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THE EFFECT OF WEDGE HEIGHT ON THE GAIT OF NORMAL SUBJECTS WEARING A SWIFT CAST

by

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Declaration

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

Signed:

Date

Acknowledgments

First of all, I would like to thank my supervisor Professor Philip Rowe for his guidance and advice throughout the duration of this project. More importantly I want to thank him for the help with the electronics involved in the design and his ongoing enthusiasm.

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Abstract

Regaining functional walking is one of the central rehabilitation goals for stroke patients. Ankle foot orthoses (AFOs) are regularly prescribed to help achieve this goal for stroke patients who have suffered from strokes or other neurological disorders with lower limb disabilities. When customising AFOs evidence suggests that tuning the orthosis to optimise the biomechanics of gait will improve the patient's overall gait pattern and rehabilitation. This tuning does not always occur and importantly, not always correctly, when prescribing an AFO.

This study designed a prototype active wedge device that would adjust the heel angle of a participant. The aim was to create a device that could be adjusted remotely and was simple to use so that in future it might advance clinical practice.

The active wedge device was created and tested on ten healthy participants to evaluate the device's ability to tune an AFO and hence alter the kinematics and kinetics of gait. Participants were asked to wear a soft scotch ankle foot cast to mirror the effect of an AFO. Four wedge angles were chosen for evaluation however the device had the capability to move between the angles 0° to 23°.

Motion analysis data suggested that the prototype successfully altered the gait kinematics and kinetics, specifically during mid-stance which is an important phase when clinically optimising the biomechanics. Future improvements are suggested as the active wedge device demonstrated great potential to improve to clinical practice.

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Chapter 1 Introduction

1.1 Background

Impaired balance control, a major problem for many stroke survivors, restricts and affects their mobility (Geurts et al. 2005) and the majority of stroke patients stress that walking is their top priority for rehabilitation (Chan et al. 1997). An ankle foot orthosis (AFO) is commonly prescribed to help improve gait abnormalities; the orthosis aims to position the foot in optimal alignment with the lower limb to restore more normal gait. Controversy around its effectiveness is noted in the literature: a review by Tyson & Kent (2013) demonstrated that more current research shows that an AFO improves balance and locomotion post stroke, but further research is required. Despite limited research the clinical recommendation is for early AFO use, with best results achieved with a customized AFO (Condie E et al. 2004).

Very few studies consider the optimal biomechanics of AFOs which are crucial for improving gait (Jagadamma et al. 2009). Biomechanical optimisation can be called “tuning” which was recognised initially in the mid-1970s (Cook & Cozzens 1976). The aim of tuning an AFO is to optimise the alignment of lower limbs to manipulate the ground reaction force (GRF) by using a variety of heel wedges, rockers, flares and AFO materials (Eddison & Chockalingam 2013). Specifically the addition of heel wedges have been found to alter the shank to vertical angle (SVA) which helps re-adjust the GRF with regard to the knee and hip joints, resulting in the potential to improve gait (Jagadamma et al. 2009).

Ankle foot orthoses are regularly considered and used in the treatment and rehabilitation of neurological disorders, principally those that have issues with limited ankle dorsiflexion in swing and at initial contact and with imbalance in during stance (Bregman et al. 2009). The purpose of an AFO for post stroke survivors is to enhance early rehabilitation and recovery by:

- Supporting, limiting or controlling the rotational moments of the ankle, knee and hip joints in stance and swing phase.
- Altering the heel strike and the alignments of the ground reaction forces.

In clinical practice these aims seem to be achieved as research illustrates that the use of AFOs can lead to improvements in spatiotemporal parameters of gait (Bregman et al. 2010; Franceschini et al. 2003; Pavlik 2008). On the other hand long term use is questioned based on a small volume of research (Papi 2012).

Current clinical practice is to make custom AFOs to fit the patients. The AFO is made normally from polypropylene by trained orthotists (Hsu et al. 2003). This can be time consuming and difficult for patients who have recently suffered a stroke. Often the NHS has a waiting list for this service therefore individuals do not obtain an AFO in the very early stages of rehabilitation but only after several weeks. Prefabricated “off the shelf” AFOs have limited, temporary use (Bowers & Ross 2010); these AFOs demonstrated improvement in walking ability for acute stroke sufferers but not for chronic stroke sufferers (Wang et al. 2005). Prefabricated orthoses are of limited value to post stroke patients.

Custom made AFOs are the most appropriate in stroke, however, there is great controversy surrounding the best fit or optimal biomechanics. Improving the biomechanics of an AFO will improve the biomechanics of the patient’s walking ability. Currently to carry out and understand biomechanical assessments requires multi-team collaboration which is not always achievable in different departments and hospitals.

A soft scotch ankle foot cast (SWIFT Cast) is an alternative to prefabricated AFOs and long term rigid AFOs. These SWIFT Casts are very adaptable to each individual patient’s need. Pomeroy et al. (2012) gives four advantages of the SWIFT Cast:

- There is reduced risk of unwanted pain and fatigue of the lower limb or of redness due to pressure and rubbing.
- Cost effective, much cheaper than a rigid device
- Can be made quickly by many people, not just orthotists
- Clinically more acceptable than a prefabricated AFO as it is custom made

1.2 Aim

The purpose of this study was to develop an active wedge device that could be used to improve the tuning process of AFOs. The aim was to evaluate and examine the prototype and consider the feasibility of altering a heel wedge remotely using software. A secondary aim was to determine the influence of increasing and decreasing the heel wedge on able-bodied subjects with a SWIFT Cast during gait on the knee joint kinematics and kinetics.

The device was linked to the gait analysis, assessment equipment so that it could be easily controlled and incorporated to a standard biomechanical assessment for the future. The idea behind the study was that the results gathered would add new information and techniques pertaining to AFO tuning and should be seen as a first step towards improving clinical practice towards optimal AFO design linked to the needs of each patient.

The AFO soft scotch ankle-foot cast (SWIFT Cast) was employed. It is currently being investigated as a temporary support cast that can be easily and quickly custom made so it can be fitted early, post stroke, potentially to see the best improvement in walking. The aim of this study was to investigate the feasibility of the method, not to comment on the SWIFT Cast effects on gait. However, this study and future research potentially might contribute to the ability to tune a SWIFT Cast, further improving and in turn leading to better SWIFT Cast prescription, decision making and matching of

SWIFT Cast properties to gait deviations of stroke patients. This new device also may have potential to assist in tuning SWIFT Casts for a variety of clinical requirements such as facilitating tuning of SWIFT Cast devices for children with cerebral palsy, who may not have the patience to persist in putting on and off the SWIFT Cast.

The overall aim of this project was to create an active wedge that was linked to the biomechanical assessment equipment with the purpose of improving clinical practice for tuning AFOs.

Chapter 2 Literature review

2.1 Introduction

The literature review intends to provide the reader with the relevant background information about why AFOs are required and the necessary need to improve their tuning capabilities. The current relevant published research will be summarized and presented.

2.2 Medical Conditions

Stroke is a significant, worldwide, public health issue which results in death and/or disability. The stroke rate is estimated to be around 152,000 per year in the UK alone (Townsend et al. 2012) with 1.1 million people suffering and in need of treatment. Scotland is renowned and known to have the highest prevalence rates compared to the rest of the UK (Townsend et al. 2012). Stroke is repeatedly reported to be the most common cause of complex disability (Adamson et al. 2004) and survivors can have a range of effects requiring treatment and rehabilitation. Hemiparesis (impaired motor control on one side) is the main characteristic of stroke, affecting 80% of patients (Intercollegiate Stroke Working Party 2012) and is suggested to be the single most disabling factor, undoubtedly in terms of reducing mobility. Lower limb hemiplegia causes: shorter step length; reduced velocity and asymmetric gait pattern (Hill et al. 1994; Waters & Mulroy 1999) which importantly restricts activities of daily life. Stroke survivors have reported that for them walking is the most important priority for rehabilitation (Chan et al. 1997) hence walking is one of the main goals in stroke rehabilitation.

Abnormal gait is also evident in children with a range of medical conditions, especially cerebral palsy (CP). The NHS estimates that 1 in 400 people in the UK is affected by CP. This neurodisability normally is apparent before the child is three years old and illustrates symptoms such as muscle spasticity or paralysis, muscle weakness, uncontrolled movements and balance

problems. Children with CP like hemiplegic stroke patients may achieve ambulation, however the efficiency of the gait is poor. Ankle foot orthoses for these conditions and others are commonly prescribed to help improve gait impairments.

2.3 Features of Normal Gait

Analysis of human locomotion involves a variety of characteristics; spatial and temporal parameters, joint kinematics and kinetics and muscle activity. Previous studies have investigated normal and pathological gait in children and adults (Inman et al. 1981; Perry & Davids 2010; Winter 2009). Bipedal locomotion has been portrayed as a neurobiomechanical action requiring coordination and complex interaction among major joints of the lower limbs (Nordin & Ranklin 2001). Normal gait is nearly symmetrical, with only small variances evident between the left and right side.

Gait is a cyclic activity which is often simplified for analysis to one cycle, ie from heel strike to heel strike (Onley 2005). Gait consists of two main phases; stance and swing. Stance phase, when the foot is in contact with the ground, is approximately 60% of the cycle and the swing phase, when the foot is no longer in contact with the ground, is approximately 40% (Nordin & Ranklin 2001). These two main phases are then divided into sub-phases and classification terminologies depend on what system is used to describe the events within the gait cycle, examples are the traditional or Rancho Los Amigos illustrated in Figure 2-1. Employing these terminologies means it is easier to understand and describe the gait cycle. These classifications describe the timing of gait events, but when using motion analysis (used often for tuning AFOs) an observational point in time is used for mid-stance rather than a percentage of total gait, so the traditional classification is used more regularly.

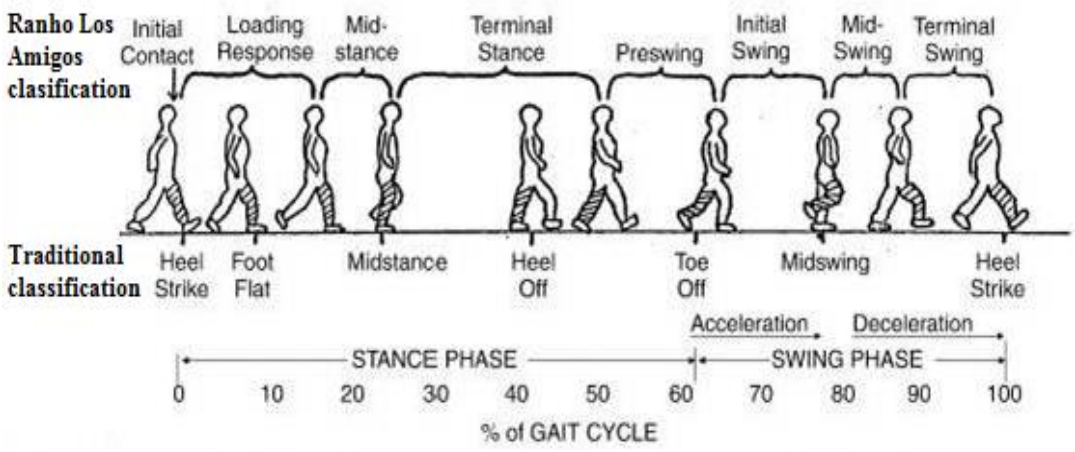

Figure 2- 1 the Traditional and Rango Los Amigos systems for classifying the sub-phases of gait. Adapted from (Whittle 2002)

2.3.1 Spatial and Temporal Parameters

There are many parameters that can be used to describe and analyse gait, the spatial and temporal parameters are most often described as they are considered clinically significant. In papers the most relevant and reported parameters are: cadence; walking speed; stride length; step width; single support time; double support; swing time and stance time. There is a range in the parameter values across literature; Kirtley (2006) suggests the wide variety is due to environmental influence on the participants.

2.3.2 Kinematic and kinetic data

When describing gait, joint kinematics and kinetics are key variables. These are of high interest in this study.

Kinematics describes the movement of gait disregarding the cause of the motion (Robertson 2004). Kinematic descriptions include: joint motion; displacement; velocity and acceleration of body segments. A variety of studies have investigated the range of joint motion in all three planes (Sutherland 2002). There are often differences in joint angles between individuals, however for healthy adults, the curve obtained from joint angle vs

time will be very similar shapes. Figure 2.2 illustrates the joint kinematics for normal healthy adults in sagittal, transverse and frontal planes.

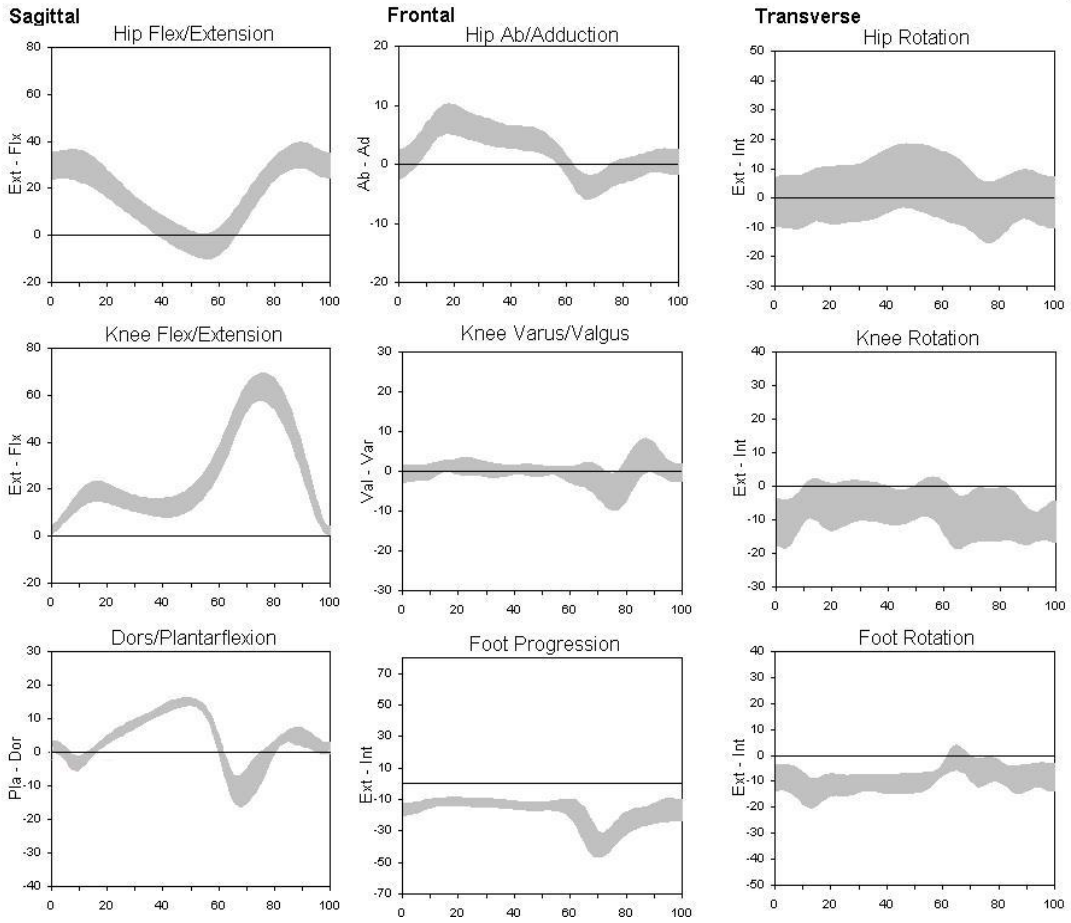

Figure 2- 2 Joint angles of the Healthy population. Adapted from Kirtley, (2014)

Kinetics describes the factors causing the movements, specifically the forces which produce moments and powers (Robertson 2004). During gait, forces are applied from the foot to the ground and the opposite (Onley 2005). The forces that are applied from the ground to the foot are called the Ground Reaction Force (GRF). This force is described with three components: vertical; anteroposterior and medioloateral. It is known that alignment of the ground reaction force relative to the joints throughout gait is key to achieving

a normal efficient walking pattern (Winter 2009). In comparison, the control of GRF in pathological gait is not always possible due to the stress on the neuromuscular system (Eddison & Chockalingam 2013).

The vertical component of the GRF provides essential information about the complete function of the lower leg. The GRF normally exhibits two peaks with one dip between them (Perry & Davids 2010) as illustrated in Figure 2-3. The peaks are approximately 1.2 times body weight and the dip about 0.8 times body weight. The first peak is termed Fz1 occurring shortly after heel strike and the second peak termed Fz2 occurs just prior to toe off (Williams et al. 2011). The dip between is often termed the force valley which occurs during mid-stance as the individual moves over the foot (Perry & Davids 2010).

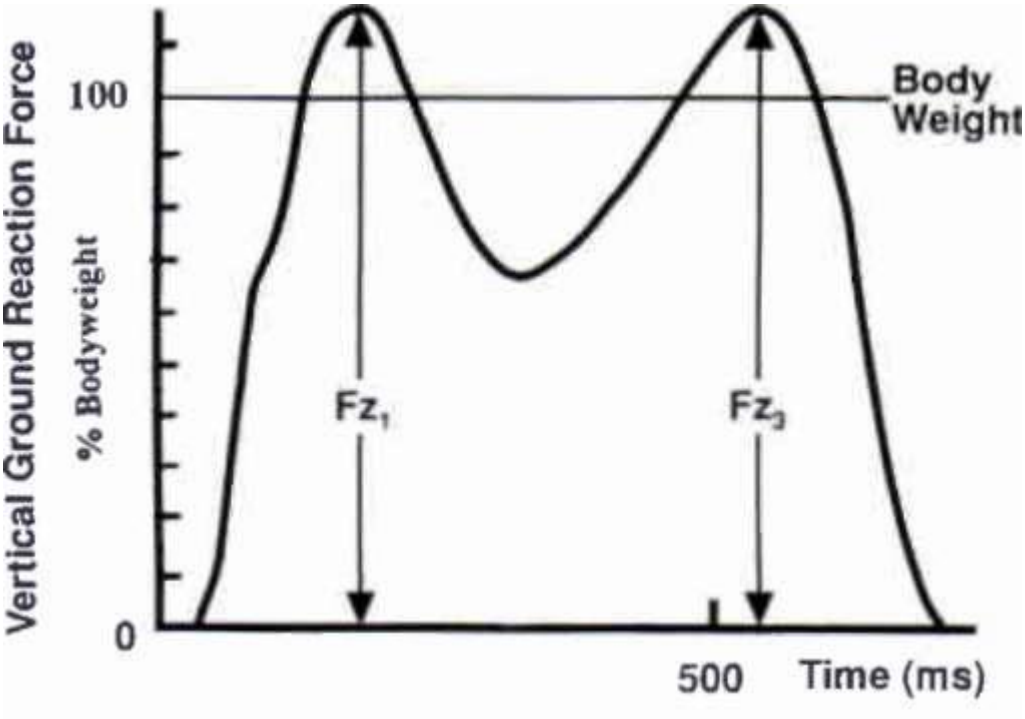

Figure 2- 3 illustrates the typical GRF during normal gait, Fz1 and Fz2 are the two peak forces.

Internal moments are created by muscles and ligaments; the GRF creates external moments acting on the ankle, knee and hip. The joint moments can be calculated with the knowledge of the point of application of the GRF and the position of the joint (Robertson et al. 2013). During normal gait the joint moments are fairly steady between the population (Robertson et al. 2013) and are illustrated in figure 2-4 The moment's scale depends on body weight and size. The ankle joint generally displays a slight dorsiflexor moment of around 15 Nm at initial contact with normal level walking (figure 2-4-a) (Robertson 2004). This moment is essential to prevent the foot from slapping uncontrollably. The moment then very quickly reverses to a plantar flexor moment of roughly 160 Nm to create an effective push off. At around 60% of the gait (around toe off) another slight dorsiflexor moment of about 10 Nm is evident (figure 2-4-a) which is required for lifting the forefoot away from the ground (Robertson 2004); this is often absent in stroke survivors.

There are four main peaks in the knee moment during gait. The most significant and important is the extensor moment in the knee joint of approximately 100 Nm and occurs in mid stance and prevents the leg from collapsing (figure 2-4-b) (Robertson 2004). Again, there are three distinctive peaks in demonstrating the hip joint (figure 2-4-c). The initial extensor peak moment follows heel strike, which then gradually decreases to around 35% of gait where it subsequently becomes a flexion moment of 40 Nm at toe off (Robertson 2004). There is then an extension moment of around 40 Nm during late swing.

Together kinematics and kinetics provide the information to help understand and tune ankle foot orthosis.

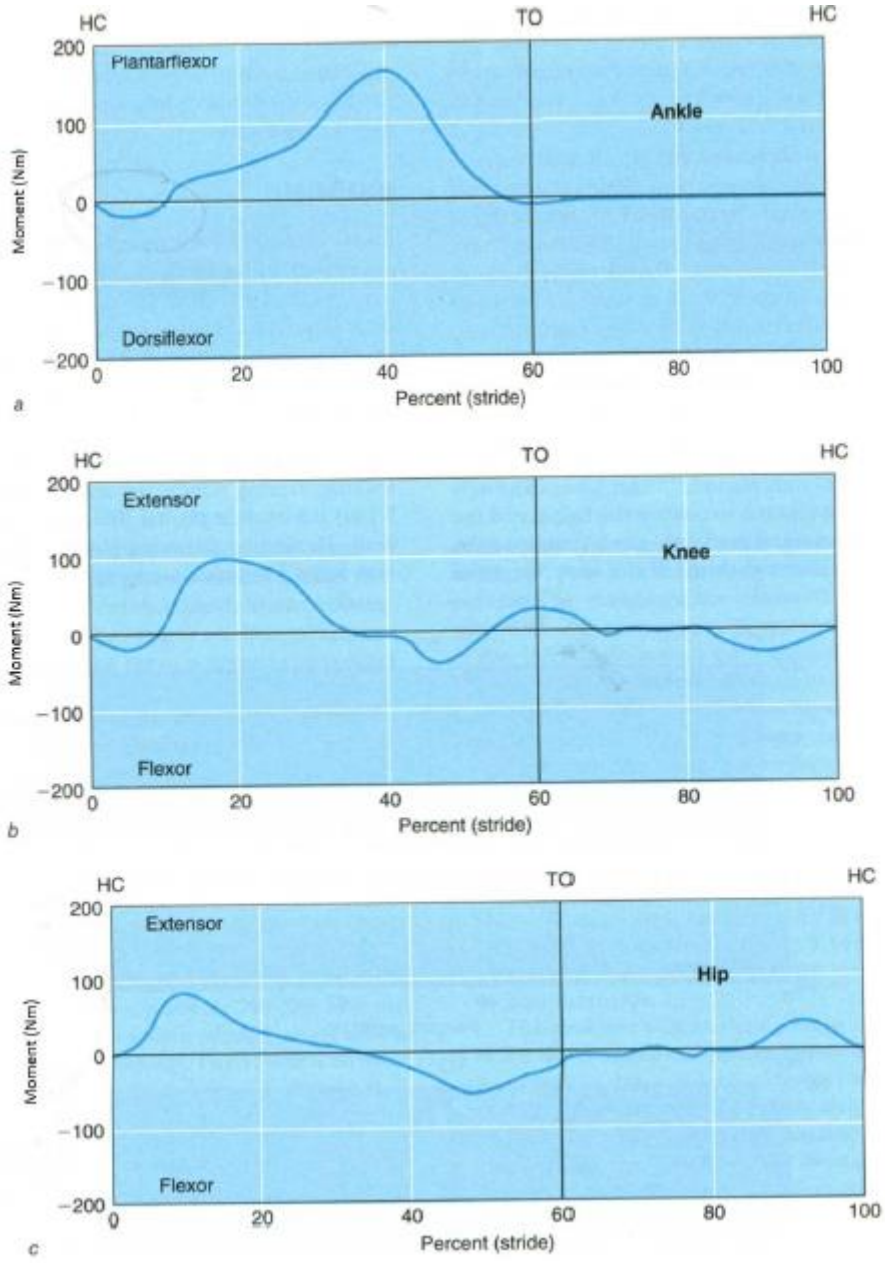

Figure 2- 4 Moments at the hip, knee and ankle during normal walking as a percentage of gait (Robertson 2004).

2.4 Features of hemiplegic gait

The loss of motor control, causing hemiplegia, is distinctive of stroke survivors. It is known that the side of the body affected by loss of motor control is contralateral to the brain damage. Studies investigating gait have demonstrated that stroke patients have altered kinematic and kinetic gait compared to normal gait and this is evident in both the magnitude (i.e. peak moment, power, angles) and pattern (i.e. profile of curves) (Kim & Eng 2004; Olney et al. 1994; Olney et al. 1998). Hemiplegic gait, at the most basic, is defined as slow and stiff with poor coordination (Lehmann et al. 1987; Kerrigan et al. 1999). It has been reported that post stroke patients after rehabilitation have a walking velocity of 0.55 m/s which is significantly slower than the normal walking gait velocity of 1.2 to 1.4 m/s (Pomeroy et al. 2012). Furthermore an asymmetric gait pattern symbolises a hemiplegic gait (Hsu et al. 2003; Roerdink & Beek 2011; Alexander et al. 2009). Hsu et al. (2003) suggest the reduced velocity is due to the weakness of affected knee and hip muscles, but the asymmetry is due to the spasticity in the affected ankle plantarflexors. However, depending on which part of the symmetric gait you are discussing depends on the cause, for example the unaffected limb swings faster, minimizing the stance duration of the affected side reducing the step length, giving asymmetry in timing and step length. The pathological moments at the knee and ankle during early stance shorten the step length (Bowers & Ross 2010). The other key feature of a hemiplegic gait is the extended time spent in double stance, which is linked to the increased energy cost in pathological gait (Franceschini et al. 2003).

Contrary to normal healthy people who have a relatively consistent gait pattern across the population, stroke patients show a large variation (Kim & Eng 2004). Several studies have subdivided stroke gait into categories, such as Kramers De Quervain et al. (1996) who described four different patterns connecting the knee and ankle motion in the sagittal plane which is in contrast to Knutsson & Richards (1979) who focus on three different muscle

activation patterns. Overall, there is a wide range of abnormalities in hemiplegic gait related to the degree of recovery and injury.

Winters et al. (1987) has divided the hemiplegic gait into four types of gait patterns:
Group 1 concerns patients with a drop foot in the swing phase. It has been suggested that drop foot (or foot drop) is the greatest deficit to the overall gait pattern (Perry & Davids 2010). Drop foot is often initiated by weakness of the dorsiflexor muscles (principally the tibialis anterior muscle) or the loss of motor control on the affected side muscles. This leads to the reduced ability to dorsiflex, evident in mid to terminal swing but not evident in the stance phase.

Group 2 also includes drop foot in addition to a tight heel cord in stance ie the foot maintains a plantarflexed position throughout the gait cycle (Meadows et al. 2008). This leads to an inefficient alignment of the GRF resulting in problematic moments and movements illustrated in figure 2-5.

Group 3 includes patients with restricted knee movement as well as the previous problems with the foot. Basically, continuous planatarflexion in stance phase resists the movement of the tibia causing knee hyperextension (Best Practice Statement 2009). Biomechanically the GRF passes anterior to the foot creating the knee hyperextension which is exemplified by the posterior positioning of the knee joint. Knee hyperextension is a common gait dysfunction in stroke patients and can be maintained into terminal stance (Kaplan et al. 2003).

Group 4 includes the addition of hip movement problems. During normal gait, hip extension is expected in mid to late stance in this category of patients, the hip is flexed and withdrawn (Meadows et al. 2008). Overall this group includes hip flexion, reduced knee movement and ankle equinovarus. The

equinovarus position of the foot in stroke patients adds to the instability of the patient (Meadows et al. 2008)

The basic abnormalities of a hemiplegic gait are: drop foot; knee extension (when it is supposed to be flexing); reduction of hip extension to the extent of potential hip flexion in mid to terminal stance and reduced time of terminal stance phase. Stroke patients often lose their functional ability on day one which then turns to spasticity as time passes (Perry & Davids 2010). As previously mentioned, the main goal in rehabilitation of stroke patients is to attempt to regain walking ability as this helps improve their capability for independent life.

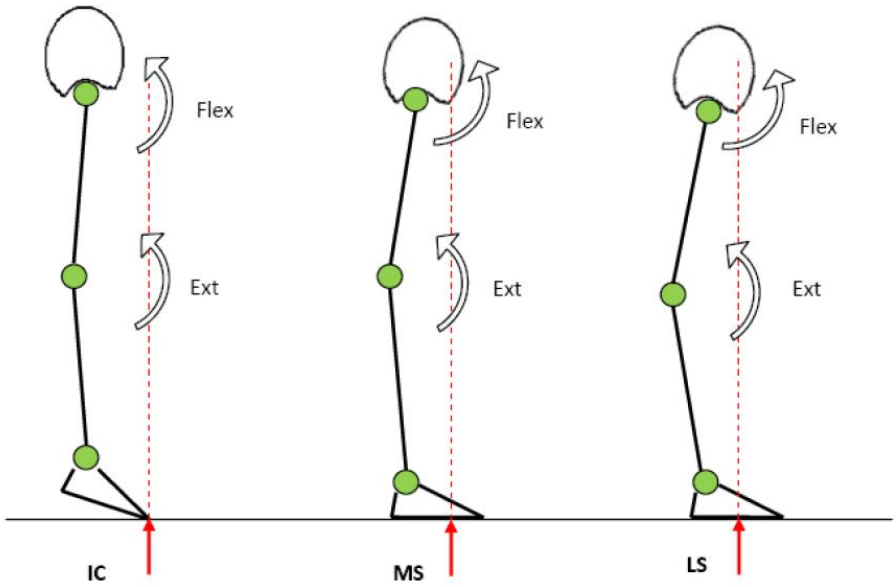

Figure 2- 5 An example of a typical stance phase of a stroke patient with hemiplegic gait. The GRF is not correctly aligned cause problems with the joints as IC (initial contact), MS (mid stance) and LS (late Stance).

2.5 Orthotic prescription for stroke survivors

The NHS Quality Improvement Scotland have recognised a clinical priority is required to improve stroke rehabilitation, this includes the use of AFOs for treatment (Bowers & Ross 2010). An AFO is regularly prescribed to improve

pathological gait and reduce falling rates (Geboers et al. 2002) however the literature is inconclusive regarding the effectiveness of AFOs on the gait and balance of individuals.

An AFO is prescribed post stroke to: compensate unwanted foot slap in stance and drop foot in swing; improve the alignment of the foot (no longer equinovarus); reduce knee hyperextension; increase hip extension in the stance phase and increase the ground clearance during swing (Best Practice Statement 2009; Condie E et al. 2004). The AFO applies forces to the foot to realign the ankle foot combination to make these changes and improve gait (Condie & Meadows 1977).The three force system used to control extreme plantarflexion is illustrated in figure 2-6. This controls the foot and prevents foot slap at initial contact while maintaining the correct position to provide ground clearance (Meadows et al. 2008). Currently there is a wide variety of materials, shapes and stiffnesses for orthoses from which to choose to give the correct fit and strength to achieve the best benefit for the patient. Potentially, due to the range of factors, this may be why the literature lacks clarity on the effectiveness of AFOs (Balaban et al. 2007).

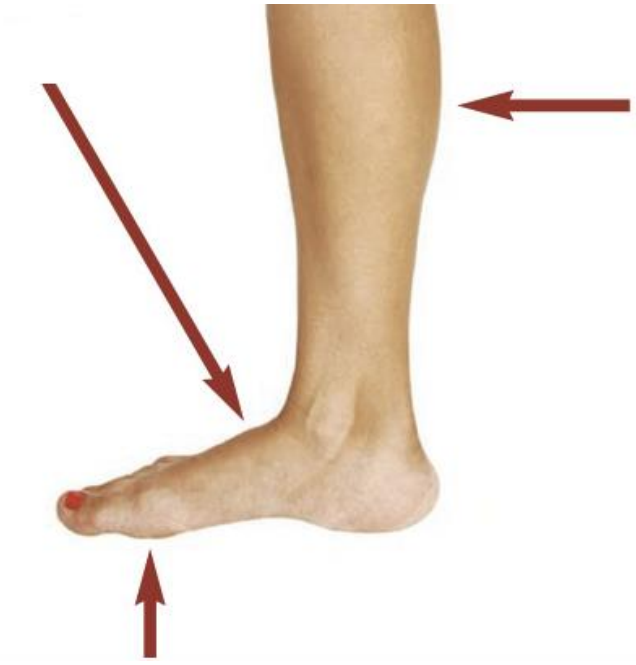

Figure 2- 6 Three point force system used to balance AFOs.

Throughout the literature the most commonly reported parameter is the effect an AFO has on walking speed. A systematic review demonstrated that seven out of nine papers illustrated an increased walking velocity with the implementation of an AFO (Leung & Moseley 2003). Other studies also reported an improvement of velocity (Gök et al. 2003) for example stroke patients walking 6m in shoes had a velocity of 15.47 m/min but increased this to 21.39 m/min with the use of an AFO (Franceschini et al. 2003) . Furthermore de Wit et al. (2004) found an increase in speed of 4.8 cm/s in favour of AFO use however, this was not clinically relevant (Bregman et al. 2010). An increase in walking speed has been evident in both acute and chronic stroke survivors with an AFO (Wening et al. 2009; Rao et al. 2008). Other research has reported no improvement in walking velocity with an AFO. The variation in research is due to a lack of uniformity, whether the patients are acute or chronic or the variety of AFOs used, but in general there are more papers that report an improvement in velocity than do not.

Cadence and step length are other parameters often reported, again the literature disagrees whether or not, with an AFO, an improvement is evident. A variety of studies have shown an increase in step length (Wening et al. 2009; Rao et al. 2008), specifically Abe et al. (2009) demonstrated an increase on both the affected and unaffected sides. (Gök et al. 2003) demonstrated an increase in step length but no increase in cadence. Tyson & Rogerson (2009) illustrated no improvement in step length, but this may be due to inappropriate orthosis selection for their patient group.

Not only spatial and temporal parameters have been investigated but also the kinetics and kinematics of gait. Ankle kinematics have been found to improve with AFOs with the extreme plantarflexion in mid swing and initial contact reduced (Fatone et al. 2009; Bregman et al. 2010; Gök et al. 2003). Interestingly it was highlighted that knee hyperextension was reduced despite not being clinically significant (Fatone et al. 2009). Focusing on initial contact Miyazaki et al. (1997) demonstrated that an AFO supported weak

dorsiflexor muscles shortly after initial contact but had no effect on the plantarflexors mid to terminal stance. Overall it is reported that AFO plantarflexor spasticity and equinovarus deformities are controlled by AFOs and most patients improve their gait by striking the ground with their heel first, improving the GRF alignment (Hesse et al. 1999).

2.6 AFO Tuning

Most AFO studies have found that their prescription has benefited the stroke patient in some fashion although the literature is spread on the exact improvements and the reasons why. The large variation in symptoms and styles of AFO is a simple explanation for the range of the results however, often these studies failed to attempt to optimise the AFOs biomechanically which also explains a variation in results. The concept of tuning (optimising the biomechanics) an AFO was initially identified in the 70's (Cook & Cozzens 1976) however only a few studies since have focussed on this potential.

Studies have consistently demonstrated that a rigid AFO with dorsiflexion improves walking in hemiplegic patients, illustrating even minor adjustments to aid the biomechanics are useful. A rigid AFO cast with a 5° dorsiflexed ankle significantly improved gait parameters including a greater flexion moment (11.7 Nm) at the knee which assisted the affected leg to swing during gait (Lehmann et al. 1987). In addition Miyazaki et al. (1997) found that in 20 hemiplegic participants an AFO set to dorsiflex with an angle of 7° prolonged a negative moment and knee hyperextension was corrected. Recent papers have suggested a dorsiflexed angle greater the 5° is key to improving gait performance (Owen 2004; Condie E et al. 2004).

There is increasing evidence that AFOs should be custom made and tuned appropriately to improve the shank and thigh kinematics which in turn will improve the overall walking pattern of the individual (Bowers & Ross 2009). The majority of published work however, focuses on children with cerebral

palsy rather than stroke rehabilitation (Bowers & Ross 2010). A case study demonstrated that knee pain was reduced and an improved knee moment was created with a tuned AFO for stroke patients however there was a lack of information on the knee kinematics and kinetics (Butler et al. 1997).

The aim of tuning is to modify the shoe, either by adjusting the heel design or height or by employing rockers, to optimise and enhance the alignment of the ground reaction force during gait at the different stages. It has been reported that correctly aligned AFOs can passively maintain the GRF acting on the knee joint in CP children, which reduces the continued energy and effort to maintain knee positioning (Butler et al. 2008). This study went on to state that tuned rigid AFOs directly altered the GRF with respect to the proximal joints. Additionally, another study reported that the tuning of an AFO controls the anterior progression of the centre of pressure, thus creating a force at toe off (Bowker 1993). It was recommended that motion analysis systems are utilised when tuning AFOs to create the optimal biomechanics of the ankle to influence the knee joint (Stallard & Woollam 2003).

Initially it was proposed that for best biomechanics the AFO was cast at 90°, conversely a shortened gastrocnemius needed to be accommodated (Best Practice Statement 2009; Owen 2005). Traditionally a 90° angle may have been assumed based on the belief that the shank was angled vertically (Owen 2010). Research on children with CP indicated that the shank was not vertical. Owen (2005) proposed an algorithm to identify the best casting angle for each individual patient (figure 2 – 7), however there remains insufficient evidence on the result of casting at 90°in comparison to casting the length of the gastronemusis.

When tuning an AFO often the angle between the shank of the tibia and the floor/foot is key to obtaining the best leg kinematics for a stable stance and optimal swing initiation (Owen 2004). The literature uses a variety of names to describe this angle: shank angle to the floor; foot shank angle or shank

and vertical angle (Pratt 2011; Loudon et al. 2012; Owen et al. 2004). From now on we will use the term shank to vertical angle (SVA).

According to anthropometric measurements for alignment of the knee joint centrally over the foot, a 10° SVA is required (Tilley & Dreyfuss 2002). In AFO tuning, for children with CP, it has been reported for optimal tuning an SVA angle between 10° and 12° incline is required (Owen 2010; Owen et al. 2004). It was highlighted that when tuning a 10° angle was a good place to begin however, in reality, for optimal biomechanics of the lower limb the SVA actually is dependent on the individual (Owen et al. 2004). Figure 2-7 illustrates the variation in SVA for 112 AFOs that were tuned, the mean angle was 11.36°± 2.08° and the majority of AFOs were between 10°-12°. The actual range however was between 7°-15°.

The SVA angle and knee joint moment arm was investigated on normal healthy children to establish a database for tuning AFOs for children (Pratt et al. 2007). The research demonstrated a mean SVA of 11.4° ± 3.4° when bare foot and 10.5° ± 3.6° when shod and confirmed Owen et al. (2004) suggestion of a 10° – 12° SVA during mid-stance. This normal database is very useful, however there is no discussion or statistics that report on the difference between shod and barefoot, as well as a lack of information regarding the heel size of the shoes worn by the children.

It is evident that a 10° -12° SVA angle is a good starting point for tuning AFOs but all the literature regarding the optimal biomechanics and SVA angles is based on children, not adults. There is a lack of published work on AFO tuning for stroke patients even though improving rehabilitation for these patients would have an economical advantage.

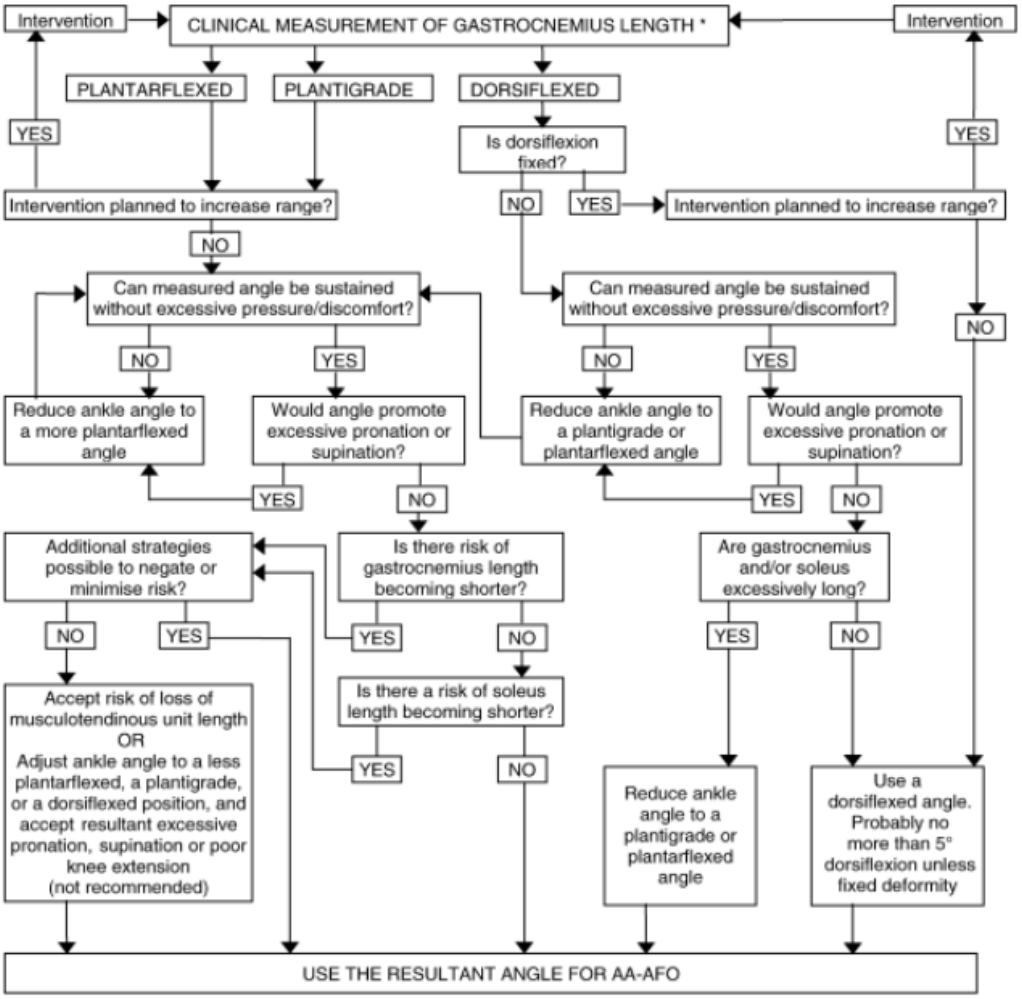

Figure 2- 7 Proposed algorithm for determining the best casting angle (Owen 2005).

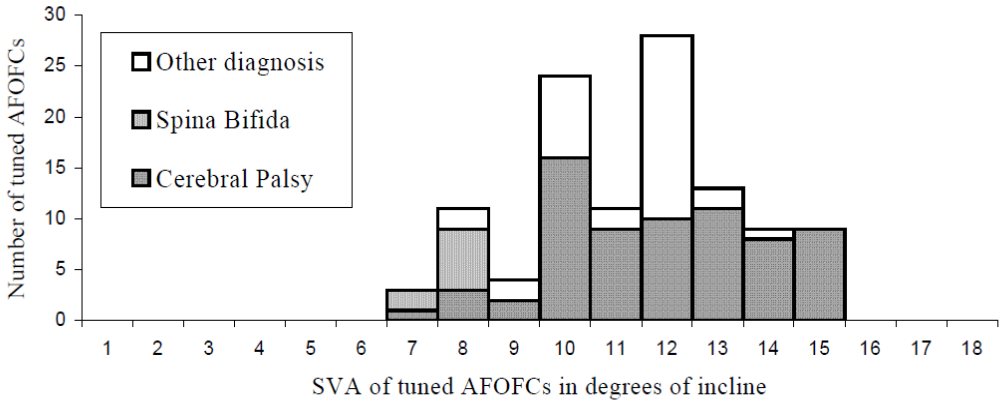

Figure 2- 8 The range of SVA angles for children with neurological disorders (Owen et al. 2004)

These studies have focussed on the SVA angle for tuning, but ultimately it is the realignment of the GRF that is key. Tuning the GRF is simple with a real time motion analysis system (Stallard & Woollam 2003) however these can be expensive. The goal of aligning the GRF is to facilitate it to pass close to or through the joint centre throughout walking however, as already discussed with pathological gait, this does not happen and causes an increase in moments. It has been proposed that fixing the ankle with a rigid AFO simplifies the alignment of the GRF as it gives greater control at the hip and knee joints (Butler & Nene 1991).

It is well known that the shoes worn with the AFO can significantly affect the optimal biomechanics of the gait. Churchill et al. (2003) demonstrated that the role of shoes in AFO rehabilitation is noticeably misjudged. It has also been suggested that inappropriate footwear can result in increased energy expenditure (Bowker 1993), which affects the patient's ability. Footwear must be considered when biomechanically optimising the AFO.

Modifying the SVA or the GRF alignment can be done using a variety of heel wedges (Jagadamma et al. 2009). Adapting the heel size can affect the shank to vertical angle which directly affects the orientation of the GRF with respect to the proximal joints. It has been reported that optimising the mid-shank kinematics ultimately optimises the gait (Owen 2004; Butler et al. 2008). Heel wedges have been reported to be employed when: the knee is hyperextending (Connolly et al. 1999; Sutherland 2002; Sutherland & Davids 1993); poor shank progression (Abel et al. 1998) and a lack of shank inclination during mid-stance (Owen 2005) is evident.

Jagadamma et al. (2009) investigated the tuning of AFOs for children with cerebral palsy by adjusting the heel wedge. They found, once tuned, that knee hyperextension during stance phase significantly decreased indication that heel wedges controlled knee hyperextension during stance. This could be interrelated to the optimisations of the SVA and GRF orientation. An increase of initial knee flexion was evident with the heel wedged AFOs in this study; the increase was not significant however it may still be clinically relevant (Jagadamma et al. 2009). Unwanted initial knee flexion needs to be considered when tuning an AFO using heel wedges and should be minimised as much as possible (Butler et al. 2007). The overall benefit of improving the knee hyperextension is required to be balanced with this initial knee flexion, further investigation is necessary but it has been highlighted that initial knee flexion is negligible (Butler et al. 2007).

A case study investigating the effects of increasing heel wedge (Jagadamma et al. 2007) demonstrated that with increasing wedge angle the SVA and flexion during stance increased. No distinct trend was evident for knee flexion for the 4° and 8° wedge however for 12° and 20° wedges there was a clear alteration. Figure 2-8 illustrates the knee flexion results for this case study where cerebral palsy children were again the focus. It suggested that 13° was the best SVA angle for optimum biomechanics, finding the balance

between knee hyperextension and increased flexion; this equates to an 8° wedge (Jagadamma et al. 2007).

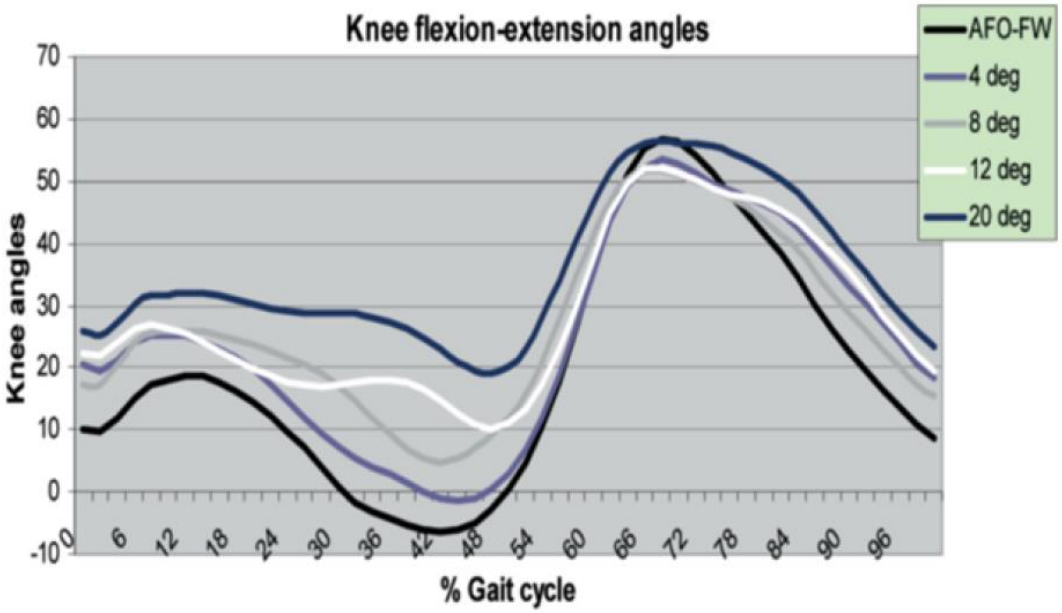

Figure 2- 9 Knee flexion results of a case study investigating 4 different heel wedges (Jagadamma et al. 2007).

A heel raise is known to maintain the origin of the GRF at the heel during early stance which results in an increased time for the knee joint to move forward (Butler et al. 1997). Owen (2010) expanded and proposed that heel wedges should be applied to AFO tuning until the GRF passes though the centre of the knee joint during mid-stance which will optimise the joint moments. The heel height required for an appropriate SVA can be calculated using trigonometry (Hullin et al. 2012) however, as the literature illustrates, there is no exact SVA for the optimal biomechanical gait, it varies between individual.

It is evident from this literature that further investigation into tuning AFOs is necessary and that there is a distinct lack of studies that focus on stroke rehabilitation. As there is no single SVA or heel angle that works for everyone, creating a device that can easily change the heel height is

important. This study is investigating the idea of creating a shoe that has an active wedge which theoretically can increase and decrease, so changing the SVA and GRF orientation without the need to remove shoes. This device is intended to be easy to use and result in faster, optimal biomechanical tuning so potentially improving the quality of rehabilitation.

Chapter 3 Wedge Design

When creating the active wedge the initial two key features needed to be safety and a device that worked with the university's D-Flow software and Motek system. In terms of safety the device needed to:

- Hold bodyweight plus 20% as a minimum
- Be lightweight
- Have a foot base which did not project outside the foot that it might cause falls or gait deviations
- Be electrically safe.

It was important that the device held 120% body weight as this is the expected forces produced during normal gait at initial contact. The first difficulty was to find an electrically controlled actuator (or similar device) that would hold 120% body weight, was lightweight and could connect to the other equipment. There are many actuators in the market that have the capability to withstand the forces required, such as GLA4000-S from Gimson Robotics with a range of lengths that would be suitable for creating an active heel wedge. However, after a thorough search of the industry, it was clear that most actuators that had the strength to hold 120% body weight were too heavy themselves. The GLA4000-S weight was 2 Kg which would be too heavy for even a healthy person to maintain a normal gait never mind a child or a stroke patient with walking difficulties.

Hence two lightweight linear actuators (L16-50-150-12-P) were sourced from Phidgets Inc, Canada. These had the bonus of being USB compatible, so could be linked to the motion analysis equipment and Motek system easily and were only 56 g each. However the maximum force suggested was 175N. The design now needed to find a simple way to hold body weight with these. It was calculated that two phidgets were appropriate as they were light and small; if more were included the size of the device would detrimentally alter gait and may have caused trip hazards to the other foot.

A variety of ideas were suggested from levers to pulleys to screws to ratchets. All design concepts were problematic due to:

- Difficulty of attachment to foot or shoe
- Only set positions being available, a range of positions was not possible
- Inability to hold 120% body weight

The final design was a simple solution; an aluminium bar cut to a specific angle attached to the two phidget actuators. The aluminium was strong enough to hold 120% body weight without crushing with the actuators controlling the position, creating different heel angles and allowing the whole range of positions to be an option. This is further explained in the next section.

3.1 Final Design

An aluminium wedge attached to two phidget actuators with a threaded screw as illustrated in figure 3-1 allowed correct alignment of the actuator which held the wedge in position. Using two nuts gave the ability to make fine adjustment to the actuators' positions while maintaining a locked position with no movement side to side. By implementing a wedge attached to the actuator phidget, it was possible to move the wedge to any point of the 50 mm stroke length of the actuator with no need to have set positions.

For simplicity, it was decided to attach the actuators and wedge directly to a shoe. This also created a constant for each participant using the same shoe so direct comparisons were possible. This project used SWIFT Casts for the AFO which the protocol required the use of a Darco Multifit Surgical Trauma Shoes (Markell shoe Co. Yonkers, NY, USA). This shoe has a strong plastic heel which was adapted to fit the aluminium wedge. An 18° wedge was cut from the shoe as demonstrated in figure 3-2 and the angle chosen was the

maximum angle possible while maintaining the shoe's integrity. The aluminium wedge was then cut to an 18° angle to fit directly into the heel of the shoe bringing it back to the original pitch, thus starting with the shoe flat with and no additional heel angle.

The attachment of the actuators to the shoe was key. The actuators came with metal brackets that fitted them specifically and each actuator had its own bracket which was screwed through the shoe with a nut holding it in place. At the position of the screw the hole was reinforced with plastic to stop the head being pulled through the shoe fabric. The plastic was covered with material tape to hold it in position and soften the area. The inside attachment is illustrated in figure 3-3.

The brackets were the main attachment to the shoe, however strong zip ties were also employed to prevent the actuators dropping when in the air and to prevent the actuators moving forwards when adjusted but also to hold them in position so that the wedge moved. For a final precaution high strength tape was added for security. The different attachments are illustrated in figure 3-4.

The phidget actuators involved electronics which connected directly to the Motek CAREN system. The basic electrical connections included two connection boxes, two USB cables and a power supply (figure 3-5). The first box was strapped to the SWIFT cast with Velcro (illustrated in figure 3-6), this position allowed normal gait as it was not disrupting the other leg and kept the cables clear. The larger junction box was extended so that it could reach the waist of any subject and an adjustable belt held it in position (figure 3-6). Extension power cable and extension USB cables were then used to link between the subject and the motion analysis system, as demonstrated in the figure 3-6.

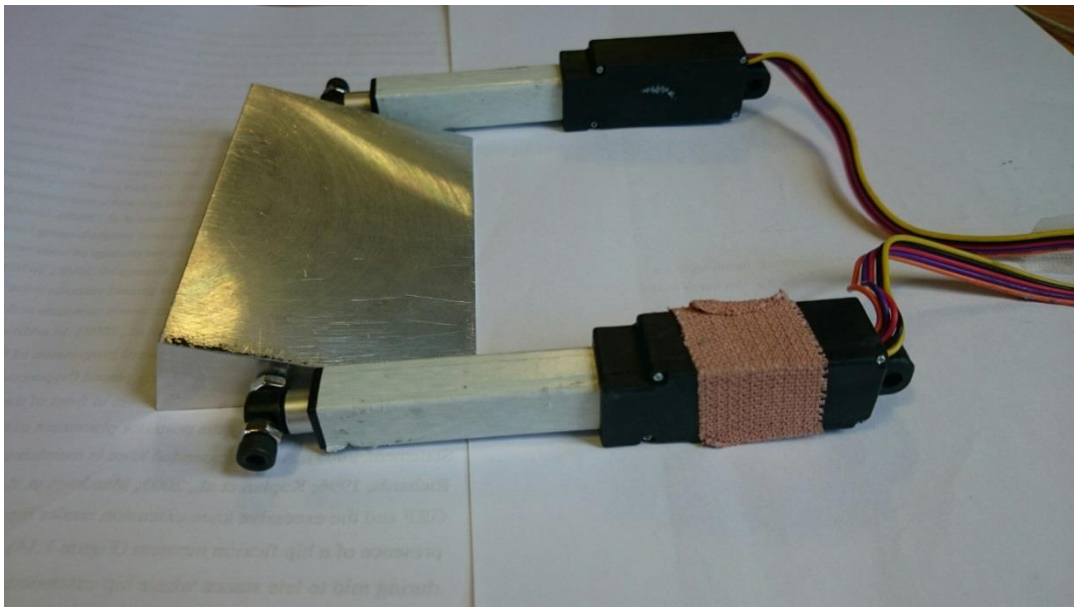

Figure 3 - 1 Illustration of the aluminium heel wedge attached to the two phidget actuators with a threaded screw.

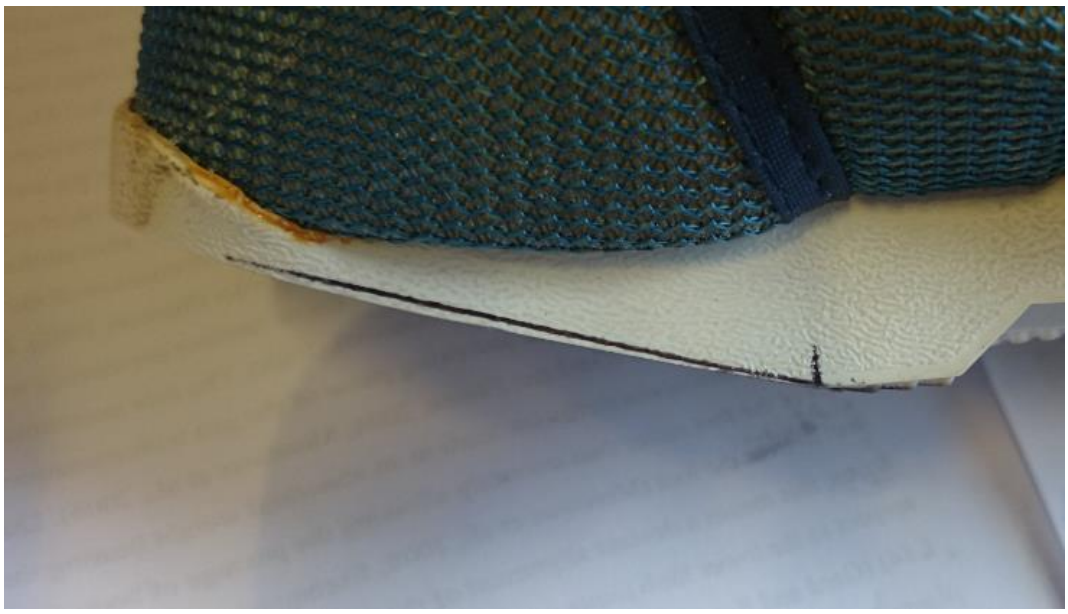

Figure 3 - 2 Illustrates the 18° wedge cut out of the shoe.

Figure 3 - 3 Illustration of the attachment of the actuator to the shoe from the inside.

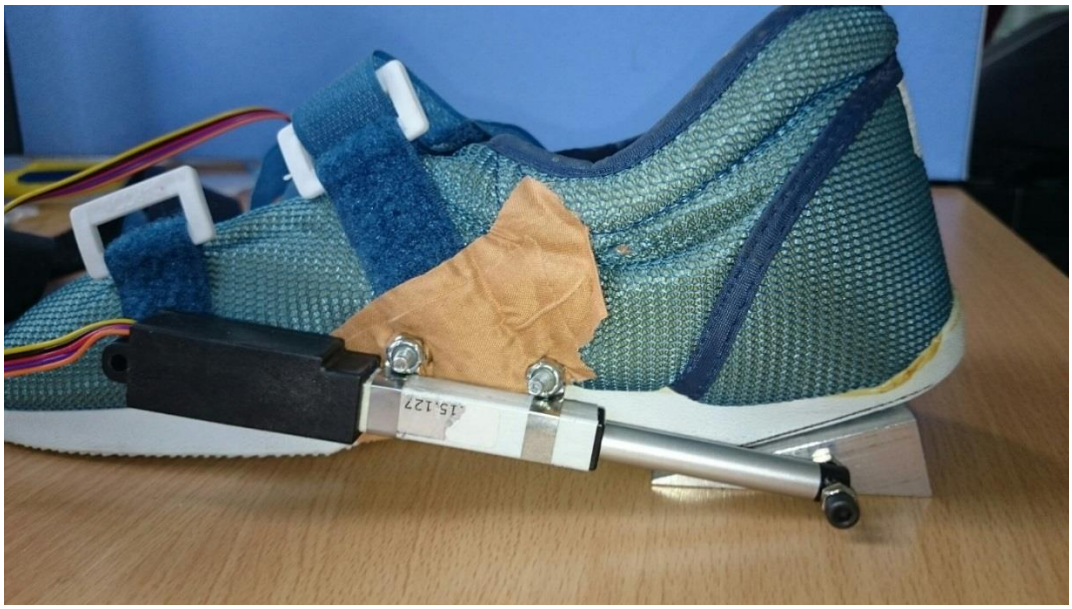

Figure 3 - 4 Demonstration of how the actuators are attached with the brackets to the shoe.

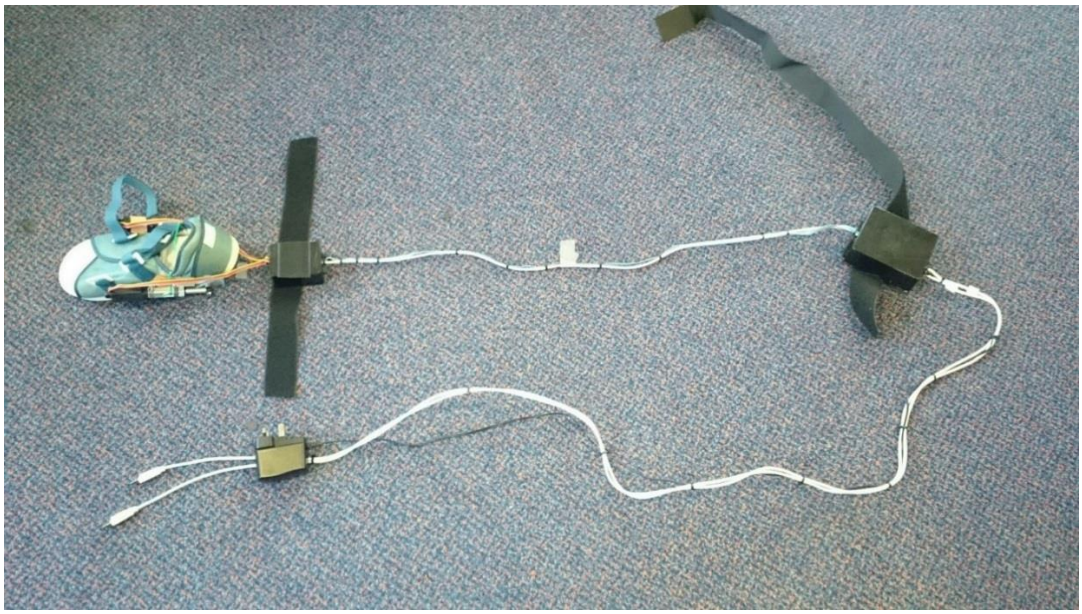

Figure 3 - 5 Demonstration of the circuit: wedge, power cables, two USB cables, motor controller box and Interface box.

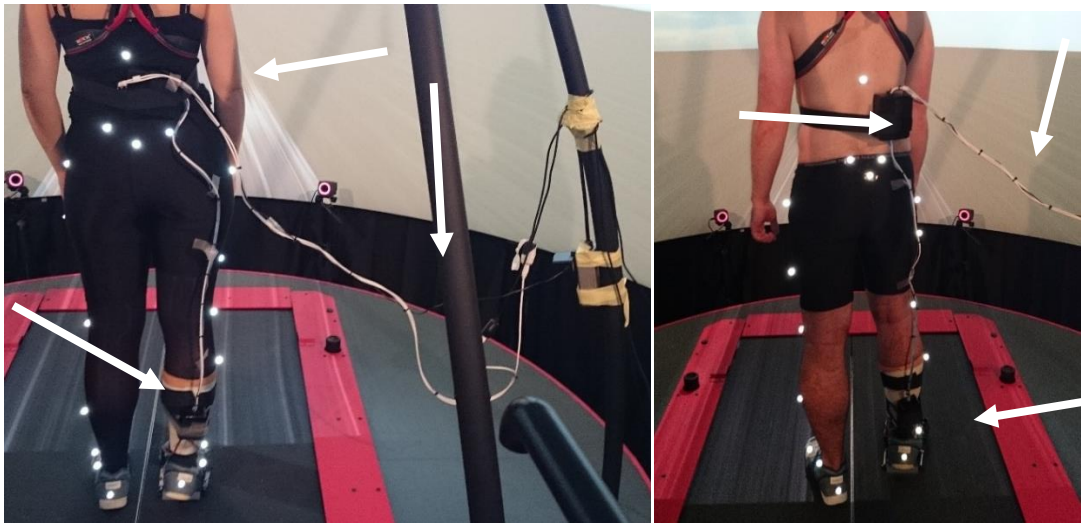

Figure 3 - 6 The Arrows demonstrate the positioning and attachment of: the Motor Controller on the SWIFT cast; the interface box around the waist of participant and the USB and power leads from the device onto the support from of the platform.

The D-Flow software was able to combine all the components of the system and allow the control of the phidget actuators with a simple click of the mouse. This was possible as the D-flow software includes a real time device manager which is responsible for synchronising and communicating with all the connected devices, including the phidgets. The D-flow editor is an interface which created the opportunity to develop the D-flow application. Controlling the phidgets was vital and simple with the use of three modules: a valuator, a script and a phidgets module. The template valuator module was altered to have a range from 1 to 4. The valuator module was connected to the script module. The script module was created to maintain the calibration of the wedges. Once the four angles for evaluating the device had been decided, the distances each of the actuators had to be moved to create these angles were calculated. Each actuator moved the same distance however they were not controlled by distance, but by an individual number scale which were different for both actuators. For example, to move the phidget to the 7° wedge position, one actuator was given a value of 2.2 and the other 3. The script was set so that when the input from the valuator equalled 1, equivalent to the 23° wedge position, the output(1) (first actuator) equalled 2 and output(2) (second actuator) equalled 0.5. Once the script was completed it was connected to a phidgets module. The phidgets module is the output control which connected the actuators to the D-Flow software. Once this application had been set up it was simple and easy to change the valuator which automatically altered the wedge.

Chapter 4 Methodology

4.1 Introduction

The purpose of this project was to test the effectiveness of the active wedge prototype, to ensure it altered the kinematics of gait and to understand any arising issues for future developments. The protocol involved custom made SWIFT Casts, while data was collected used the Motek CAREN (Computer Assisted Rehabilitation Environment) system, a unique laboratory configuration which permits biomechanical assessment of human movement.

4.2 Subjects

All subjects were recruited and data collected in this study conformed to the ethical permission granted by Department of Biomedical Engineering Ethics Committee. Ten subjects were recruited through an advertisement within the Biomedical Engineering Department. All subjects were given a participant information sheet (Appendix 1) and informed that if at any point they wanted to withdraw no questions would be asked. All volunteers were screened to meet the inclusion criteria and then were asked to give informed consent.

The criteria in which the volunteers were selected are listed below.

Inclusion criteria:

- Medically stable males and females who are aged between 17 and 65 years
- Able to give informed consent
- Able to ambulate independently, without human assistance or use of assistive devices, for a minimum of 30 minutes
- Sufficient cognitive ability to understand and follow simple instructions
- Adequate skin integrity

Exclusion criteria:

- Unable to give informed consent
- Communication problems
- Significant structural leg length discrepancy, musculoskeletal or neurological abnormalities of the lower extremity
- People who have symptoms indicating pulmonary disorder such as lower limb peripheral vascular disease
- People who have a long-term experience of or have recently worn a solid SWIFT Cast or ankle foot orthosis
- Must not be pregnant
- Allergies to the SWIFT Cast Materials

4.3 Manufacturing of Soft Scotch ankle foot cast

The researcher was fully trained in the protocol for fitting and creating SWIFT Casts from a physiotherapist who had been involved in developing the cast. All ten subjects had a custom made SWIFT Cast on their right leg. Making and fitting of the SWIFT Casts was completed a minimum of two days prior to gait analysis.

The participants were asked to wear loose or short trousers to enable easy access to the lower leg. Prior to casting, an area was set aside close to a sink with hot water, then this casting area was covered with plastic sheeting and a suitable chair placed on top. The following materials and equipment were set out before the participant arrived for casting.

- An Apron
- A pair of gloves
- 3 inch stockingnet
- 2 rolls of 4 inch soft cast
- 2 rolls of 4 inch scotch cast

- 2 rolls of crepe bandage
- A tube
- A measuring tape
- Blunt end scissors
- Permanent marker pen
- Towels
- 1 roll of Micropore
- 1 roll of Microfoam
- 1 roll of Leukotape

4.3.1 Fitting procedure

The volunteers were reminded that the fitting could take up to an hour and then asked to sit on the chair with their right trouser leg rolled up to above the knee unless the subject was wearing shorts. The participant was then asked to put on two stockingnets with a tube going down the anterior side of the leg between the two stockingnets (figure 4-1). The participants were then asked to arrange their hips, knees and ankles in a 90° flexed position. With the foot in the correct position, it was then marked on the plastic with the permanent marker to ensure the same position was maintained throughout casting. The length of the back slab was then measured; approximately the level of the fibula down the posterior side of the leg, along the dorsum of the foot and finished just beyond the toes. The measured length was then laid out onto the plastic sheet away from the subject and marked at both ends for a fitting guide. The researcher then ensured they were wearing gloves and an apron for their protection.

The back slab was then created by using the marked length to roll out Scotch cast layers. A minimum of six layers was built up and often two packs were required. This was the section that provided the main proportion of stiffness. The material was left to begin to harden while one pack of soft cast was wrapped around the right leg. The wrapping began around the fibula head

and overlapped about 50% until the ankle was reached. At the ankle a figure of eight technique was employed before wrapping to the toe.

The back slab was then positioned posterior to the calf and dorsum of the foot. If there was any excess material protruding at the heel it was cut to improve the folding and attachment. The back slab was then shaped by hand to each individual's lower leg (figure 4-2). A 90° ankle angle was checked and maintained.

The second roll of soft cast was then opened and placed briefly in the sink full of water; the water activated the polyurethane resin within the soft cast tape. The wet roll was then wrapped around the lower leg in a similar manner to the first soft cast roll. With wet gloves, the cast was then moulded to the shape of the lower leg and manipulated into the correct position, before two wet crepe bandages were wrapped around the cast and left in place for a minimum of 5 minutes (figure 4-3).

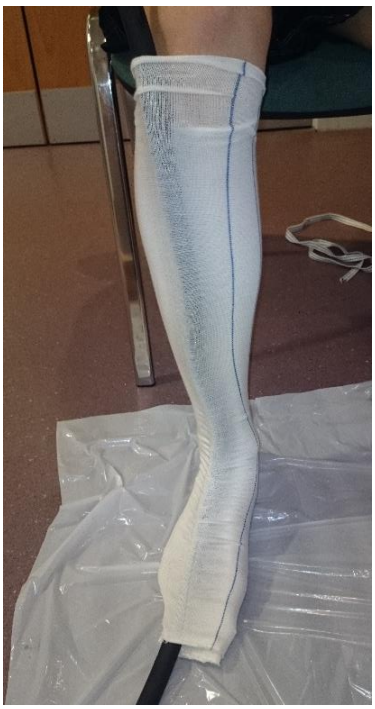

Figure 4 - 1 Demonstrates two layers of stockingnet with the rubber tube that acts as a spacer between them.

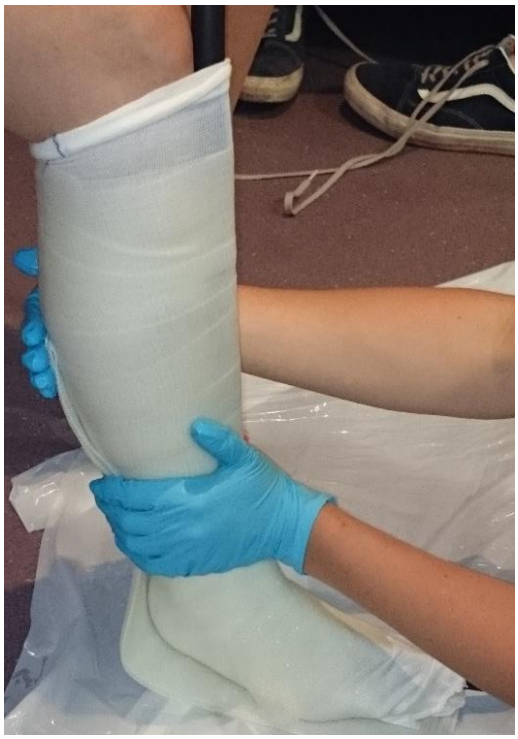

Figure 4 - 2 Demonstrates the shaping of the back slab.

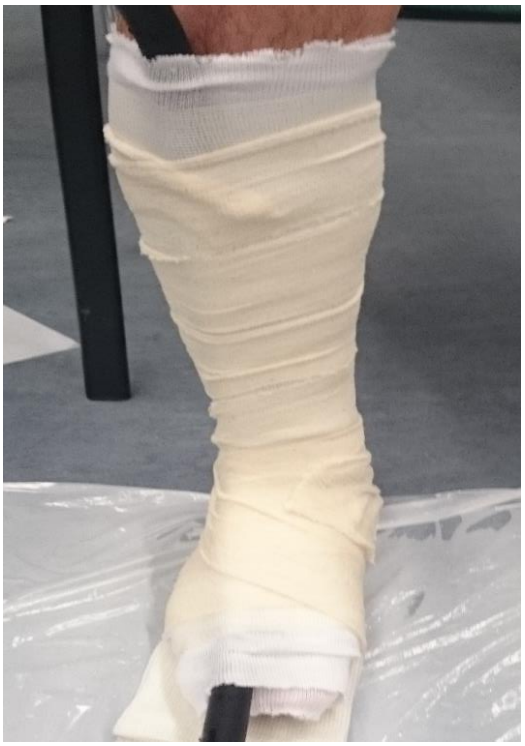

Figure 4 - 3 Demonstrated the SWIFT cast wrapped in a wet crepe bandage.

The crepe bandages were removed and the cast cut along the tube using the blunt ended scissors (figure 4-4). Once the cast was removed the toes' length was marked and the participant's leg checked for redness; these areas were also marked on the cast. The cast was symmetrically cut along trim lines that removed the anterior section, leaving the posterior of the shank and under the foot.

The cast was then left to harden for the next 24 to 72 hrs after which any sharp edges were removed. Leukotape (BFN Medical Ltd., Hull, UK) is applied to the edges (figure 4-5) certifying there was no separation between layers. Two Velcro straps were attached to the tibia section. The cast was now ready, but the fit and alignment were double checked on the participant prior to gait analysis.

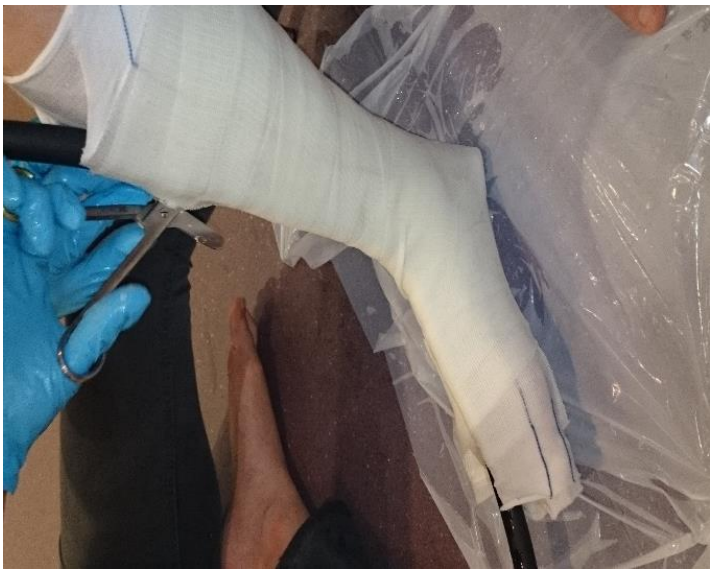

Figure 4 - 4 Demonstration of a SWIFT cast being removed.

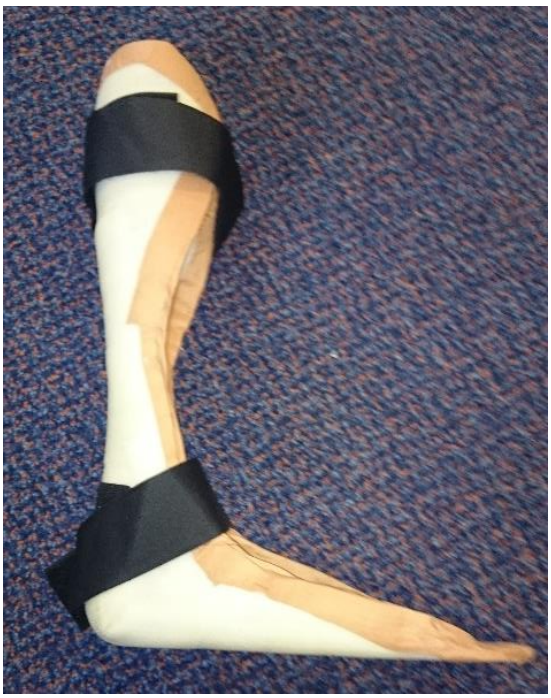

Figure 4 - 5 Final SWIFT cast product

4.3.2 Gait Analysis

The movements of the lower limb body segments and joints, and specifically if they alter with the use of the heel wedge, were the key biomechanical measurements in this study. All biomechanical assessments took place in the biomechanics 2 laboratory on level one of the Wolfston Building, University of Strathclyde, UK. This laboratory contained the Motek CAREN system. The system hardware contains: a 6 degrees-of-freedom motion platform; a dual belt force instrumented treadmill; a motion capture system and a large diameter 180° projection screen for displaying virtual reality environments to participants (figure 4-6). Together the hardware creates a large base platform mounted on 6 hydraulic rams, a treadmill which is embedded in the base platform, force measuring apparatus which is embedded in the treadmill, a Vicon motion capture system which is used to track how a person is moving when on the system, and the projection screen which can be used to display any kind of virtual environment or biofeedback to system users.

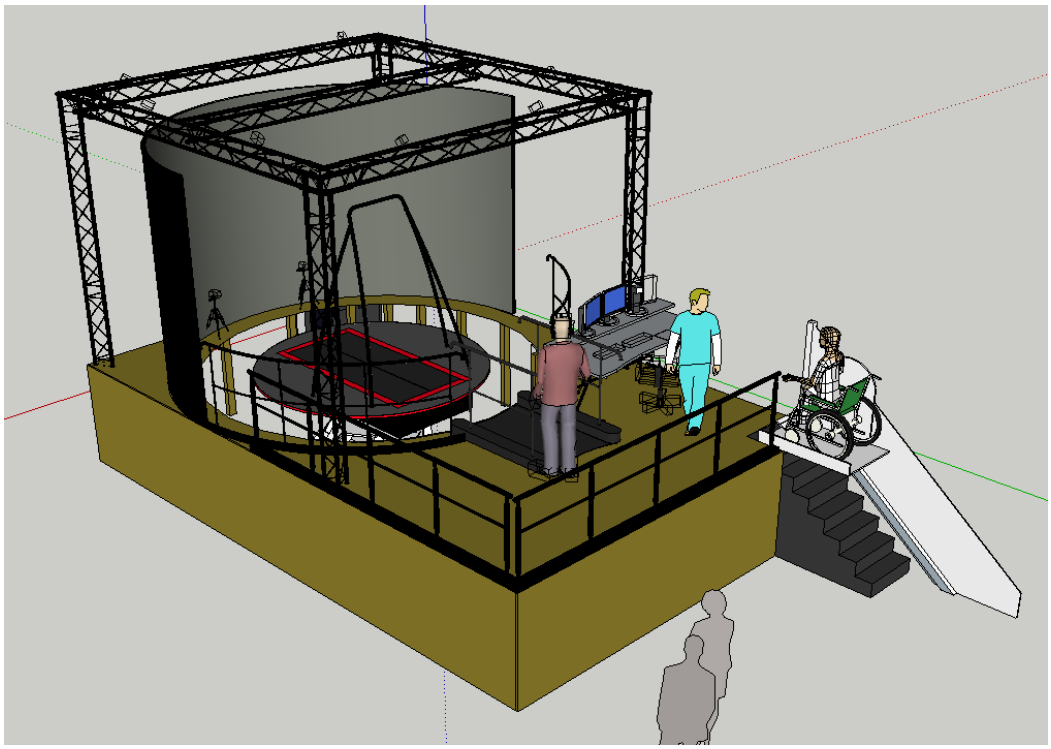

Figure 4 - 6 Diagram of the motion analysis Motek CAREN system.

The features of the system relevant to this study included the Vicon MX system which consists of 12 B-10 cameras with a resolution of 1 megapixel and a sampling frequency of 100 Hz. Figure 4-7 illustrates an example of a camera. The Vicon B-10 system is an optical motion measurement system which follows and records three dimensional data. Data collection is primarily done by the use of the cameras which track the position of retro-reflective surface markers that are tactically positioned on the subject. A minimum of two cameras is required to identify and calculate the three dimensional position of each retro-reflective marker at any time. The Force plates were another key feature of the system for this project as they were used for indirect measurement of the ground reaction force and moments. The wide instrumented bertec fore plates have a sampling frequency of 100 Hz. All parameters driving the CAREN hardware were under operator control at all times with the use of D-Flow software (1.1.2) and Vicon Nexsus (1.8.4).

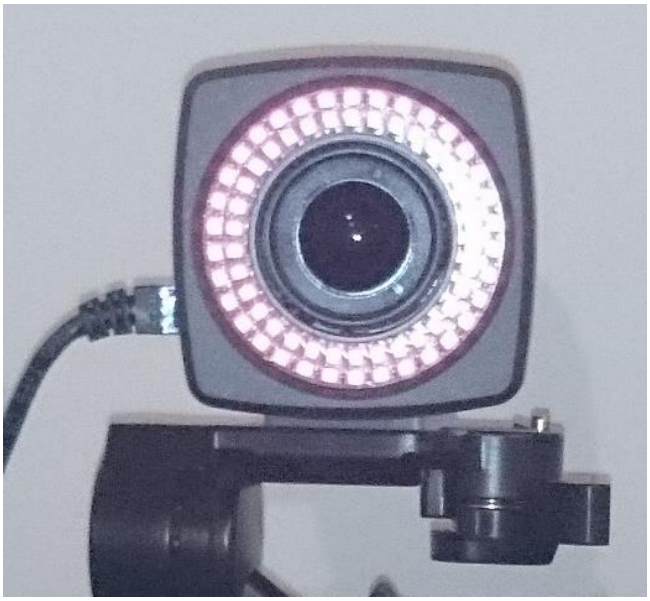

Figure 4 - 7 Illustrates a Vicon B 10 camera.

The D-Flow software was vital to this project, it not only controlled the treadmill, motion capture and force data but also the active wedge. This

simple to use software meant the researcher could change the angle of the wedge at any point when the phidgets were connected. Figure 4-8 demonstrates the D-Flow software set up, with the treadmill control in one box and the wedge script and valuator applications open as well. For health and safely the subject was always stopped and informed when the wedge was moving.

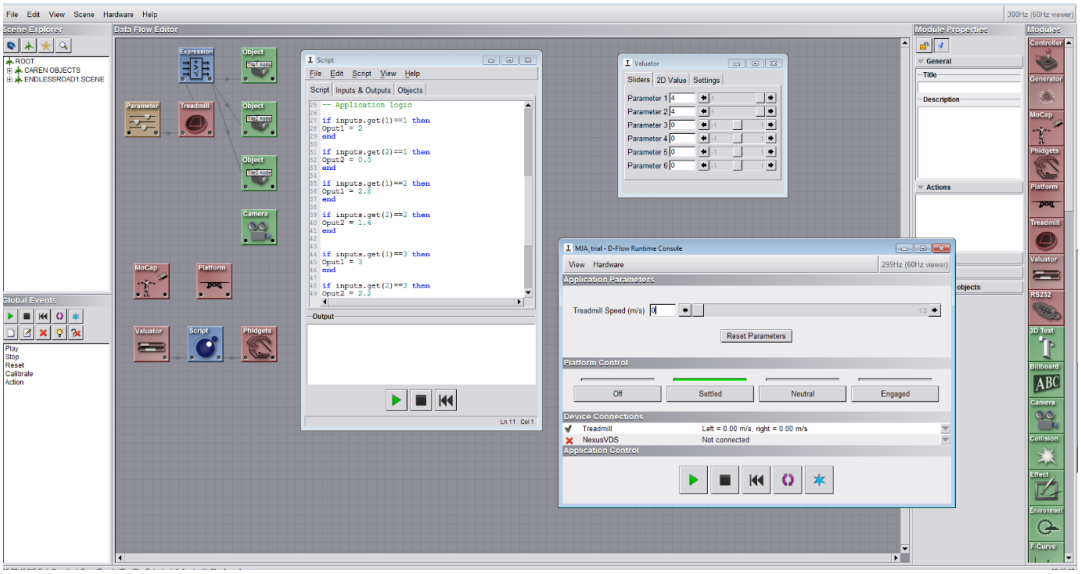

Figure 4 - 8 Illustrates the D-Flow software Application used for this study.

4.4 Measurement protocol

Before the participant arrived the system was calibrated and the extension wires for the active wedge were attached to the cage. Vicon system calibration occurred in two stages: dynamic calibration and set volume. Initially a dynamic calibration was conducted of the capture volume which calibrated the physical position and orientation of each camera by dynamically moving a wand (set to strobe) through the capture volume. The software automatically calibrated the Vicon system from this data; as the system knew the wand geometry and could calculate the camera position accordingly. Secondly, the origin was set by changing the wand from strobe to static and placing it on the treadmill in the location illustrated in figure 4-9. The Vicon system was now calibrated, and from this data the D-Flow

software calibrated the motion analysis application. Before the participant stood on the treadmill, the force plates were zeroed and calibrated through D-Flow (it was vital that there was no extra weight on the treadmill at this time).

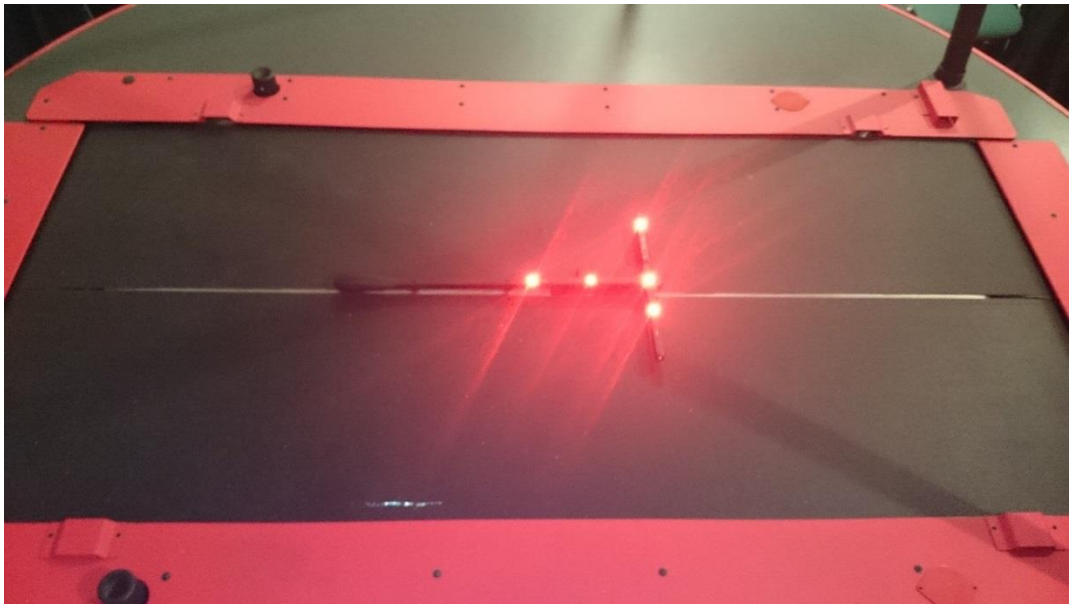

Figure 4 - 9 Illustration of the position of the wand when calibrating the set volume.

On the day of gait testing the participant was asked to wear tight clothing, for example a tight Lycra suit. Once the system was calibrated, the participant arrived and their anthropometric data was calculated using force plates and an anthropometer. The anthropometric data recorded included the participant's weight, knee width and ankle width. This data was entered into the D-Flow software.

The marker set used in this study was the lower limb human body model (HBM). The markers used were 14 mm in diameter (figure 4-10) and attached with double sided sticky tape to either the participant's skin or their Lycra clothing. Twenty-five markers were used in total.

Figure 4 - 10 An example of the reflective markers used in this study.

Four markers were positioned on the torso at the:

- Sternum (STRN)
- Xiphiod process (XYPH)
- Nave (NAVE)
- Spinous process of the tenth vertebrae (T10)

To identify the thigh, shank and foot segments, markers were placed over the:

- Left and right anterior superior iliac spine (ASIS)
- Left and right posterior superior iliac spine (PISI)
- Sacral (SACR)
- Left and right greater trochanter (GTRO)
- Left and right lateral epicondyle (LEK)
- Left and right lateral malleoulus (LM)
- Left and right calcaneous (HEE)
- Left and right fifth metatarsal head (MT5)
- Left and right Hallux distal phalanx (TOE)

Additional markers were placed between the greater trochanter marker and the lateral epicondyle marker on both the left and right side (THI), and between the lateral epicondyle marker and the lateral malleoulus on both sides (ATI).

Figure 4-11 demonstrates the positions of the markers on a participant. The participants were required to wear the SWIFT Cast, shoes and a shoulder harness at this point so that all the markers could be placed correctly.

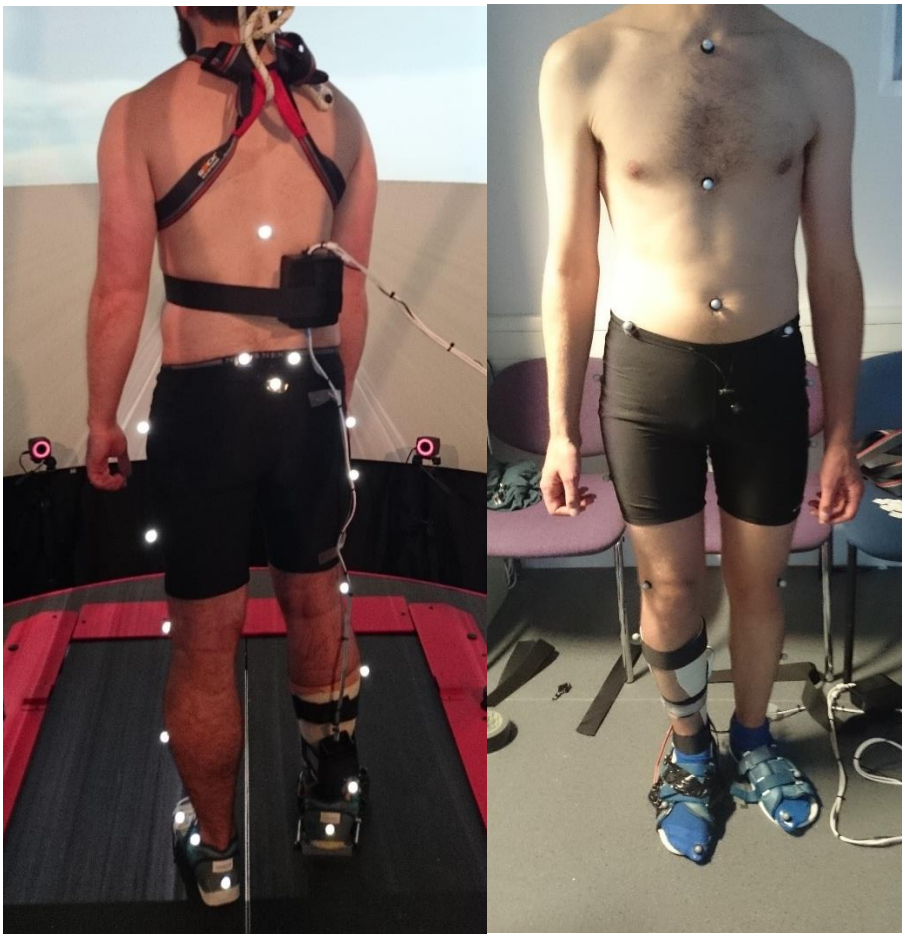

Figure 4 - 11 Demonstration of the reflective markers position from a posterior and anterior view.

For the purposes of testing *and to* maintain consistency 4 heel angles were chosen to test: 0°, 7°, 12° and 23°. The actuators were calibrated and a D-Flow script was created so that both actuators would move to these positions when instructed.

Once the participants were markered up, they were asked to walk carefully onto the platform. When they reached the middle of the platform the harness was attached to the support framework so that if the participant tripped or fell while performing the test they were safe. The wedge was then connected to the power supply and to the computer. The wedge was then put into each chosen position to confirm the connection.

The platform was then isolated and lights switched off, the subject was then calibrated to identify the marker locations. The subject calibration consisted of a routine of movements that included: a T pose; bending forwards and backwards; moving side to side and rotation all lower limb joints. The Vicon Nexus software then ran the subject calibration pipeline and automatically labelled the markers. The markers were then double checked to be in the correct location and if there were any problems they were adjusted manually. The system and subject were now ready to begin testing.

With the platform in engaged mode the participant was warned that the treadmill was about to start at a slow pace. Using the CAREN system the treadmill was slowly started and increased to a maximum speed of 0.6 m/s. The participant then walked for a total of 5 minutes. This gave them time to adjust their walking and feel comfortable with the SWIFT Cast and heel angle. During the last minute of the trial 30 s of data (kinematic and kinetic) was recorded for analysis. The treadmill was then slowed down and halted. The participant was asked to hold onto the framework and unload their right foot, as demonstrated in figure 4-12. The wedge was then moved to the next position before the foot was loaded again. This process was repeated for all four heel angle positions.

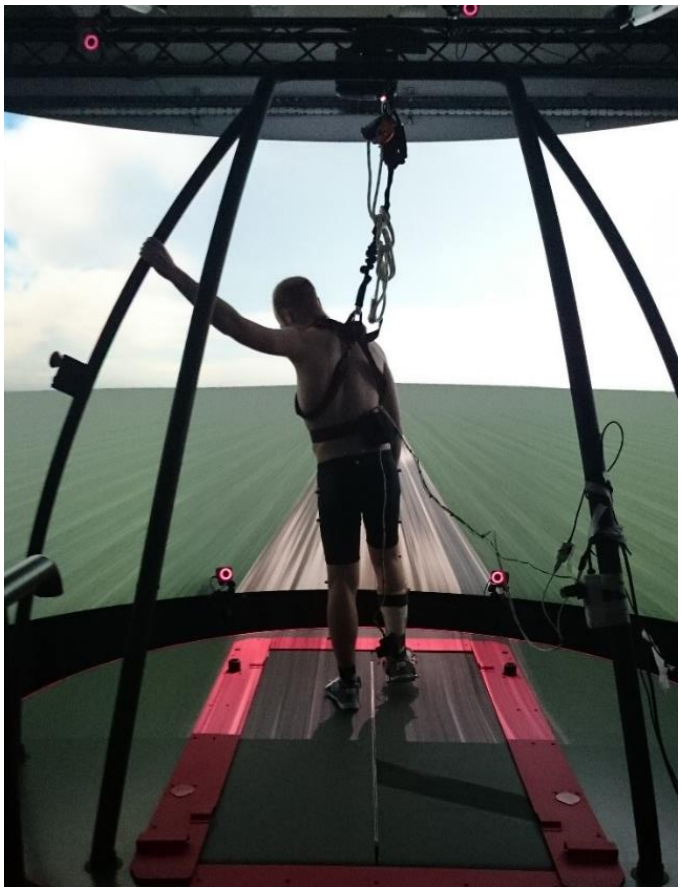

Figure 4 - 12 Demonstration of the participant holding the support frame and unloading their right foot so the active wedge can move effectively.

Once the data was collected the active wedge was disconnected from the computer power supply and the shoulder harness removed. All the markers and the SWIFT Cast were removed before the subject left.

4.5 Data Processing

Data was processed and extracted for the 4 walking conditions (4 heel angles) for each of the 10 participants. 30 s of kinematic data and kinetic data were collected during the testing process. Once the participant had left, each trial was individually processed to insure there were no gaps in the data or unlabelled markers. The processing was first done automatically using standard pipelines and manually visualised to insure there were no

problems. The automatic pipeline operation was called Woltring Fill Gap for a maximum of 25 gaps, all gaps greater than 25 were manually filled using the choice of the best pipeline (either spine or another marker) which depended on the researcher's judgement. Finally, all unlabelled trajectories were deleted.

For each trial the data was cropped to include twenty strides (ten on each leg), the researcher deemed this an appropriate amount of data to analyse, however all the raw data was saved if required. Vicon Nexus then ran each processed trial separately and while this trial was running the D-flow software recorded another set of data (final data). The D-Flow software was able to automatically define the lower limb human body model with the correct anthropometric measurements for each subject by employing the GRAIL (the Gait Real-time Analysis Interactive Lab) software which was used to define all the body segments. This software also output many variables including: knee flexion angle; hip flexion angle; ground reaction force and the position of all 25 markers. After saving all the data it was exported to Excel 2010.

Each trial was individually analysed by the researcher to identify: initial contact (IC); mid-stance (MS) and terminal contact (TC). These important points of gait were identified using the force plate data as illustrated in figure 4-13. From the known data points an estimation of the position of flat foot (FF) and heel rise (HR) was calculated. FF was estimated to be 35% of the distance between IC and MS, and HR was estimated to be 48% of the distance between MS and TC. The data was extracted and entered directly into a custom made excel file created to analyse the data. All the appropriate data was transferred to this file for analysis.

The gait outcomes reported in this study included: knee flexion angle at IC, FF, MS, HR, TC; peak knee flexion-extension in stance and swing; peak knee extension moment and flexion in stance and stance time. All statistical analysis in this study were carried out using statistical software (SPSS

version 20.0). Statistical variances of the knee flexion-extension angles and knee moments between wedge angle (0°, 7°, 12°, 23°) were determined by repeated measures analysis of variance (ANOVA) Statistical significance was taken at < 0.05. Data reported are mean ± S.D.

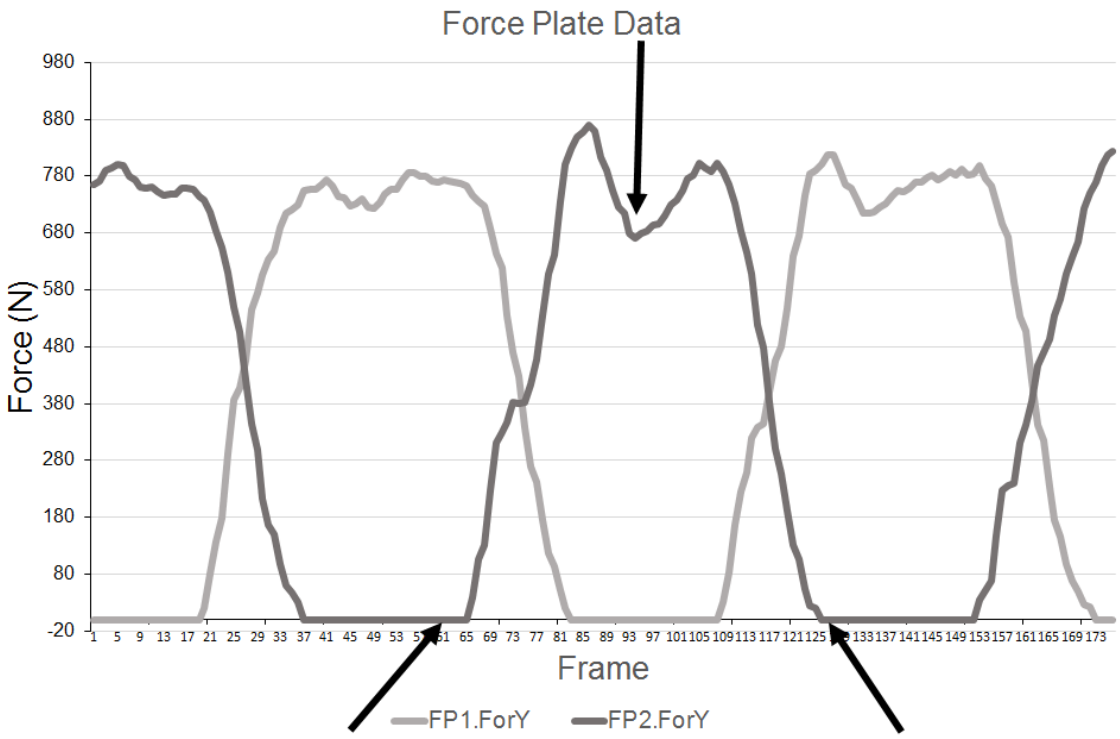

Figure 4 - 13 An example of the force data used to identify initial contact, mid-stance and terminal contact.

Chapter 5 Results

Heel wedge angle significantly affected the peak knee flexion angle during stance phase ($p < 0.05$). As the heel wedge angle increased, an increase in the peak knee flexion angle during stance was evident (figure 5.1). The heel wedge angle had no effect on the peak knee flexion angle during swing phase (figure 5.1).

Altering the heel wedge significantly affected the knee flexion-extension angle at some points in the gait cycle but not at all point. The knee flexion-extension angles are given in Table 5 - 1. During the flat foot stage of gait, there was a significant increase in flexion angle from the 0° wedge to the 12° and 23° wedges. Notably, the 7° wedge did not show a significant difference to the other wedges for knee flexion angle at flat foot, although the mean did follow the same increase trend as the others. Knee flexion-extension angle during mid-stance resulted in a significant increase in angle for all four wedge angles (table 5-1). During heel rise the 12° and 23° wedges had significantly ($p < 0.05$) larger knee flexion-extension angles than the 0° and 7° wedges. The 0° and 7° wedges did not show a significant effect, however again, they did follow the same trend.

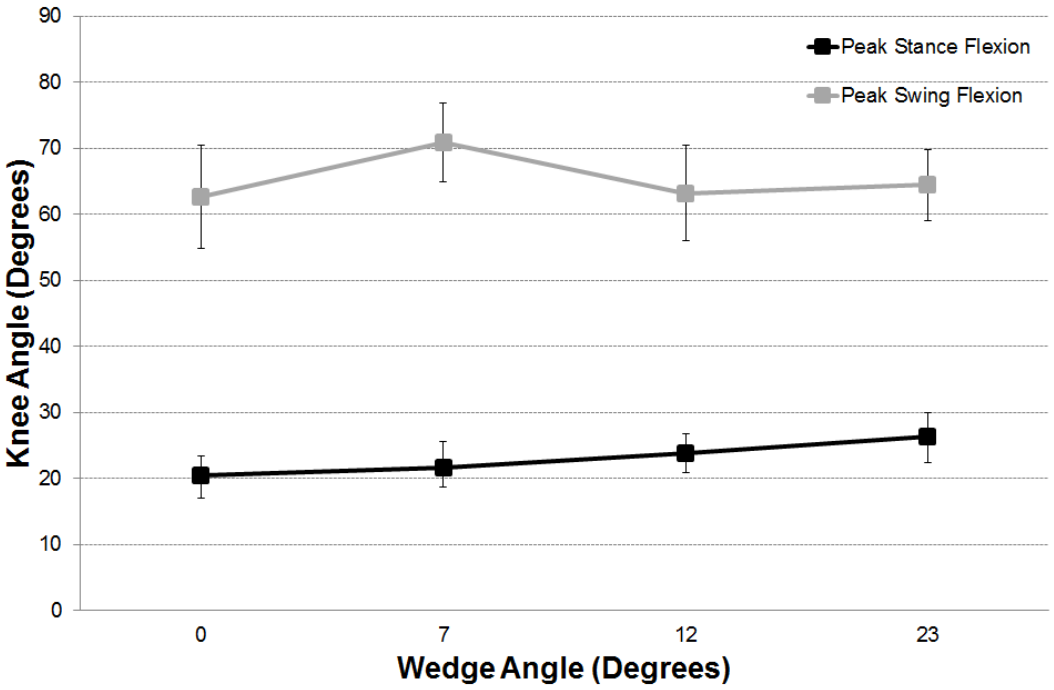

Figure 5 - 1 Mean peak knee flexion during stance and mean peak knee extension angle during swing for the four chosen wedge angles.

Gait Position	0° Wedge	7° Wedge	12° Wedge	23° Wedge
Initial Contact	15.2 (8.2)	15.6 (7.6)	16.5 (7.9)	16.5 (9.3)
Flat Foot	18.6 (8.8) *	19.1 (6.8)	21.3 (7.4) *	22.2 (9.4) *
Mid-Swing	16.8 (8.6) *	18 (8) *	19.4 (8.5) *	21.4 (9.8) *
Heel Rise	12.3 (7.9)	12.7 (7.5)	13.5 (7.6) *	14.6 (8) *
Terminal Contact	38.4 (10)	40.4 (7.8)	41.4 (9.9)	41.1 (10.2)

Table 5 - 1 Mean (SD) of the knee flexion-extension angles during different positions of gait. Significant results p< 0.05) are highlighted.

Overall heel wedge angle had no effect on peak extension and flexion moment during stance (table 5 - 2). Markedly, the 0° wedge had a significantly smaller peak extension moment than the other wedges. The 7° wedge had a significantly different peak extension moment to the other wedges.

Typical force plate data is illustrated in figure 5 - 3 demonstrating the difference between the right and left foot. Figures 5 - 4 and 5 - 5 demonstrate the knee flexion-extension angle and knee moments of the right leg for a participants trail. The mean stance time for all participants was 1.2 s (0.3).

Parameters	0° Wedge	7° Wedge	12° Wedge	23° Wedge
Peak Flexion Moment (Nm)	8.2 (2.3)	9.6 (4.1) *	7 (3.2)	8.5 (2.7)
Peak Extension Moment (Nm)	-7.5 (8.5)	-10.4 (9.9)	-11.2 (12.5)	-13.4 (14.3)

Table 5 - 2 Mean (SD) moments during the stance phase of the gait cycle. Significant ($p < 0.05$) results are highlighted.

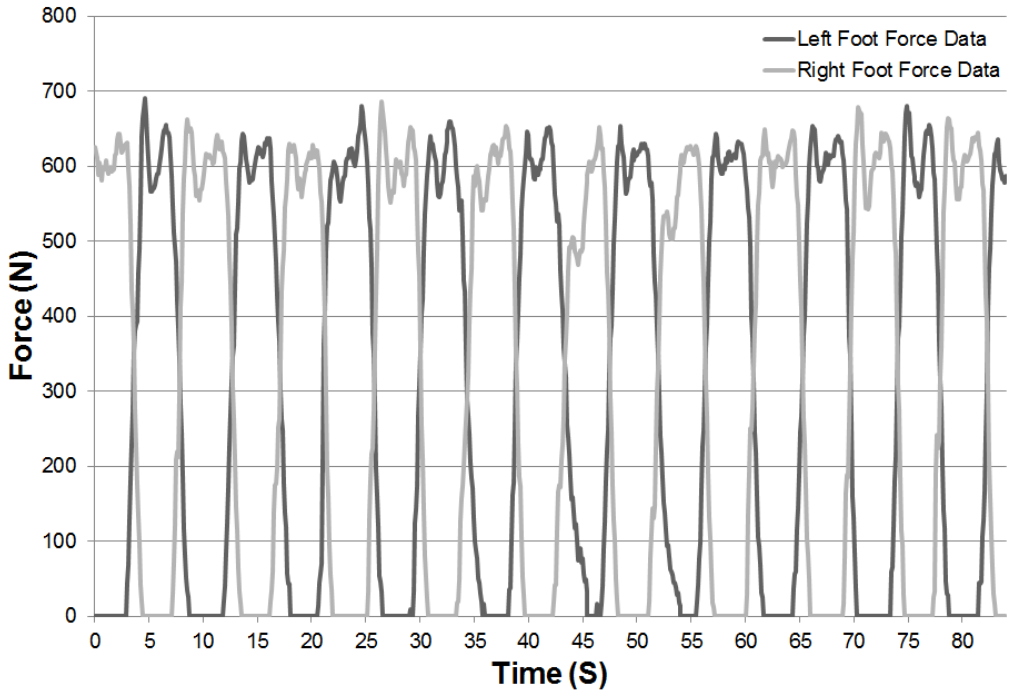

Figure 5 - 2 Example force data, illustrating initial contact, mid-stance and terminal contact.

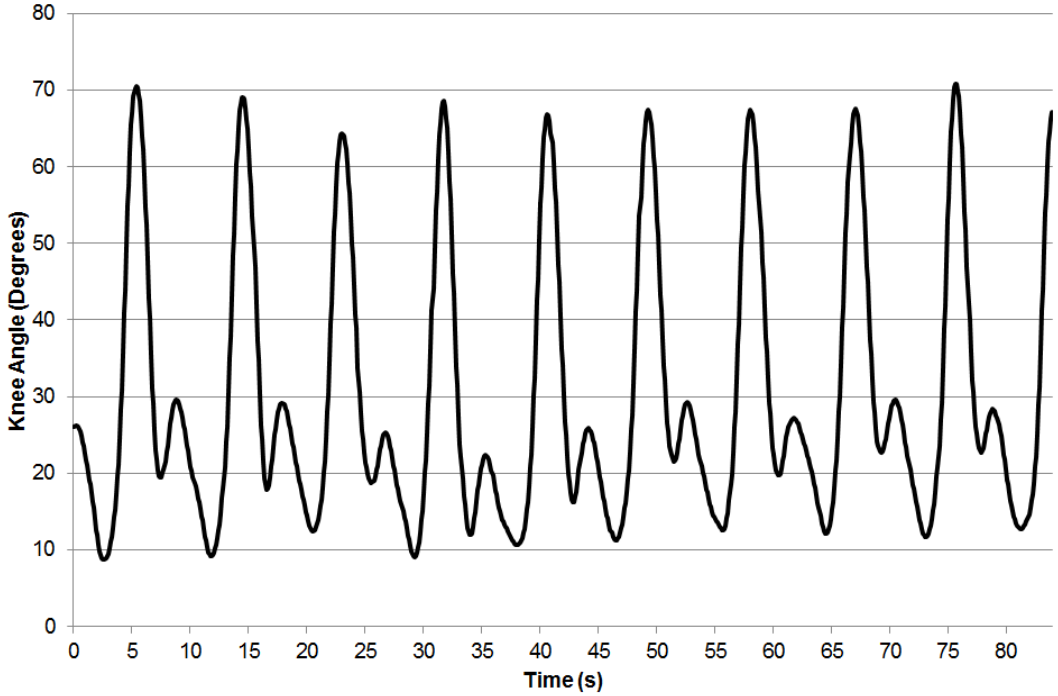

Figure 5 - 3 Example data of the knee flexion-extension angles during the gait cycle of the right limb.

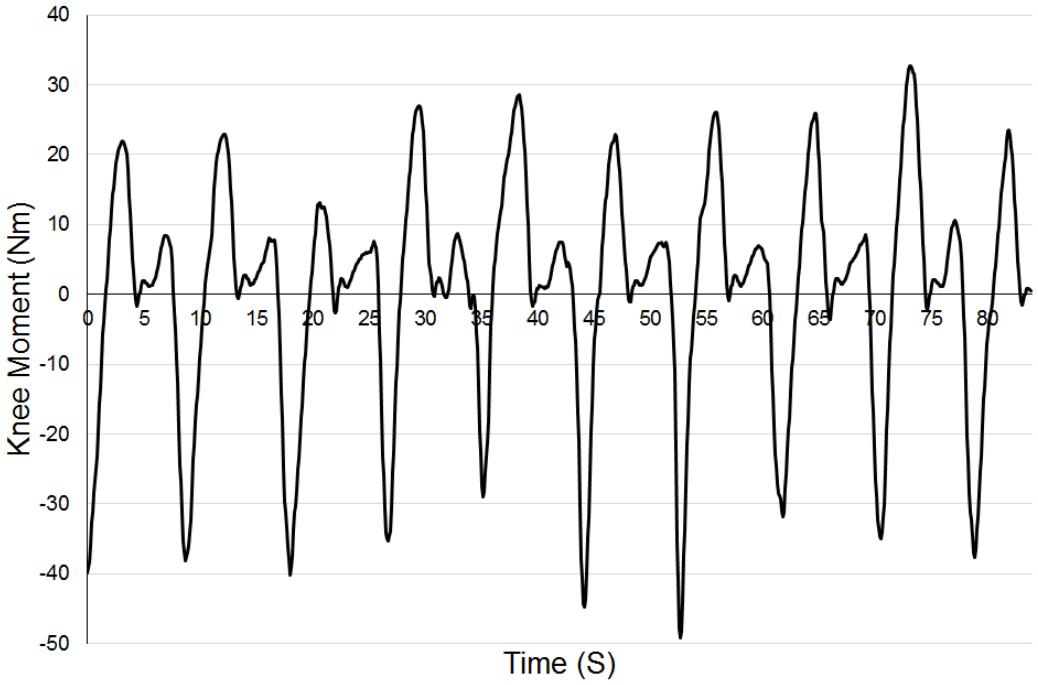

Figure 5 - 4 Example data of the knee moment of the right leg during gait.

Chapter 6 Discussion

The main aim of this study was to evaluate and examine the active wedge device prototype.

6.1 General review

The knee flexion extension angles reported in this study are comparable to existing literature (Jagadamma et al. 2007). A case study investigating four different heel wedges (0º, 8º, 12º and 20º) for tuning a fixed AFO for a child with cerebral palsy discovered that with the increase of wedge angle there was an increase in flexion during stance. The increase demonstrated in the case study is also evident in this study; with an increase of wedge angle there is a significant increase in peak flexion during stance, from 20.4º to 26.4º. A further study investigating the tuning of AFOs found that peak knee flexion of non tuned AFOs had a 19.7º (9.3) angle and tuned AFOs had 25.2º (5.3) (Jagadamma et al., 2009), again demonstrating that there was a trend toward increased flexion during stance, similar to the current study.

Mid-stance has been acknowledged to be a vital phase in the gait cycle when tuning AFOs (Butler & Nene 1991; Owen et al. 2004). Our results indicate that increasing the heel wedge angle significantly alters the knee flexion during mid-stance. There is an increase from 16.8º to 21.4º at mid-stance, suggesting that the active wedge device has the capability to adjust the gait of the participant, specifically the knee flexion angle at mid-stance, highlighting its potential to improve tuning of SWIFT casts and AFOs. It was important to measure the mid-stance angles during gait as there is a lack of evidence linking the knee angle at mid-stance when static to mid-stance while walking (Owen 2004).

Jagadamma et al. (2009) illustrated an increasing knee flexion between non tuned and tuned AFO during initial contact for children with CP: this was not statistically significant, but they suggested it was clinically relevant. Our study follows the same pattern; with increasing wedge there is an increase in flexion at initial contact however it is not statistically relevant. A further study on a stroke patient found an increase in knee flexion at initial contact immediately after tuning (Jagadamma et al. 2010). The 18.3° flexion angle after tuning is closer to the results of this study than the 8.1° angle reported prior to tuning demonstrating that the participants had a much improved base line gait compared to that of stroke patients, and highlights that small changes may not be significant but may be clinically useful when implemented under the correct circumstances.

Butler & Nene (1991) identified that only a small alteration in knee flexion in the gait cycle is clinically relevant as this can considerably adjust the GRF alignment resulting in improved gait. The current study found that all the measured gait phases, which included: initial contact; flat foot; mid-stance; heel rise and terminal contact, indicated an increase in knee flexion but not all demonstrated a significant difference. However, as only a small difference is needed for clinical relevance it is believed the changes in knee flexion are clinically relevant.

In the case study Jagadamma et al, (2007) also found that, when investigating the knee moment during stance, there was no distinct pattern between the wedges. This was similar to our results as no clear pattern was evident in the knee extension or flexion moments during stance. Since peak knee flexion during the swing phase did not vary, this confirmed, as expected, that changing the heel angle did not alter the swing phase.

It is clear from the kinematic results that the active wedge prototype works successfully to adapt the gait of the participants during stance, as desired. The kinematic data demonstrate a range of differences which have been altered by adjusting the heel wedge remotely using the device. The concept of an active wedge was successful.

The device has demonstrated great potential, however there were a variety of problems during tests. One potential reason for a lack of significant changes during initial contact may be due to the identification process of this point during gait. The experiment used the force data to identify the initial contact point however, while testing, when the actuators were fully extended for the 0° wedge angle the wedge noticeably hit the ground before the initial contact point of gait, this is illustrated in figure 6-1. Due to the weight of the aluminium wedge this caused an increase in force before initial contact making identification difficult. Video data would have helped with the identification of the different stages of gait.

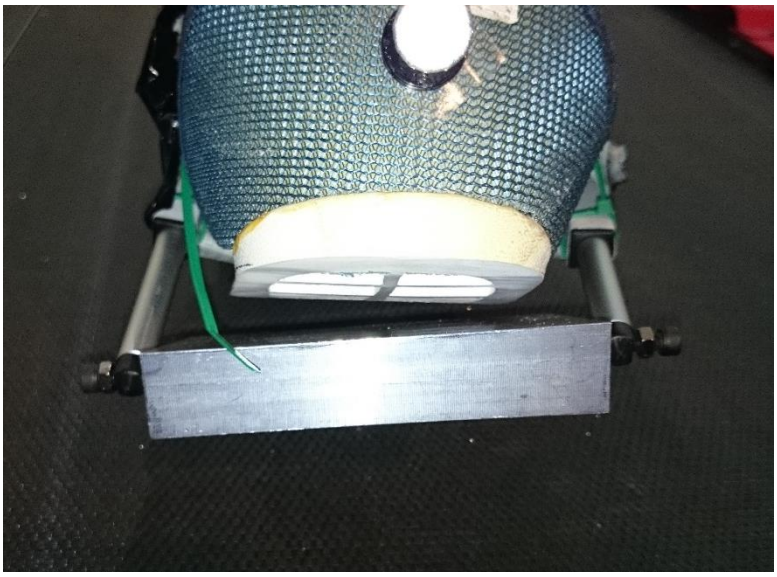

Figure 6 - 1 Demonstration of the aluminium wedge becoming unattached to the heel of the shoe.

The active wedge device successfully changed position when altered remotely by the D-Flow software. Although this study only investigated the difference of four set heel wedge angles, the device has the ability to move to any angle between 0° and 23° which could improve clinical practice due to this ease of adjustment. This device also shows the ability to improve fine tuning as it has the potential to make very small adjustments quickly. However, throughout testing the two actuators did not always move at the same time, causing the wedge to twist slightly and involved time consuming adjustments to fix the misalignment. There was a constant need to unload the foot when changing the wedge as the actuators did not have sufficient strength to manoeuvre the wedge when fully loaded. Under clinical conditions (ie if the participant had suffered from a stroke) this technique would not be acceptable as asking a patient to balance on one foot would compromise the safety of the patient.

The use of the active wedge did highlight that tuning a SWIFT cast has the potential to be simple. If SWIFT cast became part of clinical protocol to improve stroke rehabilitation it would be simple to further customise these casts by tuning. If the SWIFT casts were tuned they may improve the speed of rehabilitation.

6.2 Limitations and future work

This study has generated a variety of ideas for future work to which will improve the device. There are also limitations to the study that may be overcome with further work.

Our study was based on healthy able participants, this does not describe the patient group using SWIFT casts or AFOs well. It can be assumed that healthy individuals already had a normal gait, nevertheless this study detrimentally adjusted their gait as they were required to walk in a SWIFT

cast which locked their ankle. Although each participant was given over 4 minutes to adapt their gait to the SWIFT cast and heel angle the results may have been affected as these participants were not used to walking with their ankle locked. Since the aim of the study was to investigate the device's capability to alter the kinematics and kinetics of the participant and not comment on whether the gait parameters improved, it was felt that the limitation of using healthy subjects was acceptable in this case.

Another consideration should be the stiffness of the SWIFT cast. As the participants were healthy individuals, the SWIFT cast may not have been stiff enough to fully lock the participant's ankle. Future work should investigate if the SWIFT cast has the strength to secure the ankle joint efficiently.

Due to the lack of force of the actuators, the participants were required to unload the device when the wedge needed to be moved (illustrated in figure 4 - 12). Future devices should implement actuators that have more power. The sensitivity of the actuators necessitates improvement to allow them to stay in the correct location, not jump around. It was noted that for certain locations (not those angles chosen for this study) the actuators did not remain still but moved in and out, as if they were confused to the location of correct position. Future devices should use actuators with a greater force and improved sensitivity.

Since the attachment of the wedge to the heel when fully extended was insufficient (illustrated figure 6.1), in future designs it would be useful to have a groove or slot in the shoe the wedge to slide into, thus enabling the wedge to stay in place at all times and ensure there was never a space between the wedge and the heel of the shoe (figure 6.1). Furthermore, the aesthetics of the device need to be improved as its appearance could be concerning to

already vulnerable patients. Improving the attachment of the device could improve its aesthetics.

It was useful to have the device as a shoe as this meant that once assembled no further attachment was required, however this limits the device's use for clinical practice therefore merits consideration in future designs. For example, the device has the potential to be used to tune AFOs for children with CP however, children may want to wear their own shoes, so the next generation of this device should be capable of attaching to any shoe not only Darco Multifit Surgical Trauma Shoes. Another future design consideration would be to extend the connection wiring between the interface box and motor control box (figure 3-5), which would allow the larger box to be attached to the support framework of the treadmill instead of strapped to the participant's waist. Removing excess weight and awkwardness of the box for participants this may alter their gait pattern and allow an improved marker tracking of the posterior superior iliac spine reflective markers.

As the velocity of walking was set to 0.6 m/s the stance time did not alter between participants or between wedge angles. Future studies could use a self-paced treadmill to investigate further the spatial-temporal parameters of gait.

To improve the design of the study the lack of adjustment to the left leg in order to balance the increase in heel height on the right foot should be considered. As this was a pilot investigation, it was felt that this was not necessary.

Finally, extracting the shank to vertical angle from the Vicon data would improve the gait analysis. This would allow greater comparisons with other

studies. As the participants were healthy and due to the constraints of time, it was felt the knee flexion-extension angle would be sufficient to demonstrate if the device worked successfully.

Chapter 7 Conclusion

This study designed an active wedge prototype and assessed the design's ability to be used as a tool for tuning a SWIFT cast or an AFO. The main conclusion found the device to successfully alter the heel angle of the participant which in turn led to alteration in the kinematics and kinetics of gait. The study demonstrated a significant change in peak knee flexion during stance and the flexion angle at mid-stance. These demonstrated that the active wedge device had the capability to alter the participant's gait remotely.

Although this prototype was able to adjust the participant's gait, this project has highlighted many areas to consider for enhancement. The key adjustments included: actuators with a larger force output and better-quality positioning sensitivity; improved attachment to the shoe (specifically when actuators fully extended) or a device that may be attached to any shoe.

As the shoe was adjusted remotely using D-Flow software, this holds great potential for the future improvement of clinical practice for tuning ankle foot orthosis or SWIFT casts. The simplicity of this design and software the way forward to progress ankle foot orthosis tuning thus giving patients the precision necessary to improve their walking without long complicated gait assessment sessions.

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Appendix

Participant Information Sheet

Name of department:

Biomedical Engineering Department

Title of the study: The effect of wedge height on the gait of normal subjects wearing a Swiftcast

Introduction

My name is Megan Austin and I am a postgraduate student undertaking the MSc in Biomedical Engineering at the University of Strathclyde. This information sheet details a project I am undertaking which needs some volunteers for its success. Thank you for taking the time to read this information sheet and for showing interest in my project.

If you have any questions regarding this investigation, please don't hesitate to contact me via e-mail or phone of which contact details can be found at the end of this document.

What is the purpose of this investigation?

The majority of stroke patients stress that walking is their top priority for rehabilitation so commonly an AFO is prescribed to facilitate this. Very few studies consider the optimal biomechanics of AFOs which is crucial for improving gait (Jagadamma et al. 2009). Biomechanical optimisation can be called "tuning", the aim of tuning is to optimise the alignment of lower limbs to manipulate the ground reaction force (GRF) by using a variety of heel wedges, rockers, flares and AFO materials (Eddison & Chockalingam 2013). Specifically the addition of heel wedges have been found to alter the shank to vertical angle (SVA) which helps re-adjust the GRF with regard to the knee and hip joints, resulting in the potential to improve gait (Jagadamma et al. 2009). Currently, the orthotist uses a range of set wedges to tune the AFO but this is time consuming and may fatigue the patient. To help with tuning, we have developed a tool which provides an active wedge that can move between 0° and 30° without having to remove the shoes etc. This device is an altered shoe that has a bar that moves changing the heel angle. This investigation

aims to investigate if this device successfully changes the shank to vertical angle by altering the heel wedge.

The objectives of this experiment are to:

- Measure the position of the heel wedge using the developed tool
- Measure the position of the shank to vertical angle
- Measure the knee and hip joint kinematics

Do you have to take part?

No. Participation is entirely voluntary, and even if you volunteer, you may withdraw at any time up until the end of your testing session. As the data collected is anonymous, you cannot withdraw after your testing session has finished as there is no way to identify the relevant data. Furthermore, participation in or withdrawal will not affect, in any way, your standing or relationship with the University.

What will you do in the project?
Testing will be carried out at:

Biomechanics laboratory #2

Wolfson Building

University of Strathclyde

106 Rottenrow

Glasgow, G4 0NW

If you volunteer, you will be asked to arrive on 2 different occasions at the agreed time and date.

During visit one you will be required to:

- Wear shorts or loose trousers to enable the lower leg to be easily exposed (we can provide or you can take your own)
- A soft scotch ankle-foot cast (SWIFT cast) AFO will then be customized to the lower limb

The SWIFT cast procedure will take a maximum of 45 mins, once removed it is the left for 2 days to cure. You will then be asked to return at a later date for gait analysis.

During walking trials you will be required to:

- Wear shorts and tight clothing (we can provide or you can take your own) so reflective markers can be attached
- Walk at a comfortable speed on a treadmill with the custom made SWIFT cast and active wedge attached
- As the wedge is part of the shoe, you will be provided with a pair of shoes to use
- When changing the angle of the heel wedge you will be asked to stop and hold your position briefly.
- Walk for 4 minutes with each wedge size, 0°, 5°, 10°, 15°, 20°, 25°, 30°

The whole procedure should last no longer than 2 hours.

What are the potential risks to you in taking part?

We believe this experiment involves minimal risk. You may suffer a small of loss of skin integrity to the lower limb in contact with the AFO, this is unlikely as the AFO is custom made but if there is any problem the trials will stop immediately.

What happens to the information in the project?

All data collected will be completely anonymous and will be stored indefinitely on a password protected University computer. This study will be written-up to be academic report. The work will be published in an academic journal".

The University of Strathclyde is registered with the Information Commissioner's Office who implements the Data Protection Act 1998. All personal data on participants will be processed in accordance with the provisions of the Data Protection Act 1998.

What happens next?

If you are happy to be involved in this project please email (megan.j.austin@strath.ac.uk) to confirm. Please sign the attached consent form to confirm your participation and bring it along to the testing session. If you would not like to be involved then thank you for your time. If you have any questions please contact us at the address below:

Researcher Contact Details:

Megan J Austin

MSc student

Chief Investigator Details:

Prof. Philip Rowe

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University of Strathclyde
megan.j.austin@strath.ac.uk
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University of Strathclyde
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This investigation was granted ethical approval by the Departmental Ethics Committee.

If you have any questions/concerns, during or after the investigation, or wish to contact an independent person to whom any questions may be directed or further information may be sought from, please contact:

Linda Gilmour

Secretary to the Departmental Ethics Committee
National Centre for Prosthetics and Orthotics
Department of Biomedical Engineering
Curran Building, 131 St James Road
Glasgow G4 0LS
Tel: 0141 548 3298 E-mail: linda.gilmour@strath.ac.uk