A preliminary study into the immediate effects of ankle foot orthoses of varying design on the walking of people in the early stages of stroke recovery and healthy individuals.

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Statement of Sources

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Abstract

Ankle foot orthoses (AFO's) are prescribed to patients who have ankle impairments causing difficulty walking following stroke. The evidence regarding the benefit of prescribing AFO's, particularly with regard to type of AFO and timing of intervention, is unclear. There are few studies that investigate the effect of AFO's in the subacute phase following stroke and few studies that compare different types of AFO. There is little evidence regarding the effect of AFO's on the gait of normal healthy individuals. This study aimed to compare the effects on walking in different AFO's, of varying degrees of rigidity, in participants in the early stages of stroke walking recovery and in healthy individuals.

Thirteen participants (ten male) in the subacute phase of stroke recovery, aged 23-71 years (M=52.3 \pm 13.9), and thirteen age and gender matched healthy participants, aged 26-70 years (M=52.2 \pm 13.1), were recruited to the study. Stroke participants were included if they had a unilateral hemiparesis, were less than 20 weeks post stroke, able to walk with or without supervision and had a motor deficit of the ankle dorsiflexors.

Temporal distance gait measures were collected using the GAITRite mat (CIR Systems GRG-24, United States, 80Hz) and knee angles throughout the stance phase, were collected using Silicon Coach Pro software™ (version 7, Silicon Coach Pty Ltd, Dunedin, New Zealand). Stroke participants were tested across three consecutive days, whilst the healthy participants were tested on a single occasion in barefoot, shoes, and three AFO types of varying rigidity: push aequi brace, spring leaf AFO and in a fibreglass cast Each group of participants were familiarised to walking in each AFO. Group differences across the five conditions were assessed using the Friedman's Test. The 'smallest real difference' measure was used to

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determine the degree of individual improvement with use of the AFOs compared to the shod walking

The results indicated the healthy participants walking performance exceeded that of the stroke participants for velocity, cadence, double limb support, step length, single support phase, single support symmetry, but not swing phase or knee angle at initial contact, midstance or terminal stance for each of conditions tested. Group analysis demonstrated that use of an AFO did not improve walking for the stroke participants: who walked at 46.0 cm/sec (SD: 25.9) in shoes, compared with 46.9 cm/sec (SD: 24.4) in an AFO (p= 0.507). However it caused deterioration in walking in the healthy participants, as demonstrated by a 11.9cm/sec deterioration in a AFO (120.1cm/sec +14.2) in comparison to shoes (132.0cm/sec +16.1) (p=0.002) with similar deteriorations in cadence (shoe: 113.1 steps/minute +7.1; AFO: 102.2 +30.7; p=0.009), step length (shoe: 69.9cm +7.9; AFO: 66.0 +7.2; p=0.002), single stance phase (shoe: 37.1% +1.3; AFO 36.0 +1.3; p=0.009), swing phase (shoe: 37.2% +1.4; AFO: 37.7 +1.1; p=0.039), stance symmetry (shoe: -0.63 +2.9; AFO: -4.9 +3.1; p=0.004) and knee angle at initial contact (shoe: 1.92 degrees +3.9; AFO:3.6 +2.6; p=0.049). The results demonstrating the more rigid the AFO the greater the deterioration for the healthy participants. The smallest real differences of the stroke group indicated that for five participants at least one type of AFO improved their walking.

The findings of this study do not support the routine prescription of AFO's following stroke to patients with ankle impairment. As the walking of the healthy participants deteriorated, there is the suggestion that the application of an AFO may be detrimental. As AFO's have been demonstrated to improve walking performance by increasing velocity, step length or affected leg stance percentage of the gait cycle

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for some participants the prescription of an AFO should not be discounted. Prior to prescription of an AFO to a stroke patient careful assessment should occur. Following the prescription of an AFO ongoing assessment is required to examine whether the AFO yields a benefit. Future research should consider the analysis of individual responses in addition to group analysis.

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Chapter 1 INTRODUCTION AND OVERVIEW OF

PROJECT

1.0 Introduction and overview of project

Stroke is one of the most common diseases of the cardiovascular system in the western world. In 2003, over 40,000 stroke events occurred and there were over 340,000 Australians whom had suffered a stroke at some point in their lives (AIHW: Senes, 2006). A stroke occurs when the blood supply to the brain is interrupted (National Stroke Foundation, 2008) resulting in irreversible cell damage. A stroke can affect all physical and cognitive domains including strength, sensation, proprioception, muscle tone, vision, the ability to swallow, attention, concentration, memory, orientation, language and executive functions such as initiation and inhibition of behaviours, planning and problem solving (National Stroke Foundation, 2005). The consequences of stroke can bring about changes in an individuals' ability to carry out basic tasks of day to day living.

The loss of the ability to walk is a common consequence of stroke. Fifty to 80% of patients will regain some level of walking function following stroke (Skilbeck, Wade, Hewer, & Wood, 1983), with 62% of patients being able to walk independently six months post stroke (Kollen, Kwakkel, & Lindeman, 2006). It is the aim of health professionals to limit the deleterious effects of stroke by maximising an individual's functional level in the physical, cognitive and social domains (AIHW: Senes, 2006). The prescription of an ankle foot orthosis (AFO) is one intervention used to address physical function; specifically for those patients who have ankle impairments resulting in difficulty walking after a stroke. An AFO provides assistance to the affected leg through the stance and swing phases of gait in order to improve the performance in walking.

The use of AFO's in stroke is widespread (Teasell, McRae, Foley, & Bhardwaj, 2001), however there is little evidence regarding the efficacy of AFO's in the literature (Condie, 2003), particularly in the early stages of walking recovery following stroke. Due to the limited research regarding the use of AFO's in stroke it remains unclear if specific AFO's are suitable for particular patient groups. There are many types of AFO, each having different effects on the biomechanics of the foot/ankle complex or lower limb in general during gait. There is little gait research specific to early stroke recovery, and less examining AFO's with different biomechanical purposes. Therefore, the current clinical recommendations are inadequate due to the lack of research studies. The aim of this study was to identify differences in walking performance using different AFO's.

1.1 Ankle Foot Orthosis

AFO's can allow stroke patients more independence or greater efficiency in their walking by assisting the swing and/or stance phases of gait. These benefits can reduce the burden of care and everyday task participation restriction, which can be significant following stroke. Specifically AFO's have been found to improve walking velocity (Franceschini, Massucci, Ferrari, Agosti, & Paroli, 2003; Gok, Kucukdeveci, Altinkaynak, Yavuzer, & Ergin, 2003; Hesse, Luecke, Jahnke, & Mauritz, 1996; Leung & Moseley, 2003; Pavlik, 2008; Wang, Lin, Lee, & Yang, 2007; Wang et al., 2005), step length (Gok et al., 2003; Hesse, et al., 1996; Leung & Moseley, 2003; Wang et al., 2007) and step symmetry (Hesse, Werner, Matthias, Stephen, & Berteanu, 1999).

There are many AFO options available to prescribe, as is evidenced by the variety that have been examined and reported in the literature (Chen, Yeung, Wang, Chu, & Yeh, 1999; Corcoran, Jebsen, Brengelmann, & Simons, 1970; de Wit, Buurke, Nijlant, MJ, & Hermens, 2004; Diamond & Ottenbacher, 1990; Dieli, Ayyappa, & Hornbeak, 1997; Fatone & Hansen, 2007; Franceschini et al., 2003; Gok et al., 2003; Hesse et al., 1996; Wang et al., 2005). These include custom-made and mass produced AFO options. Whilst there is evidence that AFO's can be of benefit, there is also a belief that AFO's could reduce the ultimate recovery of volitional muscle activity of the ankle by limiting the movement available at that joint (Leung & Moseley, 2003). The impact of AFO use on recovery of volitional muscle activity at the ankle has not yet been fully investigated.

Clinical markers used to assist in prescribing AFO's in stroke have not been established. Prescription is currently based on the clinical experience of the clinician, without a sound evidence base established to guide practice (Condie, 2003). The clinician should assess the impairments of their patient and decide on the characteristics of the AFO which will effectively address these impairments. Relationships between impairments and brace characteristics have not been established. A need has been identified to further understand the timing of the application of AFO's and the type of AFO's prescribed (including comparing pre-fabricated AFO's with custommade AFO's) (National Stroke Foundation, 2005; Tyson & Kent, 2009).

Most studies compare walking with and without a single type of AFO in the chronic stage post stroke (Chen et al., 1999; Danielsson & Stibrant, 2004; de Wit et al., 2004; Dieli et al., 1997; Fatone & Hansen, 2007; Franceschini et

al., 2003; Hesse et al., 1996; Hesse et al., 1999; Mojica et al., 1988; Tyson & Thornton, 2001; Wang et al., 2005). The current study focused on patients in the early stages of recovery following stroke and examined AFO's of varying rigidity. This was considered significant as no study has described a similar methodology and the outcomes of such a methodology might allow more accurate prescription of AFO's and may improve outcomes for people with stroke.

The current literature regarding AFO prescription, particularly in the early stages of walking recovery following stroke, leaves a significant number of unanswered questions. These questions include; are certain populations of patients likely to benefit from an AFO? Do differences in the type of AFO used alter walking performance? Further to this, do specific physical impairments indicate a particular type of AFO to be more appropriate? These questions could be answered via a scientific investigation into the use of AFO's in patients in the early stages of recovery following stroke.

1.2 General Objectives

The questions mentioned above, positioned this study to be of significance and unique. This formed the objectives of the study, which are:

 To compare walking performance of patients in the early stages of walking recovery following stroke against healthy, age and gender matched controls.

 To compare walking performance in this target population under different AFO conditions against healthy, age and gender matched controls.

1.3 Research Hypotheses

The following hypotheses were proposed to measure the effect of different AFO's use on walking performance in comparison to walking in shoes in the early stages of walking recovery following stroke. The study also considered the effect of different AFO's on an age and aged matched normative comparison group. AFO's with differing levels of rigidity and ankle support were utilised in the study. A comparison between shod walking and barefoot walking will also be considered as walking in barefoot may also influence performance due to direct contact to the ground, which may increase kinaesthetic feedback. Analysis of symmetry in walking is necessary as stroke commonly cause unilateral deficits, resulting in differing performances between the left and right sides of the body. Symmetrical gait can be considered to be left and right sided performance not differing by more than ten percent (Balasubramanian, Bowden, Neptune, & Kautz, 2007).

 By using an AFO's a sample of patients in the early stages of walking recovery following stroke will improve in their walking performance as measured by GAITRite [™].

- By using an AFO a sample of patients in the early stages of walking recovery following stroke will be more symmetrical in spatial and temporal parameters of walking as measured by GAITRiteTM.
- Participants with a greater degree of ankle impairment will improve in their walking performance as measured by GAITRite [™] when using more rigid bracing.
- Normative participants will deteriorate in the walking performance as measured by GAITRite [™] when using AFO's.
- Normative participants will be less symmetrical in spatial and temporal parameters of walking as measured by GAITRite[™] when using AFO's
- Normative participants will show greater deterioration in their walking performance as measure by GAITRite[™] when using more rigid AFO's.

1.4 Summary

Ankle foot orthoses can be used to improve walking performance in certain patients following stroke. AFO's have been demonstrated to assist in various parameters of walking performance (Leung & Moseley, 2003). These parameters have not been well described in patients with stroke in the early stages of their walking recovery, nor have ankle impairments been used to better describe which AFO's may be of benefit. Studies have not controlled for the impairment of the ankle, and few have controlled for the stroke.

This study is of scientific merit as it aims to answer gaps within the scientific literature. The gaps in knowledge pertaining to the use of AFO's are: the immediate effects of AFO's in the early stages of walking recovery, the effects of ankle impairment on the use of AFO's and the effects of the application of varying types of AFO's in the early stages of walking recovery. This study was unique as it focused on patients in the early stages of walking recovery, controlled for three different types of AFO's to healthy walking.

Chapter 2

LITERATURE REVIEW

2.0 Literature Review

This section reviews the prevalence and aetiology of stroke. The consequences of stroke are discussed followed by the impact of these consequences. The impact of alterations in the capacity to walk is highlighted as one such consequence. Ankle foot orthoses (AFO's) are introduced as one method to assist in limiting the impact of stroke on walking. Areas requiring further research into the prescription of AFO's are identified. Following this, a method in which identifies factors suggestive of the prescription of AFO's was designed.

2.1 Stroke

Stroke is one of the most common diseases of the cardiovascular system in the western world. The overall cost of stroke to Australia is estimated to be \$2.14 billion a year (National Stroke Foundation, 2010). These figures indicate that stroke is a significant disease affecting many individuals and the community at large. A stroke occurs when the blood supply to the brain is interrupted (National Stroke Foundation, 2008), resulting in irreversible cell damage as the neural cells that make up the brain do not store their own energy (Durukan & Tatlisumak, 2007). A stroke can affect all physical and cognitive domains, including: strength, sensation, proprioception, muscle tone, vision, the ability to swallow, attention, concentration, memory, orientation, language and executive functions such as initiation and inhibition of behaviours, planning and problem solving (National Stroke Foundation, 2005). These consequences can bring about changes in an individual's ability to carry out basic tasks of day to day living.

2.1.1 Causes of Stroke

Stroke is categorized into ischaemic and haemorrhagic infarctions, and these subsets are further divided according to their aetiology (Figure 2.1). Infarctions account for 87% of all strokes, with haemorrhagic strokes accounting for the remainder (Rosamond et al., 2007). Whilst the pathophysiology of both types of strokes is different, the ensuing neurologic deficits are the same, however the mortality associated with haemorrhagic strokes is much greater than infarction (Rosamond et al., 2007). Fatality within the first thirty days following infarction is 10% and for intracerebral haemorrhage it is 50% (Bamford, Sandercock, Dennis, Burn, & Warlow, 1990).

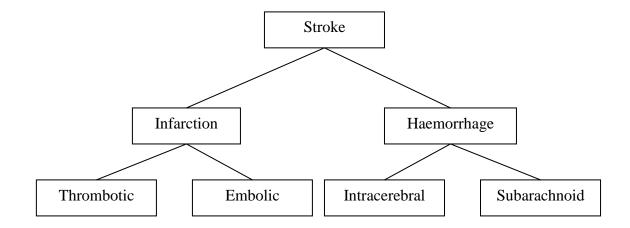
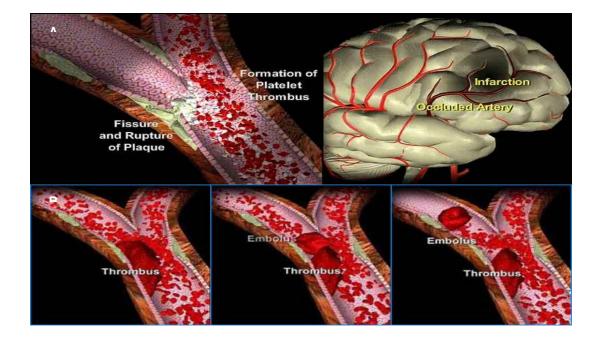


Figure 2.1: Outline of the subsections of stroke

The two subsets of an ischaemic infarction are thrombotic or embolic. A thrombotic stroke occurs when a thrombus, or blood clot, develops within the cerebral circulation usually due to turbulent blood flow (Figure 2.2). Turbulent blood flow occurs due to atherosclerosis or where the artery bifurcates. In both instances the change in the lumen of the artery causes the turbulence which in turn allows clots to form or lodge. An embolic stroke occurs when an embolus, from a distant thrombus, is dislodged and travels to the cerebral circulation where it lodges causing a blockage. Risk factors for both thrombotic and embolic infarction are cumulative and include age (Thrift, Dewey, Macdonell, McNeil, & Donnan, 2000; Wolf, D'Agostino, Belanger, & Kannel, 1991), gender (Kelly-Hayes et al., 2003; Thrift et al., 2000), family history (National Stroke Foundation, 2005), smoking (Wolf, D'Agostino, Kannel, Bonita, & Belanger, 1988), atrial fibrillation (Wolf, Abbott, & Kannel, 1991; Wolf, D'Agostino et al., 1991), hypertension (Seshadri et al., 2006), high cholesterol, diabetes, and obesity (Wolf, D'Agostino et al., 1991). The presence of more than one risk factor increases the risk of stroke proportionally to the severity of each risk factor (Wolf, D'Agostino et al., 1991).



<u>Figure 2.2.</u> Pathogenesis and pathophysiology of stroke. (a) Turbulent flow due to atherosclerosis (fissure and rupture of plaque) that develops into a thrombus. (b) Complications of a thrombus; the development of an embolus, from a distant thrombus that can cause an (c) occluded (blocked) artery. Diagrams from www.strokecenter.com

A haemorrhagic stroke is a reduction in blood supply to the brain due to the splitting or bursting of a cerebral artery due to changes in the arterial wall or malformations of the arterio-venous system within the brain. Haemorrhagic strokes can be classified into two main categories: intracerebral and subarachnoid haemorrhage. Intracerebral haemorrhages are usually the result of arterial hypertension causing a rupture in the arterial wall and bleeding into the surrounding tissue. This has a two-fold effect. The disruption of blood supply starves the cerebral tissue, the artery supplies of oxygen and nutrients, and the bleeding into the cerebral tissue raises the pressure within the brain (intra-cerebral pressure) causing further cerebral damage. A subarachnoid haemorrhage is a rupture of an artery within the subarachnoid space, a small space between the outer covering of the brain and the two outer layers of the brain (dura mater and arachnoid mater) and is usually filled with cerebrospinal fluid. Subarachnoid haemorrhages may result from a rupture of an aneurysm of an artery within the subarachnoid space, an extension of an intracerebral haemorrhage or vascular malformation.

One factor that can increase the risk of stroke is age (Thrift et al., 2000; Wolf, D'Agostino et al., 1991). Therefore as the population is ageing (Australian Bureau of Statistics, 2008) the incidence of stroke is expected to rise. Over 100,000 strokes per year are expected to occur in Australia by 2030, an increase from over 40,000 in 1997 (AIHW: Senes, 2006). The incidence of the burden of stroke on individuals and their families can also be expected to rise. Resources from both within hospitals and the community can be expected to be further stretched as demand increases.

2.1.2 Consequences of Stroke

Many survivors of stroke experience disability following stroke. Disability is best described by the classification system outlined by the World Health Organisation (WHO) which provides a framework for explaining the affect of illness and disability. The International Classification of Functioning, Disability and Health (ICF) includes all factors which influence disability, recognizing that the interaction between factors such as environment, personal and physical factors influence their ability to participate in activity (WHO, 2001).

The WHO describes difficulties an individual has in executing activities as an activity limitation and a problem an individual experiences in involvement in life situations as a participation restriction (2001). Following stroke a large number of survivors are unable to complete activities that formed the basis of their pre-stroke lives, reporting difficulties with living independently, such as requiring assistance with mobility, personal and household tasks (Paul et al., 2005). This category of survivors can be defined as having activity limitations and participation restrictions which can significantly reduce the quality of their lives (Sturm et al., 2004). The findings of Paul et al. (2005) can be extrapolated to include difficulties in maintaining a career or providing assistance to other family members. The range of activities that can be negatively influenced by stroke is endless, from the most basic to the highest functional level possible. In 2003 81% of stroke survivors had a disability of some form (AIHW: Senes, 2006). Seventy-three percent of those survivors were moderately to profoundly limited in core activities, such as communication, mobility and self care (AIHW: Senes, 2006). The cost of addressing activity limitations is great, both in monetary terms (Dewey et al., 2001) and in the time and the emotional burden placed on family members who become carers (Dewey et al., 2002).

The outcome following stroke is of great interest to patients, their families and those health professionals providing their care. One in five people die as a result of stroke within one month, and one in three within 12 months (Thrift et al., 2000). Fifty percent of three-day survivors survive five years (Hankey, Jamrozik, Broadhurst, Forbes, & Anderson, 2002). Nearly all people are disabled to some degree immediately following their stroke (AIHW:

Senes, 2006). The prevalence of disability following stroke has been measured between 36% to 81%, (AIHW: Senes, 2006; Hankey et al., 2002). Sixty-six percent of cases surveyed reported an incomplete recovery at 12 months, the greatest limitations being in physical independence and being able to engage in personally important occupations (Sturm, Dewey et al., 2002). At the end of 12 months about half of all survivors are dependent on others for activities of daily living (Hankey et al., 2002). Of the stroke survivors with disability, half needed help with health care, mobility, household chores and transport and a quarter needed help with self care and cognitive tasks (Senes, 2004).

A study which evaluated quality of life following stroke found a normally distributed result where some participants reported that the stroke did not change the quality of their life at all, and another participant reported that having a stroke resulted in a quality of life worse than death (Sturm, Osborne et al., 2002). The awareness of the effect of depression post-stroke, and other psychological disorders on quality of life and the ability to participate in activities of importance is increasing (Paolucci et al., 1999). It is the aim of health professionals to limit the deleterious effects of stroke by maximising an individual's functional level in the physical, cognitive and social domains (AIHW: Senes, 2006). Maximising an individual's functional level can reduce activity limitations and increase participation levels. This could limit the negative effects and potentially reduce the burden of disability.

2.1.3 <u>Recovery following stroke</u>

Reduction of disability following stroke is due to the recovery of function due to neuroplasticity (Ward & Cohen, 2004) and the adoption of compensatory strategies to mitigate for the loss of movement and function.

2.1.3.1 Neuroplasticity/Recovery of Function from Stroke

Recovery in function following injury to the central nervous system (CNS) such as from stroke is thought to be due to a reorganization of the CNS (Ward & Cohen, 2004). Recovery is improved in the therapeutic setting (Kalra & Ratan, 2008) and both are influenced by behavioural experience (Nudo, 2007). Recovery and re-organisation of the brain occurs in the very early stages following stroke as demonstrated in an animal (mouse) model by Brown, Wong and Murphy (2008). This suggests that the reorganization of the brain can be influenced by behavioural or environmental exposure during the acute phase post stroke. There is however limited research into the early recovery following stroke in humans (Hodics, Cohen, & Cramer, 2006), with many of the conclusions in regards to recovery in the early stages drawn from studies on animals (Cramer & Riley, 2008; Nudo, 2007). These results may or may not be entirely applicable to humans.

A number of cellular changes occur within the brain to aid recovery (Cramer, 2008). Neuroplasticity can be maximised by utilising experience of the environment to direct the neuronal plastic recovery process towards functional and meaningful activities. It has been shown that providing demand through forced use of the paretic upper limb increases cerebral activity and size (Nudo, 2007). Conversely, a lack of demand results in reduced cerebral

representation (Nudo, 2007). Areas of the brain that are involved in the reorganisation are task related areas within the affected hemisphere, periinfarct regions, regions of the affected hemisphere linked (but distant to) the infarct area and homologus areas of the unaffected hemisphere (Kreisel, Bazner, & Hennerici, 2006; Rijntjes, 2006). The reorganisation is highly dynamic in the early stages of recovery (Van Peppen et al., 2004) and poorly understood (Kreisel, Hennerici, & Bazner, 2007). The pathophysiological process of recovery commences seconds following the initial insult and continue for days or weeks (Kreisel et al., 2006). There are five phases of recovery following stroke; a hyperacute phase (less than 6 hours post stoke), an acute phase (up to four days post stroke), a subacute phase (two to three weeks post stroke), a consolidation phase (months post stroke) and a chronic phase (several months post stroke (Kreisel et al., 2006) ;see Figure 2.3). Each phase overlaps and represents different processes in the function of neuronal plasticity and recovery (Table 2.1).

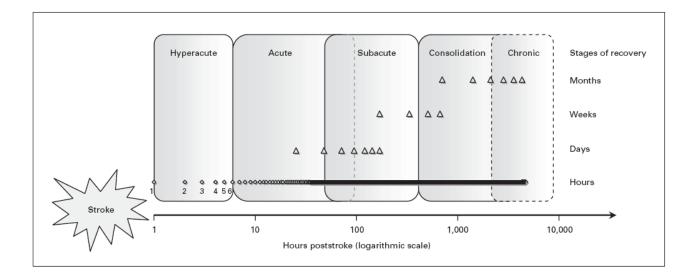


Figure 2.3: Schematic representation of the five phases of recovery following stroke (Kreisel et al., 2006),

As the subacute phase is a period of great neuroplastic recovery (Kreisel et al., 2006) it is of great importance to clinicians because there is the potential for significant recovery to occur, which could be harnessed to maximise function. This must be utilised carefully as there is also potential for reorganisation to occur which is inappropriate and may be negative in effect (Huitema et al., 2004). It is unclear how the intrinsic recovery processes interact with the recovery processes driven by extrinsic factors such as the environment, treatment and remaining motor activity (Forrester, Wheaton, & Luft, 2008; Krakauer, 2006; Kreisel et al., 2006; Nudo, 2007). The evidence for the effects of experience and environmental interaction suggest that the extrinsic processes play a significant role (Liepert, Graef, Uhde, Leidner, & Weiller, 2000; Nudo, 2007; Rijntjes, 2006; Ward & Cohen, 2004). If it is accepted that extrinsic processes are of great significance, care must be taken to ensure these extrinsic processes are appropriate.

Phase	Summary of neural recovery occurring
Hyperacute	Lesion core does not participate in the network.
Acute	Lesion core does not participate in the network.
	Penumbra contributes to resolution (positively or negatively
	depending if the penumbra is recruited to the affected network).
Subacute	Network highly active, adapting to internal changes (the lesion) and
	external mechanisms (compensating for loss of function). Highly
	plastic phase
Consolidation	Slowing of the subacute phase,
Chronic	Recovery of function is due to compensation

<u>Table 2.1</u>: Description of the phases of recovery following stroke.

Recovery of function can also occur due to compensatory changes established by the body in response to the original loss of function (Bensoussan, Mesure, Viton, & Delarque, 2006; Kerrigan, Bang, & Burke, 1999; Kerrigan, Frates, Rogan, & Riley, 2000). These compensations can be useful in restoring function but some clinicians believe that they can interfere in optimal movement being attained (Pollock, Baer, Langhorne, & Pomeroy, 2007). There are currently no clinical guidelines or direction from the scientific literature as to when compensatory techniques should be instituted in the treatment of patients with stroke, if at all. It is accepted that the most rapid neuroplastic changes occur within three months (Boake et al., 2007), although this is currently being challenged in the literature (Fritz, Pittman, Robinson, Orton, & Rivers, 2007; Page, Gater, & Bach-y-Rita, 2004). Individuals certainly continue to make gains in function after the three month point (Paolucci et al., 2001). Whether this is mediated via neuroplastic processes or via compensatory processes is unclear (Bensoussan et al., 2006; Page et al., 2004). This does highlight the potential for patients to improve. Clinical interaction, or treatment, with the patient has the potential for positive and negative effects. Therefore, the clinician must take care to ensure they do not limit their patients' outcome. AFO's can be thought to be a compensatory strategy as they mitigate impaired stance or swing phases of gait. However people with stroke attempting to walk without ankle control may also adopt maladaptive intra and interlimb compensatory strategies (Chen, Chen, Tang, Wu, Cheng & Hong, 2003). Using the principles of neuroplasticity, constraining the ankle in an AFO may reduce the environmental demand on the ankle and limit motor recovery. This limitation in recovery may in turn impact on the ultimate functional outcome due to the lack of demand on recovery.

2.1.4 Treatment Approaches Following Stroke

The importance of maximising the capacity to bring about recovery of movement and therefore improving functional outcome in the early stages of stroke is paramount. This has the potential to limit participation restrictions commonly suffered by individuals with stroke. Physiotherapists and other clinicians utilize a number of different strategies to address the changes in

gait patterns following stroke. Treatment techniques include 'The Bobath Concept', task specific training, proprioceptive neuromuscular facilitation and stretching. These techniques are all based upon neurophysiological concepts, as outlined earlier, and motor relearning principles (Hesse, 2003; Pollock et al., 2007). The goal of rehabilitation is to address impairments and restore functional abilities to limit or eliminate disability (Pomeroy & Tallis, 2002). No specific physiotherapy treatment has been identified to be more advantageous in the treatment of stroke, and all therapeutic approaches have been found to be better than no treatment at all (Pollock et al., 2007).

Physiotherapists' treat movement disorders by identifying how and why a movement differs from normal, before attempting to restore the missing element (Moseley, Wales, Herbert, Schurr, & Moore, 1993). Physiotherapists attempt to restore function without using compensatory techniques or encouraging compensatory movements. This is particularly important in the early stages of recovery when the neurological system is in its' neuroplastic phase (Kreisel et al., 2006) as there is the potential to train compensatory movements to the detriment of overall outcome. Techniques that use compensation such as orthoses, walking aids or deliberately altering the way in which a patient moves in comparison to healthy need to be considered carefully in the subacute stage of recovery. Once the patient plateaus in their recovery, there is less concern about utilising compensation strategies to achieve a desired functional level.

2.1.5 Walking

Walking is a basic (fundamental) human activity. The loss of the ability to walk is commonly reported following stroke (National Stroke Foundation, 2005). This limits an individual's activities and restricts their ability to participate in home, work or recreational related tasks. The loss of the ability to walk can influence an individual's capacity to participate in a broad range of activities. These activities can be as simple as walking to the toilet or playing in the park with grandchildren, maintaining a career or supporting other family members, potentially diminishing their family role and affecting their psychological wellbeing (Paul et al., 2005).

2.1.5.1 Normal Gait

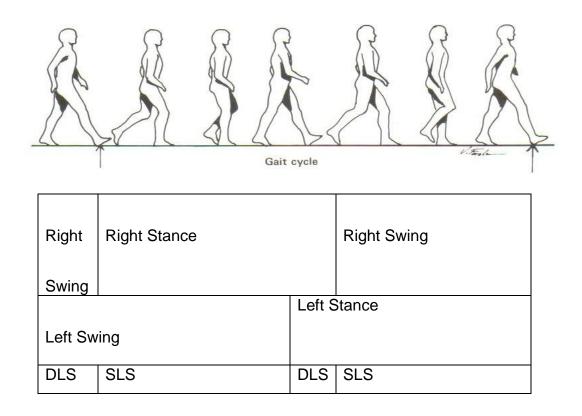
Walking, whilst being highly individualized, has a number of elements consistently similar despite differences in its appearance (Norkin & Levange, 1992). The motor control of gait is under the control of a number of the body systems that interact to modify the output (walking) to ensure that the task is completed in the manner in which it was originally being intended. There are three sensory systems involved in the control of balance and gait (Shumway-Cook & Woollacott, 2007; Winter, 1995; Woollacott, 2000). The visual system (i) evaluates non-tactile information regarding the body's position from the environment (Shumway-Cook & Woollacott, 2007; Woollacott, 2007; Woollacott, 2000), (ii) the vestibular system senses linear and angular acceleration of the body (Shumway-Cook & Woollacott, 2007; Winter, 1995); and (iii) the somatosensory system detects the position and velocity of all body segments

in relation to gravity and the environment (Shumway-Cook & Woollacott, 2007; Winter, 1995). A continuous cycle of processing sensory information and executing motor responses, defined as a postural control strategy, occurs where: (i) sensory information from the cutaneous, proprioceptive and vestibular receptors are relayed to the CNS; (ii) within the CNS the information is interpreted, a movement strategy is formulated and initiated; and (iii) a movement response is executed in the periphery (Shumway-Cook & Woollacott, 2007).

Walking is a complex activity that requires postural control in order to maintain balance. This is mediated by the sensory systems outlined above. As each step is taken a perturbation occurs which destabilises the individual. These perturbations are due to movements produced by the individual to propel themselves forwards (i.e. stepping their leg through). The perturbations are also caused by external influences such as those produced by the foot striking the ground. Muscle activity is required for stabilisation to ensure an upright posture is maintained. Alterations in the ability to provide that stabilisation due to pathologic processes such as stroke limit the strategies available to produce that particular movement in response to the perturbation (Heiderscheit, Hamill, & van Emmerik, 2002). This results in the reduced performance of walking. This performance can be measured and reported in a number of ways.

Walking can be measured, in simple terms, using a number of variables such as speed, the length of the step and the contact the foot makes with the ground, including any differences between the left and right sides. The way in which we walk can also be represented by the movements that

take place at each joint of the body as we walk (Winter, 1991). These movements can be better described by identifying the stage of the walking cycle which they occur. The phases of gait are traditionally divided into stance phase and swing phase, with further description within each phase (Lehmann, 1993) (Figure 2.3). There are two conventions in describing the phases of gait, both phases have been outlined below (Table 2.2) and represent the same periods of the gait cycle. There are periods of overlap between each cycle for the left and right sides where both limbs are in contact with the ground. These periods are known as double limb support (DLS). Periods of DLS allow for a brief period of stabilisation, prior to the commencement of the next single leg stance period (Winter, 1995). The time spent in double limb support, as percentage of the gait cycle, is used to determine the control of balance in gait. For example, as the control of walking increases, the time spent in DLS reduces.



<u>Figure 2.4</u>. Phases of the gait cycle, from Norkin and Levange, 'Joint Structure & Function: A comprehensive analysis' 1993 pg 451. DLS = double limb support; SLS = single limb support.

Table 2.2: Description of the two phases of gait (from Norkin and Levange

1993)

Stance Phase	
Heelstrike	Commencement of stance phase, and end of swing
or	phase. Occurs the moment the heel of the swinging leg
Initial Contact	strikes the ground
Foot flat	When the foot is flat on the ground and the contralateral
or	leg begins its swing phase
Loading response	
Midstance	Body weight progresses directly over the foot
HeelOff	The heel of the stance leg begins to leave the ground,
or	occurs just prior to initial contact of the contralateral leg
Terminal Stance	
Toe Off	Only the toe is in contact with the ground of the stance
or	limb. The progression from heel off towards toe off
Preswing	
Swing Phase	
Accelaration	Begins once the toe leave the ground and continues
or	until maximal knee flexion has occurred and the limb is
Initial Swing	directly below the body
Midswing	Occurs from maximal knee flexion until the tibia is in a
	vertical position
Deceleration	The tibia progresses from its vertical position in
or	midswing, extending the knee in preparation for heel
Terminal swing	strike/initial contact

There are accepted degrees of what constitutes "normal" values for the movements at each joint and parameters such as walking velocity. These variables can be affected by age, height, weight, body morphology, habit, psychological status and any disease process that is present (Norkin & Levange, 1992). A number of studies have identified what constitutes normal values for parameters such as velocity. Comfortable walking speed for men varies between 124 cm/sec to 146.2 cm/sec depending on age, whilst women varying between 112.5 cm/sec and 141.5 cm/sec (Bohannon, 1997; Chao,

Laughman, Schneider, & Stauffer, 1983). Small changes in gait speed can have significant functional implications. Being able to walk faster than 40cm/sec is indicative of an individual being able to access the community in a limited fashion and being able to walk faster than 80cm/sec is indicative of being a "full" community walker (Perry, Garrett, Gronley, & Mulroy, 1995; Schmid et al., 2007). Potter, Evans and Duncan (1995) examined a sample of geriatric patients and reported that gait speeds of less than 25cm/sec indicated likely dependence in activities of daily living. Progression between these speeds can indicate substantial improvements in an individual's ability to be active in the community.

Normal values for time spent in single and double limb stance has been established and commonly reported as a percentage of the gait cycle (Goldie, Matyas, & Evans, 2001; Winter, 1991). Stance times of normal gait comprising 58-61% of the gait cycle and swing times 39-42% with double stance comprising 16-22% of the cycle (Chao et al., 1983; Norkin & Levange, 1992; Winter, 1991). Step length is another common parameter used to measure gait performance, both in raw measurements and in measurements of symmetry (Balasubramanian et al., 2007). Further to this, more specific temporal measures of the gait cycle can be reported as a raw score (seconds) or expressed as a percentage of the gait cycle. Examples of such measures include time spent in single leg stance of a specific leg, time spent in double limb support or swing time of a specific leg. Comparison of each side of these values can be used to describe symmetry of the gait single. Normative gait tends to be symmetric (Kim & Eng, 2003) whilst gait following stroke tends to be asymmetric (Patterson et al., 2008). Examination of such specifics of the

gait cycle may enable greater description of the quality of walking. Furthermore, comparison of such parameters of performance of each leg in the gait cycle may describe the relative symmetry and asymmetry of walking and therefore indicate the presence of a pathological gait pattern (Goldie et al., 2001; Kim & Eng, 2003; Patterson et al., 2008).

2.1.5.2 Measuring Walking

Walking can be described and measured using a number of different measurement tools. These range from simple observational measurements (Eastlack, Arvidson, Snyder-Mackler, Danoff, & McGarvey, 1991; Williams, Morris, Schache, & McCrory, 2009) to complex laboratory based equipment including force platforms, three dimensional motion capture systems (e.g. Vicon), electromyography (EMG), contact/pressure mats (e.g. Gaitrite) and footswitch systems. These tools provide detailed information regarding walking performance, muscle activity, movements occurring at each joint, the pattern in which the foot contacts the ground and the amount of force produced when the foot contacts the ground. These factors are important to clinicians, however utilising such measures can be time consuming and not practical in regards to access. Gait laboratories require large areas and can often be distant to clinical areas or located at separate sites. In the clinical setting, therapists use tools that allow instantaneous feedback to the clinician and patient.

GAITRite ® is an electronic instrumented walkway system which measures spatiotemporal parameters of gait. GaitRite® has been shown to have strong concurrent validity and test-retest reliability across all

spatiotemporal parameters in healthy subjects (Bilney, Morris, & Webster, 2003; van Uden & Besser, 2004), and older adults (Hollman et al., 2010; Menz, Latt, Tiedemann, Mun San Kwan, & Lord, 2004). However, GAITrite® has been demonstrated to have reduced reliability for variability measures in dual task walking conditions (Hollman et al., 2010). Validity has also been demonstrated in regards to averaged and individual step characteristics following knee replacement surgery (Webster, Wittwer, & Feller, 2005). Base of support and toe in/out angle have reduced reliability, possibly due to the spatial resolution of GaitRite ® or perhaps inherent variability of these parameters (Menz et al., 2004). GaitRite ® is easy to use, provides instantaneous feedback and is relatively portable. It provides more detailed information than gained by examining gait using a 10 m walk, which is a commonly used clinical tool.

Laboratory testing is the ultimate method used to analyse walking for clinical purposes. It was decided not to use a full Gait Laboratory in this study. The reasons behind this decision were: (1) a gait laboratory was not colocated with the patients; (2) the patients were admitted to a hospital whilst participating in the study; (3) to transport the patients to a gait laboratory over three consecutive days would negatively impact the patients' availability for necessary routine rehabilitative therapies, therefore being potentially detrimental to their rehabilitation outcome; and (4) quantitative measurement devices which capture commonly reported gait data were available on site which have demonstrated reliability. While acknowledging the limitations of the gait analysis equipment in the clinical setting compared to a gait laboratory, the opportunity to capture the data of stroke survivors in the early

stages of walking recovery enabled analysis of a patient group which has had minimal attention.

2.1.6 Walking post stroke

It is difficult to determine why an individual loses their ability to walk following a stroke; nevertheless their ability to walk is a primary objective for recovery (Olney & Richards, 1996; Viosca et al., 2005). The ability to walk following a stroke varies throughout the recovery of the individual. Fifty to 80% of patients will regain some sort of walking ability following stroke (Skilbeck et al., 1983) with 62% of patients being able to walk independently six months post stroke (Kollen et al., 2006). The altered pattern of walking following a stroke is due to the primary neural lesion, adaptive changes as a result of impairments due to the lesion and the interaction of these factors with the motor control system or as a learned adaptive response (Moseley et al., 1993). The degree of the change is partly dependent on the severity of the neurological insult (Olney & Richards, 1996).

Hemiplegic gait has been well described in regards to the stance and swing phases at the pelvis, hip and knee (Moore, Schurr, Wales, Moseley, & Herbert, 1993; Moseley et al., 1993) (see Table 2.3) resulting in decreases in velocity, increases in stance time of the unaffected leg and decreases in stance time of the affected leg (Olney, Griffin, & McBride, 1994). The kinematics of the ankle joint in stroke gait has had limited examination in the literature. The importance of the ankle and foot in walking has been well established in healthy subjects and a number of studies into elements of

hemiplegic walking have described the importance of the ankle and foot though there is limited supporting evidence to date.

<u>Table 2.3:</u> Hemiplegic gait. The altered biomechanics during the stance and swing phases. (Moore et al., 1993; Moseley et al., 1993)

Stance – Kinematic Deviation	Swing – Kinematic Deviation
Decreased hip extension in late stance	Decreased peak hip flexion
Decreased lateral pelvic displacement	Decreased peak knee flexion
Increased lateral pelvic displacement	Decreased knee extension prior to knee strike
Knee hyperextension	Decreased dorsiflexion/toe clearance
Increased knee flexion at midstance	
Decreased ankle plantar flexion at toe-off	

Walking speed and other spatiotemporal parameters are reduced in ambulant stroke populations when compared with normative data (Olney & Richards, 1996). Generally speaking, the more severe the hemiplegia, the greater the change in the parameters from normal (Hesse, 2003; Olney & Richards, 1996). However, more severely affected individuals can perform better than those less affected due to more efficient compensatory movement patterns (Bowden, Balasubramanian, Neptune, & Kautz, 2006). Olney and Richards (1996) reviewed 17 studies which reported the spatiotemporal parameters of hemiplegic subjects. Average walking speeds in hemiplegic subjects ranged from 0.23 m/s to 0.73 m/s. They reported that hemiplegic patients spent more time in double limb support than healthy subjects when walking at comparable speeds. In comparison, comfortable walking speeds in healthy older adults have been reported at 1.41 m/s for men and 1.30 m/s for women (Bohannon, Andrews, & Thomas, 1996). Titianova, Pitkanen, Paakkonen, Sivenius and Tarkka (2007) found an average hemiparetic step length of 41.3 cm (SD 15.5cm), with a step length of 39.4cm for the non-affected leg in comparison of 73cm in age matched controls. Reduced step length is related to reduced paretic leg propulsion and is not related to gait speed in patients with stroke (Balasubramanian et al., 2007). Put more simply, some stroke survivors will have a reduced step length irrespective of the speed at which they walk. (Goldie et al., 2001) found increases in time spent in DLS and unaffected single limb support of stroke patients in comparison to age and gender matched controls. Unfortunately data for these parameters was normalised (i.e. presented as a ratio) and cannot be reported as a meaningful value. Table 2.4 describes data regarding normative values of gait in people with stroke.

<u>Table 2.4:</u> Summary of reported values for spatiotemporal parameters of people with stroke

Gait Characteristic	Value
Velocity	0.45 m/sec ⁻¹ +/- 0.21 (Olney & Richards, 1996)
Normative value for older	0.89 – 0.94 m/sec (Flansbjer, Holmback,
adults: 102-113 cm/sec	Downham, Patten, & Lexell, 2005)
(Hollman, McDade and	44.5 cm/sec +/- 24.8 (Goldie et al., 2001)
Petersen, 2011)	41 cm/sec +/- 18 (Lamontagne & Fung, 2004)
	46 cm/sec +/- 22.8 (Lord, McPherson,
	McNaughton, Rochester, & Weatherall, 2008)
	81 cm/sec +/- 18cm/sec (Kim & Eng, 2003)
DLS (%)	45% (Olney & Richards, 1996)
26.3-30.3% (Hollman et al,	31% (Evans, Goldie, & Hill, 1997)
2011)	
Unaffected SLS (sec)	0.53 secs (Evans et al., 1997)
0.38-0.44 sec (Hollman et	0.49 +/- 0.11 (Kim & Eng, 2003)
al, 2011)	
Affected SLS (sec)	0.43 secs (Evans et al., 1997)
	0.37 +/- 0.07 secs (Kim & Eng, 2003)
Step Length Affected	47.5cm (Kim & Eng, 2003)
59-69cm (Hollman et al,	
2011)	
Step Length Unafffected	48.5cm (Kim & Eng, 2003)
(cm)	

As has been discussed earlier, asymmetry can be an indicator of pathological gait. Asymmetry has been demonstrated in the gait of stroke patients (Goldie et al., 2001; Kim & Eng, 2003; Patterson et al., 2008) and thus should be considered describe the quality of walking of patients following stroke. As normal walking is considered to be symmetrical, reductions in

asymmetry of gait parameters of stroke patients could be interpreted as indicators of improvement/recovery.

2.1.6.1 Ankle Impairments in Stroke

There is a lack of empirical data regarding specific impairments around the ankle. Most studies investigating mobility alterations following stroke comment on lower limb impairments as an inclusion criteria without describing specific impairments to the ankle. Alterations to strength, sensation, proprioception and tone affect the ankle as they do other regions of the body following stroke. These range from no impairment to significant degrees of impairment. More specifically to the ankle, in the following articles impairment criteria were used to recruit participants or were reported as patient characteristics, however defined parameters were not used. Examples of these are: reduced strength or motor control (Abe, Michimata, Sugawara, Sugaya, & Izumi, 2009; Burdett, Borello-France, Blatchly, & Potter, 1988; Chen et al., 1999; Danielsson & Stibrant, 2004; de Wit et al., 2004; Diamond & Ottenbacher, 1990; Fatone, Gard, & Malas, 2009; Lehmann, Condon, Price, & DeLateur, 1987; Mojica et al., 1988; Ring, Treger, Gruendlinger, & Hausdorff, 2009; Roehrig & Yates, 2008; Wang et al., 2007), alterations in tone or spasticity (Beckerman, Becher, Lankhorst, & Verbeek, 1996; Burdett et al., 1988; Danielsson & Stibrant, 2004; Dieli et al., 1997; Franceschini et al., 2003; Gok et al., 2003; Hesse, Brandl-Hesse, Bardeleben, Werner, & Funk, 2001; Hesse et al., 1996; Mojica et al., 1988) and contracture or reductions in range of movement (Beckerman et al., 1996; Burdett et al., 1988; Dieli et al., 1997; Fatone et al., 2009; Gok et al., 2003; Hesse et al., 1996; Iwata et al.,

2003; Lehmann et al., 1987; Mojica et al., 1988; Ring et al., 2009; Roehrig & Yates, 2008; Tyson, Thornton, & Downes, 1998; Tyson & Thornton, 2001)

Alterations to walking performance can be attributable to impairments of the joints and neuromuscular activity of the lower limbs. (Lamontagne, Malouin, Richards, & Dumas, 2002). Hsu, Tang and Jan (2003) found that reduced hip flexor strength accounted for the observed reductions in gait velocity, and plantar flexor spasticity accounted for the asymmetrical gait pattern. However they excluded participants with reduced ankle range of movement (ROM). Alterations in ankle function are one factor that can contribute to changes in walking ability following stroke (Lamontagne, Malouin, & Richards, 2000; Lin, Yang, Cheng, & Wang, 2006). The effect of ankle impairments on walking can be significantly disabling. Reduced dorsi flexor strength of the affected limb correlates highly with the reduction in gait velocity due to increasing swing time and reduced eccentric loading ability during midstance (Lin et al., 2006). Plantar flexor spasticity moderately correlated with the reduced ability to transfer the weight onto the affected leg through the stance phase and is highly correlated with a reduced step length of the unaffected side (Lin et al., 2006). Alterations in sensation or proprioception may also influence walking performance as impaired joint position sense may also have accounted for temporal asymmetries (Lin et al., 2006).

2.2 Ankle Foot Orthoses

Ankle foot orthoses (AFO's) are devices used to correct for abnormalities of ankle function through the stance and swing phases of gait in a variety of clinical conditions including stroke (Leung & Moseley, 2003), multiple sclerosis (Sheffler et al., 2008), cerebral palsy (Brehm et al., 2008; Westberry et al., 2007) and poliomyelitis (Waring, Maynard, Grady, Grady, & Boyles, 1989) . The role of the AFO is to compensate for impaired or absent ankle movement which hinders the ability to walk. There is a suggestion, but limited evidence, that an AFO (Hesse et al., 1999) may reduce the muscle activity around the ankle (Leung & Moseley, 2003), thereby limiting the extent of a patients recovery.

The literature describing the effect of AFO's and the use of AFO's following stroke is described in this section. The effects of AFO's used in stroke on these parameters was discussed, as was the prescription of AFO's to stroke patients. Subsequent to this a method which increases the knowledge regarding AFO prescription was proposed.

2.2.1 Biomechanics of AFO's

An AFO is commonly prescribed in stroke to prevent unrestricted plantar flexion (foot drop) through the swing phase of gait. AFO's are also thought to provide stability through the stance phase, although this may depend on the construct of the AFO. Using the spring leaf AFO as an example, the foot plate (Figure 2.4) holds the foot in a neutral position, whilst the upright (posterior shell) and strap (Figure 2.4) ensure the AFO is well secured against the leg.

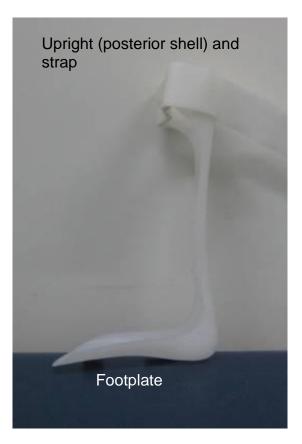


Figure 2.5. A Spring Leaf AFO indicating its components

The material by which an AFO is constructed will also affect function. Less rigid materials provide less resistance to unrestricted plantar flexion, whilst more rigid materials will provide more resistance. The majority of research into AFO's has been regarding their functional effects such as gait parameters rather than biomechanical influences (Chu, 2001). Research into differences of AFO's of different design or construction has not occurred.

2.2.2 The effect of AFO's on walking

The prescription of an ankle foot orthosis (AFO) has been reported to be used around 22% of the time at discharge from an inpatient rehabilitation program (de Vries, 1991; Teasell et al., 2001). AFO's are prescribed in stroke

as they are considered to improve the quality and efficiency of walking, and thereby improve function (Hesse et al., 1996; Leung & Moseley, 2003). AFO's are designed to improve walking by minimizing gait deviations caused by dysfunction around the ankle, providing stability through the stance phase and assistance in the swing phase improving temporal and kinematic parameters (Leung & Moseley, 2003) and by making walking more efficient (Danielsson & Stibrant, 2004). Specific parameters of the gait cycle that AFO's that have been found to improve in stroke patients are walking speed (Gok et al., 2003; Hesse et al., 1996; Mojica et al., 1988; Wang et al., 2007; Wang et al., 2005), cadence (Gok et al., 2003; Wang et al., 2005), step length (Gok et al., 2003; Hesse et al., 1996; Lehmann et al., 1987; Wang et al., 2007), ankle dorsi flexion in the swing phase (Gok et al., 2003), foot contact patterns (Hesse et al., 1996; Mojica et al., 1988; Pohl & Mehrholz, 2006), improved stance times (Hesse et al., 1999; Lehmann et al., 1987), and improved symmetry of the gait cycle (Pohl & Mehrholz, 2006).

Whilst there is general agreement within the literature regarding the benefits of AFO's in some stroke patients there is no clear consensus regarding which stroke patients will benefit. The work of Hesse et al. (1996) suggests that AFO's will benefit stroke patients with spasticity of the plantar flexors. However, they excluded patients who were unable to attain a plantigrade ankle position. Most of the literature reported are suggestive of impaired ankle movements and or strength but do not define or quantify the actual motor impairment.

2.2.2.1 Prescription of AFO's

The International Society of Prosthetist's and Orthotist's (ISPO) met in 2003 to discuss AFO prescription in stroke and an in depth review of the literature resulted. The conference reached a consensus that AFO's were of benefit, however, the proceedings of this conference indicated that there is little scientific evidence on the prescription of AFO's in this patient population. Most of the guidelines developed for the prescription of AFO's are justified by the following statement by Condie (2003) - "...recommended best practice based on clinical experience of the guideline development group". The prescription of AFO's in stroke is controversial as clinicians and academics have been unable to reach a consensus on their use in stroke (Leung & Moseley, 2003). The beneficial effects of AFO's on temporal and kinematic parameters of walking on a broad, undefined population of stroke patients is accepted; the effects of AFO use on muscle activity is unclear (Leung & Moseley, 2003). No evidence had been identified regarding the timing of the application of an AFO following stroke or the impairments suggestive towards the benefits of an AFO (Tyson & Kent, 2009). As such, there is no evidence regarding AFO prescription, much of it being based on clinical experience and knowledge (Condie, 2003; van Til, Renzenbrink, Dolan, & Ijzerman, 2008). A Cochrane review by Tyson and Kent (2009) investigating the effect of AFO's in stroke indicated that AFO's have an immediate effect on walking performance. The effect of long term use of AFO's is not clear, nor are the guidelines regarding their application, particularly in regards to the timing of application and which particular AFO should be applied. They identified the

areas which required further research as: the long term effects of AFO use, optimal timing and duration of use and optimal design of the AFO. Specifically off the shelf AFO's require comparison with custom made AFO's, and further studies are required to identify which AFO's should be used and when.

Patients in the early stages following stroke exhibit the same or similar impairments around the ankle as those patients in the chronic stages of stroke recovery. These impairments can change the ability of, and the quality of walking. An AFO can potentially correct some or all of these impairments. Therefore, the clinician needs to consider the effect that an AFO can have on the recovery of ankle function, and whether this could limit the final functional outcome of their patient (Hanna & Harvey, 2001). The need for functional restoration of the ankle as an outcome has to be balanced against the benefit of walking independently in the early stages of walking recovery. Ideally, a balance between both philosophies' is required.

2.2.2.2 The use of AFO's in stroke

There is little consistency between the types of AFO used in the literature examining the use of AFO's in stroke, other than authors with multiple publications utilising the same orthoses in their study design. AFO's were fixed (Beckerman et al., 1996; Burdett et al., 1988; Chen et al., 1999; Danielsson & Stibrant, 2004; de Wit et al., 2004; Dieli et al., 1997; Gok et al., 2003; Pohl & Mehrholz, 2006; Tyson & Thornton, 2001; Wang et al., 2007; Wang et al., 2005), or articulated at the ankle (Beckerman et al., 1996; Hesse et al., 1999; Tyson & Thornton, 2001). There are studies that have also examined custom-made (Beckerman et al., 1996; Chen et al.,

1999; Dieli et al., 1997; Fatone & Hansen, 2007; Gok et al., 2003; Mojica et al., 1988; Pavlik, 2008; Pohl & Mehrholz, 2006; Tyson & Thornton, 2001) and off the shelf AFO's (Burdett et al., 1988; de Wit et al., 2004; Hesse et al., 1996; Hesse et al., 1999; Wang et al., 2007; Wang et al., 2005) of varying designs. Franceschini, Massucci, Ferrari, Agosti and Paroli (2003) did not adequately describe the design or construct of the AFO's used in their study. Table 2.5 lists examples of types of AFO described in the literature, the biomechanical effects of each type of AFO and the clinical indications for each type. Although the scientific support of the clinical indication is weak, inadequate or absent (Condie, 2003; van Til et al., 2008).

Further to the studies reported above there have been a number of studies have been identified, in addition to those reported by Leung and Moseley (2003), which compare the use of AFO's in stroke. Each study involved comparisons of orthoses with other orthoses or unaided walking. A summary of these studies is provided in Table 2.6. Each study examined the immediate effects of an AFO(s) on walking, compared with shod or barefoot walking.

<u>Table 2.5:</u> A summary of the types of AFO's, a brief explanation of their actions and an indicator of their parameters suggesting prescription

	Туре	Example	Biomechanical action	Indication for prescription
Less Rigid	Soft	Air Stirrup	Provide mediolateral stability of the ankle	Control inversion
		Push Aequi	Unrestricted plantar flexion and dorsi flexion	Less severe
		ASO		(Burdett et al., 1988)
	Plastic	Spring Leaf	Prevent plantar flexion in swing phase	Ankle and knee dysfunction
			Allow some dorsi flexion in stance phase	(Condie, 2003; Gok et al., 2003)
	Rigid	Custom made	Prevent plantar flexion in swing phase	Ankle and knee dysfunction
	Articulated		Allow some ankle movement in stance phase,	Minimal tone
			but control the amount of movement	(Condie, 2003; Hesse et al., 1999)

	Rigid non-	Custom made	Prevent plantar flexion in swing phase	Ankle and knee dysfunction
	articulated		More stability in stance phase	Reduced dorsiflexion range
				Moderate tone
				(Condie, 2003; Gok et al., 2003)
-	Ground	Custom made	Prevent plantar flexion in swing phase	Ankle and significant knee dysfunction
	Reaction		Assist stabilising the knee in the stance phase	Varying degrees of dorsiflexion range
			May allow ankle movement, depending on	limitation
			design	Varying degrees of tone
lore Rigid				(Condie, 2003)

Of the studies identified in Table 2.6 only eight compare AFO's of varying types. In each of these comparisons, the difference in the biomechanical properties of each AFO compared is limited. Gok et al., (2003) compared metallic and plastic AFO's is a study designed to compare the effect of altering the construction material of AFO's. Diamond and Otternbacher (1990) compared an AFO used to reduce the effects of tone and a standard AFO whilst Kitaoka et al., (2006) examined standard and articulated AFO's on the gait of healthy participants. There has been no study comparing AFO's with significantly different biomechanical properties. More specifically, comparisons of very restrictive AFO's with less restrictive AFO's in clinical populations have not occurred. The research of Kitaoka et al. (2006) on the effects of AFO's in healthy participants is of use in examining the effects of AFO prescription. AFO's are prescribed in order to improve gait, this is assessed by determining if gait becomes more normal. Kitaoka et al. (2006) found that AFO's caused deterioration in gait in healthy individuals, but did not report on parameters such as velocity and step length commonly assessed in gait analysis. This raises that suggestion that AFO prescription could have a negative effect in some cases.

כ	Participants	Acuity	Inclusion/ Exclusion Criteria	Participant Characteristics	Walking Conditions/ AFO's Used	Outcome Measures	Results											
1	16 participants	Duration of lesion range:	Inclusion criteria: Unilateral	Not defined	Various AFO's – articulated and	Stride length	Improved stability of gait performance											
	29-79 years	2-113.8 months	hemiparesis caused by cerebrovascular		non-articulated	Step length	(measured by coefficient of											
	5 infarctions 11		disease Walk 8m four times		Barefoot	Symmetry	variation)											
	haemorrhages		in barefeet				Improved walking speed											
			Able to follow			Cadence	Improved step											
			commands			Functional	length											
			phenomena No history of orthopaedic problems related to										phe	No neglect phenomena			Ambulation Classification	Improved stride
							Improved cadence											
			the lower extremity				Improved symmet											
							Improved FAC											

Table 2.6: Studies identified which assess or compare AFO's

Ref.	Participants	Acuity	Inclusion/ Exclusion Criteria	Participant Characteristics	Walking Conditions/ AFO's Used	Outcome Measures	Results
9	60 participants Average age: 58 years (20- 72) 45 infarctions 15 haemorrhages	Average duration of lesion 34 months (5- 185)	Inclusion criteria: First time stroke resulting in hemiplegia At least 4 months post stroke Walking problems caused by spastic equinus or equinovarus Exclusion criteria: More than one stroke Unable to walk independently Brainstem infarction Nil condition influencing the ability to ambulate Shortening of soleus or gastrocnemius muscles Skin lesions/	Clonus present in varying degrees in all participants	Thermocoagulatio n of the tibial nerve and placebo Polypropylene AFO and placebo	Sickness Impact Profile (SIP) Walking speed	Nil significant

Ref.	Participants	Acuity	Inclusion/ Exclusion Criteria	Participant Characteristics	Walking Conditions/ AFO's Used	Outcome Measures	Results
19	19 participants	Not defined	Inclusion criteria: Diagnosis of stroke Ambulate unassisted with or without a gait aid	15 participants had increased plantar flexion or plantar flexion/inversion tone 3 participants had normal plantar flexio/inversion	Metallic AFO's, limiting plantar flexion and with 5-10 ⁰ dorsiflexion range or Plastic AFO's set at plantigrade or	Stride time Stride length Speed Base of support Step length	Improved paretic side step length using either Air Stirrup or AFO Improved ankle position at footstrike, toe off using either Air Stirrup or AFO
				tone 1 participant had reduced plantar flexio/inversion tone	5 ⁰ dorsiflexion Air Stirrup Brace Shoes	Toe-out angle Sagittal plane joint angles Calcaneal angle	Improved calcaneal inversion position using the Air Stirrup Brace
				2 participants could dorsiflex through range 10 participants could partially initiate dorsiflexion			

Ref.	Participants	Acuity	Inclusion/ Exclusion Criteria	Participant Characteristics	Walking Conditions/ AFO's Used	Outcome Measures	Results
22	24 participants	Average duration of	Inclusion criteria: Unilateral		Anterior leaf spring AFO	Static postural sway	Improved lateral weight shift to the
	Average age 58.9 years (43- 76)	lesion 13 months (3- 120)	hemiparesis caused by cerebral vascular disease		Barefoot	Postural sway symmetry	affected leg
	,	,	Stand without support for 60 seconds and shift weight forwards, backwards and to the sides			Maximal balance range anterior- posterior	weightbearing through the affected leg
			Able to follow commands	e to follow balan	Maximal balance range lateral		
			Nil orthopaedic problems in the foot			Centre of pressure	

Ref.	Participants	Acuity	Inclusion/ Exclusion Criteria	Participant Characteristics	Walking Conditions/ AFO's Used	Outcome Measures	Results	
25	38.6 years (25- Stroke patients identified by their	Socks	Stride length	Improved stride length using shoes				
	•	38.6 years (25- 60)	•		Shoes	Cycle time	± AFO	
	60)		requiring an AFO		AFO – custom moulded	Velocity		
					mediaed	Cadence		
						Stance time		
						Swing time		
						Swing velocity		
32	10 participants	Average duration of lesion 16 months (7- 96)	Inclusion criteria: Stroke diagnosis	Leg motor function on Fugyl-Meyer	Carbon composite AFO	VO ₂₋ oxygen consumption	Improved self- selected speed	
	Average age 52 years (30-63)		lesion 16 months (7-	At least 6 months post stroke	Sensorimotor Assessment: median 20 (16-23)	Shoes	VCO _{2 -} carbon dioxide output	Reduced energy cost
	5 infarctions			96) Walk for 5 minutes ± gait aid	Increased plantor flexion muscles tone:		Respiratory exchange ratio	
	5 haemorrhages		Habituated to using a carbon composite AFO	4 (2-4) Modified Ashworth Scale		(RER)		
			Exclusion criteria: Severe Heart Disease	Used an AFO for 12		Heart Rate		
				months (4-21)		Ventilation Rate		
			Leg wounds			Self -selected		
			Pain			speed		
			Non – stroke gait disability			Perceived exertion		

Ref.	Participants	Acuity	Inclusion/ Exclusion Criteria	Participant Characteristics	Walking Conditions/ AFO's Used	Outcome Measures	Results
34	20 participants Average age 61.2 years (41- 73) 18 infarction 2 haemorrhagic		Inclusion criteria: Diagnosis of stroke, MCA artery territory 40-75 years of age At least 6 months post stroke Used and AFO daily for at least 6 months Walking independently ± AFO	Motricity Index (MI) of affected Limb - 58 (IQR – 27) FAC - 4.5 (IQR 1)	Plastic non- articulated AFO's of three different types Shoes AFO's were not compared to each other	Comfortable walking speed Timed Up and Go (TUG) Stairs Test Patient subjective impressions	Improved walking speed, TUG and stairs test, but not clinically relevant. Patients more confident using an AFO
37	1 participant 32 years old	9 months post	Nil described	Partial control of isolated movements at the hip, knee and ankle	Barefoot Prefabricated polypropylene AFO Custom designed tone inhibiting AFO (TIAFO)	Velocity Step length Cadence Hemiparetic stance time	AFO and TIAFO improved velocity, step length, cadence and stance time than barefoot TIAFO improved velocity and step length compared with AFO

Ref.	Participants	Acuity	Inclusion/ Exclusion Criteria	Participant Characteristics	Walking Conditions/ AFO's Used	Outcome Measures	Results
38	3 participants		Inclusion criteria: Able to walk 10m		Polypropylene posterior leaf	Velocity	Nil statistical analysis performed
			without a gait aid		spring AFO	Stride length	
		Able to achieve plantigrade at the ankle		Dynamic AFO (DAFO)	Cadence		
					Barefoot	Stance and swing time	
			Tone: 1-3 Modified Ashworth Scale		Baroroot	Ū	
						Single support	

44	13 participants	Average	Nil indicated	All bar one had	Customised,	Roll over shape	Reduced plantar
	Average age	duration of lesion 8.2 ±		dorsiflexion ROM available at	thermoplastic AFO, free	(ROS)	flexion angle at initial contact
	51.5 years (43-	4.5 years		midstance	dorsiflexion, 90 ⁰	Self selected	
	66)				plantar flexion stop	walking speed	More symmetrical step length
					•	Step length	
					Shoes		Improved ROS

Ref.	Participants	Acuity	Inclusion/ Exclusion Criteria	Participant Characteristics	Walking Conditions/ AFO's Used	Outcome Measures	Results
43	16 participants	Average duration of	Inclusion criteria: Hemiplegia	Not defined	Shoes	Walking speed	No difference in walking speed
	Average age 53	4 6 years	following stroke Minimum 24 months		Articulated AFO with 90 ⁰ plantar	Kinematics	between the 3 AFO's
	years (43-66)		post stroke		flexion stop, full length footplate		Reduced plantar
			40-70 years of age		Heel height		flexion at initial contact and mid-
			No major involvement of the contralateral limb		compensated AFO (HHCAFO)		swing for all 3 AFO's
			Wearing or had		³ / ₄ length		AFO's created a
			previously worn an AFO		HHCAFO		knee extension moment in early stance
47	9 participants with hemiplegia	Average duration of	Inclusion criteria: Walk independently	Nil indicated	Customised AFO	Stride time	Reduced energy cost
		lesion: 39	6 minutes ± walking aids		Shoes	Stance time	Increased an edd
	66.5 ± 14.5 years	months (2- 244)				Swing Time	Increased speed
	yours	,	Hypertonic equinus in the swing phase			Single support	Reduced stride duration
			Customised AFO			time	Doducod stance
						Double support time	Reduced stance time
						Energy Cost	Reduced double support time

Ref.	Participants	Acuity	Inclusion/ Exclusion Criteria	Participant Characteristics	Walking Conditions/ AFO's Used	Outcome Measures	Results
49	12 participants Average age:	Average duration of lesion: 67		Nil ankle deformity	Polypropylene AFO	Kinematics: Ankle dorsiflexion	Metallic AFO improved speed
	54 (39-65)	days (30- 270)		3 patients had tone (2-3/5	Metallic AFO	(swing) Ankle	Metallic and polypropylene AFO
	Nil breakdown			Ashworth scale)	Shoes (Not clear)	dorsiflexion (stance)	improved speed and step length
	regarding infarction and haemorrhage					Kinetic Knee flexion moment	Metallic and polypropylene AFO reduced dorsiflexion in
						Gait: Cadence	stance and swing, metallic more so than polypropylene
						Gait speed	Metallic AFO
						Single step time	improved knee flexion moment
						Double support time	
						Step Length	

Ref.	Participants	Acuity	Inclusion/ Exclusion Criteria	Participant Characteristics	Walking Conditions/ AFO's Used	Outcome Measures	Results
59	19 participants	Average duration of	Inclusion criteria: Able to walk 20m	Median Modified Ashworth Score	Valens Calliper	Velocity	AFO compared with barefoot
	Average age 55.2 years (30-	lesion 5.1 months (1.5-	without support	3.7/5 (3-5 range)	Barefoot	Cadence	improved: velocity, cadence stride
	79)	16)	Newly prescribed AFO		Shoes	Stride length	length, gait line
	10 infarctions 5 haemorrhagic 3 tumour		Marked plantar flexor spasticity			Stance symmetry	Shoes compared with barefoot improved: velocity,
	surgery (unclear		No obvious ankle contracture			Swing symmetry	stride length, double support, gait
	regarding the 19 th patient)		No other neurological or			Double stance duration	line
			orthopaedic impairment limiting ambulation			Gait line	

Ref.	Participants	Acuity	Inclusion/ Exclusion Criteria	Participant Characteristics	Walking Conditions/ AFO's Used	Outcome Measures	Results
60	21 hemiparetic patients	Avg duration of lesion: 4.9		ROM – not defined	Valens Calliper	Gait Velocity	Increased stance of affected limb
	•	month (1.5-			Barefoot	Cadence	
	Average age	16 months).		Tone: 3.6			Improved swing
	58.2 years (30- 79)			Ashworth scale (3-5)		Mean stride length	time symmetry
				· · /		·	Improved loading
	17 infarcts 3			Strength: not defined		Ankle dorsiflexion	rate of affected limb
	haemorrhages						Improved ankle
	1 tumour					Vertical GRF	dorsiflexion excursion
						Stance Time	in stance – affected limb
						Swing Time	
						- 0 -	Reduced affected
						Double limb support time	tibialis anterior muscle activity
						Surface EMG	Increased vastus lateralis muscle activity

Ref.	Participants	Acuity	Inclusion/ Exclusion Criteria	Participant Characteristics	Walking Conditions/ AFO's Used	Outcome Measures	Results
67	17 participants	Average duration of	Inclusion criteria: At least 6 months	Control: Tone: Ashworth	AFO ± inhibitor bar	Maximal walking speed	Inhibitor bar increased walking
	9 treatment group 62.2 ± 7.8 years	lesion Treatment	post stroke Used an AFO for at	range 0-3 Treatment:	9 participants used an inhibitor	Stride length	speed, stride length and cadence
	5 infarctions	group:	least a month	Tone: Ashworth	bar, 8 did not	Cadence	
	4 haemorrhages	35 ± 21months	Exclusion criteria: Foot contracture	range 0-4	(control group)	Patient perception	
	8 control group 61.4 ± 10.4 years 5 infarctions 3 haemorrhages	Control group: 27 ± 15 months	Toe pain			р от оор нот	

Ref.	Participants	Acuity	Inclusion/ Exclusion Criteria	Participant Characteristics	Walking Conditions/ AFO's Used	Outcome Measures	Results
73	20 normative subjects Average age 46 years (27-65)	N/A	Criteria	N/A		Ground Reaction Force Ankle Kinematics	AFO and HFO-R reduced plantarflexion compared with Shoe and HFO-A AFO/HFO-R/HFO- A reduced hindfoot inversion HFO-A – smaller midfoot plantarflexion AFO/HFO-R/HFO- A reduced the amount of push-off force
							A improved cadence

Ref.	Participants	Acuity	Inclusion/ Exclusion Criteria	Participant Characteristics	Walking Conditions/ AFO's Used	Outcome Measures	Results
81	7 participants	3-13 years post stroke		3 participants had limited dorsi	Shoes	Joint moments	Improved walking speed
	59-75 years	p		flexion	AFO set at 5 ⁰	Ground	
					dorsiflexion	Reaction Forces	An AFO set at 5 ⁰
	Age and height			No participants			dorsiflexion
	matched controls			had isolated active motor	AFO set at 5 ⁰ plantar flexion	Walking speed	increases a knee flexion moment
				control at the ankle		Cadence	through stance
				6 participants		Step length	Normalised heel strike
				used an AFO everyday		Stance duration	SUIKE
				everyddy		Swing duration	
						Double support time	
92	8 participants	Average		Normal passive	Custom-made,	Balance:	Reduced body
	46-66 years	duration of		ROM	laminated AFO	Body sway/	sway/COP
		lesion 20.7				Centre of	movement
		weeks (7-32)		"Mild to	Barefoot	Pressure (COP)	
				moderate"			Improved speed,
				hypertonia		Gait:	cadence and stride
						Speed	length
				Motor recovery 2- 3 Brunnstrom Scale		Cadence	
						Stride Length	

Ref.	Participants	Acuity	Inclusion/ Exclusion Criteria	Participant Characteristics	Walking Conditions/ AFO's Used	Outcome Measures	Results
110	4 participants Average age 60 ±13.4 years	Average duration of lesion 75 months (10- 120)	Inclusion criteria: secondary Infarction, 6 months – 10 years post AFO use for at least 6 months Able to walk +/-AFO Exclusion criteria: >1 stroke Co morbidities that affected their	Not defined	Custom fitted polypropylene AFO, 2 participants AFO's were articulated, 2 were not	Walking speed TUG Shoes Step length Stride length Rating of perceived exertion (RPE)	Improved walking speed, step and stride lengths
113	28 participants Average age: 51.7 years (23- 77) 20 strokes (undefined) 8 Traumatic Brain Injury (TBI)	Average duration of lesion: 2.6 months (1-6)	walking	Undefined	Individually constructed short AFO with a rigid sole plate, fibreglass and softcast materials Shoe	Balance:Postural Sway:eyes open andeyes closedWeightbearingsymmetryGait:Ground ReactionForcesStance TimeDouble LimbSupport	The AFO: Improved postural sway with eyes open Improved weightbearing symmetry Improved stance duration Improved double limb support

Ref.	Participants	Acuity	Inclusion/ Exclusion Criteria	Participant Characteristics	Walking Conditions/ AFO's Used	Outcome Measures	Results
119	15 participants Average age 52.2 ± 3.6 years 12 stroke patients 3 traumatic brain injury patients	Average duration of lesion 5.9 ± 1.5 years	Inclusion criteria: Diagnosis of an upper motor neuron lesion >6 months post diagnosis Footdrop AFO use Neutral ankle ROM Able to walk 10m independently Able to follow multistage commands Exclusion criteria: Cardiac pacemaker Skin lesion at electrode site	Not defined	AFO's Used Varied AFO's Neuroprosthesis (neuromuscular stimulation)	Velocity Stride time Swing time variability Swing assymmetry	No differences at 4 weeks of use Improved stride time and swing time variability at 8 weeks

Ref.	Participants	Acuity	Inclusion/ Exclusion Criteria	Participant Characteristics	Walking Conditions/ AFO's Used	Outcome Measures	Results
121	1 participant	4.5 years post stroke		Quadriceps strength 3+/5	Double upright metal AFO with	Velocity	Nil statistical analysis
	69 years old			Dorsiflexion only	dorsiflexion spring assist, no	Cadence	
				as an associated reaction	plantar flexion stop	Step length	
					,	Stride length	
				Shortened plantar flexors	Double upright BiCAAL AFO with an extended steel	-	
					shank and rocker sole		
141	4 participants reported as single	3 years post	Inclusion criteria: 18-65 years of age	Able to walk with/without AFO (1)	Hinged AFO (1)	Velocity	Improvements of 3 participants in all
	case designs:	stroke (1)				Stride length	aspects. No
		0 manth nast	Hemiplegic	Lineble to well:	AFO (inadequately	Ctor longth	improvement of one
	65 year old female (1),	9 month post Subdural	Dynamic standing	Unable to walk without and AFO (2)	described) (2)	Step length	participant
	('), 34 yo man (2),	haemorrhage (2)	balance			Patients Perception	Variable patient perception
			Step the weak leg	Able to walk without	AFO (inadequately		
		1 year post	Plantigrade at both	the AFO (3)	described) (3)		
		stroke (3)	ankles		AFO not described, fitted 1 day prior to		
	52 yo man (3),	8 months post		Assisted to walk (4)	testing (4)		
	24 yo man, ICH 8 months ago (4),	haemorrhage (4)					

Ref.	Participants	Acuity	Inclusion/ Exclusion Criteria	Participant Characteristics	Walking Conditions/ AFO's Used	Outcome Measures	Results
142	25 participants	Average	Inclusion criteria:	Nil indicated	Shoes	Functional	Improved FAC
	49.9 ±1 years	duration of lesion 8.3 ±	Hemiplegia following stroke		Customised,	Ambulation Classification	score
		5.5 months			hinged AFO	(FAC)	Improved stride length of the
						Stride length	affected and non-
			Able to weightbear			Step Length	
			and step the affected leg			Velocity	Improved velocity
			C C				Improved cadence
			Able to attain plantigrade ankle			Cadence	96% participants
			position		Patient perception of their AFO	felt they walked better with an AFC	

duration of Average age 60.36 years (26-84)duration of lesion: 3.29Dorsiflexion Strength: 26.72lbWeightbearing distributiondistribution60.36 years (26-84)months (1-6 months)(± 11.57lb)Shoes (unclear)Impro- Stability (LOS)Impro- speed39 infarcts39 infarctsJamba Strength: 26.72lbJamba Strength: 26.72lbShoes (unclear)Impro- speed	weightbearing oution
(±3.97) Range: length 17-32 Cadence Impro Cycle time length Swing time Impro width Single support time Correl betwe Double support LOS a	oved step n oved stride n oved base

Ref.	Participants	Acuity	Inclusion/ Exclusion Criteria	Participant Characteristics	Walking Conditions/ AFO's Used	Outcome Measures	Results
149	42 participants with a hemiparesis less than 6 months (Group 1) 59.9 years ±13 years	Group 1: 101 ±53.3 days Group 2: 1043.6 ± 1104.9 days	Inclusion Criteria: Unilateral hemiparesis less than six months or more than 12 months duration Stand without support for 60 seconds Walk 10m ±	Nil Indicated	Plastic AFO Shoes	Balance: Static: weightbearing distribution, eyes open and closed on foam and firm surfaces Dynamic:	Group 1: AFO's improved weightbearing distribution, body sway on foam, LOS to the affected and non-affected sides, gait speed and cadence
	61 participants with a hemiparesis greater than 12 months (Group 2) 62.3 years ± 11.8 years		Able to follow commands No history of significant orthopaedic problems			Limit of stability (LOS) with arm movement Berg Balance Scale Gait: Speed	Group 2: AFO's did not significantly improve on any of the measurements used.
						Cadence	

There is little homogeneity in the methods of the studies identified in Table 2.6 limiting the ability to compare the results. Aspects of the methods that particularly limit comparison are the types of AFO compared the point of recovery from stroke at which the AFO is compared, the impairments of the ankle, and their walking ability. Key methodological constraints of certain studies outlined in Table 2.6 will be discussed below.

2.2.2.2.1 Type of AFO

Of the 26 studies listed in Table 2.6, the majority (N =18) compared one type of AFO with walking in shoes and/or barefoot. For these studies, a variety of AFO's were utilised, of either plastic, metal or carbon construction and off the shelf or custom made. Some studies involved individually prescribed AFO's (Abe et al., 2009; Churchill et al., 2003; Fatone & Hansen, 2007; Franceschini et al., 2003; Mojica et al., 1988; Pavlik, 2008; Pohl & Mehrholz, 2006; Ring et al., 2009; Tyson & Thornton, 2001), without investigating differences between the types of AFOs utilised by participants. Two studies (Burdett et al., 1988; Gok et al., 2003) compared AFO's of different construction materials (plastic and metal) both finding improvement in speed and/or step length between walking with either AFO and without but not between AFO's. Burdett et al. (1988) also examined a minimally rigid air stirrup brace finding it equivocal to a plastic or metal AFO's. Five other studies (Diamond & Ottenbacher, 1990; Dieli et al., 1997; Fatone et al., 2009; Kitaoka et al., 2006; Lehmann et al., 1987) compared different types of AFO. Kitaoka et al. (2006) found the more rigid the AFO the less movement at the ankle in healthy participants. Lehmann et al. (1987) determined that altering the setting of the ankle angle changed knee flexion through stance, but did not alter walking speed. Fatone et al. (2009) found no difference in walking speed between an articulated and two heel height compensated AFO's of varying footplate length, but that the longer the footplate the greater the plantar flexion moment. The construction of the

AFO's in this study did not vary greatly, which may account for their results. Dieli et al. (1997) did not perform statistical analysis when comparing a polypropylene AFO with a dynamic AFO, whilst Diamond and Ottenbacher (1990) only assessed one participant in an polypropylene AFO or custom designed tone inhibiting AFO. To date, no studies have attempted to match clinical characteristics of patients following stroke (e.g. presence of increased tone in calf muscles) with type of AFO.

2.2.2.2.2 The effect of ankle impairments on response to AFO

Similarly there is a lack of consistency with regard to ankle impairments in inclusion and exclusion criteria in the listed studies. Differences in ankle impairment may account for differences in study outcomes. Wang et al. (2007) did not control for ankle strength of their participants. The mean dorsiflexion strength of the participants was greater than 25 pounds (range: 12.95 – 45.19 pounds) in the affected leg of these subjects, indicating the availability of significant levels of ankle strength. An ankle that is able to produce over 25 pounds of strength may not be considered greatly impaired. The clinical appropriateness of prescribing an AFO to a patient with ankle movement and strength in the early stages of walking recovery, as in Wang et al. (2007) is difficult to justify.

Hesse et al. (1996) endeavoured to use ankle impairment as a determinant to prescribe an AFO by specifying that their participants had plantar flexor spasticity of at least three (Ashworth Scale) and were able to achieve a plantigrade position of the ankle. A Valens calliper (AFO) shoed and barefoot walking were compared. Walking with the calliper and shoes improved walking velocity and improved contact of the foot during roll-over. However there was no comparison of the Valens calliper in individuals with differing levels of ankle spasticity, nor a comparison with an AFO that was hinged.

Such comparisons may have allowed a conclusion that ankle impairment may be used to assist in AFO prescription. In a separate study, with the same inclusion criteria,

Hesse et al. (1999) looked at the effects of a Valens Caliper on balance parameters in people with stroke, finding that an AFO improves dynamic balance measures. This study also utilised surface EMG to compare the muscle activity when using an AFO. In particular they found that vastus lateralis activity increased with the use of an AFO and tibialis anterior activity decreased with an AFO. Additionally the use of the AFO contributed to premature muscle activity of gastrocnemius. This is the only study which provides evidence in support of the belief that an AFO may negatively influence tibialis anterior activity, although the long term effects are not established. Other than the two studies by Hesse et al, there is very little investigation into the relationship between ankle impairment and the effects of AFO's.

2.2.2.3 The duration following stroke at which an AFO was assessed

There is also disparity amongst the studies regarding the time point following stroke. In 15 of the 26 studies, the mean time from stroke for participants exceeded nine months. Thirteen of these studies found improvements in gait speed when an AFO was utilised. Due to the chronicity of their strokes these patients may have adapted to the use of an AFO and so would deteriorate in their walking without it. In these studies with participants with chronic stroke, 10 included participants who were already using an AFO, in 5 of these studies prior use of an AFO was unclear. Five studies included both those in the subacute and chronic phases of stroke (Abe et al., 2009; Beckerman et al., 1996; Chen et al., 1999; Danielsson & Stibrant, 2004; Franceschini et al., 2003). In contrast Gok et al. (2003) compared two types of AFO with each other and walking without an orthosis in twelve participants, with most at an earlier stage of recovery (mean: 67 days; 30-270 day range). Another study with participants in

the consolidation stage of recovery was that of Pohl and Mehrholz (2006) whose participants had a mean duration of 2.6 months post stroke (range 1-6 months). Similar to the studies of chronic stroke patients identified above, these two acute studies also found differences in walking velocity. In conclusion, few studies have focused on patients with stroke in the early stages of walking recovery who have not used an AFO prior to the study.

2.2.2.2.4 The walking ability of participants at assessment

The walking ability of the participants may also influence the outcomes resulting from the application an AFO. Similarly to the influence that the duration of recovery may have on walking, the length of time that the participant had walked prior to assessment may have an effect. None of the studies identified in Table 2.6 considered or controlled for the length of time that the participant had been walking prior to assessment.

2.2.3 Summary of gait variable considerations regarding AFO prescription

Whilst there is evidence to suggest that an AFO can be of benefit in improving various parameters of gait performance following stroke there are few investigations in patients in the early stages of walking recovery. Most of the studies included participants in the chronic phase of recovery who have already been prescribed an AFO. Other than a reduction in tibialis anterior activation, identified by Hesse et al. (1999), and discussed in the systematic review of Leung and Mosley (2003), no study identifies potential risks of AFO prescription. There has also been limited comparison between differing types of AFO's. The effect of AFO use on normal gait is not clear for walking velocity, step length, single stance phase, swing phase, stance symmetry and knee angle during the stance phase.

Using our understanding of the principles regarding recovery in stroke and the positive role that interacting with the environment has on recovery there is the potential that AFO's may be deleterious in their effect, particularly more restrictive AFO's. These potential negative effects need to be balanced by the positive effects that the prescription of an AFO can have on walking – as measured by gait velocity in the studies identified. Other benefits to gait parameters identified by the literature review include step length, stance time and double limb support percentages. There has been no examination of the effect on walking of various AFO's in patients with stroke with an ankle impairment limiting walking performance who have not yet been prescribed an AFO.

Despite the evidence supporting the use of AFO's in stroke, questions remain regarding the application of AFO's in stroke. It remains unclear if specific AFO's are suitable for particular patient groups and the optimum timing of the introduction of AFO's following stroke.

2.3 Summary

AFO's can be prescribed to people who have had a stroke and have difficulty walking as a result of impairments around the ankle. There are many factors to consider when prescribing an orthosis, such as the type of orthosis and the timing of the application of the orthosis, for which there is little evidence.

It is accepted that AFO's are beneficial in terms of improving gait parameters such as velocity, step length and symmetry in stroke patients in the consolidation and chronic stages of recovery. The differences in effects on walking of AFO's of varying rigidity is less clearly understood. It has been suggested that AFO prescription may limit potential recovery of ankle function in the early stages following stroke, as neuroplasticity is greatest at this time (Leung & Moseley, 2003). It is important to have objective evidence of the effects of various types of AFO when used in the early stages post stroke.

The objectives of this study were established to; (1) examine the walking performance in patients in the early stages of walking recovery following stroke ; (2) to examine the effects of AFO's of varying rigidity on walking performance in patients in the early stages of walking recovery following stroke; (3) to examine the effects of AFO's on walking performance in healthy individuals; (4) to determine differences on walking performance under the different AFO conditions between individuals in the early stages of walking recovery following stroke and healthy individuals.

This study was the first to compare AFO's with varying biomechanical properties to determine differences in gait performance under each different AFO conditions in the early stages of walking recovery following stroke. By being the first study to compare AFO's of differing properties under the same conditions at the same functional stage of recovery it is anticipated that inferences can be drawn that can be used clinically to aid prescription of AFO's in these patients. Additionally, the examination of the effects on walking of these AFO's on healthy participants will further describe the influence of AFO's on gait. Chapter 3

METHODS

3.0 Methods

This chapter describes the identification, selection, and recruitment of participants. Their assessment, intervention and follow-up procedures are also outlined. There are two sections to the study design: (1) a comparison of gait whilst walking under varying ankle foot orthoses (AFO) conditions in a group of people who have suffered a stroke, and (2) a comparison of gait whilst walking under various AFO conditions in a group of age and gender matched healthy (control) participants. In addition a sub study was conducted to examine the reliability of kinematic data.

This chapter is divided into the following sections:

- 3.1) Research Design
- 3.2) Participants
- 3.3) Measures
- 3.4) Interventions
- 3.5) Procedures
- 3. 6) Data analysis

This project received Human Research Ethics Committee approval from St Vincent's Hospital Melbourne (HREC-A 028/08, refer to Appendix A) and from Australian Catholic University (V200708 112, refer to Appendix B).

3.1 Research Design

The major component of this study was a within subject repeated measures design to analyse the effect of each AFO on walking and a case control group comparison design in order to identify differences between stroke and healthy participants. A sub-study examined the test-retest reliability and inter-rater reliability of the kinematic data relating to knee position in stance.

3.2 Participants

3.2.1 <u>Recruitment of Stroke participants</u>

Patients with a diagnosis of stroke were recruited from the Rehabilitation Units of St Vincent's Hospital Melbourne for this study. The selection process sought to identify patients with an ankle impairment which may have contributed to their altered walking performance. The consent forms for stroke participants can be found in Appendix C.

Patients were recruited from the sub-acute wards of a large public hospital. All patients with a diagnosis of stroke were assessed by physiotherapy staff for alterations to their walking abilities. Physiotherapists within the hospital were briefed of the research project and informed of the inclusion criteria of the study. The treating physiotherapist informed the patient of the study if the patient met the inclusion criteria. If the patient expressed an interest in volunteering to participate in the study,

the investigator was then contacted. The investigator met with the patient to fully explain the study and the assessment procedure, and also provide a written information letter about the study. Each patient was given the opportunity to ask questions or seek clarification prior to being asked to consent to participate in the study.

3.2.2 Recruitment of Healthy participants

Thirteen healthy individuals were recruited from staff, family and friends of St Vincent's Health to act as a control group. Healthy participants were age matched (+/-5 years) and gender matched to the previously recruited participants with a diagnosis of stroke. The consent form for the healthy participants can found in Appendix D.

In order to recruit healthy participants the staff of St Vincent's Hospital Physiotherapy Department were emailed to determine levels of interest. Potential participants were encouraged to contact the student investigator for further discussion. Potential participants were screened for their eligibility at that point. If they met the inclusion criteria (age and gender match, healthy and no history of stroke) they were provided with a Participant Information and Consent Form, and were recruited to the study after given the opportunity to ask questions and consider their participation.

3.2.3 Inclusion/Exclusion Criteria

The inclusion and exclusion criteria are outlined below for the stroke participants (Tables 3.1 and 3.2) and the inclusion criteria for the healthy participants (Table 3.3).

3.2.3.1 Inclusion/Exclusion Criteria Stroke Participants

The criteria applied in order to determine eligibility for recruitment to the study are summarised in Tables 3.1 and 3.2 below. Following is a justification of these criteria.

<u>Table 3.1:</u> Inclusion criteria for the stroke participants
--

Inclusion Criteria				
Diagnosis of stroke				
Unilateral hemiparesis				
Less than 20 weeks post stroke				
Able to walk with or without supervision, with or without a gait aid				
Motor deficit of the ankle dorsiflexors (STREAM <2 and/or Oxford Scale <3)				
Able to give informed consent; or carer or person responsible able to give				
informed consent				

Table 3.2: Exclusion criteria of the stroke participants	
--	--

Exclusion Criteria				
Atovio				
Ataxia				
Orthopaedic impairment limiting mobility pre-morbidly				
Ankle dorsiflexor strength greater than or equal to three, as measured by the				
Oxford Scale				
Wounds or fragile skin on the hemiplegic lower limb that would preclude the				
application of a fibreglass cast				

Ataxia was considered to be exclusion criteria because it can negatively affect walking performance irrespective of alterations in ankle function. Not excluding patients with ataxia could misrepresent the effect of the AFO's used. Similarly, impaired walking prior to their stroke could confound the effects of the AFO on walking performance. The premorbid walking impairment could produce a ceiling effect which would not enable accurate measurement of the effects of the AFO's. Having ankle strength greater than grade three on the Oxford Scale indicates that the patient has the motor ability to be able to clear the foot during the swing phase of gait. AFO's would not be indicated in this instance. Including such patients would be misrepresentative of the population of stroke patients who benefit most from AFO prescription. The application of a fibreglass cast can put fragile skin at risk of wounds or pressure areas. Such incidents can significantly impact on a patients' outcome. It was deemed unethical to put patients at such risk.

Two hundred and twenty people were admitted to the sub acute wards of St Vincent's Health with a diagnosis of stroke during the course of the study. Thirteen patients met the eligibility criteria as identified by their treating therapist and all consented to participate in the study after agreeing to discuss their participation with the student investigator. No participant withdrew from this study.

Of the 207 people with a diagnosis of stroke who were ineligible for this study the main reason for exclusion was either no difficulty walking, inability to walk without assistance, or minimal impairments around the ankle.

3.2.3.2 Inclusion Criteria Healthy participants

Healthy participants were eligible to participate if they met the inclusion criteria summarised in Table 3.3:

<u>Table 3.3:</u> Inclusion criteria for the healthy participants

Inclusion criteria				
N	lo history of musculoskeletal abnormality of the foot and ankle			
No	history of neurological conditions that affect balance or walking			
	Do not use an ankle support device			
	Were able to give informed consent			

3.2.4 Participant Groups

Thirteen participants were eligible for this study and were recruited. Accordingly, thirteen healthy participants were also recruited. Their demographic information is recorded below.

3.2.4.1 Stroke Group

The stroke group included ten males and three females (mean age 52.31 years ± 13.9 ; mean height 1.74m ± 0.08 ; mean body mass 80.7kg ± 15.8). Eight participants had a haemorrhagic stroke whilst five had an infarct. The mean duration of their stroke was 51.15 days (standard deviation 27.5 days). Seven participants were affected on the left side, whilst six were right side affected.

3.2.4.2 Healthy Group

The mean age of the healthy group was 52.2 years (standard deviation 13.1 years); mean height was 1.72 m (standard deviation 0.06 m); and body mass was 83.7 kg (standard deviation 14.6 kg)

3.3 Measures

This section describes the methods in which the participant's gait was assessed. It is divided into spatiotemporal measures and kinematic measures, which are summarised in Table 3.4

3.3.1 Spatiotemporal measures of gait

Spatio temporal gait characteristics collected were velocity, cadence, percentage of gait cycle in double limb support, affected leg single support phase, the symmetry between the affected and non-affected single leg stance times (Stance Symmetry Ratio), affected leg step length, and affected leg swing phase percentage of gait cycle. The single leg stance times between the affected and unaffected limb was determined using the Symmetry Index (SI) as proposed by Robinson, Herzog and Nigg (1987) and reported by Sadeghi, Allard, Prince and Labelle (2000; Equation 3.1). Whilst this index has limitations (Sadeghi, Allard, Prince, & Labelle, 2000), it has been demonstrated to show improvements in gait symmetry following ankle fractures in young adults (Becker, Rosenbaum, Kriese, Gerngross, & Claes, 1995).

 $SI = \frac{Affected \ leg \ single \ stance \ time - Unaffected \ leg \ single \ stance \ time}{(Affected \ leg \ single \ stance \ time + Unaffected \ leg \ single \ stance \ time)/2} \times 100$

Equation 3.1: Calculation of symmetry index

GAITRite®, as seen in Figure 3.1, is an electronic instrumented walkway system which measures spatiotemporal parameters of gait. It consists of a portable walkway, embedded with pressure sensitive sensors, positioned beneath a vinyl with square thread reinforced fabric walkway on a on an open cell rubber base. The walkway is linked to a compatible computer by a serial interface cable, which then records each footfall and analyses and stores the data to produce the spatiotemporal parameters. The walkway used measures 810cm long, 89cm wide and 0.625cm thick and has an active recording area of 720cm by 60cm (GAITRite ®, CIR Systems GRG-24, United States, 80Hz). Each sensor is pressure activated as each foot contacts the mat, triggering multiple sensors in pattern of the foot contact. Multiple foot contacts are analysed over a known time period (triggered by first foot contact to last foot contact over the active area of the walkway) to determine velocity, step length, cadence, time in single and double support among multiple other parameters. The degree of toe in or out of the foot can also be determined by the angle of the foot contact on the gait mat.

GaitRite® has strong concurrent validity and test-retest reliability across all spatiotemporal parameters in healthy subjects (Bilney et al., 2003; van Uden & Besser, 2004), as well as in older individuals (Menz et al., 2004). Its validity has also been established in regards to averaged and individual step characteristics following knee replacement surgery (Webster et al., 2005). Base of support and toe in/out angle have reduced reliability, possibly due to the spatial resolution of GaitRite® or perhaps inherent variability of these parameters (Menz et al., 2004).



Figure 3.1: Photograph of the GaitRite® Mat used in the study

3.3.2 Kinematic Measures

The angle of the knee joint was assessed through the stance phase of gait as occurs in clinical practice in which the effect on knee hyperextension after the application of an AFO is noted. Knee hyperextension is a common gait abnormality following a stroke, which puts the knee at risk of potential trauma. AFO's have the potential to cause hyperextension, depending on their construction (Condie, 2003; Lehmann, 1993). The presence of knee hyperextension may indicate that an AFO is not appropriate (Condie, 2003). However, certain types of AFO may be utilised to prevent knee hyperextension, though there are no studies investigating this to date. Knee hyperextension analysis was required to ensure participant safety. Silicon

Coach Pro software[™] (version 7, Silicon Coach Pty Ltd, Dunedin, New Zealand) was used to measure the angle of the knee through stance phase. Silicon Coach has been demonstrated to be a reliable kinematic technique for measuring ROM at the knee joint (Cronin, Nash, & Whatman, 2006), however there are no studies investigating the validity of the measure. The reliability has not been determined in regards to stroke. Although the SiliconCoach software lacks established reliability and validity research evidence, superior motion analysis tools such as Vicon, were not available. The resulting kinematic data was examined in order to determine if the application of an AFO caused knee hyperextension. A summary of the dependent variables is outlined in Table 3. 8.

Laboratory Tool	Parameter	Measure
GAITRite	Velocity	cm/sec
	Cadence	Steps/minute
	Affected/Matched leg	cm
	step length	
	Double limb stance	% of gait cycle
	Affected/Matched leg	% of gait cycle
	single support phase	
	Single leg stance	Ratio (Equation 3.1)
	symmetry	
	Affected/Matched leg	% of gait cycle
	swing phase	
Video	Knee angle	degrees

Table 3.4: Summary of Dependent Variables

3.3.3 <u>Demographics Assessment</u>

The medical history of the participant was reviewed and in particular any radiological investigation that confirmed the diagnosis and location of the cerebral lesion.

3.3.4 Physical Assessment Tests

Alterations to the strength and movement of the ankle are common after stroke. A thorough examination of the neuromuscular performance of the ankle is routinely performed during the examination of patients following stroke.

3.3.4.1 Range of Movement

A reduction in dorsiflexion range of movement (ROM) can significantly impact on the ability to walk and on the quality of walking (Lehmann, 1993). A normal range of ankle dorsiflexion is 20 degrees (Norkin & Levange, 1992). Reductions in dorsiflexion ROM can contribute to alterations in walking performance in stroke (Lamontagne et al., 2000; Rydahl & Brouwer, 2004).

3.3.4.2 *Tone*

Spasticity is one of the impairments that follows an upper motor neuron lesion. Spasticity is characterized by a velocity dependent increase in tonic stretch reflexes. The Modified Tardieu Scale is used as a measurement of spasticity, which records

the degree of the muscle reaction and the velocity of the stretch at which it occurs (Mehrholz et al., 2005) (Table 3.5, Appendix E). The Tardieu Scale is a more accurate measure to differentiate spasticity from contracture compared to other clinical measures of tone (Patrick & Ada, 2006). The Tardieu Scale is both a valid and reliable measure of spasticity (Mehrholz et al., 2005). Tone is a common occurrence following stroke and can negatively affect the ability to walk and the quality of walking (Hsu et al., 2003; Lamontagne, Malouin, & Richards, 2001; Lin et al., 2006).

Test	Score	Description	
	V1	Slow as possible (minimizing stretch reflex)	
Velocity of	V2	Speed of the limb segment falling under gravity	
stretch	V3	As fast as possible (faster than the rate of the	
	V3	natural drop of the limb segment under gravity)	
	0	No resistance throughout the course of the passive	
	0	movement	
		Slight resistance throughout the course of the	
	1	passive movement, with no clear catch at a precise	
Quality of		angle	
muscle	2	Clear catch at a precise angle, interrupting the	
reaction	2 action	passive movement, followed by release	
	3	Fatigable clonus (<10 seconds when maintaining	
	3	pressure) occurring at a precise angle	
	4	Infatigable clonus (>10 seconds when maintaining	
	4	pressure) occurring at a precise angle	

Table 3.5: Modified Tardieu Scale (Gracies et al., 2000)

3.3.4.3 Active Motor Control

The ability to produce voluntary movements can be impaired following stroke. These impairments can result in a reduced functional level. (Hsu et al., 2003; Lamontagne et al., 2002) The loss of the ability to produce movement is due to alterations in the neuromuscular unit as well as a reduction in muscular strength. Alterations to the neuromuscular unit occur due to changes at a cortical level eliminating or reducing the ability to initiate the movement required. The change in the ability to actively produce motor control is the impairment in this case. The manifestation of a loss of active motor control is a loss of strength. The Stroke Rehabilitation Assessment of Movement (STREAM) evaluates the quality and ability to produce basic movements and gait activities with an excellent degree of reliability (Daley, Mayo, & Wood-Dauphinee, 1999) (Table 3.6). The ankle subsection of STREAM was used to evaluate the degree of motor control impairment in the current study. Additionally, the strength of the participant was assessed using the Oxford Scale (Table 3.7). The Oxford Scale has been used by a number of investigators (Florence et al., 1992; Savic, Bergstrom, Frankel, Jamous, & Jones, 2007). The reliability of the Oxford Scale is thought to be moderate to strong (Paternostro-Sluga et al., 2008; Savic et al., 2007; Wadsworth, Krishnan, Sear, Harrold, & Nielsen, 1987), and has very strong reliability in relation to assessing movements with a score less than 3/5 (Florence et al., 1992). Strength of the ankle and knee was further assessed using a handheld dynamometer (Model 01163, Lafayette Muscle Tester,

Lafayette Instrument Company, Lafayette) to provide a quantitative assessment of the strength of the ankle.

<u>Table 3.6:</u> STREAM. An outline of the scoring definitions for this scale. (Daley et al., 1999)

Score	Description
0	Unable to perform the movement through any appreciable range (includes
	flickers and slight movements)
1a	Able to perform only part of the movement, and with marked deviations from
	the normal pattern
1b	Able to perform only part of the movement, but in a manner comparable to
	the unaffected side
1c	Able complete the movement, but only with marked deviation from the
	normal pattern
2	Able to complete the movement in a manner that is comparable to the
	unaffected side

<u>Table 3.7:</u> Oxford Scale. Examination of the dorsiflexion movement (Hislop, Montgomeroy, Connolly, Daniels, & Worthingham, 1995)

Oxford Grading	Muscle Activity
0	No palpable contraction of the tibialis anterior tendon
1	Palpable contraction or tendon will stand out as visualised by the
	investigator
2	Only able to complete part of the range of movement
3	Able to complete the full available ROM and can hold the end
	position without resistance from the investigator.
4	Able to complete full range of movement against moderate
	resistance from the investigator
5	Able to complete full range of movement and holds against maximal
	resistance from the investigator

3.3.4.4 Sensation and Proprioception

Alterations in sensation and proprioception can occur in stroke. This can affect the ability to walk due to reductions in balance due a lack of awareness of where that limb is or what it is doing (Carr & Shepherd, 1998)

3.4 Interventions – AFO's

There were five different conditions (interventions) which each participant were assessed. : Nil orthosis (shoed), barefoot, spring leaf AFO, Push Aequi Brace (sports brace) and fibreglass cast. The three orthoses conditions are illustrated in Figure 3.2. The participants walked in their own shoes. These AFO's were chosen as they represent AFO's of varying rigidity and will have different biomechanical effects. It is intended that these differences in biomechanical action will allow representation of different walking performance.



Figure 3.2: A: Spring Leaf AFO; B: Push Aequei; C: Fibreglass Cast and plasterboot

3.4.1 Push Aequi Brace (PAB)

A Push Aequi brace (PCT/NL98/00002, Nea International, The Netherlands) is a sport brace used to stabilize the ankle via a rigid support on the medial side and a pre-formed foam lateral wall. It is secured by two velcro straps that wrap around the ankle. There are three sizes of Push Aequi Brace (PAB) in left and right styles, measured by the circumference of the affected ankle. The PAB predominately stabilizes inversion and eversion of the ankle, but allow some dorsiflexion support though the swing phase of gait, particularly at the rear foot. During the stance phase the PAB provides minimal restriction to plantar flexion and dorsiflexion, thus allowing the normal kinematics of heel strike and rollover.

3.4.2 Spring Leaf AFO (SLAFO)

Spring Leaf AFOs (L2012, L2013, L2014, L2015, L2017, L2018, L2019, L2020, Grenace[™], Australia) are mass produced polypropylene AFOs. They come in three different sizes for both men's and women's models. The Spring Leaf AFO (SLAFO) is fitted inside the patient's shoe and is secured to the calf by a velcro strap. This AFO is designed to prevent plantar flexion during the swing phase of gait, but allows some plantar flexion and dorsiflexion during the stance phase due to the construction of the AFO. The degree of dorsiflexion available is dependent on the rigidity of the polypropylene.

3.4.3 Fibreglass Cast (FGC)

Each participant was cast in a below knee fibreglass cast (Dynacast® Extra 4793 71362-00, BSN medical Ltd, England). The casting was undertaken whilst the patient was in a seated position with the ankle positioned in plantigrade (zero degrees dorsiflexion), or as close to plantigrade as the participants ankle allowed.

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The method of casting is described in Table 3.7. Fibreglass casting is a commonly used assessment tool used by orthotists and physiotherapist's to test the suitability of an individual to use a custom-made orthosis, particularly for a Ground Reaction Ankle Foot Orthosis (GRAFO).

A GRAFO is an orthosis designed to utilize ground reaction forces and the muscle strength of the hip to provide a stabilization force around the knee. GRAFO's are custom-made, taking many days or weeks to manufacture. The cost of manufacturing a GRAFO can also be significant. Due to these practical considerations, a FGC was chosen to mimic the actions of a GRAFO.

3.5 Procedures

This section describes the methods for data collection for the physical assessment, and the gait assessment. The assessment process was performed by the student investigator in the physiotherapy department of the large public hospital. A flow chart describing the process following recruitment is described in Figure 3.3 Procedures are described in the order of delivery to the participant.

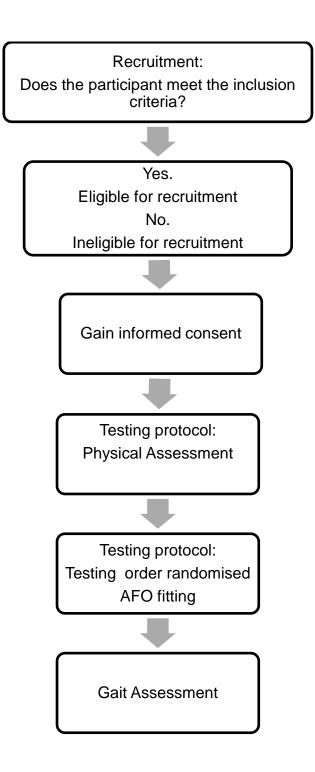


Figure 3.3: Flowchart of examination and testing

3.5.1 Physical Assessment

This section describes the procedure for the data collection of the physical assessment of the participants. It is divided into demographics, range of movement, tone, active motor control, sensation and proprioception.

3.5.1.1 *Demographics* Assessment

The participants' height, body mass, and leg length were measured. Height was measured using a stadiometer fixed to the wall (SECA 206, SECA GMBH and Co, Hamburg, Germany), whilst body mass was measured using scales accurate to 0.05 kg (KW-11, @Weigh Pty Ltd, Moorabbin) The participant's leg length was measured using a steel anthropometry tape (Alimed Measuring Tape 5560, Alimed, Dedham, MA). with the patient lying in a supine position on a bench (Neurological Bobath Table 50061, HealthTec, Yeerongpilly, Qld) from the anterior superior iliac spine (ASIS) to the medial malleolus of the ankle (Beattie, Isaacson, Riddle, & Rothstein, 1990; Gurney, 2002).

3.5.1.2 Range of Movement

The degree of movement available at the ankle was assessed whilst barefoot in a prone position using a goniometer (Baseline plastic 360⁰ ISOM (STFR) 12-1000, Fabrication Enterprises, New York). Two measurements were taken; the first with the knee in full extension (Figure 3.4) and, the second, with the knee positioned with 90 degrees of flexion (Figure 3.5) (Elveru, Rothstein, Lamb, & Riddle, 1988). The researcher positioned the participants' foot into the maximum degree of dorsiflexion range available. The goniometric measurement was with reference to the fifth metatarsal head (proximal goniometer arm), lateral malleolus (goniometer axis), and the line of the fibula (distal goniometer arm) (Figure 3.6). If the participant was not able to be positioned in a prone position, the measurements were then taken in a supine using the same reference points.



Figure 3.4: ROM assessment in prone, knee extended



Figure 3.5: ROM assessment in prone, knee flexed



Figure 3.6: ROM assessment, position of the goniometer

3.5.1.3 Tone

The participant was assessed whilst in the supine position with the hip and knee in a neutral position (0^0 of flexion) for gastrocnemius, and the knee positioned in 90 degrees of flexion for soleus. The tone of the plantar flexors determined at the fastest stretch possible (V3 on the Tardieu Scale; Table 3.5) The ankle was stabilized over the joint line with one hand, and the other hand attempted to provide a rapid dorsiflexion movement to elicit a "catch" in the range (Gracies et al., 2000)(Figure 3.7). The point at which a catch occurs was noted, as was the degree of the catch.



Figure 3.7: Assessment of spasticity

3.5.1.4 Active motor control

STREAM, the Oxford Scale and MMT were used to quantify active motor control and muscle strength of the tibialis anterior muscle. The Oxford Scale and MMT were used to quantify the strength of the quadriceps muscle.

3.5.1.4.1 Quadriceps

The participant was positioned in supine on a plinth (Neurological Bobath Table 50061, HealthTec, Yeerongpilly, Qld). The knee was positioned in 30 degrees of flexion using a rolled towel to maintain the posture. For ease of assessment both the Oxford scaling and dynamometry occurred in this position. The femur was stabilised with one hand of the student researcher (depending which leg was assessed), with the other hand positioned over the distal tibia either with or without the dynamometer (Model 01163, Lafayette Muscle Tester, Lafayette Instrument Company, Lafayette) (Figure 3.8). The participant was asked to straighten their leg against the resistance. The student researcher continued to apply resistance until the participants effort was "broken" (Phillips, Lo, & Mastaglia, 2000). This was then scored as an Oxford scale level and recorded or the dynamometry result was record. Three trials occurred for each test (six in total).



Figure 3.8: Assessment of quadriceps strength

3.5.1.4.2 Tibialis anterior

The participant remained in supine following the quadriceps assessment. The participants distal tibia was stabilised by one hand of the student researcher, whilst the other provided resistance to the distal, dorsal aspect of the participants foot (Figure 3.9). This occurred both with and without a dynamometer. The participant was asked to dorsiflex with their maximal effort, with the student researcher providing resistance until the participant's effort was "broken". This was then scored as an Oxford scale level and recorded or the dynamometry result was record. Three trials occurred for each test (six in total).



Figure 3.9: Assessment of tibialis anterior strength

To score STREAM the participant was positioned in sitting, with the foot being assessed slightly in front of the other and asked to "keep your heal on the ground and lift your toes of the ground as far as you can" (Daley et al., 1999) (Figure 3.10). The student research then rated the participant's performance according to the scale.



Figure 3.10: STREAM assessment, a visual observation of the ankle dorsiflexing whilst the participant is positioned in a chair

3.5.1.5 Sensation and Proprioception

Sensation to light tough of the foot and lower limb of the affected limb was tested. The sensation of the heel, first metatarsal head, dorsum of the foot, lateral and medial malleoli were tested with a light tissue touch, and were rated as either normal, impaired or absent (Carr & Shepherd, 1998).

Testing of proprioception was also determined at the knee, ankle and great toe of the affected limb with the participant in a supine position. Participants were asked to determine the position of their joint after it had been passively positioned by the investigator. The investigator demonstrated the test on the participants' unimpaired leg first to confirm understanding of the task. The knee, ankle and great toe was positioned by the investigator at the end of each available range (i.e. flexion or extension). This was then described as either "up" or "down". The participant was instructed to close their eyes whilst the investigator positioned the joint. The participant was then asked to indicate whether that position was either up or down. Five tests were completed at each joint. Proprioception was rated as normal for a score of five out of five, impaired for a score of one to four out of five, and absent for a score of zero out of five (Carr & Shepherd, 1998; School of Physiotherapy, 2009). This procedure of testing is the most common method of assessing sensation and proprioception in neurological patients (School of Physiotherapy, 2009).

3.5.2 Gait assessment procedure

The order of AFO conditions was randomised between participants in each group. Each participant walked over an electronic walkway. For participants with a diagnosis of stroke the testing was conducted across three days to minimize the effect of fatigue. Whereas healthy participants were tested over one day. The leg which the healthy participants wore an AFO was matched to that of their age and gender matched stroke participant. This was considered the "matched leg" rather than affected leg. Before each test the participants with a diagnosis of stroke were provided with a 40 minute acclimatization period to become used to each new orthosis, during which they will spend no more than 15 minutes of actual walking. Healthy participants were provided with a 15 minutes acclimatization period and a self-selected amount of rest following this. Once acclimatized to the orthosis condition, the participant performed four overground walking trials at a self-selected,

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comfortable, pace under each orthotic condition along the walkway and force platform. The method of applying the fibreglass cast is outlined in Table 3.8 Patients were instructed to walk at a pace that felt comfortable and safe. Four trials were completed for each condition, resulting in twenty trials in total. Trials that result in poor or inaccurate data due to the participant's performance, such as by stepping off the GaitRite® walkway, were excluded and repeated. A flowchart describing the testing procedure can be seen in Figure 3.11.

Participants began walking 2m before the Gaitrite walkway and finished 2m after (Figure 3.11). This was to enable a stable walking pace prior to data collection (Goldie, et al., 2001). This allowed for a five metre walk test which has been found to be the most valid for assessing walking velocity in stroke patients (Salbach et al., 2001).

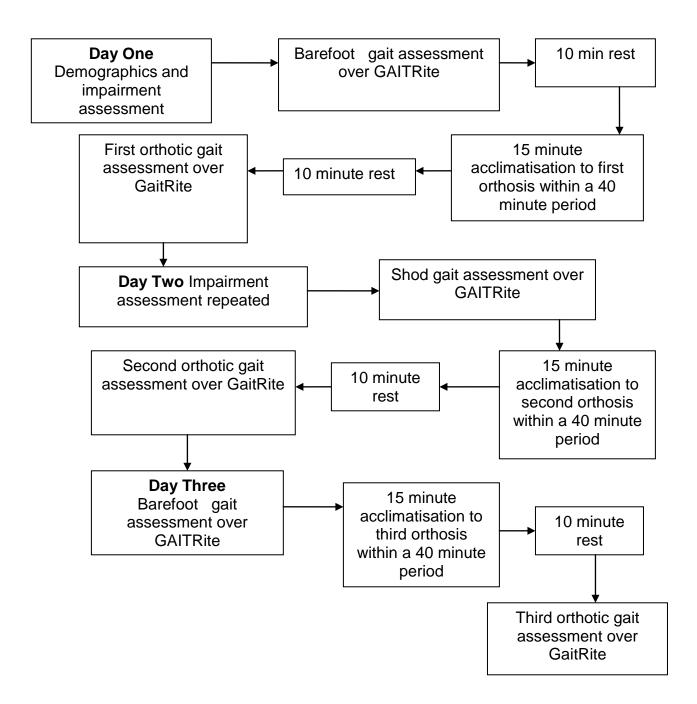


Figure 3.11: Flowchart of testing procedure for participants with a diagnosis of stroke.

Step	Method of application
1	Position the participant in sitting, with the affected limb exposed
	and the ankle positioned at plantigrade and neutral supination/
	pronation
2	Check the skin for any wounds or lesions that would preclude the
	individual from having a cast applied.
3	Apply a stockinet from below the toes too above the knee
4	Wrap the limb in an overlapping under-wrap to protect the skin
	from the metatarsal heads to below the knee
5	Soak the DynaCast in cold water as per the manufacturer's
	instructions
6	Begin wrapping the affected limb with dynacast from the below the
	knee, down to the metatarsal heads with overlapping layers
	dynacast , ensuring the ankle is positioned in as much dorsiflexion
	range as available but not past plantigrade
7	Whilst maintaining the dorsi flexion ROM allow the cast to cure
8	A Plaster boot will be fitted over the cast for use in walking. Each
	participant will wear their own shoes on their non-hemiplegic foot
9	Once cured the testing protocol will be completed. When the trials
	have been completed the fibreglass cast will be removed with an
	electrical saw by an experienced clinician. The skin will be
	checked for any areas of rubbing due to the cast or grazes due
	the removal of the cast with the plaster saw

3.5.2.1 *Reliability procedure*

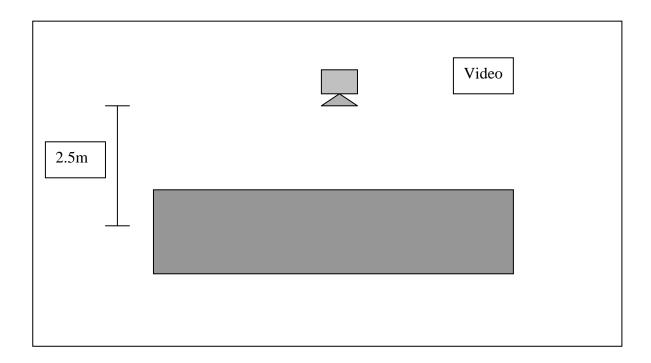
In order to establish the test retest reliability the kinematic data of the barefoot walks conducted on Days One and Three (Figure 3.11) were utilised. The student investigator and a senior physiotherapist each marked the anatomical landmarks of the lower limb on the videotaped knee angle on the computer screen at initial contact, midstance and terminal stance (as defined below) independently. To determine the interrater reliability the kinematic results of barefoot walk of day one and the kinematic results of the FGC on Day 1 were compared. Barefoot walking was chosen as there were data taken over multiple days and the FGC condition was chosen as it was the most rigid of the AFO's and therefore has the potential to be more likely to have a negative kinematic effect.

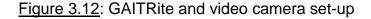
3.5.3 Spatiotemporal data

Results generated by GAITRite were downloaded into an Excel spreadsheet for further statistical analysis.

3.5.4 Kinematic data

The participants were videoed from the affected limb side whilst walking on the GAITRite® walkway. A video camera (Sony HandyCam DCR-DVD 608e, Sony Corporation, Tokyo, 50Hz) was positioned on a tripod, perpendicular to the GAITRite® walkway (Figure 3.12), to capture the entire leg for at least two steps.





In this study a step is defined was from heel contact of one foot to the heel contact of the other foot that followed. Specifically for this study, the ground contact phase kinematics of the affected limb was of interest, therefore the video captured heel contact of the affected limb followed by heel contact of the unaffected limb. Participants were videoed for each walking condition. The resulting footage of all participants was compiled into one video in a random order, known only to the investigator. The Silicon Coach software was then utilised to assess the knee angle at three points during the stance (ground contact phase) of the affected limb at heel contact (initial contact), midstance (when the hip is vertically aligned over the ankle), and terminal stance (toe-off). Marker points of the greater trochanter, midpoint of the

knee joint line and the lateral malleolus were identified using visual analysis and measured using the software to generate the angle of the femur and tibia/fibula to indicate angle of the knee (Figure 3.13). To date the validity of the Silicon Coach software has yet to be established, to do so was beyond the scope of this study.

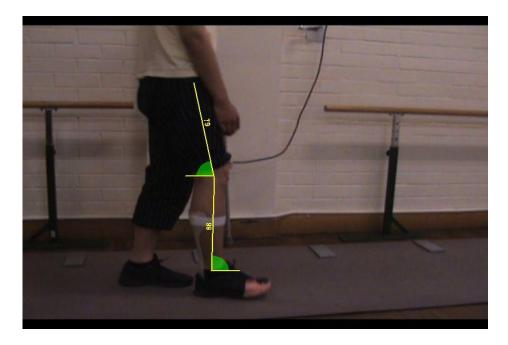


Figure 3.13. Example of the output generated by SiliconCoach

3.5 Data Analysis

As this study was preliminary in nature there was no data available to perform an appropriate sample size calculation. Following data collection the data was exported from GAITRite to an Microsoft Excel spreadsheet, to allow the determination of the median, mean and standard deviation for each of the trials. The data was then exported from Microsoft Excel to the Statistical Package for the Social Sciences (SPSS, version 18, SPSS Inc., Chicago IL). Data was analysed for normality via established standards (Macellari, Giacomozzi, & Saggini, 1999; Portney & Watkins, 2000). The assumptions of normality were that the participants were randomly selected and were representative of the population of interest. The distribution of the data scores of this population were considered normal where the homogeneity of variance is not violated, the data did not exceed ±2 for skewness and kurtosis and that the data is ordinal. The distribution of the data were viewed as histograms for spread and the presence of outliers. Normality calculations using Shapiro-Wilk indicated variation in the normality of distribution. In light of the small sample size involved and the variation in the normality of distribution the conservative option of non-parametric analysis was chosen. The data for outliers was kept in the analysis due to the small sample size and the statistical analyses chosen. Descriptive statistics were calculated and displayed graphically.

Once normality was reviewed four separate analyses were performed: (1) the walking performance of the stroke participants were compared to the healthy participants, (2) the walking performance of the stroke group with AFO's grouped together and under each different condition was performed, (3) the walking performance of the control group with AFO's grouped together and under each different condition was performed. Post hoc analysis were used to detect the presence of differences for each group under each different walking condition. (4) Individual analysis of participants occurred using Smallest Real Difference (SRD) methods to determine clinically relevant effects, if any. SRD was utilised as it was envisaged that the stroke patients responses might by varied and those responses

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may not be reflected in the group analysis. Therefore to explore if individuals may benefit from an AFO SRD were used. Those that were considered to positively respond to AFO prescription were defined as thus; a change in gait performance greater than the SRD for at least one AFO in at least one gait parameter. Subsequent to this, the physical impairment characteristics of those that demonstrated changes greater than the SRD were examined. To limit the number of comparisons, ankle ROM, dorsiflexion strength and spasticity were categorised according to Table 3.9. Mean muscle activity of tibialis anterior and quadriceps muscles were reported according to MMT. Those individuals which responded to more than one AFO were further analysed, with differences greater than the SRD noted. Furthermore, following individual analysis using smallest real differences case studies will be presented to further describe the attributes of those stroke participants who improved using an AFO.

Parameter	High impairment category	Low impairment category
Ankle ROM	Less than 0 degrees dorsiflexion	Greater than 0 degrees dorsiflexion
Dorsiflexion strength (Oxford Scale)	Score of less than 2/5	Score of 2/5
Spasticity (Tardieu Scale)	Increased tone present	Increased tone not present

Table 3.9: Categorisation of ankle impairment for responders or non-responders

The data of the stroke group and the healthy participant group were analysed using non-parametric testing for dependent samples (Friedman's Test), a significant finding resulting in post-hoc testing using Wilcoxon's Test. The alpha level for these analyses was set at .05 (α = .05). Bonferroni corrections were not performed as the variables examined are closely related (Turk et al., 2008) increasing the risk of Type 2 error.

As the evidence from the literature suggests that the effect of AFO use is varied, and the range of results was large, the response of individuals to the application of AFO's was of interest. Using the data from the shoe trials as a baseline to calculate SRD was calculated, with confidence levels set at 95%, using the following equation (Equation 3.2; (Stevenson, 2001; Stratford & Goldsmith, 1997):

 $SRD = SEM \times 1.96 \times \overline{2}$

where; SRD = Smallest Real Difference, SEM = Standard Error of the Mean

In order to determine the reliability of the baseline (shod) data an Intraclass Correlation Coefficient (ICC) was calculated. Two way, mixed single measures (ICC 3, 1) was used. To enable SRD to be calculated the four raw scores from each of the trials for each of the individual participants was exported from a Microsoft Excel spreadsheet onto SPSS. Using Equation 3.2 the values required were entered into an Microsoft Excel spreadsheet for the SRD calculation. Using median scores each individuals' difference in barefoot, PAB, SLAFO and FGC from their shod baseline was determined.

The difference of each individual's performance from their baseline (shod walk) to barefoot, PAB, SLAFO and FGC were displayed graphically as bar graphs for velocity, cadence, double limb support, affected leg single support percentage of gait cycle, single support symmetry ratio, affected leg swing percentage of gait cycle and affected leg step length. The SRD indicator points were indicated on these graphs. Individual's results were also displayed as box plots to indicate the spread of the results.

The reliability of the assessment of knee angle was assessed using an intraclass correlation coefficient (ICC). The ICC utilised was (2, 1), with results interpreted according the criteria of Altman (1999): $\kappa < 0.20 = \text{poor}, \kappa$: 0.21–0.40 = fair, κ : 0.41–0.60 = moderate, κ : 0.61–0.80 = good, κ : 0.81–1.0 = very good.

Chapter 4 RESULTS

4.0 Results

The results of this study are presented in six sections related to the populations tested; the stroke participants and the healthy participants. Each section will compare the stroke participants with the healthy participants, and compare individual performance within each group of participants. The selected case studies will further examine the individual performance of certain stroke participants. The sections are divided according to the walking conditions compared. Prior to the main analyses, the sub-study to establish the reliability of the measure of knee kinematics is presented.

- 1. Reliability sub-study
- 2. General group characteristics comparison
- 3. Shod walking compared to barefoot walking
- 4. Shod walking compared to ankle foot orthoses (AFO) walking
- 5. Shod walking compared to walking with specific types of AFO's
- 6. Individual analysis of the stroke participants
- 7. Individual analysis of the healthy participants

The results are generally reported as means (standard deviations [SD]). Due to some measures breaching normality criteria, non-parametric testing was employed and therefore medians and inter-quartile ranges (IQR) will also be reported where appropriate.

4.1 Reliability sub-study

This section reports the results of the test retest reliability and the interrater reliability for knee angle measures in participants with stroke.

4.1.1 Test retest reliability

The test retest reliability of barefoot walking on Day 1 and Day 3 for the student investigator and a senior physiotherapist are reported in Table 4.1. Each of the three variables resulting in very good reliability according to the criteria of Altmann (1999) for the student investigator and the senior physiotherapist.

Variable		Tester 1	Tester 2
Barefoot Initial Contact	r:	0.94	0.97
	p:	0.001	0.001
Barefoot Midstance	r:	0.98	0.98
	p:	0.001	0.001
Barefoot Terminal Stance	r:	0.98	0.99
	p:	0.001	0.001

<u>Table 4.1:</u> Test retest reliability (Tester 1 = student investigator, Tester 2 = Senior Physiotherapist)

4.1.2 Interrater reliability

The interater reliability of the student investigator and a senior physiotherapist is reported in Table 4.2. Three of the variables resulted in very good interrater reliability, one with good reliability and two variables with fair reliability according to the according to the criteria of Altmann (1999). Measurements at terminal stance had the lowest interrater reliability (0.60 and 0.41).

Variable		Reliability
Barefoot Initial Contact	r:	0.80
	p:	0.001
Barefoot Midstance	r:	0.93
	p:	0.001
Barefoot Terminal Stance	r:	0.60
	p:	0.001
FGC Initial Contact	r:	0.92
	p:	0.001
FGC Midstance	r:	0.92
	p:	0.001
FGC Terminal Stance	r:	0.41
	p:	0.001

<u>Table 4.2:</u> Interrater reliability between Tester 1 and Tester 2 (Tester 1 = student investigator, Tester 2 = Senior Physiotherapist)

4.2 General characteristics of stroke participants and healthy participants

Analysis of the demographic data, as presented in Tables 4.3 and 4.4, indicated that there were no differences in age (Z = -0.026, p=0.980), stature (Z = -0.026, p=0.980), stature (Z=-0.026), 0.540, p=0.589) or mass (Z=-0.359, p=0.719) between the stroke and healthy participants (Table 4.5). There were significant differences however in ankle range of motion (ROM) between the stroke and the healthy participants (Table 4.6). Healthy participants had increased dorsiflexion ROM compared to stroke participants (Table 4.6), when assessed with their knee in flexion (Z=-3.461, p=0.001), or with their knee in extension (Z=-3.265, p=0.001). Healthy participants had stronger dorsiflexion movement, as evidenced by significantly greater scores when assessed using the Oxford Scale (Z=-4.693, p=0.0001), STREAM (Z=-4.668, p=0.0001) and manual muscle dynamometry (Z= -4.284, p=0.0001). Healthy participants also had significantly stronger quadriceps muscle activation on assessment via the Oxford Scale (Z=-4.747, p=0.0001) and manual muscle dynamometry (Z=-3.513, p=0.0001). The stroke participants had a significantly increased amount of plantar flexor group muscle spasticity (Z = -2.4587, p = 0.044). More specific examination of the differences in ankle impairment of the stroke participants is demonstrated in Table 4.7 and in Table 4.8 for the healthy participants.

<u>Table 4.3</u>: A demographic description of the stroke group (Haem = Haemorrhagic stroke; Isch = Ischaemic stroke)

Participant	Gender	Age	Туре	Affected	Duration	Height	Mass
ID		(Years)	of stroke	Side	(days)	(m)	(kg)
S1	Female	51	Haem	Right	48	1.75	75.0
S2	Male	23	Haem	Left	68	1.81	76.5
S3	Male	58	Haem	Right	74	1.75	103.0
S4	Male	61	Haem	Right	91	1.73	107.5
S5	Male	67	Isch	Right	11	1.6	54.0
S6	Female	42	Isch	Right	34	1.74	94.0
S7	Male	33	Haem	Left	37	1.87	85.0
S8	Female	54	Haem	Right	100	1.60	84.0
S9	Male	71	Isch	Left	56	1.70	75.0
S10	Male	57	Haem	Left	9	1.80	76.5
S11	Male	41	Haem	Left	33	1.77	74.0
S12	Male	57	lsch	Left	58	1.68	55.4
S13	Male	65	lsch	Left	46	1.78	89.4
Median		57			48	1.75	76.5
(IQR)		(42-63)			(34-71)	(1.69-1.79)	(74.5-91.7)
Mean		52			51	1.74	80.7
(SD)		(14)			(28)	(0.08)	(15.8)

Participant ID	Gender	Age	Height	Mass
		(Years)	(m)	(kg)
H1	Female	51	1.64	74.0
H2	Male	26	1.8	76.0
H3	Male	58	1.75	110.0
H4	Male	61	1.7	83.0
H5	Male	65	1.75	87.0
H6	Female	43	1.64	60.0
H7	Male	32	1.73	77.0
H8	Female	53	1.65	74.0
H9	Male	70	1.71	71.0
H10	Male	57	1.79	90.0
H11	Male	42	1.79	90.0
H12	Male	58	1.66	85.0
H13	Male	63	1.78	111.0
Median		57	1.73	83.0
(IQR)		(42.5- 62)	(1.65- 1.78)	(74-90)
Mean (SD)		52.2	1.72	83.7
		(13.1)	(0.06)	(14.6)

Table 4.4 A demographic description of the healthy participant group

Table 4.5: A comparison between	the demographics	of the stroke and healthy
participant groups (*p<0.05).		

	Age (years)	Stature (m)	Mass (kg)
Stroke Participants			
Median	57.0	1.75	76.5
(IQR)	(41.3-63.0)	(1.69-1.79)	(74.5-91.7)
Mean (SD)	52.3 (13.9)	1.74 (.08)	80.7(15.8)
Healthy Participants			
Median	57.0	1.73	83.0
(IQR)	(42.5-62.0)	(1.65-1.78)	(74.0-90.0)
Mean (SD)	52.2 (13.1)	1.72 (0.06)	83.7(14.6)
Significance	Z=-0.026	Z=-0.540	Z=-0.359
	p=0.980	p=0.589	p=0.719

	Dorsi Flexion ROM Knee Flexed	Dorsi Flexion ROM Knee Extended	Dorsi Flexion Oxford	STREAM Dorsi Flexion	Tardieu Ankle	MMT Dorsi Flexion	Quadriceps Oxford	MMT Quadriceps
Stroke Participants								
Median (IQR)	15 (0-17.5)	10 (0-13)	2 (1-2)	1a (0-1b)	1 V3 (0 V3-2 V3)	2.6 (0.8-5.2)	2 (2-3)	13.2 (8.6-16.8)
Mean (SD)	10 (11)	6 (11)			,	3.2 (2.6)		12.5 (5.2)
Healthy Participants								
Median (IQR)	25.0 (18.5 – 28)	20.0 (14.5-25)	5	2	0	13.6 (11.8-21.6)	5	21.0 (19-25.8)
Mean (SD)	23.6 (6.7)	19.9 (6.6)				16.1 (6.3)		21.5 (4.8)
Significance	Z=-3.461 p=0.001*	Z=-3.265 p=0.001*	Z=-4.693 p=0.0001*	Z=-4.668 p=0.0001*	Z=-2.458 p=0.044*	Z=-4.284 p=0.0001*	Z=-4.747 p=0.0001*	Z=-3.513 p=0.0001*

<u>Table 4.6:</u> A comparison of the physical characteristics of the stroke and healthy participant groups; where ROM= Range of Movement and MMT = Manual Muscle Test (*p<0.05).

Participant	Dorsi Flexion ROM Knee Flexed	Dorsi Flexion ROM Knee Extended	Dorsi Flexion Oxford	STREAM Dorsi Flexion	Tardieu Ankle	MMT Dorsi Flexion	Quadriceps Oxford	MMT Quadriceps
1	5	5	2	1b	0 V3	2.6	3	16.7
2	1	10	0	0	3 V3	0.0	2	13.3
3	-5	-4	1	1b	0 V3	2.6	2	15.6
4	-5	-10	1	1a	1 V3	1.3	2	2.0
5	10	10	1	0	2 V3	2.0	2	8.6
6	15	10	2	1a	0 V3	3.8	2	16.8
7	20	15	2	1b	1 V3	8.4	2	21.7
8	15	5	2	1a	1 V3	5.5	2	7.9
9	-10	-18	1	0	0 V3	0.2	3	8.6
10	14	9	2	1a	1 V3	5.0	2	10.3
11	24	20	2	1b	0 V3	6.7	4	17.6
12	22	15	2	1b	1 V3	3.3	2	9.9
13	15	10	0	0	0 V3	0.0	3	13.2
Median (IQR)	15	10	2	1a	1 V3	2.6	2	13.2
	(0-17.5)	(0-13)	(1-2)	(0-1b)	(0 V3-2 V3)	(0.8-5.2)	(2-3)	(8.6-16.8)
Mean (SD)	10	6				3.2		12.5
	(11)	(11)				(2.6)		(5.2)

<u>Table 4.7:</u> Results of the pre-testing screening assessment for the stroke group where; ROM= Range of Movement and MMT = Manual Muscle Test.

<u>Table 4.8:</u> Results of the pre-testing screening assessment for the healthy group where; ROM= Range of Movement and MMT = Manual Muscle Test.

Participant	Dorsi	Dorsi	Dorsi	STREAM	Tardieu	MMT Dorsi	Quadriceps	MMT
Number	Flexion	Flexion	Flexion	Dorsi	Ankle	Flexion	Oxford	Quadriceps
	ROM Knee	ROM Knee	Oxford	Flexion	74110			
	Flexed	Extended						
1	20	10	5	2	0	18.8	5	22.1
2	26	23	5	2	0	25.9	5	27.8
3	12	10	5	2	0	12.2	5	23
4	19	16	5	2	0	7.1	5	19.3
5	18	15	5	2	0	11.1	5	11.9
6	33	29	5	2	0	11.3	5	19.2
7	35	25	5	2	0	27.6	5	27.5
8	22	22	5	2	0	13.6	5	16.3
9	25	25	5	2	0	13	5	18.8
10	16	14	5	2	0	16.5	5	28.5
11	26	19	5	2	0	24.4	5	19.4
12	25	20	5	2	0	12.8	5	24.1
13	30	30	5	2	0	15.1	5	21
Median	25.0	20.0				13.6		21.0
(IQR)	(18.5 – 28)	(14.5-25)				(11.75-		(19-25.8)
						21.6)		
Mean(SD)	23.6 (6.7)	19.9 (6.6)				16.1 (6.3)		21.5 (4.8)

4.3 Shod walking compared to barefoot walking

This section is divided into three components. Comparisons of the walking performance when shod (wearing shoes) and whilst barefoot for the stroke and the healthy participants. Then the differences between each condition for the stroke participants and the healthy participants are compared as individual groups.

4.3.1 Stroke participants compared to healthy participants

A comparison of barefoot walking between the stroke participants and healthy participants revealed that the healthy participants had a significantly faster walking velocity (Z=-3.180, p=0.0001). The healthy participants were 81.5 cm/sec faster than the stroke participants (Table 4.9). Similarly, healthy participants demonstrated significantly improved performances, compared to the stroke participants having a faster cadence (Z=-3.180, p=0.001), reduced double limb support (Z=-3.180, p=0.001), increased affected leg step length (Z=-3.180, p=0.001) (Table 4.10), increased affected leg single support phase (Z=-3.180, p=0.001), and lower stance symmetry ratio (Z=-3.110, p=0.002; Table 4.11). There were no differences in performance between the stroke participants and the healthy participants for affected leg swing phase (Z=-1.853, p=0.064; Table 4.11) or knee angles at initial ground contact (Z=-.890, p=0.373), mid stance (Z=-. .890, p=0.373); or terminal stance (Z=-1.112, p=0.266; Table 4.12)

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<u>Table 4.9:</u> A comparison of velocity and, cadence, for the stroke and healthy participants walking in barefoot and shoes; and a comparison of barefoot walking and shod walking between the healthy and stroke participants (*p<0.05).

	Str	oke	Noi	mal	Stroke v	/s Normal
	Barefoot	Shoe	Barefoot	Shoe	Barefoot vs Barefoot	Shoe vs Shoe
Velocity (cm/sec)						
Median	39.5	47.1	121.0	131.5	Z=-3.180	Z=-3.180
(IQR)	(16.5-55.3)	(21.7–62.8)	(113.8-130.9)	(119.7 – 144.0)	p= 0.001 [*]	p= 0.001 [*]
Mean (SD)	38.8 (22.9)	46.0 (25.9)	122.9 (16.7)	132.0 (16.1)		
-	Z= -2.691	, p=0.007 [*]	Z=-2.900,	· · · · ·		
Cadence (Steps/Minute)						
Median	62.5	68.2	115.9	113.7	Z=-3.180	Z=-3.180
(IQR)	(36.0-79.1)	(41.0-80.5)	(110.6-120.3)	(106.6-119.1)	p=0.001 [*]	p=0.001*
Mean (SD)	60.8 (22.8)	63.8 (21.9)	114.9 (6.7)	113.1 (7.1)		
	Z=-2.201	, p=0.028*	Z=-0.664	, p=0.507		

<u>Table 4.10</u>: A comparison of double limb support (DLS) and affected leg step length for the stroke and healthy participants walking in barefoot and shoes; and a comparison of barefoot walking and shod walking between the healthy and stroke participants (*p<0.05).

	Str	oke	No	rmal	Stroke vs Normal		
	Barefoot	Shoe	Barefoot	Shoe	Barefoot vs Barefoot	Shoe vs Shoe	
DLS (%)							
Median	36.4	39.0	21.9	25.9	Z=-3.180	Z=-3.040	
(IQR)	(30.1-54.5)	(30.6 – 52.8)	(20.1-23.9)	(24.1 – 27.8)	p= 0.001 [*]	p=0 .002 [*]	
Mean (SD)	42.0 (14.0)	41.5 (12.0)	22.2 (2.0)	25.9 (2.5)			
	Z=-0.384	, p=0.701	Z=-3.181	, p=0.001 [*]			
Step Length (cm)							
Median	39.2	43.3	63.3	68.4	Z=-3.180	Z=-3.180	
(IQR)	(29.1-44.8)	(33.4 – 52.5)	(59.6-67.3)	(63.6 – 76.3)	p=0.001*	p=0.001	
Mean (SD)	37.0 (9.4)	41.6 (10.6)	64.3 (6.9)	69.9 (7.9)			
	Z=-2.970,	p=0.003 [*]	Z=-3.180	, p=0.001 [*]			

<u>Table 4.11:</u> A comparison of affected/matched leg single stance (%), affected/matched leg swing (%) and the single stance time symmetry for the stroke and healthy participants walking in barefoot and shoes; and a comparison of barefoot walking and shod walking between the healthy and stroke participants (*p<0.05).

	Sti	oke	Noi	rmal	Stroke v	/s Normal
	Barefoot	Shoe	Barefoot	Shoe	Barefoot vs Barefoot	Shoe vs Shoe
Single stance (%Gait Cycle)						
Median	24.7	25.2	39.0	37.4	Z=-3.180	Z=-3.180
(IQR)	(12.9-29.8)	(14.3-29.1)	(38.0-39.9)	(35.7-38.3)	p= 0.001*	p=0.001*
Mean(SD)	22.2 (9.1)	22.4(8.2)	38.8(1.2)	37.1(1.3)		
	Z= -0.17	5, p=0.861	Z=-3.112,	p=0.002*	-	
Swing (%gait cycle)						
					Z=-1.853	Z=-0.105
Median	35.0	38.4	39.3	37.6	p= 0.064	p= 0.916
(IQR)	(31.8-41.5)	(32.3-40.9)	(38.3-39.8)	(36.3-37.9)		
Mean (SD)	36.0 (6.1)	36.7 (5.3)	39.2(1.3)	37.2(1.4)		
	Z=-0.524	, p=0.600	Z=-3.184,	p=0.001 [*]	-	
Stance symmetry ratio						
Median	-44.8	-41.3	-1.6	97	Z=-3.110	Z=-3.110
(IQR)	(-32.280.0)	(-31.577.6)	(-3.3-1.4)	(-3.0 – 1.7)	p=0.002 [*]	p= 0.002 [*]
Mean (SD)	-55.2 (33.2)	-50.2 (32.8)	99 (3.8)	63 (2.9)		
	Z=-1.503	, p=0.133	Z=874,	p=0.382	-	

<u>Table 4.12:</u> A comparison of the knee angle at initial contact, midstance and terminal stance for the stroke and healthy participants walking in barefoot and shoes; and a comparison of barefoot walking and shod walking between the healthy and stroke participants (*p<0.05).

	St	troke	Noi	rmal	Stroke v	/s Normal
	Barefoot	Shoe	Barefoot	Shoe	Barefoot vs Barefoot	Shoe vs Shoe
Knee angle						
initial contact						
(degrees)					Z=-0.890	Z=-1.071
Median	6	4.0	2.0	2.5	p=0.373	p=0.284
(IQR)	(-2-15)	(-1.0 – 9.0)	(0.0-7.0)	(5 – 4.8)		
Mean (SD)	7.3 (11.1)	5.3 (7.0)	3.5 (4.4)	1.92 (3.9)		
· · · · ·	· · ·	6, p=0.814	· · ·	, p=0.222	_	
Knee angle midstance					7 0 000	7 . 0.014
(degrees)	o -				Z=0.890	Z=-0.044
Median	-2.5	5.0	4.5	3.0	p=0.374	p=0.965
(IQR)	(-6.5-5.75)	(-9.0 – 14.3)	(4.0-7.0)	(2.0 – 9.0)		
Mean (SD)	.3 (10.7)	3.75 (11.7)	5 (3.9)	5.2 (4.0)		
_	Z=-0.623	3, p=0.533	Z=-0.315	, p=0.753		
Knee angle						
terminal stance						
(degrees)					Z=-1.112	Z=-0.356
Median	0	2.0	3.5	2.5	p=0.266	p=0.722
(IQR)	(-4.8-1.8)	(-3.5 – 16.8)	(1.0-13.0)	(0 – 8.0)		
Mean (SD)	1.0 (11.0)	5.8 (11.7)	7.3 (7.9)	5.2 (6.8)		
· · ·	Z=-1.336	6, p=0.182	Z=-0.937,	p=0.349	-	

4.3.2 Shod walking compared to barefoot walking of stroke participants

The walking velocity of the stroke participants was significantly faster when they wore shoes (47.1cm/sec) when compared to when barefoot (39.5 cm/sec) (Z=-2.691, p=0.007), due to a significant increase in cadence of 5.7 steps/min (Z=-2.201, p=0.028; Table 4.9), and a 4.1cm increase in affected leg step length (Z=-2.970, p=0.003; Table 4.10. There were no other differences between shod and barefoot walking.

4.3.3 Shod walking compared to barefoot walking of healthy participants

The walking velocity of the healthy participants was also significantly faster when they wore shoes (131.5 cm/sec) in comparison to barefoot (121.0 cm/sec) (Z=-2.900, p=0.004) due to an increased step length (Z=-3.180, p=0.001), but not cadence (Z=-0.664, p=0.507; Table 4.9). Healthy participants also demonstrated a significantly longer time in double limb support in shoes (25.9%) in comparison to barefoot (21.9%); (Z=-3.181, p=0.001; Table 4.10). Healthy participants also spent longer in matched leg single support phase (Z=-3.112, p=0.002) in barefoot and a longer matched leg swing phase (Z=-2.062, p=0.039) in barefoot in comparison to shod walking (Table 4.11). There were no differences in stance symmetry ratio (Z=-0.874, p=0.382; Table 4.11), or the knee angle at initial contact (Z=-1.222, p=0.222); midstance (Z=-0.315, p=0.753) or terminal stance (Z=-0.937, p=0.349; Table 4.12) in the shod and barefoot walking of healthy participants.

4.4 Shod walking compared to all AFO's

This section is divided into three components. The walking performance in shoes and all of the AFO's combined of the stroke participants and the healthy participants is compared, then the differences between each condition for the stroke participants and the healthy participants is compared as individual groups.

4.4.1 <u>Stroke participants compared to healthy participants</u>

The healthy participants' walking velocity when wearing an AFO was 69.9 cm/sec faster when compared to the stroke participants (Z=13.000, p=0.0001; Table 4.13). Further significant differences were found for cadence (Z=-9.308, p=0.0002; Table 4.13), double limb support (Z=-9.308, p=0.0002; Table 4.13), double limb support (Z=-9.308, p=0.0002; Table 4.14), affected/matched leg step length (Z=13.000, p=0.0001; Table 4.14), affected/matched leg single support phase (Z=-3.180, p=0.001; Table 4.15) and stance symmetry ratio (Z=13.000, p=0.0001; Table 4.15). The healthy participants exceeding the stroke participants' performance for each parameter (Tables 4.13, 4.14 and 4.15). There were no differences between the stroke participants and healthy participants in regards to affected leg swing phase (Z=-0.943, p=0.345; Table 4.15) or the knee angle at initial contact (Z=0.091, p=0.763); midstance (Z=0.818, p=0.366); or terminal stance (Z=1.923, p=0.166; Table 4.16).

<u>Table 4.13:</u> A comparison of velocity and cadence, for the stroke and healthy participants walking in shoes and all AFO's ; and a comparison of shod walking and walking in all AFO's between the healthy and stroke participants (*p<0.05).

	St	roke	Nor	mal	Stroke vs Normal
	Shoe	All AFO	Shoe	All AFO	All AFO vs All AFO
Velocity					
(cm/sec)					Z=13.000
Median	47.1	48.2	131.5	118.1	p=0.0001*
(IQR)	(21.7–62.8)	(24.3 – 65.2)	(119.7 – 144.0)	(109.6 – 126.9)	
	46.0(25.9)	46.9(24.4)	132.0(16.1)	120.1(14.2)	
Mean (SD)	Z= -0.66	4, p=0.507	Z= -3.040,	p= 0.002*	
Cadence		•		•	
(Steps/Minute)					Z=9.308
					p=0.002*
Median	68.2	67.4	113.7	110.0	
(IQR)	(41.0-80.5)	(44.4-82.1)	(106.6 – 119.1)	(102.9 – 115.6)	
	63.8(21.9)	64.6(20.9)	113.1(7.1)	102.2(30.7)	
Mean (SD)	Z=-0.594	4, p=0.552	Z=-2.621,	p=0.009 [*]	

<u>Table 4.14:</u> A comparison of double limb support (DLS) and affected/matched leg step length for the stroke and healthy participants walking in shoes and all AFO's ; and a comparison of shod walking and walking in all AFO's between the healthy and stroke participants (*p<0.05).

	Str	oke	Nor	rmal	Stroke vs Normal
	Shoes	All AFO	Shoes	All AFO	All AFO vs All AFO
DLS (%)					
					Z=9.308
Median	39.0	38.2	25.9	26.6	p=0 .002*
(IQR)	(30.6 – 52.8)	(30.3 – 50.0)	(24.1 – 27.8)	(25.0 – 27.9)	
Mean (SD)	41.5 (12.0)	41.0 (11.7)	25.9 (2.5)	26.5 (2.0)	
	Z= -0.105	p=0.916	Z= -1.153	p= 0.249	
Step Length (cm)				·	Z=13.000 p=0.0001 [*]
Median					
(IQR)	43.3	46.1	68.4	67.3	
	(33.4 – 52.5)	(34.9 – 51.8)	(63.6 – 76.3)	(59.0 – 71.9)	
Mean (SD)	41.6 (10.6)	42.3 (10.7)	69.9 (7.9)	66.0 (7.2)	
	Z= -1.363	p=0 .173	Z= -3.110	p=0.002*	

<u>Table 4.15</u>: A comparison of affected/matched leg single stance(%), affected/matched leg swing (%) and the single stance time symmetry for the stroke and healthy participants walking in shoes and all AFO's ; and a comparison of shod walking and walking in all AFO's between the healthy and stroke participants (*p<0.05).

	Str	oke	No	rmal	Stroke vs Normal
	Shoe	All AFO	Shoe	All AFO	All AFO vs All AFO
Single stance (%Gait Cycle)					
Median	25.2	26.7	37.4	35.6	
(IQR)	(14.3-29.1)	(15.1-28.9)	(35.7-38.3)	(34.9-36.9)	Z=-3.180
((14.3-23.1)	(13.1-20.3)	(33.7-30.3)	(34.9-30.9)	
Mean(SD)	22.4 (8.2)	22.5 (7.9)	37.1 (1.3)	36.0 (1.3)	p=0.001
	Z= -0.384		Z= -2.621	p= 0.009*	
Swing (%gait cycle)					
Median	38.4	35.3	39.3	37.6	Z=-0.943
(IQR)	(32.2-40.9)	(32.9-41.3)	(38.3-39.8)	(36.8-38.6)	p=0.345
Mean (SD)					
()	36.7(5.3)	36.3 (5.3)	37.2 (1.4)	37.7 (1.1)	
	Z= -0.524	p=0 .600	Z= -2.062	p=0 .039*	
Stance					
symmetry ratio					
Median	-41.3	-40.6	97	-4.8	
(IQR)	(-31.577.6)	(-63.133.3)	(-3.0 – 1.7)	(-6.93.0)	Z=13.000
					p=0.0001 [*]
Mean (SD)	-50.2 (32.8)	-49.1 (21.4)	63 (2.9)	-4.9 (3.1)	
	Z= -0.314	p= 0.753	Z= -2.900	p=0 .004 [*]	

<u>Table 4.16:</u> A comparison the knee angle at initial contact, midstance and terminal stance for the stroke and healthy participants walking in shoes and all AFO's ; and a comparison of shod walking and walking in all AFO's between the healthy and stroke participants (*p<0.05).

	Stro	ke	Nor	mal	Stroke vs Normal
	Shoe	All AFO	Shoe	All AFO	All AFO vs All AFC
Knee angle initial					
contact (degrees)					
Median	4.0	4.7	2.5	3.3	
(IQR)	(-1.0 – 9.0)	(3.1 – 11.9)	(5 – 4.8)	(.8-6.3)	Z=0.091
					p=0.763
Mean (SD)	5.3 (7.0)	7.9 (7.7)	1.92 (3.9)	3.6 (2.6)	·
-	Z= -1.883	p=0.060	Z=-1.969	p=0.049*	_
Knee angle					
midstance					
(degrees)					
Median	5.0	1.0	3.0	4.7	Z=0.818
(IQR)	(-9.0 – 14.3)	(-3.6 – 8.3)	(2.0 – 9.0)	(3.4-10.3)	p=0.366
Mean (SD)	3.75 (11.7)	2.1 (8.1)	5.2 (4.0)	6.7 (4.9)	
-	Z= -0.044	p= 0.965	Z=-1.099	p=0.272	_
Knee angle		1			
terminal stance					
(degrees)					
Median	2.0	3.3	2.5	3.0	
(IQR)	(-3.5 – 16.8)	(8 – 9.3)	(0 - 8.0)	(1.2-6.5)	Z=0.091
	· · · · /	· · · /	· · · · /	· /	p=0.763
Mean (SD)	5.8 (11.7)	4.4 (6.3)	5.2 (6.8)	3.9 (2.9)	r
	Z= 0.0001	p= 1.000	Z=-0.267	p=0.789	_

4.4.2 Shod walking compared to walking in all AFO's of stroke participants

In regards to the stroke participants no differences were identified for any of the parameters examined when walking in shoes was compared to walking in an AFO. Walking velocity was not significantly faster in an AFO when compared to shod walking (Z=-0.664, p=0.507; Table 4.13). None of the other gait parameters showed significant differences when shod walking was compared to walking in an AFO (Table 4.16).

4.4.3 Shod walking compared to walking in all AFO's of healthy participants

The walking velocity of healthy participants was significantly slower (*Z*=-3.040, p=0.002) when wearing an AFO (118.1cm/sec) in comparison to shod walking (131.5cm/sec) due to an significantly slower cadence (*Z*=-2.621, p=0.009) in an AFO (110.0 steps/minute) compared to shod (113.7 steps/minute), and a significantly shorter (*Z*= -3.110, p= 0.002) affected/matched leg step length in an AFO (67.3cm) when compared to shod walking (68.4cm; Table 4.14). Affected/matched leg single support and swing phase were less (stance: *Z*=-2.621, p=0.009; swing: *Z*=-2.062, p= 0.039) in an AFO compared to shod walking. Single support stance time ratio was less symmetrical (*Z*=-2.900, p= 0.004) when using an AFO (-4.8), as opposed to shod walking (-0.97).

Using an AFO caused the healthy participants to have a slightly flexed knee (3.3 degrees) at initial contact (Z=-1.969, p=.049) in comparison to shod walking (2.5 degrees). There were no differences at midstance (Z= -1.099,

p=0.272) or terminal stance (Z=-0.267, p=0.789) in regards to the same comparison (Table 4.16).

4.5 Shod walking in comparison to AFO's of varying rigidity

This section is divided into three components. The walking performance in shoes and the PAB, SLAFO or FGC of the stroke participants and the healthy participants is compared, then the differences between each condition for the stroke participants and the healthy participants is compared as individual groups.

4.5.1 Stroke participants compared to healthy participants

As was similar to the earlier section, where the AFO's of varying rigidity were considered as a group the healthy participants performance was superior to that of the stroke participants in regards to all but four parameters. The four parameters in which there were no differences are affected/matched leg swing phase knee angle at initial contact, knee angle at midstance and knee angle at terminal stance. For the participants with stroke, no significant differences were identified between the different types of AFO for any parameter tested, other than an increase in knee flexion at initial contact for the FGC condition. For healthy participants, significant differences were found between AFO's for several parameters. In comparison to shod walking the use of an AFO caused a deterioration in velocity, cadence, matched leg single support phase, matched leg swing phase, matched leg step length, single support stance symmetry ratio

and knee angle at initial contact. There were no differences in performance regarding double limb support or knee angles at midstance or terminal stance. It is best to consider each AFO separately to elucidate the differences between the stroke and healthy participants.

4.5.1.1 Comparison of the push aequi brace between stroke and healthy participants

The healthy participants walked at a faster velocity than the stroke participants (Z=18.788, p=0.0001; Table 4.17) due to an increased cadence (Z=13.444, p=0.0001; Table 4.18) and longer affected/matched leg step length (Z =18.336, p=0.0001; Table 4.20). Healthy participants spent less time in double limb support (Z=14.207, p=0.0001; Table 4.19). The affected/matched leg single support phase was significantly greater for the healthy participants (Z=18.797, p=0.0001; Table 4.21) but not for the affected/matched leg swing phase (Z=-0.513, p=0.614; Table 4.22). The symmetry of single leg stance time was more symmetrical (Z=13.444, p=0.0001) for the healthy participants (Table 4.23). There was no difference of the knee angle between the stroke participants and the healthy participants at initial contact (Z=0.409, p=0.522; Table 4.24) or terminal stance (Z=0.484, p=0.487; Table 4.26). However, at mid stance the healthy participants were in more flexed knee position (5.5 degrees) than the stroke participants (-1.0 degrees) who were in a slight hyperextended position (Z=4.841, p=0.028; Table 4.25).

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4.5.1.2 Comparison of the spring leaf AFO between stroke and healthy participants

As was determined for the PAB, the healthy participants walked at a faster velocity than the stroke participants when using a SLAFO (Z=18.778, p=0.0001) due to an increased cadence (Z=13.444, p=0.0001; Table 4.17) and a longer affected leg step length (Z=17.468, p= 0.0001; Table 4.20). Healthy participants spent less time in double limb support (Z=12.703, p=0.0001; Table 4.19) and spent longer in affected/matched leg single support (Z=18.784, p=0.0001; Table 4.21) than stroke participants. No difference in affected/matched leg swing phase was found between the stroke and healthy participants when using a SLAFO (Z=-0.744, p=0.479; Table 4.22). However, the single stance symmetry ratio between the stroke and healthy participants was significantly different (Z=18.336, p=0.0001) indicating the stroke group were more asymmetrical (Table 4.23). No differences were determined regarding the knee angle at initial contact (Z=1.274, p=0.259, Table 4.24), midstance (Z=1.344, p=0.246; Table 4.25) or terminal stance (Z=0.085, p=0.771; Table 4.26) between the stroke and healthy participants.

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4.5.1.3 Comparison of the fibreglass cast between stroke and healthy participants

When walking in a FGC healthy participants walked at a faster velocity that the stroke participants (Z=17.468, p=0.0001; Table 4.17), due to an increased cadence (Z=11.634, p=0.001; Table 4.18) and affected/matched leg step length (Z=16.621, p=0.0001; Table 4.20). When wearing a FGC healthy participants spent less time in double limb support (Z=11.283, p=0.001; Table 4.19) and a shorter affected/matched leg step length (Z=15.391, p=0.0001; Table 4.20). Healthy participants spent longer in affected/matched leg single stance (Z=18.778, p=0.001; Table 4.21) but not affected/matched leg swing phase (Z=-0.924, p=0.362; Table 4.22) than the stroke participants. The healthy participants had a significantly more symmetrical stance ratio (Z=13.444, p=0.0001) when compared to stroke participants (Table 4.23). As was the case for spring leaf AFO's there were no difference in the knee angle between stroke and healthy participants at initial contact (Z=3.779, p=0.052; Table 4.24), midstance (Z=2.104, p=1.147; Table 4.25) or terminal stance (Z=1.047, p=1.829; Table 4.26).

<u>Table 4.17:</u> A comparison of the walking velocity (cm/sec) of the stroke participants and the healthy participants walking in shoes and each of push aequi brace (PAB), spring leaf AFO (SLAFO) and fibreglass cast (FGC); and comparison between the stroke and healthy participants in each of the orthotic conditions (*p<0.05).

		Str	oke			Nor	mal	
	Shoe	PAB	SLAFO	FGC	Shoe	PAB	SLAFO	FGC
Median (IQR)	47.1 (21.7-62.8)	46.9 (22.3-68.6)	51.2 (22.6-64.5)	49 (26.9-64.8)	131.45 (119.7 – 144.0)	125.1 (118.7 – 138.9)	119.9 (110.2 – 124.9)	108.2 (98.1 – 129.3)
Mean (SD)	46.0 (25.9)	46.9 (25.6)	46.1 (24.5)	47.1 (24.5)	132.0 (16.1)	128.5 (13.2)	120.8 (14.9)	110.9 (18.3)
PAB	Z=-0.454 p=0.650				Z=-1.623 p=0.100			
SLAFO	Z=-1.049 p=0.294	Z=-0.035 p=0.972			Z=-2.900 p=0.004 [*]	Z=-2.551 p=0.011 [*]		
FGC	Z=-0.245 p=0.807	Z=-0.384 p=0.701	Z=-0.035 p=0.972		Z=-3.18 p=0.001 [*]	Z=-2.900 p=0.004 [*]	Z=-2.691 p=0.007 [*]	
St	roke v Normal							
	PAB x PAB					3.778 0001 [*]		
SL	AFO x SLAFC)				3. 77 8 0001 [*]		
	FGC x FGC					7.468 0001 [*]		

<u>Table 4.18:</u> A comparison of the cadence (steps/minute) of the stroke participants and the healthy participants walking in shoes and each of push aequi brace (PAB), spring leaf AFO (SLAFO) and fibreglass cast (FGC); and comparison between the stroke and healthy participants in each of the orthotic conditions (*p<0.05).

		Str	oke			Noi	mal	
	Shoe	PAB	SLAFO	FGC	Shoe	PAB	SLAFO	FGC
Median	68.2	66.6	66.8	68.4	114.3	112.2	111.4	106.6
(IQR)	(41.0-80.5)	(42.8-80.1)	(42.9-81.7)	(45.2-85.3)	(106.7-	(107.5-	(105.3-	(102.3-
					119.1)	117.4)	115.1)	114.9)
Mean (SD)	64.1(21.5)	63.5 (20.8)	64.1 (20.3)	65.9 (22.8)	113.7 (6.9)	112.5 (5.8)	110.2 (5.3)	108.0 (7.4)
PAB	Z=-0.559				Z=-1.328			
	p=0.576				p=0.184			
SLAFO	Z=-0.280	Z=-0.628			Z=-2.341	Z=-2.377		
	p=0.780	p=0.520			p=0.019*	p=0.017*		
FGC	Z=-1.013	Z=-1.223	Z=-0.874		Z=-2.831	Z=-2.551	Z=-1.680	
	p=0.311	p=0.221	p=0.382		p=0.005*	p=0.011*	p=0.093	
St	troke v Normal							
	PAB x PAB				Z=13	3.444		
					p=0.0	0001*		
SL	AFO x SLAFC)			Z=13	3.444		
					p=0.0	0001*		
	FGCxFGC				Z=11	1.634		
					p=0.	.001*		

<u>Table 4.19</u>: A comparison of the double limb stance (DLS; %of gait cycles) of the stroke participants and the healthy participants walking in shoes and each of push aequi brace (PAB), spring leaf AFO (SLAFO) and fibreglass cast (FGC); and comparison between the stroke and healthy participants in each of the orthotic conditions (*p<0.05).

		Str	oke		Normal				
	Shoe	PAB	SLAFO	FGC	Shoe	PAB	SLAFO	FGC	
Median	39.0	39.3	40.8	39.2	26.0	26.4	27.8	25.4	
(IQR)	(30.6-52.8)	(29.7-49.6)	(31.9-53.2)	(30.4-49.8)	(24.1 –	(24.8 –	(25.7 –	(23.9 –	
					27.8)	27.7)	29.7)	28.49)	
Mean (SD)	41.5 (12.0)	40.2 (11.2)	41.9 (11.6)	40.8 (13.0)	25.9 (2.5)	26.28 (1.95)	27.3 (2.25)	25.8 (2.58)	
PAB	Z=-1.363				Z=-0.594				
	p=0.173				p=0.552				
SLAFO	Z=524	Z=-1.922			Z=-3.040	Z=-2.551			
	p=0.600	p=0.055			p=0.002*	p=0.011*			
FGC	Z=-0.245	Z=-0.664	Z=-0.454		Z=-0.245	Z=-0.943	Z=-2.431		
	p=0.807	p=0.507	p=0.650		p=0.807	p=0.345	p=0.019*		
S	troke v Normal								
	PAB x PAB				Z=1	4.207			
					p=0.	.0001*			
SI	LAFO x SLAFC)			Z=12.703				
					p=0.	.0001*			
	FGCxFGC				Z=1	1.283			
					p=0	0.001*			

<u>Table 4.20:</u> A comparison of the affected/matched leg step length (cm) of the stroke participants and the healthy participants walking in shoes and each of push aequi brace (PAB), spring leaf AFO (SLAFO) and cast (FGC); and comparison between the stroke and healthy participants in each of the orthotic conditions (*p<0.05).

		Str	oke		Norr	mal		
	Shoe	PAB	SLAFO	FGC	Shoe	PAB	SLAFO	FGC
Median	43.3	47.0	44.9	44.5	68.4	68.9	66.4	64.9
(IQR)	(33.4-52.5)	(34.2-52.2)	(33.1-52.9)	(37.3-49.2)	(63.6 –	(62.1–75.9)	(61.6 –	(54.9 –
					76.3)		71.2)	69.8)
Mean (SD)	41.6 (10.6)	42.9 (11.9)	42.4 (12.0)	42.7 (9.2)	69.9 (7.9)	68.7 (7.0)	66.5 (7.6)	62.8 (8.0
PAB	Z=-0.664	x 7			Z=-1.433			
	p=0.507				p=0.152			
SLAFO	Z=-0.524	Z=-0.035			Z=-2.970	Z=-2.201		
	p=0.600	p=0.972			p=0.003*	p=0.028*		
FGC	Z=0.664	Z=-0.245	Z=-0.035		Z=-3.110	Z=-2.970	Z=-2.411	
	p=0.507	p=0.907	p=0.972		p=0.002*	p=0.003*	p=0.016*	
St	troke v Normal							
	PAB x PAB		Z=18.336					
					p=0.	.0001*		
SL	AFO x SLAFC)			Z=1	7.468		
					p=0.	.0001*		
	FGCxFGC				Z=1	6.621		
					p=0.	.0001*		

<u>Table 4.21</u>: A comparison of the affected/matched leg single stance (%) of the stroke participants and the healthy participants walking in shoes and each of push aequi brace (PAB), spring leaf AFO (SLAFO) and fibreglass cast (FGC); and comparison between the stroke and healthy participants in each of the orthotic conditions (*p<0.05).

		Str	oke			No	rmal		
-	Shoe	PAB	SLAFO	FGC	Shoe	PAB	SLAFO	FGC	
Median	25.2	25.6	25.7	24.1	37.4	36.7	35.3	35.6	
(IQR)	(14.3-29.1)	(15.5-30.8)	(14.4-28.8)	(15.6-28.2)	(35.7-38.3)	(35.4-37.4)	(34.7-37.4))	(33.9-37.5)	
Mean (SD)	22.4(8.2)	23.1(8.5)	22.3(7.9)	22.2(7.8)	37.1(1.3)	36.6 (1.1)	35.9 (1.6)	35.5(1.9)	
PAB	Z=-1.189 p=0.235				Z=-1.785 p=0.074				
SLAFO	Z=-0.420 p=0.675	Z=-1.433 p=0.152			Z=-2.204 p=0.028*	Z=-1.782 p=0.075			
FGC	Z=-0.454 p= 0.650	Z=-1.468 p=0.142	Z=-0.210 p=0.834		Z=-2.482 p=0.013*	Z=-1.923 p=0.054	Z=-0.175 p=0.861		
St	roke v Normal								
	PAB x PAB				7–18	8.797			
				p=0.0001*					
SLAFO x SLAFO				Z=18.784					
					p=0.0	0001*			
	FGCxFGC					8.778			
					p=0.0	0001*			

<u>Table 4.22</u>: A comparison of the affected/matched leg swing phase (%) of the stroke participants and the healthy participants walking in shoes and each of push aequi brace (PAB), spring leaf AFO (SLAFO) and fibreglass cast (FGC); and comparison between the stroke and healthy participants in each of the orthotic conditions (*p<0.05).

		Str	oke		Normal				
	Shoe	PAB	SLAFO	FGC	Shoe	PAB	SLAFO	FGC	
Median	38.4	36.6	36.3	37.5	37.6	37.2	37.4	38.4	
(IQR)	(32.3-40.9)	(33.5-40.8)	(29.3-40.9)	(30.8-40.4)	(36.3-37.9)	(36.6-38.4)	(35.6-38.2)	(37.5-39.8	
<i>Mean</i> (SD)	36.7(5.3)	36.9 (4.8)	35.4(5.6)	36.5(6.7)	37.2(1.4)	37.3 (1.2)	37.1 (1.3)	38.7 (1.4)	
PAB	Z=-0.140				Z=-0.560				
	p=0.889				p=0.576				
SLAFO	Z=-1.4685	Z=-1.608			Z=-0.525	Z=-0.699			
	p=0.142	p=0.108			p=0.600	p=0.484			
FGC	Z=-0.105	Z=-0.454	Z=-1.223		Z=-3.111	Z=-2.622	Z=-3.111		
	p= 0.917	p=0.650	p=0.221		p=0.002*	p=0.009*	p=0.002*		
St	troke v Normal								
	PAB x PAB				Z=-().513			
					p=0	.614			
SL	AFO x SLAFC)			Z=-().744			
					p=0	.479			
FGCxFGC				Z=-0.924					
					p=0	.362			

<u>Table 4.23:</u> A comparison of the single stance symmetry ratio of the stroke participants and the healthy participants walking in shoes and each of push aequi brace (PAB), spring leaf AFO (SLAFO) and fibreglass cast (FGC); and comparison between the stroke and healthy participants in each of the orthotic conditions (*p<0.05).

		Str	oke		Normal				
	Shoe	PAB	SLAFO	FGC	Shoe	PAB	SLAFO	FGC	
Median	-41.3	-44.9	-42.9	-47.6	975	-2.10	-3.27	-7.57	
(IQR)	(-31.5 -	(-22.8-	(-26.6-	(-34.4-	(3.04 –	(-4.6828)	(-6.63 -	(-11.12 -	
	-77.6)	-74.7)	-72.8)	-72.2)	1.70)		60)	-5.73)	
Mean (SD)	-50.2 (32.8)	-48.5 (36.3)	-49.3 (30.7)	-55.6 (28.0)	-0.63(2.9)	-2.08 (3.08)	-3.2 (52)	-8.5 (4.9)	
PAB	Z=-0.594				Z=-1.922				
	p=0.552				p=0.055				
SLAFO	Z=-0.454	Z=-0.175			Z=-1.503	Z=524			
	p=0.650	p=0.861			p=0.133	p=0.600			
FGC	Z=-0.454	Z=-0.943	Z=-0.454		Z=-3.180	Z=-3.110	Z=-2.76		
	p= 0.650	p=0.345	p=0.650		p=0.001*	p=0.002*	p=0.006*		
St	troke v Normal								
	PAB x PAB				Z=1	3.444			
					p=0.	0001*			
SL	AFO x SLAFC)			Z=1	8.336			
					p=0.	.0001*			
FGCxFGC				Z=13.444					
					р=0.	0001*			

<u>Table 4.24</u>: A comparison of the knee angle at initial contact (degrees) of the stroke participants and the healthy participants walking in shoes and each of push aequi brace (PAB), spring leaf AFO (SLAFO) and fibreglass cast (FGC); and comparison between the stroke and healthy participants in each of the orthotic conditions (*p<0.05).

		Str	oke		Normal				
-	Shoe	PAB	SLAFO	FGC	Shoe	PAB	SLAFO	FGC	
Median	4.0	4.0	7.5	8.5	2.5	2.5	3	3	
(IQR)	(-1.0- 9.0)	(0.25- 12.5)	(0.5- 12.25)	(1.75 – 15.25)	(-1.0 – 5.0)	(1.0 – 6.0)	(1.0 – 7.0)	(2.0 – 6.0)	
Mean (SD)	5.3(7.0)	6.4(9.0)	7.8 (7.1)	9.6 (8.7)	1.9 (3.9)	3.5 (3.5)	4.3 (4.6)	3.5 (3.1)	
PAB	Z=-0.792 p=0.428				Z=-1.329 p=0.184				
SLAFO	Z=-1.338 p=0.181	Z=-0.045 p=0.964			Z=-1.546 p=0.122	Z=-0.205 p=0.838			
FGC	Z=-2.585 p=0.010*	Z=-2.233 p=0.026*	Z=-0.935 p=0.350		Z=-1.499 p=0.134	Z=514 p=0.607	Z=-0.561 p=0.575		

Stroke v Normal		
PAB x PAB	Z=0.409	
	p=0.522	
SLAFO x SLAFO	Z=1.274	
	p=0.259	
FGCxFGC	Z=3.779	
	p=0.052	

<u>Table 4.25:</u> A comparison of the knee angle at midstance (degrees) of the stroke participants and the healthy participants walking in shoes and each of push aequi brace (PAB), spring leaf AFO (SLAFO) and fibreglass cast (FGC); and comparison between the stroke and healthy participants in each of the orthotic conditions (*p<0.05).

		Str	oke		Normal				
	Shoe	PAB	SLAFO	FGC	Shoe	PAB	SLAFO	FGC	
Median	5.0	-1.0	2.5	-0.5	3	5.5	4	6	
(IQR)	(-9 -14.25)	(-6.0- 6.5)	(-1.8 -11.0)	(-4.0 -9.0)	(2.0 – 9.0)	(3.0 – 14.0)	(1.0 – 14.0)	(2.0 – 10.0)	
Mean (SD)	3.8 (11.7)	0.33 (9.9)	4.25 (9.8)	1.6 (7.3)	5.2 (4.0)	7.3 (5.2)	7.3 (7.4)	6.2 (4.6)	
PAB	Z=-1.161				Z=-1.476				
	p=0.246				p=0.140				
SLAFO	Z=-0.746	Z=-1.603			Z=-0.934	Z=-0.411			
	p=0.456	p=0.109			p=0.350	p=0.681			
FGC	Z=-0.118	Z=-0.786	Z=-1.158		Z=-1.188	Z=-0.890	Z=-0.489		
	p=0.906	p=0.432	p=0.247		p=0.235	p=0.373	p=0.624		
St	troke v Normal								
	PAB x PAB				Z=4	1.841			
					p=0	.028*			
SL	AFO x SLAFC)			Z=1	.344			
					p=0).246			
	FGCxFGC				Z=2	2.104			
					p=0).147			

<u>Table 4.26:</u> A comparison of the knee angle at terminal stance (degrees) of the stroke participants and the healthy participants walking in shoes and each of push aequi brace (PAB), spring leaf AFO (SLAFO) and fibreglass cast (FGC); and comparison between the stroke and healthy participants in each of the orthotic conditions (*p<0.05).

		St	roke		Nor	mal		
	Shoe	PAB	SLAFO	FGC	Shoe	PAB	SLAFO	FGC
Median	2.0	3.0	4.0	4.5	2.5	5	3.5	3
(IQR)	(-3.5 -16.8)	(8– 9.8	(-3.0 -12.8)	(.3 - 9.0)	(0 – 8.0)	(2.0 – 9.0)	(2.0 – 7.0)	(0 – 7.0)
Mean (SD)	5.8 (11.7)	5.1 (7.7)	4.25 (8.2)	3.9 (5.3)	5.2 (6.8)	5.7 (5.5)	5.3 (5.7)	4.3 (6.3)
PAB	Z=-0.102				Z=-0.315			
	p=0.919				p=0.753			
SLAFO	Z=-0.472	Z=-0.579			Z=-0.512	Z=-0.359		
	p=0.637	p=0.563			p=0.609	p=0.719		
FGC	Z=-0.157	Z=-0.422	Z=-0.157		Z=-0.712	Z=-1.491	Z=-1.030	
	p=0.875	p=0.673	p=0.875		p=0.476	p=0.136	p=0.303	
Si	troke v Normal							
	PAB x PAB				Z=0).484		
					p=0	.487		
SL	AFO x SLAFO				Z=0	0.085		
					P=().771		
FGCxFGC						0.047		
					p=C	0.829		

4.5.2 <u>Comparison of shod walking and AFO's of varying rigidity in stroke</u> participants

The study did not identify any significant differences in temporal spatial gait parameters between the four conditions of shoes and the three AFO options (Tables 4.17 - 4.23). The angle of the knee at initial contact was more flexed when walking in the more rigid fibreglass cast (8.5 degrees) when compared to shoes (4.0 degrees; Z=-2.585, p=0.010; Table 4.24) or the minimally rigid push aequi brace (4.0 degrees; Z=-2.233, p=0.026; Table 4.25). No other differences between AFO's for knee angle were identified (Tables 4.24, 4.25, and 2.26).

4.5.3 <u>Comparison of shod walking and AFO's of varying rigidity in healthy</u> participants

The effect of more rigid AFO's was more marked in the healthy participants. There was no difference between shod walking velocity and that of the minimally rigid PAB (Z=-1.623, p=0.100). However, as the rigidity increased the walking velocity of the healthy participants decreased (Table 4.17). Walking velocity in the moderately rigid SLAFO was 119.9cm/sec in comparison to shod walking of 131.5 cm/sec (Z=-2.900, p=0.004); and even slower at 108.2cm/sec using the most rigid FGC (Z=-3.180, p=.001). This pattern continued when comparing the PAB (125.1cm/sec) to the SLAFO (Z=-2.551, p=0.011), or the FGC (Z=-2.900, p=0.004). SLAFO walking velocity was significantly slower in comparison to FGC (Z=-2.691, p=0.007) for healthy participants. These velocity changes were due to a decreased cadence (Table 4.18) using a FGC. There was

no difference between the cadence of SLAFO or the FGC (Z=-1.680, p=0.093). The velocity changes were also due to an increased affected leg step length, which demonstrated significant reductions in performance between conditions following the same pattern as for walking velocity (Table 4.17). The greater the rigidity of the AFO the worse the walking performance in regards to cadence and affected leg step length. Differences were also noted when double limb support was considered. Healthy participants spent more time in double limb stance when using a SLAFO (27.8%) in comparison to shoes (26.0%; Z=-3.040, p=0.002; Table 4.19). There were no significant differences between shoes and the other AFO's for percentage time in double limb stance. Regarding affected leg single support phase there were no differences between shoes and PAB (Z=-1.785, p=0.074), but there was a decrease in affected leg single support phase between shoes and SLAFO (Z=-2.204, p=0.028) and shoes and FGC (Z=-2.482, p=0.013).

In comparison to shoes, the affected leg swing phase was significantly longer in FGC (Z=3.111, p=0.002), PAB (Z=-2.622, p=0.009) and SLAFO (Z=-3.111, p=0.002) but not for any of the other comparisons. The most rigid fibreglass cast also caused single stance duration ratio to become more asymmetrical in comparison to shoes, PAB and SLAFO (Table 4.23). The difference was greatest between shoes (-0.975) and FGC (-7.57, Z=-3.180, p=0.001) and reduced as the rigidity of the comparison AFO increased. The ratio of the PAB (-2.10) was not significantly different to shoes (Z=-1.922, p0=.055) but was significantly different to fibreglass cast (Z=-3.110, p=0.002). Similarly there

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was no difference between shoes and SLAFO (-3.27; Z=-1.503, p=0.133) but there was a difference between SLAFO and FGC (Z=-2.760, p=0.006). There was no difference between the single stance symmetry ratio of PAB and SLAFO (Z=-0.524, p=0.600).

There were no differences in knee angle at initial contact (Table 4.24), midstance (Table 4.25) or terminal stance (Table 4.26) when comparing shoes to the orthotic conditions or the orthotic conditions to each other.

4.6 Smallest real differences of the stroke group

4.6.1 Stroke participants' smallest real differences

In order to examine the effects for AFO's on each individual participant, a SRD was calculated. The SRD was used to determine changes in performance for each parameter in comparison to each individuals shod walking. The values representing the SRD, as calculated by using each individuals shoe trial, and the reliability values are described in Table 4.27.

Variable	Smallest Real Difference Value	Baseline Reliability
Velocity	6.3 cm/sec	0.99
		p<0.000
DLS	7.8%	0.99
		p<0.000
Affected leg single	14.1%	0.97
support		p<0.000
Stance Symmetry Ratio	18.35	0.98
		p<0.000
Step Length	7.79cm	0.98
		p<0.000
Affected leg swing	40.3%	0.97
		p<0.000
Cadence	31.6 steps/min	0.99
		p<0.000
Knee angle – initial	19.3 degrees	0.943
contact		p<0.000
Knee angle - midstance	20.1 degrees	0.979
		p< 0.000
Knee angle – terminal	19.5 degrees	0.980
stance		p< 0.000

<u>Table 4.27:</u> Stroke participants' values indicating the smallest real difference at a 95% confidence level for each spatiotemporal parameter

4.6.2 Stroke participants' Individual Responses

Each participant's difference in velocity when comparing their shod (baseline) walking to barefoot, PAB, SLAFO and FGC are described in Figure 4.1 Individual descriptive results, in the form of box plots are displayed in Appendix F. Similarly, double limb support differences in performance are displayed in Figure 4.2; affected leg single support symmetry ratio differences in Figure 4.3, affected leg step length in Figure 4.4. As there were no individuals who exceeded by an amount greater than the SRD for cadence, affected leg single support phase or affected leg swing phase graphs for these results have also been displayed in the Appendices (Appendices H, L, and N). Individual descriptive results for all parameters can be found in Appendices G, I, J, K, M, O, P, Q, and R). Only changes greater than SRD are reported below.

4.6.2.1 Shod versus barefoot for individual participants

Five participants' velocity decreased when walking barefoot. This was participants 1, 3, 5, 7 and 13. Two of these participants' also had shorter step lengths when barefoot (Participant 3 and 5). Participant 3's knee angle at initial contact was more flexed than when walking with shoes, but more extended at terminal contact. Participant 4 was more extended at the knee in barefoot at midstance and terminal stance.

4.6.2.2 Shod versus PAB

Two participants' walking velocity improved using a PAB (participants 6, by 17.65 cm/secs, and 7), and one participant's velocity decreased using a PAB (participant 5). Regarding knee angles, participant 4 was more extended during midstance using the PAB.

4.6.2.3 Shod versus SLAFO

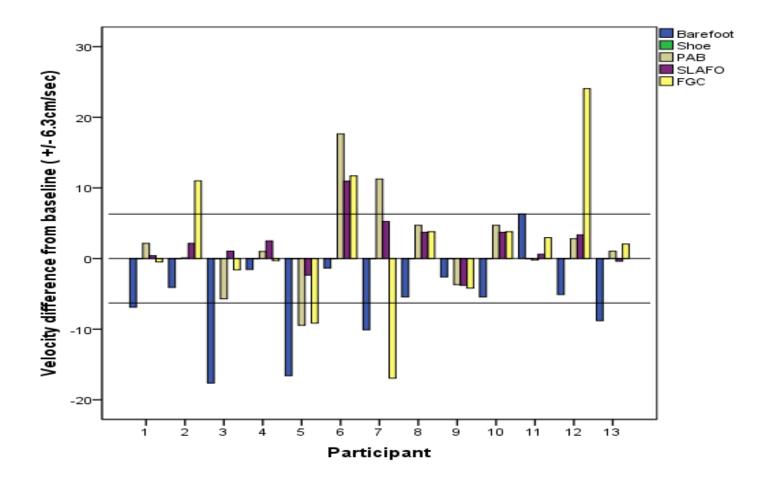
One participant's velocity improved using a SLAFO (participant 6), Participant 13's single stance time symmetry improved whilst participants 3, 8 and 10 demonstrated deteriorations in single stance time symmetry.

4.6.2.4 Shod versus FGC

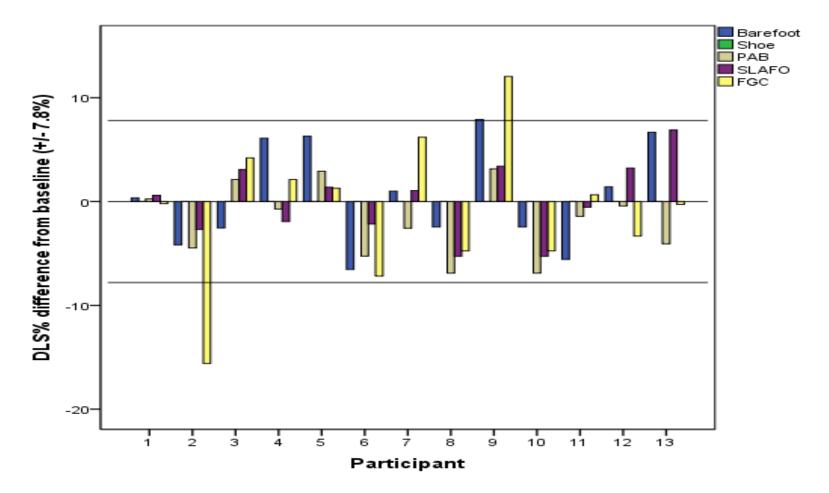
Three participants' walking velocity improved using a FGC (participants 2, 6 and 12, the latter by 24.05 cm/sec), with one participant (participant 7) walking 16.95 cm/sec slower in FGC than in shoes. For participant 2, DLS percentage improved by 15.6% and step length also improved. Double limb support percentage worsened by 12.1% for participant 9 and step length shortened for two participants (Participant 3 and 5). Participant 4's knee was more extended in FGC in comparison to shoes at midstance and terminal stance.

4.6.2.5 Differences between AFO conditions

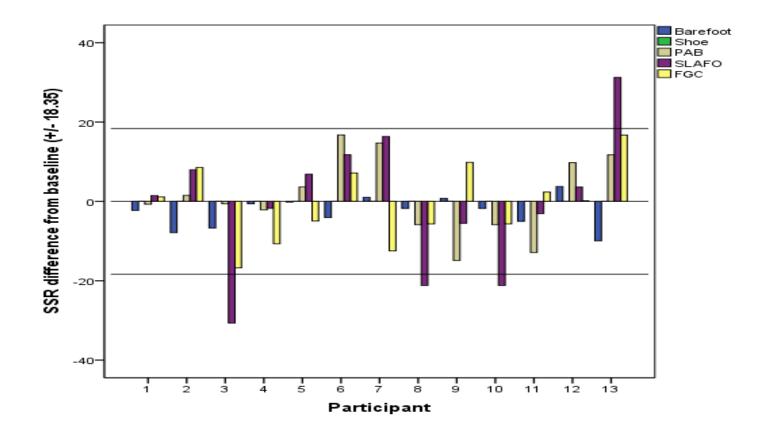
Five of the 13 participant's with stroke showed benefits for at least one condition of AFO greater than the SRD. Velocity improved in all AFO conditions for participant 6, and therefore the SRD was used to determine if one AFO was likely to be superior for the participant. When walking in the PAB participant 6's velocity was faster than the FGC by an amount greater than the SRD. Six participants showed deterioration in at least one gait parameter. Participant 7 demonstrated improved velocity with the PAB and reduced velocity with the FGC. Three participants (1, 4 & 11) did not show any differences. There were no differences of the knee angle between AFO conditions.



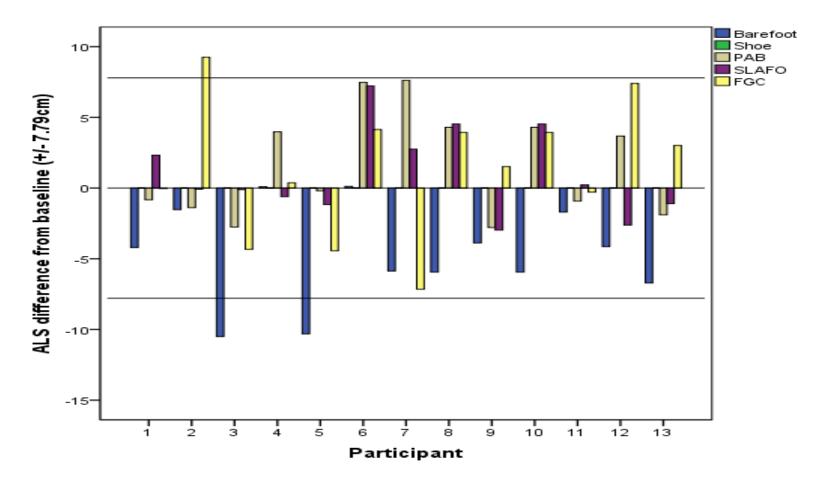
<u>Figure 4.1</u>: Stroke group bar graph demonstrating mean difference of velocity from baseline (shoe result) under each testing condition. Values above or below lines indicate changes a result greater or less than the SRD (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



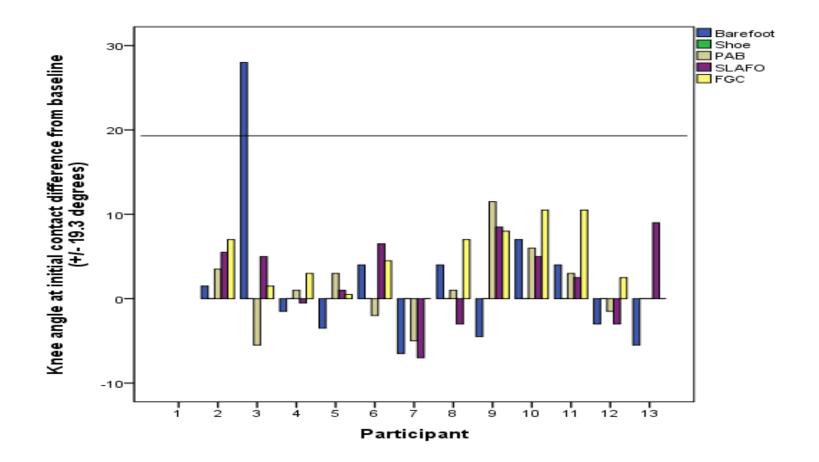
<u>Figure 4.2:</u> Stroke group bar graph demonstrating mean difference of double limb stance percentage from baseline (shoe result) under each testing condition. Values above or below lines indicate changes a result greater or less than the SRD (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



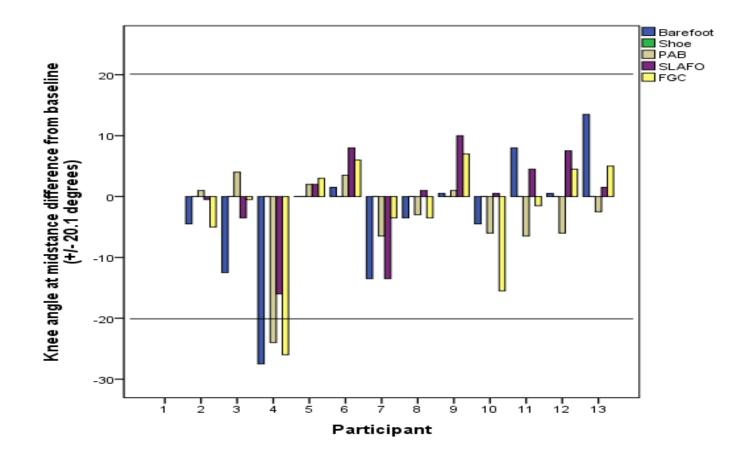
<u>Figure 4.3</u>: Stroke group bar graph demonstrating mean difference of stance symmetry ratio from baseline (shoe result) under each testing condition. Values above or below lines indicate changes a result greater or less than the SRD (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



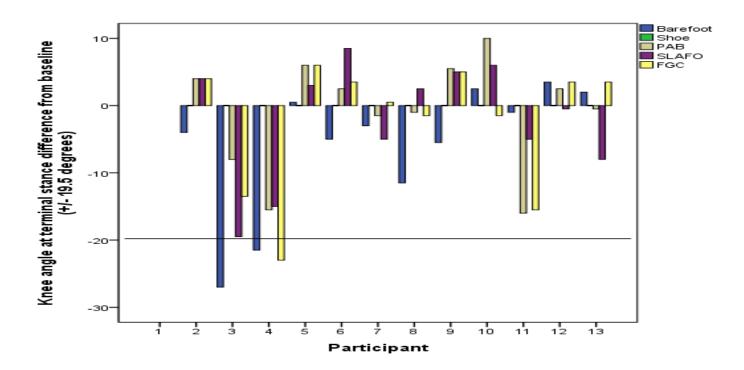
<u>Figure 4.4</u>: Stroke group bar graph demonstrating mean difference of affected leg step length from baseline (shoe result) under each testing condition. Values above or below lines indicate changes a result greater or less than the SRD (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



<u>Figure 4.5:</u> Stroke group bar graph demonstrating mean difference of knee angle at initial contact from baseline (shoe result) under each testing condition. Values above or below lines indicate changes a result greater or less than the SRD (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



<u>Figure 4.6</u>: Stroke group bar graph demonstrating mean difference of knee angle at midstance from baseline (shoe result) under each testing condition. Values above or below lines indicate changes a result greater or less than the SRD (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



<u>Figure 4.7:</u> Stroke group bar graph demonstrating mean difference of knee angle at terminal stance from baseline (shoe result) under each testing condition. Values above or below lines indicate changes a result greater or less than the SRD (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast).

4.6.3 Stroke participants' identification of responders and non responders

The characteristics of the stroke participants' ankle impairments are described in Table 4.28. It is notable that the ages of the responders tended to be younger than the non-responders. A description of the physical impairments of those participants who demonstrated a positive response and those who were non responders to an AFO are described in Table 4.8 Examination of this data does not yield any observable trends towards physical impairments common to responders versus non responders. Of those who had a positive response, there were no participants who had a dorsiflexion range limitation. In comparison, the three participants with a dorsiflexion range limitation all failed to respond to AFO. One of whom (participant 4) walked with a more extended knee at midstance and terminal stance in the PAB and FGC. Therefore no analysis of sub-groups was undertaken.

<u>Table 4.28:</u> Categorisation of ankle impairments of stroke participants of those who demonstrated a positive response to at least one AFO and those that did not (non responder)

	Impairment categorization	Responder (n=5)	Non-Responder (n=8)
Age	Mean	44.0	57.5
	(Standard Deviation)	(17.1)	(9.4)
	Range	23-65	51-71
Ankle ROM	<0 degrees	0	3
	>0 degrees	5	5
Dorsiflexion Oxford	0 or 1 Oxford Scale	2	4
Scale	2	3	4
Plantar Flexor	Present	3	4
Spasticity	Not Present	2	4
MMT Tibialis	Mean	3.1	3.2
Anterior	(Standard Deviation)	(3.5)	(2.3)
MMT Quadriceps	Mean	15.0	10.9
	(Standard Deviation)	(4.5)	(5.3)

4.6.4 Case Studies

In order to further examine the physical characteristics of the ankle of the stroke participants who demonstrated a positive response in their walking performance in an AFO, individual case studies are now presented. Stroke participants were chosen for individual case analysis if they improved in one or more spatio-temporal parameter for one specific AFO, or if they improved in one or more spatio-temporal parameter for multiple AFO's (Table 4.28). As a consequence, participants' two, six and thirteen are presented as case studies.

4.6.4.1 Stroke Participant Two

Participant Two was a 23 year old male who suffered a left parietal haemorrhage 68 days prior to day one of assessment for this study. He was 1.81 m in stature with a mass of 76.5 kg. Physical assessment of his ankle indicated a dorsi flexion range of movement of 15 degrees with the knee extended, and ten degrees with the knee flexed. He had no palpable or identifiable dorsiflexion muscle activity when assessed using the Oxford Scale, STREAM or manual muscle dynamometry. He was able to exert 13.3 kg of force with his quadriceps muscle on assessment with manual muscle dynamometry and scored 2/5 using the Oxford Scale. Plantar flexor muscle spasticity was identified, scoring 3 at V3, indicating fatigable clonus occurring at a precise angle.

Participant Two's walking velocity at baseline of 20.0 cm/sec (\pm 1.2) (Table 4.30) was similar to the minimally rigid push aequi brace (20.5 cm/sec \pm 1.5) and spring leaf AFO (23.3 cm/sec \pm 2.0), but walking in a fibreglass cast (32.0 cm/sec \pm 2.9) was 60% faster than shod. Walking in a fibreglass cast improved double limb support (decreased by 39%), affected leg single stance time (increased by 12%), and affected leg step length (increased by 35%) in comparison to shod walking. Whilst the other parameters did not change by an amount greater than the SRD value examination of the raw data indicated further trends suggesting

the fibreglass cast was of benefit to this individual. Cadence improved (increased by 20%) whilst the other parameters displayed marginal differences in performance between different AFO's.

4.6.4.2 Stroke Participant Six

Participant Six was a 42 year old female with left sided deficits. Her stature was 1.74 m and body mass was 94 kg. She was 34 days post event at the commencement of this study. Her dorsiflexion range of movement was ten degrees beyond plantigrade with her knee extended and 15 degrees beyond plantigrade with her knee flexed. There was markedly abnormal dorsi flexor movement as represent by her STREAM score, and evidenced by an Oxford Scale grading of 1/5 and manual muscle test value of 3.8 kg. There was no evidence of plantar spasticity and her quadriceps muscle strength was graded as 2/5 with a manual muscle test value of 16.8 kg.

Using the SRD, Participant Six's walking velocity increased in comparison to shod walking in all orthotic conditions (Table 4.31). The orthosis which resulted in the best walking velocity performance was the least rigid push aequi brace which improved by 16.1cm/sec in comparison to shod walking. The spring leaf AFO and fibreglass cast resulted in similar improvements to walking velocity. No other parameter improved due to walking in an AFO using either SRD or examination of the raw scores.

4.6.4.3 Stroke Participant 7

Stroke Participant Seven was a 33 year old male who had a right sided haemorrhage resulting in left sided deficits. He was 1.87 m tall with a body mass of 85.0 kg. His walking was assessed 37 days following his stroke. He had 15 to 20 degrees of dorsiflexion range of movement depending if his knee was flexed or extended. He scored 2/5 on the Oxford Scale for strength with moderately abnormal movement pattern as evidenced by his STREAM score. He was able to produce 8.4 kg of tibialis anterior strength on assessment by manual muscle dynamometry. He had mild plantar flexor spasticity. He scored 2/5 on the Oxford Scale for quadriceps strength and was able to produce 21.7 kg of quadriceps force on manual muscle dynamometry.

Participants Seven's responses to walking velocity performance, as assessed using SRD, unique. Using a PAB his velocity was faster than shod walking by 13.8 cm/sec. Yet in a FGC he was 20.3 cm/sec than shod walking. There is no indication from his ankle impairment characteristics above as to why this was the case. No other gait parameter improved by an amount greater than the SRD.

4.7 Smallest real differences of the healthy participant group

In order to examine the effects for AFO's on each individual participant SRD was calculated and compared to actual performance for each parameter examined. Each individuals shod walking was used as the baseline for the comparison. The values representing the SRD and the reliability values are described in Table 4.29

Variable	Smallest Real Difference Value	ICC (3,1)
Velocity (cm/sec)	10.17cm/sec	0.99
		p<0 .000
DLS	2.84%	0.96
		p<0.000
Matched leg single support	12.6%	0.92
		p<0.000
Stance Symmetry Ratio	6.65	0.79
		p<0.000
Step Length	4.13cm	0.99
		p<0.000
Cadence	25.1 steps/min	0.99
		p<0.000
Matched leg swing	12.2%	0.97
		P<0.000
Knee angle – initial contact	18.9 degrees	0.785
		p= 0.009
Knee angle – midstance	14.6 degrees	0.898
		p< 0.000
Knee angle – terminal	10.9 degrees	0.983
stance		p< 0.000

<u>Table 4.29</u>: Healthy participants' values indicating the smallest real difference at a 95% confidence level for each spatiotemporal parameter

4.7.1 Individual Responses

Each participants difference in velocity when comparing their shod (baseline) walking to BF, PAB, SLAFO and FGC is described in Figure 4.8 Individual descriptive results for velocity, in the form of box plots are displayed in Appendix S.. Similarly, double limb support differences in performance are displayed in Figure 4.9; matched leg single support phase differences in Figure 4.10; matched leg step length in Figure 4.11 and matched leg knee angle at midstance in Figure 4.12. As there were no individuals who exceeded by an amount greater than the SRD for cadence, matched leg single support phase, matched leg swing phase or knee angles at initial contact or terminal stance graphs for these results have not been displayed below but as a appendices' (Appendices U, Y, AA, AC, and AE). Individual descriptive graphical results for all parameters can be found in Appendices, T, V, W, X, Z, AB, AD, AF and AG)..

4.7.1.1 Shod vs Barefoot

Five healthy participants walking velocity deteriorated when walking barefoot (participants 1, 2, 10, 11 and 13). Further no participants walking velocity increased in barefoot. The duration of the gait cycle spent in double limb support also deteriorated when barefoot. Ten of the thirteen healthy participants' performance worsened (participants 1, 2, 3, 4, 5, 7, 9, 10, 11, 12). Similarly eight of participants' matched leg step length reduced in barefoot (participants 1, 2, 4, 7, 9, 11, 12, 13). Only one participant's knee angle altered from baseline in barefoot. Participant 6 was more flexed for this walking condition.

4.7.1.2 Shod vs PAB

Two participants walking velocity and affected leg step length reduced in the PAB (Participant 6 and 7). Whilst participant 6 increased in time spent in double limb support using the PAB. Participant 6 was more flexed in a PAB whilst participant 7 was more extended at the knee at terminal stance.

4.7.1.3 Shod vs SLAFO

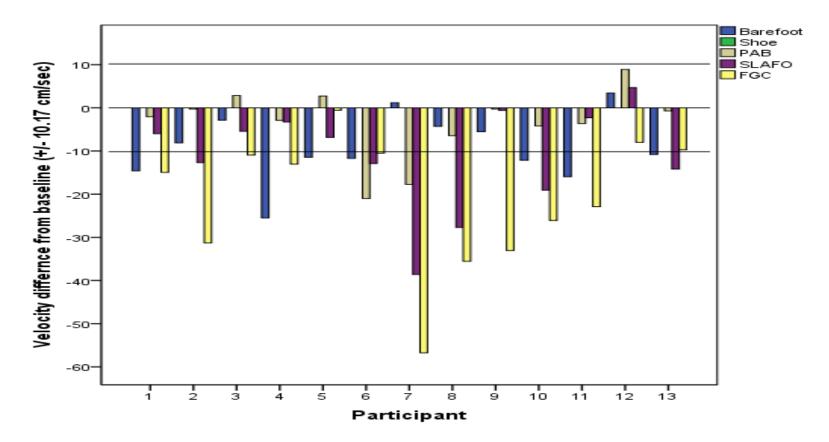
Six healthy participants' walking velocity deteriorated in the SLAFO (participants 2, 6, 7, 8, 10 and 13). Participants seven and eight both increased the time spent in double limb support and reduced their matched leg step length. Three participants' single support stance symmetry ratio worsened (participants 7, 8 and 13). Participant 7 was more extended in the SLAFO at terminal stance.

4.7.1.4 Shod vs FGC

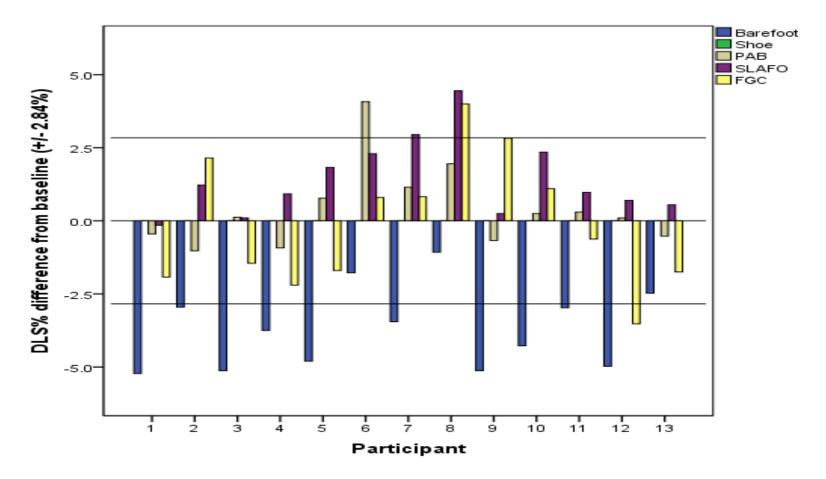
Ten of the thirteen healthy participants' walking velocity decreased in the FGC (participants 1, 2, 3, 4, 6, 7, 8, 9, 10 and 11) and also for matched leg step length (participants 1, 2, 4, 6, 7, 8, 9, 10, 11 and 13). Five participants single support stance symmetry ratio worsened (participants 3, 7, 8, 9, and 12). Two participants spent increased time in double limb support (participants' 8 and 9) whilst one spent less time (participants 12). Participant Seven was more extended during terminal stance in the FGC.

4.7.1.5 Differences between AFO conditions

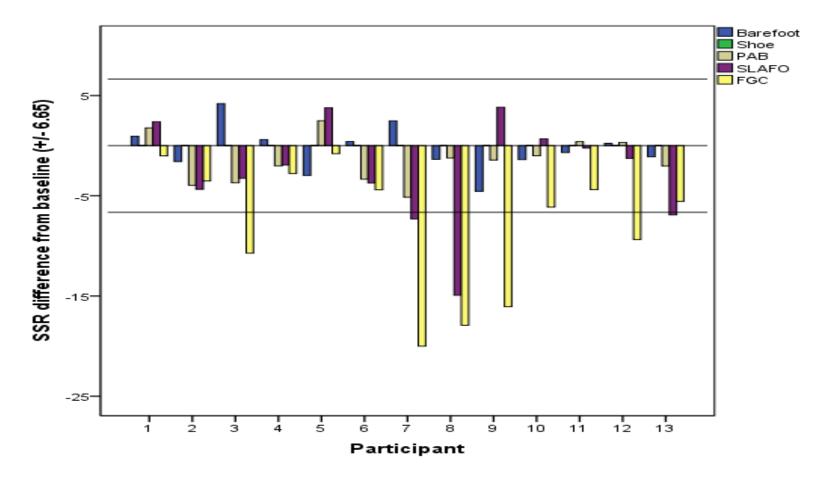
Two healthy participants' walking velocities decreased in two AFO's. Participants Two and Seven decreased in the SLAFO and the FGC. In both instances walking in the FGC was slower than the SLAFO by and amount greater than the SRD. Participant 7 also improved in the PAB but slower in the SLAFO by an amount greater than the SRD. Similarly, participant 7's matched leg step length was less in the FGC compared to the SLAFO by an amount greater than the SRD. This was also the case when SLAFO compared to PAB. Regarding single support stance symmetry ratio the FGC was less symmetrical than the SLAFO by an amount greater than the SRD. Participant 7 had differences greater than the SRD for each AFO condition but had not differences between AFO's.



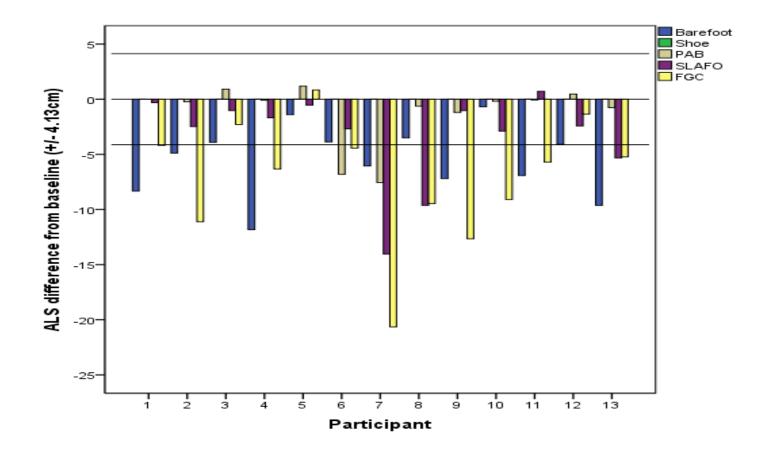
<u>Figure 4.8</u>: Healthy participant individual bar graph demonstrating difference of velocity from baseline (shoe result) under each testing condition. Values above or below lines indicate changes a result greater or less than the SRD (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



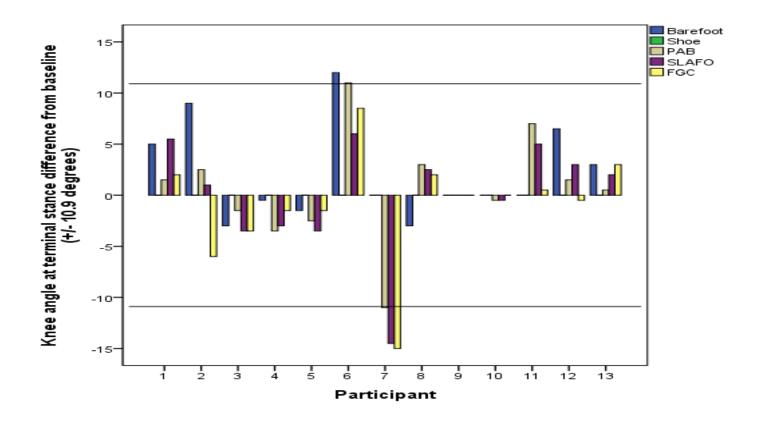
<u>Figure 4.9</u>: Healthy participant individual bar graph demonstrating difference of double limb support from baseline (shoe result) under each testing condition. Values above or below lines indicate changes a result greater or less than the SRD (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



<u>Figure 4.10</u>: Healthy participant individual bar graph demonstrating difference of stance symmetry ratio from baseline (shoe result) under each testing condition. Values above or below lines indicate changes a result greater or less than the SRD (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



<u>Figure 4.11</u>: Healthy participant individual bar graph demonstrating difference of matched leg step length from baseline (shoe result) under each testing condition. Values above or below lines indicate changes a result greater or less than the SRD (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



<u>Figure 4.12</u>: Healthy participant individual bar graph demonstrating difference of knee angle at terminal stance from baseline (shoe result) under each testing condition. Values above or below lines indicate changes a result greater or less than the SRD (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)

Chapter 5

DISCUSSION

5.0 Discussion

This chapter addresses the aims of the study as outlined earlier in the introduction chapter. Principally topics that will be covered are: (1) the effects of walking in AFO's in the early stages of walking recovery following stroke; (2) the effects walking in AFO's of varying rigidity in the early stages of walking recovery following stroke; (3) the effects of AFO's on the walking of healthy participants; the effects of walking in AFO's of varying rigidity in healthy participants; (4) and how the walking, with and without AFO's, of stroke and healthy participants compares.

5.1 The effects of AFO's on spatio temporal variables of gait following stroke

The results of this study indicate that the routine prescription of AFO's to individuals in the early stages of walking recovery following stroke with ankle impairments cannot be recommended. The application of the three AFO's examined (PAB, SLAFO or FGC) did not demonstrate significant improvements in the group analysis for the parameters of velocity, cadence, double limb support, affected leg single stance support phase, affected leg swing phase, affected leg step length or single support symmetry were considered. No changes in knee angle at initial contact, midstance or terminal stance when using AFO's were identified. However, individual analysis using SRD indicated that some individuals in the early stages of walking recovery following stroke may improve their walking performance when using an AFO, and that AFO's of differing rigidity can have different effects. Individual analysis also indicated that some stroke participants walking can deteriorate following AFO prescription. These results suggest that in certain cases an AFO may be of benefit, but not all, and that different AFO's may have different effects. This finding is supported by Mulroy et al. (2010) who found that the presence of ankle contracture can influence which AFO will be of most benefit.

There have been thirteen studies identified which have reported increased walking velocity when an AFO is prescribed (Table 5.1; (Abe et al., 2009; Churchill et al., 2003; Danielsson & Stibrant, 2004; de Wit et al., 2004; Franceschini et al., 2003; Gok et al., 2003; Hesse et al., 1996; Lehmann et al., 1987; Mojica et al., 1988; Pavlik, 2008; Tyson & Thornton, 2001; Wang et al., 2007; Wang et al., 2005). Four studies found an AFO made no difference to walking velocity (Burdett et al., 1988; Fatone & Hansen, 2007; Hesse et al., 2005).

Study	Comparison	Duration	Experience with AFO's	Ankle impairment	Baseline Velocity	Findings
This Study	Push Aequi Spring Leaf Fibreglass Cast Barefoot Shoes	51 (9-100) days post stroke	None	2/5 or less dorsiflexion Variable spasticity	Barefoot: 39.5cm/sec (22.9) Shoes: 47.1cm/sec (25.9)	Slower velocity in barefoot AFO: no change to velocity, cadence, double limb support, single stance, swing, stance symmetry or knee angles
Abe et al. (2009)	Articulated AFO or Fixed AFO Barefoot	2-114 months post stroke	Not defined	Able to obtain plantigrade	Barefoot: 18.1cm/sec (8.1)	AFO: Increased velocity 22.9cm/sec (6.8) Improved step length Improved cadence
Burdett et al. (1988)	Air Stirrup Brace Shoes	114.5 (108.5) days post stroke	11 of 19 participants previously used an AFO	Increased tone Reduced range Decreased strength	Shoes: 57.9cm/sec (19.1)	AFO: No change to velocity 62.9cm/sec (27.4) Increased step length

Table 5.1: Summary table of results for studies similar to this study

Churchill et al. (2003)	Own previously prescribed AFO – not defined Barefoot Shoes	Not defined	Not defined	Not defined	Barefoot: 31.0cm/sec (2.0) Shoes: 32.0cm/sec (2.0)	AFO: Increased velocity 35.0cm/sec (2.0) No change to cadence
Danielsson and Stibrant (2004)	Carbon composite (non- articulated) Shoes	At least 6 months post stroke	At least 4 months	Increased tone (not defined)	Shoes (Treadmill): 27.0cm/sec (3.0)	AFO: Increased velocity – 34.0cm/sec (6.0)
De Wit et al. (2004)	Plastic non- articulated AFO – 1 of 3 different types Shoes	At least 6 months post stroke	At least 6 months	Not defined	Shoes: 44.9cm/sec (24.0)	AFO: Increased velocity – 49.6cm/sec (24.3)
Fatone and Hansen (2007)	Custom made articulated AFO Shoes	8.2 (4.5) years post stroke	2 weeks	At least - 5degrees dorsiflexion Strength not defined	Shoes: 57.0cm/sec	AFO: No change to velocity (63.0cm/sec) or step length

Fatone et al. (2009)	Conventional AFO Articulated AFO ³ / ₄ length AFO Shoe	At least 2 years post stroke Previously used an AFO	2 weeks	Not defined	Not provided	Report no change
Franceschini et al. (2003)	Own AFO previously prescribed (not defined) Not defined (??shoes)	39 months post stroke (2- 244)	Not defined	Hypertonic equinus	Baseline: 25.8cm/sec (11.6)	AFO: Improved velocity – 35.7cm/sec (12.2)
Gok et al. (2003)	Non articulated plastic Non articulated metallic Not defined (??shoes)	67 days post stroke (30- 270)	Not defined	No ankle deformity No ankle control	Baseline: 32.0cm/sec (20.6)	Metallic AFO increased velocity in comparison to plastic and baseline Metallic and plastic AFO increased step length in comparison to baseline No change to cadence

Hesse et al. (1996)	Articulated AFO Barefoot	5.1 months post stroke (1.5-16)	Less than 1 week	At least 3/5 Ashworth Scale	Barefoot: 33cm/sec (17)	AFO: Improved velocity – 55cm/sec (27)
	Shoe			No contracture	Shoes: 43cm/sec (21)	Improved cadence
Hesse et al. (1999)	Articulated AFO Barefoot	4.9 months post stroke (1.5-16)	Less than 1 week	At least 3/5 Ashworth Scale	Barefoot: 32.0cm/sec (17.0)	AFO: No change to velocity – 33.0cm/sec (15.0); or cadence
				No contracture		Improved Double limb support and swing phase %
Lehmann et al. (1987)	Fixed AFO's @ 5 degrees dorsiflexion and plantar flexion	3-13 years post stroke	"Everyday ambulation"	Normal passive ROM Unable to	Shoes: 46.3cm/sec	AFO in 5 degrees dorsiflexion increased velocity – 49.3 cm/sec
	Shoes			normally dorsiflex		

Mojica et al. (1988)	Custom made non articulated AFO Not defined (??barefoot)	20.7 weeks post stroke (7- 32)	7.5 weeks (2 days – 18 weeks)	Not defined	Baseline: 54.7cm/sec (41.6)	AFO: Increased velocity – 69.3cm/sec (50.9) Increased cadence
Pavlik (2008)	Either articulated or non articulated Shoes	75 months post stroke (10-120) AFO use of at least 6 months	"Daily"	Not defined	Shoes: 33.9cm/sec (27.9)	AFO: Increased velocity – 55.4cm/sec (40.0) Increased step length
Pohl and Mehrholz (2006)	Custom made soft cast temporary AFO Not defined (Shoes)	2.6 months post stroke (1- 6)	Less than 1 week	No ankle contracture No increased tone	Velocity not described	AFO: Increased double limb support percentage 21.1% baseline to 25.9% AFO
Tyson and Thornton (2001)	Hinged AFO (1 month habituation) Shoes	8.3(5.5) months post stroke	One month	Able to obtain plantigrade	Shoes: 18.0cm/sec (10.0)	AFO: Increased velocity – 25.0cm/sec (10.0) Improved cadence No change to step length

Wang et al. (2005)	Polypropylene Non-articulated Shoes	Short: <6 month duration	Not defined	No control for ankle impairment	Short: 58cm/sec (29)	AFO Short: Increased velocity 69.0cm/sec (41)
		Long:>6 month			Long: 61cm/sec	Improved cadence
		duration			(31.2)	Long: No change to velocity or cadence
Wang et al. (2007)	Polypropylene Non-articulated	3.29 (1.2) months post stroke	None	Poorly defined	Shoes: 62.8cm/sec (26.7)	AFO: Increased velocity – 66.9cm/sec (29.5)
	Unclear (?Shoes)	(1-6 months)		26.7 pounds dorsiflexion force		Improved step length No effect on cadence

AFO's considered by previous studies outline in Table 5.1 were different to those examined in this study, which may account for the differences to the results described earlier. Additionally, only one of the studies recruited participants with an acuity of stroke similar to this study (Gok et al., (2003). In Gok et al. (2003) participants were 67 days (30-270) post stroke in comparison to 51 (9-100) days of this study. They found a metallic AFO improved velocity in comparison to baseline, which was not defined as shoes or barefoot. This may account for the difference in findings, in that this study did find differences between shoes and barefoot, but not shoes and AFO's. Conceivably, Gok et al. (2003) may have compared the differences between barefoot and AFO's.

Seven studies reported a similar baseline velocity to this study, six of which demonstrated improvement with AFO use. None of the seven considered similar AFO's to those in this study, and six of the seven considered participants who were in the chronic phase of recovery in contrast to this study. The definition of ankle impairments was either not considered or not uniform. As such, comparison of results is difficult to interpret.

Of the eighteen previous studies, only one compared an AFO with walking whilst barefoot or wearing shoes. Hesse et al., (1996), found walking in shoes faster than barefoot, and walking in an AFO faster than shoes. However, they considered an articulated AFO which was markedly different to those of this study.

As outlined in Table 5.1 six studies reported on cadence and affected leg step length: five described a longer step length and four reported improvements in cadence. The results of double limb support were mixed, one study finding an improvement and the other deterioration in this parameter. Additionally, only one study found an improvement in the swing phase. Similarly to velocity the differences in participant acuity, type of AFO examined, ankle impairment and baseline walking performances do not allow comparison to this study. Further discussion of the issues limiting the ability to compare studies will be found in later sections of this chapter.

In this study each participant had deficits of foot and ankle function that could potentially be compensated for by wearing of an AFO. However, many participants did not show a benefit in the spatio temporal variables of gait. There are a number of reasons that may have contributed to this. AFO's are hypothesised to increased foot and ankle stability (Wang, et al., 2007). However, the negative effects of AFO's on gait shown in the healthy participants in this study may over ride this benefit. In the current study, the participants had limited time to familiarise with the AFO's, further experience with the AFO's may have shown greater changes. The results of this study are in accordance with the National Guidelines for stroke (National Stroke Foundation, 2005), in that routine prescription of AFO's following stroke is not supported.

The review of the literature has indicated that AFO's can be of benefit to stroke patients and the use of AFO's is common (Leung & Moseley, 2003). An assumption can be made that clinicians, such as physiotherapists, orthotists and

rehabilitation physicians, believe AFO's to be useful, and that some patients share the same feelings as they continue to wear their AFO's (de Wit et al., 2004; Tyson & Thornton, 2001). It is also possible that AFO's may have benefits that were not assessed in this study; such as improving a patient's perception of their safety whilst walking, despite no identifiable change to their walking performance. Similarly, a physiotherapist may perceive a patient to walk more safely with an AFO, but on formative analysis or testing no discernible benefit was identified. It is clear, however, that the prescription of AFO's should include a thorough physical assessment and include assessment of gait parameters such as velocity, cadence, step length, stance and swing phases to ensure appropriate prescription to each individual patient (Condie, 2003; Tyson & Kent, 2009).

5.2 The effect of AFO's on healthy participants

The careful consideration of prescription of AFO's in the early stages of walking recovery following stroke was further supported by the effect that AFO's have on healthy participants. When walking in an AFO the gait performance of healthy participants deteriorates. The findings of this study indicate that the more rigid the AFO, the greater the reduction in walking velocity, cadence, matched leg step length, and deterioration in matched leg swing time and the symmetry of single support stance.

The methodology of other investigations into the effect of AFO's on the gait of healthy participants does not allow for easy comparison. Differences in the type of AFO examined and the age of the participants may account for differences in results. Kitaoka et al., (2006) did not examine velocity but found differences in cadence comparing shod walking to various AFO's and differences in cadence when comparing AFO's of differing construction. In this instance the least rigid AFO the PAB resulted in a cadence and velocity not differing significantly to shod walking and better than more restrictive AFO's. Guillebastre, Calmels and Rougier (2009) demonstrated differences in velocity of AFO's of varying construction, but not between AFO's and barefoot walking; less rigid AFO being faster than the more rigid AFO.

The deterioration in walking of the healthy participants and the lack of improvement in walking of the stroke participants indicates that the effects of AFO prescription on gait may result in a negative outcome.

5.3 The effects of AFO's of varying rigidity

The distinction in performance between AFO's of varying rigidity is important. More rigid AFO's, such as GRAFO's (as represented by fibreglass casting) restrict the foot and ankle complex action resulting in reduced performance, as demonstrated by the deterioration in gait parameters seen in healthy participants in this study. This needs to be considered when prescribing AFO's in pathologic situations. Clinicians should have an understanding of how the brace being prescribed affects normal gait in order to ensure that their

prescription compensates in the desired manner. Differences in construction material and the inclusion of ankle articulations will alter the biomechanical effects of the AFO (Lehmann et al., 1987), namely less restrictive bracing will have different effects than more rigid AFO's. No study has compared AFO's of different modes of ankle control or rigidity (Table 5.1), and so comparison to this study is limited. The lack of a significant main effect in the stroke participants of this study, and the variability in response of participants, indicates that there can be no general recommendation from this study for prescribing AFO's following stroke. The effect of reducing walking performance with increasing rigidity in healthy participants and the individual case differences suggests further examination is warranted. This is further supported by Burdett et al. (1988) who found a minimally restrictive AFO sufficient to improve step length but not velocity in chronic stroke participants. Considering the results of the healthy participants, clinicians may consider prescribing the least rigid form of bracing that achieves improvement in gait parameters. However, more research in this area is needed before drawing a definitive conclusion in this regard.

5.4 Other considerations Knee analysis

5.4.1 Reliability of the kinematic data

The reliability sub-study has indicated that in regards to the assessment of knee angle at initial contact, midstance has good interrater reliability and very good intrarater reliability. This result is similar to that of Cronin et al. (2006) who established similar reliability of knee angle in ten healthy males. Regarding terminal stance the interrater reliability could only be considered fair. However the clinical implication of lower reliability at terminal stance where the leg takes less body weight may reduce the clinical risk associated.

5.4.2 Knee analysis of the stroke group

A group analysis of the knee angle at initial contact, mid stance and terminal stance indicated that there was no difference under each AFO testing condition. With regard to differences between AFOs, a significant increase in knee flexion was seen at initial contact in the FGC condition compared to shod.

The following section examines the effect of AFO use on knee angle at three points throughout the stance phase. It is divided into three points: initial contact, mid stance and terminal stance. Two studies have included the effect of AFO's on knee angle (Fatone et al., 2009; Lehmann et al., 1987). Fatone et al. (2009) divided their participants into those who did or did not hyperextend and found that the design and construction of the AFO can influence the position of the knee through the stance phase. More specifically, for those that hyperextended, a more rigid design can assist in preventing that hyperextension. Lehmann et al. (1987) also found that the angle the AFO was set at effects the angle of the knee through the stance phase, further emphasising the influence an AFO can have on knee angle. When the knee angles were considered, two individual stroke participants performance changed using an AFO. One participant improved using PAB and FGC. However, the small number of participants whose knee angles changed means that trends or conclusions cannot be drawn from these results. Three of stroke participants who did not respond to an AFO were not able to achieve plantigrade due to either increased tone or reduced muscle length. These individuals may not have responded to an AFO as the limitation to their ankle range of movement would suggest the aim of achieving plantigrade in an AFO was not possible.

The lack of definitive knee angle analysis from the use of motion capture technology (e.g. VICON), makes it difficult to interpret these results with confidence. However, the angle of the knee through the stance phase is of importance as it is believed that the knee can potentially be put at risk of structural damage if repeated hyperextension occurs. This must be considered if an AFO is being prescribed. Indeed the kinematics of the ankle, knee and hip through stance and swing phases when using an AFO is of interest and is yet to be focused on in any great detail.

5.4.3 Knee analysis of the healthy group

Similar to the stroke group, the angle of the knee at three points of the gait cycle were examined; initial contact, mid stance and terminal stance. No differences were detected at each of these points when comparing the five testing conditions. Individual analysis found that one participants' knee angle changed at terminal stance in each of the three AFO's. Having such a small number of responders does not allow any conclusions to be drawn. Considering that AFO's can be designed to deliberately alter the position of the knee through the stance phase (Lehmann, Warren, & DeLateur, 1970) the lack of a clear effect on the knee angle of healthy participants indicates that; healthy participants can modulate their walking in some way to compensate for the altered kinematics of the ankle, or the effects of the AFO are reduced secondary to an intact neuromuscular system.

5.5 Potential indicators of responders to AFO's

The characteristics of individuals who are likely to benefit from AFO's were unable to be determined from this study as there was no clear pattern regarding ROM, strength or spasticity that indicated that an AFO may be of benefit. It was noted that those with a dorsiflexion range less than plantigrade did not benefit from an AFO. The area of ankle impairment characteristics as a potential indicator for AFO prescription is one that needs to be considered in further studies. There was an indication of the responders being younger than the nonresponders, as indicated by Table 4.26. However the disparate and small sample sizes did not allow for relevant statistical analyses.

5.6 Issues regarding variability in study design in the AFO literature

As demonstrated in Table 5.1 there is wide variation in the studies to date, making comparison of outcomes difficult. Study design is a factor that may influence these outcomes. The issues regarding the study design are considered in this section.

5.6.1 Inclusion/ Exclusion criteria

As has already been identified, the lack of similarity participant characteristics in studies similar to this may have resulted in different outcomes. Whilst not allowing easy comparison the differences in these characteristics may suggest they are of importance when considering AFO prescription. These

influences can be considered as: walking ability, ankle impairments, previous use of an AFO and duration since stroke.

5.6.1.1 Walking ability

Each of the stroke group participants' was able to walk either with supervision or independently to be eligible for this study. Six participants walked for one or more condition with a velocity less than 0.4 m/sec which is indicative of being a household ambulator only (Perry et al., 1995) and only two participants were able to walk faster than 0.8 m/sec, indicating the ability to walk in the community (Perry et al., 1995). For eleven of the thirteen participants their walking velocity was limited to such a degree that could limit their abilities to engage in community activity. Of the studies identified in Table 5.1 the baseline velocities had a wide range of response (18cm/sec – 61 cm/sec) indicating that there is little homogeneity in participant groups studied and that little comparisons can be drawn.

To be eligible for this study an ankle impairment that may lend itself to the prescription was present. As each participant was able to walk without an AFO, their ankle impairments may have not been the primary factor limiting their ability to walk. They may have already learnt to compensate for their impairment thereby reducing its functional influence. These factors may explain the limited positive effects of AFO's demonstrated in this study.

5.6.1.2 Ankle Impairment

There is little conformity between each study identified in Table 5.1 as to the nature or degree of ankle impairment of the participants. Only four studies identify or quantify muscle strength. Eleven studies indicated the presence of spasticity or ankle range of movement. Eight studies did not include any information about ankle impairments. Due to limitations in reporting ankle impairment characteristics it is difficult to determine similarities or differences between participants assessed. Further studies should consider better defining ankle characteristics in order to allow better definitions of those individuals with stroke who may benefit from an AFO.

5.6.1.3 Previous AFO use

Eight studies identified in Table 5.1 required use of an AFO for at least one month prior. This suggests that because an AFO had been previously prescribed it had already been determined that an AFO was of benefit and that the individual had ample opportunity to practice with their AFO. There was also the potential that the AFO had been prescribed to assist the individual to regain the ability to walk. Then, following achieving the ability to walk with an AFO, the individual learnt the ability to walk without and AFO. Under those circumstances the assumption is that walking with an AFO is the preferred option. In those cases, the results cannot be generalised to patients with stroke who have not used an AFO previously and, therefore, it is likely that the effectiveness of AFO's may be overstated.

Two previous studies included patients who had not been prescribed an AFO (Gok et al., 2003; Wang et al., 2007). In both instances, significant differences were found for velocity, but not cadence. Wang et al. (2007) also found differences for step length, stride length and stance width. In each of these instances clinical relevance of the demonstrated difference was questionable, such as improvement in walking velocity of 4.45cm/sec in an AFO compared to without. The participants' characteristics or protocol of each study were such that comparison would not yield relevant discussion regarding this study. Wang et al. (2007) included participants who did not have ankle impairment as demonstrated by mean tibialis anterior strength of the stroke patients of 22 pounds of force. Gok et al. (2003) examined different AFO's to this study, primarily comparing metallic and plastic AFO's. Whilst Gok et al. (2003) compared AFO's of varying rigidity the differences may not have been as marked, such as is the case in this study.

5.6.1.4 Duration of stroke

The studies describing AFO use in stroke (Table 5.1) describe participants at varied points of their recovery. Ten studies were of patients only in the chronic phase and six included patients in the subacute and chronic. The subacute phase and chronic phase post stroke are different stages in rehabilitation and it is likely that these phases should be investigated separately (Kreisel et al., 2007).

This study aimed to assess those participants in the early stages of walking recovery following stroke, once they had attained the ability to walk and in the presence of ankle impairment. Ten of the eighteen studies reported in Table 5.1 assessed participants who were at least six months post stroke, many of who had used an AFO for many months prior to assessment (as discussed above). The individuals in the chronic phase of their recovery or whose functional performance has stabilised will respond differently to those who are in the early stages of walking recovery for whom improvements in performance are still expected. Those who are in the acute phase of recovery may improve in their function due to practice, rehabilitation or natural recovery in addition to any adaptive device prescribed. Additionally, the findings of this study, in that an AFO may not be of benefit and that the healthy participants walking performance deteriorates raises the question of the use of AFO's during the acute and subacute phases of stroke recovery. In that the prescription of an AFO may be detrimental due to inhibiting movement (Boake et al., 2007; Levy et al., 2007) when the brains ability to recover due to neuroplasticity is at its greatest (Nudo, 2007; Ward, 2004). However, and AFO may provide benefit as an AFO may improve mobility in circumstances more difficult than walking indoors on a level surface, such as indicated in improved stair climbing in the study of De Wit et al. (2004), so AFO use should not be discounted.

5.7 Limitations of the Study

This study did not control for neglect or perceptual changes affecting balance, other than participants being able to walk without hands-on assistance. The presence of a neglect or perceptual change may influence an individual's gait performance. As perception or neglect was not measured the influence of those factors cannot be accurately assessed. Therefore any influence, positive or negative, that an AFO has on these impairments cannot be commented on. This raises the possibility that other factors that influence gait performance were not measured or controlled for which may have also influence the results of this study.

A number of methodological limitations influenced the results of this study. Some of these have been commented on earlier in this chapter. The main limitation of the study is the characteristics of the stroke group. Survivors of stroke can display a wide range of characteristics. Any conclusions made using the results of this study as support should only be applied to those with similar characteristics. Perhaps the weakest element of this is the exclusion of those who could only walk with assistance of a therapist as these individuals may benefit most from being prescribed an AFO. Tyson and Thornton (2001) endeavoured to include these participants but by doing so their results for gait velocity may have been influenced by the effect of the person assisting the participant and not the intrinsic gait performance of the participant.

To spend a total of fifteen minutes acclimatizing to a new orthosis for individuals who had only recently begun to walk following stroke may have also affected the results. Further experience and practice with the AFO's may have had stronger effects on the gait variables. However, allowing more experience with each AFO would have required extending the assessments over a number of days to limit fatigue. Results may then have been affected by recovery, as the participants were engaged in a comprehensive rehabilitation programme in the subacute stage of stroke where recovery is considerable.

Further limiting the study is the small sample size of each group and the lack of a power calculation to establish the appropriate sample size. The sample sizes weakened the statistical analysis and limited the ability to make conclusions regarding a wider group of patients. A larger sample size may have allowed for parametric statistical analysis to be performed.

The measurement tools used also limited the depth to which any results could be explained however provided measures that may be more commonly available in specialist rehabilitation centres that commonly treat stroke patients. Spatio-temporal parameters of walking can be significantly supplemented and explained by kinematic analysis, ground reaction force results and electromyographic (EMG) data. Such data would help to explain why the results occurred, and not just a description of what results occurred. Particularly, the results of the angle of the knee through the stance phase should be regarded with caution. The Silicon Coach software was not available during data collection, thus markers were not attached to the greater trochanter, knee joint line or lateral

malleolus (in keeping with SiliconCoach protocol), however use of markers may have facilitated better identification of the knee angle. The decision to use Silicon Coach was made because only one of the studies reviewed in Table 5.1 (Fatone et al, 2009) considered the knee angle in a group of stroke participants. In an ideal methodology, laboratory based measures would be included. Measurement tools which record the parameters identified above were not co-located with the participants. This limitation is mitigated to a certain extent by the good inter-rater reliability regarding initial contact and midstance but not in regards to terminal stance. This study was limited in it assessed the effect of AFO's on spatiotemporal parameters such as velocity and step length and knee angle. An AFO may also improve the energy cost of walking, perception of safety and reduce falls.

Further limiting this study was that participants from a single rehabilitation unit were recruited. The philosophy and work practices of that unit may have influenced when a participant was eligible for recruitment. Particularly that the patients' therapist may limit a patients walking until they have adequate lower limb control or balance to not be at risk of musculoskeletal injury such as via knee hyperextension. The study did not include walking on uneven or outdoors environments when an AFO may have brought about greater advantage. The varied use of gait aids by the stroke participants may have also influenced the results.

The inclusion of a follow-up component to the analysis would have strengthened the study. To re-assess the stroke participant three or six months

following their initial assessment would have indicated how people with stroke recover and the number of who continued to use an AFO. Differences in performance of those that continued to use an AFO to their baseline data could also be enlightening.

It is hoped, that as a preliminary study, the limitations identified in this study can utilised to develop better controlled studies and the methods improved to allow a greater understanding of the effects of AFO's on the gait of stroke survivors and of healthy participants. These can be summarised succinctly. Greater sample sizes are required, preferably via a multicentre trial as suggested by Condie (2003). A methodology that identifies spatiotemporal parameters of stroke survivors who require assistance to walk with reliability and validity would allow analysis of individuals for who an AFO may provide most benefit. Analysis of impairments at the trunk, pelvis, hip, knee and ankle as well gait performance should be considered in order to potentially develop a tool which better identifies those individuals best suited to AFO prescription. Particular attention could be made to those who are prescribed AFO's, assessing how their gait progresses and how, or if, their orthotic requirements change.

In regards to the healthy participants similar methods should be applied. The most important advancement of the effect of AFO's on healthy gait would be to assess spatiotemporal, kinematic, ground reaction force and EMG data in a broad cross section of the community.

5.8 Implications for further research

As has been demonstrated the benefit of AFO's following stroke is varied. There is the potential for improvements to walking following AFO prescription, but equally there is the potential of no benefit. Further research is required to attempt to better identify who will benefit most and to which type of AFO will be most appropriate. Multicentre trials should be considered to control for local clinical practices and multiple AFO's should be compared to determine their effects in stroke participants of differing abilities. These trials should include AFO's of different design and construction materials to ensure broad variety of AFO type is considered, including articulated AFO's. The ankle impairments of participants should be thoroughly assessed and reported to allow better comparison between studies and deeper understanding of the effect that ankle characteristics have on AFO response.

The reliability of Silicon Coach software in the assessment of kinematics in stroke also requires further attention including a larger number of participants and any influence of marking key anatomical points may have. Electromyographic assessment may be used to examine muscle activity when walking in an AFO.

Broader aspects of the benefits of AFO prescription should also be considered, including energy cost, patients perceived benefits, the effects on

AFO's of reducing falls and the potential of AFO's to improve walking on uneven ground or outdoors may be of interest.

It is hoped that the suggestions made above will allow greater understanding of the effect of AFO's on stroke participants and more accurate prescription.

5.9 Conclusion

This study examined the effect of five different walking conditions (barefoot, shoes and three different AFO's) on various spatiotemporal parameters of gait on thirteen people following a stroke who had recently begun to walk without assistance had specific impairment of ankle function. Thirteen healthy individual were also assessed in the same manner. The group of stroke participants and the group of healthy participants were examined in isolation of the other and comparatively. An analysis of individuals was also applied.

The analysis of the data of the stroke group demonstrated that overall, AFO's did not improve gait performance in relation to the parameters measured. Thus the initial hypotheses were not supported. Individual analyses demonstrated differential responses to AFO's, both in terms of whether there was a benefit, and the type of AFO providing the benefit. This study demonstrated that some individuals who respond to AFO use with improvements in gait parameters greater than the SRD. This was counterbalanced by individuals whose performance deteriorated when using an AFO by an amount greater than

the SRD. This indicates that AFO's may be of benefit but also have the potential to negatively affect walking. The design of the study was such that the hypotheses could not be well tested due to the small sample size. Attempts to clarify physical characteristics of ankle impairments which may indicate that the prescription of an AFO is warranted were not able to establish any clinical markers for AFO prescription.

Larger sample sizes may allow these questions to be elucidated. The analysis of the data of the healthy individuals was more conclusive. The findings were that the more rigid the AFO, as demonstrated by the results for FGC, brought about deterioration to the gait parameters.

In summary, this study adds further evidence to the literature regarding the effect of AFO's on the gait of people with stroke in the early stages of their walking recovery; and the effect of AFO's on the gait of healthy individuals. Despite no clear trend regarding the effect of differing AFO's there is an indication that AFO's can be of benefit to the gait of some stroke survivors. However, clinicians should be aware of potential negative effects of AFO use and ensure individualised prescription of an AFO and careful, ongoing, assessment of the effects of the AFO. Further research into the immediate and long term effects of AFO's on walking of stroke survivors and to the effects of AFO use on the gait of healthy individuals is warranted. Research into identifying which individuals would benefit most from an AFO following stroke is required. It is necessary to consider this research in order to best optimise recovery from stroke to allow maximal possible participation and best possible quality of life of stroke survivors.

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APPENDICES

Appendix A – Ethics approval from St. Vincent's Health

Research and Grants Unit Ph: (03) 9288 3930 Fax: (03) 9288 3949

Friday, 23 May 2008

Mr R Mehan St Georges Health SVH

, o box 2900 Fitzroy Victoria 3065 Australia Telephone 03 9288 2211 <u>www.svhm.org.au</u>

FILE COPY

PO Box 2900

Dear Mr Mehan St. Vincent's Hospital (Melbourne) Limited Protocol No: HREC-A 028/08 Incorporating: Caritas Christi Hospice St. George's Health Service Prague House 'A preliminary study into the effectiveness of various foot orthoses on gait parameters in early stroke patients with varying ankle impairments. Dr V Rice Dr K Brock ABN 22 052 110 755 Mr R Mehan **Dr E Bradshaw**

The Professional Secretariat of Human Research Ethics Committee-A (HREC-A) has agreed that your latest correspondence dated Monday 12 May 2008, has satisfied the conditions imposed and granted full approval for this project to be undertaken at the following site/s:

St Vincent's Hospital (Melbourne)

HREC-A is constituted and operates in accordance with the NHMRC National Statement on Ethical Conduct in Research Involving Humans 1999 (including supplementary note 7 dated November 1992).

HREC-A has a policy of granting approval for four years. Ethical approval is valid for four years from the date of this letter. Approval may be renewed at the end of this period by resubmission to HREC-A.

Approval is subject to:

- 1. immediate notification to HREC-A and sponsor of any serious adverse effects on participants;
- immediate notification of any unforeseen events that may affect the continuing ethical 2. acceptability of the project;
- notification and reasons for ceasing the project prior to its expected date of completion; 3.
- 4. the completion of an annual report on progress of the project;
- 5. HREC-A approval of any proposed modification to the project; and
- 6. the submission of a final report and papers published on completion of project



HREC Approval includes the following:

Approval to Examine Medical Records for Research Purposes. (Please Note the change in procedure in relation to Approval to Examine Medical Records for Research Purposes in the attached information Update.)

Please contact the department/s providing support listed below in time to allow them to prepare for the start of the trial:

Health Information Services

This approval is for the following participant information and consent form(s):

- Participant Information and Consent Form version 2 dated 14 April 2008
- Participant Information and Consent Form (Next of Kin or Carer) version 2 dated 11 April 2008

The following documents are enclosed:

- One signed copy of page 1 of the application form

Yours sincerely

Jan Can la

Ms Jane Carolan

Secretary, Human Research Ethics Committee-A

Appendix B – Reciprocal ethics approval from Australian Catholic University

Australian Catholic University Brisbane Sydney Canberra Ballarat Melbourne

ACU National

Human Research Ethics Committee

Committee Approval Form

Principal Investigator/Supervisor: Dr Liz Bradshaw Melbourne Campus

Co-Investigators: Dr Vanessa Rice, Dr Kim Brock Melbourne Campus

Student Researcher: Robert Mehan Melbourne Campus

Ethics approval has been granted for the following project: A preliminary study into the effectiveness of various foot orthoses on gait parameters in early stroke patients with varying ankle impairments.

for the period: 19.09.2008 to 01.04.2011

Human Research Ethics Committee (HREC) Register Number: V200708 112

The following <u>standard</u> conditions as stipulated in the *National Statement on Ethical Conduct in Research Involving Humans* (2007) apply:

- that Principal Investigators / Supervisors provide, on the form supplied by the Human Research Ethics Committee, annual reports on matters such as:
 - security of records
 - · compliance with approved consent procedures and documentation
 - compliance with special conditions, and

 that researchers report to the HREC immediately any matter that might affect the ethical acceptability of the protocol, such as:

- proposed changes to the protocol
- unforeseen circumstances or events
- adverse effects on participants

The HREC will conduct an audit each year of all projects deemed to be of more than low risk. There will also be random audits of a sample of projects considered to be of negligible risk and low risk on all campuses each year.

Within one month of the conclusion of the project, researchers are required to complete a *Final Report Form* and submit it to the local Research Services Officer.

If the project continues for more than one year, researchers are required to complete an *Annual Progress Report Form* and submit it to the local Research Services Officer within one month of the anniversary date of the ethics approval.

(Committee Approval.dot @21/11/2007)

Page 1 of 1

Appendix C – Stroke Participant's Consent Form

PARTICIPANT INFORMATION AND CONSENT FORM

St Vincent's Hospital, Melbourne, Australian Catholic University

Version 7: Dated 8/10/2010

Site: St Vincent's Hospital and St George's Hospital in association with Australian Catholic University

Full Project Title: A preliminary study into the effectiveness of various foot orthoses on gait parameters in early stroke patients with varying ankle impairments.

Principal Researcher: Dr Elizabeth Bradshaw

Associate Researchers: Dr Vanessa Rice (Australian Catholic University)

Kim Brock (St Vincent's)

Student Researcher: Robert Mehan (St Vincent's)

This Participant Information and Consent Form is 5 pages long. Please make sure you have all the pages.

You are invited to take part in this research project, which looks at the effect on walking of multiple types of ankle splints. Your physiotherapist has suggested you as a possible participant because you are having difficulty controlling your foot when walking following your stroke. The research project aims to investigate the different ankle splints available and determine the most appropriate splint for the different foot control problems that can occur following stroke.

This Participant Information and Consent Form tells you about the research project. It explains what is involved to help you decide if you want to take part.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local health worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you may be asked to sign the consent section. By signing it you are telling us that you:

- understand what you have read;
- consent to take part in the research project;
- consent to be involved in the procedures described;
- consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2. What is the purpose of this research project?

The purpose of this project is to look for differences in the way people walk in the early stages following stroke whilst wearing different ankle splints. There is very little research into what happens to people's walking in the early stages following stroke whilst wearing ankle splints, even though these splints are commonly used. This project will measure walking ability while wearing different types of splints, and compare this with the level of control the person has over their foot and ankle. Thirty people who are currently receiving rehabilitation will be invited to participate in this project. Each participant will be involved in testing each type of ankle splint. Participants will be divided into two groups depending on how their stroke has affected their foot and ankle function. Healthy, aged matched, participants will also be recruited to enable further comparison.

The results of this research will be used by the researcher, Robert Mehan, to obtain a Masters of Exercise Science (Research) Degree, at Australian Catholic University.

This research has been funded by the St. Vincent's Research Endowment Fund.

3. What does participation in this research project involve?

Participation in this project will involve a testing protocol over three consecutive days, for about 1.5hours on each occasion. Twelve weeks following your initial testing you will be followed up for further testing on one day only for approximately 1.5 hours. The testing will occur at the Physiotherapy Department, St Vincent's Hospital, Fitzroy Campus as it houses the necessary equipment to record the information required.

Your first assessment will involve the physiotherapist assessing the strength and flexibility of your foot and ankle while you are sitting comfortably in a chair and lying on a bed. The walking tests will involve walking along a 10.5m runway which records the way in which you walk and walking over a second runway with a plate embedded which records pressure (approximately 5m). You will i walk along the runway in barefoot with no splint. You will then be tested wearing the ankle splints. Two of the ankle splints are ready made and sit inside your shoe. The third splint is a light fibreglass plaster cast which will be applied to your lower leg and then removed as soon as the test is over. The cast is removed using a vibrating plaster saw. Should you not have appropriate footwear, then it will be provided. When wearing the fiberglass cast special plaster boots will be provided. Your relative will be videotaped from side on to examine what movement is occurring at the knee joint under each testing condition.

You will have time to practice walking and get used to each splint before the test is carried out. There are rest times built into the testing procedure so that you do not become tired. If you are tired, the testing can be stopped for a rest at any time. A physiotherapist will supervise your walking at all times and provide you with assistance if you require it. You can use any walking aid that you are currently using. The testing will take place over 3 days, 2 tests on the first day, 2 tests on the second day and one test on the third day. The assessment of your ankle will be repeated before the second and third days testing. Healthy participants will be tested over a single session.

You will be contacted approximately 12 weeks after your testing to arrange your follow-up. On this day the initial physiotherapy assessment will be repeated and you will walk on the walkway in your shoes without a splint. If you are wearing an ankle splint at this time, we will ask you to walk with your usual splint. Again, a physiotherapist will supervise your walking at all times and provide you with assistance if you require it.

Reimbursement

You will not be paid for your participation in this project. If required, reimbursement of taxi fares for the follow up visit can be provided.

4. What are the possible benefits?

The results of your tests will be provided to your physiotherapist and the in depth analysis may assist in deciding the suitability of ankle splints for you. However, we can not guarantee that you will receive any benefit from participating in the study. If the project is successful we hope it will allow the identification of patients who will benefit from ankle splints in the early stages following stroke.

5. What are the possible risks?

There are very few risks associated with participation in this project. Each aspect of intervention could reasonably occur in your normal physiotherapy treatment.

There is a very small risk of a plaster saw grazing the skin when the fibreglass cast if removed with a plaster saw. The risks are minimised by using a large amount of padding beneath the plaster cast. The researcher who applies the fibreglass cast will be an experienced physiotherapist who has at least 5 years experience of applying fibreglass casts to individuals who have suffered strokes.

On occasions the other ankle splints can be uncomfortable to wear. The discomfort can usually be eliminated by reapplication of the splint.

There is a risk of losing balance and falling whilst walking. Your physiotherapist is trained in assessing the suitability you to be able to participate safely.

6. Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at a later stage.

Your decision whether or not to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with St Vincent's Hospital.

7. How will I be informed of the final results of this research project?

If you wish to find out about the results of the study please let your physiotherapist know and we will forward a brief summary of the results to you, when the project is complete.

8. What will happen to information about me?

The information we gather regarding your stroke, the movement in your leg and your walking will be recorded. After the data collection is finished, we will allocate a code number to your data and no details that identify you will be stored. The data will be stored in a locked filing cabinet or in password protected computer files for seven years. After this period, the data will be destroyed.

Any information obtained in connection with this project and that can identify you will remain confidential. It will only be disclosed with your permission, except as required by law. If you give us your permission by signing the Consent Form, we plan to publish the results of the study in a thesis and in a physiotherapy journal. In any publication, information will be provided in such a way that you cannot be identified.

9. Can I access research information kept about me?

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. Please contact one of the researchers named at the end of this document if you would like to access your information.

In addition, in accordance with regulatory guidelines, the information collected in this research project will be kept for at least seven years. You must be aware that the information collected about you will not be able to be identified as outlined in point 8. Access to information about you at this point will not be possible.

10. Is this research project approved?

The ethical aspects of this research project have been approved by the Human Research Ethics Committee of St Vincent's Hospital and by the Human Research Ethics Committee of Australian Catholic University.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)* produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

11. Consent

I have read, or have had this document read to me in a language that I understand, and I understand the purposes, procedures and risks of this research project as described within it.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project, as described.

I understand that I will be given a signed copy of this document to keep.

Participant's name (printed)	
------------------------------	--

Signature

Name of witness to participants signature (printed)

Signature

Date

Date

Declaration by researcher*: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Researcher's name (printed)	
Signature	Date

Note: All parties signing the consent section must date their own signature.

12. Who can I contact?

The person you may need to contact will depend on the nature of your query. Therefore, please note the following:

For further information or appointments:

If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project (for example, feelings of distress), you can contact the principal researcher (Dr Elizabeth Bradshaw) on 9953 3030 or Dr Kim Brock on 9288 2211 or Robert Mehan on 9816 0444).

Complaints

If you have any complaints about any aspect of the study or the way in which it is being conducted you may contact the Patient Liaison Officer at St Vincent's Hospital (Melbourne) on Telephone: (03) 9288 3108. You will need to tell the Patient Liaison Officer the name of the person who is noted above as principal investigator.

Alternatively you are able to contact the Chair of the Human Research and Ethics Committee, Australian Catholic University via the contact details below. The Patient Liaison Officer at St Vincent's should be contacted in the first instance.

VIC:Chair, HREC C/o Research Services Australian Catholic University Melbourne Campus Locked Bag 4115 FITZROY VIC 3065 Tel: 03 9953 3158 Fax: 03 9953 3315

Research Participants Rights

If you have any questions about your rights as a research participant, then you may contact the Executive Officer Research at St. Vincent's Health on Telephone: 9288 3930 or the Chair of the Human Research and Ethics Committee, via the contact details listed above.

Appendix D – Healthy Participant Consent Form

PARTICIPANT INFORMATION and consent form (Control) St Vincent's Hospital, Melbourne, Australian Catholic University Version 1: Dated 8/10/2010 Site: St Vincent's Hospital and St George's Hospital in association with Australian Catholic University

Full Project Title: A preliminary study into the effectiveness of various foot orthoses on gait parameters in early stroke patients with varying ankle impairments.

Principal Researcher: Dr Elizabeth Bradshaw Associate Researchers: Dr Vanessa Rice (Australian Catholic University) Kim Brock (St Vincent's) Student Researcher: Robert Mehan (St Vincent's)

This Participant Information and Consent Form is 5 pages long. Please make sure you have all the pages.

You are invited to take part in this research project, which looks at the effect on walking of multiple types of ankle splints. You have received initial information regarding this project via email seeking volunteers for healthy participants. The research project aims to investigate the different ankle splints available and determine the most appropriate splint for the different foot control problems that can occur following stroke.

This Participant Information and Consent Form tells you about the research project. It explains what is involved to help you decide if you want to take part.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local health worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

If you decide you want to take part in the research project, you may be asked to sign the consent section. By signing it you are telling us that you:

- understand what you have read;
- consent to take part in the research project;
- consent to be involved in the procedures described;

consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2. What is the purpose of this research project?

The purpose of this project is to look for differences in the way people walk whilst wearing different ankle splints. Then compare that to how similarly aged people walk in ankle splints following a stroke. There is very little research into what happens to people's walking in the early stages following stroke whilst wearing ankle splints, even though these splints are commonly used. This project will measure walking ability while wearing different types of splints. Each participant will be involved in testing each type of ankle splint. The results of this research will be used by the researcher, Robert Mehan, to obtain a Masters of Exercise Science (Research) Degree, at Australian Catholic University.

This research has been funded by the St. Vincent's Research Endowment Fund.

3. What does participation in this research project involve?

Participation in this project will involve a testing protocol over a single day, for about 1.5 hours. The testing will occur at the Physiotherapy Department, St Vincent's Hospital, Fitzroy Campus as it houses the necessary equipment to record the information required.

Your first assessment will involve the physiotherapist assessing the strength and flexibility of your foot and ankle while you are sitting comfortably in a chair and lying on a bed. The walking tests will involve walking along a 10.5m runway which records the way in which you walk and walking over a second runway with a plate embedded which records pressure (approximately 5m). You will walk along the runway in barefoot with no splint. You will then be tested wearing the ankle splints and in shoes. Two of

the ankle splints are ready made and sit inside your shoe. The third splint is a light fibreglass plaster cast which will be applied to your lower leg and then removed as soon as the test is over. The cast is removed using a vibrating plaster saw. Should you not have appropriate footwear, then it will be provided. When wearing the fiberglass cast special plaster boots will be provided. Your relative will be videotaped from side on to examine what movement is occurring at the knee joint under each testing condition. You will have time to practice walking and get used to each splint before the test is carried out. There are rest times built into the testing procedure so that you do not become tired. If you are tired, the testing can be stopped for a rest at any time. A physiotherapist will supervise your walking at all times and provide you with assistance if you require it. You can use any walking aid that you are currently using.

Reimbursement

You will not be paid for your participation in this project. If required, reimbursement of taxi fares for the follow up visit can be provided.

4. What are the possible benefits?

The results of your tests will be provided to your physiotherapist and the in depth analysis may assist in deciding the suitability of ankle splints for you. However, we can not guarantee that you will receive any benefit from participating in the study. If the project is successful we hope it will allow the identification of patients who will benefit from ankle splints in the early stages following stroke.

5. What are the possible risks?

There are very few risks associated with participation in this project. Each aspect of intervention could reasonably occur in your normal physiotherapy treatment.

There is a very small risk of a plaster saw grazing the skin when the fibreglass cast if removed with a plaster saw. The risks are minimised by using a large amount of padding beneath the plaster cast. The researcher who applies the fibreglass cast will be an experienced physiotherapist who has at least 5 years experience of applying fibreglass casts to individuals who have suffered strokes.

On occasions the other ankle splints can be uncomfortable to wear. The discomfort can usually be eliminated by reapplication of the splint.

There is a risk of losing balance and falling whilst walking. Your physiotherapist is trained in assessing the suitability you to be able to participate safely.

6. Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at a later stage. Your decision whether or not to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with St Vincent's Hospital.

7. How will I be informed of the final results of this research project?

If you wish to find out about the results of the study please let your physiotherapist know and we will forward a brief summary of the results to you, when the project is complete.

8. What will happen to information about me?

The information we gather, the movement in your leg and your walking will be recorded. After the data collection is finished, we will allocate a code number to your data and no details that identify you will be stored. The data will be stored in a locked filing cabinet or in password protected computer files for seven years. After this period, the data will be destroyed.

Any information obtained in connection with this project and that can identify you will remain confidential. It will only be disclosed with your permission, except as required by law. If you give us your permission by signing the Consent Form, we plan to publish the results of the study in a thesis and in a physiotherapy journal. In any publication, information will be provided in such a way that you cannot be identified.

9. Can I access research information kept about me?

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. Please contact one of the researchers named at the end of this document if you would like to access your information.

In addition, in accordance with regulatory guidelines, the information collected in this research project will be kept for at least seven years. You must be aware that the information collected about you will not be

able to be identified as outlined in point 8. Access to information about you at this point will not be possible.

10. Is this research project approved?

The ethical aspects of this research project have been approved by the Human Research Ethics Committee of St Vincent's Hospital and by the Human Research Ethics Committee of Australian Catholic University. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)* produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

11. Consent

I have read, or have had this document read to me in a language that I understand, and I understand the purposes, procedures and risks of this research project as described within it.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project, as described.

I understand that I will be given a signed copy of this document to keep.

Participant's name (printed)

 Signature
 Date

 Name of witness to participants signature (printed)
 Date

 Signature
 Date

 Declaration by researcher*: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

 Researcher's name (printed)
 Researcher's name (printed)

Signature

Note: All parties signing the consent section must date their own signature.

12. Who can I contact?

The person you may need to contact will depend on the nature of your query. Therefore, please note the following:

Date

For further information or appointments:

If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project (for example, feelings of distress), you can contact the principal researcher (Dr Elizabeth Bradshaw) on 9953 3030 or Dr Kim Brock on 9288 2211 or Robert Mehan on 9816 0444).

Complaints

If you have any complaints about any aspect of the study or the way in which it is being conducted you may contact the Patient Liaison Officer at St Vincent's Hospital (Melbourne) on Telephone: (03) 9288 3108. You will need to tell the Patient Liaison Officer the name of the person who is noted above as principal investigator.

Alternatively you are able to contact the Chair of the Human Research and Ethics Committee, Australian Catholic University via the contact details below. The Patient Liaison Officer at St Vincent's should be contacted in the first instance.

VIC:Chair, HREC C/o Research Services Australian Catholic University Melbourne Campus Locked Bag 4115

FITZROY VIC 3065 Tel: 03 9953 3158 Fax: 03 9953 3315

Research Participants Rights

If you have any questions about your rights as a research participant, then you may contact the Executive Officer Research at St. Vincent's Health on Telephone: 9288 3930 or the Chair of the Human Research and Ethics Committee, via the contact details listed above.

Appendix E – Summary of the Tardieu Scale

Tardieu Scale – from (Gracies, et al., 2000)

Grading is always performed at the same time of the day, in a constant position of the body for a given limb. Other joint, particularly the neck, must also remain in a constant position throughout the test and between tests. For each muscle group, reaction to stretch is rated at a specified stretch velocity with 2 parameters, X and Y.

Velocity of stretch:

V1: As slow as possible (minimizing stretch reflex).

V2: Speed of the limb segment falling under gravity.

V3: As fast as possible (faster than the rate of the natural drop of the limb segment under gravity).

Quality of muscle reaction (X):

0: No resistance throughout the course of the passive movement.

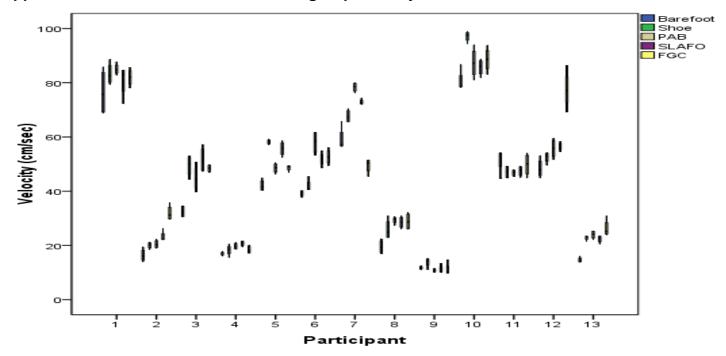
1: Slight resistance throughout the course of the passive movement, with no clear catch at a precise angle.

2: Clear catch at a precise angle, interrupting the passive movement, followed by release.

3: Fatigable clonus (<10 seconds when maintaining pressure) occurring at a precise angle.

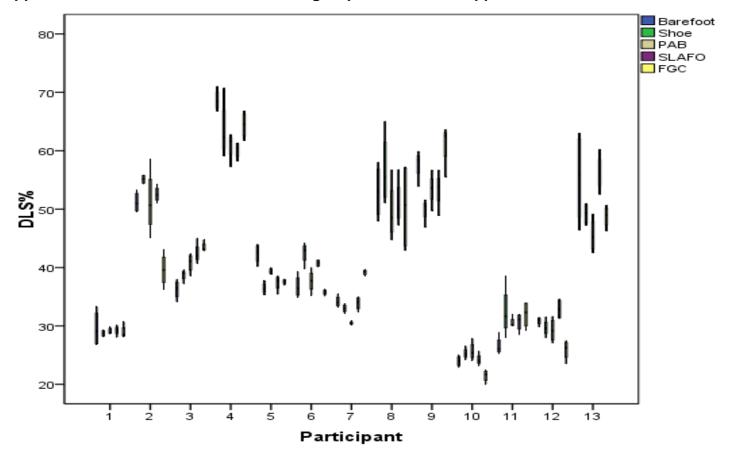
4: Infatigable clonus (>10 seconds when maintaining pressure) occurring at a precise angle.

Angle of muscle reaction (Y): measured relative to the position of minimal stretch of the muscle (corresponding to angle 0) for all joints except hip, where it is relative to the resting anatomic position



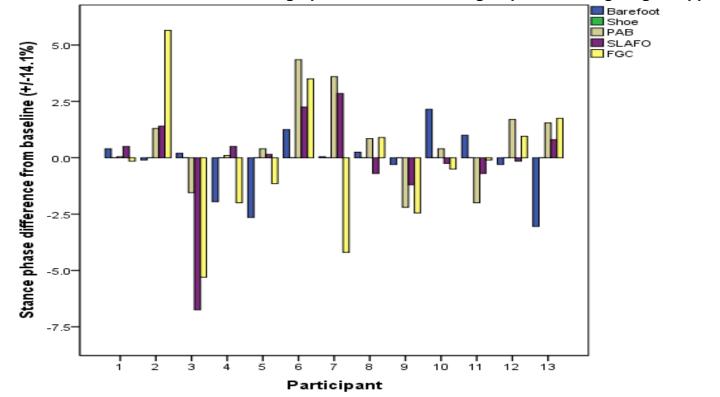
Appendix F Box Plot – Individual stroke group velocity

Stroke group box plot (median, IQR) – individual velocity results of each participant under each testing condition (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



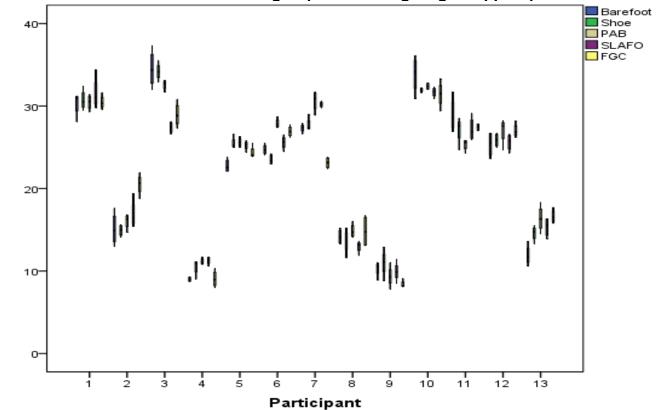
Appendix G Box Plot – Individual stroke group double limb support

Stroke group box plot (median, IQR) – individual double limb support percentage results of each participant under each testing condition. (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



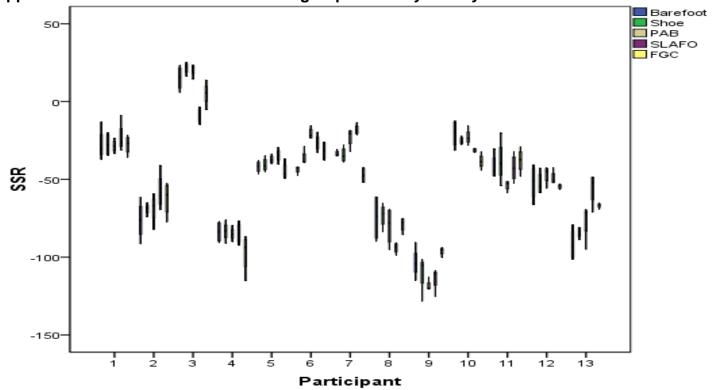
Appendix H: Smallest Real difference bar graph- Individual stroke group affected leg single support phase

Stroke participant individual bar graph demonstrating difference of affected leg single support phase from baseline (shoe result) under each testing condition. Values above or below lines indicate changes a result greater or less than the smallest real difference (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



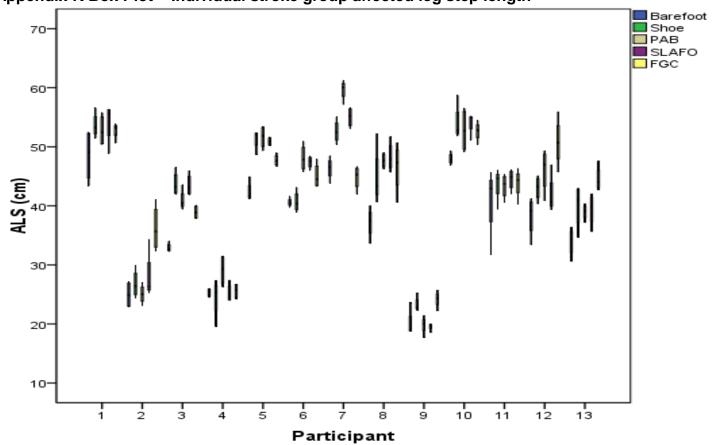
Appendix I Box Plot – Individual stroke group affected leg single support phase

Stroke group box plot (median, IQR) – individual affect leg single stance percentage results of each participant under each testing condition (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



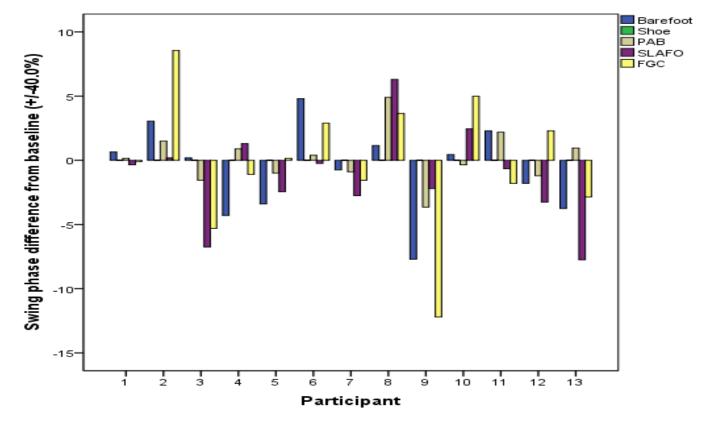
Appendix J Box Plot – Individual stroke group stance symmetry ratio

Stroke group box plot (median, IQR) – individual stance symmetry ratio results of each participant under each testing condition (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



Appendix K Box Plot – Individual stroke group affected leg step length

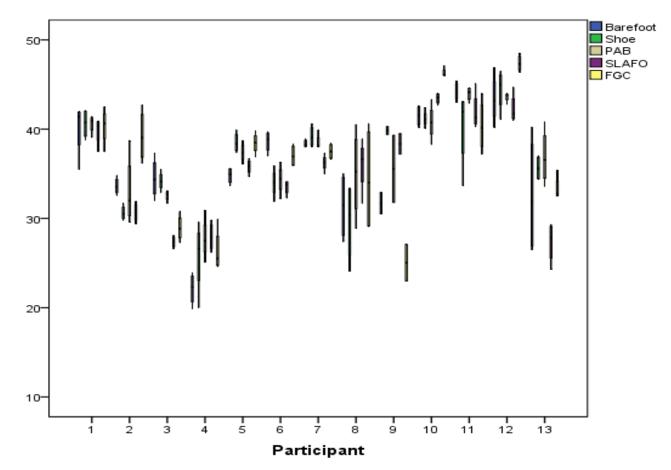
Stroke group box plot (median, IQR) – individual affected leg step length results of each participant under each testing condition (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



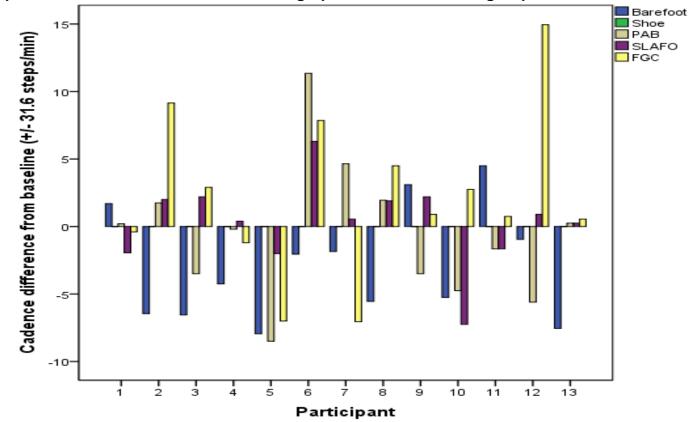
Appendix L Smallest Real difference bar graph- Individual stroke group affected leg swing phase

Stroke participant individual bar graph demonstrating difference of affected leg swing phase from baseline (shoe result) under each testing condition. Values above or below lines indicate changes a result greater or less than the smallest real difference (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)

Appendix M Box Plot – Individual stroke group affected leg swing phase

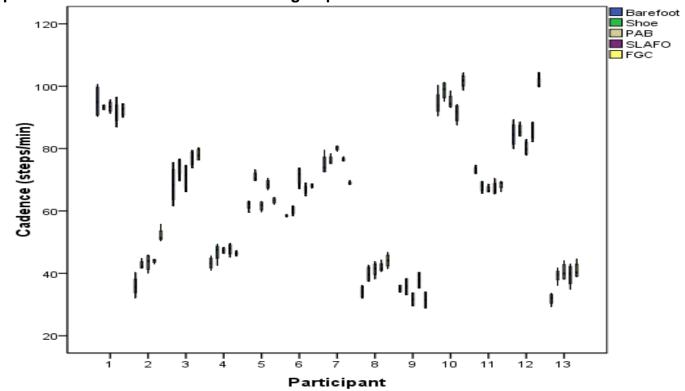


Stroke group box plot (median, IQR) – individual affected leg swing results of each participant under each testing condition (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



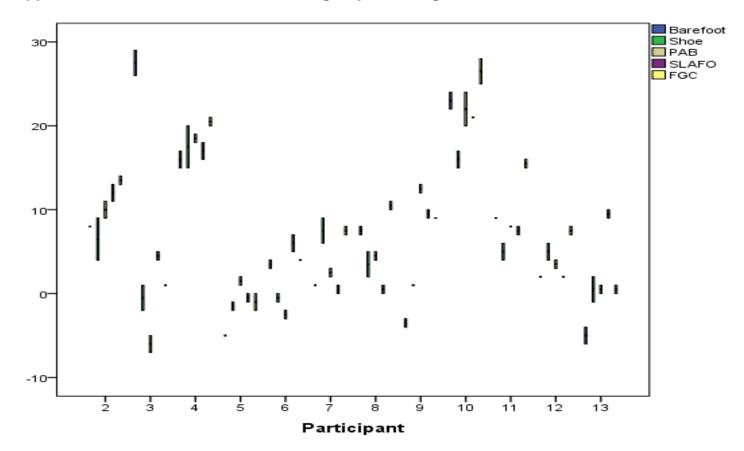
Appendix N Smallest Real difference bar graph- Individual stroke group cadence

Stroke participant individual bar graph demonstrating difference of cadence from baseline (shoe result) under each testing condition. Values above or below lines indicate changes a result greater or less than the smallest real difference (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



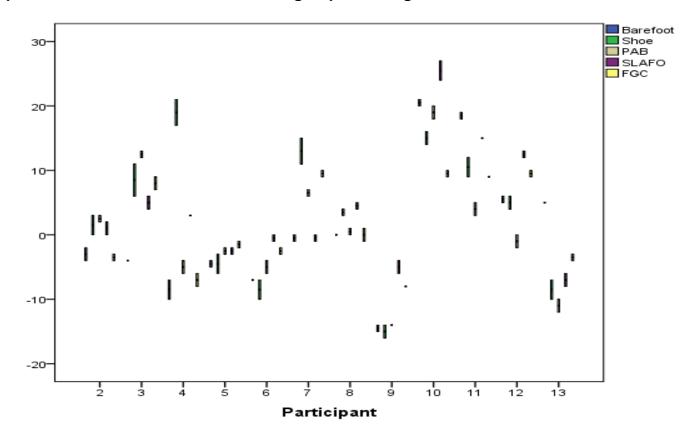
Appendix O Box Plot – Individual stroke group cadence

Stroke group box plot (median, IQR) – individual cadence results of each participant under each testing condition (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



Appendix P Box Plot – Individual stroke group knee angle at initial contact

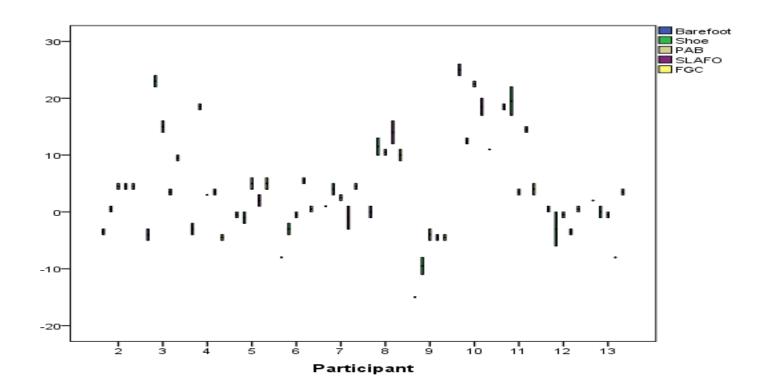
Stroke group box plot (median, IQR) – individual knee angle at initial contact results of each participant under each testing condition (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



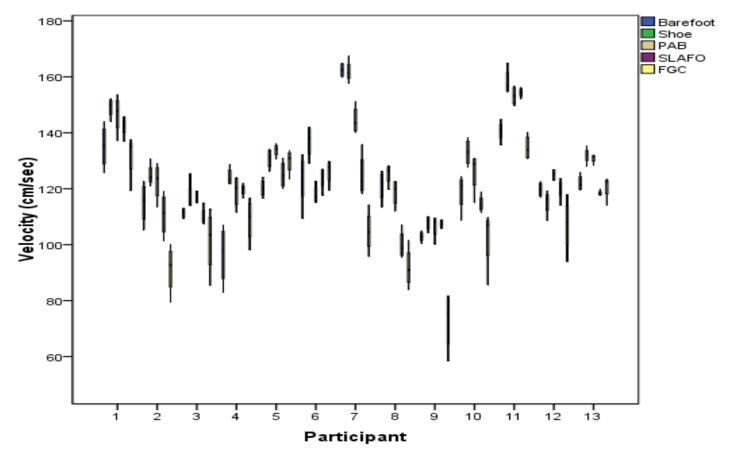
Appendix Q Box Plot – Individual stroke group knee angle at midstance

Stroke group box plot (median, IQR) – individual knee angle at midstance results of each participant under each testing condition (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)

Appendix R Box Plot – Individual stroke group knee angle at terminal stance

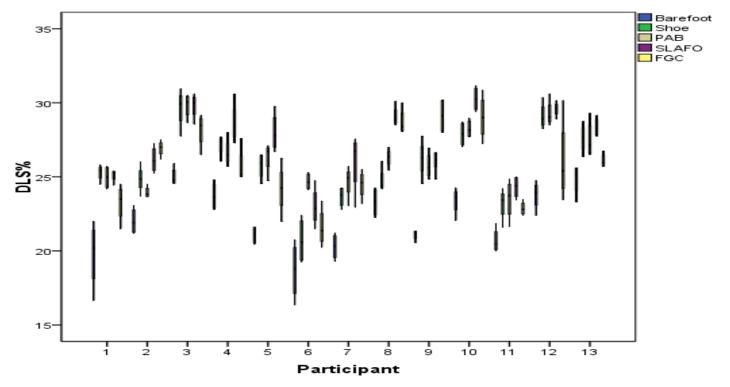


Stroke group box plot (median, IQR) – individual knee angle at terminal stance results of each participant under each testing condition (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



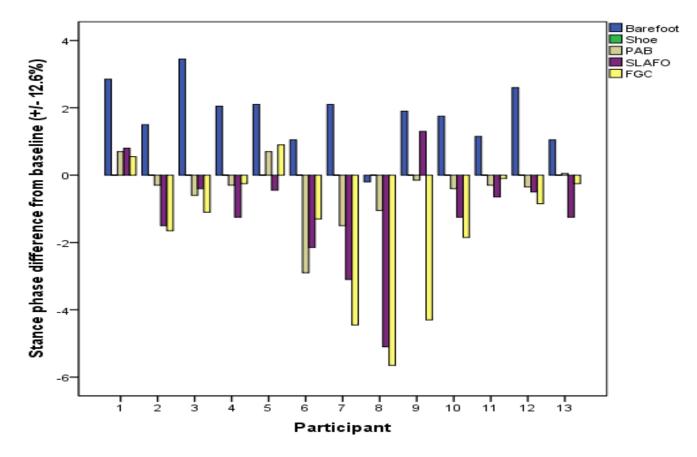
Appendix S Box Plot – Individual healthy group velocity

Healthy Participant individual box plot (median, IQR) – individual velocity results of each participant under each testing condition (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



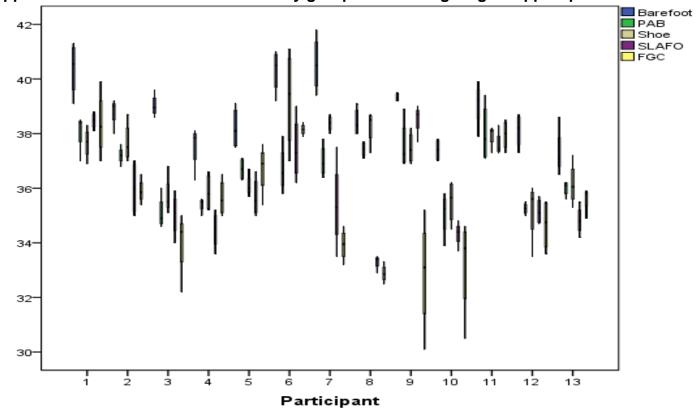
Appendix T Box Plot – Individual healthy group double limb support

Participant individual box plot (median, IQR) – individual double limb support percentage results of each participant under each testing condition (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



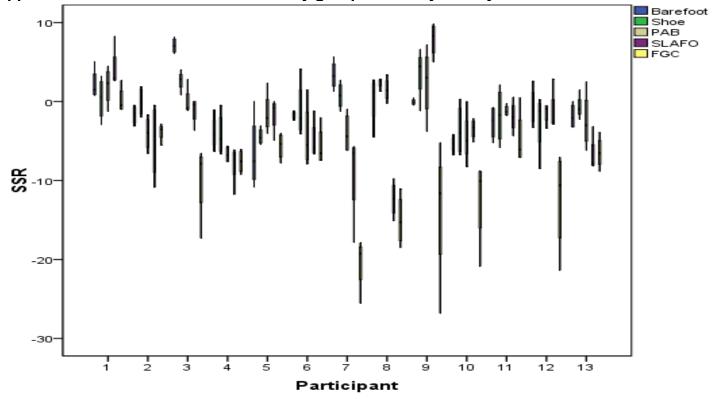
Appendix U Smallest Real difference bar graph- Individual healthy group matched leg single support phase

Healthy participant individual bar graph demonstrating difference of affected leg single support phase from baseline (shoe result) under each testing condition. Values above or below lines indicate changes a result greater or less than the smallest real difference (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



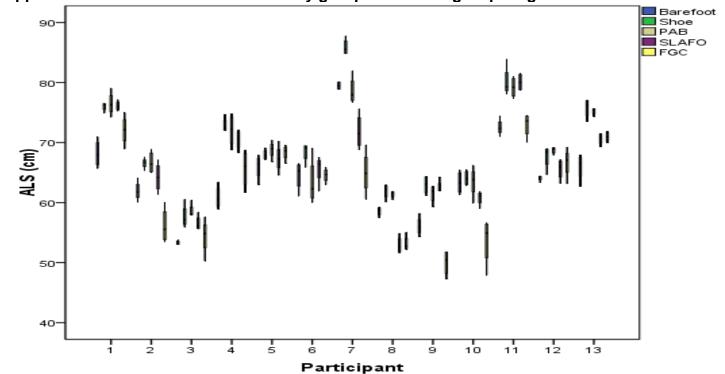
Appendix V Box Plot – Individual healthy group matched leg single support phase

Healthy Participant individual box plot (median, IQR) – individual matched leg single support percentage results of each participant under each testing condition (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



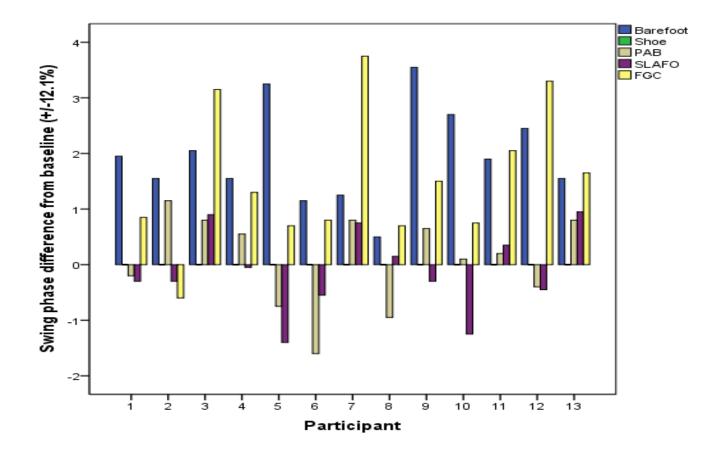
Appendix W Box Plot – Individual healthy group stance symmetry ratio

Healthy Participant individual box plot (median, IQR) – individual stance symmetry ratio results of each participant under each testing condition (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



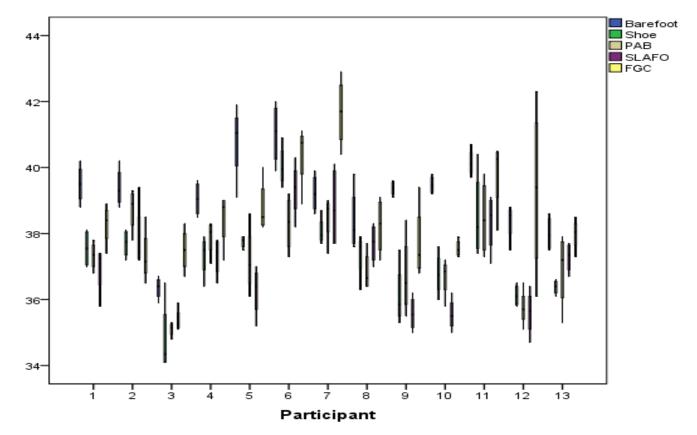
Appendix X Box Plot – Individual healthy group matched leg step length

Healthy participant individual box plot (median, IQR) – individual matched leg step length results of each participant under each testing condition. (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



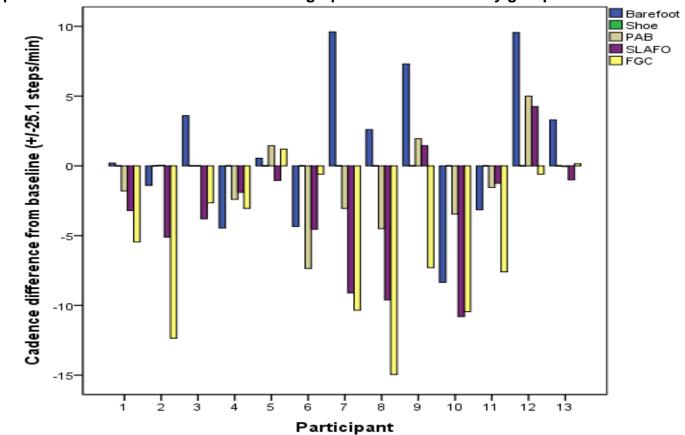
Appendix Y Smallest Real difference bar graph – Individual healthy group matched leg swing phase

Healthy participant individual bar graph demonstrating difference of matched leg swing phase from baseline (shoe result) under each testing condition. Values above or below lines indicate changes a result greater or less than the smallest real difference (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



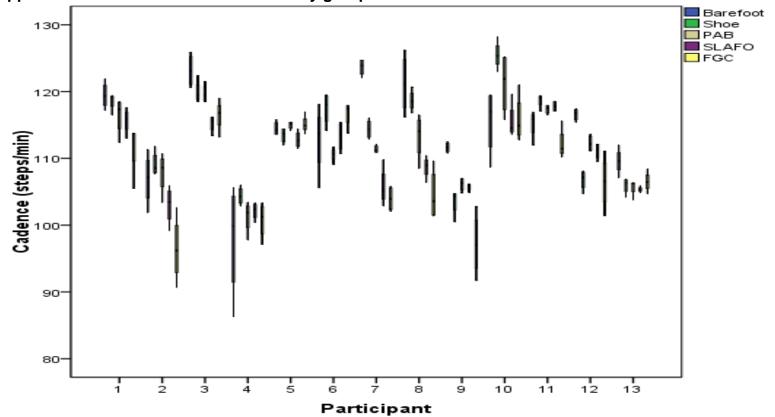
Appendix Z Box Plot – Individual healthy group matched leg swing phase

Healthy Participant individual box plot (median, IQR) – individual matched leg swing phase results of each participant under each testing condition. (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



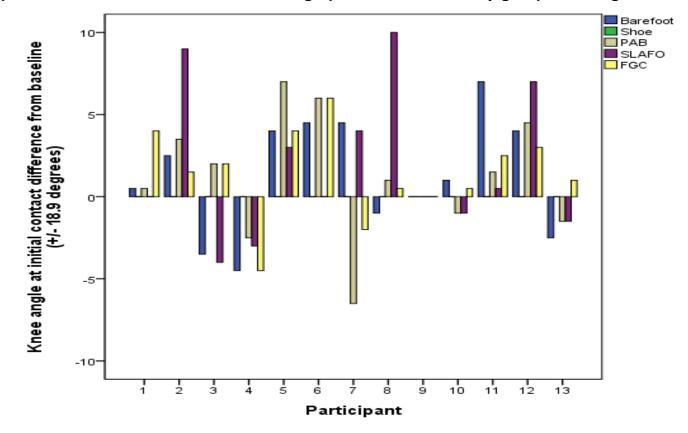


Healthy participant individual bar graph demonstrating difference of cadence from baseline (shoe result) under each testing condition. Values above or below lines indicate changes a result greater or less than the smallest real difference (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



Appendix AB Box Plot – Individual healthy group cadence

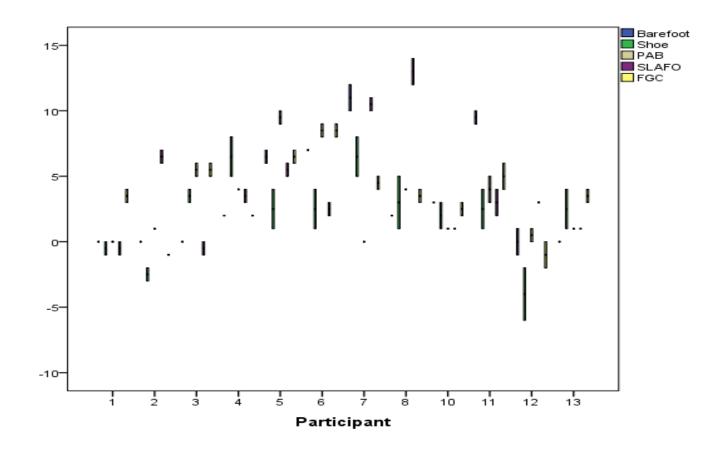
Healthy Participant individual box plot (median, IQR) – individual cadence results of each participant under each testing condition. (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



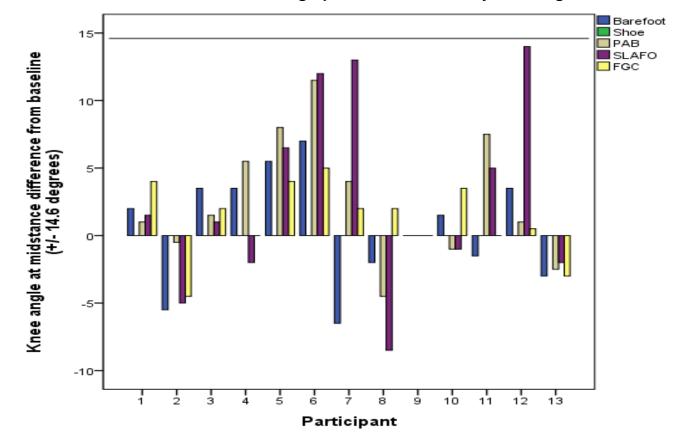
Appendix AC Smallest Real difference bar graph- Individual healthy group knee angle at initial contact

Healthy participant individual bar graph demonstrating difference of knee angle at initial contact from baseline (shoe result) under each testing condition. Values above or below lines indicate changes a result greater or less than the smallest real difference (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)

Appendix AD Box Plot – Individual healthy group knee angle at initial contact



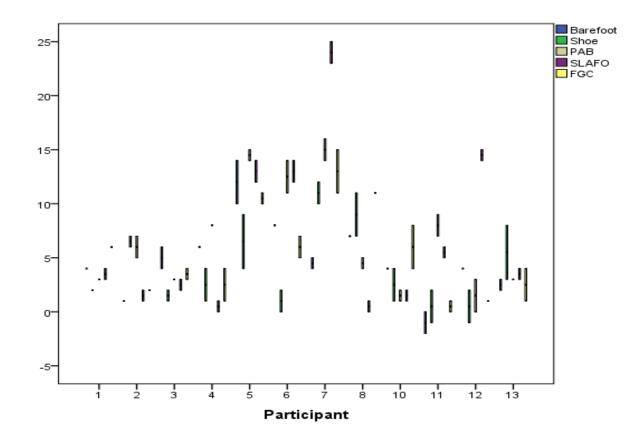
Healthy Participant individual box plot (median, IQR) – individual knee angle at initial contact results of each participant under each testing condition (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



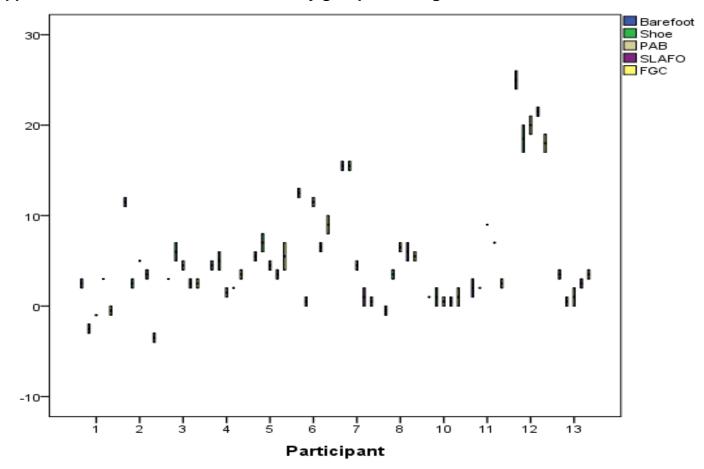


Healthy participant individual bar graph demonstrating difference of knee angle at midstance from baseline (shoe result) under each testing condition. Values above or below lines indicate changes a result greater or less than the smallest real difference (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)





Healthy Participant individual box plot (median, IQR) – individual knee angle at midstance results of each participant under each testing condition (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)



Appendix AG Box Plot – Individual healthy group knee angle at terminal stance

Healthy Participant individual box plot (median, IQR) – individual knee angle at terminal stance results of each participant under each testing condition (PAB – Push Aequi Brace; SLAFO – Spring Leaf AFO; FGC – Fibreglass Cast)