropriately tuned rigid AFOs may directly modify the GRF in relation to the proximal joints. This would reduce abnormal moments acting on knee and hip, decreasing knee hyper-extension during stance phase and improving hip flexion. Furthermore, Condie and Meadows (1993) suggested that tuning probably controls the forward progression of the Centre Of Pressure (COP), thereby generating push-off force. They also noted that inappropriate AFO-FC can lead to increased energy expenditure in comparison to barefoot gait.

While tuning is commonly carried out through visual observation, the use of motion analysis systems is recommended (Stallard and Woollam 2003). Although it is ideal to look at kinematic and kinetic data through 3D motion analysis before a prescription for tuning is made, it might not be possible in all clinical settings. However, several clinical settings have access to video vector analysis. For this reason, certain indicators are usually used to tune the AFO-FCs, most commonly the angle made between the shank of the tibia and the floor, and orientation of the GRF in relation to the proximal joints.

7.2 Shank of the tibia to the floor/foot angle

Authors have used different terms and measures to express the angle between the shank of the tibia and the floor or foot. Owen (2002) used the term ‘shank angle to floor' (SAF) angle, while Hullin, Robb and Loudon (1992) used 'foot-shank angle' and Pratt, Durham and Ewins (2007) used 'shank and the vertical angle' (SAV). Owen (2002) and Pratt, Durham and Ewins (2007) measured the angle made by the shank of the tibia to an imaginary line drawn perpendicular to the ground, whereas Hullin, Robb and Loudon (1992) measured the angle between the shank of the tibia and floor or foot. In the present study the term 'shank to vertical angle' (SVA) will be used, denoting the angle made by shank of the tibia to the imaginary line drawn perpendicular to the ground. Anthropometric measures indicate that for the knee joint centre to be directly above the middle of the foot, the SVA must be 10° (Tilley, 1993 cited in Owen, 2004b). For children with CP, the SVA can be very variable. The SVA can either be a negative value, zero, or a positive value when the shank is reclined, vertical, or inclined, respectively (Owen 2004b). The SVA is considered to have a greater influence on gait than the angle of the ankle in the AFO (AAAFO). For children using rigid AFOs, the SVA becomes more relevant, as it has been identified that rigid AFOs restrict the motion of the tibia over the foot (Abel et al. 1998). Hullin, Robb and Loudon (1992) noted that making small changes to the foot–shank angle can have considerable influence on knee joint motion.

In a study which tried to establish a normal database for orthotic tuning, the authors investigated the SVA and the moment arm at the knee throughout the stance phase (Pratt, Durham, and Ewins 2007). Using a sample of 11 healthy children, data were collected in barefoot and shod conditions. The authors reported a mean SVA in mid-stance of 11.4± 3.4° in the barefoot condition and 10.5 ± 3.6° in the shod condition (which was at 45% ± 2% and 44% ± 2% of the gait cycle in barefoot and shod conditions respectively). While the study was the only one of its kind, the authors did not investigate whether the difference between barefoot and shod was statistically significant. They also failed to discuss the reason for the difference between shod and barefoot conditions, and no reference was made to the differences in thickness between the heels and soles of the shoes used.

Owen (2002) reported the SVAs of tuned AFO-FCs used in children with CP, Spina Bifida and other conditions. Of the total sample of 75, 50 were children with CP. It was noted that irrespective of the angle at which the AFOs were casted, all the children had an inclined SVA after tuning. While the mean SVA for all the AFO-FCs (n = 112) after tuning was 11.36 ± 2.08° (range = 7 – 15), the mean for AFO-FCs used by children with CP (number of legs = 69) after tuning was 11.86 ± 2.05° (range = 7 – 15). The author concluded that 12° is a good SVA as a starting point for tuning. While this study undoubtedly establishes the SVA as one key indicator in tuning, the author failed to mention the method used to measure the SVA. Owen (2004b) stated that the SVA can be measured in standing, but the accuracy and repeatability of this in children with CP has not been investigated. As yet there has been no attempt to correlate the SVA measured in standing, to the SVA measured during actual mid-stance.

7.3 Orientation of the Ground Reaction Force and tuning

While Owen (2002, 2004b) considered SVA as the key starting point for tuning, most authors recommend orientation of the GRF with respect to the proximal joints as the key parameter for the tuning process (Butler and Nene 1991; Meadows 1984; Owen 2004b; Stallard and Woollam 2003). The principle behind this is that the GRF passes near to, or through, the joint centre throughout the gait cycle; if it is perturbed and the GRF passes away from the joint centre or inappropriately with respect to the joints, it will cause high moment arms. This causes high external moments which then need to be opposed by greater muscle activity. In children with CP, orientation of the GRF is disturbed by abnormal joint positions; and correction of this will optimise gait (Butler and Nene 1991). It is not difficult to tune AFO-FC through GRF optimisation, since the GRF alignment can be visualised in real time with most motion analysis systems available today (Stallard and Woollam 2003). Butler and Nene (1991) suggested that the use of rigid AFOs will eliminate ankle motion, which may then give more control over GRF alignment at the knee and hip joints when tuning.

Stallard and Woollam (2003) investigated the effectiveness of a newly developed video vector system as an aid to orthotic prescription. Sixty-one patients with various gait pathologies, most of them of neurological origin, were assessed; decision-making with regard to the tuning of the orthotic prescription was made on the basis of the suggestions by Butler and Nene (1991). The study investigated whether the tuning brought about an improvement, with realignment of the GRF by a minimum of 10 mms to reach the ideal specified by the physiotherapist. Decision-making involved the physiotherapist involved in the child's management. The new system collected video and force data which were overlapped to enable assessment of the force vector alignment in relation to the joints. Modifications to the shoe were suggested so as to achieve an alignment of the GRF as close to normal as possible. Any difference of more than 10 mms in the alignment of the GRF was considered significant. The authors found that the biomechanical alignment of lower limb joints improved in more than 68% of patients and only two of the 61 patients did not show a satisfactory improvement. While these results indicated the effectiveness of tuning of orthoses in gait, the study presented some limitations. The authors failed to mention the type of disorders, as well as the severity of gait pathology involved. While 23 patients demonstrated improvement in alignment of the GRF in the sagittal plane, two patients improved in the coronal plane and seven in both planes. The authors did not mention which joints had been investigated, and quantitative analysis of kinematic and kinetic data had not been attempted. The authors concluded that the use of this method to tune AFO-FCs was effective and also reported that confidence among physiotherapists and orthotists in practising this method was increasing.

7.4 Role of footwear and modifications

Footwear is considered a vital part of AFO fitting. Several authors considered the AFO-FC as a single unit (Meadows 1984; Owen 2002; Owen 2004b). Footwear has been shown to influence the biomechanical alignment of AFOs (Condie and Meadows 1993; Owen 2004b; Wesdock and Edge 2003). It plays a vital part in the 'three-point force system,' which prevents abnormal plantar-flexion by applying pressure over the dorsum of the foot (Condie and Meadows 1993). The properties of the soles of the shoes (such as sole profile and heel height) can influence alignment of the GRF in relation to the lower limb joints, and the alignment and movement of the tibial shank (Condie and Meadows 1993; Owen 2004b).

Churchill, Halligan and Wade (2003) investigated the relative contribution of footwear to the effectiveness of rigid AFOs. Five stroke patients who were prescribed AFOs were included in the study and temporal and spatial data were collected using a 2D motion analysis system. Comparisons were made between barefoot, footwear alone, and AFO with footwear. A significant difference was seen in stride-length, which showed an increase of 0.5 m with footwear in comparison to barefoot, and a further increase of 0.5 m was seen with AFO use. The authors attributed the former to footwear, and the latter to AFOs, and suggested that footwear is as important as AFOs in some patients (Churchill, Halligan, and Wade 2003). Hesse et al. (1996) compared functional gait parameters between between barefoot walking, walking with shoes and when using a type of rigid AFO (Valens calliper) in 19 adults with hemiparesis. They reported significant increases in walking speed and stride-length, and a significant decrease in initial double stance duration with shoes and AFOs compared to barefoot. Similar changes were seen with AFOs compared to walking with shoes. Furthermore, cadence also increased with the use of AFO compared to the other two conditions.

Both studies (Hesse et al. 1996; Churchill, Halligan and Wade 2003) supported the role of footwear in AFO intervention. Churchill, Halligan and Wade (2003) failed to mention whether the patients were given ample time to become accustomed to the AFOs, while Hesse et al. (1996) provided less than a week for this purpose. In addition, the shoes were not biomechanically optimised, and according to Condie and Meadows (1993), inappropriate AFO-FC can lead to increased energy expenditure when compared with barefoot gait. Kinematic data were also not available in either study. Considering these limitations, the role of shoes in AFO intervention found by Churchill, Halligan and Wade (2003) and Hesse et al. (1996) may substantially underestimate the actual influence.

Different aspects of the soles of footwear may influence the kinetics and kinematics of gait; authors have identified potential influences in the heel height, type and design of the heel, and presence of a rocker (Hullin, Robb and Loudon 1992; Meadows 1984; Owen 2004b; Wiest et al. 1979; Wu, Rosenbaum, and Su 2004).

Owen (2004b) hypothesised that heel type, heel height, and rocker, tune initial stance, mid-stance and terminal stance respectively, Hullin, Robb and Loudon (1992) recommended the use of rockers to tune mid- and terminal stance for certain patient populations, such as Spina Bifida and CP. There is lack of published evidence regarding all three specific components of tuning.

7.4.1 Modification of heel height in tuning of AFO-FC

Heel height can be modified by the use of wedges (heel raise). A heel raise will tip the shank of the tibia forward, thus increasing the inclination (Owen 2004b). An appropriate SVA can be gained by adding wedges to the heel as required. The heel height necessary to generate the required degree of SVA can be calculated using trigonometry (Hullin, Robb and Loudon 1992). The SVA cannot be determined by heel height alone, while it can be by the difference between the height of the shoes at the heel and at the metatarsal heads. This difference is termed as the 'Heel Sole Differential' (HSD) (Owen 2004b).

It can be inferred that wedges can be used to increase the shank inclination where there is a reclined, vertical or a less inclined shank. These are commonly seen in extending knee gait (Sutherland and Davids 1993), in which the knee joint is either hyperextending, or extending, during mid-stance. In some cases of extending knee gait, the shank might move in a reverse direction, further complicating the situation (Connolly et al. 1999). Inadequate shank progression can also be seen in flexed knee gait, predominantly when the shank kinematics are affected by a rigid AFO, as it has been identified that rigid AFOs restrict the motion of the tibia over the foot (Abel et al. 1998). In patterns where there is lack of inclination of the tibial shank during mid-stance, the GRF is oriented anterior to the knee joint, thus producing high knee extension moments that lead to hyper-extension of the knee (Butler and Nene 1991). Condie and Meadows (1993) suggested the use of heel wedges and/or rockers to reduce the knee extension moment. The use of a heel raise maintains the origin of the GRF at the heel during early stance, thus providing the knee joint with time to move forward (Butler and Nene 1991). Owen (2004b) suggested the use of heel wedges until the GRF passes through the middle of the knee joint during mid-stance, which will then optimise the moments. It was thus hypothesised by Owen (2004b) that wedges are useful in tuning mid-stance. Butler et al. (2007) reported that while wedges can reorient tibial inclination and reduce knee hyper-extension during mid-stance in children with recurvatum knee gait, they can also produce increased knee flexion during initial stance. They also stated that this disadvantage is negligible while considering the effects of wedges on overall kinematics and kinetics of gait.

In an earlier study Cook and Cozzens (1976) investigated the effect of different heel heights and ankle foot orthosis configurations on weight line location. The authors used a single healthy adult and compared three different heel heights combined with a plantar flexed AFO, neutral AFO, dorsi-flexed AFO and without AFO. The authors found that the while the weight line was unaffected without AFO for different heel heights, it was affected when the participant wore AFOs. The weight line moved according to whether the combination of heel and AFO tipped the shank forward or backward. The authors concluded that the heel height and AFO configuration should be matched to produce the best results.

Heel wedges can also be used in children presenting with fixed flexion deformities of the hip and knee, or fixed equinus, in order to modify tibial alignment in relation to the floor and thereby compensate for fixed flexion deformities (Morris 2002a). Wesdock and Edge (2003) investigated the effects of wedged shoes and rigid AFOs on standing balance and knee extension in children with CP who crouch. A repeated measures design was used where 11 children with CP used shoes and rigid AFOs for the first four weeks, and wedged shoes with AFOs (WAFO) for the second four weeks. Participants stood with no AFOs, AFOs and WAFOs while maximum knee extension and standing balance were measured. The results demonstrated non-significant differences in knee extension when the conditions of AFO and non-AFO were compared. There was no statistical significance in the duration of static standing balance between the conditions AFO and WAFO, and no AFO and WAFO. When the data were analysed separately for a subset of four participants who were able to stand for at least 15 seconds, the use of WAFO showed significant improvements compared to the other two conditions. Post hoc power analysis revealed a 32% probability that a type II error had occurred for the standing balance data. The authors concluded that although no statistical significance was found, the subset data and the power analysis results support the need for further research with greater sample sizes, modified inclusion criteria and functional outcome measures (Wesdock and Edge 2003). It should be noted that that the wedge used was not designed according to the alignment of the GRF or SVA, which is crucial for any improvement in the alignment of proximal joints (Butler and Nene 1991; Owen 2004b). Furthermore, the study did not investigate the effects on gait. It is also worth mentioning that Butler et al. (2007) reported that successful tuning using wedges is only likely when maximum knee flexion during the first third of the gait cycle is less than 20°, and when minimum knee flexion during the second third is less than 10°, suggesting that wedges may not be effective in children who crouch.

7.4.2 Heel designs in tuning of AFO-FC

During the first rocker of gait, there is acceptance of body weight and the tibia rolls forward while the ankle plantar flexes. Since the heel protrudes posteriorly from the ankle joint, a lever is created between the ankle joint and the point of heel contact which makes the first rocker possible (Wiest et al. 1979; Perry 1992). Thus, it can be inferred that through modifying the lever, the first rocker can be influenced. Owen (2004b) hypothesised that the use of heels with different shock absorption qualities and design can influence shank kinematics during the loading response.

Wiest et al. (1979) compared the effect of different heel designs used with rigid AFOs on different gait parameters in nine healthy adults. The authors compared the solid ankle cushion heel (SACH) heel, beveled heel (normal heel with its posterior edge ground off), crepe heel (latex foam material) and standard factory rubber heel. Of the four, the SACH heel was the most compressible, followed by the crepe heel. The beveled and standard heels were made of the same material, which was the hardest. Tibial advancement torque, knee and ankle motion and temporal and spatial parameters were analysed. The authors found that the tibial advancement torque was highest with the standard heel (24.8 Nm), which decreased by 12% with the crepe heel (21.8 Nm), 24% with the bevelled heel (18.8 Nm), and 31% with the SACH heel

(17.1 Nm). They also found that when a force of 445 N was applied, the heel lever was shortened by 1.3 cm with the SACH heel, 0.9 cm with the crepe heel and 0.2 cm with the standard heel. Considering these results, the authors concluded that there is a direct relationship between the heel lever length and tibial advancement torque. While the crepe heel and the SACH heel had lower tibial advancement torques owing to their compressibility, the bevelled heel had a shorter lever owing to its design, and hence a lower tibial advancement torque. The authors reported no significant changes in knee and ankle motion. However there was a significant increase in stride-length with the crepe heel compared to the bevelled heel, attributed to the difference in the length of the lever. Stride-length with the standard heel was lower than that with the SACH and bevelled heels, and was explained as the result of a higher knee flexion torque with the standard heel. It can be deduced from the findings of Wiest et al. (1979) that tibial advancement torque can be altered by modifying the heel lever, which in turn can be brought about by either changing the compressibility, or actual length, of the lever.

The findings by Wiest et al. (1979) support suggestions by Owen (2004b) regarding the use of different heels to regulate shank kinematics in initial stance. Various heel types were proposed, including: positive heel, negative heel, cushion heel, or a plain heel (Owen 2004b, Owen 2005). According to Owen (2004b, 2005), while the plain heel is the normal heel used on shoes, positive heels extend further behind the soles of the feet. In order to make a negative heel, the posterior edge of the plain heel is ground away, and for a cushion heel a compressible material is inserted at the posterior aspect of the heel. Positive heels produce increased moments at the ankle and knee compared with the plain heel. In contrast, the cushion and negative heels reduce the flexion moment at the ankle and knee compared to a plain heel. (Owen 2004b, Owen 2005). While the study by Wiest et al. (1979) and work by Owen (2004b, 2005) provide guidelines about the use of heels for various conditions, there is not enough information available to enable standardisation in the use of heels. For example, the distance to which the heel should be extended to produce a desired effect is not known. Types of heels are probably the least researched component of tuning.

7.4.3 Use of rockers in tuning of AFO-FC

At the third rocker of the gait, the ankle joint is fixed, and the shank of the tibia rolls over the metatarsophalangeal joint (MTPJ) (Perry 1992). In order to generate adequate push off force at toe-off, the GRF should be aligned anterior to the knee and posterior to the hip. In some children with CP, this orientation is perturbed, thus affecting the push-off force (Meadows 1984). This can be seen with both inadequately inclined and excessively inclined shanks. It is suggested that the use of different types of rockers can compensate for the lack of anatomical third rocker and/or normalise the shank kinematics during terminal stance (Hullin and Robb 1991; Hullin, Robb and Loudon 1992; Meadows 1984; Owen 2004a; Owen 2004b; Owen 2005). Owen (2004b) suggested the use of two types of rockers – rounded, and point loading rockers (PLR). The rounded rocker compensates for the third rocker, and also increases the speed of progression of the tibia; the PLR prevents heel lift until the centre of pressure progression (COPP) reaches the PLR. For any rocker, the position of the apex of the rocker, and the angle which it makes with the sole of the shoes (toe spring angle), are considered important.

Hullin and Robb (1991) investigated the effects of nine different rockers when used with a plaster cast on one healthy adult. They compared temporal and spatial parameters, COPP, tibial progression, vertical forces, and knee moment. No differences in temporal and spatial parameters were seen, whereas the results were variable with all other parameters. The COPP showed rapid progression with one of the flat sole rockers, and delayed progression with all the point loading rockers and one rounded rocker. The progression was normal for the control and the remaining three rounded rockers. While tibial progression was affected, there was no consistent pattern. Three rockers – two rounded and one point loader – demonstrated a tibial progression of more than 25°/second. Vertical forces did not reach body weight during the second peak for three of the point loaders. The results of knee moments also varied and only one of the rounded rockers provided the normal zero moment during pelvic high point. The authors concluded that an ideal rocker should not only control the origin of the GRF, but allow progression of the tibia over the stationary ankle joint. While the commercially available rockers had more deleterious effects, none of them were biomechanically optimised according to the need of the participant. It is clear from the study that the rockers have the potential to regulate tibial progression and the origin of the GRF.

Owen (2004a) reported the effect of PLRs in children with CP, Spina Bifida and other conditions, using rigid AFOs. Twelve children experienced tuning to optimise mid-stance and terminal stance. All the children were tuned for their terminal stance using PLRs, and the point loader was located at a mean of 78% of the length of the footwear, with a mean toe-spring angle of 33°. The author stated that although the MTPJ is located at 72% of the length of the foot, the boots used were large and hence the point loader was to be placed ahead of the actual MTPJ. The author found that the point of heel-lift was determined by the position of the PLR; furthermore, a sufficient toe spring angle was necessary to prevent the distal end of the sole from touching the ground. While this study indicated the importance of PLRs in tuning, the author did not attempt to compare pre- and post-tuning using kinematic or kinetic data. Although it was stated that the PLR is useful for children with an inclined shank, it was not mentioned whether the sample used presented with an inclined or a reclined shank.

In another study, the effect of AFOs and PLRs on children with low-level myelomeningocele was investigated (Hullin, Robb and Loudon 1992). A sample of six children was used, and gait data was collected in barefoot and with AFO. PLRs were used for two children. All the children presented knee flexion deformity and had knee flexion moments throughout the stance phase in barefoot. There was no COPP and tibial progression was brought about by persistent dorsi-flexion. Use of AFOs reduced a knee flexion moment, which became extending in two children. With AFOs, the COPP was rapid, but heel-lift was not present. Two children who presented with knee extensor moments used AFOs casted at 90°, whereas for the others the AFOs were casted at 10° of dorsi-flexion. It was noted that tibial progression halted in children with hyper-extension, and PLRs were then used to regulate the extensor moment in those two children. The authors preferred the PLR to a heel raise for the reason that the heel raise does not influence heel-lift or the

COPP, whereas the PLR does. They found that the PLR controls the origin of the GRF at the position of the point loader, and allows roll-over of the tibia, thus allowing normal shank kinematics. It should be noted that the PLR was placed at 77% of the length of the sole, which will not then influence shank kinematics until the COPP reaches the point loader. It is possible that the shank kinematics of the two children were more or less normal until late stance, which possibly precluded the use of the heel raise to modify the mid-stance shank alignment. Nevertheless, the study indicates the use of PLR in decreased shank movement during late stance, which needs to be investigated further.

Wu, Rosenbaum and Su (2004) investigated the effects of a rocker sole and a solid ankle cushion heel (SACH) on the gait parameters of healthy individuals. Motion of the fore-foot and hind-foot was compared between modified and traditional shoes. The parameters were investigated using a 3D motion analysis system during level walking, stair-climbing and stair-descending. The study reported that with modified shoes there was reduced movement at the ankle joint in the sagittal plane during level walking. Reduced excursion was noted in the fore-foot joint during all the three activities with modified shoes compared to traditional. The authors attributed this reduction in fore-foot movement to the ability of rocker soles to imitate fore-foot movement, including dorsi-flexion and the fore-foot rocker of gait. It was concluded that rockers can be advantageous whenever there is movement restriction in the foot joints as in the case of AFOs (Wu, Rosenbaum and Su 2004). It should be noted that this study was conducted on healthy volunteers, whose fore-foot and ankle joints were free to move. The authors failed to mention whether the sole profiles of the shoes were hard enough to restrict movement at the fore-foot joint. Considering the above factors, the possibility of the results being different for children with CP cannot be ignored.

Although the limited published evidence provides a guideline for the prescription of rockers in tuning, more research is required. The influences of different types of rockers, with different toe spring angles, on the parameters of gait have never been investigated.

7.5 Evidence for the effects of tuning on gait parameters

There have been very few studies to investigate the effects of tuning on children with CP (Butler et al. 2007; Butler, Thompson and Major 1992; Stallard and Woollam 2003). The study by Stallard and Woollam (2003) has been discussed in Section 7.3, and the authors reported that 68% of the sample showed improvements in the alignment of the GRF after tuning.

In a study conducted by Butler, Thompson and Major (1992), the authors investigated the effect of tuned AFOs in conjunction with balance training exercises. The sample was comprised of five children with CP who had hyper-extension of the knee joint during mid-stance and an increased knee-extending moment arm during mid-stance. Gait assessment and clinical examination were conducted before, and four-to-six months after, the start of the treatment. The high knee-extending moment arm decreased to a significant level ($p < 0.01$) and was closer to normal. There was no significant change in walking speed. Three out of five children retained the improvement in barefoot, and were weaned from the AFOs. The authors attributed this effect to motor learning, which might have been facilitated through the use of biomechanically appropriate AFOs. While this study was successful in pointing out the importance of tuning the AFOs, it presented some limitations. The effects cannot be specifically attributed to tuning, since there was a combination of treatments, the lack of detail regarding materials and methods used for tuning, and lack of comparison between tuned and non-tuned AFOs.

Butler et al. (2007) used a retrospective analysis to identify the characteristics of children with CP that can be used as predictors of success in tuning. Data from 21 children with CP were retrospectively analysed. Parameters were identified by statistically comparing (independent t – tests/ Mann-Whitney U) the data from children, who were successfully tuned, with data from children who were not. The most useful parameters were included in a logistic regression to locate predictors of successful tuning. The authors found the best predictors to be: maximum knee flexion during the initial one third of stance, and minimum knee flexion during the next third of stance. They reported that successful tuning is only likely when maximum knee flexion during the first third is less than 20°, and minimum knee flexion during the second third is less than 10°. The authors concluded that it is possible to improve knee kinematics and kinetics by tuning the AFO-FC in toe-walkers, and the children who are most likely to gain from tuning can be identified from knee kinematics. While this study was the first of its kind relating to tuning, the results should be taken with caution. The authors have predominantly considered knee kinetics and kinematics as indicators for successful tuning, whereas hip and pelvis movement, and temporal and spatial parameters, are also vital. The authors also failed to mention whether long-term effects were considered before they decided that tuning had been unsuccessful. Finally, comparisons were made between barefoot and tuned AFOs, which make it difficult to identify whether the effects achieved were due to tuning or just the use of AFOs.

While there is a substantial lack of evidence in the form of published literature in the area of tuning of AFO-FC, all the studies have reported positive outcomes. None of the studies have looked into the effects of tuning on quality of life, or on other joints besides the ankle and knee. More research to establish these findings is required.

7.6 Relevance to the project

- There is a lack of published evidence in the area of tuning.
- While initially the use of wedges was suggested for tuning, the use of different types of heels and rockers has also been suggested. Tuning has evolved as a complex intervention over the years.
- While some studies have investigated the effects of tuning using wedges, evidence regarding the effects of heels and rockers is empirical at best.
- There is a lack of information regarding the types of heels used in previous research, which makes it difficult to standardise the type of heel used.
- Comparisons between rockers with different toe-spring angles have not been carried out.
- None of the studies has considered investigating the effects of tuning on quality of life, and the kinematics and kinetics of children with CP.

CHAPTER 8 A CRITIQUE OF VARIABLES OF INTEREST AND RELEVANT OUTCOME MEASURES

8.1 Introduction

Outcome evaluation is a vital part of any research or clinical intervention. In a condition like Cerebral Palsy (CP), where the disability has an immense effect on quality of life and persists across the lifespan, outcome evaluation is multifaceted. The International Classification of Function, Health and Disability (ICF), published by the World Health Organisation (WHO), has provided a new framework that should be applied to assessment, management and outcome evaluation of children with childhood disabilities (WHO 2001). The ICF recognises disability at not only the structural/functional level, but also considers limitations in activity and participation. Use of this framework, along with greater focus on the influences of intrinsic (eg: spasticity, contractures) and extrinsic determinants (eg: school environment) of the child and the developmental changes on outcomes, has led to a shift in the focus of outcome evaluation (Majnemer and Mazer 2004). Majnemer and Mazer (2004) reviewed studies from the past two decades and reported use of a broader range of measures, including function, health and quality of life, in the past ten years when compared with the previous ten years.

Since tuning of AFO-FC primarily aims to improve the gait of children with CP, in the current study, evaluation of kinematics and kinetics of gait in addition to the measurement of muscle and joint properties, measurement of gait function and quality of life provides valuable information. In this chapter, literature regarding the gait assessment, measurement of tone, muscle power, joint range of motion (ROM), and quality of life in CP will be considered.

8.2 Gait assessment

Previous chapters have discussed the measurement of gait (Chapter 4, pages 32-34), errors associated with measurement (Chapter 4, pages 34-39), and gait assessment in children with CP (Chapter 5, page 52-55). For a condition like CP, multiple impairments and the involvement of multiple joints requires the generation of large amounts of complex gait data. This makes it difficult to derive meaningful conclusions when investigating the effects of an intervention, as some mechanism to synthesise the data is required. Hence, there is a need for quantifying gait by synthesising data into a single score. While several indices to quantify gait have been proposed before, the Gillette Gait Index (GGI) (Romei et al. 2004) is most extensively used. However, the GGI is complex to implement and analyse, and in order to address this, a new measure was developed: the Gait Deviation Index (GDI) (Schwartz and Rozumalski 2008). The original article relating to its development explained the method used to contruct the measure, as well as addressing its concurrent validity with the GGI and the Gillette Functional Assessment Questionnaire Walking Scale (FAQ). The authors reported moderate correlations between the GDI and the GGI ($r^2 = 0.56$), and identified that the GDI demonstrated adequate sensitivity to differentiate between levels of FAQ. Furthermore, the GDI was identified as sensitive to topographical classification of CP (Schwartz and Rozumalski 2008).

The validity of the GDI was further addressed by Molloy et al. (in press), who investigated the relationship between the GDI and gross motor function using the Gross Motor Function Measure (GMFM). They also evaluated the sensitivity of the GDI to differentiate between levels of classification in the Gross Motor Function Classification System (GMFCS) in a sample of 184 children with CP. The authors reported significant differences in GDI score between levels of the GMFCS classification, and strong relationships between components of the GMFM and GDI score ($r = 0.67$ to 0.70).

As a relatively new index, the reliability and validity of the GDI have not been extensively investigated. Furthermore, the sensitivity of the GDI in detecting changes in response to conservative management strategies, such as AFOs, or tuning of AFOs, has not been addressed. The GDI incorporates joint kinematics in all three planes of the pelvis and hip, in the sagittal plane for the knee and ankle, and also includes the foot progression angle. However, it does not consider kinetics or temporal-spatial parameters.

8.2 Assessment of muscle tone

Impaired tone is one of the most common features of CP, which can manifest as abnormal increases or decreases in tone. However, only the increase in tone, commonly termed as spasticity, is relevant to the present study. Traditionally, spasticity is referred to as a velocity-dependent increase in tone, and is commonly held responsible for poor motor performance in children with CP. While the complicated nature of the condition makes it difficult to investigate the influence of individual problems on function, there has been some evidence regarding the influence of spasticity on strength and function (Damiano et al. 2001). Damiano et al. (2001) demonstrated that muscle weakness of the antagonists was correlated to a higher resistance torque due to spasticity, and muscle stiffness of the agonist muscles. The relationship between spasticity and function was fair to moderate, whereas strength was highly correlated with function. It should be noted that the investigation was restricted to the quadriceps and hamstrings only. Another study investigated the relationships between spasticity, strength, gait parameters and function in children with spastic diplegia (Ross and Engsberg 2007). They found that while strength had a high correlation with function, spasticity had a low correlation. The authors attributed the disagreement with the findings of Damiano et al. (2001) to differences in the sample, and differences in the velocity of movement employed. Another study by the same authors reported no relationship between strength and spasticity of either of the same muscle groups, or the antagonists (Ross and Engsberg 2002).

Abel et al. (2003) investigated the relationship of impairment measures such as passive range of motion, spasticity, and gait, with functional measures such as the gross motor function measure (GMFM) and pediatric outcomes data collection instrument (PODCI). It was reported that the individual impairment measures had only weak correlations with function. Step-wise regression analysis with different combinations revealed that the highest variability was accounted for by a combination of four variables, including the mean score on the Ashworth scale, although this still amounted only to 33%. The authors stated that including strength as a variable might have improved the predictability. The ambiguity in the direct relationship between spasticity and function can be attributed to the complexity of the condition, the levels of severity, variability in the influence of different muscle groups on function, and differences in the methods used to measure spasticity. Nevertheless, there is little argument regarding the importance of objectively measuring spasticity prior to and after an intervention.

Muscle tone can be measured using electrophysiological methods like Electromyography (EMG), an isokinetic dynamometer, or clinical scales. While the first two methods are considered more objective (Damiano et al. 2002), clinical scales like the Modified Ashworth Scale (Bohannon and Smith 1987) and the Tardieu scale, are commonly used owing to their simplicity and lower administration costs (Clopton et al. 2005).

While the reliability of MAS in adults is well investigated, in children with CP it is little researched. In a study investigating the inter- and intra-rater reliability of MAS in children with hypertonia, the authors calculated Intra-Class Correlation (ICC) coefficients of the MAS scores for the following muscles: elbow flexors, hip adductors, quadriceps, hamstrings, gastrocnemius and soleus (Clopton et al. 2005). The only lower limb muscles which had good inter-rater reliability (ICC >0.75) were the hamstrings, with all other lower limb muscles scoring poorly for ICCs (<0.5). However, for intra-rater reliability, hamstrings had good correlation (> 0.75) and all other lower limb muscles had moderate ICCs (between 0.5 and 0.75). It was also noted that the plantar flexors had the lowest reliability amongst the muscle groups tested. However, the raters were inexperienced, which probably had an effect on inter-rater reliability. It is worth mentioning that the level of reliability assigned for the band of ICC quotients was based on guidance by Portney and Watkins (2000), whereas according to Fleiss (1986), an ICC of over 0.75 demonstrates excellent reliability, and an ICC of between 0.4 and 0.75 demonstrates fair-to-good reliability. Another study with two experienced raters compared the inter-rater reliability of the MAS and Tardieu scales in children with CP. The investigators followed standardised procedures for both the scores, and measured hip adductors and ankle plantar flexors, each with the knee flexed and extended. The authors reported low repeatability, as the ICC coefficient was less than 0.75 in all cases (Yam and Leung 2006). However, it should be noted that of the four conditions compared, two had ICC of greater than 0.5 for both the MAS and Tardieu scales, which may be considered as demonstrating moderate reliability according to Fleiss (1986) and is greater than the results of Clopton et al. (2005). Fosang et al. (2003) reported poor inter-rater (ICC - 0.27 to 0.58), and variable intra-rater reliability (ICC - 0.21 to 0.82) for the MAS in a study which compared it with passive ROM and the modified Tardieu scale (MTS). The hamstrings and hip adductors tended to produce more reliable results using the MAS compared to calf muscles. While the authors reported acceptable inter-rater reliability for the MTS, the intra-rater reliability varied across the raters for all the measures.

It can be concluded that reliability of the MAS varies across patient groups, muscles tested, and protocol followed. In a review of 13 assessment instruments available for clinical assessment of spasticity for children with CP, it was concluded that only the Tardieu scale met the terms of definition of spasticity. However, the Tardieu scale was also reported to be time consuming and lacking in standardisation regarding the speed of muscle stretch (Scholtes et al. 2006b). In a systematic review of spasticity and function, the authors concluded that inter-rater reliability was higher when less heavy limbs were assessed (Platz et al. 2005), which was also reported by Clopton et al (2005). However, from the studies it can be inferred that inter-rater reliability of the MAS was more of a concern than the intra-rater reliability, and therefore some advocate using the same rater to assess the same patient (Biering-Sorensen, Nielsen, and Klinge 2006; Fosang et al. 2003). It is also suggested that a standardised procedure should be followed and that the rater should be sufficiently trained when the MAS is used for research purposes (Biering-Sorensen, Nielsen and Klinge 2006).

8.3 Assessment of muscle strength

Another characteristic feature of CP is muscle weakness, identified at the time the condition was named. However, clinicians have been sceptical about dealing with muscle weakness, owing to the complexity of the condition. In a literature review, Dodd, Taylor and Damiano (2002) derived the probable reasons for this scepticism about strengthening exercises as due to lack of improvements in function, the possibility of exacerbation of spasticity, and possible impediment to carrying out muscle strengthening due to a decrease in selective motor control. However, studies have shown the relationship between strength, and function and gait parameters; strengthening has been effectively used in the rehabilitation of children with CP (Damiano and Abel 1998; Desloovere et al. 2006; Ross and Engsberg 2007).

In a retrospective analysis of data from 97 children with spastic diplegia, Ross and Engsberg (2007) showed that strength was highly correlated to function measured using the GMFM ($r = 0.83$) and stride-length ($r = 0.71$). They also reported a moderate correlation between strength and gait speed ($r = 0.61$). Similar results were reported by Damiano et al. (2001) who found high correlation between GMFM scores and strength of hamstrings and quadriceps. Using a six-week strengthening program, Damiano and Abel (1998) showed significant strength gains and improvements in gait speed and cadence in 11 children with CP. They also demonstrated an improvement in function, which showed a potential relationship between strength and function. However, there was no improvement in energy expenditure. A recent systematic review on the effectiveness of strengthening in children with CP concluded that strength training potentially improves activity and function in children with CP (Dodd, Taylor, and Damiano 2002).

Traditionally, strength is assessed manually using the hands. Technological advancement has led to the development of objective measurement methods using stationary equipment such as isokinetic and handheld devices. However, the manual method is still commonly used clinically, as equipment is expensive and more time consuming (Cuthbert and Goodheart 2007). The Manual Muscle Test (MMT) is the most frequently used method by physiotherapists for assessing muscle strength. Of the several methods of conducting the MMT, neurologists prefer the Medical Research Council (MRC) scale, which uses a five point scoring system (Florence et al. 1992).

Although the MMT is commonly used by clinicians to assess muscle strength in children with CP, the reliability and validity of the technique is little investigated.

While the literature search revealed studies using the MMT, MRC grading was sparingly researched. However, the principles upon which all the MMT methods are based are the same, and all use comparable criteria (Florence et al. 1992).

In a study investigating intra-rater reliability of the MMT using the MRC scale in children with Duchene's Muscular Dystrophy, the authors reported high intra-rater repeatability of the scoring method (Florence et al. 1992). A total of 18 muscles were scored by four examiners in a sample of 102. Repeatability was analysed using kappa statistics and all the lower limb muscles investigated had a correlation coefficient of more than 0.7. It was also noticed that measurement of the proximal musculature was more reliable than the distal. However, it should be noted that the patient group in the above study did not have spasticity (Florence et al. 1992). Another study with a sample that included patients with Duchenne Muscular Dystrophy compared the inter-rater reliability of the MMT using a modified MRC scale and a quantitative measuring technique (QMT) that used equipment based on a strain gauge (Escolar et al. 2001). The results showed that the QMT was reliable, with excellent inter-rater reliability ($ICC > 0.75$), whereas the MMT was not as reliable when conducted by inexperienced raters, demonstrating moderate inter-rater reliability ($ICC < 0.75$). When training was provided, inter-rater reliability of the MMT improved, with an ICC of 0.87, although no information was provided regarding standardisation of the protocol followed for the MMT. The authors concluded that the QMT was a more reliable measurement technique.

Perry et al. (2004) investigated the reliability and discriminant validity of measuring hip extensor strength using the MMT in supine with a sample of 16 patients with post polio paralysis, and 18 without. The peak hip extension torque was also measured using a cable tensiometer. The results showed that the two raters had excellent agreement (82%). The patients with post polio paralysis had a significantly lower mean torque, and healthy adults had a significant difference between grades four and five. Another study compared intra-rater reliability of the MMT and the hand-held dynamometer (DMT) using 11 participants. The correlation was tested using a Pearson's coefficient. The authors reported correlation coefficients (for different muscles) between 0.63 and 0.98 for the MMT and 0.69 and 0.9 for the DMT. Both the techniques were deemed reliable by the authors (Perry et al. 2004). However, the statistical method employed was questionable.

Although the MMT seems reasonably reliable, the literature search did not reveal any study which looked at the repeatability of MRC grading in children with CP. It can therefore be inferred that for research purposes, where muscle strength is the primary outcome measure, other devices may be considered. Many authors suggest the use of a standardised protocol that indicates the position of the patient, stabilisation, and direction of movement (Cuthbert and Goodheart 2007). Experience of the examiner is also a relevant consideration (Escolar et al. 2001).

8.4 Assessment of joint range of motion (ROM)

Impaired muscle strength and tone, and abnormal posture, lead to tightness, contractures, and deformities. These in turn limit ROM. Limited ROM, combined with impaired strength, affects gait and plays a vital role in the development of abnormal gait patterns (Rodda et al. 2004; Sutherland and Cooper 1978). Three studies have tried to correlate passive range of motion (PROM) with gait parameters to detect any influences of reduced range on gait (Desloovere et al. 2006; McMulkin et al. 2000; Orendurff, Chung, and Pierce 1998). One further study correlated PROM with gait and functional ability (Abel et al. 2003). Results from all three studies demonstrated a lack of correlation. McMulkin et al. (2000) reported all the r values to be less than 0.5, with almost half of the correlations less than 0.1. Orendurff and colleagues (1998) did not have any r^2 value above 0.2, indicating that no variance in a dynamic variable of more than 20% was explained by a static variable. While these studies indicated that gait deviations are not purely dependent on PROM, the range of PROM of joints investigated was not reported in both studies. Furthermore, the studies did not group the children based on gait patterns. Since the gait deviation in CP hugely varies, it is possible that some gait patterns are more dependent on PROM than others.

Desloovere et al. (2006) investigated correlations between clinical measurements such as spasticity, strength and PROM, and gait parameters in children with CP, and reported Pearson's correlation coefficients of less than 0.6 between PROM and gait parameters. However, multiple regression analysis revealed that the relationship between clinical measurements and gait parameters improved when adding measures such as spasticity, strength, and selectivity to the PROM data. Nevertheless, the r^2 values remained low even with the combined model (< 0.35), indicating possible roles of other factors. However, the study showed that interplay between various aspects such as strength, spasticity and ROM is influential, rather than a single parameter. This suggests that all three should be measured. A study by Abel et al. (2003) (explained in Section 8.2, page 88), reported correlations between PROM and functional ability that ranged from +/- 0.17 to 0.42, indicating that no variance of more than 17% in functional ability was explained by PROM. When exploring relationships between PROM and gait parameters, *r* values for all but one parameter ranged from +/- 0.19 to 0.41. Knee extension during stance demonstrated a moderate inverse correlation (r = -0.64) with passive knee extension. Abel et al. (2003) also did not group children based on gait patterns.

Since spasticity has a strong association with ROM, most interventions aiming to reduce spasticity improve ROM, and vice versa (Wright et al. 1998). In cases with a spasticity-related decrease in ROM, the assessment of ROM can be used to record status and monitor changes (Platz et al. 2005).

The most commonly employed method for measuring PROM is handheld goniometry. While methods like electrogoniometry, and 2D and 3D motion analysis exist, they are preferred for the measurement of dynamic ROM. A systematic review on the psychometric properties of various tools used for measuring knee joint position and movement concluded that the hand-held goniometer is a reliable tool for measuring knee joint movement when measured by the same rater (Piriyaprasarth and Morris 2007). They reported that all the measurements had high intra-rater reliability of more than 0.75 (ICC) when measured in the same session, although this was less than 0.75 when measured during different sessions. However, the inter-rater reliability varied for different measurements (0.43 to 0.99).

There have been several studies investigating the reliability of goniometry in children with CP (Keenan et al. 2004; Kilgour, McNair, and Stott 2003; McDowell et al. 2000; McWhirk and Glanzman 2006; Stuberg, Fuchs, and Miedaner 1988). It is difficult to compare the studies, owing to the differences in movements assessed, participant characteristics, procedures followed and statistical methods employed. However, certain conclusions can be drawn from their findings. All the studies which investigated intra-rater reliability using different sessions reported low reliability when compared with measurements taken within the same sessions (Kilgour, McNair and Stott 2003; McDowell et al. 2000; Stuberg, Fuchs and Miedaner 1988). The same studies also reported that inter-rater reliability was less than intra-rater reliability, and was unacceptable within the same session. However, McWhirk and Glanzman (2006) found acceptable inter-rater agreement for all movements except hip extension using the Thomas test. The authors acknowledged the possibility that the presence of an examiner to hold the legs or stabilise the proximal part might have caused measurement bias. Results reported by Keenan et al. (2004) emphasise the possibility of procuring acceptable limits of inter-observer agreement in some, but not all, joint ROM measurements. While the authors reported lower inter-rater reliability than intra-rater reliability, both were within the acceptable limits, with the exception of hip flexion. One possible reason for the results is that the end ROM of joints was defined *a priori*, as the point when any movement started to occur in either of the adjacent joints. Definition of the end range probably standardised the measurement more between raters, as according to Kilgour, McNair and Stott (2003), the major source of error is in positioning of the joint in the end range; none of the other studies defined the end range, which probably explains the better results of Keenan et al. (2004).

Of the studies, the only one which included healthy controls reported that intra-observer reliability across the sessions was poor both in children with CP and healthy controls (Kilgour, McNair and Stott 2003). The authors concluded that the measurement error cannot be attributed to spasticity. This contradicts the finding by Stuberg et al. (1988) that hypertonicity is a source of error. Stuberg et al. (1988) made this assumption based on comparison with a different study on healthy individuals, as they did not have a control group. Thus, the validity of this assumption is questionable since the comparison was made to a study which followed different methodology. In contrast, Kilgour, McNair and Stott (2003) included both groups, and followed the same procedure for each, thus producing more reliable comparison.

It was also noticed that joints with fewer degrees of freedom were more reliable compared to joints with more degrees of freedom. For example, measurement of knee extension was more repeatable than hip extension (Keenan et al. 2004; McWhirk and Glanzman 2006). While most studies did not attempt to identify their sources of errors, Kilgour, McNair and Stott (2003) identified their primary source of error as determining the end range of movement, followed by errors during placing, and reading the goniometer. The importance of positioning of the goniometer, as well as the patient (especially using standardised protocol), is well emphasised (Rothstein, Miller, and Roettger 1983). While standard hand-held goniometry is most commonly used, alternative measures like photography were investigated. The aim of using photography was to reduce the rater and goniometric errors (Karkouti and Marks 1997). Use of digital photography has potential for reducing assessment time, and is less dependent on the experience of the rater, as it does not require skill in positioning and reading a goniometer (Georgeu, Mayfield, and Logan 2002).

There have not been many studies investigating the reliability of photographic methods. Active ROM of the finger joints was estimated using both hand-held goniometry and lateral digital photography with computer goniometry, and the correlation between the two was calculated (Georgeu, Mayfield and Logan 2002). A digital camera was used to photograph the movement and joint angles were estimated using a computer assisted program. The results showed that both the methods were highly correlated with each other ($r^2 = 0.98$). Another study compared test-retest reliability of measuring knee and ankle angles in standing, using photography (Karkouti and Marks 1997). Reflective markers were attached to the pre-defined bony landmarks, identified by palpation, and fixed measurement repeatability of both methods were assessed on the same day, after seven days, and after 30 days. The results showed that while same-day repeatability was high (ICC > 0.8) repeatability at seven days and at 30 days was fair (ICC between 0.4 and 0.59). While the authors aligned the camera perpendicular to the leg, it is not clear whether it was repositioned for each movement, since active movement was being measured. This may have caused parallax error, which is a disadvantage of any 2D analysis. No study has investigated the use of digital photography to measure PROM using a standardised protocol of measurement as for standard hand-held goniometry.

8.5 Assessement of quality of life

Including Quality of Life (QOL) as an outcome measure in research involving children with CP has become increasingly more common. The ICF has recognised participation restrictions, personal and environmental factors as vital considerations in disability, urging the use of outcome measures to evaluate psychosocial factors and well-being (Majnemer and Mazer 2004). It is commonly seen that QOL is confused with functioning (Shelly et al. 2008) and in studies with children with CP, it is not uncommon for studies to use evaluative measures for function and QOL measures interchangeably. Health-related QOL (HRQL) is another measure commonly used with children with CP. HRQOL can be described as a sub-domain of QOL which is directly related to the health of the individual, whereas QOL is related to overall well-being, including various sub-domains other than health (Bjornson and McLaughlin 2001). In a review of the conceptual underpinnings of paediatric QOL instruments, QOL and HRQOL were found to be commonly described as measures of function and health status (Davis et al. 2006). The review emphasised that a QOL instrument should be based on a definition and a theory of QOL, and should include all the important domains with well-constructed items. According to the authors, functional status describes the ability of a child to do things, whereas QOL describes how a child feels. The review suggested that terms such as QOL, HRQOL, health status, and function should not be used interchangeably (Davis et al. 2006). It is clear that the question which needs to be addressed is not what the child is capable of doing, but rather how the child feels about it. And no evidence suggests whether there is a relationship between the two (Shelly et al. 2008).

There are several HRQOL measures available for assessing children with CP, including the Child Health Questionnaire (CHQ), Pediatric Outcomes Data Collection Instruments (PODCI), and Pediatric Quality of Life Inventory (PedsQL™). All the above instruments have been deemed reliable. The PedsQL™ has several disease-specific modules and a generic module, all of which have been widely investigated for reliability and validity (Varni et al. 2006; Varni, Limbers, and Burwinkle 2007a; Varni, Limbers, and Burwinkle 2007b; Varni, Seid, and Kurtin 2001a).

The generic module (PedsQL™ 4.0 generic core scales) was developed for measuring healthy children and children with chronic diseases (Varni, Seid, and Kurtin 2001b). While the CP-specific module has sections that are more related to physical function and daily activities, the generic module has emotional, social and school-related sections that may be more representative of well-being. Shelly et al. (2008) criticised the PedsQL™ CP module for including questions such as whether the child has difficulty using scissors, which probably evaluates the activity of the child and not well-being.

The PedsQL™ 4.0 generic module (both self-reported and parent-reported) was used in a study comparing the HRQOL of children across ten different disease clusters, each of them benchmarked against normal (Varni, Limbers and Burwinkle 2007a). A total of 2500 paediatric patients from 33 disease categories, classified into ten disease clusters, were included. The healthy sample exceeded 9500 children. CP was one of the clusters being compared. The results showed that HRQOL was lower in paediatric patients when compared with healthy children. Within the paediatric patients HRQOL varied across the clusters. The overall HRQOL was reported lowest by both children and parents in the CP cluster when compared with other clusters. Other sections where both children and parents of CP cluster reported the lowest scores were physical health, social functioning, and school functioning. For psychosocial health, while parents of children with CP still reported the lowest scores, patients with psychiatric illness had lowest score in the self-reported module. While this study shows the utility of the generic module of the PedsQL™, the reliability and validity issues were not addressed. Although the CP cluster was concluded to have low HRQOL scores, there were no statistically significant differences between scores for the CP cluster and some of the other clusters in both self-reported and parent-reported versions.

The measurement properties of the generic module and CP-specific module of The PedsQL™ were investigated in a sample of 245 (Varni et al. 2006). Both parent-reported and child self-reported versions of the PedsQL™ were used. Internal consistency, reliability, and sensitivity were investigated. The results showed that both versions of the two modules exceeded the acceptable value of 0.7 for Cronbach's alpha. Both the scales were sensitive to severity, as children with quadriplegia scored significantly lower than those with hemiplegia and diplegia. While the total generic score was not significantly different between individuals with GMFM levels I, II and III, the physical functioning scores of the generic module were sensitive to most of the GMFM diagnostic categories. It did not distinguish between GMFM levels I and II, nor between levels II and III. It should also be noted that levels I and II were not distinguished by any of the sub-domains of the CP module either (Varni et al. 2006). However, the total score of the generic module is also dependent on psychosocial scores, which are not measured by the GMFM and might not be different between adjacent levels.

In another study which investigated the reliability and validity of the PedsQL™ Version 4 generic scale in healthy and patient populations, the authors concluded that the scale is reliable and valid (Varni, Seid, and Kurtin 2001c). High internal consistency was reported, with a Cronbach's alpha of more than 0.8 for all the sub-sections and total scores of parent-reported and child self-reported scores. The PedsQL™ distinguished between healthy and patient populations, and between acute and chronic patient populations. Both child-reported and parent-reported scales were related to indicators of morbidity and illness.

It has been emphasised in an earlier review that the information gathered through proxy-reporting is not as the same as self-reporting (Sprangers and Aaronson 1992).

However, in a later review the same authors concluded that proxy-reporting by 'significant others' on HRQOL is 'reasonably accurate', and also suggested 'tempering' their old conclusion (Sneeuw, Sprangers, and Aaronson 2002). Certain circumstances like illness, fatigue, and a lack of cognitive ability, makes self-reporting difficult, thus calling for proxy-reporting instead (Varni, Limbers and Burwinkle 2007b). A study investigated the reliability and validity of the PedsQL™ 4.0 generic scale (parent reported) across age sub-groups in a sample of 13,878 children (Varni, Limbers and Burwinkle 2007b). Only 2.1% of items were missing responses, indicating feasibility. The internal consistency of the total scale score across the age sub-groups exceeded 0.9 (Cronbach's alpha), suggesting that the scale can be recommended for analysis of individual patient scores. Also, the Cronbach's alpha for all sub-sections exceeded 0.7, which is the minimum acceptable score for the scale to be used for group comparisons. The construct validity of the scale was also demonstrated by comparing the total scores of children with chronic conditions, with healthy children across all age groups. The HRQOL was significantly different between the two groups across all ages.

8.6 Relevance to the project

- The prognosis of CP is affected by various factors, which should all be considered in outcome evaluation. It can also be inferred from the literature that the interplay between spasticity, strength and ROM is more influential in relation to gait than a single parameter, and hence all should be measured.
- Although the MAS and the MMT are not the most reliable measures available for recording spasticity and strength respectively, the more objective modern tools are expensive and often cumbersome and time consuming, which makes to former preferred in clinical settings. Where strength and tone are not the primary outcome measures, these may be preferred.
- Factors influencing the reliability of measuring spasticity using the MAS include using a standardised protocol and experience/training of the tester. It was also seen that intra-rater reliability was better for the MAS than inter-rater. All the above factors should be considered and it would be best for a

single tester to perform all the measurements in a research study, to ensure maximum repeatability.

- Factors influencing reliability of the MMT include using a standardised protocol that states the position of the patient, stabilisation and direction of the movement, and experience or training of the tester. Intra-rater reliability was better for the MMT than inter-rater. These factors should be considered
- when planning a research study, and a single tester should perform all the measurements to ensure maximum repeatability.
- Sources of errors in measuring PROM using goniometry include error in determining end range of movement, placement of the goniometer, and reading of the goniometer. The photographic method has the merits of reducing the time required for assessment and rater and goniometric errors. Where time is a factor in planning a data collection session, the photographic method may be a feasible alternative to goniometry. Reliability of PROM measurement using the photographic method has not been frequently investigated. As it has been shown that spasticity is not a source of error for measuring PROM, a reliability study with normal adults may be beneficial.
- QOL measures are commonly confused with functional measures, but focus on well-being rather than function. The PedsQL™ is reliable and valid equipment to measure the HRQOL of children with CP. While the generic module is not as related to measures like GMFM as the disease-specific module for CP, it emphasises well-being, while the latter focuses on activity and function.

CHAPTER 9 METHODS - INSTRUMENTATION AND MATERIALS

In this project gait parameters, muscle and joint properties and quality of life were investigated to derive conclusions about how tuning of AFO-FC can influence children with Cerebral Palsy (CP). Hence, kinetic and kinematic data, results of physical examination, and quality of life scores were recorded. Data collection was carried out in two different laboratories – the Queen Margaret University, Edinburgh gait laboratory (lab. 1) and the Anderson gait laboratory (lab. 2), Edinburgh.

9.1 Kinematic data acquisition

Kinematic data were collected using the VICON motion analysis system (Oxford Metrics Ltd., Oxford, UK), installed in both laboratories. This is considered to be state of the art equipment in motion analysis. The VICON motion analysis system is a self-contained, computerised system with hardware and software components that make motion analysis possible.

Hardware includes:

- camera units with camera mounting devices
- camera interface units
- VICON datastation
- a workstation personal computer
- calibration objects and markers

Software includes:

- VICON workstation software
- Polygon authoring tool
- VICON body builder software

In brief, the cameras capture the positions of the reflective markers, and transmit them to the datastation, which conveys the data to the workstation. The workstation software obtains the two dimensional (2D) data from each camera and combines it with previous calibration data. From this it calculates three-dimensional (3D) co-ordinates for each marker, to reconstruct 3D motion.

9.1.1 Camera units and the datastation

Both laboratories used infra-red M-Cam 2 cameras (M-Cam 2, Oxford Metrics Ltd., Oxford, UK) for data capture. There were eight cameras available in lab. 1, and six cameras in lab. 2. Each camera consists of an LED strobe ring fitted using a magnetic strip around the lens (Figure 9.1). The LED strobe emits infra-red rays which are reflected from the retro-reflective body markers. Reflected rays are captured by the lens through an optical filter. The optical filter only allows light with the same characteristics as that emitted by the strobe to pass through the lens. The cameras can be adjusted to change the aperture and focus, and can be zoomed in and out. For this project, cameras were positioned on scaffolding in lab. 1, and were wall-mounted in lab. 2, to enable an adequate capture volume. The set-up of each laboratory is shown in Figures 9.1 and 9.2. Cables are used to carry data from the cameras to the datastation. Signals from three cameras are combined in the camera interface units, from where they are transported to the datastation via a single cable.

The datastation resembles a Central Processing Unit (CPU), and is the link between the cameras and the workstation PC. It also controls the strobes and the cameras. The datastation consists of a 12-channel video converter and a 64-channel analogue-to-digital converter; the latter transforms analogue input data into bits that are readable by the computer. Non-kinematic data (for example, force plate output) can also be recorded by the datastation, using the A-D convertor; this is then synchronised with the kinematic data.

Figure 9.1 M-cam 2 camera with LED strobe and lens

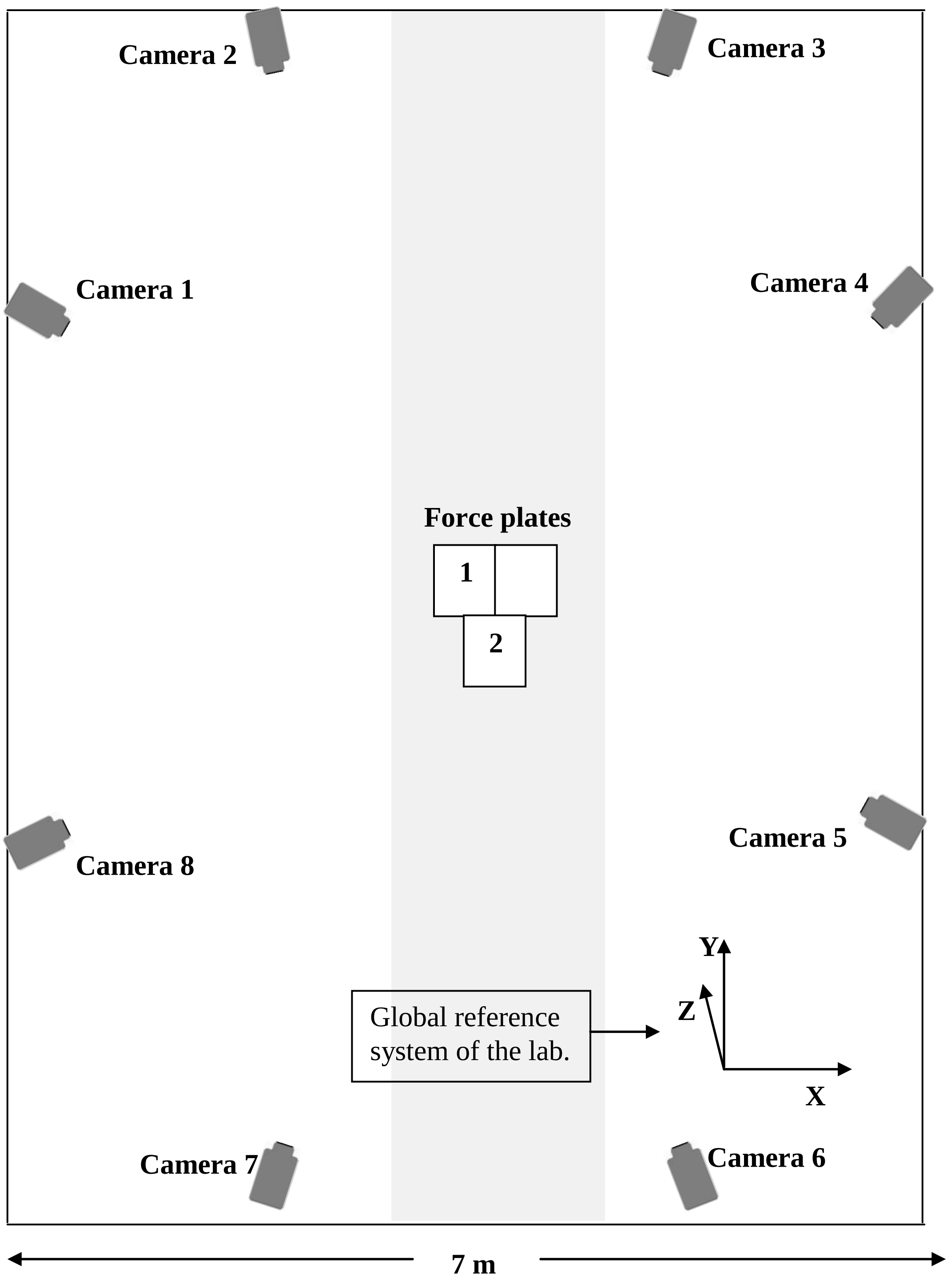


Figure 9.2 Set-up of lab. 1

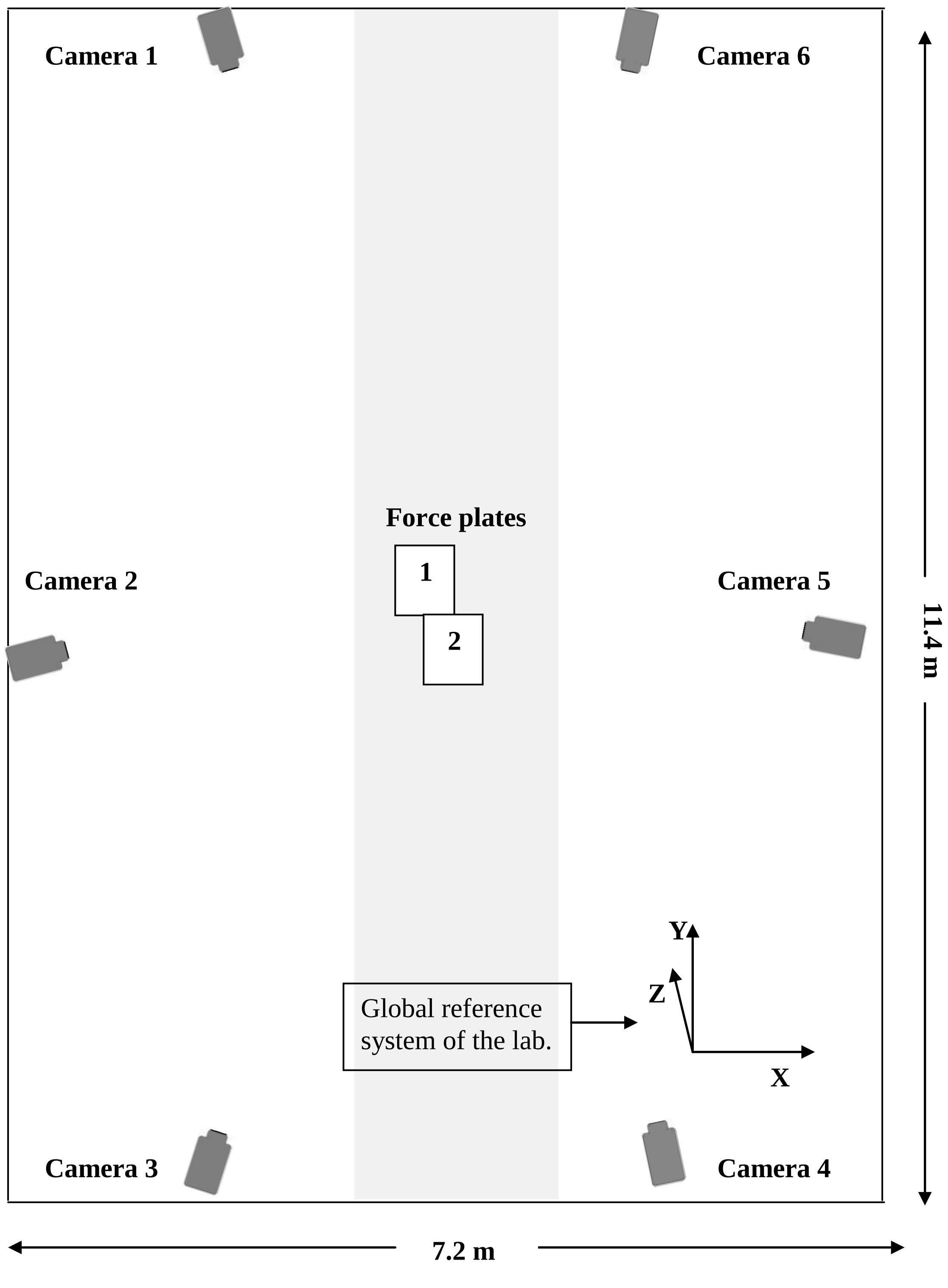


Figure 9.3 Set-up of lab. 2

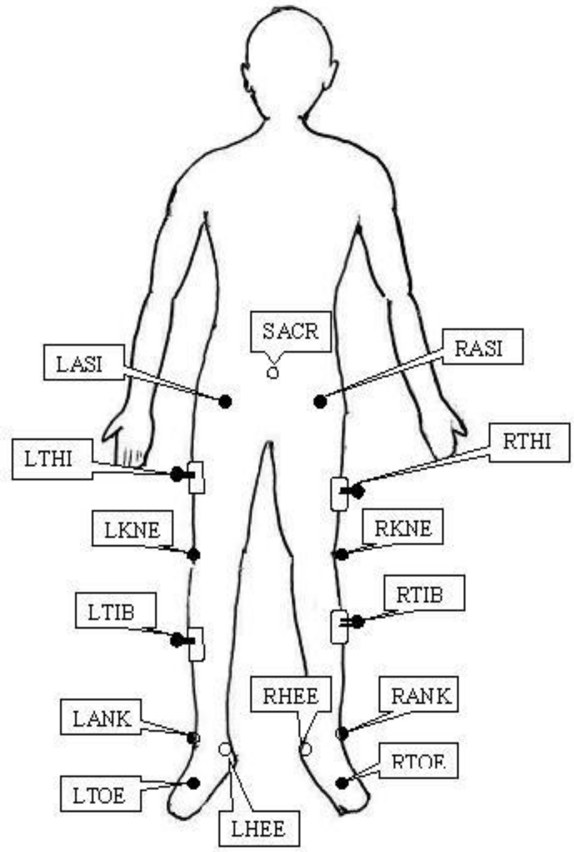
9.1.2 Workstation PC and the software

The workstation PC is connected to the datastation by a network. In this study Intel Pentium 4 PCs with Windows XP operating systems were used in both the laboratories. The software necessary for motion analysis was installed in the PCs, including VICON Workstation (version 4.6) and the Polygon authoring tool (version 2.4). Workstation software is the master control of the VICON motion analysis system. It not only provides the user with a control interface, but also performs functions such as calibration and data capture, management, reconstruction, and basic editing of data. Once data are edited and processed by the workstation reporting and presenting is conducted using the Polygon authoring tool. Polygon constructs reports with graphs to portray kinetics and kinematics, and is also capable of creating Microsoft Excel files with numerical representations of the data.

9.1.3 Markers

Markers are small spheres covered with retro-reflective material. In this study, markers of 14 mm diameter were attached to the participant's body using double-sided tape. The markers are normally attached to bony landmarks and are assumed to represent the underlying skeleton, which makes their positioning crucial. The system also requires calibration data to make reconstruction possible. The equipment used for calibration is explained later in this section.

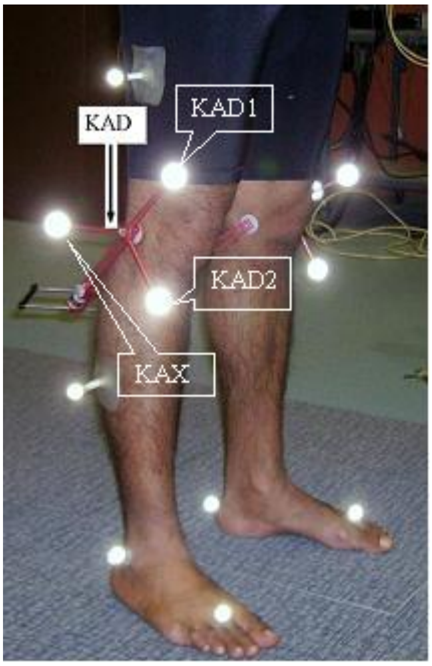
Several marker sets can be used for gait analysis; these differ from one another in relation to the number and positioning of the markers. This project used the Plug In Gait (PIG) marker set, provided by VICON, which is a modified version of the Helen Hayes marker system (Davis et al. 1991; Kadaba, Ramakrishnan and Wootten 1990). While the whole body marker set is available in the PIG set and was used in one of the studies in the present project, only lower limb kinematics and kinetics were considered for data analysis. Hence, only the lower body marker set is explained here (Figure 9.4). The full body marker set is illustrated in Appendix 1. A reliability study was conducted to compare three different marker methods at the start of the project. Of the three marker sets, two were based on the Helen Hayes marker system and were variations of the PIG marker set (Knee Alignment Device (KAD) method and mirror method). The third method was a modified version of the calibrated anatomical systems technique (CAST) (Cappozzo et al. 1995) which was based on the Cleveland marker system. The KAD and mirror methods were different only in the way that the knee joint axis was estimated. The PIG model suggests the use of the KAD to determine the knee axis. A modification was proposed by some clinical movement analysts, involving determination of the knee axis using the thigh wand marker aligned using a mirror. The three marker methods are further explained in the reliability study comparing the three methods (Section 11.3.2, pages 137-140). Based on the results of the reliability study, the PIG marker set with KAD was used in the project. The guidelines provided by VICON for PIG marker placement are provided in Appendix I.



Marker	Description
SACR	Sacral
RASI	Right anterior superior iliac spine
LASI	Left anterior superior iliac spine
RTHI	Right thigh – marker on a wand
LTHI	Left thigh – marker on a wand
RKNE	Right knee
LKNE	Left knee
RTIB	Right tibia
LTIB	Left tibia
RANK	Right ankle
LANK	Left ankle
RHEE	Right heel
LHEE	Left heel
RTOE	Right toe
LTOE	Left toe

Figure 9.4 Lower body marker set used with the Plug In Gait model for dynamic trials (markers or parts of markers coloured white are covered by the body)

The KAD consists of a frame with three markers on it which is attached to the knee joint while a static data capture is made (Figure 9.5). The three markers on the KAD lie in three planes which, together with information on knee width, allow the software to derive the position of the knee joint and the orientation of the knee joint axes.



Marker	Description
KAD1	Knee alignment device 1
KAD2	Knee alignment device 2
KAX	Knee alignment device - axis

Figure 9.5 The Knee Alignment Device (KAD) used for static capture while using the Plug In Gait marker set

9.1.4 Calibration objects

Calibration is a vital part of data collection, as the system requires the resulting data for reconstruction of 3D motion. Calibration was carried out prior to each session of data collection. A triangular frame and a T-cal wand were used for static and dynamic calibration, respectively (Figure 9.6). The triangular frame has three side lengths of 280 mm that meet at 90 degree angles; this has four 14 mm markers on it. The wand is T shaped and has three 14 mm markers on it. Static calibration using the triangular frame enables the system to determine the orientation of the capture volume, whereas dynamic calibration using the T-cal wand is required to estimate the relative camera positions.

Triangular frame T-cal wand

Figure 9.6 Calibration objects

Kinematic data provide only one part of the picture in the absence of kinetic data. A force measurement system was used in this project to record kinetic data. This can be analysed using inverse dynamics to derive the forces and moments acting on joints (Kirtley 2006).

9.2 Force measurement system

Recording and analysis of kinetic data allow investigation of the forces and moments acting on the joints during gait. This project investigates the influences of tuned AFO-FC on forces and moments during the gait of children with CP. Both laboratories made use of Advanced Medical Technology, Inc. (AMTI) multi-axis force platforms for the collection of force data (AMTI, Watertown, MA, USA). Two force platforms were used in lab. 1 (model OR6-7-1000) and lab. 2 (model BP4006001). All force plates measured 464 mm × 508 mm × 82.5 mm (width × length × height). They are capable of detecting the force applied onto their surface. A force platform consists of two plates that are connected to one another by a connector in the centre, and separated by sensing elements at each corner. Any force applied to the top plate is detected by these sensing elements, which are strain gauge transducers. The gauges form six electrically wired bridges, each with four active arms and eight or more gauges. The transducer measures both the force and moment components in X, Y and Z axes; the force components being denoted as Fx, Fy and Fz, and moment components as Mx, My and Mz. The AMTI force platforms follow a right-hand co-ordinate system; this means that the positive z axis is oriented downwards, the positive y axis is oriented away from the connector, and the positive x axis towards the left when facing in the positive y direction.

All the channels require an input voltage (V_0) of about five to ten volts so that the six component transducer will produce analogous output voltage for each of the six input components (Fx, Fy, Fz, Mx, My, Mz). This output voltage is augmented using an amplifier which is usually capable of producing an amplifier gain of up to 4000. This amplified voltage is then digitised using an Analog to Digital converter (A/D Converter) so that it can be read by the computer (AMTI, 2002). The voltage is carried from the force platforms to the amplifier, and then to the A/D converter using shielded cables. In this project the data from the forceplates were carried to the VICON datastation which performed the analogue to digital conversion. These digitised signals are converted to meaningful units by the software, such as Newtons (N) for force, or Nm/kg for moments which is carried out by the software. In the present project the force data were processed by the VICON workstation software which also synchronised the kinetic and kinematic data. The reports and excel files made by the polygon software displayed the force and moment data both graphically and quantitatively.

9.3 Ankle Foot Orthoses (AFO)

In this project, all participants with CP were wearing at least one AFO. The AFOs used in the project were made of polypropylene and did not have any joints. The AFOs were custom-made for each participant by the orthotist. The ankle angles of the AFOs were casted ranging from 90° (plantigrade) to varying degrees of plantar-flexion as appropriate for the participants (Figure 9.7) (procedure explained in section 12.4, page 155). All the AFOs had their trim lines at the ankle, anterior to the malleoli; they had two straps, one at the top end and one at the ankle. Whenever an AFO was casted in plantar-flexion at the ankle, a heel wedge was used to maintain the alignment of the AFO so that it stood vertical (Figure 9.7).

9.7 a) AFO casted in 90°　　　9.7 b) AFO casted in plantar-flexion

Figure 9.7 Ankle Foot Orthoses used in the current project

9.4 Materials for tuning

In this project, wedges and rockers were used to tune the AFO-FC. These materials were used during data collection sessions to investigate how they each affect the gait of healthy participants and of participants with CP, as well as to find an optimum tuning configuration for each participant with CP. Where permanent adaptations were to be made to a participant’s AFO-FC, footwear was modified by the orthotist according to the prescription developed following data collection and analysis.

Wedges were made of high density Ethyl Vinyl Acetate (EVA). They were custom-made by the orthotist, according to the shoe size of the child being tested. The wedges were categorised according to the angle made by the top surface of the wedge to the perpendicular. The height, length and inclination of the wedge were estimated to produce the required angle for each shoe size. The calculations used to estimate wedge sizes are given in Figure 9.8. Wedges of angles 1°, 2°, 4°, 8°, 12°, 16° and 20° were used throughout the whole project (Figure 9.9 and 9.12).

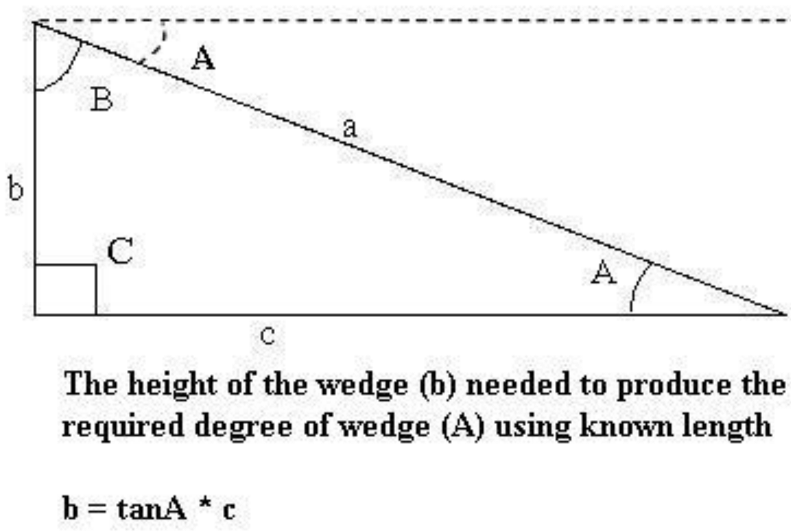


Figure 9.8 Calculations used to estimate wedge size

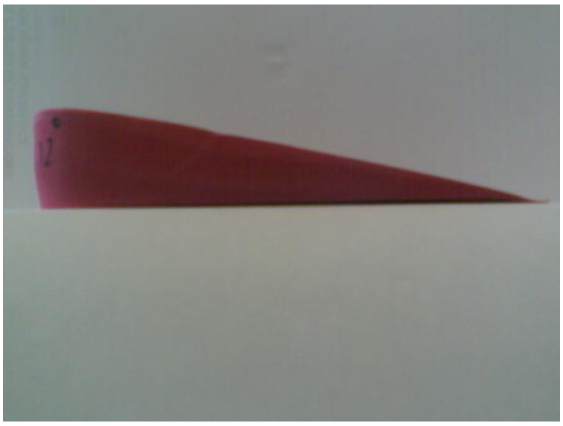


Figure 9.9 High density Ethyl Vinyl Acetate (EVA) wedge (12°) used in the project

Two types of rockers were used for the project - rounded profile rockers and Point Loading Rockers (PLR). For temporary modifications during data collection sessions, PLRs were hand made using plastizote (Figure 9.12). However, when final modifications were made to shoes to investigate the short-term effects of tuning, the soles of the shoes were made into PLRs or rounded profile rockers, as appropriate for the participant. In the rounded profile versions, the rocker was flat from the heel up until (or around) the metatarso-phalangeal joint, where it was rounded smoothly to meet the tip of the shoe (Figure 9.10). Rounded profile rockers were used for children with inadequate shank progression during terminal stance (eg: extended knee gait). The PLR formed a sharp edge at, or around, the metatarsal head (point of PLR) and was then steeply inclined to meet the tip of the shoe (Figure 9.11). PLRs were used for children with excessive shank inclination (eg: crouch knee gait). The thickness of the rocker was determined by the Toe Spring Angle (TSA) required. The TSA is the angle formed by the ground to the slope of the rocker from the point of PLR to the tip of the shoe. The calculations used to estimate the rocker thickness are given in Figure 9.13.

Figure 9.10 Modified shoes with a rounded profile rocker.

Figure 9.11 Modified shoes with a Point Loading Rocker (PLR).

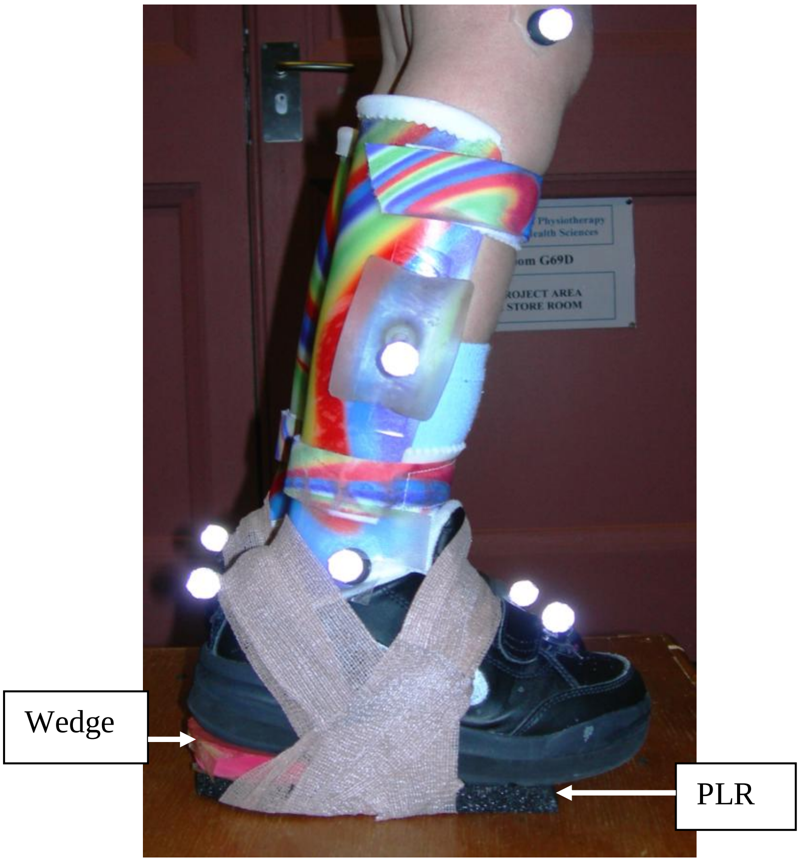


Figure 9.12 Shoes with temporary modifications (wedge and Point Loading Rocker (PLR)) during tuning session

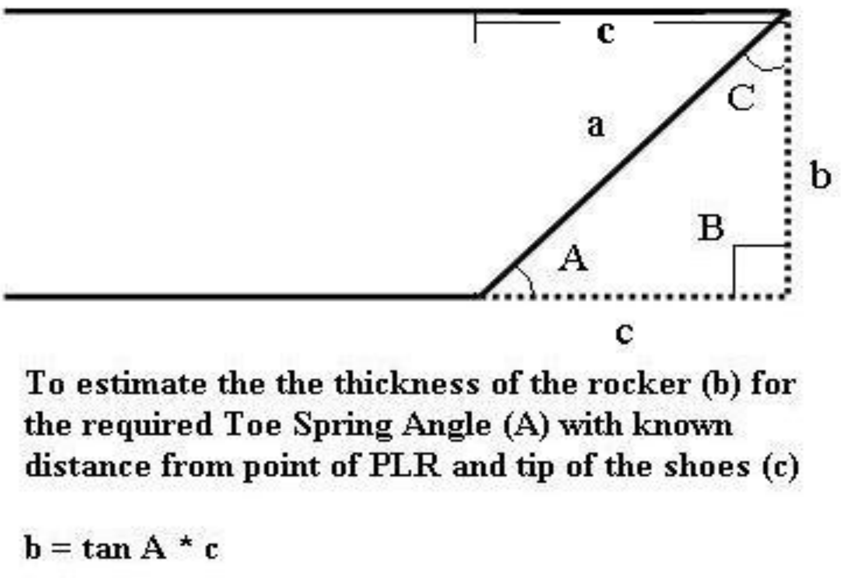


Figure 9.13 Calculations used to estimate thickness of the Point Loading Rocker (PLR)

CHAPTER 10 METHODS - GENERAL PROTOCOLS

10.1 Sample

Four different groups of participants were recruited for the project (Table 10.1):

- 5 healthy adults for the reliability study of marker sets,
- 14 healthy adults (undergraduate students) for a reliability study of the mid-stance identification method,
- 11 healthy children for the normal database and study on the effects of shoes, wedges and rockers on gait parameters in healthy children (Study 1),
- 8 children with CP to investigate the effects of non-tuned AFO-FC, immediate effects of tuning, and increasing sizes of wedges and rockers on gait parameters, and for a feasibility study on the short-term effects of tuning (Studies 2 to 4),

10.1.1 Inclusion and exclusion criteria

Table 10.1 provides the inclusion and exclusion criteria of the various samples included in the project.

10.1.2 Ethics and consent

For the investigations involving healthy adults, ethical approval was gained from the Queen Margaret University Ethics Committee. For the investigations involving healthy children and children with CP, ethical approval was gained from the National Health Service (NHS) - Lothian Research Ethics Committee 1, Edinburgh. All ethical guidelines were met to ensure the safety and well-being of the participants and the researcher. Detailed information sheets were prepared for all studies to provide all information required in order to make decisions regarding participation in the project. Separate information sheets were provided for each study, with versions developed for different age groups of participants, specifically five to eight, eight to 12, and 13 to 15. Information sheets were also provided for parents (Appendices II a to II j). All the adult participants and parents of the children were required to sign consent forms before any data collection was carried out. Children were given childfriendly assent forms, and if they wished to participate, were asked to sign or write their names where able. The consent forms and assent forms are given in Appendices III a to III c, and Appendix IV respectively.

Table 10.1 Samples included for each study in the current project, including inclusion and exclusion criteria

Investigation	Inclusion criteria	Exclusion Criteria
Reliability study of marker sets	1. Healthy adults with no known neurological or orthopaedic deficits 2. Ability to follow instructions	1. Unwilling to give consent 2. Not a student/staff member of Queen Margaret University
Reliability of mid-stance identification	1. Final year physiotherapy students	1. Anyone who has not completed four clinical placements 2. Unwilling to give consent
<u>Study 1</u>: Effects of shoes and effects of wedges and rockers on the gait of healthy children	1. Healthy children between the ages of five and 15 2. No known neurological or orthopaedic deficits. 3. Ability to follow instructions	1. Unwilling to give consent/assent
<u>Study 2</u>: Effects of non-tuned AFO-FC on the gait of children with Cerebral Palsy (CP) and immediate effects of tuning <u>Study 3</u>: Effects of wedges and rockers on the gait of children with CP <u>Study 4</u>: Feasibility study of short-term effects of tuning	1. Children with CP between five to 15 years of age 2. Diagnosed as having hemiplegia or diplegia 3. Ability to walk independently or with non-human support for a minimum of ten metres 4. Using or prescribed rigid AFOs for unilateral or bilateral use	1. Any lengthening surgery in the past one year 2. Given botulinum toxin A or baclofen in the past six months 3. Diagnosed as having severe dystonia or ataxia 4. Diagnosed as having severe behaviour problems

10.1.3 Recruitment Procedure

Convenience sampling was used for all studies. For the studies which investigated the reliability of marker placement and mid-stance identification methods, a Queen Margaret University moderator email notice was sent to groups of students eligible for recruitment. Acquaintances of the researcher and the team were also contacted. All were given information sheets before hand. For recruiting healthy children, group emails were sent to employees at QMU who had children, and personal acquaintances of the researcher and the team were contacted. Most healthy children were recruited by the manager of lab. 2, who collaborated in this project and had access to the data for other purposes. A total of 11 healthy children were recruited.

A total of 12 children with CP were required for the project. Initially all the hospitals in Edinburgh with paediatric physiotherapy departments were contacted and information packets were sent to the physiotherapists concerned. The physiotherapists then contacted the parents of suitable children. If interested, their contact details were sent to the researcher and a detailed information packet was then sent to them. Potential participants were given time to consider whether or not to participate. The researcher was only able to recruit five children in a ten-month period. As a result, the decision was taken to extend participant recruitment beyond Edinburgh to the Borders, Fife, Forth Valley, Tayside and Glasgow. A notice of substantial amendment was submitted to the NHS Lothian Research Ethics Committee 1 for this change and approval was granted (dated 09/07/2007). Despite this, only eight children participated in the study.

10.1.4 Sample Characteristics

The sample characteristics of children with CP, healthy children and healthy adults are given in Tables 10.2, 10.3 and 10.4 respectively. It can be seen that data from all eight children with cerebral palsy were used to investigate the effects of non-tuned AFO-FC and immediate effects of tuning (study 2). However, only five children completed the feasibility study investigating short-term effects of tuning (study 4) (Table 10.2). Case studies from the sample were used in study 3. In the whole sample, it can be seen that there were four children with diplegia and four with hemiplegia. While all the children with hemiplegia used rigid AFOs on their affected legs, only two children with diplegia used rigid AFOs on both legs. One child with diplegia was using a dynamic AFO on one leg, whereas another child with diplegia did not use any orthosis on one leg. Hence the total number of legs under consideration was ten.

In the sub-sample for the feasibility study there were three children with diplegia. Two of them used rigid AFOs on both legs, and one had a dynamic AFO on one leg. Hence the total number of legs under consideration for the feasibility study was seven.

Table 10.2 Sample characteristics of children with Cerebral Palsy

Study	Sample size	Mean age (SD) in years	Mean height (SD) in m	Mean weight (SD) in Kg	Sex		Diagnosis	
					M	F	Hemiplegia	Diplegia
Study 2	8	9 (2.9)	1.30 (0.15)	27.3 (9.2)	3	5	4	4
Study 4	5	8.8 (3.4)	1.25 (0.16)	26.5 (9.8)	2	3	2	3

Table 10.3 Sample characteristics of healthy children (Study 1)

Number of Participants	Mean Age (SD) in years	Mean height (SD) in m	Mean weight (SD) in kg	Males	Females
11	10 (2.1)	1.44 (0.15)	38.5 (10.3)	6	5

Table 10.4 Sample characteristics of healthy adults (reliability of marker placement study)

Number of Participants	Mean Age (SD) in years	Mean height (SD) in m	Mean weight (SD) in kg	Males	Females
5	25.2 (4.9)	1.69 (0.11)	65.7 (12.5)	4	1

10.2 Gait analysis

Although the design and procedure differed between the eight studies involved in this project, the protocol for calibration of the VICON 3D motion analysis system was the same. The general gait analysis protocol followed in all the studies was also the same, although adaptations were made to meet the various needs of each study, explained in respective chapters.

10.2.1 Calibration

Proper calibration prior to motion capture is vital. It is through calibration that the software calculates the relative position of the cameras. These measurements enable the VICON Workstation software to calculate the accurate position of the markers in space during reconstruction. Calibration involves two stages – static calibration and dynamic calibration. Static calibration enables the VICON Workstation software to determine the orientation of the capture volume, whereas dynamic calibration is used to calculate the relative positions of the cameras.

The triangular frame (Figure 9.6, page: 109) was placed in the centre of the capture volume; in this case on the left hand corner of force plate two. All the cameras were then checked to make sure that they were viewing only the four markers on the frame. This can be done using the option "live monitors" in the system menu of the workstation. A calibration dialogue box was then opened from the same menu. It was ensured that all eight cameras and the proper calibration object (Wand and triangular frame) were selected. The calibration process started when a static calibration dialogue box opened. The software collected 20 frames of static data and then automatically opened the dynamic capture dialogue box. The triangular frame was then replaced with a person holding the wand. As the system started capturing data, the wand was waved to cover all positions in the capture volume in all orientations. This was continued for about 15,000 to 20,000 frames, after which the dialogue box was closed, allowing the system to carry out the calculation. This process concluded with a dialogue box containing the results of calibration.

The calibration was accepted or rejected based on the residual values. The residual value for each camera is the root mean square of the distance between the infrared ray coming from the centre of the strobe ring of the camera to the marker, and the ray reflected back. This is a measure of accuracy and increases as the distance between the cameras and the markers increases. In this study calibration was considered satisfactory once the residuals were between 1.3 mm and 1.9 mm for each camera. If the residual value for any of the cameras fell outside this range, or no residual value was calculated for any of the cameras, the calibration was considered to have failed and was repeated.

10.2.2 Data acquisition

Gait analysis was the primary mode of data collection in this project. All studies involved gait analysis which was predominantly based on a single protocol, with specific adaptations that will be described in respective sections.

After explaining the research project to the participant, he or she was given a tight fitting pair of lycra cycling shorts to wear. This was to minimise marker displacement that occurs when markers are attached to loose clothing. Anthropometric measurements (height and weight) were then recorded. The participant was then asked to lie down on a plinth. Using a measuring tape, leg length was measured in centimetres for both lower limbs. The measurement was taken from the inferior tip of the anterior superior iliac spine to the inferior tip of the medial malleolus of the ipsilateral limb.

The participant was then asked to sit on the plinth which was positioned to keep his or her hip and knee at 90°, with their feet resting on a stool. Tibial torsion was then measured; a ruled A4 note book was placed on the stool under the foot to be measured. The hip and knee were kept in line with the tibial tubercle pointing forward. The leg was then passively swung in the antero-posterior direction to ensure that the tibia moved perpendicularly to the printed lines in the note book. The foot was then placed on the note book and an outline of the foot was drawn. A mark was made in line with the centre of the lateral malleolus on the outline drawn, and was repeated for the medial malleolus. The foot was then taken off the note book and the two points were joined using a straight line. The angle made by this straight line to the printed lines of the note book was then measured. This angle was taken as the degree of tibial torsion; negative for lateral rotation and positive for medial rotation.

Measurement callipers were used to measure the width of the ankle - the distance between the centres of both malleoli. The knee joint axis was then established. In order to do this, the lateral knee joint line was palpated and a mark was put on the lateral condyle at about 1.5 cm above the joint line. The knee joint was then alternately flexed and extended to ensure that the mark lay on the area with least skin movement. This was repeated until the point with the least skin movement was identified. This was then repeated for the medial side, and then for the contra-lateral limb. Knee width was then measured using the callipers, which is the distance between the two marks on the medial and lateral condyles. All the measurements taken were documented for use by the VICON Workstation software.

Following the anthropometric measurements, gait analysis commenced. All retro-reflective markers were then attached to the participant according to the marker set used, with the exception of the knee markers. The participant was then asked to stand in the middle of the walkway and KADs were attached to the knees. The participant was asked to stand still for a few seconds while a static capture was made. Once it had been ensured that all the markers were visible in the static trial capture, the KADs were removed and normal markers were attached to the lateral condyles of both knees. Dynamic capture was then made while the participant walked from one end of the walkway to the other. After every walk the data were checked to ensure that all the markers were visible for one complete gait cycle and that the participant had stepped properly on the force plate, embedded in the walkway. The trials were repeated until three walks had been recorded that satisfied both requirements. Once the required walks were recorded, the markers were removed and the session was concluded.

10.2.3 Data Processing

The data were then processed to enable further interpretation and analysis. The walks with complete gait cycles and forces were selected. To derive joint kinematics and kinetics, data processing was carried out using the Plug In Gait Model (PIG) provided by VICON. One static trial and the appropriate walking trials were prepared for processing first. This involved several steps, the first of which was identifying markers, conducted manually for the static trial. For dynamic trials, after manually labelling a single walking trial, auto label parameters were created; these enabled the software to label all the other walks automatically. The automatically labelled walks were then checked for any unlabelled markers within the complete gait cycle and these were manually labelled. Following this, the trials were cleaned up by deleting the unlabelled trajectories, de-fragmenting the trajectories to avoid duplication of markers, and finally by filling the gaps within the trajectories. These all were done using the appropriate commands in the software. The size of the gap to be filled was also pre-set. Once a trial was cleaned, gait events were detected for one complete gait cycle. Although the workstation allowed automatic detection of gait events whenever force data were available, manual detection was generally required. Preparation was completed by entering the anthropological measurements. Once the preparation was complete, modelling was carried out, first for the static trial and then for dynamic trials. Modelling of the static trial was carried out by running a static gait model. This was then followed by running a dynamic gait model with the VICON Clinical Manager (VCM) splines to filter out noise in the data. During modelling, real marker data and anthropological data were used to create virtual marker trajectories corresponding to kinematics and kinetics. The PIG model normally consists of different models of lower body and upper body kinematics and kinetics. However, the present study only considered lower body kinematics and kinetics. The kinematic modelling created rigid body segments and calculated the joint centres, and the kinetic model then estimated joint reactions using moments of inertia and masses; both models can be briefly explained as follows -

Kinematic modelling:

During kinematic modelling, the pelvis segment is defined first with the origin taken as the mid-point of two anterior superior iliac spine (ASIS) markers. The hip joint centre is determined in the pelvis segment using the Newington–Gage model (Davis et al. 1991; Kadaba, Ramakrishnan and Wootten 1990). A KAD is used to determine the plane of the knee joint centre (KJC) during static processing. This process also involves determination of the relative rotation of the thigh wand marker, which is then used in dynamic modelling. To determine the knee joint centre, a virtual marker (KNE) is created at an equal distance from all three markers of the KAD. The knee joint centre is determined using the chord function of PIG modelling, which requires the hip joint centre, the KNE marker, and the axis marker of the KAD (KAX). In the chord function, the three points used to define a segment are assumed to be the required joint centre, a previously calculated joint centre, and a real marker at a known perpendicular distance from the required joint centre. In situations where a plane definition marker is used to determine the plane of the segment (for example, determining knee joint centre in dynamic trials) a modified chord function is used. Whenever the plane definition marker is rotated out of the plane of the segment as defined by three points, the modified version of the chord function takes the known degree of rotation of the plane definition marker to calculate the required joint centre. For static trials without the KAD (eg: mirror method), the position of the knee joint centre in the coronal plane is determined using the thigh wand marker. The femur segment is defined with the knee joint centre as the origin, making use of the hip joint centre and the KNE marker to create enough axes to define the segment.

The ankle joint centre (AJC) is determined in a similar manner to the knee joint centre during static processing. For this, the modified chord function is used with the knee joint centre, ankle marker and the required ankle joint centre as three points used to define the segment. Tibial torsion is the degree of rotation of the plane of the ankle joint axis from the plane of the knee joint axis (tibial rotation offset). During this process the shank marker rotation offset in relation to the plane defined above is determined. For static trials without the KAD (eg: mirror method), and dynamic trials, a modified chord function is used with all the points used to define the segment in static modelling with the KAD, the tibial rotation offset, and the shank marker rotation offset. The tibial segment is defined twice, once taking the tibial torsion into consideration, and once without considering tibial torsion. The torsioned tibia is used to represent the distal segment of the tibia and the non-torsioned tibia is used to represent the proximal segment of the tibia (for calculating the knee joint angles). Similarly, two foot segments were created. The main segment is created using the line connecting the toe and heel markers as the primary axis (Z axis), the direction of the Y axis of the non-tortioned tibia as the secondary axis (Y axis), and the X axis perpendicular to both the above axes. The secondary foot segment uses the line connecting the ankle joint centre and the toe marker as the primary axis (Z axis) and the secondary axis (Y axis), and the X axis as for the main segment. Cardan angles in XYZ order (rotating from the secondary foot segment to primary) between the segments are then used to calculate the plantar-flexion offset (rotation around Y axis) and the rotation offset (rotation around X axis) of the segment.

Kinetic modelling:

From the known global reference system of the laboratory, the relative position of the local co-ordinate system of each segment can be determined, allowing calculation of the relative position of one segment to the other. Joint angles are derived by calculating the relative positions of embedded coordinate systems in proximal and distal segments around a joint centre. Similarly, angular joint velocity can be calculated from the relative velocities of the segments proximal and distal to the joint centre.

The force plates record ground reaction forces (GRF) in three planes. Kinetic modelling is used to convert the forces recorded into moments (torque). It is also used to estimate the masses of each segment from the total body mass, to identify the position of the centre of mass, and to calculate the moment of inertia and radius of gyration of each segment. These data, along with the estimated joint centres and GRF data, are used to calculate joint moments using a mathematical process known as inverse dynamics. For this, the body segments are treated as separate rigid segments and moments are estimated from distal to proximal; for example, the foot segment is considered first. In order to estimate ankle moments, the ankle reaction force in each axis is estimated first with measured GRF and acceleration in respective axes and mass of the segment. The moment is then estimated by summing the product of force (GRF and ankle reaction force) in each direction, and the moment arm of the force about the centre of mass (CoM), and the product of the moment of inertia and angular acceleration of foot. Once ankle moments are calculated, similar equations are applied to the shank segment to estimate knee joint moments, and to the thigh segment to estimate hip moments.

The processed data are then ready to be reported using the Polygon authoring tool. A report is created in the workstation under the respective session, which redirects the user to the Polygon authoring tool. The processed trials are then imported into the report and attached to the respective walks. The report includes graphical representation of the kinematics and kinetics of the data captured. The data are then exported to Excel files and saved in the respective folders. The Excel files include numerical data for the temporal and spatial parameters, kinematics, and kinetics of the movement recorded.

CHAPTER 11 METHODS PRE-TRIALS: VALIDITY AND RELIABILITY OF MEASUREMENTS

11.1 Precision and accuracy of the motion analysis system

11.1.1 Aim

The aim of this pre-trial study was to estimate the precision and accuracy of 3D motion analysis systems used in laboratories 1 and 2 in estimating distances and angles between markers.

11.1.2 Method

Precision and accuracy of the VICON motion analysis systems in both the laboratories were investigated. Distance and angle measurements by VICON were under consideration. For each laboratory, all measurements were taken on the same day by the researcher. The methodology employed to estimate the precision and accuracy of the motion analysis system has been adopted from Durward, Baer and Rowe (1999).

To examine the precision of distance measurement, two markers were placed at a known distance apart on a ruler, and the ruler was moved randomly for at least five seconds in the capture volume. This was repeated five times for a single distance and the entire process was repeated for five different distances. In order to examine the precision of angle measurement, three markers were placed at five different angles and static data were captured five times for each angle. The distances and angles measured by VICON were noted from the VICON Workstation display and data were analysed using Microsoft Excel 2003. Standard deviations of the five measurements for each distance and angle were estimated and mean standard deviation and mean coefficient of variation (COV) were calculated as the measures of precision.

To examine accuracy of the system in measuring distance, two markers were stuck to a ruler at ten different distances apart and data were captured while the ruler was randomly moved in the calibration volume for about five seconds. To determine the accuracy of measuring angles, one marker was stuck on each of the arms of a goniometer and one on the axis, and the arms were placed at ten different angles while static data were collected by VICON for each angle. All the distances and angles were noted from the VICON Workstation display and data were analysed in Microsoft Excel 2003. The differences between the reference value and the value measured by VICON (measured value) were calculated and were termed errors. Absolute errors were then calculated by omitting the signs +/-. The mean absolute error and maximum absolute error were also estimated, and percentage linearity was calculated by dividing the maximum absolute error by the range of measurements.

Linear relationships between reference values and measured values for distances and angles were plotted, and the line of best fit through the points on each plot was created using statistical regression in Microsoft Excel 2003. From the equation of the line of best fit ($Y= m.X + c$), the slope of the line (m) and intercept of the line with the Y axis (c) were deduced. As a further measure of accuracy, the differences between measured Y and predicted Y values were estimated and termed residual errors; the absolute residual errors were then calculated by omitting the signs +/-. The mean absolute residual error, maximum absolute residual error and range of absolute residual errors were also estimated to report accuracy.

11.1.3 Results and discussion

The mean standard deviations for distance and angle were 0.12 mm and 0.05° respectively for lab. 1, and 0.48 mm and 0.07° respectively for lab. 2 (Table 11.1). Thus it can be estimated that 95% of all distance measurements will lie within + or – 0.96 mms (2 standard deviations) and 95% of all angle measurements will lie within + or – 0.14° of the true value during repeated measurements. The proportion of errors in relation to the range of values (COV) was also low. The highest of the mean COVs among the laboratories was only 0.2% for distance and 0.4% for angle.

Table 11.1 Precision of motion analysis system: results of analysis

Lab.	Measure	Standard deviation (SD)	Mean (SD) of Coefficient of Variation % (COV)	Range of COV %
Lab. 1	Distance (mm)	0.12	0.04 (0.02)	0.02 - 0.07
	Angle (°)	0.05	0.35 (0.5)	0 - 1.3
Lab. 2	Distance (mm)	0.48	0.19 (0.11)	0.09 - 0.36
	Angle (°)	0.07	0.06 (0.11)	0 - 0.3

Table 11.2 Accuracy of the VICON motion analysis system: results of analysis

Lab	Measure	Mean absolute error	Percentage linearity	Intercept	Absolute residual error	
					Mean	Maximum
Lab. 1	Distance (mm)	0.38	0.04	-0.1	0.32	0.82
	Angle (°)	0.36	0.4	0.22	0.24	0.69
Lab. 2	Distance (mm)	0.6	0.06	-0.7	0.51	1.33
	Angle (°)	0.5	0.6	0.6	0.58	1.90

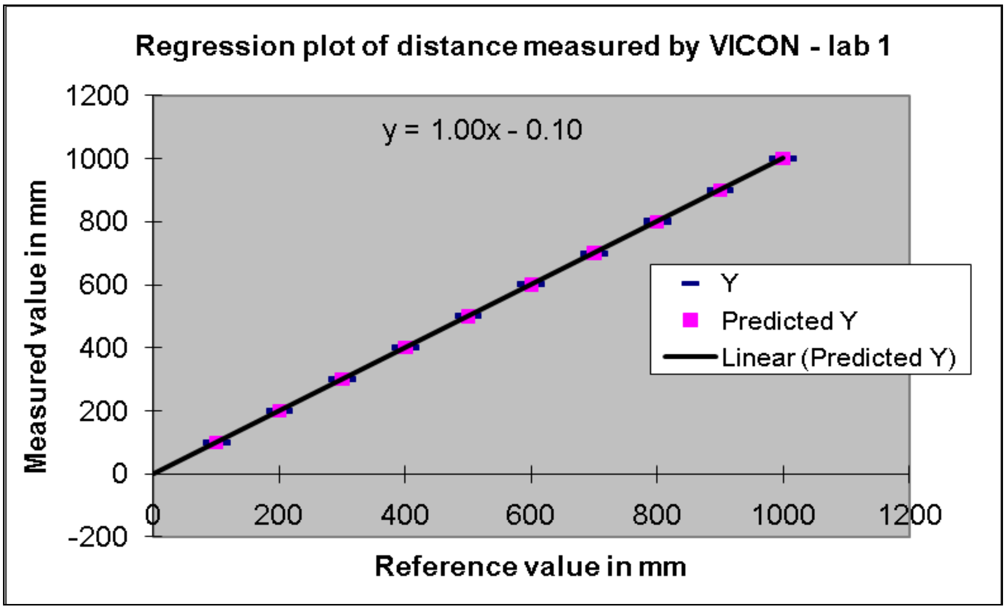


Figure 11.1 Regression plot and equation of distance in mm measured by the ruler (X axis) against the VICON (Y axis) for lab. 1

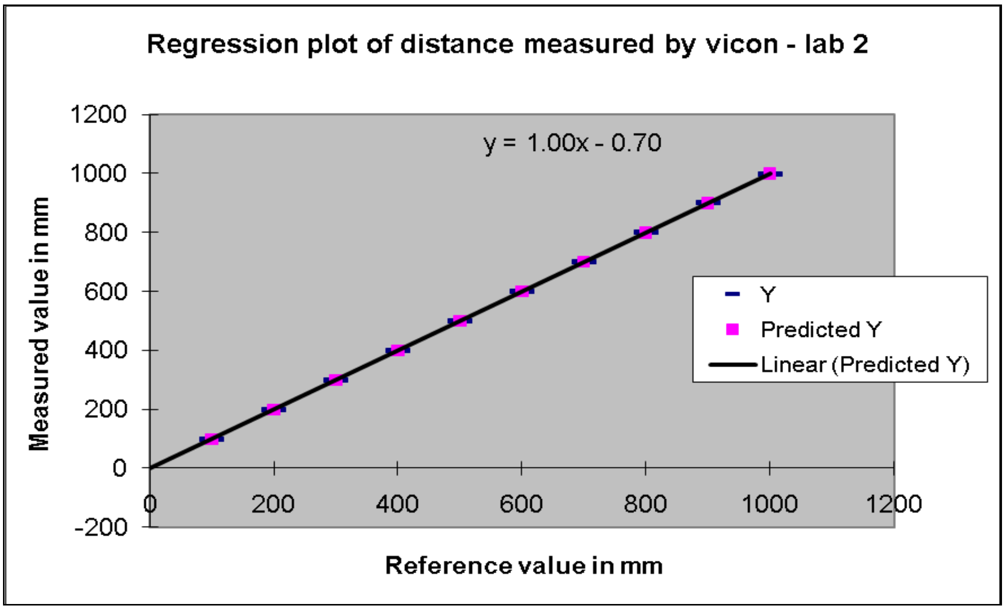


Figure 11.2 Regression plot and equation of distance in mm measured by the ruler (X axis) against the VICON (Y axis) for lab. 2

The results of accuracy testing are given in Table 11.2 and Figures 11.1 to 11.4. The accuracy of VICON in measuring distance and angle was high with percentage linearities of 0.04% and 0.4% respectively for lab. 1, and 0.2% and 0.1% respectively for lab. 2. The mean absolute errors and the mean absolute residual errors were low. The measurement of distance was accurate to 0.3 mm on average, and 0.8 mm at worst, and the measurement of angle was accurate to 0.2° on average, and 0.7° at worst for lab. 1. For lab. 2, the measurement of distance was accurate to 0.5 mm on average, and 1.3 mm at worst and the measurement of angle was accurate to 0.6° on average and 1.9° at worst. From the regression plots it can be seen that the slopes were equivalent to one for both angles and distance for both the laboratories, which suggests that both laboratories recorded one mm for each one mm input and one degree for each one degree input. The intercept for distance was -0.01 mm and angle was 0.2° for lab. 1, and 0.7 mm and 0.6° for lab. 2; this was regarded as negligible for the purpose of this study. The slope and intercept suggest excellent linear relationships between reference values and measured values

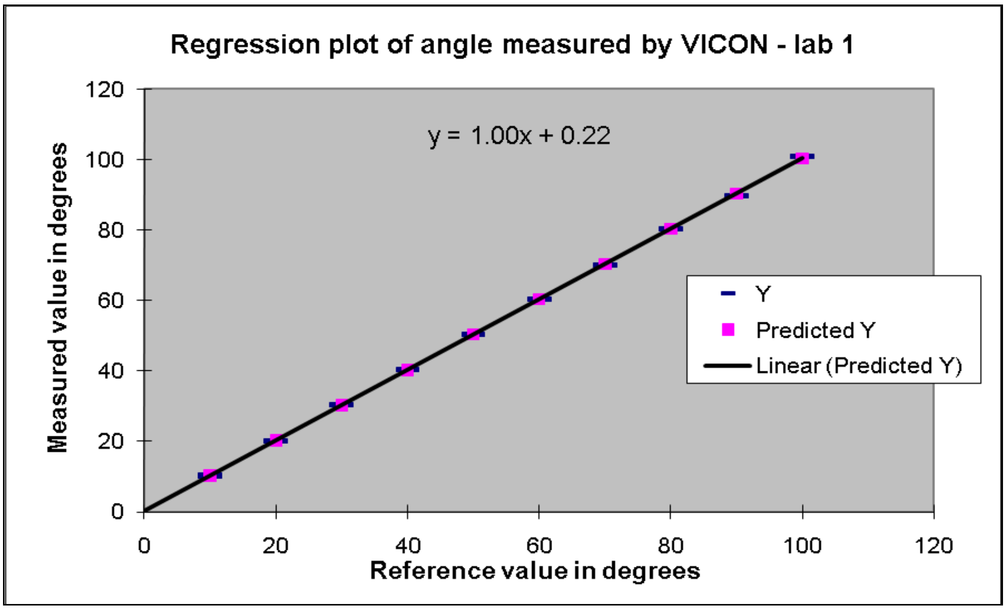


Figure 11.3 Regression plot and equation of angle in degrees measured by the universal goniometer (X axis) against the VICON (Y axis) for lab. 1

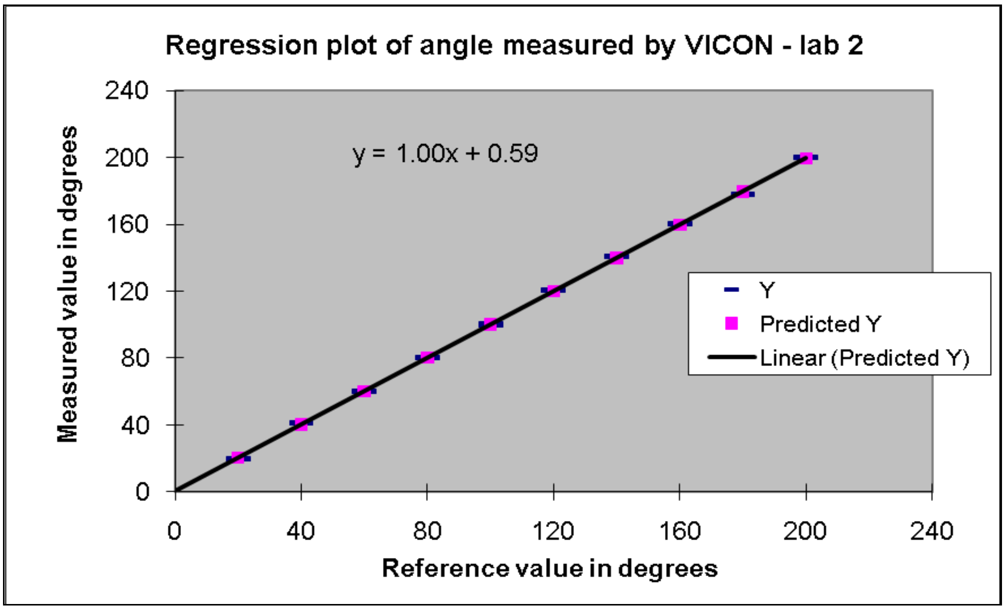


Figure 11.4 Regression plot and equation of angle in degrees measured by the universal goniometer (X axis) against the VICON (Y axis) for lab. 2

11.1.4 Conclusion

The precision and accuracy of VICON in measuring distances and angles were found to be excellent.

11.2 Precision and accuracy of force plates

11.2.1 Aim

The aim of this pre-trial was to estimate the precision and accuracy of the AMTI force plates in laboratories 1 and 2 in measuring vertical forces.

11.2.2 Method

In order to estimate precision, five different known weights (5, 10, 20, 50 and 75 kg) were individually placed on each of the force plates, and data were captured for at least five seconds by VICON; this process was repeated five times for each weight. The average force exerted by each of the weights as recorded by the force plates was extracted from the VICON Workstation display. The mean, standard deviation, and coefficient of variation (COV) of force were estimated for each of the weights and the mean standard deviation and mean COV were calculated as final measures of precision.

In order to estimate accuracy, five different known weights (5, 10, 20, 50 and 75 kg) were placed on the force plates while data were recorded each time. The force exerted by the weights as recorded by the force plates was extracted from VICON. The actual force exerted by the weights was calculated by multiplying the weight by a gravitational constant g (9.81 N/Kg). The difference between actual force (reference value) and measured force was calculated (error). Mean absolute error and percentage linearity were also estimated. The actual forces and measured forces were compared using linear regression. The mean absolute residual error, maximum absolute residual error and range of absolute residual error were estimated. From the regression equation, the intercept and slope of the line were calculated.

The variability of measurement of forces when applied to various points of the force plates were also estimated for both laboratories. To achieve this, a known weight (20kg) was applied separately to each corner of the force plate, and data were recorded each time. The standard deviation and coefficient of variation of force recorded by the four points of application (POA) were calculated. The possibility of error due to drift was also investigated. Because the force plates make use of strain gauge transducers, they are vulnerable to drift due to increased temperature when used for a long time. The data collection sessions in the present project were between two and three hours long. Therefore drift was estimated after force plates had been switched on for two hours and for three hours. In order to do this, a known weight (20kg) was placed on the force plate immediately after it was switched on and data were recorded. The force plate was then left switched on and the procedure was repeated after two hours and again after another hour. The same procedure was repeated for the two force plates in each laboratory. Data were analysed by plotting a graph of force against time.

11.2.3 Results and discussion

Among the mean standard deviations of the forces recorded by different force plates, the highest was 0.44 N (Table 11.3). It was thus estimated that the highest error margin for the measurement of forces was 0.88 N (2 standard deviations) during repeated measurements. The highest mean coefficient of variation (COV) for all the force plates was 0.15% and the highest COV among all the data was 0.37%. This demonstrated that the force plates were precise in their measurement.

Table 11.3 Precision of force plates: results of analysis

Lab.	Measure (N)	Standard deviation (SD)	Mean (SD) of Coefficient Of Variation % (COV)	Range of COV %
Lab. 1	Force plate 1	0.44	0.15 (0.15)	0.01 - 0.37
	Force plate 2	0.19	0.12 (0.09)	0.01 - 0.25
Lab. 2	Force plate 1	0.22	0.05 (0.22)	0 - 0.08
	Force plate 2	0.14	0.11 (0.14)	0.01 - 0.31

The results of analysis of force plate accuracy are given in the Table 11.4 and Figures 11.5 to 11.8. The accuracy of both force plates in both laboratories in measuring forces was high, with the highest percentage linearity as 0.5%. The mean absolute errors and the mean absolute residual errors were also small. For lab. 1, measurement of forces by force plate 1 was accurate to 3.3 N on average and 5.9 N at worst, and by force plate 2 was accurate to 2.8 N on average and 7.2 N at worst. For lab. 2 the measurement of forces by force plate 1 was accurate to 2.7 N on average and 7.2 N at worst, and by force plate 2 was accurate to 1.8 Non average and 4.9 Nat worst. The maximum absolute error for all the force plates was produced by the 75 kg weights. However, the maximum absolute errors were within 1% of the input force (735 N), and in the present study kinetics were only measured in children who weighed less than 50 kg. Therefore the accuracy of the force plates was considered acceptable for the present study.

Table 11.4 Accuracy of force plates: results of analysis

Lab	Measure (N)	Absolute error		Percentage linearity	Intercept	Absolute residual error	
		Mean	Maximum			Mean	Maximum
lab. 1	Force plate 1	3.3	5.9	0.5	0.16	0.23	0.52
	Force plate 2	2.8	7.2	0.4	0.31	0.20	0.49
lab. 2	Force plate 1	2.7	7.2	0.4	-0.4	0.25	0.46
	Force plate 2	1.8	4.9	0.3	-0.4	0.15	0.39

From the regression plots it can be seen that the slopes were equivalent to one for all force plates. For lab. 1, the intercept for force plate 1 was 0.16 and force plate 2 was 0.31; for lab. 2 the intercepts for both the force plates were -0.4 which was negligible (Figures 11.5 to 11.8).

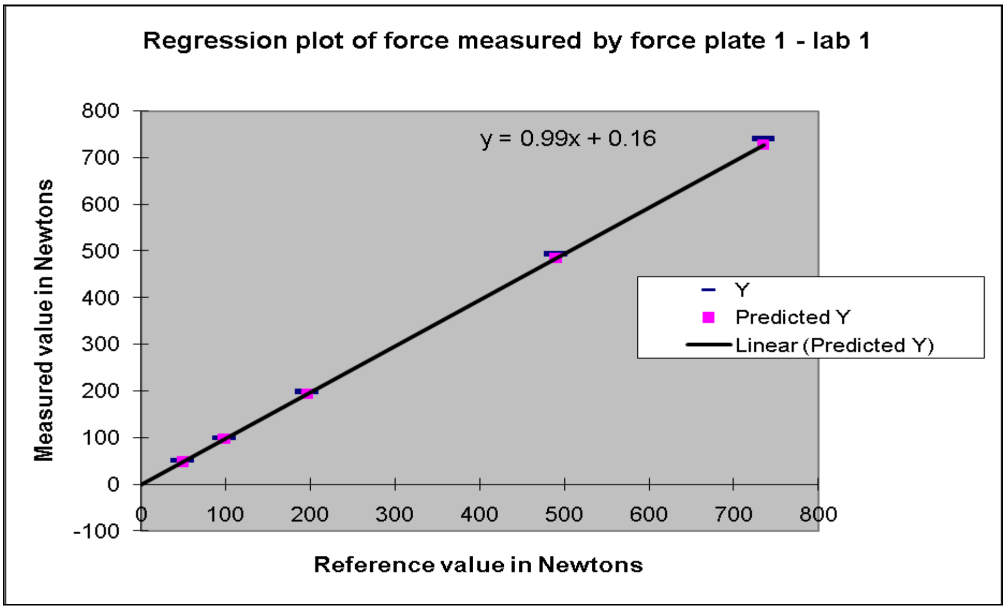


Figure 11.5 Regression plot and equation of forces in newtons (N) measured by force plate 1 (Y axis) against known forces (X axis) in lab. 1

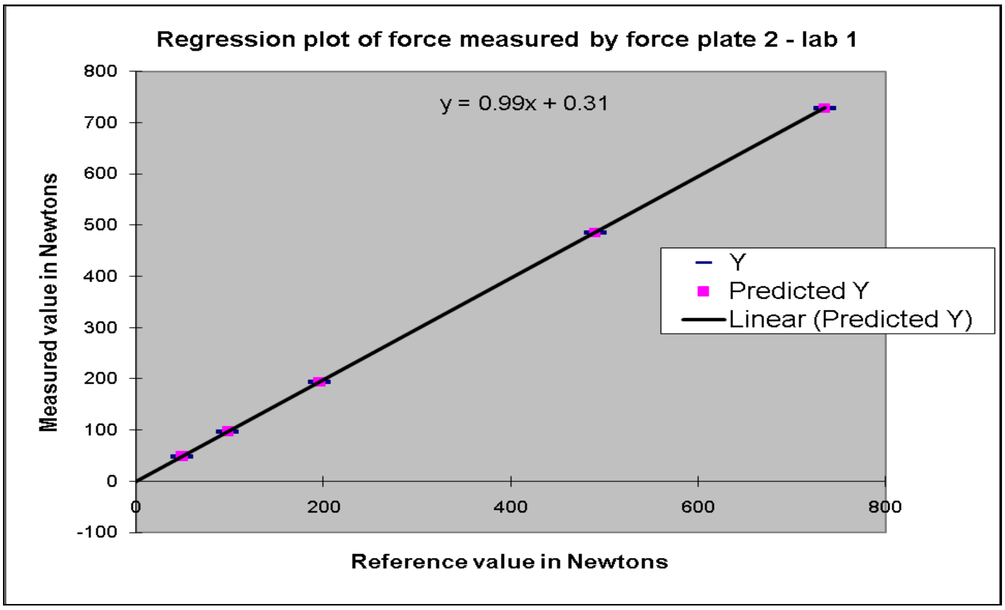


Figure 11.6 Regression plot and equation of forces in newtons (N) measured by force plate 2 (Y axis) against known forces (X axis) in lab. 1

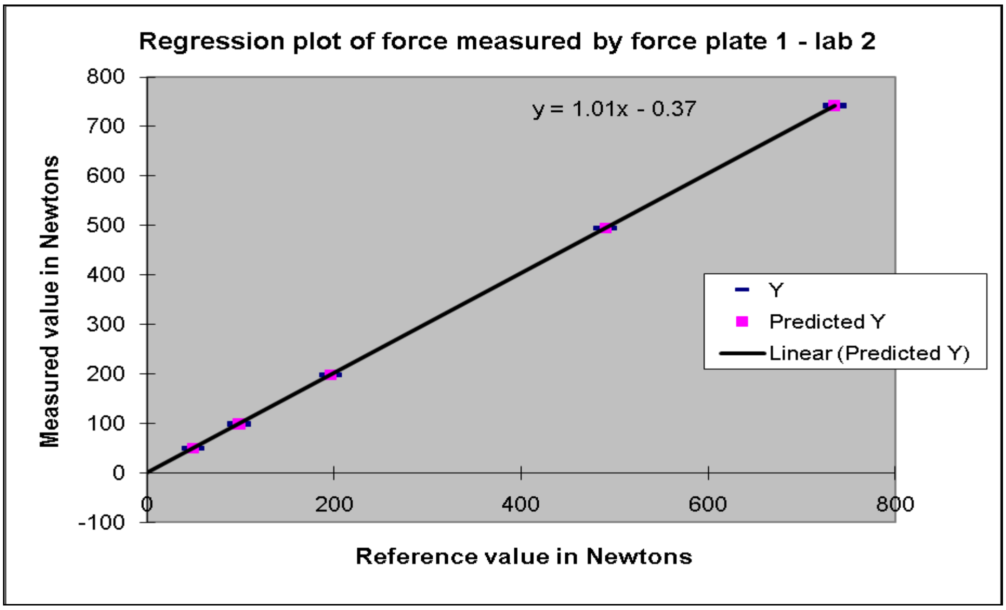


Figure 11.7 Regression plot and equation of forces in newtons (N) measured by force plate 1 (Y axis) against known forces (X axis) in lab. 2

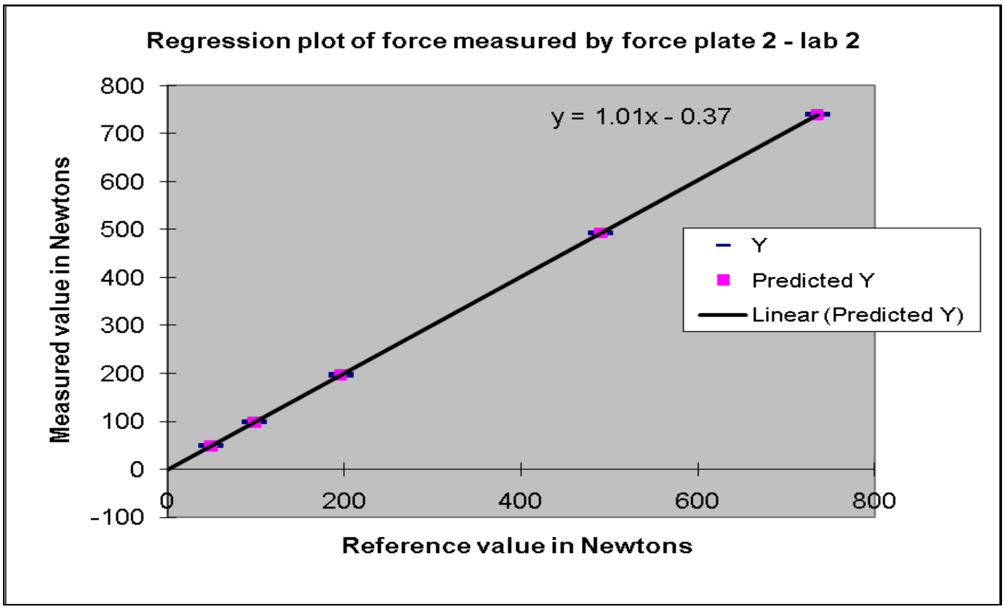


Figure 11.8 Regression plot and equation of forces in newtons (N) measured by force plate 2 (Y axis) against known forces (X axis) in lab. 2

Results of the comparison between four different points of weight application to each of the force plates are given in Table 11.5. The highest variability between the points was seen in force plate 1 with a standard deviation of 0.9 N and COV of 0.5%, both of which were negligible.

Table 11.5 Forces recorded by the force plates when weights were applied to four different points on each: results of analysis

Lab	Measure (N)	Standard deviation (N)	Coefficient of Variation (%)
Lab. 1	Force plate 1	0.88	0.46
	Force plate 2	0.53	0.27
Lab. 2	Force plate 1	0.72	0.36
	Force plate 2	0.77	0.39

Table 11.6 Drift in forces recorded by the force plates over three hours: results of analysis

	Measure (N)	Standard deviation (N)	Coefficient of Variation (%)
Lab. 1	Force plate 1	0.06	0.03
	Force plate 2	0.06	0.03
Lab. 2	Force plate 1	0.49	0.25
	Force plate 2	0.57	0.29

Results of the analysis of drift in forces recorded by force plates in both laboratories are given in Table 11.6 and Figures 11.9 and 11.10. The variability of forces recorded over time was negligible, with the highest demonstrated in lab. 2 (standard deviation of 0.6 N and COV of 0.3%). None of the force plates demonstrated a consistent trend over time (Figures 11.9 and 11.10).

Figure 11.9 Graph showing drift in the data recorded by force plates in lab. 1 over three hours.

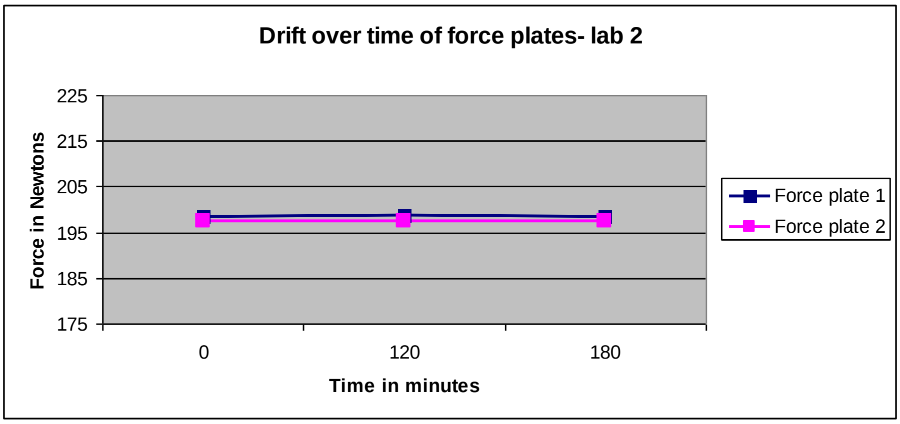


Figure 11.10 Graph showing drift in the data recorded by force plates in lab. 2 over three hours.

11.2.4 Conclusion

From the results it can be concluded that both force plates were accurate and precise in measuring forces.

11.3 Accuracy and reliability of gait analysis – comparison of three marker sets.

11.3.1 Aims

The aims of this pre-trial study were to compare the accuracy of three marker sets and investigate the intra- and inter-rater reliability of gait analysis using the chosen marker set.

11.3.2 Method

Recruitment and sample characteristics are given in Section 10.1 (pages 115-118) and Table 10.4 (page 118). In order to compare the accuracy of the marker systems, additional data collected for a previous MSc dissertation project were included. Data collected by three different raters were included to compare the measurement error associated with the three marker sets. Rater 3 collected data on 15 participants, whilst raters 1 and 2 collected data on five each. The three different marker methods used were: the Knee Alignment Device (KAD) method, the mirror method and the Calibrated Anatomical System Technique (CAST). The first two are based on the Helen Hayes marker set (Davis et al. 1991; Kadaba, Ramakrishnan and Wootten 1990) and involve slight variations of the Plug In Gait (PIG) marker set. The CAST marker method was based on the Cleveland marker system (Kirtley 2006; Sutherland 2002). The difference between the PIG models (KAD and mirror methods) and the CAST lies in how the bone-embedded frames (local co-ordinates of rigid body segment) are defined.

The PIG model uses anthropological data and marker positions to predict joint centres. With the PIG model, kinematics and kinetics are estimated based on the bone-embedded frames calculated using the instantaneous positions of bony landmarks determined by the positions of superficial markers during dynamic trials. Modelling with the PIG model is explained in detail in Section 10.2.3 (pages: 121 to 125). The KAD is used to determine the knee joint centre during static modelling. For this the three markers of KAD (KAD1, KAD2 and KAX) are used to create a virtual knee marker (KNE), used along with the KAX marker and hip joint centre. During static modelling, the angle between the thigh wand and the plane perpendicular to the line connecting hip and knee joint centres is also estimated (thigh marker rotation offset). For dynamic trials the surface knee marker (KNE), hip joint centre, and thigh wand marker are used to determine the knee joint centre, using the thigh marker rotation offset to estimate the anterior-posterior position of the knee joint (VICON Systems Manual 2002). However, with the PIG without the KAD, static processing is carried out in precisely the same way as dynamic processing, and hence the positions of the wand markers become crucial. This principle is also utilised in the mirror method which requires the tester to align the thigh marker in the same plane as the greater trochanter, and lateral knee markers and tibial marker in the same plane as the lateral malleolus and lateral knee markers respectively with the help of a mirror. No KADs are used for static trials.

The CAST system uses two local frames to determine the bone embedded frame, namely the technical and the anatomical frames (Cappozzo et al. 1995; Cappozzo et al. 2005). The technical frame includes a cluster of at least three markers, non co-linear to each other, placed on the body surface without any predetermined relationship to the anatomical land marks. The anatomical frame is a local frame of the segment defined using three bony land marks. The relationship between the two frames is established by the process called anatomical calibration. This is done during static trials by pointing a wand with attached markers at the bony landmarks. Once the relationship is established, it is possible to estimate the bone embedded frame with only the technical frame during dynamic trials (Cappello et al. 1997; Cappozzo et al. 1995; Cappozzo et al. 2005). In this study a modified version of the CAST protocol was implemented. This was previously applied in a study of hip rotation of children in CP (van der Linden et al. 2003). In this modified version of the CAST method, anatomical calibration was carried out using surface markers attached to the landmarks which can be removed during the subsequent walking trials. Three extra markers were applied to both the thigh and shank of tibia for all trials, and one extra marker was applied to both the medial condyle of femur and the medial malleolus for both legs during static trials.

Calibration and gait analysis were carried out in lab. 1 by all testers, as explained in the general protocol section (Section 10.2, page: 118 to 121), with two differences. Firstly, no force data were collected, and secondly, three different static trials were captured for all participants, one each for each marker set. Static capture for the mirror method was carried out first. For this, all the lower limb markers, including the lateral knee marker, were applied first. An extra marker was applied to the greater trochanter on each side. The participant was then asked to stand side-on to a mirror. The tester then placed the thigh marker, with the help of the mirror, in alignment with the trochanter and the lateral knee markers. The tibial marker was placed next, aligned with the lateral knee and ankle markers with the help of the mirror. The markers on the greater trochanters were then removed and a static trial was captured. This was followed by static capture for the KAD method. For this, the knee markers were removed, KADs were applied, and another static trial was captured. A static trial using the CAST model was carried out next, for which the KADs were removed and the lateral and medial knee markers and the medial ankle markers were applied. Three technical markers were applied to the thigh and shank of the tibia. The third static trial was then recorded. The medial knee and medial ankle markers were then removed and six dynamic trials were recorded. The participants were asked to come back for a second session after a week and the same procedure was repeated. Five of the participants were tested by two raters to investigate inter-rater repeatability.

The data were processed and knee parameters such as peak knee flexion, peak knee extension, knee range of motion (ROM) in the the sagital plane, peak knee abduction (varus), peak knee adduction (valgus) and knee ROM in the coronal plane were extracted using Matlab and Microsoft Excel 2003. For comparing measurement error, knee varus, valgus and ROM in the coronal plane as recorded by three testers were statistically compared between the three marker sets using repeated measures ANOVA, or Friedman's ANOVA, depending on the distribution of the data. Post hoc pair-wise comparisons were carried out using a paired t –test, or Wilcoxon signed rank test with Bonferroni correction, depending on the distribution of the data. The coronal plane movements of the knee joint were considered to be criteria for error, based on the fact that defining the knee joint flexion-extension axis is one of the common sources of error. Improper alignment of the knee joint flexion-extension axis results in knee joint angle cross-talk. This not only affects the reliability of the knee flexion-extension angles, but also results in erroneous estimation of knee movement in both coronal and transverse planes, and hip joint rotations (Schache, Baker and Lamoreux 2008). Hence, it was assumed that the higher the recorded coronal plane movement, the greater the error. Based on the results for measurement error, one marker set was chosen and both inter- and intra-rater reliability were investigated. Peak knee extension, peak knee flexion and knee ROM in the sagittal plane were compared between the raters for inter-rater reliability, and between the two sessions for intra-rater reliability. Intra Class Correlations (ICC) and Bland and Altman Limits of Agreement (LOA) were used for both comparisons.

11.3.3 Results and discussion

Results of the comparison of accuracy between the three marker sets are given in Table 11.7 and Figures 11.11 and 11.12. No consistent pattern in valgus or varus exists between the raters (Table 11.7). However, the total frontal plane motion for all the raters was highest with the CAST method, followed by the mirror method and the least frontal plane motion was seen using the KAD method. All the differences were statistically significant (Figure 11.11). The means and standard deviations of total knee ROM in the frontal plane for all raters with each of the three marker sets are given in Figure 11.12.

Table 11.7 Means (SD) of varus, valgus angles of the knee joint for all the three raters.

Raters	Knee Varus Mean (SD) (°)			Knee Valgus Mean (SD) (°)		
	KAD	Mirror	CAST	KAD	Mirror	CAST
1	3.9 (2.7)	3.0 (3.6)	6.3 (6.3)	-3.9 (3.9)	-7.0 (5.8)	-6.1 (6.7)
2	10.3 (6.7)	5.8 (4.5)	7.0 (5.4)	-0.5 (4.2)	-7.3 (9.6)	-4.9 (3.7)
3	4.5 (4.5)	3.9 (5.3)	5.4 (4.0)	-4.6 (3.7)	-6.1 (4.9)	-5.2 (4.1)

NB: For raters 1 and 2, n = 5 and rater 3, n = 15.

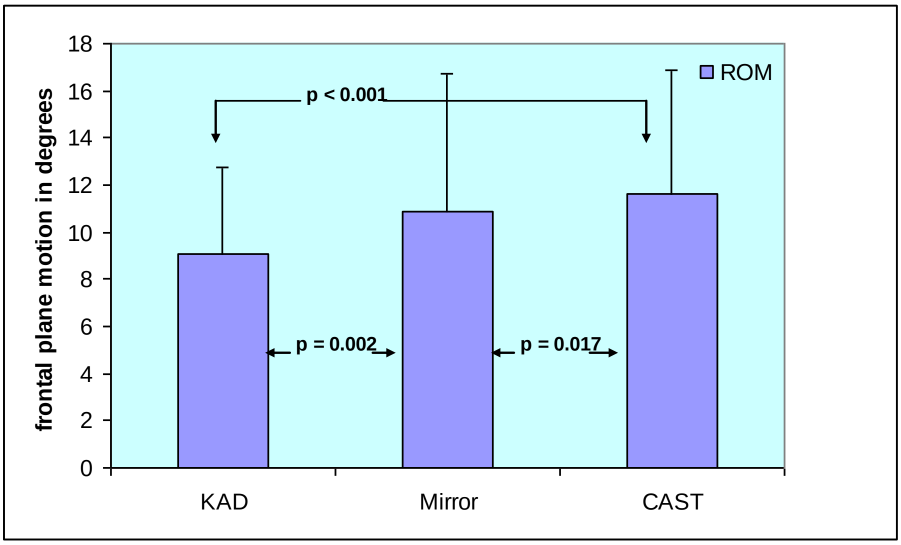


Figure 11.11 Comparison of the total range of frontal plane knee motion (ROM) for each of the three marker methods (with the level of significance between the marker methods)

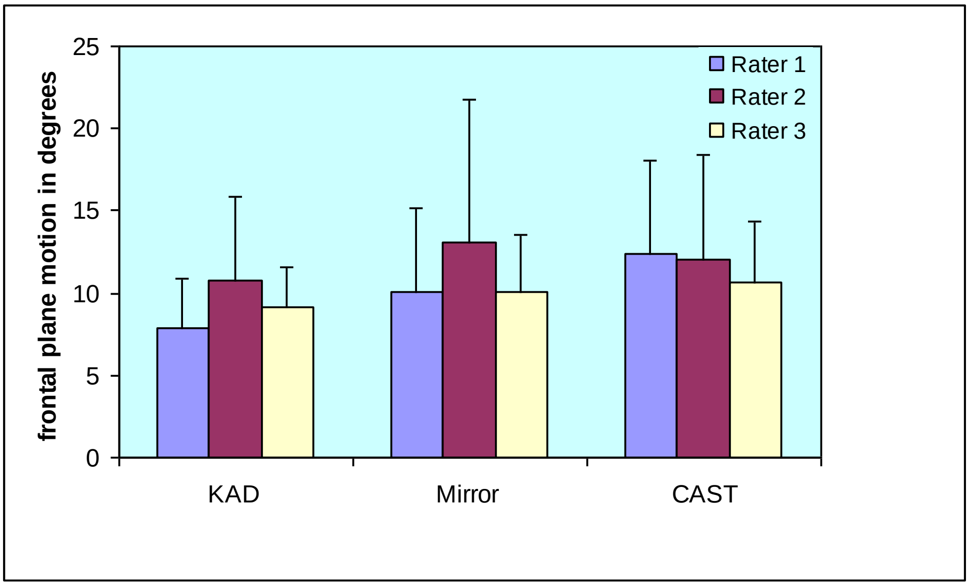


Figure 11.12 Comparison of the average total range of frontal plane knee motion (ROM) for each rater with each marker method

The results suggest that of the three methods, the KAD demonstrates the least knee angle cross-talk during gait analysis. There are, however, considerable standard deviations, despite careful teaching and application of each marker method. The KAD demonstrated smaller standard deviations than the mirror and CAST method, for all three raters. It is possible that the mirror and CAST methods require more training for novice raters in comparison to the KAD. It was observed that there was considerable movement of the thigh markers in the CAST method, which could have contributed to the variability in the results. This suggests that an optimal marker position for the thigh markers in the CAST method needs to be investigated.

Considering factors such as lack of experience of researcher, ease of use of the KAD compared to the other two methods, and results from the accuracy study, the KAD method was chosen as the most appropriate for the PhD project. The results of intra- and inter-rater repeatability studies are given in Tables 11.8 to 11.11. For all the knee parameters, intra-rater reliability was excellent (ICC> 0.8) (Table 11.8).

Table 11.8. Intra-rater reliability: Intra-class correlation (ICC) and significance level for selected knee parameters between two sessions

Parameters	ICC	p value
Peak knee extension	0.97	0.002
Peak knee flexion	0.93	0.01
Knee ROM	0.93	0.01

From Table 11.9 it can be seen that, for the same rater

- 95% of all peak knee extension measurements will lie within +/- 2.02° of the true value,
- 95% of all peak knee flexion measurements will lie within +/- 2.2° of the true value and
- 95% of all knee ROM measurements will lie within +/- 2.2° of the true value.

Since the zero falls within the 95% LOA (Table 11.9) it can be assumed that no systematic error exists between two sessions when tested by same rater (Lexell and Downham 2005).

Table 11.9 Intra-rater reliability: Mean difference, standard error and 95% limits of agreement of the mean difference between two sessions for selected knee parameters.

Parameters	Mean Difference	Standard Error	95% limits of agreement	
Peak knee extension	0.10	1.01	2.12	-1.93
Peak knee flexion	0.17	1.10	2.38	-2.04
Knee ROM	0.07	1.12	2.30	-2.16

Table 11.10 Inter-rater reliability: Intra class correlation (ICC) and significance level for selected knee parameters between two raters.

Parameters	ICC	p value
Peak knee extension	.973	.002
Peak knee flexion	.855	.044
Knee ROM	.927	.013

For all the knee parameters, inter-rater reliability was excellent (> 0.8) (Table 11.10). From Table 11.11 it can be seen that between the raters;

- 95% of all peak knee extension measurements will lie within +/- 2.78° of the true value ,
- 95% of all peak knee flexion measurements will lie within +/- 1.96° of the true value and
- 95% of all knee ROM measurements will lie within +/- 1.24 of the true value

However, since zero does not fall within the 95% LOA for peak knee flexion, it can be assumed that systematic error was present for peak knee flexion measurement between the raters.

Table 11.11 Inter-rater reliability: Mean difference, standard error, and 95% limits of agreement of the mean difference between two raters for selected knee parameters

Parameters	Mean Difference	Standard Error	95% limits of agreement	
Peak knee extension	-2.75	1.39	0.03	-5.54
Peak knee flexion	-2.89	0.98	-0.92	-4.85
Knee ROM	-0.13	0.67	1.21	-1.47

While the results show excellent ICCs for the knee kinematic parameters between raters and between sessions, there is a systematic change between the raters for peak knee flexion since the 95% LOA does not include zero (Lexell and Downham 2005). The intra-rater reliability values of the parameters are promising. However, the highest 95% LOA of the mean difference between two sessions for the same rater suggest that, between sessions, any change in knee parameters of less than 2.2° should be interpreted carefully.

13.3.4 Conclusion

This study suggests that the KAD is the most reliable marker method for those who are less experienced in clinical gait analysis. It is possible that the outcome would be different for raters who are experienced in the respective marker methods. The intra-rater reliability of measuring knee kinematics using the KAD method is better than inter-rater reliability and hence placement of markers and data collection should be carried out by the same person to improve the reliability of the results.

11.4 Reliability of mid-stance identification using kinematics definition.

11.4.1 Aims:

The aims of this study were to investigate the intra-rater and inter-rater reliability of the method used in the present study (kinematic method) to identify mid-stance for tuning purposes and compare the kinematic method with temporal method of identifying mid-stance.

11.4.2 Methodology

Sample details are provided in Section 10.1 and Table 10.1 (page. 115 and 116). A single VICON Workstation video footage file was used from barefoot walking data for each of eight children with CP and eight healthy children. Separate analyses were carried out of the data from the two groups of children. Inter-rater and intra-rater reliability of the kinematic method, and correlations between the kinematic method and the temporal method, were investigated. The definitions of both methods are given in Section 3.2 (page: 26). Temporal mid-stance was identified by the researcher based on the definition provided in Section 3.2 (page: 26). For each of the VICON footage files heel-strike and toe-off for the reference leg were identified with the help of force plates. The frames were noted and the exact mid-point of the stance phase was estimated.

Fourteen raters identified kinematic mid-stance. The raters were asked to identify mid-stance for one leg in all the footage files, with the gait cycle highlighted using the event markers in the VICON footage. All the raters were shown the VICON footage on the computer and were asked indicate mid-stance in the gait cycle based on the kinematic definition by marking the frame number on the form provided. This was repeated after two weeks with the same data set, presented in a different order.

The reliability of mid-stance identification was estimated using a mix of Intra Class Correlation (ICC) statistics and Bland and Altman limits of agreement (LOA). All the data were originally in the form of frame numbers, which were converted into time using the known variable – sample frequency. For inter-rater reliability, ICCs for data from 14 raters were calculated separately for data collected from children with CP and from healthy children; one way ANOVA was used to estimate the standard error of measurement. For intra-rater reliability the averages of the data from 14 raters for sessions 1 and 2 were compared using ICC and Bland and Altman LOA, first for children with CP and then for healthy children. Comparisons between temporal identification data and average data for kinematic identification by 14 raters were carried out for each group of children.

11.4.3 Results

Inter- rater reliability of mid-stance identification

Excellent correlations (ICC = 0.8 and 0.99) between the raters were seen for the kinematic method of mid-stance identification for the data from both healthy and children with CP (Table 11.12). Furthermore, the standard error of measurement was 0.04% for kinematic method of mid-stance identification for the data from both healthy and children with CP (Table 11.13).

Table 11.12 ICC for inter-rater reliability of kinematic method of mid-stance identification

		95% Confidence Interval	
	ICC	Lower Bound	Upper Bound
Healthy	0.81	0.636	0.949
CP	0.99	0.964	0.996

Table 11.13 Results from one way ANOVA testing for standard error of measurement (SEM%) of kinematic method of mid-stance identification

	Mean Square	SEM%
Healthy	0.001	0.04
CP	0.002	0.04

Intra rater reliability of mid-stance identification

Table 11.14 shows the results of reliability analysis standard error of measurement (SEM).

Table 11.14 Intra Class Correlation (ICC) and Standard Error of Measurement (SEM%) for intra-rater reliability of kinematic method of mid-stance identification

	ICC	95% Confidence Interval		SEM%
		Lower Bound	Upper Bound	
Healthy	0.99	0.982	0.999	1.0
CP	0.99	0.996	1.000	0.5

Excellent correlations (ICC = 0.99) were seen between the raters using kinematic method of mid-stance identification for the data from both healthy and children with CP (Table 11.14). Furthermore, the standard error of measurement was as low as 1% for data from healthy children and 0.5% for data from children with CP for kinematic method of mid-stance identification.

Figure 11.13 and 11.14 depict scatter plots plotted using mean data of 14 raters from two occasions with data from healthy children and children with CP respectively. The X-axis has the mean of point of mid-stance of two occasions, the Y –Axis has difference between the two occasions. The central line represents the mean difference between the two occasions and the two lines represent 2 times standard deviation of the difference which gives the 95% Limits Of Agreement (LOA). In both figures zero lies within the 95% LOA. With the data of healthy children (Figure 11.13) and the 95% LOA extends from -0.006 to 0.011 seconds and with the data of children with CP (Figure 11.14), the 95% LOA extends from -0.001 to 0.006.

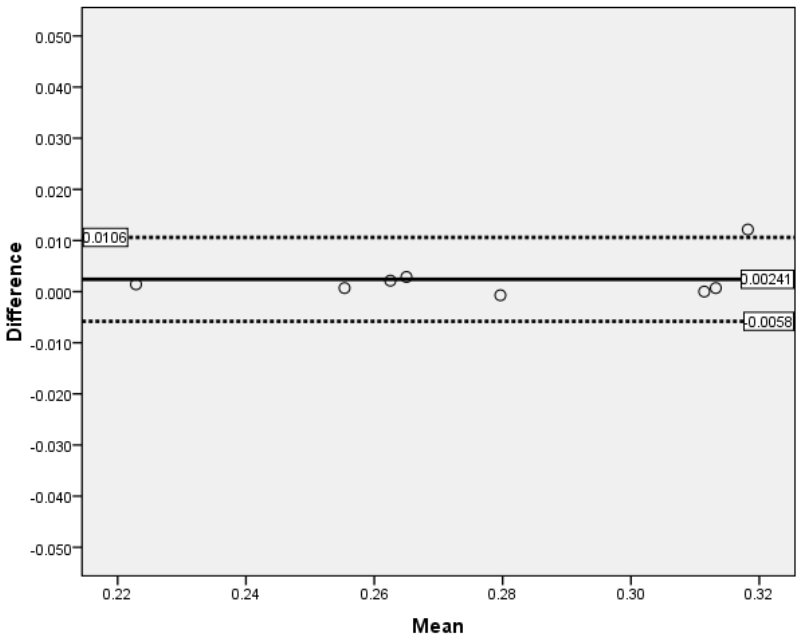


Figure 11.13 Bland & Altman plot with 95% confidence interval (dashed line) of the mean difference (solid line) between the two occasions using data from healthy children.

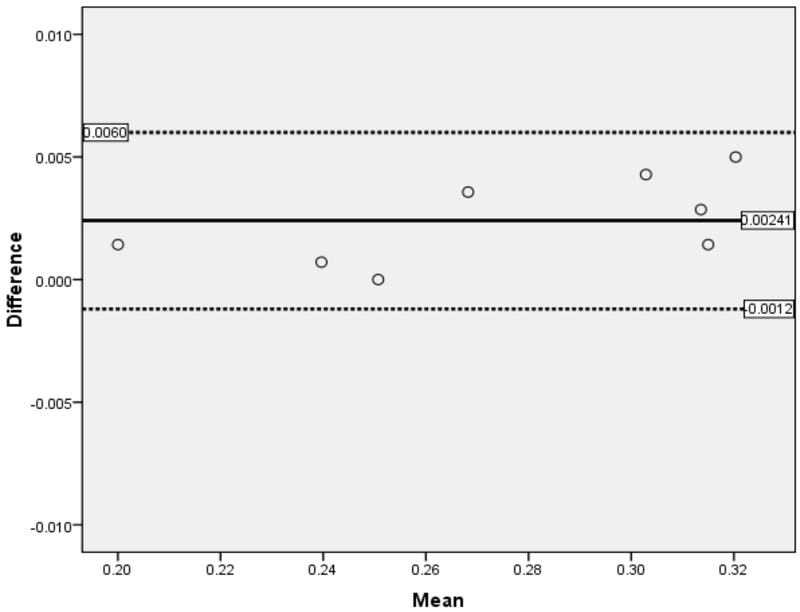


Figure 11.14 Bland & Altman plot with 95% confidence interval (dashed line) of the mean difference (solid line) between the two occasions using data from children with CP

Kinematic versus temporal methods

Kinematic and temporal methods of mid-stance identification were compared using Bland & Altman limits of agreement (LOA). Figure 11.15 and11.16 depict scatterplots plotted using mean data from kinematic and temporal methods with data from healthy children and children with CP respectively. The X-axis has the mean of point of mid-stance identified by two methods, the Y –Axis has difference between the two methods. The central line represents the mean difference between the two methods and the two lines represent 2 times standard deviation of the difference which gives the 95% Limits Of Agreement (LOA).

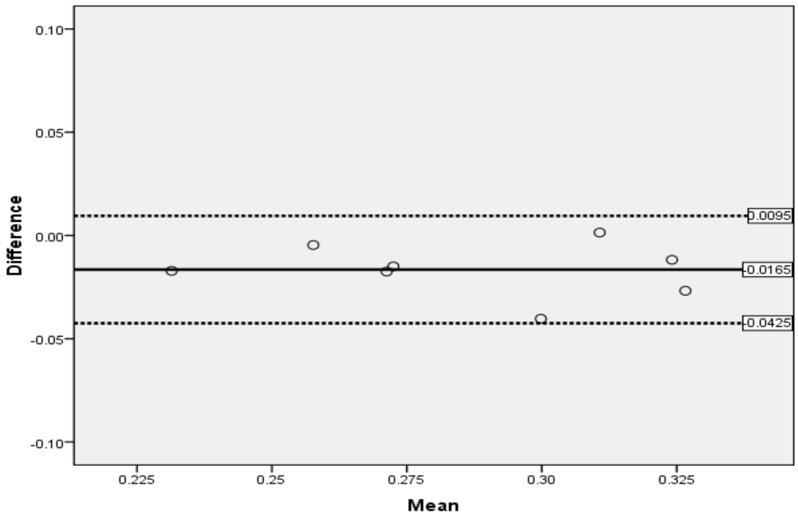


Figure 11.15 Bland & Altman plot with 95% confidence interval (dashed line) of the mean difference (solid line) between the two methods using data from healthy children.

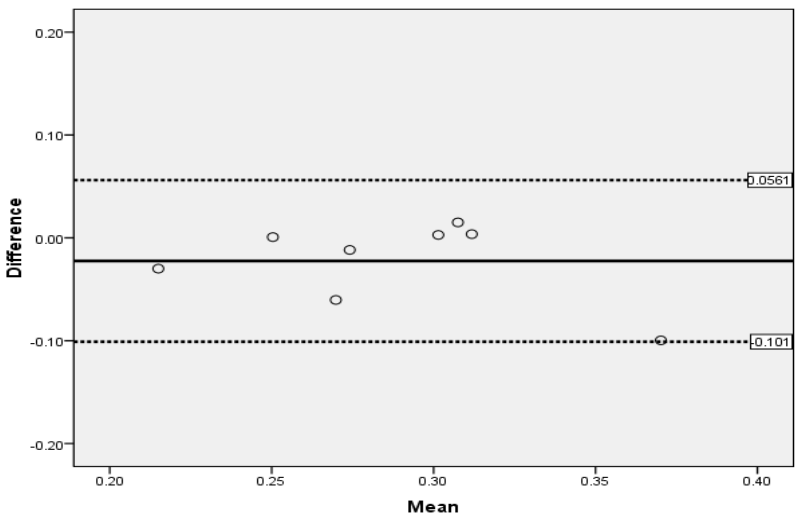


Figure 11.16 Bland & Altman plot with 95% confidence interval (dashed line) of the mean difference (solid line) between the two methods using data from children with CP.

It can be seen from the figures that zero lies within the 95% LOA. With the data of healthy children (Figure 11.15) and the 95% LOA extends from -0.043 to 0.01 seconds and with the data of children with CP (Figure 11.16), the 95% LOA extends from -0.1 to 0.056.

11.4.4 Discussion

One of the basic premises of tuning is the optimisation of the GRF during mid-stance (Butler et al. 2007; Butler, Thompson and Major 1992; Butler and Nene 1991; Owen 2004b) and hence defining mid-stance is vital in tuning. Various definitions of mid-stance and their relevance to the project is discussed in the Section 3.2 (page: 26) For the purpose of tuning, the definition termed as kinematic mid-stance was used. While the kinetic definition of mid-stance in which mid-stance is when GRF is vertical in sagittal plane, was also proposed by an earlier study (Gibson, Jeffery, and Bakheit 2006) it was not used in the present study. The reasons being difficulty in identifying the discrete point with vertical GRF and as Gibson, Jeffery and Bakheit (2006) themselves stated, alignment of GRF is participant to variation in patients with pathological gait. While, one study investigated the relationships between various definitions of mid-stance in healthy children (Gibson, Jeffery and Bakheit 2006), the repeatability of the definitions was not investigated. For tuning, mid-stance is identified as point when the opposite limb crosses the reference limb. According to Gibson, Jeffery and Bakheit (2006), the kinematic definition may be problematic for participants who have problems in foot kinematics in stance which questions the use of kinematic or similar definitions in children with CP. It was essential to investigate the relationship between temporal (gold standard) and kinematic definitions and repeatability of the kinematic definition in children with CP.

In contrast to Gibson, Jeffrey and Bakheit (2006) who compared percentage of gait cycle for the temporal method, time in seconds was used in the present study. The reason for this being the influence of variability of data on ICC. If the percentage of gait cycle was used, the variability within the sample would have been too small to get a meaningful ICC. In the present study the association between temporal and kinematic methods was excellent for healthy children and good for children with CP.

Gibson, Jeffery and Bakheit (2006) reported moderate agreement between temporal and kinematic timings in healthy children. However, unlike present study, Gibson and colleagues (2006) employed Pearson's coefficient to investigate strength of association. Using Pearson's correlation coefficient to investigate agreement between methods is not considered ideal since it only measures the strength of association and not the level of agreement between methods (Altman 1991; Bland and Altman 1986) In the present study, Bland & Altman Limits of Agreement (LOA) was used to investigate the agreement between two methods (Altman 1991). From the Bland and Altman plot, it can be assumed that the agreement between two methods was good for data from healthy children. Firstly the 95% LOA was only +/- 0.01s which shows that the agreement between the methods falls within +/- 1 frame of VICON data. Secondly, zero was with in the 95% LOA which shows that there was no systematic difference between the two methods (Lexell and Downham 2005). For the data from children with CP, the 95% LOA was +/- 0.03s which shows that the agreement between the methods falls within +/- three frames of VICON footage. Furthermore, zero lies within the 95% LOA which rejects the possibility of systematic difference between the two.

For investigating inter rater repeatability of kinematic method ICC was used. Bland and Altman LOA was not attempted due to the complexity of analysis required with the number of raters in the present study (n=14) (Rankin and Stokes 1998). ICC of more than 0.75 (Fliess 1986) for both healthy children and children with CP suggest excellent inter rater reliability of kinematic method. For establishing intra-rater reliability, ICC and Bland & Altman LOA were used. Further analysis was carried out by measuring Standard Error of Measurement percentage (SEM%). Both the data from healthy children and children with CP yielded ICC of more than 0.75 suggesting excellent intra rater reliability. SEM% suggests that measurement variability within in the same raters were as low as 1% and 0.5% for data from healthy children and children with CP respectively. The Bland & Altman plots revealed good agreement between sessions for the same raters. For data from healthy children, the 95% LOA of +/- 0.003s shows that the agreement between the methods falls within +/- 1/3rd of a frame of VICON footage. For data from children with CP, the 95% LOA was +/- 0.001s which represents $1/10^{th}$ of a frame. Furthermore, for data from both the groups, zero lied within 95% LOA rejecting the possibility of systematic difference.

Since the orientation of GRF during mid-stance is considered vital in tuning (Owen 2004b; Butler and Nene 1991), the method of identification of mid-stance gains importance. The current study showed that traditionally used method in tuning (Kinematic definition (Gibson, Jeffrey and Bakheit 2006)) has excellent inter-rater and intra-rater reliability. However, translating these findings into clinical practice is not completely straight forward. In clinical practice, mostly tuning is carried out by video vector analysis which overlaps video on to vertical force data (Stallard and Woollam 2003). While using video vector, mid-stance has to be identified from actual video and not VICON footage which may have different reliability.

11.4.5 Conclusion

It can be concluded that the kinematic method of mid-stance identification has excellent inter-rater and intra-rater reliability and excellent agreement with temporal method.

CHAPTER 12 METHODS – TESTING PROTOCOLS FOR MAIN STUDIES

12.1 Overview

Chapter 10 explained the general protocols followed for gait analysis. These were tailored to different participant groups. This chapter provides the overall design of the project and detailed information on the data collection procedures, including gait analysis and other outcome measurements, for each participant group.

12.2 Design

The primary aims of this project were to investigate the effects of tuning of AFO-FC on the gait of children with CP, and to look at the feasibility of investigating the short-term effects of tuning on gait, muscle and joint properties, and quality of life. All the studies conducted as a part of the project either directly or indirectly contributed to achievement of the primary aims. Figure 10.1 shows the various studies conducted as a part of the project, their relevance, and relationships between them. The pre-trials were designed to establish the accuracy and precision of the 3D motion analysis systems and force plates, identify an appropriate marker set, and to establish the reliability of motion analysis using the chosen marker set. The results from the pre-trials were relevant for all other studies, since they informed the margin of error and reliability of equipment and processes. The results from healthy children provided reference gait data, reported the role of shoes in gait and the effects of wedges and rockers. This information was compared with data regarding the effects of wedges, rockers and tuning on the gait of children with CP. Similarly, investigation of the effects of wedges and rockers on the gait of children with CP enabled interpretation of the results from the study that looked into the immediate effects of tuning, and the feasibility study regarding short-term effects of tuning. Investigating the reliability of mid-stance identification related to one vital aspect of the reliability of the tuning procedure, which in turn is a key feasibility issue. Finally, the two main studies – one looking at the immediate effects of tuning, and one investigating the short-term effects of tuning, were designed to inform the clinical utility of tuning as well as the feasibility of conducting a larger project.

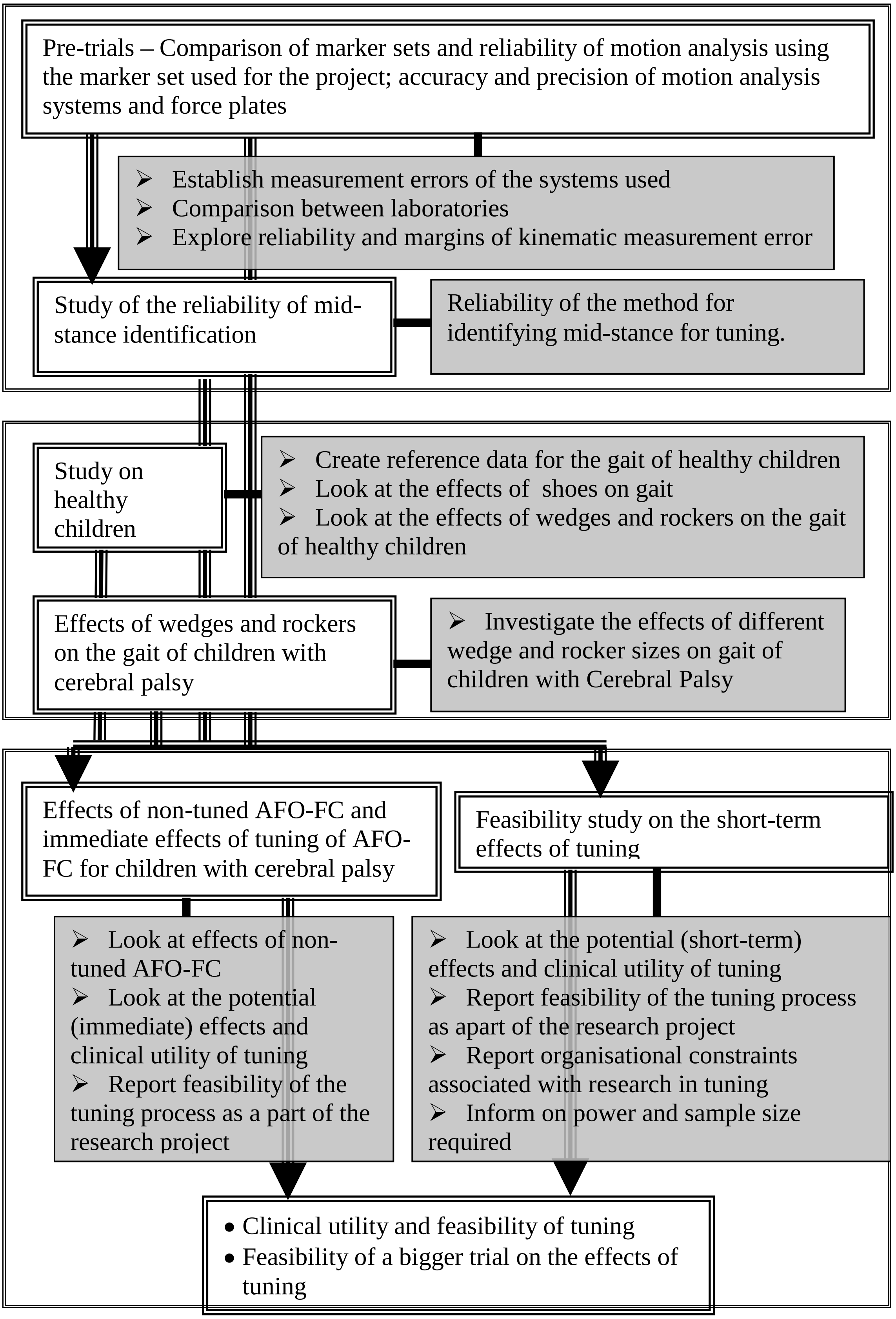


Figure 12.1 Flow chart showing relationships between different studies in the project – grey boxes state the relevance of each study (white box) to which they are linked.

12.3 Collection and processing of data from healthy children

All data from healthy children were collected in lab. 2 with the VICON 312 motion analysis system and two AMTI force plates embedded in the walkway in the middle of the lab. The whole body plugin marker set with KAD was used (Appendix I). For all children, standardised shoes with flexible soles were used. This was to standardise the baseline to make it comparable. Wedges of sizes 4° 12°, and 20° were used and customised for each shoe size. Point Loading Rockers (PLRs) of 75% length of the shoe and 30° Toe Spring Angle (TSA) were also used and customised for each shoe size. All the wedges and rockers were attached to the shoes with double-sided tape and elastic adhesive bandages. The starting point and finishing point for walking were marked with coloured rubber strips laid on the walkway.

All the participants visited the gait lab once. The system was calibrated and prepared. Each participant was asked to perform walks with six different conditions – barefoot, with shoes only, with wedges, and with PLRs attached to the soles of the shoes. The barefoot was always performed first, followed by the other conditions in a random order; the order was randomised by asking the participant to pick from a lot. The barefoot condition was not included in randomisation because the markers were to be re-attached for the shod condition, and any change in marker attachment required a new static trial to be captured. No consistent recovery time was given to the participants between the walks except for the time taken to attach or remove the wedges, rockers and heels, which was never more than five minutes. However, adequate rest periods were given whenever required.

The wedges and rockers were attached to the soles of the shoes with double-sided tape and an elastic adhesive bandage to reinforce the attachment, ensuring safety and preventing movement between the attachment and the shoes. Every time a wedge or a rocker was attached, photographs of both legs were taken in standing to gain a lateral view of the knee, tibia and foot. The participant walked until three clean strikes on the force plates, by either of the legs, were obtained. The kinematic data acquisition and processing are explained in Sections 10.2.2 and 10.2.3 (pages: 121 to 125).

12.4 Collection and processing of data from children with CP

Data collection involving children with CP was carried out in three sessions. Before data collection commenced, all participants were checked for the appropriateness of the AFO. An AFO was deemed inappropriate if: a) the AFO buckled at the ankle on manual pressure, or there were marks at the ankle indicating buckling during walking, b) the angle of the ankle of the AFO was not casted to accommodate shortening of gastrocnemius, c) the anterior trim-lines at the ankle were not anterior to the malleoli, and d) when stood vertically on a bench, the shank of the AFO was inclined or reclined to the vertical. If an AFO was deemed inappropriate, a session was arranged with the orthotist to cast a new AFO prior to the first data collection session. During the casting, the angle in which the AFO was to be casted was determined. In order to do this, the ankle joint was moved in the direction of plantar-flexion to dorsi-flexion until any resistance due to spasticity or tightness in gastrocnemius was encountered, which was taken as the angle of ankle at which the AFO was to be casted. A heel wedge was attached to the AFO to accommodate for the plantar-flexion so that when stood vertically, the shank of the AFO was perpendicular to the ground. Any modifications to accommodate for differences in limb length were also made to the shoes. Once the new AFOs were made, the participants were given at least one week to become accustomed to the new AFOs before the commencement of data collection.

The first two data collection sessions were one-to-two weeks apart, after which permanent modifications were made to the shoes. The last session was two-to-four months after the participants had started to use the permanently modified shoes. In the first session kinematic and kinetic baseline data were collected, followed by tuning. Kinematic and kinetic data with different sizes of wedges or rockers were collected in the second session. Baseline physical examination data and quality of life data were collected in one of the first two sessions. After the first two sessions, the participants used tuned AFO-FC before coming back for the final session, when kinematic and kinetic data were collected while participants walked barefoot and using the final tuned prescription. Physical examination data and quality of life data were also collected in the final session. Figure 12.2 gives an overview of the number of visits and different tests carried out in each session.

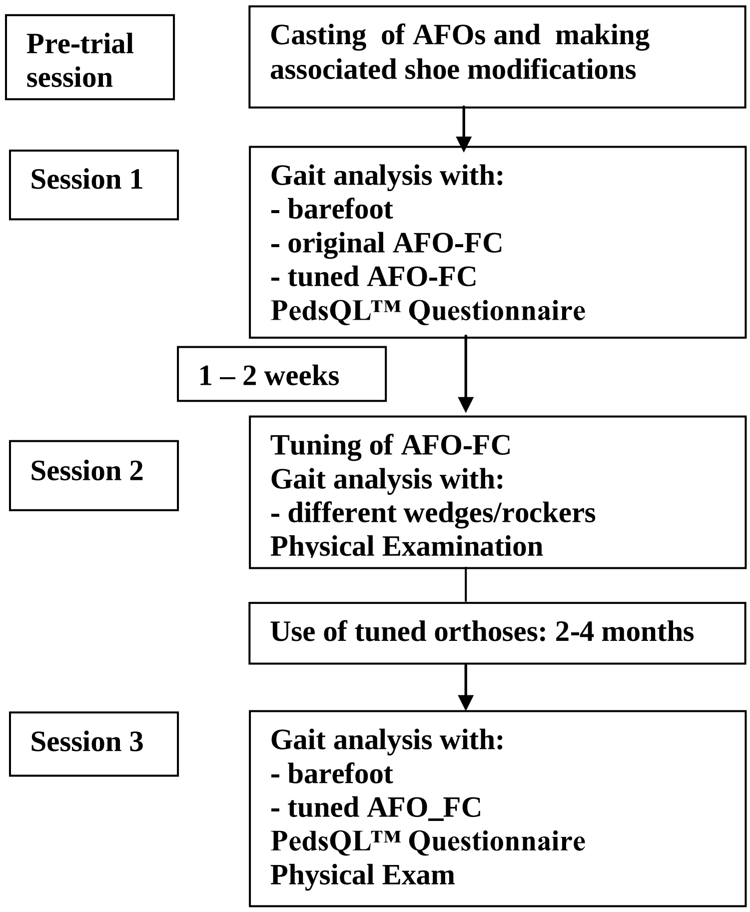


Figure 12.2 Flow chart showing the different visits by children with cerebral palsy and the measurements and/or interventions conducted during each session

Data collection occurred in both laboratories. However, the first two sessions for any participant were carried out in the same gait lab and the third session for all the children was carried out in gait lab. 2. The lower body and trunk marker set was used (Appendix I) and the same researcher placed the markers for all the children. Application of the heel marker was different from the standard protocol for the legs with AFOs. Instead of placing the heel marker in line with the toe marker, the placement was modified to account for the angle of the ankle in the AFO. For this the position of heel within the AFO was roughly estimated and the marker was placed on the AFO in line with the actual heel of the participant and the toe marker. Kinetic data were also collected using the AMTI force plates embedded in the walkway in both laboratories. Wedges of sizes 1°, 2°, 4°, 8°, 12°, 16° and 20° were used, customised according to shoe sizes. Point Loading Rockers (PLRs) of 20° and 30° toe spring angles were used. No standardised shoes or trainers were provided, as the shoes or trainers used by children were mostly customised to adapt the limb length differences or modifications on the splints. The data collection procedure with children with CP involved several steps. Data collection was carried out while the participant walked barefoot and with the non-tuned AFO-FC during the first session, followed by the tuning process (Figure 12.3).

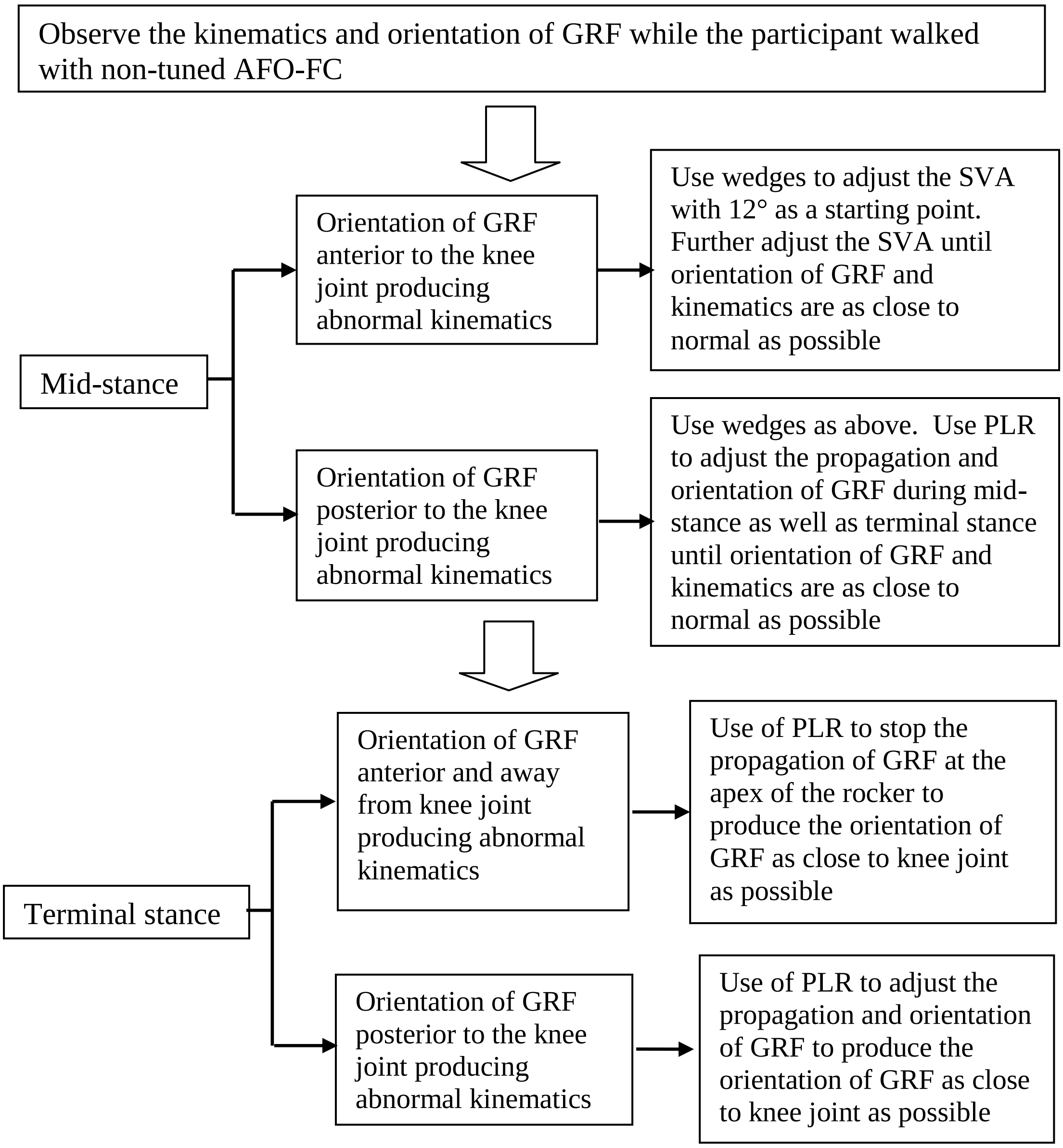


Figure 12. 3 Flow chart demonstrating the process of tuning using wedges and point loading rockers (PLRs) during data collection sessions.

While kinematic data acquisition was not an essential process of the tuning procedure, it was carried out to collect data at each stage of tuning. The tuning procedure was carried out in a particular order. The procedure was based on previous suggestions by Owen (2005) and Butler and Nene (1991).

Mid-stance tuning began by measurement of shank to vertical angle (SVA), which is the angle made by shank of the tibia to an imaginary vertical line perpendicular to the ground. The SVA was measured in standing using a goniometer. A photograph was also taken of the relevant leg to capture a lateral view of the base of support, foot, shank of tibia, and knee. Wedges were added to the shoes while measuring the SVA with each wedge until a SVA of 12° was obtained. The size of the initial wedge depended on the SVA of non-tuned AFO-FC. For example, if the SVA of the non-tuned AFO-FC was 4°, an 8° wedge was used, after which the wedge size was increased or decreased depending on the resultant SVA. This was continued until a SVA of 12° was obtained. The wedges were then stuck to the sole of the shoes with double-sided tape and reinforced by an elastic adhesive bandage. The participant then walked with the modified AFO-FC until three clean foot strikes on the force plates were obtained.

The orientation of the GRF during mid-stance was then visualised. For this, the researcher visually analysed the walk that demonstrated a clean strike on the force plate on the VICON Workstation display, to identify the orientation of the GRF in relation to the knee during mid-stance. Mid-stance was identified as the point where the ankle joint of the swinging leg crossed the weight-bearing leg. No more wedges were added if the GRF passed through the centre of the knee. However, if the GRF did not pass through the centre of the knee, the procedure was repeated with more or fewer wedges, data collection, and visual analysis of the GRF, until the wedge size which allowed the GRF to pass as close to the knee as possible during mid-stance was identified.

Following on from mid-stance, terminal stance was tuned. This was only attempted for children whose GRF was not aligned posterior to the hip joint and anterior to the knee joint during terminal stance. When the orientation of the GRF during terminal stance was not optimal, a PLR was added, with the apex of the rocker at 75% of the shoe length. The GRF orientation was then visually analysed and the length was increased or decreased depending on the orientation of the GRF. For example, if the aim was to move the GRF further anterior during terminal stance, a longer rocker was used. This was continued until the alignment of the GRF was as optimal as possible. Once the prescription was finalised, the session was concluded.

Some of the data for the analysis of the effects of wedges were collected as a part of the tuning protocol; the rest was collected during the second visit, where there was randomised use of pre-determined wedge sizes. The rocker data were collected separately for one child in the second visit. The original plan was to collect data for wedge sizes 4°, 8°, 12°, 16° and 20°. However, 8° and 12° were given priority, owing to the 4° being really small, and the 16° and 20° wedges being too big. Prioritisation was conducted on the basis that children with CP tire very easily, making it less likely that all the data could be collected as planned. Because tuning of the AFO-FC and data collection for 8° and 12° wedges were given priority it was not possible to randomise the wedges or rockers used.

The baseline physical examination was carried out in one of the first two sessions, depending on the availability of time. It involved assessment of passive range of motion (PROM), muscle strength, and muscle tone. For muscle strength, manual muscle testing was carried out using Medical Research Council (MRC) grading. The positioning and procedure are explained in Appendix V. Muscles were scored for strength, ranging from zero to five. The scoring sheet is also provided in Appendix VIII. Muscle tone was analysed using the Modified Ashworth Scale (MAS), in which muscles were scored between zero and five. The protocol for tone assessment is given in Appendix VI and the scoring sheet is given in Appendix VIII. PROM was assessed manually, as explained in Appendix VII. The parent was then asked to fill in the PedsQL™ generic module questionnaire to gather baseline data for quality of life. The questionnaire and instructions are given in Appendix IX.

After the first two sessions, the AFO-FCs were permanently modified according to the prescriptions that were decided during the tuning session. The prescription was completed using a format designed by the orthotist and was sent away to the technicians, who made permanent modifications to the shoes. The permanent modifications were always made using high density micro rubber. The prescription sheet is provided in Appendix X. Once permanent modifications had been made, they were checked against the prescription; where they were not appropriate, the shoes were sent back for appropriate alteration. The modified shoes with the AFOs were then regularly used by the children until the final session.

During the final session kinematic and kinetic data were collected while the participants walked barefoot and with modified AFO-FC. This was followed by the physical examination procedure, as for the baseline data collection session. The parent was then asked to fill in the PedsQL questionnaire for a second time to gather the final data for quality of life.

12.6 Data analysis

Data analysis was carried out using the following software: SPSS version 15 and 16, Microsoft Excel 2003 and Matlab version R2008a. Data analysis involved a mixture of statistical analysis and qualitative interpretation of line graphs that portrayed kinematics and kinetics. With the exception of the study into reliability of mid-stance identification, all investigations compared the following variables:

a) Temporal-spatial parameters: selected temporal-spatial parameters such as walking speed, cadence, and stride-length. These data were extracted from Microsoft Excel output files created by the Polygon authoring tool

b) Shank to Vertical Angle (SVA): The SVAs recorded during sessions were used in comparisons.

c) Gait Deviation Index GDI): The Excel file provided as an addendum to the original paper published on the GDI (Schwartz and Rozumalski 2008) was used to calculate the GDI for each child. To calculate the GDI, the data from healthy children was entered first in the relevant cells.The data used were the kinematics of the pelvis and hip in all three planes, knee and ankle in sagittal plane and foot progression angle. This was followed by entering the data of the participant with cerebral palsy, for the condition of which the GDI was to be estimated in the relevant cells (for example barefoot data from participant 1). The GDI value produced by the excel file was then noted. This was repeated for all participants and all conditions compared.

d) Kinematic and Kinetic data points: The list of kinematic and kinetic data points compared and their definitions are given in Appendix XI. Key data points were identified in sagittal plane kinematics and kinetics; a Matlab programme was used to extract the data points for each of the walks from Microsoft Excel output files created by the Polygon authoring tool. The average of the data points for each participant for each condition (e.g.: barefoot, non-tuned AFO-FC, tuned AFO-FC) was taken wherever appropriate to enable further comparison between conditions.

To portray kinematics or moments of joints, line graphs were created in Microsoft Excel 2003. All the line graphs had the percentage gait cycle represented in the X-axis and degrees of movement represented in the Y-axis. For all comparisons, graphs of sagittal plane kinematics were created for the pelvis, hip and knee joints. Ankle joint kinematics were considered only for the data from healthy children, and for barefoot data from children with Cerebral Palsy. Graphs of sagittal plane moments were created for the hip, knee and ankle. Only external moments were considered in this project. In the kinematics graphs, hip and knee flexion movements were represented by a positive value and extension by negative. For the pelvis, increases in value represented increased anterior tilt, and decreases represented increased posterior tilt. For the ankle, positive values indicated dorsi-flexion and negative values indicated plantar-flexion. In the moments graphs, for the hip and knee joints, positive values were indicative of flexion moments and negative values of extension moments. However, for ankle joint moments positive values represented dorsi-flexion moments and negative values represented plantar-flexion moments. More detailed data analyses for specific data sets are provided in subsequent sections.

12.6.1 Data from healthy children

Data for kinematics and kinetics of all the lower limb joints for barefoot walking were used to form the normal database. For this, the averages of the data series of six walks for kinematics and three walks for kinetics for each of the 11 participants were established. Finally, the mean and standard deviations for all 11 participants were calculated. Further data analysis was conducted by comparing data for barefoot with shod; shod with four different sizes of wedges; and shod with rocker. Descriptive statistics, including means and standard deviations, were estimated for all the data points for all conditions. The Shapiro-Wilk's test was carried out to check whether all the data points in all the conditions were normally distributed.

Inferential analyses were carried out with a mixture of tests based on the number of conditions compared and distribution of the data. For comparisons between data for barefoot and shod, and shod and rocker, the paired t- test or the Wilcoxon signed rank test was used depending on the distribution of the data. For the comparison between data for the shod condition and wedges, the repeated measures ANOVA or Friedman's ANOVA was used depending on the distribution of data. For the data points with significant changes, post hoc pair-wise analysis was carried out using the paired t-test or the Wilcoxon signed rank test depending on the distribution of the data. For all the primary comparisons the significance level (p) was pre-determined at 0.05. For the post hoc pair-wise comparisons the significance level was adjusted using the Bonferonni correction (Portney and Watkins 2000). Line graphs portraying kinematics and kinetics of each of the joints were constructed using average data series for 11 participants for all the conditions.

12.6.2 Data from children with CP

Several comparisons were made between different data sets to look at the effects of AFOs, the immediate effects of tuning, effects over time, and effects of different wedges, rockers and heels. Data analysis involved a mixture of group-wise comparisons and case studies owing to small sample size. Since the sample included children with different gait patterns, the possibility existed that tuning might produce different effects on kinematic and kinetic data points in different children. Taking this possibility into consideration, the decision was taken to analyse the immediate effects of tuning as a group, as well as through individual case studies.

To investigate the effects of AFOs on walking, the kinematic and kinetic data points, temporal-spatial parameters, the SVA and GDI were compared statistically for barefoot and for the non-tuned AFO-FC. Means and standard deviations were estimated for all the data points. The Shapiro-Wilk's test was used to check the distribution of the data. For normally distributed data, the paired t-test was used to statistically compare the data points between conditions: AFO-FC and barefoot; the Wilcoxon Signed rank test was used for data points which were not normally distributed. The significance level was predetermined as 0.05. Similar analysis was performed to compare the effects of the non-tuned and tuned AFO-FCs. Further comparison was conducted using individual case studies. The kinematic data points were compared statistically between the conditions barefoot and non-tuned AFO-FC, and non-tuned AFO-FC and tuned AFO-FC, for each of the case studies using a paired t-test. However, kinetic data points were not compared statistically since there were only three walks with kinetic data. Line graphs comparing sagittal kinematics and kinetics between barefoot, non-tuned AFO-FC, and tuned AFO-FC were also used to look into the overall gait cycle.

To investigate the effects of tuning over time, the kinematic and kinetic data points, temporal-spatial parameters, the SVA and the GDI were compared between the following conditions:

- data from barefoot at baseline (barefoot baseline) and barefoot after three months (barefoot final),
- data from the tuned prescription in the first session (tuned immediate) and with the modified AFO-FC after shor-term intervention (tuned final), and
- data from the original prescription in the first session (non-tuned AFO-FC) and with the modified AFO-FC after short-term intervention (tuned final).

To negate the effects of growth on the comparison of temporal-spatial parameters, normalisation was carried out based on formulae previously discussed in Section 3.3 (page: 29). Comparisons were also made between baseline and final data for physical examination measures such as muscle tone, muscle strength and passive range of motion (PROM), and quality of life data using the PedsQL™. Means and standard deviations were calculated for all the measures compared. The Shapiro Wilk's test was used to check the distribution of data for all the parametric measures, including kinematic and kinetic data points and PROM between baseline and final. Kinematic and kinetic data points were statistically compared between barefoot baseline and barefoot final, tuned immediate and tuned final, and non-tuned AFO-FC and tuned final using the paired t-test or the Wilcoxon signed rank test depending on the distribution of the data. Measures with non parametric data included Modified Ashworth Scale (MAS) for muscle tone, the MRC scale for muscle strength, and the PedsQL™ scores for four domains and total score for quality of life. These were statistically compared between baseline and final using the Wilcoxon signed rank test. Power analysis was carried out, in which statistical power and effect size of differences in gait deviation index (GDI) and temporal-spatial parameters were calculated for the comparisons, barefoot baseline – barefoot final and non-tuned AFO-FC – tuned final. Sample size required to detect a change of medium effect size in GDI with a power of 0.8 and $p < 0.05$ was determined.

The effects of wedges and rocker were investigated using case studies. Three different cases studies of children with different gait patterns were used to look into the effects of different sizes of wedges. One case study was used to compare the non-tuned AFO-FC with two Point Loading Rockers (PLRs). Means and standard deviations of the kinematic data points were estimated. The kinematic data points, SVA and temporal-spatial parameters were compared statistically between the non-tuned AFO-FC and wedges or rockers using repeated measures ANOVA. For all the data points with significant main effects, post hoc analysis was carried out using paired t-tests with Bonferroni correction. However, the kinetic data points were not compared statistically since there were only three walks with kinetic data. In addition, while comparing rockers with the shod condition, peak vertical forces (FZ1 and FZ2) (Appendix XI) were also included. Line graphs comparing sagittal kinematics and kinetics between the conditions were also used to look into the overall gait cycle.

Table 12.1 Different comparisons carried out in the present project and analysis used

Sample	Studies	Comparisons - Type of comparison		Analysis
Healthy children	Study 1: Effects of shoes and effects of wedges and rockers	Barefoot - shod	Group-wise	Paired t-test / Wilcoxon signed rank test. Qualitative analysis of graphs
		Wedges - shod	Group-wise	Repeated measures ANOVA /Friedman's ANOVA, post hoc analysis using paired t-test / Wilcoxon signed rank test Qualitative analysis of graphs
		Rocker - shod	Group-wise	Paired t-test / Wilcoxon signed rank test. Qualitative analysis of graphs
Children with Cerebral Palsy	Study 3: Effects on different sizes of wedges and rockers	Non tuned AFO-FC – wedges	Case studies	Repeated measures ANOVA /Friedman's ANOVA. Qualitative analysis of graphs
		Non tuned AFO-FC – Rocker	Case studies	Repeated measures ANOVA /Friedman's ANOVA. Qualitative analysis of graphs
	Study 2: Effects of AFOs and immediate effects of tuning of AFO-FC	Barefoot – non tuned AFO-FC	Group-wise	Paired t-test / Wilcoxon signed rank test.
			Case studies	Paired t-test / Wilcoxon signed rank test. Qualitative analysis of graphs
		Non tuned AFO-FC – tuned AFO-FC	Group-wise	Paired t-test / Wilcoxon signed rank test. Qualitative analysis of graphs
	Study 4: Feasibility study on short-term effects of tuning	Barefoot baseline – barefoot after short-term intervention	Group-wise	Paired t-test / Wilcoxon signed rank test.
		Non tuned AFO-FC – Tuned AFO-FC after short-term intervention	Group-wise	Paired t-test / Wilcoxon signed rank test.
		Tuned AFO-FC before short-term intervention – tuned AFO-FC after short-term intervention	Group-wise	Paired t-test / Wilcoxon signed rank test.

CHAPTER 13 EFFECTS OF SHOES, ROCKERS AND WEDGES ON GAIT OF HEALTHY CHILDREN: RESULTS AND DISCUSSION

13.1 Introduction

The aims of this study were to:

- generate reference data for the gait of healthy children for comparison,
- investigate the role of shoes in gait, and
- investigate the influences of rockers and wedges on gait in healthy children.

Meeting these aims will enable identification of the compensatory mechanisms of normal children in adapting to Point Loading Rockers (PLR) and wedges, which may then be compared with those of children with Cerebral Palsy (CP).

Although kinetic and kinematic paediatric gait plots are available in the literature (Davis and Ounpuu 2004; Ounpuu, Gage, and Davis 1991; Sutherland et al. 1988), it was considered optimal to use control data collected by the researchers in this study, using the same equipment, and within same age group, as the patients. The role of footwear in AFO intervention has been investigated before (Churchill, Halligan and Wade 2003; Hesse et al. 1996), but there are limited published data on the effects of shoes on the gait of healthy children. One study which focused on this used a younger age range and shoes which were not standardised (Oeffinger et al. 1999).

No studies investigating the effects of heel raises (wedges), or point loading rockers (PLRs) on the gait of healthy children were found. It is envisaged that the data collected from this study will provide insights into how children adapt, or compensate, when their alignment is perturbed; this might be of assistance in interpreting data collected from children with CP. Analysis of the gait patterns of healthy adults has been conducted with modifications such as heel raises and PLRs (Eisenhardt et al. 1996; Franklin et al. 1995; Hullin and Robb 1991; Long et al. 2007; Myers et al. 2003; Myers et al. 2006; Opila-Correia 1990; Peterson, Perry, and Montgomery 1985; Snow and Williams 1994; Wu, Rosenbaum and Su 2004). Although direct comparisons between gait data from adults and children cannot be made, the patterns of adaptation demonstrated by healthy adults may be useful.

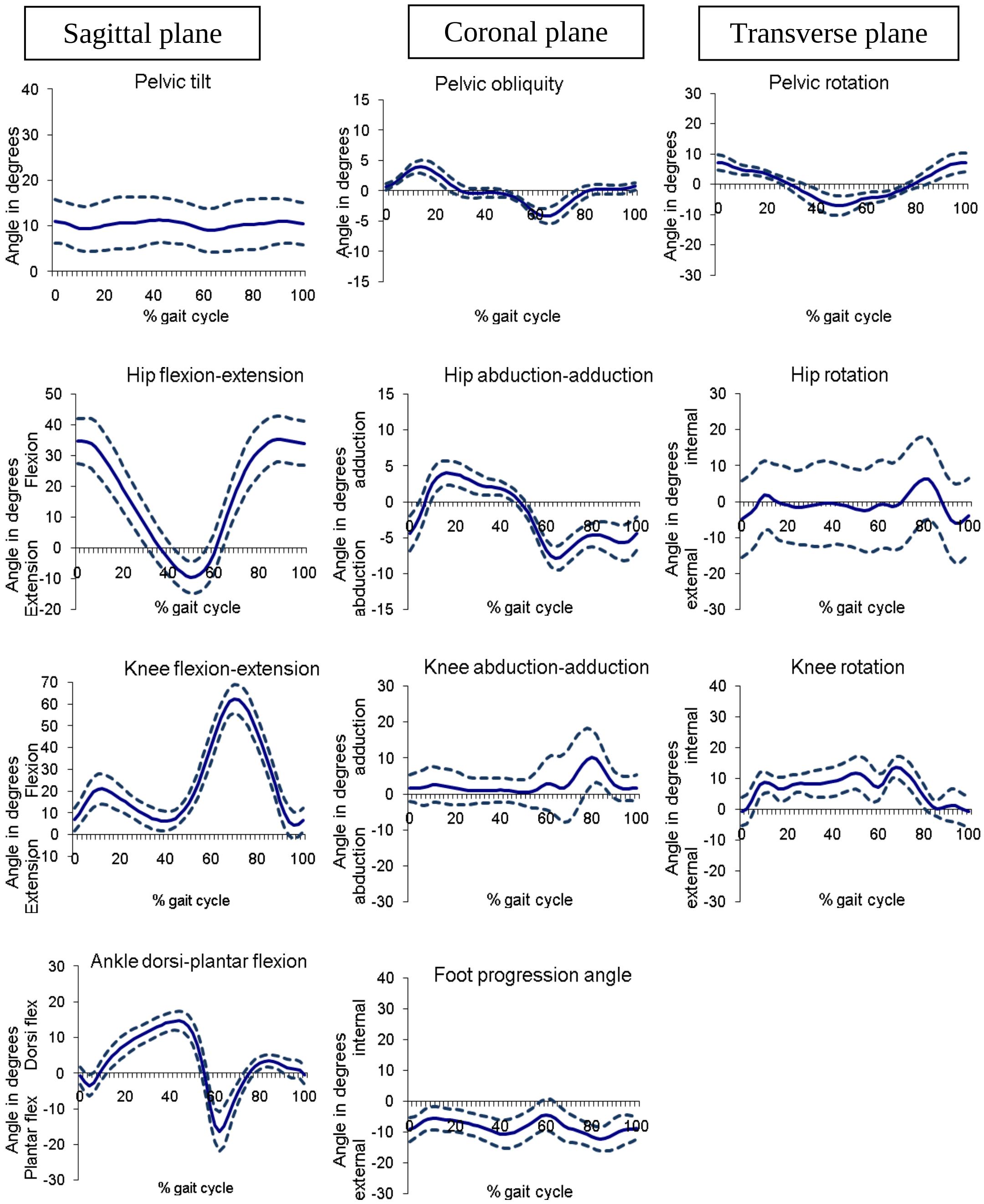


Figure 13.1 Graphs demonstrating average (± SD) lower limb joint kinematics of healthy children (n = 11) for one complete gait cycle.

Note: Continuous line denotes average and dotted lines denote ± 1 standard deviation.

13.2 Results

In order to investigate the separate effects of shoes, wedges and rockers, comparisons between several conditions were made. The conditions compared (acronyms/short forms used given in brackets) were:

a. barefoot walking (barefoot) – walking with shoes (shod)
b. walking with shoes (shod) – walking with a 4° wedge (4DW), 12° wedge (12DW) and 20° wedge (20DW) attached to the shoes
c. walking with shoes (shod) – walking with a PLR attached to the shoes

Data analysis in this study was carried out by statistically analysing the selected temporal-spatial parameters and sagittal plane kinematic and kinetic data points between the conditions compared, as well as through qualitative (descriptive) analysis of the kinematic and kinetic plots. However, it should be noted that the plots illustrate average gait patterns from all 11 healthy participants. Each participant walked at a self-selected walking speed, so the timing of the kinematic and kinetic data points was lost for each individual participant in the plots.

13.2.1 Healthy reference data

Healthy reference data are presented as kinematic plots of the pelvis, hip, knee and ankle, and kinetic plots of hip, knee and ankle, in all three planes. This enabled comparison between the data in the present study and in the existing literature. Figures 13.1 and 13.2 represent the kinematic and kinetic data from 11 healthy children walking barefoot for one complete gait cycle. The continuous line represents the average for 11 children, and the dotted lines represent ± 1 standard deviations (SD).

The greatest variability in kinematics was seen in hip rotation, followed by knee abduction-adduction (Figure 13.1). In the kinetics, the variability was observed to be larger in the plots illustrating peak hip extension, peak knee flexion and peak ankle dorsi-flexion moments, when compared with other parts of the gait cycle (Figure 13.2). However, it must be remembered that the individual timings for peaks and troughs are not represented in the graphs.

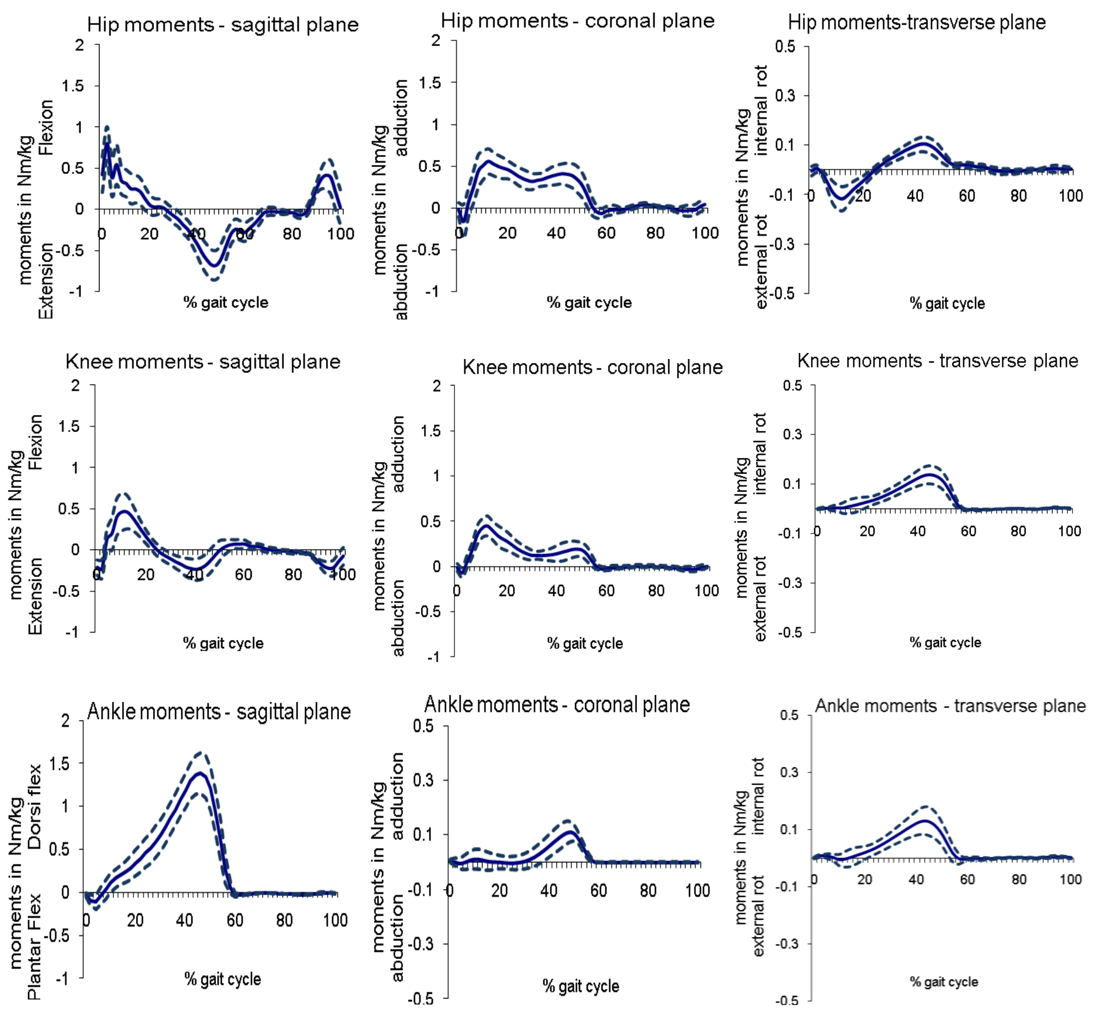


Figure 13.2 Graphs demonstrating average (± SD) lower limb joint kinematics of healthy children (n = 11) for one complete gait cycle.

Note: Continuous line represents average and dotted lines represent ± 1 standard deviation.

13.2.2 Comparison between barefoot and shod walking

In this comparison, temporal-spatial parameters and kinematic and kinetics data points were considered as well as average kinematic and kinetic plots. The influence of shoes on gait was evident, with significant changes in temporal-spatial parameters and kinetics and kinematics of hip, knee and ankle. However, the key changes observed were in stride-length, ankle moments, ankle dorsi-flexion and knee flexion at initial contact, and knee and hip ROM.

Table 13.1 shows temporal-spatial data. There was increased stride-length ($p<0.001$) and decreased cadence ($p<0.004$) with shoes compared to barefoot, demonstrating that with shoes, participants were taking longer steps, but fewer per minute.

Table 13.1 Descriptive and inferential analysis of selected temporal-spatial parameters in healthy children - shod and barefoot

Variables	Descriptive analysis		Inferential analysis			
	Barefoot	Shod	D (SD)	95% CI of the D		*p* value
	Mean (SD)	Mean (SD)		Lower	Upper	
Cadence (steps/minute)	**132.4 (19.8)**	**119.7 (15.5)**	**12.64 (6.2)**	**8.44**	**16.83**	**0.004**
Stride-length (m)	**1.3 (0.1)**	**1.4 (0.2)**	**-0.14 (0.1)**	**-0.20**	**-0.08**	**<0.001**
Walking speed (m/s)	1.4 (0.2)	1.4 (0.2)	-0.01 (0.1)	-0.09	0.07	0.59
Key: (SD) Standard Deviation, (D) Mean Difference, (CI) Confidence Interval, significance level *p*<0.05, Significant results in **bold**						

Kinematic changes were more prevalent in the proximal joints than in the ankle joint (Table 13.2). However, although statistically significant, these changes were small; mean differences fewer than 3° were evident in proximal joints, including higher peak knee flexion ($p = 0.04$), peak hip flexion ($p=0.001$), and peak hip flexion during stance ($p=0.01$) in shod compared to barefoot. The key changes include: increases in hip ROM ($p = 0.001$) and knee ROM ($p = 0.02$) in shod compared to barefoot, which were probably related to an increase in stride-length. Furthermore, there were key changes during initial contact, such as a 6° increase in ankle dorsi-flexion ($p = 0.001$), and a 4.4° decrease in knee flexion ($p = 0.005$) in shod compared to barefoot (Table 13.2).

Table 13.2 Descriptive and inferential analysis of selected kinematic data points in healthy children - shod and barefoot

Variables	Descriptive analysis		Inferential analysis			
	Barefoot	Shod	D (SD)	95% CI of the D		*p* value
	Mean (SD)	Mean (SD)		Lower	Upper	
Pelvic Kinematics						
Peak anterior pelvic tilt	12.8 (5.5)	12.8 (5.5)	0.04 (1.2)	-0.74	0.82	0.91
Peak posterior pelvic tilt	7.8 (4.7)	7.7 (5.0)	0.15 (1.1)	-0.61	0.91	0.68
Pelvic tilt ROM	5.0 (1.0)	5.1 (0.9)	-0.11 (0.7)	-0.60	0.39	0.64
Knee Kinematics						
Knee flexion at IC	**6.9 (5.2)**	**2.5 (4.4)**	**4.37 (4.0)**	**1.69**	**7.06**	**0.005**
Peak knee flexion (stance)	21.5 (7.1)	20.9 (6.2)	0.61 (3.7)	-1.86	3.07	0.60
Peak knee extension	5.6 (4.2)	4.1 (2.8)	1.47 (4.4)	-1.47	4.41	0.29
Peak knee flexion	**62.9 (6.4)**	**65.8 (5.2)**	**-2.89 (4.0)**	**-5.57**	**-0.22**	**0.04**
Knee ROM	**57.3 (4.1)**	**61.6 (5.6)**	**-4.36 (5.1)**	**-7.78**	**-0.95**	**0.02**
Hip kinematics						
Peak Hip flexion	**36.9 (7.6)**	**39.6 (8.0)**	**-2.69 (2.0)**	**-4.04**	**-1.33**	**0.001**
Peak Hip extension	-9.8 (5.2)	-11.3 (5.7)	1.48 (2.7)	-0.34	3.31	0.10
Peak hip flexion (stance)	**35.2 (7.6)**	**37.4 (8.2)**	**-2.18 (2.3)**	**-3.71**	**-0.66**	**0.01**
Hip ROM	**46.7 (5.4)**	**50.9 (6.2)**	**-4.17 (3.1)**	**-6.25**	**-2.09**	**0.001**
Ankle Kinematics						
Ankle angle in sagittal plane at initial contact	**-0.7 (2.4)**	**5.3 (3.8)**	**-5.97 (4.5)**	**-9.01**	**-2.93**	**0.001**
Peak dorsi-flexion	15.4 (2.3)	15.0 (3.2)	0.39 (2.9)	-1.57	2.35	0.59
Peak Plantar-flexion	-17.3 (5.4)	-16.5 (4.7)	-0.82 (2.6)	-2.56	0.93	0.33
Ankle ROM	32.7 (6.1)	31.7 (4.9)	1.07 (3.7)	-1.42	3.57	0.36

Key: (SD) Standard Deviation, (D) Mean Difference, (CI) Confidence Interval, significance level $p<0.05$, all values except p values in degrees, significant results in **bold**

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Unlike kinematics, the kinetic changes were predominantly seen at the ankle joint (Table 13.3), with higher peak ankle dorsi-flexion moments (p = 0.04) and peak ankle plantar-flexion moments (p < 0.01) in shod compared to barefoot. Among the proximal joints, only the peak hip extension moments were significantly higher (p = 0.01) in shod compared to barefoot conditions.

Table 13.3 Descriptive and inferential analysis of selected kinetic data points in healthy children - shod and barefoot

Variables	Descriptive analysis		Inferential analysis			
	Barefoot	Shod	D (SD)	95% CI of the D		*p* value
	Mean (SD)	Mean (SD)		Lower	Upper	
Hip moments						
Peak hip flexion moments	0.88 (0.2)	0.95 (0.2)	-0.07 (0.2)	-0.20	0.05	0.23
Peak hip extension moments	**-0.71 (0.2)**	**-0.82 (0.1)**	**0.11 (0.1)**	**0.03**	**0.19**	**0.01**
Knee moments						
Peak knee flexion moments	0.50 (0.2)	0.47 (0.2)	0.03 (0.2)	-0.11	0.17	0.79
Peak knee extension moments	-0.27 (0.1)	-0.28 (0.1)	0.01 (0.1)	-0.06	0.08	0.83
Ankle moments						
Peak ankle dorsi-flexion moments	**1.41 (0.2)**	**1.48 (0.2)**	**-0.07 (0.1)**	**-0.15**	**0.00**	**0.04**
Peak ankle plantar-flexion moments	**-0.14 (0.1)**	**-0.25 (0.1)**	**0.11 (0.1)**	**0.05**	**0.17**	**0.002**
Key: (SD) Standard Deviation, (D) Mean Difference, (C)I) Confidence Interval, significance level *p*<0.05, all values except p values in Nm/kg, significant results in **bold**						

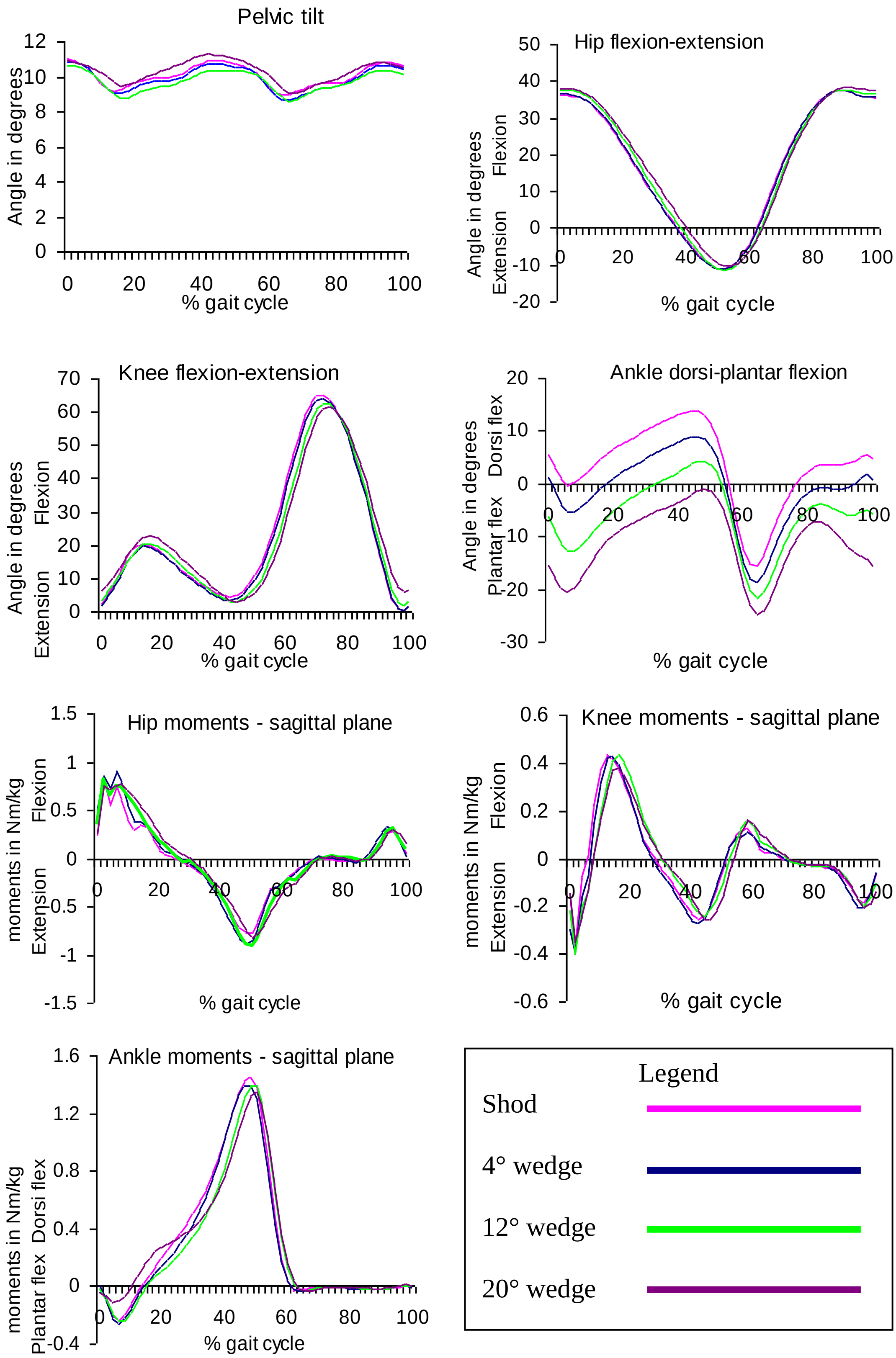


Figure 13.3 Graph comparing kinematics and kinetics in the sagittal plane between shod walking, and walking with 4° wedge,12° wedge and 20° during one complete gait cycle in healthy children

13.2.3 Comparisons between shod walking and walking with wedges

The key changes suggest that the influence of wedges was predominantly seen at the ankle joint (Figure 13.3, Tables 13.4 to 13.110). There were changes in knee joint kinematics, most frequently with the 20° wedge and occasionally with the 12° wedge.

Among the temporal-spatial parameters compared, stride-length ($p<0.001$, $F = 9.15$) and walking speed ($p = 0.02$, $F = 3.96$) showed significant main effects (Table 13.4). Pair-wise comparisons produced no significant differences in walking speed, and only two pairs were significantly different for stride-length: the 20° wedge produced a lower stride-length compared to shod and to the 4° wedge (Table 13.5). However, it should be noted that Bonferroni corrections were applied to the pair-wise comparisons.

Table 13.4 Results of statistical comparisons of temporal-spatial parameters between conditions – shod, 4° wedge, 12° wedge and 20° wedge

Variables	Shod Mean (SD)	4° wedge Mean (SD)	12° wedge Mean (SD)	20° wedge Mean (SD)	*p* value
Cadence (steps/minute)	119.7 (15.5)	125.1 (21.6)	122.9 (18.7)	124.2 (19.4)	0.53
Stride-length (m)	**1.39 (0.18)**	**1.39 (0.17)**	**1.36 (0.15)**	**1.30 (0.17)**	**<0.001**
Walking speed (m/s)	**1.38 (0.17)**	**1.43 (0.17)**	**1.38 (0.18)**	**1.32 (0.14)**	**0.02**
Key: (SD) Standard Deviation, significance level *p*<0.05, Significant results in **bold**					

Table 13.5 Results of statistical pair-wise comparisons of selected temporal-spatial parameters between conditions – shod, 4° wedge, 12° wedge and 20° wedge.

Variables	Pairs compared		Mean Difference	*p* value*	95% CI for Difference	
					Lower	Upper
Walking speed (m/s)	Shod	4DW	-0.05	0.09	-0.15	0.04
	Shod	12DW	-0.003	0.92	-0.10	0.10
	Shod	20DW	0.06	0.15	-0.06	0.17
	4DW	12DW	0.05	0.16	-0.06	0.16
	4DW	20DW	0.11	0.01	-0.003	0.22
	12DW	20DW	0.06	0.05	-0.03	0.15
Stride-length (m)	Shod	4DW	0.002	0.93	-0.06	0.06
	Shod	12DW	0.03	0.08	-0.02	0.08
	Shod	**20DW**	**.095**	**0.005**	**0.01**	**0.18**
	4DW	12DW	0.03	0.18	-0.04	0.09
	4DW	**20DW**	**.093**	**0.002**	**0.02**	**0.17**
	12DW	20DW	0.06	0.01	-0.002	0.13
Key: (CI) Confidence Interval, significance level *p*<0.008, Significant results in **bold**						

Table 13.6 Results of statistical comparison of selected kinematic data points between conditions – shod, 4° wedge, 12° wedge and 20° wedge

Variables	Shod Mean (SD)	4° wedge Mean (SD)	12° wedge Mean (SD)	20° wedge Mean (SD)	p value
Pelvic Kinematics					
Peak anterior pelvic tilt	12.8 (5.5)	12.4 (5.8)	12.6 (5.8)	13.0 (5.2)	0.58
Peak posterior pelvic tilt	7.7 (5.0)	7.3 (5.7)	7.0 (5.3)	7.7 (5.0)	0.27
Pelvic tilt ROM	5.1 (0.9)	5.2 (1.0)	5.6 (0.8)	5.3 (1.0)	0.27
Knee Kinematics					
Knee flexion at IC	**2.5 (4.4)**	**2.2 (4.3)**	**3.8 (5.1)**	**6.5 (7.1)**	**<0.001**
Peak knee flexion (stance)	**20.9 (6.2)**	**20.1 (5.3)**	**21.3 (6.8)**	**23.5 (6.9)**	**0.01**
Peak knee extension (stance)	**4.1 (2.8)**	**3.0 (2.9)**	**2.2 (4.1)**	**1.9 (3.9)**	**0.01**
Peak knee flexion	**65.8 (5.2)**	**64.7 (5.6)**	**63.1 (5.7)**	**61.9 (6.5)**	**<0.001**
Knee ROM	**61.6 (5.6)**	**61.8 (5.9)**	**60.9 (6.5)**	**59.9 (6.2)**	**0.03**
Hip Kinematics					
Peak hip flexion	**39.6 (8.0)**	**39.2 (7.7)**	**40.1 (7.9)**	**40.7 (7.7)**	**0.04**
Peak hip extension	-11.3 (5.7)	-11.5 (5.9)	-11.6 (5.9)	-10.7 (5.5)	0.26
Peak hip flexion (stance)	**37.4 (8.2)**	**37.2 (7.4)**	**38.4 (8.2)**	**38.8 (7.5)**	**0.02**
Hip ROM	50.9 (6.2)	50.7 (4.7)	51.7 (5.6)	51.3 (5.1)	0.52
Ankle Kinematics					
Ankle angle in sagittal plane at initial contact	**5.3 (3.8)**	**1.1 (3.7)**	**-6.4 (4.4)**	**-15.7 (4.9)**	**<0.001**
Peak dorsi-flexion	**15.0 (3.2)**	**10.3 (2.9)**	**5.5 (3.3)**	**-0.2 (2.6)**	**<0.001**
Peak plantar-flexion	**-16.5 (4.7)**	**-20.4 (4.6)**	**-23.2 (4.0)**	**-26.4 (4.5)**	**<0.001**
Ankle ROM	**31.7 (4.9)**	**30.7 (4.9)**	**28.7 (4.2)**	**26.2 (4.0)**	**<0.001**
Key: (SD) Standard Deviation, all values except p values are in degrees, significance level *p*<0.05, significant results in **bold**					

The results from statistical comparison of the kinematic data points between shod and wedges for main effect are given in Table 13.6. There were significant differences in ankle angle in the sagittal plane at IC (p <0.001, *F* = 135.65), peak dorsi-flexion (p <0.001, Chi-Square = 33.00), peak plantar-flexion (p <0.001, Chi-Square = 26.78), ankle ROM (p<0.001, *F* = 20.01), knee flexion during IC (p <0.001, *F* = 9.03), peak knee flexion during stance (p = 0.01, *F* = 5.19), peak knee extension (p = 0.01, Chi-Square = 10.75), peak knee flexion (p<0.001, *F* = 10.26), knee ROM (p = 0.03, *F* = 4.22), peak hip flexion during stance (p = 0.02, *F* = 3.94) and peak hip flexion during swing (p = 0.04, *F* = 3.08) (Table 13.6).

Table 13.7 Results of statistical pair-wise comparisons of selected kinematic data points related to ankle joint between conditions – shod, 4°, 12° and 20° wedges

	Pairs compared		Mean Difference	*p* value *	95% CI for Difference	
					Lower	Upper
Ankle angle in sagittal plane at initial contact	**Shod**	**4DW**	**4.143**	**<0.001**	**1.52**	**6.77**
	Shod	**12DW**	**11.669**	**<0.001**	**9.13**	**14.20**
	Shod	**20DW**	**21.002**	**<0.001**	**15.90**	**26.11**
	4DW	**12DW**	**7.526**	**<0.001**	**5.21**	**9.84**
	4DW	**20DW**	**16.859**	**<0.001**	**12.26**	**21.46**
	12DW	**20DW**	**9.334**	**<0.001**	**5.45**	**13.22**
Peak dorsi-flexion	**Shod**	**4DW**	**4.704**	**<0.001**	**2.02**	**7.39**
	Shod	**12DW**	**9.521**	**<0.001**	**6.31**	**12.74**
	Shod	**20DW**	**15.204**	**0.003**	**12.81**	**17.60**
	4DW	**12DW**	**4.817**	**<0.001**	**3.44**	**6.19**
	4DW	**20DW**	**10.500**	**0.003**	**8.04**	**12.96**
	12DW	**20DW**	**5.683**	**0.003**	**3.08**	**8.29**
Peak Plantar-flexion	**Shod**	**4DW**	**3.863**	**0.003**	**2.45**	**5.27**
	Shod	**12DW**	**6.711**	**0.003**	**3.22**	**10.20**
	Shod	**20DW**	**9.913**	**0.003**	**5.99**	**13.83**
	4DW	12DW	2.85	0.01	-0.08	5.77
	4DW	**20DW**	**6.049**	**0.004**	**2.63**	**9.47**
	12DW	20DW	3.20	0.02	-0.23	6.64
Ankle ROM	Shod	4DW	0.96	0.22	-1.44	3.36
	Shod	**12DW**	**2.948**	**<0.001**	**1.15**	**4.75**
	Shod	**20DW**	**5.430**	**<0.001**	**2.24**	**8.62**
	4DW	12DW	1.99	0.02	-0.31	4.28
	4DW	**20DW**	**4.469**	**<0.001**	**1.59**	**7.34**
	12DW	**20DW**	**2.482**	**0.003**	**0.37**	**4.60**

Key: (CI) Confidence Interval, significance level *p*<0.008, all values except p values in degrees, significant results in **bold**

Table 13.8 Results of pair-wise comparison of selected knee kinematic data points between conditions – shod, 4° wedge, 12° wedge and 20° wedge

	Pairs compared		Mean Difference	*p* value*	95% CI for Difference	
					Lower	Upper
Knee flexion at initial contact	Shod	4DW	0.37	0.56	-1.68	2.42
	Shod	12DW	-1.23	0.17	-3.91	1.44
	Shod	**20DW**	**-3.924**	**0.01**	**-7.69**	**-0.15**
	4DW	12DW	-1.61	0.02	-3.52	0.31
	4DW	**20DW**	**-4.298**	**0.003**	**-7.97**	**-0.62**
	12DW	20DW	-2.69	0.03	-6.04	0.66
Peak knee flexion (stance)	Shod	4DW	0.78	0.23	-1.23	2.79
	Shod	12DW	-0.39	0.69	-3.45	2.68
	Shod	20DW	-2.66	0.02	-5.70	0.38
	4DW	12DW	-1.17	0.20	-3.92	1.59
	4DW	20DW	-3.44	0.01	-7.04	0.15
	12DW	20DW	-2.27	0.05	-5.60	1.05
Peak knee extension (stance)	Shod	4DW	1.18	0.03	-0.44	2.80
	Shod	12DW	1.92	0.04	-0.81	4.65
	Shod	20DW	2.21	0.03	-0.54	4.96
	4DW	12DW	0.74	0.25	-1.42	2.90
	4DW	20DW	1.03	0.21	-1.25	3.32
	12DW	20DW	0.29	0.58	-1.40	1.99
Peak knee flexion	Shod	4DW	1.04	0.07	-0.61	2.69
	Shod	**12DW**	**2.7**	**0.005**	**0.21**	**5.04**
	Shod	**20DW**	**3.9**	**0.003**	**0.59**	**7.19**
	4DW	12DW	1.58	0.05	-0.68	3.85
	4DW	20DW	2.86	0.01	-0.23	5.94
	12DW	20DW	1.27	0.04	-0.44	2.98
Knee ROM	Shod	4DW	-0.14	0.56	-0.90	0.62
	Shod	12DW	0.70	0.26	-1.25	2.66
	Shod	20DW	1.68	0.02	-0.21	3.57
	4DW	12DW	0.85	0.24	-1.36	3.06
	4DW	**20DW**	**1.9**	**0.007**	**0.06**	**3.58**
	12DW	20DW	0.98	0.194	-1.32	3.28

Key: (CI) Confidence Interval; significance level $p<0.008$, all values in degrees except p values, significant results in **bold**

Pair-wise comparisons of the kinematic data points related to the ankle with significant main effect are given in Table 13.7. There were significant difference in all pairs except four – two for peak plantar-flexion (4° and 12° wedges, 12° and 20° wedges) and two for ankle ROM (shod and 4° wedge, 4° and 12° wedges) (Table 13.7). The changes in ankle kinematic data points and the ankle kinematics graph showed distinct patterns of change – increasing plantar-flexion throughout the gait cycle, and decreasing ankle ROM with increasing size of wedges (Table 13.7 and Figure 13.3).

Pair-wise comparisons of knee kinematic data points with significant main effect revealed that most of the changes were seen with the 20° wedge (Table 13.8). Only two pairs were significantly different from each other for peak knee flexion (12° wedge and shod, and 20° wedge and shod), in which wedges produced less knee flexion compared to shod. The 20° wedge had significantly less knee ROM compared to shod, and higher knee flexion at initial contact compared to both shod and the 4° wedge. Pair-wise comparisons of the kinematic data points relating to the hip with significant main effect are given in Table 13.9. Statistical significance was achieved between the 4° wedge and 20° wedge only for peak hip flexion in stance, with that for the 20° wedge being higher. However, the mean difference was only 1.5°.

Table 13.9 Results of pair-wise comparison of selected kinematic data points related to hip joints between conditions – shod and 4°, 12° and 20° wedges

	Pairs compared		Mean Difference	*p* value *	95% CI for Difference	
					Lower	Upper
Peak hip flexion (stance)	Shod	4DW	0.13	0.82	-1.63	1.89
	Shod	12DW	-1.08	0.11	-3.12	0.96
	Shod	20DW	-1.39	0.05	-3.44	0.66
	4DW	12DW	-1.21	0.05	-2.95	0.53
	4DW	**20DW**	**-1.52**	**0.002**	**-2.68**	**-0.36**
	12DW	20DW	-0.31	0.58	-2.10	1.47
Peak Hip flexion	Shod	4DW	0.41	0.41	-1.15	1.98
	Shod	12DW	-0.43	0.40	-2.04	1.19
	Shod	20DW	-1.03	0.04	-2.43	0.38
	4DW	12DW	-0.84	0.06	-2.12	0.44
	4DW	20DW	-1.44	0.02	-3.19	0.31
	12DW	20DW	-0.60	0.36	-2.64	1.44
Key: (CI) Confidence Interval, all values except p values in degrees, significance level $p<0.008$, Significant results in **bold**						

Table 13.10 Results of statistical comparison of selected kinetic data points between conditions – shod, 4° wedge, 12° wedge and 20° wedge.

Variables	Shod Mean (SD)	4° wedge Mean (SD)	12° wedge Mean (SD)	20° wedge Mean (SD)	*p* value
Hip moments					
Peak hip flexion moment	0.95 (0.21)	1.10 (0.27)	1.01 (0.18)	1.03 (0.24)	0.22
Peak hip extension moment	**-0.82 (0.12)**	**-0.93 (0.13)**	**-0.97 (0.13)**	**-0.90 (0.16)**	**0.01**
Knee moments					
Peak knee flexion moment	0.47 (0.18)	0.48 (0.18)	0.48 (0.25)	0.44 (0.24)	0.90
Peak knee extension moment	-0.28 (0.12)	-0.31 (0.14)	-0.26 (0.17)	-0.29 (0.13)	0.42
Ankle moments					
Peak dorsi-flexion moment	1.48 (0.21)	1.47 (0.28)	1.49 (0.21)	1.39 (0.27)	0.06
Peak plantar-flexion moment	**-0.25 (0.08)**	**-0.28 (0.06)**	**-0.27 (0.07)**	**-0.17 (0.08)**	**<0.001**
Key: (SD) Standard Deviation, all values except p values are in Nm/kg, significance level *p*<0.05, significant results in **bold**					

Table 13.11 Results of statistical pair-wise comparison of selected kinetic data points between conditions– shod, 4° wedge, 12° wedge and 20° wedge.

	Pairs compared		Mean Difference	*p* value*	95% CI for Difference	
					Lower	Upper
Ankle moments						
Peak ankle plantar-flexion moments	**Shod**	**4DW**	**.034**	**0.03**	**0.002**	**0.07**
	Shod	12DW	0.02	1.00	-0.03	0.07
	Shod	20DW	-0.08	0.06	-0.17	0.003
	4DW	12DW	-0.01	1.00	-0.06	0.04
	4DW	**20DW**	**-.116**	**0.01**	**-0.20**	**-0.03**
	12DW	**20DW**	**-.104**	**0.002**	**-0.17**	**-0.04**
Hip moments						
Peak hip extension moments	**Shod**	**4DW**	**.115**	**0.02**	**0.02**	**0.22**
	Shod	**12DW**	**.151**	**0.01**	**0.04**	**0.26**
	Shod	20DW	0.08	0.36	-0.06	0.22
	4DW	12DW	0.04	1.00	-0.06	0.13
	4DW	20DW	-0.04	1.00	-0.14	0.07
	12DW	20DW	-0.07	1.00	-0.21	0.07
Key: (CI) Confidence Interval, all values except p values in Nm/kg, significance level *p*<0.05, significant results in **bold**						

The results of statistical comparison of kinetic data points between shod and wedges for main effect are given in Table 13.10. Significant main effects were seen in the peak ankle plantar-flexion moments (p = 0.001, F = 14.92), and hip extension moments (p = 0.01, Chi-Square = 12.38) (Table 13.10).

Post hoc pair-wise comparisons of kinetic data points with significant main effect are given in Table 13.11. The peak ankle plantar-flexion moments were higher in shod and with 20° wedges when compared with the 4° wedge, and were also higher with the 20° wedge compared with the 12° wedge. Post hoc pair-wise comparisons of the hip kinetic data points revealed that the 4° wedge and 12° wedge produced significantly larger hip extension moments than shod (Table 13.11).

13.2.4 Comparison of Shod walking to walking with Point Loading Rocker (PLR)

Similar to wedges, the influence of PLRs on joint kinematics and kinetics was seen predominantly at the ankle joint. None of the temporal-spatial parameters were significantly different (Table 13.12).

Table 13.12 Descriptive and inferential analysis of selected temporal-spatial parameters in healthy children - shod and PLR

Variables	Descriptive analysis		Inferential analysis			
	Shod	PLR	D (SD)	95% CI of the D		*p* value
	Mean (SD)	Mean (SD)		Lower	Upper	
Cadence (steps/minute)	119.7 (15.5)	119.3 (14.8)	0.49 (7.0)	-4.19	5.18	0.82
Stride-length (m)	1.4 (0.2)	1.3 (0.2)	0.09 (0.1)	-0.01	0.18	0.06
Walking speed (m/s)	1.4 (0.2)	1.3 (0.1)	0.10 (0.2)	-0.04	0.23	0.13
Key: (PLR) Point Loading Rocker, (SD) Standard Deviation, (D) Mean Difference, (CI) Confidence Interval, significance level p<0.05, Significant results in **bold**						

Table 13.13 Descriptive and statistical analysis of selected kinematic data points in healthy children - shod and PLR

Variables	Descriptive analysis		Inferential analysis			
	Shod	PLR	D (SD)	95% CI of the D		p value
	Mean (SD)	Mean (SD)		Lower	Upper	
Pelvic Kinematics						
Peak anterior pelvic tilt	12.8 (5.5)	13.0 (5.6)	-0.16 (1.7)	-1.29	0.97	0.76
Peak posterior pelvic tilt	7.7 (5.0)	7.3 (5.4)	0.41 (1.6)	-0.64	1.47	0.40
Pelvic tilt ROM	5.1 (0.9)	5.7 (1.1)	-0.57 (1.0)	-1.21	0.06	0.07
Knee Kinematics						
Knee flexion at initial contact	2.5 (4.4)	4.2 (6.6)	-1.63 (3.5)	-3.99	0.74	0.16
Peak knee flexion (stance)	20.9 (6.2)	19.7 (6.7)	1.18 (3.9)	-1.47	3.83	0.34
Peak knee extension (stance)	4.1 (2.8)	3.5 (4.2)	0.64 (3.4)	-1.62	2.91	0.54
Peak knee flexion	**65.8 (5.2)**	**62.9 (6.1)**	**2.85 (2.5)**	**1.20**	**4.51**	**.003**
Knee ROM	61.6 (5.6)	59.4 (6.2)	2.21 (3.4)	-0.06	4.48	0.06
Hip kinematics						
Peak Hip flexion	39.6 (8.0)	39.1 (8.6)	0.54 (2.3)	-0.97	2.05	0.44
Peak Hip extension	**-11.3 (5.7)**	**-9.1 (5.8)**	**-2.19 (3.3)**	**-4.39**	**0.002**	**0.05**
Peak hip flexion (stance)	37.4 (8.2)	36.2 (8.2)	1.21 (2.9)	-0.72	3.14	0.19
Hip ROM	50.9 (6.2)	48.2 (4.2)	2.74 (4.3)	-0.13	5.60	0.06
Ankle Kinematics						
Ankle angle in sagittal plane at initial contact	**5.3 (3.8)**	**2.0 (5.1)**	**3.29 (2.3)**	**1.75**	**4.82**	**0.001**
Peak dorsi-flexion	15.0 (3.2)	14.1 (4.9)	0.91 (2.8)	-0.92	2.75	0.29
Peak plantar-flexion	-16.5 (4.7)	-14.5 (5.9)	-1.98 (4.8)	-5.21	1.25	0.20
Ankle ROM	**31.7 (4.9)**	**28.6 (4.8)**	**3.03 (3.93)**	**0.39**	**5.67**	**0.03**

Key: (PLR) Point Loading Rocker, (SD) Standard Deviation, (D) Mean Difference, (CI) Confidence Interval, all values except p values in degrees, significance level $p<0.05$, significant results in **bold**

The statistical comparisons of kinematic data points between shod and PLR are given in Table 13.13. Ankle dorsi-flexion at initial contact ($p < 0.001$) and total ankle ROM ($p = 0.03$) were smaller with the PLR in comparison to shod. The two other changes seen in kinematics were lower peak knee flexion in swing ($p = 0.003$) and higher peak hip extension ($p = 0.05$) with PLR compared to shod (Table 13.13). However, the mean differences were low for peak knee flexion (2.9°) and peak hip extension (2.2°).

The mean data and standard deviations as well as statistical comparison of kinetic data between shod and PLR are given in Table 13.14. The peak ankle dorsi-flexion moments were significantly smaller ($p = 0.002$) and peak ankle plantar-flexion moments were significantly higher ($p < 0.04$) with PLR compared to shod. No other parameters were significantly different.

Table 13.14 Descriptive and inferential analysis of selected kinetic data points in healthy children - shod and PLR

Variables	Descriptive analysis		Inferential analysis			
	Shod	PLR	D (SD)	95% CI of the D		*p* value
	Mean (SD)	Mean (SD)		Lower	Upper	
Hip moments						
Peak hip flexion moments	0.95 (0.21)	0.93 (0.26)	0.03 (0.2)	-0.12	0.18	0.72
Peak hip extension moments	-0.82 (0.12)	-0.79 (0.17)	-0.03 (0.2)	-0.14	0.08	0.59
Knee moments						
Peak knee flexion moments	0.47 (0.18)	0.49 (0.23)	-0.01 (0.2)	-0.15	0.12	0.82
Peak knee extension moments	-0.28 (0.12)	-0.27 (0.14)	-0.01 (0.1)	-0.07	0.05	0.72
Ankle moments						
Peak ankle dorsi-flexion moments	**1.48 (0.21)**	**1.31 (0.21)**	**0.17 (0.1)**	**0.08**	**0.26**	**0.002**
Peak ankle plantar-flexion moments	**-0.25 (0.08)**	**-0.32 (0.15)**	**0.07 (0.2)**	**0.01**	**0.13**	**0.04**
Key: (PLR) Point Loading Rocker, (SD) Standard Deviation, (D) Mean Difference, (CI) Confidence Interval, significance level *p*<0.05, all values except p values in Nm/kg, significant results in **bold**						

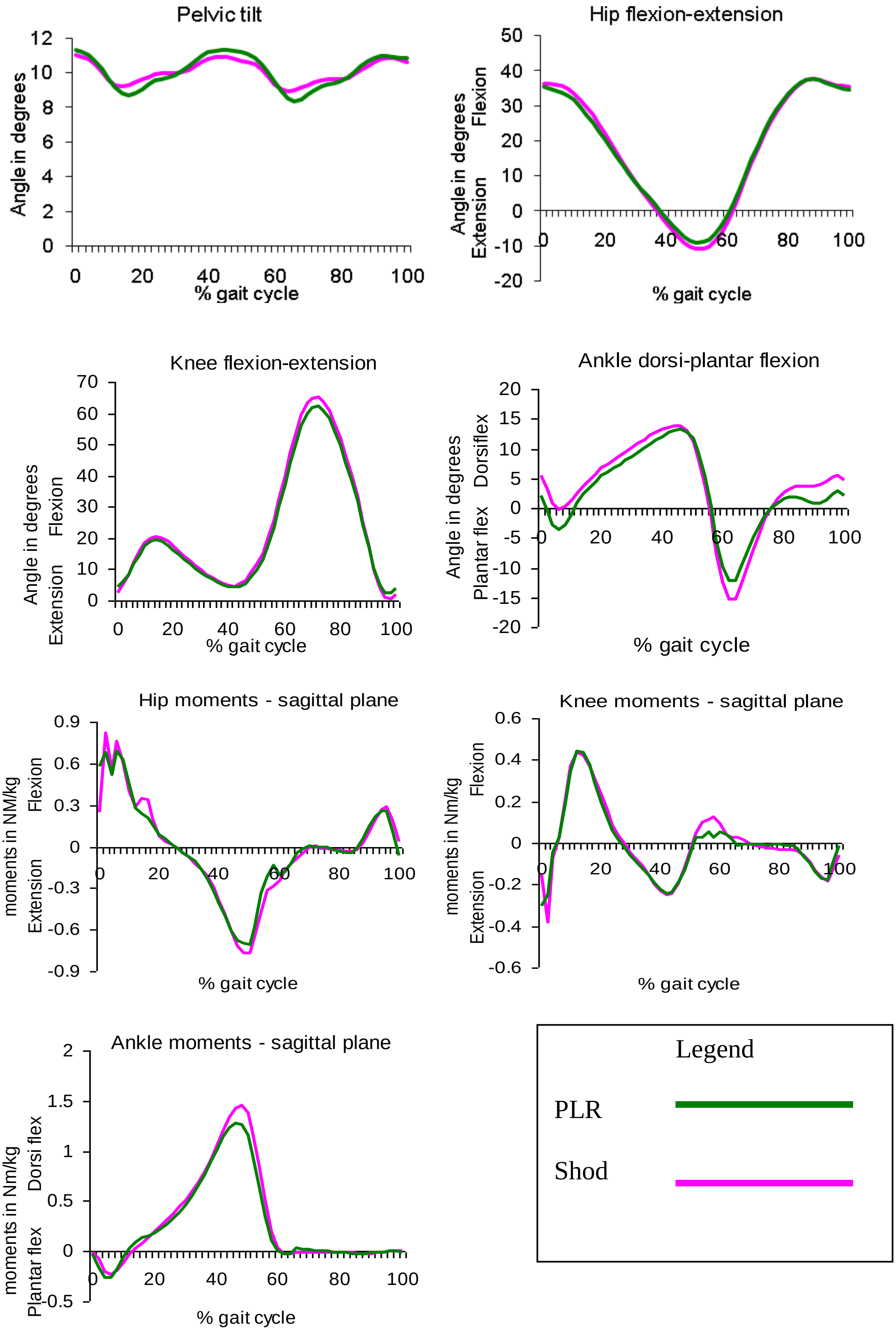


Figure 13.4 Graphs comparing sagittal plane kinematics and external moments between shod walking and walking with point loading rocker (PLR) during one complete gait cycle in healthy children.

The significant changes in the data points were also seen in the gait cycle graphs (Figure 13.4). The graphs showing hip and knee moments show an irregular pattern with PLR during pre-swing. Also, ankle dorsi-flexion during terminal stance was less with the PLR compared to shod (Figure 13.4). These were not statistically tested but should be noted for future discussion.

13.2.5 Summary of results – Healthy reference data

- Higher variability was seen with hip rotation and knee abduction-adduction movement through the gait cycle in the healthy reference data.
- The participants walked with longer strides and fewer steps per minute with shoes compared to barefoot. The knee and hip ROMs were higher with shod compared to barefoot. During initial contact, the ankle was more dorsiflexed and knee was less flexed with shoes compared to barefoot. Peak ankle plantar-flexion and dorsi-flexion moments, and peak hip extension moments were greater with shod compared to barefoot.
- Walking with wedges predominantly influenced the ankle joint kinematics by increasing plantar-flexion more with increased size of wedge compared to shod walking. The influence of wedges on the knee joint was mainly seen with the 20° wedge, with greatest peak knee flexion and knee flexion at initial contact, and lowest ROM.
- The influence of wedges on moments was much less than that on kinematics, with no consistent pattern. Peak ankle plantar-flexion moments were lower for the 20° wedge than for other wedges. Changes in the proximal joint kinetics were mainly seen with the 12° wedge, with the highest peak hip extension moments.
- Similar to wedges, walking with the PLR predominantly affected the ankle joint. There was decreased ankle ROM, ankle dorsi-flexion during intial contact, peak ankle dorsi-flexion moments, and increased peak ankle plantar-flexion moments with the PLR compared to shod.

13.3 Discussion

The aims of this study were to generate reference data for the gait of healthy children, and investigate the role of shoes and influences of wedges and PLRs on their gait. These aims are discussed in turn.

The kinematic and kinetic data presented using the group averages, ± 1 standard deviation (SD) for 11 healthy children in the current study are comparable with data reported by Ounpuu, Gage and Davis (1991). The age range selected by Ounpuu and colleagues (1991) (5 to 16 years) was close to that reported in the current study. While the plots of average kinematics and kinetics were similar between the studies, the variability (± 1 SD) was less in the current study compared with the study by Ounpuu, Gage and Davis (1991). The differences in variability may relate to differences in the systems used. Ounpuu, Gage and Davis (1991) used three infra-red television cameras which collected data at 30 frames per second, whereas the present study made use of six high resolution cameras with a sampling rate of 100 frames per second.

Hip rotation has been rendered prone to error owing to the high risk of soft tissue artefacts, and the femoral frontal plane being dependent on definition of the knee flexion extension axis (Schache, Baker, and Lamoreux 2008). The latter is likely to have contributed to the higher variability of hip rotation in the current sample, suggested by variability in the abduction-adduction movement of the knee. Another contributory factor is likely to be the illustration of average gait patterns from 11 healthy participants in kinetic and kinematic plots, losing individual timings of peaks and troughs. This is one of the disadvantages of averaging gait cycle data; however, the differences for healthy participants were small. Data processing for healthy children was conducted in a similar manner to that for the children with CP, where averaging is required because of the degree of individual variability.

13.3.1 Effects of shoes on the gait of healthy children

The results of the current study were comparable to those of a previous study (Oeffinger et al. 1999) that compared gait parameters between shod and barefoot walking in healthy children in a younger age group (7 to 10 years). The significant increase in stride-length and unchanged walking speed with the use of shoes in the current study were similar.

Oeffinger et al. (1999) attributed the change in stride-length to two different possibilities; firstly, increase in distal mass causing increased inertia during the swing phase, and thereby an increased stride-length; and children being more comfortable with shoes compared to barefoot. The increase in hip and knee ROM, along with the increase in stride-length, suggest that children were probably more comfortable walking with shoes. It was seen in the current study that while children were walking with longer steps, they were taking fewer steps with shoes, which probably contributed to the unchanged walking speed. The increased knee and hip ROM may also be associated with the increase in stride-length. Interestingly, an increase in stride-length with shoes compared to barefoot was reported by Hesse et al (1996) and Churchill, Halligan and Wade (2003), who made the comparison in adult patient populations.

Lower knee flexion and higher ankle dorsi-flexion at initial contact with shoes compared to barefoot in the current study also corroborates the findings of Oeffinger et al. (1999). In the current study it was observed that while walking barefoot, children preferred to enter the stance phase more flat-footed when compared to the shod condition, which may also explain the higher ankle dorsi-flexion with shoes at initial contact. Higher knee flexion at initial contact and reduced hip flexion during initial stance and terminal swing with barefoot may take place to compensate for the lack of dorsi-flexion. It is possible that children are trying to reduce the impact of heel strike during barefoot through this compensation.

The increased plantar-flexion moments during initial stance with shoes compared to barefoot in the current study may have resulted from the higher impact during initial contact due to non-compressible soles of the shoes. Weist and Waters (1979) compared four different heels with varying compressibility using a case study approach and reported that the least compressible material produced the highest tibial advancement torque. This may account for the altered kinematics in the current study. Oeffinger et al (1999) did not find increased plantar-flexion moments during initial stance with shoes. However, they reported increased dorsi-flexion moments during terminal stance with shoes compared to barefoot which was the case in the current study. The differences between the present study and that of Oeffinger et al. (1999) may be attributed to the difference in standardisation of shoes. While standardised shoes were used in the current study, the shoes used by Oeffinger et al. (1999) were not identical, which might have resulted in more variability and thus a lack of significant changes. However, comparisons cannot be made owing to the fact that Oeffinger et al. (1999) did not provide mean differences, standard deviations of the differences, or confidence intervals for their data.

Even though there were statistically significant differences in several gait parameters between shod and barefoot walking, the clinical significance of this has been questioned before by Oeffinger et al. (1999); they suggested that the influence of shoes is negligible when evaluating the effectiveness of orthoses using clinical gait analysis. However, in the current study there were mean differences in kinematics as high as 6° in ankle dorsi-flexion during initial contact. Furthermore, the use of shoes influenced the torque production at ankle and hip, and increased stride-length. This suggests that shoes do influence key variables of gait in healthy children and should be taken into consideration when reviewing the gait of children with CP.

13.3.2 Effects of wedges on the gait pattern of healthy children

The findings of the current study demonstrated predominant changes in the ankle joint with most of the wedges, and some changes in proximal joints and temporal-spatial parameters with higher wedges. Interestingly, these findings were similar to the existing literature, although the previous studies used adult samples and used different heel heights and not wedges. Comparison of the results from the current study with the existing literature becomes further limited because of the differences in standardisation of heels in previous studies (Eisenhardt et al. 1996; Franklin et al. 1995; Johanson et al. 2006; Opila-Correia 1990; Snow and Williams 1994; Valentini et al. 2009). While the current study relied on the inclination of the top surface of the wedges to standardise wedge size, all the studies used height of the heel as standard. In most of the studies different shoes were used for different heel heights (Eisenhardt et al. 1996; Franklin et al. 1995; Opila-Correia 1990; Snow and Williams 1994), whereas Valentini et al (2009) attached heel lifts directly to the soles of the feet.

In the current study there is a shift towards plantar-flexion throughout the gait cycle, which increases proportionally to the wedge size. Similar findings were reported in the adult population by Snow, Keith and Williams (1994). While the post hoc pair-wise comparisons revealed two pairs which were not statistically significant, it was clear from the mean values and mean graphs (Table 13.7 and Figure 13.3) that there is a shift towards plantar-flexion. This is understandable, considering the inclination of wedges. It could be seen from the graph comparing ankle kinematics that ankle joint plantar-flexion was also higher with larger sized wedges during terminal swing. The ankle was kept plantar flexed during heel strike with wedges, probably to acquire a more flat foot contact to reduce foot-slap during the loading response. It is also possible that healthy children were adapting to the increasing sizes of wedges predominantly at the ankle joint, thereby leaving the proximal joints largely unaffected. The decrease in peak plantar-flexion moments with the 20° wedge is probably associated with the highly plantar flexed position of the foot during initial contact, negating the need for external plantar-flexion moments.

Among the knee parameters in the current study, while all the data points were significant for the main effect, post hoc analyses showed only a few significant differences. Interestingly, most changes seen occurred with use of the 20° wedge in comparison to shod, or to the 4° wedge. In healthy adults, Opila-Correia (1990) and Snow, Keith and Williams (1994) also reported changes in knee kinematics with high heels, which may be considered equivalent to the largest wedge in the present study. The increase in knee flexion during initial contact and peak knee flexion during stance with the 20° wedge compared to shod corroborated the findings of Opila-

Correia (1990). Increased knee flexion at initial contact was found to aid the plantar flexed ankle at initial contact, resulting in a flat foot entry to the stance phase. This in turn might have reduced the work of pretibtial muscles to prevent the foot-slap that would result from rapid shift of weight bearing to the fore-foot. The decrease in peak knee flexion with the 12° wedge and 20° wedge compared to shod was in line with the findings of Opila-Correia (1990) and Snow, Keith and Williams (1994), who reported decreased knee flexion during swing with high heels in healthy adults. Although reduction in knee flexion during swing was not expected to be directly related to heel height (Snow, Keith and Williams 1994), it might reflect the lack of comfort and confidence of children with the 20° wedge, resulting in shorter strides. The decrease in stride-length with the 20° wedge in the current study was similar to the findings of Opila-Correia et al. (1990) in healthy adults. The reduction in knee ROM with the 20° wedge in the current study may be attributed to the reduction in peak knee flexion during swing, since peak knee extension did not differ between conditions.

It could be seen from the kinematic data points and plots that the kinematics were mostly affected by the highest heel, whereas the results for shoes and the 4° wedge were similar. The shift to plantar-flexion was probably an attempt to maintain the centre of mass (COM) within the base of support. Snow, Keith and Williams (1994) noted that the COM moves anteriorly with high heeled shoes. Another study noted that pressure under the fifth and third metatarsal heads peaked earlier with high heels (Eisenhardt et al. 1996). It was clear that most of the adaptation to the wedges was happening at the ankle joint, except for the 20° wedge, with which the hip and knee joints showed some changes.

It is possible that healthy children were compensating predominantly at the ankle joint with increasing sizes of wedges. However, with the highest wedge there were changes in proximal joint kinematics. It was noticed that the changes in proximal joint kinetics were less compared to changes in kinematics; this suggests that the participants may have started compensating, with changes in proximal joint kinematics to maintain the optimal moments. However, this is conjecture and cannot be ratified by the current literature. Nevertheless, such a phenomenon is not unheard of. Selles et al. (2004) suggested two possible strategies in trans-tibial amputees to enable adaptation to mass perturbations; these were the kinematic invariance strategy and the kinetic invariance strategy. In the kinematic invariance strategy the kinematics remain the same while kinetics change, whereas in the kinetics invariance strategy the opposite occurs. More investigation is needed with smaller increments of wedge sizes and statistical analysis of gait pattern as a whole (e.g. Fourier analysis of time series) to arrive at more definite conclusions.

It was evident that healthy children compensated for the increasing size of wedge at the ankle joint, which raises the question of what happens when ankle movement is restricted.

13.3.3 Effects of the point loading rocker (PLR) in gait parameters of healthy children

Several studies have looked into the effects of rockers on kinematics and kinetics of gait (Hullin and Robb 1991; Hullin, Robb and Loudon 1992; Long et al. 2007; Myers et al. 2003; Myers et al. 2006; Peterson, Perry, and Montgomery 1985; Wu, Rosenbaum and Su 2004), but comparison of their results with the present study has limitations. Most of the studies used different designs of rocker (Long et al. 2007; Myers et al. 2006; Wu, Rosenbaum and Su 2004; Peterson, Perry, and Montgomery 1985), and all the studies except one (Hullin, Robb and Loudon 1992) were based on adults. Among the two studies (Hullin and Robb 1991; Hullin, Robb and Loudon 1992), which used a PLR that was similar to that used in the current study, Hullin and Robb (1991) conducted an adult case study with immobilised ankle, and Hullin Robb and Louden (1992) studied a sample of children with myelomeningocele who were using AFOs.

It is of note that the finding of no significant differences in the temporal-spatial parameters in the current study is corroborated by most of the studies, conducted in different populations (Hullin and Robb 1991; Hullin, Robb and Loudon 1992; Long et al. 2007; Myers et al. 2003; Myers et al. 2006; Peterson, Perry and Montgomery

1985; Van Bogart et al. 2005; Wu, Rosenbaum and Su 2004). The higher dorsi-flexion with shoes compared to the PLR during initial contact in the current study was similar to the findings of Peterson, Perry and Montgomery (1985) who investigated the effects of rockers in healthy women. This may occur as an attempt to reduce the work required by pretibial muscles to prevent foot-slapping, since for all the participants in the current study, the PLR made the sole of the foot rigid as well as increased the height of the heel. The decrease in ankle ROM in the present study may also be attributed to the presence of a rigid sole and the decreased plantar-flexion during pre-swing and initial swing. Wu, Rosenbaum and Su (2004) also reported reduced ROM in the sagittal plane between the hind-foot and tibia when a rocker was used.

The higher peak plantar-flexion moments and smaller peak dorsi-flexion moments with PLRs seen in the current study represented the loading response and terminal stance respectively. Similar findings were reported by Myers et al. (2006). Reductions in dorsi-flexion moments during terminal stance were also reported by Van Bogart et al. (2005) and Long et al. (2007). The reduction in dorsi-flexion moments during terminal stance in the current study might be due to the PLR assisting the third rocker of gait, which in turn reduced the demand on plantar flexors. Peterson, Perry and Montgomery (1985) also noted an increased rate of unloading in vertical forces during terminal stance with rocker shoes.

While none of the kinetic data for proximal joints were significantly different between walking with shoes and PLRs, the sagittal plane moments graphs revealed irregular patterns during pre-swing. This might be caused by a lack of smooth transition of force at the apex of the PLR during terminal stance. The lack of smooth transition from stance to swing was also observed by Peterson, Perry and Montgomery (1985) in healthy women. The higher peak plantar-flexion moments with PLRs in the current study might have been due to the increased height of heel, resulting in an increased heel lever, thus causing an increased moment arm at the ankle.

It was evident that the rocker did not have a major influence on the gait parameters of healthy children except at the ankle joint. The healthy children predominantly compensated for the PLR at the ankle. While in healthy children the metatarso-phalyngeal, tarso-metatarsal and mid-tarsal joints provide the third rocker of gait, this might not be the case for children with CP who use AFOs, potentially affecting their already deficient ability to produce an effective third rocker of gait. Wu, Rosenbaum and Su (2004) noted a reduction in fore-foot movement in healthy adults with the use of a rocker, which was attributed to the ability of the rocker to imitate the fore-foot movement. Hullin, Robb and Loudon (1992) suggested that the use of a PLR controls the position of the GRF at the apex of a PLR and thereby allows roll-over of the tibia. Small but statistically significant changes in the current and previous studies indicate that a PLR can be used to influence the GRF vector and enhance the third rocker of gait.

13.4 Conclusion

The data from healthy children not only provided reference data for comparison, but, also demonstrated compensatory mechanisms adopted by children without any gait abnormalities in response to the addition of wedges and rockers. The role of shoes in walking was evident, with differences in temporal-spatial parameters and joint kinematics and kinetics, affecting proximal joints. While the PLR did not have a great influence on the proximal joints, several adaptations at the ankle were seen. Similarly, healthy children responded to increasing sizes of wedge by compensating at the ankle. This study provided an insight into the role of shoes and effects of wedges and PLRs on the gait of healthy children. This may help to explain the biomechanics of tuning of AFO-FC in children with CP.

CHAPTER 14 EFFECTS OF NON-TUNED AFO-FC AND IMMEDIATE EFFECTS OF TUNED AFO-FC: RESULTS AND DISCUSSION

14.1 Introduction

The aims of this study were to:

- investigate the effects of non-tuned AFO-FC compared to barefoot on gait of children with CP,
- investigate immediate effects of tuned AFO-FC compared to non-tuned AFO-FC on gait of children with CP.

Several studies have investigated the effects of rigid AFOs on gait of the children with CP. However, ambiguity still exists in the literature relating to AFO intervention. A detailed account of existing literature on AFO intervention for CP is given in Chapter 6, (Page: 56). The ambiguity has been associated with lack of uniformity in sample sizes and participant characteristics (Balaban et al. 2007). Other considerations which were not considered by most the published studies include comparisons between different diagnostic groups, comparison between different gait patterns, appropriateness of AFO-FC and biomechanical optimisation (tuning) of AFO-FC.

The first section (part A) of this study takes into consideration the first three factors listed, while looking into the effects of AFO-FCs for children with CP. Part B of this study investigates the effects of tuning of AFO-FC on the gait of children with CP and takes into consideration diagnostic groups and gait patterns. The very few studies which investigated the effects of tuning of AFO-FC invariably reported positive results (Butler, Thompson and Major 1992; Stallard and Woollam 2003; Butler et al. 2007). However, there is a lack of evidence regarding effects of tuning of AFO-FC. Furthermore, comparisons between different diagnostic groups and gait patterns relating to the effects of tuning have not been considered. In order to achieve the comparisons between diagnostic categories and gait patterns, case study analysis was carried out in both parts of the study, as well as group comparisons.

The following definitions were applied in the present study: knee extension of less than 5° of flexion during mid and terminal stance was defined as knee hyperextension (Hullin, Robb and Loudon 1996); a change in any parameter towards normal was defined as improvement; and the opposite was defined as deterioration.

14.2 Results

This section presents the group comparisons and case study analysis of both parts of the study (parts A & B), structured to avoid repetition of information. In order to achieve this, the section is divided into three – first section (14.2.1) includes the group comparisons addressing part A of the study, namely the effects of non-tuned AFO-FC on gait of children with CP. The second section (14.2.2) includes the group comparisons addressing part B of the study, namely the immediate effects of tuning of AFO-FC on the gait of children with CP. Finally, the third section (14.2.3) includes the case study analysis that addresses the barefoot gait patterns of participants, and parts A and B of the study. The variables compared were – sagittal plane kinematic and kinetic data points, temporal-spatial parameters, shank to vertical angle (SVA) and gait deviation index (GDI)

14.2.1 Effects of non-tuned AFO-FC on gait of children with CP: group comparison of part A

This section elaborates on the comparison of all the variables between barefoot walking and walking with a non-tuned AFO-FC using the whole sample as one group. The key changes seen with the use of AFO-FC compared to barefoot include improvements in most of the temporal-spatial parameters and changes in kinetic data points. Improvements were also seen in a few kinematic data points.

Comparison of temporal-spatial parameters is given in Table 14.1. Stride-length was 0.16m longer ($p = 0.01$) and walking speed was 0.15 m/s faster ($p = 0.04$) with non-tuned AFO-FC compared to barefoot. The difference in cadence was not statistically significant, but there was a mean difference of 5 steps/minute and a wide confidence interval (-20.23 to 11.10). There was no significant difference in the gait deviation index. The SVA showed an improvement, with 3.4° greater mean shank inclination with non-tuned AFO-FC compared to barefoot ($p = 0.05$) (Table 14.1).

Table 14.1 Descriptive and inferential analysis of temporal-spatial parameters, GDI, and SVA between the conditions barefoot and non-tuned AFO-FC

	Descriptive analysis		Inferential analysis			
	Barefoot Mean (SD)	Non-tuned AFO-FC Mean (SD)	D (SD)	95% Confidence Interval of the difference		*p* value
				Lower	Upper	
Cadence (steps/minute)	117.7 (27.0)	122.3 (14.7)	-4.7 (21.9)	-20.2	11.1	0.53
Stride-length (m)	**0.82 (0.27)**	**0.98 (0.21)**	**-0.16 (0.11)**	**-0.24**	**-0.07**	**0.01**
Walking speed (m/s)	**0.84 (0.36)**	**0.99 (0.24)**	**-0.15 (0.20)**	**-0.30**	**-0.01**	**0.04**
GDI	79.9 (10.7)	79.5 (11.9)	0.36 (6.72)	-4.45	5.17	0.87
SVA (°)	**3.1 (3.9)**	**6.5 (2.5)**	**-3.4 (4.6)**	**-6.7**	**-0.1**	**0.04**
Key: SD- Standard deviation, SVA – Shank to Vertical Angle, GDI – Gait Deviation Index, significance level p < 0.05, significant results in **bold**						

Table 14.2 Descriptive and inferential analysis of kinematic data points between the conditions barefoot and non-tuned AFO-FC

	Descriptive analysis		Inferential analysis			
	Barefoot	Non-tuned AFO-FC	D(SD)	95% Confidence Interval of the D		*p* value
	Mean (SD)	Mean (SD)		Lower	Upper	
Pelvis kinematics						
Peak anterior pelvic tilt	21.8 (6.7)	23.0 (8.3)	-1.1 (3.1)	-3.3	1.1	0.27
Peak posterior pelvic tilt	13.4 (7.1)	14.4 (8.1)	-1.0 (3.2)	-3.3	1.3	0.35
Pelvic tilt ROM	8.4 (2.4)	8.5 (2.6)	-0.1 (1.5)	-1.2	1.0	0.81
Hip Kinematics						
Peak Hip flexion	44.2 (9.7)	46.1 (11.0)	-1.9 (6.3)	-6.4	2.6	0.37
Peak Hip extension	3.4 (8.8)	0.5 (8.1)	2.9 (5.4)	-0.9	6.8	0.12
Peak hip flexion (stance)	38.8 (10.9)	42.9 (12.3)	-4.0 (6.4)	-8.6	0.5	0.08
Hip ROM	**40.8 (9.0)**	**45.7 (6.2)**	**-4.8 (6.2)**	**-9.3**	**-0.4**	**0.04**
Knee kinematics						
Knee flexion at initial contact	19.1 (8.2)	20.7 (12.4)	-1.5 (9.0)	-8.0	4.9	0.60
Peak knee flexion (stance)	22.4 (8.4)	27.0 (12.2)	-4.6 (9.2)	-11.1	2.0	0.15
Peak knee extension (stance)	7.6 (9.9)	7.1 (12.2)	0.5 (8.4)	-5.6	6.5	0.86
Peak knee flexion	52.5 (5.7)	56.0 (6.4)	-3.4 (8.3)	-9.4	2.5	0.23
Knee ROM	**45.0 (12.6)**	**48.9 (14.4)**	**-3.9 (4.6)**	**-7.2**	**-0.6**	**0.02**
Key: SD- Standard deviation, D- mean difference, all values except p values in degrees, significance level p < 0.05, significant results in **bold**						

Comparison of kinematics is given in Table 14.2. Increases were seen in knee ROM (p = 0.02) and hip ROM (p = 0.04), of 4° and 5° respectively, with non-tuned AFO-FC compared to barefoot. No other kinematic variables demonstrated statistically significant changes. However, peak knee flexion during stance and swing, and peak hip flexion during stance, demonstrated considerable mean differences between barefoot and non-tuned AFO-FC, with trends of increase and wide confidence intervals.

There were more differences seen in kinetics than in kinematics between barefoot and non-tuned AFO-FC (Table 14.3). Both peak ankle dorsi-flexion moments during terminal stance (p = 0.04) and peak ankle plantar-flexion moments during initial stance (p = 0.02) increased towards normal values with non-tuned AFO-FC compared to barefoot. Peak knee flexion moments were significantly higher with non-tuned AFO-FC compared to barefoot, with a mean difference of 0.4 Nm/kg. Although not statistically significant, the peak knee extension moments tended to decrease towards normal with non-tuned AFO-FC compared to barefoot, with a mean difference of 0.08 Nm/kg and wide confidence intervals (-0.26 to 0.11). While peak hip extension moments improved, with an increase of 0.39 Nm/kg with non-tuned AFO-FC, the peak hip flexion moments were further away from normal compared to barefoot.

14.2.2 Immediate effects of tuning of AFO-FC on gait of children with CP - group comparison

This section elaborates on comparison of all the variables between non-tuned AFO-FC and AFO-FC immediately after tuning (tuned immediate) using the whole sample as one group.

There was no significant difference in GDI between the barefoot condition and non-tuned AFO-FC (Table 14.4). The SVA improved with an increase of inclination by 6.2° with tuned AFO-FC compared to non-tuned AFO-FC ($p < 0.001$). There were no significant differences in temporal-spatial parameters between tuned and non-tuned AFO-FCs (Table 14.4). However, comparison of temporal-spatial parameters based on diagnosis showed different trends (Table 14.5).

Table 14.3 Descriptive and inferential analysis of kinetic data points between the conditions barefoot and non-tuned AFO-FC

	Descriptive analysis		Inferential analysis			
	Barefoot	Non-tuned AFO-FC	D (SD)	95% Confidence Interval of the D		*p* value
	Mean	Mean		Lower	Upper	
Hip moments						
Peak hip flexion moments	**0.77 (0.37)**	**1.14 (0.44)**	**-0.36 (0.20)**	**-0.51**	**-0.22**	**<0.001**
Peak hip extension moments	**-0.34 (0.19)**	**-0.69 (0.21)**	**0.35 (0.34)**	**0.11**	**0.60**	**0.01**
Knee moments						
Peak knee flexion moments	**0.26 (0.24)**	**0.66 (0.41)**	**-0.40 (0.49)**	**-0.75**	**-0.05**	**0.03**
Peak knee extension moments	-0.38 (0.28)	-0.30 (0.13)	-0.08 (0.26)	-0.26	0.11	0.38
Knee flexion/extension moments at mid-stance	0.04 (0.23)	0.04 (0.14)	0.00 (0.17)	-0.13	0.12	0.95
Ankle moments						
Peak ankle dorsi-flexion moments	**0.84 (0.27)**	**1.00 (0.19)**	**-0.16 (0.21)**	**-0.31**	**-0.01**	**0.04**
Peak ankle plantar-flexion moments	**-0.01 (0.05)**	**-0.17 (0.17)**	**0.16 (0.17)**	**0.04**	**0.28**	**0.02**
Key: SD- Standard deviation, D – mean difference, all values except p values in Nm/kg, significance level p < 0.05, significant results in **bold**						

Table 14.4 Descriptive and inferential analysis of temporal-spatial parameters, GDI and SVA between the conditions non-tuned AFO-FC and tuned immediate

	Descriptive analysis		Inferential analysis			
	Non-tuned AFO-FC Mean (SD)	Tuned Immediate Mean (SD)	D (SD)	95% Confidence Interval of D		p value
				Lower	Upper	
Cadence (steps/minute)	122.3 (15)	123.0 (9)	-0.72 (15.5)	-11.8	10.4	0.89
Stride-length(m)	0.98 (0.21)	0.97 (0.23)	0.00 (0.07)	-0.05	0.05	0.96
Walking speed (m/s)	0.99 (0.24)	0.99 (0.21)	0.00 (0.16)	-0.12	0.12	0.65
GDI	79.5 (11.6)	78.7 (13.6)	0.83 (3.53)	-1.70	3.36	0.48
SVA (degrees)	**6.5 (2.5)**	**12.7 (1.7)**	**-6.2 (1.8)**	**-7.5**	**-4.9**	**<0.001**
Key: SD- Standard deviation, D-mean difference, SVA – Shank to Vertical Angle, GDI – Gait Deviation Index, significance level p < 0.05, significant results in **bold**						

Although all three parameters tended to deteriorate, with a trend of decrease with the use of tuned AFO-FC compared to non-tuned for children with diplegia, they tended to improve with trends of increase in children with hemiplegia (Table 14.5).

Table 14.5 Descriptive analysis of temporal-spatial parameters based on the types of CP between the conditions non-tuned AFO-FC and tuned immediate

Type of Cerebral Palsy	Conditions	Parameters (Mean (SD))		
		Velocity (m/s)	Cadence (steps/min)	Stride-length (m)
Diplegia	Non-tuned AFO-FC	0.98 (0.25)	131 (12)	0.90 (0.23)
	Tuned immediate	0.89 (0.19)	125.9 (7.3)	0.85 (0.21)
Hemiplegia	Non-tuned AFO-FC	1.03 (0.24)	114 (17.6)	1.07 (0.14)
	Tuned immediate	1.15 (0.11)	121.1 (13.3)	1.15 (0.11)
Key: SD – Standard deviation				

Among the kinematic parameters (Table 14.6), peak knee extension decreased from 7.1° of flexion with non-tuned AFO-FC to 10.3° of flexion with tuned AFO-FC. Knee ROM decreased by 6° with use of tuned AFO-FC compared to non-tuned.

Table 14.6 Descriptive and inferential analysis of kinematic data points between the conditions non-tuned AFO-FC and tuned immediate

	Descriptive analysis		Inferential analysis			
	Non-tuned AFO-FC	Tuned immediate	D (SD)	95% Confidence Interval of the D		p value
	Mean (SD)	Mean (SD)		Lower	Upper	
Pelvis kinematics						
Peak anterior pelvic tilt	23.0 (8.3)	22.9 (10.9)	0.1 (3.5)	-2.4	2.6	0.92
Peak posterior pelvic tilt	14.4 (8.1)	14.3 (9.8)	0.1 (3.2)	-2.2	2.4	0.92
Pelvic tilt ROM	8.5 (2.6)	8.5 (2.7)	0.0 (1.0)	-0.7	0.7	1.00
Hip kinematics						
Peak Hip flexion	46.1 (11.0)	46.8 (13.7)	-0.7 (4.4)	-3.8	2.4	0.63
Peak Hip extension	0.5 (8.1)	2.6 (10.9)	-2.2 (4.4)	-5.3	1.0	0.15
Peak hip flexion (stance)	42.9 (12.3)	44.7 (12.8)	-1.8 (4.3)	-4.9	1.2	0.21
Hip ROM	45.7 (6.2)	44.2 (6.9)	1.5 (4.2)	-1.5	4.5	0.30
Knee kinematics						
Knee flexion at initial contact	20.7 (12.4)	22.1 (9.1)	-1.4 (5.7)	-5.5	2.7	0.45
Peak knee flexion (stance)	27.0 (2.2)	29.7 (8.0)	-2.7 (5.6)	-6.7	1.3	0.17
Peak knee extension (stance)	**7.1 (12.2)**	**10.3 (9.5)**	**-3.2 (4.3)**	**-6.3**	**-0.1**	**0.04**
Peak knee flexion	56.0 (6.4)	53.4 (6.9)	2.6 (4.0)	-0.3	5.4	0.07
Knee ROM	**48.9 (14.4)**	**43.1 (13.5)**	**5.8 (6.3)**	**1.2**	**10.3**	**0.02**
Key: SD- Standard deviation, D – mean difference, all values except p values in degrees, significance level $p < 0.05$, significant results in **bold**						

Table 14.7 Descriptive and inferential analysis of kinetic data points between the conditions non-tuned AFO-FC and tuned immediate

	Descriptive analysis		Inferential analysis			
	Non tuned AFO-FC	Tuned AFO-FC	D (SD)	95% Confidence Interval of the D		p value
	Mean (SD)	Mean (SD)		Lower	Upper	
Hip moments						
Peak hip flexion moments	1.14 (0.44)	0.9 (0.4)	0.3 (0.4)	-0.02	0.5	0.07
Peak hip extension moments	-0.69 (0.21)	-0.60 (0.15)	-0.08 (0.24)	-0.25	0.09	0.29
Knee moments						
Peak knee flexion moments	0.66 (0.41)	0.71 (0.24)	-0.05 (0.42)	-0.35	0.25	0.70
Peak knee extension moments	**-0.30 (0.13)**	**-0.17 (0.12)**	**-0.13 (0.09)**	**-0.20**	**-0.07**	**0.001**
Knee flexion/extension moments at mid-stance	0.04 (0.14)	0.11 (0.18)	-0.07 (0.18)	-0.20	0.06	0.25
Ankle moments						
Peak ankle dorsi-flexion moments	1.00 (0.19)	0.95 (0.19)	0.06 (0.15)	-0.05	0.17	0.28
Peak ankle plantar-flexion moments	**-0.17 (0.17)**	**-0.31 (0.13)**	**0.15 (0.13)**	**0.05**	**0.24**	**0.01**
Key: SD-Standard deviation, D-mean difference, all values except p values in Nm/kg, significance level $p < 0.05$, significant results in **bold**						

Comparison of kinetic data points are given in Table 14.7. The peak ankle plantar-flexion moments during initial stance were significantly higher ($p = 0.01$) and peak knee extension moments were significantly lower ($p = 0.001$) with tuned AFO-FC compared to non-tuned. Peak knee flexion moments demonstrated a trend of increase and knee flexion/extension moments during mid-stance tended to be more flexing with wide confidence intervals. Similarly the kinetic data points related to the hip, although not significant, had wide confidence intervals and high mean differences.

14.2.3 Case study analysis of the effects of non-tuned AFO-FC and immediate effects of tuning of AFO-FC on the gait of children with CP

Case study analysis was carried out considering the possibility that children with different gait patterns may respond differently to interventions such as AFO and tuning. This section includes eight case studies that compare sagittal plane kinematics and kinetics, and temporal-spatial parameters between barefoot, non tuned AFO-FC and tuned AFO-FC. All the sample characteristics are provided in Section 10.1.4. To achieve better presentation of data, this section is divided into two. The first subsection (14.2.3.1) includes qualitative analysis of gait patterns from line graphs that show average sagittal plane movement of the pelvis, hip, knee and ankle, and sagittal plane moments of the hip, knee and ankle. The graphs of ankle kinematics only represent barefoot walking; the effects of non-tuned and tuned AFO-FC on ankle kinematics were not considered in the present study as the ankle joint was assumed to be rigid with non-tuned AFO-FC. Qualitative analysis of graphs focuses on gait patterns in general in barefoot and with AFO-FC. The changes with non-tuned and tuned AFO-FC are also briefly explained.

The second subsection (14.2.3.2) includes results from the comparison of kinematic and kinetic data points between barefoot and non-tuned AFO-FC, and non-tuned AFO-FC and tuned AFO-FC. Statistical analysis of kinematic data points and temporal-spatial parameters for each case study was carried out and summary tables are included (Tables 14.8 and 14.9, pages 221 and 223).

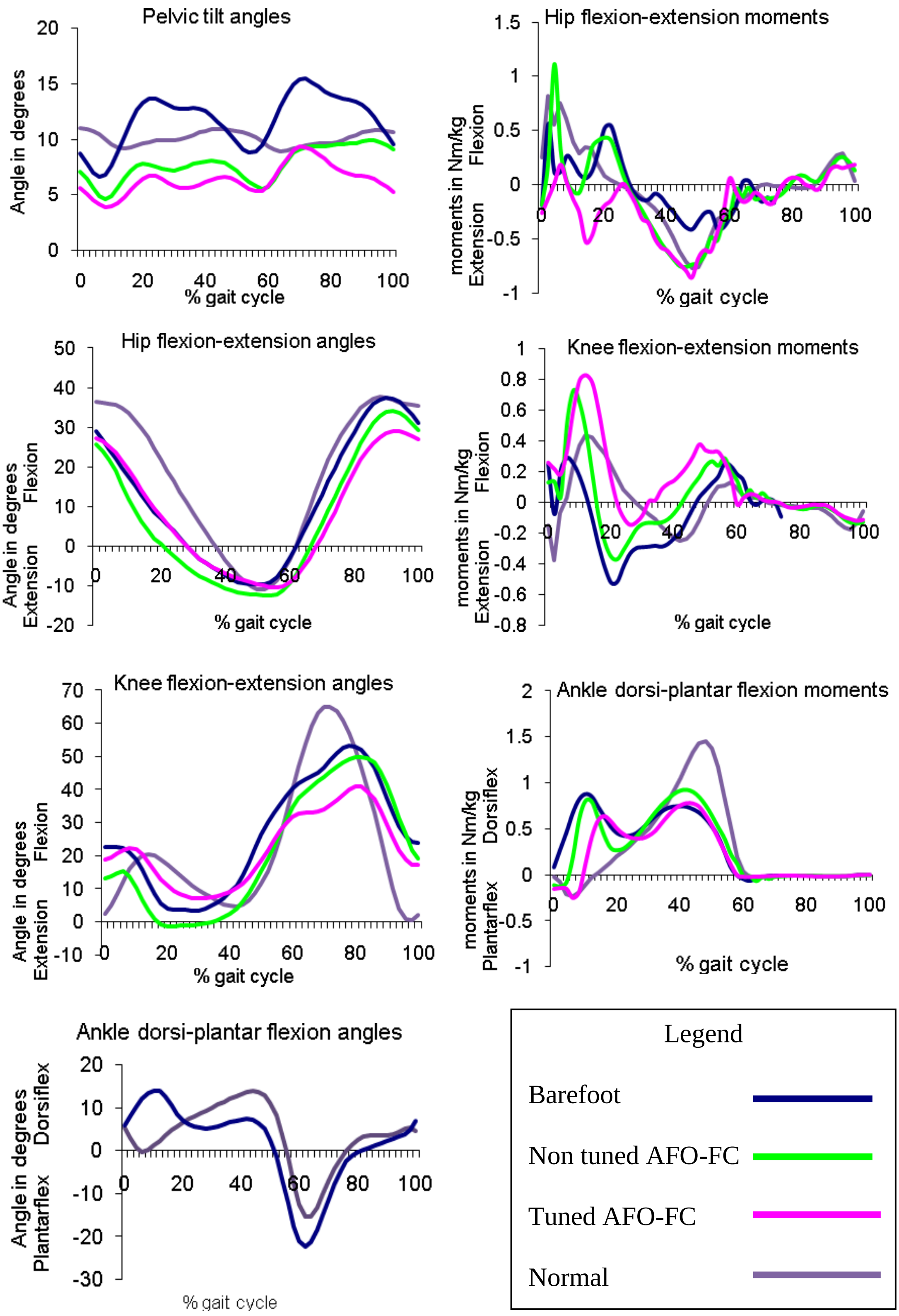


Figure 14.1 Graphs comparing kinematics and kinetics in the sagittal plane between barefoot walking, walking in non-tuned AFO-FC and tuned AFO-FC with reference to normal during one complete gait cycle of case study 1 (participant 1)

The tables for individual case studies are given in Appendix XII. Reporting of all the parameters individually is not included; instead, any patterns of change seen across the sample or across categories of sample are reported.

14.2.3.1 Qualitative analysis of patterns

Case study 1 (Figure 14.1):

The first participant was a 5.6 year-old male with diplegia who used a dynamic AFO on the left leg and a rigid AFO on the right leg; therefore only the right leg was considered. The rigid AFO was cast at plantigrade (90°), with the trimlines anterior to the malleoli. The AFO was stiff at the metatarsophalyngeal joints. The participant walked independently, but slower than normal (1.09 m/s). While his strides were shorter than normal (0.79 m), the cadence (165 steps/minute) was higher than normal. On static clinical examination, the participant demonstrated a popliteal angle of 138° and a passive hip extension of 18° on the right side. There was increased spasticity in the right triceps surae muscle. While the gait pattern did not fit completely in any category previously explained, it was similar to the true equinus pattern explained by Rodda et al. (2004). The ankle joint demonstrated equinus during terminal stance as explained by Rodda et al. (2004) whereas during initial stance and mid-stance, there were two peaks of dorsi-flexion. During terminal swing, the ankle returned to dorsi-flexion as explained in the ankle double bump pattern by O’Bryne, Jenkinson and O’Brien (1998). There was increased knee flexion during initial stance and late swing, whereas during terminal stance the knee was hyper-extending (< 5° in this case). This was in line with the true equinus pattern described by Rodda et al. (2004). Other similarities with Rodda et al (2004) were a slightly anteriorly tilted pelvis, and normal hip extension. The kinetic double bump pattern seen in the ankle moments was similar to the kinetic pattern of the ankle in the jump knee group explained by Lin et al. (2000).

Wearing the non-tuned AFO-FC, the participant demonstrated normal knee flexion during initial stance, with increased knee hyper-extension during mid-stance compared to barefoot.

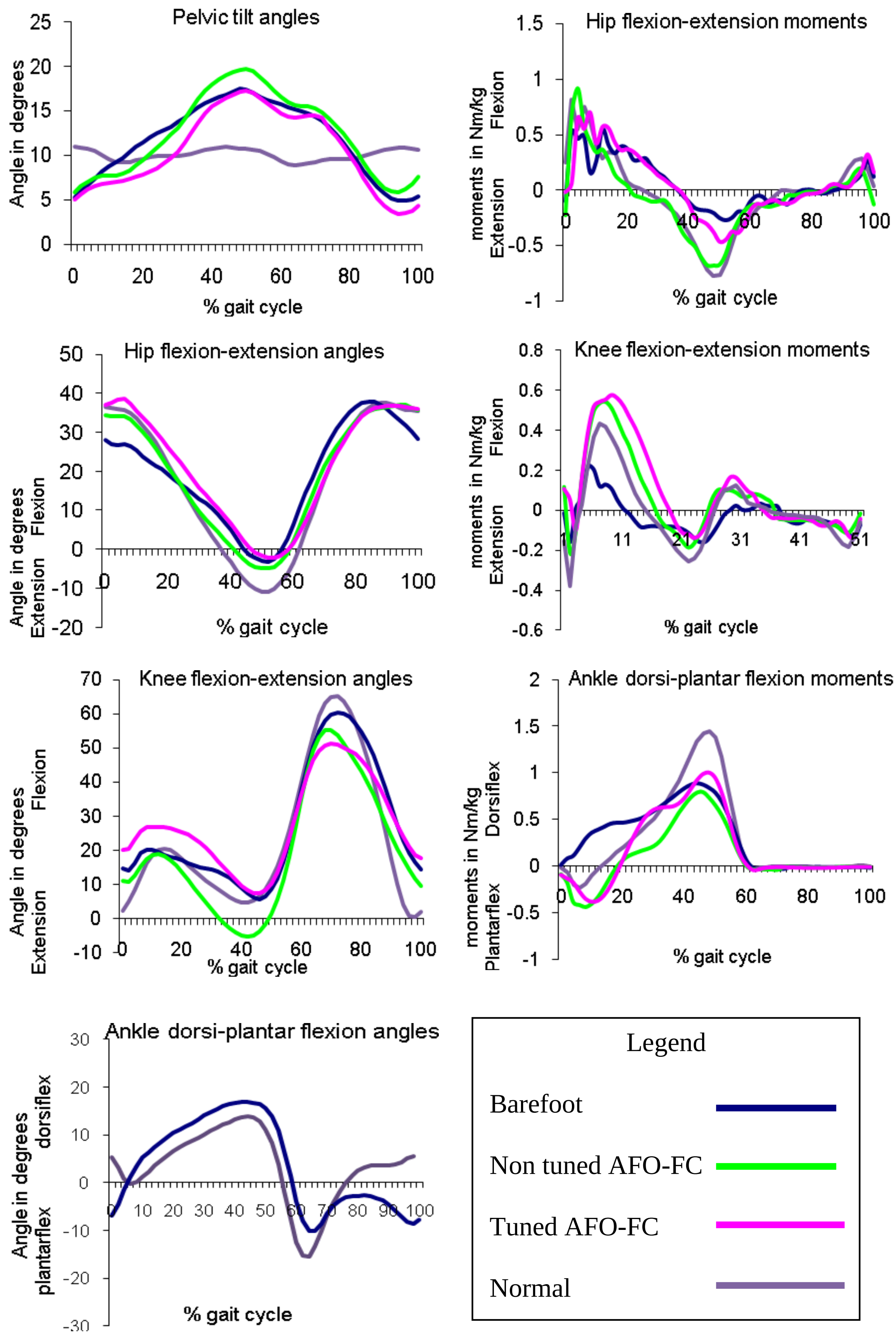


Figure 14.2 Graph comparing kinematics and kinetics in the sagittal plane between barefoot walking, walking in non-tuned AFO-FC and tuned AFO-FC during one complete gait cycle of case study 2 (participant 2).

There was no change in the abnormal first peak of dorsi-flexion moments of the double bump kinetic pattern of the ankle. The pelvic tilt was less anterior with the non-tuned AFO-FC compared to barefoot.

Immediately after tuning, knee hyper-extension decreased, knee flexion during initial stance increased, and peak knee flexion during swing decreased when compared to non-tuned AFO-FC. Among the moments, peak knee extension moments and peak hip flexion moments decreased with tuning. The undesirable initial dorsi-flexion moments were reduced with tuned AFO-FC compared to non-tuned.

Case study 2 (Figure 14.2):

Participant 2 was a 12.5 year old female with right hemiplegia who used a rigid AFO on the affected side. The AFO was cast at 12° plantar-flexion and was stiff at the metatarsal phalyngeal joints (MTPJ). The trimlines were anterior to the malleoli, and a heel wedge was attached to the AFO to accommodate for the plantar-flexed position of the AFO, thereby producing a stable base. The participant walked independently. However, her gait was slower than normal (0.82 m/s), and she used shorter strides than normal (0.85). On static clinical examination, the participant demonstrated a popliteal angle of 126° and a passive hip extension of 3° on the right side. Right triceps surae demonstrated increased spasticity. In barefoot the affected side demonstrated a gait pattern similar to that described for Winters' group 1 (Winters, Gage and Hicks 1987), with loss of ankle dorsi-flexion during swing, but normal dorsi-flexion during stance. The knee joint demonstrated slightly increased knee flexion during initial contact, loading response, and terminal swing, as explained by Winters, Gage and Hicks (1987). However, the characteristic increase in hip flexion and anterior tilt of pelvis explained by Winters, Gage and Hicks (1987) were not seen. Instead, there was a single bump pattern of the pelvis and reduced hip movement, suggesting a lack of dissociation between pelvis and hip. Increased ankle dorsi-flexion moments during initial stance (absent plantar-flexion moments) was another characteristic of participant 2 which was similar to the kinetic pattern of the ankle in the mild group described by Lin et al. (2000).

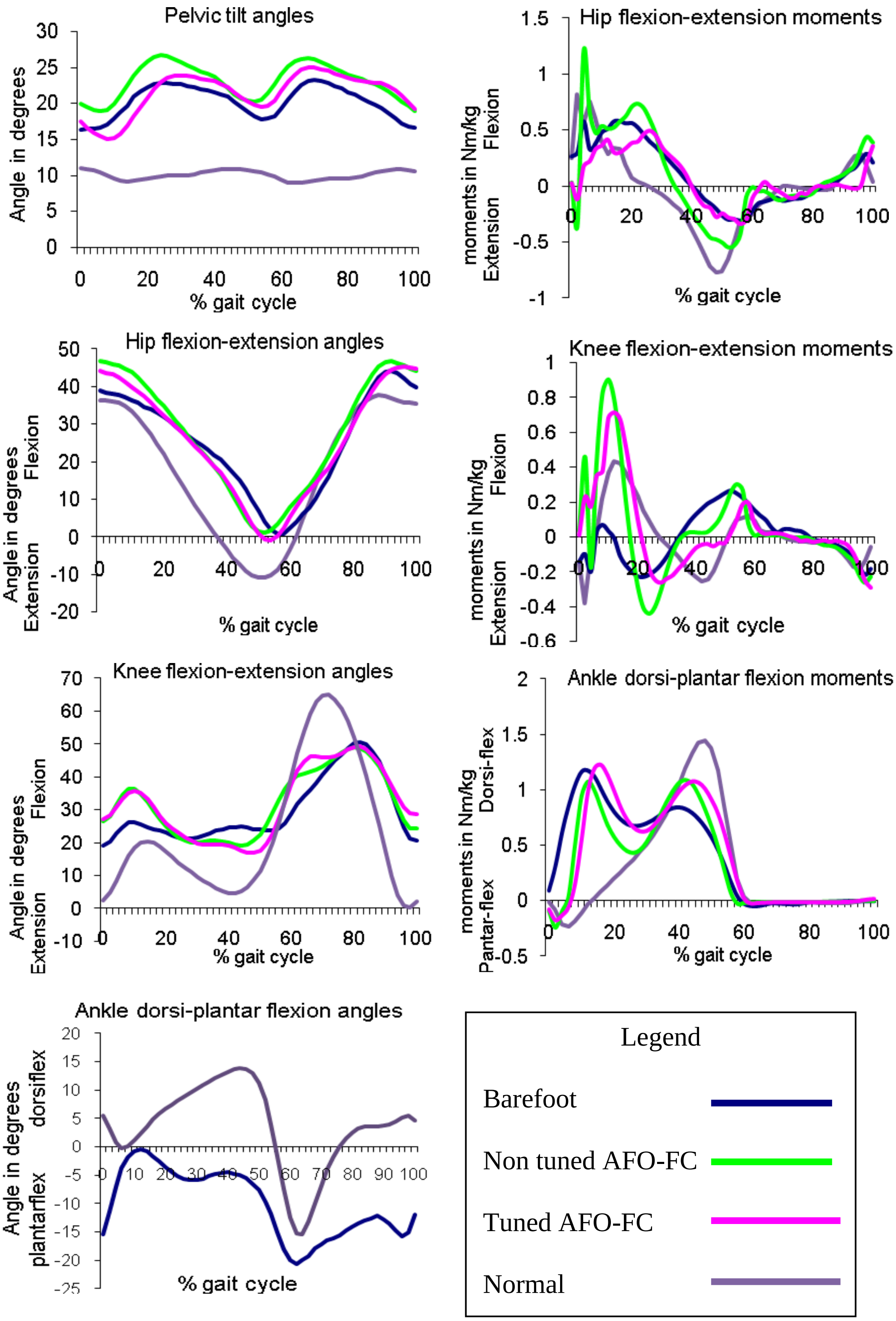


Figure 14.3 Graph comparing kinematics and kinetics in the sagittal plane between barefoot walking, walking in non-tuned AFO-FC and tuned AFO-FC during one complete gait cycle of case study 3 (participant 3).

Wearing the non-tuned AFO-FC, the knee assumed slightly less flexion during initial stance but demonstrated hyper-extension during mid to terminal stance. The pelvis remained the same compared to barefoot. Peak knee flexion moments were high and ankle moments were less dorsiflexing during initial and mid-stance with non-tuned AFO-FC compared to barefoot. Furthermore, the non-tuned AFO-FC produced plantar-flexion moments during initial stance, which were not seen in barefoot.

Wearing the tuned AFO-FC, knee hyper-extension decreased, knee flexion during initial stance increased, and peak knee flexion during stance decreased when compared with non-tuned AFO-FC. Peak knee extension moments and peak hip extension moments decreased with tuned AFO-FC compared to non-tuned. The ankle kinetics showed a steep hike in dorsi-flexion moments around mid-stance with tuned AFO-FC compared to non-tuned.

Case study 3 (Figure 14.3):

Participant 3 was a 7.8 year old female with diplegia, who used a rigid AFO only on the right leg. The AFO was cast at 10° plantar-flexion, was rigid at the MTPJ, and had the trimlines anterior to the malleoli. A heel raise was attached to the AFO to compensate for the plantar-flexed position of the AFO and create a stable base. The participant walked independently, but slower than normal (0.86 m/s), and with strides shorter than normal (0.85 m). Static clinical examination demonstrated a popliteal angle of 113° and passive hip extension of 12° on the affected side. Increased spasticity was seen in the right triceps surae muscle. While the gait pattern did not completely fit in any of the previously explained gait categories, the pattern was similar to crouch gait with equinus, as described by Huck et al. (1987) and Bleck (1987) and to mobile crouch described by O’Bryne, Jenkinson and O’Brien (1998). As in the descriptions by these authors, the ankle was predominantly in equinus throughout the gait cycle. While the knee joint was flexed throughout the gait cycle, this was not as high as described in the crouch with dorsi-flexion gait pattern (Sutherland and Davids 1993). Dissimilarities in the gait pattern of participant 3 from the mobile crouch pattern were that hip extension reached neutral and the hip was not hyperflexed.

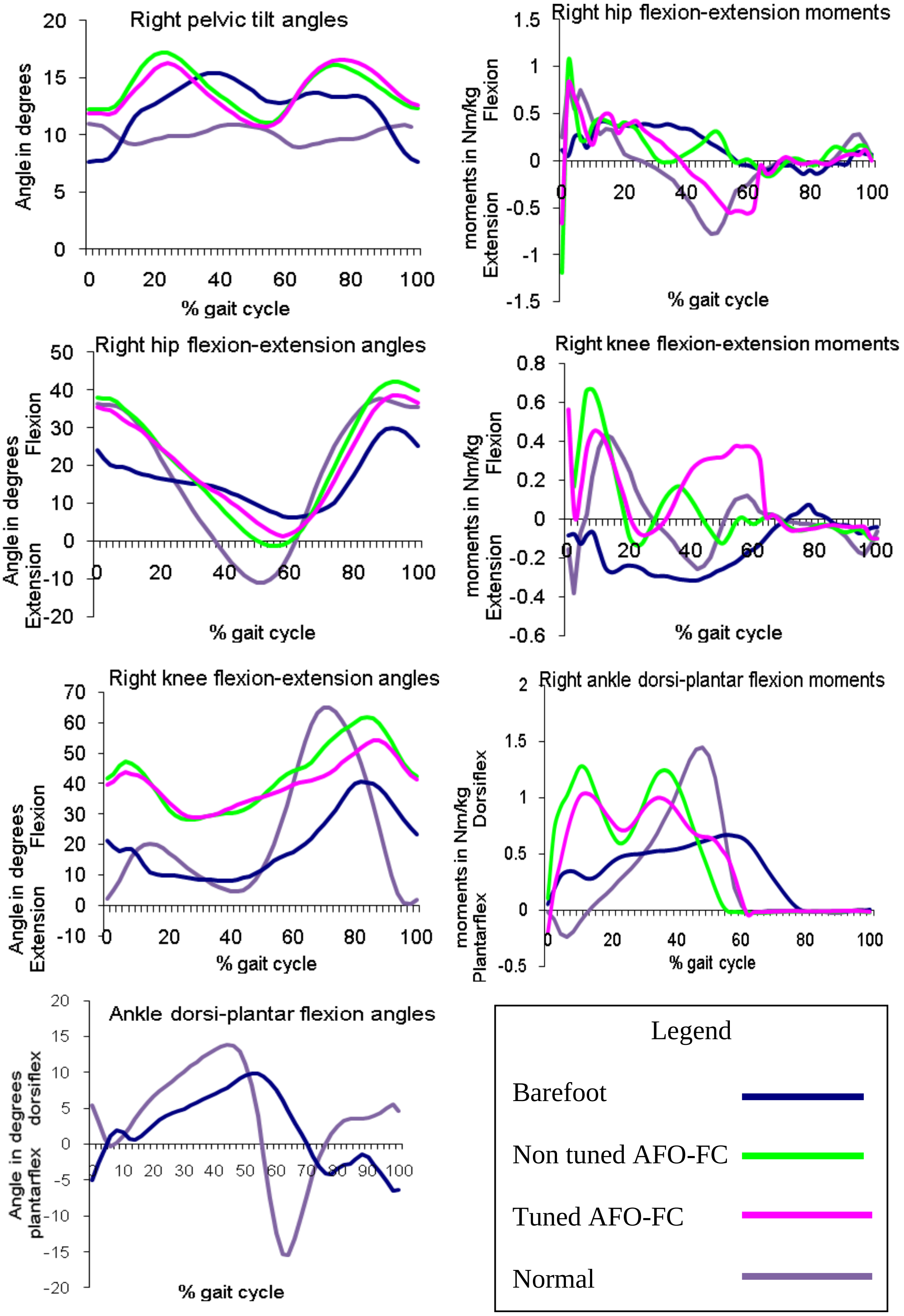


Figure 14.4 Graph comparing kinematics and kinetics in the sagittal plane of the right lower limb between barefoot walking, walking in non-tuned AFO-FC and tuned AFO-FC during one complete gait cycle of case study 4 (participant 4)

The ankle joint demonstrated the kinetic double bump pattern, suggesting a tight gastrocnemius (Ounpuu 2004). Plantar-flexion moments during initial stance were absent.

With the non-tuned AFO-FC, the knee joint retained the crouch pattern. The already high knee flexion during initial stance increased further. The peak knee flexion moments, peak knee extension moments, peak hip flexion moments and peak hip extension moments increased with AFO-FC compared to barefoot. There was normal plantar-flexion moments during initial stance with non-tuned AFO-FC compared barefoot. The kinetic double bump pattern of the ankle remained with non-tuned AFO-FC.

With the tuned AFO-FC, the knee joint retained the crouch pattern. However, the peak knee flexion moments and peak knee extension moments decreased with tuned AFO-FC compared to non-tuned. Similarly, peak hip flexion moments and peak hip extension moments decreased with tuned AFO-FC compared to non-tuned. The unwanted first peak of ankle dorsi-flexion moments increased with tuned AFO-FC compared to non-tuned.

Case study 4 (Figures 14.4 and 14.5):

Participant 4 was a 7.2 year old male with diplegia, who used rigid AFOs on both legs. The rigid AFOs were cast at 15° plantar-flexion on both sides, with appropriate heel wedges to compensate for the plantar-flexion so that the AFO had a stable base. Both the AFOs were stiff at the MTPJs and had trimlines anterior to the malleoli. The participant walked independently and demonstrated a very slow gait (0.22 m/s) with very short strides (0.35 m) and very low cadence (79 steps/minute). Static clinical examination revealed poplitieal angles of 120° and 110° on the right and left sides, respectively. Passive hip extension was restricted to 13° on the right and 8° on the left. Passive knee extension was limited to 15° of flexion on the left side. Increased tone was seen in triceps surae and hip adductors on both sides. An asymmetric gait pattern was evident. The right leg demonstrated a pattern similar to severe crouch as described by O’Bryne, Jenkinson and O’Brien (1998), with ankle

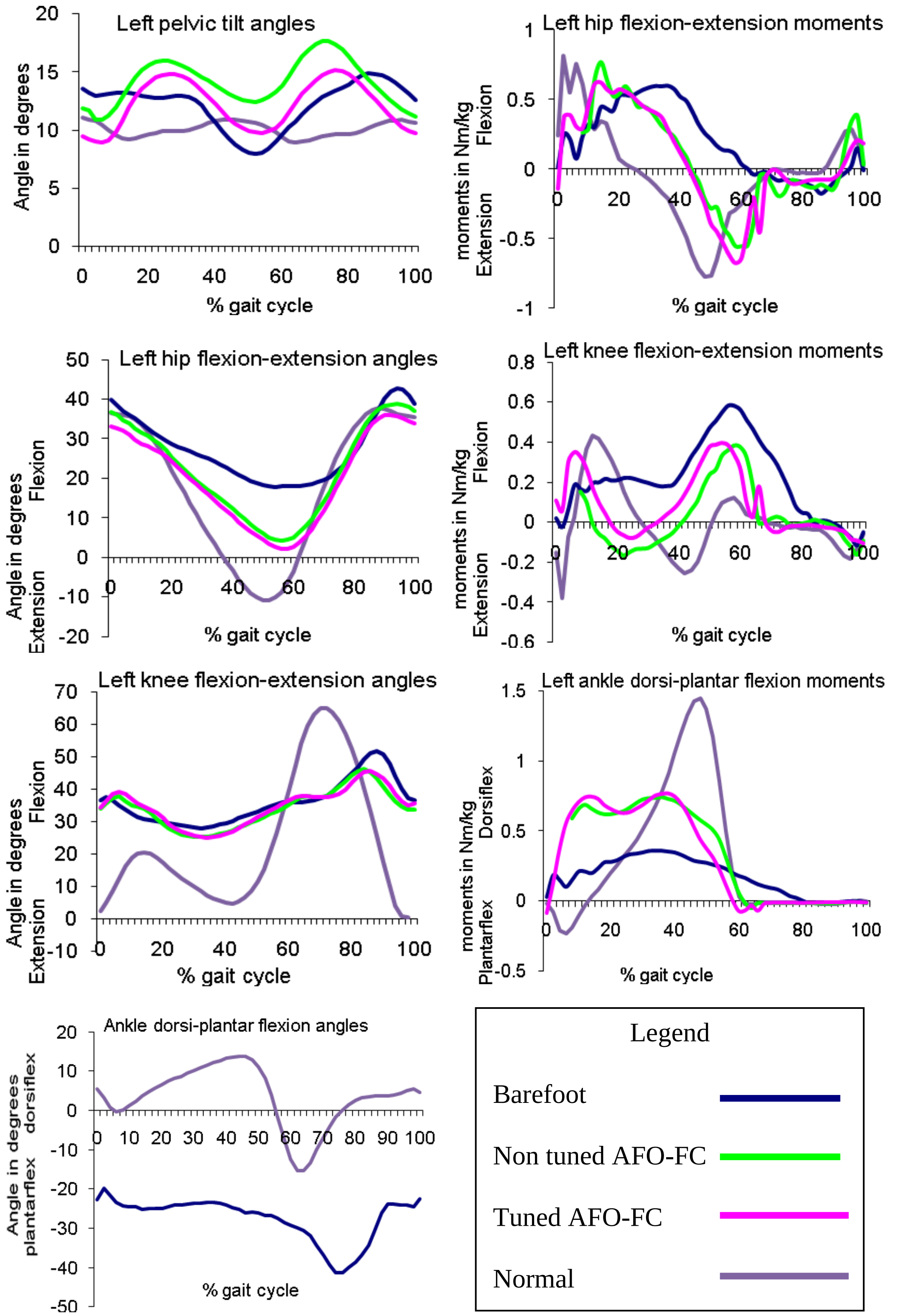


Figure 14.5 Graph comparing kinematics and kinetics in the sagittal plane of the left lower limb between barefoot walking, walking in non-tuned AFO-FC and tuned AFO-FC during one complete gait cycle of case study 4 (participant 4)

dorsi-flexion throughout stance, and knee flexion throughout the gait cycle, with reduced knee ROM and poor hip ROM. The left leg of participant 4 demonstrated a gait pattern similar to pattern 1 (crouch with equinus pattern), as described by Huk et al (1987) and stiff crouch with toe walking described by O'Bryne, Jenkinson and O'Brien (1998). In this case the knee and hip were excessively flexed and the ankle was in equinus throughout the gait cycle.

With the non-tuned AFO-FC the knee joint was much more flexed on the right side, whereas it remained the same on the left side when compared to barefoot. Hip and pelvis kinematic patterns were more normalised and hip motion increased with the non-tuned AFO-FCs compared to barefoot. The ankle demonstrated a kinetic double bump pattern on both sides with non-tuned AFO-FC.

With the tuned AFO-FC the peak knee flexion moments during initial stance, and peak knee extension moments on both sides decreased when compared with non-tuned AFO-FC. The abnormal initial peak of dorsi-flexion moments and normal peak of dorsi-flexion moments during terminal stance decreased with tuning on the right side.

Case study 5 (Figure 14.6):

Participant 5 was a 6.2 year-old female with hemiplegia who used a rigid AFO on the affected side. The Rigid AFO was cast at 15° plantar-flexion, with a heel raise to compensate for the plantar-flexion and thereby provide the AFO with a stable base. The AFO was stiff at the MTPJs and the trimlines were anterior to the malleoli. The participant walked independently, but slower than normal (0.69 m/s) and with a shorter stride-length than normal (0.75 m). Static clinical examination revealed a popliteal angle of 146° and passive hip extension of 9° on the right side. There was increased spasticity in triceps surae on the right side. In barefoot, the affected side demonstrated a gait pattern similar to Winters' group II (Winters, Gage and Hicks 1987). The equinus position of the ankle throughout the gait cycle, knee hyper-extension during stance, slightly increased hip flexion during stance and increased anterior pelvic tilt showed that the kinematics of participant 5 were in line with the

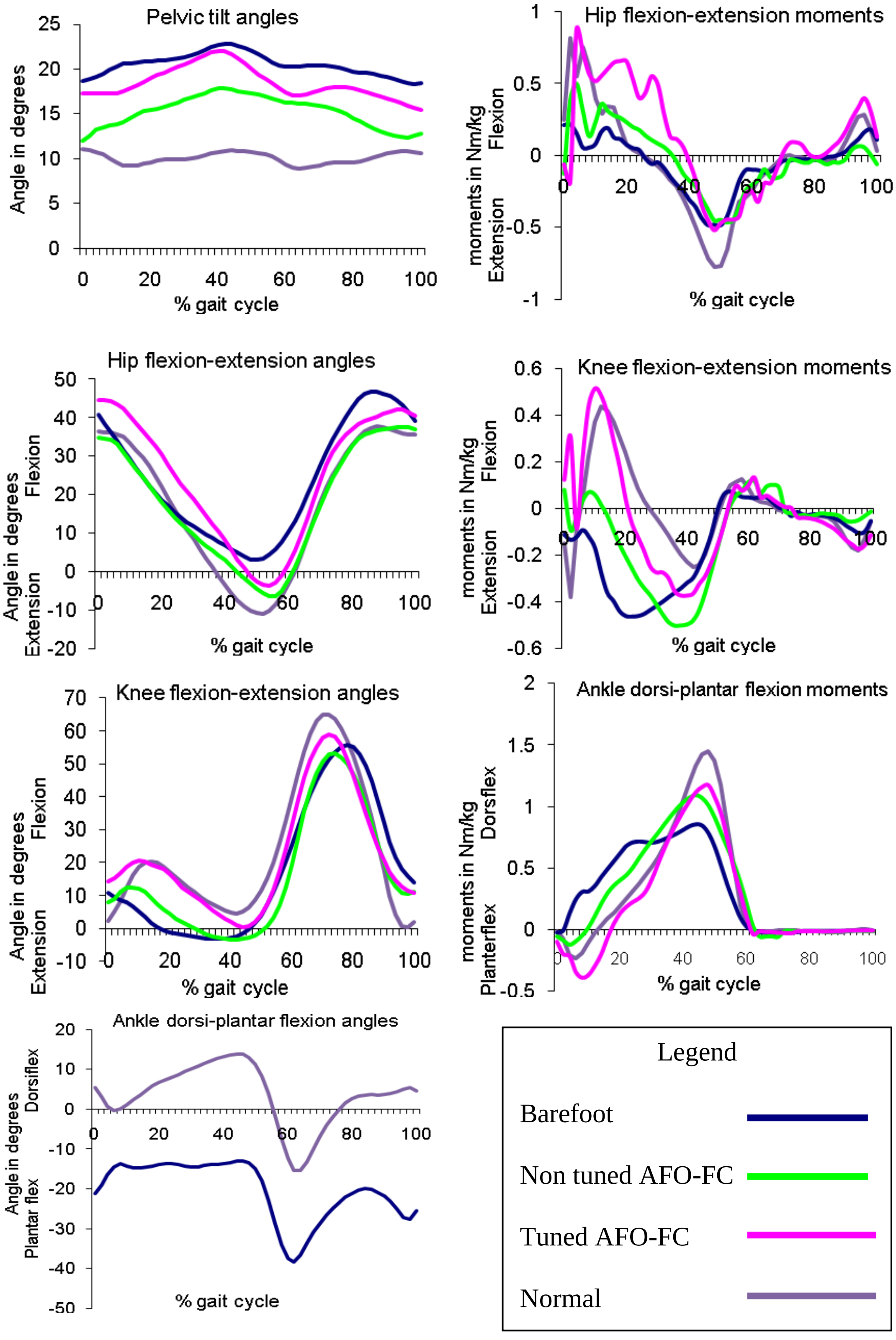


Figure 14.6 Graph comparing kinematics and kinetics in the sagittal plane between barefoot walking, walking with non-tuned AFO-FC and tuned AFO-FC during one complete gait cycle of case study 5 (participant 5).

description of Winters' group II. All features were also characteristic of the severe recurvatum group described by O'Bryne, Jenkinson and O'Brien (1998), although knee hyper-extension was not as severe as in their description. The pelvis demonstrated a single bump pattern suggesting lack of dissociation between hip and pelvis. While there was no kinetic double bump pattern at the ankle, there were increased dorsi-flexion moments during initial and mid-stance.

When the non-tuned AFO-FC was compared to barefoot, knee hyper-extension was retained, knee moments were still predominantly extending, hip ROM and extension increased, anterior tilt of the pelvis decreased and the ankle kinetic pattern was more normalised.

Wearing the tuned AFO-FC, knee hyper-extension decreased, and both knee flexion during initial stance and peak knee flexion during swing increased compared to non-tuned. Peak hip flexion moments and peak knee flexion moments increased and peak knee extension moments decreased with tuned AFO-FC compared to non-tuned.

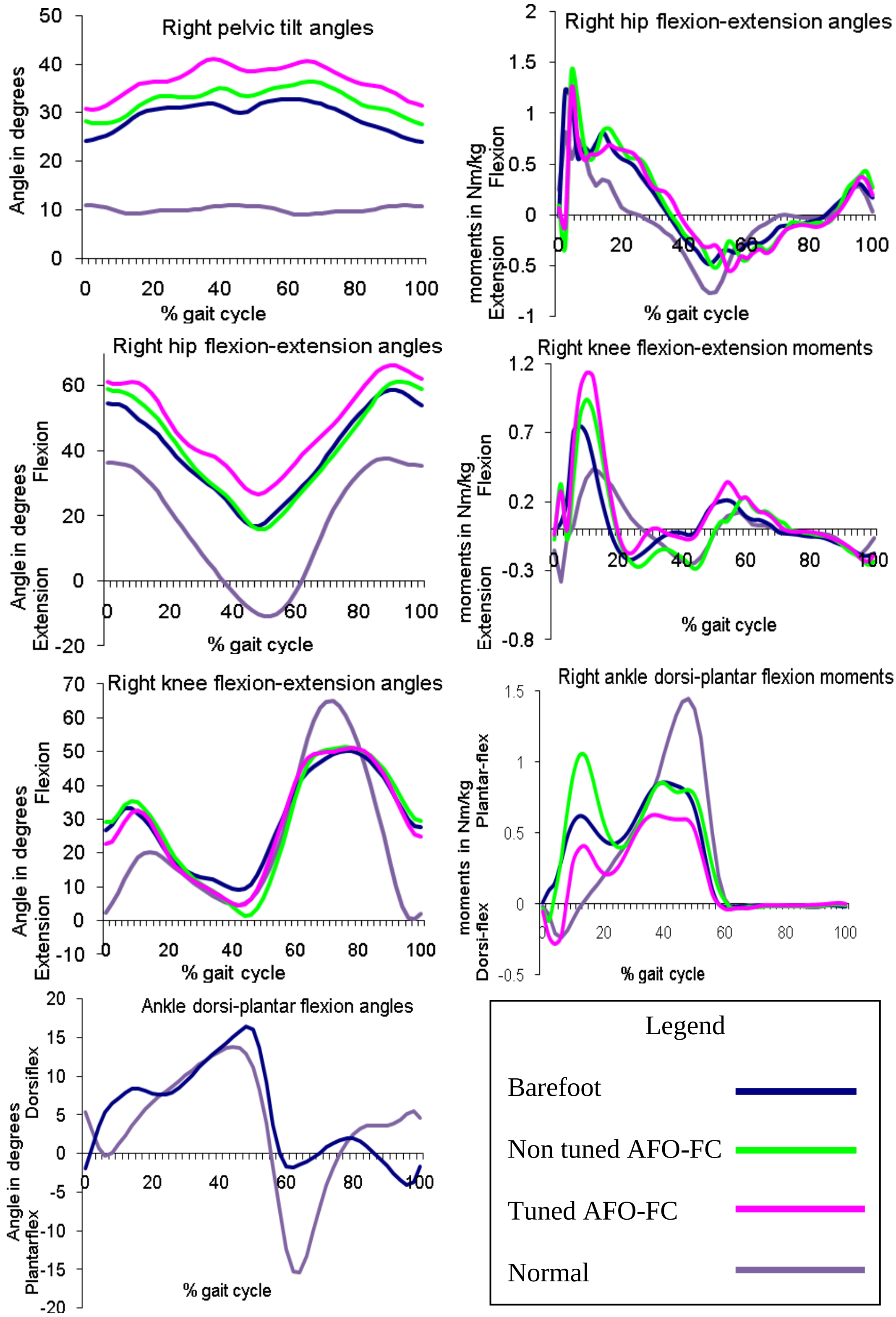


Figure 14.7 Graph comparing kinematics and kinetics in the sagittal plane of the right lower limb between barefoot walking, walking with non-tuned AFO-FC and tuned AFO-FC during one complete gait cycle of case study 6 (participant 6)

Case study 6 (Figures 14.7 and 14.8):

Participant 6 was 12.5 year-old female with diplegia, who used rigid AFOs on both legs. The AFOs were cast at 12° plantar-flexion on the right and 14° plantar-flexion on the left. On both sides heel raises were attached to compensate for the plantar-flexed position of the AFOs. Both AFOs had trimlines anterior to the malleoli and were stiff at the MTPJ. The participant walked independently, but with a walking speed that was less than normal (1.1 m/s) and strides that were shorter than normal (1.1 m). On static clinical examination, the participant demonstrated popliteal angles of 123° on the right and 120° on the left. Passive hip extension was limited to 7° on the right and 12° on the left, whereas passive knee extension demonstrated 6° and 8° of hyperextension on the right and left sides, respectively. There was increased spasticity in triceps surae muscle on both sides. Gait patterns shown by both legs were similar to jump knee gait as described by Sutherland and Davids (1993) in both legs in barefoot. Both legs demonstrated slightly increased dorsi-flexion during initial stance and reduced plantar-flexion during late stance at the ankle, increased knee flexion during initial stance, near normal knee extension during terminal stance, increased hip flexion and increased anterior pelvic tilt throughout the gait cycle. All of these were described as characteristics of jump knee gait by Sutherland and Davids (1993). While both ankle joints demonstrated kinetic double bump patterns, the initial peak of dorsi-flexion moments during mid-stance in the left ankle was lower when compared to the right.

With non-tuned AFO-FC compared to barefoot, initial stance knee flexion remained high on the right side and further increased on the left. On both sides peak knee extension during terminal stance increased to reach normal on the left, and hyper-extension on the right. Pelvic tilt was slightly more anterior on both sides. The kinetic double bump pattern of the ankle became worse on both sides, with an increase in initial peak dorsi-flexion – worse on the right than the left.

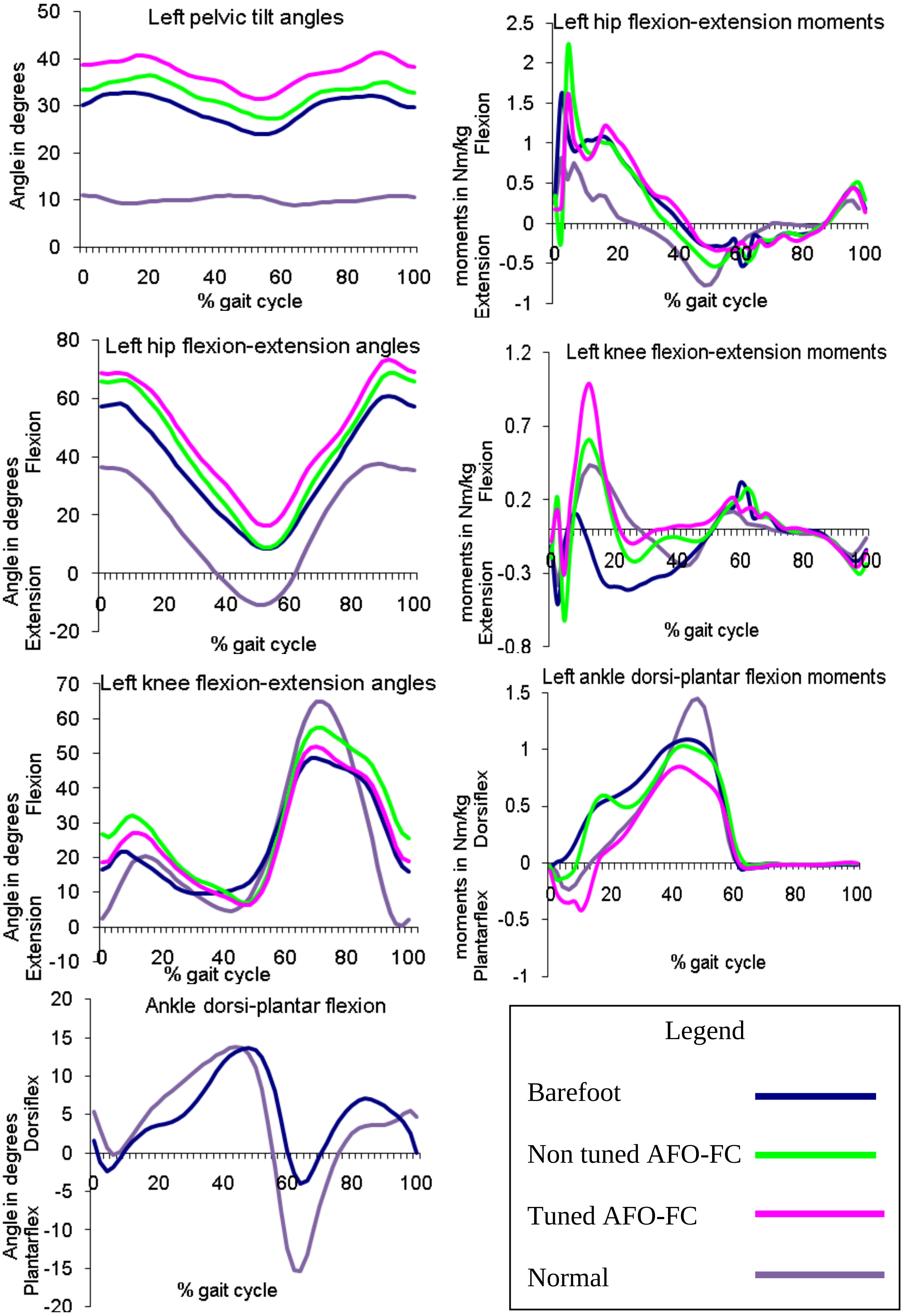


Figure 14.8 Graph comparing kinematics and kinetics in the sagittal plane of the left lower limb between barefoot walking, walking with non-tuned AFO-FC and tuned AFO-FC during one complete gait cycle of case study 6 (participant 6)

When wearing tuned AFO-FC, the anterior pelvic tilt and lack of hip extension further increased when compared with the non-tuned AFO-FC. The high knee flexion during initial stance that was evident with non-tuned AFO-FC, decreased bilaterally with tuned AFO-FC. Knee hyper-extension on the right knee decreased with tuned AFO-FC compared with non-tuned. The peak knee flexion moments during initial stance increased and peak knee extension moments decreased with tuned AFO-FC compared with non-tuned. The undesirable initial dorsi-flexion moments of the ankle kinetic double bump pattern decreased on both sides with tuned AFO-FC compared to non-tuned.

Case study 7 (Figure 14.9):

Participant seven was an 8.3 year-old female with right hemiplegia, who used a rigid AFO on the affected leg. The AFO was cast at 17° plantar-flexion and a heel raise was applied to the AFO to compensate for the plantar-flexed position of the AFO. The trimlines were anterior to the malleoli and the AFO was stiff at the MTPJs. The participant walked independently, and with a speed closer to normal (1.2 m/s) when compared with other participants. However, the participant demonstrated a stride-length that was lower than normal (0.97), and cadence that was higher than normal (149 steps/minute). On static clinical examination, the participant demonstrated a popliteal angle of 128° and passive hip extension of 15° on the right side. The right triceps surae muscle demonstrated increased spasticity. In barefoot the participant demonstrated a gait pattern with knee hyper-extension (< 5°), which was similar to the mild recurvatum group described by O'Bryne, Jenkinson and O'Brien (1998), Winters' group II (Winters, Gage and Hicks 1987), and Group IV with knee hyper-extension and tibial arrest described by Hullin Robb and Loudon (1996). The ankle was in plantar-flexion through most of the gait cycle. The knee demonstrated hyper-extension during early mid-stance, which may be attributed to over-active calf muscles (Simon et al. 1978). Also seen was the sudden increase in knee extension moments as described by Hullin, Robb and Loudon (1996). The hip demonstrated near neutral extension during stance phase. The ankle kinetic graph demonstrated a peak of dorsi-flexion moments during mid-stance, which also indicates over-activity of gastrocnemius. The pelvis demonstrated a single bump pattern, suggesting a lack of dissociation between hip and pelvis.

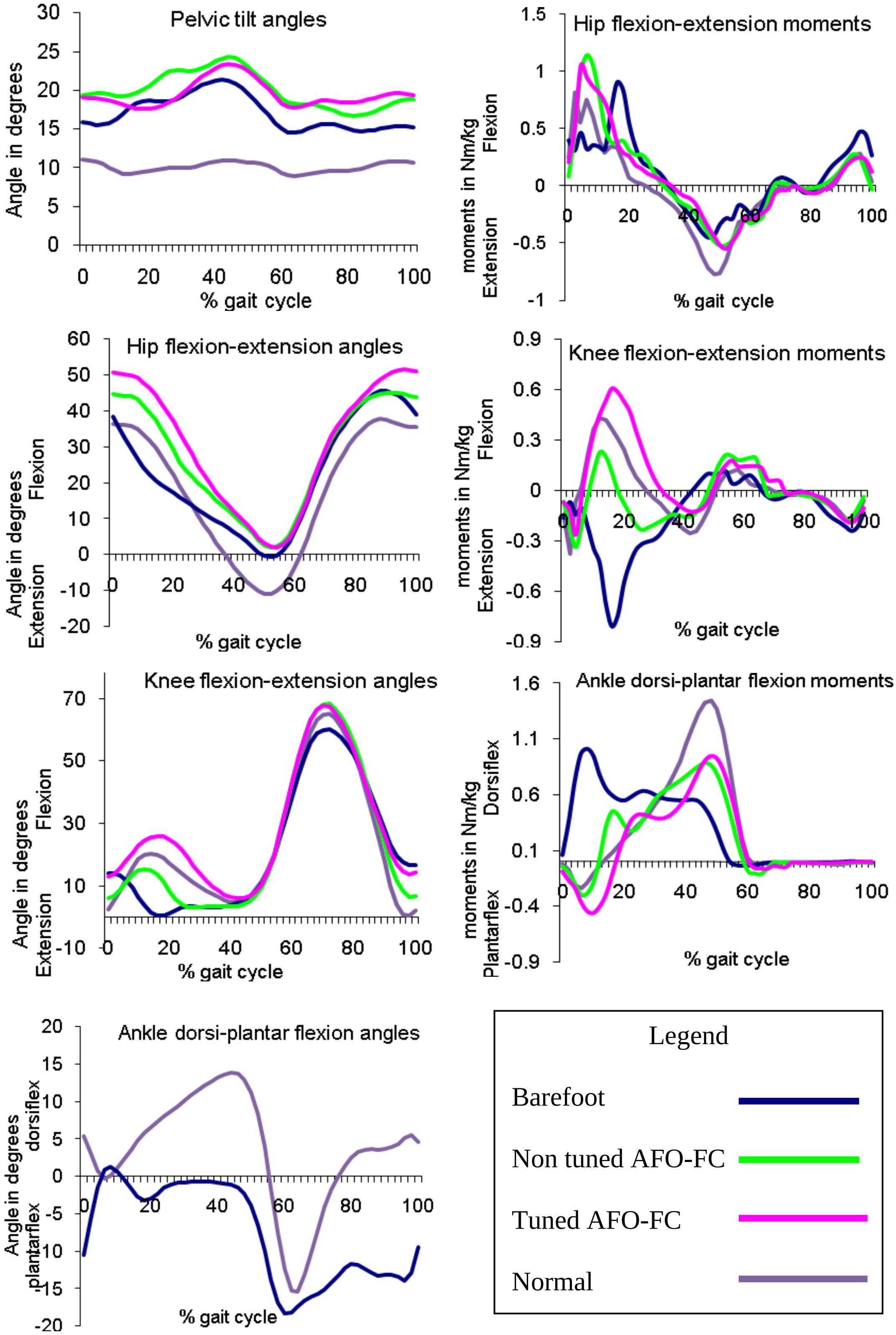


Figure 14.9 Graph comparing kinematics and kinetics in the sagittal plane between barefoot walking, walking with non-tuned AFO-FC and tuned AFO-FC during one complete gait cycle of case study 7 (participant 7)

With non-tuned AFO-FC compared to barefoot, knee hyper-extension was retained whereas the knee moments were more normalised. While the ankle kinetic pattern still had a double bump pattern, it was more normal, with a reduction in the unwanted initial peak of dorsi-flexion moments.

Wearing the tuned AFO-FC, knee hyper-extension decreased and initial stance knee flexion increased, when compared with non-tuned AFO-FC. Peak knee flexion moments increased and peak knee extension moments decreased with tuned AFO-FC compared with non-tuned. The unwanted initial peak of dorsi-flexion moments stayed the same with tuned AFO-FC compared to non-tuned.

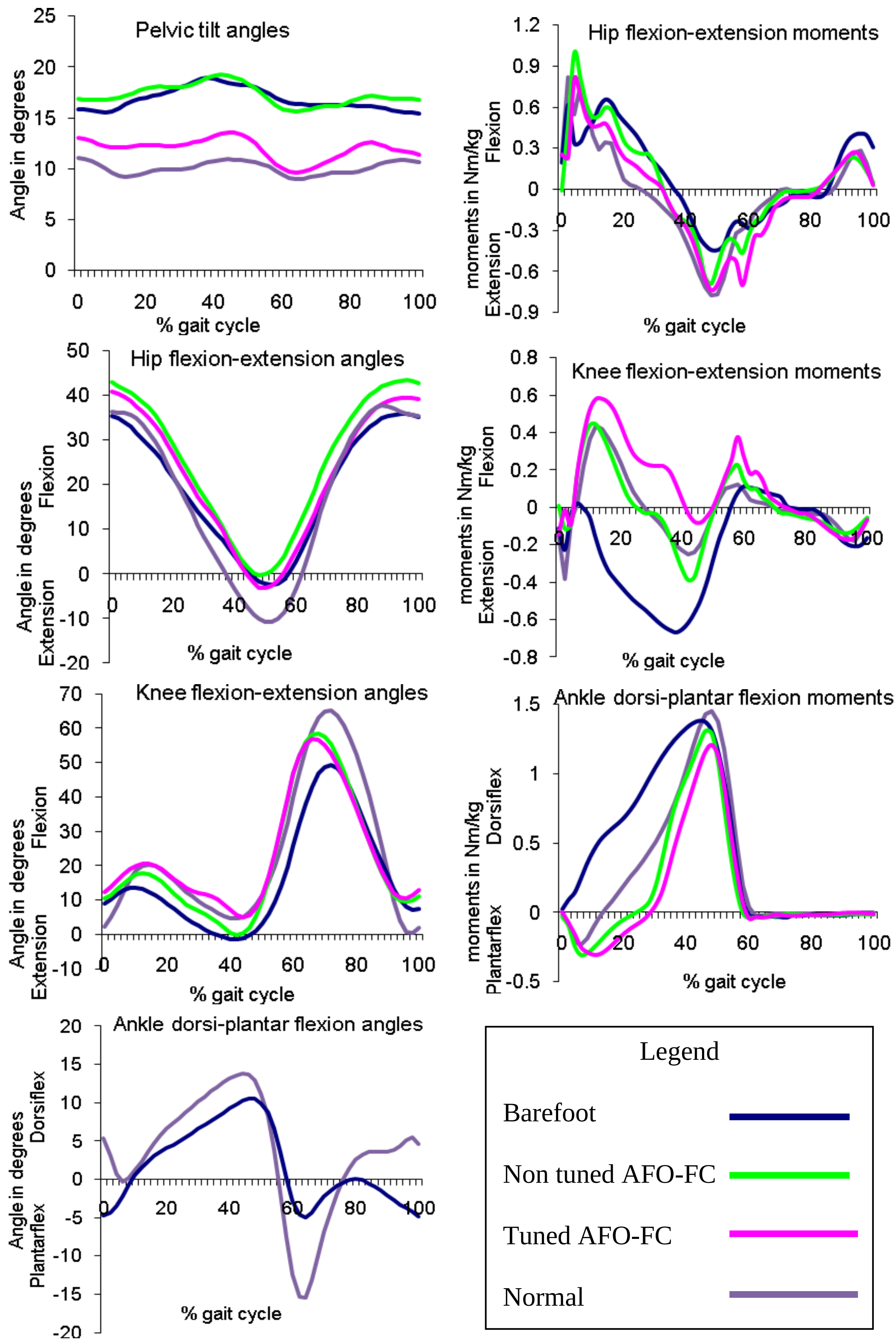


Figure 14.10 Graph comparing kinematics and kinetics in the sagittal plane between barefoot walking, walking with non-tuned AFO-FC and tuned AFO-FC during one complete gait cycle of participant 8

Case study 8 (Figure 13.16):

This case study is based on participant eight who was an 11.8 year-old male with left hemiplegia. He used a rigid AFO on the affected leg, which was cast at plantigrade. The AFO was rigid at the MTPJs and the trimlines were anterior to the malleoli. The participant walked independently. However, the walking speed (1.05 m/s) and stride-length were less than normal (1.01 m), whereas cadence was higher than normal (150 steps/minute). On static clinical examination the participant demonstrated a popliteal angle of 115°, and passive hip extension of 9° on the left side. Passive knee extension demonstrated 7° of hyperextension on the left side. The left triceps surae muscle demonstrated increased spasticity. In barefoot, the affected leg demonstrated a gait pattern similar to Group V - knee hyper-extension with ankle dorsi-flexion group, as described by Hullin, Robb and Loudon (1996) and Huk et al. (1987). The following characteristics, described by Hullin, Robb and Loudon (1996) were seen in participant 8: normal ankle dorsi-flexion, limited ankle plantar-flexion during terminal stance and swing, knee hyper-extension during terminal stance, and knee extension moments starting from the heel strike. The participant also demonstrated a single bump pattern at a slightly anterior tilted pelvis.

With AFO-FC, while there was slight increase towards normal in knee flexion during initial stance, and knee flexion during swing; knee hyper-extension was retained. Knee and ankle kinetics patterns were more normal with non-tuned AFO-FC compared to barefoot.

With tuned AFO-FC the anterior pelvic tilt and knee hyper-extension decreased, whereas knee flexion during initial stance increased compared to non-tuned AFO-FC. Peak knee extension moments decreased and peak knee flexion moments increased with tuned AFO-FC compared to non-tuned.

Table 14.8 Compilation of results from case studies comparing the effects of non-tuned AFO-FC with barefoot

	Change with non-tuned AFO-FC compared to barefoot according to participant number and right or lef leg									
	1R	2R	3R	4R	4L	5R	6R	6L	7R	8L
Peak anterior pelvic tilt	↓	↓	↑	-	-	-	↑	↑	↑	-
Peak posterior pelvic tilt	-	-	-	-	-	↑	↓	↓	↓	-
Pelvic tilt ROM	↓	-	-	-	-	↑	-	-	-	-
Knee flexion at IC	↓	↓	-	↑	-	-	↑	↑	↓	-
Peak knee flexion (stance)	↓	-	↑	↑	-	-	↑	↑	-	-
Peak knee extension (stance)	-	↑	-	↓	-	-	↓	-	↑	-
Peak knee flexion	-	↓	-	↑	↓	-	-	↑	↑	↑
Knee ROM	-	↑	-	-	-	-	↑	↑	↑	↑
Peak hip flexion	-	-	↑	↑	↓	↓	↑	↑	-	↑
Peak hip extension	↑	-	-	-	↑	↑	-	-	↓	↓
Peak hip flexion (stance)	-	↑	↑	↑	↓	-	↑	↑	↑	↑
Hip ROM	-	-	-	↑	↑	-	↑	↑	-	↑
Peak hip flexion moments	↑	↑	↑	↑	↑	↑	↑	↑	↑	↑
Peak hip extension moments	↑	↑	↑	↑	↑	-	-	↑	↑	↑
Peak knee flexion moments	↑	↑	↑	↑	↓	↑	↑	↑	↑	↑
Peak knee extension moments	↓	-	↑	↓	↑	-	↑	↓	↓	↓
Knee flex/ext moments at mid-stance	↓	↓	↑	↓	↑	↑	↑	-	-	↓
Peak ankle DF moments	↑	-	↑	↑	↑	↑	-	-	↑	-
Peak ankle PF moments	↑	↑	↑	-	-	-	↑	↑	↑	↑
Cadence	↓	-	↑	↑	↑	-	-	-	↓	-
Stride-length	-	↑	↑	↑		-	↑		↑	↑
Walking speed	-	↑	↑	↑		-	↑		-	↑

Key: '↑' indicates increase and '↓' indicates decrease, shaded area denotes increase
ROM – range of motion, IC – initial contact, flex – flexion, ext – extension,
R – right, L - left

14.2.3.2 Comparison of kinematic and kinetic data points

Tables 14.8 and 14.9 provide compiled data from all eight participants. The individual tables for each participant with statistical analysis are given in Appendix XII. While it can be seen that all the parameters changed significantly in at least one participant in both comparisons, not all of them are of interest for the present study. Hence, only those changes which demonstrated some kind of pattern across the sample or categories of sample are reported in this section.

Results from the individual case studies on the effects of non-tuned AFO-FC compared with barefoot were in line with the group comparison (Table 14.8). While stride-length (six out of eight participants) and walking speed (five out of eight participants) demonstrated improvement in most of the sample with non-tuned AFO-FC compared to barefoot, cadence showed mixed results. The peak ankle plantar-flexion moments increased in seven out of 10 legs and the peak dorsi-flexion moments increased in six out of 10 legs with non-tuned AFO-FC compared to barefoot. Furthermore, no participants demonstrated a decrease in either of the ankle kinetics variables with non-tuned AFO-FC compared to barefoot. All except one leg (participant four- left leg) demonstrated increases in peak knee flexion moments, whereas the left leg of participant four demonstrated a decrease with non-tuned AFO-FC compared to barefoot. In contrast, peak knee extension moments demonstrated no consistent pattern. All legs demonstrated increases in peak hip flexion moments and all except three demonstrated increase in peak hip extension moments with non-tuned AFO-FC compared to barefoot. While the improvement in hip and knee ROM was limited to only half the sample, none of the participants demonstrated any deterioration with non-tuned AFO-FC compared to barefoot. No consistent patterns were seen with other variables.

Table 14.9 Compilation of results from case studies comparing the effects of non-tuned AFO-FC with AFO-FC immediately after tuning (Tuned immediate)

	Change with tuned immediate compared to non-tuned AFO-FC according to participant number and right or lef leg									
	1R	2R	3R	4R	4L	5R	6R	6L	7R	8L
Peak anterior pelvic tilt	-	-	-	-	-	-	↑	↑	-	↓
Peak posterior pelvic tilt	-	-	-	-	-	↓	↓	↓	-	↑
Pelvic tilt ROM	-	-	-	-	-	-	↑	-	-	-
Knee flexion at IC	-	↑	-	-	-	-	↓	↓	↑	-
Peak knee flexion (stance)	-	↑	-	↓	-	↑	↓	↓	↑	↑
Peak knee extension (stance)	↓	↓	-	-	-	-	↓	-	↓	↓
Peak knee flexion	↓	↓	-	↓	-	-	-	↓	-	-
Knee ROM	↓	↓	-	↓	-	-	↓	-	-	-
Peak hip flexion	-	-	-	↓	↓	-	↑	↑	↑	↓
Peak hip extension	-	↓	-	-	-	-	↓	↓	-	-
Peak hip flexion (stance)	-	-	-	↓	-	↑	↑	↑	↑	↓
Hip ROM	-	-	-	-	-	-	↓	↓	↑	-
Peak hip flexion moments	↓	↓	↓	↓	↓	↑	↓	↓	-	↓
Peak hip extension moments	-	↓	↓	↓	↑	↑	-	↓	-	-
Peak knee flexion moments	↑	-	↓	↓	↑	↑	↑	↑	↑	↑
Peak knee extension moments	↓	-	↓	↓	↓	-	↓	↓	↓	↓
Knee flex/ext moments at mid-stance	↓	-	↑	↓	↓	-	↓	↓	↓	-
Peak ankle DF moments	↓	↑	-	↓	-	↑	↓	↓	↑	↓
Peak ankle PF moments	↑	↓	-	↑	↑	↑	↑	↑	↑	-
Cadence	-	-	-	-	-	-	↓	-	-	-
Stride-length	-	-	-	-		-	↓		↑	-
Walking speed	-	-	↓	-		-	↓		-	-
Key: '↑' indicates increase and '↓' indicates decrease, shaded area denotes increase ROM – range of motion, IC – initial contact, flex – flexion, ext – extension, R – right, L - left										

The changes with tuned AFO-FCs compared to non-tuned AFO-FC seen in individual case studies were not completely in line with the group comparison (Table 14.9). Among the children with diplegia (participants 1, 3, 4 and 6), peak ankle dorsi-flexion moments decreased for four out of six legs, while no difference was seen in the other two legs with tuned AFO-FC compared to non-tuned. Among the children with hemiplegia the peak dorsi-flexion moments increased for three out of four legs, whereas it decreased in the remaining leg when comparing tuned AFO-FC with non-tuned. The knee flexion/extension moments at mid-stance was more flexing in six out of eight legs, whereas in one leg (participant 3) it was more extending with tuned AFO-FC compared to non-tuned. However, peak knee extension moments decreased with tuning in the majority of the legs. Peak hip flexion moments decreased in seven and increased in two out of ten legs with tuned AFO-FC compared to non-tuned, whereas this remained the same for one leg.

Interesting patterns were seen in knee kinematics with tuning. Knee ROM decreased for half of the sample, while the other half did not yield any change with tuned AFO-FC compared to non-tuned. Among the participants who demonstrated extended knee gait without increased knee flexion during initial stance while walking with non-tuned AFO-FC (participants 1,2,5,7 and 8), four out of five legs managed to produce decreases in hyper-extension, but also demonstrated in increased peak knee flexion during initial stance with tuned AFO-FC compared to non-tuned. One leg remained unaffected for each of the two variables above. For the participants who demonstrated crouch knee gait with non-tuned AFO-FC (participants 3 and 4), none of the three legs demonstrated any change in peak knee extension and knee flexion at initial contact, whereas one leg (participant 4 – right leg) showed decreases in peak knee flexion during stance and swing, and in knee ROM, with tuned AFO-FC compared to non-tuned. Both legs of participant 6, who had jump knee gait with non-tuned AFO-FC, demonstrated decreases in knee flexion at initial contact and peak knee flexion during stance with tuning. Interestingly, the right leg of participant 6, which demonstrated hyper-extension of the knee during stance phase with non-tuned AFO-FC showed decreased peak knee extension with tuning, whereas the other leg with normal knee extension remained unchanged.

14.2.4 Summary of findings

Summary of group comparisons

- With AFO compared with barefoot there were: significant improvements in stride-length and walking speed and significantly better and more inclined SVA, no changes in GDI, improvements (increases) in hip ROM, knee ROM, peak hip extension moments, peak ankle plantar-flexion moments and peak ankle dorsi-flexion moments; movement of peak hip flexion moments and peak knee flexion moments were further away from normal.
- With tuned AFO-FC compared with non-tuned there were: no significant changes in temporal-spatial parameters, however, children with hemiplegia showed trends of improvement and children with diplegia showed trends of deterioration; no changes in GDI; improved SVA, with significantly higher inclination; reduced peak knee extension, knee ROM and peak knee extension moments, and increased peak ankle plantar-flexion moments.
- Several parameters with statistically non significant changes between barefoot and non-tuned AFO-FC, and non-tuned AFO-FC and tuned immediate, showed high mean differences and wide confidence intervals.

Summary of case studies

- The gait patterns of the participants in barefoot were explained. However, it was seen that the patterns were affected by non-tuned AFO-FC.
- All participants with diplegia (6 legs) and one participant with hemiplegia demonstrated the ankle kinetic double bump pattern with non-tuned AFO-FC, of which four legs demonstrated trend of decrease in first peak of dorsi-flexion moments with tuned AFO-FC.
- The effects of tuning were different on the knee kinematics of participants with different gait patterns. In addition, differences were more prevalent between groups when grouped based on gait patterns with AFO-FC than in barefoot. Most of the variables with significant differences in the group comparison demonstrated similar trends in case study analysis.

14.3 Discussion

This section is comprised of two sub-sections. The first sub-section discusses the effects of non-tuned AFO-FC on the gait of children with CP when compared with barefoot, whereas the second sub-section discusses the effects of tuned AFO-FC on the gait of children with CP when compared with non-tuned.

14.3.1 Effects of AFO-FC (non-tuned) on the gait of children with CP.

The increase in stride-length and walking speed with the use of AFOs when compared with barefoot corroborates the findings of several previous studies (Abel et al. 1998; Brunner, Meier and Ruepp 1998; Dursun, Dursun and Alican 2002; Thompson et al. 2002; White et al. 2002). However, some studies found significant increases in stride-length, with no change in velocity (Buckon et al. 2001; Buckon et al. 2004; Carlson et al. 1997; Lam et al. 2005; Radtka et al. 1997; Radtka, Skinner and Johanson 2005). In the current study, six out of eight children demonstrated improvement in at least one of the temporal-spatial parameters.

The current study found no consistent differences in the effects of non-tuned AFO-FC on temporal-spatial parameters between children with diplegia and hemiplegia, or between children with different gait patterns. Comparisons between the effects of AFO in different diagnostic groups are sparse in the literature. Direct comparisons between the results from studies with children with hemiplegia to those of studies with diplegia are limited, due to differences in study designs. Two studies which included all children with CP, and compared those with hemiplegia and diplegia, produced conflicting results (Radtka et al. 1997; White et al. 2002). While Radtka et al. (1997) did not find any significant differences between children with hemiplegia and diplegia, they had a small sample size and reported a lack of power. White et al. (2002) observed that an increase in walking velocity with the use of AFOs was greater in children with hemiplegia, compared with diplegia. However, the authors did not attempt statistical comparison between the groups; furthermore, the groups included children who used rigid AFOs as well as hinged AFOs (White et al. 2002). Two other studies, by Buckon et al. (2001) and Buckon et al. (2004) used the same study design in samples of children with hemiplegia and diplegia respectively, and found similar changes in temporal-spatial parameters. However, it was not possible to statistically compare between the two groups as they were included in different studies.

Improvements in temporal-spatial parameters in the current study may be related to the changes in proximal joint kinematics. The significant improvement in knee ROM and hip ROM with the use of AFO-FCs compared to barefoot in the current study were contradictory to the findings of Carlson et al. (1997), Smiley et al. (2002), Buckon et al. (2004), Radtka, Skinner and Johanson (2005) and Radtka et al. (1997). These previous studies reported no influence of AFOs on proximal joint kinematics at all. However, Abel et al. (1998) reported increased hip, knee and pelvic ROM with AFOs compared to barefoot. While increased hip ROM was observed by Brunner, Meier and Ruepp (1998), they also reported decreased knee ROM with AFOs compared to barefoot.

Several previous studies have investigated the effects of AFOs on temporal-spatial parameters as well as proximal joint kinematics. Among these, the only two studies who reported increased hip ROM also found increased walking speed and stride-length (Abel et al. 1998; Brunner, Meier and Ruepp 1998). Furthermore, the studies which did not report any change in hip ROM also reported no change in walking velocity with AFOs, with the exception of Thompson et al. (2002). While Thompson et al. (2002) reported increased walking velocity with AFOs, the values reported seemed erroneous (2.2 m/s in barefoot and 2.4 m/s with AFOs). This supports the possibility that the changes in temporal-spatial parameters and hip ROM with AFO intervention may be related.

The current study demonstrated that, although not statistically significant, peak knee flexion and peak hip flexion during stance tend to be higher with AFO-FC compared to barefoot. However, wide confidence intervals suggest a lack of power. Rethlefson et al. (1999) reported significant changes in peak knee flexion during stance. It is possible that the participants were using increased hip and knee flexion to achieve an initial contact with a flatter foot, when compared with barefoot where the ankle was mostly plantar flexed during initial contact.

The shank to vertical angle (SVA) in standing was significantly more inclined with AFO-FC compared to barefoot. A previous study reported a mean (SD) SVA of 11.4° (3.4) while walking barefoot and 10.5° (3.5) while walking shod in healthy children (Pratt, Durham and Ewins 2007). In the current study the children with CP demonstrated a mean (SD) SVA of 3.1° (3.9) in barefoot and 6.5° (2.5) in shod. The results from the current study demonstrate the abnormality in SVA in children with CP. However, it should be considered that the measurement of SVA in the present study was carried out in standing whereas Pratt and colleagues (2007) conducted this measurement in walking. It could be seen that while AFO-FC improved the tibial inclination when compared with barefoot, it was still not adequate when compared with normal.

The significant increase in peak dorsi-flexion moments during terminal stance with AFO-FC compared to barefoot corroborates the findings of previous studies (Carlson et al. 1997; Abel et al. 1998; Rethlefsen et al. 1999; Radtka, Skinner and Johanson 2005; Lam et al. 2005). It was suggested that the increase in peak dorsi-flexion moments during terminal stance may be due to the fact that there is a slight dorsi-flexed position of the calf muscles with AFOs when compared with barefoot, providing a biomechanical advantage for push off (Lam et al 2005). However, this suggestion is questionable, as there is a significant limitation of ankle movement within the AFOs, thus limiting the potential for any available biomechanical advantage to be transferred as push-off force. Another possibility is that the moment arm may have been less in barefoot compared to AFO-FC, with the ankle being plantar flexed during terminal stance. In contrast, with AFO-FC, the lack of active plantar-flexion, and the foot segment being rigid, may have resulted in a higher moment arm, thereby increasing moments.

The current study found that increased peak ankle plantar-flexion moments during initial stance with non-tuned AFO-FC compared to barefoot; this was contradictory to the findings of Lam et al. (2005) and Abel et al. (1998), who did not find any significant differences in ankle joint moments during initial stance. The differences in peak plantar-flexion moments in the current study may be due to two reasons. Firstly, the presence of a hard sole compared to barefoot might have produced increased moments. A previous case study by Weist and Waters (1979) compared four different heels and reported that the least compressible material produced the highest flexion moments on tibia. Similarly, in the current study, the comparison was made between barefoot walking and walking with AFO-FC, and so the role of shoes cannot be neglected.

Secondly, the difference may also be related to positioning of the foot during initial contact. From the kinetic plots of eight case studies in the current study (Figures 14.1 to 14.10) it can be seen that none of the 10 legs under investigation demonstrated plantar-flexion moments during initial stance in barefoot, whereas with AFO-FC all but participant four demonstrated plantar-flexion moments. None of the children had proper heel strike during barefoot, which may have resulted in the GRF being oriented anteriorly to the ankle joint, thus producing dorsi-flexion moments. In contrast, with AFO-FCs the orientation of GRF may have moved posterior to the ankle joint which probably resulted in higher plantar-flexion moments during initial stance.

The fact that changes in peak plantar-flexion moments in the current study contradict the findings of previous literature (Abel et al. 1998; Lam et al. 1998) may result from the difference in the angle at which AFOs were casted in the current study. This may have allowed better alignment during initial contact than casting of AFOs in previous studies. While the influence of the various positions of ankle and knee on the activity of gastrocnemius has been investigated before (Arampatzis et al. 2006), there is little evidence regarding the influence of the angle of the ankle in AFOs (AAAFO). It has been hypothesised that casting AAFO at the available length of gastrocnemius influences knee motion during gait (Owen 2004b), which may be attributed to the moment arm ratio of around 3:2 between ankle and knee for gastrocnemius when the ankle and knee are at 0° (Stewart, Robert and Jonkers 2004). Casting of AFOs to accommodate the tightness of gastrocnemius has been recommended as vital for children with CP (Bowers and Ross 2009), as well as for adults with stroke (NHS Quality Improvement 2009).

In the current study, while peak hip extension moments increased towards normal, the peak hip flexion moments and peak knee flexion moments increased further away from normal with non tuned AFO-FC compared to barefoot. None of the previous studies which investigated proximal joint kinetics reported significant differences (Carlson et al. 1997; Rethlefsen et al. 1999; Abel et al. 1998; Buckon et al. 2004; Lam et al. 2005; Radtka, Skinner and Johanson 2005; Buckon et al. 2001). The peak knee flexion moments and peak hip flexion moments are in line with the changes in peak knee flexion during stance and peak hip flexion during stance. However, among the changes in proximal joint kinetics, only change in the peak hip extension moments can be considered improvement.

As explained previously, the trends of increase in knee flexion and peak hip flexion may have resulted from different alignment of the ankle joint during initial contact. The increase in peak hip flexion moments and peak knee flexion moments may have been a result of change of alignment in the GRF achieved by heel strike, and changes in the kinematics of knee and hip.

The gait patterns of individual participants revealed the influences of AFO-FC on the overall gait pattern of participants. It was seen that the use of AFO-FC influenced gait patterns differently for each participant. While AFO-FC significantly limited ankle joint motion for all the participants, effects on proximal joints were different. It is not traditional to categorise children wearing AFOs into gait patterns based on knee joint kinematics. However, in the current study such a categorisation is attempted, owing to the fact that the effects of tuning of AFO-FC are investigated by comparing the kinematics and kinetics with tuned AFO-FC to non-tuned AFO-FC and not barefoot.

Barefoot gait pattern	Gait pattern with AFO-FC
Participant 1: True equinus pattern with near normal knee extension	Extended knee gait with knee hyper-extension
Participant 2: Winters' group I with slight knee flexion	Extended knee gait with knee hyper-extension
Participant 3: Crouch knee gait with increased knee flexion	Crouch knee gait with increased knee flexion
Participant 4 right leg: Crouch knee gait with increased knee flexion	Crouch knee gait with further increased knee flexion
Participant 4 left leg: Crouch knee gait with increased knee flexion	Crouch knee gait with increased knee flexion
Participant 5: Winters' group II with knee hyper-extension	Extended knee gait with knee hyper-extension
Participant 6 right leg: Jump knee gait with slight knee flexion	Jump knee gait with knee hyper-extension
Participant 6 left leg: Jump knee gait with slight knee flexion	Jump knee gait with normal knee extension
Participant 7: Winters' group II with knee hyper-extension	Extended knee gait with knee hyper-extension
Participant 8: Group V (Huk et al. 1987) with knee hyper-extension	Extended knee gait with knee hyper-extension

Figure 14.11 The gait patterns of participants in barefoot and gait patterns with non-tuned AFO-FC - with knee kinematics during mid to terminal stance

With non-tuned AFO-FC, all participants with hyper-extended knees in barefoot (participants 1, 5, 7 and 8) retained the extended knee pattern with normal or less than normal initial stance knee flexion. Furthermore, participant 2, who demonstrated most abnormalities in their ankle kinematics in barefoot, also demonstrated an extended knee pattern with AFO-FC. All the other children (participants 3, 4, 6), who already had high initial stance knee flexion either retained or had further increased knee flexion during initial stance. While participant 6 demonstrated normal (right) and hyper (left) extension at the knee, participants 3 and 4 retained the increased knee flexion. To sum up, five participants demonstrated an extended knee pattern (participants 1, 2, 5, 7 and 8), two participants (three legs) demonstrated crouch knee gait (participants 3 and 4) and one participant (two legs) demonstrated jump knee gait (participant 6) with non-tuned AFO-FC (Figure 14.11).

Despite all the improvements with the use of AFO-FC, several parameters (especially related to the knee joint) did not yield any significant changes. Furthermore, the influence of AFO-FC on gait patterns was negative in several participants. In comparison to barefoot, use of AFO-FC produced knee hyper-extension during mid and terminal stance in three participants (participants 1,2 and 6). Knee flexion further increased during initial stance for one participant (participant 6 left leg), and throughout stance phase for another (participant 4 right leg). Overall, it was evident that AFO-FC intervention requires further improvement. Tuning of AFO-FC has been recommended to optimise the use of AFO-FC (Butler and Nene 1991; Owen 2004b; Bowers and Ross 2009).

One factor which may have influenced the results in the current study is the role of shoes. While no studies were located that had investigated the role of shoes in AFO intervention in children with CP, two relevant studies in adult populations have been conducted (Hesse et al. 1996; Churchill, Haligan and Wade 2003). Both studies found that there was significant improvement in temporal-spatial parameters with shoes, which further improved with AFOs. In the current study, no comparison was conducted between shoes and AFOs in children with CP. The influence of shoes on stride-length in healthy individuals has previously been attributed to the increase in distal mass (Oeffinger et al. 1999), which may also be relevant in children with CP. However, in the current study it is not possible to estimate the contribution of footwear alone, while the AFO- foot wear combination produced an increase of 0.16 m in stride-length and 0.15 m/s in walking velocity.

One major difference between the current study and existing literature is that AFOs were cast to accommodate the available length of gastrocnemius, whereas all previous studies casted in plantigrade. The angle of ankle in AFO is considered vital and is discussed earlier in the current section (pages: 229 to 230). It should also be noted that the AFOs which were already being used by 6 children (8 out of 10 AFOs) in the current study were deemed inappropriate and were recast, since they were all originally cast in plantigrade. Other characteristics of the current study which might have influenced the results are, firstly, that children were already using AFOs, and hence they were accustomed to them, and secondly, that the comparisons were made between walking in barefoot and walking with AFOs. All the studies which gave children time to get accustomed to AFOs, and compared barefoot with AFO use, reported significant improvement in at least one of the temporal-spatial parameters (Radtka et al. 1997; Buckon et al. 2001; Dursun, Dursun and Alican 2002; Thompson et al. 2002; White et al. 2002; Buckon et al. 2004 and Radtka, Skinner and Johanson 2005).

To summarise, it is evident from the current study that rigid AFOs produced significant improvements in the gait of children with CP, provided factors such as the appropriateness of AFO-FC and familiarisation with AFO-FC are addressed. However, it is also evident that the use of AFO-FC requires further optimisation through tuning.

14.3.2 Immediate effects of tuning of AFO-FC on gait characteristics of children with CP

In the present study none of the temporal-spatial parameters yielded significant differences between tuned and non-tuned AFO-FCs. The one study which has investigated the effects of tuning of AFO-FCs on temporal-spatial parameters only looked into the change in speed over time (four to six months). No differences were found in comparison with walking barefoot, and a reduction in speed was found in comparison with non-tuned AFO-FC (Butler, Thompson and Major 1992).

In the current study, trends were different between groups of children with diplegia and children with hemiplegia. While there was a trend of decrease in all three temporal-spatial parameters with the use of tuned AFO-FC in children with diplegia, the children with hemiplegia presented a trend of increase. While the trends appear considerable, the lack of a large enough sample prevented any statistical analysis and no literature is available comparing the effects of tuning on children with hemiplegia and diplegia.

One explanation of the variability between children with hemiplegia and diplegia may be that the groups differed in their ability to become accustomed to the new prescription, in which their usual alignment was altered. Since all children were accustomed to AFOs, no such difference in ability was observable during the comparison between AFO and barefoot. Another possible explanation for the trend of decrease in temporal-spatial parameters with tuned AFO-FC in children with diplegia is that tuning might have increased their stability in walking, thus decreasing their walking speed and stride-length. The results may be different after a period of familiarisation. Such a possibility is supported by findings from a case study involving an adult with hemiplegia, in which the effects of tuning were investigated over a period of three months (Jagadamma et al. 2007). The authors reported that while there was no improvement in temporal-spatial parameters immediately after tuning, there was increase in velocity, step length and single support time after three months.

The shank to vertical angle (SVA) was more inclined and closer to normal with tuned AFO-FC compared to non-tuned in the current study. This is in line with the previous study which reported the SVA of children with Spina Bifida and CP (Owen 2002). Owen (2002) reported a mean (SD) SVA of 11.86° (2.05) for tuned AFO-FCs in 50 children with CP. Another previous study reported a mean (SD) SVA of 11.4° (3.4) in healthy children, while walking barefoot and 10.5° (3.5) while walking shod (Pratt, Durham and Ewins 2007). In the current study the mean (SD) SVA was 6.5° (2.5) for the non-tuned, and 12.7° (1.7) for the tuned condition. This indicates that for children with CP with AFOs, the tibial shank was upright compared to normal, which improved after tuning. A recent recommendation from the ISPO (International Society for Prosthetics and Orthotics) advocates for the use of some level of tibial inclination to optimise gait in children with CP (Bowers and Ross 2009). However, neither an ideal value, nor range of values for SVA was given. In contrast, for AFO in patients with stroke, a tibial inclination of approximately 10° has been recommended for optimal gait (NHS Quality Improvement 2009).

In the current study peak plantar-flexion moments during initial stance were significantly higher with tuned AFO-FC compared to non-tuned. As suggested by Wiest et al. (1979), the design of the heel may have a vital influence on torque acting on the tibia. Wiest et al. (1979) investigated the effects of different heel designs on tibial advancement torque using a case study, and reported that a harder heel produced a higher torque. While in the present comparison the shoes worn by both groups were the same, there was alteration at the heels in tuned AFO-FC, through the use of wedges. With non-tuned AFO-FC, children wore shoes with rubber soles, whereas with tuned AFO-FCs, wedges that were made with high density ethyl vinyl acetate (EVA), and/or point loading rockers (PLR) made with high density plastazoate were attached to the shoes. Both attachments were harder than the rubber soles and also increased the lever arm of the heel, thus increasing the moment arm at the ankle joint.

Seven out of ten legs in the current study demonstrated a kinetic ankle double bump pattern, which is generally associated with spasticity, and/or clonus of the plantar flexor muscles, and lack of ankle dorsi-flexion during initial contact (Piercre 1997; Ounpuu 2004). When compared based on diagnosis, it was seen that all the participants (6 legs) with diplegia, and only one of the four participants with hemiplegia, demonstrated the kinetic ankle double bump pattern. Furthermore, among participants with diplegia, four out of six legs demonstrated improvement, with decreases in the first peak of dorsi-flexion moments with tuning. The only participant with hemiplegia and the double bump pattern demonstrated no change in dorsi-flexion moments following tuning. However, the pattern was more normal for all six legs. While no statistical analysis was employed to investigate the immediate effects of tuning on the peaking of dorsi-flexion moments during mid-stance, the trends indicated that tuning may have been influential in the current sample.

Historically, kinematics and kinetics of the knee joint have been given much attention whenever gait patterns of children with CP have been discussed (Simon et al 1978; Winters, Gage, and Hicks 1987; Sutherland and Davids 1993). Furthermore, most of the studies with tuning emphasised the effects of tuning on the knee joint (Butler, Thompson and Major 1992; Butler, Farmer and Major 1997; Butler et al. 2007). During tuning the alignment of the shank is modified using wedges, until the orientation of the GRF is as close to the knee joint as possible during mid-stance (Butler and Nene 1991). Since all participants were wearing rigid AFOs, changes in design and alignment of the footwear were expected to predominantly affect the shank of the tibia and the knee joint. For the above reasons, it was considered to be vital that the current study emphasises changes in knee kinetics and kinematics. The influences of tuning of AFO-FC on knee kinematics and kinetics were evident. However, the case study analysis revealed that gait patterns while wearing AFO-FC may have influenced the effects of tuning on knee kinematics.

Table 14.10 Immediate effects of tuning on knee kinematics of children with different gait patterns compared with non-tuned AFO-FCs.

Parameters	Extended knee gait	Crouch knee gait	Jump knee gait
Knee flex at IC	- ↑ - ↑ -	- - -	↓ ↓
Peak knee flex (stance)	- ↑ ↑ ↑ ↑	- ↓ -	↓ ↓
Peak knee extension	↓ ↓ - ↓ ↓	- - -	↓ -
Peak knee flexion	↓ ↓ - - -	- ↓ -	- ↓
ROM	↓ ↓ - - -	- ↓ -	↓ ↓

NB: Each symbol (↓, ↑ or -) represents one leg and '↓' indicates significant decrease, '↑' indicates significant increase and '- ' no change.

In the current study, peak knee extension during stance and knee ROM were significantly lower with tuned AFO-FC compared to non-tuned. The reduction in knee ROM was probably due to the reductions in knee hyper-extension and peak knee flexion in parts of the sample. Even though the mean knee angle was greater in flexion with tuned AFO-FC compared to non-tuned during peak knee extension of stance phase, case study analyses provide a different picture (Table 14.10). The five children who had extended knee gait with non-tuned AFO-FC demonstrated knee hyper-extension (peak knee extension < 5° of flexion) and immediately after tuning, peak knee extension further decreased in four of the five. However, the children with crouch knee gait with non-tuned AFO-FC did not yield any significant difference with tuning. Of the two legs with a jump knee pattern with AFO-FC, the leg which demonstrated hyper-extension of the knee showed a significant decrease in peak knee extension, while the other leg which had normal knee extension did not show any difference after tuning. Therefore, it could be assumed that tuning of AFO-FC normalised knee extension for the majority of the sample. While no study has investigated the effects of tuning on knee kinematics of children with CP before, an adult case study has reported similar findings (Jagadamma et al. 2007). The normalisation of knee extension may be attributed to re-orientation of the GRF closer to the knee joint, as suggested by Butler and Nene (1991). The use of wedges might have changed the alignment of the shank, as no movement was available at the ankle joint to adapt to the change in heel height. Knee joint moments are dependent on magnitude of the GRF vector, and the distance between the joint centre and the vector (moment arm). Butler, Thompson and Major (1992) and Butler, Farmer and Major (1997) reported that reorientation of the GRF using tuning reduced the moment arm, after the tuned orthoses were used for a period of time. While the moment arm was not investigated in the current study, knee joint external moments were, and are explained later in this section.

In the current study, the knee flexion at initial contact, peak knee flexion during initial stance, and peak knee flexion did not show any statistically significant differences. A previous study noted increased knee flexion during initial stance as a demerit of tuning (Butler et al. 2007). However, Butler et al. (2007) stated that the overall benefits of tuning compensate for this disadvantage. In the current study, comparisons based on gait patterns showed that children with extended knee gait while using non-tuned AFO-FC were prone to an unwanted increase in knee flexion during initial stance (Table 14.10). This was not the case with the other two gait patterns; the legs which had jump knee gait showed a trend of decrease of already high initial stance flexion; and of the three legs with crouch gait, two remained unchanged and one showed a trend of decrease of already high knee flexion during initial stance. However, since there was a limited sample in each category, these changes have limited generalisability and can only be considered as indications that influences of tuning may vary across the different gait patterns that were represented when using non tuned AFO-FC. Nonetheless, the need for grouping children with CP based on their gait pattern is indicated

A significant reduction in peak knee extension moments was also reported which may be attributed to the fact that tuning brought the GRF closer to the knee joint. In contrast, the knee moments during mid-stance were not significantly different with tuned AFO-FC compared to non-tuned. As explained previously, knee joint moments are dependent on the moment arm, as well as magnitude of the GRF. It has been reported previously that tuning of AFOs reduced the moment arm at the knee joint (Butler, Thompson and Major 1992; Butler, Farmer and Major 1997). Furthermore, looking at the case studies, it can be seen that for eight of the10 legs peak knee extension moments showed a trend of decrease with tuning. It should be considered that six out of 10 legs demonstrated knee hyper-extension with non-tuned AFO-FCs. Some (participants 1,2, 5, 6, 7,8) had knee joint extension moments of less than or equal to the mean normal value (0.26 Nm/kg). These were then decreased by reorientation of the GRF, and were thus even further from normal. Two participants had peak knee extension moments that were higher than the normal value (participants 1 and 5), and were reduced to become closer to the normal value. This suggests that the changes in knee joint moments may have not been synchronous with the moment arms. This may be due to the difference in the magnitude of the GRF vector. Hence, although with tuned AFO-FC the mean peak knee extension moments moved away from normal, this change may be considered to be an improvement.

The peak knee flexion moments were not significantly different between tuned and non tuned AFO-FCs in the current study. However, the mean difference between tuned and non-tuned AFO-FCs demonstrated a trend of increase in peak knee flexion moments and wide confidence intervals, which suggest the possibility of type II error. Furthermore, comparison based on the gait patterns indicates that all the children with extending knee gait pattern showed trends of increase in peak knee flexion moments during the stance phase with tuned AFO-FC compared to non-tuned. This is in line with the kinematic data, where an increasing trend of peak knee flexion during stance was seen in children with extending knee gait. This may have resulted in increased demand on the quadriceps muscle, which may be a disadvantage of tuning. However, all the children with flexed knee gait (crouch and jump knee gait) demonstrated decreased peak knee flexion moments during stance with tuned AFO-FC, with the exception of the left knee of participant four.

The increase in knee flexion and knee flexion moments during initial stance may be attributed the size and design of the heel in tuned AFO-FC. The influence of heel designs in regulating initial stance kinetics has been suggested before (Owen 2004b; Owen 2005). Weist and Waters (1979) reported that there is a direct relationship between the heel lever length and tibial advancement torque. According to Owen (2004b, 2005), a positive heel (heel flaring out) will produce increased moment arm at the knee during initial contact, and hence can be used in patients with decreased shank velocity at initial stance. However, no standardisation exists regarding the size of the flare, or the hardness of the heel needed to produce an adequate amount of tibial advancement. In the current study it was seen that use of a neutral heel (without any flare) that was high produced increased plantar-flexion moments, peak knee flexion moments and knee flexion during initial contact in children with extended knee gait. Butler et al. (2007) suggested that the increased flexion during initial stance is a disadvantage of tuning, which was corroborated by the present study. Owen (2004a) advocated for the use either a positive or neutral heel for children with neurological impairments. The question arises as to whether the use of a positive/neutral heel will be optimal when tuning AFO-FC for children with extended knee gait, or whether a bevelled heel may be better. The evidence relating to the use of different heel designs (positive, neutral and negative) in tuning of AFOs is empirical at best. The findings from the current study suggest that more research is required before integrating the use of different heel designs as part of tuning.

There was considerable mean reduction in peak hip flexion moments, with wide confidence intervals with tuned AFO-FC compared to non-tuned, although statistical significance was not reached, Furthermore, there were decreases in peak hip flexion moments in eight out of 10 legs. Hip flexion moments were probably influenced by reorientation of the GRF during initial stance due to the increased heel height.

There were no statistically significant differences in pelvic kinematics in the group comparisons. However, of the three participants with a pelvic single bump pattern, two demonstrated more normal patterns with tuning. In contrast, three legs demonstrated a greater than normal anterior pelvic tilt with tuned AFO-FC compared to non-tuned. Hence it could be suggested that a mixture of changes were produced at the pelvis by tuning.

One clear message from the findings of the current study is that children who demonstrate different gait patterns respond differently to tuning. For clinical purposes it is useful to know whether it is possible to predict tunability based on already existing gait pathologies. Butler et al. (2007) attempted to develop a screening tool to identify the best predictors of tunability and identified knee flexion during the first third, and second third, of stance as the best predictors. The authors categorised children with less than 20° flexion during initial stance, and less than 10° flexion during mid-stance, as mostly likely to benefit from tuning. If knee flexion was above 20° and 10° during the first and second thirds of stance, they were less likely to benefit from tuned. This explains the fact that fewest changes were seen in children with crouch gait in the current study. It should also be noted that Butler et al. (2007) considered only knee kinematic and kinetic parameters during stance phase, clinical examination results, and ankle motion to identify the key parameters influencing tunability. They did not consider all lower limb kinematics and kinetics. However, the emphasis on both knee and ankle joints is justifiable, as most of the sagittal gait classifications emphasised the knee joint when categorising gait patterns, while some also considered the ankle joint (Winters, Gage, and Hicks 1987; Sutherland and Davids 1993; Rodda et al. 2004).

It should be noted that Butler et al. (2007) used the gait pattern of children in barefoot as baseline and comparison was done between barefoot gait and gait with tuned AFO to categorise tunability. The comparisons were made between non-tuned and tuned AFO-FCs in the present study. One possibility observed in the current study was that tunability may be more definable using gait patterns demonstrated by children while wearing their original AFO-FCs. The two participants who demonstrated least improvement at the knee joint (three and four) demonstrated a gait pattern (crouch) categorised as non-tunable by Butler et al. (2007) while wearing their original AFO-FC. Butler et al. (2007) also categorised children with increased flexion during initial stance, followed by near full extension during mid-stance (jumb knee gait) in barefoot, as non-tunable. In the current study, participant six, who had a jump knee pattern when wearing AFO-FCs, demonstrated improvement. To sum up, in the current study the children with extended knee gait and jump knee gait with AFO-FC demonstrated improvements in knee kinematics, whereas the children with crouch knee gait remained mostly unchanged. A possibility exist that tunability may be best predicted when gait patterns analysed during use of non-tuned AFO-FC are taken as a baseline.

14.4 Conclusion

The findings of the current study demonstrate positive influences of the non-tuned AFO-FC on gait of children with CP. While it is possible that some of the changes might have been influenced by footwear alone, no actual comparison of gait with footwear alone was carried out due to the already lengthy data collection sessions. More changes were seen in kinetics than in kinematics for children with CP when comparing non-tuned AFO-FC with barefoot. In contrast, the results of tuning demonstrated mixed changes, and were visible predominantly at the knee joint. It was also seen that there may be strategies specific to gait patterns (while wearing AFO-FC) that cause adaptations to modifications made to the AFO-FC. While children with extended knee gait and jump knee gait demonstrated improvements in knee kinematics, children with crouch gait were less affected. It was also noticed that there were unwanted increases in knee flexion during initial stance for children with extended knee gait. However, some changes in knee kinetics were visible for both participants with crouch knee gait. Furthermore, even in participants with definite improvements, tuning did not bring improvements uniformly to all lower limb joints. On the contrary, a combination of improvement and deterioration in lower limb kinematics and kinetics was seen.

The influence of non-tuned and tuned AFO-FC on gait patterns was evident. Hence, with a larger sample, categorisation of participants into groups based on gait patterns may provide more useful information while investigating the effectiveness of interventions like AFOs. However, while investigating the effects of tuning, gait patterns analysed with non-tuned AFO-FC instead of barefoot might be more useful as a baseline.

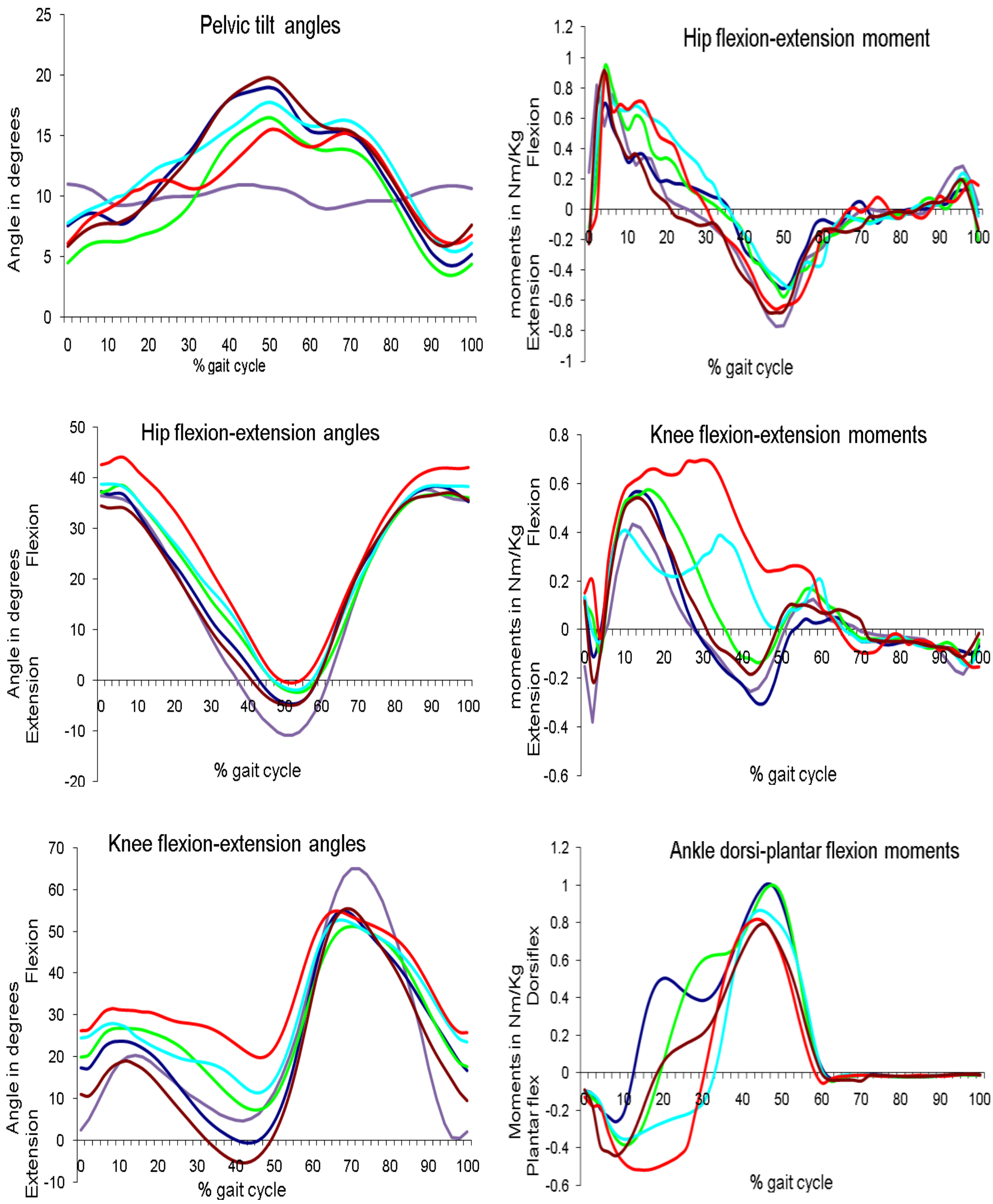
CHAPTER 15 EFFECTS OF WEDGES AND POINT LOADING ROCKERS (PLR) ON THE GAIT OF CHILDREN WITH CEREBRAL PALSY – CASE SERIES: RESULTS AND DISCUSSION

15.1 Introduction

Several studies have investigated the effects of tuning using wedges on the gait of children with CP. However, no studies have investigated the effects of incremental wedge sizes. It has been demonstrated previously that attaining an optimal alignment of the Ground Reaction Force (GRF) in relation to the knee joint is possible using wedges (Stallard and Woollam, 2003). However, the precision of the size of the wedge to attain optimal alignment is not clear. Tuning is not always conducted with the help of a motion analysis system in clinical practice, and attaining an optimal alignment of the GRF in such contexts may be difficult. Hence, it is important to know the effects of different wedge sizes (smaller or bigger than optimal), on the gait of children with Cerebral Palsy (CP). Furthermore, information on the compensatory mechanisms of children with CP with different gait patterns with increasing sizes of wedges may provide further insight into the biomechanics of tuning.

Point Loading Rockers (PLRs) have been recommended for use in the process of tuning by more than one author (Hullin, Robb and Loudon 1991; Owen, 2005), although there is a lack of published data investigating their effects on gait in children with CP. One published abstract has considered the use of PLRs in children with CP (Owen, 2004a), and reported the mean ideal length of PLR to be 78% of the length of footwear, with a mean toe spring angle of 33°. However, Owen (2004a) did not look at the effects of PLRs on gait. The lack of objective data looking at effects of PLRs on the gait of children with CP is evident. In order to address this, the aims of this study were to:

- investigate the effects of increasing sizes of wedges on the gait of children with CP, and
- investigate the effects of PLRs on the gait of the children with CP



Legend
AFO-FC 4° wedge 8° wedge 12° wedge 20° wedge Normal

Figure 15.1 Graph showing kinematics and moments in the sagittal plane with non tuned AFO-FC and different wedge sizes with reference to normal during one complete gait cycle of case study A (participant 2)

This section compares the results from three case studies (A, B, and C) looking at the effects of increasing sizes of wedges, and one case study (D) looking at the effects of two sizes of PLR on the gait of children with CP. The initial goal was to investigate the effects of standard sizes of wedges and PLRs on a larger group of participants. However, a small sample size resulting from low recruitment led to a decision to conduct a case-series analysis. Three case studies looked at the effects of the wedges, in children who demonstrated different gait patterns while wearing AFO-FC.

The following definitions were applied in the current study – knee extension of less than 5° of flexion during mid and terminal stance was defined as knee hyper-extension (Hullin, Robb and Loudon 1996); a change in any parameter towards normal was defined as improvement; and the opposite was defined as deterioration.

15.2 Results

In order to analyse data in the current study, Comparisons between conditions were drawn through graphical analyses of pelvis, hip and knee joint movements, and hip, knee and ankle moments in the sagittal plane. The kinematic and kinetic data points and temporal-spatial parameters were also extracted for all case studies. In addition, the Shank to Vertical Angle (SVA) was compared for case studies A, B and C, and the peaks of vertical GRF were compared for case study D. The effects of wedges on the kinematic data points and temporal-spatial parameters were statistically analysed for each participant. All data except the comparisons of kinematic and kinetic data points are presented in this section. The comparison of kinematic and kinetic data points is given in Appendix XIII.

15.2.1 Case study A:

This case study is based on participant 2 who had hemiplegia. The barefoot gait pattern of participant 2 is explained in Section 14.2.3.1 (page 204). When using AFO-FC, the knee joint demonstrated hyper-extension and the pelvis demonstrated a single bump pattern (Figure 15.1). In this case study, the effects of wedge sizes 4°, 8°, 12° and 20° were compared with non-tuned AFO-FC. No statistical analysis was attempted in this case study owing to an insufficient number of trials for each wedge.

Table 15.1 Descriptive analysis of temporal-spatial parameters and SVA between non-tuned AFO-FC and different sizes of wedges for case study A (participant 2)

	AFO-FC Mean	4° Wedge Mean	8° Wedge Mean	12° Wedge Mean	20° Wedge Mean
Cadence (steps/minute)	106.4 (2.3)	106.7 (4.7)	104.8 (9.7)	111.9 (5.2)	110.9 (3.4)
Stride-length (m)	1.15 (0.14)	1.16 (0.07)	1.16 (0.08)	1.15 (0.02)	1.20 (0.07)
Walking Speed (m/s)	1.02 (0.12)	1.03 (0.10)	1.02 (0.15)	1.07 (0.03)	1.11 (0.09)
SVA (°)	10	12	13	19	22
Key: SD- Standard Deviation, SVA – Shank to Vertical Angle					

The key changes were seen at the knee joint kinematics, with an increase in knee flexion during initial stance, and decrease in knee extension during mid to terminal stance with increasing sizes of wedges. There were changes in knee and ankle joint kinematics as well, but without any consistent pattern.

No consistent trends in temporal-spatial parameters were seen, except at the higher walking speed when comparing the 20° wedge with AFO-FC. The SVA was increasingly inclined with increasing sizes of wedges (Table 15.1). Knee flexion during initial contact and loading response showed trends of increase, whereas peak knee extension during mid to terminal stance showed a trend of decrease with increasing sizes of wedges. A shift towards flexion during the stance phase was apparent. The pelvis retained an anterior tilt with a single bump pattern for all conditions (Figure 15.1).

The knee flexion-extension moments graph (Figure 15.1) shows a steady decrease in extension moments during mid- to terminal stance with increasing size of wedges. However, the non-tuned AFO-FC produced a lower knee extension moments than the 4° wedge. While the non-tuned AFO-FC and smaller wedges produced a steady shift from peak flexion moments to extension moments during mid-stance, there were irregular patterns, with a second peak of knee flexion moments demonstrated with the 12° and 20° wedges. At the ankle joint, while there was no obvious ankle kinetic double bump pattern, all conditions except the 20° and 12° wedges produced a hike in dorsi-flexion moments during mid-stance (Figure 15.1).

It was evident that the increasing sizes of wedges influenced predominantly the knee and ankle joints. There was linear increase in knee flexion and inclination of SVA with increasing sizes of wedges

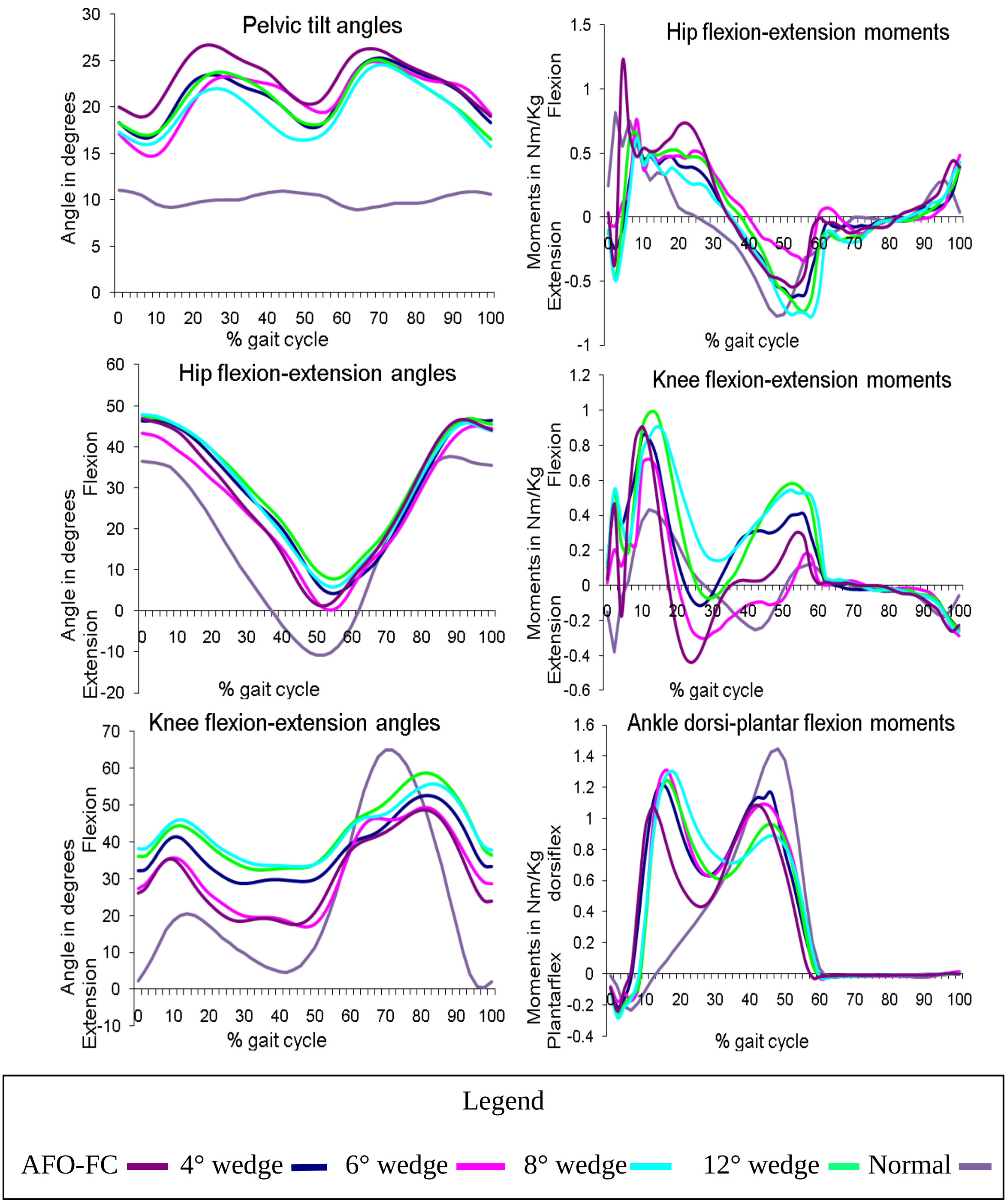


Figure 15.2 Graph showing kinematics and moments in the sagittal plane with non-tuned AFO-FC and different wedge sizes during one complete gait cycle of case study B (participant 3)

15.2.2 Case study B

This case study is based on participant 3, who had diplegia and used an AFO on her right leg only. The barefoot gait pattern of participant 3 is explained in Section 14.2.3.1 (page 206). With the non-tuned AFO-FC the participant demonstrated crouch gait with increased knee flexion during stance, and a kinetic ankle double bump pattern (Figure 15.2). In this case study comparisons were made between non-tuned AFO-FC and the 4°, 6°, 8° and 12° wedges.

The kinematics, kinetics, SVA and temporal-spatial parameters were different with the 6° wedge when compared with the other wedges. The comparison of temporal-spatial parameters and SVA are given in Table 15.2. Walking velocity and cadence were the lowest with 6° wedge compared to other wedges and AFO-FC. The SVA was least inclined with AFO-FC and the inclination was higher with all wedges. However, among the wedges, the inclination was lowest and closest to normal with the 6° wedge.

Table 15.2 Results from statistical analysis of temporal-spatial parameters and SVA between AFO-FC and different sizes of wedges for case study B (participant 3)

	AFO-FC Mean (SD)	4° Wedge Mean (SD)	6° Wedge Mean (SD)	8° Wedge Mean (SD)	12° Wedge Mean (SD)	p value
Cadence (steps/minute)	**139.6 (14.9)**	**129.1 (4.8)**	**126.6 (6.7)**	**141.1 (3.4)**	**143.9 (7.0)**	**0.002**
Stride-length (m)	**0.99 (0.06)**	**0.95 (0.07)**	**0.92 (0.10)**	**0.91 (0.06)**	**0.89 (0.04)**	**0.04**
Walking speed (m/s)	**1.15 (0.11)**	**1.03 (0.09)**	**0.97 (0.10)**	**1.07 (0.06)**	**1.07 (0.08)**	**0.002**
SVA (°)	6	14	13	17	20	**---**
Key: SD – Standard Deviation, SVA – Shank to Vertical Angle, Significance level $p < 0.05$, significant results in **bold**						

Knee flexion during initial contact and loading response showed an increasing trend with increasing sizes of wedges, with the exception of the 6° wedge, which gave similar results to the AFO-FC. Peak knee extension during stance was highest with the 6° wedge and AFO-FC, when compared with the other wedges. Similarly, peak hip extension was higher with AFO-FC and the 6° wedge compared to other conditions (Figure 15.2).

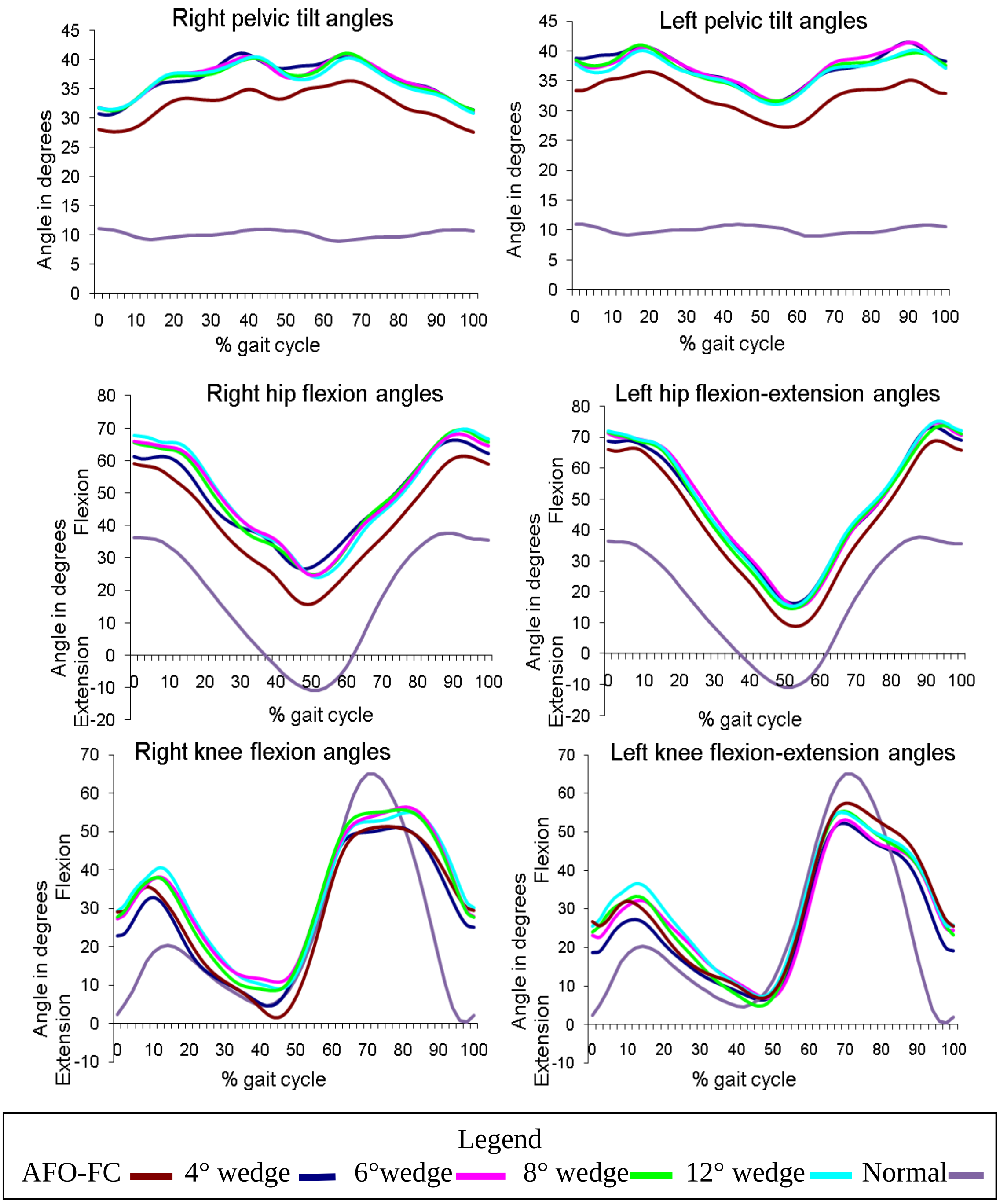


Figure 15.3 Graph showing kinematics of both lower limbs in the sagittal plane with non-tuned AFO-FC and different wedge sizes during one complete gait cycle of case study C (participant 6)

Among the kinetics (Figure 15.2), the peak knee extension moments during mid-stance were highest with the non-tuned AFO-FC, followed by the 6° wedge which further decreased, but without any consistent pattern with 4°, 8° and 12° wedges.

Peak knee flexion moments during initial stance were lowest with the 6° wedge compared to AFO-FC and other wedges. The ankle moments retained the double bump pattern in all the conditions and the abnormal first peak of dorsi-flexion moments was higher with all wedges compared to non-tuned AFO-FC.

It was evident that all wedges except the 6° wedge produced more abnormal kinetics and kinematics compared to AFO-FC. On the contrary, the 6° wedge produced kinematics and kinetics that were predominantly similar to, and occasionally more normal (knee moments), than AFO-FC.

15.2.3 Case study C

This case study is based on participant 6 who had diplegia and used rigid AFOs on both legs, therefore both legs are considered here. The barefoot gait pattern is explained in Section 14.2.3.1 (page 214). Use of non-tuned AFO-FC produced gait patterns with normal (left side) and hyper-extension (right side) of the knee during mid and terminal stances, and increased flexion during initial stance on the left side (Figure 15.3). There was also an ankle kinetic double bump pattern on both sides (Figure 15.4). In this case study, comparisons were made between the original AFO-FC, and 4°, 6°, 8° and 12° wedges.

Similarly to case study B, the results produced by a specific wedge size (4° wedge) were different from other wedges and AFO-FC for case study C. Changes were seen in kinematics and kinetics of all lower limb joints.

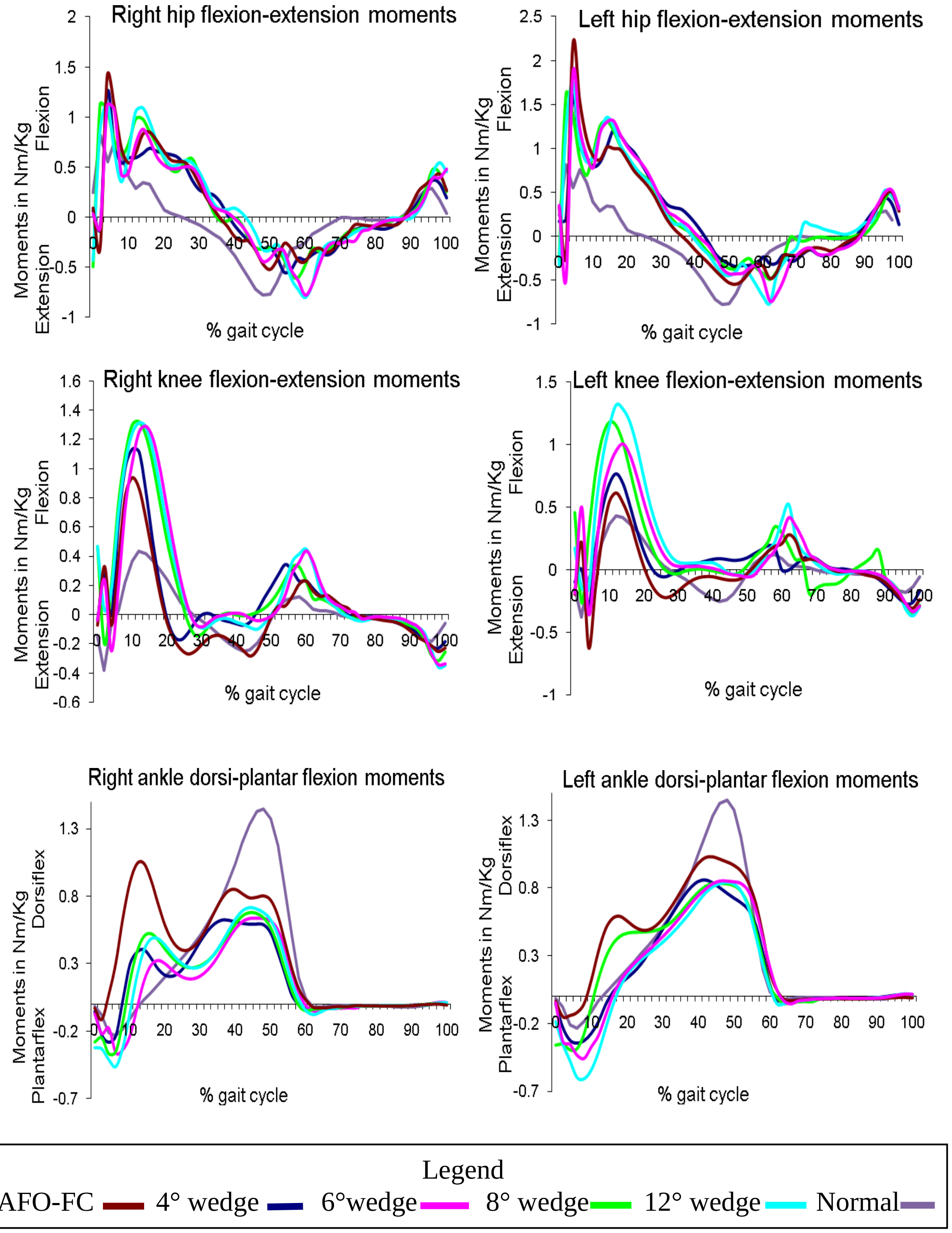


Figure 15.4 Graph showing kinematics of both lower limbs in the sagittal plane with non-tuned AFO-FC and different wedge sizes during one complete gait cycle of case study C (participant 6)

Comparison of temporal-spatial parameters and SVA are given in Table 15.3.

All temporal-spatial parameters were lowest for the 4° wedge, and none of the wedges had any values that were higher than those produced by the non-tuned AFO-FC. The SVA increased with increasing sizes of wedges (Table 15.3).

Table 15.3 Results from statistical analysis of temporal-spatial parameters and SVA between non-tuned AFO-FC and different sizes of wedges for case study C (participant 6)

	AFO-FC Mean	4° Wedge Mean	6° Wedge Mean	8° Wedge Mean	12° Wedge Mean	p value
Cadence (steps/minute)	**123.5 (1.5)**	**117.1 (6.4)**	**117.9 (3.2)**	**125.1 (4.6)**	**120.6 (1.7)**	**0.02**
Stride-length (m)	**1.18 (0.04)**	**1.11 (0.05)**	**1.16 (0.04)**	**1.16 (0.03)**	**1.17 (0.01)**	**0.02**
Walking speed (m/s)	**1.21 (0.05)**	**1.08 (0.10)**	**1.14 (0.06)**	**1.21 (0.07)**	**1.17 (0.03)**	**0.003**
Right SVA(°)	10	10	13	16	16	**---**
Left SVA (°)	6	9	12	15	16	**---**
Key: SD – Standard Deviation, SVA – Shank to Vertical Angle, Significance level $p < 0.05$, significant results in **bold**						

Changes were evident in knee kinematics (Figure 15.3). Knee flexion at initial contact and loading response were higher than normal on both sides with AFO-FC. Knee flexion at initial contact was reduced with the 4° wedge on both sides, whereas with the other wedges it remained almost the same. Similarly, peak knee flexion during initial stance was reduced with the 4° wedge on both sides, whereas with other wedges, it remained almost the same on the left side (except for the 12° wedge) and increased further on the right side. Peak knee extension, which was near normal on the left side with AFO-FC, did not change with the wedges. However, on the right side there was hyper-extension (< 5° of flexion) with AFO-FC which decreased to a normal level of flexion with the 4° wedge and became further flexed with the other wedges.

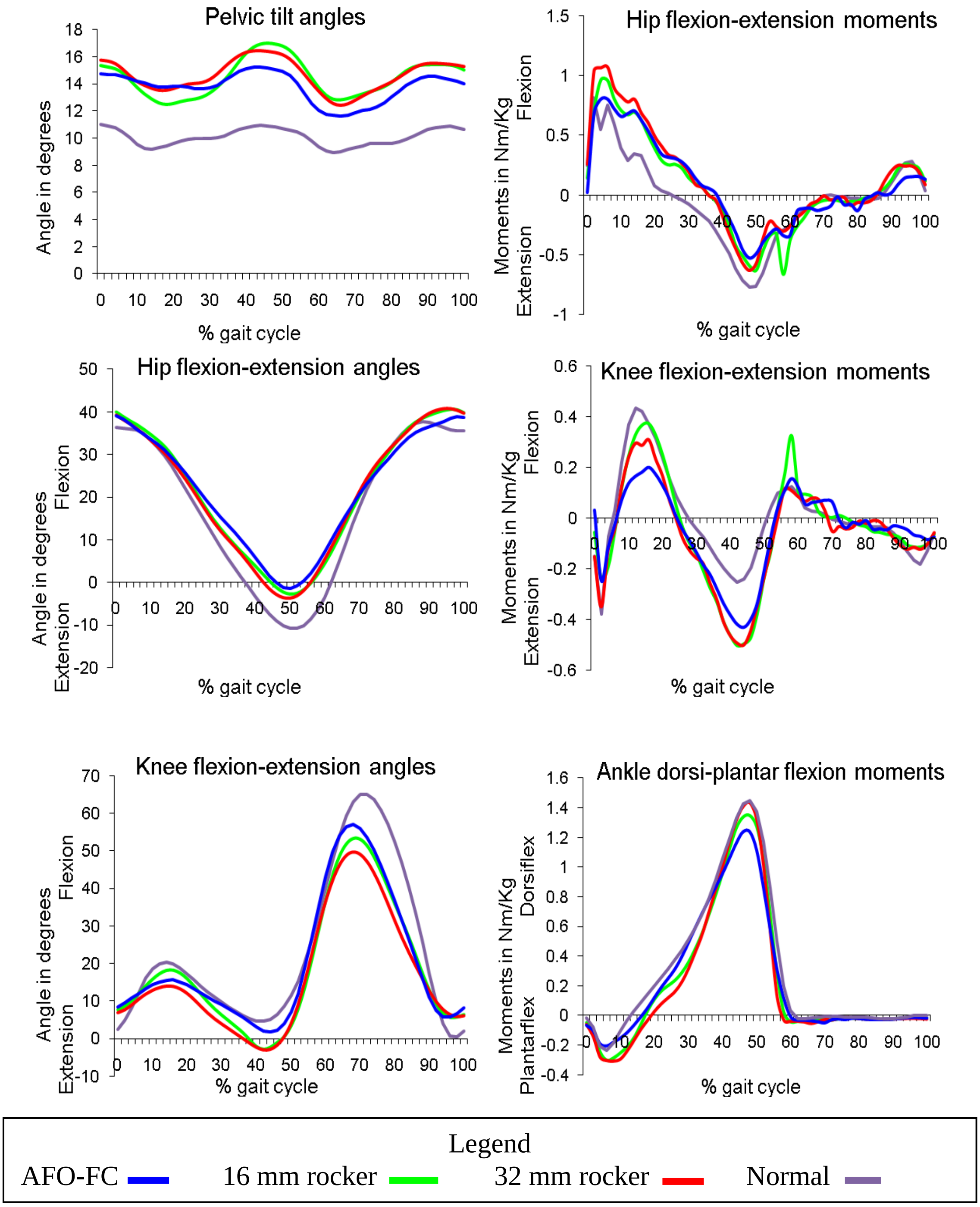


Figure 15.5 Graph showing kinematics and moments in the sagittal plane with non-tuned AFO-FC, 16 mm rocker and 32 mm rocker during one complete gait cycle of case study D (participant 8)

Hip flexion and anterior pelvic tilt were already higher than normal throughout the gait cycle with AFO-FC, which further increased with all the wedges. Interestingly, peak hip flexion during initial stance and terminal stance were slightly lower with the 4° wedge compared to other wedges on both sides (Figure 15.3).

The comparison of moments between AFO-FC and wedges are given in Figure 15.4. On both sides, the abnormal initial peak of ankle dorsi-flexion moments during initial to mid-stance were less with wedges compared to AFO-FC. However, the peak ankle dorsi-flexion moments during terminal stance also decreased with wedges compared to AFO-FC. Peak knee flexion moments during initial stance were higher with wedges compared to non-tuned AFO-FC. However, among the wedges, the peak knee flexion moments were lower with the 4° wedge compared to the others. Knee extension moments during mid and terminal stance were lower with wedges compared to AFO-FC. The peak hip flexion moments during initial stance was higher than normal with AFO-FC and decreased with the wedges, with the lowest being the 4° wedge on the left side and 6° wedge on the right.

It was evident that all except the 4° wedge produced predominantly less normal kinetics and kinematics compared to AFO-FC. In contrast, the 4° wedge produced the most normal results in several parameters, especially at the knee joint.

15.2.4 Case study D

This case study was based on participant 8, who had hemiplegia. The barefoot gait pattern is explained in Section 14.2.3.1 (page 220). With the original AFO-FC, the participant demonstrated a single bump pattern of the pelvis with increased anterior tilt. The knee joint demonstrated hyper-extension (< 5° flexion) during terminal stance (Figure 5.5). This case study compared the three conditions: the non-tuned AFO-FC, a 16 mm thick PLR and 32mm thick PLR. The lengths of both the PLRs were determined in order to locate the apex at 75% of the length of the shoes from the heel. The key changes were seen in temporal-spatial parameters, kinematics and kinetics with PLRs compared to AFO-FC.

Table 15.4 Results from statistical analysis of temporal-spatial parameters between non-tuned AFO-FC and different sizes of PLRs for case study D (participant 8)

	AFO-FC Mean (SD)	16 mm Rocker Mean (SD)	32 mm Rocker Mean (SD)	p value
Cadence (steps/minute)	**114.5 (5.4)**	**119.7 (3.3)**	**129.1 (2.6)**	**0.004**
Stride-length (m)	**1.13 (0.05)**	**1.23 (0.03)**	**1.26 (0.04)**	**0.01**
Walking Speed (m/s)	**1.08 (0.10)**	**1.23 (0.06)**	**1.35 (0.04)**	**0.003**
Key: SD – Standard Deviation, Significance level $p < 0.05$, significant results in **bold**				

Table 15.5 Descriptive analysis of two peaks of vertical force data in newtons (N) between non-tuned AFO-FC and different sizes of rockers for case study D (participant 8)

Side	parameter	AFO-FC Mean (SD)	16mm Rocker Mean (SD)	32mm Rocker Mean (SD)
Left	FZ1 (peak 1)	447.0 (8.5)	496.4 (19.7)	498.5 (26.7)
	FZ2 (peak 2)	437.9 (14.3)	465.9 (1.8)	466.6 (13.1)
Right	FZ1 (peak 1)	506.6 (5.5)	542.4 (36.3)	526.2 (--)
	FZ2 (peak 2)	432.0 (0.4)	466.2 (34.4)	469.6 (--)
Key: FZ1 – First peak of vertical force, FZ2 second peak of vertical force SD – Standard deviation, (--) – no standard deviation available				

Comparison of temporal-spatial parameters is given in Table 15.4. Cadence, stride-length and walking speed were higher with PLRs compared to AFO-FC. Between the PLRs, cadence and walking speed were higher with the 32 mm PLR compared to the 16 mm PLR.

A few changes were seen in hip and knee kinematics (Figure 15.5). Peak knee flexion during initial stance was not very different between AFO-FC and the 30mm PLR, but it was higher with the 16 mm PLR. Peak knee extension during stance was higher with both rockers compared to AFO-FC. While peak knee flexion decreased with rockers compared to AFO-FC, it was lowest for the 30 mm PLR. Peak hip flexion during terminal swing and peak hip extension during terminal stance were higher with both rockers compared to AFO-FC.

Comparisons of lower limb joint moments are given in Figure 15.5. The peak plantar-flexion moments and peak dorsi-flexion moments were higher with PLRs compared to non-tuned AFO-FC. Peak dorsi-flexion moments were higher for the 32 mm PLR compared to the 16 mm PLR. The peak knee flexion moments during initial stance and knee extension moments during terminal stance were higher with both rockers compared to non-tuned AFO-FC, between which the 16 mm PLR produced the highest knee flexion moments. Peak hip flexion moments during initial stance increased with increasing size of rockers. Both the peaks of vertical forces tended to be higher with rockers compared to non-tuned AFO-FC for both legs (Table 15.5).

It was evident that PLRs changed the results obtained for AFO-FC alone. Most of the changes were desirable except for the increase in peak knee extension during mid to terminal stance. Between the rockers, the16 mm PLR produced better kinematics and kinetics on a small number of occasions. However, it should be noted that the participant walked faster with the 32 mm PLR.

15.2.4 Summary of case studies A to D:

- For case study A, changes at the knee were linear with an increasingly inclined SVA and increasingly flexed knee joint during stance phase with increasing sizes of wedges. The knee extension moments during terminal stance decreased with increasing size of wedges.
- For case study B, walking speed and cadence were lowest with the 6° wedge. It was evident that all the wedges except the 6° wedge produced less normal kinetics and kinematics compared to AFO-FC. The 6° wedge produced kinematics and kinetics that were predominantly similar to, and occasionally better than (knee moments and peak knee extension), non-tuned AFO-FC.
- For case study C, temporal-spatial parameters were reduced with the 4° wedge compared to other conditions. It was evident that all except the 4° wedge produced predominantly less optimal kinetics and kinematics compared to AFO-FC. In contrast, the 4° wedge produced optimal kinematics of the knee joint. The abnormal peak of the dorsi-flexion moments during mid-stance seen with AFO-FC decreased with wedges.
- For case study D, temporal-spatial parameters increased with rockers compared to AFO-FC. Most of the changes in kinematics and kinetics were favourable with rockers, including peak knee flexion during stance, peak hip extension, knee flexion moments and peak plantar-flexion moments during initial stance, peak dorsi-flexion moments during terminal stance, and peak vertical forces. However, the knee joint was already hyper-extended during mid to terminal stance with the non-tuned AFO-FC, and showed further increase in knee extension with rockers.

15.3 Discussion

In this section, the case studies investigating the effects of wedges are discussed first, followed by the case study on the effects of PLRs. It should also be noted that the generalisability of results from the case studies is limited. Nevertheless, they can provide information useful for future research in this area by providing insight into various compensatory mechanisms that can be adopted by children with CP in response to different sizes of wedges and PLRs.

In case study A, participant 2 demonstrated a barefoot gait pattern similar to Winters group 1 (Winters, Gage and Hicks 1987). However, wearing non-tuned AFO-FC produced more of an extended knee gait. The change in knee kinematics was in line with the change in SVA, which increased with increasing size of wedges. The use of wedges increased the inclination of the shank of the tibia since the participant had hyper-extended knee with a lack of inclination of the shank and an immovable ankle joint. While there is no research literature which has looked at the effects of increasing sizes of wedges/heel raises on children with CP, one case study investigated the effect of heel raises on a healthy adult with and without AFO. This found that the shank was inclined forward and the weight line was shifted forwards with the use of both heel raise and AFO (Cook and Cozzens 1976). A recent review recommended tibial inclination to optimise the gait of children with CP (Bowers and Ross 2009). The influence of SVA on knee kinematics has been emphasised by several authors (Hullin, Robb and Loudon 1992; Owen 2002; Owen 2004b). The linear response of increased knee flexion and tibial inclination with increasing sizes of wedges for participant 2 may be associated with the gait pattern. Since the knee joint demonstrated reduced knee flexion during initial stance and increased knee extension during mid to terminal stance, increasing the shank inclination was capable of progressively increasing knee flexion.

The trend of decrease in the peak knee extension moments with increasing sizes of wedges was in line with knee kinematics. However, the sudden increase in the knee flexion moments during mid-stance with 12° and 20° wedges suggests the increased activity of knee extensors, probably owing to the constantly increased eccentric activity to regulate the increased knee flexion. Similarly, the hike in the dorsi-flexion moments during mid-stance with AFO-FC and smaller wedges may be produced by the GRF orientation, whereas with higher wedges (20 and 12°) there was no such pattern. This may be associated with the influence of wedges on the knee and joint and shank of the tibia. The use of increasing sizes of wedges increased knee flexion during stance for participant 2, which might have affected the orientation of GRF in relation to ankle joint.

In case study B, participant 3 demonstrated a crouch gait with non-tuned AFO-FC. It could be seen from the results that for participant 3 all the wedges except the 6° wedge produced deterioration in kinetics and kinematics when compared with non-tuned AFO-FC. In contrast, the 6° wedge produced kinematics and kinetics which were predominantly similar to and occasionally better than AFO-FC. Interestingly, the cadence and walking speed were lowest with the 6° wedge compared to others. This reduction might be explained by the participant attaining greater stability with the optimum wedge.

While knee joint flexion during initial stance remained the same with AFO-FC and the 6° wedge, it decreased slightly during terminal stance. In this case, the SVA with AFO-FC was only 6°, suggesting a lack of tibial inclination, whereas the SVA with 6° wedge was closer to normal (13°). Interestingly, the SVA with the 4° wedge was greater than that with the 6° wedge, and so was knee flexion. While case study A, demonstrated linear relationships between increasing wedge sizes, SVA and knee kinematics, this was not the case in case study B. This may be attributed to the difference in gait patterns. In the second case study knee flexion extension moments were closer to normal with the 6° wedge compared to other wedges and AFO-FC. The difference in SVA and knee moments suggest that the 6° wedge might have produced a better orientation of GRF in relation to the knee joint, in comparison to non-tuned AFO-FC and other wedges. While the response in case study B may be due to the fact that the participant had crouch gait and hence only minimal compensation was possible, whereas the extended knee gait pattern allowed more compensation with wedges.

In case study C, participant 6 demonstrated a jump knee gait (Sutherland and Davids 1993) in both legs in barefoot. With the use of AFO-FC the participant retained jump knee pattern for both legs. Compared to normal this participant had increased hip flexion and increased anterior pelvic tilt on both sides, and double bump kinetic pattern at the ankle. Similar to case study B, the cadence, stride-length and walking speed were lowest with one specific wedge size (4°) which also produced optimal knee kinematics. This again supports the argument that children with diplegia may attain more stability with an optimal wedge size, resulting in lower walking speed, cadence and stride-length.

When examining the knee, it was found that increased knee flexion during initial stance (both sides) and increased knee extension during mid to terminal stance (right side) were more normalised by the use of the 4° wedge. In contrast, the higher wedges mainly produced increasing trends of knee flexion during one or more parts of stance phase. Interestingly the SVA increased in a linear fashion with increasing wedge sizes on both sides.

The knee extension moments were less with wedges for both legs, probably due to the change in alignment of the GRF with wedges. It has been reported before that use of wedges in children with CP and patients with other neurological impairments can influence alignment of the GRF and knee moment arm (Butler, Thompson and Major 1992; Butler and Nene 1991; Stallard and Woollam 2003). Decreases in the first peak of dorsi-flexion moments during mid-stance with all the wedges compared to AFO-FC on both legs suggests better orientation of the GRF. However, the reduction of dorsi-flexion moments during terminal stance with wedges compared to AFO-FC was away from normal.

Increased hip flexion and anterior pelvic tilt is often seen in jump knee gait pattern (Rodda et al. 2004). In participant 6, use of an AFO had already increased the anterior pelvic tilt in comparison to barefoot, which was further increased by wedges.

This can be deemed undesirable, as walking with anteriorly tilted pelvis and flexed hip may lead to hip flexion contractures.

The case studies A, B and C indicate that children with different gait patterns may rely on strategies specific to those gait patterns (while wearing AFO-FC). These may cause adaptations to increasing sizes of wedges, especially at the knee joint. Further research is indicated with an adequately powered sample in each category of gait pattern. While the effects of increasing wedge sizes and increase in knee flexion seemed to show a linear relationship for the participant with extended knee gait pattern, this was not the case for others. One important possibility, suggested by the case studies, is that while an optimal size of wedge may produce improved kinematics and kinetics of one or more joints, wedge sizes that differ as little as 2° from the optimum may not have any effects, or may even produce negative effects. A more standardised approach to increasing sizes of wedges may be necessary to find out the effects of incremental sizes of wedges, starting from no wedge, and increasing by 2° increments to as high as a 20° wedge. However, in order to achieve that, longer sessions or multiple visits by children with CP may become necessary, therefore the feasibility of this approach is doubtful.

The results from the case studies also indicated that none of the wedge sizes were capable of producing optimal kinematics and kinetics uniformly for all the joints. While one size of wedge may be capable of producing better kinematics at one or more joints, it may have negative effects on others. However, when it comes to children with CP, it may be impossible to optimise the kinematics and kinetics of all joints; instead, the changes which contribute to overall improvement of gait for each participant should be identified and considered vital.

In case study D, participant 8 demonstrated a barefoot gait pattern similar to group V (knee hyper-extension with ankle dorsi-flexion group) described by Hullin, Robb and Loudon (1996) and Huk et al. (1987). However, with AFO-FC the gait pattern was more of an extended knee gait. No published data were found on the effects of PLR on gait parameters in children with CP. However, recommendations exist regarding use of PLRs to improve the gait of children with CP (Bowers and Ross, 2009; Hullin, Robb and Loudon, 1992; Owen 2004a).

The increasing trend seen in plantar-flexion moments during initial stance with both rockers when compared to AFO-FC was probably associated with the difference in the height of the heel between AFO-FC and rockers. Owen (2004b) suggested that the use of rockers influences terminal stance, whereas the use of heels influences initial stance. However, the rockers may have contributed to increases in plantar-flexion moments by increasing the heel lever, which in turn increased the moment arm. Another factor which may have contributed to increases in plantar-flexion moments is the increase in the magnitude of the vertical force. Both the rockers resulted in a high first peak (FZ1) of vertical force when compared with AFO-FC.

Peak dorsi-flexion moments during terminal stance also showed an increasing trend with PLRs compared to AFO-FCs, with the 32 mm rocker being the highest, and closest to the normal. In the current comparison, the participant was wearing an AFO-FC, which prevented ankle movement and peak dorsi-flexion moments were less than normal. It has been suggested before that rockers at the metatarsophalyngeal joints can act as an anatomical rocker and influence push-off force in children with CP if oriented properly (Meadows 1984). In the current comparison, the rocker apices for both rockers were at 75% of the shoe length, and were not specifically oriented to optimise the GRF position in relation to hip and knee. However, it could be seen from the force data that the second peak of vertical force (FZ2) was higher with the rockers when compared with AFO-FC, which probably contributed to the improvement in dorsi-flexion moments. These findings suggest the potential of PLRs in improving kinetics of the ankle joint.

The knee joint was more extended with rockers all through mid-stance until terminal stance with rockers compared to AFO-FC. While Hullin, Robb and Loudon (1992) suggested the use of rocker for children with hyper-extended knees, their suggestion was to use a rocker with a raised heel end, which would have increased the shank inclination to produce better shank kinematics. In this case, since the rockers did not have a raised heel, they might have produced a less inclined tibial shank and anterior alignment of the GRF. Furthermore, the apices of the PLRs were not positioned to optimise the GRF position during terminal stance. The increase in knee hyper-extension with the use of PLRs suggests that it may not be ideal to use a PLR in which the apex has not been positioned to optimise GRF orientation in relation to the proximal joints.

The increases in terminal stance knee extension moments away from normal with PLRs were in line with the kinematics of the knee joint. However, peak knee flexion moments during stance tended to be higher and closer to normal with PLRs compared to AFO-FC. Even though there were some differences in kinematics and kinetics between the PLRs, these were not consistent. The differences may be associated with the fact that the participant was walking faster with the 32 mm PLR compared with the 16 mm PLR.

The increase in hip extension moments and peak hip extension during terminal stance with PLRs was favourable. It has been suggested before that the orientation of the GRF posterior to the hip and resultant hip extension moments, are influential in generating push-off force, especially in children with CP (Meadows 1984; Owen 2004b). The use of PLRs may have helped to maintain optimal GRF position and supplement the fore-foot rocker, generating increased push-off force. This can be seen from the higher FZ2 seen with rockers compared to AFO-FC.

The findings from the current comparison suggest the potential clinical utility of PLRs for children with CP. However, the influences on knee kinematics and kinetics of the participant demonstrated that if not used judiciously, PLRs may have negative effects on gait. It is important to recognise that the results are not generalisable, as the current comparison was based on a case study. Furthermore, in the current study, the effects of two PLRs with their apexes at 75% length of the footwear were investigated, which may not have produced an optimal GRF orientation for the participant. More research with an adequate sample size is required to explore the effects of optimised PLRs on the gait children with CP who demosntrate different gait patterns.

15.4 Conclusion

The effects of wedges and PLRs on gait were evident in the current sample. The case studies A, B and C indicate that children with different gait patterns may rely on strategies specific to those gait patterns (while wearing AFO-FC). These may cause adaptations to increasing sizes of wedges, especially at the knee joint. The case study D demonstrated the potential utility of PLR as a part of tuning. However, the possibility of non-optimal PLRs having negative effects on gait on children with CP was also identified. Further research is indicated with an adequately powered sample in each category of gait pattern.

CHAPTER 16 FEASIBILITY STUDY ON THE SHORT-TERM EFFECTS OF TUNING OF AFO-FC FOR CHILDREN WITH CEREBRAL PALSY: RESULTS AND DISCUSSION

16.1 Introduction

Although biomechanical optimisation or "tuning" of AFOs was suggested decades ago (Cook and Cozzens 1976; Wiest et al. 1979; Nuzzo 1980; Meadows 1984), there is a lack of evidence and consensus regarding tuning of AFOs. The few studies regarding effects of tuning invariably report positive results (Butler, Thompson and Major 1992; Stallard and Woollam 2003; Butler et al. 2007). The only previous study which looked at the short-term effects of tuning (over four to six months) did not report kinematics (Butler, Thompson and Major 1992).

As described previously in the introduction (page 3) and literature review (Section:7.1, Pages 71-72), tuning of AFO-FCs has evolved into a complex intervention and can be investigated using the Medical Research Council framework for developing and evaluating complex interventions for improving health (Medical Research Council 2000). While the framework identifies the importance of the Randomised Controlled Trial (RCT) as a study design in research, it also identifies difficulties associated with the evaluation of a complex intervention and suggests a staged approach. The current level of evidence in tuning requires exploration of the feasibility (Phase II or exploratory trial stage) of conducting a definitive RCT.
Furthermore, while tuning of AFO-FC has been recommended for children with CP (Morris and Condie 2009), the feasibility of tuning as a clinical service needs to be addressed. No studies to date have looked into the feasibility of research studies in tuning, which is a complex intervention tailored for each individual patient. Hence, a study to inform appropriate outcome measures, organisational considerations, power and sample size is required. In order to address these, the aims of this study were to investigate:

- the feasibility of conducting a larger trial looking into short-term effects of tuning of AFO-FC for children with CP, and

- the short-term effects of tuning of AFO-FC on gait, muscle and joint characteristics, and quality of life of children with CP.

The comparisons reported in this section are as follows (abbreviated terms/acronyms used are given in brackets)

a. Kinematic and kinetic data points in sagittal plane, temporal-spatial parameters, gait deviation index (GDI) and shank to vertical angle (SVA) were compared between:
   - barefoot at baseline (barefoot baseline) with barefoot after short-term intervention (barefoot final),
   - non-tuned AFO-FC before short-term intervention (Non-tuned AFO-FC) with tuned AFO-FC after short-term intervention (Tuned final),
   - tuned AFO-FC before short-term intervention (Tuned immediate) and tuned AFO-FC after short-term intervention (Tuned final);
b. Results of physical examination: muscle power using Medical Research Council (MRC) grading, muscle tone using the Modified Ashworth Scale (MAS), and passive range of motion (PROM) of the lower limb joints were compared between baseline and after short-term intervention (final);
c. Quality of life (QOL) using PedsQL™ generic score was compared between baseline and after short-term intervention (final).

Table 16.1 Descriptive and inferential analysis of temporal-spatial parameters, GDI and SVA between barefoot at baseline (barefoot baseline) and barefoot after short-term intervention (barefoot final)

	Descriptive analysis		Inferential analysis			
	Barefoot baseline Mean (SD)	Barefoot final Mean (SD)	D (SD)	95% Confidence Interval of D		p value
				Lower	Upper	
Cadence (steps/minute)	115.32 (31.4)	131.98 (22.8)	-16.66 (20.6)	-42.23	8.9	0.15
Stride-length (m)	0.79 (0.28)	0.90 (0.24)	-0.12 (0.12)	-0.27	0.02	0.08
Walking speed (m/s)	**0.78 (0.36)**	**0.98 (0.24)**	**-0.20 (0.16)**	**-0.40**	**-0.003**	**0.05**
GDI	77.61 (12.3)	79.38 (6.7)	-1.77 (9.5)	-10.54	7.00	0.64
SVA (degrees)	4.1 (3.6)	5.4 (3.5)	-1.3 (3.5)	-4.6	2.0	0.37
Key: SD- Standard deviation, SVA – Shank to Vertical Angle, GDI – Gait Deviation Index, Statistical tests used – Paired t-test/Wilcoxon signed rank test, significance level p < 0.05, significant results in **bold,**						

Table 16.2 Descriptive and inferential analysis of normalised temporal-spatial parameters between barefoot at baseline (barefoot baseline) and barefoot after short-term intervention (barefoot final)

	D (SD)	95% Confidence Interval of the D		p value
		Lower	Upper	
Cadence (steps/minute)	-5.9 (7.1)	-14.68	2.9	0.14
Stride-length (m)	-0.10 (0.09)	-0.21	0.17	0.08
Walking speed (m/s)	**-0.06 (0.05)**	**-0.12**	**-0.001**	**0.05**
Key: SD – standard deviation, D – mean difference, significance level p < 0.05, significant results in **bold**				

16.2 Results

This study included a sample of five participants. The sample characteristics are provided in Section 10.1.4 (pages: 117 to 118). This section is subdivided according to the comparisons made.

16.2.1 Barefoot at baseline (barefoot baseline) compared with barefoot after short-term intervention (barefoot final)

In this comparison the most important changes seen were in walking speed, which was significantly higher ($p = 0.05$) at barefoot final compared to baseline (Table 16.1).

Considering the effect of growth of children on temporal-spatial parameters, normalisation was carried out (Table 16.2). After normalisation, walking speeds ($p = 0.05$) were significantly higher with barefoot final compared to baseline, which indicates improvement. The differences between GDI and SVA were not significant. However, there was a trend of increase in stride-length, cadence and SVA after short-term intervention, with wide 95% confidence intervals for the mean difference.

Table 16.3 Descriptive and inferential analysis of kinematic data points between barefoot at baseline (barefoot baseline) and barefoot after short-term intervention (barefoot final)

	Descriptive analysis		Inferential analysis			
	Barefoot baseline Mean (SD)	Barefoot final Mean (SD)	D (SD)	95% Confidence Interval of the D		p value
				Lower	Upper	
Pelvic kinematics						
Peak anterior pelvic tilt	21.9 (8.1)	20.2 (6.0)	1.8 (2.7)	-0.68	4.26	0.13
Peak posterior pelvic tilt	12.8 (8.6)	10.7 (6.8)	2.1 (2.8)	-0.49	4.73	0.09
Pelvic tilt ROM	9.2 (2.2)	9.5 (1.4)	-0.3 (1.7)	-1.93	1.26	0.63
Knee kinematics						
Knee flexion at initial contact	21.3 (8.5)	23.2 (7.8)	-2.0 (5.3)	-6.89	2.92	0.36
Peak knee flexion (stance)	24.2 (8.8)	26.8 (9.0)	-2.6 (5.1)	-7.39	2.12	0.22
Peak knee extension (stance)	8.0 (9.6)	9.4 (12.1)	-1.4 (6.1)	-7.02	4.18	0.56
Peak knee flexion	52.1 (6.1)	53.9 (5.8)	-1.8 (4.5)	-5.92	2.42	0.34
Knee ROM	44.1(12.3)	44.4 (15.9)	-0.3 (5.1)	-5.05	4.39	0.87
Hip Kinematics						
Peak Hip flexion	45.1 (11.3)	46.9 (13.4)	-1.8 (7.0)	-8.23	4.65	0.52
Peak Hip extension	**5.3 (10.0)**	**2.8 (10.2)**	**2.5 (2.5)**	**0.17**	**4.81**	**0.04**
Peak hip flexion (stance)	39.3 (13.3)	42.1 (14.1)	-2.7 (8.5)	-10.60	5.13	0.43
Hip ROM	39.8 (10.6)	44.1 (10.7)	-4.3 (5.8)	-9.62	1.06	0.10
Ankle Kinematics						
Ankle dorsi-flexion at initial contact	-7.2 (10.9)	-5.5 (7.5)	-1.6 (10.9)	-11.73	8.47	0.71
Peak dorsi-flexion	6.5 (14.6)	7.8 (6.1)	-1.2 (11.0)	-11.45	8.97	0.78
Peak Plantar-flexion	-19.0 (16.8)	-18.0 (9.3)	-1.0 (11.9)	-12.02	10.02	0.83
Ankle ROM	25.6 (7.2)	25.8 (4.8)	-0.2 (5.6)	-5.45	4.98	0.92

Key: SD- Standard deviation, D – mean difference, all values except p values in degrees, statistical tests used- Paired t-test/Wilcoxon signed rank test, significance level $p < 0.05$, significant results in **bold.**

None of the kinematic data points except peak hip extension was significantly different between barefoot baseline and barefoot final (Table 16.3). Peak hip extension was closer to normal at barefoot final compared to baseline ($p = 0.04$). However, the mean difference was only 2.5°. The difference in hip ROM showed a trend of increase, with a mean difference of 4.3° and wide confidence intervals.

None of the kinetic data points were significantly different between the conditions (Table 16.4). However, all the parameters except peak ankle plantar-flexion moments showed wide confidence intervals. Mean values of peak hip flexion moments, peak hip extension moments, peak knee flexion moments and peak ankle dorsi-flexion moments tended to be higher and closer to normal with barefoot final than barefoot baseline. Knee flexion/extension moments during mid-stance tended to be more flexing, and closer to normal, with barefoot final compared to barefoot baseline (Table 16.4).

Table 16.4 Descriptive and inferential analysis of kinetic data points between barefoot at baseline (barefoot baseline) and barefoot after short-term intervention (barefoot final)

	Descriptive analysis		Inferential analysis			
	Barefoot baseline mean	Barefoot final mean	D (SD)	95% Confidence Interval of the D		p value
				Lower	Upper	
Hip moments						
Peak hip flexion moments	0.79 (0.45)	0.84 (0.57)	-0.06 (0.22)	-0.26	0.15	0.51
Peak hip extension moments	-0.30 (0.22)	-0.46 (0.21)	0.15 (0.32)	-0.15	0.45	0.26
Knee moments						
Peak knee flexion moments	0.31 (0.27)	0.43 (0.28)	-0.13 (0.15)	-0.27	0.01	0.07
Peak knee extension moments	-0.29 (0.24)	-0.30 (0.31)	0.01 (0.16)	-0.14	0.15	0.92
Knee flex/ext moments at mid-stance	0.05 (0.23)	0.13 (0.33)	-0.09 (0.26)	-0.33	0.15	0.41
Ankle moments						
Peak ankle dorsi-flexion moments	0.79 (0.23)	0.85 (0.28)	-0.06 (0.13)	-0.17	0.06	0.29
Peak ankle plantar-flexion moments	-0.01 (0.05)	-0.01 (0.05)	0.00 (0.08)	-0.07	0.07	0.94

Key: SD- Standard deviation, D – mean difference, all values except p values in Nm/kg, statistical tests used- Paired t-test/Wilcoxon signed rank test, significance level $p < 0.05$,

Table 16.5 Descriptive and inferential analysis of temporal-spatial parameters, GDI and SVA between non-tuned AFO-FC before short-term intervention (non-tuned AFO-FC) and tuned AFO-FC after short-term intervention (tuned final)

	Descriptive analysis		Inferential analysis			
	Non-tuned AFO-FC Mean (SD)	Tuned Final Mean (SD)	D (SD)	95% Confidence Interval of D		p value
				Lower	Upper	
Cadence (steps/minute)	116.8 (18.5)	116.5 (9.3)	0.3 (9.8)	-11.86	12.43	0.95
Stride-length (m)	0.92 (0.23)	1.06 (0.3)	-0.13 (0.13)	-0.29	0.02	0.08
Walking speed (m/s)	0.90 (0.23)	1.01 (0.3)	-0.12 (0.16)	-0.31	0.07	0.17
GDI	76.2 (12.8)	77.0 (10.2)	-0.80 (5.6)	-6.00	4.40	0.72
SVA (degrees)	**7.3 (2.2)**	**10.4**	**-3.1 (2.2)**	**-5.2**	**-1.1**	**0.01**
Key: SD- Standard deviation, D – Mean difference, SVA – Shank to Vertical Angle, GDI – Gait Deviation Index, statistical tests used – Paired t-test/Wilcoxon signed rank test, significance level $p < 0.05$, significant results in **bold**						

Table 16.6 Statistical analysis of normalised temporal-spatial parameters between non tuned AFO-FC before short-term intervention (non-tuned AFO-FC) and tuned AFO-FC after short-term intervention (tuned final)

	D (SD)	95% Confidence Interval of D		p value
		Lower	Upper	
Cadence (steps/minute)	0.05 (3.3)	-4.06	4.16	0.97
Stride-length (m)	-0.11 (0.1)	-0.23	0.01	0.08
Walking speed (m/s)	-0.03 (0.05)	-0.09	0.02	0.17
Key: SD- Standard deviation, D- Mean Difference statistical tests used – Paired t-test/Wilcoxon signed rank test, significance level $p < 0.05$, significant results in **bold**				

16.2.2 Non-tuned AFO-FC before short-term intervention (non-tuned AFO-FC) compared with tuned AFO-FC after short-term intervention (Tuned final)

The key changes seen were in peak ankle plantar-flexion moments. There were no significant differences in temporal-spatial parameters and GDI (Tables 16.5 and 16.6). However, the normalised stride-length and walking speed demonstrated wide confidence intervals. The SVA was 3.1° more inclined and closer to normal with tuned final compared to non-tuned AFO-FC (p = 0.01) (Table 16.5).

Table 16.7 Descriptive and inferential analysis of kinematic data points between non-tuned AFO-FC before short-term intervention (non-tuned AFO-FC) and tuned AFO-FC after short-term intervention (tuned final)

	Non-tuned AFO-FC mean (SD)	Tuned Final mean (SD)	D (SD)	95% Confidence Interval of D		p value
				Lower	Upper	
Pelvic kinematics						
Peak anterior pelvic tilt	22.7 (9.9)	22.0 (11.0)	0.6 (5.4)	-4.38	5.60	0.77
Peak posterior pelvic tilt	13.6 (9.7)	14.1 (9.6)	-0.5 (5.4)	-5.54	4.47	0.80
Pelvic tilt ROM	**9.1 (2.6)**	**8.0 (3.1)**	**1.1 (0.7)**	**0.47**	**1.82**	**0.01**
Knee kinematics						
Knee flexion at IC	23.4 (12.8)	24.1 (11.0)	-0.7 (4.6)	-4.89	3.50	0.70
Peak knee flexion (stance)	28.6 (13.0)	32.3 (9.4)	-3.7 (5.6)	-9.07	1.62	0.14
Peak knee extension	7.2 (13.8)	11.8 (12.3)	-4.6 (5.0)	-9.19	0.01	0.05
Peak knee flexion	54.5 (5.1)	53.5 (6.6)	1.0 (8.8)	-7.20	9.18	0.78
Knee ROM	47.3(14.2)	41.7 (15.5)	5.6 (6.3)	-0.22	11.37	0.06
Hip Kinematics						
Peak Hip flexion	46.2 (13.5)	47.7 (14.1)	-1.5 (8.9)	-9.74	6.69	0.67
Peak Hip extension	0.3 (9.9)	1.0 (9.2)	-1.0 (4.1)	-4.47	3.17	0.69
Peak hip flexion (stance)	42.0 (15.0)	45.9 (14.0)	-3.9 (8.8)	-12.06	4.28	0.29
Hip ROM	45.8 (7.5)	46.7 (8.8)	-0.9 (5.5)	-5.96	4.20	0.69
Key: SD- Standard deviation, D – mean difference, IC – initial contact, all values except p values in degrees, significance level p < 0.05, significant results in **bold.**						

None of the kinematic data points except pelvic tilt ROM yielded a statistically significant difference (p = 0.01) (Table 16.7). However, the mean difference in pelvic tilt ROM was only 1°, with narrow 95% confidence intervals (0.41 to 1.82). Peak knee flexion during stance showed an increasing trend, and peak knee extension and knee ROM showed decreasing trends with tuned final compared to non-tuned AFO-FC. Furthermore, the differences in these parameters demonstrated wide 95% confidence intervals.

Table 16.8 Descriptive and inferential analysis of kinetic data points between non-tuned AFO-FC before short-term intervention (non-tuned AFO-FC) and tuned AFO-FC after short-term intervention (tuned final)

	Descriptive analysis		Inferential analysis			
	Non-tuned AFO-FC Mean (SD)	Tuned Final Mean (SD)	D (SD)	95% Confidence Interval of the D		p value
				Lower	Upper	
Hip moments						
Peak hip flexion moments	1.14 (0.5)	0.94 (0.6)	0.20 (0.4)	-0.21	0.61	0.27
Peak hip extension moments	-0.69 (0.2)	-0.54 (0.2)	-0.14 (0.2)	-0.37	0.08	0.17
Knee moments						
Peak knee flexion moments	0.71 (0.5)	0.64 (0.2)	0.07 (0.4)	-0.33	0.47	0.68
Peak knee extension moments	-0.27 (0.1)	-0.16 (0.3)	-0.12 (0.2)	-0.31	0.08	0.19
Knee flexion/extension moments at mid-stance	0.03 (0.2)	0.12 (0.3)	-0.09 (0.3)	-0.34	0.17	0.43
Ankle moments						
Peak ankle dorsi-flexion Moments	1.00 (0.2)	1.01 (0.2)	-0.01 (0.2)	-0.16	0.13	0.82
Peak ankle plantar-flexion moments	**-0.12 (0.2)**	**-0.20 (0.2)**	**0.08 (0.1)**	**0.02**	**0.14**	**0.02**
Key: SD- Standard deviation, D – mean difference, all values except p values in Nm/kg, significance level p < 0.05, significant results in **bold.**						

Table 16.9 Descriptive and inferential analysis of temporal-spatial parameters, GDI and SVA between tuned AFO-FC before short-term intervention (tuned immediate) and tuned AFO-FC after short-term intervention (tuned final)

	Descriptive analysis		Inferential analysis			
	Tuned Immediate mean (SD)	Tuned Final Mean (SD)	D (SD)	95% Confidence Interval of the D		*p* value
				Lower	Upper	
Cadence (steps/minute)	123.2 (12.7)	116.5 (14.2)	6.7 (14.2)	-10.9	24.3	0.35
Stride-length (m)	**0.92 (0.23)**	**1.06 (0.29)**	**-0.13 (0.13)**	**-0.24**	**-0.03**	**0.03**
Walking speed (m/s)	0.94 (0.20)	1.01 (0.25)	-0.08 (0.15)	-0.26	0.11	0.33
GDI	74.72 (14.6)	77.03 (10.2)	-2.30 (6.5)	-8.31	3.70	0.38
SVA (degrees)	**13.1 (1.3)**	**10.4 (2.0)**	**2.7 (2.0)**	**1.0**	**4.5**	**0.01**
Key: SD- Standard deviation, D – Mean difference, SVA – Shank to Vertical Angle, GDI – Gait Deviation Index, significance level p < 0.05, significant results in **bold**						

Among the kinetic data points compared, only the peak ankle plantar-flexion moments yielded statistical significance (Table 16.8), which was greater and closer to normal in tuned final compared to non-tuned AFO-FC. Peak hip flexion and extension moments and peak knee flexion and extension moments tended to be lower in tuned final compared to non-tuned AFO-FC and demonstrated wide 95% confidence intervals for the differences.

16.2.3 Tuned AFO before short-term intervention (Tuned immediate) compared with Tuned AFO after short-term intervention (Tuned final)

The mean stride-length was significantly higher with tuned final compared to tuned immediate, with a mean difference of 0.13 m ($p = 0.03$) (Table 16.9). After normalisation the stride-length was significantly better with tuned final compared to tuned immediate ($p = 0.02$) (Table 16.10). There was no significant difference in GDI. The SVA was closer to normal, demonstrating 3° less inclination with tuned final compared to tuned immediate ($p = 0.01$) (Table 16.9).

Table 16.10 Descriptive and inferential analysis of normalised temporal-spatial parameters, GDI and SVA between tuned AFO-FC before short-term intervention (tuned immediate) and tuned AFO-FC after short-term intervention (tuned final)

	Mean difference (D)	SD	95% Confidence Interval of the D		p value
			Lower	Upper	
Cadence	2.23	4.9	-3.93	8.41	0.37
Stride-length	**-0.10**	**0.06**	**-0.18**	**-0.03**	**0.02**
Walking speed	-0.02	0.04	-0.07	0.03	0.35
Key: SD- Standard deviation, D – Mean difference, significance level p < 0.05, significant results in **bold**					

Table 16.11 Descriptive and inferential analysis of kinematic data points between tuned AFO-FC before short-term intervention (tuned immediate) and tuned AFO-FC after short-term intervention (tuned final)

	Descriptives		Statistical analysis			
	Tuned Immediate mean (SD)	Tuned Final Mean (SD)	D (SD)	95% Confidence Interval of the D		*p* value
				Lower	Upper	
Pelvic kinematics						
Peak anterior pelvic tilt	23.7 (12.7)	22.0 (10.6)	1.7 (6.2)	-4.1	7.4	0.51
Peak posterior pelvic tilt	14.5 (11.8)	14.1 (9.6)	0.5 (5.4)	-4.5	5.4	0.82
Pelvic tilt ROM	9.2 (2.5)	8.0 (3.09)	1.2 (1.2)	0.1	2.3	**0.03**
Knee kinematics						
Knee flexion at IC	24.0 (9.3)	24.1 (11.0)	-0.0 (6.9)	-6.4	6.4	0.99
Peak knee flexion (stance)	30.6 (8.6)	32.1 (9.4)	-1.7 (4.9)	-6.3	2.8	0.39
Peak knee extension	10.8 (11.0)	11.8 (12.3)	-0.9 (6.7)	-7.1	5.2	0.72
Peak knee flexion	51.4 (5.2)	53.5 (6.5)	-2.1 (6.1)	-7.8	3.6	0.40
Knee ROM	40.6 (13.2)	41.7 (15.5)	-1.2 (4.3)	-5.1	2.8	0.50
Hip Kinematics						
Peak Hip flexion	46.9 (16.5)	47.7 (14.1)	-0.7 (7.0)	-7.2	5.7	0.79
Peak Hip extension	4.1 (13.0)	1.0 (9.2)	3.2 (6.4)	-2.8	9.1	0.24
Peak hip flexion (stance)	44.4 (15.4)	45.9 (14.0)	-1.5 (5.7)	-6.7	3.8	0.52
Hip ROM	42.8 (7.8)	46.7 (8.8)	-4.0 (3.6)	-7.3	-0.5	**0.03**
Key: SD- Standard deviation, D – mean difference, IC – initial contact, all values except p values in degrees, significance level $p < 0.05$, significant results in **bold.**						

None of the kinematic data points were significantly different, with the exception of pelvic tilt ROM and hip ROM. However, pelvic tilt ROM was only 1° higher with tuned final compared to tuned immediate, with narrow 95% confidence intervals (0.1 to 2.3). Hip ROM improved, with an increase of 4° with tuned final compared to tuned immediate (p = 0.03) (Table 16.11).

Table 16.12 Descriptive and inferential analysis of kinetic data points between tuned AFO-FC before short-term intervention (tuned immediate) and tuned AFO-FC after short-term intervention (tuned final)

	Tuned Immediate mean (SD)	Tuned Final Mean (SD)	D (SD)	95% Confidence Interval of the D		*p* value
				Lower	Upper	
Hip moments						
Peak hip flexion moments	0.90 (0.45)	0.94 (0.58)	-0.04 (0.37)	-0.38	0.30	0.79
Peak hip extension moments	-0.62 (0.14)	-0.54 (0.16)	-0.08 (0.18)	-0.25	0.08	0.27
Knee moments						
Peak knee flexion moments	0.74 (0.29)	0.64 (0.22)	0.10 (0.28)	-0.16	0.36	0.37
Peak knee extension moments	-0.17 (0.13)	-0.16 (0.25)	-0.01 (0.19)	-0.19	0.16	0.86
Knee flex/ext moments at mid-stance	0.17 (0.21)	0.12 (0.33)	0.06 (0.17)	-0.10	0.22	0.42
Ankle moments						
Peak ankle dorsi-flexion moments	0.89 (0.19)	1.01 (0.18)	-0.12 (0.21)	-0.31	0.08	0.18
Peak ankle plantar-flexion moments	**-0.30 (0.13)**	**-0.20 (0.15)**	**-0.10 (0.10)**	**-0.20**	**-0.01**	**0.04**
Key: SD- Standard deviation, D – mean difference, all values except p values in Nm/kg, statistical tests used- Paired t-test/Wilcoxon signed rank test, significance level p < 0.05, significant results in **bold.**						

None of the kinetic data points except peak ankle plantar flexion moments were significantly different between the conditions (Table 16.12). The peak ankle plantar flexion moments were significantly less with tuned final compared to tuned immediate. Furthermore, peak hip extension moments and peak knee flexion moments tended to be lower, and peak ankle dorsi-flexion moments tended to be higher, with tuned final compared to tuned immediate. Furthermore, the differences showed wide 95% confidence intervals.

Table 16.13 Descriptive and inferential analysis individual components and total score of quality of life using the PedsQL™ between baseline and after short-term intervention (final)

	Baseline Mean (SD)	Final Mean Mean (SD)	D (SD)	p value
Physical	28.1 (14.7)	38.1 (9.7)	-10.0 (13.9)	0.14
Emotional	58.0 (10.4)	64.0 (10.8)	-6.0 (17.1)	0.59
Social	57.0 (11.6)	58.0 (11.5)	-1.0 (20.4)	0.71
School	65.0 (9.4)	60.0 (13.2)	5.0 (19.7)	0.79
Total QOL	52.0 (8.4)	55.0 (9.0)	-3.0 (14.6)	0.72
Key: SD- Standard deviation, D- Mean Difference statistical tests used –Wilcoxon signed rank test, significance level $p < 0.05$				

Table 16.14 Inferential analysis of muscle tone using the Modified Ashworth Scale (MAS) between baseline and after short-term intervention (final)

	Baseline Median	Range	Final Median	Range	p value
Hip flexors	1	1	0	1	0.18
Adductors	1	3	1	2	0.41
Internal Rotators	0	2	0	0	0.10
Rectus Femoris	1	1	1	1	0.56
Medial Hamstrings	0	0	0	1	0.32
Lateral Hamstrings	0	1	0	0	0.32
Tibialis Anterior	0	1	0	1	0.32
Extensor Digitorum	0	0	0	0	1.00
Extensor Hallucis	0	1	0	0	0.32
Triceps Surae	3	2	3	2	0.32
Tibialis Posterior	1	4	0	2	0.10
Flexor Digitorum	0	0	0	0	1.00
Flexor Hallucis	0	1	0	0	0.32
Peronei	0	3	0	3	0.32
Key: Wilcoxon signed rank test, significance level $p < 0.05$					

Table 16.15 Comparison of muscle power using Medical Research Council grading between baseline and after short-term intervention (final)

	Baseline Median	Range	Final Median	Range	p value
Quadriceps power	4	2	5	1	0.10
Hamstrings power	4	0	4	1	0.06
Hip flexors power	4	1	5	1	1.00
Dorsiflexors power	3	2	4	2	0.06
Triceps surae power	3.5	1	4	1	0.06
Gluteus power	3	1	4	2	0.56
Key: Wilcoxon signed rank test, significance level $p < 0.05$					

16.2.4 Quality of Life

Table 16.13 provides the results of individual components and the total score of PedsQL™ generic module questionnaire. No statistically significant differences were found in the total score or in individual components. It is noticeable from the Table that for children with CP, the physical component has the lowest score. Also, the mean difference in physical component tends to show the greatest difference, with a trend of increase between baseline and final. However, the standard deviations of the mean differences were rather high, indicating variability within the group.

16.2.5 Results from physical examination

Table 16.14 shows the MAS of selected muscles. None of the changes between baseline and final were statistically significant. The comparison of muscle power using MRC grading is given in Table 16.15. None of the differences in muscle power were statistically significant.

It can be seen from Table 16.16 that none of the ROM parameters were significantly different between baseline and final. Parameters such as hip flexion with extended knee, hip extension and hip internal rotation and catch in plantar flexors showed a trend of increase from baseline to final. In contrast, dorsi-flexion with the knee flexed and extended demonstrated decreasing trends from baseline to final. Differences between baseline and final in all the above parameters demonstrated wide confidence intervals.

Table 16.16 Descriptive and inferential analysis of range of motion (ROM) measures for selected joints between baseline and after short-term intervention (Final)

	Descriptive analysis		Inferential analysis			
	Baseline mean (SD)	Final mean (SD)	D (SD)	95% Confidence Interval of D		p value
				Lower	Upper	
Hip flexion knee flexed	69.3 (10.5)	74.7 (9.6)	-5.43 (9.8)	-14.41	3.55	0.19
Hip flexion knee extended	27.3 (8.3)	28.4 (13.3)	-1.14 (7.4)	-7.99	5.70	0.61
Hip Abduction	23.1 (8.1)	21.3 (3.5)	1.86 (5.9)	-3.57	7.29	0.53
Hip Adduction	13.6 (6.7)	14.7 (5.5)	-1.14 (2.6)	-3.56	1.27	0.29
Hip Extension	8.7 (3.6)	11.3 (3.2)	-3.50 (6.2)	-13.44	6.44	0.34
Hip Internal Rotation	42.0 (5.1)	48.8 (7.5)	-6.80 (10.9)	-20.33	6.73	0.14
Hip External Rotation	8.5 (17.3)	12.6 (16.2)	4.07 (7.3)	-9.33	13.83	0.58
Femoral Anteversion	17.0 (9.0)	18.6 (9.7)	-1.57 (18.5)	-26.51	19.31	0.69
Popliteal angle	124.7 (9.7)	125.0(11.9)	-0.29 (7.4)	-7.12	6.55	0.92
Knee extension	0.9 (7.6)	-1.4 (5.7)	2.29 (3.1)	-0.58	5.15	0.10
Dorsi-flexion – Knee flexed	1.9 (7.9)	-1.4 (9.3)	3.29 (5.8)	-2.07	8.64	0.18
Dorsi-flexion – Knee extended	-4.0 (5.7)	-7.9 (8.1)	3.86 (5.2)	-0.90	8.62	0.09
Plantar-flexion - Knee extended	47.3 (7.0)	46.8 (9.2)	0.50 (3.6)	-3.24	4.24	0.75
Catch in Plantar flexors	21.7 (7.9)	24.8 (7.9)	-3.17 (5.8)	-9.26	2.93	0.24
Key: SD- Standard deviation, D- Mean Difference statistical tests used – Paired t-test/Wilcoxon signed rank test, significance level $p < 0.05$, significant results in **bold**						

Table 16.17 Standardised effect sizes and powers of the differences in temporal-spatial parameters and GDI in two comparisons

	Barefoot baseline – barefoot final		Non-tuned AFO-FC – tuned final	
	Effect size	Power	Effect size	Power
Velocity (m/s)	0.84	0.5	0.42	0.18
Cadence (steps/minute)	0.58	0.3	-0.01	0.05
Stride-length (m)	0.78	0.5	0.77	0.5
GDI	0.13	0.07	0.10	0.06
Key: GDI – gait deviation index, barefoot baseline - barefoot at baseline, barefoot final - barefoot after long-term intervention, non-tuned AFO-FC- non tuned AFO-FC before short-term intervention, tuned final- tuned AFO-FC after short-term intervention				

16.2.6 Power analysis

Table 16.17 provides the standardised effect sizes and powers of temporal-spatial parameters and GDI when compared between barefoot baseline and barefoot final and between non-tuned AFO-FC and tuned final.

When compared between barefoot baseline and barefoot final all three temporal-spatial parameters yielded medium effect sizes, whereas GDI demonstrated a small effect size (Cohen 1988). In contrast, when compared between non-tuned AFO-FC and tuned final, stride-length demonstrated medium effect sizes, while velocity, cadence and GDI yielded only small effect sizes. The highest statistical power ($1 - \beta$) for temporal-spatial parameters when compared between barefoot baseline and barefoot final was for velocity (0.53). Furthermore, when compared between non-tuned AFO-FC and tuned final, velocity yielded a power of 0.18 and cadence demonstrated an even lower power (0.05). GDI demonstrated low powers for both comparisons (Table 16.17).

The sample sizes required to detect a medium effect size for GDI at $p < 0.05$ and a power of 0.8, when compared between barefoot baseline and barefoot final, and non-tuned AFO-FC and tuned final, were also estimated. The difference in means of GDI which would produce a medium effect size for the current sample was determined first, and sample size was estimated based on that mean difference. Both are presented in Table 16.18. It can be seen that at $p < 0.05$ and a power of 0.8, a sample of 18 will be adequate to detect a change of 6.7 in GDI.

Table 16.18 Differences in the means of gait deviation index (GDI) required to gain a medium effect size, and sample size required to detect the medium effect size.

	Mean difference required for a medium effect size	Sample size required
Barefoot baseline – barefoot final	6.7	18
Non-tuned AFO-FC – tuned final	4.0	17
Key: barefoot baseline - barefoot at baseline, barefoot final - barefoot after long-term intervention, non-tuned AFO-FC- non tuned AFO-FC before short-term intervention, tuned final- tuned AFO-FC after short-term intervention		

16.2.7 Summary of findings from the feasibility study

- Normalised walking speed improved with barefoot final compared to barefoot baseline. No significant differences in SVA and GDI were found between barefoot baseline and barefoot final. Peak hip extension significantly increased towards normal with barefoot final in comparison to barefoot baseline.
- Peak plantar-flexion moments increased towards normal with tuned AFO-FC after short-term intervention compared to non-tuned AFO-FC before short-term intervention. SVA was more inclined and closer to normal with tuned final compared to non-tuned AFO-FC.
- Normalised stride-length and hip ROM were better and SVA was less inclined (closer to normal) with tuned AFO-FC after short-term intervention compared to tuned AFO-FC before short term intervention. There was no significant difference in GDI.
- No significant difference was found in any of the domain scores or total score of PedsQL™ generic module. No significant changes were found in muscle tone, power or passive ROM measurements.
- Several parameters with statistically non-significant changes showed considerable mean differences and wide confidence intervals.
- It was determined that a sample of 18 will be required to detect a change in GDI worth a medium effect size.

16.3 Discussion

This section is further divided into four sub-sections. The first discusses the short-term effects of tuning of AFO-FC on children with CP. This includes the results from comparison of temporal-spatial parameters, kinematic and kinetic data points while walking barefoot before and after short-term intervention, and results from comparison of muscle tone, muscle power, passive joint range of motion (ROM) and quality of life at baseline and after short-term intervention. The second sub-section discusses the differences in walking with non-tuned AFO-FC before short-term intervention and tuned AFO-FC after short-term intervention, including temporal-spatial parameters and kinematic and kinetic data points. The third sub-section discusses the comparison between walking with tuned AFO-FC before short-term intervention and tuned AFO-FC after short-term intervention, including temporal-spatial parameters, and kinematic and kinetic data points. Finally, the fourth sub-section discusses the results of power analysis and sample size calculations, and feasibility issues associated with the current study.

16.3.1 Short-term therapeutic effects of tuning on barefoot gait, quality of life, muscle strength and tone, and passive joint range of motion

It was assumed in the current study that the changes seen in barefoot gait parameters and physical examination may be considered as short-term therapeutic effects of tuning, as these parameters were expected to demonstrate whether any of the changes acheived with the use of tuned AFO-FC, has been retained. There is a lack of literature on the effects of tuning over time. The only study which looked into the long-term effects of tuning on children with CP allowed the children to use tuned AFOs for four to six months (Butler, Thompson and Major 1992), whereas in the current study children used tuned AFO-FC for two-to-four months. Another study, which explored long-term effects of tuned orthoses in an adult with traumatic brain injury, conducted follow-up lasting until four years after the first visit (Butler, Farmer and Major 1997). In the current study, it must be acknowledged that two-to-four months may not be an adequate time for investigating any permanent changes due to therapeutic effects. However, the primary aim of the current study was to investigate the feasibility of conducting a larger trial.

Walking speed increased significantly after short-term intervention when compared between barefoot baseline and barefoot final. Normalisation of walking speed, stride-length and cadence was carried out to negate the effects of growth of children on the parameters, as stride-length and walking velocity are affected by limb length (Hof 1996; van der Linden et al. 2002). The previous study which investigated the effects of tuned AFOs on gait parameters reported no significant difference in walking speed over time (Butler, Thompson and Major 1992). A case study which investigated the effects of tuning of AFO-FC on the gait of an adult with hemiplegia reported that while a decrease in mean walking speed was seen immediately after tuning, it increased after three months (Jagadamma et al. 2007). However, the comparison in the case study was made between non-tuned and tuned AFO-FC, and not in barefoot.

While the mean increases in walking speed (0.2 m/s) in the current sample are promising, they should be interpreted with caution. There was no control group and hence the increase in walking speed could be explained as a natural increase over time. This limitation exists in most studies of children with CP using a pre-post design with no control group. Normalised stride-length and cadence demonstrated medium effect sizes based on Cohen’s classification of standardised effect sizes (Cohen 1988). The trends of increase, wide confidence intervals of the differences and the medium effect sizes demonstrated by normalised stride-length and cadence suggest the possibility of type II error. The increased walking speed and trends seen in stride-length and cadence indicate the possibility that participants were walking more comfortably after using tuned AFO-FC for two-to-four months, and suggest the need for further investigation with an adequate sample and a control group.

No previous studies have looked into the effects of tuning of AFOs on knee kinematics in children with CP. The studies which considered kinetics found that the knee extension moment arm decreased after using tuned AFOs over time (Butler, Farmer and Major 1997; Butler, Thompson and Major 1992). However, none of the changes in the knee moments were significant in the current study. One reason might be that Butler, Thompson and Major (1992) investigated the effects of tuned orthoses in conjunction with balance exercises, while Butler, Farmer and Major (1997) used a single case study of an adult with traumatic brain injury, limiting the comparison. Another possible reason for a lack of significant changes in kinematics and kinetics of the knee is that two-to-four months did not provide sufficient time for any permanent changes to occur. Finally, moments are dependent on the moment arm as well as the magnitude of the vertical force, and previous studies have reported only moment arms.

Among the hip parameters, there was a significant increase in peak hip extension. While there was no statistical significance, the hip ROM had a mean increase of 4°, with a wide confidence interval (-9.6 to 1.1). This suggests the possibility of Type II error. The increase peak hip extension may be related to the trend seen in hip ROM. In addition, there were trends of increase in peak hip flexion moments and peak hip extension moments with wide confidence intervals. All of these changes may be attributed to participants becoming familiarised with the prescription, with transfer of benefits of tuning to barefoot walking after the short-term intervention.

There was no change reported in gait deviation index (GDI). Considering the lack of improvement in joint kinematics in the current study, it was not surprising to see the lack of change in GDI. However, while GDI is sensitive enough to differentiate between children with CP of different topographical involvement and belonging to different levels of Gross Motor Function Measure (GMFM) classification (Molloy et al. (in press); Schwartz and Rozumalski 2008), the utility of GDI in detecting changes following interventions is not clear. Furthermore, GDI does not take the temporal-spatial parameters or kinetics into consideration.

None of the changes in passive ROM significantly changed after the children used tuned AFO-FCs over time. None of the previous studies have investigated the effects of tuning on the ROM of lower limb joints to the same extent as the current study. However, Butler, Thompson and Major (1992) reported the effects of tuned orthoses and balance training on passive hyper-extension of the knee and passive dorsi-flexion of ankle. They reported no difference in passive hyper-extension of the knee, but four out of five children minimally lost range. The results are similar to those in the current study, where passive extension of the knee and dorsi-flexion of the ankle were not significantly different. Similar to Butler, Thompson and Major (1992), there was a trend of reduced dorsi-flexion at the final time point, compared to baseline. While the difference in dorsi-flexion was not statistically significant, there was a mean difference of 3.9°, with wide confidence intervals (-0.9 to 8.6). However, even the highest limit of the confidence interval falls within the range of measurement errors reported by previous studies (Keenan et al. 2004; McDowell et al. 2000). Other movements with wider limits shown in the confidence intervals were hip flexion with flexed knee, and hip internal rotation. The former showed a trend of improvement, whereas hip internal rotation and femoral anteversion showed trends of deterioration. While the repeatability of the photographic method on the patient population is not clear, it is possible that this method may reduce rater and goniometric error (Karkouti and Marks 1997). However, 2D photography may present the risk of parallax error. The small sample number and difficulty in recruitment prevented investigation of the repeatability of the photographic method in the current project. A reliability study of the method employed is also vital for further research.

The results of the current study did not reveal any change in muscle tone. However, it could be seen that median values for the Modified Ashworth Score (MAS) were near normal at baseline. The distal musculature presented with higher tone compared to proximal. Earlier studies explored relationships between spasticity, gait parameters and function, and reported low correlations (Ross and Engsberg 2007). The median values at final assessment did not show any trend of improvement or deterioration compared to baseline. The lack of change in scores may be due to the lack of tone abnormalities in the sample. The effects of AFO use or similar interventions on spasticity have not been sufficiently investigated. Among the muscles assessed for strength, no significant differences were seen. There were trends of increase in the strength of all muscles investigated, with the exception of the hamstrings, although even these differences were not significant. In the current study there was improvement in walking speed. Ross and Engsberg (2007) found that walking speed was moderate correlated with muscle strength.

There were no improvements in any of the domains of PedsQL™ with tuning. However, there was an increasing trend in the physical domain. The social and school domains showed a trend of decrease. Varni et al. (2006) reported that the total generic PedsQL™ score did not distinguish between children belonging to GMFM level I and II, or between GMFM level II and III, whereas the physical domain was sensitive to the GMFM classifications. It is possible that the generic module was not sensitive enough for determining change in quality of life for an intervention such as tuning. Furthermore, interventions which do not bring about a drastic change in lifestyle (e.g. surgery), may take time to lead to change in any QOL instrument, or may not lead to detectable change due to other influences. No studies were found which investigated changes in QOL with the use of orthoses in children with CP, or which have explored possible relationships between PedsQL™ scores and changes in gait parameters.

The results from comparison of kinematic and kinetic data points, passive ROM, muscle strength, muscle tone, GDI and PedsQL™ did not produce any significant differences between baseline and after short-term intervention. However, some variables demonstrated considerable mean differences, with wide confidence intervals, suggesting a lack of power. More importantly, there were significant improvements in temporal-spatial parameters with the short-term intervention, which suggest the utility of tuning for children with CP.

16.3.2 Comparison between non-tuned AFO-FC and tuned AFO-FC after three months (tuned final)

Comparisons were made between gait data collected with non-tuned AFO-FC at the start of project and tuned AFO-FC after two-to-four months (tuned final). This comparison was essential to determine the effects of tuning after the participants became accustomed to the prescription. However, confounding factors such as effects of growth, and natural improvement or deterioration existed owing to the absence of a control group. Nevertheless, the findings serve the purpose of informing the feasibility of a larger trial with information on significant changes, trends and power.

Among the normalised temporal-spatial parameters compared between non-tuned AFO-FC and tuned final, there were no statistically significant improvements. This was not in line with the findings of a previous case study on tuning for an adult with hemiplegia, which reported increased walking speed after the use of tuned AFO-FC for three months (Jagadamma et al. 2007). However, the comparison is limited since the latter was a single case study of an adult with hemiplegia. In addition, the difference in walking speed and stride-length demonstrated medium effect sizes based on Cohen's classification of standardised effect sizes (Cohen 1988), and wide confidence intervals. Further investigation with an adequately powered sample is warranted.

The SVA measured in standing was significantly different between non-tuned AFO-FC and tuned final. It could be seen that the mean (SD) of SVA increased from 7.3° (2.2) in non-tuned AFO-FC to 10.4° (2.0) in tuned final. With the tuned final, the SVA was closer to the findings of Owen (2002). Owen (2002) reported a mean (SD) SVA of 11.86° (2.05) for 50 children with CP wearing tuned AFO-FCs. It could also be seen that the SVA was closer to the normal values (10.5°) previously reported (Pratt, Durham and Ewins 2007) with tuned AFO-FC after short-term intervention.

Among the sagittal moments at the ankle joint, peak ankle plantar-flexion moments were higher and closer to normal with tuned final compared to non-tuned AFO-FC. As discussed previously, the presence of a higher heel may have produced an increased heel lever, thereby increasing the moment arm at the ankle joint, which may have resulted in higher plantar-flexion moments with tuned AFO-FC compared to non-tuned.

Among the knee kinematic parameters, the trend of decrease in peak knee extension with tuned, compared to non-tuned AFO-FC, and the wide confidence interval of the difference, suggest lack of power. However, since case study analysis was not carried out for the short term results, it could not be established whether the peak knee extension remained closer to normal. Similarly, although not statistically significant, the differences in peak knee flexion during stance demonstrated trend of increase and knee ROM demonstrated trend of decrease, and had wide confidence intervals (-9.19 to 1.62 and -0.22 to 11.37 respectively). Butler et al. (2007) noted increased knee flexion during initial stance as a disadvantage of tuning. All of the above suggests further investigation is required in a sample with adequate power.

Although none of sagittal plane knee moments were significantly different between the conditions, the peak knee extension moments and knee extension moments during mid-stance tended to decrease, and demonstrated wide confidence intervals. Hence, it is likely that the lack of significance is due to a lack of power. Butler, Thompson and Major (1992) and Butler, Farmer and Major (1997) reported reductions in the knee extension moment arm as a result of tuning. However, the comparisons in these two studies were between barefoot data. Similarly, the peak knee flexion moments during stance demonstrated a decreasing trend with wide confidence intervals, which suggests the possibility of knee flexion moments being normalised over time with an adequately powered sample. However, the lack of statistical significance prevents any conclusions and a larger study is required. Similarly the considerable mean differences in peak hip flexion moments and peak hip extension moments and wide confidence intervals suggest lack of power.

Among the pelvic kinematic parameters, only pelvic tilt ROM demonstrated a significant difference. However, there was only a mean difference of 1.1° between non-tuned AFO-FC and tuned final. The narrow confidence interval (0.47 to 1.82) suggests that statistical significance was attained due to lack of variability in data. The clinical relevance of such small difference is questionable. However, the statistically significant change and confidence intervals suggest that the change was uniform within the sample. It may be concluded that the pelvic ROM was smaller and closer to normal with tuned final in comparison to non-tuned AFO-FC, although the difference may not be clinically relevant.

To summarise, the comparison between non-tuned AFO-FC before short-term intervention and tuned AFO-FC after short-term intervention yielded significant differences only SVA and peak plantar-flexion moments, all of which demonstrated improvements. There were several other parameters which demonstrated lack of power and hence suggest the value of conducting further research with larger samples.

16.3.3 Comparison between tuned AFO-FC before short-term intervention (tuned immediate) and tuned AFO-FC after short-term intervention (tuned final)

This comparison was carried out to look at whether effects while using tuned AFO-FC were maintained after the short-term intervention. It should be noted that tuned immediate comprised of data collected immediately after tuning, i.e., not with the permanently modified shoes and tuned final comprised of data collected with permanently modified shoes. While it was made sure that the shoes were made according to prescription in all the cases, differences existed in properties of the shoes, such as flexibility and profile of the sole. However, the heel sole differential was maintained for all the shoes.

Among the temporal-spatial parameters, the only significant difference seen was in normalised stride-length, which was higher with tuned final compared to tuned immediate. In contrast, in a previous case study of an adult with hemiplegia, it was seen that in comparison to non-tuned AFO-FC and tuned AFO-FC immediately after tuning, the patient demonstrated increased walking speed after using the tuning AFO-FC for three months (Jagadamma et al. 2007). However, the comparison is limited, since the previous study was a case study on an adult with hemiplegia. The increase in stride-length in the current study may be related to increased hip ROM.

The SVA in standing significantly reduced after the participants used the prescription over time. The mean (SD) of SVA with final tuned (10.5 (2.0)) was close to the findings of Owen (2002), who reported a mean (SD) SVA of 11.86 (2.05) for tuned

AFO-FCs in 50 children with CP, and to SVAs measured in healthy children (Pratt, Durham and Ewins 2007).

Among the sagittal plane moments at the ankle, peak plantar-flexion moments showed a significant decrease with tuned final in comparison to tuned immediate. Comparison of non-tuned AFO-FC with tuned final also revealed a significant difference, with higher plantar-flexion moments with tuned final. The current results suggest that while peak plantar-flexion moments decreased from tuned immediate to tuned final, they were still higher than for non-tuned AFO-FC. Looking at the mean values, those for tuned immediate and tuned final were closer to normal when compared with non-tuned AFO-FC. The difference between tuned immediate and tuned final may be due to one or both of the following reasons. Firstly, the children might have adapted their gait pattern over time, thus influencing the magnitude and/or orientation of the GRF during initial stance. Secondly, there were differences in the compressibility of the heel. While in the current study heel compressibility was not analysed, the wedges used for tuning were non-compressible ethyl vinyl acetate (EVA) and the shoes were modified using rubber soles. It is possible that higher plantar-flexion moments were produced by the EVA wedges, in comparison to the modified shoes. Wiest et al. (1979) reported the influence of compressibility and design of heels on tibial advancement torque, and Owen (2004b) suggested using a compressible cushion heel to reduce ankle and knee moments.

While the peak ankle dorsi-flexion moments did not show any statistically significant difference, they showed an increasing trend with wide confidence intervals (-0.31 to 0.07). If the lack of significance in the comparison was because of lack of power, there is a possibility that the ankle kinetics during terminal stance might have become closer to normal once children became accustomed to the tuned AFO-FC. Further research with an adequately powered sample is indicated before definite conclusions can be reached.

Among the knee parameters, none of the kinematic or kinetic parameters were significantly different between tuned immediate and tuned final. No trends with clinically relevant mean differences were seen. One possible reason for the lack of significant differences is that the effects of tuning on the knee joint were more or less maintained over time. Among the hip parameters, there was a significant increase in hip ROM with tuned final compared to tuned immediate. This might be because the participants were walking more comfortably once they had become familiar with the prescription. The increase in stride-length may also be related to the increase in hip ROM. The peak hip extension tended to be higher with tuned final compared to tuned immediate. While the difference was not significant, the wide confidence interval suggests the possibility of a Type II error (-2.78 to 9.07). This possible trend of increase in hip extension might be the reason for increased hip ROM, considering the lack of change in any flexion parameters relating to the hip. Among the hip moments, while there were no significant differences, peak hip extension moments showed a decreasing trend. From the results of immediate effects, a similar trend was seen. For both the comparisons the confidence intervals were wide.

Similar to the comparison between non tuned AFO-FC and final tuned, the current comparison also revealed no significant differences in any of the pelvic parameters except pelvic tilt ROM. The mean difference in pelvic tilt ROM was only 1.2°, with a narrow confidence interval (0.12 to 2.26) which was comparable to results of the comparison between non-tuned AFO-FC and final tuned. Hence, as stated for this previous comparison, while the pelvic tilt ROM became closer to normal with tuned final compared to tuned immediate, the clinical relevance of this change is questionable.

To summarise, in the comparison between tuned immediate and tuned final, while the knee parameters predominantly retained the same stride-length, SVA and hip ROM demonstrated improvement. These changes suggest the possibility that the participants may have become more comfortable in walking with tuned final compared to tuned immediate. Furthermore, several parameters demonstrated considerable mean differences with wide confidence intervals, indicating the need for further research with an adequately powered sample.

16.3.4 Statistical power analysis

Similarly to most studies involving children with CP, the generalisability of findings is limited by the small sample in the current study. Nevertheless, the current study provides valuable information regarding research design considerations such as effect size, power and sample size. Standardised effect sizes were estimated based on Portney and Watkins (2000) and statistical power and sample size for the future trial were calculated using a computer program available from the internet (Lenth 2006). Effect sizes and power of selected variables such as walking speed, cadence, stride-length and Gait Deviation Index (GDI) were investigated. Not all variables were considered for power analysis, as it was clear from the results that for kinematic and kinetic variables, mean differences for the whole sample may not represent the actual effects of tuning. Instead, comparison based on gait patterns is optimal. Improvement in temporal-spatial parameters and GDI may be representative of actual improvement in gait. Furthermore, while three different comparisons were made in this study, only two comparisons (barefoot baseline – barefoot final, and non-tuned AFO-FC- tuned final) were considered for power analysis. This was due to the fact that only these comparisons aimed to demonstrate the effectiveness of tuning, whereas the comparison between tuned immediate and tuned final was to investigate whether any changes achieved by tuning had been maintained.

Based on Cohen's classification of standardised effect sizes (Cohen 1988), when compared between barefoot baseline and barefoot final, the difference in normalised walking speed and stride-length demonstrated medium effect sizes, and GDI demonstrated a low effect size. When compared between non-tuned AFO-FC and tuned final, stride-length demonstrated medium effect size, and velocity, cadence and GDI yielded low effect sizes. It could be seen that all the parameters which demonstrated significant changes had at least medium effect sizes, which explains the findings of the current study. GDI demonstrated low power in both comparisons. Sample size estimation was carried out using GDI, since this is the only outcome measure which attempted to quantify the gait abnormalities. As reported, the GDI demonstrated low effect sizes in both comparisons; the mean difference required to produce a medium effect size for GDI in the present sample was estimated. The sample required to detect a medium effect size for GDI at $p<0.05$ and a power of 0.8 was determined to be 18 in one arm of the study.

GDI was included in the current study due to the fact that that it may not be meaningful to statistically analyse the change in group means of kinetics and kinematics especially of the knee joint, as the direction of change may differ for children with different gait patterns. However, there were no significant changes in GDI. Considering the fact that GDI does not consider joint kinetics and temporal-spatial parameters, additional meaningful outcome measures may be considered for any future trial. The possible lack of sensitivity of QOL measures to conservative management such as tuning underlines such a need. One possible solution is to use individualised goals as outcomes. A mixture of goals related to kinematic and kinetics, and personal goals of the participants, may be identified.

16.4 Conclusion

The current study reported the feasibility of conducting a larger trial investigating effects of tuning of AFO-FC in children with CP. While there were not many statistically significant changes in kinematic and kinetic data points, QOL, or muscle and joint properties, the statistically significant improvements and trends in temporal-spatial parameters are promising. Furthermore, several parameters demonstrated considerable mean differences, with wide confidence intervals, suggesting a lack of power. Hence a study with a larger sample is indicated. It was estimated that a sample of 18 will be required in each group to detect a change worth a medium effect size in GDI at a power of 0.8 and $p < 0.05$. Feasibility issues identified in the current study are explored further in Chapter 17.

CHAPTER 17 GENERAL DISCUSSION

17.1 Introduction

In each of the preceding four chapters the empirical observations made have largely been discussed independently of one another. The purpose of this chapter is to synthesise and integrate these chapter-specific findings to derive clinically meaningful conclusions regarding the clinical and functional value of tuning of Ankle Foot Orthosis – Footwear Combination (AFO-FC) for children with Cerebral Palsy (CP). The general aims of this thesis were to investigate:

- the effects of rigid AFO-FC on the gait of children with CP,
- whether the gait of children improved immediately after tuning the rigid AFO-FC,
- effects of components of tuning on the gait of children with CP;
- the short-term effects (i.e. after 2 – 4 months) of tuned AFO-FC on gait, quality of life, muscle tone and strength, and passive range of motion of children with CP, and
- the feasibility of tuning as a meaningful clinical intervention that might be implemented within a clinical trial.

Any research involving children with CP poses a number of challenges; several associated impairments, and long-lasting effects of treatments such as surgery, affect inclusion and exclusion criteria for research. Furthermore, tuning has evolved into a complex intervention, which produces further difficulties (Chapter 1, page 3).

Findings from the preceding chapters are summarised in Figure 17.1. In the current chapter, the key observations of the thesis are discussed in relation to existing literature. The implications for clinical and research contexts are discussed with the identification of limitations of this study and feasibility issues that will inform future work.

Chapter 13: Study on Healthy Children (Page 163)

- ✓ Evident influence of shoes on key gait variables, healthy children accommodated for increasing sizes of wedges and PLRs predominantly at ankle joint
- ✓ Possibility of proximal joint kinematics remaining unaffected until the wedges started changing the proximal joint kinetics was identified.

Chapter 15: Effects of increasing sizes of wedges and PLRs on gait of children with cerebral palsy (Page 190)

- ✓ Children with different gait patterns responded differently to increasing sizes of wedges
- ✓ While an optimal wedge size may produce improved kinematics and kinetics in one or more joints, other wedge sizes even as close as within 2° may not.
- ✓ None of the wedge sizes was capable of producing optimal kinetics and kinematics for all the joints.
- ✓ Potential clinical utility of PLR for children with cerebral palsy was indicated.

Chapter 14: Effects of non-tuned AFO-FC and immediate effects of tuning of AFO-FC (Page 239)

- ✓ Rigid AFOs produced significant improvement in gait of children with cerebral palsy, provided, the factors such as appropriateness of AFOs and familiarisation with AFOs were taken care of.
- ✓ No significant improvement in temporal-spatial parameters with tuning. However, children with hemiplegia demonstrated trends of improvement while children with diplegia showed trends of deterioration.
- ✓ The changes with tuning were predominantly seen in knee joint and were varied depending on gait patterns.
- ✓ The changes in lower limb joints with tuning were not uniform. On the contrary, a mix of improvement and deterioration in lower limb kinematics were seen.
- ✓ While investigating effects of tuning, gait patterns with non-tuned AFO-FC instead of barefoot might be useful as a baseline

Chapter 16: Feasibility study (Page 262)

- ✓ Therapeutic effects- Improvement in walking speed when comparing barefoot at baseline and after short term intervention. No change in GDI, SVA, PedsQL™, muscle tone and strength, and passive range of motion.
- ✓ When compared between non-tuned AFO-FC at baseline with tuned AFO-FC after short term intervention – improvement in SVA and peak plantar-flexion moments.
- ✓ When compared between tuned AFO-FC at baseline with tuned AFO-FC after short term intervention – improvement in stride-length, SVA, hip ROM and peak plantar-flexion moments.
- ✓ Several parameters in both comparison demonstrated lack of power. A sample size of 18 in each group was determined to be adequate for future trials.

Figure 17.1 Four studies explained in the preceding four chapters (clear boxes) and the key findings from the studies (shaded boxes)

17.2 The influence of rigid AFO-FC on the gait of children with CP

Chapter 14 addressed the effects of non-tuned rigid AFO-FCs on the gait of children with CP. The current study reported improvements in various parameters, i.e. values that were closer to those found in the study on healthy participants (Chapter 13, Tables 13.1, 13.2 and 13.3, pages 170 -173). Several changes in the current study were also reported in previous research, such as increases in walking speed and stride-length (Abel et al. 1998; Brunner, Meier and Ruepp 1998; Dursun, Dursun and Alican 2002; Thompson et al. 2002; White et al. 2002), increase in hip range of movement (ROM) (Abel et al. 1998, Brunner, Meier and Ruepp 1998), increase in knee ROM (Abel et al. 1998), and increase in peak dorsi-flexion moments (Carlson et al. 1997; Abel et al. 1998; Rethlefsen et al. 1999; Radtka, Skinner and Johanson 2005; Lam et al. 2005). However, the increases in peak ankle plantar-flexion moments during initial stance, peak hip flexion moments, and peak hip extension moments were not reported by any previous studies. In addition, no previous studies investigated the Shank to Vertical Angle (SVA).

All the changes with non-tuned rigid AFO-FC in the current study were closer to normal, with the exceptions of peak hip flexion moments and peak knee flexion moments (Chapter 14, page 225). The children were able to walk faster and with longer steps, both of which suggest improvement in walking ability.

While some of the previously mentioned studies ensured that participants were given time to familiarise themselves with the prescription, all the studies used AFOs casted in plantigrade. However, in the current study, AFOs were casted to accommodate the available length of Gastrocnemius, and participants were familiarised with the prescription before data collection. The improvements with the use of non-tuned AFO-FC in the current study were attributed to these factors (Chapter 14, page 232 - 233).

Despite all the improvements with the use of rigid AFO-FC, the findings indicate that the addition of tuning may further improve the gait of children with CP (Chapter 14, page 232).

This was based on the lack of changes in many kinetic and kinematic parameters, especially relating to the knee (Chapter 14, Tables 14.2 and 14.3, pages 195 and 197), and to negative influences of rigid AFO-FC on participants' gait patterns (Chapter 14, page 231-232). For example, in children with hyper-extension of the knee during stance phase in barefoot, hyper-extension further increased with the use of non-tuned AFO-FC.

17.3 Influences of tuning of AFO-FC

Several parameters improved with the use of tuned AFO-FC. However, influences on these changes were observed. These parameters and influences are discussed in turn.

Influence of familiarisation of the prescription on temporal-spatial parameters

In Chapter 14 (Table 14.4, page 197), no significant changes were observed in temporal-spatial parameters such as walking speed, stride-length and cadence, immediately after tuning. However, walking speed improved, as evident in values measured while walking barefoot after the short-term intervention when compared with baseline (Chapter 16, Table 16.2, page 268). Furthermore, when walking with tuned AFO-FC after short-term intervention was compared with tuned AFO-FC at baseline, improvement in stride-length was observed (Chapter 16, Table 16.10, page 275).

It was observed in Chapter 14 (Table 14.5, page 198) that while participants with hemiplegia demonstrated trends of improvement, participants with diplegia showed trends of deterioration in temporal-spatial parameters immediately after tuning. It was theorised that the trends of decreasing walking speed and stride-length in children with diplegia immediately after tuning may be due to increased stability (Chapter 14, page 234). While no literature was found to support this argument, similar changes were shown by the case studies of children with diplegia in Chapter 15 (pages 260-261). These demonstrated that optimal wedge sizes produced decreases in walking speed and stride-length compared to AFO-FC and other wedges, which was also attributed to the participants achieving stability. However, the increase in stride-length with tuned AFO-FC after short-term intervention, when compared with tuned AFO-FCs at baseline, indicated that familiarisation of the prescription may have influenced the changes in temporal-spatial parameters. Furthermore, the increase in walking speed while walking barefoot after the short-term intervention, when compared with baseline, indicate improvements in the walking ability of all (i.e. hemiplegic and diplegic) participants.

Influence of heel sizes and designs on plantar-flexion moments

Increases in plantar-flexion moments in initial stance with tuning were evident immediately after tuning (Chapter 14, Table 14.7, page 199) and with tuned AFO-FC after short-term intervention (Chapter 16 Table 16.8, page 274), when compared with non-tuned AFO-FC at baseline. The non-tuned AFO-FC produced lower than normal moments, which increased to higher than normal immediately after tuning. The higher moments with tuned prescriptions compared to non-tuned were associated with the difference in the size of the heel, which in turn may have increased the length of heel lever, and thereby the moment arm (Chapter 14, page 235 and Chapter 16, page 288).

Plantar-flexion moments were lower after short-term intervention than when measured immediately post-tuning (Chapter 16, Table 16.12, page 277). This was attributed to the possible difference in compressibility of the heels (Chapter 16, page 291). A previous case study reported the influence of different types of heels on tibial advancement torque, and found that the hardest heel produced the highest torque (Wiest et al. 1979). Owen (2004b) suggested using different designs of heels to moderate GRF orientation during initial stance. However, the evidence is empirical at best. Nevertheless, for the current sample, the final tuned prescription produced improved plantar-flexion moments during initial stance, i.e. closer to the values found in healthy participants (Chapter 13, Table 13.3, page 172).

The effects of tuning on knee joint kinematics and kinetics

The basic premise of tuning is reorientation of the GRF in relation to lower limb joints, which is then expected to reduce abnormal forces acting on joints (Butler & Nene 1992; Owen 2004b; Meadows, Bowers and Owen 2008; NHS Quality Improvement 2009). However, compensations for the modifications made to shoe designs involve a mixture of kinetic and kinematic changes. The possibility of healthy children using similar general strategies to compensate for increasing sizes of wedges was identified in Chapter 13 (Page 190). While no single general strategy was followed by the participants with CP, Chapter 14 (page 241) and Chapter 15 (page 262) identified that there may be strategies specific to different gait patterns (while wearing AFO-FC) that cause adaptations to modifications made to the shoes, especially at the knee joint.

The importance of considering knee joint parameters while investigating the effects of tuning has been emphasised before (Chapter 14, page 236). It was also identified in Chapter 14 that grouping children based on gait patterns with non-tuned AFO-FC, rather than while barefoot, was relevant for the current sample (Chapter 14, pages 231-232). Three gait patterns were identified from the current sample: extended knee gait, crouch knee gait and jump knee gait. The influences of tuning on knee joint kinematics were different for each group; most changes were seen in extended knee gait, followed by jump knee gait; while crouch knee gait demonstrated least improvement (Chapter 14, Table 14.10, page 236). Immediately after tuning, the legs with extended knee gait demonstrated an increase in knee flexion throughout the stance phase, thereby achieving reduction in knee hyper-extension. Legs with jump knee gait demonstrated a decrease in their abnormally high knee flexion in early stance, and knee hyper-extension, thus normalising stance phase kinematics. Legs with crouch knee gait did not change (Chapter 14, pages 236-237). Reduction of knee hyper-extension with tuning of AFO-FC has been suggested previously in both children with CP and adults with stroke (Butler and Nene 1991; Jagadamma et al. 2007). Butler et al. (2007) suggested that children with high knee flexion throughout the gait cycle may be non-tunable. Although participants with crouch gait in the current study did not demonstrate many changes in knee kinematics with tuning, some changes in knee kinetics were visible for both participants (Chapter 14, pages 238-239).

Chapter 14 reported statistically significant changes in peak knee extension moments (Table 14.7, page 199) and knee ROM (Table 14.6, page 198) immediately after tuning in the comparison that included the whole sample. The reductions in knee extension moments were associated with reorientation of the GRF. Although this change was in a direction away from normal, it was considered to be an improvement, as it led to a reduction in hyper-extension for the majority of the sample (Chapter 14, page 238). The decrease in knee ROM immediately after tuning was undesirable and was associated with reductions in knee hyper-extension and peak knee flexion in some of the sample (Chapter 14, page 236). While these two changes were not seen when compared between non-tuned AFO-FC at baseline and tuned AFO-FC after short-term intervention, (Chapter 16, Table 16.7 and16.8, pages 273-274), similar trends with wide confidence intervals were evident.

Another parameter which demonstrated improvement with tuning and was closely related to the knee joint was the SVA. Chapter 14 (page 234 - 235) reported that in comparison to non-tuned AFO-FC, SVA with tuned AFO-FC was much closer to the previously reported normal values (Pratt, Durham and Ewins 2007), values with tuned AFO-FCs (Owen 2002), and existing recommendations (Bowers and Ross 2009; NHS Quality improvement 2009). While investigating the short-term effects, it was seen that the SVA did not differ when measured in barefoot at baseline and in barefoot after the short-term intervention (Chapter 16, Table 16.1, page 268). However, it was closer to normal with tuned AFO-FC after short-term intervention, when compared with non-tuned AFO-FC at baseline (Chapter 16, Table 16.5, page 272). Overall, the SVA was closer to normal while the participants wore tuned AFO-FC compared to other conditions.

The findings from the current study indicate that the immediate effects of tuning on knee kinematics varied depending on gait patterns identified while participants were wearing AFO-FC. There were undesired effects with tuning, such as reduction in knee ROM for the whole sample, and increase in knee flexion during initial stance for participants with extended knee gait. Nevertheless, the improvements in gait were evident through changes in knee extension moments and SVA for the whole sample, and more selectively through improved knee kinematics of participants with extended knee gait and jump knee gait.

Effects of tuning on hip kinematics and kinetics

Hip ROM was not significantly affected by tuning when comparing non-tuned and tuned AFO-FC, either immediately after tuning (Chapter 14, Table 14.6, page 198), or after short-term intervention (Chapter 16, Table 16.7, page 273). However, between tuned AFO-FC before short-term intervention, and tuned AFO-FC after short-term intervention, the hip ROM was significantly higher with the latter (Chapter 16, Table 16.11, page 276). Furthermore, when walking barefoot after short-term intervention was compared to baseline, a mean increase in hip ROM, with wide confidence intervals, was reported (Chapter 16, Table 16.3, page 270). These changes were considered to be improvements, as the changes were towards normal. They were attributed to participants becoming familiarised with the prescription (Chapter 16, page, 292) with transfer of these benefits to barefoot walking after the short-term intervention (Chapter 16, page 285).

Chapter 16 (Table 16.4, page 271) reported trends of improvements in peak hip flexion and extension moments, supported by wide confidence intervals, in barefoot after short-term intervention when compared with baseline. These trends towards normal were attributed to the possibility that participants may have transferred some benefits of tuning to barefoot walking (Chapter 16, page 285). No previous studies have investigated the effects of tuning on hip moments.

A mixture of positive and negative changes in the kinematics and kinetics of the lower limb joints were reported immediately after tuning (Chapter 14, page 241) and with optimal size of wedge among increasing sizes of wedges (Chapter 15, page 262). It was concluded that it might not be possible improve kinematic and kinetics of all lower limb joints; instead, relevant parameters should be identified for each individual (Chapter 15, page 262).

Furthermore, the effects of familiarisation cannot be neglected. While the influence of gait patterns on the short-term effects were not addressed in the present study, several parameters demonstrated improvement in the group comparisons.

The improvements achieved due to tuning of AFO-FC in the current study were evident in temporal-spatial parameters, ankle plantar-flexion moments, knee kinematics and kinetics, and hip ROM. However, the findings in kinematics and kinetics did not translate into improvement in quality of life (Chapter 16, Table 16.13, page 278). It was concluded in Chapter 16 (page 287) that this may have been due to a lack of sensitivity in the quality of life measure, preventing potential identification of changes produced by conservative management such as tuning.

Table 17.1 Limitations and feasibility issues identified in the current study and possible solutions

Limitations/Feasibility issues	Possible actions for future research
Sample recruitment: this was severely affected by 1. the exclusion criteria in the present study, 2. lack of awareness among the clinicians regarding the intervention, and 3. Number and duration of sessions.	1. Create more awareness among clinicians. 2. Extract and explore user experiences from the patient/parent group in the current study. 3. Conduct multi-centre trial.
Participant drop-out: the reasons were 1. delay in fabrication of AFO and shoes, 2. parent being unhappy about the cosmetic appearance of the shoes, 3. parent being unhappy about casting the AFO in plantar-flexion, and 4. change in treatment plan.	Provide more information on the appearance of shoes and casting angle of AFOs. Reduce the duration taken for fabricating AFOs and for modifying the shoes.
Reliability: this was not investigated for motion analysis for children with CP, or for the photographic method of measuring passive ROM for children with CP.	Integrate reliability studies in future research, especially for a novel method such as the photographic method for passive ROM measurement.
AFO and shoe fabrication: time required for fabrications ranged from 2 weeks to one month. Products not being compliant with the prescription led to return of the products for correction and thereby further delay.	One possible alternative to address this issue is to have an orthotist involved in a future project, and use local facilities for fabrication and modification.
Duration of sessions: Each session lasted around 3 hours, which may not be clinically feasible.	In future research data collection can be optimised by not collecting data during each stage of tuning. For tuning in a clinical service, as no data collection is required, the session will last for less than two hours. Alternative methods such as video vector analysis may reduce cost and time.

Table continued in next page

Table 17.1 followed from previous page

Limitations/Feasibility issues	Possible actions for future research
Number of patient appointment sessions: The number of sessions involved in the fabrication of AFO and footwear, and in data collection, may not be feasible clinically, and may cause difficulties while conducting research.	A large number of sessions would still be required in a future research study, but the number of sessions could be reduced in service delivery to make the clinical application more cost effective.
Study design: one limitation of the current study was the lack of a control group. Achieving an adequately powered sample is not enough for the comparison to be rigorous; the highest rigour in research is always associated with a randomised controlled trial design. The sample and design of the current study also prevented collection of adequate data on the effects of wedges, rockers and heels.	A sample of 36 (18 per group) is adequately powered to identify differences. With optimally designed sessions, additional data may be collected looking at the effects of different types of wedges, rockers and heels.
Sampling procedures: 1. Both healthy participants and participants with CP were recruited by convenience sampling which affects the external validity of the findings. 2. Since data from both legs were used from two participants, a possibility of bias due to sample inflation exists as the data may have been related between the legs. This was followed owing to the small sample size in the project.	1. Random sampling may be used whenever possible. However, considering the difficulty in recruiting participants with CP, random sampling may not be possible with the patient group. 2. It may be appropriate to investigate correlations between two legs whenever data from both legs of a participant are considered and use the data from only one leg (random selection) if the data are correlated between the legs

17.4 Implications of the findings from the thesis

As a feasibility study with a small sample, the generalisability of results is limited. Important feasibility issues and limitations are listed in Table 17.1. Despite the limitations, the information provided by this new knowledge and the in-depth analysis are clinically valuable and vital to further research.

Clinical implications

The effects of tuning on the gait of children with CP were addressed in the previous section. It was concluded that tuning produced improvements in several gait parameters for children with CP. The question remains as to whether it is worthwhile to include tuning in a clinical service. The feasibility of tuning as a clinical service cannot be addressed without an economic analysis. However, the enduring nature of the condition, and the impact of any slight improvement in walking on the condition, underline the relevance of tuning as a clinical service.

Integration of tuning into a clinical service requires careful planning and consideration of the lessons learnt from the current project. The methodology currently employed for tuning in clinical settings varies from ‘eye-balling’ to technologies such as video vector analysis (VVA) and 3D motion analysis. While robust, the latter is expensive and time consuming. VVA has proven to be a useful

technology for tuning (Stallard and Woollam 2003), that may not be as robust as 3D motion analysis for research, but may be appropriate in clinical settings

The current study informs clinicians that the immediate outcomes of tuning on knee kinematics may vary according to the gait patterns of children with CP. However, the possible benefits for other joints and temporal-spatial parameters, along with effects of familiarisation, must be taken into consideration, as the benefits may not be equal between children.

It was seen that while a wedge of optimal size may produce optimal gait, a difference in wedge size as small as 2° was capable of being counter-productive. Furthermore, while changes in knee kinematics may be in one direction with increasing wedges size for children with extended knee gait, they may vary for children with jump knee gait and crouch knee gait, which was also the case with SVA (Chapter 15, page 262). These are important considerations, especially for clinicians who rely on ‘eye-balling’ for tuning.

Recent recommendations suggest that tuning of AFO-FC is gaining recognition among the clinicians in the UK (Bowers and Ross 2009; NHS Quality improvement 2009). However, the current evidence and findings from the current study are not enough to argue the case to implement tuning as part of a clinical service. Hence, the focus should be on conducting further research.

Implications for future research

A Randomised Controlled Trial is required to establish the effects of tuned AFO-FC in comparison to non-tuned. Appropriate responses to the feasibility issues identified in the current study will enable optimal use of available resources, which is vital for the success of an RCT. In addition, power analysis was carried out in the current study in order to identify the sample size required for an RCT. The difficulties associated with outcome measures were identified, and use of individualised goals to measure outcomes was suggested as an additional outcome measure (Chapter 16, page 294).

There is a need for further research into the potential for grouping children with CP based on gait patterns determined while wearing AFO-FC. This should build on the seminal work by Butler et al. (2007), by comparing gait patterns identified in barefoot, with gait patterns identified when wearing AFO-FC, and establishing which might be best when evaluating predictors of the impacts of tuning.

17.5 Strengths of the current study

When compared with previous research in the area (Butler, Thompson and Major 1992; Butler, Thompson and Farmer 1996, Butler et al. 2007), the current study reported a more detailed kinematic and kinetic analysis of the effects of tuning of AFO-FCs for children with CP.

Previous studies made comparisons either between barefoot walking pre and post – intervention, or between barefoot walking and tuned AFO-FC. In contrast, the current study compared non-tuned AFO-FC to tuned AFO-FC, which is relevant to the question of whether the AFO-FC needs to be tuned. Comparison between barefoot walking before and after the short-term tuning intervention was also carried out in order to identify any effects retained by participants while not wearing AFO-FC.

The combination of data analyses, conducted to address the complexity of outcome measurement, was different to previous literature. Case study analysis provided insights into the influences of gait patterns on tuning, and the need for grouping based on gait patterns when investigating conservative interventions such as tuning. Group comparisons addressed parameters and outcomes not influenced by gait patterns, and enabled estimation of power and sample size.

The findings from this thesis provide in-depth exploration of tuning of AFO-FC in children with CP, and promote discussion of the division of gait kinematics and kinetics by gait pattern, rather than observing the mean of the total population, as carried out by previously published literature. This thesis also explored the feasibility of conducting a larger trial.

CHAPTER 18 CONCLUSIONS & DIRECTION OF FUTURE RESEARCH

18.1 Introduction

The purpose of this chapter is to briefly delineate the conclusions drawn from the current study with reference to the original aims of the study, and identify the key directions to future research.

In contrast to the previous studies, the current study used a detailed kinematic and kinetic analysis of effects of tuning of AFO-FC and explored the feasibility of moving this research forwards. As mentioned in the introduction, tuning can be investigated using the Medical Research Council (MRC) framework for developing and evaluating complex interventions for improving healthy (Medical Research Council 2000). It was also identified that the current level of evidence in tuning requires investigation into the effects of components of tuning (Phase I or modelling stage) and exploration of the feasibility (Phase II or exploratory trial stage). The mixture of case study analysis and group comparison used in the current study made the exploration fruitful. This combination of analysis provided information on not only the feasibility of conducting a larger trial, but relevance of gait patterns while investigating a complex intervention such as tuning. In order to draw conclusions with reference to the aims of the current study, reiteration of aims are required.

The aims of the current study were:

1) examine the ambiguity in the literature relating to AFO intervention and identify possible reasons;
2) investigate the influence of rigid AFOs on the sagittal plane gait parameters of children with CP
3) explore the effects of components of tuning on the sagittal plane gait parameters of children with CP;
4) investigate the immediate effects of tuning on the sagittal plane gait parameters of children with CP;

5) investigate the feasibility of tuning as a meaningful clinical intervention that might be implemented within a clinical trial;
6) investigate the short-term effects of tuning on the gait, muscle tone and strength, passive range of motion and quality of life of children with CP

18.2 Conclusions from the current study

It was concluded from the literature review that ambiguity exists in the literature relating to AFO intervention in children with CP. The ambiguity was associated with the differences in sample size (lack of power in some studies), characteristics of the patient population such as diagnostic category and gait pattern, appropriateness of AFO-FC, and the lack of biomechanical optimisation (tuning) of AFO-FC.

In the current study, non-tuned rigid AFO-FC demonstrated significant improvements in the gait parameters of children with CP when compared to barefoot. It was concluded that rigid AFO-FCs were beneficial to children with CP, provided that factors such as the appropriateness of AFO-FC, and familiarisation with AFO-FC are addressed.

The impact of AFO-FC on gait patterns of children with CP was also evident from present study. It was seen that in the current sample, the gait pattern based on knee kinematics with non-tuned AFO-FC acted as better determinant for tunability than barefoot.

It was found that wedges or rockers alone, or in combination with each other, can improve aspects of kinematics and kinetics of children with CP, but should be used judiciously for tuning. However, the effects of both different sizes of wedges and tuning depended on the gait patterns demonstrated by children while wearing non-tuned AFO-FC. The current findings contradicted existing expert opinion regarding use of heel designs (positive, neutral and negative heels) to modify kinematics and kinetics of lower limb joints during initial stance. Further investigation is required before using different heel designs as a part of tuning of AFO-FC.

It was concluded that the immediate effects of tuning on kinematics and kinetics of children with CP were predominantly seen at the ankle and knee joints, and varied according to gait patterns demonstrated by the children while wearing non-tuned AFO-FC. Tuning was most influential in children with extended knee gait, followed by jump knee gait, whereas children with crouch gait were the least responsive.

Furthermore, the short-term effects of wearing tuned AFO-FC for two-to-four months were evident, with improvements in walking speed during barefoot walking. No improvement was seen in GDI, PedsQL™, and muscle and joint properties with short-term intervention. Overall, it could be concluded that the potential effectiveness of tuning of AFO-FC for children with CP was evident, with the level of effectiveness being dependent on their gait patterns determined while wearing AFO-FCs. The short-term use of tuned AFO-FC produced further improvement.

18.3 Directions of future research:

- The findings from the present study indicate the need for an adequately powered randomised controlled trial to investigate long-term effects of tuning, with consideration of the feasibility issues identified in the current study.
- Further research is needed into the effects of different heel designs in children with various gait patterns before using them as a part of tuning.
- Further research is required to compare the effects of casting AFOs at an angle to accommodate for tightness of gastrocnemius, to casting AFOs at plantigrade.
- In addition to the outcome measures used in the current study, it may be useful to use individualised goals for each participant for outcome measurement
- Further research is needed to establish whether it is possible to group children with CP according to gait patterns based on knee kinematics with non-tuned rigid AFO-FC; this may be useful as a baseline to predict tunability in children with CP. It may be achievable through retrospective analysis of existing gait data.
- As a follow-up to the seminal work done by Butler et al. (2007), further research is required to determine the predictors of tunability using gait patterns based on knee kinematics with non-tuned rigid AFO-FC as a baseline.
- Effects of tuning in all three planes of movement and moments should be considered.

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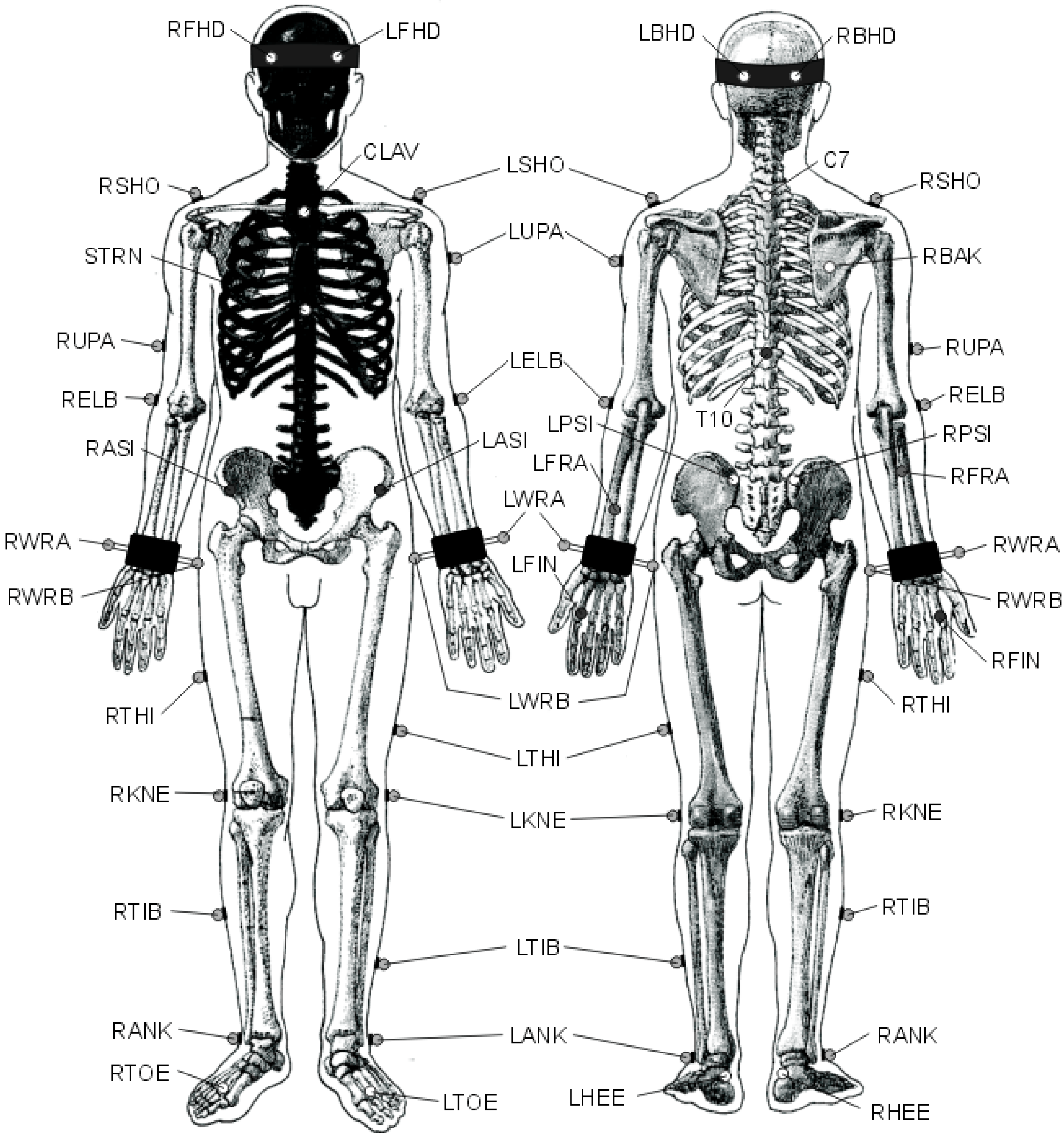
Appendix I – Plug In Gait (PIG) Marker Set

Plug-in-Gait Marker Placement



The following describes in detail where the Plug-in-Gait markers should be placed on the participant. Where left side markers only are listed, the positioning is identical for the right side.

Upper Body

Head Markers

LFHD	Left front head	Located approximately over the left temple
RFHD	Right front head	Located approximately over the right temple
LBHD	Left back head	Placed on the back of the head, roughly in a horizontal plane of the front head markers
RBHD	Right back head	Placed on the back of the head, roughly in a horizontal plane of the front head markers

The markers over the temples define the origin, and the scale of the head. The rear markers define its orientation. If they cannot be placed level with the front markers, and the head is level in the static trial, tick the "Head Level" check box under options on “Run static model” in the pipeline when processing the static trial. Many users buy a headband and permanently attach markers to it.

Torso Markers

C7	7th Cervical Vertebrae	Spinous process of the 7th cervical vertebrae
T10	10th Thoracic Vertebrae	Spinous Process of the 10th thoracic vertebrae
CLAV	Clavicle	Jugular Notch where the clavicles meet the sternum
STRN	Sternum	Xiphoid process of the Sternum
RBAK	Right Back	Placed in the middle of the right scapula. This marker has no symmetrical marker on the left side. This asymmetry helps the auto-labeling routine determine right from left on the participant.

C7, T10, CLAV, STRN define a plane hence their lateral positioning is most important.

Arm Markers

LSHO	Left shoulder marker	Placed on the Acromio-clavicular joint
LUPA	Left upper arm marker	Placed on the upper arm between the elbow and shoulder markers. Should be placed asymmetrically with RUPA
LELB	Left elbow	Placed on lateral epicondyle approximating elbow joint axis
LFRA	Left forearm marker	Placed on the lower arm between the wrist and elbow markers. Should be placed asymmetrically with RFRA
LWRA	Left wrist marker A	Left wrist bar thumb side
LWRB	Left wrist marker B	Left wrist bar pinkie side

The wrist markers are placed at the ends of a bar attached symmetrically with a wristband on the posterior of the wrist, as close to the wrist joint center as possible.

LFIN	Left fingers	Actually placed on the dorsum of the hand just below the head of the second metacarpal

Lower Body

Pelvis

LASI	Left ASIS	Placed directly over the left anterior superior iliac spine
RASI	Right ASIS	Placed directly over the right anterior superior iliac spine

The above markers may need to be placed medially to the ASIS to get the marker to the correct position due to the curvature of the abdomen. In some patients, especially those who are obese, the markers either can't be placed exactly anterior to the ASIS, or are invisible in this position to cameras. In these cases, move each marker laterally by an equal amount, along the ASIS-ASIS axis. The true inter-ASIS Distance must then be recorded and entered on the participant parameters form. These markers, together with the sacral marker or LPSI and RPSI markers, define the pelvic axes.

LPSI	Left PSIS	Placed directly over the left posterior superior iliac spine
RPSI	Right PSIS	Placed directly over the right posterior superior iliac spine

LPSI and RPSI markers are placed on the slight bony prominences that can be felt immediately below the dimples (sacro-iliac joints), at the point where the spine joins the pelvis.

SACR	Sacral wand marker	Placed on the skin mid-way between the posterior superior iliac spines (PSIS). An alternative to LPSI and RPSI.

SACR may be used as an alternative to the LPSI and RPSI markers to overcome the problem of losing visibility of the sacral marker (if this occurs), the standard marker kit contains a base plate and selection of short "sticks" or "wands" to allow the marker to be extended away from the body, if necessary. In this case it must be positioned to lie in the plane formed by the ASIS and PSIS points.

Leg Markers

LKNE	Left knee	Placed on the lateral epicondyle of the left knee

To locate the "precise" point for the knee marker placement, passively flex and extend the knee a little while watching the skin surface on the lateral aspect of the knee joint. Identify where knee joint axis passes through the lateral side of the knee by finding the lateral skin surface that comes closest to remaining fixed in the thigh. This landmark should also be the point about which the lower leg appears to rotate. Mark this point with a pen. With an adult patient standing, this pen mark should be about 1.5 cm above the joint line, mid-way between the front and back of the joint. Attach the marker at this point.

LTHI	Left thigh	Place the marker over the lower lateral 1/3 surface of the thigh, just below the swing of the hand, although the height is not critical.

The thigh markers are used to calculate the knee flexion axis location and orientation. Place the marker over the lower lateral 1/3 surface of the thigh, just below the swing of the hand, although the height is not critical. The antero-posterior placement of the marker is critical for correct alignment of the knee flexion axis. Try to keep the thigh marker off the belly of the muscle, but place the thigh marker at least two marker diameters proximal of the knee marker. Adjust the position of the marker so that it is aligned in the plane that contains the hip and knee joint centers and the knee flexion/extension axis. There is also another method that uses a mirror to align this marker, allowing the operator to better judge the positioning.

LANK	Left ankle	Placed on the lateral malleolus along an imaginary line that passes through the transmalleolar axis
LTIB	Left tibial wand marker	Similar to the thigh markers, these are placed over the lower 1/3 of the shank to determine the alignment of the ankle flexion axis

The tibial marker should lie in the plane that contains the knee and ankle joint centers and the ankle flexion/extension axis. In a normal participant the ankle joint axis, between the medial and lateral malleoli, is externally rotated by between 5 and 15 degrees with respect to the knee flexion axis. The placements of the shank markers should reflect this.

Foot Markers

LTOE	Left toe	Placed over the second metatarsal head, on the mid-foot side of the equinus break between fore-foot and mid-foot
LHEE	Left heel	Placed on the calcaneous at the same height above the plantar surface of the foot as the toe marker

Appendix II – Information sheets

Appendix II a) Information sheet for healthy participants up to the age of eight years – main study

Study Title: Modifying the splints and shoes for children with difficulty in walking

Queen Margaret University
EDINBURGH

Information sheet for children

What is research? Why is this project being done?

Research is a careful experiment to find out the answer to an important question. This project is to see if modifying the special type of shoes used by children with difficulty in walking could help them walk better.
We are asking if you would agree to take part in this study.

Why have I been asked to take part?

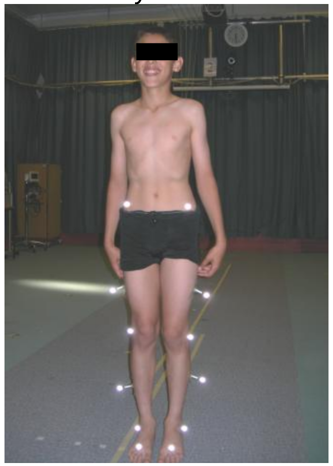
You have been chosen for this study because you are healthy and between 5 and 8 yrs old. We need to know how children of your age walk with some special shoes.

Do I have to take part?

No! It is up to you. Nobody will force you to take part. It is entirely up to you to decide whether you want to take part or not

What happens to me if I take part?

If you take part, you have to come to the University once. You need to bring cycle shorts and T-shirt or swim suit or you can borrow some of ours
First we will check how you walk through cameras. We will stick little balls called markers on your legs, so we can see clearly how your legs move. Then you have to walk for a very short distance at least 30 times with different things attached to your shoes. You will get a lot of time to rest in between and ofcourse **your parents can be there while you are doing these**
See the boy with markers on.



Is there anything to be worried about?

There is nothing to worry about as it is just walking up and down a room with various shoes.

Will joining in help me?

No, But this may help us to find out a treatment for children with difficulty in walking to help them walk better.

What if I don't want to do the research any more?

If at any time you don't want to do the research anymore, just tell your parents. They will not be cross with you.

Appendix II b) Information sheet for healthy participants: eight to 12 years old – main study

Information Sheet for participants (age 9 to 12)

Part 1 – to give you first thoughts about the project

Study Title: **Modifying the special shoes for children with difficulty in walking**

What is research? Why is this project being done?
Research is a careful experiment to find out the answer to an important question. This project is to see if modifying the special type of shoes used by children with difficulty in walking could help them walk better.

We are asking if you would agree to take part in this study.

Why have I been asked to take part?
You have been chosen for this study because you are healthy and between 9 and 12 yrs old. We need to know how children of your age walk with some special shoes.

Did anyone else check the study is OK to do?
Before any research is allowed to happen, it has to be checked by a group of people called an Ethics Committee. They make sure that the research is OK to do. This project has been checked by the Lothian Research Ethics Committee.

Do I have to take part?
No! It is up to you. Nobody will force you to take part. It is entirely up to you to decide whether you want to take part or not

What will happen to me if I take part?
If you take part, you have to come to the University once with cycle shorts and T-shirt or swim suit. We also have some suitable shorts with us. First we will record your height and weight and then we will check how you walk using special cameras. For this you will be asked to wear gym shorts/swim suit. We will stick little balls called markers on your legs, so we can see clearly how your legs move.
Then you have to walk for a very short distance for at least 30 times with different things attached to your shoes. You will get a lot of time to rest in between. Your parents can be present during these tests

Is there anything to be worried about?
There is nothing to worry about as it is just walking up and down a room with various shoes.

Will joining in help me?
No, but this may help us to develop a treatment for children with difficulty in walking to help them walk better.

What if there is a problem or something goes wrong?
If anything goes wrong due to our fault, the college will take care of that and you may get compensation for that.

Will anyone else know I'm doing this?
Only the people involved in this will know. No other will know that you are doing this and we will not put your name and details in information given to others

What if I don't want to do the research any more?
If at any time you don't want to do the research anymore, just tell your parents. They will not be cross with you.

Thank you for reading this.

Appendix II c) Information sheet for healthy participants: 13 to 15 years old - main study

Queen Margaret University
EDINBURGH

Stage 1

Information Sheet for participants (age 13 to 15)

Part 1 – to give you first thoughts about the project

Study Title: **Modifying the special shoes for children with difficulty in walking**

We are looking for volunteers to participate in a research study to find the answer to the question – Is it possible to help children who have Cerebral Palsy (a brain defect which causes difficulty in movement), walk better by making modifications on the special shoes used by them? We are asking if you would agree to take part in this study. Before you decide on whether to join or not it is important to know why this research is being done and what would be your role as a part of it. So please read this leaflet carefully. Talk about it with your family, friends, physiotherapist or nurse if you want to. You can contact me on the number given at the end of this leaflet and ask me any doubts you have.

Why are we doing this research?
There are many children like you who cannot move their hands or legs easily. Many of them use special shoes and splints which helps them to walk better. Many studies have shown that making certain modifications to the shoes may help them walk better. We are doing this research to find out that what modifications can be helpful and how they exactly work.

Why have I been asked to take part?
You have been chosen for this study because you use splints and special shoes and you are in the age group of 13 – 15 yrs. We are studying the modifications of shoes for children with Cerebral Palsy who are of your age group and for this we need to know the effects of different shoes modifications on your walking.

Do I have to take part?
No! It is up to you. If you do,

- You have to sign a form giving your consent
- You will be given a copy of this information sheet and your signed form to keep
- You are free to stop taking part at any time during the research without giving a reason.

What will happen to me if I take part?
If you take part, you have to come to Queen Margaret University College twice with cycle shorts and T-shirt or swim suit. We will also have a selection of suitable shorts available. In the first visit we will record your height and weight and we will analyse

how you walk. For this you will be asked to wear gym shorts/swim suit. We will stick little balls called markers on your legs, so we can see clearly how your legs move.
Then you will be asked to walk for a 7 metre distance for at least 30 times with various modifications attached to your shoes and splints and your walking will be recorded by special cameras.

We will also measure your legs, to see how far your hips, knees and ankles move, and see how strong you are. Your visit to the University takes about 1 hour and 30 minutes. You will have plenty of rest in between the walks and can sit and rest any time you want. In the second visit we will measure your legs, hips, knees and ankles and your strength again. Your parents can be present while these tests are being carried out.

Is there anything to be worried about?
There is nothing to worry about as it is just walking up and down a room with various shoes.

What are the possible benefits of taking part?
You may not be directly benefited from this stage of the study but this will help us to develop a treatment for children for Cerebral Palsy to help them walk better. The details which we collect can be useful to your doctor and therapist.

Contact details:
If you have any questions you can contact Mr. Kavi Jagadamma or Dr. Marietta van der Linden between 9.00 AM and 5.00 PM
The contact details are

Mr. Kavi Jagadamma
Research Student
Queen Margaret University
Queen Margaret University Drive
Edinburgh EH21 6UU
Tel: 0131 474 0000
E-mail: kjagadamma@qmu.ac.uk

Dr. Marietta van der Linden
Research Fellow - Physiotherapy
Queen Margaret University
Queen Margaret University Drive
Edinburgh EH21 6UU
Tel: 0131 474 0000
Email: mvanderlinden@qmu.ac.uk

Thank you for reading so far – if you are still interested, please go to part 2:

Part 2 – more detail – information you need to know if you still want to take part.

What if there is a problem or something goes wrong?
If anything goes wrong due to negligence from our part, the college has an insurance scheme for compensation.

Will anyone else know I'm doing this?
Yes, some people from the university and the hospital will know about this as to make sure the project is done properly. All information which is collected about you will be kept strictly confidential. Any information which leaves the university will have your name and address removed so that you cannot be recognised from it.
Your doctor will be informed in writing about your participation in this study

Who is organising and funding the research?
Queen Margaret University College will pay for including you in the study.

Who has reviewed the study?
Every research is checked by an ethics committee to make sure it is OK to do. This research has been checked and approved by the Lothian Research Ethics Committee.

Thank you for reading this. You are welcome to ask any questions on this research.

Appendix II d) Information sheet for parents of healthy participants– main study

Queen Margaret University
EDINBURGH

Information sheet for parents

Part 1
Study Title: **Orthotic management for Children with Cerebral Palsy**

I am looking for volunteers to participate in this research study. This information sheet is given to you because your child has been invited to take part in this study. I feel it is quite important for you to know about the study before you decide. Please Read this information sheet carefully, talk to others about the study if you wish.

- Part 1 tells you the purpose of the study and what will happen to your child if your child takes part
- Part 2 gives you more detailed information about the conduct of the study

If you have any questions, you can talk to us. Take your time to decide whether or not you wish to take part.

What is the purpose of the Study?
Cerebral Palsy (CP) is a group of disorders caused by damage to brain at or around birth. The Children with Cerebral Palsy have difficulties with posture and movement such as walking. For this reason, many devices have been developed to help children with Cerebral Palsy to walk, such as splints (Ankle Foot Orthoses). Researches have shown that modifying ('Tuning') the splints and shoes (AFO-FWC) using wedges etc can bring about important changes in the walking pattern of children with Cerebral Palsy, but unfortunately no precise protocol exists for tuning of splints and footwear. This study aims at developing an appropriate protocol for tuning of splints and footwear as well as investigating the effect of tuning compared to non tuned splints and footwear on walking pattern, muscle characteristics, functional capabilities and daily activity of children with Cerebral Palsy.

Why has my child been chosen?
In order to develop a protocol, we need to know the effects of different sizes of wedges and rockers on the walking pattern of normal children, so that we can compare the data with those of children with Cerebral Palsy and finally develop a protocol. Your child has been chosen because he/she is healthy and he/she is within the age group of 5 to 15 years. We intend to select 10 children from Edinburgh for this study.

Does my child have take part?
It is entirely up to your child to decide whether or not he/she should take part in this study. You or your child are not required to give a reason if if your child decides not to take part and if your child decides to take part; he/she is free to withdraw from the study at any time without giving a reason. If your child decides to take part, you will be given this information sheet to keep and your child will be asked to sign a consent form. If your child is not capable of doing that you may sign on his/her behalf.

What will happen to my child if he/she takes part?
He/she has to report to QMUC motion analysis laboratory once and needs to bring swimwear or a t-shirt and tight fitting 'cycle shorts'. We will also have a selection of suitable shorts available.
He/she will undergo the following procedure:
The procedure will be explained to the child and his/her height and weight will be recorded. Then little reflective balls called markers will be stuck on to his/her body, and he/she will be asked to walk about 7 metres. Your child will be asked to do this for at least 30 times with wedges or rockers attached to his/her footwear. The computer linked cameras will record the movement of his/her limbs.
The whole procedure will last for not more than one and a half hours. The child will get plenty of rest periods in between and can sit down and rest any time he/she wants.
You can be present in the lab while all these tests are being carried out.

What are the possible disadvantages and risks of taking part?
The procedure involved is a safe and common clinical assessment. However, there exist minimal risks such as possibility to fall, trip etc. A risk assessment of the procedure has taken place prior to that start of the study.

What are the possible benefits of taking part?
There are no direct benefits to your child from this study. But the information we get will help us to develop a protocol for the tuning of splints and footwear for children with Cerebral Palsy which is intended to bring about improvement in quality of life of children with Cerebral Palsy who use splints.

What if there is a problem?
Any complaint about the study, the way you have been dealt with during the study or any possible harm your child might suffer will be addressed. Detailed information is given in part 2

Will my child taking part in the study will be kept Confidential?
All information collected about the participants is kept strictly confidential; details are included in part 2.

Contact Details:

Mr. Kavi Jagadamma
Research Student
Queen Margaret University
Queen Margaret University Drive
Edinburgh EH21 6UU
Tel: 0131 474 0000
E-mail: kjagadamma@qmu.ac.uk

Dr. Marietta van der Linden
Research Fellow - Physiotherapy
Queen Margaret University
Queen Margaret University Drive
Edinburgh EH21 6UU
Tel: 0131 474 0000
Email: mvanderlinden@qmu.ac.uk

This completes Part 1 of the information sheet.
If the information in Part 1 has interested you and you are considering the participation, please continue to read the additional information in Part 2 before making any decision.

Part 2

What if there is a problem?

Any complaint about the study, the way you have been dealt with during the study or any possible harm you might suffer due to negligence will be addressed. Queen Margaret University College has a liability insurance scheme for compensation as a result of harm caused due to the negligence on the part of the researcher in connection with the above mentioned study but no compensation arrangements are there for non negligence harm

Will my child taking part in the study will be kept confidential?

All information collected about the participants is kept strictly confidential. The data will be stored securely in locked cabinets in Queen Margaret University College. Every participant is given a code number right from the beginning of the study. Care is taken through removing the participants name and address on any information presented, published or taken out of the university for any reason.

The data will be accessed only by researchers involved in the study and the research committee responsible for monitoring the quality of research.

The results of the study will be published as a thesis at Queen Margaret University College as well as research papers in scientific journals. Care will be taken that the participants are not identifiable in any of the materials published and all the data collected will be kept for 10 years and will be then disposed carefully.

What will happen to the results of the research study?

The results of the study will be published as a thesis at Queen Margaret University College as well as research papers in scientific journals. Care will be taken that the participants are not identifiable in any of the materials published

Who is organising and funding the Research?

Queen Margaret University College funds this study as a PhD degree. The study is conducted by Kavi Jagadamma, a research student of Queen Margaret University College, Edinburgh

Who has Reviewed the study?

This study was given a favourable ethical opinion for conduct at Queen Margaret University College by the Lothian Research Ethical Committee

Thank you for your valuable time. If you or your child have any questions you are welcome to contact Mr. Kavi Jagadamma during office hours. If you want to talk to an independent and responsible person about the research, please contact Dr. Alison Richardson during office hours.

Independent Contact:
Dr. Alison Richardson
Clinical Specialist Physiotherapist,
Anderson Gait Analysis Laboratory, SMART Centre,
Astley Ainslie Hospital, Edinburgh – EH9 2HL
Ph: 0131 5379435
E-mail: AlisonM.Richardson@lpct.nhs.scot.uk

Appendix II e) Information sheet for participants with cerebral palsy up to the age of eight years – main study

Study Title: Modifying the splints and shoes for children with difficulty in walking

Stage 1

Queen Margaret University
EDINBURGH

Information sheet for children

What is research? Why is this project being done?

Research is a careful experiment to find out the answer to an important question. This project is to see if modifying the special type of shoes used by children with difficulty in walking could help them walk better. We are asking if you would agree to take part in this study.

Why have I been asked to take part?

You have been chosen for this study because you are wearing splints and you are between 5 and 8 yrs old. We need to know the effect of some special shoes on your walking.

Do I have to take part?

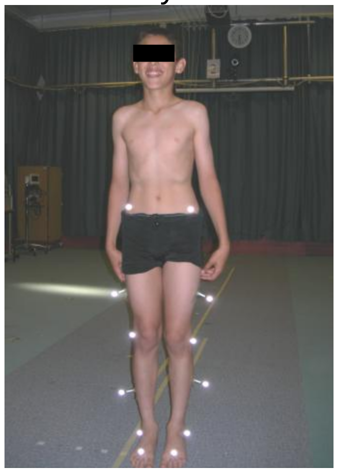
No! It is up to you. Nobody will force you to take part. It is entirely up to you to decide on you want to take part or not

What happens to me if I take part?

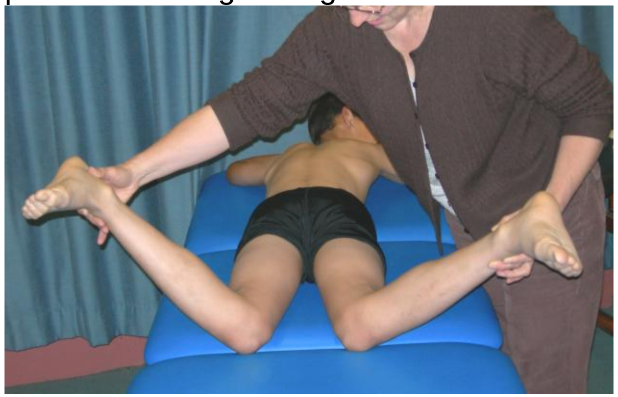
If you take part, you have to come to University three times. In this study we may put you in one group where you will use your normal splints and shoes or the other group where you will use changed splints and shoes You need to bring cycle shorts and T-shirt or swim suit or you can borrow some of ours

In the first visit we will check how you walk through cameras. We will stick little balls called markers on your legs, so we can see clearly how your legs move.

See the boy with his markers on.



Then you have to walk for a very short distance for at least 30 times with different things attached to your shoes. You can sit down and rest whenever you want. Then we will measure your legs, to see how strong you are and take photographs of your legs to see how far your hips, knees and ankles move. The boy in this picture is having his legs measured



You have to come back again after1 to 2 weeks and this time we will repeat everything with different set of things attached to your shoes and ofcourse your parents can be there while you are doing these

After the visit we may ask you to wear the same splints and shoes or different shoes and splints for three months. In the final visit the same will be repeated again and ofcourse your parents can be there while you are doing these

Is there anything to be worried about?

There is nothing to worry about as it is just walking up and down a room with various shoes and using the shoes which are given to you at home and school. If you ever have any discomfort using the shoes, it will be changed immediately

Will joining in help me?

We hope that this study will help you to walk better but we can't be sure. The details which we collect can be helpful to your doctor.

What if I don't want to do the research any more?

If at any time you don't want to do the research anymore, just tell your parents. They will not be cross with you.

Appendix II f) Information sheet for participants with Cerebral Palsy: between eight and 12 years old – main study

Queen Margaret University
EDINBURGH

Stage 1

Information sheet for parents

Part 1 – to give you first thoughts about the project

Study Title: **Modifying the special shoes for children with difficulty in walking**

What is research? Why is this project being done?
Research is a careful experiment to find out the answer to an important question. This project is to see if modifying the special type of shoes used by children with difficulty in walking could help them walk better.

We are asking if you would agree to take part in this study.

Why have I been asked to take part?
You have been chosen for this study because you are wearing a splint and are between 9 and 12 yrs old. We need to know how children of your age walk with changes to their splints and shoes.

Did anyone else check the study is OK to do?
Before any research is allowed to happen, it has to be checked by a group of people called an Ethics Committee. They make sure that the research is OK to do. This project has been checked by the Lothian Research Ethics Committee.

Do I have to take part?
No! It is up to you. Nobody will force you to take part. It is entirely up to you to decide whether you want to take part or not.

What will happen to me if I take part?
If you take part, you have to come to Queen Margaret University College three times. In this study we put children into two groups and we will test your walking with different things attached to your shoes. You need to bring cycle shorts and T-shirt or swim suit. We also have some suitable shorts with us. First we will record your height and weight and then we will check how you walk using special cameras. For this you will be asked to wear gym shorts/swim suit. We will stick little balls called markers on your legs, so we can see clearly how your legs move.
Then you have to walk for a very short distance. This will be repeated at least 30 times with different things attached to your shoes. We will also measure your legs to see how strong you are, and will take photographs of your legs to see how far your hips, knees and ankles move. You will get a lot of time to rest in between.

In the second visit the whole procedure will be repeated again and this time you will have one or a combination of modifications attached to your shoes while you walk. Your parents can be there during these tests. After the visit we may ask you to wear the same splints and shoes or different shoes and splints for three months depending on which group you belong to. In the final visit the same will be repeated once more. Your parents can be there during these tests

Is there anything to be worried about?
There is nothing to worry about as it is just walking up and down a room with various shoes.

Will joining in help me?
No, but this may help us to develop a treatment for children with difficulty in walking to help them walk better.

What if there is a problem or something goes wrong?
If anything goes wrong due to our fault, the college will take care of that and you may get compensation for that.

Will anyone else know I'm doing this?
Only the people involved in this will know. No others will know that you are doing this and we will not put your name and details in information given to others. We will also tell your doctor about this.

What if I don't want to do the research any more?
If at any time you don't want to do the research anymore, just tell your parents. They will not be cross with you.

Thank you for reading this.

Appendix II g) Information sheet for participants with Cerebral Palsy: between 13 and 15 years old – main study

Queen Margaret University
EDINBURGH

Stage 1

Information sheet for parents

Part 1 – to give you first thoughts about the project

Study Title: **Modifying the special shoes for children with difficulty in walking**

We are looking for volunteers to participate in a research study to find the answer to the question – Is it possible to help children who have Cerebral Palsy (a brain defect which causes difficulty in movement), walk better by making modifications on the special shoes used by them? We are asking if you would agree to take part in this study. Before you decide on whether to join or not it is important to know why this research is being done and what would be your role as a part of it. So please read this leaflet carefully. Talk about it with your family, friends, physiotherapist or nurse if you want to. You can contact me on the number given at the end of this leaflet and ask me any doubts you have.

Why are we doing this research?
There are many children like you who cannot move their hands or legs easily. Many of them use special shoes and splints which helps them to walk better. Many studies have shown that making certain modifications to the shoes may help them walk better. We are doing this research to find out that what modifications can be helpful and how they exactly work.

Why have I been asked to take part?
You have been chosen for this study because you use splints and special shoes and you are in the age group of 13 – 15 yrs. We are studying the modifications of shoes for children with Cerebral Palsy who are of your age group and for this we need to know the effects of different shoes modifications on your walking.

Do I have to take part?
No! It is up to you. If you do,

- You have to sign a form giving your consent
- You will be given a copy of this information sheet and your signed form to keep
- You are free to stop taking part at any time during the research without giving a reason.

What will happen to me if I take part?
If you take part, you have to come to Queen Margaret University College three times with cycle shorts and T-shirt or swim suit. We will also have a selection of suitable shorts available. In this study we will put children into two groups. In the first visit we will record your height and weight and we will analyse how you walk. For this you

will be asked to wear gym shorts/swim suit. We will stick little balls called markers on your legs, so we can see clearly how your legs move.
Then you will be asked to walk for a 7 metre distance for at least 30 times with various modifications attached to your shoes and splints and your walking will be recorded by special cameras.
We will measure your legs to see how strong you are and will take photographs of your legs, to see how far your hips, knees and ankles move. Your visit to the University takes about 2 hours. You will have plenty of rest in between the walks and can sit and rest any time you want. In the second visit the whole procedure will be repeated once more and this time you will have one or a combination of modifications attached to your shoes while you walk. After this visit you will be either given a modified splint/shoes or the normal one which you were using before, depending on which group you belong to and you have to use it for three months.
In the final visit the procedure will be same as first visit but you have to walk for at least 18 times. Your parents can be present while these tests are being carried out.

Is there anything to be worried about?
There is nothing to worry about as it is just walking up and down a room with various shoes.

What are the possible benefits of taking part?
You may not be directly benefited from this stage of the study but this will help us to develop a treatment for children for Cerebral Palsy to help them walk better. The details which we collect can be useful to your doctor and therapist.

Contact details:

If you have any questions you can contact Mr. Kavi Jagadamma or Dr. Marietta van der Linden between 9.00 AM and 5.00 PM
The contact details are

Mr. Kavi Jagadamma
Research Student
Queen Margaret University
Queen Margaret University Drive
Edinburgh EH21 6UU
Tel: 0131 474 0000
E-mail: kjagadamma@qmu.ac.uk

Dr. Marietta van der Linden
Research Fellow - Physiotherapy
Queen Margaret University
Queen Margaret University Drive
Edinburgh EH21 6UU
Tel: 0131 474 0000
Email: mvanderlinden@qmu.ac.uk

Thank you for reading so far – if you are still interested, please go to part 2:

Part 2 – more detail – information you need to know if you still want to take part.

What if there is a problem or something goes wrong?
If anything goes wrong due to negligence from our part, the college has an insurance scheme for compensation.

Will anyone else know I'm doing this?
Yes, some people from the university and the hospital will know about this as to make sure the project is done properly. All information which is collected about you will be kept strictly confidential. Any information which leaves the university will have your name and address removed so that you cannot be recognised from it. You will not be identifiable in any of the photographs taken.

Your doctor will be informed in writing about your participation in this study

Who is organising and funding the research?
Queen Margaret University College will pay for including you in the study.

Who has reviewed the study?
Every research is checked by an ethics committee to make sure it is OK to do. This research has been checked and approved by the Lothian Research Ethics Committee.

Thank you for reading this. You are welcome to ask any questions on this research.

Appendix II h) Information sheet for parents of participants with Cerebral Palsy – main study

Stage 1

Information sheet for parents

Part 1

Study Title: **Orthotic management for Children with Cerebral Palsy**

I am looking for volunteers to participate in this research study. This information sheet is given to you because your child has been invited to take part in this study. I feel it is quite important for you to know about the study before you decide. Please read this information sheet carefully, talk to others about the study if you wish.

- Part 1 tells you the purpose of the study and what will happen to your child if your child takes part
- Part 2 gives you more detailed information about the conduct of the study

If you have any questions, you can talk to us. Take your time to decide whether or not you wish to take part.

What is the purpose of the Study?
Cerebral Palsy (CP) is a group of disorders caused by damage to brain at or around birth. Children with Cerebral Palsy have difficulties with posture and movement such as walking. For this reason, many devices have been developed to help children with Cerebral Palsy to walk, such as splints (Ankle Foot Orthoses). Researches have shown that modifying ('Tuning') the splints and shoes (AFO-FWC) using wedges etc can bring about important changes in the walking pattern of children with Cerebral Palsy, but unfortunately no precise protocol exists for tuning of splints and footwear. This study aims at developing an appropriate protocol for tuning of splints and footwear as well as investigating the effect of tuning compared to non tuned splints and footwear on walking pattern, muscle characteristics, functional capabilities and daily activity of children with Cerebral Palsy.

Why has my child been chosen?
In order to develop a protocol, we need to know the effects of different sizes of wedges and rockers on the walking pattern of children with Cerebral Palsy, so that we can compare the data with those of normal children and finally develop a protocol. We have collected a list of children with Cerebral Palsy from physiotherapists and consultants in the Lothian who are suitable for this study and may benefit from tuning of splints.

Does my child have to take part?
It is entirely up to your child to decide whether or not to take part in this study. You or your child are not required to give a reason if he/she decides not to take part and if your child decides to take part; he/she is free to withdraw from the study at any time without giving a reason. If your child decides to take part, you will be given this

information sheet to keep and your child will be asked to sign a consent form. If your child is not capable of doing that you may sign on his/her behalf.

What will happen to my child if he/she takes part?

In this stage of study we are planning to develop a protocol for tuning of splints and conduct a feasibility study to see whether children who use modified splints and shoes for 12 weeks improve their walking and function compared to children who don't. For this we will need two groups of children, a 'treatment group', which is the group who use modified splints for 12 weeks and a 'control group', which use the splints they normally wear. To which group your child will be allocated is entirely decided by random chance.

The children in both groups will be involved in this study for 14 weeks. This means that your child will visit the university three times; first visit at the beginning of the study, second visit after one to two weeks and final visit after three months from the second visit. For the assessment of your child's walking, he/she needs to bring swimwear or a t-shirt and tight fitting 'cycle shorts'. We will also have a selection of suitable shorts available.

He/she will undergo the following procedure:

On first visit:

A procedure will be explained to the child and his/her height and weight will be recorded. There will be a physical examination similar to that done by clinicians to look at the characteristics of muscles and joints. This involves moving the joints, assessing the power and taking photographs of the child's joints to measure the range of movement available in a joint.

Then little reflective balls called markers will be stuck on to his/her body, and he/she will be asked to walk for a 7 metre distance. Your child will be asked to do this for at least 30 times out of which 6 walks will be with the standard splints and footwear used by the child and the other walks with different sizes of wedges/rockers/heels attached to the footwear of the child. The computer linked cameras will record the movement of his/her limbs.

The whole procedure will last for not more than two hours. The child will get plenty of rest periods in between and can sit down and rest any time he/she wants.

On second visit:

The second visit will be after 1 to 2 weeks of the first visit and in this session the same procedure will be repeated and this time the child will be asked to walk with one or a combination of the modifications attached to his/her footwear to determine the optimum amount of tuning required. You can be present in the lab while all these tests are being carried out. You will also be given a questionnaire to fill in which takes not more than 15 minutes.

The children in the one group will continue to use their normal splints where as the other group will be using the tuned splints for 3months/12weeks.

On final visit:

The same procedure as during first visit will be carried out. This time the child has to do a total of 18 walks; 6 barefoot, 6 with splints and 6 with tuned splints. You will be again given the same questionnaire as in second visit to fill.

You may be present in the lab with the child when all these tests are being carried out.

What are the possible disadvantages and risks of taking part?

The procedure involved is a safe and common clinical assessment. However, there exist minimal risks such as possibility to fall, trip etc. A risk assessment of the procedure has taken place prior to that start of the study.

What are the possible benefits of taking part?
There will not be any direct benefit to your child by taking part in this stage of the study but the information we get from this study may help us to treat children with Cerebral Palsy better.
Also, your child's muscles and walking pattern will be analysed in detail. This information can be used by your child's physiotherapist and doctor in the planning of treatment

What if there is a problem?
Any complaint about the study, the way you have been dealt with during the study or any possible harm your child might suffer will be addressed. Detailed information on this is given in part 2

Will my child taking part in the study will be kept Confidential?
All information collected about the participants is kept strictly confidential; details are included in part 2.

Contact Details:

Mr. Kavi Jagadamma
Research Student
Queen Margaret University
Queen Margaret University Drive
Edinburgh EH21 6UU
Tel: 0131 474 0000
E-mail: kjagadamma@qmu.ac.uk

Dr. Marietta van der Linden
Research Fellow - Physiotherapy
Queen Margaret University
Queen Margaret University Drive
Edinburgh EH21 6UU
Tel: 0131 474 0000
Email: mvanderlinden@qmu.ac.uk

This completes Part 1 of the information sheet.
If the information in Part 1 has interested you and you are considering the participation, please continue to read the additional information in Part 2 before making any decision.

Part 2
What if there is a problem?
Any complaint about the study, the way you have been dealt with during the study or any possible harm you might suffer due to negligence will be addressed. Queen Margaret University College has a liability insurance scheme for compensation as a result of harm caused due to the negligence on the part of the researcher in connection with the above mentioned study but no compensation arrangements are there for non negligence harm

Will my child taking part in the study will be kept Confidential?
All information collected about the participants is kept strictly confidential. The data will be stored securely in locked cabinets in Queen Margaret University College. Every participant is given a code number right from the beginning of the study. Care is taken through removing the participants name and address on any information presented, published or taken out of the premises for any reason. The child will not be identifiable in any of the photographs taken which will be stored in the participant file in a locked cabinet.
Your General Practitioner/Consultant will be informed in writing about the participation of your child in the study. The data will be accessed only by researchers involved in the study and the research committee responsible for monitoring the quality of research.

The results of the study will be published as a thesis at Queen Margaret University College as well as research papers in scientific journals. Care will be taken that the participants are not identifiable in any of the materials published and all the data collected will be kept for 10 years and will be then disposed carefully.

What will happen to the results of the research study?
The results of the study will be published as a thesis at Queen Margaret University College as well as research papers in scientific journals. Care will be taken that the participants are not identifiable in any of the materials published

Who is organising and funding the Research?
Queen Margaret University College funds this study as a PhD degree. The study is conducted by Kavi Jagadamma, a research student of Queen Margaret University College, Edinburgh

Who has reviewed the study?
This study was given a favourable ethical opinion for conduct at Queen Margaret University College by the Lothian Research Ethical Committee

Thank you for your valuable time. If you or your child have any questions you are welcome to contact Mr. Kavi Jagadamma during office hours. If you want to talk to an independent and responsible person about the research, please contact Dr. Alison Richardson during office hours.

Independent Contact:
Dr. Alison Richardson
Clinical Specialist Physiotherapist
Anderson Gait Analysis Laboratory
SMART Centre
Astley Ainslie Hospital
Edinburgh – EH9 2HL
Ph: 0131 5379435
E-mail: AlisonM.Richardson@lpct.nhs.scot.uk

Appendix II i) Information sheet for healthy adults – reliability study of motion analysis system

Queen Margaret University College

EDINBURGH

Information sheet for participants

Comparison of the validity and repeatability of three different body marker configurations for three dimensional gait analysis

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is three dimensional gait analysis?

Gait analysis is the study of walking - a detailed examination of how the skeleton and muscles work together when we walk. In clinical gait analysis complex walking problems in adults and children are studied. This is used in planning patient management and in evaluating outcomes of treatment. It is also an important outcome measure in research.

What is involved?

Small reflective markers are applied to the legs, pelvis with sticky tape, and are used by computer linked-cameras to track the movement of the limbs when walking. You will than asked to walk 6-10 times a distance of about 7 meters. Following these tests, a few measurements will be taken such as leg length, knee and ankle width, height and weight.

What should you wear?

The special markers must be stuck on (or close to) the skin, so you should wear close fitting (lycra) shorts. Lycra shorts are available here if required.

What is the purpose of the study?

There are different configurations of the reflective markers which are applied to the legs and pelvis. We would like to compare the data obtained using these different configurations, so that we can decide which one is the most appropriate for clinical assessment and research protocols.

Do I have to take part?

It is up to you if you decide to take part or not. If you decide to take part you are still free to withdraw at any time and without giving a reason. Under no circumstances will your care be affected should you choose not to be included or decide to withdraw at any time.

What happens if I agree to take part in the study?
If you do decide to take part we will arrange a suitable time for you to come to the gait analysis laboratory at the Duke street campus of Queen Margaret University College. We will analyse your gait by attaching a total of 30 small light reflecting balls to your legs and pelvis and recording your walking using special cameras. Between 1 and 3 weeks later, we will invite you to the gait analysis laboratory again to repeat the walking tests. Each visit will last not more than one hour.

Time scale of the study
If you agree to take part in the study we will invite you to the gait analysis laboratory at QMUC two times: The second visit will be around one to three weeks after the first visit. For all visits we will arrange a time and day which is suitable for you.

Will my taking part be kept confidential?
Research regulatory bodies may check the data we collect on you in order to check on the progress of the research.
All data and information gathered during the project will be entirely confidential, and nothing will be published which might identify you. Any information about you which leaves Queen Margaret University College will have your name and address removed so that you cannot be recognised from it. We will keep your name, address and phone number at Queen Margaret University College so that we can contact you to make or change appointments should this be necessary. This information will only be available to the researchers involved in the study and will be kept in a locked filing cabinet.

What will happen to the results of the research study?
We will publish the results of this study in a series of international medical journal publications. However it can often take up to two years after completion of the study for the research to be published. If you would like a copy of the published results you can contact us. We also intend to send a report on the outcome of the research in lay terms to all participants in the study.

What if something goes wrong?
Although this is very unlikely, if you are harmed due to someone’s *negligence*, then compensation is the responsibility of Queen Margaret University College for the assessment procedures. If you are harmed by taking part in this research project by an unforeseen accident, (*non-negligent harm*) then there are no special compensation arrangements in place. However this is thought to be very unlikely. In such cases you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms will be available to you.

Contact for further information:
Marietta van der Linden, Research Fellow Physiotherapy, Queen Margaret University College, Duke Street, Edinburgh EH6 8HF, Tel 0131 317 3820

Thank you very much for reading this information

Vicky Cameron, Francis Fatoye, Kavi Jagadamma, William McMurrich
Postgraduate Research Students, Queen Margaret University College, Edinburgh.
Dr Marietta van der Linden, Research Fellow, Queen Margaret University College, Edinburgh.

Appendix II j) Information sheet for healthy adults – reliability study of mid-stance definitions

Queen Margaret University

EDINBURGH

Information Sheet for Potential Participants

We are undergraduate students from the School of Health and Science at Queen Margaret University in Edinburgh. As part of our degree course (Bsc Physiotherapy) we are undertaking a research project for my Honours project. The title of our project is: A reliability study of observational gait analysis to identify mid-stance in healthy children (HC) and those with Cerebral Palsy (CP), by final year physiotherapy students.

This study will investigate how reliable participants are at identifying a stage in a gait cycle for “normal” and “pathological” gait.

We are looking for volunteers to participate in the project. The inclusion criteria are male or female physiotherapy students in their final year who have completed 4 clinical placements.

If you agree to participate in the study, you will be asked to watch computerised motion data and to identify in which frame mid-stance occurs. The whole procedure should take no longer than two 20 minute sessions (two weeks apart). You will be free to withdraw from the study at any stage and you would not have to give a reason.

All data will be anonymised as much as possible, your name will be replaced with a participant number, and it will not be possible for you to be identified in any reporting of the data gathered. The data will be kept in a locked cabinet.

The results may be published in a journal or presented at a conference.

If you would like to contact an independent person, who knows about this project but is not involved in it, you are welcome to contact Kath Nicol. Her contact details are given below.

If you have read and understood this information sheet, any questions you had have been answered, and you would like to be a participant in the study, please now see the consent form.

Contact details of the researchers

Name of researchers: Donna Carver, Jo Freeman, Michelle Middleton and Roisin McCann

Address: School of Health Sciences
Queen Margaret University
Queen Margaret University Drive
Musselburgh
EH21 6UU
UK

Email : 05000910@qmu.ac.uk

Contact details of the independent adviser

Name of adviser: Kath Nicol

Address: School of Health Sciences
Queen Margaret University
Queen Margaret University Drive
Musselburgh
EH21 6UU
UK

Email / Telephone: knicol@qmu.ac.uk

Appendix III Consent forms

Appendix III a) Consent forms for children and parents – main study

Queen Margaret University
EDINBURGH

Participant's Identification number:

Consent Form

Title of the Project: "Modifying the special shoes for children with difficulty in walking"

Name and address of the Researcher: Kavi Jagadamma
Research Student, Physiotherapy
Queen Margaret University
Queen Margaret University Drive
Edinburgh EH21 6UU
Tel: 0131 474 0000
E-mail: kjagadamma@qmuc.ac.uk

Please initial box

I have read and understood the information sheet and this consent form and have had an opportunity to ask questions about my participation. ☐

I understand that I am under no obligation to take part in this study. ☐

I understand that I have the right to withdraw from this study at any stage without giving any reason. ☐

I understand that I need to be photographed; the photographs need to be kept for research purposes and I will not be identifiable in any of the photographs ☐

I agree to participate in this study. ☐

____________________	____________	________________
Name of the child In capital letters	Date	Signature
____________________	____________	________________
Name of Person giving consent (If different from the child)	Date	Signature
____________________	____________	________________
Researcher	Date	Signature

When completed, 1 for patient; 1 for researcher site file; 1 (original) to be kept in medical notes

Appendix III b) Consent forms for healthy adults – reliability study of motion analysis system

Queen Margaret University College

EDINBURGH

Centre Number:
Study Number
Patient Identification Number for this trial:

CONSENT FORM

Title of Project: **Comparison of the validity and repeatability of three different body marker configurations for three dimensional gait analysis**

Name of Researcher: Dr Marietta van der Linden

Please initial box

1. I confirm that I have read and understand the information sheet dated Febr 2006 (version 1) for the above study and have had the opportunity to ask questions.
2. I understand that my participation is voluntary and that I am free to withdraw at, any time without giving any reason, without my medical care or legal rights being affected.
3. I understand that sections of any of my medical notes may be looked at by responsible individuals from QMUC or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.
4. I understand that taking part in this study is at my own risk
5. I agree to take part in the above study.

Name of Participant	Date	Signature
Researcher	Date	Signature

1 for participant; 1 for researcher; 1 to be kept with hospital notes

Appendix III c) Consent forms for healthy adults – reliability study of mid-stance definitions

Queen Margaret University

EDINBURGH

A reliability study of observational gait analysis to identify mid-stance in healthy children and those with Cerebral Palsy by final year physiotherapy students.

I have read and understood the information sheet and this consent form. I have had an opportunity to ask questions about my participation.

I understand that I am under no obligation to take part in this study.

I understand that I have the right to withdraw from this study at any stage without giving any reason.

I agree to participate in this study.

Name of participant: ______________________________________

Signature of participant: ______________________________________

Signature of researcher: Donna Carver, Jo. Freeman, Roisin McCann, Michelle Middleton ______________________________________

Date: ________________

Contact details of the researcher

Name of researchers: Donna Carver, Jo. Freeman, Roisin McCann, Michelle Middleton

Address: School of Health Sciences
Queen Margaret University
Queen Margaret University Drive
Musselburgh
EH21 6UU
UK

Email :05004851@qmu.ac.uk 05003880@qmu.ac.uk 05000910@qmu.ac.uk 05003747@qmu.ac.uk

Appendix IV Assent form for children – main study

Queen Margaret University
EDINBURGH

ASSENT FORM FOR CHILDREN
(To be completed by the child and their parent/guardian)

Title of the Project: "Modifying the special shoes for children with difficulty in walking"

Child (or if unable, parent on their behalf) /young person to circle all they agree with please:

Has somebody explained this project to you?	Yes ☺/☹No
Do you understand what this project is about?	Yes ☺/☹No
Do you understand it's OK to stop taking part at any time?	Yes ☺/☹No
Are you happy to take part?	Yes ☺/☹No

If <u>any</u> answers are ' ☹No' or you **don't** want to take part, **don't** sign your name!

If you <u>do</u> want to take part, ☺please write your name and today's date (If you can't write yet, you can colour the happy face)

Your name ______________________________

Date ______________________________

Your parent or guardian must write their name here too if they are happy for you to do the project

Print Name ______________________________

Sign ______________________________

Date ______________________________

The doctor who explained this project to you needs to sign too:

Print Name ______________________________

Sign ______________________________

Date ______________________________

Thank you for your help.

Appendix V

MRC grading of muscle power

0 – No movement
1 – Flicker of movement
2 – Movement possible with gravity eliminated
3 – Movement possible against gravity, but not resistance
4 – Movement against some resistance applied by the examiner
5 – Normal power

Testing positions:

Gluteus Maximus: The patient lies prone with the legs flexed over the end of the plinth from the hips. The opposite leg is positioned in flexion sufficient to flatten the lumbar spine, supported by the examiner. Hip under examination is extended while the knee is maintained in flexion by the examiner.

Hamstrings: Position as for Gluteus Maximus test but with extended knee.

Abductors: The patient lies on his side with bottom leg flexed, and top leg (leg under examination) in line with body. The top leg is lifted in line with body.

Hip flexors: Supine lying with hip extended and knee flexed over the end of the bed. The hip under examination is flexed with knee flexed.

Quadriceps: Position same as hip flexors. The knee under examination is extended.

Dorsiflexors: Test in high sitting, with legs hanging down. Patient is asked to dorsiflex the ankle under examinations.

Plantarflexors: Active range against gravity is tested in prone with feet dangling over the edge of the plinth. 'With resistance' test is carried out in standing on tiptoe (giving minimal support for balance) to full available range of plantar-flexion.

Appendix VI Protocol for spasticity measurement using modified Ashworth's scale (MAS)

MAS grading of spasticity

0. No increase in muscle tone.
1. Slight increase in tone with a catch andrelease or minimal resistance at end of range.
2. As 2 but with minimal resistance through range following catch.
3. More marked increase tone through range of movement but easily moved.
4. Considerable increase in tone, passive movement difficult.
5. Affected part rigid in flexion or extension.

Testing protocol:

Hip flexors: The patient lies on his side with his top leg (leg under examination) flexed. The examiner supports the thigh and lower leg with one had maintaining the knee and hip flexion, while stabilising pelvis with the other hand. The hip joint is passively extended to the end range of motion in a brisk motion.

Hip adductors: The patient lies in supine with both lower limbs in line with the trunk. The leg under examination is supported with both the hands by the examiner and passively moved from the neutral position to end range of abduction in a brisk motion.

Internal rotators: Patient lies in supine with the hip and knee of the lower limb under examination passively maintained in 90° flexion by the examiner. The hip joint is then passively rotated to the end range of external rotation in a brisk motion.

Rectus Femoris: Patient lies in prone. The examiner holds the ankle of the leg under examination and stabilises the pelvis with the other hand. The knee joint is then passively flexed from the neutral to the end range of knee flexion in a brisk motion.

Medial and lateral hamstrings: Patient lies in supine on the edge of the plinth with leg under examination dangling over the side of the plinth at the knee joint. The examiner holds the ankle with one hand while stabilising the thigh with other hand. The knee joint is passively extended in a brisk motion with the shank of tibia rotated laterally at the knee joint for medial hamstrings and medially for lateral hamstrings.

Tibialis Anterior and posterior: Patient lies supine with the foot under examination over the edge of the plinth. The examiner holds the foot with one hand while stabilising the tibia with the other. In a brisk motion, the foot is passively everted and plantar flexed to the end range for tibialis anterior and everted and dorsi-flexed to the end range for tibialis posterior.

Extensor hallucis and extensor digitorum: In the same postion as above, in a brisk motion, the examiner passively flexes the first toe at meta-tarso phalyngeal and inter-phalyngeal joints for extensor hallucis, and second to fifth toes at meta-tarso phalyngeal and inter-phalyngeal joint for extensor digitorum.

Flexor hallucis and flexor digitorum: In the same postion as above, in a brisk motion, the examiner passively extends the first toe from neutral to end range at meta-tarso phalyngeal and inter-phalyngeal joints for extensor hallucis, and second to fifth toes at meta-tarso phalyngeal and inter-phalyngeal joint for extensor digitorum.

Peronei: In the same position as above, the examiner passively inverts the foot from neutral to the end range in a brisk motion.

Triceps Surae: In the same position as above, the ankle is passively moved from neutral to end range of dors-flexion in a brisk motion

Appendix VII Protocol for measuring Passive Range of Motion (PROM) of joints

General

Keep the head midline, in neutral extension relative to the body, and if there is difficulty inhibiting extension or flexion, turn the head to the other side. When spasticity is present, apply the stretch gradually. With two joint muscle begin in the position in which the muscle is at maximum shortness. If necessary, use positioning and pressure points to overcome the spasticity. Avoid skin contact over the muscle being stretched.

Body land marks to be marked.

Both anterior superior iliac spine, for the leg under examination – Greater trochanter, Lateral condyle of femur, Middle of the superior pole of the patella, Middle of lateral malleolus, Tubercle of calcaneum, Base of fifth meta tarsal and head of fifth meta tarsal

Hip flexion knee flexed

Position and movement: Patient supine, flex hip and knee with one hand, feel the lumbar spine with the other and stop at the point when the lumbar spine becomes flattened.

Photography: Camera held at the level of hip joint, horizontally in line with the body. The base of the photo aligned to the plinth.

Measurement: Angle made between line connecting greater trochanter of hip and lateral condyle of femur and mid line of trunk

Popliteal angle

Position and movement: Patient supine, the opposite leg flexed sufficient to flatten the lumbar spine. The hip is flexed to 90 degrees and the foot is slowly lifted as high as possible, taking care not to flatten the lumbar spine further.

Photography: Camera held at the level of knee, horizontally in line with the body . The base of the photo aligned to the plinth.

Measurement: Ankle made by the line connecting greater trochanter of hip and lateral condyle of femur to the line connecting lateral condyle of femur and lateral malleolus.

Hip flexion knee extended

Position and movement: Patient supine: lift limb slowly, gradually lifting to the limit of motion, with the opposite limb flat on the plinth. Stop when lumbar spine is flat. If the lumbar spine does not flatten, and the knee begins to flex, flex the opposite leg slightly until the lumbar spine is flat. Take care not to over-flatten the lumbar spine.

Avoid causing activity in the hamstrings or quads, use light pressure behind the knee to control knee extension.

Photography: As for hip flexion knee flexed. Maintain enough distance to include trunk, hip marker, knee marker and ankle marker in the photograph.

Measurement: Angle made between line connecting greater trochanter of hip and lateral condyle of femur and mid line of trunk

Hip abduction knee flexed

Position and procedure: Patient in supine, knees flexed over the end of the plinth. Abduct the hip being measured, keeping hips extended, pelvis level. Avoid rotation of the pelvis; stop when pelvis starts to rotate.

Photography: Camera operator standing on a chair on the side of leg examined. Camera held horizontally in line with the body. Maintain enough distance to include both ASIS markers and patellar marker in the photograph

Measurement: Angle between the line connecting two ASIS and line connecting ASIS and mid point of superior pole of patella is measured.

Hip extension

Position and procedure: The patient lies prone with the legs dangling over the end of the plinth from the hips. One leg is positioned in flexion sufficient to flatten the lumbar spine. The examiner places one hand over the sacrum/ lower lumbar spine to detect any movement, and the other leg is supported by the examiner and lifted to maximum extension.

Photography: Camera held at the level of hip joint, horizontally in line with the body. The base of the photo aligned to the plinth.

Measurement: Angle made between line connecting greater trochanter of hip and lateral condyle of femur and mid line of trunk

Adduction

Position and procedure: Position same as hip abduction. Adduct one hip below the other.

Photography: Same as hip abduction

Measurement: Angle between the line connecting two ASIS and line connecting ASIS and mid point of superior pole of patella is measured.

Internal and external rotation

Patient prone, legs parallel, neutral, and knees flexed. The trunk should be straight, pelvis level. Adjust the plinth if necessary to accommodate hip flexion contractures. Rotate the hips outwards together (internal rotation of hips), making sure the pelvis remains level. Then rotate inwards for external rotation, and outwards for internal rotation with the other leg flat. Keep firm pressure over the ischium to prevent rotation of the pelvis. Hold a ruler vertically (perpendicular to plinth) on the buttocks on the side examined

Photography: Position camera horizontally at the end of the plinth centred on the centre of the knee joint, pointing along the long axis of the thigh.

Measurement: The angle made by the shin of the tibia and the ruler is measured.

Femoral anteversion

The patient is placed prone, with the hips as close to neutral as possible. The examiner stands on the opposite side of the plinth from the limb to be tested and palpates both the anterior and posterior margins of the greater trochanter. The knee is flexed to 90° and the limb is rotated out (into internal rotation of the hip). The point when greater trochanter is most prominent is identified. The ruler is held vertically on the buttocks similar to while measuring internal rotation.

Photography: Position camera horizontally at the end of the plinth centred on the centre of the knee joint, pointing along the long axis of the thigh.
Measurement: The angle made by the shin of the tibia and the ruler is measured.

Knee extension
Position and procedure: In supine, knee is fully extended with gentle pressure, avoiding direct pressure through down through the knee cap.
Photography: Camera held at the level of knee, horizontally in line with the body . The base of the photo aligned to the plinth.
Measurement: Angle made by the line connecting greater trochanter of hip and lateral condyle of femur to the line connecting lateral condyle of femur and lateral malleolus.
.
Dorsi-flexion knee flexed
Position and procedure: In supine, knee flexed at least 90 degrees. Dorsi-flexion achieved by applying pressure with hand flat against the sole of the foot.
Photography: Photography: Camera held at the level of knee, horizontally in line with the body. The base of the photo aligned to the plinth.
Measurement: Angle made by the line connecting medial malleolus and lateral condyle of femur and the line connecting tubercle of calcaneum and base of fifth meta tarsal

Dorsi-flexion knee extended
Position and procedure: Same as dorsi-flexion knee flexed with the only difference being, the knee is maintained in extension here.
Photography: Photography: Camera held at the level of knee, horizontally in line with the body. The base of the photo aligned to the plinth.
Measurement: Angle made by the line connecting medial malleolus and lateral condyle of femur and the line connecting tubercle of calcaneum and base of fifth meta tarsal

Plantar-flexion
Position and procedure: In supine, knee flexed, plantarflex the foot to the available range
Photography: Photography: Camera held at the level of knee, horizontally in line with the body. The base of the photo aligned to the plinth.
Measurement: Angle made by the line connecting medial malleolus and lateral condyle of femur and the line connecting tubercle of calcaneum and base of fifth meta tarsal

Catch in Plantar flexors:
Position and procedure: In supine, with knee extended, dorsiflex the foot until the first sign of resistance.
Photography: Photography: Camera held at the level of knee, horizontally in line with the body. The base of the photo aligned to the plinth.
Measurement: Angle made by the line connecting medial malleolus and lateral condyle of femur and the line connecting tubercle of calcaneum and base of fifth meta tarsal

Appendix VIII Scoring sheet for physical examination

Physical Examination chart

PROM

	Right	Left
Hip		
Hip flexion knee flexed		
Hip flexion knee extended		
Abduction		
Adduction		
Hip Extension		
Internal Rotation *prone*		
External Rotation *prone*		
Femoral Anteversion *prone*		
Knee		
Knee extension		
Popliteal angle		
Ankle/foot		
Dorsi-flexion – foot neutral & Knee flexed		
Dorsi-flexion – foot neutral & Knee extended		
Plantar-flexion - foot neutral & Knee flexed		
Catch in Plantar flexors		

Muscle Tone

Hip flexors		
Adductors		
Internal Rotators		
Rectus Femoris		
Medial Hamstrings		
Lateral Hamstrings		
Tibialis Anterior(ev+pf)		
Extensor Digitorum		
Extensor Hallucis		
Triceps Surae		
Tibialis Posterior(ev+df)		
Flexor Digitorum		
Flexor Hallucis		
Peronei(inv)		

Muscle Power

Quadriceps		
Hamstrings		
Hip flexors		
Dorsiflexors		
Triceps surae		
Gluteus		

Appendix IX PedsQL™ - Instructions and questionnaires

PedsQL ™ 4.0 Generic Core Scales

CHILD and PARENT reports for:

Young Children (ages 5-7)
Children (ages 8-12)
Teens (ages 13-18)

Updated version June 2005

Appendix IX

MAPI RESEARCH TRUST
Education Information Dissemination

The **Child and Parent Reports** of the **PedsQL** ™ 4.0 Generic Core Scales for:

- Young Children (ages 5-7),
- Children (ages 8-12),
- And Teens (ages 13-18),

are composed of 23 items comprising 4 dimensions.

DESCRIPTION OF THE QUESTIONNAIRE:

Dimensions	Number of Items	Cluster of Items	Reversed scoring	Direction of Dimensions
Physical Functioning	8	1-8	1-8	Higher scores indicate better HRQOL.
Emotional Functioning	5	1-5	1-5	
Social Functioning	5	1-5	1-5	
School Functioning	5	1-5	1-5	

SCORING OF DIMENSIONS:

Item Scaling	5-point Likert scale from 0 (Never) to 4 (Almost always) 3-point scale: 0 (Not at all), 2 (Sometimes) and 4 (A lot) for the Young Child (ages 5-7) child report
Weighting of Items	No
Extension of the Scoring Scale	Scores are transformed on a scale from 0 to 100.
Scoring Procedure	**Step 1: Transform Score** Items are reversed scored and linearly transformed to a 0-100 scale as follows: 0=100, 1=75, 2=50, 3=25, 4=0. **Step 2: Calculate Scores** Score by Dimensions: • If more than 50% of the items in the scale are missing, the scale scores should not be computed, • Mean score= Sum of the items over the number of items answered. Psychosocial Health Summary Score = Sum of the items over the number of items answered in the Emotional, Social, and School Functioning Scales. Physical Health Summary Score = Physical Functioning Scale Score

Updated version June 2005

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Appendix IX

	Total Score: Sum of all the items over the number of items answered on all the Scales.
Interpretation and Analysis of Missing Data	If more than 50% of the items in the scale are missing, the Scale Scores should not be computed. If 50% or more items are completed: Impute the mean of the completed items in a scale.

Appendix IX

ID# ____________________

Date: ____________________

PedsQL ™

Pediatric Quality of Life
Inventory (UK)

Version 4.0

PARENT REPORT for **YOUNG CHILDREN** (ages **5-7**)

DIRECTIONS

On the following page is a list of things that might be a problem for **your child**. Please tell us **how much of a problem** each one has been for **your child** during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

*In the past **ONE month,** how much of a **problem** has your child had with …*

PedsQL 4.0 - Parent (5-7) Not to be reproduced without permission
UK Translation

Appendix IX

PHYSICAL FUNCTIONING (PROBLEMS WITH...)	Never	Almost Never	Some-times	Often	Almost Always
1. Walking down the road a little bit	0	1	2	3	4
2. Running	0	1	2	3	4
3. Participating in sports or running games	0	1	2	3	4
4. Lifting heavy things	0	1	2	3	4
5. Having a bath or shower by him or herself	0	1	2	3	4
6. Helping to pick up his or her toys	0	1	2	3	4
7. Having hurts or aches	0	1	2	3	4
8. Feeling very tired	0	1	2	3	4

EMOTIONAL FUNCTIONING *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Feeling afraid or scared	0	1	2	3	4
2. Feeling sad or unhappy	0	1	2	3	4
3. Feeling angry or cross	0	1	2	3	4
4. Trouble sleeping at night	0	1	2	3	4
5. Worrying about what will happen to him or her	0	1	2	3	4

SOCIAL FUNCTIONING *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Getting on with other children	0	1	2	3	4
2. Other kids not wanting to be his or her friend	0	1	2	3	4
3. Getting bullied by other children	0	1	2	3	4
4. Not able to do things that other children his or her age can do	0	1	2	3	4
5. Keeping up when playing with other children	0	1	2	3	4

SCHOOL FUNCTIONING *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Paying attention in class	0	1	2	3	4
2. Forgetting things	0	1	2	3	4
3. Keeping up with school activities	0	1	2	3	4
4. Having days off school because of not feeling well	0	1	2	3	4
5. Having days off school to go to the doctor or hospital	0	1	2	3	4

Appendix IX

ID# ______________________

Date: ______________________

PedsQL™

Pediatric Quality of Life Inventory (UK)

Version 4.0

PARENT REPORT for **CHILDREN** (ages **8-12**)

DIRECTIONS

On the following page is a list of things that might be a problem for **your child**. Please tell us **how much of a problem** each one has been for **your child** during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

*In the past **ONE month,** how much of a **problem** has your child had with …*

PedsQL 4.0 - Parent (8-12)
09/01 UK Translation

Appendix IX

PedsQL 2

PHYSICAL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Walking down the road a little bit	0	1	2	3	4
2. Running	0	1	2	3	4
3. Participating in sports or running games	0	1	2	3	4
4. Lifting heavy things	0	1	2	3	4
5. Having a bath or shower by him or herself	0	1	2	3	4
6. Tidying up around the house	0	1	2	3	4
7. Having hurts or aches	0	1	2	3	4
8. Feeling very tired	0	1	2	3	4

EMOTIONAL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Feeling afraid or scared	0	1	2	3	4
2. Feeling sad or unhappy	0	1	2	3	4
3. Feeling angry or cross	0	1	2	3	4
4. Trouble sleeping at night	0	1	2	3	4
5. Worrying about what will happen to him or her	0	1	2	3	4

SOCIAL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Getting on with other children	0	1	2	3	4
2. Other kids not wanting to be his or her friend	0	1	2	3	4
3. Getting bullied by other children	0	1	2	3	4
4. Not able to do things that other children his or her age can do	0	1	2	3	4
5. Keeping up when playing with other children	0	1	2	3	4

SCHOOL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Paying attention in class	0	1	2	3	4
2. Forgetting things	0	1	2	3	4
3. Keeping up with schoolwork	0	1	2	3	4
4. Having days off school because of not feeling well	0	1	2	3	4
5. Having days off school to go to the doctor or hospital	0	1	2	3	4

PedsQL 4.0 - Parent (8-12) 09/01 UK Translation

Appendix IX

ID#____________________

Date:____________________

PedsQL™

Pediatric Quality of Life Inventory (UK)

Version 4.0

PARENT REPORT for TEENAGERS (ages 13-18)

DIRECTIONS

On the following page is a list of things that might be a problem for **your teenager.** Please tell us **how much of a problem** each one has been for **your teenager** during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

PedsQL 4.0 - Parent (13-18) Not to be reproduced without permission
09/01 UK Translation

Appendix IX

*In the past **ONE month,** how much of a **problem** has your teenager had with …*

PHYSICAL FUNCTIONING *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Walking down the road a little bit	0	1	2	3	4
2. Running	0	1	2	3	4
3. Participating in sports or running games	0	1	2	3	4
4. Lifting heavy things	0	1	2	3	4
5. Having a bath or shower by him or herself	0	1	2	3	4
6. Tidying up around the house	0	1	2	3	4
7. Having hurts or aches	0	1	2	3	4
8. Feeling very tired	0	1	2	3	4

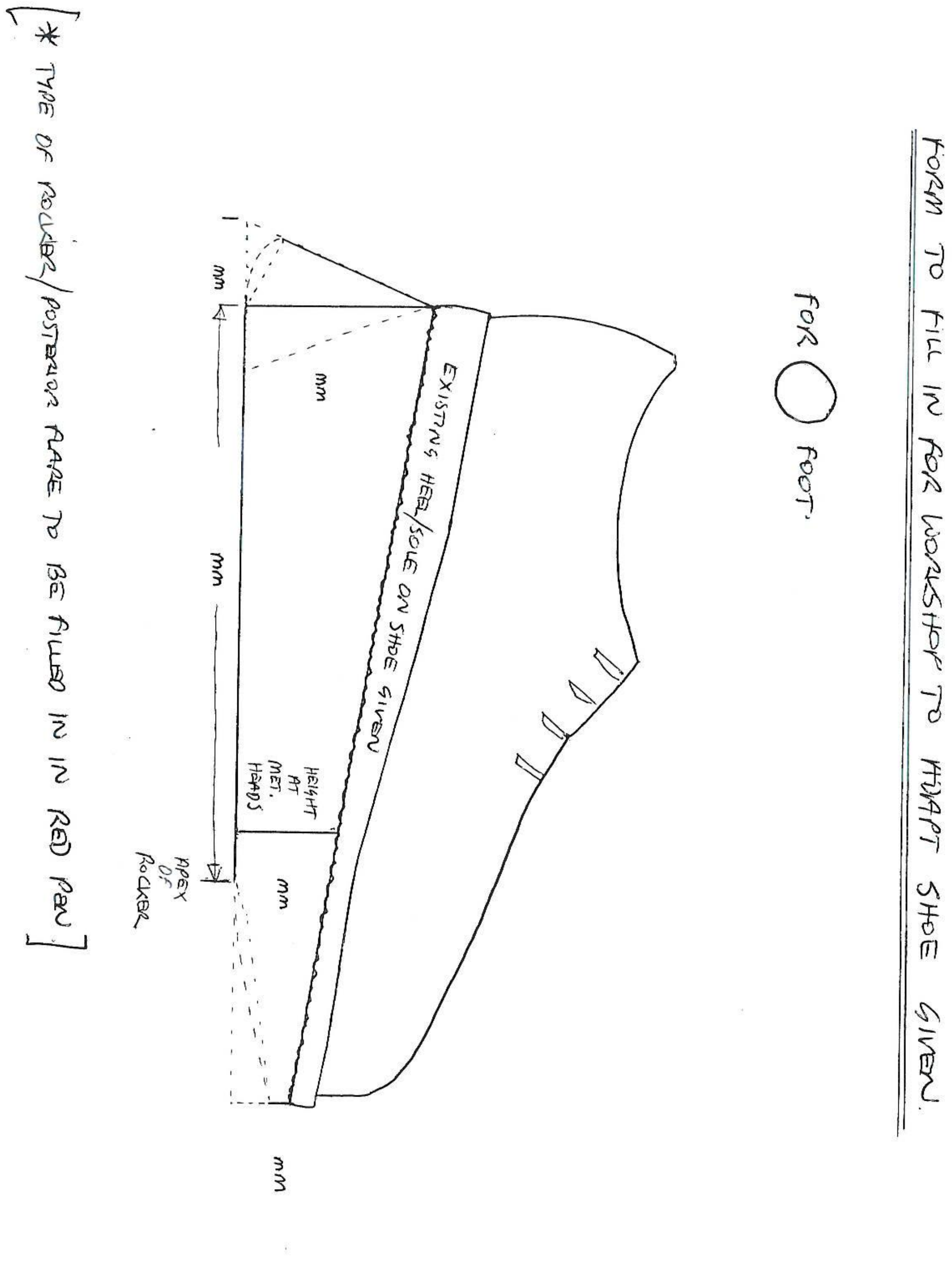
EMOTIONAL FUNCTIONING *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Feeling afraid or scared	0	1	2	3	4
2. Feeling sad or unhappy	0	1	2	3	4
3. Feeling angry or cross	0	1	2	3	4
4. Trouble sleeping at night	0	1	2	3	4
5. Worrying about what will happen to him or her	0	1	2	3	4

SOCIAL FUNCTIONING *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Getting on with other teenagers	0	1	2	3	4
2. Other teenagers not wanting to be his or her friend	0	1	2	3	4
3. Getting bullied by other teenagers	0	1	2	3	4
4. Not able to do things that other teenagers his or her age can do	0	1	2	3	4
5. Keeping up with other teenagers during activities	0	1	2	3	4

SCHOOL FUNCTIONING *(problems with...)*	Never	Almost Never	Some-times	Often	Almost Always
1. Paying attention in class	0	1	2	3	4
2. Forgetting things	0	1	2	3	4
3. Keeping up with schoolwork	0	1	2	3	4
4. Having days off school because of not feeling well	0	1	2	3	4
5. Having days off school to go to the doctor or hospital	0	1	2	3	4

PedsQL 4.0 - Parent (13-18)
09/01 UK Translation

Appendix X Prescription sheet for modification of shoes



Appendix XI Kinematic and Kinetic data points compared

The kinematic and kinetic data points used in the present study with a brief description of each data point is given below:

Peak anterior pelvic tilt: The highest angle achieved by pelvis in sagittal plane at any point during gait cycle

Peak posterior pelvic tilt: The highest angle achieved by pelvis in sagittal plane at any point during gait cycle

Pelvic tilt ROM: The difference between peak anterior pelvic tilt and peak posterior tilt.

Knee flexion at IC: The degree of knee flexion/extension at the point of foot contact

Peak knee flexion (stance): The highest angle achieved by the knee joint in sagittal plane during stance phase

Peak knee extension (stance): The lowest angle achieved by knee joint in sagittal plane during mid-stance to pre-swing (10% to 60% of gait cycle)

Peak knee flexion: The highest angle achieved by the knee joint in sagittal plane during the whole gait cycle

Knee ROM: The difference between lowest angle and highest angle achieved by knee joint in sagittal plane during the whole gait cycle

Peak hip flexion: The highest angle achieved by the hip joint in sagittal plane during the whole gait cycle

Peak hip extension: The lowest angle achieved by the hip joint in sagittal plane during the whole gait cycle

Peak hip flexion (stance): The highest angle achieved by the hip joint in sagittal plane during the stance phase of gait cycle

Hip ROM: The difference between lowest angle and highest angle achieved by hip joint in sagittal plane during the whole gait cycle

Ankle angle in sagittal plane at IC: The degree of ankle dorsi-flexion/plantar-flexion at the point of foot contact

Peak dorsi-flexion: The highest angle achieved by ankle joint in sagittal plane during stance phase.

Peak plantar-flexion: The highest angle achieved by ankle joint in sagittal plane during stance phase.

Ankle ROM: The difference between lowest angle and highest angle achieved by ankle joint in sagittal plane during the whole gait cycle.

Peak hip flexion moment: The highest moment achieved by the hip joint in sagittal plane during stance phase

Peak hip extension moment: The lowest moment achieved by the hip joint in sagittal plane during stance phase

Peak knee flexion moment: The highest moment achieved by the knee joint in sagittal plane during stance phase

Peak knee extension moment: The lowest moment achieved by the knee joint in sagittal plane during stance phase

Knee flexion/extension moment during mid-stance: The value of moment achieved at the point of the mid-stance event (in this case 30% of gait cycle).

Peak ankle DF moment: The highest moment achieved by ankle joint in sagittal plane during terminal stance to pre-swing (40% to 60% of gait cycle)

Peak ankle PF moment: The lowest moment achieved by ankle joint in sagittal plane during stance phase

FZ1(peak 1): The highest value achieved during first peak of vertical force.

FZ2 (peak 2): The highest value achieved during second peak of vertical force.

Appendix XII Results from case studies

This Appendix provides tables with statistical comparisons of kinematic and kinetic data points, and temporal-spatial parameters compared between the conditions barefoot, non-tuned AFO-FC and tuned immediate for the eight case studies.

Case study 1

Table XII.1 Results from descriptive analysis of kinetic data points between between barefoot, non-tuned AFO-FC and tuned AFO-FC for case study 1 (participant 1)

	Barefoot Mean	SD	AFO-FC non-tuned Mean	SD	AFO-FC tuned Mean	SD
Hip moments						
Peak hip flexion moment	0.56	-	1.11	0.39	0.18	-
Peak hip extension moment	-0.41	-	-0.80	0.12	-0.85	-
Knee moments						
Peak knee flexion moment	0.29	-	0.73	0.11	0.83	-
Peak knee extension moment	-0.52	-	-0.40	0.07	-0.15	-
Knee flex/ext moment at mid-stance	0.08	-	0.23	0.15	0.34	-
Ankle moments						
Peak ankle DF moment	0.75	-	0.93	0.14	0.78	-
Peak ankle PF moment	0.00	-	-0.14	0.04	-0.25	-
Key: SD – Standard Deviation, all values in Nm/kg						

Appendix XII

Table XII.2 Results from descriptive and statistical analysis of kinematic data points and temporal-spatial parameters between barefoot, non-tuned AFO-FC and tuned AFO-FC for case study 1 (participant 1)

	Barefoot Mean	SD	AFO-FC non-tuned Mean	SD	Tuned AFO-FC Mean	SD	Group 1[ά] *p* value*	Group 2[ά] *p* value*
Pelvic kinematics								
Peak anterior pelvic tilt	15.59	0.91	10.76	2.74	10.03	4.07	**0.01**	0.79
Peak posterior pelvic tilt	6.23	2.41	4.23	2.83	3.29	4.20	0.09	0.71
Pelvic tilt ROM	9.36	1.98	6.53	1.61	6.73	0.64	**0.02**	0.78
Knee kinematics								
Knee flexion at IC	22.55	7.05	13.22	2.85	18.81	4.76	**0.03**	0.11
Peak knee flexion (stance)	23.65	7.18	15.69	2.25	22.58	5.52	**0.03**	0.07
Peak knee extension (stance)	2.38	6.72	-1.93	2.85	5.77	2.14	0.08	**0.005**
Peak knee flexion	53.92	8.72	52.06	4.58	43.54	3.35	0.67	**0.01**
Knee ROM	51.54	5.43	53.99	5.32	37.77	3.11	0.39	**<0.001**
Hip kinematics								
Peak Hip flexion	37.60	3.80	34.33	4.39	29.29	3.93	0.22	0.14
Peak Hip extension	-9.85	2.43	-12.68	2.30	-11.53	2.69	**0.01**	0.52
Peak hip flexion (stance)	29.05	5.93	25.60	3.65	27.11	4.13	0.11	0.62
Hip ROM	47.45	2.39	47.02	4.10	40.83	3.90	0.84	0.10
Temporal-spatial parameters								
Cadence (steps/minute)	165.13	12.06	144.91	12.27	134.91	16.93	**0.04**	0.22
Stride-length (m)	0.79	0.03	0.73	0.08	0.77	0.09	0.15	0.52
Walking speed (m/s)	1.09	0.09	0.88	0.15	0.86	0.16	0.06	0.88

Key: SD – Standard deviation, Significance level $p < 0.05$, all values except p values in degrees, significant results in **bold**
[ά]Group 1 – Barefoot and AFO-FC non-tuned, group 2 – AFO-FC non-tuned and tuned AFO-FC

Appendix XII

Case study 2

Table XII.3 Results from descriptive analysis of kinetic data points between between barefoot, non-tuned AFO-FC and tuned AFO-FC for case study 2 (participant 2)

	Barefoot Mean	SD	AFO-FC non-tuned Mean	SD	AFO-FC tuned Mean	SD
Hip moments						
Peak hip flexion moment	0.65	0.14	1.02	0.25	0.89	0.22
Peak hip extension moment	-0.33	0.04	-0.69	0.15	-0.53	0.13
Knee moments						
Peak knee flexion moment	0.25	0.07	0.55	0.09	0.58	0.07
Peak knee extension moment	-0.19	0.16	-0.18	0.18	-0.16	0.10
Knee flexion/extension moment at mid-stance	-0.12	0.17	0.06	0.11	0.01	0.11
Ankle moments						
Peak ankle DF moment	0.89	0.16	0.81	0.21	1.01	0.04
Peak ankle PF moment	0.01	0.02	-0.45	0.13	-0.38	0.02
Key: SD – Standard Deviation, all values in Nm/kg						

Appendix XII

Table XII.4 Results from descriptive and statistical analysis of kinematic data points and temporal-spatial parameters between barefoot, non-tuned AFO-FC and tuned AFO-FC for (case study 2) participant 2

	Barefoot Mean	SD	AFO-FC non-tuned Mean	SD	Tuned AFO-FC Mean	SD	Group 1[ά] *p* value*	Group 2[ά] *p* value*
Pelvic kinematics								
Peak anterior pelvic tilit	15.59	0.91	10.76	2.74	10.03	4.07	**0.01**	0.80
Peak posterior pelvic tilt	4.40	1.57	5.19	1.99	3.92	2.10	0.77	0.23
Pelvic tilt ROM	13.15	1.24	14.60	1.95	13.54	0.76	0.27	0.27
Knee kinematics								
Knee flexion at IC	14.53	3.18	10.95	2.95	19.96	2.82	**0.02**	**0.001**
Peak knee flexion (stance)	20.49	3.18	18.52	3.06	27.21	2.92	0.17	**0.01**
Peak knee extension (stance)	5.41	4.52	-5.66	0.81	6.60	2.69	**0.003**	**<0.001**
Peak knee flexion	61.15	1.80	55.61	1.74	51.90	2.50	**0.004**	**0.01**
Knee ROM	55.74	4.28	61.27	2.00	45.30	4.52	**0.02**	**<0.001**
Hip kinematics								
Peak Hip flexion	37.96	1.80	37.40	1.32	39.04	2.33	0.46	0.29
Peak Hip extension	-3.70	1.54	-5.05	1.08	-2.54	1.89	0.37	**0.01**
Peak hip flexion (stance)	28.28	1.68	33.52	4.24	38.74	2.69	**0.02**	0.17
Hip ROM	41.67	2.98	42.45	1.13	41.59	2.75	0.87	0.19
Temporal-spatial parameters								
Cadence (steps/minute)	106.55	8.97	106.39	2.34	104.83	9.68	0.97	0.71
Stride-length (m)	0.93	0.06	1.15	0.14	1.16	0.08	**0.003**	0.83
Walking speed (m/s)	0.83	0.11	1.02	0.12	1.02	0.15	**0.01**	0.95

Key: SD – Standard deviation, Significance level $p < 0.05$, all values except p values in degrees, significant results in **bold**

[ά]Group 1 – Barefoot and AFO-FC non-tuned, group 2 – AFO-FC non-tuned and tuned AFO-FC

Appendix XII

Case study 3

Table XII.5 Results from descriptive analysis of kinetic data points between between barefoot, non-tuned AFO-FC and tuned AFO-FC for case study 3 (participant 3).

	Barefoot Mean	SD	AFO-FC non-tuned Mean	SD	AFO-FC tuned Mean	SD
Hip moments						
Peak hip flexion moment	0.62	0.06	1.22	0.21	0.54	0.18
Peak hip extension moment	-0.32	0.04	-0.83	0.36	-0.36	0.08
Knee moments						
Peak knee flexion moment	0.27	0.04	0.92	0.23	0.72	0.10
Peak knee extension moment	-0.23	0.06	-0.44	0.04	-0.26	0.10
Knee flex/ext moment at mid-stance	0.25	0.04	0.17	0.15	-0.03	0.08
Ankle moments						
Peak ankle DF moment	0.85	0.11	1.11	0.23	1.08	0.14
Peak ankle PF moment	0.03	0.05	-0.24	0.17	-0.21	0.03
Key: SD – Standard Deviation, all values in Nm/kg						

Appendix XII

Table XII.6 Results from descriptive and statistical analysis of kinematic data points and temporal-spatial parameters between barefoot, non-tuned AFO-FC and tuned AFO-FC for case study 3 (participant 3).

	Barefoot Mean	SD	AFO-FC non-tuned Mean	SD	AFO-FC tuned Mean	SD	Group 1 ^{ά} *p* value*	Group 2 ^{ά} *p* value*
Pelvic kinematics								
Peak anterior pelvic tilt	23.86	0.85	27.28	3.12	25.20	1.18	**0.04**	0.24
Peak posterior pelvic tilt	15.92	0.73	18.08	3.33	15.09	0.73	0.16	0.11
Pelvic tilt ROM	7.93	1.05	9.20	1.15	10.11	1.68	0.19	0.28
Knee kinematics								
Knee flexion at IC	19.25	1.52	26.59	5.12	27.24	2.33	0.06	0.60
Peak knee flexion (stance)	26.52	1.51	36.74	5.56	35.85	1.87	**0.02**	0.90
Peak knee extension (stance)	21.01	1.39	18.24	4.21	16.37	7.33	0.16	0.73
Peak knee flexion	50.74	6.16	51.04	2.97	49.53	2.82	0.49	0.75
Knee ROM	29.74	7.37	32.81	4.40	33.16	6.36	0.14	0.79
Hip kinematics								
Peak Hip flexion	44.32	2.62	47.83	2.30	46.30	1.35	**0.02**	0.18
Peak Hip extension	0.58	1.66	0.83	2.82	-1.15	2.01	0.87	0.12
Peak hip flexion (stance)	39.04	0.93	46.96	2.95	44.16	2.44	**0.003**	0.29
Hip ROM	43.75	3.68	47.00	3.85	47.45	2.89	0.14	0.44
Temporal-spatial parameters								
Cadence	120.07	6.12	139.58	14.93	126.61	6.68	**0.04**	0.06
Stride-length	0.86	0.05	0.99	0.06	0.92	0.10	**0.01**	0.06
Walking speed	0.86	0.08	1.15	0.11	0.97	0.10	**0.003**	**<0.001**

Key: SD – Standard deviation, Significance level $p < 0.05$, all values except p values in degrees, significant results in **bold**

^{ά}Group 1 – Barefoot and AFO-FC non-tuned, group 2 – AFO-FC non-tuned and tuned AFO-FC

Appendix XII

Case study 4

Table XII.7 Results from descriptive analysis of kinetic data points between between barefoot, non-tuned AFO-FC and tuned AFO-FC for case study 4 (participant 4) (right side)

	Barefoot Mean	SD	AFO-FC non-tuned Mean	SD	AFO-FC tuned Mean	SD
Hip moments						
Peak hip flexion moment	0.44	0.12	1.04	-	0.83	-
Peak hip extension moment	-0.04	0.09	-1.19	-	-0.67	-
Knee moments						
Peak knee flexion moment	-0.04	0.04	1.58	-	0.56	-
Peak knee extension moment	-0.33	0.04	-0.13	-	-0.08	-
Knee flex/ext moment at mid-stance	-0.25	0.05	-0.13	-	0.32	-
Ankle moments						
Peak ankle DF moment	0.70	0.12	1.24	-	1.00	-
Peak ankle PF moment	0.06	0.04	-0.01	-	-0.20	-
Key: SD – Standard Deviation, all values in Nm/kg						

Table XII.8 Results from descriptive analysis of kinetic data points between between barefoot, non-tuned AFO-FC and tuned AFO-FC for case study 4 (participant 4) (left side)

	Barefoot Mean	SD	AFO-FC non-tuned Mean	SD	AFO-FC tuned Mean	SD
Hip moments						
Peak hip flexion moment	0.60	-	0.77	-	0.63	-
Peak hip extension moment	0.02	-	-0.55	-	-0.68	-
Knee moments						
Peak knee flexion moment	0.58	-	0.39	-	0.45	0.02
Peak knee extension moment	0.16	-	-0.17	-	-0.08	0.07
Knee flex/ext moment at mid-stance	0.47	-	0.24	-	0.38	0.10
Ankle moments						
Peak ankle DF moment	0.36	-	0.74	-	0.77	-
Peak ankle PF moment	0.03	-	0.18	-	-0.09	-
Key: SD – Standard Deviation, all values in Nm/kg						

Appendix XII

Table XII.9 Results from descriptive and statistical analysis of kinematic data points and temporal-spatial parameters between barefoot, non-tuned AFO-FC and tuned AFO-FC for case study 4 (participant 4) (right side)

	Barefoot Mean	SD	AFO-FC non-tuned Mean	SD	AFO-FC tuned Mean	SD	Group 1 [ά] *p* value*	Group 2 [ά] *p* value*
Pelvic kinematics								
Peak anterior pelvic tilt	15.93	2.37	17.69	1.99	17.11	2.27	0.16	0.53
Peak posterior pelvic tilt	7.00	2.26	10.18	2.39	10.11	2.92	0.06	0.94
Pelvic tilt ROM	8.93	2.04	7.51	0.71	7.00	0.96	0.17	0.12
Knee kinematics								
Knee flexion at IC	21.46	4.02	41.57	1.88	39.63	2.24	**0.001**	0.15
Peak knee flexion (stance)	21.57	3.91	47.34	2.14	44.02	2.59	**<0.001**	**0.05**
Peak knee extension (stance)	7.49	3.42	28.05	2.36	28.62	3.36	**0.001**	0.73
Peak knee flexion	41.54	3.69	62.68	6.41	54.24	1.70	**0.004**	**0.04**
Knee ROM	34.05	1.57	34.64	7.10	25.62	1.94	0.86	**0.05**
Hip kinematics								
Peak Hip flexion	30.45	2.60	42.82	1.72	38.92	0.81	**0.002**	**0.01**
Peak Hip extension	5.48	5.14	-1.48	3.01	2.13	6.84	0.08	0.30
Peak hip flexion (stance)	24.17	2.84	38.16	0.94	36.13	1.56	**0.001**	**0.01**
Hip ROM	24.98	3.68	44.31	3.87	36.79	6.67	**0.004**	0.15
Temporal-spatial parameters								
Cadence (steps/minute)	78.68	12.89	118.01	9.96	124.75	13.74	**0.01**	0.26
Stride-length (m)	0.35	0.10	0.69	0.05	0.61	0.04	**0.001**	0.05
Walking speed (m/s)	0.22	0.04	0.68	0.09	0.63	0.06	**<0.001**	0.28

Key: SD – Standard deviation, Significance level $p < 0.05$, all values except p values in degrees, significant results in **bold**

[ά]Group 1 – Barefoot and AFO-FC non-tuned, group 2 – AFO-FC non-tuned and tuned AFO-FC

Appendix XII

Table XII.10 Results from descriptive and statistical analysis of of kinematic data points between barefoot, original AFO-FC and tuned AFO-FC for case study 4 (participant 4) (left side)

	Barefoot Mean	SD	AFO-FC non-tuned Mean	SD	AFO-FC tuned Mean	SD	Group 1 [ά] *p* value*	Group 2 [ά] *p* value*
Pelvic kinematics								
Peak anterior pelvic tilt	15.35	2.30	18.24	2.13	15.90	3.24	0.05	0.25
Peak posterior pelvic tilt	7.25	2.49	10.07	2.73	8.06	3.38	0.10	0.39
Pelvic tilt ROM	8.11	1.78	8.17	1.04	7.84	1.71	0.96	0.78
Knee kinematics								
Knee flexion at IC	36.46	3.54	33.99	1.28	34.20	1.28	0.20	0.87
Peak knee flexion (stance)	37.42	3.48	37.91	2.01	39.26	1.56	0.97	0.38
Peak knee extension (stance)	27.16	1.90	24.87	4.27	24.26	1.95	0.31	0.92
Peak knee flexion	52.78	2.39	46.57	4.12	46.12	1.97	**0.04**	0.96
Knee ROM	25.62	1.76	21.69	5.51	21.85	1.73	0.14	0.88
Hip kinematics								
Peak Hip flexion	42.97	1.39	39.06	0.98	36.49	1.01	**0.002**	**0.004**
Peak Hip extension	17.51	3.63	4.01	3.00	1.93	1.88	**0.01**	0.25
Peak hip flexion (stance)	39.84	1.06	35.87	2.39	33.32	2.21	**0.02**	0.15
Hip ROM	25.46	3.96	35.05	2.59	34.57	2.51	**0.02**	0.56

Key: SD – Standard deviation, Significance level $p < 0.05$, all values except p values in degrees, significant results in **bold**
[ά]Group 1 – Barefoot and AFO-FC non-tuned, group 2 – AFO-FC non-tuned and tuned AFO-FC

Appendix XII

Case study 5

Table XII.11 Results from descriptive analysis of kinetic data points between between barefoot, non-tuned AFO-FC and tuned AFO-FC for case study 5 (participant 5).

	Barefoot Mean	SD	AFO-FC non-tuned Mean	SD	AFO-FC tuned Mean	SD
Hip moments						
Peak hip flexion moment	0.43	0.05	0.50	0.09	1.02	0.39
Peak hip extension moment	-0.55	0.15	-0.51	0.25	-0.64	0.16
Knee moments						
Peak knee flexion moment	0.15	0.13	0.20	0.09	0.57	0.16
Peak knee extension moment	-0.52	0.44	-0.51	0.17	-0.46	0.20
Knee flex/ext moment at mid-stance	0.00	0.26	-0.17	0.10	-0.16	0.29
Ankle moments						
Peak ankle DF moment	0.89	0.03	1.09	0.07	1.19	0.23
Peak ankle PF moment	-0.11	0.27	-0.13	0.04	-0.39	0.11
Key: SD – Standard Deviation, all values in Nm/kg						

Appendix XII

Table XII.12 Results from descriptive and statistical analysis of kinematic data points and temporal-spatial parameters between barefoot, non-tuned AFO-FC and tuned AFO-FC for case study 5 (participant 5).

	Barefoot Mean	SD	AFO-FC non-tuned Mean	SD	AFO-FC tuned Mean	SD	Group 1 [ά] *p* value*	Group 2 [ά] *p* value*
Pelvic kinematics								
Peak anterior pelvic tilt	23.14	2.62	19.05	2.55	22.29	4.47	0.07	0.25
Peak posterior pelvic tilt	17.34	1.93	10.57	1.73	14.63	1.99	**0.001**	**0.01**
Pelvic tilt ROM	5.80	1.37	8.48	1.30	7.66	4.82	**0.04**	0.75
Knee kinematics								
Knee flexion at IC	10.93	12.93	8.06	4.24	14.22	2.25	0.67	0.06
Peak knee flexion (stance)	10.93	12.93	12.99	4.87	21.00	2.96	0.73	**0.01**
Peak knee extension (stance)	-4.21	9.41	-3.62	1.15	-0.26	3.29	0.88	0.08
Peak knee flexion	55.85	2.62	55.17	4.39	59.44	5.97	0.76	0.30
Knee ROM	60.06	11.08	58.78	4.30	59.70	4.43	0.82	0.75
Hip kinematics								
Peak Hip flexion	47.06	2.52	38.90	2.58	44.87	3.97	**0.002**	0.06
Peak Hip extension	2.54	2.54	-7.28	1.84	-3.98	4.36	**0.001**	0.14
Peak hip flexion (stance)	40.78	4.96	35.08	4.43	44.84	3.98	0.08	**0.03**
Hip ROM	44.52	4.47	46.18	4.01	48.85	1.89	0.54	0.28
Temporal-spatial parameters								
Cadence (steps/minute)	109.11	9.38	93.56	14.85	134.53	30.59	0.12	0.07
Stride-length (m)	0.75	0.05	0.88	0.13	0.97	0.06	0.13	0.25
Walking speed (m/s)	0.69	0.08	0.69	0.21	1.10	0.30	0.95	0.09

Key: SD – Standard deviation, Significance level $p < 0.05$, all values except p values in degrees, significant results in **bold**
[ά]Group 1 – Barefoot and AFO-FC non-tuned, group 2 – AFO-FC non-tuned and tuned AFO-FC

Appendix XII

Case study 6

Table XII.13 Results from descriptive analysis of kinetic data points between between barefoot, non-tuned AFO-FC and tuned AFO-FC for case study 6 (participant 6) (right side)

	Barefoot Mean	SD	AFO-FC non-tuned Mean	SD	AFO-FC tuned Mean	SD
Hip moments						
Peak hip flexion moment	1.22	0.07	1.40	0.08	1.24	0.12
Peak hip extension moment	-0.51	0.04	-0.54	0.11	-0.59	0.06
Knee moments						
Peak knee flexion moment	0.75	0.03	0.94	0.09	1.18	0.03
Peak knee extension moment	-0.22	0.07	-0.30	0.08	-0.18	0.04
Knee flex/ext moment at mid-stance	0.19	0.03	-0.01	0.04	0.19	0.05
Ankle moments						
Peak ankle DF moment	0.86	0.04	0.88	0.08	0.63	0.04
Peak ankle PF moment	-0.01	0.02	-0.12	0.01	-0.29	0.05
Key: SD – Standard Deviation, all values in Nm/kg						

Table XII.14 Results from descriptive analysis of kinetic data points between between barefoot, non-tuned AFO-FC and tuned AFO-FC for case study 6 (participant 6) (left side)

	Barefoot Mean	SD	AFO-FC non-tuned Mean	SD	AFO-FC tuned Mean	SD
Hip moments						
Peak hip flexion moment	1.60	0.07	2.17	0.19	1.59	0.09
Peak hip extension moment	-0.32	0.06	-0.54	0.07	-0.41	0.05
Knee moments						
Peak knee flexion moment	0.17	0.05	0.61	0.12	0.99	0.38
Peak knee extension moment	-0.42	0.07	-0.22	0.03	-0.10	0.07
Knee flex/ext moment at mid-stance	-0.04	0.02	-0.03	0.04	0.06	0.10
Ankle moments						
Peak ankle DF moment	1.09	0.05	1.03	0.03	0.85	0.03
Peak ankle PF moment	-0.04	0.01	-0.15	0.01	-0.46	0.20
Key: SD – Standard Deviation, all values in Nm/kg						

Appendix XII

Table XII.15 Results from descriptive and statistical analysis of kinematic data points and temporal-spatial parameters between barefoot, non-tuned AFO-FC and tuned AFO-FC for case study 6 (participant 6) (right side)

	Barefoot Mean	SD	AFO-FC non-tuned Mean	SD	AFO-FC tuned Mean	SD	Group 1 [ά] *p* value*	Group 2 [ά] *p* value*
Pelvic kinematics								
Peak anterior pelvic tilt	33.16	0.93	36.49	0.86	41.48	0.60	**0.005***	**0.001***
Peak posterior pelvic tilt	23.60	0.22	27.28	0.79	30.40	1.26	**0.001***	**0.002***
Pelvic tilt ROM	9.56	1.07	9.21	0.90	11.08	0.97	0.62	**0.04***
Knee kinematics								
Knee flexion at IC	26.62	0.72	29.06	1.24	22.77	0.47	**0.01***	**0.001***
Peak knee flexion (stance)	33.41	0.96	35.55	1.22	32.76	1.52	**0.05***	**0.005***
Peak knee extension (stance)	8.78	1.78	1.48	1.57	4.39	2.13	**0.001***	**0.03***
Peak knee flexion	50.35	1.09	51.64	0.95	52.18	1.53	0.06	0.37
Knee ROM	41.57	1.91	50.16	2.23	47.79	2.68	**0.001***	**0.02***
Hip Kinematics								
Peak Hip flexion	58.87	0.50	61.51	0.77	66.39	0.85	**0.001***	**0.001***
Peak Hip extension	16.59	1.19	15.73	0.82	26.56	2.45	0.25	**0.001***
Peak hip flexion (stance)	54.87	1.07	59.07	1.82	61.72	2.58	**0.01***	**0.05***
Hip ROM	42.28	1.20	45.79	1.04	39.83	3.23	**0.01***	**0.01***
Temporal-spatial parameters								
Cadence (steps/minute)	122.92	2.33	123.49	1.55	117.12	6.38	0.69	**0.05***
Stride-length (m)	1.08	0.04	1.18	0.04	1.11	0.05	**0.02***	**0.01***
Walking speed (m/s)	1.10	0.05	1.21	0.05	1.08	0.10	**0.04***	**0.01***

Key: SD – Standard deviation, Significance level $p < 0.05$, all values except p values in degrees, significant results in **bold**
[ά]Group 1 – Barefoot and AFO-FC non-tuned, group 2 – AFO-FC non-tuned and tuned AFO-FC

Appendix XII

Table XII.16 Results from descriptive and statistical analysis of of kinematic data points and temporal-spatial parameters between barefoot, non-tuned AFO-FC and tuned AFO-FC for case study 6 (participant 6) (left side)

	Barefoot Mean	SD	AFO-FC non-tuned Mean	SD	AFO-FC tuned Mean	SD	Group 1 [ά] *p* value*	Group 2 [ά] *p* value*
Pelvic kinematics								
Peak anterior pelvic tilt	33.17	0.91	36.51	0.83	41.60	1.13	**0.003**	**<0.001**
Peak posterior pelvic tilt	23.90	0.62	27.20	0.82	31.34	1.42	**<0.001**	**<0.001**
Pelvic tilt ROM	9.26	1.46	9.31	1.13	10.25	0.92	0.95	0.16
Knee kinematics								
Knee flexion at IC	16.47	0.82	26.78	1.02	18.61	0.89	**<0.001**	**<0.001**
Peak knee flexion (stance)	21.86	2.02	32.08	2.20	27.23	1.67	**0.001**	**0.003**
Peak knee extension (stance)	9.13	0.81	6.97	1.81	6.30	3.74	0.08	0.76
Peak knee flexion	49.18	1.96	57.56	1.58	52.29	2.16	**0.001**	**0.01**
Knee ROM	40.05	1.51	50.59	2.33	45.99	5.44	**<0.001**	0.19
Hip Kinematics								
Peak Hip flexion	60.92	0.58	69.03	1.10	73.54	1.60	**<0.001**	**0.005**
Peak Hip extension	8.38	0.84	8.91	0.50	16.16	1.55	0.35	**<0.001**
Peak hip flexion (stance)	58.34	1.26	66.67	1.00	68.98	2.22	**<0.001**	**0.02**
Hip ROM	52.54	1.18	60.12	1.11	57.38	2.45	**<0.001**	**0.04**
Temporal-spatial parameters								
Cadence (steps/minute)	124.91	3.12	123.71	2.39	117.27	6.18	0.45	0.07
Stride-length (m)	1.08	0.04	1.19	0.04	1.13	0.04	**0.02**	**0.04**
Walking speed (m/s)	1.13	0.06	1.23	0.05	1.11	0.09	0.06	**0.01**

Key: SD – Standard deviation, Significance level $p < 0.05$, all values except p values in degrees, significant results in **bold**
[ά]Group 1 – Barefoot and AFO-FC non-tuned, group 2 – AFO-FC non-tuned and tuned AFO-FC

Appendix XII

Case study 7

Table XII.17 Results from descriptive analysis of kinetic data points between between barefoot, non-tuned AFO-FC and tuned AFO-FC for case study 7 (participant 7)

	Barefoot Mean	SD	AFO-FC non-tuned Mean	SD	AFO-FC tuned Mean	SD
Hip moments						
Peak hip flexion moment	0.93	0.18	1.14	0.10	1.10	0.12
Peak hip extension moment	-0.46	0.09	-0.53	0.10	-0.55	0.08
Knee moments						
Peak knee flexion moment	0.12	0.01	0.24	0.03	0.61	0.14
Peak knee extension moment	-0.82	0.10	-0.24	0.10	-0.13	0.03
Knee flex/ext moment at mid-stance	0.10	0.02	0.09	0.04	0.01	0.03
Ankle moments						
Peak ankle DF moment	0.64	0.17	0.88	0.02	0.95	0.04
Peak ankle PF moment	-0.04	0.02	-0.30	0.07	-0.50	0.02
Key: SD – Standard Deviation, all values in Nm/kg						

Appendix XII

Table XII.18 Results from descriptive and statistical analysis of kinematic data points and temporal-spatial parameters between barefoot, non-tuned AFO-FC and tuned AFO-FC for case study 7 (participant 7)

	Barefoot Mean	SD	AFO-FC non-tuned Mean	SD	AFO-FC tuned Mean	SD	Group 1 [ά] *p* value*	Group 2 [ά] *p* value*
Pelvic kinematics								
Peak anterior pelvic tilt	21.58	1.21	24.33	0.87	23.65	1.18	**0.01**	0.37
Peak posterior pelvic tilt	13.83	0.63	16.41	1.32	17.10	1.54	**0.02**	0.44
Pelvic tilt ROM	7.75	0.73	7.92	1.15	6.55	0.68	0.71	0.07
Knee kinematics								
Knee flexion at IC	13.94	3.00	5.92	2.29	13.12	1.70	**0.01**	**0.003**
Peak knee flexion (stance)	14.38	3.40	15.39	1.65	26.06	3.25	0.62	**0.001**
Peak knee extension (stance)	0.04	0.71	2.80	0.63	5.85	1.93	**0.001**	**0.03**
Peak knee flexion	60.36	3.48	68.72	3.40	67.93	2.95	**0.01**	0.64
Knee ROM	60.32	3.55	65.92	3.15	62.08	3.87	**0.02**	0.10
Hip Kinematics								
Peak Hip flexion	45.65	1.41	46.20	1.64	52.09	0.83	0.57	**<0.001**
Peak Hip extension	-0.96	1.33	1.92	1.05	1.87	1.80	**0.02**	0.94
Peak hip flexion (stance)	38.50	2.89	44.77	1.57	50.89	2.15	**0.01**	**0.01**
Hip ROM	46.61	1.73	44.27	1.76	50.22	1.47	0.09	**0.001**
Temporal-spatial parameters								
Cadence (steps/minute)	147.31	8.15	132.49	3.24	128.75	6.95	**0.01**	0.30
Stride-length (m)	0.97	0.05	1.09	0.05	1.17	0.04	**0.02**	**0.02**
Walking speed (m/s)	1.19	0.13	1.21	0.06	1.25	0.09	0.82	0.31

Key: SD – Standard deviation, Significance level $p < 0.05$, all values except p values in degrees, significant results in **bold**
[ά]Group 1 – Barefoot and AFO-FC non-tuned, group 2 – AFO-FC non-tuned and tuned AFO-FC

Appendix XII

Case study 8

Table XII.19 Results from descriptive analysis of kinetic data points between between barefoot, non-tuned AFO-FC and tuned AFO-FC for case study 8 (participant 8)

	Barefoot Mean	SD	AFO-FC non-tuned Mean	SD	AFO-FC tuned Mean	SD
Hip moments						
Peak hip flexion moment	0.69	0.06	1.00	0.05	0.81	0.10
Peak hip extension moment	-0.45	0.06	-0.70	0.10	-0.74	0.08
Knee moments						
Peak knee flexion moment	0.08	0.02	0.46	0.11	0.60	0.11
Peak knee extension moment	-0.67	0.03	-0.40	0.08	-0.08	0.09
Knee flex/ext moment at mid-stance	-0.28	0.01	-0.03	0.07	0.00	0.04
Ankle moments						
Peak ankle DF moment	1.38	0.04	1.33	0.09	1.20	0.07
Peak ankle PF moment	-0.01	0.02	-0.31	0.01	-0.31	0.03
Key: SD – Standard Deviation, all values in Nm/kg						

Appendix XII

Table XII.20 Results from descriptive and statistical analysis of kinematic data points and temporal-spatial parameters between barefoot, non-tuned AFO-FC and tuned AFO-FC for case study 8 (participant 8)

	Barefoot Mean	SD	AFO-FC non-tuned Mean	SD	AFO-FC tuned Mean	SD	Group 1 [ά] *p* value	Group 2 [ά] *p* value
Pelvic kinematics								
Peak anterior pelvic tilt	19.03	1.79	19.56	0.95	13.89	1.63	0.91	**0.002***
Peak posterior pelvic tilt	14.76	1.58	15.17	0.97	9.37	1.76	0.99	**0.004***
Pelvic tilt ROM	4.28	0.49	4.38	0.54	4.53	0.63	0.71	0.57
Knee kinematics								
Knee flexion at IC	9.02	2.16	10.37	0.58	12.17	1.95	0.11	0.12
Peak knee flexion (stance)	14.24	1.72	17.76	2.44	20.71	1.61	0.11	**0.05***
Peak knee extension (stance)	-1.56	1.59	-0.26	1.21	4.97	2.06	0.13	**0.02***
Peak knee flexion	49.56	3.49	58.64	2.50	56.93	2.47	**0.02***	0.51
Knee ROM	51.12	3.00	58.90	3.43	51.95	4.28	**0.02***	0.10
Hip Kinematics								
Peak Hip flexion	36.44	2.16	44.03	1.26	41.09	1.96	**<0.001***	**0.03***
Peak Hip extension	-2.60	1.24	-0.39	1.66	-3.30	1.91	**0.001***	0.14
Peak hip flexion (stance)	35.49	1.51	42.97	1.34	40.91	1.97	**0.001***	**0.04***
Hip ROM	39.04	2.59	44.42	2.24	44.40	3.04	**<0.001***	0.94
Temporal-spatial parameters								
Cadence (steps/minute)	124.49	7.29	118.18	1.98	118.58	4.46	0.19	0.96
Stride-length (m)	1.01	0.03	1.27	0.02	1.23	0.05	**<0.001***	0.16
Walking speed (m/s)	1.05	0.06	1.26	0.04	1.22	0.09	**0.01***	0.31

Key: SD – Standard deviation, Significance level $p < 0.05$, all values except p values in degrees, significant results in **bold**
[ά]Group 1 – Barefoot and AFO-FC non-tuned, group 2 – AFO-FC non-tuned and tuned AFO-FC

Appendix XIII

Case studies investigating effects of increasing sizes of weges and Point Loading Rockers (PLR) on gait of children with cerebral palsy – tables with descriptive/statistical analysis of kinematic and kinetic data points.

Case study A

Table XIII.1 Results from descriptive analysis of kinematic data points between non-tuned AFO-FC and different sizes of wedges for case study A (participant 2)

	AFO-FC Mean	4°Wedge Mean	8°Wedge Mean	12°Wedge Mean	20°Wedge Mean
Pelvic kinematics					
Peak anterior pelvic tilt	19.8 (2.9)	19.2 (1.8)	16.7 (1.6)	18.2 (1.3)	15.9 (2.7)
Peak posterior pelvic tilt	5.2 (2.0)	4.7 (2.1)	3.2 (1.2)	5.2 (2.1)	5.6 (1.9)
Pelvic tilt ROM	14.6 (1.9)	14.4 (1.9)	13.5 (0.8)	13.0 (1.9)	10.4 (1.5)
Knee kinematics					
Knee flexion at IC	11.0 (2.9)	17.4 (4.6)	20.0 (2.8)	24.5 (2.0)	26.2 (1.6)
Peak knee flexion (stance)	26.2 (5.7)	29.9 (5.3)	30.8 (4.3)	35.4 (5.2)	42.1 (7.9)
Peak knee extension (stance)	-5.7 (0.8)	-0.7 (0.9)	6.5 (2.6)	10.9 (2.0)	19.2 (3.4)
Peak knee flexion	55.6 (1.7)	55.3 (2.8)	51.9 (2.5)	52.7 (3.0)	56.2 (3.2)
Knee ROM	31.9 (5.6)	30.6 (5.6)	24.3 (6.5)	24.5 (5.6)	22.9 (5.5)
Hip Kinematics					
Peak Hip flexion	37.4 (1.3)	38.8 (0.7)	39.0 (2.3)	39.3 (1.1)	43.7 (1.2)
Peak Hip extension	-5.1 (1.1)	-4.7 (1.0)	-2.5 (1.9)	-1.9 (1.9)	-1.1 (2.2)
Peak hip flexion (stance)	33.5 (4.2)	37.8 (1.7)	38.7 (2.7)	38.1 (2.6)	42.3 (4.3)
Hip ROM	42.4 (1.1)	43.5 (1.2)	41.6 (2.8)	41.3 (1.4)	44.8 (2.8)
Key: SD – Standard deviation, Significance level p < 0.05, all values except p values in degrees, significant results in **bold**					

Appendix XIII

Table XIII.2 Descriptive analysis of kinetic data points between non-tuned AFO-FC and different sizes of wedges for case study A (participant 2)

	AFO-FC Mean (SD)	4°Wedge Mean (SD)	8°Wedge Mean (SD)	12°Wedge Mean (SD)	20°Wedge Mean (SD)
Hip moments					
Peak hip flexion moment	1.02 (0.25)	0.70 (0.19)	0.95 (0.24)	0.97 (0.08)	0.94 (0.26)
Peak hip extension moment	-0.69 (0.15)	-0.52 (0.03)	-0.61 (0.03)	-0.52 (0.09)	-0.66 (0.21)
Knee moments					
Peak knee flexion moment	0.55 (0.09)	0.58 (0.00)	0.58 (0.07)	0.46 (0.11)	0.74 (0.14)
Peak knee extension moment	-0.18 (0.18)	-0.31 (0.06)	-0.16 (0.10)	0.00 (0.05)	0.17 (0.16)
Ankle moments					
Peak ankle dorsi-flexion moment	0.81 (0.21)	1.01 (0.07)	1.01 (0.04)	0.87 (0.05)	0.82 (0.20)
Peak ankle plantar-flexion moment	-0.45 (0.13)	-0.26 (0.04)	-0.38 (0.02)	-0.36 (0.08)	-0.52 (0.14)
Key: SD- Standard Deviation, all values in Nm/kg					

Case study B

Table XIII.3 Results from descriptive analysis of kinetic data points between non-tuned AFO-FC and different sizes of wedges for case study B (participant 3)

	AFO-FC Mean (SD)	4°Wedge Mean (SD)	6°Wedge Mean (SD)	8°Wedge Mean (SD)	12°Wedge Mean (SD)
Hip moments					
Peak hip flexion moment	1.22 (0.21)	0.73 (0.23)	0.76 (0.14)	0.70 (0.13)	0.65 (0.13)
Peak hip extension moment	-0.83 (0.36)	-0.62 (0.17)	-0.34 (0.05)	-0.75 (0.12)	-0.78 (0.15)
Knee moments					
Peak knee flexion moment	0.92 (0.23)	0.88 (0.24)	0.74 (0.14)	0.99 (0.05)	0.90 (0.21)
Peak knee extension moment	-0.44 (0.04)	-0.12 (0.03)	-0.31 (0.10)	-0.08 (0.08)	0.13 (0.12)
Ankle moments					
Peak ankle dorsi-flexion moment	1.11 (0.23)	1.27 (0.04)	1.31 (0.06)	1.27 (0.15)	1.33 (0.07)
Peak ankle plantar-flexion moment	-0.24 (0.17)	-0.22 (0.06)	-0.23 (0.01)	-0.25 (0.04)	-0.28 (0.04)
Key: SD – Standard Deviation, all values in Nm/kg					

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Table XIII.4 Results from statistical analysis of kinematic data points between non-tuned AFO-FC and different sizes of wedges for case study B (participant 3)

	AFO-FC Mean (SD)	4°Wedge Mean (SD)	6°Wedge Mean (SD)	8°Wedge Mean (SD)	12°Wedge Mean (SD)	p value
Pelvic kinematics						
Peak anterior pelvic tilt	27.3 (3.1)	25.5 (1.5)	25.1 (1.1)	25.2 (1.8)	25.0 (2.1)	0.20
Peak posterior pelvic tilt	18.1 (3.3)	16.3 (1.3)	14.7 (1.1)	16.1 (0.9)	15.0 (1.7)	**0.02**
Pelvic tilt ROM	9.2 (1.1)	9.1 (0.8)	9.7 (1.7)	9.2 (1.1)	10.0 (1.0)	0.67
Knee kinematics						
Knee flexion at initial contact	26.1 (4.7)	32.2 (2.5)	27.2 (2.3)	36.0 (2.7)	38.2 (1.4)	**0.00**
Peak knee flexion (stance)	37.0 (5.4)	41.5 (1.8)	36.8 (2.8)	46.0 (2.4)	46.8 (3.3)	**0.00**
Peak knee extension (stance)	16.8 (5.1)	28.4 (0.8)	16.0 (7.4)	31.0 (1.4)	32.4 (3.3)	**0.00**
Peak knee flexion	50.5 (2.9)	52.6 (4.0)	49.5 (2.8)	58.8 (2.2)	56.3 (2.3)	**0.00**
Knee ROM	20.1 (4.1)	13.1 (1.1)	20.8 (5.6)	14.9 (2.0)	14.4 (0.8)	**0.04**
Hip Kinematics						
Peak Hip flexion	47.8 (2.3)	47.3 (1.9)	46.0 (1.5)	48.0 (1.0)	48.0 (3.2)	0.29
Peak Hip extension	0.8 (2.8)	4.0 (2.4)	-0.2 (3.0)	7.5 (2.7)	5.8 (3.6)	**0.00**
Peak hip flexion (stance)	47.0 (2.9)	46.5 (2.1)	43.4 (2.9)	47.6 (1.3)	48.0 (3.2)	**0.03**
Hip ROM	47.0 (3.8)	43.3 (2.6)	46.1 (4.1)	40.5 (3.1)	42.3 (5.5)	**0.05**
Key: SD – Standard deviation, Significance level $p < 0.05$, all values except p values in degrees, significant results in **bold**						

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Case study C

Table XIII.5 Reuslts from statistical analysis of left kinematic data points between non-tuned AFO-FC and different sizes of wedges for case study C (participant 6)

	AFO-FC Mean(SD)	4°Wedge Mean(SD)	6°Wedge Mean(SD)	8°Wedge Mean(SD)	12°Wedge Mean(SD)	p value
Pelvic kinematics						
Peak anterior pelvic tilt	36.5 (0.8)	41.6 (1.1)	41.5 (1.6)	41.2 (1.8)	40.5 (1.0)	**<0.001**
Peak posterior pelvic tilt	27.2 (0.8)	31.3 (1.4)	31.5 (0.7)	31.4 (1.0)	31.0 (0.9)	**<0.001**
Pelvic tilt ROM	9.3 (1.1)	10.3 (0.9)	9.9 (1.5)	9.8 (1.4)	9.5 (1.5)	0.77
Knee kinematics						
Knee flexion at initial contact	26.8 (1.0)	18.6 (0.9)	23.2 (1.9)	24.0 (1.5)	25.5 (2.3)	**<0.001**
Peak knee flexion (stance)	32.1 (2.2)	27.8 (1.5)	32.3 (2.5)	33.6 (1.2)	36.8 (1.7)	**<0.001**
Peak knee extension (stance)	6.8 (1.7)	6.1 (3.8)	6.8 (2.2)	4.5 (2.7)	7.1 (3.0)	0.41
Peak knee flexion	57.6 (1.6)	52.3 (2.2)	53.4 (3.5)	55.6 (1.8)	55.5 (2.2)	**0.01**
Knee ROM	25.3 (2.6)	21.8 (3.9)	25.5 (2.5)	29.2 (2.4)	29.6 (2.1)	**<0.001**
Hip Kinematics						
Peak Hip flexion	69.0 (1.1)	73.5 (1.6)	74.7 (2.0)	74.0 (1.7)	75.3 (0.4)	**<0.001**
Peak Hip extension	8.9 (0.5)	16.2 (1.6)	15.1 (0.9)	14.3 (1.6)	15.1 (0.8)	**<0.001**
Peak hip flexion (stance)	66.7 (1.0)	69.0 (2.2)	71.3 (2.1)	71.7 (1.6)	72.0 (2.2)	**<0.001**
Hip ROM	60.1 (1.1)	57.4 (2.5)	59.6 (2.4)	59.7 (2.1)	60.2 (1.0)	**0.02**
Key: SD – Standard deviation, Significance level $p < 0.05$, all values except p values in degrees, significant results in **bold**						

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Table XIII.6 Reuslts from statistical analysis of right kinematic data points between non-tuned AFO-FC and different sizes of wedges for case study C (participant 6)

	AFO-FC Mean(SD)	4°Wedge Mean(SD)	6°Wedge Mean(SD)	8°Wedge Mean(SD)	12°Wedge Mean(SD)	p value
Pelvic kinematics						
Peak anterior pelvic tilt	36.5 (0.9)	41.5 (0.6)	41.4 (1.6)	41.3 (1.8)	41.1 (0.7)	**<0.001**
Peak posterior pelvic tilt	27.3 (0.8)	30.4 (1.3)	30.8 (0.9)	31.1 (1.1)	30.8 (1.5)	**<0.001**
Pelvic tilt ROM	9.2 (0.9)	11.1 (1.0)	10.6 (1.3)	10.2 (1.8)	10.3 (1.7)	0.26
Hip Kinematics						
Knee flexion at initial contact	29.1 (1.2)	22.8 (0.5)	27.2 (2.1)	27.8 (2.0)	29.4 (0.7)	**<0.001**
Peak knee flexion (stance)	35.5 (1.2)	35.8 (2.2)	38.7 (2.3)	38.4 (1.2)	40.9 (1.2)	**<0.001**
Peak knee extension (stance)	1.5 (1.6)	4.4 (2.1)	10.3 (3.3)	8.5 (1.4)	8.9 (2.6)	**<0.001**
Peak knee flexion	51.6 (1.0)	52.2 (1.5)	56.6 (1.3)	56.7 (1.5)	55.6 (1.2)	**<0.001**
Knee ROM	34.1 (1.0)	31.4 (3.8)	28.4 (1.6)	29.9 (1.9)	32.0 (2.7)	**<0.001**
Knee kinematics						
Peak Hip flexion	61.5 (0.8)	66.4 (0.9)	68.4 (1.4)	69.5 (1.2)	69.7 (1.4)	**<0.001**
Peak Hip extension	15.7 (0.8)	26.6 (2.4)	24.4 (1.6)	24.9 (1.6)	23.9 (1.0)	**<0.001**
Peak hip flexion (stance)	59.1 (1.8)	61.7 (2.6)	66.0 (1.2)	65.8 (1.8)	67.7 (2.3)	**<0.001**
Hip ROM	45.8 (1.0)	39.8 (3.2)	44.1 (2.0)	44.6 (2.0)	45.8 (2.0)	**<0.001**
Key: SD – Standard deviation, Significance level p < 0.05, all values except p values in degrees, significant results in **bold**						

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Table XIII.7 Results from descriptive analysis of left kinetic data points between non-tuned AFO-FC and different sizes of wedges for case study C (participant 6)

	AFO-FC Mean (SD)	4°Wedge Mean (SD)	6°Wedge Mean (SD)	8°Wedge Mean (SD)	12°Wedge Mean (SD)
Hip moments					
Peak hip flexion moment	2.17 (0.19)	1.57 (0.10)	1.85 (0.26)	1.76 (0.36)	1.88 (0.02)
Peak hip extension moment	-0.54 (0.07)	-0.42 (0.06)	-0.52 (0.10)	-0.62 (0.21)	-0.48 (0.04)
Knee moments					
Peak knee flexion moment	0.61 (0.12)	0.77 (0.08)	1.01 (0.05)	1.18 (0.07)	1.32 (0.14)
Peak knee extension moment	-0.22 (0.03)	-0.05 (0.02)	-0.06 (0.01)	-0.04 (0.00)	-0.05 (0.02)
Ankle moments					
Peak ankle dorsi-flexion moment	1.03 (0.03)	0.86 (0.03)	0.87 (0.05)	0.84 (0.02)	0.85 (0.05)
Peak ankle plantar-flexion moment	-0.15 (0.01)	-0.35 (0.01)	-0.46 (0.02)	-0.40 (0.06)	-0.63 (0.07)
Key: SD – Standard Deviation, all values in Nm/kg					

Table XIII.8 Results from descriptive analysis of right kinetic data points between non-tuned AFO-FC and different sizes of wedges for case study C (participant 6)

	AFO-FC Mean	4°Wedge Mean	6°Wedge Mean	8°Wedge Mean	12°Wedge Mean
Hip moments					
Peak hip flexion moment	1.40 (0.08)	1.24 (0.12)	1.18 (0.22)	1.20 (0.51)	1.48 (0.17)
Peak hip extension moment	-0.54 (0.11)	-0.59 (0.06)	-0.64 (0.01)	-0.77 (0.06)	-0.72 (0.07)
Knee moments					
Peak knee flexion moment	0.94 (0.09)	1.18 (0.03)	1.29 (0.03)	1.35 (0.33)	1.34 (0.22)
Peak knee extension moment	-0.30 (0.08)	-0.18 (0.04)	-0.08 (0.03)	-0.15 (0.06)	-0.13 (0.04)
Ankle moments					
Peak ankle dorsi-flexion moment	1.05 (0.08)	0.63 (0.04)	0.64 (0.05)	0.68 (0.21)	0.73 (0.03)
Peak ankle plantar-flexion moment	-0.12 (0.01)	-0.29 (0.05)	-0.37 (0.00)	-0.40 (0.10)	-0.47 (0.11)
Key: SD – Standard Deviation, all values in Nm/kg					

Appendix XIII

Case study D

Table XIII.9 Results of statistical analysis of kinematic data points between non-tuned AFO-FC and different sizes of rockers for case study D (participant 8)

	AFO-FC Mean (SD)	16mm Rocker Mean (SD)	32mm Rocker Mean (SD)	p value
Pelvic kinematics				
Peak anterior pelvic tilt	15.5 (0.8)	17.2 (0.5)	16.7 (0.8)	**0.02**
Peak posterior pelvic tilt	11.5 (0.8)	12.1 (1.1)	12.3 (0.8)	0.37
Pelvic tilt ROM	4.0 (0.6)	5.0 (0.6)	4.4 (0.6)	0.07
Knee kinematics				
Knee flexion at IC	8.4 (1.3)	7.8 (0.8)	7.0 (0.8)	0.22
Peak knee flexion (stance)	15.8 (2.2)	18.4 (0.5)	14.1 (1.8)	**0.007**
Peak knee extension (stance)	1.5 (2.5)	-3.0 (3.4)	-3.0 (1.2)	**0.004**
Peak knee flexion	57.2 (1.1)	53.8 (3.3)	50.0 (0.7)	**<0.001**
Knee ROM	55.6 (3.6)	56.8 (5.2)	52.9 (1.7)	**0.02**
Hip Kinematics				
Peak Hip flexion	39.8 (1.0)	41.3 (0.7)	41.2 (1.1)	**0.03**
Peak Hip extension	-1.5 (1.3)	-2.8 (2.0)	-3.8 (0.7)	**0.04**
Peak hip flexion (stance)	39.1 (1.6)	40.0 (1.1)	39.3 (0.8)	0.5
Hip ROM	41.3 (1.7)	44.0 (2.0)	45.0 (1.5)	**0.002**
Key: SD – Standard deviation, Significance level p < 0.05, all values except p values in degrees, significant results in **bold**				

Table XIV.10 Reuslts from descriptive analysis of kinetic data points between non-tuned AFO-FC and different sizes of rockers for case study D (participant 8)

	AFO-FC Mean (SD)	16mm Rocker Mean (SD)	32mm Rocker Mean (SD)
Hip moments			
Peak hip flexion moment	0.86 (0.28)	0.96 (0.06)	1.16 (0.10)
Peak hip extension moment	-0.54 (0.22)	-0.72 (0.12)	-0.64 (0.07)
Knee moments			
Peak knee flexion moment	0.20 (0.02)	0.40 (0.00)	0.33 (0.06)
Peak knee extension moment	-0.44 (0.05)	-0.51 (0.09)	-0.51 (0.02)
Ankle moments			
Peak ankle dorsi-flexion moment	1.26 (0.08)	1.35 (0.10)	1.44 (0.03)
Peak ankle plantar-flexion moment	-0.21 (0.01)	-0.30 (0.04)	-0.32 (0.06)
Key: SD – Standard Deviation, all values in Nm/kg			