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THE EFFECT OF ORTHOTIC TUNING ON THE ENERGY COST OF WALKING IN CHILDREN WITH CEREBRAL PALSY

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ABSTRACT

Introduction

Children with cerebral palsy (CP) often have to wear orthoses to help them walk. There is a growing body of evidence that orthotic tuning, that is, optimisation of the ground reaction forces in the lower limbs during walking, is recommended to ensure the maximum potential benefit for each child. Research demonstrates that orthoses can reduce the energy cost of walking for children with CP, but to-date there is no evidence as to whether this tuning process results in further energy efficiency or not [1].

Aim

The aim of this research programme was to validate a method that would help to determine when an orthosis was optimised for each child; and then to investigate whether the use of orthoses that were optimally tuned for each child allowed a further reduction in energy cost during walking, compared with orthoses that had not been optimally tuned.

Method

A video vector system was used to allow visualisation of the alignment of ground reaction forces in relation to the lower limbs during walking. A simple measurement tool was validated that allowed quantification of the moment arm at the knee in stance, which was used to confirm when optimal alignment had occurred following orthotic tuning. The energy cost of walking was measured using the Total Heart Beat Index (THBI). Data were collected barefoot, with the original 'un-tuned' orthosis and with the final 'tuned' orthosis.

Results

Analysis of energy cost showed that for some children, energy cost was further reduced through orthotic tuning, but that this was not the case for all children. Preliminary findings suggest the influence of underlying level of disability, as determined by the GMFCS.

Conclusion

Orthotic tuning may help to reduce the energy cost of walking for some children with CP, especially those with greater levels of disability. Further studies with large participant numbers are warranted to further investigate this area.

PUBLICATIONS

Reference data for the Total Heart Beat Index for children, aged 7-16 years, without walking problems. Evans, H and Pinnington, L. Presented at 10th Annual Meeting of the Clinical Movement Analysis Society, 2011, London, UK.

The effect of orthotic tuning on the energy cost of walking in children with cerebral palsy. Evans, H and Pinnington, L. Presented at 17th Annual Meeting of the Clinical Movement Analysis Society, 2018, Dublin, Ireland.

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ABBREVIATIONS

AAAFO	Angle of the Ankle in the Ankle Foot Orthosis
AFO	Ankle Foot Orthosis
AFOFWC	Ankle Foot Orthosis Footwear Combination
ASIS	Anterior Superior Iliac Spine
Ba	Barefoot at 1st session (pilot clinical trial)
Bb	Barefoot at 2nd session (pilot clinical trial)
BTXA	Botulinum Toxin A
CHQ	Child Health Questionnaire
CMAS	Clinical Movement Analysis Society
CP	Cerebral Palsy
CV	Coefficient of Variation
DAFO	Dynamic Ankle Foot Orthosis
DF	Dorsiflexion
DVD	Digital Video Disc
ECG	Echo Cardiogram
EEI	Energy Expenditure Index
EMG	Electromyogram
ER	External Rotation
FAFO	Fixed Ankle Foot Orthosis
FES	Functional Electrical Stimulation
GC	Gait Cycle
GMFCS	Gross Motor Function Classification Scale
GMFM	Gross Motor Function Measure
GRF	Ground Reaction Force
GRFO	Ground Reaction Force Orthosis
HAFO	Hinged Ankle Foot Orthosis
HRM	Heart Rate Monitor
HR_{net}	Net Heart Rate
IC	Initial Contact
ICC	Intra-Class Correlation

IQR	Inter-Quartile Range
IR	Internal Rotation
ISPO	International Society for Prosthetics and Orthotics
LAPSE	Long-term Ambulatory Physiological Surveillance Equip.
MAS	Modified Ashworth Scale
Movement ABC	Movement Assessment Battery for Children
MSt	Mid-stance
MTP	Metatarsophalangeal
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
OGS	Observational Gait Scale
ORLAU	Orthotic Research and Locomotor Assessment Unit
PBS	Paediatric Balance Scale
PCI	Physiological Cost Index
PCCI	Propulsion Cardiac Cost Index
PEDI	Pediatric Evaluation of Disability Inventory
PF	Plantarflexion
PLS	Posterior Leaf Spring (orthosis)
PODCI	Paediatric Outcome Data Collection Instrument
RER	Respiratory Exchange Ratio
RG	Reference Group
ROM	Range of Motion
RHR	Resting Heart Rate
SAFAFO	Shank Angle to Floor of the Ankle Foot Orthosis
SAFAFOFWC	Shank Angle to Floor of the AFO-Footwear Combination
SCI	Spinal Cord Injury
SDR	Selective Dorsal Rhizotomy
SMO	Supra-Malleolar Orthosis
SWOC	Standardised Walking Obstacle Course
T	Tuned (pilot clinical trial)
THBI	Total Heart Beat Index

TO	Toe-off
TSt	Terminal Stance
U	Un-tuned (pilot clinical trial)
UL	Upper Limb
VCR	Video Cassette Recorder
VE_{net}	Ventilatory Cost of Walking
VO_{2net}	Oxygen Cost of Walking
VVS	Video Vector System
WeeFIM	Children's Functional Independence Measure
WHR	Walking Heart Rate

CHAPTER 1: INTRODUCTION

1.1 Background

Children with cerebral palsy (CP) frequently have problems with their walking. Orthoses (splints) are commonly used to help support the feet and ankles of these children during walking [1]. Whilst there is an abundance of research highlighting the overall benefits of orthoses for this population, more recent research has suggested that further improvements in gait pattern can be obtained by adjusting the prescription of the orthosis for each child, and is therefore recommended [1]. However, this field of orthotic optimisation is still relatively new and further research is required to clarify the benefits for different aspects of walking problems, in particular on the energy cost of walking [1].

Determination of the benefits of an intervention for a patient group is an important part of their management to ensure that they receive a treatment that has a recognised evidence base.

The aim of this research was to develop a method to assist in ensuring that orthotic prescription was optimised, and further to examine the effects of this optimisation on the efficiency of walking in children with CP.

This chapter (1) aims to provide a background and rationale for each of the studies undertaken and discussed in this thesis. Chapters two and three provide an introduction to cerebral palsy and in particular walking problems in CP and the treatment options available to improve walking. Chapter 4 describes the technological background for the video based system used to determine orthotic optimisation; and Chapter 5 discusses the methods available to assess energy cost of walking as an outcome measure, highlighting the protocol used within the pilot clinical trial.

Chapter 6 provides a background and extensive critical appraisal of the use of orthoses in the management of walking problems in CP, placing the current research plan and findings into context. It critiques the methods used within published literature to assess the effect of orthoses on walking, justifying the rationale behind the protocol selected for the pilot clinical trial.

The aims and objectives of the series of studies are then presented (Chapter 7), along with the study hypotheses and thesis plan.

In the subsequent chapters the various studies are described and results presented and discussed in line with the aims of the research: Chapter 8 outlines Study One: a national survey of gait laboratories to determine current practice in use motion analysis equipment and energy cost measures for orthotic tuning; Chapter 9 presents Study Two, which investigates the validity and reliability of the outcome measures; and Chapter 10 provides the results from Study Three: the pilot clinical trial, in which data for these outcome measures were obtained from a group of children with CP before and after orthotic tuning, and from a group of children without CP.

Chapter 11 provides an overall discussion of the research programme and findings in relation to the study aims and hypotheses, and considers the implications for clinical practice; and concludes the research findings, making suggestions for future research.

CHAPTER 2: CEREBRAL PALSY

2.1 Introduction

Cerebral Palsy (CP) has been defined as "a group of permanent 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" [2].

Asides from the motor dysfunctions, CP is often associated with problems with cognition, communication, behaviour, sensation and perception, as well as epilepsy and secondary musculoskeletal effects [2]. It is generally accepted that the term cerebral palsy (CP) may be applied to any brain abnormality that develops in-utero, around the time of birth or in 'early infancy' without any clear definition of this time [2-4]. This therefore includes acquired brain injuries (e.g. head injury, stroke, meningitis) at any stage in 'early' childhood, where the presentation is of similar patterns of neurological impairment to those affected around the time of birth [4].

2.2 Epidemiology

CP affects approximately 1 in every 400 children (1.5-3/1,000 live births) [5, 6], resulting in around 1,800 new diagnoses in Great Britain each year [7]. With improvements in health care provision, the number of very premature or underweight babies surviving the neo-natal period has increased dramatically, leading to a rise in the number of severely affected children with a diagnosis of CP [5, 8], which remains the most common cause of severe physical disability in childhood [9, 10]. There is a slightly higher incidence in males than females (1.33:1 [5]).

The exact cause of cerebral insult or injury is often unknown, especially in cases where the onset is either ante- or peri-natal [3]. Possible causes or risk factors can be postulated for each period of onset of cerebral damage.

Antenatal causes include maternal infection during pregnancy (especially early in pregnancy), abnormal brain development without clear cause, or very rarely a genetic disorder. Incidents during labour or the birth process include prematurity [11, 12], multiple births [11], complications in labour and problems with delivery including birth asphyxia or hypoxia, or low birth weight [5, 12]. Causes during early infancy may include illness or infection (e.g. meningitis or encephalitis), cerebral tumour, traumatic acquired brain injury (e.g. head injuries) or a cerebro-vascular accident, such as a cerebral bleed or blocked vessel, which can occur at any stage of brain development.

An increased risk of CP has been found to occur where the mother is over 40 years old, either parent is under 20 years old, or where the child is either the first born, or the fifth child onwards [5]. A combination of risk factors, including multiple births [11], will also increase the probability of a child having CP.

2.3 Presentation

The signs and symptoms of CP are widespread due to the varied nature and location of the causative cerebral damage. Thus, each person with CP is completely unique in his or her presentation and needs, which may range from a minor physical or learning problem, to severe and disabling dysfunctions of daily activity and learning. In addition, the presenting characteristics may alter over time (although the original brain injury is non-progressive) as a result of the effects of growth, development and therapeutic intervention [13, 14].

Specific problems secondary to growth and development, such as mal-rotated long bones, shortened soft tissues and altered muscle function occur due to the abnormal postures, delayed developmental milestones (such as standing and walking, and hence weight-bearing), and reduced

mobility often associated with this condition [15]. These are features peculiar to neurological damage to a developing brain and musculoskeletal system, as compared with damage to a mature system, such as occurs in adults with acquired brain injury, although the effects of abnormal posturing and immobility are similar in both groups.

Depending on the site, nature and severity of the brain injury, the presenting features may include any of the following [5]:

- Neuro-motor dysfunction – causing movement problems, as well as poor balance, control and posture. This is the main area of disability seen in CP.
- Sensory-perceptual impairment
- Problems with vision, hearing or speech
- Epilepsy
- Gastro-intestinal problems, commonly linked to poor gut motility
- Learning difficulties

Although the presenting features may be varied, the most common problem is one of motor control. Subsequently, a classification system based on motor dysfunction is often used:

- Spastic CP – where damage to the cerebral cortex results in poor control of movement and an alteration in muscle tone. This is the most common form of CP, affecting up to 86% of people with CP [5].
- Dyskinetic (athetoid) CP – in which basal ganglia damage presents as uncontrolled and involuntary changes in muscle tone, seen as spasms or jerks of the affected limb/s or whole body. It affects around 6% of the CP population [5].
- Ataxic CP – resulting from cerebellar damage and characterised by poor balance and spatial awareness, which manifests itself as a poorly co-ordinated and unsteady gait pattern, and / or tremors. This type affects around 4% of the CP population [5].
- The remaining small percentage (4%) are undefined [2]

Despite these classifications, a child commonly presents with a mixed pattern of features [5]. In order to define the features further, the pattern of limb involvement can also be described. The four main categories of involvement and their incidence are [5, 16]:

- Diplegia – where both lower limbs are affected to a greater extent than the upper limbs. This group accounts for anywhere between 22% and 55% of the CP population.
- Hemiplegia – where there is predominantly unilateral involvement (e.g. right upper and lower limbs affected more than the left side). Around 22% - 29% of people with CP have hemiplegia.
- Quadriplegia / tetraplegia – in which all four limbs are affected, often in combination with the head and trunk (around 25% population).

Monoplegia (single limb involvement) and triplegia (three limbs involved) are less commonly seen (incidence of around 1% for each).

Lastly, children can be classified according to their motor abilities. This can often be a useful prognostic tool, giving a prediction of future function as well as helping to highlight their current functional abilities and difficulties. The Gross Motor Function Classification Scale (GMFCS), presented and validated by Palisano et al [17], aims to do just this using a scale from I to V according to ability (see Appendix 1). Reliability testing across multiple centres and including 77 children, revealed excellent inter-rater reliability (0.93), and good test-retest reliability (0.79). This reliability has been corroborated further by Wood & Rosenbaum [18] in a further 85 children aged 2-12 years, and Bodkin et al [19] in 30 children. A child rated as GMFCS I has only very mild limitations in motor function, such as limited ability to run and jump or reduced exercise tolerance; whereas a child rated at level V on the GMFCS requires significant support to sit and be positioned, often has very little independent motor control over their head, trunk or limbs, and requires 24-hour care. Subsequently, the GMFCS is commonly used as a descriptor in the presentation of children with CP, allowing monitoring of their functional abilities over time, and more specifically has been

recommended as a standard demographic requirement of interventional studies involving children with CP [20].

2.4 Impact of CP on Gait.

As discussed earlier, the extent of disability can vary greatly in CP and many individuals are so severely affected that they are unable to walk (GMFCS level V). However, many do remain ambulatory for some, or most of their lives.

Gait problems are common in children with CP, with gait pattern, exercise tolerance or overall functional ability all being affected to a varying degree. The effect of these limitations on the child's development and psychosocial wellbeing should not be underestimated [21] and treatment planning should include modalities to optimise gait in the short term, in order to preserve walking function in the longer term.

Gait can be affected by several factors involved in the pathophysiology of CP. Torsional deformities of the lower limb bones (mainly the femur and tibia) can influence the overall alignment of the lower limb. However, they can also affect muscle biomechanics by altering the direction of muscle pull or lever arm of the muscle unit. Decreased, or more commonly increased muscle tone (spasticity) can lead to under or over-activity of certain muscle groups, leading to muscle imbalance, which can have a significant effect on gait pattern. Soft tissue shortening, and more severely, contracture, can affect the available range of motion at the joint, which can lead to compensatory patterns of movement at neighbouring joints in order to preserve function. Lastly, muscle weakness, often occurring in conjunction with altered muscle tone and tightness, increases this muscle imbalance and makes standing upright against gravity and the control of body segments difficult. [22-25].

2.5 Management of Gait Problems.

A range of treatment options are available to manage gait problems in CP, all of which aim to optimise gait by improving the biomechanical function of the lower limbs. This may involve focussing treatment on normalising bony alignment (which in turn promotes more normal muscle functioning); working to improve muscle imbalances in terms of muscle strength in synergistic and antagonistic muscle groups, and optimising muscle and soft tissue lengths to promote more normal functioning; and normalising muscle tone, which again facilitates more normal muscle functioning.

The treatment options available include:

- Physiotherapy
- Orthoses
- Surgery
- Pharmacological agents
- Functional Electrical Stimulation (FES)

These interventions are discussed below with reference to related research and to highlight their relevance to gait management in children with CP and to the aims of this research.

2.5.1 Physiotherapy

Physiotherapy often provides the mainstay of treatment for children with CP [6, 9], with the aim of helping to attain maximum functional potential [6], which often includes optimising gait.

The intensity of physiotherapy treatment and exact theories or techniques used may vary over time depending on the child's treatment goals and expertise of the treating therapist. To this end, the goals are specific to the child and their family and will vary greatly according to need, presentation and development over time. Research is inconclusive with regards to the effect of intensity of physiotherapy treatment on outcome [26, 27]. With

regards to treatment techniques used to facilitate gait, these include hands-on facilitation of normal movement and alignment [9], stretches and strengthening [28-30], positioning and functional activities to encourage attainment of specific developmental milestones [31] and to help normalise tone; hydrotherapy; the use of orthoses, standing frames and gaiters; as well as advice and education to parents, carers and teaching staff. Physiotherapists regularly assess gait problems and often provide specific gait re-education.

In summary, physiotherapists provide a range of therapeutic modalities to children with CP, and often have regular contact with the child and family. They are therefore able to monitor changes in ability or needs over time, which may include monitoring changes in gait function and orthotic requirement. Physiotherapy treatment can also influence orthotic prescription through treatments to optimise the range of ankle motion and muscle function around the lower limbs, which may influence the type of orthosis required.

2.5.2 Surgery

Surgery has always been a common intervention for gait problems in CP [32] and can involve improving bony alignment in the lower limbs; reinstating more normal muscle length (e.g. releasing contractures) to permit better muscle function; reducing spastic muscle tone [33], which in turn helps to reduce or minimise the development of deformity; and also directly affecting muscle function through specific muscle or tendon transfer techniques to restore muscle balance around a joint. The outcome of surgery can subsequently influence the orthotic prescription required, for example, by releasing a contracture of the calf, which will influence the position in which the ankle can be held in an orthosis and the functional requirements of the device. Furthermore, the use of an optimised orthosis can conversely influence the need for, and influence the type of surgery

required, for example, by helping to prevent contracture development, which may influence orthotic prescription.

The overarching aim of surgery is to improve or maintain a patient's function and thereby potential. The techniques by which these aims are met can be wide-ranging and vary according to the personal experience of the surgeon and institutional preferences [34], as well as emerging research into new techniques.

Selective Dorsal Rhizotomy (SDR) is another surgical approach, which is increasing in popularity for children with CP. In the UK, it is yet to be granted full NHS funding and research is currently being undertaken to investigate the effect of SDR on various outcomes. SDR works on the spasticity element of the underlying pathology, by surgical dissection of a portion (selective) of the sensory (dorsal) nerves (rhizomes) that are causing spasticity [35, 36]. Research is inconclusive and a long-term follow-up by a Swedish team [37] who present data from a study following 18 children for 15-20 years following SDR, identifies that, although improvements in spasticity were maintained, functional improvements were not sustained over time and in fact a deterioration in function is frequently seen. However, they report a reduction in pain over the longer term.

In contrast, the Dutch team of Bolster et al [38] present findings of a 10 year follow-up in 29 children with CP following SDR and report improvements in functional ability (using the GMFM) at the 5 and 10 year stages without any children reporting a deterioration in function.

It is due to these discrepancies that a current UK study (Commissioning Through Evaluation) is being undertaken to further understand the efficacy of this treatment [39].

2.5.3 Pharmacological Agents

Botulinum Toxin Injections

Injecting Botulinum Toxin A (BTXA) into spastic muscles is a common treatment intervention for children with CP [40-44], and acts on the normalisation of muscle tone element of management. BTXA is one of the neurotoxins produced by the bacterium Clostridium Botulinum [41]. Its therapeutic effect is based on the inhibition of acetylcholine release at pre-synaptic terminals of neuromuscular junctions [40, 41], thereby temporarily paralysing the affected muscle [41, 42]. This results in the elimination or reduction of muscle activity in the previously spastic or overactive muscle [43]. The effect is not permanent due to nerve re-growth via sprouting [42]. However, in the time period where the neuromuscular junction is paralysed, normal growth of the musculo-tendinous unit is permitted. The effect of BTXA is variable and cannot be predicted, with some patients experiencing immediate and long lasting effects, while others receive minimal, short-lasting or imperceptible benefit from the injections [43, 44].

During the period where the toxin is effective, a regime of stretches is usually applied with the aim of regaining soft tissue length. In terms of the effect on gait, an improved lower limb joint range often allows a more normal stance posture, with the heels closer to the floor and the knees more extended [40] allowing, for example, a better orthotic position to be cast. In addition to the stretching programme, exercises are often given to strengthen the antagonists, often weak in relation to the over-active spastic muscles. For example, dorsiflexors are strengthened following the use of BTXA for overactive plantarflexors. These benefits then allow a more normal gait pattern to be re-educated, with better heel strike, more normal kinematics at the hip, knee and ankle [40, 42], improved EMG activity [42] and improved gait parameters [40].

The effect of orthoses in promoting normal lower limb alignment and function during this period is key in augmenting the functional gains made from the combined BTXA and exercise programme.

Many children with CP will therefore have BTXA therapy in conjunction with orthotic management to control the spasticity element of the underlying gait problem but for the purposes of research, receipt of 'recent' BTXA should be an exclusion where BTXA itself is not under investigation.

Baclofen

Baclofen is an anti-spasticity agent that works globally to reduce tone by reducing the release of excitatory neurotransmitters [45]. It can be given orally or via an intra-thecal pump whereby the drug is given at spinal cord level. Side-effects can be a problem, with somnolence being predominantly reported using the oral method [46]. Both methods allow daily dosage, which can reduce the cyclical pattern seen with Botulinum toxin.

NICE guidelines recognise the benefits of oral baclofen in controlling spasticity that is reducing functional ability, or causing muscle spasm or pain [3], and the use of intrathecal baclofen for spasticity that isn't managed using non-invasive treatments, and where posture or function are affected as well as in the management of pain and to allow self-care. It highlights that suitable candidates are normally those with a GMFCS of III or more. However, a recent literature review [45] found low quality of evidence of any improvements using oral baclofen and called for further robust research.

In relation to orthotic management, children who take baclofen may have some reduction in overall tone, which can aid in optimal orthotic alignment.

2.5.4 Functional Electrical Stimulation (FES)

FES is a treatment modality used to stimulate muscle activity in a muscle that is not working to its full potential, often due to weakness. In the context of gait problems, its main use is to control ankle dorsiflexion and eversion during walking by stimulating tibialis anterior and the peronei muscles appropriately during the gait cycle (predominantly during the swing phase but with some carry-over during loading response, to help with forefoot lowering). It therefore promotes ankle dorsiflexion and eversion during swing, ensuring ground clearance to help prevent tripping; and pre-positions the foot and ankle ready for weight acceptance at the next step.

Postans & Granat [47] advocate the use of FES in the treatment of gait abnormalities in CP. In a study involving eight children, an increase in swing phase dorsiflexion, along with an increase in heel strike at initial contact in some patients was seen. They did note, however, that the benefits were restricted to some patients, with three children showing no change at all throughout the study.

More recently, Prosser et al [48] studied the use of FES in 21 children with CP (GMFCS levels I-II). They also found an increase in ankle dorsiflexion in swing and at ground contact over 7 months, and good compliance with the treatment (18 children completing data collection and deciding to continue with FES treatment). The study team excluded children who had received Botulinum toxin treatment, but highlight that a combination of the two may be an advantageous method of treatment for this group of patients. Limitations in sample size and length of follow-up were acknowledged.

Clinical experience suggests that FES may be useful for patients for whom orthotic management is not very well tolerated, and is a growing area for children with CP. However, it has some clinical limitations in that sufficient ankle range is required for it to be beneficial, and higher levels of spasticity in the plantarflexors can render it less effective. Lastly, tolerance of the sensation in children can be a problem, especially in younger ages, although

the paper above reports relatively good acceptability of this treatment for their selected cohort [48]. Furthermore, funding is currently limited within the UK, and an individual funding request may have to be made to gain approval for provision of this intervention, with some regional differences in agreement for this approval.

In relation to this study programme, FES is highlighted as a possible alternative to orthotic management for children CP but with limitations in terms of availability and acceptability in this young population.

2.5.5 Orthoses

Orthoses are external devices used to support or control a joint or limb [49]. Lower limb orthoses are often a key treatment modality for patients with walking problems, which includes, but is not exclusive to, children with CP [50-56] as well as those with other neurological conditions such as stroke [57], Spina Bifida [58, 59] and spinal cord injury [60].

The most commonly used orthoses prescribed to improve walking include those that are designed to control the foot and ankle during weightbearing, known generically as ankle-foot orthoses (AFOs) [61] and are therefore the focus of this research.

Orthoses have been used for many years to facilitate walking by controlling the position of the ankle and foot in an optimal alignment; assisting in controlling movements in place of weakened muscles; and resisting the action of spastic muscles, which may be creating unwanted movements. By controlling the alignment of the joints within the foot and ankle, AFOs can also promote more normal alignment in proximal joints such as the knee and hip; facilitate optimal muscle length for function; and prevent development of bony deformity throughout the lower limbs [16, 61-63]. Furthermore, muscular balance around the lower limb joints can be improved through a more optimal joint alignment [10]. All of the above can

lead to more normal sensory feedback during walking, which can in turn promote a more efficient gait [52, 61]. It is hypothesised that there is a reduction of pathological reflex patterns and abnormal tone [64-67], although clear evidence of this has yet to be found.

The specific prescription and function of AFOs depends on the exact underlying pathology and biomechanics of the foot and ankle. Individual assessment, fitting and re-assessment are required in order to ensure that the orthosis is optimised for each child. Although the prescription process is based on individual clinical examination, and hence orthoses are patient-specific, it is accepted that some adjustment is often required to the final orthosis once manufactured to make it absolutely optimum for each child and indeed each limb [1, 20].

In the case of ambulant children with CP there are many factors that affect their potential mobility. The stage of development is important, with research showing that the gait of healthy children continues to develop until at least the age of four years [68], with some authors arguing that changes continue to occur until the age of seven [69]. Developments include changes in foot-strike pattern (from flat foot contact towards heel strike) and in individual joint motion. Several factors may affect the gait of a child with CP, including their 'corrected' age versus actual age, allowing some compensation for prematurity, as well as frequent delay in attainment of developmental milestones. For example, a child with CP aged five years, may only have been walking for 1-2 years, compared with a healthy child who may have been walking for up to four years by this age.

Children's feet are very mobile during development and are at risk from the long-term effects of any poor alignment on ligamentous stability and bony development [16, 62, 63]. In CP, this is further compounded by the altered neuro-muscular function seen, and presents them with a high risk of developing foot deformity.

Additional factors that can affect the gait pattern of a child with CP include their underlying presentation and the effect of this on skeletal growth, muscle tone and imbalance; learning and behavioural issues; altered sensation; relative immobility and other co-morbidities. As a consequence, ambulant children with CP often require orthoses at some point during their childhood in order to facilitate standing, walking and 'normal' musculoskeletal growth, and all of the above factors need to be taken into account during the orthotic prescription process [70].

These proposed orthotic benefits have led to the prescription of orthoses being commonplace in the management of gait problems in children with CP.

Chapter 6 will provide further details about the range of orthoses available as well as a critical appraisal of the evidence base underpinning their use in the management of children with CP.

2.6 Summary

Gait problems in children with CP are complex, heterogeneous and can change over time as the child grows physically and matures developmentally. Management of these gait problems can involve a range of treatment modalities, each with the aim of restoring normal muscle and lower limb alignment and function. Use of orthoses is commonplace for many children who remain ambulant, often in association with other treatment methods. It is essential, therefore, that the orthotic prescription is optimised for each child, to ensure that maximal functional gains are possible.

CHAPTER 3: GAIT ANALYSIS.

3.1 Normal Gait

Walking is a term used to describe the reciprocal movement of the legs to support and propel the body forwards, whilst maintaining contact with at least one leg on the floor at all times (to distinguish it from running) [25]. The term 'gait' refers to the pattern of walking such that the gait pattern of different individuals can be described. Scientists have studied and described gait for many years, in increasing detail and complexity thanks to the advancement of camera and computer technology. From a series of still images depicting the body as a whole, to more specific methods that highlight body segments, the study of gait has progressed to the highly complex level of detail permissible today. Analysis within a gait laboratory, using state-of-the-art technology allows the study of joint kinematics, kinetics, temporo-spatial parameters and muscle activity (using EMG).

Because of the repetitive nature of walking, gait can be described as a series of gait cycles (GC), in which the legs move through a series of known movements. In turn, each gait cycle can be described as a series of phases, during which a set of known events or actions occur [25] for all humans who have reached the age of gait maturity [68] and whose gait is unimpaired. The description of these phases allows gait to be assessed and any anomalies described in an objective way to aid comparison over time and between individuals.

There are two distinct phases, the stance phase and the swing phase during which the limb is either in contact with the floor (stance) or is being moved forwards in preparation for the next step (swing). Each of these phases can be divided further into a number of sub-phases to allow greater definition of specific events.

Although some variations occur, a widely accepted breakdown of the gait phases is as follows [25]:

- *Initial contact*: a single point in time at which the foot contacts the floor, and signifies the start of the gait cycle and the stance phase.
- *Loading response*: a short phase (~ 10% GC) during which weight is transferred onto the stance limb and the forefoot is lowered to the floor. Weight is simultaneously offloaded from the opposing limb, as it enters swing phase.
- *Mid-stance*: during this phase (~10% to 30% GC) the walker stands on one limb (single leg stance) whilst the opposing limb is in swing phase, and moves from behind to in front of the stance limb. Stability of the stance limb is therefore paramount during this phase. The swing limb moves past the stance limb around mid-point of this phase, which for the purposes of this thesis is defined as 'mid mid-stance'. Perry [22] highlights that the ground reaction forces at the knee are minimised at this point in time, which is of specific interest to this thesis.
- *Terminal stance*: this phase (~ 30% to 50% GC) ends at the point at which the opposing limb contacts the floor. During terminal stance, momentum and progression forwards are maintained prior to transfer of weight onto the contralateral limb.
- *Pre-swing*: this is the final 10% of the stance phase (~ 50% to 60% GC) and is the second period of double support whereby weight is transferred onto the contralateral limb. Pre-swing ends as the foot is lifted off the floor and enters the swing phase.
- The *swing phase* is divided into three phases to describe the foot moving off the floor (initial swing), crossing the stance limb (mid-swing) and extending forwards in preparation for ground contact again (terminal swing).

3.2 Measurement of Gait

In order to detect and treat abnormalities in gait, we must be able to analyse and measure the gait pattern objectively. In this way, changes in gait over time or following an intervention can be determined, for clinical or research purposes.

There are many different methods by which gait can be assessed, each with their own advantages and disadvantages. The available methods are presented and their relative merits and downfalls discussed, particularly in relation to the assessment of gait following use of orthoses, in order to justify the methods used within this research. These include the following:

- Observation
- Video analysis
- Observational gait scales
- Computerised gait analysis
- EMG
- Video vector analysis
- Energy cost analysis
- Functional scales

3.2.1 Observation

Observation is the only way in which a true representation of the overall functioning of the person can be determined. It is inexpensive, requiring only the sight of the assessor. However, its limitations lead to limited reliability in the recording of findings (Kappa coefficients of 0.11-0.52, indicating slight to moderate inter-rater agreement [71]; ICC of 0.73 for between raters and Pearson product-moment correlation of 0.60 for within-rater agreement, indicating moderate reliability [72]). Observation alone requires the assessor to be able to absorb information from the whole body simultaneously and dynamically and can only occur in one plane at a time. The assessor must either make notes during the session or describe the features from memory once the patient has left, which threatens the

accuracy of the report. Furthermore, there are limitations in what can be described without a formal recording method (see section 3.2.3). Experience of the observer may also influence the reported findings. Lastly, this method also requires the patient to be able to walk for a sufficient number of passes for the assessor to observe all aspects of gait in sufficient detail to be able to comment upon them. This is not always possible when patients have limited mobility.

3.2.2 Video Analysis

A more functional method, at minimal expense, is video analysis. A permanent record can be made of an individual's gait for future reference. This record also allows the clinician to make detailed notes by viewing the gait pattern repeatedly until sufficient detail is gained, without the patient having to be present. This recording should be done with a static camera aligned perpendicular to the plane of motion being assessed, which may be moved to assess more than one plane [73]. Many departments in hospital or community settings now have access to a camera to allow a basic gait assessment to be undertaken. Most gait labs are equipped with a bi-planar video system, allowing simultaneous monitoring of the coronal and sagittal planes of motion (Fig. 1).



Figure 1. Bi-planar video image

Advancement of technology has seen several different recording and playback functions. Most simply, a video player with 'jog and shuttle'

function allows the motion to be viewed one frame at a time. A DVD recorder provides a similar function with a faster capture rate, and lastly recording directly onto the computer using video capture software allows the video to be reviewed directly onto the computer, with the ability to capture 'still images' easily from the video to insert into a report. All of these functions allow a detailed analysis, with the ability to pause the image to observe the interplay of different segmental levels and planes at each time point. This is impossible through real-time observation alone.

Observational analysis (both in real-time and with video recording) provides detailed information about very specific changes in gait (e.g. foot fall characteristics or subtle postural changes), which may be missed by the more technical methods that use a simplified model of the lower limb segments. Additionally, movements and involvement of the trunk and upper limbs can be assessed, which may not be modelled using motion analysis, but may play an important part in the overall gait pattern. A video also provides an accurate record of function on the assessment day. However, logging the narrative of a gait assessment even from a video still relies on the recording methods and styles of the assessor, and is open to great subjectivity leading to limited reliability [71, 72].

3.2.3 Observational Gait Scales

A range of observational gait scales are available that attempt to quantify the features noted from a gait assessment [10, 74-76]. These can be used during observational or video-based gait analysis. Each measure selects the features considered to be important to record, and many use an ordinal rating scale [76] to allow grading of the overall gait pattern, and a means of comparing repeat analyses objectively. Many of these have been validated and have varying levels of reported inter and intra-rater reliability, providing a simple and inexpensive tool for clinicians in the clinical setting. The Edinburgh Visual Gait Score [76] has been designed specifically for use in CP, and demonstrates good intra-observer and inter-observer reliability

(mean agreement of 70% between scores) in most dimensions; sensitivity to change; and a good correlation with computerised gait analysis (mean agreement of 64% between scores).

Mackey et al [75] examined the validity of the Observational Gait Scale (OGS), which is modified from the Physician Rating Scale, in children with spastic diplegia. They compared the results to those taken from concurrent 3D gait analysis but reliability testing found variable levels of reliability for different aspects of the scale (kappa values from 0.29 – 0.94).

Other scales, including the Visual Gait Assessment Scale for children with hemiplegic CP [77] have been developed, but none have been accepted universally as being valid and reliable for all children with CP.

It can be seen from the evidence discussed that, although there are several observational gait scores available, the reliability and validity of each are not fully substantiated. Furthermore, the sensitivity of the scales for determining orthotic efficacy has yet to be investigated.

3.2.4 Computerised Motion Analysis

Where a more specific and quantitative measurement of gait is required, for example prior to surgical treatment planning, 3D computerised motion analysis systems [78] can provide this in specialist gait laboratories. These systems, although relatively expensive, are becoming more widely accessible to clinicians and are now considered to be the gold standard for gait analysis [76], especially for people with CP [79] where gait patterns are often complex and treatment planning may involve multi-level surgery and multiple treatment options. Indeed, the recent NICE guidelines for SDR surgery [80] include the requirement for a 3D gait analysis prior to surgery. Motion analysis has the ability to provide accurate sets of data detailing the joint movements and forces involved, from which decisions regarding

treatment and management changes can be made, often in conjunction with video analysis.

Understanding the effect of the forces generated in the lower limbs during walking is key to the methods used within this research programme.

Motion analysis systems are based on the principle of modelling the body (often confined to the lower limbs for gait assessment) using markers, allowing the definition of segments (e.g. pelvis, thigh (femur), shank (tibia and fibula) and foot) and hence segment rotations, via complex mathematical calculations embedded in the software. The systems vary according to the type of marker used and method by which these are tracked during walking. Passive marker systems (e.g. Vicon[a], BTS[b], Qualisys[c]) use retro-reflective markers, which are tracked by cameras due to their luminescence, and require post-processing to label each marker. Active marker systems (e.g. CODA[d]) use markers that emit a unique signal of infra-red light, allowing automatic tracking of individual markers during data acquisition.

Both of these types of systems provide information about the movement of each joint during walking, which is presented as a set of kinematic graphs depicting the joint motion in three orthogonal planes (sagittal, coronal and transverse) throughout one gait cycle. Data are usually reported against a set of normative reference data collected within the same laboratory, from a comparable local population (i.e. age-matched), which allows identification of abnormal features or patterns. Published normative data sets are also available [22, 68, 81].

Where force plates are available, calculation of ground reaction forces in three orthogonal directions is permitted, allowing joint moment and

[a] Vicon, Oxford, UK. www.vicon.com
[b] BTS, Milan, Italy. www.btsbioengineering.com
[c] Qualisys Motion Capture Systems, Gothemburg, Sweden.www.qualisys.com
[d] Charnwood Dynamics Limited, Rothley, UK. www.codamotion.com

powers to be presented (kinetic data). This can be useful when considering interventions that may affect the underlying power generating abilities of the muscle groups [78]. Furthermore, alignment of these forces to the lower limb joints has been highlighted as an important factor in optimising efficiency of gait [56] and this concept underpins the theory used within this research programme.

Temporo-spatial parameters of gait can also be calculated using 3D motion analysis. These parameters can be compared against reference values and are frequently used to determine change secondary to treatment. Parameters such as walking speed, stride and step lengths, and cadence can be calculated as part of the motion data capture and are easy, single values to record and analyse. Care must be taken to compare to age-matched reference data, as factors such as height and age can affect the normative values. Furthermore, in children, the effect of development in both of these areas will naturally cause a change in these parameters over time, regardless of treatment or pathology – step length will generally increase with a gain in height and as a result speed often also increases (up to an optimal speed and certain age).

The disadvantage of these motion systems, apart from the cost and technical expertise required, is that segment definition can be limited, especially in relation to the foot, although progress has been made in this area more recently. Analysis is often confined to the lower limb; therefore, spinal and upper limb features are not noted. The accuracy of the data gained from these systems also depends on the reliability of the clinician performing the assessment, and within-centre variability can be high. Noonan et al [34] report the results of gait analysis in 11 patients with CP who were assessed in four different gait analysis laboratories, three of which used the same marker model. The study revealed high variability in kinematic joint motion measured between the centres, with up to 20° of difference highlighted. The transverse plane showed the worst consistency, with the sagittal plane being the most consistent. The implications of

Noonan's study suggest that the treatment outcomes recommended in different centres may vary according to the kinematic results obtained there, although they recognise that within-centre and intra-rater reliabilities are likely to be higher, therefore re-assessment within the same centre post-intervention is more likely to yield a true representation of change [34].

Skaggs and colleagues [82] have also investigated the reliability of gait analysis interpretation between centres, and found variable levels of agreement in the identification of problems and subsequent recommendations for surgery, concluding that although gait analysis provides more detailed information for the decision-making process, the interpretation of this data remained somewhat subjective, concurring therefore with Noonan et al [34].

Maynard et al [83] investigated the intra-rater and inter-rater reliability of the CODAmpx30 motion analysis system (used within Study Two, Chapter 9) and found similar outcomes to those described above with variable reliability for different outcomes (ICCs ranging from -0.41 to 0.94). They found better reliability for kinetic (ICC up to 0.94) than kinematic data (ICC up to 0.84); greater reliability for the knee kinematics (ICC 0.54-0.72) than the hip (ICC 0.15-0.50, for inter-rater reliability at different points in the gait cycle); and greater reliability with the same clinician between trials (ICC up to 0.94 compared with up to 0.76 for different clinicians).

Computerised motion analysis can therefore generate accurate and reliable data, which can be used to determine treatment effect. Moreover, it has led to a greater understanding of the mechanics of gait. However, as highlighted, the process can be cumbersome and time consuming, and limitations on segment definition will be further compounded by the use of an orthosis, which prevents accurate marker placement over certain bony landmarks.

3.2.5 Electromyography (EMG)

Where soft tissue surgery or Botulinum toxin therapy are being considered, knowledge of the activation pattern of the muscles involved during gait is useful [84]. EMG assessment is commonly included in gait analysis, and provides information about the timing, nature and duration of muscle contraction during walking [79]. Its relation to power is controversial due to the effect of placement, sub-cutaneous tissue, conductivity and temperature [79]. Therefore, clinical uses of EMG are usually limited to studying the activation pattern of the muscle. Often absent, prolonged or out-of-phase muscle activity is noted, suggesting weakness, poor innervation or spasticity, which may be addressed during surgery, or considered prior to rehabilitation. The effect of surgery or Botulinum toxin on this abnormal pattern can also then be reviewed post-surgery to determine the effectiveness of treatment [84].

EMG activity is determined by the use of surface or fine-wire electrodes. Surface EMG permits the assessment of superficial muscles only, but does not require indwelling electrodes to be inserted, a potential disadvantage when assessing children. Fine-wire EMG permits some of the deeper muscles to be assessed, but has some obvious disadvantages, such as pain and risk of muscle cramping [79] due to its invasive nature, and is not used routinely in paediatrics.

EMG analysis of lower limb muscles during orthotic use can be limited by the orthosis covering the muscle of interest (for example gastrocnemius).

3.2.6 Video Vector Analysis

The concept of the video vector system is based on visualisation of the ground reaction force vector in relation to the lower limb joints on a video image, permitting the immediate estimation of the kinetics about these joints without the need for full gait analysis. More specifically, alignment of the ground reaction forces in relation to the lower limb joints and segments

can be observed easily and the effect of treatments such as orthoses on this alignment can be determined. It can be used in young children and those who cannot tolerate full gait analysis. This method of assessment is growing in popularity for the assessment of orthoses due to its usefulness in determining the effect of orthoses on the alignment of the ground reaction forces in the lower limbs, and its ability to inform the tuning process [85]. It is for this reason that this method is selected for use in the study protocol. Chapter 4 provides a more detailed description of this type of analysis and its relevance to the research presented in this thesis.

3.2.7 Energy Cost Measurement

The assessment of energy consumption during gait has been used for decades as a means of evaluating the outcome of intervention in both able-bodied and disabled populations [86-91]. It is recognised that there are links between severity of disability, functional ability and energy cost [89, 92-95].

Children with CP are known to have increased levels of energy consumption during walking, compared with typically developing children of the same age [86, 96], which will affect functional capacity. Furthermore, there is a known relationship between severity of disability and energy cost [97]. High energy cost is often due to altered gait patterns, which include muscle over-activity, poor synergy between antagonistic muscle groups (co-spasticity) and hypertonia.

The main purpose of many treatment modalities aimed at improving gait is to gain a more efficient and biomechanically sound gait pattern. Therefore, a measurement system capable of observing and quantifying these improvements is key in recording this. Whilst motion analysis systems provide highly detailed and accurate information about the kinematic and kinetic changes seen following an intervention, they do not provide information about global function or efficiency.

Given the link between energy efficiency and functional ability, energy cost measures provide an objective outcome tool that correlates with functional potential [87, 93] and could provide a useful outcome measure to determine the benefits of orthotic tuning. A lack of prior evidence as to the effect of orthotic tuning on energy cost [1] led to this theory being tested within this study protocol.

Further information about energy cost measurements and a critical appraisal of the accompanying literature is found in Chapter 5.

3.2.8 Functional Scales

Many different functional scales exist that claim to detect changes in motor function over time or following an intervention [41]. These scales are more global than gait observation scales. Examples include the following, although many more exist [98]:

- Gross Motor Function Measure (GMFM) [99]
- Wee-Functional Independence Measure (Wee-FIM) [100]
- Child Health Questionnaire (CHQ) [43]
- Pediatric Evaluation of Disability Inventory (PEDI) [101]
- Movement Assessment Battery for Children (movement ABC) [102]

Each scale consists of different assessed dimensions and generates an overall score, as well as dimensional scores, that can be compared against reference values, and to previously collected data for an individual. Whilst they claim to be quantitative, they usually rely on the interpretation of the scale and the child's ability by an observer, who may be prone to bias or poor reliability.

Ketelaar et al [103] performed a systematic review of assessment measures of functional performance in children with CP, examining measurement tools commonly used in paediatric therapy and rehabilitation. The number

of studies or participants examined are not reported, but the review found 17 different reported measurement tools. This followed previous work (reported in Keetlar) examining publications from 1978 and 1989, which found that most measures were not valid or reliable, despite their common use. Keetlar et al found only two measures (GMFM and PEDI) that were valid, reliable and sensitive as discriminatory and evaluative measures. Whilst they accepted that other measures were valid and reliable as either discriminative or evaluative measures independently, they noted that if a measure is to be used repeatedly to assess children with CP over time, it needed to be capable of detecting small changes in behaviour and be able to discriminate between groupings. The authors found that many of the other measures, although claiming to be able to evaluate clinical change, lacked evidence of their reliability in this area. They also conclude that these two measures would complement each other in the assessment of a child with CP, as their focus was different, with the GMFM being scored by the therapist, and the PEDI being scored by the caregiver or someone more familiar with the child.

Caution should be taken, therefore, in using functional outcome measures to analyse change, to ensure that the required function is actually measured by the tool, and that validity and reliability are acceptable. However, it is acknowledged that the use of functional scales may provide meaningful feedback to clinicians and patients, as to the effect of disability and intervention on quality of life for this population.

3.2.9 Summary

There is a plethora of methods with which different aspects of gait can be assessed, both clinically and for research purposes. Each method has its advantages and disadvantages in terms of ease of data collection, sensitivity as an outcome measure, and functional relevance to the question being posed. Clinicians must therefore choose a method that is easy to apply in the clinical setting, and one that gives them clinically relevant information

in relation to their treatment aims. Researchers must select a method that gives them accurate and reliable data with which to support or refute their research hypothesis, which in itself should be clinically relevant to the population being studied.

Consideration was given to the limitations in use of simple video assessment, full motion analysis (including EMG assessment) and outcome scales for the assessment of orthoses, combined with the growing emergence of the use of a video vector system for orthotic tuning. Based on this, and a gap in the evidence of the effect of orthoses on energy cost, the study hypotheses (highlighted in Chapter 7) and methodologies were selected. A video vector system is used to provide a clinically relevant outcome measure during the assessment process to help determine optimal treatment, and an energy cost measure is used as a clinician-friendly, but functionally specific outcome measure to answer the study hypothesis. Study Two provides evidence of validity and reliability of the chosen measures.

CHAPTER 4: VIDEO VECTOR SYSTEM

This chapter describes the biomechanical principles underpinning the video vector system and its clinical application in the assessment of gait and orthoses.

4.1 Biomechanics

In accordance with Newton's III Law of Motion, it is recognised that each action has an equal and opposite reaction [25]. During walking the body exerts a force (due to its mass) on the floor, and the ground reaction force (GRF) exerts an opposing force on the body from this impact. If this force is applied about a pivot, then movement will occur. In the human body, the consequence of the GRF acting on the lower limb is movement of body segments about a joint. This is graphically represented in Figure 2.

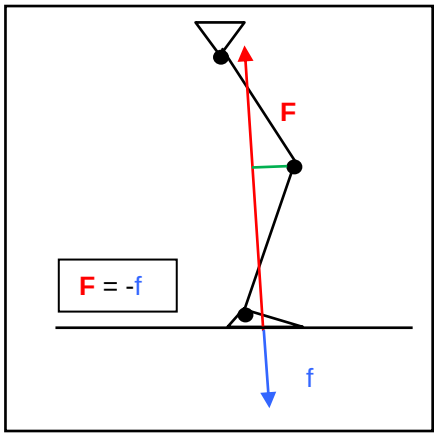


Figure 2. Illustration of ground reaction forces in gait.

A moment about each joint is generated that depends on the magnitude of the GRF, and the perpendicular distance at which this force acts from the joint (the moment arm), summarised by the equation:

$$\boldsymbol{M}oment\ (in\ Nm) = \boldsymbol{F}orce\ (in\ N)x\ \boldsymbol{d}istance\ (in\ m)$$

In the example of the knee joint, a GRF acting behind the knee will generate an external flexor moment, (Fig. 3), thereby creating knee flexion.

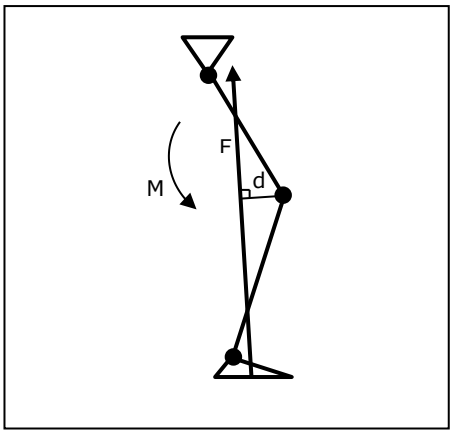


Figure 3. Illustration of moments and moment arm during gait.

In order to prevent collapse of the knee into flexion in the example shown above, the quadriceps muscle (knee extensors) would contract, creating an opposing internal extensor moment to that generated by the GRF [22]. If these two moments were equal, then collapse into flexion would be avoided, and this posture would be maintained, in equilibrium. Other smaller passive internal moments are generated by the ligaments, tendons and bone-on-bone forces, but these are generally considered to be insignificant in relation to the muscle generated internal moments [22, 25].

From this, we can deduce that the larger the moment created by the ground reaction force about the joint, the larger the opposing internal moment required by the opposing muscle group to counteract this, and therefore the greater the energy expenditure of that muscle.

From the equation M = F x d, the moment may be increased either by an increase in the force, F, or the distance, d, or both. Therefore, the greater the magnitude of the ground reaction force, and/or the greater the distance between the force vector and the joint centre (the moment arm), the greater the magnitude of the moment, and therefore of the opposing muscle contraction required to counteract it.

4.2 Clinical Implications of Ground Reaction Force

Kinetic data (moments, forces and powers) can be calculated during 3D gait analysis if the patient walks over a force plate during data collection. This can be helpful in determining the underlying causes of gait abnormalities, and in information potential management strategies. Data are compared with known reference values [25, 81, 104] and there is good understanding of the biomechanical significance of kinetic data. Furthermore, data from before and after intervention can be analysed to determine treatment efficacy. However, the results take time to collect and process.

In orthotic management, the need for repeated alterations to a device in order to optimise its fit and function takes considerable time. If the clinician was able to assess the device instantaneously during walking, make minor alterations and then re-assess to determine the optimal prescription, all within a session, then repeated appointments for fitting and assessment could be avoided, having both time and cost-saving implications for patient and clinician alike.

It has been shown that assessment of the position of the ground reaction force in relation to the knee, in the sagittal plane, is of great significance and clinical usefulness in orthotic management [52, 56, 105-107]. Not only are video vector systems being used clinically to assess the effectiveness of orthoses in children with CP [16, 52, 53, 78, 108] but also in the assessment of other conditions including Juvenile Idiopathic Arthritis [109], Muscular Dystrophy [110] and following traumatic brain injury [56]. By visually determining the position of the GRF in relation to the knee joint, in real-time, it is possible to deduce the likely effect on the joint in terms of an approximation of the external moment generated, and therefore the required internal moment to counteract this. For example, if the GRF could be viewed in the sagittal plane, and its distance from the knee joint centre visualised and measured (assuming to be posterior to the knee in this example), the resulting internal moment generated by the quadriceps

muscle could also be estimated, and the effect of an intervention, such as an orthosis, on these moments could be viewed immediately during the session. In this way, the benefits of an orthosis could be shown, and fine-tuning permitted (through alteration of components of the orthosis) to obtain the optimal and most efficient gait pattern for the patient.

Preliminary research [22, 52, 56, 107, 108, 111] has shown that the GRF lies close to, if not through the knee joint centre in the sagittal plane, during most of mid-stance in adults and children without walking problems. This means that the external and therefore opposing internal moments about that joint are minimal. In a child with CP, the position of the GRF is seen to vary greatly, but is commonly at some distance from the knee joint centre, either anteriorly or posteriorly (see examples in Fig. 4). Large *external* moments about the joint are therefore produced, and thus large opposing *internal* moments (muscle activity) are required to maintain an upright stance.

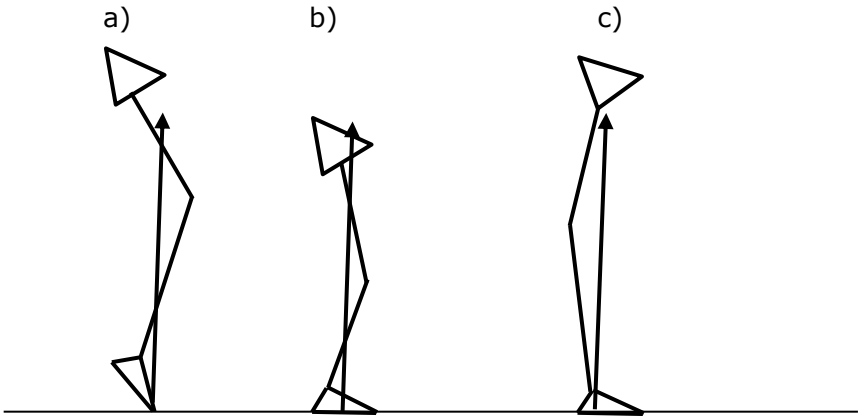


Figure 4. Examples of moment arm about joints in different gait postures.

Figure 4 illustrates some typical gait postures seen in CP. Examples a) and b) demonstrate crouch type patterns with large knee flexor moments, and smaller ankle dorsiflexor and hip flexor moments. Example c) shows a typical genu recurvatum posture, with a large knee extending moment causing the knee to hyperextend, and with smaller moments at the hip and ankle. This lower limb posture can also be seen with other causes of genu recurvatum, all allowing hyperextension of the posterior knee soft tissues.

With experience, it is possible for the clinician to assess these findings and decide what orthotic adaptations may be useful to correct the current discrepancy. If these changes can be made immediately, (even if initially temporarily) for assessment purposes, the child can be reassessed instantly, and the benefits seen. Thus, the process of fine-tuning an orthosis is possible, within a short space of time [1, 112].

Whilst it is possible to view this ground reaction force alignment within 3D gait analysis systems (visual representation of the GRF on a stick figure representation of the lower limb segments), it still requires full lower limb modelling. This can be problematic over orthoses and footwear (as marker placements have to be estimated), and takes time.

More recently video vector systems (VVS) have been developed which allow the ground reaction force vector to be viewed in real-time, concurrently with a video image of the person walking (un-hindered by markers or leads). As long as these two images are aligned and scaled accurately, the position of the GRF vector on the person can be viewed, and its distance from the joint of interest measured, and therefore the moments estimated (Fig. 5). The methods by which these types of system are set-up vary according to equipment and the technical expertise available within each laboratory, but the resultant image remains consistent.



Figure 5. Example of video vector image with vector overlaid onto video image.

4.3 Evidence-Base

Since the late 1970's it has been recognised that a reasonable estimation of torque or moment about a joint can be gained from the visual inspection of the ground reaction force and its position in relation to the lower limb joints [113-115]. This relationship between position of GRF and joint centre (i.e. magnitude of moment arm) influences the potential for movement about the joint, and hence the amount of muscle activity (and therefore energy) required to control this movement [61, 114, 116]. Furthermore, it has been recognised that through minimisation of the moment arm about the joint, energy can be conserved during walking [61, 105].

In 1979, Tait & Rose [115] described a VVS developed following earlier work by Cook et al (referenced in Tait & Rose, 1979), acknowledging that the assessment of calculated kinetics is not 'clinician-friendly', and that simple visualisation of the ground reaction force allows the clinician to assess its effect on the lower limb joints immediately, without the need for more complex kinetic calculations. The system uses force data fed from a force platform, along with video images gained from a simple video camera to generate an image illustrating the vertical ground reaction force superimposed onto the video image. They also highlight the potential clinical use of this system to assess the effect of an intervention such as orthotic prescription, on the gait of patients with a variety of conditions including CP.

Cook (1981) [114] further emphasises the clinical usefulness of the VVS, permitting rapid assessment and the ability to estimate moment arms from the relatively simple data.

However, Wells (1981) [116] reported some problems with using a projected GRF vector to estimate joint moments, comparing this method with the 'link segment method' which he considers to be more accurate and therefore the standard for comparison. Eight subjects with a range of

pathologies were studied, aged 7 – 72 years. He highlighted the neglect of the gravitational and inertial properties of the moving segments using the projected method. Whilst Wells' data highlights some problems with estimation of the moments about the hip, especially at the faster walking speeds attained by unimpaired participants (correlation coefficient of around r=0.7 for error of moment between the two systems and walking speed), data from the knee and ankle show a very good agreement between the projected moment calculation, and the model used as the gold standard (mean error between systems of <2.5Nm for all subjects, and <1Nm for most). Wells found that data from initial contact and pre-swing were the least reliable using the projected method due to the greater segmental accelerations found at these points. However, these were again mostly an issue at the hip. No further statistical analysis was performed in this small study.

Following this early work, the ORLAU[e] team in Oswestry, UK produced a commercial VVS, followed by many papers highlighting the benefits of using the VVS and its potential range of clinical usage [52, 53, 56, 85, 107, 108]. Eddison [1] completed a literature review on the effect of orthotic tuning on gait in CP, but found varying methods used to determine the tuning process and clearly highlighted the lack of quality evidence for this process. They found 947 papers relating to the study of AFOs, 153 of which involved children with CP, and 27 of which included some reference to orthotic tuning (although not all of these 27 related to children with CP). 15 papers were included in the final analysis, all relating to orthotic tuning in children with CP, from a variety of institutions. To date there are no published randomised controlled trials using a VVS either as a method to ensure optimal orthotic alignment or as an outcome measure in gait analysis, and only a few small within-subject case studies illustrating its beneficial use for specific interventions. This paucity highlights the need for further

[e]Orthotic Research Locomotor Assessment Unit, Oswestry, UK

investigatory work that could help to inform a larger randomised controlled trial.

Stallard [107] describes the benefits of a video vector system for the assessment of gait, and provides some description of the resultant GRF alignment in relation to the lower limb joints during normal walking. He identifies that, for most of stance, the GRF vector is aligned very close to the hip and knee joint centres in the sagittal plane, thereby minimising the joint moments and subsequently the opposing muscle action required. This is important for orthotic tuning and relates directly to the theory underpinning the proposed research question.

Butler & Nene [52] described the biomechanics of fixed AFOs in children with CP. Although their paper is mainly theoretical, it clearly describes the benefits of using a video vector system in the determination of optimal orthotic prescription, and, using single case-studies, highlights the fine-tuning process possible with VVS technology. Additionally, the paper illustrates the normal vector position in relation to the lower limb joints in a healthy adult. It represents a key paper for any clinician looking at the fine-tuning process, providing the essential principles underlying the biomechanical considerations of the fine-tuning process. One criticism of this paper is the lack of use of any objective outcome to quantify the benefits proclaimed in the text. Whilst it is clear to see the improvements in most of the examples, in subtler cases the implementation of these principles would be harder to apply without an objective measure.

Following this, Butler and co-workers [53] used their VVS principles more directly to assess the effect of orthoses, on six children with CP who demonstrated excessive knee extension in stance. This paper also presents a graphical illustration of the normal moment arm (as a percentage of height) throughout the stance phase, based on data from five non-disabled children, along with moment arms calculated from Winter's adult study [117]. This study included five children with hemiplegia and one with

diplegia, although abnormalities in the ground reaction forces were found bilaterally in four of the hemiplegic children. These children were each supplied with fixed AFOs (five children bilaterally, one child on the hemiplegic side only). Following a familiarisation period, the orthoses were then optimised using a VVS to bring the ground reaction force as close to normal alignment as possible at the knee. These children were then reassessed four to six months later, with a reduction in their orthotic prescription possible in three of the children (i.e. one side orthosis discontinued). This was only permitted once an improvement (towards normal) in the alignment of the vector at the knee during barefoot walking was gained. Statistical analysis showed a significant reduction in the maximum knee-extending moment arm at the knee compared with the barefoot data from the start of the study.

Further analysis of the videos of these children showed an improvement in footfall characteristics following intervention (heel strike achieved in some children who previously had a flat foot strike; and flat foot strike in a previous toe-striker). The authors propose a motor-learning theory to explain the improvements, suggesting that the learning experience of more normal sensory and motor inputs gained from optimal biomechanical alignment, led to the ability to maintain a more normal alignment even when barefoot, following the intervention period. This paper provides an objective outcome measure for the use with the VVS, with automatic calculation of the moment arm at the knee. However, it requires the use of their specific commercial system to generate this data, which excludes users of in-house systems. It clearly shows the advantages of using an objective measure, however, as they were able to clearly demonstrate the changes seen throughout the gait cycle, and furthermore they were able to provide statistical evidence of the improvements observed.

In a more recent paper, Butler and other co-workers [56] used the VVS to assess an adult following traumatic brain injury. An orthosis was provided following assessment, which was finely-tuned using a VVS to optimise the

GRF alignment at the knee. Once again, a commercial system was used to calculate the knee moment arm during stance to highlight the changes pre- and post-orthotic use. The illustrations show the difference that the fine-tuning process can make to the biomechanical functioning of the lower limb. Furthermore, long-term follow-up of this patient at four years showed an improvement in gait, even when barefoot. This paper also suggests a motor learning effect, given that barefoot improvements were found following intervention for a specific problem that was managed 11 years after the initial morbidity.

Farmer, along with different ORLAU co-workers, has also reported the benefits of VVS use in orthotic analysis. The papers are mostly abstracts, with case studies reported or the theoretical benefits of the system highlighted during conference proceedings [85, 118, 119]. In a case report [106] Farmer et al demonstrate the use of the VVS during an alternative treatment approach. The VVS is used to ensure optimal alignment in standing during 'Targeted Training'. Outcome measures include standing posture, mode of foot contact during gait, knee flexion angles during gait and popliteal angle. The study found improvements in standing posture, heel strike (with orthoses), and knee flexion during stance following three months of intervention. Popliteal angle did not alter after the first three months but was shown to be reducing at the six and nine-month follow-ups.

In different patient groups, only three papers were found to use the VVS as an outcome measure. Fairburn et al [109] used the VVS to categorise the different gait patterns found in 15 children with Juvenile Idiopathic Arthritis. Their VVS was developed in-house and resulted in a video image recorded onto VCR (as in Study Two of this thesis) with the GRF vector overlaid onto the image of the patient. Along with pedobarograph data the researchers were able to identify four gait patterns in this population. The authors comment that it would have been difficult to predict these findings using other clinical assessment methods. However, there is a lack of a clear objective outcome for the VVS assessment.

In a much earlier paper, using the ORLAU vector generator, Khodadadeh et al [110] assessed the moments and illustrated the GRF alignments in seven boys with Duchenne Muscular Dystrophy, and 21 boys without walking problems. The paper did not involve assessment of any intervention but reports on the importance of a knee extensor moment for these patients (generated by the plantarflexors), which is used to stabilise the knee in the presence of muscle weakness, which were highlighted using the VVS.

In 2002, Morris reported on the orthotic management of children with CP [120], highlighting the evidence-base for all aspects of their care. In the section on walking he clearly acknowledges the relevance of the assessment of the alignment of the ground reaction force in relation to the lower limb joints in the orthotic management of children with CP. His illustrations demonstrate the alignments of forces during different lower limb postures and the effect that orthoses can have on these force alignments.

Elaine Owen, a paediatric physiotherapist, has undertaken a range of research examining the tuning of orthoses and footwear combinations [70, 121-123]. In particular she has focussed on tuning the angle of the orthosis at the ankle to take into account the available range of motion, spasticity and aim of the intervention. She also considers tuning the resultant angle of the orthosis within the footwear (in terms of the inclination of the shank relative to the floor) to achieve optimal alignment of the knee at mid-stance. This is achieved by altering the pitch of the shoe to affect the inclination of the shank during standing. Furthermore, consideration is given to the design of the footwear (entry and exit rockers and heel-sole differential) and the importance of considering the whole orthotic-footwear combination is highlighted. It is Owen's work that originally fuelled this research, by recognising the importance of orthotic tuning and the potential for the use of the video vector system within this process.

Jagadamma has performed repeated work highlighting the importance of orthotic tuning in children with CP as well as adults with hemiplegia [124-126], helping to reduce abnormal knee hyperextension and extending moment in stance with an associated reduction in knee pain, as well as improving some temporo-spatial parameters. Jagadamma also found that improvements were greatest in children with knee hyperextension, compared with those with a crouch knee gait. Use of a video vector system was key in these studies.

Pratt et al [111], report a normal database for orthotic tuning in children. They used the above principles and a vector system to present the moment arm about the knee in 11 healthy children (aged 5-16 years). They also present normal values for shank inclination, highlighted as important from Owen's work. This paper is the first to present a normal paediatric database with more than five subjects. They used an in-house VVS system and normalised their data to leg length. Mean values at mid-mid-stance are presented, highlighting the importance of this point in time for orthotic tuning.

Quinn et al [127] report on the practicalities of a tuning service, with results from 27 children with CP (and 3 typically developing children). Children were assessing in 'usual AFO-FC' (AFO-footwear combination) and 'tuned AFO-FC'. They emphasise that the benefits of orthotic tuning using a video vector system are not only confined to specific gait benefits for their patients, but also that the process allows 'cost-effective minor adaptations' to 'increase AFO performance', and that visual feedback given to the patients can help compliance and understanding of the patient and family.

Lastly, Cole et al [128] evaluated the impact of the use of a gait laboratory during the rehabilitation of lower limb amputees, highlighting the benefits of VVS based assessment for various pathologies.

Although the findings from these papers are promising and suggest the clinical usefulness of the VVS, they are limited in number, generally use small subject groups, and rely either on visual estimation of any improvements, or on the use of a specific commercial system to allow a more objective measure to be obtained. In order to provide clear, objective, research-based evidence that the VVS can highlight deviations from normal, and can assess the effect of an intervention, the method by which its findings are assessed must be made more quantitative.

Further research into the use of the video vector system, especially in the field of orthotic analysis in children with CP where it is most commonly being used, is required to assess its benefits. Furthermore, the need for a clinician-friendly generic measurement tool is essential, to allow the benefits of the system to be defined objectively.

CHAPTER 5: ENERGY COST MEASUREMENT

5.1 Introduction

There are a number of different energy measurement tools available to clinicians and researchers. Each has its own merits and downfalls to consider prior to selection. A significant amount of published research has been carried out to compare and contrast these systems in normal and pathological populations [86, 87, 90, 95, 129-131]. However, despite this wealth of research, no conclusive decisions regarding the 'optimal' measure to use have been made. Each clinician or researcher must therefore make an informed decision as to which measure to use based on current research and available resources.

Clinically the two most popular methods of measuring energy efficiency are indirect calorimetry and indices based on heart rate measures [86, 87, 89, 90, 132].

5.2 Indirect Calorimetry

This involves the collection of inspiratory (O_2) and / or expiratory (CO_2) respiratory gases during walking. To do this, the participant must breathe in and out through a mouth or nosepiece to allow the respiratory gases to be collected. They also usually have to wear, or be attached to, the gas collection chamber. This specialist equipment can be costly. Within the field of paediatric gait analysis, it is widely felt that this kind of data collection is not suitable for this population [132-137], given the likely increase in anxiety and effort used during walking with this kind of system. Furthermore, it has been recognised that these methods of oxygen analysis assume a completely aerobic gait, which may not be valid in children with CP [87].

5.3 Heart Rate Indices

Heart rate measures are more widely used within the field of paediatric gait analysis due to their less imposing methodology [88, 89, 93, 129, 132, 138, 139]. They require the child to walk with nothing more than a lightweight heart rate monitor in situ, allowing unrestricted gait to be monitored.

One of the first researchers to suggest the use of heart rate monitoring in the estimation of energy expenditure was Andrews in 1967 [133]. He recognised that respiratory measures (calorimetry) were the accepted gold standard for measuring energy expenditure, but that the procedure for this data collection was somewhat invasive as well as time-consuming, which could negatively influence the results. His paper builds on previous work in the 1950's which examined a linear regression analysis of heart rate and energy expenditure values, and clearly showed a linear relationship between the increase in heart rate during exercise (working heart rate – resting heart rate) and energy expenditure (kcal/min). He did recognise, however, that the type of exercise (with or without arms) affected the exact details of the linear regression equation. Andrews also recognised that other internal (participant) and external (environmental) factors also have some influence on this relationship, an issue that should be considered when using heart rate measures.

Rose et al's paper later in 1989 [130] compared heart rate measures to oxygen uptake (ml/kg/min) in 18 unimpaired children, and 13 with CP (aged 7-17 years). The children walked on a treadmill at increasing walking speeds whilst heart rate and respiratory gases were collected. They also found a linear relationship between heart rate and oxygen uptake for increasing walking speeds in both groups, once weight was taken into consideration. This further substantiates the validity of using energy cost indices based on heart rate measures for the assessment of walking in children, including those with CP.

Davies [134] continued Andrew's work into the use of heart rate measures and further acknowledged the linear relationship between heart rate and work measures. Davies also recognised that external factors such as emotion, room temperature, noise and food intake can influence heart rate measures and suggested control of these factors during assessment. Davies reported the use of heart rate and speed measures separately to assess orthoses in a single-case study. Results showed an increase in walking speed, reduction in walking heart rate, and increase in overall distance walked during the assessment with orthotic use. She suggested, therefore, that measures of heart rate and speed could be used to assess the effectiveness and validity of orthoses for improving walking performance, where plain video recordings may show little change in overall gait pattern.

Stallard et al [137, 140], working from the same centre as Davies (ORLAU), continued studying the assessment of orthoses using heart rate and speed. They acknowledged that orthoses should reduce energy expenditure during gait, and that therefore a means of measuring this was required which was less cumbersome and more clinician-friendly than indirect calorimetry methods. They found similar results to Davies whereby patients gained an increase in walking speed with a reduction in heart rate whilst wearing orthoses. Their work highlights the advantages of being able to assess the effects of orthoses in the disabled population, and the ease with which these raw data (heart rate and speed) can be collected in this group.

Meanwhile, Macgregor [135] also considered the use of heart rate and speed for functional monitoring. His paper was the first to suggest combining the measures of heart rate and speed into an index to quantify energy expenditure during walking - the Physiological Cost Index (PCI). In this paper Macgregor identified that assessment of function must be included in order to assess disability comprehensively, and that some functional deficits do not show up during static testing. Macgregor recognised that small changes such as total walking distance, walking speed or effort required to achieve a task may alter during a period of 'illness',

therefore requiring a holistic approach to assessment. His measurement system (LAPSE[f]) enabled the individual to be monitored over a number of hours, and assessed function by means of monitoring movement of the thigh segment (to detect supine, upright and walking states). He highlights that walking is an easy function to observe, universally performed on a daily basis and was generally repeatable within individuals. From his research, he developed the PCI as an overall measure of the energy cost of walking. This index is now commonly used in the assessment of function and energy cost, and is especially used in the assessment of children with CP [88, 89, 93, 129, 132, 138, 139].

5.3.1 Physiological Cost Index (PCI)

The PCI is defined by the following simple equation:

$$PCI = \frac{Walking\ heart\ rate\ (WHR) - \ Resting\ heart\ rate\ (RHR)}{Walking\ speed}$$

It is therefore representative of the additional number of heartbeats (above resting level) required to walk at any given speed. With heart rate measured in beats per minute, and speed measured in metres per minute, the index results in a unit of beats per metre (bpm).

From this study [135] and further work [136], Macgregor found that the relationship between the PCI and speed was not linear, but in fact curvi-linear, and that the optimal (i.e. lowest) PCI was found at an individual's normal self-selected walking speed. Thus, walking at faster and slower speeds results in an increase in PCI. Macgregor's work also suggests an acceptable repeatability level (confidence interval) for PCI with a 99% CI range of 0.11 – 0.51bpm for unimpaired adults, and a mean of 0.31 ± 0.08bpm.

[f]LAPSE - Long-term Ambulatory Physiological Surveillance Equipment

Butler et al [132] continued this work on the PCI, and generated a reference database for unimpaired children (72 children, aged 3-12 years), with a mean PCI of 0.4 ± 0.13bpm whilst wearing shoes, and 0.38 ± 0.11bpm whilst barefoot. They also collected repeatability data from ten children, ten weeks later, and found changes of less than 0.2bpm in nine out of ten children (no statistical analysis). In addition to the reference database, they examined four children with gait problems (two with Spina Bifida, and two with CP, aged 6-11 years). They found that these children had PCI values significantly higher than unimpaired children. Furthermore, the reductions in PCI once wearing orthoses were markedly greater than the day-to-day variability seen in unimpaired children (improvements of 0.5 to 3.1bpm), suggesting a true clinical improvement (no statistical analysis).

Nene [141] provides a reference database of the PCI for adolescents (54 participants, aged 11-16 years) and adults (40 participants, aged 19-60 years). The found a mean PCI of 0.35bpm (±0.09, range 0.15 – 0.65bpm) for adolescents, and 0.36bpm (±0.08, range 0.2 – 0.55bpm) for adults.

The American group of Rose et al published research using the Energy Expenditure Index (EEI) [79, 90, 91, 130], which is mathematically identical to the PCI. Their work is also primarily with children (both unimpaired and with CP), and they further validate the linearity of heart rate measures against oxygen measures [130], with correlational coefficients (linear regression analysis) of 0.98-0.99 for individuals comparing the two measures, and a mean group coefficient of 0.83 in 18 unimpaired children and 0.84 in 13 children with CP. In a later paper [142] studying 102 healthy children (aged 6-18 years) they found a mean EEI of 0.49 ± 0.11bpm for girls, and 0.45 ± 0.14bpm for boys at self-selected walking speed. Further case studies in this paper involving three children with CP demonstrate the use of energy cost analysis to determine the benefit of intervention. They demonstrated improvements in the energy cost of walking with a specific walking aid (canes rather than walker) for one child; improvements following surgery for a second; and a lack of evidence of improvement when

using orthoses for a third child, resulting in the recommendation that orthoses were not required for this individual.

This latter paper [142] also compared the children walking at different speeds using a treadmill. Their results concurred with Macgregor's findings that an individual's most economic walking speed (minimum PCI/EEI) occurs at self-selected comfortable walking speed, suggesting an automatic conservation of energy during walking. The benefit of this during assessment is that subjects can walk at their own natural walking pace, rather than having an imposed consistent speed, allowing comparisons to be made (as the index includes walking speed value). This allows changes in the individual's gait parameters to be monitored (e.g. walking speed, cadence…) as well as the energy cost of walking.

Heart rate is generally measured during walking using a heart rate monitor, or using a telemetric ECG (electro-cardiogram) system to give a continuous heart rate reading. In theory, manual palpation of heart rate could be used, but this can only be applied after walking is completed, therefore not permitting calculation of a true mean walking heart rate.

Speed can be measured very simply using a stopwatch to record the time taken to cover a known distance.

The PCI has been used on various unimpaired and clinical populations ranging from adults and children with CP, to patients with spinal cord injury, amputees, paraplegics and adults post-stroke, in clinical and research settings. Changes in PCI post-intervention suggest that it is clinically useful, and it has been used to highlight the functional benefits of orthotic use in children with CP [88, 132, 143-148] and in adults with paraplegia [149].

However, despite this research base, the reliability and sensitivity of the PCI measure is still questioned [86, 87, 150] leading to some criticism of its use as an outcome measure.

5.3.2 Total Heart Beat Index (THBI)

An alternative heart rate measure is the Total Heart Beat Index (THBI) devised by Hood et al [151]. It uses the total sum of heart beats during the walking period, rather than the mean WHR used in the PCI. Instead of the mean walking speed, the total number of heartbeats is divided by the total distance covered, also giving a unit of beats per metre.

$$THBI = \frac{(total\ number\ of\ heart\ beats\ during\ walking\ period)}{total\ distance\ walked}$$

Hood et al suggest that the THBI has an improved reliability compared with PCI for unimpaired adults as well as patients with spinal cord injury, due to the fact that it does not rely on a stable resting heart rate reading within the calculation, or the attainment of a steady state during walking, both of which could significantly affect PCI results.

This well-designed study assessed 20 unimpaired adults and 17 patients with spinal cord injury (SCI). They compared their new index with oxygen consumption, oxygen cost and PCI, and investigated different proposed indices (using extra heart beats required during exercise; total number of beats during exercise; extra number of heart beats during recovery and total number of heart beats during recovery) before determining the optimal new index (THBI). Furthermore, both steady-state and non-steady-state conditions were examined to determine their influence on the outcome. The patients with SCI were divided into two groups. One group were assessed using their usual method of mobility (mainly a wheelchair) and then with their orthoses. A second group comprised patients who were participating in another European study (CREST) investigating the effect of Functional Electrical Stimulation (FES) on walking. They were therefore

assessed using their usual walking aid, and then again using FES. The steady-state test was performed using a figure-of-eight track, whilst the non-steady-state test was performed using a treadmill at increasing speeds.

The results demonstrate several findings:

- Steady-state walking in unimpaired adults occurred within three minutes of walking.
- A linear relationship exists between oxygen consumption and heart rate under both steady-state and non-steady-state conditions.
- Repeatability of 0.744 (ICC) for PCI for steady-state walking, and of 0.589 for non-steady-state walking.
- Repeatability of 0.950 for THBI for steady-state walking, and of 0.893 for non-steady-state walking.
- The THBI was sensitive to the differences in energy cost of walking for patients with SCI mobilising with their wheelchair compared with walking using FES.

The linear relationship to oxygen consumption and improved repeatability of the THBI should make it a more sensitive and more reliable measure for studying the energy cost of walking than the PCI. Furthermore, the high reliability for both steady-state and non-steady-state conditions makes it applicable to patient groups where steady-state walking is unlikely to be achieved, including children with CP. It is becoming more widely used, with recognition being given for its ability to determine energy cost in pathologies where steady state walking is not achieved [152].

Karimi [152] studied participants with flat feet and spinal cord injury, and healthy volunteers. They compared the PCI and THBI and concluded that neither were sensitive enough to quantify improvements with orthotic use, but in these subjects, the orthoses consisted of insoles or footwear alone.

Kanade et al [153] used the THBI in conjunction with walking speed and average daily strides, to assess 84 patients with a progressive range of foot

complications associated with diabetes (no history of ulceration; current and previous foot ulcers; trans-tibial amputation). THBI was found to increase with progression of foot problems, indicating its sensitivity to severity of disability.

Kim et al [154] assessed walking capacity in 50 patients with incomplete SCI, comparing the THBI and PCI. As expected, this study found that the THBI and PCI were lowest at the patient's self-selected walking capacity, rather than at an imposed level. The authors highlight the importance of allowing self-selection of walking speeds for clinical trials, to optimise walking ability for individuals.

Hartigan [155] report preliminary findings (conference abstract) from their investigation into the use of robotic exoskeletons for patients with SCI and following stroke, using THBI to determine walking efficiency. No specific THBI values are reported, but improvements in efficiency were noted with exoskeleton use.

Coutinho, Neto and Beraldo published two separate papers in 2014 [156, 157] comparing the THBI with PCI and a propulsion cardiac cost index (PCCI) during wheelchair propulsion. All three indices were reproducible, but the PCCI was more responsive in this population. Furthermore, the THBI and PCCI had a greater correlation to oxygen uptake than PCI for this group.

Meier [158] investigated three different prosthetic knee joints using THBI to determine differences in energy efficiency with differences noted with specific knee prescriptions, again highlighting the discriminatory sensitivity of the THBI.

Plasschaert et al [159] assessed the effect of simulating weight gain in children with CP. They studied 42 children with CP, and 42 unimpaired controls, aged 5-16 years. Their study provides a reference value of

1.49bpm (± 0.23) for the unimpaired group, and a mean of 2.64bpm (± 1.04) in their CP group, both without added weight. Both groups noted an increase in THBI with added weight (carried on a waist-mounted belt). It should be noted, however, that this study also collected indirect calorimetry data using a Cosmed K4b^2 system, which required the child to wear a facemask, and carry an analysis and logging unit on their chest. This additional weight in itself, and the use of the facemask over the nose and mouth, may have affected the results due to anxiety, alteration in breathing pattern due to facemask use, and increased energy expenditure due to carrying the logging unit and attachments. They furthermore report that they excluded data points with a respiratory quotient of 0.90 or greater as this was considered to represent anaerobic activity, highlighting the limitations in oxygen analysis for patients who go into an anaerobic state during walking. It is not clear if this also resulted in some heart rate data being excluded, which could influence the final THBI score calculated.

Horioka et al [160] used the THBI to investigate the relationship between lower limb strength and walking efficiency in 22 children with spastic diplegic CP. They tested lower limb strength and THBI in all subjects and then divided the cohort by GMFCS and then by walking efficiency (into two groups) and completed correlational analysis. They noted more children from GMFCS level I in the higher efficiency walking group, but no correlation with muscle strength. In the lower efficiency group, there were more children with GMFCS level II and a greater correlation with muscle strength. They concluded that muscle strength training may be more efficient for those with lower walking efficiency (higher THBI).

Due to the fact that the THBI proposes a greater reliability and sensitivity than the PCI, but has limited published evidence, for the purposes of the validation and reliability study (Chapter 9) both the THBI and PCI were investigated to provide further evidence for the reliability of each measure. This allowed the most reliable measure to be determined for the clinical trial (Chapter 10).

5.4 Energy Cost Protocols

Despite the array of evidence both for and against the use of the PCI for the measurement of energy cost, no consensus appears to exist as to the best protocol to use for data collection. The original paper [136] does not define the walking distance or time period to be used, nor the optimal walking track configuration for consistency, and lastly the protocol for defining walking and resting heart rate (i.e. whole of walk and rest periods, end of period, or last 'x' minutes of period) remains contentious. This issue may be the key to affecting reliability of the measure, and certainly presents a quandary for new researchers or clinicians wishing to start using energy cost measures.

Similarly, the THBI requires definition of the walking period and track configuration for consistency. Although Hood et al [151] clearly define their protocol, the paper by Kanade et al [153] uses just a 2-minute walk test and their track configuration (figure-of-eight, circular or straight track) and length remains undefined.

For this study, the relevant literature was examined to determine the optimal protocol for each index within the facilities available for testing.

5.4.1 Physiological Cost Index

Key papers using the PCI as a primary outcome were used to investigate the variability of methodology used, in order to inform the protocol used for Study Two within this thesis. Each aspect of the protocol is considered in light of the search findings.

For **resting heart rate** a period of one [161] to ten [87] minutes was used (where stated), with some additional requirements of positioning or further

resting once in standing [141, 150], where a supine position was used during initial resting.

During walking, a wide range of **activity durations** was found, from periods of two to ten minutes of walking (where stated) [87, 90, 142, 162] or distances of 24 [139] to 598 [86] metres. This area is least clearly defined within literature, with further variation in the **walking track configuration** used, from a straight path of varying length [139, 141, 142, 161], requiring a turn at either end, to figure-of-eight tracks [136] and treadmills [129].

Frequency of heart rate monitoring varied between every five and 15 seconds where stated [86-88, 151, 162, 163], or as a single value taken from the end of the walking or resting period [89, 138].

Definition of the **period** of time used for calculating working heart rate varied from the whole of the walking phase [86, 87, 139, 151] to heart rate at the end of each walk [89, 132, 138, 141] or a specific period of time at the end of walking varying from the last 10 seconds [90, 129], to the last three minutes of walking [88]. This is probably the most unreliable area, as the use of heart rate after walking, as compared with during walking is likely to produce differing results. As can be seen in Chapter 9, heart rate drops immediately after walking ceases, and therefore taking WHR values from the period after walking (up to one minute [161]) or even in the first few seconds after walking ceases, would produce lower results than calculations using heart rates during walking. Furthermore, the time taken to cover the very short distances reported by some [139, 161] could have been as low as 5 seconds for a healthy adult, which allows for very little change in heart rate.

For the validation and reliability study the following protocol for the collection of data for the calculation of the PCI was based on appraisal of the papers reported above.

5.4.1.1 The Resting Heart Rate

Resting heart rate was recorded over a period of five minutes, with the subject sat on a supportive chair, but ready to stand and walk once the testing started. This allowed the subject to become familiar with the test environment, to recover from the journey, and to relax into the session, allowing the heart rate to stabilise. Data from the last two minutes and the whole of this resting time (i.e. five minutes) were both investigated for the calculation of PCI, and the reliability of these was examined (section 9.3.4.2).

5.4.1.2 Working Heart Rate and Activity Duration

The walking period for the pilot clinical trial needed to be long enough to achieve steady-state walking, whilst remaining achievable for children with CP. Previous research indicates that steady-state walking is achieved after around three minutes [163, 164], and clinical experience suggested that a maximum of ten minutes walking time would be appropriate for the CP group. Therefore, for the validation study a ten-minute walking period was selected to allow the reliability of both a five-minute and ten-minute walking period to be investigated. Working heart rate was calculated both for the whole and for the last two minutes of these periods. Reliability of these different sets of data was tested and the results, presented in section 9.3.4.2, informed the final protocol for the clinical trial.

5.4.1.3 Walking Track Configuration

Critical appraisal of walking track configuration considered that use of a straight track would require repeated turns at the end of each walk, which would affect walking speed and could influence heart-rate if participants found turning more difficult than walking. Use of a circular track was deemed to have the potential for leg bias in subjects with asymmetric pathology, as the same leg would remain innermost throughout the walk.

Therefore, a figure-of-eight track design was used (see Figures 6 & 7) to ensure continuous walking for the whole of the testing period, with no leg bias. A 25-metre track was used for the validation study (Study Two), and a 20-metre track was used for the clinical trial (Study Three). The differences were due to a change in location of the study and the available space in which to mark out the tracks.

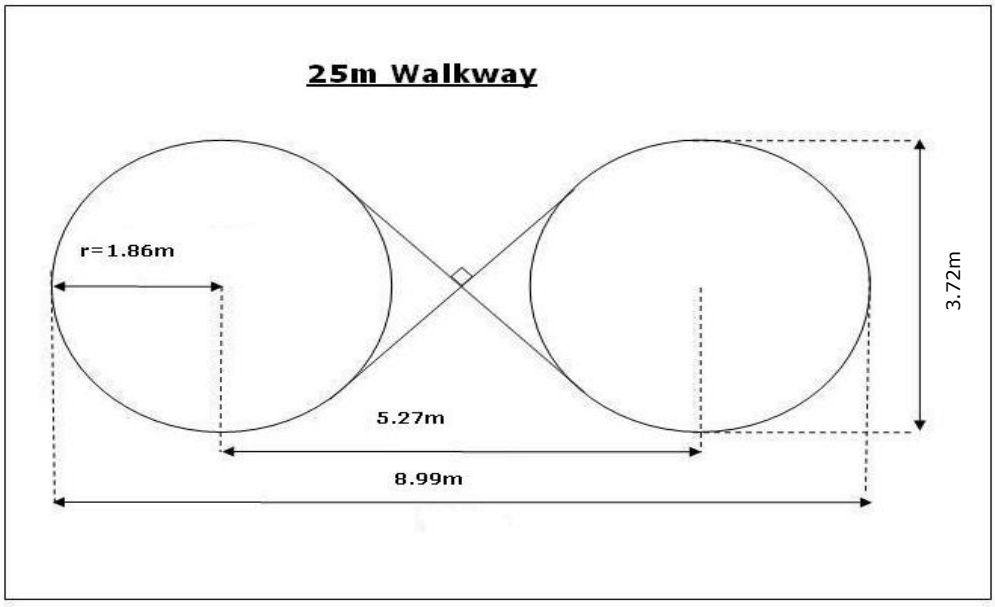


Figure 6. 25-metre figure-of-eight walkway schematic

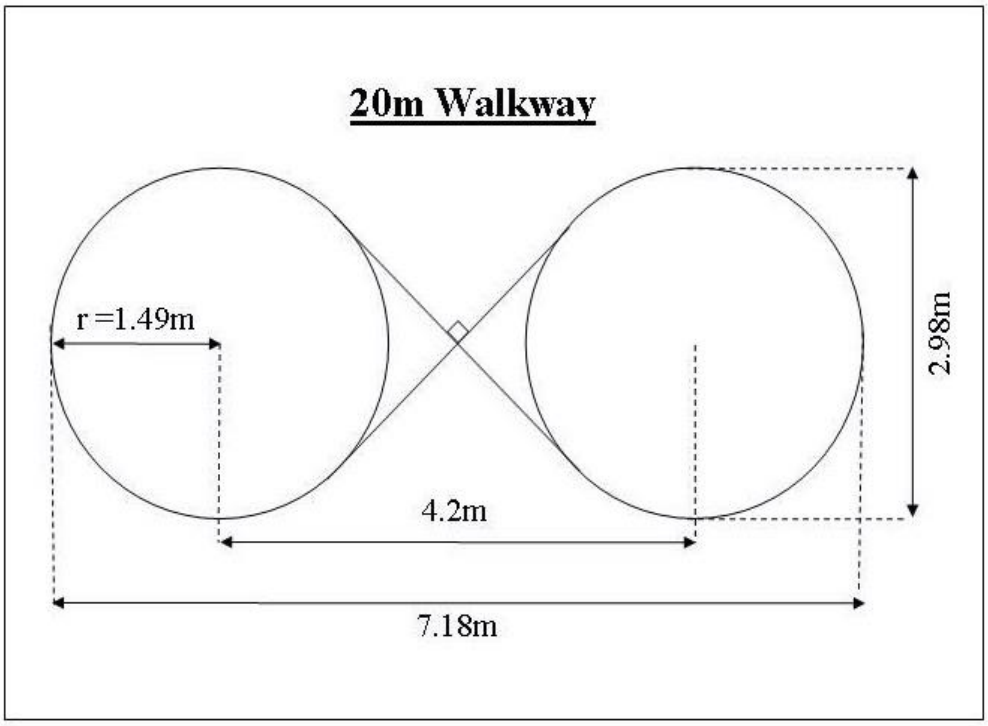


Figure 7. 20-metre figure-of-eight walkway schematic

5.4.1.4 Walking speed

Distances walked after five minutes and ten minutes were recorded, allowing average walking speeds for these periods to be calculated.

5.4.1.5 Frequency of Heart Rate Recording

For the validity study (Study Two) heart rate was recorded every five seconds using a Sport Tester Polar Heart Rate Monitor, to maximise the number of heart rate values available for the calculation of mean heart rate during rest and walking. For the pilot clinical trial (Study Three) heart rate was recorded every second using a newer RS800cx Bike Polar Heart Rate Monitor. Data from both were downloaded into the associated Polar software to allow it to be exported into Excel for analysis.

5.4.2 Total Heart Beat Index

The THBI used data from the whole of the walking period for both studies. For Study Two, the data used for the PCI calculation was also applicable to calculation of the THBI, and therefore the same protocol was utilised, that being:

- Resting period of five minutes to acclimatise to the laboratory, temperature, test procedure and eliminate any stress or anxiety from the journey to the session.
- Walking period of ten minutes, around a 25-metre figure-of-eight track, which was split into an initial five-minute and a total ten-minute walk for data comparison.

Heart rate was recorded as for the PCI. Walking distances were noted for the five-minute and ten-minute walking periods from markings on the walking track.

Total number of heart beats for the five and ten-minute walks were calculated by summing the heart rates (beats per minute) from each five-second period for each walk, and then dividing this by 12 to give total number of heart beats (12 five-second periods during each minute). THBI was subsequently calculated for the five and ten-minute walks.

For Study Three, the pilot clinical trial, an amended protocol was used for the THBI following the results of Study Two. Reasons are explained in Chapter 10 (Pilot Clinical Trial), but details are as follows. Participants rested for two minutes before starting a five-minute walk around a 20-metre figure-of-eight track. Heart rate was recorded every second on the newer heart rate monitor. This allowed the total for each walk to be calculated by summing the heart rate values for each second and then dividing by 60 to give total number of heart beats. Total distance walked was noted and THBI subsequently calculated.

CHAPTER 6: ORTHOSES

6.1 Introduction

As already noted, orthoses work by controlling the alignment of joints within the lower limbs, and as a result can affect the alignment of the ground reaction forces in the lower limb joints. The design features of an orthosis are crucial in determining its function. A difference in contact points, length and material can affect the forces that the orthosis applies to the limb and the movements that it controls [1, 165]. Ankle-foot orthoses may be categorised into groups according to their fundamental design. However, individual orthoses can be adapted in an infinite number of ways according to the needs of the user.

6.1.1 Types of Orthoses.

The following paragraphs provide brief descriptions of five basic orthotic designs often prescribed for children with CP.

The **fixed ankle foot orthosis** (FAFO) (Fig. 8) extends from the upper posterior shank (lower leg), across the back of the ankle joint and along to the toes. Its rigid nature, long lever, and three-point harnessing allows control of plantarflexion and dorsiflexion [49, 166], as well as motion in the coronal and transverse planes. Many different adaptations can be incorporated into the design to allow fine-tuning such as alteration in cast angle, trim lines around the malleoli and metatarsal heads, and thickness of material used. One limitation of this type of orthosis is that its rigid structure prevents normal shank motion during walking (movement of the tibia from a reclined to inclined position during the second rocker of the gait cycle; and ankle plantarflexion during the third rocker)[166], and can interfere with other functional activities such as sit-to-stand, squatting and stair climbing [167]. However, it remains the most commonly prescribed AFO in children with CP [1].



Figure 8. FAFO

The **hinged ankle foot orthosis** (HAFO) (Fig. 9) is essentially a FAFO that is cut across the ankle joint during manufacture, with a hinge inserted to allow free dorsiflexion, whilst preventing plantarflexion (the posterior sections abut). The HAFO allows more normal shank motion during the stance phase than a fixed AFO in patients who have sufficient range and minimal spasticity, giving a dynamic stretch to the calf complex, and makes squatting and sit-to-stand type movements easier [167].



Figure 9. HAFO

The **dynamic ankle foot orthosis** (DAFO) (Fig. 10) actually refers to the tone-reducing features of this type of orthosis, usually including a metatarsal dome to prevent toe clawing, and a raise under the first

metatarsal to reduce extensor spasticity. Advances in orthotic technology even in the last few years mean that a DAFO style insert can now be used with a more traditional AFO, but during the clinical trial within this study, DAFOs were generally a separate orthosis, shorter in length than either the FAFO or HAFO, extending just above the malleoli. The DAFO design is more closely moulded to the contours of the foot than a traditional AFO [166, 168]. It is made out of thinner material than the FAFO, which allows some flexibility. The DAFO usually controls plantarflexion through the solid posterior section, but allows free dorsiflexion as it is open anteriorly and the shank is not strapped back. The orthosis extends around the anterior and dorsal part of the foot allowing close control of the midfoot and subtalar joints [51, 169]. Adaptations can include a split in the posterior section to permit some plantarflexion if required.

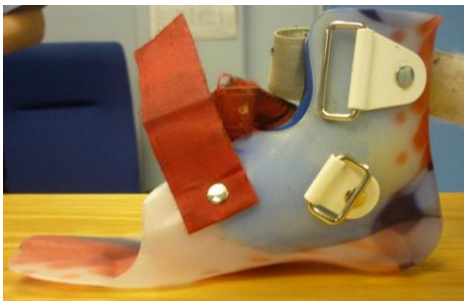


Figure 10. DAFO

The **ground reaction force orthosis** (GRFO) (Fig. 11) aims to control excessive knee flexion by preventing shank advancement over the foot during second rocker, and subsequently preventing early progression of the GRF vector along the foot or behind the knee [166]. It extends anteriorly on the shank up to the knee with a patellar notch which presses on the patellar tendon to promote knee extension [170]. The orthosis extends laterally and then posteriorly along the lower part of the shank to provide resistance to plantarflexion as well, thereby limiting the third rocker. Its design is based on the original Saltiel orthosis used for post-polio patients [166, 170], who presented with poor knee control. An alternative design is essentially a normal fixed AFO with an additional front plate (or shell), which provides the additional extensor force to the knee. This type of orthosis is not suitable

for patients either with a fixed knee flexion deformity of greater than 10° or genu recurvatum [166].



Figure 11. GRFO

An alternative, the **posterior leaf spring orthosis** (PLS) is often used to control ankle dorsiflexion during the swing phase, and provide some propulsion during toe-off [166] (Fig. 12). The PLS is less commonly used for patients with CP (based on local clinical practice) as it offers limited resistance to plantarflexor spasticity, but is mentioned here as it is referred to within the research papers discussed later in this section. The PLS is very narrow posteriorly, and made from a thinner thermoplastic which allows some flexibility [166]. It is not designed to resist strong plantarflexion, but allows some dorsiflexion during second rocker. Theoretically, this orthosis provides some power to plantarflexion at toe-off by 'springing' back to neutral from the dorsiflexion gained during stance, thereby assisting in propulsion at toe-off. However, the evidence to substantiate this is contradictory [143, 144, 171, 172].



Figure 12. PLS

A critical appraisal of the evidence of the effect of different orthoses is found within the literature review in section 6.3. More recently, it has been acknowledged that orthoses must be adjusted for each child to ensure optimal fit if they are to be effective, and it is felt that it is this 'prescription process' which influences the degree of success achieved.

6.1.2 Orthotic Prescription Process

The prescription process involves consideration of several different patient-specific factors as well as the expertise of the prescribing clinician. The prescriber's decision-making is partly subjective and is dependent upon experience, personal opinion, and the outcome of 'trial and error' [55]. The following considerations have been selected on the basis of prior clinical experience and the extensive work carried out by Elaine Owen and colleagues within this speciality [70, 85], which is becoming more widely accepted as a necessary part of the orthotic prescription process [1, 20, 173].

6.1.2.1 Patient Presentation Factors

A thorough examination of the lower limb is required prior to prescription, in order to gain information about the available passive ranges of movement, resting and dynamic muscle tone, active control and

biomechanics of the foot and ankle complex to highlight any structural mal-alignment or deformity [70, 173].

Range of available motion at the ankle is a key consideration, but the presence of hip or knee flexion contractures will also influence the final prescription detail, possibly requiring some wedging at the heel to accommodate these and facilitate heel contact. More specifically, available range of motion in the gastrocnemius muscle with the knee extended is an essential factor in determining not only the type of orthosis that is suitable, but also the cast angle of the ankle within the orthosis, and any subsequent wedging required [173, 174]. It is also acknowledged that failure to appropriately accommodate the gastrocnemius length can inhibit the tuning process of an AFO [173].

Dynamic spasticity, especially in the calf complex, influences the angle at which the orthosis can be cast without stimulating the calf reflex during walking. Casting the orthosis in an angle which is too acute for the underlying spasticity may result in over-stimulation of the calf muscles during walking, and often results in a poor fit as the ankle attempts to plantarflex, lifting the heel or everting the midfoot, with resulting soft tissue damage and poor patient compliance. Casting slightly off this maximum range can be enough to avoid over-stimulation of the spastic calf complex sufficiently to allow maintenance of heel contact during stance (personal experience). This may take some 'trial and error', but can often result in improved long-term fit and compliance. An assessment of dynamic spasticity is therefore integral to the prescription process [173].

Assessment of underlying strength of the main functional muscles is also important to determine what level of control is required.

Once the above details have been determined, and the presenting gait problems identified, then the aim of orthotic intervention for each child is determined and the appropriate orthotic design and prescription selected.

6.1.2.2 Orthotic Design Factors

Once the aim of the orthosis has been determined, the following considerations are undertaken when finalising the orthotic prescription.

Orthotic design

The range of available orthoses are considered to select the most appropriate type for the required function [1, 123] – for example, where complete isolation of ankle movement is required, a fixed AFO would be selected; whereas should some dorsiflexion be permitted, then a hinged AFO, DAFO or PLS can be considered.

Cast angle

The optimal cast angle for the orthosis is determined to maximise joint alignment at the ankle and proximally at the knee and hip [123], giving consideration to the available range and presence of spasticity as noted above. This is reported within this thesis as the 'angle of the ankle in the AFO' (AAAFO) [123, 173].

Shank inclination

The resultant angle that the shank makes in relation to the floor (shank-to-floor angle) when wearing the orthosis can be adjusted through the use of heel (or less commonly, toe) wedges to align the shank whilst the whole of the sole plate (foot section) is in contact with the floor. This can be done either to the orthosis itself, giving a resultant 'shank-to-floor angle of the AFO' (SAFAFO) and/or to the footwear by adjusting the heel-sole differential (difference between heel height and height at the forefoot) [173], reported as the 'shank-angle to floor of the AFO-footwear combination' (SAFAFOFWC) [121]. Adjustment of these values allows the overall inclination of the shank to be adjusted to control not only the ankle movements, but also alignment of the proximal segments and is key to ensuring optimal orthotic alignment. Much focus is now being placed on the alignment of the shank during stance [1], with the importance of slight shank inclination being highlighted [121, 123, 175].

Additional features

Consideration of additional features such as tone-reducing components; trim lines to facilitate or prevent the third rocker and ease any permitted dorsiflexion; addition of corrective straps (e.g. over the metatarsal area to control toe adduction, or navicular strap to help control sub-talar joint eversion) are carried out before the orthosis is ordered.

Footwear design

Also integral to the function of an orthosis is the footwear in which it is worn [173]. The inclination of the sole of the shoe (determined by the heel-sole differential), and shape and location of the heel and forefoot rockers [123, 176] influence the overall inclination of the shank and the progression of weight forwards along the foot. Difficulties can arise during the tuning process with this aspect of orthotic function in that most people wear a range of footwear, with variable sole profiles that will alter the overall function of the orthosis-footwear combination. Furthermore, footwear is often purchased *after* receiving a new orthosis, to ensure correct fitting, which means that tuning cannot necessarily take place at the same time as the orthotic fitting itself.

Once the required orthotic detail is determined, the child is then cast for the required orthosis ensuring correct anatomical alignment of all segments during the casting process. Once the cast is made, the child usually returns for a fitting appointment to ensure correct fit and functioning of the orthosis. Any minor adjustments can then be made before the child starts wearing the orthosis during walking. An assessment of the effectiveness of the new orthosis is useful to ensure that it is working as expected and to highlight any further adjustments. This assessment process may simply involve clinical observation of the child walking whilst wearing the orthosis, or it may involve video recording, or further motion analysis within a more formal setting (for example in a gait laboratory or clinic with video vector tuning capability) [1, 70].

All of these above factors (both patient presentation and orthotic design factors) determine how much further fine-tuning (adjusting of prescription elements) an orthosis will need after fitting. This process of fine-tuning is made easier by the availability of an objective measurement system capable of informing the process.

6.2 Orthotic tuning

It is now widely recognised that orthotic tuning (biomechanical optimisation) is an essential part of the prescription process [1, 20, 46, 177], with the International Society of Prosthetists and Orthotists (ISPO) reporting on this issue [178]. Consensus is beginning to form as to the factors to be considered, and methods to be used during this process. Indeed, the NHS for Scotland recognise [179] that providing fixed AFOs without tuning could in fact "introduce further neuro-biomechanical challenges to patients " and advised that orthotic tuning be standard practice during **all** AFO provision.

The process of orthotic tuning involves making minor adjustments to the orthotic prescription such as the cast angle, material, trim lines, design of the orthosis, additional wedging at the toe or heel to alter the overall inclination of the shank, and possible alterations in the sole profile of footwear to control the lower limb during weight acceptance and at pre-swing. The purpose of making these minor adjustments is to ensure optimal alignment of the foot, ankle and shank (lower leg) throughout the gait cycle, and consequently to improve the overall gait pattern and gait function.

Work completed and published by Elaine Owen and others [126, 180] has shown that inclination of the shank during the gait cycle, and alignment of the ground reaction forces to the lower limb joints, are key features in determining optimal gait and hence are important for orthotic tuning. A growing body of evidence is developing to highlight the reference values for

these key features, and of the effect of orthotic tuning on gait outcomes. Butler & Nene [52] reported over 25 years ago that an increase in moment or moment arm about a joint results in an increase in muscle control required, and recognised that minimising the moment, predominantly by reduction in the moment arm, would help to optimise energy efficiency. However, further evidence is still required to substantiate these early findings and to investigate areas as yet unstudied, **such as the effect of orthotic tuning on the energy cost of walking** (as highlighted by Eddison & Chockalingam [1] and proposed by Butler & Nene [52]).

A literature review in 2013 [1] highlighted the current body of evidence for orthotic tuning, giving detailed descriptions of the merits and gaps within each study, and summarising the outcomes of orthotic tuning on outcome measures in CP gait. The literature review found only 15 papers that investigated the effect of orthotic tuning on gait outcomes, including 3 that reported only theoretical findings. Of the remaining 12 papers, many had gaps in the description of the either the individual orthotic design or the methods using for the tuning process. Number of participants ranged from 5 to 62, with 7 of the studies involving 20 participants or less, highlighting the limited nature of the research and the need for more robust investigation. The authors also identify a frequent lack of comparison of outcomes specifically between un-tuned and tuned AFO-footwear combinations, and furthermore the particular dearth of evidence on the effect of tuning on energy efficiency.

A recent literature review using the following search strategy (Table 1) identified just 20 relevant papers pertaining to ‘orthotic tuning’, and 3 papers using the term ‘biomechanical optimisation’.

Table 1. Search strategy for identifying orthotic tuning literature.

Number	Search term	No. titles	Abstracts reviewed
1	Orthos$.mp	53975	
2	Tuning.mp	17555	
3	1 and 2	75	
4	3, deduped	55	20
5	Orthot$.mp	58694	
6	5 and 2	46	
7	6, deduped	36	12*
8	Biomechanical optimisation.mp	4 (1 duplicate)	3

*All duplicates to search #4

Of the 20 relevant papers identified as pertaining to 'orthotic tuning', five related to participants following stroke (three of which related to the same study); two involved healthy participants only; one involved children with Duchenne Muscular Dystrophy; five others did not refer to any patient data (purely theoretical, response letters only, survey of clinical practice and literature review only); and two were only available as abstracts and appeared to relate to the same study involving adjustment of stiffness properties only with no detail of tuning methods. Five papers related to children with CP. Of the titles referring to 'biomechanical optimisation', only one paper related to children with CP, the others involving elbows and orthodontics. Of the six papers relating to CP, two are already described in Eddison's literature review.

Kerkum et al [181] investigated the effect of an acclimatization period of orthotic use on gait outcomes in 10 children with CP. They report that the AFOFWC was tuned according to 'clinical protocol' but do not describe this process. Data are compared immediately post-tuning and 4 weeks later, with no significant differences being found. There is no specific comparison to either a pre-tuned condition or a non-AFO condition (barefoot or shoes

only) and therefore a tuning specific effect cannot be deduced. They conclude that no acclimatization period is required following tuning, but one may argue that evidence that tuning has actually taken place is not presented.

More recently, in 2017, these same authors detail the advantages of orthotic tuning, specifically through alteration in AFO stiffness, on abnormal trunk movements and energy efficiency in 15 children with CP, highlighting the importance of assessing trunk posture in addition to specific lower limb alignments in orthotic management [182].

Data from Jagadamma et al [183] are only available in abstract format, but the study compared data between barefoot, un-tuned AFOFWC and tuned AFOFWC conditions, in eight children with CP. The tuning process is briefly described, and involves optimisation of the alignment of the ground reaction force to the lower limb joints. Kinematic, kinetic and spatio-temporal parameters are studied with significant differences highlighted. Not surprisingly, a reduction in peak knee extension moments is found when using the tuned AFOFWC, along with an associated reduction in peak knee extension and knee range of motion. They conclude that tuning is useful for children with certain gait patterns, but was least effective in those with crouch gait. Further study is recommended with greater numbers.

Lastly, the Quinn study [127] previously described highlights the benefits of orthotic tuning on the prescription process, improvements in gait, and for patient education and compliance. Limited description of the tuning process is made in this abstract but the researchers recognise that not all participants could be tuned and that alternative management needed to be employed for some. Their main study objective was to determine the usefulness of the tuning process, and no specific outcome measures are reported.

Of those not pertaining to CP, the following benefits of orthotic tuning are reported: Charlton [184] reports the benefits for use of orthoses in stroke rehabilitation and acknowledges the benefits of orthotic tuning for this group in this theoretical article. Carse et al [185] highlight the benefits of orthotic intervention on spatiotemporal gait parameters in early stroke rehabilitation, reiterating the importance of orthotic tuning in the prescription process.

Bromwich et al [186] use orthotic tuning during their investigation of the use of AFOs in 10 children with Duchenne Muscular Dystrophy. Whilst their primary research question was whether AFOs benefitted these children, they specifically mention that the orthoses were tuned, recognising the importance of this element of the prescription process.

In addition to their research into tuning in CP, Kerkum and co-workers [187] explored the effect of altering heel height and footplate stiffness in healthy adults, highlighting the importance of these factors in orthotic tuning due the impact on shank inclination of these variables.

These literature findings highlight that the area of orthotic tuning is becoming increasingly recognised and investigated, but furthermore highlights the lack of sufficient evidence of the effect of orthotic tuning on gait outcomes, and more specifically on energy efficiency.

Recently Ridgewell et al [20] presented "A systematic review determining best practice reporting guidelines for AFO interventions in studies involving children with cerebral palsy". Their recommendations for orthotic research highlight the level of detail required (in sample description, AFO detail and testing protocol) to ensure that the research can be interpreted accurately but also reinforce the importance of optimal orthotic prescription to ensure that the intervention itself (and not just the testing protocol) is of high quality.

6.3 Critical Appraisal of Orthoses by Methods of Analysis

As one of the aims of this research was to develop an orthotic measurement tool, the following literature review includes a critique of the outcome measures currently available, as well as the efficacy of orthotic intervention for this population.

Although there is a plethora of published research assessing the effectiveness of different types of orthoses for children with CP, the evidence base is inconclusive because of variability in the following aspects of orthotic research:

- Methodology [54, 188-190]
- Participant presentation [188] [190] [50]
- Orthotic design [51, 143, 168, 190]
- Participant numbers [16] [63, 189]
- Quality and type of publication

However, a number of common significant findings are reported, providing some evidence for the use of orthoses. For this literature review, the Ovid search tool was used. The literature review was repeated several times throughout the course of the study, most recently in 2017. In addition, the reference lists of available papers were hand-searched to highlight any further relevant publications. The on-line search strategy is summarised in Appendix 5.

The subsequent sections provide a critical analysis of some of the key publications highlighted in Table 2. The analysis has been divided into outcome measures used, to indicate the advantages and disadvantages of each available methodology, as well as illustrating the benefits of orthotic intervention for children with CP. Eight main outcome measures were found, and these are discussed below (sections 6.3.1 - 10). The following variables have been considered in the appraisal of the selected papers for discussion within this section: patient group, limitations of the

methodology employed, orthotic design features and considerations, comparison to appropriate reference data and recognition of the study limitations.

Table 2. Summary of orthotic literature.

Reference and type	Study Design	Sample Size	Characteristics of Participants	Intervention	Control	Outcome Measures	Key Findings
[188] Journal article	Prospective Single Case Study	1	Spastic Quadriplegia 4 years	Inhibitive orthoses	Barefoot	Balance Subjective assessment	↑Balance with orthosis. ↑posture symmetry.
[65] Journal article	Prospective Single Case Study	1	Spastic Diplegia 4 years	FAFO HAFO	Shoes	Kinematics Kinetics	HAFO allows DF in stance FAFO prevents DF in stance HAFO ↓knee extensor moments in stance.
[191] Abstract	Prospective Within-Participant Comparison	10	Spastic Diplegia 1-5 years	1 arch and 3 arch AFOs	No AFO	Gait parameters Video analysis Subjective assessment	No difference in gait parameters between orthoses. ↓toe-strike pattern in some children.
[88] Journal article	Prospective Within-Participant Comparison	18	Spastic Diplegia 3-14 years	FAFO	No AFO	Energy cost	↓energy cost for most patients (13/18). Individual assessment required.
[53] Journal article	Prospective Within-Participant Comparison	6	CP 3-6 years	FAFO tuned	?barefoot	Kinetics Gait parameters Video analysis	↓moment arm after tuning and on follow-up. No change in speed ↑heel strike in some patients. Some longer-term benefits from tuning seen during barefoot walking.
[192] Abstract	Prospective RCT	34	CP 12-48 months	Physiotherapy and orthoses	Physiotherapy without orthoses	Functional measures - GMFM & GMPM Ankle ROM	No difference between the groups for any outcome. NB: unclear if orthosis worn for assessment as assessor 'blinded'.
[193] Journal article	Single Case Study	1	Spastic Diplegia 47 months	HAFO	FAFO	Subjective observational assessment of gait changes	↑ heel strike. ↓ high-guard UL posture. ↓ internal rotation of hips. ↑balance. ↑step length.

Table 2 (continued)

Reference	Study Design	Sample Size	Characteristics of Participants	Intervention	Control	Outcome Measures	Key Findings
[172] Journal article	Retrospective Within-Participant Comparison	31	Hemiplegia (19) Spastic Diplegia (12) Mean age 10 years	PLS	Barefoot	Kinematics Kinetics	↑ankle posture at terminal swing. ↓PF during swing and at third rocker. DF allowed at second rocker. ↑peak PF moment but ↓power generation in stance. No change in walking velocity.
[169] Journal article	Prospective Within-Participant Comparison	11	Spastic Diplegia 4-11 years	FAFO SMO	Shoes	Kinematics Kinetics Gait parameters	↑stride length with both types. ↓ankle ROM with FAFO. ↑ankle DF at IC with FAFO. ↑peak ankle PF moment with FAFO. ↑ankle power with SMO (compared with FAFO) ↓ankle power with FAFO.
[10] Journal article	Prospective Within-Participant Comparison Alternating treatment	12	Hemiplegia (4) Spastic Diplegia (8) 3-7 years	AFO (9 HAFO, 3 FAFO)	Not stated	Kinetics - subjective assessment Video analysis Passive ROM	↓passive ankle range following no-AFO periods. Forces suggest worsening of medio-lateral forces during no-AFO periods at 1st occasion, but not at 2nd. ↓ gait during AFO free periods, but not statistically different.
[168] Journal article	Prospective Within-Participant Comparison Repeated measures	10	Hemiplegia (4) Spastic Diplegia (6) 3-8 years	FAFO DAFO	Barefoot	Kinematics Gait parameters Video analysis EMG	↑stride length and ↓cadence. No difference in joint motion at pelvis, hip or knee at IC or MSt. Both orthoses ↓ankle PF at IC and MSt. ↑EMG activity compared with normal (for hemi & di). No effect on muscle firing. DAFO lighter and preferred cosmesis, but longer learning and weaning-in phase.

Table 2 (continued)

Reference	Study Design	Sample Size	Characteristics of Participants	Intervention	Control	Outcome Measures	Key Findings
[171] Journal article	Prospective Within-Participant Comparison	14	Hemiplegia 6-20 years	FAFO Spring-type	Barefoot	Kinematics Kinetics Gait parameters Video analysis	↓toe-walking with both orthoses. ↑kinetics with either type. ↑Push-off with spring-type. ↑gait params, spring> FAFO. Spring type allowed more DF in stance than FAFO. ↑arm motion (subjective).
[194] Journal article	Prospective Within-Participant Comparison and against normals	15, plus 20 controls	Spastic Diplegia 2-5 years	HAFO FAFO (locked HAFO)	Barefoot and control group	Kinematics ROM Speed of sit-to-stand motion	↑(worsened) sit-to-stand time in participants whose barefoot time was within normal limits. ↓(improved) sit-to-stand time in participants whose barefoot time was slower than normal (equinus present) - HAFO>AFO.
[16] Journal article	Retrospective Within-Participant Comparison	35	Spastic Diplegia 2-19 years	FAFO	Barefoot	Kinematics Kinetics Gait parameters	↑gait parameters. ↑ROM at pelvis, hip and knee, and ↓ROM at ankle. ?ankle posture at IC, but restriction of PF at TO.
[195] Abstract	Prospective Within-Participant Comparison	9	Spastic Diplegia 6-11 years	Tall DAFO SMO DAFO Tall FAFO SMO FAFO	Shoes	Kinematics Kinetics Gait parameters Video analysis X-rays	No change in gait parameters, pelvis or hip movement. All orthoses restricted ankle ROM, but no difference between types. ↓power generation at TO with both tall AFOs. ↑power generation in both SMO types. No change in video analysis. Patient preference for SMO DAFO (8/9)
[55] Journal article	Prospective Within-Participant Comparison Repeated measures	21	Spastic Diplegia 5-13 years	FAFO HAFO	Shoes	Kinematics Kinetics EMG	↑ankle DF at IC with AFOs. ↑DF at TSt with HAFO vs FAFO or shoes. ↑PF moment at TO compared with shoes alone. ↓PF power at TO in FAFO vs HAFO and shoes. No change in gait parameters. No change in calf EMG.

Table 2 (continued)

Reference	Study Design	Sample Size	Characteristics of Participants	Intervention	Control	Outcome Measures	Key Findings
[62] Journal article	Prospective Within-Participant Comparison	8	Spastic Diplegia 4-11 years	HAFO HAFO with tone-reducing features (HAFO_TR) DAFO (PF allowed)	Shoes	Kinematics Kinetics Gait parameters	↑stride length for HAFO with TR features vs shoes. ↑ankle posture at IC, and prevention of PF (at TO and maximum PF) with HAFO & HAFO_TR. No diff. between DAFO & shoes or between HAFO & HAFO_TR.
[189] Journal article	Prospective Within-Participant Comparison	10	Spastic Diplegia Mean age 9 years	HAFO	Shoes	Gait parameters Energy cost Functional measures - GMFM used	↓oxygen cost of walk. No effect on respiratory exchange ratio. ↓ventilatory cost of walking at slow speeds in HAFO. No effect on cardiovascular cost of walking. No effect on GMFM scores or walking speed.
[144] Journal article	Prospective Within-Participant Comparison	30	Hemiplegia 5-15 years	FAFO HAFO PLS	Barefoot	Kinematics Kinetics Energy cost Functional measures ROM	↑ankle posture at IC (HAFO & FAFO > PLS) Ankle rockers restored. ↓power generation in stance (FAFO > HAFO or PLS). HAFO controlled knee hyperextension. PLS improved knee extension in patients with crouch. ↑stride and step length with all orthoses. ↑energy efficiency (21/30), 13 best with HAFO & PLS. Function most improved with HAFO and PLS.
[196] Abstract	Prospective Within-Participant Comparison	16	Spastic Diplegia 5-13 years	HAFO DAFO	Barefoot	Kinematics Gait parameters Balance Functional measures - GMFM & PODCI	↑cadence, speed & stride/step length in both types. Improvements in balance measures, details limited. No diff. in functional measures.

Table 2 (continued)

Reference	Study Design	Sample Size	Characteristics of Participants	Intervention	Control	Outcome Measures	Key Findings
[63] Journal article	Retrospective Within-Participant Comparison	115	Spastic Diplegia (97) Hemiplegia (18) 5-15 years	FAFO HAFO	Barefoot and normal	Gait parameters	↑velocity, stride length, step length and single leg stance in gait cycle compared with barefoot. No change in cadence.
[51] Journal article	Prospective Within-Participant Comparison	12	Hemiplegia 7-22 years	DAFO HAFO	Barefoot and normal	Kinematics Kinetics Gait parameters	↑heel strike - 12 participants for HAFO, 4 participants for DAFO. ↑stride and step lengths, DAFO & HAFO vs barefoot. No difference between orthoses. ↑velocity (non-significant) with both types. Improved ankle posture at IC, HAFO > DAFO. ↓PF at toe-off with HAFO, but barefoot was normal. Abnormal PF moment in early stance and ↓PF moment in late stance under all conditions. ↓power generation at toe-off, under all conditions.
[50] Journal article	Prospective Within-Participant Comparison	18	Hemiplegia 5-11 years	FAFO	Barefoot and normal	Musculoskeletal modeling of hamstring length	↑knee extension at IC due to control of ankle posture. Restoration of normal hamstring length during walking with AFOs.

Table 2 (continued)

Reference	Study Design	Sample Size	Characteristics of Participants	Intervention	Control	Outcome Measures	Key Findings
[143] Journal article	Prospective Within-Participant Comparison	16	Spastic Diplegia 4-11 years	FAFO HAFO PLS	Barefoot and normal (shoes for energy consumption)	Kinematics Kinetics Gait parameters Energy cost Functional measures (GMFM, GMPM, PEDI) Passive ROM	Improved ankle posture at IC. ↑DF in swing (all orthoses vs barefoot) ↑dynamic ankle range. ↓ankle power generation for all orthoses vs barefoot & normal, especially FAFO. ↑step & stride length, with all orthoses ↓cadence, below normal No change in velocity or passive ROM. ↓oxygen consumption in HAFO & FAFO vs barefoot & PLS ↑energy cost for all orthoses vs barefoot. ↑walk, run & jump dimensions of GMFM. No change in quality of movement (GMPM) or PEDI.
[190] Journal article	Prospective Within-Participant Comparison	12	Spastic Diplegia 4-16 years	FAFO HAFO	Barefoot	Kinematics Kinetics Gait parameters EMG	↑stride length – orthoses vs barefoot. No change in velocity or cadence. Prolonged firing in stance (all muscles) comp. with normal, no change with orthoses; triceps surae fired early. No change in knee kinematics. Improved ankle position at IC, MST and TST with both types. No change in knee kinetics or ankle in early stance. ↑ankle moments at TST with both types. ↓power generation at pre-swing – orthoses vs barefoot, especially with the FAFOs.

Key: RCT – randomized controlled trial; FAFO – fixed ankle foot orthosis; HAFO – hinged ankle foot orthosis; DAFO – dynamic ankle foot orthosis; SMO – supra-malleolar orthosis; PLS – posterior leaf spring orthosis; ROM – range of motion; MSt – mid- stance; TSt – terminal stance; TO – toe-off; DF- dorsiflexion; PF – plantarflexion.

The methods of orthotic analysis discussed in the following sections are:

- Video analysis
- Kinematic analysis
- Kinetic analysis
- Gait parameters
- Energy cost analysis
- Functional outcome measures
- EMG analysis
- Balance analysis

6.3.1 Video Analysis

As commented in Chapter 3, quantification of video findings can be subjective and available rating scales are not necessarily highly reliable. Nonetheless, video analysis can provide useful relevant information about changes in foot strike pattern through an intervention (i.e. toe strike, flat foot or heel strike).

Hainsworth et al [10] assessed the effect of AFOs on gait parameters in 12 children aged 3-7 years with diplegic or hemiplegic CP. Children wore their current AFOs (hinged or fixed) which were not specifically tuned. A single-participant alternating-treatment study design was used and videos were rated according to foot contact: heel-toe pattern (1), flat-foot gait (2) or toe-walking (3). Three blinded assessors ranked the video clips in a randomised order. Small increases in scores (indicating deterioration in gait) were seen during the orthotic-free periods, but these were not significant. A small sample size was acknowledged.

Brunner et al [171] studied the effects of a FAFO and a 'spring-type' orthosis that permitted some dorsiflexion but prevented plantarflexion. They studied 14 participants, (13 with spastic CP and one childhood head injury) aged 6-20 years. Details suggest they were all hemiplegic. Although the precise video analysis methodology was not clear, the authors report a toe-

strike pattern when children walked barefoot, and restoration of heel strike with either type of orthosis. A heel rise persisted during stance when wearing the fixed AFO. The authors concluded therefore, that the spring-type orthosis was preferable in that it permitted a more normal dynamic motion at the ankle.

Romkes and Brunner [51] compared dynamic and hinged orthotic configurations in 12 patients with hemiplegic CP, aged 7-22 years (11 of whom were under 14 years). All participants presented with a toe-striking pattern and excessive plantarflexion on the hemiplegic side, and wore a hinged AFO. Simultaneous sagittal and coronal plane video footage was recorded, in addition to full motion analysis. Foot strike was graded as per Hainsworth's study. Results revealed recovery of heel strike for all participants when wearing the HAFO, but in only four children with the DAFO. Other improvements were found in kinematic and kinetic outcomes, suggesting that the HAFO is superior to the DAFO for this population. One criticism of this study is that the normal reference data were derived from adults. The authors acknowledged this limitation, but defended it on the grounds that previous research has shown a mature gait pattern is achieved by the age of seven, which was the age of their youngest participant.

Use of video analysis allows the footfall characteristics of an individual's gait to be determined easily, which is not always possible using a computerised motion analysis system due to the rigid modelling of the foot. However, it is difficult to blind an assessor to the use of an AFO on a video, risking bias during analysis. Nonetheless, these studies generally found improvements in the attainment of heel strike through orthotic use, with some differences noted between orthotic designs.

6.3.2 Kinematic Analysis

Analysis of the effect of orthoses on kinematic aspects of gait is commonly reported in research, but issues with reliability, validity and practicality have to be considered.

Kinematic data are usually presented in graphical form as shown in Figure 13. Some authors argue marginal differences exist in data captured between centres due to differences in modelling, capture rate and data filtering parameters [197], whilst others report no clinical difference between systems [198]. Research studies tend to avoid these potential discrepancies by using consistent equipment and protocols throughout a study.

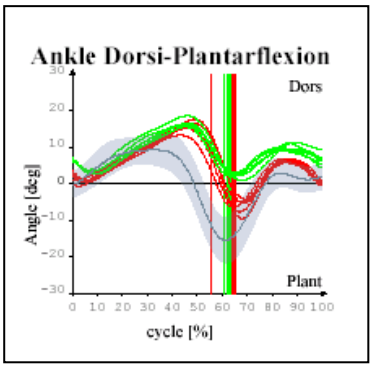


Figure 13. Illustration of ankle kinematic graph

High frequency data capture produces a large volume of potential data points for analysis. Researchers have to decide which data points to analyse. Specific points throughout the cycle may be selected (e.g. 0%, 35% gait cycle) [144, 199] for each relevant kinematic outcome (e.g. ankle dorsiflexion/plantarflexion, or knee flexion/extension). However, selection of these pre-defined points is often inconsistent between papers, making comparison difficult. Furthermore, issues such as walking speed can affect the pattern of joint motion throughout the gait cycle, such that selection of single time-points may not accurately represent the same point within the motion between individuals. Validity and reliability of this method may therefore be questioned.

Alternatively, key features may be examined, such as peak values, or joint ranges at toe-off for example [47, 84, 144]. These data points may be functionally more relevant than interim points and remove the issue of variable event timings, which should improve reliability. However, this often limits the number of data points available to analyse, depending on the pattern of movement for that joint and some could argue against the functional relevance of these data peaks.

Dynamic joint range of motion [144] excludes the issues of specific point selection and event timing. However, an indication of the actual position of the joint is also important to understand the clinical relevance of this range. For example, an ankle range of 20° in the sagittal plane throughout stance may sound acceptable, but if all of this movement occurs with the ankle plantarflexed, this indicates a significant ankle problem, which is overlooked by simply stating the dynamic range.

Commonly a mixture of data points is selected to answer a specific question, as highlighted by the papers below.

Buckon et al [144] studied the effect of three different orthotic designs (HAFO, FAFO, PLS) on different kinematic parameters in 29 children with spastic hemiplegia, aged 5-15 years. A mixture of specific points and peak values were assessed at the knee and ankle, as well as dynamic ankle range of motion. All orthoses improved ankle DF at contact and peak DF in stance, as well as reducing dynamic ankle range through elimination of abnormal plantarflexion (hence restoring a more normal range), compared with barefoot. Differences were noted between orthotic designs. None of the orthoses impacted on abnormal knee flexion at contact, but the fixed AFO generated abnormal knee hyperextension at contact for some children (7/9) whose knee flexion was normal when walking barefoot. None of the orthotic designs improved those with knee hyperextension at contact but all did improve knee hyperextension occurring during the remainder of stance, with minimal difference between designs. There was no orthotic

effect on peak knee flexion in swing. Interestingly, the effect of orthotic control at the ankle during swing is ignored, despite this being a common indicator for orthotic use. Furthermore, comparisons were not made with reference data, but were all referenced to barefoot data collected at the start of the study, making clinical relevance of the findings difficult to decipher. In addition, all orthoses were made at the start of the study, but each design was worn in a random order over a period of nine months. The fit of an orthosis nine months after casting may have been sub-optimal, affecting results. Lastly, the cast angle of each orthosis was standardised and there is no comment on orthotic tuning, putting into question the specificity of each orthosis for each participant.

These authors also employed the same methodology to study 16 children with spastic diplegia aged 4-11 years [143]. Normative data are reported but not included in analysis. A more detailed kinematic analysis of the same three orthotic designs included 24 data points. Interestingly the authors report no significant differences between orthotic conditions at the pelvis, hip or knee (ungrouped here), although the data does show increased peak knee flexion in stance when barefoot, compared with normal, which is unchanged with orthotic use. Peak knee flexion in swing was normal and remained unchanged with orthotic use. At the ankle, abnormal plantarflexion was noted at contact when barefoot, which was reduced (to dorsiflexion) through orthotic use (all designs), suggesting an improvement. However, close examination of the reference data suggests that some plantarflexion at contact is normal, questioning the clinical implications of the orthotic 'improvements'. Similarly, an increase in ankle DF in stance and swing through orthotic use (compared with barefoot) is reported, but again these increases represent the ankle being brought into excessive DF in stance compared with reference values, particularly with the HAFO design. Similarly, during swing, some plantarflexion is normal, but all orthoses limit this. Dynamic ankle range was reduced with all orthotic designs, compared with normal values obtained when barefoot. Clinical implications of this are not discussed and therefore the usefulness

of this value for orthotic analysis may be questioned. Previous criticisms have been addressed through the presentation of reference data in this paper and consideration of swing phase. However, a lack of fine-tuning, and a single casting event remain contentious issues.

The study previously described by Romkes & Brunner [51], also studied sagittal plane kinematic data. A normative database is used, allowing evaluation of the clinical relevance of findings, but comprised only adult subjects as justified previously. A mixture of specific data points, peak values and event timings are analysed at the hip, knee and ankle. Toe-off appears to have been defined consistently for all participants, even though specific timing may vary depending on gait pattern and speed. This could also affect peak plantarflexion in swing, as this value is often found very close to this delineation. Increased ankle PF at contact was found for those with CP compared with their reference data, which was reduced with orthotic use, particularly with the HAFO. Abnormal peak stance dorsiflexion when barefoot was returned to normal limits with both orthotic designs. Participants had normal ankle PF at toe-off when barefoot which was not affected with DAFO use, but which was significantly reduced with HAFO use. Participants had excessive ankle PF in swing, which was excessively restricted with the HAFO design, whilst the DAFO promoted a normal range of motion.

In contrast to the range of knee posture presentations reported by Buckon et al [144], this study found abnormal excessive knee flexion at contact for all participants, which was unaffected by orthotic use. There was no effect on peak extension during stance with any orthoses. In a further distinction from previous work, an increase in peak knee flexion in swing was found for all participants with both orthoses, compared with both barefoot and reference data. This may be the result of a smaller sample size, wider age range or differing presentation of this population. Acknowledgement of the limitations of the study were given, in terms of having adult reference data, and of the potential for issues related to marker placement over orthoses

(requiring some estimation of anatomical landmarks). Again, the lack of specificity and tuning of orthotic prescription is criticised within this study, with the likelihood of an optimal outcome being questioned. Clinical examination data clearly shows several participants having ankle contractures, yet being assessed in HAFOs, whose function requires some anatomical dorsiflexion range. Two participants had knee flexion contractures with no indication of any accommodation of this, and the description of the DAFO does not convey a sufficient understanding of degree of motion permitted or controlled.

Radtka et al studied the effect of FAFOs and HAFOs in 12 children with spastic diplegia aged 4-16 years [190]. Specific orthotic design details are provided and the authors clearly state that orthoses were custom-made for each child. Orthoses were worn in a random order and barefoot was used as a control measure. Sagittal plane data at the knee were examined at four pre-selected points in stance. There were no significant differences between orthotic conditions (including barefoot) at any point, in concordance with Buckon et al [143] and Romkes & Brunner [51]. However, examination of their graphs clearly shows increased knee flexion throughout early and late stance compared with their reference data, although this is not commented on. Abnormal ankle PF is found at initial contact, mid-stance and terminal stance when walking barefoot, compared with reference values. Both orthotic designs reduce this at all points in stance, with the HAFO promoting further DF at terminal stance than the FAFO, but also encouraging excessive DF during loading compared with barefoot and reference data. A restriction of this study, apart from small participant numbers, is the limited selection of data points, and insufficient detail of their definition – mid-stance and loading response are phases, not single time points, but single values are reported. However, presentation of full kinematic graphs allows the reader to assess subjectively any other differences not reported.

Several other studies [16, 62, 81, 169, 171, 196] have also investigated the effect of orthoses on kinematic outcomes in children with CP, with the main common finding being improvement of the ankle position at initial contact when wearing orthoses, despite the differences in orthotic design; and a limitation in plantarflexion at toe-off when using a fixed-design orthosis. Additionally, the finding of little, if any, effect on the hip and knee kinematics is also corroborated [62, 196].

In summary, these findings highlight some of the issues involved in analysing kinematic data. Whilst it provides an immense number of potential data points to analyse, increasing the chance of highlighting any significant differences between conditions, this also increases the chance of a type I error. Moreover, with a wide range of potential outcomes to select from, the likelihood of different studies choosing the same outcomes is limited, leading to problems of comparing findings between studies, and therefore being able to generate an evidence-based argument for an intervention.

Where studies have used consistent outcome measures, some of the benefits of orthoses for children with CP are highlighted. An improvement in ankle posture at initial contact (from one of excessive PF) was found consistently, along with increased DF in stance. A reduction in dynamic ankle range, and a beneficial effect on the ankle during the swing phase was also agreed. Furthermore, the limited effect of orthoses on hip and knee motion was commonly reported. Differences in orthotic design affected the degree of ankle control during stance and swing, in particular the extent of plantarflexion limitation. Conclusions about the relative benefits and drawbacks to each type of orthosis remain divided, and possibly depend primarily on the presentation of each patient, and therefore the individual aims of intervention, and the methods by which the conditions are assessed.

One of the main criticisms of orthotic research to date is the lack of detail about the individual orthoses, in terms of justification for prescription and

information regarding any tuning that has taken place. In view of the advancement in technology and evidence of the importance of tuning, further quality research is required to provide a stronger evidence base for orthotic use.

6.3.3 Kinetic Analysis

Kinetic analysis describes the study of the forces involved in gait, and the subsequent moments and powers generated [25] (Fig. 14).

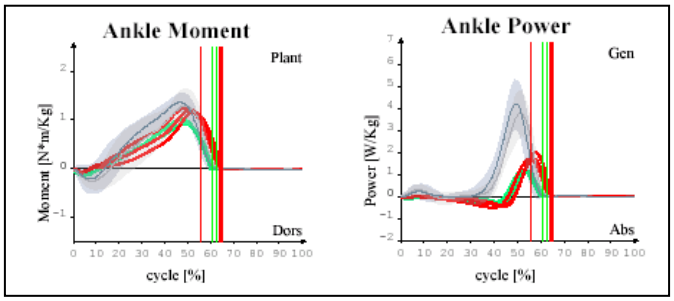


Figure 14. Illustration of ankle kinetic graphs.

Controlling the position and dynamic motion of the foot and ankle with an orthosis can have an effect on the generation of moments and alignment of forces at all of the lower limb joints. There are fewer studies pertaining to the effect of orthoses on kinetic outcomes, compared with kinematic studies, possibly due to the difficulties in data collection in children. A short step length means that obtaining 'clean' force plate strikes (i.e. with one foot only) is more difficult, and subsequently more attempts are often required to collect sufficient data, which can affect compliance. However, acknowledgement of the impact of an altered gait pattern on the generation of moments (often abnormal) about the lower limb joints, and appreciation of the impact of intervention on these abnormal moments can be very useful.

Similar problems with specific data point selection as those seen in kinematic data analysis exist, as highlighted by the selected papers below.

The Radtka et al [190] study, previously described, included kinetic analysis in their diplegic participants. Two children, reliant on walking aids, were excluded as their aids contacted the force plate, producing erroneous data. This study found no alteration in knee moments during stance, or in ankle moments during early stance, through orthotic use. However, they did find a significant increase in ankle moment at terminal stance towards normal values for both FAFOs and HAFOs, with no difference between orthoses. There was no change in power generation at the knee throughout stance with orthotic use, and an influence only during pre-swing at the ankle. All participants presented with reduced ankle power generation at pre-swing compared with reference data, which was further significantly reduced with the FAFO, compared with barefoot and HAFO conditions, whose difference was not significant. Underlying muscle weakness in the plantarflexors, and a limitation in dynamic ankle joint range (both common in CP) will affect the ability to generate power at the ankle, with the latter also being affected by certain orthotic designs.

Buckon et al [143] also included kinetic analysis for their diplegic participants, examining 16 kinetic outcomes at the hip, knee and ankle. They found a significantly increased peak knee extensor moment during early stance, when using the HAFO (compared with barefoot), despite a lack of change in knee kinematics at this point. Closer examination of the results table shows that the barefoot data were actually consistent with their reference data and that, in practice, all three orthoses increased peak extensor moment in early stance, above normal, with little clinical difference between them. There were significant improvements, towards normal, in peak dorsiflexor and plantarflexor moments in early stance under all orthotic conditions, compared with barefoot. However, power generation was reduced under all orthotic conditions compared with barefoot. The PLS limited power generation around the ankle the least (being the most flexible), and differed significantly from the FAFO, which was the most restrictive due to its rigid design. Importantly however, the

PLS did not improve power generation compared with barefoot, which is its theoretical intention.

An earlier study by these authors [144] investigating hemiplegic children also found a significant reduction in ankle power generation under all orthotic conditions compared with barefoot. Furthermore, the significant limitation of the FAFO over the other two orthoses was similarly highlighted.

Romkes & Brunner [51] found a large peak ankle plantarflexor moment in early stance (0-30% gait cycle) when barefoot which was not altered by orthotic use. Plantarflexor moment at terminal stance was significantly reduced under all conditions compared with normal, but was significantly higher under both orthotic conditions compared with barefoot, as found by Radtka et al [190]. However, Romkes & Brunner found significant improvements with the HAFO compared with the DAFO, which is in contrast to Radtka's study. Power generation in terminal stance was also significantly reduced under all orthotic conditions, including barefoot, compared with normal, with no significant differences between conditions.

These four studies summarise the kinetic findings of orthotic intervention, reinforcing the problems with selection of points within the gait cycle to analyse and the discrepancies in gait phase definition (early, mid, terminal stance etc). There is a greater inconsistency in findings between studies, and no true agreement was noted. However, most studies found a reduction in power generation around toe-off, specifically with a fixed AFO, along with an improvement in plantarflexor moment at terminal stance through orthotic use. There was variation in the ability of orthotic intervention to affect the abnormal generation of a plantarflexor moment in early stance, and to affect kinetics at the knee.

As argued for the kinematic findings, the apparent absence of fine-tuning of these orthoses to each patient may be the reason for their variable effect,

especially on the knee moments and their limited ability to alter the early PF moments in stance.

6.3.4 Gait Parameters

Gait parameters are one of the most commonly reported outcome measures used during orthotic analysis due to their ease of collection, reporting and interpretation. The parameters are usually single in value, and therefore simple to analyse statistically. In addition, they do not require expensive or complex equipment for data collection, and may be collected directly by different clinical staff.

Stride and step length were generally increased with orthotic use [16, 51, 62, 63, 143, 144, 169, 190, 196], although others [200] found no change. The effect of orthoses on cadence was more variable with some authors reporting a reduction [143, 144, 201]; others an orthotic-specific increase [51]; and further studies finding no change between conditions [16, 63, 190]. Changes in walking speed were also variable with some studies finding no change [51, 143, 144, 189, 190, 200], whilst others found an increase in walking speed through orthotic use [16, 63].

Although full motion analysis is not necessary to acquire temporo-spatial parameters of gait, many of the above studies acquired their data concurrently with kinematic data using computerised motion analysis. However, Maltais et al [189] calculated walking speed using a stop-watch, with participants walking along a path of pre-determined distance, highlighting the potential simplicity of data collection. Calculation of stride length and cadence is also possible using these simple methods.

Once again, these results show a lack of consensus of orthotic outcome for children with CP. This suggests that these outcomes alone may not be sensitive enough to determine orthotic differences.

6.3.5 Energy Cost Analysis

The range of energy cost measures available (as highlighted in Chapter 5) makes comparing research findings difficult. However, these measures tend to produce a single value, eliminating the problem of having to select data points to analyse.

The following publications highlight the range of methods used for children with CP, and the effect of orthotic use on energy efficiency.

Mossberg et al [88] assessed 18 children aged 3-14 years with spastic diplegia, using the PCI. They assessed each child walking with and without their usual (undefined) orthoses. Data from the last three minutes of a five-minute walk were analysed. Orthotic use resulted in a significant reduction in PCI overall, although four children experienced an increase in PCI, and one remained unaffected. Whilst this is an encouraging finding, there are several omissions in the methodology, which prevent a thorough critique of the findings. Firstly, the lack of information about each orthosis limits specificity of the findings; secondly it lacks clarification as to whether the 'without orthoses' condition was barefoot or shod; next, details of the walkway design are not given, although a corridor was used suggesting the likelihood of the participant having to turn around several times during their five-minute walk, which may have affected average speed and heart rate. Finally, the investigator walked alongside the child in order to carry the telemetry receiver for the heart rate readings, which may influence walking speed. The researchers do, however, highlight the ease of data collection with this population including young children. They recognise that oxygen analysis equipment would have been more expensive, requires use of a face mask or mouth piece, and can be too difficult for a child with CP to tolerate.

In 2001, Maltais et al [189] investigated the effect of hinged AFOs on the oxygen cost in ten children with spastic diplegia (mean age nine years). The participants walked on a treadmill at 'slow', 'comfortable' and 'fast' walking

speed, which were defined from observation of over-ground walking. Comparisons were made with and without their HAFOs, and shoes were worn for both conditions. Several metabolic and cardiopulmonary responses were recorded at each walking speed, under both orthotic conditions using a metabolic cart and heart rate monitor:

- oxygen cost of walking (VO_{2net})
- ventilatory cost of walking (VE_{net})
- respiratory exchange ratio (RER)
- net heart rate (HR_{net}),

where the $_{net}$ for each value represents steady-state minus sitting value.

This study found a significant reduction in VO_{2net} and VE_{net} with HAFO use but only at 'slow' and 'fast' walking speeds (not at 'comfortable' walking speed). There was no effect on HR_{net} or RER at any speed. The authors of this study acknowledge several limitations, particularly the problem of determining walking speed. Some difficulties were encountered in determining 'comfortable' and 'fast' walking speeds, as many children could not maintain the speeds they adopted during ground walking once walking on the treadmill, and the set speeds had to be reduced. Data suggests that there were only very minor differences in walking speeds on the treadmill. Nonetheless, all speeds were self-selected by participants and should therefore have still represented three paces, although true differences between the groups were perhaps very small.

A further criticism of this study is that during the familiarisation session children had to walk for around 15 minutes (covering around 750m at the stated 3km/h speed), which for a child with CP may have been close to or even above their usual exercise tolerance. Furthermore, during the study session they had to complete six two-minute walks at each speed, totalling 36 minutes of walking (with rests), in one session. Time was given for the heart rate to return to normal between testing, but the effect of muscle fatigue is unknown.

Buckon et al's study, described previously, [144] used a metabolic cart to investigate energy consumption in hemiplegic children. Oxygen consumption (ml O_2/kg/min) and energy cost (ml O_2/kg/m) were assessed with the children walking around a track at 'normal' and 'fast' walking speeds. There was no significant difference in oxygen consumption or energy cost between orthotic conditions at 'normal' walking speed, although a trend towards reduction in energy cost is noted. However, a significant increase in 'normal' walking speed was observed under all three orthotic conditions compared with shoes alone. During 'fast' walking there was a significant reduction in energy cost with HAFO use compared with shoes only, and a non-significant reduction with the FAFO or PLS. Oxygen consumption was unaffected, and velocity showed a non-significant increase under all orthotic conditions compared with shoes only.

A case-by-case analysis was then used due to high inter-participant variability, with a reduction of 9% in oxygen consumption considered significant (to account for day-to-day variability). They found eight children who had no change in energy cost between any orthotic conditions ("no benefit"); 13 children who had a significant decrease with one orthotic condition compared to baseline and to other orthotic conditions ("configuration benefit", i.e. improvements dependent on orthotic type); and eight children who had significant reduction in more than one orthotic condition compared with baseline ("universal benefit", i.e. improvements not dependent on orthotic type).

The authors therefore concluded that the use of AFOs in this group of patients allowed an increase in walking speed without an increase in oxygen consumption at self-selected walking pace, with a non-significant reduction in energy cost. Twenty-one children out of 29 demonstrated improvements in energy efficiency using at least one of the orthoses. However, eight experienced no change, and five of these experienced some worsening of energy efficiency with at least one type of orthosis, highlighting the need for individual assessment of the benefit of orthoses

for children with CP. There was no indication that any one type of orthosis was more effective in reducing energy cost than another, further clarifying the need for individual assessment and prescription. In addition to previous comments about this study design, use of a metabolic cart to assess energy efficiency is thought by some [132-137] to be unsuitable when assessing children with CP. Although no problems were reported in this study, the equipment may have had an effect on the findings.

As described previously, Buckon et al's second study assessed 16 children with spastic diplegia [143], using the same equipment and outcomes. They found a significant decrease in energy cost during 'normal' and 'fast' walking under all orthotic conditions compared with shoes only. Oxygen consumption was reduced significantly at both walking speeds when using the HAFO and FAFO compared with baseline. The PLS demonstrated a non-significant reduction. A between-day variation of 13% was used in this study (reasons not explained) to assess the individual benefits of each orthosis as previously. Four children found no benefit from orthotic use; seven gained the greatest benefit from either the PLS or FAFO, and five walked more efficiently in the HAFO. In summary, this study confirms the increase in energy cost of walking for children with spastic diplegia compared with age-matched controls, and highlights the benefits of orthoses in the reduction of this energy cost. Once again individual assessment and prescription is shown to be required for optimal results for each child, with no single type of orthosis offering preferential benefits. These authors recognised the variable methodology between studies, limiting comparison of results.

More recent studies include Bennett et al [145], who investigated kinetic and potential energy load in 21 children with diplegia using hinged and fixed AFOs. They found that the orthoses had the potential to reduce the workload in many of the children, but that in reality many didn't actually achieve this. Balaban et al [147] studied 11 children with hemiplegia and found a reduction in oxygen consumption with the use of hinged AFOs in

this small population. However, Brehm [146] had a considerably larger cohort of 172 children with mixed presentation and found that orthoses only reduced energy cost of walking in those with quadriplegia, with negligible changes in those with diplegia or hemiplegia. Lastly, Uckun et al [148] studied 48 children with CP wearing fixed AFOs and noted a reduction in energy cost with orthotic use. None of these studies makes reference to any orthotic tuning.

This selection of papers examining the effect of orthoses on energy efficiency highlight the lack of consensus in this area, partly due to the range of methodologies, outcome measures and exact statistical analysis employed. In general, an improvement in energy efficiency was noted, with no particular trend towards one type of orthosis proving to be more effective than any other. However, discrepancies were noted between classifications of CP and between types of orthoses used. It should also be noted that some children experienced a worsening of energy efficiency using their orthoses, suggesting that careful prescription and monitoring needs to occur to ensure that the child's functional abilities are not reduced further as a result of wearing an orthosis.

The papers also highlight the problem of differing assessment protocols, even when using the same measurement tool. The range of walking distances or durations, and exact methodology used for measuring heart rate varies between studies and to date, no optimum protocol has been defined.

6.3.6 Functional Outcome Measures

The evidence in support of using functional outcome measures to assess the benefits of orthoses is limited. In addition, the range of potential outcome measures available is quite narrow, and they lack specificity and sensitivity.

Buckon and co-workers used the walking/ running/ jumping dimensions of the GMFM and GMPM, and the functional skills and caregiver assistance–mobility domains of the PEDI to assess the effect of three orthoses on their patients with diplegia [143] and hemiplegia [144]. Interestingly, the studies found opposing results for the different presentations. Children with diplegia gained significant improvements in GMFM dimensions with all orthotic conditions indicating progression of skill, but showed no change in the quality of movements assessed within the GMPM dimensions. There was no change in mastering mobility skills or degree of independence (assessed with the PEDI) with any of the orthoses. In contrast, the hemiplegic group gained improvements in their GMPM grading for all three orthotic conditions, specifically in the co-ordination and weight shift attributes, compared with barefoot. However, their GMFM scores remained unchanged. Furthermore, PEDI scores for functional skills within the mobility dimension significantly improved under all three orthotic conditions compared with barefoot for this population.

In 2002, Hassani et al [196] used the GMFM and a standardised Paediatric Outcome Data Collection Instrument (PODCI) to compare HAFOs and DAFOs in 16 children with spastic diplegia, aged 5-13 years. They wore each type of orthosis for one month with a two-week baseline interval. No significant differences were found between orthotic types or compared with barefoot using either outcome scale, although differences were found between barefoot and both orthotic conditions in other balance measures used. This suggests that the outcome measures lacked both specificity and sensitivity for orthotic assessment.

In 1994, Evans et al [192] reported the results of a multi-centre randomised controlled trial investigating the effect of orthoses on gross motor performance in 34 children aged 12–48 months with spastic CP. Participants were randomised into two groups, both of whom received regular physiotherapy. One group wore orthoses throughout the study (four months), whilst the other group had no orthoses. The GMFM and

GMPM scales were used to determine any difference between the groups. In agreement with the Hassani study [196] no significant changes were found between the two groups at four months, suggesting the absence of any short-term effects of orthoses on gross motor function in these young children.

Functional outcome measures provide a more goal-orientated assessment of the effect of orthoses on a child's functioning than other measures. However, a wide range of scores is available and they all require time and expertise to administer reliably. They allow the clinician or researcher to establish the wider effects of intervention on the child and their family, but appear to lack sufficient sensitivity for the analysis of orthotic fine-tuning on outcome, where changes are perhaps quite subtle.

6.3.7 EMG Analysis

EMG data highlights changes in electrical activity in a muscle during a contraction (Fig. 15). Problems can arise due to interference from background noise, electrode or lead movement, and artefacts can be produced from skin movement that occurs during walking. However, EMG analysis provides useful information about the functioning of different muscles during gait, and it allows clinicians to assess the effect of different interventions on muscle activity.

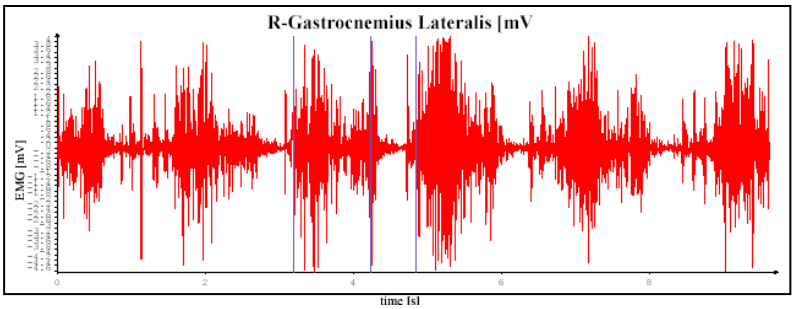


Figure 15. Illustration of EMG data.

Thomas et al's [202] abstract reports the findings of a study on the effect of AFOs on gait in 17 children with CP. Comparisons were made to barefoot data, and motion analysis was used to collect EMG data in addition to

kinematic and temporo-spatial parameters. They suggested a reduction in abnormal EMG activity whilst wearing the AFOs although specific details are not available. They also report improvements in phasic timing for tibialis anterior, gastrocnemius, vastus lateralis and medial hamstrings through orthotic use. They postulate that a reduction in co-contraction might be seen, leading to the potential for a reduction in energy consumption during walking. Further scrutiny or insinuation from the results is not possible as the data have not been published in full.

In 1997, Radtka et al [168] published results of an investigation into the effects of FAFOs and DAFOs on ten children with spastic CP aged 3-8 years (4 hemiplegic, 6 diplegic), using a repeated measures design (ABAC, with barefoot repeated). Specific information regarding the manufacture of the orthoses is provided, allowing an understanding of their function and relevance to this population. Both orthotic designs prevented plantarflexion, but the DAFO permitted dorsiflexion, as described previously. Surface EMG of gluteus maximus, hamstring (biceps femoris), rectus femoris, triceps surae (lateral gastrocnemius) and tibialis anterior muscles was analysed, with the methodology clearly described. One limitation is that muscle onset and cessation timing was defined visually by one of the authors using resting EMG as a baseline. However, they acknowledge this limitation and report ICC's of 0.79 – 0.98 for reliability testing using resting data. Results show prolonged muscle activity during stance across all four sessions, compared with unimpaired children from previously reported literature. There was no significant difference in muscle-firing patterns between the participants with diplegia and hemiplegia, or between orthotic conditions. Furthermore, there was no effect of either orthoses on muscle firing patterns compared with no orthoses.

Rethlefsen et al, [55] examined the effect of FAFOs and HAFOs in 21 children with spastic diplegia, aged 5-13 years. The FAFOs were cast in 0-3° DF, and the plantarflexion stop in the HAFOs was set at the same angle, but with

freedom of dorsiflexion. Comparisons were made to a shoes-only condition. Children wore each set of orthoses or shoes only for three days at a time, in a randomised order, for four to six weeks before testing. Surface EMG data was collected from the hip extensors, knee flexors and extensors, ankle plantarflexors and dorsiflexors, with amplitude normalised to maximum voluntary contraction. Electrodes were not moved between tests, which were completed in one session. Only the timing of peak calf EMG activity was compared between conditions, and no significant difference was found between orthotic conditions, although calf activity was premature under all conditions (around 25-27% gait cycle, compared with 40% reported in Perry [22]). No results are reported for the other muscle groups, despite their inclusion, and we cannot assume they were normal. As found by Radtka et al [168] therefore, orthotic use specifically aimed at controlling ankle motion did not influence the abnormal firing pattern of the calf muscles during gait.

More recently Radtka et al [190] examined the effect of FAFOs and HAFOs in 12 children with spastic diplegia (aged 4-16 years), compared with barefoot. Surface EMG was used to assess timing of the biceps femoris, rectus femoris, lateral gastrocnemius and anterior tibialis muscles during stance using the same electrode placement as previously [168]. On this occasion, an EMG analysing software package (QUANT) was used to determine onset and cessation timings for the muscles to allow calculation of firing duration. Comparisons were made to the same set of normal paediatric data as previously. Again, there was no significant difference in muscle timing for any muscle group under any orthotic condition. As before, they report premature firing of gastrocnemius, and prolongation of activity during stance for all muscle groups compared with normal, indicating co-contraction of both thigh and shank muscles throughout most of stance (i.e. more co-contraction than normal). This confirms the lack of effect of orthoses on abnormal gastrocnemius firing in particular, despite the control of ankle motion offered.

The main consensus from these papers is that orthoses have little, if any, effect on muscle firing, particularly for gastrocnemius. Only Thomas et al's study [202] found a reduction in abnormal activity, but this abstract provides little information to allow a critique of the methodology or results. All studies found abnormal firing patterns of the calf muscles specifically during stance compared with normal, with both Radtka papers [168, 190] also reporting abnormal firing of the quadriceps, hamstrings and anterior tibial muscles. This prolonged firing of the major lower limb muscles, especially with significant co-contraction, leads to high energy consumption during walking, as seen in previous literature [202].

These findings, combined with the limitations in analysis of EMG data, and problems with data collection from the calf complex whilst wearing orthoses, mean that it is unlikely to be the most reliable orthotic outcome measure.

6.3.8 Balance

The effect of orthoses on standing balance is reported less often, with variable methodology, making it difficult to determine key findings.

Harris & Rifle [188] present a single case study of a four year old boy with spastic quadriplegia whose balance was assessed prior to and following the use of bilateral orthoses. A stopwatch was used to measure balance time in seconds (in bilateral stance) with and without orthoses (one AFO and one DAFO). Balance quality was assessed subjectively from photographs of the child's standing posture. Inter-observer reliability of the timed balance test was determined with two observers, who agreed to within one second on 96.7% of occasions. No statistical analysis was performed. Graphical and tabulated balance times clearly show a marked improvement in balance duration whilst wearing the orthoses (193 seconds maximum) compared with barefoot (20 seconds maximum) at the last session. There was no notable improvement in barefoot balance during the orthotic wearing

phase (although no statistical analysis was performed), compared with the baseline taken prior to orthotic use, suggesting that there was no developmental learning effect during the study, and therefore the improvement in balance could be attributed to the orthoses, rather than due to natural progression. Furthermore, a progressive trend of continuing improvement over the five-week period of orthotic use was noted. Qualitative assessment of his balance suggested a more symmetrical standing posture when wearing the orthoses compared with barefoot. His gait and general mobility also appeared to improve through orthotic use.

Wesdock & Edge [203] investigated the effect of wedging the heels of the shoes, and the heels of orthoses, on standing balance (bilateral) in 11 children aged 4-13 years with CP who exhibited a crouch gait. Heel wedging was used to compensate for knee flexion contractures. They found an improvement in standing balance (measured with a stopwatch) with orthoses compared with barefoot, and with the wedged orthotic-footwear combination compared with both barefoot and the non-wedged orthotic-footwear combination. However, due to a small population, and large variation in ability among the group, these results were not significant. Further research into this area is obviously necessary. However, the findings do suggest that with some 'fine-tuning' (in this case adding the heel wedges to accommodate for knee flexion contractures) the functional outcomes of orthotic use can be improved, as hypothesised in this thesis. A criticism of this study, apart from the small participant numbers, is that the hinges of HAFOs for two participants were locked at neutral for the duration of the study, to allow comparison with the other participants. This information implies possible sub-optimal orthotic prescription for these participants, which may compromise the benefit gained from any wedging.

Kott et al [204] use the Paediatric Balance Scale (PBS) to assess the effect of orthoses on 28 participants with CP aged 5-19 years, in addition to a standardized walking obstacle course (SWOC). They found no difference in PBS or SWOC results when wearing orthoses compared with barefoot,

concluding that orthoses may have a minimal effect on functional balance outcomes in children with CP.

Studies assessing the effect of orthoses on balance are limited, with two using the clinical technique of timing balance duration, whilst the other used a balance scale. Studies using the timing method found increases in balance through orthotic use, although the sample sizes were very limited, but the PBS study found no improvement. This could suggest either that the PBS is not sensitive enough to analyse balance following orthotic use, or that the stopwatch method is prone to assessor bias. Balance is an important factor in gait (single leg balance comprises 40% of the gait cycle, allowing contralateral swing-through) and therefore increases in balance may translate into gait improvements.

6.3.9 Summary

As can be seen, the field of orthotic analysis in children with CP is well published. However, despite the extent of research activity, the issues of varying methodologies and outcome measures highlighted by this discussion mean that clear evidence for specific orthotic use remains limited. Furthermore the issues of insufficient detail about the AFO design, group demographics or evidence of specificity of orthotic prescription (i.e. tuning) for each participant reported by Ridgewell et al [20] are highlighted. The following improvements in gait parameters were found through the use of orthoses in children with CP:

- Improvement in ankle posture at initial contact, and during swing, although notable variations existed between orthotic types in the level of control provided
- Improvement in terminal stance plantarflexor moment, although with an accompanying reduction in power generation
- Increase in stride length
- Reduction in energy cost of walking

- Re-attainment of heel strike (from a toe-strike or flat foot contact)
- Improvement in standing balance ability (limited evidence available)

Interestingly, the papers report a limited change in kinematics or kinetics at the hip or knee through orthotic use, along with a lack of significant change in lower limb EMG activity, particularly in the gastrocnemius muscle. The research did, however, highlight the issue of increased abnormal co-contraction between antagonistic muscle groups, and prolonged firing duration in the lower limb muscle groups, both of which lead to increased energy consumption during gait.

Functional outcomes were less clear, suggesting that the effects of orthoses were subtler, and that functional outcome scales are perhaps not sensitive enough to allow the analysis of orthotic intervention in this population.

Another important finding, in relation to this thesis, was that for some patients, orthotic use actually increased the energy cost of walking. This implies that specific energy cost analysis would be useful in determining the true effect of orthotic intervention on each child, and also that fine-tuning of orthoses may be needed to ensure that the orthotic prescription is optimised for each child.

Conclusions as to the relative benefits of different types of orthoses are limited due to the range of specific orthotic designs used, and the heterogeneous nature of the participant groups. This also suggests that future research should ensure that the orthoses under investigation are optimised for each participant, to allow a true analysis of their benefits, although this makes grouping for orthotic type difficult.

The literature review also serves to highlight the large variation in outcome measures used for orthotic analysis, and the pros and cons of each method.

In relation to the outcomes selected for this set of studies, it can be seen that for energy cost there were a range of indices used, with no real consensus between studies. Measures using oxygen analysis are at risk of the influence of cumbersome equipment use, and may be considered unsuitable for paediatrics, in particular children with CP due to the potential anaerobic nature of their gait [87]. The Physiological Cost Index (PCI) is more commonly used, but its reliability is limited by different methodologies between studies (length of walk, type of walkway, method of monitoring heart rate etc). In terms of measures used from video analysis, foot-strike characteristics are most commonly assessed using a simple three-point rating scale to determine the method of foot contact during gait.

This critical appraisal of available literature serves not only to provide evidence of the benefit of orthoses for children with CP, but also to highlight the problem of selection of optimum methodology to analyse the effect of orthotic intervention within this population, placing the methods selected for this set of studies into context.

6.3.10 Relevance of Outcome Measure Review to the Thesis

This literature review highlights the problems associated with assessing gait, and more specifically the effect of orthoses on gait, in terms of selecting a relevant and applicable outcome measure. A large number of variables can be analysed from the range of methodologies, and this makes it difficult to select one outcome that will be repeatable, appropriate and sufficiently sensitive to determine relatively small (but clinically relevant) changes in outcome. Use of a video vector system allows kinetic aspects of gait to be assessed without the need for more in-depth computerised analysis, and is becoming more widely recommended as the method for ensuring optimal orthotic tuning [1, 20, 173].

The use of energy cost analysis to determine the extent of benefit for the child provides a single unambiguous measure to highlight any gains made,

which again should be comparable between users, provided a consistent methodology is used. Its link with abnormal moment arms and abnormal muscle firing patterns is highlighted.

Lastly, examination of footfall characteristics from video data is recognised as a clinically useful tool for determining improvements in overall gait pattern.

6.4 Requirements for Orthotic Studies

Ridgewell et al [20] provide best practice reporting guidelines for AFO studies for children with CP and summarise that the following factors should be documented for participants in AFO studies. Whilst these were published after the development of the clinical trial protocol for this study, inclusion of these details had already been considered and will be reported.

- Sample group details
    - Age
    - Diagnosis - more specifically topographical distribution and GMFCS level and some inclusion of movement disorder

They also suggest that the group should be homogenous in terms of indication for orthotic treatment, but this appears to relate more to studies testing a specific orthotic design.

- AFO details
    - Orthotic aim in relation to patient presentation
    - AFO ankle angle
    - Trim lines
    - Tuning procedure (if completed)
    - Shank-to-vertical angle
    - Mechanical properties
    - Manufacture – custom made or pre-fabricated

    - Movements – specific to the orthotic design
    - They also suggest description of the materials used to allow others to replicate the design if required.

- Testing protocol
    - Control condition
    - Order of testing (if relevant) with a suggestion that a return to baseline should be used where possible
    - Acclimatisation period

Inclusion of all of these factors in the write up of an AFO study allows the reader to determine the exact procedure undertaken and to form an opinion as to whether optimal orthotic prescription and practice has been followed for each participant.

CHAPTER 7: STUDY PLAN AND HYPOTHESES

From the previous sections, it can be seen that there is a gap in the research with regards to investigating the effect of fine-tuning orthoses on aspects of gait in children with CP.

The aim of this thesis was to investigate a method by which orthotic tuning could be quantified and then examine the effect of tuning on the energy cost of walking in children with CP. A series of studies were designed in order to achieve this aim:

Study One presents the results of a National Survey, which examined the availability of the equipment required for the tuning process and of the current clinical practice in orthotic management.

Study Two investigated the validity and reliability of the objective measurement taken from the video based system (measurement of the moment arm at the knee in the sagittal plane) by comparing the results with the same measure taken from a gold standard measurement tool. Reliability of two possible energy cost methods was also tested. This study involved healthy adult participants.

Study Three was designed to investigate the effect of specific orthotic tuning on energy cost of walking in a cohort of children with CP, whilst also providing reference values for both outcome measures (energy cost and moment arm measure) from healthy children.

Although research already shows that orthoses often reduce the energy cost of walking [88, 143], to date there is no published evidence on the effect of individually fine-tuning orthoses on energy efficiency [1], basically because specific fine-tuning has not taken place during the prescription process. This series of studies therefore aims to answer this specific question.

7.1 Hypotheses

Based on the aims of the study, the following hypotheses were defined:

1. Measurement of the moment arm manually using a video vector system is a valid and reliable measurement tool.

2. The Total Heart Beat Index (THBI) is a more reliable measure of energy cost during walking than the Physiological Cost Index (PCI).

3. Use of tuned orthoses reduces the energy cost of walking above that of orthoses that have not been specifically tuned, for children with CP.

CHAPTER 8: STUDY ONE: SURVEY OF GAIT LABORATORIES

8.1 Background

The availability of video vector systems (VVS) within motion analysis laboratories in the UK and Eire was not known at the start of the study, and the nature of their use varied within published literature [52, 56, 107]. In order to justify the need for research within this field, and more specifically to investigate an outcome measure for the system, the current trends in practice were investigated.

8.2 Methodology

A survey was designed to gather information about equipment availability and use within motion analysis laboratories around the UK and Eire. The main aim of this survey was to determine the availability of video vector systems within these laboratories, and to establish the methods used to analyse the data gained, so as to place the current research plan into context within the clinical setting. Additional information pertaining to the functioning of laboratories was requested to provide an overview of the use and caseload of gait laboratories.

A draft survey was developed with these aims in mind and was sent to seven local clinicians for comment, one of whom had specific gait analysis experience. Ideally a focus group of laboratory clinicians experienced in the field of gait analysis would have been chosen. However, due to the limited number of such laboratories (34) available for the final survey, it was felt that maximising the number of respondents was paramount, and as such excluding several due to involvement in a focus group would have been counter-productive. The clinicians reviewing the survey were asked to comment on the general layout and readability of the survey, with changes

made according to the comments given. The final survey tool is found in Appendix 2.

A database of motion laboratories within the UK and Eire was developed through personal knowledge within the field; contact via special interest mailing groups; and scouring the internet for motion analysis laboratories within the required location. Once the survey was finalised and the mailing list complete, the survey was sent out to each identified laboratory, with a covering letter and requested return date. Respondents were informed that consent was implied by return of the completed survey. Following this initial return date, a reminder letter was sent to the outstanding laboratories to optimise the number of returns, given the small sample population available. Each participating centre was required to fill in just one survey form per laboratory, with the information pertaining to the laboratory facilities as a whole, not from an individual within each facility.

8.3 Results

In total, 34 laboratories were contacted within the UK and Eire from September 2004 to April 2005, with a return rate of 25 respondents (74%). Within these respondents one centre was no longer running, and one centre declined to complete the survey, giving a total of 23 completed survey available for analysis, corresponding to a 67% overall response rate.

Descriptive analysis was performed for each question, which gave an excellent overall impression of the set-up of different gait laboratories in terms of equipment and staffing; as well as the nature of the clinical work being undertaken. For the purposes of this study a summary of the results is provided below in sections, with particular attention given to the areas relevant to this research question. Relevant respondent figures are provided within the body of text.

Section A: About your service (Q1-10)

This section investigated the set-up of each gait laboratory in terms of location, staffing and equipment.

Results showed that over 90% of laboratories were centred in either a hospital or university, which tied into their predominant use being clinical and research.

When asked about staffing (n=17) there was a huge range of professional roles involved and staffing levels within the gait laboratories. The predominant professions encountered were medical staff, physiotherapy and technical or engineering input, with a significant number of senior staff highlighting the need for a level of expertise and experience.

The most common equipment within each centre were force plates, which 100% of centres had; a motion analysis system, which 95.7% of laboratories (22/23) housed; and an EMG system, which was present in 78.3% of centres (18/23). Just over a third of all laboratories housed a video vector system (8/23).

Of the laboratories that gave details of their video vector system (6/8), all bar one had set it up using technology and expertise from within the laboratory, rather than purchasing any commercial system.

Almost three quarters of all centres (17/23) provided a clinical gait or orthotic analysis service, suggesting this is a key role for motion analysis laboratories within the UK and Eire, with the other centres being purely research-based. Out of the centres providing a clinical service, the length of duration of service ranged from 1.5 - 13 years, with 13/17 responses (76.5%) within a 6-10-year grouping. There was a range of 4-35 patients assessed on average through the clinical services per month, with a mean of 15. One other laboratory stated a variation in caseload according to time of year.

Out of the patients seen through the clinical services, a mean of 57% of this caseload was children with cerebral palsy, although ranging from 0-100%. Half of the centres (8/16) stated that more than 75% of their caseload was children with CP. Only three centres never saw any children with CP clinically.

This suggests that children with CP often make up a large portion of the caseload for laboratories offering a clinical gait and orthotic analysis service.

The most common sources of referral to a clinical gait analysis service were paediatric orthopaedic consultants, with physiotherapists and adult orthopaedic consultants also popular. In addition, other consultants, GP's, and neurological consultants refer into these services. This further highlights the need for specialist gait expertise in the paediatric neurological population.

These findings highlight the availability of clinical gait services to the general public and in particular to the population of children with neurological disorders. Specialist equipment and staffing are available to allow a comprehensive assessment of their gait using a range of techniques, and the data show that this population is commonly a significant proportion of the clinical work that takes place within most gait laboratories. However, the results also highlight that a range of equipment is used between laboratories, and therefore the set-up and exact data collected in each laboratory will be different. This highlights the need for objective gait data outcome measures to be applicable across software and data acquisition methods.

Section B: Video Vector System (VVS) (Q11-13)

Just over a third of all participating laboratories housed a VVS (8/23), and of these centres, 7/8 also provided a clinical gait service, suggesting the benefit of a VVS within their clinical service. However, on viewing the length of time these systems have been available, it can be seen that they were relatively new, with half of the centres having a VVS for less than five years, and two of these centres having gained their system within the previous year. Additionally, a further centre was in the process of developing their VVS. It may therefore be postulated that the availability of VVS's within motion laboratories could continue to increase in coming years, particularly considering may of the other laboratories already housed the equipment required to set up a video vector system without additional outlay.

Of those centres without access to a VVS, there was still a high proportion (64.3%) providing an orthotic assessment service using other data collection methods, mainly full motion analysis or simple video analysis. Having highlighted the availability of a video vector system within motion analysis laboratories, its comparatively new status, and given the limitation of currently available published literature to provide an evidence-base for its use in the clinical setting, the need for further research within this field is clearly indicated.

Section C: Use of the vector system (Q14-24)

The information from this section investigated the use of the video vector system. The most common uses of the system were for post-graduate teaching (5/7) and paediatric gait / orthotic analysis (4/7). The use of the VVS to assess prosthetic patients and adult gait was also indicated, areas which would also benefit from further research into the development of an outcome measure for use with this system.

Interestingly, most centres using their VVS to assess gait or orthoses visually estimated the position of the ground reaction force in relation to

the joints to be assessed (5/6), and none to-date had developed a method of quantifying this measurement, although two centres did use computerised calculation methods.

All centres assessed the position of the ground reaction force vector in relation to the ankle joint, with most additionally assessing at the knee (5/6). Furthermore, most centres assessed the whole of the stance phase of the gait cycle, although one centre did focus on mid-stance, and another reportedly assessed parts of the swing phase (although this should not include a ground reaction force vector, as the foot is not in contact with the force plate). All centres used their systems in the sagittal plane, although most also assessed the coronal plane (6/8). When using the system for orthotic analysis, the average length of an assessment was 31-60 minutes per patient, with the systems most frequently being used monthly or less often (6/8), with only two centres using their VVS weekly or more.

From a technical perspective, most centres (7/8) did an alignment check on a sessional basis, to ensure accurate overlay of the vector and image. There was no real consensus on the protocol for this, although a common factor seen was the application of a vertical load onto the force plate to allow the alignment of the ground reaction force vector this generates to be checked against the video image, where a commercial calibration check was not available within the software used for the system.

The most common equipment used within the system were Kistler force plates to record the force (6/8); an in-house system or software to generate the vector image from this force data (5/8); and either a commercial system (3/8) or in-house software (5/8) to overlay the image of the vector onto the video image of the subject. This creates a problem with use of a standard computerised method of assessing the outcome of the vector analysis.

These findings highlight the diversity of systems in use around the UK and Eire, with little evidence of any objective measures used to assess the data collected. The systems are generally not used very frequently (monthly or less) and therefore any assessment method must be easy-to-use to ensure high inter and intra-rater reliability, and encourage usage. Furthermore, the need for specific research into an objective measure to be used with the VVS is clearly highlighted to reduce the subjectivity of visually analysing the data.

Section D: Outcome Measures (Q25-27)

This section investigated other outcome measures used for gait or orthotic analysis, and found that the most commonly used outcome measure was the calculation of energy cost (8/17), with the use of observational gait scales also frequently employed (7/17). Energy cost measures were commonly used to assess gait (7/10 (two centres didn't select 'yes' for use of energy cost measures but then completed the question on use of energy cost measures), although less often for orthotic analysis (3/10). They were also used to assess the effect of FES, and also for research, although the field of this was not stated.

The indirect methods of energy cost calculation were the most popular, with the Physiological Cost Index highlighted as the measure of choice within this survey (8/9), although two centres did use the THBI and three centres employed direct methods using Cosmed[g] and/or Douglas bag[h] methodology.

[g] Manufacturer of the oxygen analysis equipment commonly used for assessment of energy cost. www.cosmed.com

[h] Method of collection of respiratory gases, similar to Cosmed system, but dating back to early 1900's.

8.4 Discussion and Conclusion

In relation to the main aim of this survey, which was to investigate the availability and use of video vector systems within motion analysis laboratories, the findings highlight several important points.

Firstly, this type of system is relatively new within laboratories, and although only around a third of laboratories had a functioning system, another was in the process of developing a VVS, and most laboratories housed the key elements required to be able to develop such a system, namely a force plate and engineering or technical staffing.

Secondly, there was a clear current clinical trend (5/6 respondents) of visually estimating the position of the GRF vector in relation to the lower limb joints (and hence the moment arm about the joint). This is a subjective method of analysis, which would therefore have questionable inter-assessor or inter-session reliability.

Centres using a VVS to assess gait analysed the vector predominantly at the knee and ankle, and generally assessed the whole of the stance phase of the gait cycle, although mid-stance was noted as an area of specific interest. Sagittal plane analysis was performed at all centres, although most also assessed in the coronal plane. These assessments were not particularly lengthy (31-60 minutes per person) and were generally shorter than for full motion analysis (which usually takes around two hours, plus processing and report time). However, most users were only using the system on a monthly basis, or less. This may reflect the specifics of their caseload, or the lack of published evidence of its beneficial use.

The range of equipment used to set up the mostly in-house systems was varied, and therefore the methods by which laboratories generate their VVS are diverse. The use of a commercial system for calculating the moment arm

would therefore be limited, or would need to be flexible enough to be incorporated into all the different video vector systems currently used.

Laboratories used their VVS for post-graduate teaching as well as for gait analysis, but less so for orthotic analysis. The reasons for this were not investigated, but this is an area for increased potential future use, especially if an objective measure existed to quantify the process, and published evidence of its beneficial application in the area of orthotic analysis was available.

Many centres without the availability of a VVS provided an orthotic or gait analysis service using alternative methods such as full motion analysis or video analysis. Video analysis remains a subjective form of assessment, and although full motion analysis is more quantitative, its application in orthotic management can be limited, as it requires further compliance and a longer assessment session to include the application of a set of markers to define the lower limb segments. Furthermore, the placement of markers to assess the effect at the ankle becomes less reliable as an estimation of bony landmarks over the top of the orthosis and footwear is required, and accurate marker placement is difficult. This is particularly difficult in hinged AFOs where the hinge is located at the lateral malleolus, a site for marker placement; and secondly where wedged AFOs are used, as the exact location of the heel within the orthotic-footwear combination has to be estimated to give a representation of ankle motion.

It may be postulated that, considering the relative youth of the VVS and its use within the UK and Eire, we might expect the number of laboratories developing these systems to increase in the coming years, further highlighting the need for an objective measure to use with the systems that is flexible enough to be utilised by a diverse range of systems and users (in terms of expertise and clinical speciality). Such a measure therefore needs to exploit the common factors between these systems, which is essentially the presence of an image of a GRF vector overlaid onto an image of the

subject. The method described and developed within this thesis would comply with all these requirements, as it is essentially a measure that is calculated externally to the video vector system and is therefore independent of the methods used to generate the images.

Additionally, the survey results endorse the use of gait and orthotic analysis for children with CP and therefore the importance of developing a system and measure that is applicable to this clinical group.

Three quarters of laboratories provided a clinical service, emphasizing this important role within the health service. However, these services were also relatively new with most running for less than 10 years. This suggests that the use of motion analysis within the clinical setting has the potential to increase further in the future as techniques and results become evidence-based through published clinical research. Within this clinical population children with CP make up a large proportion of most laboratories' caseload, with paediatric orthopaedic consultants and physiotherapists accordingly being the most frequent referrers to the clinical service.

Furthermore, section D of the survey suggested that an indirect measure of energy cost, most commonly the PCI, was employed as an additional clinically friendly outcome measure tool in the assessment of gait. The research background, as highlighted in the literature review, remains inconclusive in this area, and therefore further investigation into the reliability of different energy cost measures is warranted.

In conclusion, video vector systems are available in several motion analysis laboratories across the UK and Eire, with the suggestion that this may increase in time given the availability of other motion analysis equipment and the development of laboratories and their facilities in general. The methods by which these VVS's are set-up varies widely according to the equipment available (type of force plate etc), and currently most VVS users visually estimate the position of the ground reaction force vector in relation

to the lower limb joints throughout gait, rather than employing a more objective methodology. There is therefore a need for an objective measure to be developed, which must be applicable across systems, rather than being system-specific. The use of an energy cost measure in the analysis of gait is clinically applicable. However, the evidence-base for this remains contradictory and therefore further research and clarification in this area is paramount.

These survey data were collected early in the study period. Later in the studies it was felt that a further review of current clinical practice was required to ensure that the information summarised above remained contemporaneous. Without the facilities available to repeat the above survey, information was gathered from the UK based Clinical Movement Analysis Society (CMAS) website (www.cmasuki.org) which provides information about the facilities and services available at all of the CMAS accredited gait laboratories. This was accessed on 02.07.2014 and the following information determined: Out of the 15 laboratories that had undergone the CMAS accreditation process, all of them were offering a level of clinical service. Out of these laboratories, 10 were offering a video vector tuning service (i.e. 67% compared with around 33% of the 23 labs in the earlier survey). All of these facilities saw children with cerebral palsy as part of their caseload, with most of these being a major part of their caseload, further highlighting the need for evidence to back-up the treatment and assessment techniques used for this patient group.

Whilst this is only a very brief review of facilities, it would suggest that the use of video vector technology and the process of orthotic fine-tuning, remains contemporaneous and therefore a valid area for on-going research.

CHAPTER 9: STUDY TWO: VALIDITY AND RELIABILITY OF THE CLINICAL TRIAL OUTCOME MEASURES

9.1 Introduction

In order to fine-tune an orthosis accurately, an objective measurement is required to inform the prescription and assessment process and to help determine the optimal clinical outcome. Measurement of the moment arm at the knee has been used clinically for this purpose in several centres [52, 53, 85], but the methods used have either required specific expensive equipment, or have been subjective (visual estimation - see Survey results). This study aimed to develop a user-friendly measurement tool to be used by clinicians when adjusting and 'fine-tuning' an orthosis. Firstly, the study therefore aimed to validate this measure and report its reliability. A 3D computerised gait analysis system was used to calculate the moment arm from standard gait analysis data acting as a gold standard against which to compare the user-friendly, manual video vector measurement method. Reliability was tested at repeat sessions.

Furthermore, as highlighted previously, a lack of evidence exists into the effect of orthotic tuning on the energy cost of walking [1]. As described in Chapter 5, this can be measured clinically with relative ease using a heart rate monitor to calculate an energy cost index. As also previously highlighted, the index used most extensively to-date in research is the Physiological Cost Index (PCI). However, because of its questionable reliability, and the more recent presentation of the Total Heart Beat Index (THBI) with its greater proffered reliability, this study examines the reliability of both indices, in order that the most appropriate index be used during the subsequent clinical trial to determine the effect of orthotic fine-tuning on gait efficiency.

To ensure that the heart rate data used for the energy cost indices were recorded accurately, the validity of the heart rate monitor was first determined in a single-participant study.

9.2 Validity of the Polar Sports Tester Heart Rate Monitor

9.2.1 Previous Studies

Heart rate monitors (HRM) are a convenient, portable and relatively inexpensive way of monitoring heart rate during various exercise conditions. Polar®[i] is a major manufacturer of heart rate monitors, producing a wide range of models with a varied level of data analysis during and after exercise.

Previous studies [205, 206] have investigated the validity of a Polar HRM as a method of assessing heart rate during rest, sitting tasks, and exercise, but have all used the Polar Vantage XL model. Goodie et al [205] investigated its validity by comparing data from the HRM to that collected using ECG (electro-cardiogram) in 30 participants. They found excellent correlations (mean r=0.98) between the two measures (ECG and HRM) at rest and during two different tasks (hand grip and a mental arithmetic task). Only the data from three participants had correlations below r=0.90. Schrader et al [206] validated the Vantage XL during an upper limb exercise at sub-maximal and maximal levels of effort in 32 participants, comparing the HRM with ECG data and also found excellent correlations (r=0.99 for sub-maximal, and r=0.94 for maximal efforts) between the measures.

In order to confirm the validity of the Sport Tester model of Polar HRM, a simple comparison study was performed comparing the results of the Sports Tester HRM with those collected using conventional ECG equipment, in a single participant.

[i] Polar Electro (UK) Ltd, Warwick, England. www.polar.com/uk-en

9.2.2 Methodology

A Cardiette AR600[j] electro-cardiogram unit, using four electrodes placed on the wrists and ankles of one participant was used to detect and record cardiac electrical activity on a grid paper-feed system. A paper speed of 25mm/s was used to allow identification of the exact timing of each heart beat peak deflection to within 0.02 seconds.

Heart rate data were recorded concomitantly using a Sport Tester Polar HRM. This comprised a sensor/transmitter unit, and a receiver unit. The sensor/transmitter unit strapped around the chest of the model, more specifically at the level of the xiphisternum, using an elasticated band. This unit housed electrodes that detect cardiac impulses. These impulses are then transmitted to the receiver unit on the wrist, which calculates the time interval between each heartbeat and from this the heart rate. This is displayed continuously on the receiver unit, and data could be recorded every 5, 15 or 60 seconds. Heart rate was recorded every five seconds to maximise the amount of data available for comparison with the ECG data. The recorded data were stored on the receiver unit until they were downloaded onto a computer using the Polar software and interface unit. These data were then exported into an Excel spreadsheet for analysis.

Data were recorded for 60 seconds whilst resting seated, and then for another 60 seconds whilst standing still. It was not possible to collect data during walking for two reasons. Firstly, the sensitivity of the ECG unit to movement resulted in significant movement artefacts due to excessive lead movement. Secondly, the limited lead length would have required the assessor to walk alongside the model whilst carrying the cumbersome recording unit.

Once all of the ECG electrodes and Polar equipment were in place, and the Polar HRM was transmitting data, the ECG unit was turned on to allow its

[j] Central Medical Equipment Ltd, Nottingham.

initial set up process to complete. Recording of the Polar HRM data was then initiated, and the point at which this commenced was marked manually on the ECG trace to enable synchronisation of the two recordings.

9.2.3 Data Analysis

In order to calculate the heart rate for every five-second period from the ECG trace, and to compare it with the Polar data, the raw ECG data were processed manually as follows (Fig. 16):

- The trace was divided into '5-second periods' commencing at the peak of the first heartbeat following initialisation of Polar heart rate recording.
- The number of whole heartbeats during each period was counted from the peak deflections of the heart rate trace. The last heartbeat within each period was taken as the peak closest to the 5-second end-point. This was either just before or just after the 5-second delineation.
- The exact timings of the peak of the first heartbeat, and the last heartbeat during each period were noted, and therefore the time taken for those beats to occur was calculated (i.e. just over or under five seconds). Note the grid lines used to calculate timings are not visible in the image below due to the scanning process.
- The timing of the next set of heartbeats commenced at the peak of this last heartbeat, to ensure no heartbeats were excluded.
- At the end of the 60-second period, the last heart beat peak closest to the end of that five-second period was used to complete data analysis.

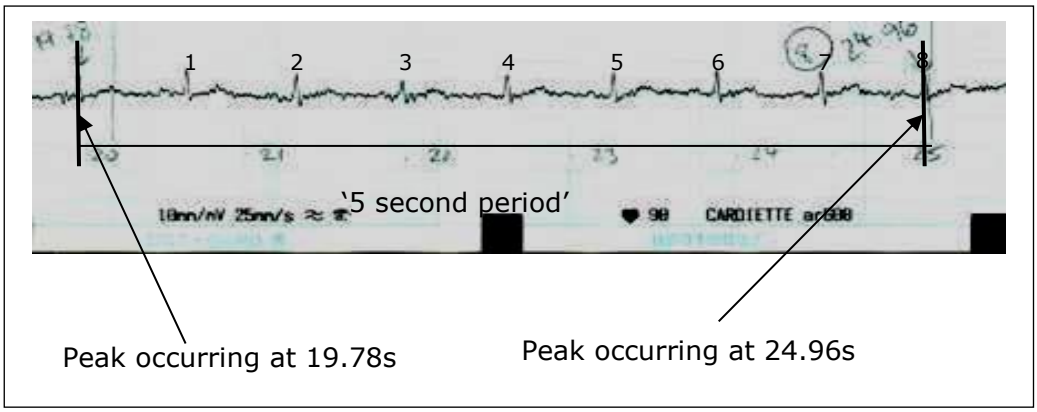


Figure 16. Illustration of manual processing of ECG data.

Using the number of heartbeats during each '5-second period' and the exact duration of each period, the mean heart rate (HR) (in beats per minute) for each '5-second period' was be calculated, and compared with the data recorded by the Polar HRM using the following equation:

$$Mean\ HR\ for\ each\ '5second\ period' = \frac{number\ of\ heart\ beats\ during\ period\ x\ 60}{duration\ of\ period}$$

In the example above (Fig. 16), there were eight heartbeats in the period from 19.78s to 24.96s, i.e. in 5.18 seconds, giving a heart rate of 92.7bpm for this '5-second period'.

9.2.4 Results

A total of 59.64 seconds of ECG data were analysed during seated resting, and 60.42 seconds during quiet standing. The mean duration for each '5-second period' was 4.97 seconds (SD 0.33s) for resting HR, and 5.04 seconds (SD 0.19s) for standing HR, providing 12 heart rates during the 60 seconds, to allow comparison with the Polar data.

Plots of ECG versus Polar heart rate data for each '5-second period' are shown in Figure 17.

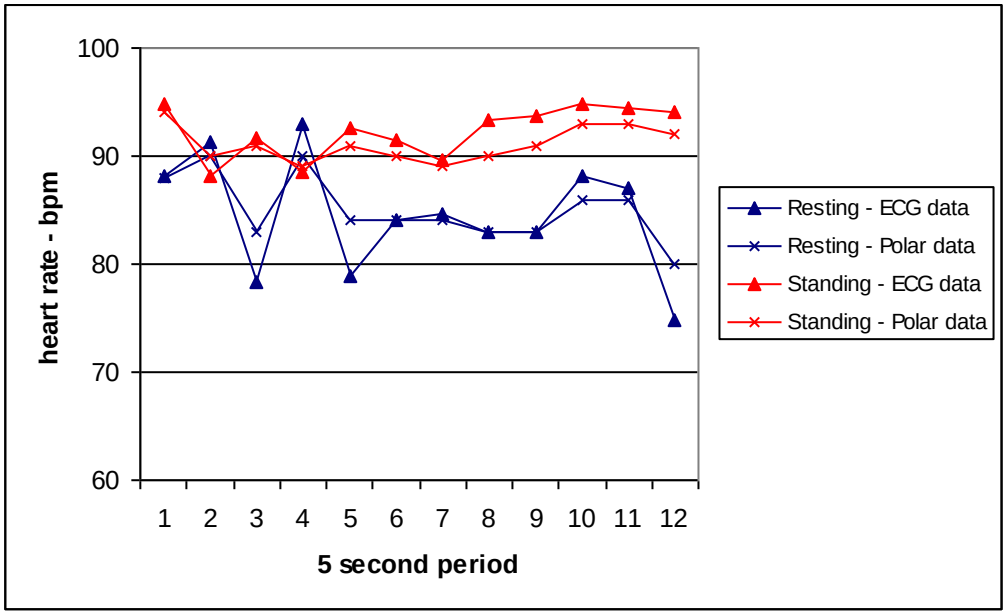


Figure 17. Comparison of heart rate measurement systems.

They show a good agreement between the heart rate recording methods, with the same pattern of peaks and troughs shown with each system. At certain points with the reading, there is some discrepancy between the two systems. The mean difference between the two measures was 1.9bpm (range: 0.0 - 5.2bpm) for resting heart rate and 1.6bpm (range: 0.4 – 3.4bpm) for standing heart rate. Neither system consistently provided a higher heart rate.

In order to clarify the agreement between the data further, the total number of heartbeats during the data collection period (60 seconds) was calculated as:

$$\frac{\Sigma \text{mean heart rates for each } '5-\text{second period}'}{12}$$

The total number of heartbeats during resting using the ECG was 84.5 beats, compared with 85.1 beats for the Polar data. During standing the total number of heartbeats was 92.3 beats using the ECG, compared with 91.1 beats using the Polar HRM. The maximum difference in total heartbeats

obtained by each measure was 1.2 beats over the 60-second period. Again, neither system gave consistently higher readings.

Additionally, the reliability of the two measures was tested using intra-class correlations, accepting that there were only two measures taken from one individual, although there were 12 sets of data for each measure. Reliability of the resting heart rate was very good (r= 0.884), as was the reliability of the standing data (r= 0.872). Whilst this is a little lower than Goodie et al found, this investigation used only one participant for feasibility, whereas their study examined 30 participants in four different situations.

9.2.5 Discussion

The difference in values for heart rate (maximum of 5.2bpm) between the two systems during each '5-second period' may be explained by the issue of synchronisation of the two sets of data at the start of recording. It was not possible within the ECG recording system to mark the commencement of Polar heart rate recording exactly, as the scribing part of the system was housed within the body of the unit, and was therefore inaccessible. The data had to be marked as close to the exit point of the paper as possible, and then the exact commencement point estimated from this. There may therefore be a shift in synchronicity of a fraction of a second between the data sets, which may account for this discrepancy. Figure 17 highlights that the discrepancy was inconsistent in terms of which measure recorded the higher heart rate (E.g. Polar higher for periods three and five, but ECG higher for periods two and four for the resting HR data), which may be explained by the suggestion above. Goodie et al found a consistent significantly higher reading from their Polar HRM compared with the ECG data. This was not found in the present study and in fact, for the standing data, the ECG values were higher for periods five to 12 for the ECG, compared with the Polar data.

The discrepancy may also be due to the slight difference in synchronicity of the 5-second periods, given that the ECG data were divided into approximate rather than exact 5-second periods, to allow an accurate calculation of the heart rate.

9.2.6 Conclusion

This single case study verifies that the heart rate data gained from a Sport Tester Polar HRM correlates highly with that gained using ECG, and therefore clarifies its validity for the measurement of heart rate during resting and standing. It was not possible to collect heart rate data using the ECG system during walking, as there was too much interference from the movement of the leads. However, further studies have shown excellent correlation between Polar Heart Rate monitors and ECG [205-207] during exercise further validating this method of recording heart rate.

These findings therefore confirm the validity of using a Sport Tester Polar HRM for the collection of heart rate, to further allow calculation of energy cost measures within this thesis.

Although a different model of Polar HRM was then used for the clinical trial (due to change of study setting and a more modern HRM being purchased), the validity of the Polar HRM technology is validated in this study, and validity of the RS800CX model used in Study Three is provided by Essner [207], albeit in canine subjects.

9.3 Validity and Reliability of the Study Outcome Measures

9.3.1 Background

The validity and reliability of the video based measurement, and the reliability of the energy costs measurements were investigated in this study. In addition, the study protocol was tested for feasibility to ensure accurate and appropriate data collection methods were selected for Study Three.

Study Two therefore collected moment arm data using the video vector system and compared the results gained against a gold standard to provide concurrent validity of the measurement tool. Furthermore, the data gained were compared against other previously published data [56, 111] for further validity. Reliability of the measurement between sessions is shown, and inter- and intra-rater reliability tested to determine the clinical usefulness of the measurement.

The relative reliabilities of the PCI and THBI over time (test-retest reliability) were compared, ensuring that the most robust measure was used in Study Three. Heart rate data for these indices were recorded using a Polar HRM, whose validity was determined in section 9.2.

Finally, the feasibility of the protocol was tested in this study, to allow amendments to be made and to facilitate accurate data collection during the subsequent pilot clinical trial (Study Three).

9.3.2 Hypotheses

The following null and experimental hypotheses apply to this phase of the study:

Null hypotheses:

1. There is no difference in reliability in PCI between data collected over five and ten minutes.

2. There is no difference in reliability in THBI between data collected over five and ten minutes.

Experimental hypotheses:

1. The THBI is more reliable than the PCI for measuring the energy cost of walking.
2. Manual moment arm measurement using the video vector system is a valid measure as compared with data processed from existing published methods (from the CODA system).
3. Moment arm data collected from the VVS are reliable between sessions.
4. Moment arm data collected from the VVS has good inter-rater reliability.
5. Moment arm data collected from the VVS has good intra-rater reliability.

9.3.3 Methodology

The data for this study were collected in the Human Performance Laboratory, within the Division of Physiotherapy Education at the University of Nottingham. Study paperwork is found in Appendix 3.

9.3.3.1 Participants

Following ethical approval from the University Medical School Ethics Committee, ten adult healthy volunteers were recruited using posters that were displayed internally. Informed, written consent was gained prior to inclusion.

Exclusion criteria included:

- History of neurological problems,
- Surgery to the lower limbs during the preceding six months,
- History of club foot
- Any conditions affecting gait.

Participants were also tested for lower limb soft tissue tightness and were excluded if they were considered to have significant tightness that would affect their gait, based on the researcher's clinical experience. During the study, it became apparent that additional exclusion criteria should include the use of medication affecting heart rate and presence of knee hyperextension during gait.

Participants were instructed not to eat anything and to avoid caffeine for at least two hours prior to each session, to minimise the effect of digestion or caffeine on heart rate.

9.3.3.2 Equipment and Technical Set-Up

9.3.3.2.a Video vector system

The video vector system was set up using equipment already available within the laboratory, with the purchase of only one small additional piece of equipment. The set-up process followed the guidelines provided by Rowe et al [208], although generation of the ground reaction force vector is different as their method was out of the scope of the expertise available within the laboratory. The video vector system consists of a single AMTI force plate[k] embedded into the walkway and covered with industrial-style flat tile carpet (i.e. hidden); the CODA motion analysis system[l]; and a portable analogue video camera situated perpendicular to the force plate centre. Figure 18 illustrates the diagrammatic set-up.

[k]Advanced Medical Technologies Inc. Massachusetts, USA. Model OR6-7.

[l] Charnwood Dynamics Ltd, Leicestershire, UK. Model mpx30.

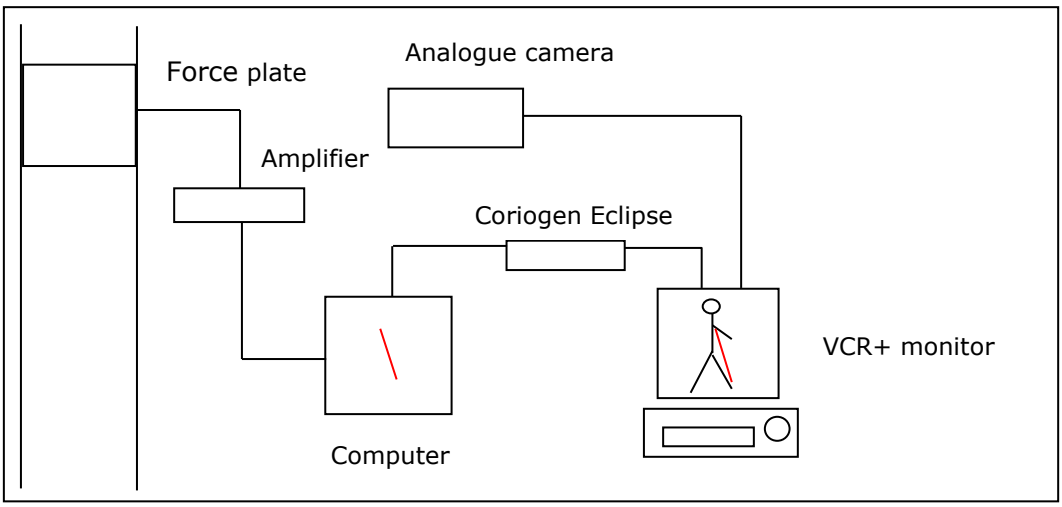


Figure 18. Diagrammatic representation of vector system set-up.

Data from the force plate were fed into the CODA motion analysis software[m] via a force plate amplifier[n], and the vertical ground reaction force (GRF) in the sagittal plane was displayed in 'fast real-time' within the 'stick figure view' on the computer screen, refreshing at a rate of around 50Hz.

As no markers were used, the computer screen showed a blank screen until the force plate was struck, when the GRF (vector) image was represented. The video camera[o] was set up with the centre of the lens 21cm above the ground (i.e. as close to the floor as possible, so as to minimise any parallax errors), positioned perpendicular to the centre of the force plate and zoomed out to view as much of the body as possible (~1.5m height at force plate centre). This image was fed through a mixer[p] before being viewed on a standard TV monitor in real-time (frame rate of around 25Hz) and recorded onto a VCR[q].

Following the technical guidelines of Rowe et al [208] a Coriogen Eclipse unit[r] was used to superimpose the image highlighting the GRF vector from

[m] CODA motion analysis software version MA5.46
[n] Advanced Medical Technologies Inc. Massachusetts, USA. Model SGA/MCA.
[o] Panasonic. Model DP200.
[p] Panasonic. Model WJ-AVE5/B
[q] Panasonic. Model NV-HS930.
[r] CoriogenEclipse, Vine Micros Ltd, Kent, UK.

the computer screen onto the video image of the force plate area on the TV screen (Fig. 19). The Coriogen Eclipse unit was purchased in 2002 at a cost of £350. Usually used to project computer images onto a screen for teaching or broadcast, it allowed the computer image to be overlaid onto the video image, with the black background of the computer image faded to show the video image beneath the vector screen.



Figure 19. Image of vector overlaid onto video image.

Alignment checks ensured that the images were overlaid accurately. The Biomedical Engineering department made a calibration rod (shown in Fig.20, p136), which was non-flexible and designed with a pointed tip at one end to allow a precise point of application of force. This was used to generate a vertical force on the force plate, and the subsequent vector image on the TV screen was checked prior to each session, to ensure accurate overlay of the force vector on the calibration rod at the point of application (Fig. 20). This process was repeated at different areas of the force plate to ensure accuracy of vector alignment over the force plate. Adjustments were made to the camera position or vector screen position and scaling to ensure accurate alignment prior to data collection.



Figure 20. Alignment check showing overlay of the vector (green) onto the calibration rod.

This alignment checking process is in accordance with that performed by all of the responding laboratories to the survey (Study One, Chapter 8) and to the standards of practice developed by the Clinical Movement Analysis Society (CMAS) of the UK and Eire for gait laboratories.

9.3.3.2.b CODA System for Kinematic and Kinetic Data Collection

The CODA motion analysis system was used in conjunction with the force plate (as used above) to record the gold standard gait kinematic and kinetic data using its standard marker model [209] and data acquisition protocol (collecting at 200Hz for five seconds). This allowed both the vertical ground reaction force, and knee moment in the sagittal plane to be recorded, and therefore the moment arm at the knee to be calculated. This was compared with the manual vector measurement to provide validity.

Markers were placed on the body either directly or via segment wands according to the manufacturer's protocol described in Monaghan's paper [209]. Figure 21 illustrates the marker placement and wand alignment. Following data acquisition and processing, data from the stance phase of the gait cycle were exported at a frequency of 100 data points to allow comparison between cycles.



Figure 21. Marker placement and wand alignment.

9.3.3.2.c Energy Cost Assessment

For energy cost measures, a Sport Tester Polar HRM[s] was used, with the transmitter attached to the participant's chest as specified in the manufacturer instructions. The monitor was set to record heart rate every five seconds for a total of 20 minutes, divided into an initial five-minute rest phase, a central ten-minute walk phase and a final further five-minute rest phase, with an audible beep signalling the change between phases. A 25-metre figure-of-eight walkway was used to collect the data for this measure, as previously described (Section 5.4.1.3). A stopwatch was used to record the lap time for each 25-metre lap to allow mean velocity and distance

[s]Polar Inc. Sport Tester Model.

walked over each time period to be calculated. A room thermometer[t] was used to ensure consistency of room temperature during data collection, which was maintained between 21 and 26°C.

9.3.3.3 Data Acquisition

Participants were asked to dress in shorts and a t-shirt to allow the lower limbs to be viewed throughout the data collection period. Anthropometric data were collected during the first session (Table 3).

Table 3. Anthropometric data collected.

Measurement	Description
Height (m)	Measured with fixed stadiometer.
Weight (kg)	Measured with electronic weighing scales.
Shank length (cm)	Lateral knee joint to lateral malleolus
Thigh length (cm)	Inferior aspect of ASIS[a] to lateral knee joint
Pelvic width (cm)	Inter-ASIS distance
Pelvic depth (cm)	ASIS to PSIS[b] depth in the sagittal plane
Knee width (cm)	Lateral epicondyle to medial epicondyle
Ankle width (cm)	Lateral malleolus to medial malleolus
Foot length (cm)	Greatest length from heel to great toe
Leg length (cm)	Inferior aspect of ASIS to tip of medial malleolus

[a]ASIS=anterior superior iliac spine, [b] PSIS = posterior superior iliac spine

9.3.3.3.a Vector analysis

Participants were asked to walk barefoot along the walkway at their own pace. The researcher adjusted the position that walking started from to ensure the participant struck the force plate consistently with the leg closest to the video camera. The video image with the real-time force vector overlaid was recorded continuously. A note was made for each walk to record whether the correct leg had struck the force plate cleanly (without overlapping the plate) and to indicate if a natural gait had been seen (without the participant lunging or taking small steps to attempt a clean contact). Data collection continued until at least three acceptable clear strikes with each leg were obtained.

[t] Boots Nursery Thermometer.

9.3.3.3.b CODA analysis

The participant rested whilst the CODA markers were applied to the lower limbs according to the marker model. Accurate alignment of the wands was ensured prior to data collection.

Participants were asked to walk along the same walkway, using the same starting points to ensure the force plate was struck. Each walk was recorded using the motion capture software only (not including the video) and details of each walk were made to record whether a clean strike had been obtained, as above. At the end of each data capture the data summaries were checked to ensure all markers were read sufficiently, and the stick figure and force graphs checked for any obvious errors. Three clear readings for each leg were taken.

Data could not be collected concurrently for the Video Vector analysis and the CODA analysis as the two assessments used different components of the same software package and could not be run concomitantly. The Video Vector system used the real-time sagittal view of the software to generate the ground reaction force vector, as described in section 9.3.2.2.a, whereas data for the CODA analysis were collected using the full data collection protocol which uses a different screen view.

9.3.3.3.c Energy efficiency measures

The participant rested again whilst the CODA markers were removed, the Polar HRM was applied to the chest, and checked for reception. The participant's wristwatch was removed to prevent any interference with transmission. The procedure was explained to the participant so that they were aware of the need to start walking once the first audible beep was emitted, and to stop once the second beep sounded. The participant sat on a chair at the centre of the figure-of-eight, and once a stable reading was obtained, the heart rate monitor timer was started and the participant instructed to rest and refrain from talking. Once the first beep was emitted

(after five minutes) the participant stood and then walked around the figure-of-eight track at their normal walking pace for 10 minutes. Each lap time was recorded to allow the lap speeds, mean speeds and distances covered to be calculated. When the second audible beep sounded the participant stopped walking and a chair was placed nearby to allow them to sit and rest for the last five minutes. The distance travelled for that lap (i.e. less than 25m) was noted to allow the total walking distance to be calculated. Once the final five-minute period was completed the heart rate recording was stopped and the transmitter removed.

After all data were collected the participants were reminded to refrain from eating and to avoid drinks containing caffeine during the two-hour period prior to the second session. The heart rate monitor data were downloaded into the associated Polar software programme and saved for analysis.

To allow reliability to be tested, the same process (excluding anthropometric data) was repeated four hours later on the same day; seven days later at the same time in the morning as the first session; and lastly four hours later on the second day (see Table 4) to determine test-retest reliability. The author, to optimise reliability of the marker placement, collected all data.

Table 4. Timetable of data collection.

Session	**A**	**B**	**C**	**D**
Day	1	1	8	8
Time	X	X+4 hrs	X	X+4 hrs
MEASUREMENTS				
Vector	✓	✓	✓	✓
CODA	✓	✓	✓	✓
Heart rate	✓	✓	✓	✓
Anthropometric data	✓	-	-	-

9.3.4 Data Analysis

The moment and heart rate data were analysed to allow the validity and reliability of the moment arm measure and the relative reliabilities of the heart rate indices to be studied. The following sections describe the data collected, and analysis procedures undertaken for each set of results.

9.3.4.1 Heart Rate Data

The following heart rate data were collected from the sessions:

- Mean resting heart rate (RHR)
- Mean walking heart rate (WHR) taken from the whole walk
- Mean WHR taken from the first five minutes of the walk
- Total number of heart beats during ten-minute walk
- Total number of heart beats during five-minute walk
- Mean speed for the whole of the walk
- Mean speed for the first five minutes of the walk
- Total distance walked (ten minutes)
- Distance walked in first five minutes

Using these data, the following energy cost measures were calculated:

$$PCI_{10} = \frac{(WHR\_whole\ walk - RHR)}{mean\ speed\_whole\ walk}$$

$$PCI_{5} = \frac{(WHR\_first\ 5\ mins - RHR)}{mean\ speed\_first\ 5\ mins}$$

$$THBI_{10} = \frac{\Sigma heart\ beats\ during\ walk}{total\ distance\ walked}$$

$$THBI_{5} = \frac{\Sigma heart\ beats\ during\ first\ 5\ mins\ of\ walk}{distance\ walked\ in\ 5\ mins}$$

The test-retest reliability of each measure was examined using an intra-class correlation coefficient (ICC3, two way mixed effects model); the variability highlighted using coefficient of variation (CV) to show the natural variation of the findings within a normal healthy population; and

the level of agreement between the measures calculated over five and ten minutes determined using Bland and Altman plots for agreement of measures [210], to inform the optimum protocol for the clinical trial.

9.3.4.2 Moment Arm Data

In order to calculate the moment arm from the **video vector data** manually, a transparency grid was used (Fig. 22) showing a scalar line with 1mm divisions (not to scale in image), and a perpendicular axis to align with the vector.

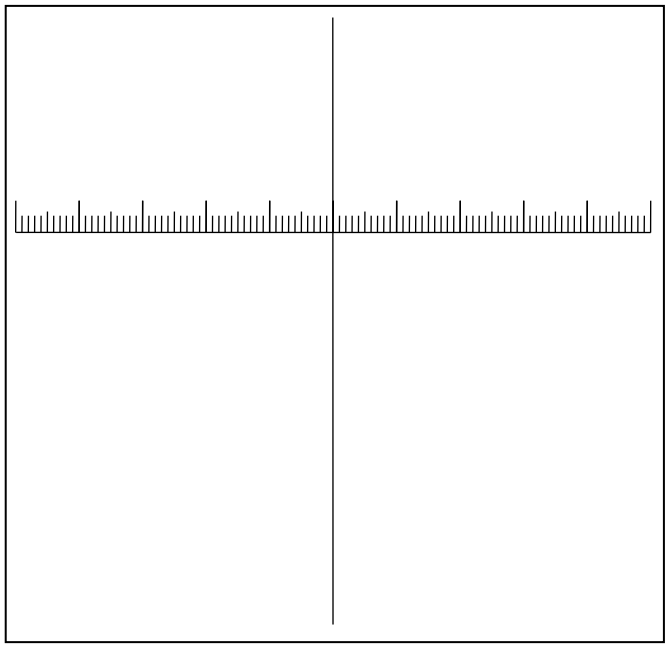


Figure 22. Transparency used for moment arm measurement.

As shown in Figure 23 the grid is placed over the video image (i.e. on the TV screen) and aligned so that the perpendicular axis is over the vector line, and the horizontal scalar axis extends through the knee joint centre (in the sagittal plane). Subsequently the distance of the vector from the knee joint centre can be read from the scale, in millimetres. This was repeated for each frame of the video to allow a comparison to be made to the moment arm

data generated from the CODA system, and to allow the test-retest, inter-rater and intra-rater reliability measures to be calculated.

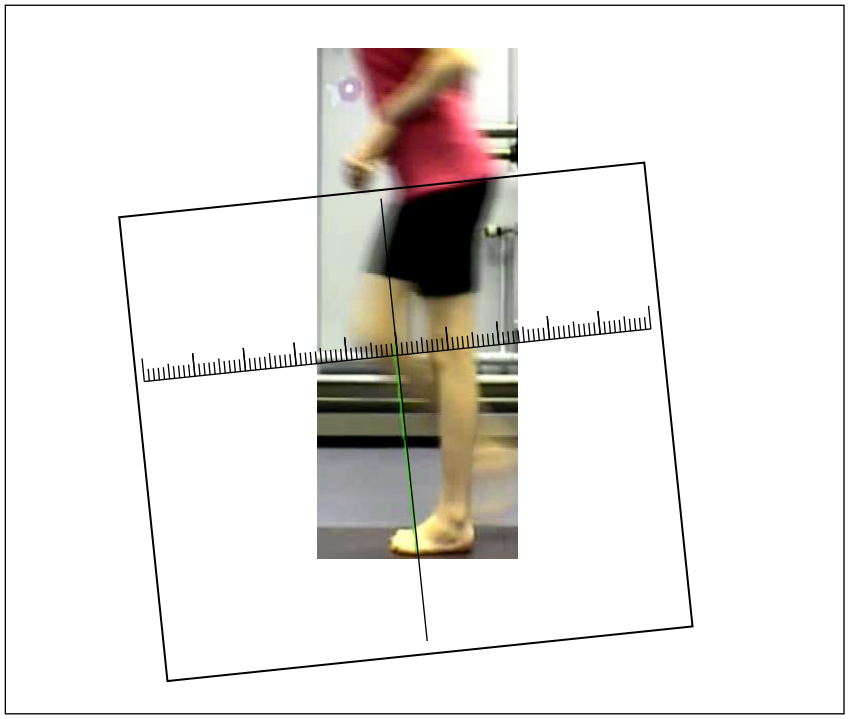


Figure 23. Illustration of measurement of moment arm with transparency.

The moment arm value was scaled post-collection for each subject to allow data from different images to be compared (i.e. the video image viewed on different TV screens, or the person walking closer to, or further away from the camera), and to allow the true moment arm value to be calculated. Other researchers have scaled the moment arm to height [53, 56, 111]. However, the author was cautious of this for several reasons. Firstly, the video image may not allow the whole of the person to be viewed (i.e. may be zoomed in to show torso and / or legs only, as in Fig. 23). Secondly, many children with CP are unable to stand completely upright and therefore a measurement of their height may not be accurate or repeatable between sessions. Fixed knee, hip and ankle contractures, as well as weakness of the anti-gravity muscles, can prevent a fully upright stance from being achieved, and these factors can change over time. Lastly, unless a standing image is recorded prior to the walking assessment, one would have to decide which video

image to use for full body height from the gait cycle. Similar problems could occur with the use of whole leg length, as well as the issues of defining measurement of whole leg length from the video screen (ASIS not easily visible in the sagittal plane).

It was therefore decided that shank length would be used as a scaling factor for these studies. Because shank length is defined from a single segment, (whereas height involves multiple body segments) its length would not be affected by varying flexion contractures over time. Shank length can easily be measured from bony landmarks both on the person (Table 3), and from the video. Shank length does not change throughout the gait cycle and therefore could be measured from the walking video, excluding the need for a separate standing image to be captured. For consistency, the mid mid-stance frame was selected for the on-screen measurement of shank length. Shank length is defined as the measurement between the lateral knee joint line and the most prominent part of the lateral malleolus.

The following equation is therefore used to obtain the true moment arm value:

$$Moment\ arm_{true} = \frac{(shank\ length_{true}\ x\ moment\ arm_{video})}{shank\ length_{video}}$$

Using this system, the change in moment arm length throughout the gait cycle could be measured from any image generated by a video vector system. This allows the measurement to be compared between individuals, and between treatment sessions providing an objective measure against which to determine the effect of an intervention (e.g. orthoses).

A brief look at the ratios of shank length to height in the population for this study showed that shank length represented a mean of 0.25 times the value of height across the group, with a small variation (SD 0.009). This suggests that it provides a similarly consistent scaling factor to height, to allow some comparison with other studies.

The number of video frames (from the video vector system) available from each cycle depended on stance phase duration and therefore on walking speed for each pass. To allow a comparison to be made between cycles, and to the CODA data, the video data were interpolated (Using R© software package, version 2.4.0), to provide 100 data points, in line with the data exported from the CODA system. Moment arm data from the video vector system were then directly compared with the moment arm data calculated from the CODA system.

In order to calculate the moment arm values from the **CODA system data**, the raw values for vertical ground reaction force and knee moment in the sagittal plane generated by the CODA software were imported into Excel. Moment arm was calculated by the following equation, throughout the gait cycle:

$$Moment\ arm(m) = \frac{moment(Nm)}{force(N)}$$

Within the CODA software, the moment data are automatically normalised to body weight, which would have given the moment arm a unit of metres / Kg. This was therefore re-scaled by multiplying the value by body weight to provide the correct unit of metres, for comparison with the video data.

Moment arm data from the video vector system and the CODA system were then compared to determine validity of the vector system measure.

9.3.4.3 Statistical Analysis

Validity of the manual moment arm measure was derived by comparing data at four specific points in the gait cycle, between the two systems. Bland and Altman plots and 95% confidence intervals were plotted to illustrate the level of agreement between the two measures, and limits of agreement

were calculated. Only data from the right leg of the first session were used for these analyses, to avoid using data that were co-dependent (i.e. right and left legs of the same person, or repeat data from the same person from different sessions). As shown in Chapter 6 (sections 6.3.2 and 6.3.3), analysis of gait data is complicated by its continuous nature (time-series data), and usually specific time points are analysed. In this study four separate points in the gait cycle were selected for analysis, these being initial contact (IC), toe-off (TO) (0 and 99% stance phase of gait cycle), peak flexor moment ('trough') and peak extensor moment ('peak') during stance. These points were selected to allow analysis from different parts of the cycle, without requiring analysis of each separate data point within the gait cycle.

Test-retest reliability was determined by comparing the four selected data points across the four data collection sessions, for each system. 95% confidence intervals were plotted and intra-class correlations coefficients (ICC3) calculated.

Due to the small sample numbers, a **case-by-case analysis** was also performed to show the level of agreement between the two measures. Graphical illustration of the mean vector and CODA data for each person (from 10-89% stance phase – see discussion) is shown (Fig. 27). Data were non-parametric and therefore similarity was analysed using Spearman's Correlation, and a Wilcoxon signed-ranks test was used to determine any significant difference between the systems. Data from the right leg were used for this analysis.

Intra-rater and **inter-rater reliability** of the manual moment arm measurement from the vector system were examined on five pre-selected points from the gait cycle (the four used for the validity testing, plus the "mid mid-stance" frame which was specifically highlighted when analysing the data), using intra-class correlation coefficients. Perry [22] defines mid-stance as being the phase in which the swing leg moves from behind to in-

front of the stance leg, and therefore "mid mid-stance" is around the point when the legs cross. For the purposes of consistency within this study, this point was defined as the video frame in which the swing side ankle moves past the stance leg, as shown in Figure 24.



Figure 24. Illustration of mid mid-stance video frame.

One assessor (HE) repeated measurement of the moment arm on a random selection of videos at least one week after initial measurement, and the results were compared to determine **intra-rater reliability** (Fig. 33). Two assessors (both physiotherapists) measured the moment arm from a selection of videos and the results were compared to determine **inter-rater reliability** (Fig. 34). Finally, a graph of the group mean moment arm throughout the stance phase of the gait cycle is illustrated (Fig. 35), to allow comparison with the limited published data available.

9.3.5 Results

9.3.5.1 Participant Demographics

Ten healthy volunteers were recruited (four males and six females), with an age range of 27-48 years, and a mean of 37.9 years. The male participant

age range was 29-48 years (mean 38.5 years), and female participant age range was 27-47 years (mean 37.5 years).

Two further volunteers were allocated participant ID's but then had to withdraw prior to data collection. A third volunteer had to be excluded following examination of the initial set of data (explained within the discussion). Participant ID's for those who completed data collection are subsequently numbered 1-6 and then 10-13.

9.3.5.2 Reliability of Energy Cost Measures

Raw heart rate data from the HRM were imported into Excel for analysis, and the mean walking heart rate during rest and walking; and the total number of heartbeats during walking, were calculated according to the protocol described in section 5.4.

Prior to analysis of the heart rate indices, the reliability of the raw heart rate data was checked. Analysis using intra-class correlation coefficients showed excellent reliability of the heart rate readings for each calculation across the four data collection sessions ($r = 0.93 – 0.96$). Reliability of calculating resting heart from the full five-minute period and from the last two minutes of this period were calculated across the sessions, both showing excellent reliability ($r=0.93$ for the full five-minute period and $r=0.95$ for the last two minutes), and furthermore showing excellent correlation between the two measures ($r=0.996$). Similarly, reliability of the heart rate data from the whole of the walking period, as compared with the last two minutes of each period was checked, and again showed excellent reliability ($r = 0.996 – 0.999$). These results highlight the reliability of the raw data used for calculation of the energy cost indices, and show that using the last two minutes of each period was as reliable as using the whole period. Data from the last two minutes of each period were then used for the following PCI calculations.

For all of the following results, the following abbreviations have been used:

PCI_5: PCI calculated for the first five minutes of walking.

PCI_{10}: PCI calculated for the whole of the ten-minute walking period.

$THBI_5$: THBI calculated for the first five minutes of walking.

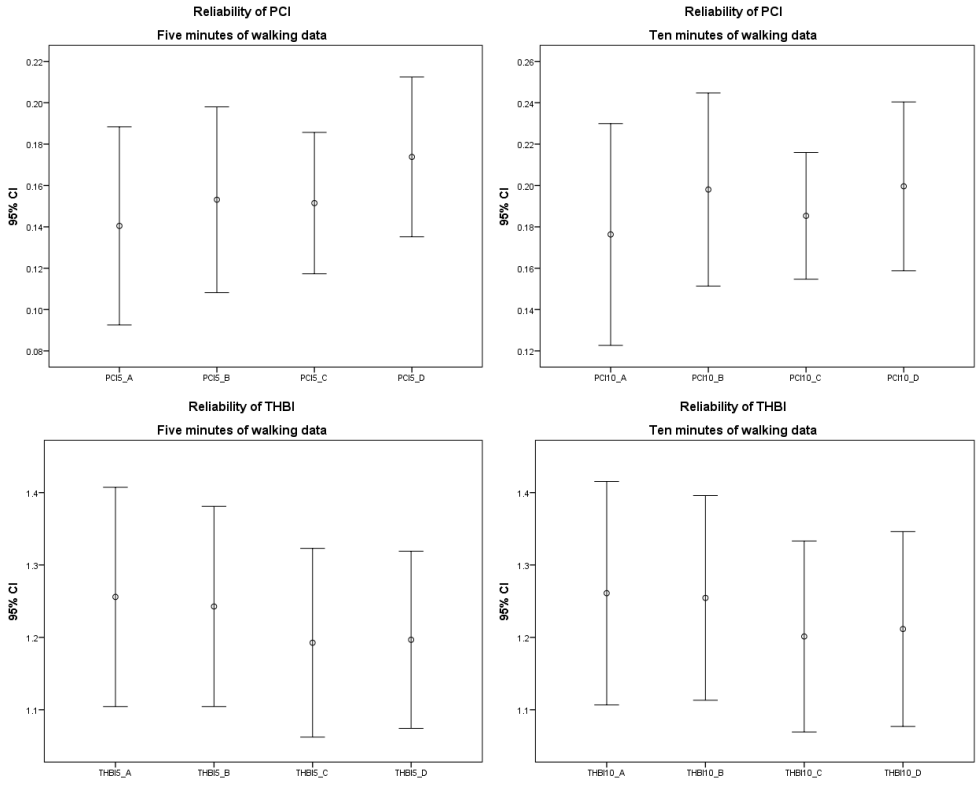
$THBI_{10}$: THBI calculated for the whole of the ten-minute walking period.

9.3.5.2.a Normality of the energy cost data

The energy cost data for each session were tested for normality using the Shapiro-Wilk test. All data were normally distributed, and were therefore subsequently analysed using parametric statistical testing methods.

9.3.5.2.b Test-retest reliability of the energy cost data

In order to check the reliability of the findings visually, the results were plotted showing 95% confidence intervals for each set of data (Fig. 25).



Key: Letter defines data collection session

Figure 25. Comparison of mean values of each energy cost measure between data collection sessions.

These graphs show reasonable consistency between the four recording sessions, although a slight diurnal pattern is seen within the PCI values (higher in the afternoons) and a lower THBI was found on the second day of data collection for both sessions.

In addition, intra-class correlation coefficients (ICC3) were calculated to determine the degree of reliability for each method of calculation over time (Table 5).

Table 5. Intra-class correlation coefficient results for test-retest reliability of the PCI and THBI over five and ten-minute periods.

Data set	R value	95% CI	
		Lower limit	Upper limit
PCI_5	0.670	0.132	0.908
PCI_{10}	0.751	0.344	0.930
$THBI_5$	0.951	0.871	0.986
$THBI_{10}$	0.961	0.898	0.989

These findings show that all data sets were reliable between sessions. However, the results clearly show that both THBI values have a much higher, and in fact, excellent correlations, suggesting that this method of calculation is much more reliable than PCI for monitoring energy expenditure using heart rate data. With regard to the 95% confidence intervals, it can be seen that the upper and lower limits for the THBI are much closer in value than those for the PCI, therefore further suggesting that the reliability of this measure is greater than that of the PCI. There is little difference in reliability between the data collected over five and ten minutes, especially for the THBI.

9.3.5.2.c Variability of energy cost data

In order to determine the variability of the data the coefficient of variation (CV) was calculated for each data set. Lower coefficients of variation were found for the THBI data (14.30 – 17.12) compared with the PCI data (23.1 –

47.68), suggesting that there is less variation within a normal population using the THBI. This therefore makes it a more sensitive measure to be able to detect changes or variations over time.

9.3.5.2.d Effect of duration of walk

Bland and Altman plots were drawn (Fig. 26) to determine the agreement between five minute and ten-minute data, and to inform the protocol to be used for the clinical trial.

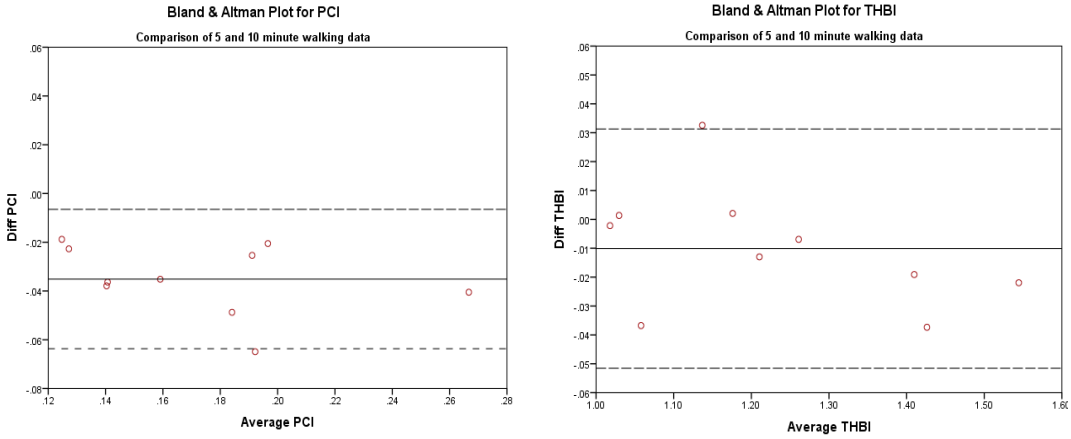


Figure 26. Bland and Altman plots of agreement for PCI and THBI comparing five and ten-minute walking periods.

Limits of agreement for the PCI ranged from -0.064 to -0.007bpm, whilst those for the THBI ranged from -0.052 to 0.031bpm.

Both sets of results show good agreement, with all participants, except one, lying within the limits of two standard deviations for each energy cost measure. However, the PCI showed a consistently higher reading for 10 minutes than for the five-minute walk.

9.3.5.2.e Reference data for energy cost indices

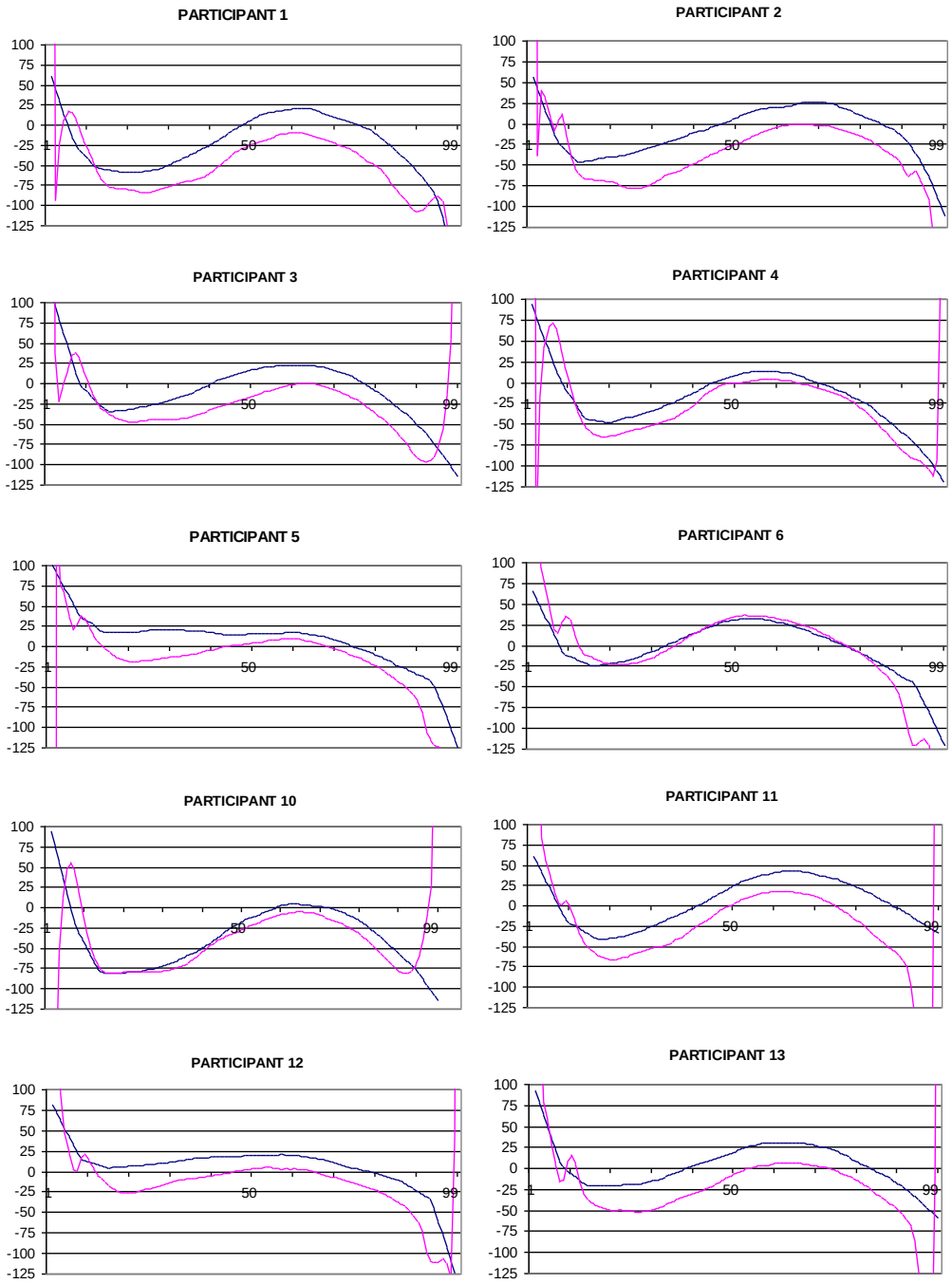
Data from this study provides reference values for the THBI and PCI for healthy adults. The mean THBI over five minutes of walking was **1.22 ± 0.18**

beats per metre (bpm), and over ten minutes of walking was **1.23 ± 0.19 bpm**. The mean PCI for five minutes of walking was **0.15 ± 0.06bpm**, and for ten minutes of walking was **0.19 ± 0.06bpm**.

9.3.5.3 Validity and Reliability of the Moment Arm Data

Moment arm data from the VVS were compared with that calculated from the CODA motion analysis system to determine concurrent validity.

Figure 27 shows the mean moment arm throughout the stance phase of the gait cycle measured from the video vector system compared with the mean moment arm calculated from the CODA motion analysis system for each participant. The graphs show similar patterns of motion for both systems, but with a consistent shift of the vector data upwards from the CODA data (i.e. representing a greater extensor moment arm) for many participants. For the middle section of the stance phase (30-80% of total stance phase) this difference is reasonably consistent. Analysis of the whole group gave a mean difference of 20.05mm between the CODA and vector graphs throughout this period. This issue is discussed further in section 9.3.5.4.

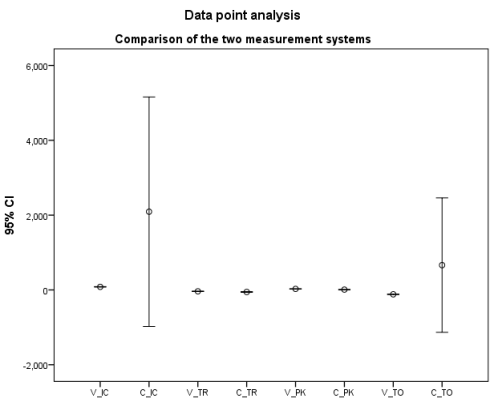


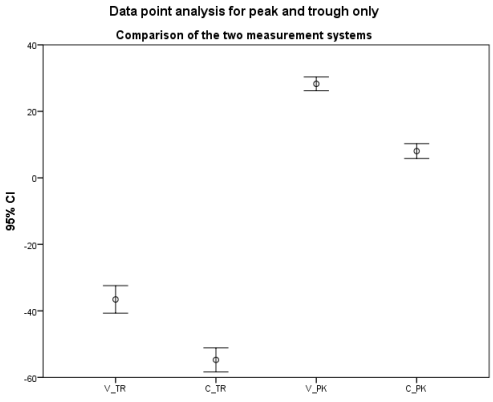
Key: Pink line represents CODA moment arm measure; blue line represents vector moment arm. X-axis represents the percentage of the stance phase of the gait cycle; y-axis represents the moment arm measurement in mm.

Figure 27. Illustration of mean moment arm throughout the gait cycle using each measurement system.

9.3.5.3.a Validity of the moment arm data

In order to check the validity of the data visually, graphs showing the 95% confidence intervals for each data point were plotted (Figures 28 & 29).





Key: V = vector, C = CODA, IC = initial contact, TR = trough (peak flexor moment), PK = peak (peak extensor moment), TO = toe-off.

Figure 28. (left) Comparison of mean moment arm values between measurement systems.

Figure 29. (right) Comparison of mean moment arm values for peak and trough data only.

These graphs show the high variability of the CODA data at initial contact and toe-off as observed from the raw data graphs. The peak and trough data show better agreement between the two systems, although there are still some differences, as highlighted in the individual plots in Figure 27.

To illustrate the agreement between the two systems, Bland and Altman plots were drawn (Fig. 30), using mean data from the right leg for each person, from the first session only.

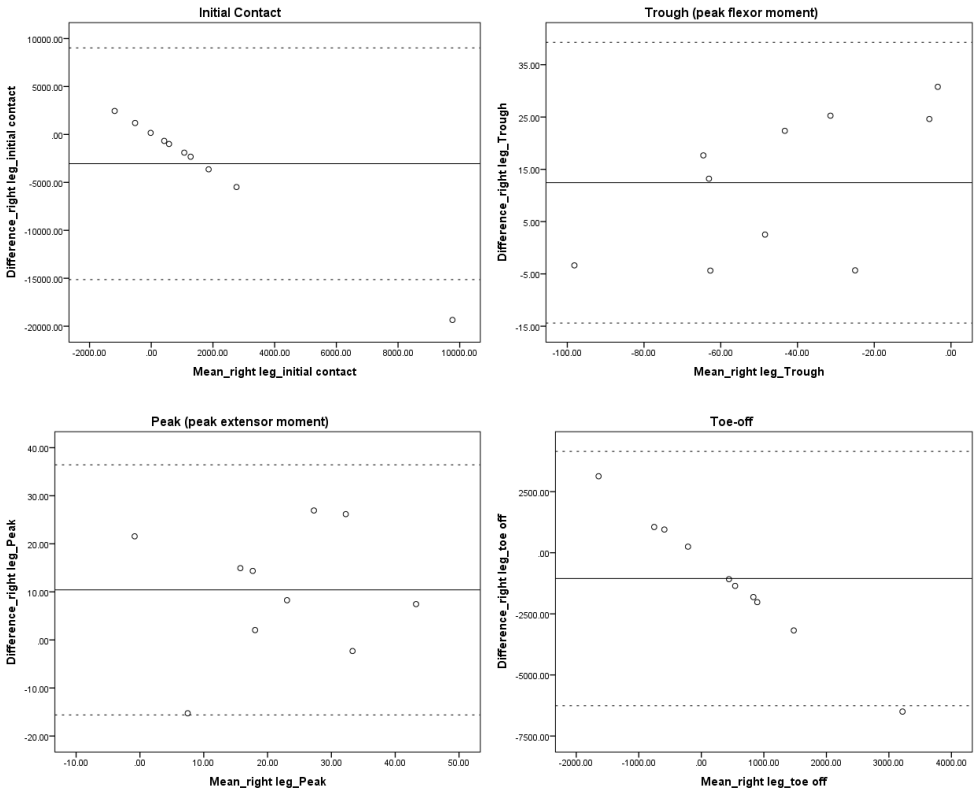


Figure 30. Bland and Altman plots for agreement between the two measures.

Limits of agreement for these data points are shown in Table 6.

Table 6. Limits of agreement for Bland and Altman plots.

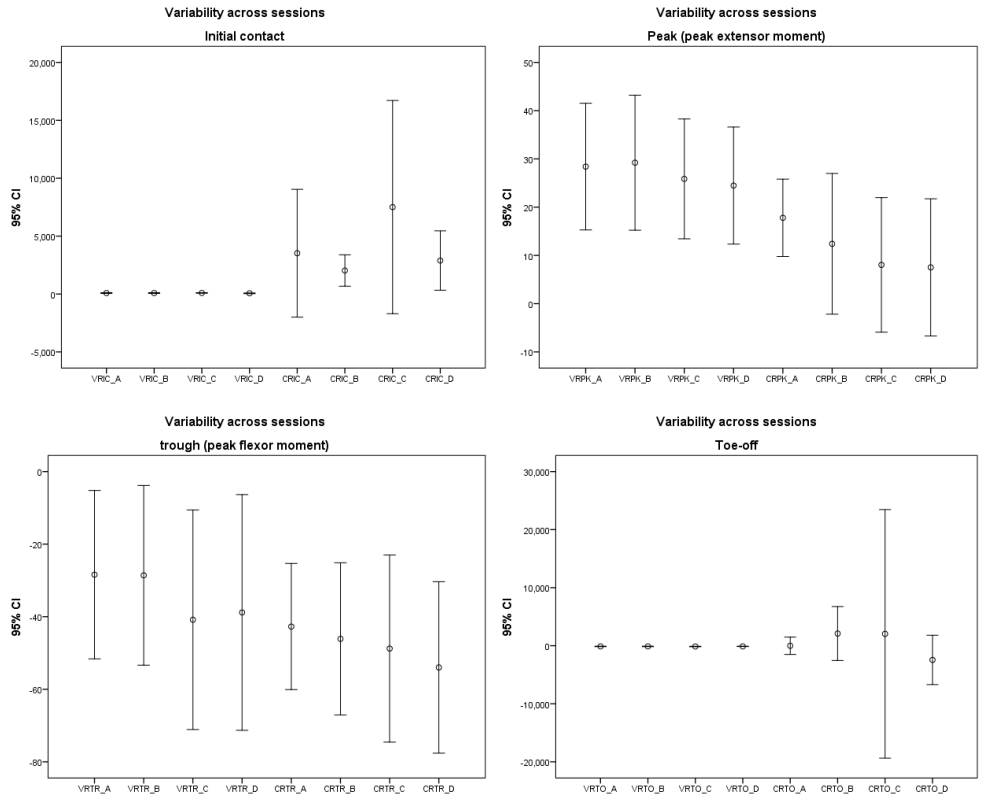
Data point	Lower limit	Upper limit
Initial contact	-15389.80	9282.45
Trough (peak flexor moment)	-14.95	39.82
Peak (peak extensor moment)	-16.13	36.97
Toe-off	-6366.37	4254.86

These data show good agreement for peak and trough data points with no data points falling outside the boundaries for two standard deviations. All data, except for one for each of initial contact and toe-off, also lay within the 95% (2SD) levels of agreement. The limits of agreement are unacceptably high for initial contact and toe-off, and are discussed in Section 9.3.5.2. Although some variability exists for the trough and peak data within this small sample, the limits of agreement are much closer at these points. The

mean difference between the measures for the peak flexor moment (trough) was 12.44mm and for the peak extensor moment (peak) was 10.42mm, both of which are considered to have minimal clinical significance. These results suggest that, as the methods show a slight consistent difference, they should not be used interchangeably for re-assessment purposes, but that either may be used for the assessment of moment arm and that validity of the manual moment arm measure is acceptable.

9.3.5.3.b Test-retest reliability of the moment arm data.

An initial analysis of repeatability was carried out by plotting the variability of the data across the four data collection sessions (A-D) using 95% confidence interval plots (Fig. 31).



Key: A - D denotes session.

Figure 31. Illustrations of variability of data across recording sessions for each data point analysed.

To highlight the initial contact and toe-off variability for the vector system, these graphs have been re-scaled and re-plotted for inspection (Fig. 32).

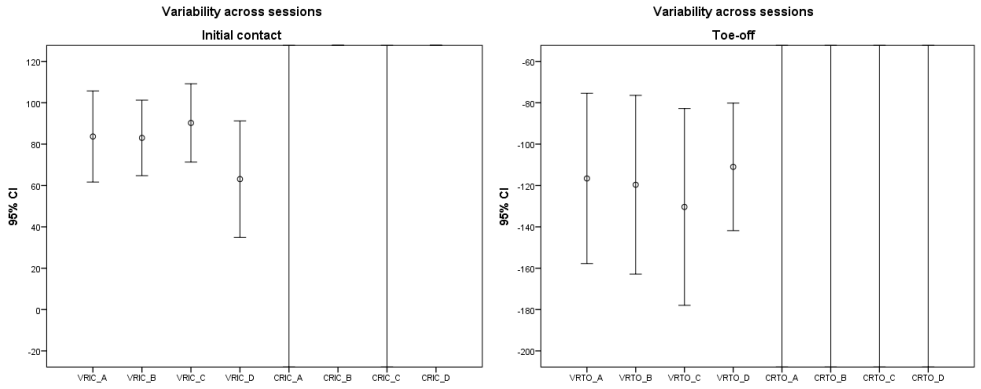


Figure 32. Illustrations of variability at initial contact and toe-off scaled to highlight vector data in greater detail.

These data (Figures 31 & 32) highlight the following findings:-

- Variability in the CODA data at initial contact, but consistency in the vector data at this point (with minor changes in session D only).
- A similar level of variability within the vector and CODA data at the trough (peak flexor moment) between sessions.
- Similarity in vector data and coda data separately across all four sessions, at the peak extensor moment. Slight visual differences between the systems is seen, but the ranges overlap, and there is a slight drift in the CODA data.
- An optimal agreement was observed between measures taken on the same day.
- There is variability in CODA data at toe-off, but good consistency in vector data.

Intra-class correlation coefficients were calculated, using Cronbach's alpha, on the four points of data for each system across the four recording sessions (Table 7).

Table 7. Intra-class correlation coefficient results for test-retest reliability of Vector and CODA data points between sessions.

Data Point	r value
Vector_IC	0.581
Vector_trough	0.937
Vector_peak	0.914
Vector_TO	0.913
Coda_IC	0.743
Coda_trough	0.969
Coda_peak	0.890
Coda_TO	0.435

These results show that for five out of eight of the data points there was excellent (r≥0.89) reliability across the four sessions. The vector data at initial contact, and CODA data at initial contact and toe-off were the least reliable (r=0.435–0.743), although still classed as moderate to substantially reliable. Once again, these findings concur with the visual review of the graphs where these latter points were seen to be least reliable. These results suggest that within the group there was good consistency of gait pattern as well as the two measurement systems over time, particularly around the middle portion of the stance phase.

9.3.5.3.c Case-by-case analysis

As this was a small pilot study, and the analysis performed above only took into consideration certain points of the gait cycle, it was decided to analyse each individual person's set of data across more of the gait cycle between the two measurement systems to get an idea of within-person agreement between the two measures (illustrated in Fig. 27).

The middle section of the stance phase of the gait cycle was used (10-89%) to exclude the erroneously variable initial contact and toe-off CODA data, providing 80 data points per individual for analysis. The mean at each time point, from across all four data sessions was calculated and used for this analysis (with six cycles used from each session, totalling 24 cycles used to generate this mean).

Normality testing, using the Shapiro-Wilk test, showed that all data sets were not normally distributed, as expected due to the nature of the data being presented. Therefore, the Spearman's Correlation was used to analyse the two sets of data for each person (Table 8).

Table 8. Spearman's Correlation results of individual participant testing.

Participant	Spearman's rho (ρ)	Significance
A1	0.971	0.000
A2	0.970	0.000
A3	0.951	0.000
A4	0.966	0.000
A5	0.224	0.046
A6	0.895	0.000
A10	0.963	0.000
A11	0.906	0.000
A12	-0.081	0.476
A13	0.881	0.000

These results show that for eight out of the ten participants there was a statistically significant high level ($\rho>0.88$) of agreement between the two sets of data. Data for participant A5 had a low level of agreement ($\rho=0.224$), although this was still significant at $p<0.05$ level. Data for participant A12 demonstrates a very poor correlation ($\rho=-0.081$). However, further analysis is provided in the discussion for these two participants.

Although there are high levels of agreement between the two measurement systems, the graphs (Fig. 27) also show an apparent and consistent difference between the measurement systems as commented previously. Therefore, the Wilcoxon signed-ranks test for non-parametric data was used to determine if this difference was significant (Table 9).

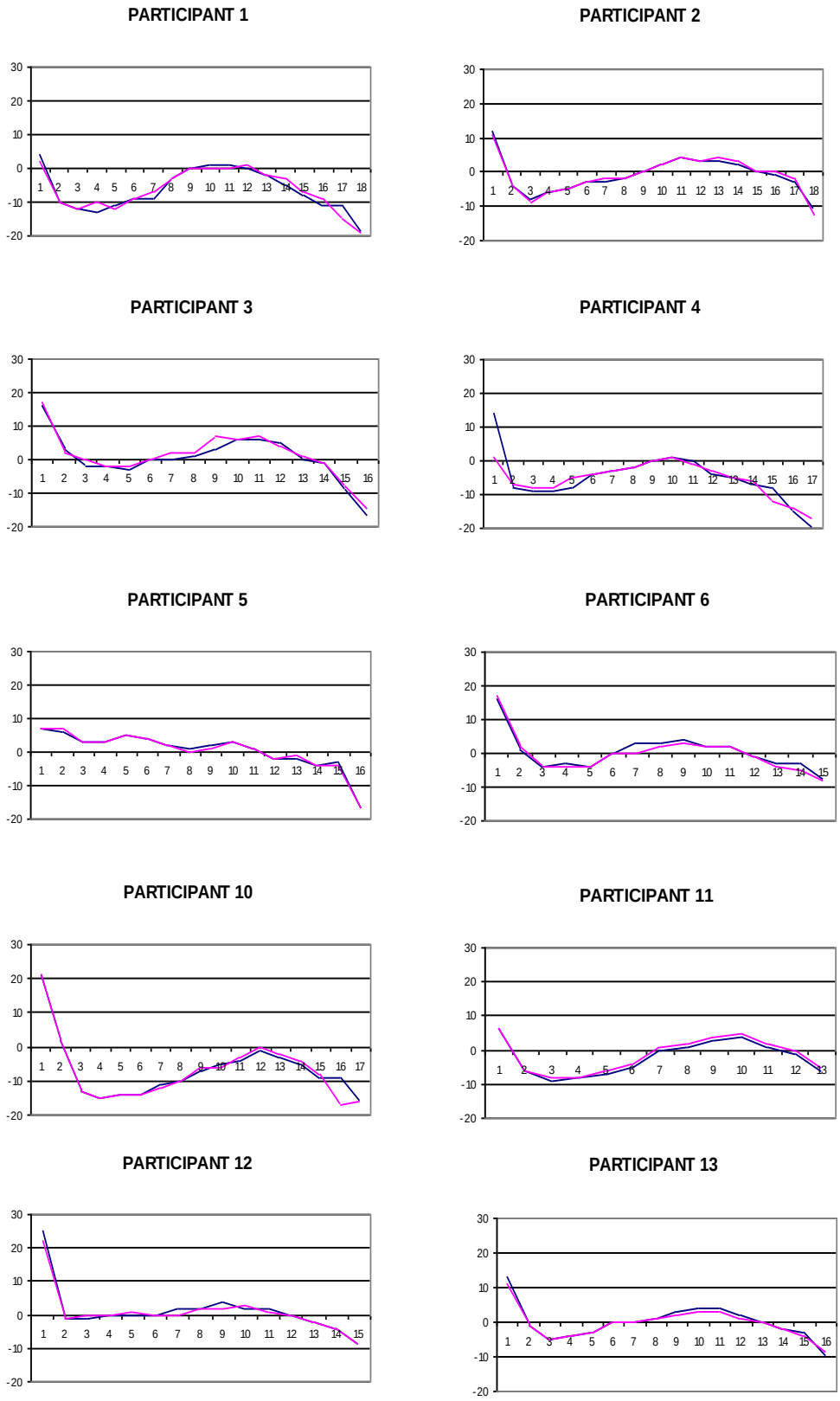
Table 9. Wilcoxon signed-ranks test results for individual participants.

Participant	P value
A1	0.000
A2	0.000
A3	0.000
A4	0.000
A5	0.000
A6	0.000
A10	0.000
A11	0.000
A12	0.000
A13	0.000

These results show that for all participants there was a significant difference between the two measurement systems. As reported previously, there was on average around 20mm difference between the two systems, with the vector system shifted towards a greater extensor moment than the CODA system. Possible reasons for this discrepancy are discussed in section 9.3.5.2.

9.3.5.3.d Intra-rater reliability of vector system measure

In order to test the intra-rater reliability of the manual measurement method used with the video vector system, ten random sets of data, one from each person, were re-measured on a different occasion by the same assessor (HE). The assessor was blinded to the original findings. The results are shown in Figure 33 and show excellent agreement between the two sets of readings. In order to further analyse this agreement, the reliability of the four pre-selected points used in the validity analysis were tested, in addition to data from mid mid-stance (as the point of clinical interest). The Shapiro-Wilk test showed that all data sets were normally distributed apart from one set (mid-stance, second reading), which was just outside normal distribution. An intra-class correlation coefficient was calculated, using Cronbach's alpha, with the results shown in Table 10.



Key: blue data = first reading; pink data = second reading; y-axis = moment arm in mm (un-scaled); x-axis = video frame within the stance phase of gait cycle.

Figure 33. Intra-rater reliability of vector moment arm measure.

Table 10. Intra-class correlation coefficient results for intra-rater reliability.

Data point	r value
Initial contact	0.908
Trough (peak flexor moment)	0.996
Mid-stance	0.983
Peak (peak extensor moment)	0.942
Toe-off	0.980

All of these results show very good agreement (r>0.9) between the two sets of measures at all of the selected points, suggesting high intra-rater reliability of this manual measurement tool.

Furthermore, examination of the raw data showed an exact agreement of the selection of the "mid mid-stance" video frame for each paired set of data (first and second reading). Additionally, there was the same number of video frames for each participant for both sets of data, indicating that identification of the start and end of the stance phase of the gait cycle was also reliable.

9.3.5.3.e Inter-rater reliability

The reliability of different assessors using the manual video vector measurement was tested to determine the usefulness of this tool within the wider clinical setting.

A second assessor, with no specific experience of the video vector system but some basic clinical gait analysis knowledge, used the same methodological protocol to measure ten randomly selected sets of data. This second assessor was blinded to the first results, and no assistance was given during the measurement. These results were then compared against the measurements for the same set of data from the first assessor.

The results are shown in Figure 34, and again show reasonable agreement between the sets of readings, each showing a similar pattern of motion with close agreement of actual measure throughout the majority of the gait cycle.

The discrepancy in number of total video frames relates to walking speed, with a higher speed resulting in fewer video frames per gait cycle, and a slower walking speed resulting in a larger number of video frames.

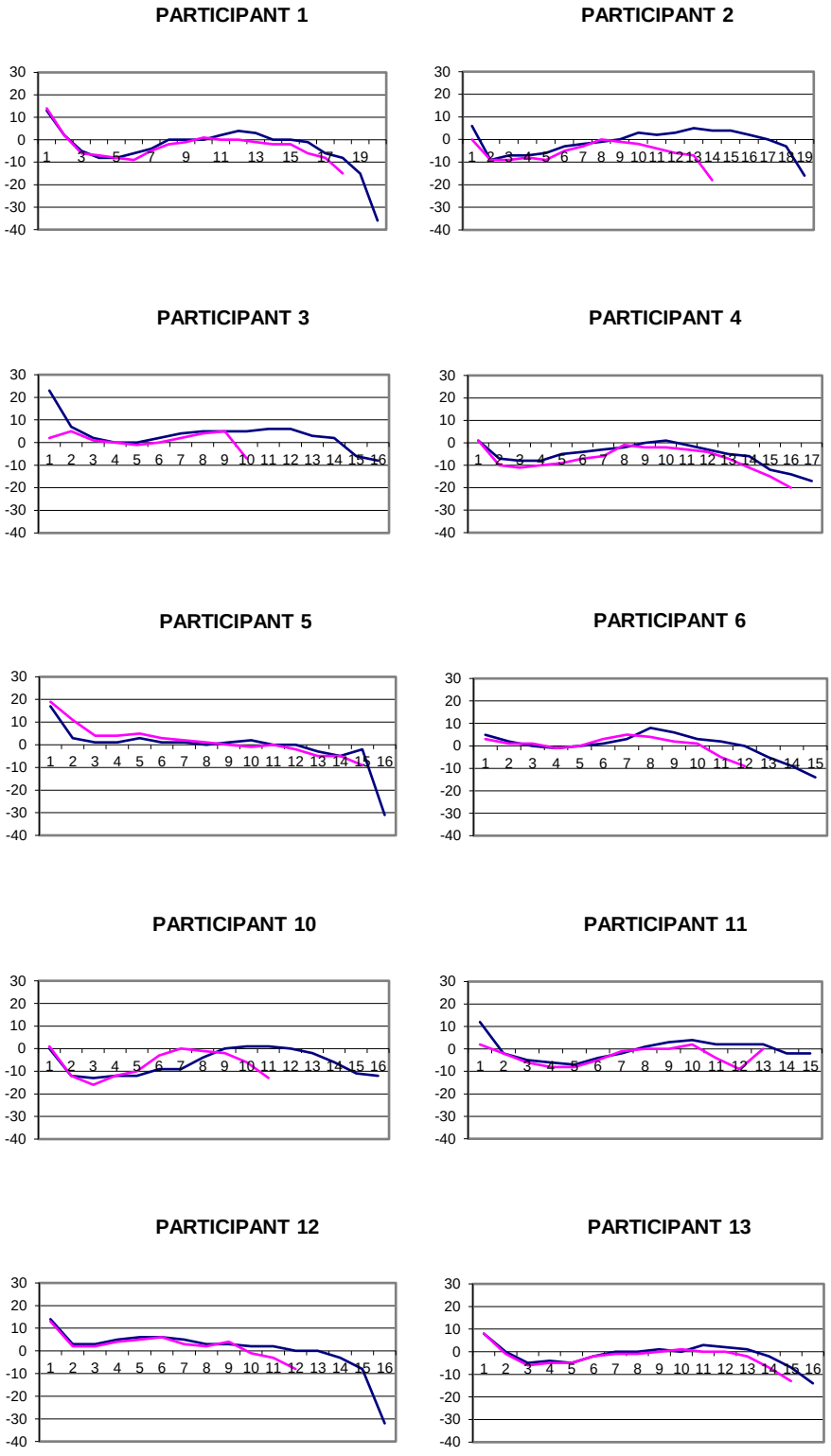
Nonetheless, there were clearly some problems with the number of video frames identified by each assessor, particularly for participants 2, 3, 10 and 12, and this issue will be examined further in the Section 9.3.5.4 but relate to a video equipment anomaly in which the equipment skipped backwards and forwards through some frames, giving some confusion as to which frames had been examined by the less experienced clinician.

Analysis was performed on the same five points of the gait cycle as for the intra-rater reliability. Data were tested using Shapiro-Wilk test, and were mostly normally distributed. An intra-class correlation coefficient was used to compare the two sets of readings between the assessors, using Cronbach's alpha (Table 11).

Table 11. Intra-class correlation coefficient results for inter-rater reliability.

Data point	r value
Initial contact	0.645
Trough (peak flexor moment)	0.978
Mid-stance	0.854
Peak (peak extensor moment)	0.930
Toe-off	0.492

These results show moderate to substantial reliability at initial contact and at toe-off, and very good agreement at the peaks, troughs and the selected mid mid-stance frame ($r>0.85$), between the assessors. This suggests that the measure remains reliable throughout the middle part of the stance phase of the gait cycle, despite the issues of differences in identification of exact number of frames, and that determination of the "mid mid-stance" frame is reliable using the given protocol, between assessors.

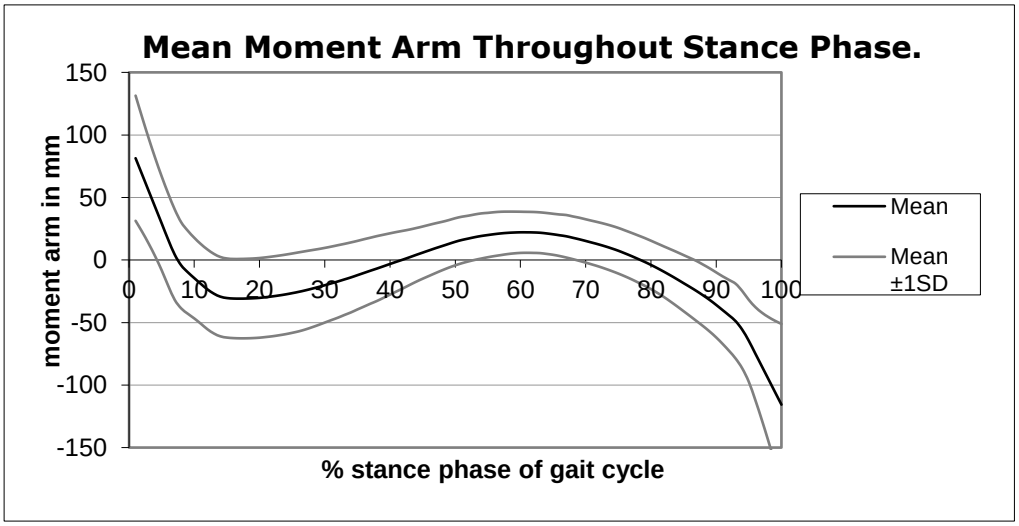


Key: blue data = author; pink data = second assessor; y-axis represents moment arm in mm (un-scaled); x-axis represents the video frame throughout stance phase of gait cycle.

Figure 34. Inter-rater reliability of vector moment arm measure.

9.3.5.4 Mean Moment Arm Data for Healthy Participants

From the above analysis, a set of mean moment arm data using the vector system from healthy participants can be presented (Fig. 35). Data from all passes and all sessions were used to generate this mean (N=10*6*4).



Note that negative moment arm values represent external knee flexor moments, and positive moment arm values represent external knee extensor moments.

Figure 35. Mean moment arm throughout the stance phase of the gait cycle from the video vector data (N=10*6*4).

This shows that the area of least variability is around the middle of the stance phase of the gait cycle. From the vector data, the frame deemed to be "mid mid-stance" for each cycle, was examined. Results show that the mean moment arm at this "mid mid-stance" frame was 7.51mm (± 21.25). This correlates with other research [56, 111] suggesting that the moment arm is close to 0mm around mid-stance.

9.3.6 Discussion

Each psychometric property of the data will be discussed in terms of potential sources of error during analysis as well as the clinical relevance of the results.

9.3.6.1 Reliability of PCI and THBI

Analysis of the energy cost data suggests that the THBI is the most reliable and least variable measure to use during walking, compared with the PCI. Furthermore, it may be collected over a five-minute walking period without compromising reliability, which would be more acceptable than a ten-minute walk for patients with limited mobility.

The key factors responsible for the difference in reliability between the THBI and the PCI are considered in the following discussion. The PCI relies on steady and consistent heart rate data. In an assessment situation, with an unfamiliar environment and assessor, it may be difficult for the person being assessed to relax comfortably to allow a true and consistent resting heart rate reading to be obtained. A true resting heart rate also requires the participant to remain quiet and relaxed, without being active (legs, trunk or arms) for a period of time, which again may be an unfamiliar request, especially for a child as would be required during the clinical trial. Furthermore, for a child with CP, sitting still may be a particularly difficult task depending on their core stability and possible fluctuating tone.

During walking, there is the need to focus on walking around the figure-of-eight track, which may reduce the influence of anxiety or distraction on heart rate compared with during resting. However, other factors such as talking during walking and difficulties following the required track may also adversely influence the heart rate values during walking for both indices.

As the PCI calculation subtracts the resting heart rate from walking heart rate, the result is often a relatively low number, which is then divided by walking speed. Subsequently, small changes in either walking or resting heart rate can have a large effect on the final energy cost measure.

In contrast, resting heart rate is not taken into account when the THBI is calculated. Therefore, the factors affecting the reliability of the resting heart rate, as described above, are less likely to influence the result. For the

calculation of THBI, the total number of heartbeats during the walking period is used, giving a much higher number to be divided by walking distance. Therefore, the impact of any slight variation in heart rate, created for example by talking during one session and not during another, is less than for the PCI. However, it is accepted that this total number of heartbeats is then divided by the total walking distance (metres), which is also larger than the value for walking speed used in the PCI.

As the total number of heartbeats is used for THBI, as well as the total walking distance, there is less risk of protocol variation between laboratories, allowing the results to be interpreted by others more easily. As seen from the literature review (Chapter 5), during the collection of PCI data factors such as the duration of resting and walking periods; the exact data used for the calculation of heart rate (whole period versus part of period); definition of walking speed; and distance walked are all factors that are individually interpreted and can affect the generalisation of the results.

Therefore, for the THBI, as long as the same walking period, and preferably the same walking track design (in terms of distance and shape) are used, results should be more repeatable between institutions than for the PCI, which relies on more factors being consistent and is less clearly defined within the literature. This present study used the same walking track design (25m figure-of-eight track), and walking duration as in the original paper by Hood et al [151], allowing direct comparison of results.

During the current study, more detailed analysis of the heart rate data showed that there was good reliability between sessions of the raw heart rate data upon which both indices are based. For the calculation of PCI, analysis showed that it was acceptable to use the last two minutes of each time period for analysis, rather than using data from the whole period, allowing heart rate to stabilise, and therefore giving a more consistent result for this index.

Minor protocol amendments were made during and following the study. Data from one participant showed unusually little change in heart rate from resting to walking, and upon questioning it was found that they were taking prescribed beta-blockers for a minor heart complaint, which are designed to stabilise heart rate. This participant was therefore excluded from the study at this point and the exclusion criteria were amended to account for participants with underlying conditions, or taking medication, affecting heart rate.

Examination of heart rate traces following data collection in two participants showed that problems with data transmission resulted in periods of absent or poor heart rate data. This problem was attributed to poor contact between the transmitter chest strap and the chest wall. Electrode transmitting gel was subsequently used to ensure that contact between the transmitter and the chest wall was constant, and therefore detection of heart rate was gained. As the gel simply acted as a transmitter of the heart's electrical impulses from the chest wall to the transmitter strap, it was judged not to interfere with data collection in any way, and no problems were reported by participants. These two participants repeated data collection without further problems.

No other equipment problems were encountered. It was felt that a heart rate monitor, from which the data can be downloaded, was a minimum requirement for the recording of heart rate data for these indices. For the THBI, manual palpation of heart rate would not allow the total number of heartbeats to be estimated accurately. A heart rate monitor without a download option would allow heart rate to be monitored regularly (although not consistently), but the total number of beats would still require some estimation. For the PCI, it may be more acceptable to monitor heart rate less frequently as it is the mean heart rate, rather than the total number of beats that is required. However, an estimation of mean heart rate may influence the reliability and sensitivity of the index between tests, and

if heart rate is taken at the end of the walk, it may reduce rapidly during the reading process as it returns towards a steady resting value.

No other problems with data collection or processing were found. Both indices were easy to calculate from the heart rate data, and collection of heart rate, walking speed and distance were easy to record. Both indices required only a relatively inexpensive downloadable heart rate monitor and stop watch, and space for the figure-of-eight track. It was felt that the THBI could be used easily within the clinical setting with minimal set-up cost.

THBI data from this study compares favourably with that obtained in the original study by Hood et al [151]. From a cohort of 20 healthy volunteers, Hood et al found a mean THBI of 1.24 beats/m ± 0.18 using a protocol exactly the same as used in the current study – ten minutes of walking at self-selected speed around a 25metre figure-of-eight track, following a five-minute resting period. In this study, from a cohort of ten healthy volunteers, a mean THBI of 1.23 beats/m ± 0.19 was found for the ten-minute walk, and 1.22 beats/m ± 0.18 for the five-minute walk. This suggests that the measure is reliable between centres and assessors, and that the results for normal healthy volunteers are consistent and stable. However, the two groups of participants still represent a small cohort when seeking to produce normative data and further research with a larger sample number would be recommended to corroborate these findings.

Interestingly, the two studies found very different results for PCI. Hood et al [151] used a slightly different protocol in that data from the whole of each period were used to calculate mean resting and walking heart rates, compared with data from the last two minutes of each period for the current study. Hood et al obtained results of 0.44 beats/m ± 0.08 for their participants, compared with 0.19 beats/m ± 0.06 for the ten-minute walk, and 0.15 beats/m ± 0.06 for the five-minute walking in the present study. The use of 'warm-up' data, prior to stabilisation of heart rate during walking and resting, could increase the mean heart rate and therefore the PCI. This

could explain this discrepancy between studies as this early walking data was excluded in the current study. These differences further highlight the issues of reliability of the PCI and question the ability to compare findings from different studies accurately, especially given the consistency of the THBI data between these studies.

Other studies reporting normal PCI values for adults find values of 0.31beats/m ±0.08 [135, 136], 0.36beats/m ±0.08 [141] and 0.55 beats/m ±0.23[163]. Nene also reports values for healthy adolescents of 0.35beats/m ±0.09, and Butler et al report healthy paediatric values of 0.38beats/m ±0.11. All of these values are higher than the mean results found in this study. Nene reports the range of adult data in his study to be 0.2 – 0.55beats/m, suggesting the present study findings fall at the lower end of the previously published reference ranges. The range of values found in the present study is 0.03-0.30beats/m for five minutes of walking, and 0.07-0.32beats/m for ten minutes of walking. Examination of the raw heart rate data reveals that this is due to the minimal differences in heart rate between resting and walking. This may be due to an unreliable resting value (due to anxiety etc.) or the level of fitness present in this population (so that heart rate was not increased significantly during walking). The investigator was not aware of any notable anxiety in any participants, most of whom were familiar with both the investigator and the test environment.

All of these issues raise questions about the validity and reliability of the Physiological Cost Index as a measure of energy efficiency. If this level of variation can occur in healthy participants and a lack of consensus exists between different studies, then using the index to measure differences over time in a population with varying mobility problems is questionable. It is concluded therefore, that the Total Heart Beat Index represents a much more robust and reliable measure of energy cost and consistent values are available for healthy adults, which are consistent between studies.

9.3.6.2 Validity of the Moment Arm

A few issues arose during the analysis of the moment arm data. Firstly, the gold standard data, measured using the CODA motion analysis system showed considerable variability, and unexpectedly high values, at two points during the gait cycle, i.e. 'initial contact' and 'toe-off'. Close inspection of the data showed that the force data at these points were particularly small in magnitude. The original protocol for the definition of initial contact within the CODA software was the point in time within the graphs whereby the vertical ground reaction force component became greater than 5N, as any value lower than this was deemed to be background noise generated by the force plate. Similarly, at toe-off the event was marked as the last point in time (at the end of the selected gait cycle) when the force remained above 5N (i.e. the next frame produced a force of less than 5N). This protocol was designed to ensure consistent definition of contact and toe-off for all sets of data, and is similar to the protocol used by Monaghan et al [209] although they used a 10N threshold. This finding of reduced reliability at initial contact and around pre-swing is consistent with that reported by Wells [116].

All data were collected at 200Hz, providing a reading every 0.005 seconds. However, the exact number of data values for each gait cycle depends on the walking speed, and therefore the 'cycle time' for each gait cycle. To allow different cycles both within and between individuals to be compared, exactly 100 data points for each gait cycle were exported into the statistical software package for analysis, (a common protocol for statistical analysis and presentation of gait data [199, 209]). In order to provide this exact number of data points, some interpolation of the data by the software was required, and as a result the end points of the data appear to have been shifted by a fraction of a second. As the ground reaction force is essentially 0, or around 0 (to account for background noise) prior to the foot striking the floor, but then rises rapidly immediately on foot strike, any shift of the data period earlier in time could have resulted in a very low force value, as found in the exported data. As calculation of the moment arm involves

dividing the moment value by the force value, an exceptionally small force results in a large moment arm value for any given moment value. These values were both positive and negative in signage, due to the fluctuations in the background noise data of the plate prior to any contact. This was deemed to be an unavoidable artefact of the motion software and exportation process, but resulted in poor correlation of the two different systems at initial contact and toe-off. Subsequently, this led to the decision to exclude the first and last 10% of data during the case-by-case analysis.

To allow a correlational analysis of the two different measures (CODA as the gold standard, against the new video vector measure), four different data points were selected for analysis. Due to the continuous nature of the data throughout the stance phase of the gait cycle (time series data), gait analysis provides a large volume of analysable data. It is not usually feasible, nor sensible to analyse every data point (as discussed in Section 6.3) as this would provide a different level of correlation for each point in time across the gait cycle. More usually, researchers select a limited number of relevant points in time to analyse [199]. The pattern of the moment arm graph was such that it provided only two clear peaks to be compared, and so these were selected in addition to the values at contact and toe-off (before the issues described above were noted). The author considered analysing the time point when the graph crossed zero on the y-axis around mid-stance. However, it was noted that some graphs did not show this pattern (i.e. remained in an extensor, or flexor moment) and therefore this would not always be possible.

Inclusion of the “mid mid-stance” data point was possible for the vector generated moment arm, as this was recorded during video analysis. It was not possible to compare this with the CODA data, as although the assessor could have observed the stick figure image within the CODA software for the same defined point in time, it would not have been possible to determine exactly which time frame this represented in the exported data, due to the interpolation issues described above.

Vector moment arm data were interpolated (to 100 points) for the validity testing against the CODA data. However, for the reliability testing (inter and intra-rater), data were not interpolated as comparisons were being made between data sets collected from the same equipment (video vector system only) and this allowed the "mid mid-stance" frame to be extracted.

During analysis of the vector data, an issue of 'split' vectors arose, resulting from an unavoidable mismatch in the refresh rate between the video (~25Hz) and the real-time CODA software (~50Hz). This resulted in some video frames showing two vector lines simultaneously. This required the assessor to decide which vector line they deemed to be the most appropriate for that time frame. This therefore had the potential to affect inter- and intra-rater reliability, as well as validity findings. Rapid progression of technology since these data were collected means that data are now recorded onto a DVD or directly onto the computer, both of which have a higher recording rate than a VCR and better synchronicity, resolving the problem of this split vector.

A second problem arising from the use of a video recorder was that, when held on pause for any length of time (i.e. whilst aligning the transparency grid, estimating knee joint centre and measuring moment arm), the VCR would often rewind by a couple of frames, and then shuffle back to the original frame. The author was familiar with this nuance and was careful to ensure the correct video frame was in view prior to measurement. However, during inter-rater reliability testing this caused confusion for the second assessor who had less experience of this machine. This may have led to frames being missed as found in Figure 34, thereby reducing the inter-rater reliability as compared with the intra-rater results. Again, this was unavoidable for this study due to the equipment available. This is no longer likely to be an issue due to advancement in technology, but should be an alert where older video recording technology is used.

The estimation of knee joint centre is a factor that could affect both the gold standard and the video vector system data. Within the CODA system, the clinician has to define the knee joint centre with a lateral knee joint marker, measurement of knee width and alignment of the femoral wands, which help to define the axial plane of the knee joint. Whilst a strict protocol was used for this process, it is accepted that this process is subjective and open to error [211]. Furthermore, for the vector system analysis, estimation of the knee joint centre relied on visual assessment of the lateral joint centre from the video for each video frame. Initially a lateral knee joint marker was used to aid in the location of the knee joint centre from the video image. However, during initial analysis it was realised that this lateral knee joint marker was prone to skin movement, and was felt to be less reliable than estimating the location of the joint centre visually. A level of clinical expertise and knowledge of joint anatomy is therefore required to gain any level of accuracy in this estimation. However, as all physiotherapists, orthotists and most other clinicians undergo prolonged and intensive pre-registration training, it is felt that this should not be a major issue during orthotic analysis. Indeed, the inter-rater and intra-rater reliability analyses calculated from these data showed very good to excellent reliability of moment arm measures ($r>0.9$ for intra-rater reliability throughout the cycle, and $r>0.85$ for inter-rater reliability for the middle section of stance, ignoring initial contact and toe-off), which required estimation of the knee joint centre, as well as the measurement of the moment arm itself. These findings therefore suggest that these issues were not a significant problem during data analysis.

Comparison of the data collected from the gold standard CODA motion analysis system with that from the manual method devised from the video vector system revealed good agreement between the measures at the peak flexor and extensor moments as highlighted from the Bland & Altman plots. Limits of agreement for these two methods were acceptable given the natural variation of human gait and were similar at both of these points.

The findings do suggest, however, that assessment of the moment arm in early stance and pre-swing is less reliable, although this appeared to stem mainly from issues with the CODA data rather than the vector data. Nonetheless, data from these phases of the gait cycle were seen to be more variable (Figures 28 & 29) as highlighted previously by Wells [116], and therefore reporting the deviation of data from pathological patients at these points would be less sensitive than from the middle portion of the stance phase of gait.

Lastly, and perhaps initially more worrying, there was a significant difference between the values produced by the two systems consistently in all ten participants, which questions the validity. This appears to be a systematic error that is relatively consistent between individuals over time. The exact reason for this difference in unknown, however, the following considerations may provide some explanation.

Visual estimation of the knee joint centre from the video is open to subjectivity, although the test-retest, inter- and intra-rater reliabilities of this measure were good. However, if the definition of the knee joint centre was consistent, but different from that defined by the CODA system, then a systematic error as found above may result. An example is shown below:

Vector moment arm off screen = 7mm;
For scaling, real shank length = 400mm, video shank length = 55mm.
Therefore, scaled moment arm length = 7 x (400/55) = 50.91mm.

If the vector moment arm off the screen was measured at 9mm (e.g. due to altered visual estimation of knee joint centre), then scaled moment arm length (to compare with CODA data) would be 9 x 400/55 = 65.45mm, i.e. a 15mm true difference for just a 2mm measurement difference on screen.

As highlighted previously, definition of the knee joint centre for CODA data collection relies on accurate alignment of the knee marker, femoral wands

and anthropometric measures. Therefore, if either the CODA definition of the knee joint centre or the visual estimation of knee joint centre were different, then a systematic difference between the two measures would be found. The author felt that around 2mm was the most by which the knee joint centre from the vector image should be affected, due to the limited area in which to define knee joint centre off the screen. Furthermore, errors in exact measurement of the shank length off-screen could affect the scaling calculation used above, and could further provide a factor in this systematic error, although their effect is much smaller.

Whilst these potential sources of error are initially concerning, it should be emphasised, that the test-retest, inter- and intra-rater reliabilities of the manual moment arm measure were very high, suggesting that definition of the knee joint centre, even with the issues of split vector and scaling, were not sufficient to cause poor reliability of the measure. This would therefore seem to suggest a consistent error in definition of knee joint centre between the two systems. Nonetheless, the findings from both systems are consistent with those found in other published research [56, 111].

9.3.6.3 Test-Retest Reliability of the Moment Arm

Moment arm analysis showed good test-retest reliability of both systems over time, especially at the peak flexor and extensor moments ($r \geq 0.89$). This suggests that both systems consistently measure the same outcome over time and therefore the vector system may be used to assess individuals at different time points to highlight change in outcome, as is required in clinical trials. The greatest reliability was found when re-testing occurred on the same day, but was still good between different days. The initial contact and toe-off data for the vector system were affected by the speed at which the moment arm changes at these points in time, resulting in a wide range of values depending on the exact timing of the first video frame in relation to the force value, and often resulting in split vectors.

9.3.6.4 Case-by-Case Analysis of the Moment Arm

On visual inspection of each individual's set of data, it was apparent that, in this small population, there was some variability in moment arm data (from both systems) between individuals, but that within individuals there was much greater consistency and better agreement visually between the two measures. Therefore, correlational analysis was performed on each individual set of data to show the level of agreement between the two measures per participant. For this correlation, as only two sets of data were being compared, analysis of all data points was performed. For this reason, the erroneous data from initial contact and toe-off were removed prior to analysis. The first and last 10% of the stance phase data were removed and the remaining 80% analysed. Results (Table 8) showed much higher agreement ($\rho>0.88$), using the Spearman's Correlation Test between the two measures for eight out of the ten participants on a case-by-case basis, as one would expect. Two participants however, demonstrated poor agreement between the two systems.

Correlation of the data from participant 5 was only $\rho=0.224$, although this remained significant at $p<0.05$. Examination of this participant's data (from Figure 27, reproduced in Figure 37) highlights a less common moment arm pattern throughout the gait cycle, more specifically a lack of any flexor moment early in stance, particularly during the vector analysis. A review of the video (highlighted by the images shown in Figure 36) collected during video vector analysis revealed that this participant's gait pattern demonstrated a 'knee-locking' type posture early in the stance phase, i.e. the knee showed little flexion on loading and tended to remain extended throughout early stance, with the ground reaction force vector remaining anterior to the knee joint centre (creating an extensor moment). By mid-stance the vector is aligned close to the knee joint centre, as expected, but there is no flexor moment early in stance.

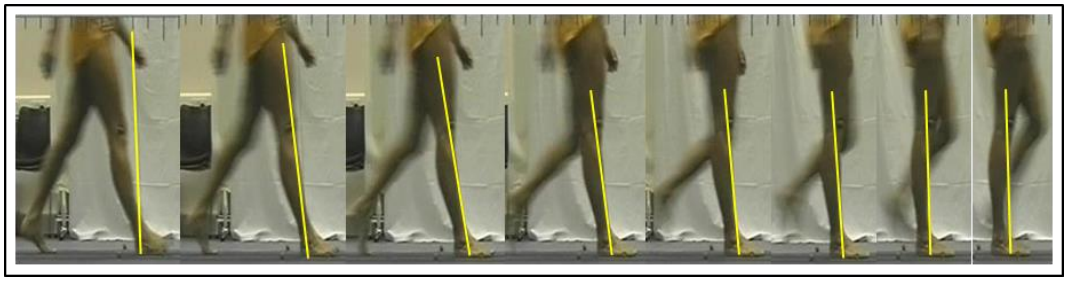


Figure 36. Illustration of the gait of participant 5 from initial contact to mid-stance.

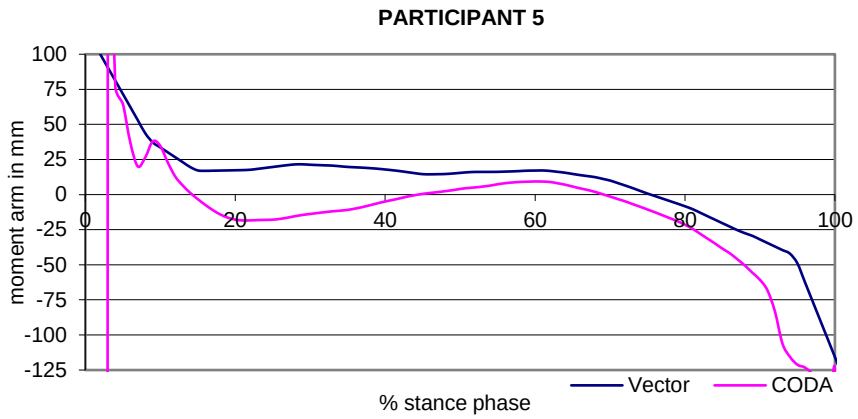


Figure 37. Moment arm graph for participant 5 comparing CODA and vector data.

Images in Figure 38 illustrate the gait of a different participant with a more typical gait pattern, demonstrating knee flexion on loading (for shock absorption) resulting in the ground reaction force vector becoming aligned posterior to the knee joint centre for most of early stance. By mid-stance the vector is aligned close to the knee joint.

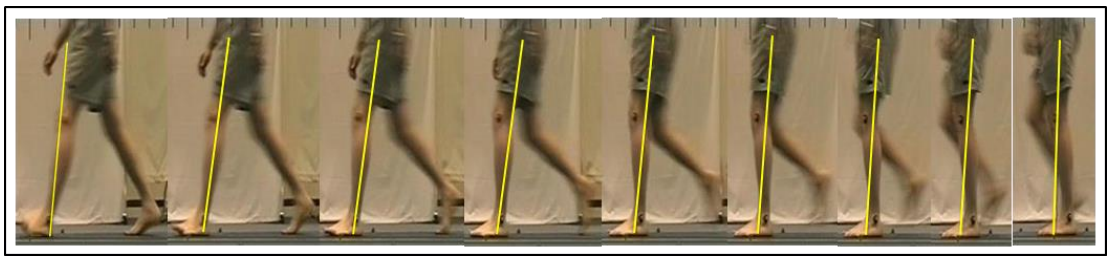


Figure 38. Illustration of the gait of participant 1, from initial contact to mid-stance.

Although this does not explain fully the correlational issues found with the data derived from participant 5, it demonstrates a less common gait pattern. For the CODA analysis, the knee joint marker was placed over the lateral knee joint mark. In the images in Figure 36, the lateral knee joint centre was marked initially with a small round marker to facilitate measurement. However, on review of the videos it was found that this marker commonly moved anterior to the expected knee joint centre due to skin movement. This may also have occurred during CODA data collection, so that definition of the knee joint centre was slightly more anterior than true joint centre, creating apparent flexor moments - GRF appearing posterior to the joint centre when in fact it is anterior. This is what appears to be shown in Figure 37.

For participant 12, a similar issue is apparent, although the graphs are more similar. Again, there is a lack of early flexor moment from the vector data, but not from the CODA data (Fig. 39), and persistence of a slightly anterior vector alignment.

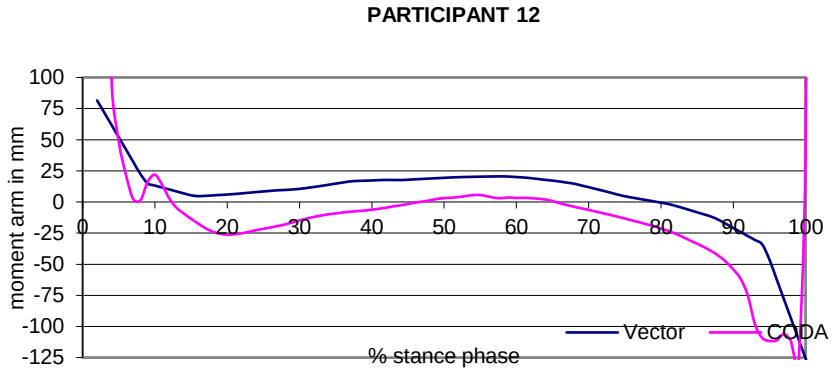


Figure 39. Moment arm graph for participant 12.

Analysis of the video images (Fig. 40) shows a similar lack of knee flexion in early stance (although this is less marked than for participant 5), with persistence of an anterior ground reaction force alignment at the knee in early stance. Towards mid-stance the knee looks fairly locked and the ground reaction force is marginally anterior to the knee, although within

normal limits. The same issues of knee joint centre modelling are likely to explain this discrepancy.

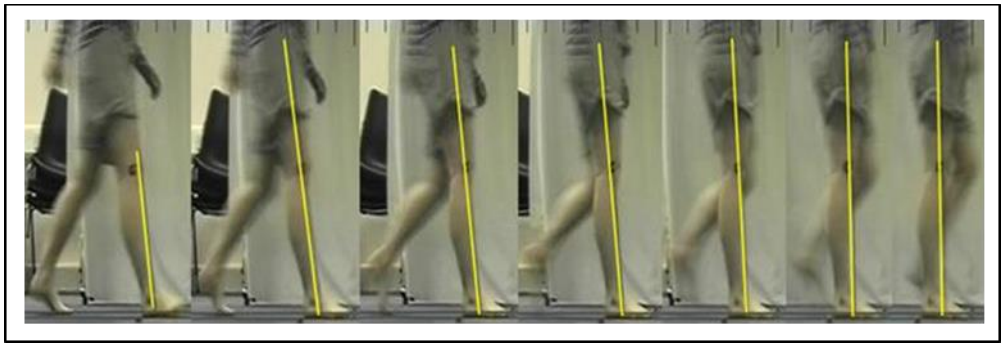


Figure 40. Illustration of the gait of participant 12, from initial contact to mid-stance.

Further analysis was performed on data collected from all four data sessions, and from *both* legs. Interestingly this provided a good correlation for participant 12 (ρ=0.929). Because of this, and the unexpected findings from repeat analysis on the *right leg* of the first session only, calculation of the results from the left leg of the first session was performed, which provides results of ρ=0.944, suggesting much better agreement for this set of data. It would therefore appear that participant 12 has some variability in his/her gait, and that perhaps the data from the right leg of session A was not completely representative of the overall pattern. The Wilcoxon signed-ranks test on this left leg data remained significant at p=0.000.

Correlations between the two systems for the remaining participants were high, indicating good validity of the measures.

9.3.6.5 Intra-Rater Reliability of the Moment Arm

Intra-rater analysis showed excellent reliability of this measure. Repeat data collection was some time after initial analysis, and the assessor was blinded to the original results. The issues of split vector and knee joint definition were therefore not enough of an issue to affect reliability of the measure when recorded by the same rater. Furthermore, data from “mid

mid-stance", where the author is particularly interested in terms of orthotic alignment, had high reliability (r=0.98). Finally, selection of the "mid mid-stance" frame was exactly the same for each reading, suggesting that the definition used for the selection of this frame was very reliable.

9.3.6.6 Inter-Rater Reliability of the Moment Arm

The results for inter-rater reliability, whilst still favourable, were lower than for intra-rater reliability, as may be expected. Issues to do with the working and nuances of the video recorder may have played a factor, as described above, along with the fact that the second assessor was less experienced in assessing video vector images and gait. At "mid mid-stance", reliability was good (r=0.85) between raters. Ideally the same clinician should assess the patient within a session, and wherever possible, between sessions, particularly for one period of tuning, to maximise the reliability and therefore sensitivity of the assessment process.

9.3.7 Comparison of Data with Other Published Findings

The plot of mean moment arm throughout the stance phase of the gait cycle is consistent with previous research findings. The data from Pratt et al [111] shows a similar pattern throughout the gait cycle, with the least variability around mid-stance as found in this study.

Furthermore, the present study found a mean mid mid-stance moment arm value of 7.51mm ± 21.25 (N=10*6*4), which is consistent with Pratt et al's [111] value of a mean of 6 ± 15mm at mid-midstance (N=11*3) in children. However, it must be noted that there is a slight difference in definition of "mid mid-stance" between the studies. Pratt defined "mid mid-stance" as the point in time when the swing side mid-shank crossed the stance leg, which would be marginally earlier in time than the definition used here. However, this later definition used in this current study would increase the moment arm value slightly, as it moves towards a greater extensor moment through stance. This study found values around zero at around 40% stance

phase of gait, which is consistent with other studies showing a similar pattern [53, 56].

9.3.8 Conclusion

From this validity and reliability study, the following conclusions can be made:

- The Sport Tester model of Polar heart rate monitor recorded consistent heart rate readings compared with ECG, for our single subject, suggesting an accurate measure of heart rate.
- The THBI was the most reliable measure (as compared with the PCI) for the calculation of energy cost during walking and will therefore be used during the clinical trial.
- Manual measurement of the moment arm at the knee, from the video vector system, is a valid, objective measure, as compared with data collected using 3d computerised motion analysis.
- Manual measurement of the moment arm is a reliable measure over time and has excellent intra-rater and good inter-rater reliability, meaning that it is applicable by a range of clinicians over time.

This allows **all of the experimental hypotheses** for this chapter to be **accepted**. Furthermore, with regards to the null hypotheses, there was a small difference in reliability of the PCI between the five and ten-minute walking periods, with greater reliability found during the longer walk, therefore this **null hypothesis is rejected**. However, for the THBI, there was no difference in reliability between the two walking periods, allowing the **null hypothesis to be accepted**.

The manual moment arm measure was simple to measure, and data analysis shows that data taken from “mid mid-stance”, defined as the point in time when the opposing swing leg foot passes the stance leg, offered high levels of reliability by same and different raters. This point in time is particularly

of interest for the process of fine-tuning, and the relationship of the moment arm at this point, to shank-to-floor angles has previously been discussed in literature [111, 123].

Data recorded were similar to those previously published and discussed in literature ([56, 111]. Therefore, the manual moment arm measure will be used in the clinical trial to optimise orthotic fine-tuning for children with CP, and the THBI will be used to determine the effect of finely tuned orthoses on walking for this population.

CHAPTER 10: STUDY THREE: PILOT CLINICAL TRIAL

10.1 Introduction

Following validation of the manual measurement of the moment arm from the video vector system data, and the reliability testing of the heart rate indices indicating the THBI as the most reliable measure of energy cost, the effect of orthotic fine-tuning on the energy cost of walking was studied in children with CP.

However, because of the paucity of sufficient normative data for children, for both the moment arm measurement at the knee during walking and the THBI, data for both of these measures were first collected from typically-developing children from within the same age-range as the criteria for the study patients referred for gait analysis. This set of data (the Reference Group) was collected first in order that the normative database could be assimilated prior to assessing the children with CP.

Once these normative values were calculated, children who already wore orthoses for walking and whom were referred to the Gait and Movement Laboratory for gait and orthotic assessment, were invited to take part in the study to determine whether their orthoses could be fine-tuned using the video vector system to improve their gait, and furthermore, to determine the effect of this fine-tuning on the energy cost of walking.

Due to the heterogeneous nature of the group of children with CP, a single case experimental design was used, with each child acting as their own control [47]. Each child's data were compared with the set of normative reference values to give an indication of their deviation from normal range, and to highlight when optimal orthotic tuning had been achieved, but energy cost values were only compared within individuals.

Some basic group analysis was performed to give an indication of overall changes in energy cost for this group, to inform future research.

10.2 Methodology

Data for this study were collected in the Gait and Movement Laboratory, within the London Road Community Hospital, Derby, which is part of the Derby Hospitals NHS Foundation Trust. The Derbyshire Research Ethics Committee and the Derby Hospitals NHS Foundation Trust R&D department granted ethical approval for this study. The University of Nottingham acted as a sponsor for the study.

10.2.1 Participants

For both of the groups (Reference Group and CP Group), children aged between seven and 16 years were invited to take part in the study, with target sample sizes of 30. For both groups age-appropriate information leaflets were designed for children aged 7-10, 11-15, 16 year olds, and for parents of all children. Written consent was obtained from all 16 year olds and all parents prior to data collection. Children aged 15 years and under provided written assent where they wished.

For the Reference Group posters inviting typically-developing children to take part in the study were displayed. Interested parties were asked to contact the Principal Investigator (PI) for further information, upon which they were sent the relevant information leaflets. The families were contacted at least one week later to see if they had further questions about the study, and if they were interested in taking part.

Inclusion criteria were as follows:

- Aged 7-16 years
- Able to walk independently for up to five minutes at a time

Exclusion criteria were:

- Lower limb surgery or injury within the past year
- Any medication / condition affecting heart rate
- Inability to comply with instructions during data collection
- Any history of orthopaedic, neurological or vascular disease affecting gait
- Leg length discrepancy of greater than 1cm
- Fixed flexion deformity of the knee of greater than 10°, or Dundee angle for hamstrings of greater than 10° (hip flexed to 45°, knee extended as far as possible, measurement taken of knee flexion from the fully extended position)
- Calf tightness (ankle dorsiflexion of less than neutral with the knee extended)
- Abnormal gait pattern as determined by PI, to include absence of heel-toe gait pattern, early heel rise in stance, toe drag during swing and knee hyperextension during stance
- Inability to understand verbal or written information in English.

Participants were also asked to avoid large meals, hot drinks and caffeine-based drinks for at least two hours prior to their appointment, to minimise the effect of caffeine and digestion on heart rate.

Once the reference group data were collected and processed to provide normative reference values for the moment arm at the knee and the THBI, children aged 7-16 years with CP who wore orthoses and were referred to the Gait and Movement Laboratory for gait and orthotic assessment were invited to take part in the study. When sending out the standard letter following receipt of their referral (asking them to contact the department to arrange an appointment), an additional study letter was included providing an introduction to the study and the relevant study information leaflets (parent and child versions). When the families subsequently contacted the laboratory to make their gait appointment they were asked if

they had any further questions about the study and if they were interested in taking part.

Inclusion criteria for the study were:

- Diagnosis of CP
- Aged 7-16 years (The lower limit was set to allow for compliance with the energy cost measure, which requires the child not to talk during their resting and walking periods. The upper limit was determined by the age at which children are transferred onto the Young Adult Team, and are managed by a different team of physiotherapists)
- Able to walk independently for up to five minutes at a time
- Requires the use of orthoses to facilitate walking
- Able to comprehend and comply with instructions for the study.

Exclusions included:

- Use of walking aid to walk independently
- Lower limb surgery within the past year
- Botulinum toxin injections to any lower limb muscle group within the past six-month period
- Change of medication affecting gait (e.g. Baclofen…) during the study period (this would result in withdrawal from the study)
- Any medication or condition affecting heart rate (e.g. beta-blockers)
- Inability to comply with orthotic use during study period (if the child did not wear their orthosis during the study period then they were withdrawn from the study)
- Fixed flexion deformity of the knee of greater than 10°, or hamstring tightness with a Dundee angle of greater than 10° (measured as for the Reference Group)
- Inability to understand verbal or written information in English.

Participants were also asked to avoid large meals, hot drinks and caffeine as per the Reference Group.

10.2.2 Equipment

10.2.2.1 Video vector system

The system in Derby used commercial video vector software (see below) written by the manufacturers of the motion analysis system used within this laboratory. It did not have its own analysis software, however, and therefore required the manual measurement of the moment arm as per the data from Nottingham collected in the Validation Study (Chapter 9).

Ground reaction force

One Kistler force plate[u] was embedded within the floor of the laboratory. Data from this force plate were fed into an amplifier[v] before being directed into the computer and relevant software. The force plate was set at an acquisition rate of 100Hz for vector analysis.

Video image

Two static CCTV analogue cameras[w] were sited within the laboratory for the VVS. One was sited perpendicular to the force plate, providing a sagittal view of the limbs during walking; and one was sited at the end of the walkway, providing a coronal view of the limbs during walking. The images from these cameras were fed through a Video Acquisition Board[x] and then into the PC and software. A split screen image was used so that sagittal and coronal views could be seen simultaneously (Fig. 41).

[u] Kistler Instrument Corp., Amherst, NY, USA. Model 9281B
[v] Kistler Type 9865 Amplifier, Amherst, NY, USA.
[w] Pc Model CSC-785 (PAL)
[x] BTS eMotion Video Acquisition Board, BTS, Milan, Italy



Figure 41. Image of split screen video image showing coronal and sagittal plane views simultaneously.

Software for the generation of the video vector image

Digivec BTS software[y] was used allowing the vector image to be overlaid onto the video image following the calibration process. This allowed real-time viewing of the video vector set-up, as well as recording of walking with the vector overlaid. The video could be instantly replayed, and the data was saved securely on the Trust's network drive.

Calibration

The BTS software included a pre-use calibration process during set-up, which ensured accurate alignment of the system by aligning the position of the four vertices of the force plate on the image from the camera. Furthermore, a simple calibration rod (as used within the lab in Nottingham) was applied to the force plate at the start of each session after the calibration process as an additional check to ensure accurate vector alignment. The force plate underwent regular quality assurance checks, as per laboratory protocol, to ensure accurate recording of forces in all planes.

10.2.2.2 Energy Cost assessment

An RS800CX Bike Polar heart rate monitor was used for the collection and recording of heart rate data. This new model allowed the heart rate to be recorded every second, providing even greater accuracy than in the

[y] BTS Digivec (release 1.7.2.0), BTS, Milan, Italy

validation study. For this study, an initial two-minute resting period was used, followed by a five-minute walking period. A shorter walking period was used following the analysis in the validation study demonstrated that the THBI was equivocal over a five minute or ten-minute walking period. The author felt that for children with CP, a five-minute walking period was sufficient, and that for many a ten-minute walking period would be unattainable. Data for both the Reference Group and the CP Group was therefore collected during a five-minute walk. Due to differences in room size a 20-metre figure-of-eight track was used, adjusting the original set-up from the validation study. One metre marks were made on the figure-of-eight to allow the total distance walked to be calculated at the end of the walking period. Once the heart rate data were downloaded, the total number of heartbeats used for the walking period and the total distance walked were computed, allowing calculation of the THBI.

A room thermometer[z] was used to monitor the room temperature, which was maintained between 21 and 24°C.

10.2.3 Data Acquisition

Participants for both groups were asked to dress in shorts and a t-shirt to allow the lower limbs to be viewed during assessment and for the ease of attaching the heart rate monitor.

10.2.3.1 Reference Group

Children were asked to attend the laboratory only once. After gaining written consent, an initial clinical examination was undertaken to screen for soft tissue tightness and to allow for measurement of the required anthropometric data (leg length and shank length). The two sets of study data were then collected in a randomised order, determined by the use of a

[z] Boots Nursery Thermometer

randomisation spreadsheet provided by the statistics department. The two sets of data collected were as detailed below.

For collection of the **moment arm data** the children were asked to walk along the central walkway and across the force plate whilst a video was recorded. Their starting position was adjusted to ensure that their left foot cleanly struck the force plate whilst walking at their own natural pace. The participants were not told where the force plate was (or indeed that there was one) prior to data collection to avoid alteration of their gait to target the force plate. Data collection continued until at least three sets of clear force plate data were recorded for the left leg. The left leg was selected as this allowed video in the coronal plane (anteriorly) to be captured simultaneously with the sagittal plane data to allow a visual inspection for any abnormal rotational alignments prior to inclusion.

For collection of the **energy cost data** a heart rate monitor was attached around the child's chest, underneath their t-shirt using the provided elasticated strapping. Sections of the strap were dampened as per the manufacturer's guidelines to ensure accurate heart rate recording. The child was seated at the centre of the figure-of-eight track and asked to rest quietly for two minutes whilst his/her resting heart rate was recorded to ensure consistency of methodology between participants. Once this two-minute period was finished and a beep sounded (automatically from the heart rate monitor), they were asked to stand up and start walking around the figure-of-eight track at their own comfortable walking speed. They were asked to refrain from talking whilst walking. Heart rate was recorded continuously every second during this period. The number of completed laps and the distance of the final partial lap were recorded so that the total walking distance for the five-minute walking period could be calculated (to the nearest metre).

The data collection was then completed, and the child was able to re-dress and go home. They were not asked to return.

From these data, the THBI values could be calculated and moment arm about the knee measured throughout the gait cycle.

10.2.3.2 Group with Cerebral Palsy

Children were asked to attend the lab twice. At their initial appointment, a brief history and a detailed clinical examination (see Appendix 4) were completed as standard for a gait analysis to allow their clinical report to be completed, for screening of exclusion criteria and to inform their management plan. Range of joint motion, muscle strength, bony torsions, leg length and spasticity were recorded. Spasticity was measured using the Modified Ashworth Scale (MAS) [212] (Appendix 4). Written parental /guardian consent and child assent (where they wished to provide) were obtained prior to data collection. Both video vector and heart rate data were collected barefoot and with their current orthoses, in an order determined by the use of a second randomisation spreadsheet.

For collection of the video vector data, children were asked to walk (barefoot and with their orthoses and shoes on) along the central walkway and across the force plate whilst a video was recorded as per the reference group. For this group data were collected for both the left and right legs, with the starting position adjusted to ensure clear force plate data were gained with targeting the plate. Up to three clear force plate strikes were recorded for each leg. Rests were provided (seated) as required during this process.

For collection of the heart rate data the same methodology as for the reference group was used – the heart rate monitor was attached and the child was asked to rest, seated, for two minutes prior to data collection. Data were then recorded for up to five minutes whilst they walked around the figure-of-eight track. Data collection was collected barefoot ('barefoot a') and with their original orthosis/es and footwear worn ('un-tuned'). If the

child was unable to complete five minutes of walking then the total walking time was recorded in addition to the total distance walked.

Once all data were recorded the child was allowed to sit / play whilst the videos were reviewed to determine the need for any orthotic fine-tuning. Once a decision had been made as to what tuning was required, the appropriate temporary adjustments were made, where possible, to the orthosis and/or footwear (e.g. additional heel or toe wedge). Once rested the child was then asked to walk along the central walkway once more whilst video data were recorded to allow a re-assessment of the effect of the fine-tuning on their moment arm to be made. This process of minor adjustments and a repeat video (short) were made until the optimal vector alignment was achieved. In some cases, this was not possible as the style of orthosis, or the angle of the ankle in the orthosis needing adjusting before further tuning could be completed.

Once an optimal orthotic prescription was made the child was allowed to go home. Once the data was reviewed and a final orthotic plan made, a report was sent to their referrer and a follow-up orthotic appointment made to allow the recommended adjustments to be made.

Once the orthotic adjustments had been made and the child had been wearing their new prescription for at least two weeks, the child was then asked to return for a repeat assessment. Data collection was repeated under barefoot ('barefoot b') and shod (with orthoses, 'tuned') conditions, for both video collection and heart rate monitoring to allow a comparison to be made. Table 12 illustrates the data collection plan for the CP group.

Table 12. Timetable of data collection for CP group

Day	1st appointment		2nd appointment	
Condition	**Barefoot**	**Un-tuned AFO**	**Barefoot**	**Tuned AFO**
Data label	**Ba**	**U**	**Bb**	**T**
Measurement				
Vector	✓	✓	✓	✓
Heart rate	✓	✓	✓	✓
Anthropometric	✓		✓*	
Clinical examination	✓			

* to check for any sudden growth.

10.2.4 Data Analysis

10.2.4.1 Reference Group

Data were analysed for normality using the Shapiro-Wilk test and were found to be non-parametrically distributed, therefore median values with inter-quartile ranges were then calculated for the THBI and moment arm at the knee at "mid-mid-stance" to provide the reference ranges for the CP group.

10.2.4.2 CP Group

Energy cost data

Normality testing was completed by inspection of histogram plots (and using the Shapiro-Wilk test). Data were found to be non-parametric. The following pairs of data were compared using the Wilcoxon signed-rank test to ensure only related data were compared:

1. Bb – Ba: to determine any difference in baseline barefoot data between sessions
2. U – Ba: to determine any difference between barefoot and un-tuned orthosis (within session, orthotic effect)
3. T – Bb: to determine any difference between barefoot tuned orthosis (within session, orthotic effect)
4. T – U: to determine if fine-tuning had any significant effect on walking efficiency (tuning effect)

Barefoot data were only compared with orthotic data from the same session to ensure change attributed to orthotic use was not affected by secondary

variables. For this reason paired data were analysed, and an ANOVA was not applied to the whole dataset.

Moment arm measure

The moment arm at the knee was measured using the same methodology as for the validation study. The measurement transparency was placed over the vector image on the computer, with the origin lined up to the knee joint centre and axis lined up with the GRF vector, such that the distance of the vector from the knee joint centre (moment arm) could be measured, as previously (Fig. 23, Section 9.3.3.2).

For each participant three sets of data (where possible) for the both legs were measured at the "mid mid-stance" point. As with the validation study, this was defined as the video frame in which the swing side ankle passed behind the stance leg (or as near as possible within the limits of the video refresh rate). The reliability of this process was clarified in the validation study.

Data were then scaled, using the same methodology as within the validation study, to give an accurate measure of moment arm, allowing comparison between participants and cycles. The shank length (true) was measured during the clinical examination, and again from the mid-mid-stance frame (video) for each cycle to provide a scaling ratio. This then allowed the moment arm measure to be scaled back to an accurate measure, as before:

$$Moment\ arm_{true} = \frac{(shank\ length_{true}\ x\ moment\ arm_{video})}{shank\ length_{video}}$$

Footfall characteristics

As a secondary measure, footfall characteristics were analysed from the video. A score of 1-3 was given to classify the initial contact of the foot with the floor as a heel strike (1), flat foot strike (2) or toe strike (3). This was completed for both legs, for each of the three gait cycles used for moment

arm analysis, and resultant mean was calculated. For the purposes of statistical analysis, a total score for both legs was calculated, with a score of two indicating bilateral heel strike and a score of six indicating bilateral toe strike. Data was tested for normality and found to be non-parametric and therefore Friedman's test was used during analysis.

10.2.5 Orthotic Protocol

For the purpose of this study the following protocol was followed:

Orthoses were custom-made for each child, apart from one child whose original orthosis was an off-the-shelf design. A range of orthotic services were involved due to the geographical spread of the participants and their associated orthotic services and therefore exact designs could not be completely controlled. However, as this study was not designed to investigate a specific orthotic design, but to study the effect of optimising each individual prescription, this was not felt to be a problem.

As orthoses were not all made locally it was not possible to collect information about exact material selection and thickness as recommended by Ridgewell et al [20]. Again, it was not specific orthotic design being investigated here.

Participants were assessed barefoot to provide a baseline value. This was repeated again at the second session to ensure clarity of interpretation of results. Whilst there is an argument towards using shoes only as the control for each participant, a counter-argument is that children who wear orthoses tend to have specific footwear that they wear with their orthoses. Reasons for this include the need for a larger size to accommodate the orthosis, and perhaps specific guidance from the orthotist to assist with overall shank inclination alignment. As a result, the investigator felt that wearing shoes that are not routinely worn (as most children wear their orthoses for most of their day, on most days of the week) as a baseline measure would not

necessarily represent their unassisted gait pattern. Children were not likely to be able to wear the same pair of shoes for the control and orthotic data collections as the shoe is often too large to wear without the orthosis. The systematic review completed by Ridgewell et al [20] found that in 29 out of 41 studies, barefoot was used as a control condition.

For all subjects, the toe-plate length was full. Specific trim line detail and orthotic design are described for each orthosis, as are the angle of the ankle in the AFO, details of heel wedging, heel-sole differential of the footwear and overall shank to vertical angle of the resultant AFO-footwear combination (SAFAFOFWC).

For those who returned for the second session, a minimum of two weeks was given for acclimatisation of the new design, although for many in practice it was longer than this due to the time taken to get them back in for a review.

Details of participants include age, gender, topographical distribution of presentation, and GMFCS level. A description of gait problems is highlighted by the initial gait assessment and baseline clinical examination details are provided, including, but not limited to, passive length of gastrocnemius, and consideration of dynamic tone within this muscle group (gastrocnemius catch).

10.2.6 Hypothesis

The third overall hypothesis is tested during this specific study, that being:

1. Use of tuned orthoses reduces the energy cost of walking above that of orthoses that have not been specifically tuned, for children with CP.

More specifically, the theory is that once the moment arm at the knee has been optimised through fine-tuning of the orthotic-footwear combination,

this should lead to a reduction in the energy cost of walking, compared with walking in orthoses that have not been finely-tuned.

10.3 Results

10.3.1 Reference Group

Thirty children (17 females:13 males) without walking problems were recruited into the study aged between seven and 16 years. Four 7 year olds were recruited and two 13 year olds, but for all other ages there were three recruits per age. The following anthropometric data represent the cohort:

Mean height: 1.49m (sd: 0.17). Range = 1.17-1.88m.
Mean weight: 44.7Kg (sd: 17.3). Range = 21.2 - 94.2Kg.
Mean BMI: 19.5 (sd: 4.4). Range = 14.2 – 34.6.

All participants completed the data collection and none withdrew, or had to be withdrawn following clinical examination screening or on review of the video data.

10.3.1.1 THBI Data

Data were tested for normality using the Shapiro-Wilk test and were non-parametrically distributed (p=0.014). For the whole group, the median THBI was **1.55 beats per metre** (IQR: 0.3), with a group overall range of 1.15 - 2.55 beats per metre.

Total walking distance ranged from 189m – 412m over the five-minute period. No participant struggled to walk for the whole five-minute period. To determine if distance covered affected THBI, this relationship was examined further.

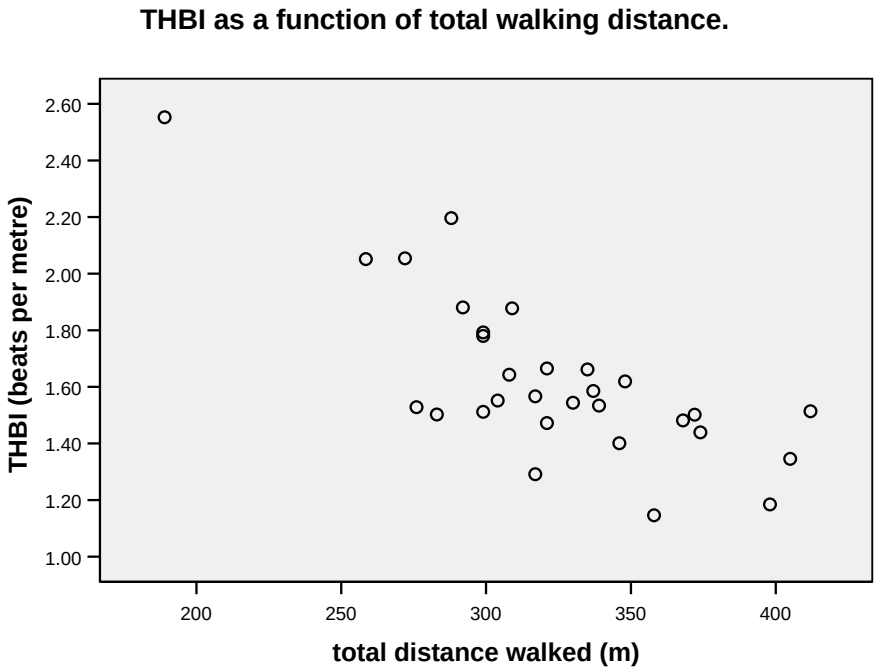


Figure 42. THBI as a function of total walking distance.

Figure 42 highlights the gradual reduction in THBI with increasing walking distance. Analysis using Spearman's rho indicates a significant correlation ($p<.001$) between THBI and walking distance, with an inversely proportional relationship. There is no obvious reason as to why this relationship exists. It may have simply been a representation of fitness of the participants (with the least fit participant only covering 189m in five minutes, and therefore perhaps having a higher heart rate during walking, resulting in a higher THBI), or may suggest relaxation of participants the more they walked, such that heart rate stabilised over the longer distances. It was not within the remit of this study to investigate this further but may warrant further study in future.



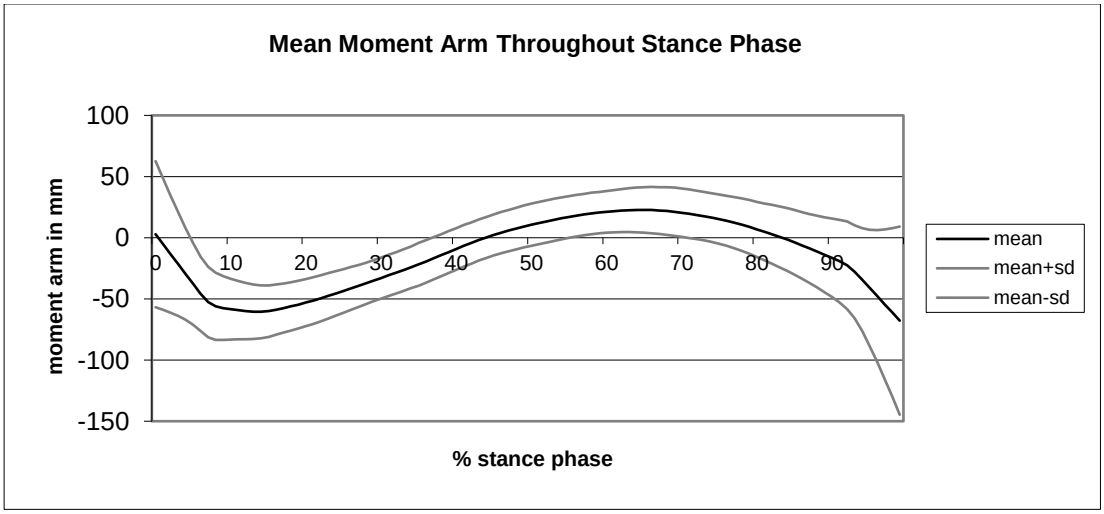
Figure 43. Relationship between age and total distance walked.

Figure 43 illustrates the relationship between walking distance and age. Statistical analysis using a Spearman's rho test indicates no significant correlation (p=0.111) between age and total walking distance. In fact, the greatest total walking distance was achieved by one of the seven year olds. The lowest walking distance was covered by a ten-year-old.

10.3.1.2 Moment Arm Data

When reviewing the video data closely for analysis it was noted only two completely clear force plate strikes were available for one participant. Therefore, there is one set of missing data resulting in 89 sets data collected and available for analysis (three sets of data per person for 29 participants and two sets of data for one participant). Graphical representation of the moment arms for all participants is found in Appendix 6.

The mean cycle for the whole group was calculated using the total 89 raw cycles, and is shown in Figure 44.



Note that negative moment arm values represent external knee flexor moments, and positive moment arm values represent external knee extensor moments.

Figure 44. Mean moment arm (±1SD) for the Reference Group.

The data from "mid mid-stance" are not normally distributed (Shapiro-Wilk p=0.045) and therefore non-parametric analysis was performed. The median "mid mid-stance" moment arm is **0.00mm**, with an inter-quartile range of 27.05, **(-9.58 to 17.31mm).** These values represent the normal range of moment arm at "mid mid-stance" for this age group of children and are used within the clinical trial to inform the orthotic tuning process.

The mid-stance data variability is shown in the box plot illustrated in Figure 45.

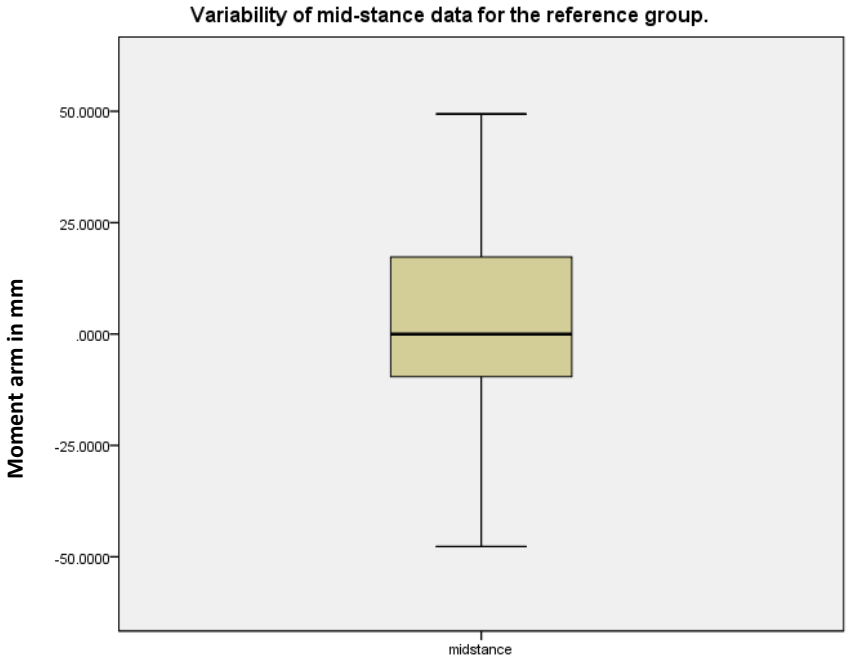


Figure 45. Mid mid-stance variability in moment arm for Reference Group.

Examination of the data shows that the frame from which the "mid mid-stance" data were taken from represents a mean position of 47.7% stance phase of the gait cycle (i.e. just before half-way through the stance phase), with a SD of ±4.5%. This is in agreement with data presented by Pratt et al [180].

10.3.2 Cerebral Palsy Group Results

Eighteen children (7 females:11 males) were recruited into this group within the study time frame, between the ages of seven and 12 years of age. There were a greater number of younger children in this group than in the reference group, with 11 children aged 7-8 years, five children aged 9-10 years and two children aged 11-12 years. This could not have been predicted prior to the collection of the reference data, hence the even spread of ages within the reference group.

Table 13. Demographics of the CP Group

ID	Age (yrs)	Gender	Diagnosis	GMFCS	Height (m)	Weight (Kg)	BMI
CP001	8	f	L hemi	II	1.265	21	13.1
CP002	12	f	L hemi	I	1.47	37.2	17.2
CP003	7	f	L hemi	II	*	*	*
CP004	7	m	R hemi	I	*	20.8	*
CP005	8	m	L mono	I	*	31	*
CP006	8	m	sp di	I	1.21	18	12.3
CP007	7	f	R hemi	II	*	36.6	*
CP008	8	m	sp di	II	1.21	20.6	14.1
CP009	9	m	sp di	I	*	36.6	*
CP010	8	f	sp di	II	*	*	*
CP011	8	m	sp di	III	*	*	*
CP012	12	m	quad	II	1.43	47.4	23.2
CP013	10	m	sp di	II	1.44	37.8	18.2
CP014	9	m	L mono	I	1.455	34.8	16.4
CP015	10	f	R hemi	II	1.3	19	11.2
CP016	8	f	sp di	II	1.23	23.6	15.6
CP017	10	m	sp di (asym)	II	1.275	23.8	14.6
CP018	7	m	L hemi	I	1.375	28	14.8
Mean (range)	**8.67** (7-12)	**7f 11m**	**8 sp di 7 hemi 2 mono 1 quad**	**7@ I 10@II 1@III**	**1.33** (1.21–1.47)	**29.1 (18-47.4)**	**15.5 (11.2–23.2)**

Key: m=male; f=female; sp di=spastic diplegia; hemi = hemiplegia; quad = quadriplegia; mono = monoplegia; L= left; R= right; GMFCS = Gross Motor Function Classification Scale. * = missing data.

10.3.2.1 Case Studies

The cohort for this group presents a fairly diverse range of presentations in terms of functional ability (GMFCS levels), limb involvement (monoplegic to quadriplegic) and is also a relatively small group due to recruitment problems. Consideration was therefore given to the optimal method of reporting the outcomes to best highlight the effect of orthotic tuning. Given the heterogeneous nature of this group, the results will be presented as a series of case studies to allow full analysis of each intervention to be examined.

Participant ID CP001

This young girl was born at 35 weeks gestation and showed signs of developmental delay within the first year. She was diagnosed with cerebral palsy and was classified as having a left hemiplegia. She started walking around the age of two years, wearing ankle-foot orthoses. At the time of the study CP001 was 8 years old and was assessed to be at level II on the GMFCS. She could walk short distances independently but relied on a wheelchair for going into town. She wore a left sided fixed AFO, which she wore from around 8am until 4pm on school days. Outside of this time she wore the orthosis for walking outside, but not for indoor play. She had recently had a new AFO made with a heel wedge, but this was causing some foot pain and so she had been wearing her old orthosis, which had no heel raise and was getting too small. She spent around 1 hour a week at home and around 15 minutes, 3 times a week at school, doing her physiotherapy exercise programme.

One year prior to inclusion in the study CP001 had undergone a right-sided periosteal release in an attempt to even out her leg length discrepancy. She had also had Botulinum toxin to her left upper limb and tibialis posterior 2 ½ years before taking part in the study, and again in the upper limb only, six months before the study.

Clinical examination:

Some forefoot plantarflexion and adductus was noted on the left side. We also found some femoral anteversion on the left side. Strength was good throughout the left side, apart from around the ankle where there was minimal selective control. There was mild spasticity in the left gastrocnemius only (MAS1), although the gastrocnemius catch angle was normal. No other spasticity was noted.

Table 14. Clinical examination data for CP001

Test	L	R	Test	L	R
Leg length discrepancy	1.5cm, left shorter		**Quads strength**	5	5
Popliteal angle	48°	35°	**Hams strength**	5	5
Dundee angle	0°	0°	**Ankle DF strength**	0/1	5
Knee fixed flexion	0°	0°	**Ankle Inv strength**	0/1	5
Ankle DF with knee flex	20°	Full	**Ankle Ev strength**	0/1	5
Ankle DF with knee ext	10°	Full	**Ankle PF strength**	Not tested	Not tested
Hip IR	72°	40°	**Gastroc spasticity (MAS)**	1	0
Hip ER	35°	30°	**Gastroc catch angle**	neutral	neutral
Ruwe angle	40°	25°			

Orthotic design:

For the trial, she was assessed in her recently acquired orthosis to see if we could tune this. Details are summarised in Table 15. The aim of her orthosis was therefore to control the ankle during swing by preventing plantarflexion, but allow use of a third rocker to progress forwards at terminal stance.

Table 15. Original orthotic detail for CP001

	L	R
Type	Fixed	
AAAFO	3°PF	
Trim lines	Behind met heads; in front of malleoli	
Other features	Strap across the midfoot	
Wedging detail	0.5cm heel wedge	
SAFAFO	7° incline	
Footwear type	Boots	
Footwear HSD	1.5cm	
Overall SAFAFOFWC	14° incline	
Sole profile of shoe	Nil of note	

Gait analysis:

When walking barefoot, CP001 achieved a flat foot strike on the left side, but a normal heel strike on the right. The ground reaction force vector was very posterior to the knee at mid-stance on the left, but was normal on the right. With her original orthosis, she achieved heel strike on the left side but the shank appeared excessively inclined at mid-stance. The alignment of the ground reaction force vector at the knee was improved, but remained posterior to the knee.

As she appeared to be excessively inclined, the heel wedging was then removed from the orthosis during this initial session to reduce her overall SAFAFOFWC and her gait re-assessed. This improved her shank inclination in mid-stance and hence improved the alignment of the ground reaction force vector at the knee.

Analysis:

From this assessment, the following conclusions were made:

- No requirement for orthosis to be cast in plantarflexion as full range of passive dorsiflexion was available with the knee extended, and very little spasticity was noted in the calf.
- Less overall shank inclination was required with the aim of preventing excessive knee flexion in stance.

Changes made to orthotic prescription:

At her review appointment (11 weeks after her first visit), CP001 had been wearing her new orthosis for 5-6 weeks. She had been cast and fitted with a new orthosis, still fixed in design but with a neutral cast angle and less overall shank inclination as suggested from her assessment (Table 16).

Table 16. Tuned orthotic detail for CP001

	L	R
Type	Fixed	
AAAFO	neutral	
Trim lines	Behind malleoli	
Other features	Strap across the midfoot	
Wedging detail	0.6cm heel wedge	
SAFAFO	3° incline	
Footwear type	Shoes	
Footwear HSD	0.5cm	
Overall SAFAFOFWC	7° incline	
Sole profile of shoe	Nil of note	



Figure 46. Final orthotic design for CP001

There were no changes in her overall health, exercise programme or orthotic usage.

Repeat gait analysis:

With her new orthosis on the ground reaction force alignment at the knee was further improved, although it continued to remain posterior to the knee and didn't quite meet normal limits. She continued to achieve a heel strike.

CP001 reported that she preferred the newer 'tuned' orthosis as it was more comfortable, allowed her to walk more easily and further than in her original orthosis. She found it more comfortable. Her mum confirmed this opinion too.

Results:

Table 17. Results for CP001

Condition	Moment Arm results (mm)		THBI results (bpm)	Foot fall (left side)
	Left	Right		
Barefoot a	-80.6	-14.8	1.6	Flat foot
'Un-tuned'	-42.8	-12.9	2.0	Heel strike
Barefoot b	-49.3	-29.8	1.6	Flat foot
'Tuned'	-23.5	-14.9	1.7	Heel strike

The results show that the moment arm on the left side is optimised with the 'tuned' orthosis, although it does still remain a little posterior to the knee compared with normal. Furthermore, considerable variability was noted in her barefoot data between sessions. With regards to the energy cost of walking, her values when walking barefoot were around normal, but there was a 25% increase in energy cost with her un-tuned orthosis. This was reduced back to the normal value when wearing her tuned orthosis.

Participant ID CP002

This young girl was 12 years old at the time of the study. She was born at 28 weeks gestation but her mum reported no initial developmental or neurological concerns. She had originally started walking around the age of 19 months. However, she then suffered a cerebro-vascular accident at the age of 2 years. Following this, she was walking again within a month but has since been classified as having a left hemiplegia and functioned at level I on the GMFCS. She had worn a fixed design AFO since the age of 2½ years and had not had any surgery at the time of the study. She had previously had a trial of intra-thecal baclofen, which failed, and at the time of the study was taking oral baclofen twice a day to help with the increased tone in her upper limb. She wore her orthosis for around 8 hours a day, all week. She spent around 4 hours a week at home and 30 minutes a week at school on her physiotherapy exercise programme. CP002 was independently mobile at the time of the study.

Clinical examination:

There was passive tightness of the left ankle, with contracture of both the gastrocnemius and soleus muscles. However, she managed to fit into her orthosis cast at 90° without any problems, suggesting that further range was available on full weightbearing. The foot tended to pull into inversion and was prone to spasm, making accurate measurement difficult. We noted spasticity throughout the left side in the hip flexors, adductors, hamstrings, with marked spasticity in the calf and tibialis posterior.

Table 18. Clinical examination data for CP002

Test	L	R	Test	L	R
Leg length discrepancy	Symmetrical		**Quads strength**	5	5
Popliteal angle	55°	57°	**Hams strength**	5	5
Dundee angle	0	0	**Ankle DF strength**	3	5
Knee fixed flexion	0	0	**Ankle Inv strength**	4+	5
Ankle DF with knee flex	10°PF	18°	**Ankle Ev strength**	Poor	5
Ankle DF with knee ext	10°PF	12°	**Ankle PF strength**	Not tested	Not tested
Hip IR	64°	Symmetrical	**Gastroc spasticity**	4	0
Hip ER	25°	Symmetrical	**Gastroc catch angle**	PF+	Neut
Ruwe angle	35°	Normal			

Orthotic design:

Her custom-made orthosis aimed to prevent plantarflexion in swing, facilitating heel strike, but allowing some flexibility for pre-swing through trim lines at the metatarsal heads.

Table 19. Original orthotic detail for CP002

	L	R
Type	Fixed	
AAAFO	90°	
Trim lines	In front of malleoli, behind met heads	
Other features	-	
Wedging detail	Nil	
SAFAFO	0°	
Footwear type	School shoes	
Footwear HSD	1cm	
Overall SAFAFOFWC	8° incline	
Sole profile of shoe	Slight forefoot rocker	

Gait analysis:

When walking barefoot CP002 achieved a toe strike bilaterally with the left ankle inverted. This toe striking resulted in the knee locking into extension on the left side shortly after contact and remaining extended, meaning that the shank could not incline during stance. The resultant ground reaction force alignment was anterior to the knee on both sides at mid-stance. On the right side, there was a vaulting pattern (rising onto her toes) to help with clearance of the left foot in swing. With her original left-sided orthosis, there were improvements in her gait and she achieved heel strike bilaterally with some improvement in ground reaction force alignment at the knee, although this remained anteriorly aligned at mid-stance.

Analysis:

We made a decision during the assessment that her orthosis design was satisfactory (despite her apparent contracture, as she tolerated her orthosis well and achieved consistent heel strike) but that she needed further inclination to bring the vector alignment through the knee rather than remaining anterior. We added further wedges during the session and found that with 8mm heel wedging on the left, the vector alignment at the knee in mid-stance was normalised. We also added a small wedge (6mm) on the right side to prevent the creation of a leg length discrepancy.

The plan was to have this additional wedge added through the Orthotics Department and then to return for her review assessment.

However, CP002 had a review appointment with her Orthopaedic Consultant prior to this review appointment and it was decided that she was suitable for some soft tissue surgery to release the Achilles tendon on the left and to transfer part of her tibialis anterior to redress the muscle imbalance around the ankle – as suggested by gait analysis. No follow-up data is therefore available for this participant.

Results:

Table 20. Results for CP002

Condition	Moment Arm results (mm)		THBI results (bpm)	Foot fall (left side)	Foot fall (right side)
	Left	Right			
Barefoot a	98.2	61.2	1.7	Toe strike	Toe strike
'Un-tuned'	28.1	28.7	1.5	Heel strike	Heel strike
'Tuned' at session 1	9.1	N/C	N/C	Heel strike	N/C

N/C – not collected

The results show that the moment arm is significantly improved with both orthoses, but is optimised with the 'tuned' orthosis. Her energy cost measurements were just within normal limits both with and without an orthosis on.

Participant ID CP003

This young girl was born at term but suffered a cerebrovascular accident (stroke) at the age of 8 months. She was sitting and pulling to stand before her stroke but took another 6-8 months to regain this function. She walked around the age of 1 ½ years with help, and was independently walking by 2 years. CP003 presented with a left hemiplegia (considered to be cerebral palsy due to her young age), and functioned at a level II on the GMFCS. She had had one dose of Botulinum toxin into her lower limb at pre-school age

with minimal effect, and 3-4 doses into her arm since, but none recently. CP003 wore a fixed AFO design orthosis for around 10 hours a day and did not have a home exercise programme. She completed 5-10 minutes of physiotherapy at school a 'few' times week. She was age 7 years at the time of her inclusion in the study.

Clinical examination:

The main issues noted from examination were of a 2cm leg length discrepancy (left side shorter) and some femoral anteversion on the left side. We only noted spasticity in the calves with the knees extended, and tibialis posterior. Her gastrocnemius catch angle was in considerable plantarflexion.

Table 21. Clinical examination data for CP003

Test	L	R	Test	L	R
Leg length discrepancy	2cm discrepancy, left side shorter		**Quads strength**	5	5
Popliteal angle	45°	Normal	**Hams strength**	5	5
Dundee angle	0	0	**Ankle DF strength**	4	5
Knee fixed flexion	0	0	**Ankle Inv strength**	4	5
Ankle DF with knee flex	2°	Normal	**Ankle Ev strength**	4	5
Ankle DF with knee ext	3°	Normal	**Ankle PF strength**	4	5
Hip IR	85°	65°	**Gastroc spasticity**	4	0
Hip ER	40°	45°	**Gastroc catch angle**	PF	Neut
Ruwe angle	34°	Normal			

Orthotic design:

CP003 wore a custom-made fixed AFO cast in plantarflexion to accommodate her spasticity. Trim lines behind the metatarsal heads to assist third rocker motion at pre-swing.

Table 22. Original orthotic details for CP003

	L	R
Type	Fixed	
AAAFO	5° PF	
Trim lines	Behind malleoli Behind metatarsal heads	
Other features	Medial flare on heel and along midfoot. Ankle and forefoot strap.	
Wedging detail	Heel ?depth	
SAFAFO	3-4° inclined	
Footwear type	Trainers	
Footwear HSD	0.5cm	
Overall SAFAFOFWC	Omitted in error, but around 5-6°	
Sole profile of shoe	Flat	

Gait analysis:

When walking barefoot CP003 achieved a flat foot strike bilaterally. On loading, the left knee snapped back into extension and remained so throughout stance. At mid-stance, the alignment of the ground reaction force to the knee was anterior on the left side, but normal on the right. With her original orthosis on she achieved heel strike bilaterally but continued to snap the left knee back on loading and therefore the alignment of the vector remained relatively unchanged.

Analysis:

From the assessment, the following decisions were made:

- To maintain the current fixed orthotic design including AAAFO to accommodate her calf tightness and spasticity, and continue to promote a heel strike.
- To increase the amount of rearfoot wedging to further incline the shank during stance to prevent the persistent knee hyperextension noted.

Changes made to orthotic prescription:

Further heel wedging was therefore added to the AFO as suggested from her analysis.

Table 23. Tuned orthotic detail for CP003

	L	R
Type	**Fixed**	
AAAFO	**5° PF**	
Trim lines	**Behind malleoli** **Behind metatarsal heads**	
Other features	**Medial flare on heel and along midfoot. Ankle and forefoot strap.**	
Wedging detail	**1.5cm**	
SAFAFO	**6° inclined**	
Footwear type	**Trainers**	
Footwear HSD	**0.5cm**	
Overall SAFAFOFWC	**11° incline**	
Sole profile of shoe	**Flat**	

Repeat gait analysis:

CP003 attended for repeat analysis 10 weeks after her initial appointment, having worn her new orthoses for the previous two weeks. Her barefoot gait continued to achieve just a flat foot strike, but again she achieved a heel strike with her 'tuned' orthosis on. This time the alignment of the ground reaction force vector at the knee was excellent and within normal limits.

At the review appointment CP003 felt that her new orthosis was more comfortable to wear (the old one was getting too small however) and felt that she could walk more easily in the 'tuned' orthosis, although they felt there was little difference between them. She preferred the colour of her newer orthosis.

Results:

Table 24. Results for CP003

Condition	**Moment arm results (mm)**		**THBI results (bpm)**	**Foot fall (left side)**	**Foot fall (right side)**
	Left	**Right**			
Barefoot a	109.0	-3.2	2.3	Flat foot	Flat foot
'Un-tuned'	85.7	31.0	2.0	Heel strike	Heel strike
Barefoot b	46.7	6.3	2.4	Flat foot	Flat foot
'Tuned'	-8.6	-7.6	2.2	Heel strike	Heel strike

These results show a clear improvement in the moment arm measurement at the left knee with her 'tuned' orthosis on compared with barefoot or with her 'un-tuned' orthosis. Energy cost was reduced with both orthoses on compared with barefoot, but there was no further improvement with the tuned orthosis. Her energy cost remained increased compared with reference values.

Participant ID CP004

This young boy was the second of twins born at 30 weeks gestation. He walked at 18 months of age and had worn bilateral orthoses for many years. He was aged 7 years at the time of the study. He had a right hemiplegia and functioned at level I on the GMFCS. He had received Botulinum toxin to his right calf 17 months before starting in the study. This did help with ease of stretching and allowed him to get his heel down, but wore off within 3 months and had not been repeated. He had not had any surgery to his lower limbs. CP004 had attended for gait analysis the previous year where we had tuned his orthoses, but his physiotherapist felt that it was worth another assessment to determine if the orthoses remained optimally tuned. His school had commented that his gait appeared better since his orthoses was 'tuned' in the previous year. He was complaining of some aching in his legs in the previous few days and still tended to lock his knee in stance. He wore his orthoses during school hours in the week and when outside at the weekends. He had around half an hour of physiotherapy programme input at school each week and did a further hour at home.

Clinical examination:

The main findings from the clinical examination were of some hamstring tightness, mainly on the left, and limited gastrocnemius length on the left. There was mild weakness around the right ankle. Some spasticity was noted in both calves, and although fairly mild his gastrocnemius catch angles were in plantarflexion.

Table 25. Clinical examination data for CP004

Test	L	R	Test	L	R
Leg length discrepancy	Symm		**Quads strength**	5	5
Popliteal angle	60°	45°	**Hams strength**	5	5
Dundee angle	0	0	**Ankle DF strength**	5	4
Knee fixed flexion	0	0	**Ankle Inv strength**	5	4
Ankle DF with knee flex	15°	20°	**Ankle Ev strength**	5	3
Ankle DF with knee ext	2°	10°	**Ankle PF strength**	Not tested	Not tested
Hip IR	Symm	Symm	**Gastroc spasticity**	2	2
Hip ER					
Ruwe angle	Normal	Normal	**Gastroc catch angle**	PF	PF

Symm = symmetrical

Orthotic design:

CP004 wore bilateral custom-made hinged AFOs to allow some normal shank motion in stance, but both cast in slight plantarflexion to accommodate the spasticity in the calf complex.

Table 26. Original orthotic detail for CP004

	L	R
Type	Hinged	Hinged
AAAFO	5°plantarflexed	7°plantarflexed
Trim lines	Behind the metatarsal heads	Behind the metatarsal heads
Other features	Ankle and top straps	Ankle, top and toe straps
Wedging detail	Heel – 1cm	Heel – 2cm
SAFAFO	3° inclined	6° inclined
Footwear type	Shoe	Shoe
Footwear HSD	1cm	1cm
Overall SAFAFOFWC	11° inclined	13° inclined
Sole profile of shoe	Normal	Normal

Gait analysis:

CP004 achieved a bilateral flat foot strike when walking barefoot. The alignment of the ground reaction force at mid-stance was slightly anterior to his knees, highlighting his tendency to hyperextend the knees,

particularly on the right side. In his orthoses, he achieved heel strike bilaterally and alignment of the ground reaction force at mid-stance was excellent bilaterally. The tendency to hyperextend the knees at mid-stance was virtually eliminated.

Analysis:

No changes were required for his orthoses as the overall SAFAFOFWC was considered to be optimal and his gait improved with normal knee moments arms when wearing the orthoses. The patient and his parents commented that his gait had been considerably improved since he had had his orthosis tuning a year ago, and that school had reported a notable improvement. We therefore did not make any changes to his orthotic prescription and he did not come back for a further review.

This case study highlights the potential longer-term benefits of orthotic tuning, in that over a year later, the gait remained improved with the orthoses on, and that notable improvements had been commented on.

Results:

Table 27. Results for CP004

Condition	Moment Arm results (mm)		THBI results (bpm)	Foot fall (left side)	Foot fall (right side)
	Left	Right			
Barefoot a	16.9	39.2	2.38	Flat foot	Flat foot
'Un-tuned'	-9.3	0.0	1.88	Heel strike	Heel strike

These results show that his moment arms are normalised with his current orthoses on, and that his energy cost data are also improved to just above reference values with orthoses on.

Participant ID CP005

This young boy was aged 8 years at inclusion in the study. He was born at around 32 weeks gestation following a difficult pregnancy with several maternal bleeds. He walked around the age of 2 years, and was finally diagnosed at 4 years old, with a left sided monoplegia. He functioned at level I on the GMFCS. He wore a left sided orthosis for 6-8 hours on school days, but less so at the weekend. He completed 15 minutes of physiotherapy at school each day but had no specific programme at home, preferring to take part in sports. He had not had any Botulinum toxin injections or lower limb surgery in the past. He commented that he tripped frequently and that his walking distance was limited compared with his peers.

Clinical examination:

There was no spasticity noted throughout either lower limb. His single leg balance was reduced on the left side.

Table 28. Clinical examination data for CP005

Test	L	R	Test	L	R
Leg length discrepancy	1cm discrepancy, left side shorter		**Quads strength**	5	5
Popliteal angle	48°	38°	**Hams strength**	5	5
Dundee angle	0	0	**Ankle DF strength**	3	5
Knee fixed flexion	0	0	**Ankle Inv strength**	3	5
Ankle DF with knee flex	11°	27°	**Ankle Ev strength**	3	5
Ankle DF with knee ext	5°	15°	**Ankle PF strength**	3-4	5
Hip IR	60°	55°			
Hip ER	35°	50°			
Ruwe angle	Normal	Normal			

Orthotic design:

He wore a left sided custom-made fixed AFO cast in neutral with the aim of controlling excessive plantarflexion in stance and swing.

Table 29. Original orthotic detail for CP005

	L	R
Type	Fixed	
AAAFO	90°	
Trim lines	Behind the metatarsal heads and through the ankle	
Other features	Nil	
Wedging detail	Nil	
SAFAFO	90°	
Footwear type	Trainers	
Footwear HSD	1cm	
Overall SAFAFOFWC	5° inclined	
Sole profile of shoe	normal	

Gait analysis:

When walking barefoot CP005 achieved either a flat foot strike or toe strike on the left side, secondary to a plantarflexed ankle in swing. The heel was lowered down on loading and remained down throughout stance. He achieved a normal heel strike on the right. The ground reaction force vector was aligned behind the knee on the left side despite the knee locking in stance. With his original orthosis, he achieved a heel strike on the left side, with improvements in the vector alignment but it still tended to remain behind the knee. Alignment on the right side was normal when barefoot and with shoes on.

Analysis:

From the assessment, we felt that he would benefit from slightly more wedging on the left side to further discourage his knee locking in stance, and to take account of his leg length discrepancy. A further 6mm was added during the session however, this resulted in increased shank inclination and an early heel rise. We therefore suggested that he be cast for trial of either a hinged AFO or a DAFO to allow him to use some of his available dorsiflexion range without lifting the heel, whilst still controlling the plantarflexion in swing.

Changes made to orthotic prescription:

Recommendations were made to consider the use of a hinged AFO or DAFO. Unfortunately, the patient failed to attend for their follow-up assessment or orthotic appointment despite reminders, and therefore had to be withdrawn from the study.

Results:

Table 30. Results for CP005

Condition	Moment Arm results (mm)		THBI results (bpm)	Foot fall (left side)	Foot fall (right side)
	Left	Right			
Barefoot a	-37.7	-7.6	1.7	Flat foot	Heel strike
'Un-tuned'	-18.1	-22.6	1.9	Heel strike	Heel strike

These results show that his moment arm was reduced in his 'un-tuned' orthosis on his affected side, but that his energy cost was actually slightly worsened with orthotic use, and remained slightly above reference values. He may have benefitted from the tuning process to ensure a more efficient gait.

Participant ID CP006

This 8-year-old boy was diagnosed with spastic diplegia following a premature birth at 29 weeks gestation. He walked around the age of 18 months and at the time of the study was able to independently walk the 10 minutes to school each day. He tended to walk on his toes but with concentration was able to walk with a better gait pattern. When tired he tended to sag into crouch. He functioned at level I on the GMFCS. He used to wear fixed AFOs but moved into DAFO style orthoses prior to inclusion in the study. Originally these were split at the back but these rubbed his Achilles tendon and so he was re-cast for full-back DAFOs. He also had gaiters for stretches in long sitting. He had not had any surgery or Botulinum toxin at the start of the study although Botulinum toxin had been discussed and was being planned. He took part in several sports including

Tae Kwando, swimming and football. He wore his orthoses all day on weekdays but not at the weekends. He completed around half an hour per week at school and at home of his physiotherapy exercise programme. This remained unchanged during the study.

Clinical examination:

The main findings from his examination were of minimal soft tissue tightness throughout the lower limbs, but of significant spasticity in the calves, with gastrocnemius catch angles down in plantarflexion. All other measurements were normal.

Table 31. Clinical examination data for CP006

Test	L	R	Test	L	R
Leg length discrepancy	0.2cm discrepancy, right side shorter		**Quads strength**	5	5
Popliteal angle	45°	45°	**Hams strength**	5	5
Dundee angle	0	0	**Ankle DF strength**	4 -	5
Knee fixed flexion	0	0	**Ankle Inv strength**	5	5
Ankle DF with knee flex	23°	30°	**Ankle Ev strength**	4 -	5
Ankle DF with knee ext	8°	15°	**Ankle PF strength**	5	5
Hip IR	60°	60°	**Gastroc spasticity**	3	3
Hip ER	30°	35°	**Gastroc catch angle**	PF	PF
Ruwe angle	30°	30°			

Orthotic design:

His original orthoses were custom-made DAFO style to allow him to use his dorsiflexion range in stance.

Table 32. Original orthotic detail for CP006

	L	R
Type	DAFO	DAFO
AAAFO	90°	90°
Trim lines	Behind the metatarsal heads	Behind the metatarsal heads
Other features	3 straps	3 straps
Wedging detail	Nil	Nil
SAFAFO	90°	90°
Footwear type	Trainers	Trainers
Footwear HSD	0	0
Overall SAFAFOFWC	90°	90°
Sole profile of shoe	Flat	Flat

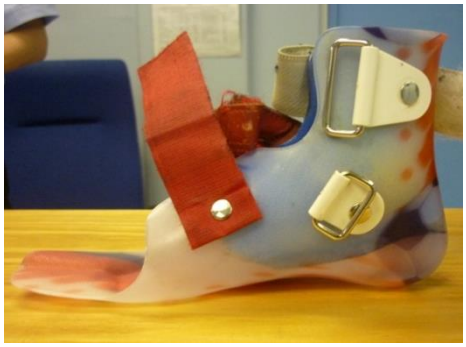


Figure 47. Un-tuned orthosis for CP006

Gait analysis:

When walking barefoot CP006 consistently achieved a flat foot strike bilaterally, with his knees flexed. At mid-stance, the ground reaction force vector was a little anterior to the knees, and the vector originated at the toes due to the crouch. With his original DAFOs on there was some improvement in heel strike, although not consistently, and he continued to take his weight quickly forwards along the foot towards his toes. The ground reaction force vector remained unchanged, and therefore still a little anterior to the knees and originating from the toes.

Analysis:

In view of the early heel rise during stance and anterior ground reaction force vector it was felt that the shank to floor angle was not inclined enough to allow for normal dorsiflexion during stance, given his underlying calf spasticity. Recommendations were therefore made to put in a small heel wedge bilaterally to allow for improved shank inclination during stance

without lifting the heels, and to bring the trim lines forwards of the metatarsal heads to discourage early heel rise.

Changes made to orthotic prescription:

To address the calf spasticity a neurological sole plate was added to both DAFOs with a dropped first ray to discourage early extensor spasticity. Additional heel wedges were added to encourage the ground reaction force forwards at the knee at mid-stance.

Table 33. Tuned orthotic detail for CP006

	L	R
Type	DAFO	DAFO
AAAFO	90°	90°
Trim lines	Behind the metatarsal heads	Behind the metatarsal heads
Other features	3 straps, neuro sole plate	3 straps, neuro sole plate
Wedging detail	0.6cm	0.6cm
SAFAFO	90°	90°
Footwear type	Trainers	Trainers
Footwear HSD	0	0
Overall SAFAFOFWC	6° incline	6 ° incline
Sole profile of shoe	Flat	flat

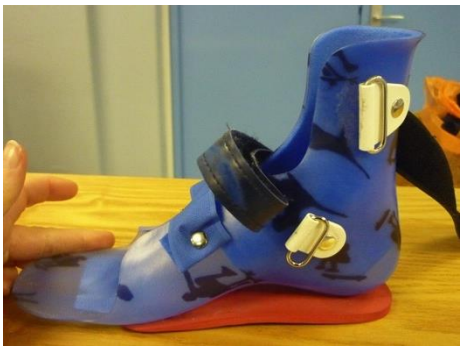


Figure 48. Tuned orthosis with heel wedging for CP006

Repeat gait analysis:

CP006 returned 16 weeks following his initial appointment. There were no changes in his therapy input or orthotic use. On repeat assessment, we obtained consistent heel strikes on each step bilaterally and improvements in ground reaction force alignment at the knee at mid-stance, indicating an improvement in heel rise timing and vector alignment.

Results:

Table 34. Results for CP006

Condition	Moment Arm results (mm)		THBI results (bpm)	Foot fall (left side)	Foot fall (right side)
	Left	Right			
Barefoot a	10.1	20.9	2.3	Flat foot	Flat foot
'Un-tuned'	16.3	17.9	1.8	Heel strike	Heel strike
Barefoot b	18.0	18.3	1.8	Heel strike	Heel strike
'Tuned'	0	-9.4	2.0	Heel strike	Heel strike

These results show optimisation of his moment arm at the knee with the 'tuned' orthoses on. The energy cost values were improved at the first session by the 'un-tuned' orthoses but at the second session his barefoot data were comparable to this. The tuned orthoses show a slight increase in energy cost of walking however.

Participant ID CP007

This young girl was aged 7 years at the time of the study. She was diagnosed with a right hemiplegia after she suffered from meningitis at the age of 6 years (15 months prior to her inclusion in the study). Her early development includes a slightly premature birth at 35 weeks gestation, and she walked around the age of 18-20 months but with no on-going problems. Following her meningitis, she was back on her feet within a month and was mobilising within 2 months of the infection. She wore a fixed AFO but this was causing some problems with rubbing. She was classed as a level II on the GMFCS, requiring a wheelchair for longer distances around town, and tending to tire quickly, but not requiring any specific walking aids for general mobility. She could manage stairs with some assistance. She had a daily home exercise programme of physiotherapy exercises and also received some input at school daily.

Her timing of cerebral insult was therefore a little older than other participants in the cohort, but her pathology still represents damage to a

developing brain and as such fits in with the definition of cerebral palsy. This illustrates the lack of clear definition of the term cerebral palsy.

Clinical examination:

The main finding from our examination was of weakness throughout the right side from the knee distally. We also noted some spasticity in the right calf with her gastrocnemius catch angle down into plantarflexion. There was mild clonus in this ankle as well.

Table 35. Clinical examination data for CP007

Test	L	R	Test	L	R
Leg length discrepancy	0.2cm discrepancy, left side shorter		**Quads strength**	5	4 – to 4
Popliteal angle	Normal	Normal	**Hams strength**	5	3
Dundee angle	0	0	**Ankle DF strength**	5	Poor sel. control
Knee fixed flexion	0 (4° hyperextension available)	0 (10° hyperextension available)	**Ankle Inv strength**	5	Poor sel. control
Ankle DF with knee flex	10°	30°	**Ankle Ev strength**	5	Poor selective control
Ankle DF with knee ext	5°	15°	**Ankle PF strength**	Not tested	Not tested
Hip IR	35°	45°	**Gastroc spasticity**	2	1
Hip ER	70°	65°	**Gastroc catch angle**	PF	PF
Ruwe angle	Not tested	Not tested			

Orthotic design:

CP007 wore a custom-made fixed AFO on the right side to control excessive plantarflexion and help prevent knee locking in stance. It was pitched in 2° plantarflexion to accommodate her calf spasticity.

Table 36. Original orthotic detail for CP007

	L	R
Type		Fixed
AAAFO		2°plantarflexed
Trim lines		Behind the metatarsal heads
Other features		Ankle strap
Wedging detail		Heel, 1.2cm
SAFAFO		6° inclined
Footwear type		Shoes
Footwear HSD		0.8cm
Overall SAFAFOFWC		12° inclined
Sole profile of shoe		flat



Figure 49. Orthosis showing heel wedging and then additional inclination through heel-sole differential for CP007

Gait analysis:

When walking barefoot we found either a low-level heel strike or flat foot strike on the left side, and a toe strike or flat foot strike on the right side. On the right side, there was poor progression of the shank over the foot, and the knee tended to remain locked in extension. There was better shank progression on the left side. The ground reaction force vector was normally aligned on the left side, but was slightly anterior to the knee on the right side on each pass, causing some knee hyperextension. The right arm was held retracted and flexed.

With her original orthosis on she achieved heel strike on each pass bilaterally, and the alignment of the ground reaction force vector at the knee

was improved on the right side to within normal limits. The hyperextension at the knee was eliminated. However, we did note that she tended to vault on the left side to ensure clearance of the right foot, and she also tended to circumduct the right leg in swing.

She was unable to complete the full five minutes walking for the energy cost measurement under either condition but did manage to walk further with her orthosis on, in a similar time.

Analysis:

A further trial was collected with some further heel wedging in an attempt to eliminate the vaulting on the left side, but this made no difference to her gait. On further examination, it was noted that the vaulting was linked to walking speed, as it was reduced with slower walking speeds.

The alignment of the ground reaction force vector was improved with the current orthosis, which was already set in slight plantarflexion to take into account her calf spasticity and resulted in a SAFAFOFWC of 12° which is reportedly the optimum [175]. No further tuning was therefore required.

Results:

Table 37. Results for CP007

Condition	Moment Arm results (mm)		THBI results (bpm)	Foot fall (left side)	Foot fall (right side)
	Left	Right			
Barefoot a	0	43.8	3.8	Heel strike / flat foot	Toe strike / flat foot
'Un-tuned'	-19.5	6.4	2.9	Heel strike	Heel strike

These results show correction of her aberrant moment arm on the right side through use of her current orthosis, which was already optimally tuned. There are clear improvements in her energy cost of walking when the orthosis is worn.

Participant ID CP008

This young boy was 8 years old at the time of the study. He was diagnosed with spastic diplegia following a premature birth at 30 weeks gestation. He walked around the age of 2 years and tended to 'W' sit (sit with his bottom on the floor between his feet, with the knees flexed and soles of the feet facing outwards, with hips internally rotated). At the time of the study, he was able to walk independently using fixed AFOs, but used a wheelchair for longer distances. He fell over frequently, but not daily. He had not had any lower limb surgery or Botulinum toxin and was not on any medication. He complained that his balance was poor and tended to toe walk. He had a 30-minute daily physiotherapy programme at home and completed a further 10-15 minutes a week at school. He was classified as grade II on the GMFCS, as he could manage stairs with a rail, found hopping hard and could run very short distances.

Clinical examination:

The main clinical findings were of a slight leg length discrepancy (left side slightly shorter) and significant hamstring tightness (worse on the left side). We also noted some calf tightness on the left and weakness throughout the left side. There was very little spasticity with just a small plantarflexion catch in the gastrocnemius on both sides.

Table 38. Clinical examination data for CP008

Test	L	R	Test	L	R
Leg length discrepancy	0.4cm discrepancy, left side shorter		**Quads strength**	4	5
Popliteal angle	60°	46°	**Hams strength**	4	5
Dundee angle	30°	10°	**Ankle DF strength**	4+	5
Knee fixed flexion	0	0	**Ankle Inv strength**	4+	5
Ankle DF with knee flex	8°	10°	**Ankle Ev strength**	4+	5
Ankle DF with knee ext	2°PF	8°	**Ankle PF strength**	Not tested	Not tested
Hip IR	72°	60°	**Gastroc spasticity**	1	1
Hip ER	40°	50°	**Gastroc catch angle**	Sl PF	Sl PF
Ruwe angle	Normal	Normal			

Orthotic design:

CP008 wore bilateral custom-made fixed AFOs to control plantarflexion in stance and swing. They were cast in plantarflexion to accommodate the contracture on the left side, and presumably for symmetry on the right side.

Table 39. Original orthotic detail for CP008

	L	R
Type	Fixed	Fixed
AAAFO	6°plantarflexed	6°plantarflexed
Trim lines	Behind the metatarsal heads	Behind the metatarsal heads
Other features	3 straps	3 straps
Wedging detail	Heel, 1cm	Heel, 1cm
SAFAFO	1° inclined	2° inclined
Footwear type	Boots	Boots
Footwear HSD	Min	Min
Overall SAFAFOFWC	2° inclined	2 ° inclined
Sole profile of shoe	Flat	Flat



Figure 50. Orthosis showing trim lines and heel wedging for CP008

Gait analysis:

When walking barefoot he varied between a low-level heel strike and flat foot strike on both sides, but was more up on his toes on the left side. His knees remained flexed throughout the cycle. Ground reaction force alignment was reasonable (slightly posterior) on both sides but the vector originated at the toes due to early progression of the weight along the foot.

With his current orthoses, he did manage to achieve heel strike bilaterally but the vector remained forwards on the foot by mid-stance due to persistence of early progression forwards onto his toes due to blocking of his usual dorsiflexion.

Analysis:

The main issue when walking barefoot was of a lack of heel strike particularly on the left side and early heel rise when wearing the orthoses as they block the use of any dorsiflexion for second rocker or third rocker.

We therefore suggested that the trim lines were cut back to behind the metatarsal heads on the left to allow a third rocker. On the right side, he had reasonable range of ankle motion and we suggested a hinged AFO on this side to allow him to use this range of motion in mid-stance to prevent early heel rise.

Changes made to orthotic prescription:

The left AFO was recast as he had outgrown it, despite advice it had been re-cast in neutral but with trim lines cut back behind the metatarsal heads as recommended. He was recast for a hinged AFO on the right side to allow him to use his available range.

Table 40. Tuned orthotic details for CP008

	L	R
Type	Fixed	Hinged
AAAFO	Neutral	Neutral
Trim lines	Behind the metatarsal heads	Behind the metatarsal heads
Other features	3 straps	3 straps
Wedging detail	Nil	Nil
SAFAFO	Neutral	Neutral
Footwear type	School shoe	School shoe
Footwear HSD	1.5cm	1.5cm
Overall SAFAFOFWC	6° inclined	5° inclined
Sole profile of shoe	Slight forefoot rocker	Slight forefoot rocker

Repeat gait analysis:

When he returned, 6 months after his initial assessment, he had got on well with the new orthoses, which he had worn for around 2 months. He was asking to wear the orthoses as he reported that his legs did not ache when he wore them.

On repeat analysis CP008 continued to walk on his toes when barefoot but achieved a more consistent heel strike bilaterally with the orthoses on. The ground reaction force vector was aligned through the knee on the right side, but still frequently remained anterior on the left side due to his early heel rise, which we felt was habitual.

Results:

Following this repeat analysis, we felt that further tuning was required for the left side. The right side was improved however, and should remain at this prescription. We felt that it was worth consideration of some Botulinum toxin for the left side to discourage the early heel rise and/or consider slight wedging on the left to keep the heel down for longer. He may have

benefitted from the orthosis remaining in some plantarflexion as recommended.

Table 41. Results for CP008

Condition	Moment Arm results (mm)		THBI results (bpm)	Foot fall (left side)	Foot fall (right side)
	Left	Right			
Barefoot a	-20.5	-9.9	2.5	Flat foot	Flat foot
'Un-tuned'	6.0	16.8	2.0	Heel strike	Heel strike
Barefoot b	100.1	13.7	1.6	Flat foot / heel strike	Heel strike / flat foot
'Tuned'	70.3	-3.8	1.7	Heel strike	Heel strike

These results show an optimal moment arm on the right side with the 'tuned' orthosis but a worsening on the left side with the extra tuning, and actually reasonable moment arm alignment at mid-stance with the 'un-tuned' orthosis. However, he remained on his toes at this point and therefore his overall gait pattern remained sub-optimal. The energy costs data show some improvements in the first session with the orthoses on. However, there is a further improvement at the second session when walking barefoot, with no further difference with the 'tuned' orthoses on. The change in barefoot data between sessions suggests either an improvement in his gait efficiency, or that he wasn't very relaxed during his first session. The moment arm data would suggest that his second prescription was not optimally tuned.

Participant ID CP009

This boy was 9 years old at the time of the study, having been born at term. He was a little slow to start walking, not getting onto his feet until around 18 months, and at times reverting to crawling. An MRI at the age of 4 years showed no signs of damage, however, he has subsequently been diagnosed as having mild spastic diplegia. At the time of the study he complained of frequent falls and his legs 'pulling inwards'. He also reported muscle spasms at night-time, which could result in him being off his feet for the next couple

of days. When not wearing his orthoses, he tended to walk on his toes. CP009 took baclofen three times a day, but had not had any previous Botulinum toxin therapy or surgery. He had previously tried Lycra socks but with minimal effect, and had worn bilateral AFOs for the previous 7 months. He wore these during school hours in the week and all day on a Saturday but not on Sundays due to other activities. He had a home physiotherapy programme, which he completed for 30-60 minutes a week. CP009 functioned at a level I on the GMFCS.

Clinical examination:

Our examination showed some tightness in hamstrings bilaterally but with reasonable ankle ranges of motion. There was some lower limb weakness bilaterally. Spasticity testing showed only a very slight gastrocnemius catch into slight plantarflexion, but no other signs of spasticity.

Table 42. Clinical examination data for CP009

Test	L	R	Test	L	R
Leg length discrepancy	Symmetrical		**Quads strength**	4+	4+
Popliteal angle	53°	53°	**Hams strength**	4+	4+
Dundee angle	0	0	**Ankle DF strength**	4	4
Knee fixed flexion	0	0	**Ankle Inv strength**	4	4
Ankle DF with knee flex	15°	15°	**Ankle Ev strength**	4	4
Ankle DF with knee ext	10°	15°	**Ankle PF strength**	4	4
Hip IR	Symmetrical ranges	Symmetrical ranges	**Gastroc spasticity**	1	1
Hip ER			**Gastroc catch angle**	Sl PF	Sl PF
Ruwe angle	Normal	Normal			

Orthotic design:

CP009 wore bilateral custom-made fixed AFOs cast in very slight dorsiflexion, and with heel wedging, giving an inclined shank alignment overall.

Table 43. Original orthotic details for CP009

	L	R
Type	Fixed	Fixed
AAAFO	3° dorsiflexed	3° dorsiflexed
Trim lines	Behind the metatarsal heads	Behind the metatarsal heads
Other features	2 straps	2 straps
Wedging detail	Heel, 0.6cm	Heel, 0.6cm
SAFAFO	8° inclined	8° inclined
Footwear type	Trainer	Trainer
Footwear HSD	0.8cm	0.8cm
Overall SAFAFOFWC	11° inclined	11° inclined
Sole profile of shoe	Flat	Flat



Figure 51. Orthoses prior to tuning for CP009

Gait analysis:

When walking barefoot CP009 achieved a flat foot strike bilaterally with his knees slightly flexed. His heels lifted early in mid-stance and pelvis was excessively anteriorly tilted leading to a lumbar hyperlordosis. The ground reaction force was therefore moved too far forwards on the foot and was variable around the knee.

With his original orthoses on he did gain a clear heel strike bilaterally however, the knees remained flexed throughout the cycle. At mid-stance, the shanks were excessively inclined so that the ground reaction force remained behind the knees, although there was now normal positioning at the foot.

Analysis:

From this assessment, it was clear that CP009 had only very mild changes, but that the spasticity we noted did compromise his ankle control during swing resulting in a flat foot strike bilaterally. The original orthoses did control this and allow a heel strike but given his underlying good range of motion and minimal spasticity it was felt that the orthoses were too controlling and perhaps too inclined as he continued to be in some knee flexion throughout. His Paediatrician was considering Botulinum toxin. As his level of spasticity was so mild, and his ankles controlled well with orthoses, our recommendation was that Botulinum toxin was not required.

Changes made to orthotic prescription:

Following discussion with the orthotist, a decision was made to allow more flexibility to the orthoses, and to reduce the heel wedging to try and discourage his excessive knee flexion.

At his review appointment (17 weeks after his initial assessment due to time taken to make his new orthoses), CP009 had only recently received his new orthoses. His new prescription was of custom-made bilateral hinged AFOs with a dorsi-assist design. Details are as below but his overall shank inclination was reduced to prevent excessive knee flexion.

Table 44. Tuned orthotic details for CP009

	L	**R**
Type	Hinged, with dorsi-assist	Hinged, with dorsi-assist
AAAFO	Neutral	Neutral
Trim lines	Behind the metatarsal heads	Behind the metatarsal heads
Other features	2 straps	2 straps
Wedging detail	Nil	Nil
SAFAFO	Neutral	Neutral
Footwear type	Trainer	Trainer
Footwear HSD	0.5cm	0.5cm
Overall SAFAFOFWC	4° inclined	4° inclined
Sole profile of shoe	Flat	Flat

There were no changes in overall health or medical management and his orthotic use and physiotherapy programme remained unchanged.

Repeat gait analysis:

At his repeat assessment, he continued to have a flat foot strike when barefoot but with his new orthoses on he consistently achieved heel strike. The ground reaction force vector alignment was now through the knee at mid-stance on each pass and the excessive knee flexion was eliminated. On questioning CP009 preferred his new orthoses, although this appeared to be based more on their pattern and his learning difficulties made it difficult to define the improvements any further. Mum felt that the tuned orthoses were more comfortable but did not feel he had worn them for long enough to determine any functional improvements. She did feel the new orthoses were more flexible which was advantageous.

Results:

Table 45. Results for CP009

Condition	Moment Arm results (mm)		THBI results (bpm)	Foot fall (left side)	Foot fall (right side)
	Left	Right			
Barefoot a	7.6	-9.7	1.9	Flat foot	Flat foot
'Un-tuned'	-37.5	-15.2	2.2	Heel strike	Heel strike
Barefoot b	-10.7	14.5	1.8	Flat foot / toe strike	Flat foot
'Tuned'	-3.5	14.5	1.8	Heel strike	Heel strike

These results show an improvement overall with his new orthoses in that he gained a heel strike, had moment arm results within normal limits (and alignment of the vector at the foot was improved, not shown above), particularly on the left side. The energy cost data show no difference between barefoot conditions or his 'tuned' orthoses but do show an increase in energy cost with his 'un-tuned' orthoses, suggesting they weren't optimal for him. All values for energy cost are slightly higher than the reference data.

Participant ID CP010

CP010 was born at term but via an emergency caesarean section secondary to the cord being wrapped around her neck. She was apnoeic at birth. She showed signs of developmental delay, and was diagnosed with spastic diplegia around the age of 2 ½ years. She walked around the age of 4 years using a walker. She had not had any surgical intervention or Botulinum toxin injections and did not take any other medication. She functioned on a level II of the GMFCS and was aged 8 years at the time of the study. At this time, she could walk independently but preferred to hold onto someone for stability when outside. She used a wheelchair for longer distances. She complained of tripping frequently and her left foot tended to roll inwards. CP010 completed around an hour a week at school and a further hour at home of physiotherapy exercises. She wore her orthoses during school hours and then when going out at the weekends. At the time of the study she wore an AFO on the left side and an SMO on the right side. She had previously worn bilateral SMOs. She also had night resting orthoses and wore a ½ length Lycra suit.

Clinical examination:

The main findings from our examination were of a slight leg length discrepancy, some hamstring tightness bilaterally and some femoral anteversion on the right side. She had mild weakness throughout the legs. There was spasticity in the adductors (MAS1), hamstrings on the left (Tardieu 2) and rectus femoris on the left (Duncan Ely 2), as well as in the plantarflexors on the left (MAS1) with a gastrocnemius catch angle just down into plantarflexion.

Table 46. Clinical examination for CP010

Test	L	R	Test	L	R
Leg length discrepancy	The left leg was 0.5cm shorter than the right.		**Quads strength**	5	5
Popliteal angle	50°	50°	**Hams strength**	4	4
Dundee angle	0	0	**Ankle DF strength**	4	4
Knee fixed flexion	0	0	**Ankle Inv strength**	4	4
Ankle DF with knee flex	22°	30°	**Ankle Ev strength**	4	4
Ankle DF with knee ext	10°	20°	**Ankle PF strength**	Not tested	Not tested
Hip IR	65°	50°	**Gastroc spasticity**	1	0
Hip ER	25°	45°	**Gastroc catch angle**	PF	neutral
Ruwe angle	35°	15°			

Orthotic design:

The custom-made AFO on the left side was fixed in design to control plantarflexion. On the right side, she wore an SMO cast in around 6° plantarflexion, but with back portion split to allow some relative dorsiflexion. The differences reflected her slight asymmetry in presentation.

Table 47. Original orthotic design for CP010

	L	R
Type	Fixed	Supramalleolar
AAAFO	90°	6°plantarflexed
Trim lines	Behind the metatarsal heads	Behind the metatarsal heads, round the malleoli, split back
Other features	3 straps	3 straps
Wedging detail	Nil	To shank neutral
SAFAFO	90	90
Footwear type	Shoes	Shoes
Footwear HSD	2cm	2cm
Overall SAFAFOFWC	7° inclined	7° inclined
Sole profile of shoe	Slight rocker at toes	Slight rocker at toes

Gait analysis:

When walking barefoot there was a flat foot strike (toe strike at times) bilaterally with increased knee flexion throughout. On loading the ankles collapsed into excessive dorsiflexion and eversion, to an extent where the

lateral border of the foot was lifted. The knees tended to scissor. As a result, the ground reaction force vector was too far forwards on the foot and then posterior to the knees. This was improved with one hand held, which slowed down her walking and allowed her to be more upright.

With her original orthoses on (left fixed AFO and right SMO) there was a persistent flat foot strike on the left with early heel rise after loading, but alignment at the knee was improved. In the coronal plane, there was clear inversion of the foot and weight was taken very laterally on the foot. It was not clear as to why this was happening. On the right side, she could achieve a heel strike and the heel remained down throughout stance so that alignment was improved at mid-stance.

Analysis:

From the assessment, it was felt that her underlying weakness was a main contributing factor in her crouch gait given her good ranges of ankle motion and minimal spasticity. To this end a decision was made to try GRAFOs in an attempt to encourage the shank to remain upright and prevent excessive inclination. The plan was to ensure a good moulding for the foot to control her foot posture within these.

Unfortunately, CP010 could not get on with the GRAFOs and her gait pattern was worse. She also experienced some pain with these orthoses. In general, her gait function had deteriorated with increased frequency of falls. A repeat video assessment was undertaken with the GRAFOs on to determine their effect and to help plan the next stage of her gait management. Interestingly when standing still in the GRAFOs she was able to stand with her knees nicely extended and with good alignment of the ground reaction force vector at the foot, knee and hip. However, during walking she went up onto her toes in the orthosis and it therefore did not have its usual function of encouraging knee extension.

A decision was made to revert back to her original prescription to provide some control of foot posture, and advice was given to work on lower limb strengthening as much as possible, with consideration of some gaiter or standing-frame work with the aim of strengthening her inner range quads to encourage upright stance. We also considered KAFOs (knee ankle foot orthoses) to provide greater control across the knees.

CP010 did not complete the second assessment due to the on-going problems with her orthoses and general gait function. Her follow-up data is therefore not available.

Results:

Table 48. Results for CP010

Condition	Moment Arm results (mm)		THBI results (bpm)	Foot fall (left side)	Foot fall (right side)
	Left	Right			
Barefoot a	-20.0	-18.7	5.33	Flat foot	Flat foot
'Un-tuned'	-6.0	-6.4	3.53	Flat foot	Flat foot / heel strike

Note that this child was only able to walk for 60 metres before needing to stop. Energy cost was therefore measured over this distance. When walking barefoot it took her 2 ½ minutes to walk 60m, and with the orthoses on she covered the same distance in 1 minute and 40 seconds. The results show a significantly increased energy cost of walking when barefoot, which was greatly reduced but still high with her original orthoses on.

Participant ID CP011

CP011 was a twin born at 28 weeks gestation, and presented with spastic diplegia at an early age. His development was delayed and he did not walk until he was 4 years old, using a frame. At the time of the study, aged 8 years, he walked with sticks but did have frequent falls, and could walk for a maximum of 200 yards. He still tended to use his walker at school in the

playground and for longer outdoor distances at home. He therefore functioned at a level III on the GMFCS. CP011 wore bilateral fixed AFOs for around 6 hours a day in the week (at school) and when playing outside at the weekend. He had not had any previous surgery but had received previous Botulinum toxin injections into his gastrocnemii and hamstrings around 1-2 years prior to the study. He had also had some Targeted Training under the care of Oswestry Gait Lab. CP011 had around 2.5 hours of physiotherapy exercise input at school per week and did a further 45 minutes per week at home.

Clinical examination:

There were bilateral fixed flexion deformities at the hips (2-5°) and knees (8-10°). Both hamstrings were tight but the ankle ranges were reasonable. Leg lengths were symmetrical. He had global lower limb weakness especially in the hip extensors and quads on the left with limited selective control around the ankles. There was also bilateral femoral anteversion. Examination also highlighted spasticity in all lower limb muscle groups but particularly in the adductors, hamstrings, rectus femoris and calves with gastrocnemius catch angles down in significant plantarflexion.

Table 49. Clinical examination data for CP011

Test	L	R	Test	L	R
Leg length discrepancy	Symmetrical		**Quads strength**	3	4
Popliteal angle	66°	65°	**Hams strength**	4 -	4 -
Dundee angle	35°	30°	**Ankle DF strength**	Minimum selective control	Minimum selective control
Knee fixed flexion	14°	8°	**Ankle Inv strength**	"	"
Ankle DF with knee flex	23°	25°	**Ankle Ev strength**	"	"
Ankle DF with knee ext	6°	12°	**Ankle PF strength**	Not tested	Not tested
Hip IR	60°	52°	**Gastroc spasticity**	4	4
Hip ER	20°	28°	**Gastroc catch angle**	PF+	PF+
Ruwe angle	35°	30°			

Orthotic design:

He wore bilateral custom-made fixed AFOs to control plantarflexion in stance and swing.

Table 50. Original orthotic design for CP011

	L	R
Type	Fixed	Fixed
AAAFO	90°	90°
Trim lines	Behind metatarsal heads and in front of malleoli	Behind metatarsal heads and in front of malleoli
Other features	2 straps	2 straps
Wedging detail	Nil	Nil
SAFAFO	90°	90°
Footwear type	Soft boots	Soft boots
Footwear HSD	1.5cm	1.5cm
Overall SAFAFOFWC	0°	0°
Sole profile of shoe	Flat	Flat

Unfortunately, it was not evident until the examination that he had fixed knee flexion deformities and therefore he had to be excluded from the study at this stage.

Gait analysis:

His video (taken for his overall gait analysis referral) highlighted that his gait was minimally changed with orthoses because of the knee flexion contractures, which prevented him from being able to stand upright with his heels down.

We did collect his energy cost index out of interest at the session and the results are presented below.

Results:

Table 51. Results for CP011

Condition	**Moment Arm results (mm)**		**THBI results (bpm)**	**Foot fall (left side)**	**Foot fall (right side)**
	Left	**Right**			
Barefoot a	-40.7	-3.4	9.8	Toe strike	Toe strike
'Un-tuned'	-31.7	-15.6	7.0	Toe strike	Toe strike

This child was only able to complete one circuit of walking (20 metres). He took 2 minutes and 8 seconds to complete this when barefoot, and 1 minute 30 seconds to complete this with his orthoses on. His results highlight his very significantly raised energy cost of walking compared with normal and with the less affected participants in the study. There was some improvement with his current orthoses on. However, we can see that his moment arm results remain abnormal on the left side in particular.

Participant ID CP012

This young boy was aged 12 years at the time of the study. He was born at term and his initial developmental progress was normal but he was involved in a road traffic accident at the age of 2 years and suffered a head injury resulting in a quadriplegia. He was walking again with a year of the incident. He functioned at a level II on the GMFCS. At the time of the study he could walk independently, wearing his orthoses, but tended to hold onto the arm of an adult for balance. He reportedly often caught his toes and stumbled, although this was improving. He could walk for around 15 minutes before needing to rest, and could manage stairs with a handrail. He wore a Lycra suit at school to help with his postural control, which was vest length. He had not had any surgery or Botulinum toxin and was not on any medication. He also wore bilateral DAFOS all day, 7 days a week. He had regular physiotherapy with around half an hour a week at home, 40-60 minutes a week at school and 20 minutes a week with his physiotherapist.

Clinical examination:

The main examination findings were of a leg length discrepancy (left side shorter) and some tightness of the left calf. We also noted some weakness around the left side. There was minimal spasticity confined to the calves only, although the gastrocnemius catch angle was down in slight plantarflexion.

Table 52. Clinical examination for CP012

Test	L	R	Test	L	R
Leg length discrepancy	2cm discrepancy, left side shorter		**Quads strength**	4+	5
Popliteal angle	40°	40°	**Hams strength**	5	5
Dundee angle	0	0	**Ankle DF strength**	4	5
Knee fixed flexion	0	5°	**Ankle Inv strength**	4+	5
Ankle DF with knee flex	5°	15°	**Ankle Ev strength**	4+	5
Ankle DF with knee ext	2°	5°	**Ankle PF strength**	Not tested	Not tested
Hip IR	65°	45°	**Gastroc spasticity**	2	2
Hip ER	35°	50°	**Gastroc catch angle**	Sl PF	Sl PF
Ruwe angle	20°	8°			

Orthotic design:

CP012 wore custom-made bilateral DAFOs to allow him to use some dorsiflexion in stance, whilst controlling excessive plantarflexion in swing.

Table 53. Original orthotic design for CP012

	L	R
Type	DAFO	DAFO
AAAFO	90°	90°
Trim lines	Behind the metatarsal heads	Behind the metatarsal heads
Other features	3 straps	3 straps
Wedging detail	Nil	Nil
SAFAFO	0	0
Footwear type	Trainers	Trainers
Footwear HSD	0.5cm	0.5cm
Overall SAFAFOFWC	3° inclined	3° inclined
Sole profile of shoe	Slight toe rocker	Slight toe rocker

Gait analysis:

When walking barefoot there was a heel strike on the left but with rapid forefoot lowering. His knee tended to lock in stance. On the right side, there was a flat foot strike and posterior pelvic tilt was used to help place the foot down. There was poor stability in stance and lateral trunk sway was noted towards each stance leg in lieu of sufficient abductor strength. The ground reaction force vector alignment on the left side was through the knee, but

the knee appeared to be a little locked in extension. On the right side the alignment at the knee was also neutral at mid-stance.

With his original orthoses on he achieved heel strike bilaterally but the left knee continued to lock during stance with the ground reaction force vector being aligned anterior to the knee. The coronal plane instability remained evident.

Analysis:

The assessment highlighted the following:

- Leg length discrepancy, which was not compensated for
- Central weakness causing poor stability
- Insufficient shank inclination on the left side leading to persistent knee locking in stance

Changes made to orthotic prescription:

The assessment suggested that further heel wedging on the left side would help to account for the leg length discrepancy (17mm added) and would also help to incline the shank further and reduce the knee locking.

Table 54. Tuned orthotic detail for CP012

	L	R
Type	DAFO	DAFO
AAAFO	90°	90°
Trim lines	Behind the metatarsal heads	Behind the metatarsal heads
Other features	3 straps	3 straps
Wedging detail	1.7cm	Nil
SAFAFO	5° incline	0
Footwear type	Trainers	Trainers
Footwear HSD	0.5cm	0.5cm
Overall SAFAFOFWC	7° inclined	3° inclined
Sole profile of shoe	Slight toe rocker	Slight toe rocker

Repeat gait analysis:

CP012 returned for repeat analysis 4 weeks after his first assessment. He had only had his new orthosis for a couple of days but was then due to travel abroad for 3 months and therefore data collection was completed before

this long gap. Repeat assessment revealed that with his new 'tuned' orthosis he achieved consistent heel strike and was more upright in his overall posture compared with previously. Alignment of the ground reaction force vector was normalised with his new orthosis. In the coronal plane, we noted considerably less lateral trunk sway and pelvic obliquity compared with previously.

Results:

Table 55. Results for CP012

Condition	Moment Arm results (mm)		THBI results (bpm)	Foot fall (left side)	Foot fall (right side)
	Left	Right			
Barefoot a	0	0	2.33	Flat foot / low level heel strike	Flat foot / heel strike
'Un-tuned'	6.6	17.4	2.37	Heel strike	Heel strike
Barefoot b	-3.2	-40.6	2.84	Flat foot	Heel strike
'Tuned'	-15.3	-3.4	2.64	Heel strike	Heel strike

When walking barefoot on both occasions he was unable to complete the full 5-minute walking time for the energy cost index, but was able to complete between 4 ½ minutes and 5 minutes on each occasion with the orthoses on. The results are difficult to interpret as they show normal moment arm values when walking barefoot. The values when 'un-tuned' are anterior to the knee, which tends to create hyperextension, and these are improved to within normal limits when wearing the tuned orthoses. The energy cost values are increased at the second session compared with the first but show some improvements with his tuned orthoses on. The values are higher than normal under all conditions.

Participant ID CP013

This boy was aged 10 years at the time of the study. He was diagnosed with spastic diplegia around the age of 3 years. He was born at full term plus 16 days and showed delay in his early developmental milestones. He did crawl and pull to standing but did not walk until he was around 4 years old, with

a walking frame. He progressed onto independent walking by the age of 6 years. He had not had any surgery of Botulinum toxin at the time of the study but had concerns about his unsteadiness and altered foot posture. Mum reported that his walking distance was not particularly limited, but that he tended to fall frequently, catching his toes on the foot and dragging his feet at times. He had worn orthoses for several years but had varied between just insoles, DAFO style and fixed style AFOs. He functioned at a level II on the GMFCS. CP013 had regular physiotherapy at school for around 30 minutes a day, and did a further 15 minutes a day at home. He wore his orthoses daily at school and then if going out when he was at home and at weekends.

Clinical examination:

The main examination findings were of some bilateral lower limb weakness, with very good soft tissue length noted bilaterally. We did not detect any spasticity throughout the lower limbs and his gastrocnemius catch angle was normal with no ankle clonus noted.

Table 56. Clinical examination for CP013

Test	L	R	Test	L	R
Leg length discrepancy	Symmetrical		**Quads strength**	4	4
Popliteal angle	Normal	Normal	**Hams strength**	4	4
Dundee angle	0	0	**Ankle DF strength**	4	4
Knee fixed flexion	0	0	**Ankle Inv strength**	4	4
Ankle DF with knee flex	15°	15°	**Ankle Ev strength**	4	4
Ankle DF with knee ext	8°	10°	**Ankle PF strength**	4	4
Hip IR	55°	35°	**Gastroc spasticity**	0	0
Hip ER	50°	65°	**Gastroc catch angle**	Neutral	Neutral
Ruwe angle	Normal	Normal			

Orthotic design:

His original orthoses were custom-made fixed AFOs, which were cast in 10° plantarflexion despite good ankle ranges and minimal spasticity.

Table 57. Original orthotic design for CP013

	L	R
Type	Fixed	Fixed
AAAFO	10°plantarflexed	10°plantarflexed
Trim lines	Behind the metatarsal heads	Behind the metatarsal heads
Other features	2 straps	2 straps
Wedging detail	Heel, 2.5cm	Heel, 2.5cm
SAFAFO	3° inclined	3° inclined
Footwear type	Trainers	Trainers
Footwear HSD	Nil	Nil
Overall SAFAFOFWC	3° inclined	3° inclined
Sole profile of shoe	Flat	Flat

Gait analysis:

When walking barefoot there was a low-level heel strike or flat foot strike bilaterally with collapse into excessive dorsiflexion and knee flexion on loading. There was increased lateral trunk sway to each side during single leg stance (indicating abductor weakness) and limited ankle control during swing. The ground reaction force vector was aligned posterior to the knees due to the collapse into crouch, especially on the left side, which was more marked.

With his original orthoses, he achieved heel strike consistently on both sides and the excessive dorsiflexion during stance was controlled. Consequently, his ground reaction force vector was in good alignment at the foot and knee during stance. He did continue to have some lateral trunk sway in the coronal plane.

Analysis:

CP013 presented with problems of low tone, rather than spasticity, affecting his posture and gait. Weakness and poor core stability were noted but there was no notable spasticity or soft tissue tightness. His original orthoses controlled his collapse into crouch by harnessing the shank back with the fixed design AFO, and as a result his gait pattern was much improved. He was cast in plantarflexion despite having good ankle ranges and no spasticity to try and encourage better knee extension and to prevent

collapse at the ankle and midfoot. No further changes were required to fine-tune this prescription.

Results:

Table 58. Results for CP013

Condition	Moment Arm results (mm)		THBI results (bpm)	Foot fall (left side)	Foot fall (right side)
	Left	Right			
Barefoot a	-22.6	-23.3	2.20	Heel strike (low level)	Flat foot
'Un-tuned'	3.17	0	2.19	Heel strike	Heel strike

This child was unable to complete the full five minutes of walking. He was able to walk for 100m on each occasion, taking just under two minutes for both conditions. The results show that his current orthoses were already optimally tuned, but that there was no effect on energy cost of walking, with his values being a little higher than normal values.

Participant ID CP014

This boy was aged 9 years at the time of the study. He was born at term but developed into a toe walker when he started mobilising. He had some physiotherapy treatment, which helped with the right side, but the left side persisted and a subsequent MRI led to a diagnosis of a left sided monoplegia. He had previously had an elongation of his Achilles tendon around 6 years prior to the study. He had only ever had one dose of Botulinum toxin injections and none recently and was not on any medication. He wore a Toe-Off orthosis but this kept breaking. He wore this during school hours and occasionally at the weekend. He functioned at a level I on the GMFCS. CP014 had a physiotherapy programme but was not very compliant with this at home or at school.

Clinical examination:

CP014 had good range of motion at the hips but some tightness of both hamstrings. There was reasonable range of ankle motion bilaterally and just a 0.5cm leg length discrepancy (left side shorter). Strength was generally good with just some mild weakness around the left ankle and inner range quadriceps. He was unable to rise onto his toes on the left side suggesting some plantarflexor weakness but single leg balance was good. There was very minimal spasticity in the left calf only.

Table 59. Clinical examination data for CP014

Test	L	R	Test	L	R
Leg length discrepancy	0.5 cm shortening on the left side.		**Quads strength**	4+	4+
Popliteal angle	60°	58°	**Hams strength**	5	5
Dundee angle	10°	0	**Ankle DF strength**	4+	5
Knee fixed flexion	0	0	**Ankle Inv strength**	4+	5
Ankle DF with knee flex	10°	20°	**Ankle Ev strength**	4+	5
Ankle DF with knee ext	6°	8°	**Ankle PF strength**	3	4
Hip IR			**Gastroc spasticity**	1	0
Hip ER	Symmetrical	Symmetrical	**Gastroc catch angle**	Sl PF	neutral
Ruwe angle	Normal	Normal			

Orthotic design:

CP014 wore a pre-fabricated left sided Allard 'Toe-Off' orthosis (www.allarduk.co.uk) which was cast at 90°. Due to its design, there were no trim lines (no material extended above the sole of the foot) with a lateral bar and anterior shell on the shank.

Table 60. Original orthotic design for CP014

	L	R
Type	'Toe-Off' Allard spiral design	
AAAFO	90°	
Trim lines	No material around ankle	
Other features	Spiral	
Wedging detail	Nil	
SAFAFO	0	
Footwear type	Boot	
Footwear HSD	0.8cm	
Overall SAFAFOFWC	10° inclined	
Sole profile of shoe	Forefoot rocker	

Gait analysis:

When walking barefoot, CP014's gait was variable with some heel strike noted but also frequent flat foot contact on the left. He progressed early onto his toes so that his knee remained flexed in stance. The ground reaction force vector therefore moved forwards on the foot too early, although it was aligned at the knee. On the right side, there was normal heel strike and good alignment of the ground reaction force vector at the knee. With his original orthosis on the left side there was a consistent heel strike but he continued to progress early towards his toes, with his heel rising a little early.

His gait was then assessed with just shoes on and he managed to gain heel strike consistently but the knee remained flexed. At this point a forefoot wedge was added to the shoe to discourage early progression forwards, and this did appear to improve alignment at the knee at mid-stance. This was then added to the orthosis and again even better alignment was noted with improved knee extension with the orthosis on compared with just shoes.

Analysis:

This child had very minor changes but without his orthosis he frequently failed to achieve heel strike and even with the orthosis on, he tended to progress his weight early onto toes and this needed to be controlled.

Changes made to orthotic prescription:

Following his assessment, he was prescribed a posterior leaf spring type of orthosis (in view of the Toe-Off breaking frequently) but with some increase in the usual rigidity posteriorly to allow some dorsiflexion at second rocker but control the ankle in swing and prevent early heel rise.

Table 61. Tuned orthotic details for CP014

	L	R
Type	PLS	Insole, moulded, ¾ length
AAAFO	90°	
Trim lines	Across the MTP joint	
Other features	2 straps	
Wedging detail	Nil	Medial at the heel
SAFAFO	0	
Footwear type	Boot	
Footwear HSD	1cm	
Overall SAFAFOFWC	10° inclined	
Sole profile of shoe	Forefoot rocker	



Figure 52. 'Tuned' PLS style orthosis for CP014

Repeat gait analysis:

His barefoot gait remained unchanged at his repeat appointment, which was timed 25 weeks after his original assessment (there was some delay in getting him back for his review appointment). He had been wearing his new orthosis for 3 months. In his new orthosis, he consistently achieved heel strike and no longer lifted his heel early in stance, as his new prescription allowed him to use some of his available dorsiflexion as normal in stance. Ground reaction force vector alignment was then normal through the knee and at the foot level.

Results:

CP014 preferred his new orthosis as he found it easier to get into his shoe than the original one and it was comfortable to wear. Both Mum and child commented that the new orthosis was better at helping him to get his heels down in and that he walked more easily in the new orthosis.

Table 62. Results for CP014

Condition	Moment Arm results (mm)		THBI results (bpm)	Foot fall (left side)	Foot fall (right side)
	Left	Right			
Barefoot a	-6.5	-6.9	1.69	Heel strike / flat foot	Heel strike
'Un-tuned'	-33.8	-29.3	1.65	Heel strike	Heel strike
Barefoot b	-22.7	-22.1	1.57	Heel strike	Heel strike
'Tuned'	-9.3	-40.6	1.59	Heel strike	Heel strike

These results show a normal moment arm when barefoot at the first session, but this was with the vector originating too far forwards on the foot. With the 'un-tuned' orthosis the moment arm was worsened at the left knee but this was then improved (with better alignment at the foot) with the 'tuned' orthosis. The moment arm does appear worse on the right with the left sided orthosis on. There is no change in energy cost, which was only marginally increased compared with reference data.

Participant ID CP015

This young lady was 10 years old at the time of the study. She was born at 31 weeks gestation, preceded by premature rupture of membranes at 19 weeks gestation. She had some respiratory problems at birth and had an MRI whilst on the neonatal ward which showed some cerebral damage and lead to a diagnosis of right hemiplegia early on. She also had bilateral positional talipes at birth but this corrected with stretching alone. She bottom-shuffled instead of crawling and walked around the age of 2 years. She wore Piedro boots initially but was in orthoses by the age of 2 ½ years.

At the time of the study she wore a fixed AFO and boots during school hours and for a couple of hours at the weekend. She could walk independently and did not feel her walking distance was limited. She had not had any surgery to her lower limbs and had only had 1 dose of Botulinum toxin into her calves, 5 years prior to the study. She was prescribed 3 different inhalers for her asthma but was not on any tone altering medication. She functioned at a high level II on the GMFCS – she was able to run but needed to use a rail when ascending stairs. She had a physiotherapy programme but with minimal time spent on exercises each week.

Clinical examination:

The main examination findings were of a 2cm leg length discrepancy (right side shorter) and tightness of the right calf. She also had a right-sided calf contracture (gastrocnemius and soleus) and some weakness throughout the right side. We noted increased tone in the right hamstrings and calf complex, with a gastrocnemius catch angle down in plantarflexion. Clonus was marked with a slow stop.

Table 63. Clinical examination data for CP015

Test	L	R	Test	L	R
Leg length discrepancy	2cm discrepancy, right side shorter.		**Quads strength**	5	4+
Popliteal angle	0	55°	**Hams strength**	5	4+
Dundee angle	0	0	**Ankle DF strength**	5	4
Knee fixed flexion	(6° hyperext'n)	0	**Ankle Inv strength**	5	Poor selective control
Ankle DF with knee flex	Normal	12°PF	**Ankle Ev strength**	5	Not tested
Ankle DF with knee ext	Normal	12°PF	**Ankle PF strength**	Not tested	Not tested
Hip IR			**Gastroc spasticity**	0	3
Hip ER	Symm	Symm	**Gastroc catch angle**	Neutral	PF
Ruwe angle	Normal	Normal			

Symm = symmetrical

Orthotic design:

The custom-made fixed AFO on the right with the cast angle in 3° plantarflexion to accommodate her calf contracture (see comment later).

Table 64. Original orthotic design for CP015

	L	R
Type		Fixed
AAAFO		3°plantarflexed
Trim lines		Behind the metatarsal heads and in front of the malleoli
Other features		Crossover strap at the ankle, plus top shank strap
Wedging detail		Heel, 0.5cm
SAFAFO		0
Footwear type		Fitzkidz boots
Footwear HSD		1cm
Overall SAFAFOFWC		7° inclined
Sole profile of shoe		flat

Gait analysis:

When walking barefoot there was a heel strike on the left side with normal progression across the foot. On the right side, there was toe strike secondary to ankle plantarflexion in swing. She remained on her toes throughout the cycle. The ankle plantarflexion-knee extension couple created a locked knee on loading and the knee remained extended throughout stance. The ground reaction force vector alignment was normal on the left but markedly anterior to the knee on the right.

When walking with her current orthosis on the right side she did achieve a heel strike on the right side as well and the knee locking was controlled to some extent. However, the ground reaction force vector remained a little anterior to the knee suggesting further inclination was required.

Analysis:

The ankle was controlled in the orthosis despite further apparent calf tightness than the cast angle. This may suggest further range was available with weightbearing. The shank inclination was still not enough so the vector remained in front of the knee creating a knee extension moment.

During the session, we added a further wedge to the right side to incline the shank further, and a compensatory wedge on the left side to prevent causing a leg length discrepancy. This resulted in improved alignment of the ground reaction force vector on the right side without compromising the left side alignment.

Changes made to orthotic prescription:

The orthosis itself was not changed but an additional heel wedge was added to increase shank inclination. A simple 5mm heel wedge was added on the left side into the shoe as compensation.

Table 65. Tuned orthotic data for CP015

	L	R
Type		Fixed
AAAFO		3°plantarflexed
Trim lines		Behind the metatarsal heads and in front of the malleoli
Other features		Crossover strap at the ankle, plus top shank strap
Wedging detail	0.5cm added to ensure symmetrical leg lengths	Heel, 0.5cm
SAFAFO		0
Footwear type		Fitzkidz boots
Footwear HSD		1cm plus additional 0.5cm heel
Overall SAFAFOFWC		12° inclined
Sole profile of shoe		flat



Figure 53. Tuned orthosis for CP015

Repeat gait analysis:

CP015 returned for repeat analysis 16 weeks after initial assessment, having had her orthosis for around 2 months at this stage, but with limited use for the first month over the summer holidays. The alignment of the ground reaction forces at mid-stance was normalised on the right side when wearing her new 'tuned' orthosis, and heel strike was maintained.

We did feel that, in view of the severity of calf tightness in both gastrocnemius and soleus, this child would be an ideal candidate for some soft tissue lengthening surgery in the near future and recommended that her Orthopaedic Surgeon consider this.

CP015 preferred her new 'tuned' orthosis as she found it more comfortable and easier to walk in. She felt her gait was improved with the tuned orthosis and the raise in her left shoe. Her parents corroborated this feeling.

Results:

Table 66. Results for CP015

Condition	Moment Arm results (mm)		THBI results (bpm)	Foot fall (left side)	Foot fall (right side)
	Left	Right			
Barefoot a	-16.2	117.6	1.76	Heel strike	Toe strike
'Un-tuned'	-12.5	20.2	1.69	Heel strike	Heel strike
Barefoot b	-15.5	44.4	1.97	Heel strike	Toe strike
'Tuned'	-9.8	0	1.76	Heel strike	Heel strike

These results show very abnormal moment arm values on the right side when barefoot on both occasions which was improved to some extent with the 'un-tuned' orthosis but was optimised with the 'tuned' orthosis. There were marginal improvements in energy cost with both orthoses (more so with the tuned orthosis) and her energy cost remained a little higher than normal all conditions.

Participant ID CP016

This young girl was aged 8 years at the time of the study. She was born at 29 weeks gestation following placental abruption. Her developmental progress was delayed and she walked around the age of 20 months on her toes. At the time of the study she functioned at a level II on the GMFCS and was classified as having spastic diplegia. She had not had any previous lower limb surgery, but had had one dose of Botulinum toxin into the calves, hamstrings and adductors around three years prior to the study, with no reported effect. She reported falls when tired, and had a tendency to lean forwards when attempting to run. She wore Lycra shorts from the age of 3 to help with postural control, and at the time of the study was wearing hinged AFOs. CP016 wore her orthoses during school hours and when outside at the weekend. She completed around 2 ½ hours of her physiotherapy programme at school weekly, and another 2 – 2 ½ hours at home per week.

Clinical examination:

On examination, we noted slight hyperextension at both knees (3°) with slight tightness of the hamstrings bilaterally. The left ankle was tight in both gastrocnemius and soleus. The right side had a normal range of motion. Leg lengths were symmetrical. There was very minimal weakness around the left hip abductors and extensors only. Neurologically there was a slight catch in both hamstrings but significant increased tone in the calves, with gastrocnemius catch angles down in plantarflexion bilaterally, especially on the left side.

Table 67. Clinical examination data for CP016

Test	L	R	Test	L	R
Leg length discrepancy	Symmetrical		**Quads strength**	5	5
Popliteal angle	50°	50°	**Hams strength**	5	5
Dundee angle	0	0	**Ankle DF strength**	5	5
Knee fixed flexion	0	0	**Ankle Inv strength**	5	5
Ankle DF with knee flex	Normal	15°	**Ankle Ev strength**	5	5
Ankle DF with knee ext	10°PF	10°	**Ankle PF strength**	4+	4+
Hip IR			**Gastroc spasticity**	3	2
Hip ER	Symm	Symm	**Gastroc catch angle**	PF+	PF
Ruwe angle	Normal	Normal			

Symm = symmetrical

Orthotic design:

She wore bilateral custom-made hinged AFOs despite the limited range in the left ankle, presumably to try and allow her some normal shank motion in stance.

Table 68. Original orthotic details for CP016

	L	R
Type	Hinged	Hinged
AAAFO	90°	90°
Trim lines	Behind the metatarsal heads	Behind the metatarsal heads
Other features	2 straps	2 straps
Wedging detail	Nil	Nil
SAFAFO	0	0
Footwear type	Shoes	Shoes
Footwear HSD	1cm	1cm
Overall SAFAFOFWC	6° inclined	6° inclined
Sole profile of shoe	Slight forefoot rocker	Slight forefoot rocker

Gait analysis:

When walking barefoot she achieved toe strike or flat foot strike on the left side, and a flat foot strike or low-level heel strike on the right side. There was early heel rise in stance bilaterally and the knees remain a little flexed throughout. With less concentration, she was more up on her toes. The ground reaction force was reasonably well aligned at the knees, being only

slightly posterior. However, the vector originated at the metatarsal heads due to her early heel rise.

With her original hinged AFOs she achieved heel strike bilaterally but she continued to rise onto her toes early on both sides, except when walking very slowly, with concentration. The alignment of the ground reaction force vector therefore remained well aligned at the knees, but again originated at the metatarsal heads due to the persistence of early heel rise.

Analysis:

It was felt that, given the lack of sufficient range on the left side, she was not suitable for a hinged AFO as she did not have the range available to make use of the hinge, and was therefore likely to collapse at the midfoot instead. The persistent early heel rise suggested that spasticity remained an issue.

Changes made to orthotic prescription:

On the left side, we changed her into a fixed AFO in view of the lack of sufficient range at the ankle, cast in plantarflexion to accommodate her tightness and spasticity. On the right side, she remained in her hinged AFO as she had the range available to make use of this.

Table 69. Tuned orthotic details for CP016

	L	R
Type	Fixed	Hinged
AAAFO	10° plantarflexion	90°
Trim lines	Behind the metatarsal heads, in front of malleoli	Behind the metatarsal heads
Other features	2 straps	2 straps
Wedging detail	2cm heel	Nil
SAFAFO	0	0
Footwear type	Shoes	Shoes
Footwear HSD	1cm	1cm
Overall SAFAFOFWC	6° inclined	6° inclined
Sole profile of shoe	Slight forefoot rocker	Slight forefoot rocker

Repeat gait analysis:

CP016 returned 24 weeks after her initial assessment, having had her new orthoses for around 3 months. With her new orthosis on the left side, and

the same prescription on the right, CP016 was walking better and mum commented she was wearing down the heels of her shoes rather than the toes. Heel rise was achieved bilaterally although she did still tend to lean forwards and lift onto her toes a little early. The ground reaction forces when barefoot were actually more abnormal than at the previous assessment, being anterior to the knees at times. With her new 'tuned' orthoses the alignment was normal at the knees, and originated more towards the midfoot on most passes which was an improvement. With faster speeds, she still tended to lean forwards which made her rise onto her toes early again. This was felt to be habitual and was going to be worked on.

Results:

Table 70. Results for CP016

Condition	Moment Arm results (mm)		THBI results (bpm)	Foot fall (left side)	Foot fall (right side)
	Left	Right			
Barefoot a	-12.5	-18.6	2.12	Flat foot / toe strike	Flat foot
'Un-tuned'	-6.1	3.1	1.91	Heel strike	Heel strike
Barefoot b	48.0	38.8	1.88	Flat foot / toe strike	Heel strike
'Tuned'	0	-13.3	1.77	Heel strike	Heel strike

These results show that on the left side her optimal moment arm data was observed with her 'tuned' orthosis on. There are clear differences in her values when barefoot between sessions however, on both sides. The energy cost values also differ a little between sessions but are minimized with the tuned orthosis on, and remained slightly higher than reference data under all conditions.

CP016 preferred the new orthoses as she felt the additional heel wedging helped her to walk better, get her heel down and stand up straighter.

Participant ID CP017

This child was 10 years old at the time of inclusion in the study. He was born at 28 weeks gestation and was known to have had some cerebral haemorrhage after birth, leading to an early diagnosis of cerebral palsy. He is classed as an asymmetric diplegic, and functioned at a level II on the GMFCS. He started walking around the age of 2 years with a Kaye walker and had progressed onto tripod sticks for short distances. He had some surgery 3 years prior to inclusion in the study consisting of Tendo-Achilles lengthenings, hamstring and psoas releases, and transfer of rectus femoris on this right side. His gait improved following this, with progression to heel contact, and since the surgery he had been able to walk independently without needing any aids. He had previously had 3 doses of Botulinum toxin into the calves and hamstrings, at least 5 years prior to the study. CP017 had hinged AFOs bilaterally (full length on the right and short length on the left) and wore these around 10 hours a day. He completed around an hour a day at school and a further hour a week at home of his physiotherapy exercise programme. When he attended for assessment he was falling a little, but Dad felt that this was due to increased independence; and he complained of problems with his orthoses with some rubbing medially on the foot.

Clinical examination:

Our examination found slight tightness of the left hip flexors (5°), global lower limb weakness, and spasticity in the adductors, hamstrings on the left and calf on the left. We also measured some external tibial torsion on the right side (thigh-foot and bi-malleolar angles were 40°).

Table 71. Clinical examination data for CP017

Test	L	R	Test	L	R
Leg length discrepancy	0.5cm left side shorter		**Quads strength**	4	4-
Popliteal angle	55°	42°	**Hams strength**	4-	4
Dundee angle	15°	0	**Ankle DF strength**	4	4-
Knee fixed flexion	Just 0	Just 0	**Ankle Inv strength**	4	4
Ankle DF with knee flex	20°	23°	**Ankle Ev strength**	4	Limited selectivity
Ankle DF with knee ext	6°	15°	**Ankle PF strength**	3	3
Hip IR	40°	50°	**Gastroc spasticity**	1	0
Hip ER	30°	45°	**Gastroc catch angle**	Sl PF	neut
Ruwe angle	20°	25°			

Orthotic design:

CP017 wore a custom-made short hinged AFO on the left side and a full length hinged AFO on the right. Both designed to allow him to use his available dorsiflexion range in stance, but prevent plantarflexion in swing.

Table 72. Original orthotic design for CP017

	L	R
Type	Short hinged	Normal length hinged
AAAFO	90°	90°
Trim lines	In front of the malleoli and behind the metatarsal heads	In front of the malleoli and behind the metatarsal heads
Other features	2 straps and base notably flat	2 straps
Wedging detail	Nil	Nil
SAFAFO	0°	0°
Footwear type	Trainers	Trainers
Footwear HSD	Nil	Nil
Overall SAFAFOFWC	0°	0°
Sole profile of shoe	Flat	Flat

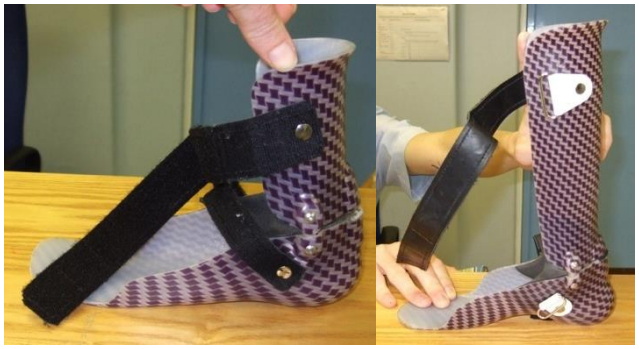


Figure 54. Orthoses prior to tuning, left (short hinged) and right sides (longer length, hinged) for CP017

Gait analysis:

When walking barefoot there was flat foot strike bilaterally with the knees slightly flexed. A third rocker was noted on the left side, but on the right side, the foot tended to evert and there was no third rocker for power generation. This caused the knee to collapse into flexion by terminal stance. There was a much longer step on the left side than the right side. Some weakness of abductors was noted with a positive Trendelenberg sign seen on the left side on loading. Vector alignment was posterior to the knees at mid-stance, particularly on the right side. Foot progression on the right side was notably external, but the patella faced slightly internally, suggesting a distal cause (i.e. his tibial torsion).

When walking with his current orthoses on there was little change to his gait. There was a low-level heel strike on the right side but the third rocker remained an issue and the ankle collapsed down into excessive dorsiflexion as when barefoot. Vector alignment remained posterior to the knees, especially on the right side.

Analysis:

At the above appointment, he had also brought in an old fixed AFO that still fitted him. We therefore assessed his gait with this on the right side with the aim of controlling the excessive collapse into dorsiflexion in stance. However, he struggled to make any progression forwards due to his foot alignment (from his tibial torsion issues, meaning that his foot progression

was not along the foot and shoe as normal, but across the plane of the shoe) and he therefore found it very difficult to walk.

We therefore felt that it would not be possible to tune his orthoses at present and that his right sided tibial torsion needed addressing. He was therefore referred back to the Orthopaedic Surgeon for consideration of tibial derotational osteotomy surgery. CP017 was therefore withdrawn from the study at this point.

Results:

Table 73. Results for CP017

Condition	Moment Arm results (mm)		THBI results (bpm)	Foot fall (left side)	Foot fall (right side)
	Left	Right			
Barefoot a	13.9	-43.4	3.52	Flat foot	Flat foot
'Un-tuned'	10.6	-17.8	2.89	Flat foot	Flat foot

This child was only able to complete 40m of walking on each occasion, taking 60-70 seconds to complete the distances. The data show some improvement in vector alignment (moment arm values) with his current orthoses on, and an improvement in energy cost data, but the values remained higher than normal.

Participant ID CP018

This young boy was aged 7 years at the time of the study. He was born at term with a known left sided talipes equinovarus, which underwent surgical correction at the age of 8 and 22 months. However, he also had early indications of altered muscle tone, and an MRI confirmed his diagnosis of cerebral palsy with a left sided hemiplegia. He first walked around the age of 3 ½ years independently but could take steps with his hands held prior to this. He had never received any Botulinum toxin into his legs, although it had been mentioned, but had several serial castings on his legs, at least 2 years prior to inclusion in the study. He was classed as a level I on

the GMFCS. The main issues at the time of the study were that he was walking up on his toes again on the left side and was walking on the outside of his foot. He was also falling more frequently and his exercise tolerance was reduced. This young boy wore a fixed orthosis on his left leg, for most of each day. He had some physiotherapy input at school for around an hour a week and did about another 45 minutes a week at home.

Clinical examination:

Our examination found tightness in both gastrocnemius and soleus on the left side with a 1cm leg length discrepancy (left side shorter) and mild weakness around the left ankle. Left sided single leg balance was reduced compared with the right side, and there was no detectable spasticity in either side. We did note some forefoot adduction of the left foot (bisection of the heel extended to the 4th toe, rather than the usual 2nd toe).

Table 74. Clinical examination data for CP018

Test	L	R	Test	L	R
Leg length discrepancy	1cm, left side shorter		**Quads strength**	5	5
Popliteal angle	40°	40°	**Hams strength**	5	5
Dundee angle	0	0	**Ankle DF strength**	4	5
Knee fixed flexion	0	0	**Ankle Inv strength**	4+	5
Ankle DF with knee flex	5°plantarflexed	20°	**Ankle Ev strength**	Poor selectivity	5
Ankle DF with knee ext	7°plantarflexed	5°	**Ankle PF strength**	Not tested	Not tested
Hip IR	70°	65°	**Gastroc spasticity**	0	0
Hip ER	35°	50°	**Gastroc catch angle**	Neutral	Neutral
Ruwe angle	25°	10°			

Orthotic design:

His custom-made orthosis was fixed in design and was cast in around 7° plantarflexion to accommodate his calf tightness.

Table 75. Original orthotic details for CP018

	L	R
Type	Fixed	
AAAFO	7°plantarflexed	
Trim lines	Behind the metatarsal heads and in front of the malleoli	
Other features	2 straps	
Wedging detail	Heel, 1.5cm	
SAFAFO	0	
Footwear type	Trainers	
Footwear HSD	1.5cm	
Overall SAFAFOFWC	5° inclined	
Sole profile of shoe	Toe rocker around the MTP	



Figure 55. Fixed AFO for CP018

Gait analysis:

When walking barefoot there was toe strike on the left side due to poor ankle control during swing. On the right side, there was a normal heel strike. On the left side, the knee was extended at contact and remained locked in hyperextension during stance. Weight bearing was essentially through the lateral border of the forefoot on the left side throughout stance. The ground reaction force originated at the forefoot on the left and was very anterior to the knee throughout stance. On the right side, alignment was normal.

With his original orthosis on there was a heel strike bilaterally at the heel remains down, and as a result the alignment of the ground reaction force was much improved on the right side and was essentially normal. There were occasions where he remained back on his heel on the left side, to avoid stretching the calf, and so the vector as slightly anterior to the knee at mid-stance, but this was infrequent.

Analysis:

We felt that his original orthotic prescription was already optimised for this child. Although he was due to have a DAFO we felt that with his calf contracture, this would not have given sufficient leverage to control the ankle position, and that his fixed AFO allowed good control of this.

This study participant therefore did not need any modifications to his orthosis and was therefore withdrawn from the trial at this stage.

Results:

Table 76. Results for CP018

Condition	Moment Arm results (mm)		THBI results (bpm)	Foot fall (left side)	Foot fall (right side)
	Left	Right			
Barefoot a	67.6	30.1	2.02	Flat foot	Heel strike but with rapid forefoot lowering
'Un-tuned'	6.47	-25.0	1.67	Heel strike	Heel strike

These results show normal values for his moment arm on the left side with his current orthosis on and an improvement in his energy cost data when walking with his orthosis on, which remained a little higher than normal values.

10.4 Group results

Out of the total cohort (n=18), nine participants completed data collection to the end. Of the remaining nine who did not complete data collection, it was considered that the original orthoses were already optimally tuned for four participants; two required consideration of surgery; one did not tolerate her orthoses despite recommended changes; one did not attend his follow-up; and one was excluded after examination due to a fixed flexion contracture at the knee which prevented optimal tuning.

Participants returned between 4 and 26 weeks after their initial assessment (due to variable lengths of time taken for orthoses to be amended by local orthotic services, and for the child to re-attend for gait analysis). The children had worn their splints for a minimum of two days (a planned extended holiday brought the reassessment forwards earlier than would have been ideal) and a maximum of 3 months, again due to difficulties with arranging a suitable review appointment.

The following table (Table 77) presents the energy cost results for the CP group as a whole cohort. It summarises the effect of orthotic use on the energy cost of walking for children with CP, and further demonstrates the effect of fine-tuning on this energy cost for the sub-group who completed full data collection. The orthoses were considered as 'finely-tuned' when the moment arm at the knee (as measured from the video vector system) was optimised at mid-stance in the sagittal plane for each involved limb. A descriptive is given as to which orthotic condition resulted in the best energy cost outcome for each child.

Table 77. Energy cost data and descriptive analysis for the CP group.

Demographics			THBI values (bpm)				Sessional orthotic improvements				Outcome summary, including most efficient orthosis
ID	**GMFCS**	**Presentation**	**Barefoot a**	**Un-tuned**	**Barefoot b**	**Tuned**	**% change (un-tuned vs barefoot a)**		**% change (tuned vs barefoot b)**		
1	II	Hemi	1.61	2.02	1.56	1.68	125.6	↑	107.7	↑	Tuned, although both increased E cost compared with barefoot
2	I	Hemi	1.71	1.50			88.1	↓			Reduction in THBI with original orthosis
3	II	Hemi	2.33	1.96	2.40	2.16	84.2	↓	90.0	↓	Un-tuned, although both reduced E cost compared with barefoot
4	I	Hemi	2.38	1.88			79.2	↓			Reduction in THBI with original orthosis
5	I	Hemi	1.75	1.87			106.6	↑			Increase in THBI with original orthosis
6	I	Sp di	2.30	1.79	1.84	2.02	77.7	↓	109.6	↑	Un-tuned
7	II	Hemi	3.84	2.86			74.5	↓			Reduction in THBI with original orthosis
8	II	Sp di	2.46	1.98	1.59	1.73	80.7	↓	109.2	↑	Un-tuned, although tuned data is lower in value
9	I	Sp di	1.90	2.21	1.75	1.83	116.1	↑	104.3	↑	Tuned, although both increased E cost compared with barefoot
10	II	Sp di	5.33	3.53			66.2	↓			Reduction in THBI with original orthosis
11	III	Sp di	9.82	6.99			71.1	↓			Reduction in THBI with original orthosis
12	II	Quad	2.33	2.37	2.84	2.64	101.8	↑	92.7	↓	Tuned, although E cost higher than during first session under both conditions

Key: Hemi = hemiplegia; Sp di = spastic diplegia; Mono = monoplegia; Quad = quadriplegia; E = energy cost

Table 77 (cont.) Energy cost data and descriptive analysis for the CP group

Demographics			THBI values (bpm)				Sessional orthotic improvements				Outcome summary, including most efficient orthosis
ID	**GMFCS**	**Presentation**	**Barefoot a**	**Un-tuned**	**Barefoot b**	**Tuned**	**% change (un-tuned vs barefoot a)**		**% change (tuned vs barefoot b)**		
13	II	Sp di	2.20	2.19			99.5	↔			No clinical difference between conditions
14	I	Mono	1.69	1.65	1.57	1.59	97.6	↓	101.6	↑	Un-tuned / min. diff between any results, only just above normal ref values
15	II	Hemi	1.76	1.69	1.97	1.76	96.1	↓	89.4	↓	Tuned, although data from first session are lower in general
16	II	Sp di	2.12	1.91	1.88	1.77	90.4	↓	94.1	↓	Un-tuned had better % improvement compared with barefoot, but tuned had lowest overall THBI
17	II	Sp di	3.52	2.89			81.9	↓			Reduction in THBI with original orthosis
18	I	Hemi	2.02	1.67			82.6	↓			Reduction in THBI with original orthosis

Key: Hemi = hemiplegia; Sp di = spastic diplegia; Mono = monoplegia; Quad = quadriplegia; E = energy cost

10.5 Statistical analysis

Some basic statistical analysis was undertaken on the data from the clinical group. However, acknowledgement is given to the fact that this cohort is relatively small in number and so caution is used when interpreting the results to avoid a type I or a type II error – i.e. to avoid over or under-interpretation of the results. Clinical significance of any differences will be discussed.

As highlighted in section 10.2.4.2, data were analysed for normality using histogram plots (in view of the small numbers) and a decision made as to whether the data were normally distributed was made based on these results.

Data labelling is as follows:

Ba (barefoot_a)	Data from the first session whilst barefoot
U (un-tuned)	Data from the first session using original orthoses
Bb (barefoot_b)	Data from the second session whilst barefoot
T (tuned)	Data from the second session using the 'tuned' orthoses

10.5.1 THBI Data

Primarily the THBI data were analysed, this being the main outcome measure. Data were non-normally distributed and so median and IQR values are reported, as summarised below.

Table 78. CP group results for THBI

Condition	N	Median	IQR
Ba	18	2.25	0.97
U	18	1.97	0.73
Bb	9	1.84	0.61
T	9	1.77	0.38

These data show an overall reduction in THBI on both occasions when walking with the orthoses on, compared to without orthoses on (U compared with Ba, and T compared with Bb). However, it also shows a reduction in the baseline energy cost reading when walking barefoot between sessions (Bb compared with Ba). The lowest energy cost reading overall was found when walking with the tuned orthoses on, tentatively suggesting that optimising orthotic alignment may result in a reduction in energy cost of walking for some children. Further discussion of these results is found in Section 10.6.1.

As described in Section 10.2.4.2, the Wilcoxon signed-rank test for comparing two related non-parametric samples was used to determine any significant difference between conditions. Results are shown in Table 79.

Table 79. Results of Wilcoxon signed-rank test for THBI data

Groups compared	N	P value	Analysis
Ba and Bb (both sets of barefoot data)	9	0.374	No significant difference
U and Ba (un-tuned compared with barefoot on the same occasion)	18	0.011	Significant difference at $p<0.05$ level
T and Bb (tuned compared with barefoot on the same occasion)	9	0.173	No significant difference
U and T (Un-tuned compared with tuned orthotic data)	9	0.594	No significant difference

These data show that there was a significant difference in the energy cost of walking when using the original (un-tuned) orthoses compared with the barefoot data from the same session. However, there was no significant difference during the second session when the tuned orthoses were used, compared with the barefoot data from that session. This is despite the value for THBI being lowest with the tuned orthoses being used. The changes in THBI values between conditions, but presence of wide variability shown in Table 78 suggest a lack of power, and the risk of a type II error. This will be discussed further in Section 10.6.1.

10.5.2 Moment Arm Data

The moment arm data were analysed as a secondary measure to determine whether we had actually been able to finely-tune the orthotic prescription, i.e. make a significant improvement in the moment arm reading towards a normal value. Data were analysed for each involved limb where an orthosis was used – for example a diplegic patient has bilateral lower limb involvement and tends to wear bilateral orthoses, whereas a hemiplegic patient only has one lower limb involved and tends to wear just one orthosis.

Examination of the normality plots suggested that the data were non-parametric. Median values for each condition are presented below.

Table 80. CP group results for the moment arm data

Condition	N (involved limbs)	Median	IQR
Barefoot a	27	-6.5	37.3
Un-tuned	27	3.1	31.9
Barefoot b	14	16.2	58.7
Tuned	15*	-3.5	9.4

*one extra limb as moment arm data were collected for one child once the orthosis was tuned in the first session, but the child didn't attend for follow-up and therefore barefoot_b data are not available.

These results show a change in the median moment arm when wearing orthoses compared with barefoot on each occasion, but also show a change in the moment arm between both barefoot sets of data. The IQR is quite large for each set of data compared with the median, which is generally around zero, suggesting there may not be an obvious difference between any of the sets of data. The tuned dataset has the lowest IQR however, suggesting that this group had the least variability. Further examination of these results shows that the median values for the moment arm at mid mid-stance under each condition are all within normal limits, when compared with reference data.

Statistical analysis of these results to determine any significant difference between conditions was undertaken using the Wilcoxon signed-rank test. Results are shown in Table 81.

Table 81. Wilcoxon signed-rank test results for moment arm data

Conditions compared	N	P value	Analysis
Ba and Bb (both sets of barefoot data)	14	0.683	No significant difference
T and U (tuned compared with un-tuned orthotic data)	15	0.776	No significant difference
U and Bb (un-tuned data compared with barefoot on the same occasion)	27	0.962	No significant difference
T and Bb (tuned data compared with barefoot on the same occasion)	14	0.064	Very near significant difference at $p<0.05$ level

These results show no significant difference between conditions. Inspection of data from the second session (barefoot versus tuned orthosis) shows a difference that is near significance, but the wide variability suggests a lack of sufficient power, and the risk of a type I error. Further testing with a larger sample is recommended. These results are discussed further in Section 10.6.1.

10.5.3 Footfall Characteristics

As described previously, a three-point ordinal scale was used in order to determine any changes in footfall characteristics following orthotic tuning. A mean was calculated for each limb under each condition, from the same three gait cycles used for the moment arm calculation. Values that are not a whole number indicate some variability in foot strike between steps (e.g. heel strike on two passes, but with flat foot strike on the third).

Table 82 shows the mean scoring for each lower limb, under each footwear condition. Boxes are shaded for the 'non-affected' limb, although it can be seen that for some children this limb also showed some alteration in gait pattern, seen as a lack of heel strike, when barefoot.

Table 82. Footfall characteristics under each footwear condition.

ID	Ba_L	Ba_R	U_L	U_R	Bb_L	Bb_R	T_L	T_R	∑ Ba	∑ U	∑ Bb	∑ T
CP001	2	1	1	1	2	1	1	1	3	2	3	2
CP002	3	3	1	1			1	1	6	2		2
CP003	2	2	1	1	2	2	1	1	4	2	4	2
CP004	2	2	1	1					4	2		
CP005	2.3	1	1	1					3.3	2		
CP006	1.7	2	1	1.3	1	1.3	1	1	3.7	2.3	2.3	2
CP007	1.5	2.7	1	1					4.2	2		
CP008	1.7	1.3	1	1	2	1.7	1	1	3	2	3.7	2
CP009	2	2	1	1	2.3	2	1	1	4	2	4.3	2
CP010	2	2	2	1.7					4	3.7		
CP011	3	3	3	3					6	6		
CP012	1.3	1.7	1	1	2	1	1	1	3	2	3	2
CP013	1	2	1	1					3	2		
CP014	1.3	1	1	1	1	1	1	1	2.3	2	2	2
CP015	1	3	1	1					4	2		
CP016	1.7	2	1	1	2.3	1	1	1	3.7	2	3.3	2
CP017	2	2	2	2					4	4		
CP018	1	1.3	1	1					2.3	2		

Key: L = left; R = right; Ba =Barefoot_a; U = un-tuned; Bb= barefoot_b; T = tuned; ∑ = total score for combined limbs under each condition.

This data highlights that for all participants who completed the data collection, heel strike was facilitated for all limbs, when using their tuned orthosis. However, it can be seen that the original 'un-tuned' orthosis also facilitated heel strike for most, but not all, children. Of those children whose footfall characteristics did not improve with the original orthosis, most did not go on to complete the fine-tuning process. In particular we were unable to tune the orthoses of children CP011 and CP017 due to significant underlying musculo-skeletal problems.

The mean total footfall score for barefoot data at the first session (Ba) was 3.75, for un-tuned orthoses (U) was 2.44, for barefoot at the second session (Bb) was 3.21 and for walking with the tuned orthoses on (T) was 2. For the

subset of children (n=8) who completed all data collection, mean values were 3.33, 2.04, 3.21 and 2 respectively.

Data were non-parametrically distributed and therefore Friedman's test was applied at $p<0.05$ level, followed by post-hoc Wilcoxon signed-rank testing to determine any differences between the groups. Bonferroni corrections were applied to the post-hoc testing giving a significance level of $p<0.017$. Results are shown in Table 83.

Table 83. Statistical Results from Footfall Data

Data sets compared Friedman's test ($p<0.05$)	**P value**	**Result**
All data compared	0.00	Significant difference
Post-hoc Wilcoxon signed-rank test (Bonferonni correction applied, $p<0.017$)		
Ba and U (n=18)	0.00	Significant difference
Bb and T (n=8*)	0.018	Borderline significance
U and T (n=9)	0.317	No significant difference

*n=8 as one child was tuned at their first appointment and did not return for the second session and therefore Bb data are missing.

These results confirm those anticipated from visual inspection of the results, where there was a non-specific orthotic effect when compared with barefoot data (Ba with U, and Bb with T, although this result was on the border of significance with Bonferroni correction applied), but no significant difference between orthotic conditions.

10.6 Discussion of Clinical Trial Results

This section aims to discuss the clinical trial results, providing some critical appraisal of the methodology, and interpretation of the results. A summary of the methodological issues and proposed suggestions for future studies is found in Table 85 at the end of this section. Recommendations for future studies based on these discussions are found in section 11.13.

A final discussion of the entire research programme is presented in Chapter 11, and makes specific reference to the original hypotheses and aims of the research.

10.6.1 Effect of Tuning on Energy Cost of Walking

The results of this pilot clinical trial showed a reduction in energy cost when participants wore either tuned or un-tuned orthoses, when compared with barefoot walking (see Table 78). This is in agreement with several research teams [88, 143, 147, 148] who also found reductions in energy cost with orthotic use. Other research has indicated a reduction at fast and slow walking speeds only but not at 'comfortable' speeds [189], and others found mixed results, with a reduction in energy cost only for children with quadriplegia and not for those with diplegia or hemiplegia [146]. Buckon et al's study involving hemiplegic patients [144] found variable results in this group, again suggesting more subtle changes in this less involved population. Consideration of the effect of severity of disability is explored further within this section.

None of the above papers makes any reference to the orthoses being tuned specifically for each participant, and furthermore, the majority of studies used the same prescription for all participants with no clear justification for this choice. Many of these papers pre-date the more recently suggested practice of orthotic tuning, but this omission may explain the inconclusive results.

It was not possible to find <u>any</u> studies specifically investigating the effect of orthotic tuning on energy efficiency for children with CP, as highlighted recently by Eddison & Chockalingham [1], and this current pilot study therefore represents novel research findings.

The lowest energy cost value was noted when tuned orthoses were worn (Table 78). At first glance this suggests that tuned orthoses result in

optimum energy efficiency. However, statistical analysis of the data showed a significant difference in energy cost between the initial barefoot data (Ba) compared with the original un-tuned orthoses (U) (p=0.011) but not between the barefoot data in the second session (Bb) compared with the tuned orthoses (T) (p=0.173), despite the individual values observed. This suggests that the tuning process did not have a significant further effect on energy efficiency.

However, several considerations should be taken into account before applying this conclusion, the first being the difference in sample size between the two sessions (n=18 for the first session (Ba vs U); but n=9 for the second session (Bb vs T)), giving greater power to the former analysis. Secondly, examination of the results also highlighted a subtle, although not statistically significant, difference in energy cost between sessions when walking barefoot, with a lower value noted at the second session. Orthotic data were therefore compared against barefoot data collected during the *same* session to allow any changes in energy cost to be attributed to specific orthotic prescription and to avoid a Type I error being applied.

One explanation for the lower barefoot energy cost data at the second session may be that this value is taken from the sub-group of children who were able to complete both data collection sessions, which happened to incorporate those with lower barefoot energy cost values. This partly highlights the issues associated with studying a heterogeneous cohort, where specific benefits for individuals are lost in analysis of group means. All participants with a THBI of greater than 3bpm were in the original cohort only, and did not go on to complete the tuning process.

Further investigation showed that the sub-group who completed session two were all from GMFCS levels I and II. For all children in these classifications, mean barefoot THBI at session one (Ba, n=17) was 2.36bpm, but for the group completing session two (n=9), mean barefoot THBI was just 1.93bpm at session two (Bb). If we go on to compare data from the same

individuals, there is also a slight, although less significant, reduction in barefoot THBI between sessions (1.93bpm for Bb vs 2.05bpm for Ba). This highlights a couple of interesting findings: the first being that the cohort completing session two had, on average, lower energy cost values than the total cohort, perhaps suggesting they were more able children; and two, that there was some variation in barefoot data even within the same individuals between sessions. This could be related to the reliability of this measure for this patient population. Reliability testing was completed in the validation study within healthy adults, but further testing may be required in children with CP, to determine its inter-session reliability. The reduction in barefoot values at the second session could also be attributed to the children being more relaxed with the testing procedure. Again, repeat testing of this would clarify the reliability. It may also be attributed to a positive effect of tuned orthotic use in the preceding weeks, but this is purely speculative. Nonetheless, this reduction in mean barefoot THBI during the second session may explain why the further reduction when wearing the tuned orthoses was not significant in this small cohort, as highlighted above. Other factors that may have affected energy cost such as BMI and general health were considered to be unchanged between the two sessions.

Out of the total cohort, 14 (78%) children had improved energy cost values when wearing their original (un-tuned) orthoses compared with their barefoot data from the same session (Table 77), confirming a generic reduction in energy cost through orthotic use ($p=0.011$), as found previously [88, 143, 144, 147, 148, 189].

Despite the lack of significant difference between conditions for the whole group, out of the nine who completed both sets of data collection, four children (44%) had better energy efficiency when wearing their tuned orthoses compared with barefoot walking during the same session, when looking at their cases individually. For these specific children therefore, the tuning process did result in further energy efficiency as hypothesised.

Closer examination of the remaining five children whose energy cost was higher in their 'tuned' orthoses compared with barefoot (from the same session), reveals that for four of these five children, their THBI values for their 'tuned' orthoses were lower than for their 'un-tuned' (original) orthoses. Whilst this could still be interpreted to suggest an overall improvement in energy efficiency following tuning, this assumption should be taken with caution due to the inconsistency in barefoot data between the sessions as discussed above, and there is a risk of a Type I error.

Out of the nine children who did not complete the second assessment session (for various reasons described previously), eight children had better energy efficiency when wearing their original orthoses compared with their barefoot data, clarifying the generic orthotic effect on energy efficiency. This did include four children whose orthoses were already deemed to be optimally tuned.

More detailed examination of the data suggested an effect of severity of disability (determined by GMFCS level) on the outcome of the tuning process, and so was investigated for the purpose of discussion. Table 84 illustrates the energy cost values in relation to GMFCS level.

Table 84. Comparison of THBI data by GMFCS level

		First session				Second session		
COLUMN ID – for ref in text		A	B	C		D	E	F
GMFCS level	**n**	**THBI_ Ba**	**THBI_U**	**% change**	**n**	**THBI_ Bb**	**THBI_ T**	**% change**
I	7	1.96	1.80	-8.6	3	1.72	1.81	5.4
II	10	2.75	2.34	-14.9	6	2.04	1.96	-4.1
III	1	9.82	6.99	-28.9	0	-	-	-

Firstly, and perhaps not surprisingly, there was a direct relationship between the GMFCS level and baseline barefoot THBI values (Ba) within this group (column A, Table 84). In other words, the higher the GMFCS level, the greater the energy cost of walking for children within this study. The child rated at GMFCS level III had a THBI which was 633% of the reference

value when walking barefoot (9.82bpm vs 1.55bpm); the mean THBI for children at GMFCS level II was 177% of the reference value (2.75bpm vs 1.55bpm); and children at GMFCS level I had a mean THBI value of 126% of the reference value when walking barefoot (1.96bpm vs 1.55bpm). This is not a surprising result given that the GMFCS was designed to indicate degree of functional severity, and therefore children with greater disability are, by classification, going to struggle more (and therefore use more energy) when completing a higher functional task, such as walking. This is in agreement with previous studies. Kamp et al [97] performed a retrospective study involving 276 children at GMFCS levels I-III. They investigated the link between energy cost (based on oxygen analysis methods) and age, body surface area and Gross Motor Function Measure (GMFM). They concluded that energy cost correlated the highest with GMFM. Findings highlighted an increase in energy cost with decreasing GMFM score (which indicates increased disability).

Johnston et al [213] examined the relationship between GMFCS level and energy cost of walking in 30 children with CP, across GMFCS levels I-IV. A metabolic cart was used to determine energy cost. Results showed a statistically significant increase in energy cost associated with increasing GMFCS level, as found in the current pilot study. They further highlight that this increase in energy cost associated with greater disability may have implications for treatment, suggesting that treatments aimed at improving energy efficiency should be considered for this population.

Thomas et al [214] investigated the natural change in energy efficiency in a group of children with and without CP over a 12-month period. They sub-divided the CP group by GMFCS and concurred that the energy cost of walking increased with GMFCS level as found by those authors above, and with the current pilot study. Furthermore, they found an increase in energy cost over the 12-month period for the CP group compared with children without CP and found that this increased with GMFCS level.

Similarly, when looking at the group of children in the pilot study in terms of lower limb involvement, THBI values were higher in those with greater lower limb involvement than in those with less involvement. For example, those with one lower limb affected (i.e. those with a monoplegia or hemiplegia) had THBI values of around 137% of the reference value (2.12bpm vs 1.55bpm); whereas children with both lower limbs affected (those with diplegia and quadriplegia) had energy cost values of around 229% of the reference value (3.55bpm vs 1.55bpm). These findings are also not unexpected, given that the task being tested was walking, which is a bilateral lower limb function. The inferences are similar to those discussed in relation to GMFCS level, in terms of greater involvement leading to a higher energy cost, but presented in more general terms of lower limb involvement rather than functional ability.

Out of all of the children included in the pilot study, 16 out of the 18 recruited had THBI values of at least 110% of the reference value (≥1.71bpm); 8/18 had values of at least 150% of the reference value (≥2.33bpm) and 4/18 had values of 200% or more of the reference value (≥3.10bpm). This adds to the body of evidence that highlights an increased energy cost of walking in ambulant children with cerebral palsy, and suggests that consideration of this is required during treatment planning. If we consider that these values were recorded during walking at self-selected speed, on a smooth, flat surface, then implications for every-day walking on uneven surfaces or slopes are that energy cost values are likely to be even higher.

If we consider improvements in energy cost with orthotic use by GMFCS level in the pilot study (columns C & F, Table 84) then we see incrementally increasing improvements in energy cost in relation to the GMFCS level, i.e. the children with the greatest impairment (in terms of disability and initial energy cost) gained the most improvement in energy efficiency with their original (un-tuned) orthosis, compared with those at lower GMFCS levels. These data were from the whole cohort. Data specifically for the tuned

orthotic condition are limited to the nine children who completed the study and this represents just three children in the GMFCS level I group, and six in the GMFCS level II group and so results are interpreted with caution. Interestingly, when comparing tuned orthosis data with barefoot data from the same session we see a *worsening* of energy efficiency for those in GMFCS level I, and only a very small improvement for those in GMFCS level II. These values are felt to be clinically insignificant. It has already been noted that barefoot energy cost values were lower during the second session for this sub-group. This could be due to the children being more relaxed during the second session, and more familiar with the testing procedure. However, it could also be interpreted as an improvement in overall efficiency secondary to the use of tuned orthoses in the weeks preceding this assessment. Whilst this may be possible for the children at GMFCS level II who see a further slight improvement in energy cost when wearing their tuned orthoses, it is difficult to concede for the children at GMFCS level I as there is a worsening of energy cost with the tuned orthosis on (although this remains lower than the original barefoot data and similar to the original orthotic data). The child at GMFCS level III experienced a 29% improvement in energy efficiency through (un-tuned) orthotic use. We could not tune him further as he had fixed flexion contractures of his knees, but he may have had potential to benefit further with correction of his contractures. Nonetheless, a reduction in energy cost such as he achieved with his original orthoses, should allow him greater ambulatory function on a daily basis, than when walking barefoot.

This finding of greater improvements in energy cost through orthotic use for patients with increased limb and functional involvement is in agreement with the results of Brehm et al [146]. They also found negligible improvements in energy cost of walking with orthotic use for children with hemiplegia and diplegia, compared with those with quadriplegia. These data were collected retrospectively over a course of 10 years and the authors acknowledge that they did not have sufficient data to determine if the orthoses were optimally tuned. Given the preliminary results of this

pilot study, further tuning may have resulted in further energy efficiency for some children, especially those with greater disability.

For those children in whom improvements in energy cost through orthotic tuning were not found, the current pilot study highlighted alternative improvements in overall gait function, such as attainment of heel strike, overall trunk posture or maintenance of heel contact in stance. Orthotic tuning therefore was not ineffective in these children, but improvement in energy efficiency was not the primary outcome of treatment.

Further to the above, children with an energy cost of 2.3bpm or higher when walking barefoot (i.e. around 150% or more of the reference value), were found to have a reduction in their energy cost whilst wearing orthoses to values of 82% or less of their original barefoot data. Only one child (CP012) with a higher energy cost (above 2.3bpm) when walking barefoot had an *increase* in their THBI results with their original orthosis, but this child benefitted from the fine-tuning process with a subsequent reduction in their energy cost, compared with barefoot (Table 77).

These results tell us that, in general, orthoses do improve the energy efficiency of walking. This is in agreement with much previously published work [88, 143, 144, 147, 148, 189]. However, the preliminary evidence from this research does not sufficiently support the hypothesis that energy efficiency of walking is improved further by orthotic fine-tuning. A number of factors have had an influence on the outcomes of this research, including: the size of the sample recruited and the number of children able to participate until the end of data collection. The well-known issue of heterogeneity in this population makes performing statistical analysis and data interpretation difficult for the whole cohort, as well as for defined sub-groups, such as by GMFCS level. For this reason, the results of this study are presented as a series of case studies initially, with statistical analysis being a secondary consideration.

The total cohort included four children whose orthoses were already tuned (and therefore only attended once, hence their data are recorded in the 'un-tuned' data set), or whose orthoses were not 'tuneable' for various reasons. Caution was therefore taken in placing too much emphasis on grouped data. Nonetheless, some case study examples do highlight further improvements in energy efficiency and overall gait pattern following orthotic tuning. The results also tentatively suggest that if un-tuned orthoses are found to **increase** the energy cost of walking, then consideration should be given to ensuring an optimal prescription, and orthotic tuning may be recommended, as this may allow a more efficient gait to be achieved.

These findings suggest that energy cost is an important aspect of walking function in children with cerebral palsy, and that the fine-tuning process can result in a more efficient gait, but that the changes were more evident in children with a greater level of disability (higher GMFCS classification) whose energy cost values were further away from the reference value and therefore had more potential to improve. Additionally, for children whose energy efficiency is only mildly impaired, analysis of energy cost may not be sensitive enough to determine any changes with orthotic tuning and therefore an alternative outcome measure should be employed. This may explain the lack of consensus in other previously published research, where improvements in energy efficiency are inconclusive [145, 146]. Further research into the effect of orthotic tuning not only on energy efficiency (in a larger cohort) but also on other outcome measures, is recommended to ascertain the benefits of this practice and to identify those patients who would benefit the most from the process.

Jagadamma [126] reported differences in orthotic tuning effect for different presentations of knee motion during the gait cycle. His findings suggest that more specific factors, other than simply GMFCS level, may be pertinent to the selection of potentially suitable children for orthotic tuning.

Karimi et al [152] investigated PCI and THBI in a total of 27 participants, including 15 healthy volunteers, 10 with flat feet and 2 with spinal cord injuries. They recognised that calculation of PCI requires heart rate to reach a steady-state, and that this does not always occur for patients with walking problems. They calculated PCI and THBI during walking and conclude that neither index was sensitive enough to detect changes in energy cost secondary to the use of orthoses such as insoles or shoes. Furthermore, they found a greater sensitivity in the PCI compared with the THBI. Whilst this study questions the use of THBI in orthotic management, it must be recognised that 25 of the 27 participants had either no walking problems or simply flat feet, which may have negligible effect on energy cost. Furthermore, the interventions studied were simply shoes or insoles, which arguably may have limited effect on overall energy efficiency compared with a more controlling AFO. However, it does suggest that further testing of the sensitivity of the THBI would be a useful task.

10.6.2 Effect of Tuning on Footfall Characteristics

A secondary outcome measure indicating footfall characteristics was used to allow a different aspect of gait to be studied, that being the attainment of heel strike. This is an important factor in the treatment of gait, as attainment of heel strike has an influence on the rest of the gait cycle in terms of weight acceptance, alignment of the proximal joints and segments, stability during stance (especially during single limb stance), progression of weight across the foot and therefore an influence on stride length and walking speed. It may also influence more normal sensory feedback throughout the gait cycle.

Ordinal data were assessed, although a mean of three gait cycles was then calculated. Whilst this final mean value may not represent one of the outcome categories, it does highlight the variability in foot strike for each individual, and the reader can determine an indication of footfall pattern from this value. Similarly, changes in the value will highlight an improvement or deterioration following intervention. This outcome

measure was simple to use, easy to determine and gave an overall indication of change between conditions.

The tuned orthoses were seen to normalise footfall in all participants (n=9), such that all children attained heel strike in both legs (whether involved or not). The original orthoses facilitated heel strike in most, but not all participants, indicating that the tuning process further benefitted some children.

10.6.3 Use of the Moment Arm as an Outcome Measure

Use of the moment arm as an outcome measure for determining optimal orthotic tuning has been used previously [53, 56, 61, 105, 115, 126, 180] and has been shown to be clinically useful.

Results from the reference group concur with the adult data from Study two, and with previously published data [53, 56, 111, 180], in that the moment arm around 'mid mid-stance' was close to zero. Direct comparison of these present studies (Two and Three) was limited by the fact that the adult data were normally distributed and so presented as a mean, whereas the paediatric data were not normally distributed and are therefore presented as a median. The greatest variability in magnitude of the moment arm was found at initial contact and toe-off, as found previously in our **(Study Two)** and other adult studies [56], due to rapid changes in the direction and size of forces generated at these transition phases.

Graphical representation of the moment arm throughout the stance phase of the gait cycle for both the adult (Fig. 35) and children (Fig. 44) reference data, are visually consistent with data previously published [53, 56, 165]. However, numbers in the current study were higher (10 adults, and 30 children in present study compared with a maximum of 11 participants in previous studies), giving more strength to these findings.

Data from the paediatric reference group allowed the range of normal values to be determined, to guide the orthotic tuning process in the CP group during the pilot clinical trial.

When examining the change in moment arm data between conditions in the clinical trial, the results were very varied, and analysis was not straightforward, highlighting the complex nature of gait problems in this group of children. It also highlights the need for a multi-factorial approach to gait analysis and orthotic management in particular, as varying factors were relevant for different participants. For example, in some children the moment arm itself was within normal limits when walking barefoot, but their overall gait pattern was considered to be sub-optimal in terms of foot strike (e.g. toe strike) and foot contact during mid-stance (e.g. early heel rise). Instances were noted where the moment arm was normal, but the child was up on his/her toes with flexed knees at mid-stance, and the 'correct' resultant alignment of the moment arm vector at the knee at this point was not a true representation of their overall gait pattern. In these instances, consideration of the alignment of the force vector on the foot, and of foot contact and overall lower limb alignment was of more relevance when describing their overall gait function. This only served to highlight that alignment of the vector at the knee itself is not sensitive enough on its own as an outcome or determiner of normal alignment to be used for all children within this group. However, once foot contact and alignment of the force vector on the foot were optimised at mid-stance, then consideration of alignment at the knee was a much more significant finding for determining optimal orthotic prescription.

Statistical analysis found no significant difference in moment arm data between un-tuned orthotic tuned orthotic conditions (Table 81). At face value, this suggests that nothing had been altered and raises questions about the validity of the tuning process. However, certain factors need to be considered in conjunction with this result. Values for the un-tuned dataset were derived from the total cohort (n=18), whereas values for the tuned

dataset were derived from the sub-group of participants who completed the study (n=9) which may influence the variability and overall mean of values between the sets of data. Furthermore, due to the relatively small sample size, the fact that the values are close to zero, and the known heterogeneous nature of this cohort, the variability within the group was quite large and therefore any significant changes in moment arm for individual children may be lost amidst the pooled data (i.e. Type II error). The interquartile range for the tuned dataset had the least variability, which could imply that tuning had been achieved more consistently, although the smaller numbers in this group may also play a part. Again, this was the reason for presenting the results primarily as a series of case studies.

Additionally, as highlighted above, in some instances the moment arm alignment at the knee was indeed 'normal' with the un-tuned orthosis, but adjustments had to be made to the prescription in order to improve the overall gait pattern, which is not reflected in this single measure.

In spite of these small numbers, in the sub-group who completed both sets of data collection (n=9), we do see a near significant result ($p=0.064$, compared with $p>0.68$ for all other pairings) when comparing the moment arm data between barefoot and tuned orthotic conditions from the second session, (but not between barefoot and un-tuned orthotic data in the first session), suggesting that clinically significant improvements in moment arm alignment were achieved during the tuning process for this group. Whilst there is a risk of a Type I error here, further investigation with a larger cohort would allow clarification of this finding.

The benefits of using a video-based system however, meant that the overall gait pattern and footfall characteristics could be determined easily and concurrently with moment arm data collection.

Largely we were able to optimise the moment arm alignment at the knee at mid-stance for most of the patients who completed data collection through

to follow-up, through fine-tuning their orthoses. For the three subjects whose moment arm data were not optimal with the 'tuned' prescription various explanations apply:

It was not possible to tune the orthosis of child CP008, and we felt that some of his gait problems were habitual (early heel rise) and that he required consideration of alternative management such as further Botulinum toxin injections into the calf to help manage these aspects of his gait. For this child therefore, improvements in foot posture at initial contact and during mid-stance were primary considerations for improvement rather than optimising ground reaction force alignment at the knee.

For child CP012 there was minimal change in moment arm alignment at the knee with their tuned orthosis (which was already within normal limits when barefoot), but overall gait pattern and posture were improved with the tuned prescription compared with the original prescription, resulting in a more upright posture and better heel strike attainment. Again, a more global approach to assessment was required here to determine the optimal outcome.

Lastly, for child CP014, the moment arm alignment when barefoot was also within normal limits, but the knee was flexed and the vector originated too far forwards on the foot. However, with fine-tuning we were able to improve these aspects of their overall gait pattern without compromising the alignment of the ground reaction force at the knee.

For those children who were unable to complete data collection (n=9), we were either able to confirm an already optimally-tuned orthotic prescription which did not therefore require any further adjustment; or determine that there were other factors present which prevented further optimisation from being completed, and in these cases, we recommended alternative treatment options to improve their gait (such as consideration of orthopaedic surgery). This group also included one child who failed to

attend for follow-up, one who was excluded due to a flexion contracture, and one who struggled with orthotic use despite a variety of prescriptions being trialled.

Overall, the moment arm measurement proved to be a useful tool in helping to determine optimal orthotic prescription, but only in conjunction with other observations such as foot contact with the floor (i.e. flat foot during mid-stance rather than remaining on toes at this point); alignment of the ground reaction force vector on the foot segment (around the midfoot rather than being towards the metatarsophalangeal joints); and an overall impression of lower limb alignment (such as the presence of excessive knee flexion or hyperextension). Once these other factors were optimised, then normalisation of moment arm values at the knee resulted in overall improvements in gait pattern and alignment of the lower limbs (and often the trunk posture as well) during walking.

10.6.4 Case Study Discussion

As reported above, due to the small cohort numbers, and variability in presentation, a case study series was the primary method of presenting the results, to allow consideration of feasibility of the methodology and an indication of the accuracy of the original hypothesis. We did have some difficulties with recruitment due to the relatively strict exclusion criteria, especially in relation to recent treatment with botulinum toxin. Current practice within the geographical location of the study was such that those children who received botulinum toxin injections into their lower limb muscles as part of their management often had this repeated at 3-6 monthly intervals, which excluded them from taking part in this study. This was not the case at the original study location, where this treatment was given less frequently. Ironically, the tuning process for orthoses is actually very relevant following botulinum toxin to ensure maximal benefit of this treatment, as a child's orthotic requirements often change following this intervention through improvements in dynamic ankle range. However, this

exclusion criterion had to be included so that the tuning process was the primary independent variable affecting outcome.

At the start of the study the author was working in a gait laboratory where an orthotic tuning clinic had been set up and children regularly attended the clinic for this purpose. This should have facilitated recruitment into the study. However, before data collection commenced on this final pilot clinical trial, the author changed employment to another gait laboratory where there was no specific clinic for orthotic tuning, although the equipment and expertise were available for this. It was not possible to continue with data collection at the original location as the service no longer ran. This meant that wider advertising of the study was required, and a greater geographical location had to be considered. This may have influenced not only the original recruitment into the study but also retention of participants, some of whom had travelled from a distance to attend and perhaps did not see the personal benefit of attending for the follow-up data collection once their optimal orthotic prescription had been determined. Travel cost reimbursement was offered to all participants in an attempt to minimise this factor.

Links with paediatric physiotherapists and the orthotic team were made prior to commencing study recruitment, including promotion of the study at staff meetings for these teams. Feedback suggested we should have anticipated a good level of referral to the service for orthotic tuning. Unfortunately, this did not occur despite wider advertising to clinicians about the study, and therefore final numbers in the clinical trial were lower than planned. An extension was given via the Ethics Committee to the recruitment period to optimise participant numbers, but eventually time constraints on the study data collection meant that recruitment had to be discontinued.

Further numbers would have offered greater power to statistical analysis and inference of the results. This study therefore serves as a pilot study to

determine feasibility and usefulness of a further larger study into orthotic tuning. Consideration for future planned studies needs to be given to the ease of recruitment of the specific patient population, with particular consideration being given to any exclusion criteria and the impact of this on recruitment potential.

Total recruitment for the cerebral palsy group was therefore 18 participants, and unfortunately this included one who had to then be excluded at the initial assessment stage, and with significant drop-out as explained previously. Final numbers were nine children from the total cohort who completed both data collection sessions. Future studies should be mindful of this large drop-out, and factor this into sample size planning to ensure sufficient numbers of participants are seen to completion. The scale of this issue was not predicted prior to the study.

One of the children (CP004) who had attended the gait laboratory for orthotic tuning a year prior to inclusion in the study, was found to remain 'optimally tuned' in terms of ground reaction force alignment at the knee at his assessment, and had parental and school reports of improvements in his gait for this period. This would suggest (as a single case study observation) that there may be long-term benefits of orthotic tuning for this population, as postulated by Butler, which further justifies continued research into this field [56].

Although full orthotic prescription details are given for each child, post-analysis of these prescriptions shows that some children were prescribed original orthoses cast at a 90° angle despite presenting with ankle contractures or significant spasticity. The specificity of their prescription may therefore be questioned. However, when each child was assessed in their original orthoses, prescriptions were only changed when issues were identified with fit (rubbing) or with sub-optimal gait findings (including vector alignment). Where the cast angle was not changed despite the apparent discrepancy in clinical examination findings, evidence of

improvements in the child's gait with this prescription are provided, with or without any further tuning (in terms of alteration in shank inclination). Although an alternative cast angle may have been recommended for a new orthosis, it was not deemed necessary to alter this on principle alone where the current prescription appeared to work effectively.

Some difficulties were found with measuring exact cast angles, heel wedge heights and overall SAFAFOs and SAFAFOFWC's. This is because of the problems with determining exact joint centres (for example knee and ankle to determine ankle angle and shank inclination) from the AFO itself. Original prescription details from the orthotist were not always available. Where heel wedges were moulded around the AFO it was not possible to measure with absolute accuracy the precise height of wedge at the heel and some estimation was required. It was easier to determine if the overall SAFAFOFWC was in incline or neutral using observation, but again, exact measurement was difficult as one had to determine inclination of the shank from the orthosis itself. This may lead to some of the prescription details appearing to be contradictory – for example in one child a heel-sole differential of 1.5cm is noted but an overall SAFAFOFWC of 0° is reported, which may seem contradictory. Similarly, exact heel-sole differentials of the footwear required some estimation as manufacturers sometimes chose to accentuate an apparent difference through choice of moulding of the heel section to give an aesthetically pleasing look, rather than a true representation of heel height versus sole height. A best determination of these values was gained at each session. Suggestions for improvements are summarised in Table 85 (section 10.5.5).

Specific goniometric measurement of the gastrocnemius catch angle was not taken during the pilot study as this was not standard clinical practice at the time in the laboratory. Instead an indication of the catch being around plantargrade, or in plantarflexion was simply noted. However, following the study the significance of this was highlighted and the current clinical protocol for examination during gait analysis now includes goniometric

measurement of gastrocnemius catch angle with the knee flexed and extended to give a more accurate understanding of the contribution of calf tone to the gait problems, and to help inform orthotic management.

A greater longitudinal follow-up for patients following tuning is recommended to allow further evidence to be collated with regards to the longer-term benefits of this process. However, this type of research faces the difficulties of a growing child who would require a regular turnover of replacement orthoses. Even if a change in orthotic prescription is not required, changes in height, variation in footwear (and subsequently heel-sole differential), changes in gait pattern (improvement or deterioration) and changes in underlying muscle length and tone, bony torsion and strength may affect the overall orthotic requirements and regular review to ensure optimal tuning would have to be completed. Additionally, alternative concurrent interventions such as Botulinum toxin, orthopaedic surgery or a change in physiotherapy management may take place, which could affect the outcome and would produce multiple independent variables for consideration.

Furthermore, in terms of determining effect on energy cost, consideration has to be given to the fact that baseline energy cost may change over time independently of treatment, as highlighted by Thomas et al [214], described previously.

10.6.5 Limitations in Study Methodology

The following table highlights the main methodological issues encountered in this study with recommendations to minimise these in future studies.

Table 85. Study limitations and recommendations for future studies

Limitations of current study	Recommendations for future studies
Recruitment was affected by: * Exclusion criteria selection (particularly use of Botulinum toxin) limited availability of suitable participants * Slow referral rate for orthotic tuning, despite discussions with potential referrers	* Exploration of current clinical practice during study design to inform selection of relevant exclusion criteria and the effect of this on recruitment. * Further promotion of orthotic tuning and service provision prior to study commencement * Consider multi-centre trial
Retention and timing of review was affected by: * Loss to follow-up * Length of time for orthotic changes to be made and altered device to be fitted to patient * Timing availability of appointments * The need for alternative treatment	* Ensuring appointment planning is made prior to inclusion to encourage completion. * Further collaboration with orthotic departments to optimise the tuning process and minimise delays in alteration and fitting. This is difficult where multiple orthotic services are involved * Involvement of orthotist in the research process * Offer range of appointment timings to suit families (e.g. after school, in holidays etc)
Reliability of the THBI was not determined in children	Further investigation into the reliability of THBI in unaffected children, and in children with CP.
Small sample size limits generalisability of results	Larger sample size to maximise complete data sets and give greater power to statistical analysis
Heterogeneity of cohort limits generalisability of results. (Whilst this isn't a novel finding, the issues of this in relation to this research question were highlighted in this study.)	* Consider larger sample size to allow sub-grouping of participants by GMFCS to determine relative differences in outcome * Consider limiting inclusion criteria to specific GMFCS to allow greater clarity of results * Consider grouping children by other gait parameters to determine relative benefits
Difficulties in measuring orthotic detail accurately, to record exact prescription	* Involvement of orthotist during the session to give better clarity of measurement. * Use of a spring type caliper to measure heel-sole differential to eliminate the problems of different external sole design confounding accurate measurements.
Available orthosis for tuning not set to optimal prescription.	* Enrolment into the study at a time when a new orthosis was required, to ensure an optimal design from the start. * Consider recasting to optimal design, but would require consideration of cost implications, increased number of appointments (to tune and follow-up after this), and time implications for family

CHAPTER 11: OVERALL DISCUSSION

11.1 Introduction

This chapter will build on the discussions already reported in Chapters 8, 9 and 10, summarising the overall findings of the three studies, and reviewing the aims and hypotheses of the thesis. Based on the study findings the hypotheses will be accepted or rejected and the evidence for these decisions will be illustrated. Recommendations for clinical practice and future studies will be made.

Results from **Study One** (Chapter 8) highlight that the assessment of children with CP is a large part of work completed by gait laboratories, and that orthotic tuning is also a key consideration. The initial survey (2004-2005) suggested that a proportion (8/23; 35%) of laboratories housed equipment that would enable orthotic tuning, and the more recent review of laboratories in 2014 suggests that this practice is increasing with further laboratories undertaking orthotic tuning as part of their clinical work (10/15: 67%). These results suggested that further work investigating outcome measures for use with the video-vector set-up would be useful. Furthermore, the survey (2004-2005) results highlighted that assessment of energy cost was in use in some laboratories but that a range of techniques were being used, highlighting the need for further clarification of an optimal measure to use.

11.2 Thesis Aims and Hypotheses

The aims of this thesis were to validate a video-based measurement of moment arm at the knee (clinician-friendly), which would facilitate orthotic tuning; determine a reliable measure of energy cost; and then investigate whether orthoses that were optimally tuned led to a further reduction in

energy cost during walking, compared with orthoses that were not optimally tuned.

The study hypotheses were as follows:
1) Measurement of the moment arm manually using a video vector system (VVS) is a valid and reliable measurement tool.
2) The Total Heart Beat Index (THBI) is a more reliable measure of energy cost during walking than the Physiological Cost Index (PCI).
3) Use of finely-tuned orthoses reduces the energy cost of walking above that of orthoses that have not been specifically tuned.

The following sections will determine whether or not these hypotheses can be accepted, based on the studies undertaken in this thesis.

11.2.1 H1: Validity and Reliability of the Moment Arm Measure

Data from the validation study (**Study Two**, Chapter 9) demonstrated a good correlation between the moment arm measurement generated from the video data, and the moment arm measurement generated from the gold standard 3-d computerised gait data, using Bland and Altman plots. As discussed previously there was a consistent systematic difference between the results for some participants, which was felt to be due to slight modelling differences of the knee joint centre between the two systems. Case-wise examination showed a high level of agreement between the sets of data for 80% of participants (Spearman's rho>0.88) with specific explanations noted for the remaining two. Data were most consistent around at the peak knee flexor and extensor moment values, and least consistent during loading and pre-swing phases due to the rapid change in magnitude and direction of forces at these points. Data for the pilot clinical trial were recorded from mid mid-stance which would include data between the two peak values, and not from the loading and pre-swing phases. Any concerns over this discrepancy between systems are alleviated by comparison of the vector data to other published work, showing

consistency in the findings [56, 180], particularly noting that the data generated by CODA often suggested a lack of the usual flexor moment after mid-stance which may explain the difference.

Furthermore, the study results confirmed excellent repeatability of the manual measurement between sessions (r>0.9, excluding initial contact); high intra-rater reliability of the measure (r>0.9) at all points throughout the gait cycle; and very good inter-rater reliability of the manual measure (r>0.85) for the peak values and for data from mid mid-stance (the point of interest for the clinical trial). Lastly, data from mid mid-stance, the area of interest for the orthotic tuning process, for both adult and paediatric groups were shown to be comparable to that of previously published findings [53, 56, 111, 180], providing further evidence of its validity. This is despite measures being taken using different equipment and software (between the adult and paediatric data within this thesis, and between published data). This allows **hypothesis 1 to be accepted**, and hence the validity and reliability of the manually measured moment arm to be confirmed.

Measurement of the moment arm at the knee in the sagittal plane using a video vector system was clinically friendly, time efficient (able to be measured whilst the patient was still present), and had good intra- and inter-rater reliability. It can also be employed with different capture systems, demonstrating flexibility of use. We also found that this system proved to be useful in terms of providing visual and meaningful feedback to patients and carers as to the benefits of their orthoses, which may influence compliance with their use. Lastly, data shows that we were able to optimise (minimise) the moment arm through the tuning process, clarifying its clinical usefulness.

11.2.2 H2: Reliability of the Total Heart Beat Index

Data from the validation study (**Study Two**, Chapter 9) also provides clear evidence that the THBI is more reliable than the PCI for measuring energy

cost of walking, with ICC values of r=0.95-0.96 indicating excellent reliability for the THBI, compared with values of r=0.67-0.75 indicating good reliability for the PCI.

THBI data collected from adults were comparable to research first presented by Hood et al [151], whilst paediatric data were collected prior to any other comparable data being available. Plasschaert et al [159] has since published reference data from 42 similarly-aged children without walking problems, with comparable results (see details below). These findings allow **hypothesis 2 to be accepted** and the THBI to be used as a measure of energy cost during walking with a high level of repeatability in adults and concurrence with data from the Plasschaert study [159] in children.

Although the PCI demonstrated good reliability, this was still much lower than those for the THBI and wider 95% confidence intervals were seen with the PCI also indicating greater variability. This was despite the reliability of the underlying heart rate values during walking being excellent (r=0.93-0.96). The PCI relies on not only the resting heart rate data, but also a mean of the walking heart rate. Depending on the methods used to record heart rate this may only give a snapshot of the variability in heart rate recorded over the whole walking period. Previous studies have used a huge variation of walking distances, from just a few metres, to several minutes of walking covering significantly further. This could have an impact not only on heart rate recorded but also speed of walking. Study Two in this thesis collected data for the PCI and THBI concurrently to eliminate any effect of protocol on the results, but nonetheless found lower reliability of PCI values between sessions compared with the THBI.

Paediatric reference data for the THBI were found to be higher than for adults collected in the validation study. Differences in data normality mean that the paediatric data were non-parametric, and the adult data were parametric, which slightly complicates a comparison. The studies found a

paediatric median THBI of 1.55bpm and an adult mean of 1.22bpm. To allow a direct comparison, a mean was calculated from the paediatric data and was found to be 1.63 ± 0.3 bpm (range: 1.15-2.55bpm). Children tend to have a slightly higher heart rate than adults [215] and this will therefore influence the energy cost calculation. Furthermore, children have a shorter stride length and slower walking speed [25], and therefore their total distance covered during the test period is likely to be lower than in adults, which will also contribute to the higher THBI (THBI = heart rate/distance). However, the IQR for the paediatric data were fairly tight (1.48-1.78bpm) which shows good consistency, even across the age range studied. As discussed above, our reference data for children is consistent with the mean of 1.49±0.23 (1.11-2.13bpm) found by Plasschaert et al [159] in a comparable population.

If we use the values gained from the Reference Group to calculate a value for minimal clinical difference then we obtain a value of 0.58bpm (sd x 1.96 from our reference group mean THBI) which represents around 36% of the normative value. This seems quite a high expected change following intervention (personal opinion). However, if we repeat this with Plasschaert's data we get a similar value of 0.45bpm as a minimal clinical difference). Perhaps further investigation on repeatability of this outcome in a normative paediatric population would help to clarify this. Interestingly if we use the normative adult data we get a minimal clinically significant difference of 0.35bpm, as the data was a little less variable. However, this still represents just under a 30% change from the mean value.

A brief visual inspection of the effect of age on THBI showed a gradual reduction in THBI with age. However, this was not a consistent relationship and a simple linear regression plotted on a scattergram in Excel shows an R^2 value of just 0.3 suggesting a weak relationship between age and THBI. Again, there may be some link with heart rate and stride length changes with increase in age and height.

Previous research into the PCI found a correlation between walking speed and PCI values in a bell-shaped curve [135, 136] which led to the conclusion that optimal energy efficiency was associated with an optimal (but not necessarily fast) walking speed, peculiar to each individual. It is possible that some children were nervous about being in a hospital environment, or by taking part in a research study, and may therefore not have walked at their usual (optimal) pace. Every effort was made to make the child feel relaxed and informed during the session, and no obvious nerves were noted in any participant, but this factor cannot be excluded. However, these same issues could have been experienced by the adults taking part in early validation study, as well as by the patient group who took part in the clinical trial.

The protocol used during this study was similar to that used by Plasschaert [159] in that the participants were rested in sitting for several minutes before being asked to walk for a set period, and then resting again following data collection.

These findings provide a set of reference data for children aged 7-16 years without walking problems, which can be used to compare the findings from the pilot clinical trial, and once published, for clinical or further research studies.

Energy cost is clearly increased in many patients with CP (barefoot values of 1.61-9.82bpm compared with 1.55bpm for the reference group), and orthotic use can have a significant effect in reducing this. The THBI proved to be more reliable than the PCI for determining energy cost and was easy to collect and calculate, allowing us to investigate the effect of different orthotic conditions during walking.

Despite this confirmation of the reliability of the THBI, further investigation into the sensitivity of this index to detect changes secondary to intervention

in future studies would strengthen the confidence in using this index as an outcome measure, as highlighted previously.

11.2.3 H3: Effect of Orthotic Tuning on Energy Cost of Walking

Results from the pilot clinical trial (**Study Three,** Chapter 10) for determining the outcome of the third hypothesis are less clear due to the difficulty in investigating a heterogeneous population of children with varying presentations. For the cohort as a whole, **hypothesis 3 has to be rejected** as statistical analysis found no significant differences in THBI for children walking in their tuned orthoses (T) compared with barefoot or with their original (un-tuned, U) orthoses. However, individual analysis highlights that for some patients, the tuning process did indeed allow a further improvement in energy cost of walking compared with barefoot and un-tuned orthoses. Additionally, three children were found to be optimally tuned at their first session, and therefore did not require further tuning. They are included in the first cohort but perhaps actually represent 'tuned' conditions. Overall, both orthotic conditions (U and T) reduced energy cost compared with barefoot walking. Furthermore, the lowest THBI values were noted in the tuned dataset (T), suggesting that the hypothesis perhaps has merit but with insufficient power in this cohort to confirm this theory. There is therefore a risk of a Type II error in this conclusion. Further testing with a larger cohort would allow this hypothesis to be clarified with more conviction.

The results therefore suggest some benefits of the tuning process on energy cost of walking (general further reduction in energy cost after tuning, although not statistically significant for the whole group), but that careful selection of the group of children for whom it will be beneficial is required. As previously discussed, those children with a greater level of disability were found to benefit the most from orthotic use, although several of these

could not complete the tuning process and required further alternative management.

Furthermore, results indicate that energy cost analysis may not be sensitive enough as an outcome measure for those with milder impairment. However, it was possible to improve the moment arm at the knee for all participants through the orthotic tuning process.

Some evidence is presented therefore, that improvement in energy cost through optimisation of the moment arm at the knee can be achieved, and furthermore that potential long-term benefits of orthotic tuning may be achievable.

11.3 Recommendations and Implications from Findings

11.3.1 Recommendations for Clinical Practice

The following clinical recommendations can be made from the results of this study:

1. Clinicians need to consider the possible benefits of orthotic tuning for children with CP and the impact that this can have not only on gait pattern and stability but also on overall body posture, orthotic compliance and energy efficiency.
2. Clinicians should consider energy cost as an outcome of treatment for children with CP, in particular for those with GMFCS of II or above where baseline values during walking were found to be notably higher than the reference value.
3. Energy cost measures based on heart rate are easy to collect and record and do not necessarily require access to a gait laboratory, although sufficient space and equipment are required.
4. The THBI was found to be more reliable than the PCI, although further testing in the paediatric population is recommended.

5. Careful consideration should be given to the orthotic prescription used for children with CP, taking into account the underlying available range of motion, strength, spasticity and functional ability of the child, in order to optimise the functional outcome for the child.
6. Clinicians should consider using video recording as a record of the child's function and to allow a more detailed assessment of different aspects of their overall gait pattern in determining the benefits of orthotic intervention. Some of these benefits are only determinable by closer examination of the gait pattern not possible with the human eye at normal walking speed.
7. Furthermore, clinicians should consider the use of a gait laboratory with video vector technology to assist with the tuning process, to ensure that tuning is optimised and advice on other aspects of CP gait and management are gained.
8. Orthotic tuning should be multi-factorial and consideration should be given to foot strike, contact of the foot during stance and overall posture of the trunk and lower limbs during stance, as well as more specifically the alignment of the ground reaction force at the knee (and foot), prior to considering any changes in energy cost. These areas can be considered both with and without the use of a gait lab.
9. Additional wedging to further incline the shank was a common adjustment made, and resulted in significant improvements in gait and posture. Therefore, consideration of this during the original prescription process may lead to a more optimal outcome prior to any further tuning, or where tuning is not available.
10. Clinicians need to remain contemporaneous with current practice recommendations in relation to CP which are becoming clearer all the time, especially in relation to the benefits of orthotic tuning. This needs to include not only orthotists themselves, but also physiotherapists, orthopaedic consultants, paediatricians and gait lab staff, all potentially involved in the management of children with CP.

11.3.2 Considerations for Management

Optimal orthotic tuning also has implications for service management. These include:

1. Consideration of investment in the orthotic tuning process to allow patients to experience the possible long-term effects of orthotic tuning. This is postulated to include fewer changes in orthotic prescription, in itself a potential cost-saver, as well as health and quality of life benefits for patients themselves.
2. Use of the vector system to aid orthotic tuning not only benefits the patients directly but also the clinicians involved who can become more knowledgeable about the benefits and methods of tuning both within and out with a more formal gait assessment setting.
3. Orthotic services need to be flexible enough to allow timely access to a tuning service either prior to or immediately following the initial fitting, to inform the prescription and ensure appropriate adjustments are made to ensure biomechanical optimisation.

11.3.3 Implications for Education

The results of this pilot clinical trial suggest that the concept of orthotic tuning and its potential benefits should be taught at under-graduate level to relevant clinicians (e.g. orthotists and physiotherapists) but also at post-graduate level to all clinicians involved in the management of children with CP, including those working in gait laboratories so that this avenue of service can be explored and marketed to relevant parties. Furthermore, the results of the literature review and studies themselves highlight the need for continued professional development of clinicians to remain up-to-date with contemporaneous research and practices [173].

11.3.4 Implications for the NHS

As with management implications, the suggestions from the research are that orthotic services should have access to a gait lab and/or tuning service

so that the care provided to children with CP who wear orthoses is of the highest standard. Implications for orthotic budgets may include a reduction in the 'trial and error' process that can occur whereby varying orthotic prescriptions are trialled, based purely on clinical experience, to find one that the patient tolerates and that has the desired outcome.

One could postulate that orthotic tuning could lead to a reduction in the need for orthopaedic surgery for these children, as optimising orthotic prescription can improve overall gait pattern, which could help children remain mobile for longer, which can have a knock-on effect on strength and range of motion in lower limb joints?

NICE guidelines [216] states that orthoses should be used to improve walking efficiency and posture, but furthermore that clinicians should "ensure that orthoses are appropriately designed for the individual…..and are sized and fitted correctly." The orthotic tuning process ensures that this principle is adhered to, giving the optimal individualised prescription.

Staff working within the NHS need to be able to access relevant continuing professional development, in order for them to remain up-to-date with contemporaneous evidence-based clinical practice techniques.

11.3.5 Improvements in Gait

The study findings highlighted several important outcomes. Firstly, further evidence that orthoses in general improved the walking pattern (in terms of overall posture and alignment, as well as in heel strike attainment, lower limb biomechanical alignment and energy efficiency) of children with CP, but furthermore that the tuning process facilitated additional improvements for most of the children. These varied from further improvements in postural alignment (less anterior trunk lean and pelvic tilt); to normalisation of alignment of the ground reaction forces at the knee; to improvements in heel strike attainment and maintenance of heel contact

during stance; and for some, a further reduction in energy cost during walking. These improvements have the potential to have a significant impact on the child's functioning on a daily basis as well as on their future ambulatory potential. A single case study (CP004) highlighted the potential longer-term benefits of orthotic tuning having had his orthoses tuned a year prior to the study. A year on, despite growth and development of gait, his orthoses remained optimally tuned and therefore confirmation of optimal prescription could be made.

Very recently published research [182] identifies a link between abnormal trunk movements and increased energy costs during walking in children with CP. Moreover, the study found a reduction in these abnormal trunk movements, and therefore in energy cost of walking through the use of orthoses, with specific consideration given to the stiffness of these orthoses (which they consider to be a tuning factor). This highlights the importance of considering overall trunk posture in the gait of children with CP, not just focussing on lower limb alignment.

11.3.6 Implications for Orthotic Services

One of the main implications for orthotic services is that consideration of tuning should be an integral part of the orthotic prescription process. This field of orthotic research is ever increasing, with the importance of the tuning process being recognised in the NICE guidelines for Stroke Management in Scotland. The process is multi-factorial with the need to consider not only a detailed clinical examination of the patient, but also an in-depth analysis of gait and posture prior to determination of the optimal orthotic choice and prescription, with follow-up tuning to ensure optimisation is achieved. This does not have to involve video vector technology, as the importance of shank inclination has been highlighted [175, 185, 187], but an assessment with greater clarity than simple observation is recommended to ensure that all factors pertinent to the tuning process are considered.

One could also postulate that in the longer-term a cost-saving potential was possible in that the tuning process provides a learning opportunity for orthotists and families alike. More optimal orthotic prescriptions are likely to lead to a reduction in the 'trial and error' process often seen for complex children, whereby a range of different orthoses are trialled until the 'best fit' is found and tolerated. Through the continued learning gained from the tuning process (from personal experience), orthotists may be more likely to 'get it right first time' for new patients, reducing the cost of trialling different styles.

From clinical experience, families can sometimes have a difficult relationship with the orthotics department due to repeated issues with the child's orthoses, in terms of rubbing, limited effect on gait, acceptance etc. Through the tuning process, a prescription that not only improves the child's gait, but also their compliance with the device by ensuring it is individually tuned, should reduce the problems of rubbing and fit. Furthermore, by illustrating the video footage of the gait pattern with and without the tuning adaptations, and explaining the alignment of the ground reaction force to the lower limb joints, a greater understanding and confidence on behalf of the families can be gained, which then improves compliance and trust with their orthotic provision. This was highlighted by Quinn et al [127] who found the vector system to be invaluable for aiding the prescription process, and furthermore report improvements in client education as well as compliance using feedback from the videos for their patients. Importantly, they also recognised that for some children, the AFOs could not be optimised and that other management plans were required, as within this study.

11.3.7 Implications for Children and Families

The results of the study suggested that for most children, orthotic tuning led to improvements in gait pattern and function, overall body posture, and for

some, energy efficiency. These will all undoubtedly impact positively on quality of life in terms of being able to do more (due to better efficiency); reduction in muscle fatigue through elimination of unnecessarily large moments; improvement in walking distance (through better efficiency); reduction in pain due to improvement in posture and elimination in abnormal moments and forces on joints; better body image and posture; improved gait pattern (and psychosocial benefits of this); and increased compliance with orthotic use. This was seen in the handful of feedback forms we received, where both the children and their families tended to prefer the tuned orthoses for many of the above reasons.

There is also the confidence in the prescription process for parents through the ability to give visual feedback (using the vector system) and the reassurance that high standards of care are being given, with every effort made to optimise the prescription for the child. This research adds to the body of evidence for orthotic tuning, which should influence clinical management of CP. If orthotic tuning is implemented then families should have to make fewer trips to hospital for orthotic appointments, with reduced time off work, and implications of this.

11.4 Strengths of the Research

The body of work presented in this thesis represents a detailed investigation into the use of video vector technology to help assess gait in children with CP and for use within the process of orthotic tuning, and the effect of this tuning on energy cost, an area specifically highlighted recently as lacking in evidence [1].

A critical appraisal of available orthotic outcome measures available identifies the issues found with these measures, allowing readers to themselves consider the strength of other orthotic research. The work justifies the outcome measure selected, based on recent NHS legislation and recommendations about orthotic use in CP within literature, focussing on

the areas of prescription currently being highlighted as paramount, but lacking in evidence. It highlights the fundamental issue of many previous studies failing to adequately describe the orthotic prescription in sufficient detail to allow full analysis of the results and to be confident that the prescription was optimised for each child during each study.

The national survey (**Study One**) places the issue and availability of orthotic tuning into clinical context, demonstrating an increase in orthotic tuning practice over time, and hence the need for further, high standard, orthotic research.

Validation of the moment arm measurement (**Study Two**) is determined using data collected concomitantly with that from a gold standard system (computerised motion analysis) allowing confidence to be placed on this measurement as a determinant of optimal tuning.

Comparison of two different energy cost indices, with evidence of the reliability of each allows confidence to be gained in the selected THBI, and normative data from an age-matched population is provided using the same protocol as for the clinical trial to allow accurate clinical inferences to be made from the patient data.

Reference data are also provided for the moment arm at the knee, in a moderate sized paediatric population, given further weight to previously published data where smaller sample sizes were used (30 in this study, compared with 5-11 participants in previous work [56, 111].

Lastly the pilot clinical trial (**Study Three**) demonstrates the difficulties in assessment in this population, but highlights the potential benefits of fine-tuning on the energy cost of walking for this population.

11.5 Key Contributions to Knowledge

The research presented in this thesis represents some key contributions to knowledge within the field of orthotic use in children with CP.

1. Orthotic tuning can, for some children, reduce energy cost of walking above that of orthoses that have not been tuned. This is a factor that has not been investigated previously. These early findings are encouraging, but warrant further exploration and confirmation.
2. Orthotic tuning has to consider a range of factors to determine when optimal outcome has been achieved, and caution should be placed on using a single outcome measure.
3. Evidence is added to the current body of knowledge identifying a relationship between GMFCS level and energy cost of walking for children with CP.
4. Further evidence is provided that children with greater levels of disability (as determined by GMFCS level or baseline energy cost) are more likely to reap greater benefits of orthotic use and tuning, compared with children with less disability. This evidence should be used to ensure that these children have access to orthotic management and that prescriptions are optimised to allow them the maximum benefit.
5. Orthotic tuning proffered additional benefits to overall gait pattern and posture in particular, in addition to any improvements in energy cost.
6. Manual measurement of the moment arm at the knee from video-based data is reliable between sessions ($r>0.91$ for peak and trough values) and between testers ($r=0.85$, for mid mid-stance), but had the greatest reliability when measured by the same clinician ($r=0.98$, at mid mid-stance).

11.6 Conclusions

There is wealth of research investigating the effect of orthoses on gait outcomes in children with CP, but due to the more recent recognition that specific fine-tuning is required to ensure optimal prescription [1], many of the outcomes of these studies are now questionable due to the lack of specificity of the orthoses used. There is now an emerging field of work looking at the effect of specific fine-tuning on gait outcomes, but the effect on energy efficiency is particularly lacking [1].

The aim of this research programme was therefore to investigate the effect of orthotic fine-tuning on the energy cost of walking, selecting robust methodological approaches to ensure optimal fine-tuning as well as using a reliable primary outcome measure (energy cost of walking). The primary hypothesis of the research was that the use of orthoses that had been specifically tuned in relation to optimisation of the moment arm at the knee during gait in children with CP, would result in a reduction in energy cost during walking, compared with the use of orthoses that had not been specifically tuned. This hypothesis was based on the biomechanical principle that reduction in the moment arm (and therefore moment) at the knee during walking would result in a reduction in the opposing muscle action required to counterbalance this moment. As muscle activity requires expenditure of energy, a reduction in muscle activity should therefore result in a subsequent reduction in energy expenditure.

This series of investigations has studied the current methods employed in gait labs around the UK (**Study One**); presents an objective method of defining the fine-tuning process that is both valid and reliable, with reference data presented from a paediatric population; determines a clinician and patient-friendly energy cost measure that has optimal reliability, presenting a paediatric reference dataset for this measure (**Studies Two and Three**); and lastly, presents results from a pilot study investigating the effect of tuned orthoses on the energy cost of walking,

compared with orthoses that have not been specifically tuned (**Study Three**). Through this pilot study, the feasibility of a larger study to give greater power to the analysis is determined, with recommendations made for future studies to inform participant selection and methodology.

As summarised in the discussion section, **Study Two** found the method of manual measurement of the moment arm at the knee in the sagittal plane to be valid and reliable. This method can be used with any video vector based system and provides an objective measure of alignment of the ground reaction force at the knee, which improves on the current clinical practice of observing the alignment and determining subjectively when changes have taken place.

Use of this measurement allowed the process of tuning orthoses to be objective, and clarified when optimal tuning had occurred. However, **Study Three** found that this single outcome measure should not be used alone to determine optimal gait pattern, and found that other considerations such as contact of the whole foot on the floor, and alignment of the ground reaction force vector at the foot were also important in determining when an optimal outcome had been achieved, as 'false' optimal alignments could be measured in situations when gait was not felt to be maximised.

Study Two highlighted that the Total Heart Beat Index for determining energy cost of walking was more reliable than the commonly used Physiological Cost Index and was just as easy to record and calculate using a modern heart rate monitor. However, further investigation into its sensitivity and reliability in the paediatric population are recommended.

During **Study Three**, the pilot clinical trial, it was found that the process of fine-tuning orthoses could improve energy cost of walking for some children, but not all and that further research was required using larger sample sizes to extrapolate the findings to a wider population. The pilot clinical trial also found that orthoses in general reduced energy cost of

walking in most children, and in particular in those with a greater level of disability, as determined by the GMFCS. Lastly, additional benefits from the tuning process were identified for most children, highlighting its scope of potential.

11.7 Recommendations for Future Research

The pilot study provided some interesting preliminary findings into the effect of orthotic tuning on energy cost of walking, however, limitations in sample size and retention of participants limits the strength of the results. The feasibility of the methodology used for the study was tested and was found to provide clinically useful information to guide the orthotic tuning process, with the outcome measure easy to collect. However, the following recommendations are made for future research into orthotic tuning in CP.

1. Further research into the effect of orthotic tuning on energy cost of walking is warranted, particularly for children with a greater level of disability (GMFCS levels II-III).

2. A larger sample size would be recommended to give further strength to the findings, especially if consideration is given to sub-dividing the cohort by GMFCS. A power calculation was performed to inform future studies using the standard deviation of the mean difference in THBI between the un-tuned and the tuned orthotic conditions (0.247bpm), with a power of 80% and significance of 0.05. If we assume a clinically significant difference in energy cost between orthotic conditions of 0.5bpm then the calculation requires just 2 participants per group; a difference of 0.2bpm requires 12 per group, and a difference of 0.15bpm requires 22 children per group.

3. Alternative outcome measures should be considered for children with lower levels of disability (GMFCS level I), perhaps focussing on functional improvements in gait pattern or personal goals (walking

distance, measures of effort, walking speed etc) rather than just energy cost. An activity monitor could be used to record levels of functional activity in the community, as a possible outcome measure but also to consider as a factor in effect of orthotic use.

4. When investigating orthoses within CP research, it is important to consider and describe in detail the orthotic prescription, to permit a full understanding of the clinical reasoning behind the orthosis used, and to ensure that an optimal prescription has been used.

5. The THBI proved to be an easy-to-use energy cost index for this population, and was found to be more reliable (in adults) than the more widely used PCI. However, further testing of the repeatability and sensitivity of the THBI to detect changes over time and following intervention in children would strengthen the confidence in its use as an outcome measure, given the changes in barefoot data noted between sessions in **Study Three**.

6. If using a heart rate based energy cost index for children with cerebral palsy, then walking for 5 minutes is a sufficiently long enough data collection time, with some children within this study failing to be able to walk for the whole duration. The protocol used in this study proved to work well with this population, and can be easily replicated.

7. Use of the manual moment arm measurement proved to be reliable and easy to use, especially with contemporaneous methods of video recording being computer based (rather than video-tape based). This method could therefore be used with any video-vector system to provide objective data for improvements in ground reaction force alignment during the orthotic tuning process. A clear protocol for definition of knee joint centre (in the sagittal plane) should be adhered to, to optimise reliability.

8. However, consideration needs to be given to other aspects of gait function in conjunction with the moment arm measure to determine optimal outcome. Use of the moment arm measure alone could lead to acceptance of a sub-optimal outcome or over-interpretation of a positive result. Consideration of foot contact with the floor and alignment of the ground reaction force at the foot prior to consideration of the moment arm measure are recommended to determine optimal outcome.

9. Consideration should be given to a longer-term study into the effect of orthotic tuning on aspects of gait for this population. Results from a single case within this study suggest that the benefits of fine-tuning can be maintained over time, with more widespread benefits being noted by parents and school a year after initial tuning. This is encouraging but requires further detailed study with clear outcome measures and a greater cohort to corroborate such findings. Assessment at perhaps six months and a year post-tuning would highlight firstly whether optimal alignment had been maintained at these periods, and as to whether any further changes in energy cost had been made. Confounding issues to longer term follow-up are the influences of physical growth and development on gait and underlying energy cost of walking, and therefore, repeat baseline measures would be recommended to highlight the natural progression of underlying gait function, as well as the benefits of orthotic management.

10. Further research is warranted into the effect of orthotic tuning on other aspects of gait such as maintenance of heel contact appropriately throughout stance which is important in controlling shank inclination; improvements in overall body posture; and the impact of orthotic tuning on overall function and quality of life.

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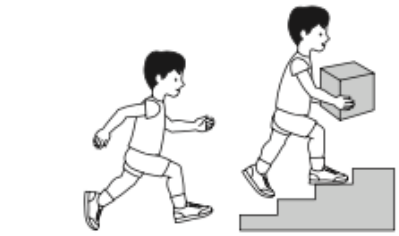
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APPENDIX 1: GROSS MOTOR FUNCTION CLASSIFICATION SYSTEM (GMFCS)

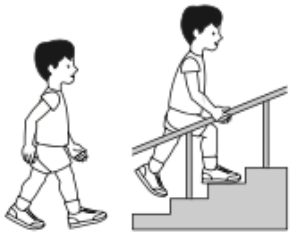
Reference: Illustrations from [217]; based on descriptions and original GMFCS by Palisano et al [17].

GMFCS E & R between 6th and 12th birthday: Descriptors and illustrations



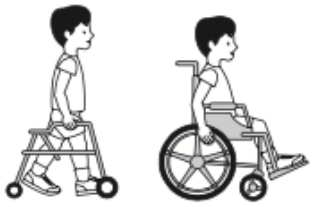
GMFCS Level I

Children walk at home, school, outdoors and in the community. They can climb stairs without the use of a railing. Children perform gross motor skills such as running and jumping, but speed, balance and coordination are limited.



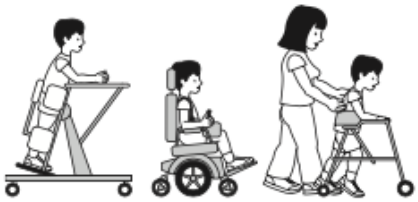
GMFCS Level II

Children walk in most settings and climb stairs holding onto a railing. They may experience difficulty walking long distances and balancing on uneven terrain, inclines, in crowded areas or confined spaces. Children may walk with physical assistance, a hand-held mobility device or used wheeled mobility over long distances. Children have only minimal ability to perform gross motor skills such as running and jumping.



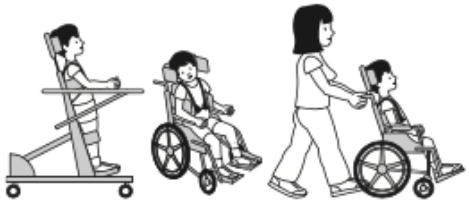
GMFCS Level III

Children walk using a hand-held mobility device in most indoor settings. They may climb stairs holding onto a railing with supervision or assistance. Children use wheeled mobility when traveling long distances and may self-propel for shorter distances.



GMFCS Level IV

Children use methods of mobility that require physical assistance or powered mobility in most settings. They may walk for short distances at home with physical assistance or use powered mobility or a body support walker when positioned. At school, outdoors and in the community children are transported in a manual wheelchair or use powered mobility.



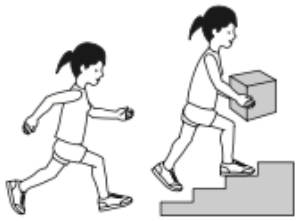
GMFCS Level V

Children are transported in a manual wheelchair in all settings. Children are limited in their ability to maintain antigravity head and trunk postures and control leg and arm movements.

GMFCS descriptors: Palisano et al. (1997) Dev Med Child Neurol 39:214-23
CanChild: www.canchild.ca

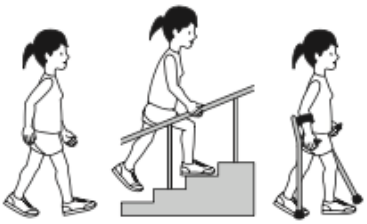
Illustrations Version 2 © Bill Reid, Kate Willoughby, Adrienne Harvey and Kerr Graham, The Royal Children's Hospital Melbourne ERC151050

GMFCS E & R between 12th and 18th birthday: Descriptors and illustrations



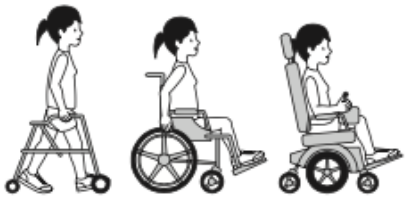
GMFCS Level I

Youth walk at home, school, outdoors and in the community. Youth are able to climb curbs and stairs without physical assistance or a railing. They perform gross motor skills such as running and jumping but speed, balance and coordination are limited.



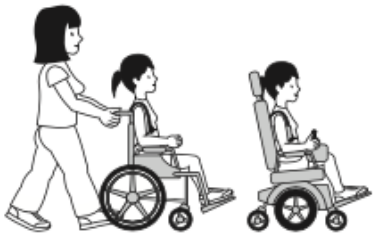
GMFCS Level II

Youth walk in most settings but environmental factors and personal choice influence mobility choices. At school or work they may require a hand held mobility device for safety and climb stairs holding onto a railing. Outdoors and in the community youth may use wheeled mobility when traveling long distances.



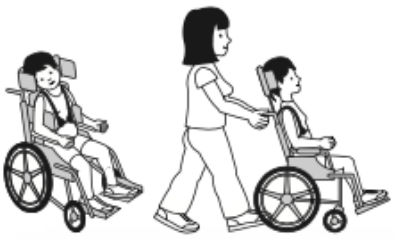
GMFCS Level III

Youth are capable of walking using a hand-held mobility device. Youth may climb stairs holding onto a railing with supervision or assistance. At school they may self-propel a manual wheelchair or use powered mobility. Outdoors and in the community youth are transported in a wheelchair or use powered mobility.



GMFCS Level IV

Youth use wheeled mobility in most settings. Physical assistance of 1-2 people is required for transfers. Indoors, youth may walk short distances with physical assistance, use wheeled mobility or a body support walker when positioned. They may operate a powered chair, otherwise are transported in a manual wheelchair.



GMFCS Level V

Youth are transported in a manual wheelchair in all settings. Youth are limited in their ability to maintain antigravity head and trunk postures and control leg and arm movements. Self-mobility is severely limited, even with the use of assistive technology.

GMFCS descriptors: Palisano et al. (1997) Dev Med Child Neurol 39:214-23
CanChild: www.canchild.ca

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APPENDIX 2: PAPERWORK FOR STUDY ONE

Study One: National Survey of Gait Laboratories

Covering Letter

Survey Proforma

Covering Letter



Investigator: Mrs Helen Evans
Contact number: 0115 8404894 / 4880
E-mail: helen.evans@nottingham.ac.uk

A baseline audit of the service structure and facilities within motion analysis laboratories.

Dear Colleague,

I am a Research Physiotherapist in the process of studying for my MPhil / PhD entitled "**The orthotic management of children with cerebral palsy**". I am planning on using a video vector system and an energy cost measure to assess orthotic intervention in this group.

I feel it necessary to determine the current trend in practice, and resources available within the UK and Eire prior to commencing, and would therefore appreciate your help.

I am therefore inviting you to take part by filling in this simple audit about the current practice and facilities in your centre, it should only take a few minutes. I can reassure you that all information gathered will be kept strictly confidential and anonymous in the write-up. Only one questionnaire per centre is required and participation is completely voluntary.

If you wish to take part, please return the questionnaire, in the stamped addressed envelope by 22-09-04.

Please indicate below if you are interested in receiving a summary of the results on completion of the research. If you wish to be informed of the findings please also supply a contact name and confirm the name and address of your centre to allow the findings to be forwarded to you. This section may be left blank if you are not interested in receiving a summary of the results.

Thank you very much for your time.

Mrs Helen Evans BSc(Hons) MCSP, SRP, APCP
Research Physiotherapist

---

* I am / am not interested in receiving a summary of the questionnaire results upon completion (*please delete as applicable).

Contact name:.....
Name of centre:.....
Address of centre:.....
.....
.....

Contact number in case of queries: .....

Survey proforma

The University of Nottingham

A baseline audit of the service structure and facilities within motion analysis laboratories.

Section A: About your service:

1. Where are you based? (please tick)

Hospital ..... ☐
University..... ☐
Private centre..... ☐
Other: please state..... ☐
.....

2. Please indicate what motion analysis equipment you have in your lab and give details of which make you have? (Please tick all that apply, and state make of each system)

- Motion analysis system ☐ .....
- Force plates ☐ .....
- EMG system ☐ .....
- Foot pressure measure ☐ .....
- Video Vector system ☐ .....
- Other ☐ .....

.....

3. Do you provide a clinical gait or orthotic analysis service? (please circle) Y / N

If No, please go to Section B.

4. How long has your motion analysis service been running? _____ years

5. How many members of staff are currently involved in the service? ____Full - time
____Part - time

6. Please indicate staff regularly involved in gait/orthotic analysis in your lab:

Job title	Number involved in analysis
Medical staff:	
Consultants	
Registrars	
SHO's	
Other	
Physiotherapists:	
Clinical Specialist	
Superintendent	
Senior I	
Senior II	
Basic grade	
Clinical Engineers / Scientists	
Bioengineers	
Technicians	
Prosthetist / orthotist	
Academics	
Other: please give details	

7. On average how many patients do you assess each month in your centre? ____

8. Out of these, approximately how many are children with Cerebral Palsy? ____

9. Where do your referrals come from? Please tick all that apply.
- Paediatric Consultant Orthopaedic Surgeons..... ☐
- Adult Consultant Orthopaedic Surgeons..... ☐
- Paediatric Consultant Neurologists..... ☐
- Adult Consultant Neurologists..... ☐
- Physiotherapists..... ☐
- GP's..... ☐
- Other Consultants..... ☐
- Other: Please state..... ☐

10. Please indicate next to the tick boxes above (Q9), the **3 most frequent referrers** in order, with 1 being the most frequent referrer to your lab.

Section B: Video Vector system:

11. Do you currently have a video vector system within your laboratory? (circle)

Y / N / developing.

If Yes, please go to Q13.

12. If No / developing, do you provide an orthotic assessment service? (circle) Y / N

a) If so, what method/s do you use to assess orthoses: (Please tick all that apply)
- Video..... ☐
- Motion analysis (e.g. CODA, Vicon, Elite ...)..... ☐
- Energy cost measure..... ☐
- Foot pressure measure..... ☐
- Other: please state ..... ☐
.....

Please go to Section D.

13. If yes, how long have you had it set up for? _____ years

Section C: Use of the vector system:

14. Please indicate what you use your vector system for: (Please tick all that apply)
- Assessment of gait / orthoses
  - children..... ☐
  - adults..... ☐
- Assessment of prostheses
  - ..... ☐
- Teaching
  - undergraduate..... ☐
  - postgraduate..... ☐
- Research
  - undergraduate..... ☐
  - postgraduate..... ☐
- Other: please state..... ☐
.....

15. If you use the system to assess gait / orthoses, please indicate which method you use to analyse the results: (Please tick all that apply)
- Eye ball position of ground reaction force in relation to a joint ..... ☐
- Calculate moment / moment arm about a joint..... ☐
- Other: please state..... ☐

16. If you use either of the 'eye-balling' or calculation of moment / moment arm methods, which joints do you assess? (Please tick all that apply)
- Hip..... ☐
- Knee..... ☐
- Ankle..... ☐

17. If you calculate the moments / moments arms, please indicate which method you use to calculate these: (please tick)
- Computer generated ..... ☐
- Manual..... ☐

18. When using your chosen method of assessment, which part of the gait cycle do you assess? (Please tick all that apply)
- Whole of stance phase..... ☐
- Part of the stance phase only: please state:..... ☐
- Other: please state..... ☐

19. Which planes do you assess with your vector system? (Please tick all that apply)
- Saggital..... ☐
- Coronal..... ☐

20. If used for orthotic assessment, how long, on average, does an assessment session take per patient? (Please tick)
- 0 - 30 mins..... ☐
- 31 - 60 mins..... ☐
- 61 - 90 mins..... ☐
- Longer..... ☐
- Not used for orthotic assessment ..... ☐

21. How often do you use the system? (Please tick)
- 3+ days a week ..... ☐
- 1-2 days a week..... ☐
- Fortnightly ..... ☐
- Monthly ..... ☐
- Less often ..... ☐

22. How often do you check the alignment of the system? (Please tick)
- Before every session ..... ☐
- Once a week (if used more often)..... ☐
- Once a month (if used more often)..... ☐
- Less often..... ☐



23. Please give a brief description of how you check the alignment of your system: (please feel free to enclose your local protocol if appropriate)

.....
.....
.....
.....
.....

24. What equipment do you use for the vector system? (Please tick one for each section, and give details where requested)

a) Force plate (make):
- AMTI..... ☐
- Kistler..... ☐
- Bertec..... ☐
- Other..... ☐

b) Vector generator:
- Own software programme..... ☐
- Using motion analysis system..... ☐
  - If so, which.....
- Commercial system..... ☐
  - If so, which.....
- Other: please state:..... ☐
  - .....

c) Method of overlaying vector and video image:
- Coriogen Eclipse adaptor..... ☐
- Commercial system as above..... ☐
- Within own software..... ☐
- Other: please state:..... ☐
  - .....

Section D: Outcome measures:

25. Do you use any outcome measures in gait analysis? (Please tick all that apply)
- Energy cost measures..... ☐ Please go to Q26.
- Gross Motor Function Measure..... ☐
- Observational gait scales..... ☐ } Please go to comments.
- Other: please state..... ☐
  - .....

26. What do you use your energy cost measures for? (Please tick all that apply)
- in the assessment of orthoses .... ☐
- in the assessment of gait ..... ☐
- for any other purpose (state) ..... ☐
  - .....

27. Which measure/s do you use? (Please tick all that apply)
- PCI ..... ☐ (Physiological Cost Index)[i]
- THBI ..... ☐ (Total Heart Beat Index)[ii]
- Cosmed (state model)..... ☐
- Douglas Bag ..... ☐
- Other: please state..... ☐
  - .....
  - .....

Any additional comments about your system / service:

.....
.....
.....
.....
.....
.....
.....
.....

THANK YOU VERY MUCH FOR YOUR TIME

Please return the questionnaire in the envelope provided.

---

[i] Physiological Cost Index = $\frac{\text{mean walking heart rate – mean resting heart rate}}{\text{speed}}$

(Macgregor, J. (1981) *The Evaluation of Patient Performance using Long-term Ambulatory Monitoring Technique in the Domiciliary Environment.* Physiotherapy, 67(2), 30-33)

[ii] Total Heart Beat Index = $\frac{\text{total number of heart beats during walking}}{\text{total distance walked}}$

(Hood, V. et al (2002) *A new method of using heart rate to represent energy expenditure: The Total Heart Beat Index.* Arch Phys Med Rehab, 83 (9), 1266-1273)

APPENDIX 3: PAPERWORK FOR STUDY TWO

Study Two: Validity and Reliability of the Clinical Trial Outcome Measures

Ethical Approval

Participant Information Leaflet

Consent Form

Data Sheet

Ethical Approval

Ethical approval for this study, protocol reference D/1/2003, was provided by Professor R Spiller, Chairman of the Nottingham University Medical School Ethics Committee on 29.01.2003.
Further confirmation can be provided upon request.

Participant Information Leaflet

University of Nottingham
Division of Physiotherapy Education
Clinical Sciences Building
City Hospital Campus
Nottingham
NG5 1PB

Title of Project:
The orthotic (splint) management of children with cerebral palsy - Phase 1.

Name of Investigator:
Helen Evans

Healthy Volunteer's Information Sheet

Invitation paragraph

You have been invited to take part in a research study. Before you decide whether to take part 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 friends and relatives if you wish to. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part or not. If you decide to take part you may keep this leaflet. Thank you for reading this.

Background

Children with cerebral palsy often need to wear special splints on their legs to help them walk. The aim of the overall study is to investigate a method of being able to ensure that the splints are made as accurately as possible for each child, and then to investigate the effect this has on their energy cost of walking.

In order to research the above ideas, it is necessary to investigate the assessment tools in more detail to make sure that the procedure is feasible, and is fully defined before starting the clinical trial.

The overall research uses a new piece of equipment to assess the effect of the splints, and therefore research needs to investigate the best way of using it in normal subjects before assessing those with cerebral palsy. Furthermore it is necessary for this protocol to measure the energy cost of walking, which involves taking readings of your heart rate while you walk.

What does the study involve?

This study will be ongoing for 1 year, but you will only be required to attend on two days (twice on each day). Each session should last no longer than 1 hour, one will be in the morning and the second on the same afternoon. The second day will take place exactly one week after the first, and has the same format as the first day (i.e. testing am and pm).

1. At the first visit you will have 6 small markers taped onto your hips, knees and ankles, whilst wearing shorts and a t-shirt. You will be asked to walk along a walkway and over a

force plate whilst being recorded on video. This will be repeated until 3 clear readings have been taken from either leg.

2. You will then be asked to wear a heart rate monitor, comprising of a chest strap and wrist watch. You will rest for 10 minutes, until a stable resting heart rate is obtained.
3. You will then walk around the room in a circuit, at your own pace, for 5 minutes, whilst your heart rate and walking speed are monitored.
4. You will then rest for at least 5 minutes, until your resting heart rate is achieved (± 5 beats).
5. You are then free until the afternoon when the whole procedure will be repeated.
6. One week later the same process will occur with the readings taken in the morning and then in the afternoon as before.

Therefore you will only be required to walk around the room with either small markers sticky taped onto your legs, or a heart rate monitor attached on four occasions, on two separate days. You will not be asked to attend any further times.

This information will provide details of your normal walking pattern, which are required for development of the assessment, and of your heart rate while you rest and walk, which will allow calculation of the energy cost of walking.

Why have you been chosen?

You have been chosen as a normal healthy adult who has no problems with their walking. There will be a total of 10 subjects taking part in this pilot study.

Do you have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.

What do I have to do?

You are asked not to have eaten in the two hours prior to the assessment, or to have done any strenuous exercise within that time, but are not bound by any other limitations.

What are the side effects of any treatment or procedures received when taking part?

As there are no treatments being applied to you during the assessment there are no side effects of taking part. You are simply asked to walk around a room.
The only possible side effect may be an allergic reaction to the adhesive tape used, but this is very unlikely, and is short lived.

What are the possible disadvantages and risks of taking part?

There are no risks or disadvantages of taking part in this study.

Please inform the investigator if you have any of the following, as they may mean you are not suitable to take part:

Any problems with your walking
A history of neurological problems
Inability to walk for 5 minutes at a time.
Any surgery to the lower limbs during the last 6 months
Cerebral Palsy
A history of clubfoot at birth.
Allergy to adhesive tape.

What if something goes wrong?
The risk of anything going wrong is extremely small, as you are not required to perform any task that is unusual to your daily routine, and you are not being asked to take any medication.

If you wish to make a complaint about your treatment during this study please contact Helen Evans on 0115 8404894 / 80. If this route fails to satisfactorily resolve your issues, please then contact the Ethics Office via the following address:
Mrs Louise Sabir,
Ethics Committee Secretary,
The Dean's Office, B Floor,
Medical School,
Queen's Medical Centre,
Nottingham NG7 2UH

Will my taking part in this study be kept confidential?
All information which is collected about you during the course of the research is required for the study, and will be kept on a password protected database and is strictly confidential. Any information about you which leaves the research unit will have your name and address removed so that you cannot be recognised from it.

What will happen to the results of the research study?
The results will be published in the final write up of the study and may be published in peer-reviewed medical journals or presented at conferences. In any report / publication / presentation all means of identification of each individual will be removed, and all results will remain completely anonymous.
If you are interested you may ask to receive a copy of the final results upon completion.

Who is organising and funding the research?
No funding is required for this pilot study, and the lead investigator is organising the research.

Who has reviewed the study?
This study has been reviewed and approved by the University of Nottingham Medical School Ethics Committee.

Contact for Further Information
For further information please contact Mrs Helen Evans, Research Physiotherapist, on 0115 8404894 / 4880, or Dr Gareth Noble, Research Supervisor, on 0115 8404889 / 4880.

Thank you for considering taking part in this project.

You can keep this information sheet, and will be given a copy of the signed consent form if you agree to take part.

Faculty of Medicine & Health Sciences
Version 2: 21/01/2003

Consent Form

University of Nottingham,
Division of Physiotherapy Education

Title of Project: The orthotic (splint) management of children with cerebral palsy -Phase 1.

Name of Investigators: Helen Evans

Healthy Volunteer's Consent Form

Please read this form and sign it once the above named or their designated representative, has explained fully the aims and procedures of the study to you

- I voluntarily agree to take part in this study.
- I confirm that I have been given a full explanation by the above named and that I have read and understand the information sheet given to me which is attached.
- I have been given the opportunity to ask questions and discuss the study with one of the above investigators or their deputies on all aspects of the study and have understood the advice and information given as a result.
- I agree to comply with the reasonable instructions of the supervising investigator and will notify her immediately of any unexpected unusual symptoms or deterioration of health.
- I authorise the investigators to disclose the results of my participation in the study but not my name.
- I understand that information about me recorded during the study will be kept in a secure database. If data is transferred to others it will be made anonymous. Data will be kept for 7 years after the results of this study have been published.
- I understand that I can ask for further instructions or explanations at any time.
- I understand that I am free to withdraw from the study at any time, without having to give a reason for withdrawing.
- I confirm that I have disclosed relevant medical information before the study.
- I have not been a subject in any other research study in the last three months which involved : taking a drug; being paid a disturbance allowance; having an invasive procedure (eg venepuncture >50ml, endoscopy) or exposure to ionising radiation.

Faculty of Medicine & Health Sciences
28/11/2002

- I confirm that I have read the exclusion criteria detailed in the information leaflet and that none of them apply to me.

Name: ……

Address: ……..

Telephone number: ……

Signature: …… **Date:** ……..

I confirm that I have fully explained the purpose of the study and what is involved to:

……

I have given the above named a copy of this form together with the information sheet.

Investigators Signature: …….. **Name**: ……

Study Volunteer Number: ……..

Faculty of Medicine & Health Sciences
28/11/2002

Data Sheet

Phase I – Pilot study.

DATA SUMMARY SHEET.

Room temp:

Subject No:	A	DOB:	
Height:		Weight:	
Leg length: L		Shank length: L	
R		R	
Mean LL:		Mean SL:	
Visit:	1st am:A	1st pm:B	
(date / time)	2nd am:C	2nd pm:D	

VECTOR:					COMMENTS:
A		V	1		
A		V	2		
A		V	3		
A		V	4		
A		V	5		
A		V	6		
A		V	7		
A		V	8		
A		V	9		
A		V	10		

CODA:					COMMENTS:
A		C	1		
A		C	2		
A		C	3		
A		C	4		
A		C	5		
A		C	6		
A		C	7		
A		C	8		
A		C	9		
A		C	10		

HEART RATE:			
RHR: pre		RHR: post	
		(time if >5')	
LAP TIME: 1		41	
2		42	
3		43	
4		44	
5		45	
6		46	
7		47	
8		48	
9		49	
10		50	
11		51	
12		52	
13		53	
14		54	
15		55	
16		56	
17		57	
18		58	
19		59	
20		60	
21		61	
22		62	
23		63	
24		64	
25		65	
26		66	
27		67	
28		68	
29		69	
30		70	
31		71	
32		72	
33		73	
34		74	
35		75	
36		76	
37		77	
38		78	
39		79	
40		80	

Total dist:
Mean speed:

APPENDIX 4: PAPERWORK FOR STUDY THREE

Study Three: Pilot Clinical Trial

Ethical Approval

Paperwork for Reference Group data collection:

- Participant Information Leaflet: children and young people aged 11-15 years
- Consent form: parent and children / young people aged 7-15 years
- Data Collection Proforma

Paperwork for CP group data collection:

- Participant Information Leaflet: children and young people aged 11-15 years
- Consent form: parent and children / young people aged 7-15 years
- Data Collection Sheet
- Clinical Examination Form
- Modified Ashworth Scale
- Subject History and Orthotic Form
- Interview Schedule – child / young person
- Interview Schedule – parent

Ethical Approval

Ethical approval for this study, protocol reference 09/H0401/76, was provided by Mr P Hopkinson, Chairman of the National Research Ethics Service – Derbyshire Research Ethics Committee on 30.11.2009.
Further confirmation can be provided upon request.

Study Paperwork for Reference Group

Participant Information Leaflet: children and young people aged 11-15 years

Further information leaflets were designed for children aged 7-10 years, young people aged 16years and for parents. Leaflet content was based on the following but language was adapted for age accordingly. These are not included here but are available on request.

Derby Hospitals NHS
NHS Foundation Trust

The University of Nottingham

STUDY INFORMATION LEAFLET –
For children and young people without walking problems.

Researchers: Mrs Helen Evans, Dr Lorraine Pinnington.
Study Title: A single-centre pilot study into the effect of fine-tuning orthoses on the energy cost of walking in children with Cerebral Palsy.

Introduction

You are being invited to take part in a project. This leaflet tells you all about the project and what you are being asked to do. You must read it all carefully before you decide if you are happy to take part. Please ask any questions you have about what you have read, and everything will be explained to you.

What is the project about?



Cerebral Palsy is a condition that can affect the way that someone can walk. It can also mean that children and young people with Cerebral Palsy use more energy to walk. They might have to wear plastic splints on their legs (like the one in the picture), to improve their walking pattern or reduce the amount of energy they use to walk. We want to look at a way of making sure that these splints are designed and fitted as best they can be, so that we can improve children's walking problems as much as possible. We are looking at two things in this project:

1) the collection of reference information from children and young people without walking problems.
2) assessment of walking in children and young people who do have walking problems to see if wearing splints helps or not

Why are we asking you to take part?

You can take part because **you don't have any walking problems**. The information we are using to tell if we have improved children's walking problems has not been collected before. Therefore we need to see children and young people without walking problems first so that we have a set of information to compare with. We need to measure two things about your walking, so that we can tell if we have made the other children's walking as easy as yours or not.

What will you have to do?

You will come to our Gait Laboratory at the hospital where we see people who have walking problems. The physiotherapist will examine your legs and take some measurements when you arrive.

We would then like to measure two different aspects of your walking. First we would like to film you walking up and down the room so that we can take some measurements from the video that we need. We will take these measurements from the recording after you have gone. We would like you to wear some shorts while you are doing this so we can see your legs.

Next we will ask you to wear a heart rate monitor around your chest (under your clothes) so that we can measure your heart rate while you walk. You will be asked to sit still for a few minutes, and then walk around a track marked on the floor for 5 minutes. We are measuring how hard your heart is working while you walk which will allow us to calculate the energy you use to walk. We need to ask you not to eat a big meal, or drink tea, coffee, coke or any energy drinks in the two hours before you come in, as they may affect your heart rate reading.

Then you are finished and can go home. We are asking you to attend the clinic for one visit only. We will use this information when we see children and young people who do have walking problems.

Will it hurt?

No, none of the things we will ask you to do will hurt. You just have to walk in our room twice while we monitor you. If you are not sure about anything you can ask and we will explain it to you, or we can show you what to do.

What do you get out of doing this?

This project doesn't help you, because you don't have any walking problems, but we hope it will help other people who can't walk as well as you. We can use your information to try and improve their walking as much as possible.

When do you have to do this?

We will speak to your parents and arrange a time that is good for you to come in and see us. If you are 15 years old, and **both you and your parents are happy**, then we don't mind you coming on your own or with someone else if that is easier to arrange. We will need to speak to your parents first though and discuss it with them. We would also need to send a form home for them to sign that they are happy for you to take part in the study, which you would need to bring with you.

If you decide that you would like to help with this project then tell your Mum or Dad and they will let us know. If you don't want to take part then it doesn't matter, again just tell your Mum or Dad.

Consent Form: Parent and child / young person aged 7-15 years.

A separate consent form was produced for young people aged 16 years who could consent for themselves. This is available on request.

The University of Nottingham

Derby Hospitals NHS
NHS Foundation Trust

CONSENT / ASSENT FORM -
Parent and child / young person without walking problems (aged 7-15 years)
(Version 1.2: 06-11-2009)

Title of Study: A single-centre pilot study into the effect of fine-tuning orthoses on the energy cost of walking in children with Cerebral Palsy.

REC ref: 09/H0401/76 **Name of Researcher:** Helen Evans

Unique Study Identifier:

Please initial box

1. I confirm that I have read and understand the information sheet version number 1.6 dated 06-11-2009 for the above study and have had the opportunity to ask questions. ☐

2. I understand that my child's participation is voluntary and that we are free to withdraw at any time, without giving any reason, and without their medical care or legal rights being affected. I understand that should we withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐

3. I understand that relevant sections of the data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my child's taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my child's participation in this study. I understand that their personal details will be kept confidential. ☐

4. I agree to images of my child's leg/s to be used for illustration purposes in the write-up of the study results (for the thesis as well as journal publication and conference presentation) (**Optional**). ☐

5. I agree to allow my child to take part in the above study. ☐

_____
Name of child

_____ _____ _____
Name of Parent / legal guardian Date Signature

_____ _____ _____
Name of Principal Investigator Date Signature

Child's assent:

1. I have read, or someone has read to me, the information leaflet about the study (version 1.6, 06-11-2009), and I understand what will happen to me in the study.
2. I am happy to take part in the study, but know I can stop doing the study if I want to at any time, without having to say why.

Child's signature: _____
Write your name here

2 copies: 1 for parent, 1 for the project notes

Data Collection Proforma

Clinical examination screening form -
comparison group participants.

Study ID: **Initials and d.o.b:**	**Date:**	**Examined by:**
KNEE	**LEFT**	**RIGHT**
Extension		
Dundee Angle (hip 45°)		
ANKLE		
Dorsiflexion, knee 0°		
Leg length (cm)		
Shank length (cm)		
Height (m)		
Weight (Kg)		

Comments:

Inclusions:

- *Aged 7-16*
- *Able to walk independently for 5 mins*

Exclusions:

- *LL surgery / injury in past year*
- *Any medication affecting heart rate*
- *Inability to comply with instructions*
- *History of orthopaedic, neurological or vascular disease affecting gait*
- *LLD of >1cm*
- *FFD knee >10°, or Dundee angle of >10°*
- *Calf tightness (<0° with knee ext)*
- *Abnormal gait – toe strike, toe drag, knee hyperextension..)*
- *Inability to understand English*

Vector passes

File name	Pass	Comments
RG _a	1	
	2	
	3	
	4	
	5	
	6	
	7	
	8	
	9	

Laps:

Paperwork for CP Group Data Collection

Participant Information Leaflet: children and young people aged 11-15 years.

Leaflets were also designed for children aged 7-10 years, young people aged 16 years and for parents. Language and text were amended from this leaflet accordingly. These are available on request.

Derby Hospitals NHS
NHS Foundation Trust

The University of Nottingham

STUDY INFORMATION LEAFLET –
For Children and Young People with Cerebral Palsy.

Researchers: Mrs Helen Evans, Dr Lorraine Pinnington
Study Title: A single-centre pilot study into the effect of fine-tuning orthoses on the energy cost of walking in children with Cerebral Palsy.

Introduction

You are being invited to take part in a project. This leaflet tells you all about the project and what you are being asked to do. You must read it all carefully before you decide if you are happy to take part. Please ask any questions you have about what you have read, and everything will be explained to you.

What is the project about?



Many children and young people with Cerebral Palsy, like you, have to wear splints on your legs to help you walk. We are looking at a way of making sure that your splints are designed and fitted as best as they can be, so that they fit you well, and make your walking as easy as possible. We then want to see if this then reduces the amount of energy you use to walk. To do these we are going to see lots of children and young people like you, try to fit all of your splints as well as possible, and then see if that has helped to make your walking easier or not.

Why have we asked you to take part?

You have been chosen because you wear splints and can walk by yourself. We want to see if we can make your splints just right, and then see if that has made your walking easier for you. We are seeing lots of children and young people like you.

What will you have to do?

You will come to our Gait Laboratory where we see people who have walking problems like yourself. The physiotherapist will have a quick look at your legs to see how well they move and how strong they are.

We will then ask you to do two lots of walking in our room while we measure different things. First we would like you to walk up and down the room while we video you walking. You will do this in your bare feet, and then with your splints and shoes on. We would like you to wear some shorts while you are doing this so we can see your legs. This is no different from what we will do in your assessment anyway to make sure your splints are fitted right. We will look closely at the video while you are there, to see if your splints need any changes to them or not.

Next we will ask you to wear a heart rate monitor around your chest (under your clothes) so that we can measure your heart rate while you walk. You will be asked to sit still for a few minutes, and then walk around a track marked on the floor for up to 5 minutes. We are measuring how hard you heart is working while you walk to allow us to calculate the energy you use when you walk with and without your splints on. We will do this in your bare feet and again with your splints and shoes on.

We need to ask you not to eat a big meal, or drink tea, coffee, coke or any energy drinks in the two hours before you come in, as they may affect your heart rate reading.

Whilst you are having a rest we will look at the videos we have taken and decide if we need to make any changes to your splints. We may ask you to walk again in your splints if we have made any changes. You are then finished and can go home.

We will then decide if we need to do anything to your splints to make them better, just like sometimes happens when you see your physiotherapist or orthotist. Once we have made these changes to your splints, we will ask you to come back and do the same thing again – walk while we video you and again while we record your heart rate. Then you are finished in the study and don't need to come back. We will work out whether making small changes to your splints has reduced the amount of energy you use to walk or not.

Will it hurt?

No, none of the things we will ask you to do will hurt. You just have to walk in our room while we video you walking and record your heart rate. If you are not sure about anything you can tell us and we will explain it to you, or we can show you what to do.

What happens next?

You can go home and don't need to come back to see us. You will wear your splints just like you normally do, and your physiotherapist will see you as usual and will keep an eye on your splints.

What do you get out of doing this?

We want to see if making these little changes to your splints makes your walking even easier, so you can do more things. If we find this works, we will know how to make sure that everyone's splints are just right for them too.

When do you have to do this?

We will collect all of this information when you come for your walking assessment, **if you would like to take part**. The only different thing in taking part in the study

will be walking whilst we listen to your heart beating. Taking part in the project, or not taking part in the project will not change how we look after you and your splints. We will speak to your parents and arrange a time that is good for you to come in and see us.

If you would like to take part in this project just tell your Mum or Dad and they can let us know when they book your appointment.

If you don't want to take part in this project it doesn't matter, just tell your Mum or Dad and they can tell us. We still need to see you to have a look at your splints, but we won't use your information for the project.

Consent form: parents and children / young people aged 7-15 years

A separate form was designed for 16 year olds who could consent for themselves.

The University of Nottingham

Derby Hospitals NHS
NHS Foundation Trust

CONSENT / ASSENT FORM –
Parent and child / young person with Cerebral Palsy (aged 7-15 years)
(Version 1.2: 06-11-2009)

Title of Study: A single-centre pilot study into the effect of fine-tuning orthoses on the energy cost of walking in children with Cerebral Palsy.

REC ref: 09/H0401/76 **Name of Researcher**: Helen Evans

Unique Study Identifier:

Please initial box

1. I confirm that I have read and understand the information sheet version number 1.6 dated 06-11-2009 for the above study and have had the opportunity to ask questions. ☐

2. I understand that my child's participation is voluntary and that we are free to withdraw at any time, without giving any reason, and without their medical care or legal rights being affected. I understand that should we withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐

3. I understand that relevant sections of my child's medical notes and data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my child's taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my child's participation in this study. I understand that my child's personal details will be kept confidential. ☐

4. I agree to images of my child's leg/s to be used for illustration purposes in the write-up of the study results (for the thesis as well as journal publication and conference presentation) (**Optional**). ☐

5. I agree to allow my child to take part in the above study. ☐

_____
Name of child

_____ _____ _____
Name of Parent / legal guardian Date Signature

_____ _____ _____
Name of Principal Investigator Date Signature

Child's assent:

1. I have read, or someone has read to me, the information leaflet about the study (version 1.6, 06-11-2009), and I understand what will happen to me in the study.
2. I am happy to take part in the study, but know I can stop doing the study if I want to at any time, without having to say why.

Child's signature: _____
Write your name here

3 copies: 1 for parent, 1 for the project notes and 1 for any medical notes available

Data Collection Sheet

Data collection sheet.

ID:							
Date of first visit: **Date of second visit:**							
BAREFOOT A:		**LEFT**			**RIGHT**		
		1	**2**	**3**	**1**	**2**	**3**
Midstance moment arm[a]							
Midstance shank length[b]							
Moment arm ratio							
Foot fall (HS, FF, TS)							
Energy cost	Distance[c]						
	Total HB's						
	THBI[d]						

UNTUNED:		**LEFT**			**RIGHT**		
		1	**2**	**3**	**1**	**2**	**3**
Midstance moment arm[a]							
Midstance shank length[b]							
Moment arm ratio							
Foot fall (HS, FF, TS)							
Energy cost	Distance[c]						
	Total HB's						
	THBI[d]						

Comments:

[a] Measured in mm
[b] Measured in mm
[c] Measured in m
[d] Measured in beats / metre

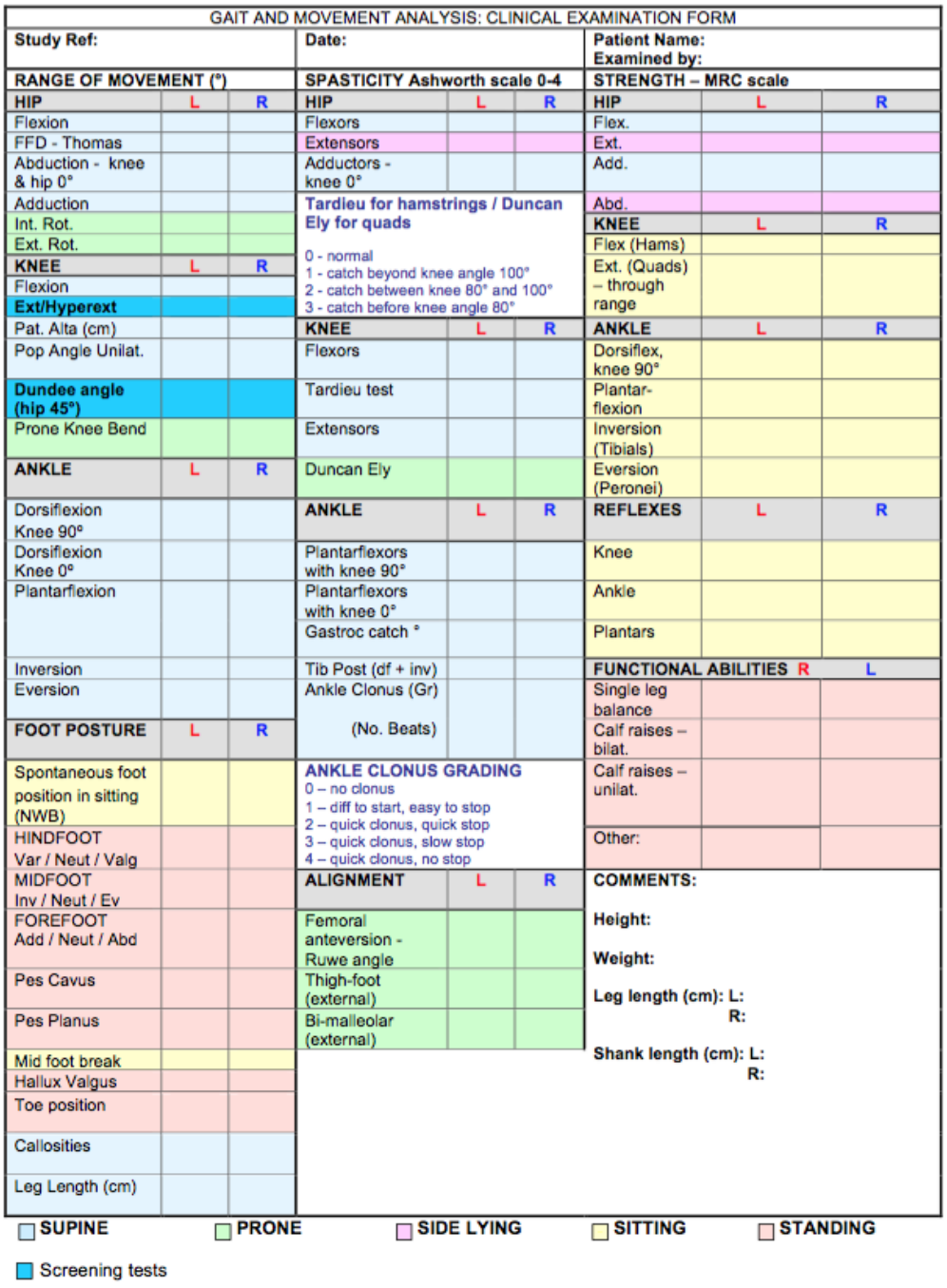
BAREFOOT B:		LEFT			RIGHT		
		1	2	3	1	2	3
Midstance moment arm[a]							
Midstance shank length[b]							
Moment arm ratio							
Foot fall (HS, FF, TS)							
Energy cost	Distance[c]						
	Total HB's						
	THBI[d]						

TUNED:		LEFT			RIGHT		
		1	2	3	1	2	3
Midstance moment arm[a]							
Midstance shank length[b]							
Moment arm ratio							
Foot fall (HS, FF, TS)							
Energy cost	Distance[c]						
	Total HB's						
	THBI[d]						

Comments:

[a] Measured in mm
[b] Measured in mm
[c] Measured in m
[d] Measured in beats / metre

Clinical Examination Form



GAIT AND MOVEMENT ANALYSIS: CLINICAL EXAMINATION FORM

Study Ref:			Date:			Patient Name: Examined by:		
RANGE OF MOVEMENT (°)			**SPASTICITY Ashworth scale 0-4**			**STRENGTH – MRC scale**		
HIP	**L**	**R**	**HIP**	**L**	**R**	**HIP**	**L**	**R**
Flexion			Flexors			Flex.		
FFD - Thomas			Extensors			Ext.		
Abduction - knee & hip 0°			Adductors - knee 0°			Add.		
Adduction			**Tardieu for hamstrings / Duncan Ely for quads**			Abd.		
Int. Rot.						**KNEE**	**L**	**R**
Ext. Rot.			0 - normal			Flex (Hams)		
KNEE	**L**	**R**	1 - catch beyond knee angle 100°			Ext. (Quads) – through range		
Flexion			2 - catch between knee 80° and 100°					
Ext/Hyperext			3 - catch before knee angle 80°					
Pat. Alta (cm)			**KNEE**	**L**	**R**	**ANKLE**	**L**	**R**
Pop Angle Unilat.			Flexors			Dorsiflex, knee 90°		
Dundee angle (hip 45°)			Tardieu test			Plantar-flexion		
Prone Knee Bend			Extensors			Inversion (Tibials)		
ANKLE	**L**	**R**	Duncan Ely			Eversion (Peronei)		
Dorsiflexion Knee 90°			**ANKLE**	**L**	**R**	**REFLEXES**	**L**	**R**
Dorsiflexion Knee 0°			Plantarflexors with knee 90°			Knee		
Plantarflexion			Plantarflexors with knee 0°			Ankle		
			Gastroc catch °			Plantars		
Inversion			Tib Post (df + inv)			**FUNCTIONAL ABILITIES**	**R**	**L**
Eversion			Ankle Clonus (Gr)			Single leg balance		
FOOT POSTURE	**L**	**R**	(No. Beats)			Calf raises – bilat.		
Spontaneous foot position in sitting (NWB)			**ANKLE CLONUS GRADING**			Calf raises – unilat.		
			0 – no clonus					
HINDFOOT Var / Neut / Valg			1 – diff to start, easy to stop			Other:		
MIDFOOT Inv / Neut / Ev			2 – quick clonus, quick stop			**COMMENTS:**		
FOREFOOT Add / Neut / Abd			3 – quick clonus, slow stop			**Height:**		
Pes Cavus			4 – quick clonus, no stop			**Weight:**		
Pes Planus			**ALIGNMENT**	**L**	**R**	**Leg length (cm): L:**		
Mid foot break			Femoral anteversion - Ruwe angle			**R:**		
Hallux Valgus			Thigh-foot (external)			**Shank length (cm): L:**		
Toe position			Bi-malleolar (external)			**R:**		
Callosities								
Leg Length (cm)								

SUPINE **PRONE** **SIDE LYING** **SITTING** **STANDING**

Screening tests

Modified Ashworth Scale

Reference: [212]

0: No increase in muscle tone
1: Slight increase in muscle tone, manifested by a catch and release or by minimal resistance at the end of the range of motion when the affected part(s) is moved in flexion or extension
1+: Slight increase in muscle tone, manifested by a catch, followed by minimal resistance throughout the remainder (less than half) of the ROM
2: More marked increase in muscle tone through most of the ROM, but affected part(s) easily moved
3: Considerable increase in muscle tone, passive movement difficult
4: Affected part(s) rigid in flexion or extension

Subject History and Orthotic Form

Subject Data Sheet

Study ID:				
Diagnosis:	**GMFCS: Level**			
Physiotherapist name & contact details:			**1st**	**2nd**
Physiotherapy input per week (approximate, in hours)		**HEP**		
		Therapist		
		School		
Orthotic Use: (hours per day)	**Session 1:**	**Session 2:**		
History:				
Birth details:				
Developmt hx:				
Orthotic hx:				
Surgical hx:				
Medical hx:				
Other hx:				

Changes during study:		
Date:	Detail:	Signature:

Orthotic details:

CURRENT prescription	LEFT	RIGHT
Type		
AAAFO[a]		
Trim lines		
Other features		
Wedging details		
SAFAFO[b]		
Footwear type		
Footwear HSD[c]		
Overall SAFAFOFWC[d]		
Other info (sole profile ...)		

FINAL prescription		
Type		
AAAFO[a]		
Trim lines		
Other features		
Wedging details		
SAFAFO[b]		
Footwear type		
Footwear HSD[c]		
Overall SAFAFOFWC[d]		
Other info (sole profile ...)		

[a] Angle of the ankle in the AFO
[b] Shank angle to floor of the AFO
[c] Heel-sole differential, measured below lateral malleolus and MTP joint on the lateral side of the shoe
[d] Shank angle to floor of the AFO-footwear combination

Interview Schedule – child / young person

Derby Hospitals NHS
NHS Foundation Trust

The University of Nottingham

INTERVIEW SCHEDULE – CHILD / YOUNG PERSON

Study Title: A single-centre pilot study into the effect of fine-tuning orthoses on the energy cost of walking in children with Cerebral Palsy.

We have made some changes to your splints after watching you walk in the gait lab when you were last here. We would like to ask you some questions about your different splints.

1) For each of the following aspects of your walking, can you tell me whether it is better in your new splints, or your original ones?

Aspect of walking	New splint/s	Original splint/s	No difference between splints
a) which splints are the most comfortable to wear?			
b) in which splints can you stand up the straightest?			
c) in which splints can get your heels down on the floor the best?			
d) in which splints can you walk the furthest?			
e) which splints are easier to walk in?			

Comments:

2) Which splints do you prefer – the original ones, or the new ones? Why?

Is there anything else you would like to tell us about your splints? (new or old ones)

Thank you for your answers, it will help us to see if making changes helps your walking or not, as well as other children and young people like you.

Interview Schedule – Parent

Derby Hospitals NHS
NHS Foundation Trust

The University of Nottingham

INTERVIEW SCHEDULE - PARENT

Study Title: A single-centre pilot study into the effect of fine-tuning orthoses on the energy cost of walking in children with Cerebral Palsy.

Your child has had his/her splints assessed and adjusted within the gait and movement laboratory, and they are also taking part in the above study. We would like to ask you about any differences you have noticed in their walking following this process.

1) Considering the following different aspects of your child's walking, please tick the box indicating which splints you think they are better in:

Aspect of walking	New splint/s	Original splint/s	No difference between splints
a) which splints are the most comfortable for them to wear?			
b) in which splints can they stand up the straightest?			
c) in which splints can they get their heels down on the floor the best?			
d) in which splints can they walk the furthest?			
e) which splints seem easier for them to walk in?			

Comments:

2) Has your child commented about the new splints at all? If so what have they said?

3) Which splints do you prefer – the original ones, or the new ones? And why?

Any other comments:

Many thanks for your feedback, it will help us to decide if the 'fine-tuning' process is useful for children with Cerebral Palsy.

APPENDIX 5: LITERATURE SEARCH STRATEGY

Summary of search strategy for orthotic literature review (section 6.3), using Ovid Search Tool.

Resources used:

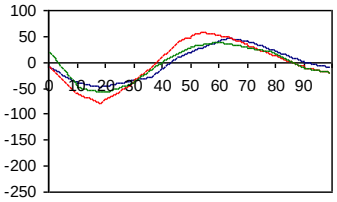
- AMED (Allied and Complementary Medicine) 1985 - June 2017
- Embase 1980-2017 Week 26
- Ovid MEDLINE (R) 1946-June Week 3 2017

Note that all searches were limited to those in the English Language and using Human subjects

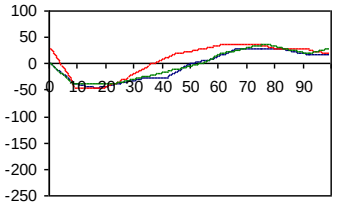
Number	Search term	No Titles	Abstracts reviewed	Articles fully reviewed
1	Child$.mp	3387458	-	
2	Orthos$.mp	53975	-	
3	Cerebral palsy.mp	47001	-	
4	1 and 2 and 3	778	-	
5	4, deduped	544	203	112
6	Video vector.mp	15	-	
7	6, deduped	10	10	10
8	Biomechanical optimisation.mp	4	4	1
9	Tuning.mp	17555	-	
10	9 and 2	75	-	
11	10, deduped	55	19	19
12	11 and 3	8	8	8
13	THBI.mp	45	-	
14	13, deduped	24	24	24
15	Walking.mp	136647	-	
16	15 and 14	6	6	6
17	Gait.mp	98551	-	
18	5 and 17	303	158	97
19	5 and 15	217	131	86

APPENDIX 6: MOMENT ARM DATA FOR REFERENCE GROUP

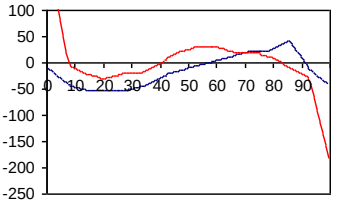
RG001



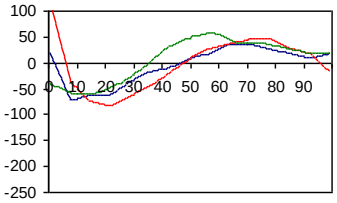
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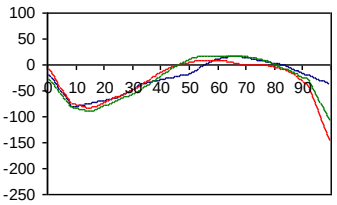
RG003



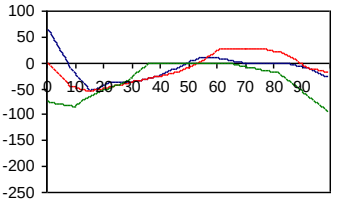
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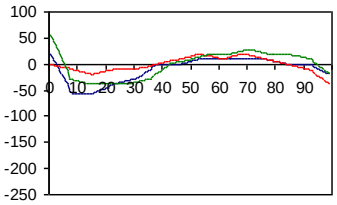
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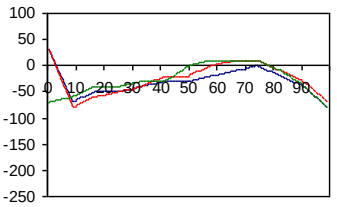
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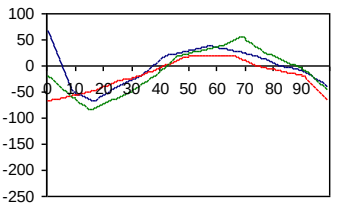
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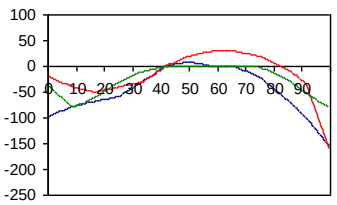
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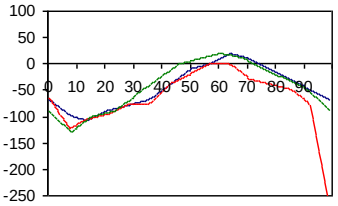
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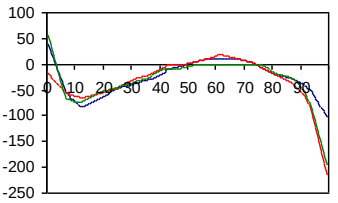
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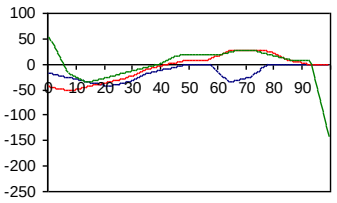
RG011



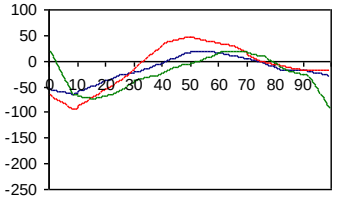
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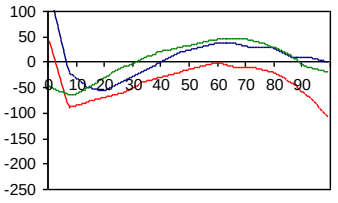
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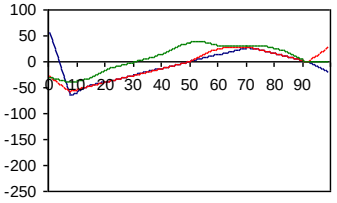
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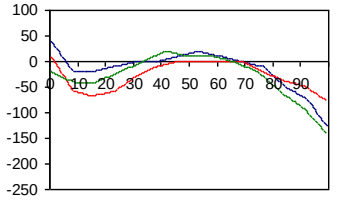
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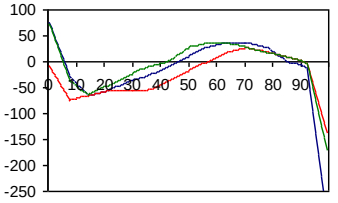
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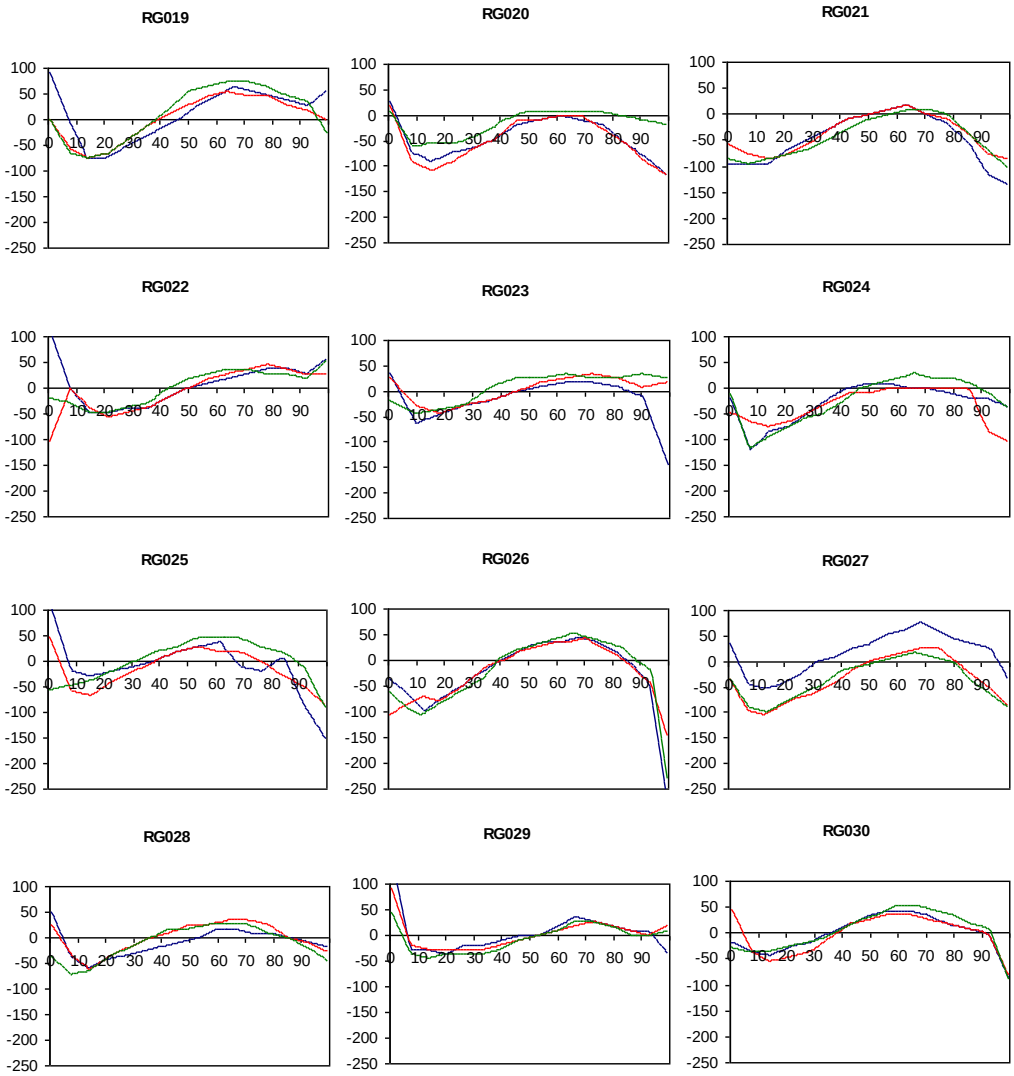


RG017



RG018





Note: RG = reference group (paediatric); y-axis denotes the moment arm in mm; x-axis denotes the percentage of the stance phase of the gait cycle; the colours represent each of the three cycles recorded.