EFFECTS OF TWO DIFFERENT TYPES OF ANKLE FOOT ORTHOSES ON GAIT OUTCOMES IN PATIENTS WITH SUBACUTE STROKE

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DEDICATION

For my husband, Sibi Karakkattil and our children, Reshma, Raina and Rachna, thank you for your support, encouragement, and patience.

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ABSTRACT

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EFFECTS OF TWO DIFFERENT TYPES OF ANKLE FOOT ORTHOSES ON GAIT OUTCOMES IN PATIENTS WITH SUBACUTE STROKE

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Ankle Foot Orthosis (AFO) is a commonly prescribed device to improve foot drop and gait in patients with stroke. The purpose of this study was to identify whether patients in the subacute stage of stroke, with foot drop, would have better gait outcomes when using a double adjustable AFO (DA AFO), or a posterior leaf spring AFO (PLS AFO). A secondary purpose was to determine whether one week of practice would significantly change gait outcomes with either of the AFO conditions when compared to baseline. Twenty participants in the subacute stage of stroke recovery completed this repeated measure study. Outcomes measured were gait endurance, gait symmetry, gait velocity and self-reported preference of AFO. Paired *t* test used to test for significance of differences revealed no significant differences between the two AFOs at baseline ($p > .05$). A repeated measures analysis of variance, used to test significant differences in gait endurance was not significant for the interaction between the AFO conditions after a week of practice ($p = .077$). Main effect of practice and main effect of type of AFO revealed statistical significance ($p < .001$, $p = .046$) A repeated measures multivariate analysis of variance (MANOVA) used to test for the gait symmetry between the AFO

conditions after a week of practice, revealed no significant interaction at self-selected velocity (p = . 397) and fast-paced velocity (p = .113). A repeated measures MANOVA, used to test for the gait velocity between the AFO conditions after a week of practice revealed no significant interaction at self-selected velocity (p = .209) and fast-paced velocity (p = .280). The main effect of practice was significant at self-selected velocity (p = .001) and at fast paced velocity (p < .001). Sixteen participants preferred using DA AFO and four participants preferred using PLS AFO for their walking. In conclusion, participants in subacute stage of stroke recovery did not differ significantly between DA AFO and PLS AFO with gait endurance, gait symmetry and gait velocity at baseline. With practice, participants significantly improved with gait endurance and gait velocity regardless of the type of AFO used.

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CHAPTER I

INTRODUCTION

Stroke is a leading cause of death and disability in the world today. According to the American Heart Association, about 795,000 people are diagnosed with stroke yearly in the United States. Stroke is also the third leading cause of death with more than 140, 000 reported annually. The annual cost of stroke from medical services and disability in our nation is $ 38.6 billion dollars (Roger et al., 2012). With the advancement in acute stroke management, the death rate has fallen in the last decade (Heidenreich et al., 2011): However, about half of stroke survivors are left with physical impairments such as weakness of one side of the body, altered reflexes and impaired sensations (Levin, Kleim, & Wolf, 2009; Pradon et al., 2011). These impairments contribute to the poor quality of life and disability experienced by the survivors (Bourland, Neville, & Pickens, 2011).

The physical impairments resulting from stroke cause gait dysfunction in a majority of survivors (Verma, Narayan, Sharma & Garg, 2012). The commonly reported gait impairments after stroke and hemiparesis are step asymmetry, wide base of support, decreased weight acceptance on the involved side, decreased foot clearance, poor knee control, poor propulsion and decreased gait velocity (McCain, Smith, & Querry, 2012). Typically, the stance phase is shortened and the swing phase longer in the paretic leg, and

these are compensated for by longer stance phase and shorter swing phase on the non-paretic leg. The resulting asymmetric gait pattern often results in increased energy expenditure, falls, abnormal joint loading, injury to joints, deformity and pain (Verma et al., 2012). Therefore gait rehabilitation is an important aspect of neurorehabilitation with focus on attaining the most functional and symmetrical gait to prevent falls, and to prevent sedentary life styles and associated comorbidities (Hesse, 2003; Simpson, Miller, & Eng, 2011).

Ankle foot orthoses (AFOs) are commonly prescribed in patients with stroke to address ankle and knee instabilities and to restore a normal and safe walking pattern (Hesse, 2003). An AFO provides foot clearance during swing phase, lateral stability to the ankle in stance phase, and promotes good heel strike at initial contact (Simons, van Asseldonk, van der Kooij, Geurts, & Buurke, 2009). The effectiveness of AFOs on various gait parameters has been reported in patients with stroke, but mostly during the chronic stages of recovery (Everaert et al., 2013; Kobayashi, Leung, Akazawa, & Hutchins, 2013; Slijper, Danielsson, & Willén, 2012) Systematic analyses have shown that use of various types of ankle foot orthoses improves walking impairments and balance, reduces energy costs, and improves knee and ankle kinematics in people in the chronic stage of stroke recovery, greater than 6 months since the onset of stroke (Tyson, Sadeghi-Demneh, & Nester, 2013; Tyson & Kent, 2013). It is reported that majority of the gait improvements occur within the first 6 months following the onset of stroke (Jørgensen, Nakayama, Raaschou, & Olsen, 1995; Kwakkel, Kollen, & Lindeman, 2004).

However, a limited number of studies have investigated the effects of AFOs within six months of stroke onset.

In a randomized trial, the effects of using two different types of AFOs during the subacute stage of stroke, less than 6 months following onset, were reported. The investigators evaluated the effects of a custom Chignon AFO, which is an articulated AFO with adjustable elastic straps, compared to an off the shelf polypropylene AFO. Participants were measured three times: on the first day the AFO was provided, 30 days after and 90 days after. The outcomes measured were gait speed, ankle range of motion, spasticity, and quality of gait through observational gait analysis. Results of this study showed that the gain in gait speed and knee and ankle control were significantly higher in participants who wore the Chignon AFO for 3 months when compared to participants wearing the polypropylene AFO for the same amount of time. Additionally, participants in the Chignon AFO group had significantly lower spasticity than those in the polypropylene AFO group (de Sèze et al., 2011).

Another study by Rao et al., (2008) investigated gait velocity, cadence, and step length with and without an AFO in 13 participants in the acute stage of stroke recovery, less than six weeks of onset. The investigators found that the use of an AFO significantly improved gait velocity, cadence and step length on the affected and unaffected side ($p < .05$) (Rao et al., 2008). Participants in this study received a custom molded AFO, however the authors did not specify whether the AFO was articulated at the ankle or not. In a more recent study, Hyun, Kim, Han and Kim (2015) evaluated the effectiveness of

using an AFO for reducing energy consumption in patients with subacute stroke. Fifteen subjects participated in a low graded treadmill stress test with and without use of an AFO. The results showed that using an AFO significantly improved VO_2 peak and 6-minute walk test scores (Hyun, Kim, Han, & Kim, 2015).

Only one study investigated the immediate spatiotemporal and kinematic effects of a custom solid AFO compared to no AFO in patients 3 weeks post onset. Eight participants received the custom solid AFO. Baseline measurements were taken at the time of casting without the AFO but with shoes. A week later, a second measurement was taken with the custom AFO. Results showed significant improvement in walking velocity, average step length and cadence. Although step symmetry improved, it was not significantly improved. There was no change in hip and knee kinematics (Carse, Bowers, Meadows, & Rowe, 2015). Although the study by Carse et al. (2015) showed improvement when using an AFO compared to no AFO, there was a week between the measurements taken without the AFO and the measurements taken with the AFO which might have also contributed to the improvement. This improvement could have been also due to the spontaneous recovery within the first month post onset.

In a recent case series report, McCain et al. (2012) observed in three participants, that using a custom double adjustable AFO (DA AFO) during the early stages of recovery after stroke resulted in more typical muscle activation patterns, gait endurance and velocity, and near normal symmetry during gait without an assistive device or an AFO. The authors suggested that the design of the DA AFO may have provided more

peripheral mechanical input to facilitate pre-injury motor function than the typical use of AFO which is often used as a compensatory strategy for gait (McCain et al., 2012). The use of this type of AFO for gait rehabilitation following stroke in the subacute stages has not been thoroughly studied.

Statement of the Problem

Patients with stroke resulting in hemiparesis and foot drop are affected by gait impairments such as poor symmetry, decreased velocity, and decreased endurance. AFOs have been shown to be an effective intervention for improving gait parameters in individuals who are in the chronic stage of stroke recovery (Tyson et al., 2013; Tyson & Kent, 2013). Although, the majority of gait improvements occur within six months of stroke (Kwakkel et al., 2004), the effect of early bracing with different types of AFOs on gait outcomes during this time frame has not been investigated thoroughly.

Purpose of the Study

The purpose of this study was to identify whether patients in the subacute stage of stroke, who demonstrate foot drop, would have better gait outcomes when using a double adjustable AFO, or a posterior leaf spring AFO. A secondary purpose was to determine whether one week of practice would significantly change gait outcomes with either of the AFO conditions when compared to baseline.

Research Questions

The current study attempted to answer the following questions:

1. Would there be differences in gait endurance, gait symmetry and gait velocity measurements at baseline when using a custom double adjustable AFO versus an over the shelf posterior leaf spring AFO in patients in the subacute stage of stroke?
2. Would there be differences in gait endurance, gait symmetry and gait velocity measurements after a week of practice when using either a custom double adjustable AFO or an over the shelf posterior leaf spring AFO in patients in the subacute stage of stroke?

Research Hypotheses

The research hypotheses of this study were as follows:

1. There would be differences in gait endurance measurements, gait symmetry measurements and gait velocity measurements at baseline when using a custom double adjustable AFO compared to an over the shelf posterior leaf spring AFO in patients in subacute stage of stroke.
2. There would be differences in gait endurance measurements, gait symmetry measurements and gait velocity measurements after one week of practice when using either a custom double adjustable AFO or an over the shelf posterior leaf spring AFO in patients in subacute stage of stroke.

Null Hypotheses

The null hypotheses for this study were as follows:

1. There would be no significant differences in gait endurance measurements gait symmetry measurements and gait velocity measurements at baseline, when using custom double adjustable AFO compared to over the shelf posterior leaf spring AFO in patients in subacute stage of stroke.
2. There would be no significant differences in gait endurance measurements, gait symmetry measurements and gait velocity measurements after one week of practice when using custom double adjustable AFO or an over the shelf posterior leaf spring AFO in patients in subacute stage of stroke.

Independent Variables

Practice time and type of AFO were the independent variables in this study. Practice time had two levels: at baseline (no practice) and after one week of practice. Type of AFO had two levels: custom double adjustable AFO, and over the shelf posterior leaf spring AFO.

Dependent Variables

The dependent variables in this study were the following: Gait endurance measured by 6 Minute Walk Test (6MWT), gait symmetry measured using GAITRite gait analysis system, and gait velocity measured using GAITRite gait analysis system.

Gait symmetry and velocity were measured at the participants' self-selected walking speed as well as their maximal walking speed. Participants' subjective preference of the type of AFO to walk with was also assessed.

Operational Definitions

The following operational definitions were used for this study:

Subacute Stroke: Onset of stroke at least 4 weeks prior to, but not later than 20 weeks prior to initiation in the study.

Double adjustable AFO (DA AFO): A custom fabricated thermoplastic AFO with metal double action joints and metal upright. The medial and lateral joints have two channels, one anterior and one posterior to the metal upright. Each of the posterior channels have a stiff spring and each of the anterior channels have a pin. The springs provide dorsiflexion assist during swing phase and resistance to plantar flexion during loading response. The pins in the anterior channels provide controlled tibial advancement during stance into dorsiflexion (see Appendix A) (McCain et al., 2012).

Posterior leaf spring AFO (PLS AFO): An over the shelf plastic AFO, trimmed posterior to the malleoli, which positions the foot in dorsiflexion during swing phase and allows controlled plantar flexion at loading response. The flexibility of the plastic allows dorsiflexion range of motion during late midstance and terminal stance (see Appendix B) (Bowers, 2013; Lin et al., 2003).

Baseline measurements: Participants were measured on the day they received the custom AFO using all AFO conditions. These were considered baseline measurements.

Practice time: Participants wore each AFO for one week each using a prescribed wearing schedule. Participants were asked to use their AFO for all ambulation during the assigned week according to the wearing schedule. This one week of wearing each AFO was their practice time.

After practice measurements: Participants were measured with type of AFO they were practicing with after one week of practice time.

Gait endurance: The distance ambulated on a level indoor surface as measured by the 6 Minute Walk Test (6MWT) and recorded in meters. Participants were allowed to use their assistive device if they were using any, and the same device was used for all testing conditions.

Gait Symmetry: The ratio of the affected step length in cm to unaffected step length in cm. The step length was measured using GAITRite gait analysis system for self-selected pace walking and fast paced walking.

Gait velocity: The velocity of walking measured using GAITRite gait analysis system in cm/sec and converted to m/sec when walking at self-selected pace and also when walking at a fast pace.

Self-Selected Velocity (SSV): Participants were asked to walk at their comfortable speed safely.

Fast-Paced Velocity (FPV): Participants were asked to walk as fast as they could safely.

Assumptions

The following assumptions were made for this study:

1. Participants exerted their maximum effort while performing all tests in all testing conditions.
2. Participants understood the instructions provided by the investigator.
3. Participants enrolled in this study are representative of patients with stroke in the subacute stage of recovery and gait impairments.
4. Randomization of the testing order and practice order negated the carryover effect and natural progression.
5. Participants provided truthful answers to the question of their preferred AFO to walk with.

Limitations

The following limitations were recognized in this study:

1. The primary investigator was not blinded to testing conditions.
2. The result of this study can only be generalized to the specific AFO designs used in this study.

3. There could have been a carry over effect as this was a repeated measures design, however through randomization of testing we tried to minimize this limitation.

4. There could have been an effect of natural progression during the practice time, and also the added effect of practice with one type of AFO in the first week might have contributed to the practice with the other type of AFO in the second week. We tried to minimize this limitation through randomization of the order of AFO used to practice with.

5. Small sample size in this study might have affected the study results.

6. All participants were receiving physical therapy at the time of enrollment in this study. Though we did not control for the physical therapy interventions, the variability and intensity of different physical therapy interventions might have affected the study outcome

Significance of the Study

Stroke is a leading cause of death and disability (Roger et al., 2012), and a majority of the survivors of stroke have gait and balance impairments (Eng, Pang, & Ashe, 2008; Lamb et al., 2003). Therefore, an important goal of stroke rehabilitation is to improve gait outcomes (Hesse, 2003). Although there are several theories behind gait rehabilitation following stroke, task oriented, high repetition training during the early stages of recovery has been shown to be an effective way to improve functional recovery (Belda-Lois et al., 2011). An AFO is commonly prescribed as an adaptive strategy to

compensate for foot drop: However, gait outcomes have not been thoroughly investigated following the use of AFOs in the subacute stroke population. There are different designs of AFOs available for clinicians to choose from inexpensive over the shelf AFOs to expensive custom AFOs (Mulroy, Eberly, Gronely, Weiss & Newsam, 2010). The effect of different designs of AFOs also were not investigated in the subacute population. Additionally, high variability of stroke manifestation makes it difficult to compare two groups of patients affected by stroke using different AFO designs. The current study used two different types of AFOs as adaptive strategies to compensate for foot drop during the subacute stage of recovery in the same group of patients to control for the variability of stroke presentation. The results of this study provide valuable information about the effects of early bracing to address gait impairments in the subacute stroke population. The outcomes of this study also provide valuable information to clinicians in choosing the design of AFO for improving gait endurance, gait symmetry and gait velocity in this population in a cost-effective way.

Stroke is one of the neurological diseases associated with increased falls in the elderly (Eng et al., 2008). It is also reported that in community dwelling stroke survivors, 55% of the falls resulted in injury (Mackintosh, Hill, Dodd, Goldie, & Culham, 2005). Stroke survivors are at higher risk for sustaining hip fractures from a fall (45%–59%) than people without stroke (Weerdesteyn, de Niet, van Duijnhoven, Hanneke J. R., & Geurts, 2008). Among stroke survivors, falls commonly occur during walking (Harris, Eng, Marigold, Tokuno, & Louis, 2005). Gait velocity has been reported to be

significantly correlated (r = .53) with fear of falls in patients with stroke. As gait velocity improves, patients are less fearful of falls when walking (Rosén, Sunnerhagen, & Kreuter, 2005). Eighty eight percent of patients with stroke who sustained a fall reported having a fear of falling, leading to decreased physical activity, deconditioning, decreased participation and care giver dependency (Schmid & Rittman, 2009; Watanabe, 2005). Although my study was not specifically looking at falls as an outcome, it would be reasonable to infer that improving gait outcomes could potentially decrease fall risk. Results of this study further provide evidence for choosing a relatively inexpensive AFO design at the earlier stage of stroke recovery to decrease future costs associated with falls and fall related hospitalizations.

Reintegration to normal living is an ultimate goal of stroke rehabilitation. Difficulty in walking independently, especially outdoors, is reported as the most disabling consequence of stroke. The frustration with inability to leave the home has been reported to be associated with mood disorders (Pound, Gompertz, & Ebrahim, 1998). Even after rehabilitation, 63% of community dwelling stroke survivors reported dependency on others for community ambulation (Lord, McPherson, McNaughton, Rochester, & Weatherall, 2004). Ability to ambulate in the community has been shown to decrease dependency for both indoor and outdoor activities and to increase community participation (Ada, Dean, Lindley, & Lloyd, 2009). Gait velocity has been identified as a factor which predicts independent community ambulation in stroke survivors (Rosa, Marques, Demain, & Metcalf, 2015). Gait speed and gait endurance are also identified as

predictors for community ambulation after stroke (Bijleveld-Uitman, van, & Kwakkel, 2013). Although my study was not looking at community ambulation specifically as an outcome, it is reasonable to assume that improvement in gait velocity and gait endurance with use of an AFO can impact a stroke survivor's ability to become an independent community ambulator, improve participation in the community, and decrease caregiver dependency.

Seventy five percent of stroke survivors are affected by cardiovascular diseases and about one third of these individuals experience recurrent stroke within five years of initial onset (MacKay-Lyons, Macko, & Howlett, 2006). Due to decreased physical mobility, patients with stroke generally have decreased exercise capacity. The amount of oxygen consumed during peak effort exercise (VO_2 peak) is a commonly used outcome to measure exercise capacity. The reported VO_2 peak within 30 days post stroke phase is only 60% of the predicted normative values and it is only 25–45% of the normative values even after 6 months of onset (Stoller, de Bruin, Knols, & Hunt, 2012). In community dwelling stroke survivors, VO_2 peak is associated with high arterial stiffness in carotid and femoral arteries (Tang et al., 2014). Because of motor deficits, patients with stroke require 1.5 to 3.0 times the oxygen of a healthy person to ambulate on level surfaces (MacKay-Lyons et al., 2006). Use of an AFO has been shown to improve VO_2 peak and gait endurance in patients in the subacute stage of stroke, thus decreasing energy expenditure during ambulation (Hyun et al., 2015). Although my study was not directly measuring exercise capacity, or secondary complications of stroke, it would be

reasonable to deduct that improving gait outcomes especially gait endurance while using a particular design of AFO will improve exercise capacity and decrease energy expenditure with ambulation. This improvement in physical capacity will in turn, potentially help reduce secondary cardiovascular complications and associated hospitalization costs.

CHAPTER II

REVIEW OF THE LITERATURE

Patients with stroke resulting in hemiparesis and foot drop are affected by gait abnormalities such as poor symmetry, decreased velocity, and decreased endurance. AFOs have been shown to be an effective intervention in the chronic stage of stroke recovery to improve various gait parameters (Tyson et al., 2013; Tyson & Kent, 2013). Although, it is reported that a majority of functional improvements occur within 6 months of stroke (Kwakkel et al., 2004), the effect of early bracing with different types of AFOs on gait outcomes have not been investigated thoroughly. The purpose of this study was to identify whether patients in the subacute stage of stroke, who demonstrate foot drop, will have better gait outcomes when using a custom double adjustable AFO, or an over the shelf posterior leaf spring AFO. This chapter summarizes the literature related to definition and classification of stroke, medical and surgical management of stroke, impairments, functional limitations and disability post stroke, recovery following stroke, measurement issues in stroke, physical therapy interventions post stroke and gait rehabilitation using an AFO.

Definition and Classification of Stroke

The World Health Organization defined stroke in the 1970s as

> rapidly developing clinical signs of focal disturbance of cerebral function, lasting more than 24 hours or leading to death with rapidly developing clinical signs of focal (or global) disturbance of cerebral function, with symptoms lasting 24 hours or longer or leading to death, with no apparent cause other than of vascular origin (Capildeo, Haberman, & Rose, 1978, p. 178).

Within the last four decades since the original definition was formulated, understanding of stroke has advanced based on clinical presentation, risk factors, lab results and neuroimaging (Mehndiratta, Chapman Smith, & Worrall, 2015).

Based on the etiology, stroke can be classified broadly into ischemic or hemorrhagic stroke. The American Stroke Association (ASA) defines ischemic stroke as "an episode of neurological dysfunction caused by focal cerebral, spinal, or retinal infarction" (Sacco et al., 2013, p. 3). Ischemic stroke accounts for 80%–85% of all strokes (Mehndiratta et al., 2015). There are several established classification systems of ischemic stroke based on clinical features and diagnostic imaging. Causative Classification of Stroke is a widely used classification system based on clinical evaluation, brain imaging, extracranial and intracranial vascular survey, heart evaluations, and work up for uncommon causes of stroke (Ay et al., 2007). The Causative Classifications of Stroke are (a) supra-aortic large artery atherosclerosis, (b) cardio-aortic

embolism, (c) small artery occlusion, (d) stroke of other determined cause/uncommon causes, and (e) stroke of undetermined causes/cryptogenic stroke (Chen et al., 2012). Supra-aortic large artery atherosclerosis is defined as clinical findings and imaging with more than 50% stenosis of a large artery secondary to atherosclerosis. It involves atherosclerosis of the carotid artery, vertebral artery or other intracranial arteries.

The cardio-aortic embolism classification includes patients with large vessel or branch vessel occlusions due to a cardiac source of embolism. The potential sources of embolism are atrial fibrillation, weak left ventricle, mechanical heart valves, infective endocarditis and aortic arch atherosclerosis. Small artery occlusion is defined as small brainstem or subcortical infarct with no identifiable cardiac or large artery source of embolism or thrombosis. For small artery occlusion, also known as lacunar infarcts, the lesion size is less than 20 mm in diameter commonly affecting pons, thalamus, basal ganglia or cerebellum. The resulting lacunar syndromes are typically pure motor hemiparesis, pure sensory syndrome, ataxic hemiparesis, or clumsy hand syndrome without cortical signs such as neglect, vision changes or speech changes. Stroke of uncommon cause is defined as stroke due to rare causes such as non-atherosclerotic vasculopathies and hypercoagulable conditions. The vasculopathies include non-inflammatory conditions such as fibromuscular dysplasia and vasospasm, and inflammatory conditions such as autoimmune disorders, post infectious causes and neoplasms. The hypercoagulable conditions are associated with malignancy and cerebral venous sinus thrombosis with pregnancy, postpartum and oral contraceptive use.

Cryptogenic stroke is defined as stroke of no clear etiology despite an exhaustive evaluation.(Ay et al., 2007; Chen et al., 2012; Mehndiratta et al., 2015).

Hemorrhagic strokes are caused by rupture of cerebral vasculature. Only 15–20% of all strokes account for hemorrhagic stroke. However, mortality and morbidity rates are higher compared to ischemic stroke. Hemorrhagic strokes can be broadly classified into intracerebral and subarachnoid (Mehndiratta et al., 2015). The ASA defines intracerebral hemorrhagic stroke as rapidly developing clinical signs of neurological dysfunction attributable to a focal collection of blood within the brain parenchyma or ventricular system that is not caused by trauma (Sacco et al., 2013). Subarachnoid hemorrhagic stroke is defined as rapidly developing signs of neurological dysfunction and/or headache because of bleeding into the subarachnoid space (the space between the arachnoid membrane and the pia mater of the brain or spinal cord), which is not caused by trauma (Sacco et al., 2013). The risk factors for hemorrhagic stroke include hypertension, amyloid angioplasty, presence of aneurysm or atrioventricular malformations, female gender and tobacco and alcohol abuse (Connolly et al., 2012).

Transient ischemic attack (TIA) is a brief episode of neurologic dysfunction caused by focal brain or retinal ischemia, with clinical symptoms typically lasting less than one hour, and without evidence of acute infarction. ASA defines TIA as a transient episode of neurological dysfunction caused by focal brain, spinal cord, or retinal ischemia without acute infarction (Sacco et al., 2013).

Stroke Medical and Surgical Management

Although stroke is still a leading cause of death in the United States, it has dropped from being the third deadliest disease to fourth since 2008. American Heart Association (AHA) and American Stroke Association's (ASA) efforts for prevention of stroke and early and timely management of stroke helped achieve this. AHA's guideline for stroke management recommends timely brain imaging to identify location, size, presence of bleeding or ischemia for early diagnosis and management. Pharmacological fibrinolysis with the use of intravenous recombinant tissue-type plasminogen activator (rtPA) within three to four and a half hours of onset of symptoms in ischemic stroke has been shown to have improved outcomes. However, treatment with rtPA might have the side effect of intracranial hemorrhage, if patients are not selected carefully. Intra-arterial fibrinolysis is a treatment option for patients with major ischemic stroke of less than six hours' duration caused by occlusion of the middle cerebral artery. Mechanical thrombectomy is another recommended treatment for patients who do not respond to pharmacological fibrinolysis. Historically, anticoagulants were used to halt the worsening of neurological symptoms; however, their use is not recommended by the ASA guideline for acute ischemic stroke. Antiplatelet agents such as aspirin have been shown to prevent recurrent stroke and for prophylaxis for deep vein thrombosis and are recommended within 24 to 48 hours after onset of ischemic stroke. Additionally, cardiovascular issues such as hypertension and hyperlipidemia should be controlled (Jauch et al., 2013).

Although hemorrhagic stroke is less common than ischemic stroke, 25% of those diagnosed with hemorrhagic stroke die and more than 50% of the survivors are left with persistent neurological deficits. AHA guidelines recommend management of hypertension, avoiding tobacco use and alcohol misuse as preventive methods for this type of stroke. Additionally, early repair of aneurysm, management of complications such as hydrocephalous, and delayed cerebral ischemia are recommended as treatment for better outcomes.(Connolly et al., 2012).

Impairments, Activity Limitations, and Participation Restriction after Stroke

The advancement in early medical and surgical management following stroke has decreased the mortality rate associated with stroke in the last decade by 35.8%. However, the majority of stroke survivors are still left with neurological deficits requiring rehabilitation for functional recovery (Winstein et al., 2016). The specificity of impairments following stroke onset depends on the location, mechanism, and extent of the lesion. These impairments can be primary impairments as a result of the extent of injury and can be secondary impairments or complications. Primary impairments include deficits in somatosensory, motor, cognitive, visual, perceptual and language deficits with hemiplegia, or hemiparesis on the side of the body opposite to the brain lesion. Secondary impairments include swallowing problems, deep vein thrombosis, pain, falls, fatigue, malnutrition, and bowel/bladder dysfunction (Duncan et al., 2005; Winstein et al., 2016)

Somatosensory Impairments

Sensation arising from the skin, muscles and joints are referred to as somatosensation, and includes light touch, proprioception and stereognosis. Reported somatosensory loss following stroke ranges from 11% to 85% based on the type of sensation (Meyer, Karttunen, Thijs, Feys, & Verheyden, 2014).With cortical lesions, sensory impairment will be more specific and localized. Diffused sensory involvement of the whole affected side is present in lesions involving deeper areas such as the thalamus. Brain stem lesions can lead to ipsilateral facial impairments with contralateral trunk and limb involvement (O'Sullivan & Schmitz, 2007).

Motor Impairments

Traditionally, the early stage of stroke recovery is characterized by flaccidity with no voluntary movement, followed by development of spasticity, and mass patterns of movement called synergies (Brunnstrom, 1966). As recovery advances, the spasticity and synergies decrease, and voluntary movement patterns become possible. Brunnstrom classified these recovery periods into 6 stages (Table 1). With the Brunnstrom staging of recovery, not all persons reach the last stage and the recovery process can plateau at any stage. Motor impairments include weakness of the muscles on the affected side, spasticity typically in the antigravity muscles, and synergy patterns. Additionally, balance reactions including righting, equilibrium, and protective extension reactions are affected (Winstein et al., 2016)

Table 1

Brunnstrom Stages of Recovery

Stage 1	• Period of flaccidity • No voluntary movement following acute episode
Stage 2	• Spasticity develops • Movement synergies or components of movement synergies in response to a stimulus or with voluntary movement.
Stage 3	• Spasticity increases • Voluntary control of the movement synergies.
Stage 4	• Spasticity declines • Some movement combinations out of synergy.
Stage 5	• More difficult movement combinations out of synergy.
Stage 6	• Spasticity disappears • Individual joint movements and coordination approaches normal.

Recent advancement in neuroscience research suggests that weakness is the cause of compromised motor function rather than spasticity (Patten, Lexell, & Brown, 2004). Weakness post stroke is referred to as hemiparesis with mild to moderate degrees of weakness of one side of the body, and hemiplegia with severe or complete loss of motor

function on one side of the body. Post stroke weakness is characterized by impaired force magnitude, slowness to produce force, rapid fatigue, needing excessive effort, and difficulty producing force effectively within the context of a task (Patten, Lexell, & Brown, 2004). The reported pattern of lower extremity strength that is preserved in patients with moderate hemiplegia is 37% for ankle plantar flexion, 45% for ankle dorsiflexion, 51% for knee extension, 53% for knee flexion, 64% for hip extension, and 68% for hip flexion. This indicates that the weakness is more profound distally than proximally (Patten et al., 2004).

Patients with cerebellar and basal ganglia lesions present with incoordination and ataxia and can also demonstrate motor programming deficits. Typically, patients with right hemiplegia (Left CVA) have difficulty initiating and sequencing movements and may have apraxia. Apraxia is the inability to perform purposive movements even in the absence of sensory or motor impairments. Patients with left hemiplegia typically have inability to sustain a movement or posture. (O'Sullivan & Schmitz, 2007).

Cognitive and Emotional Impairments

Patients with stroke can be affected by a variety of cognitive impairments depending on the location of the lesion. These deficits include impairments in orientation, attention, information processing speed, conceptual abilities, executive functioning, memory and learning. Patients with left CVA have difficulty processing information in sequence. Typically, they are cautious, slower, anxious, and depressed. However, they

are aware of their existing impairments. On the contrary patients with right CVA have difficulty with overall organization of an activity. They tend to be quick and impulsive with poor judgment and often are unaware of their impairments. Patients with lesions in the frontal lobe and limbic systems tend to have emotional impairments, such as motional lability. These patients tend to have spontaneous laughing and crying with slight provocation (O'Sullivan & Schmitz, 2007).

Visual Impairments

Various types of visual impairments can also be present based on the location of pathology. Visual field deficits called homonymous hemianopsia cause blindness in the nasal half of one eye and in the temporal half of the other eye. Depth perception is another issue which affects spatial relationships. If muscles used for eye movements are affected, patients will have forced gaze deviation. With cortical lesions, patients look away from the hemiplegic side and with brainstem lesions, patients look toward the hemiplegic side (O'Sullivan & Schmitz, 2007).

Perceptual Impairments

Perceptual deficits are common in lesions involving the parietal lobe of the right hemisphere. These deficits include visuospatial distortions, disturbances in body scheme and image, and unilateral neglect. Visuospatial distortions make it difficult to judge distance, size, position, rate of movement, form or relation of parts to the whole. Impairments in body scheme and image make it difficult for patients to position

themselves in upright posture. Patients with unilateral neglect tend to be unaware of the affected side of the body typically the left side (O'Sullivan & Schmitz, 2007).

Speech, Language and Orofacial Impairments.

Speech and language impairments are common in pathology involving the parietooccipital cortex of the dominant hemisphere. These patients can be affected by aphasia, dysarthria, and dysphagia. Aphasia is a communication disorder characterized by impairment of language comprehension, formulation and use. Dysarthria is a motor speech disorder from impaired movement of the muscles used for speech production, including the lips, tongue, vocal folds, and/or diaphragm. Dysphagia is the inability or difficulty with swallowing and is common in injuries to the medullary brainstem (O'Sullivan & Schmitz, 2007).

Secondary Impairments

The primary impairments described above can lead to several secondary impairments. Due to lack of voluntary movements and immobilization, decrease in range of motion, contractures, and deformities can develop. Deep vein thrombosis, pulmonary embolism, and cardiovascular deconditioning are other consequences of immobility and decreased mobility. Pain in the affected shoulder associated with shoulder subluxation occurs in 70–84% of patients affected by stroke. Pain can also result from muscle imbalance, improper movement patterns, musculoskeletal strain, and poor alignment.

Psychologically, patients experience anxiety, depression or denial because of immobility, dependence, and frustrations with communication and thinking. (Duncan et al., 2005)

Activity Limitations

As impairments can vary in each patient following stroke based on the lesion, activity limitations also vary. Activity limitations are due to the combined effect of the different types of impairments present. Generally, all basic activities of daily living such as dressing, eating, walking, toileting, and hygiene and instrumental activities of daily living such as shopping, accounting, transportation, housekeeping, and food preparation may be affected (Winstein, 2016).

Participation Restriction

The International Classification of Functioning, Disability and Health (ICF) transformed the concept of disability into participation restriction. Participation restriction is interconnected with impairments at body structure and function, leading to limitation of activities and participation while interacting with environmental and personal factors (Albert & Kesselring, 2012). For a person who has experienced a stroke, the participation restriction could be due to impairments in muscle strength (body function), limitations in walking (activity), and restrictions in returning to work (participation). Interactions with environmental factors, such as having a supportive family, or with personal factors, such as having strong faith to overcome difficulties, and environmental factors such as having a wheelchair-accessible bathroom, can have a direct

positive or negative impact on the level of functioning. As a result, participation restriction following stroke varies tremendously based on different factors (Dahl, 2002). Chau, Thompson, Twinn, Chang and Woo (2009) investigated the predictors of participation restriction at 12 months after stroke and found that functional ability measured by the Barthel Index had the largest direct effect on participation restriction, while the other predictors were depression, low self-esteem, female gender, older age and living in a residential care facility (Chau, Thompson, Twinn, Chang & Woo, 2009).

Recovery Following Stroke

Stroke survivors typically make measurable neurological and functional recovery in the first month following onset. This spontaneous recovery results from reduction of edema, absorption of damaged tissue, improved local circulation and cellular metabolism allowing intact neurons that were inhibited to resume function. Spontaneous recovery takes place typically within 3 to 4 weeks of onset (Duncan, Lai & Keighley, 2000). The nervous system also modifies itself in response to changes in activity and environment. This ability of the nervous system to change and repair itself is called neuroplasticity. Neuroplasticity of the brain enhances further function induced recovery after the spontaneous recovery (Kleim & Jones, 2008). Longitudinal studies show that the majority of functional improvement occurs within 6 months since the onset of stroke (Kwakkel et al., 2004).

Measurement Issues in Stroke Rehabilitation Research

Because of the heterogeneous nature of stroke manifestations and recovery, there are several challenges related to measurements in stroke research. The effect of spontaneous neurological recovery is difficult to measure directly (Kwakkel et al., 2004). In the published literature, outcomes are measured in different ways, at different stages of recovery, and at the level of impairment in body functions and structure, activity limitation, or participation restriction. Because of the complexity of the central nervous system, impairments can vary extensively, making it difficult to compare for the effects of interventions between participants or groups. Various comorbidities such as psychosocial and emotional status also affect the prognosis of each patient affected with stroke. apart from the interventions. In addition, there are a wide variety of tests to assess impairments, making it difficult to compare different studies (Kleim, 2006; Kwakkel et al., 2004).

Physical Therapy Interventions Post Stroke

As the impairments, activity limitations and participation restrictions following stroke onset vary from individual to individual, physical therapy interventions also vary based on each situation. The primary physical therapy goal in stroke rehabilitation is to maximize function and minimize impairments within the constraints of pathology, comorbidities and available resources to decrease physical contributions to participation restriction (Duncan, 1994). Neurologic rehabilitation following stroke, has evolved over

the past few decades as the basic understanding of the adaptive capacity of the central nervous system has advanced. Although there are various approaches to physical therapy in the stroke rehabilitation, it can be broadly categorized to a neurophysiological approach or motor learning approach (Pollock, Baer, Langhorne, & Pomeroy, 2007).

In the 1970s, Berta and Karel Bobath established Bobath's neuro developmental treatment (NDT) using a neurophysiological approach. The principles of NDT were to suppress abnormal tone and atypical patterns of coordination and to control unwanted movements while facilitating normal muscle activity (Mayston, 2008). Bobath classified stages of recovery as initial flaccid stage, stage of spasticity and stage of relative recovery. The focus of therapy was to obtain normal posture and movement during the flaccid stage, while the focus was to decrease spasticity by weight bearing on the affected side, and balance recovery in sitting and standing during the spastic stage. Gait training or active rehabilitation was only started during the stage of relative recovery and was implemented through the facilitation of normal movement and posture (Seneviratne, 2013).

The motor learning approach developed by Carr and Shepherd in the 1980s promoted relearning of normal activities through task and context specific training. The patient is also involved in goal setting to obtain active participation. As part of the motor learning approach, the patient practices and relearns everyday tasks while the clinician provides feedback. The practice order of the task can be divided into blocked, serial, or random order. Blocked order tends to promote early acquisition of skills, while serial and

random order of practice tend to promote acquisition and retention of tasks (Wulf & Schmidt, 1997). Additionally, the treatment progresses from a structured environment to everyday situations. Contrary to the NDT approach, active rehabilitation is initiated as soon as possible from the onset of stroke (Carr & Shepherd, 1989; Seneviratne, 2013).

In the 1990s, advancement in the neuroscience research led to validation of the motor learning approach for better outcomes. Research done in animals by prominent neuroscience researchers Jenkins, Merzenich, Kleim, and Nudo led to better understanding of reorganization of the adult brain post injury. Their research revealed that learning novel behaviors and sensory experiences triggers neuronal growth in the motor and somatosensory cortices. This adaptive capacity of the central nervous system is known as neuroplasticity (Kleim, Barbay, & Nudo, 1998; Recanzone, Merzenich, Jenkins, Grajski, & Dinse, 1992). This understanding of neuroplasticity led to the development of various neuro rehabilitation interventions.

Based on their understanding of neuroplasticity, Kleim and Jones (2008) reported 10 principles of neuroplasticity relevant to rehabilitation. These principles are (a) use it or lose it, (b) use it and improve it, (c) specificity, (d) repetition matters, (e) intensity matters, (f) time matters, (g) salience matters, (h) age matters, (i) transference, and (j) interference (Kleim & Jones, 2008). Contemporary physical therapy interventions use several of these principles to improve functional outcomes after adult brain damage.

One of the contemporary rehabilitation interventions that use the neuroplasticity principle is constraint induced movement therapy. Constraint induced movement therapy, developed by Taub, promotes use of the affected upper extremity for several hours a day over 10–14 days while the unaffected upper extremity is constrained in a sling to improve upper extremity function (Taub & Wolf, 1997). Another rehabilitation intervention is body weight supported treadmill training. Body weight supported treadmill training facilitates normal walking patterns by providing task specific, repetitive, and high intensity training. Utilization of high intensity gait training during early stages of post stroke has been shown to improve gait outcomes (McCain, Smith, Polo, Coleman, & Baker, 2011; Peurala et al., 2009). Resistance training has also been shown to improve various outcomes post stroke (Patten et al., 2004). Aerobic exercises have been shown to increase brain derived neurotrophic factor which is believed to induce neuroplasticity (Mang, Campbell, Ross, & Boyd, 2013). Utilization of various designs of orthoses with and without functional electrical stimulation also promotes improved gait outcomes following stroke (Everaert et al., 2013; Lewallen, Miedaner, Amyx, & Sherman, 2010).

Recently, there is reported evidence for high intensity variable stepping training after stroke for improving temporal gait outcomes and joint kinematics (Mahtani, et al., 2017). The high intensity variable stepping training involves reciprocal stepping in different directions (forward, backward and sideways) on different surfaces (treadmill, over ground, stairs, incline) at high aerobic intensity (70% to 80% of heart rate reserve) (Holleran, Straube, Kinnaird, Leddy, & Hornby, 2014). Mental imaging and mirror

therapy are two emerging interventions in the field of neuro rehabilitation. The concept behind mental imagery is that there is activation of the brain areas and pathways of actual movement with mental imaging of the movement (Hwang et al., 2010). Similarly, mirror therapy focuses on moving the unimpaired limb while watching the mirror reflection to create a visual illusion to facilitate functional reorganization of the motor cortex (Arya, Pandian & Kumar, 2017).

Gait Rehabilitation Following Stroke Using Ankle Foot Orthoses

Gait Substitutions in Stroke with Foot Drop

Stroke survivors have ranked restoration of walking as one of the most important goals for rehabilitation (Bohannon, Horton, & Wikholm, 1991). Consequently, gait rehabilitation is the most important goal of stroke rehabilitation. Patients with stroke typically have difficulty advancing the paretic leg during the swing phase of gait (Little, McGuirk & Patten, 2014). The inability to advance the limb can be from weakness of the ankle dorsiflexors or from increased tone or spasticity of the plantar flexors and can clinically manifest as foot drop (Bowers, 2013). The gait substitutions present with foot drop include difficulty clearing the foot in swing phase, lack of initial contact with the heel, sagittal plane knee instability in midstance, mediolateral ankle instability in stance, wide base of support, and longer step length on the hemiplegic side compared to the unaffected side. The temporal (related to time) gait deviations include shorter stance time on the affected side, longer swing time on the affected side, slower walking speed, and

increased double limb support time. The spatial (related to distance) gait deviations include uneven step length, shorter stride length and wide base of support (Verma et al., 2012).

In normal gait, during stance phase the ground exerts a force against the body in the same magnitude and in opposite direction of the force exerted by the foot on the ground and is called ground reaction force (GRF). In patients with stroke, location and magnitude of GRF varies due to abnormal neurological control and muscle power. Inadequate dorsiflexion active range of motion and decreased tibial advancement in stance phase, causes the GRF to be in anterior to the knee joint, creating a large knee extension moment and causing the knee to hyperextend. The hyperextended knee position is a stable position that requires no muscle activity, but causes difficulty initiating hip and knee flexion in early swing phase. Additionally, having the GRF in front of the hip joint during stance phase, a hip flexor moment that requires hip extensors to work through midstance and late stance, causing an abnormal muscle response (Bowers, 2013).

Designs and Properties of AFOs used in Stroke Rehabilitation

AFOs are commonly prescribed to improve gait outcomes after stroke. AFOs have a direct and an indirect effect on improving gait outcomes. The direct effect is by improving alignment of the ankle and foot to prevent foot drop, and the indirect effect is by improving alignment of the GRF in relation to the joint centers and thus improving hip and knee joint alignment in gait (Bowers, 2013). Additionally, AFOs facilitate weight

bearing on the paretic leg by shifting the center of pressure over the foot and improving knee movements in stance phase (Tyson et al., 2013). There are various AFO designs from pre-fabricated over the counter designs to custom made designs (Bowers, 2013). Some of the commonly available AFO designs are described here.

The PLS AFO is a pre-fabricated AFO designed to assist correction of foot drop in the swing phase. The PLS AFO is trimmed posterior to the malleoli, which positions the foot in dorsiflexion during swing phase and allows controlled plantar flexion at loading response. The plastic used in the construction of a PLS AFO is flexible, allowing dorsiflexion range of motion during late midstance and terminal stance. However, this AFO does not provide mediolateral stability of the foot or knee control in the stance phase of gait. The pre-fabricated carbon fiber AFO is lightweight and positions the foot in neutral dorsiflexion to assist with the swing phase of gait. This type of AFO can also improve push off at the end of stance phase. Solid AFOs are AFOs which allow no mobility at the ankle joint and can be prefabricated or custom made. This type of AFO positions the ankle in a fixed position and can be useful when spasticity and contractures in the plantar flexor muscles are a problem. The hinged AFO is a custom designed AFO which has an ankle joint to allow ankle mobility. The hinged AFO restricts plantar flexion to 90 degrees but allows dorsiflexion (Bowers, 2013).

The DA AFO is a custom fabricated thermoplastic AFO with metal double action joints and metal uprights. The medial and lateral joints have two channels, one anterior and one posterior to the metal upright on each side. Each of the posterior channels has a

stiff spring and each of the anterior channels has a pin. The springs provide dorsiflexion assist during swing phase and resistance to plantar flexion during loading response. The pins in the anterior channels provide controlled tibial advancement during stance into dorsiflexion (McCain et al., 2012). There are several reported studies which examined various gait outcomes following stroke with different AFO designs or with and without use of AFOs. A majority of the studies were done during the chronic stage of recovery following stroke, while a few studies were done in the subacute stage. The following section summarizes these findings.

Gait Outcomes with AFOs in the Chronic Stage of Stroke Recovery

Tyson et al., (2013) systematically reviewed the effects of an AFO when compared to not using an AFO on gait biomechanics after stroke. They evaluated 20 trials with 314 participants. Of the 20 trials only 3 of them had time since onset under 6 months. The type of AFOs used in each study ranged extensively, but the control condition was not using an AFO. Results of this analysis showed significant improvements in ankle dorsiflexion range of motion at initial contact ($p < .001$), peak ankle dorsiflexion range of motion in stance phase ($p < .001$), and peak ankle dorsiflexion range of motion in swing phase ($p < .001$) when wearing an AFO compared to not wearing an AFO. Significant improvements were also found in knee flexion at initial contact ($p < .02$), peak knee flexion range of motion at loading response ($p = .0007$), and peak knee extension range of motion in stance phase ($p < .001$) while using an AFO when compared to not using the AFO. However, no significant effect was found in peak

knee flexion range of motion in swing phase ($p = .72$) when using an AFO. Similarly, peak hip flexion range of motion at initial contact ($p = .89$) and peak hip extension range of motion ($p = .18$) during stance phase were not significant with AFO use. Tyson et al. (2013) also found significant change in center of pressure excursion under the affected foot in stance while wearing an AFO ($p < .001$). Similarly, energy cost with walking ($p < .004$) and physiological cost index ($p < .001$) were significantly different with AFO use when compared to the control. The authors concluded that use of an AFO can reduce energy cost of walking, improve weight transfer over to the paretic leg and improve knee and ankle kinematics.(Tyson et al., 2013) Though this review compared the use of an AFO to no AFO, the type of AFO used varied widely and did not address the effect of different AFO designs.

In a meta-analysis, Tyson and Kent (2013) looked at the evidence for using an AFO on balance and walking post stroke when compared to no AFO. Tyson and Kent evaluated 13 studies with 334 participants. Only two of the 13 trials had time since onset of stroke under six months. The type of AFO used also varied substantially, and the control was use of no AFO. This analysis found that more participants walked independently using an AFO ($p < .001$) when compared to not using an AFO. Walking speed was also significantly better when using an AFO compared to not using AFO ($p < .0001$). Similarly, there was significant improvement in step length ($p = .02$) and stride length of the affected side ($p = .001$), and improvement in balance ($p = .001$) with use of an AFO. Significant improvement in weight shifting to the affected side was also noted

with use of an AFO (p = .003). With timed stair negotiation and timed up and go, although participants walked faster with an AFO than without an AFO, the difference was not statistically significant (p = .07, p = .09, respectively). Similarly, though postural sway was better when wearing an AFO compared to not wearing one, the differences were not statistically significant (p = .10). The authors concluded that the use of an AFO improves walking and some components of balance when compared to not using an AFO in patients with stroke during various stages of recovery (Tyson & Kent, 2013). Similar to the prior systematic review, this meta-analysis included studies with different AFO designs and the effect of the designs of the AFO was not reported.

In another study, Simons, van Asseldonk, van der Kooij, Geurts, and Buurke (2009) used a repeated measures design to compare the effects of AFOs to no AFO on balance control, weight bearing asymmetry, and functional mobility in patients with stroke. Twenty participants with an average of 39 months (Range = 5–127 months) since the onset of stroke participated in this study. Each participant used the AFO that they owned and had used for an average of 34 months. The type of AFOs used by the participants were flexible or rigid. The flexible types were a polypropylene non-articulated AFO with a small posterior steel component and a polypropylene non-articulated AFO with two posterior steel components and an open heel. The rigid types were a polypropylene non-articulated AFO with large posterior steel component and an articulated metal AFO attached to the shoe. Measurements were taken in a random order on two separate days within a week; one time with their personal AFO and one time

without wearing their AFO. Weight bearing asymmetry was measured with a static posturographic test. Relative contribution of each individual's lower limb to balance control was tested using a dynamic posturographic test. Berg balance scale, timed up and go test, timed balance test (timed bilateral stance in five different positions), 10-meter walk test, and functional ambulation categories were evaluated to assess function. This study found no significant difference between wearing an AFO and not wearing the AFO on measures of weight bearing asymmetry and balance control ($p = .991$, $p = .380$ respectively). However, the functional tests ($p < .001$) all except for timed balance test ($p = .051$) showed statistically significant improvement while wearing the AFO compared not wearing the AFO. The investigators concluded that although wearing an AFO had no significant effect on weight bearing asymmetry and dynamic balance control of the paretic leg, it improves function through compensatory mechanisms (Simons et al., 2009). This study used 4 different designs of AFOs but did not compare for the effect of the different designs of AFO on the above variables.

Lewallen et al., (2010) evaluated the effects of three different designs of AFOs and no AFO on gait outcomes in 13 participants during the chronic phase of recovery (more than 8 months since onset). All participants were tested with three different designs of custom AFOs: (1) a solid AFO which prevented ankle dorsiflexion and plantar flexion; (2) an articulated AFO with Tamarack ankle joints and a plantar flexion stop at 90 degrees which allowed free dorsiflexion but no plantar flexion; (3) a PLS AFO which allowed graded amounts of both plantar flexion and dorsiflexion. The participants were

tested for step length on the affected and unaffected side, speed, and single support time. The results of this study showed significant differences between the solid AFO and all other AFO conditions for gait speed ($p < .001$), for unaffected side step length ($p < .001$) and affected side step length ($p < .05$). Differences between the orthotic conditions on single support time was not significant ($p > .05$). When asked about preference, 8 participants preferred the PLS AFO, 5 participants preferred the articulated AFO, and none preferred the solid AFO. Lewallen et al., (2010) recommended against the use of a solid AFO in the chronic stroke population. In the above described study, all AFO designs were custom made and likely had similar costs. It would have been important to also compare a less expensive, easily available over the shelf design AFO.

Slijper et al., (2012) compared the effects of a custom dynamic hinged AFO with a 90-degree plantar flexion stop with a prefabricated carbon AFO on gait distance, participant's perceived exertion, gait velocity, physiological cost index, and timed stairs test. The investigators also assessed participant's perceived confidence in using either of the AFOs. Median time since onset of stroke was 25 months (range = 7–312 months). Participants were tested using both types of AFO twice, a week apart. The first measurement was used only as a practice session and the measurements from the second visit were used for data analysis. Each participant had the custom AFO for a varied length of time, but the carbon AFO was given for a week to practice with. The order of testing was with the carbon AFO first, then the custom hinged AFO. Results of testing showed significant improvement in gait distance ($p = .019$), timed stair test ($p = .005$), and

perceived confidence with the type of AFO to walk in (p = .003) when using the dynamic hinged AFO compared to carbon AFO. No significant difference was found for physiological cost index (p = .320) and gait velocity (p = .127). Slijper et al., (2012) recommended use of the custom dynamic hinged AFO as the participants were more confident with the use of it to walk with than the carbon AFO. This study, however, did not provide equal practice time with each AFO. Slijper et al (2012) also did not randomize the order of testing, which might have contributed to a practice effect with participants performing better with the second AFO condition which was the custom hinged AFO.

In a multicenter randomized controlled trial, Everaert et al. (2013), investigated the effects of a functional electrical stimulation-based orthosis for foot drop called Walkaide and a conventional AFO on walking performance in 93 patients with stroke and foot drop. Figure-8 walking speed, physiological cost index, 10-meter walk test, perceived safety level, and device preference were evaluated. Average time since onset of stroke was 6.4 months. The study consisted of three groups with a crossover design for the first two groups. Participants in the first group used Walkaide first, then the conventional AFO. The second group used the conventional AFO first and then Walkaide, and the third group used only the conventional AFO in both phases. The crossover of devices in group one and two occurred at 6 weeks. Participants were tested at initial visit, then 3, 6, 9, and 12 weeks after. This study found that regardless of the type of AFO used, gait speed measured using the Figure-8 and 10-meter walk tests

improved over time in all groups but differences between the groups did not reach statistical significance. Significant difference between the types of device used was found only for physiological cost index. Physiological cost index was significantly better (lower) in the AFO only group compared to the Walkaide group (p = .032). Self-perceived safety in walking without using conventional AFO or Walkaide was higher in the Walkaide group than the conventional AFO group, but when using either the conventional AFO or the Walkaide, there was no difference in the perception of safety for walking. Walkaide was also the preferred device over the conventional AFO. In this study, the investigators did not give any information about the type of AFO used as the "conventional" AFO, and additionally, the study was funded by the Walkaide manufactures (Everaert et al., 2013).

Pardo, Galen, Gahimer and Goldberg (2015) studied the effects of a custom made articulated AFO, a prefabricated articulated AFO, and no AFO on gait and functional mobility in 14 individuals with stroke. Onset of stroke ranged from 2–48 months with an average of 13.5 months. Participants owned the custom AFO previously (not reported for how long) and the prefabricated AFO was provided at the time of testing. Gait speed, step length of both the paretic and non-paretic leg were measured using GAITRite walkway. Timed up and go test (TUG) and sit to stand on a force plate were also evaluated. All measurements were performed at a single visit with the participant's custom AFO, prefabricated hinged AFO, and with only shoes, but the testing order was randomized. The study did not report whether participants were provided any time to practice with the

prefabricated AFO. Results of this study found that there were significant differences between the no AFO condition and each of the 2 AFO conditions ($p < .05$) for gait speed, step length of the paretic and non-paretic leg, TUG, and sit to stand symmetry. However, no significant differences were noted between the custom articulated AFO and prefabricated articulated AFO for any of these outcome measures ($p > .05$) (Pardo et al., 2015). The design of both AFOs in this study had hinged joints at the ankle and could have contributed to similar gait mechanics which might have affected the outcomes of this study.

Tyson et al. (2018) investigated the effects of two designs of AFOs; a custom bespoke AFO and an over the shelf Posterior Leaf Spring AFO in participants with stroke in the chronic stage of recovery. In a 12-week randomized trial, 64 participants were assigned to the over the shelf PLS group and 62 participants to the custom bespoke group. Average time since onset for the bespoke group was 112 weeks and for the over the shelf group was 83 weeks. Measurements were taken at baseline, and at 6 weeks and 12 weeks follow up. There were no significant differences in gait speed and step length between the two designs of AFO at 6 weeks follow up ($p > .05$) or at 12 weeks follow up ($p > .05$). Participant satisfaction with using the AFOs was evaluated using a questionnaire and the satisfaction scores were in favor of the over the shelf AFO at the 6 week and 12 week follow up (no *p* values were reported) (Tyson et al., 2018). The design of the bespoke AFO was not provided in the study other than it was custom made by the

orthotist. Also, there was no training or practice recommendation after the AFOs were provided.

In a case series report, investigators observed that using a custom double adjustable AFO during the early stages of recovery after stroke resulted in more typical muscle activation patterns, gait endurance and velocity, and near normal symmetry during gait without an assistive device or an AFO in three participants. In this study the participants were trained early post stroke onset wearing of the double adjustable AFO One participant wore the AFO for 12 weeks, and the other two participants wore it for 8 weeks. The measurements reported were taken after over 6 months post wearing time with their AFO. The double adjustable AFO used in this study has springs in the posterior channel which provides dorsiflexion assist during swing phase and initial contact and provides plantar flexion resistance during loading response. The pins present in the anterior channel allow tibial advancement during stance phase and thus facilitate firing of the calf muscles as in a normal gait cycle. McCain et al., (2012) suggested that the design of the double adjustable AFO provided more peripheral mechanical input to facilitate pre-injury motor function than the compensatory gait pattern typically seen when wearing an AFO. The design of the AFO described in this case series looks promising to improve gait outcomes. Therefore, the effects of the double adjustable AFO used in this case series needs to be investigated more thoroughly.

Gait Outcomes with AFOs in the Subacute Stage of Stroke Recovery

Rao et al., (2008) investigated the immediate effects of using an AFO on temporospatial gait parameters in 13 participants in the acute phase of stroke recovery (mean time since stroke onset 0.68 months) and in 27 participants in the chronic phase of stroke recovery (mean time since stroke onset 50.76 months). Participants in the acute phase received their custom polypropylene AFO less than 5 days prior to testing, while the participants in the chronic phase had already been using their AFO for at least a month. Results of this study found that gait velocity and cadence were significantly better in both groups with AFO ($p < .001$) when compared to not using an AFO. Similarly step length of the affected and unaffected side improved significantly in both groups ($p < .001$) when using the AFO compared to not using the AFO. Rao et al., (2008) concluded that use of an AFO significantly improves gait velocity, cadence, and step length in patients with stroke in the acute and chronic phases of recovery. In this study, participants were reported to have received a custom AFO, but no information was provided on the design of the AFO.

In another study, Carse et al. (2015) investigated the immediate spatiotemporal and kinematic effects of a custom solid AFO compared to no AFO in patients 3 weeks post stroke onset. Eight participants received the custom solid AFO. Baseline measurements were taken at the time of casting without the AFO but with shoes. A week later, a second measurement was taken with the custom AFO. Results showed significant improvement in walking velocity ($p = .021$), average step length ($p = .021$) and cadence

(p = .042) when wearing the AFO compared to wearing no AFO. Although step symmetry improved, it was not significantly improved (p = .082). There were no changes in hip and knee kinematics (Carse et al., 2015). Although this study showed improvement when using an AFO compared to no AFO on measures of temporospatial gait parameters, retesting using the AFO was done one week later. Time is an important variable in the early stage of stroke recovery; however, this study did not address the effect of time at all. Additionally, with the design of the AFO being a rigid solid AFO, not allowing ankle mobility could be the reason for the lack of change in hip and knee kinematics.

Hyun et al., (2015) investigated effects of using an AFO compared to no AFO on aerobic capacity during the subacute stage of recovery. Fifteen individuals within 3 months onset of stroke participated in this study. Participants were tested with a custom molded posterior leaf plastic AFO and without an AFO while performing a graded exercise test on a treadmill. The order of testing was randomized, but the measurements with each AFO were done 48 hours apart. Significant differences were found for peak VO_2 and 6 minute walk test scores ($p < .05$), in favor of AFO use (Hyun et al., 2015). This study also agrees with most of the other reported studies of improved outcomes with use of an AFO compared to no AFO.

In a randomized trial, de Sèze et al. (2011) evaluated the effects of using two different types of AFOs during the subacute stage of stroke recovery, less than 6 months following stroke onset. The investigators evaluated the effects of a custom Chignon AFO, which is an articulated AFO with adjustable elastic straps, compared to an off the shelf

polypropylene AFO. Thirteen participants were randomized to the Chignon group and 15 participants to the off the shelf AFO group. Participants were measured three times: on the first day the AFO was provided, 30 days after, and 90 days after. The outcomes measured were gait speed, ankle range of motion, spasticity, and quality of gait through observational gait analysis. Results of this study showed that the gain in gait speed on the 10-meter walk test when compared to wearing no AFO was significantly higher in the Chignon group compared to the over the shelf AFO group at baseline (p = .0006), after 30 days (p = .0004) and at 90 days (p = .04). However, the difference between the AFOs were not significant. The ankle dorsiflexion range of motion was significantly better in the Chignon group at the 90-day measurement than the off the shelf AFO group (p = 0.01). Additionally, participants in the Chignon AFO group had significantly lower spasticity at 90 days (p = .01) than the polypropylene AFO group as measured by percentage of patients taking oral medications for spasticity (de Sèze et al., 2011). Since the two AFO designs compared were used in two different groups, individual differences in participant characteristics in the two groups may have contributed to the reported effect. Though participants were randomized, eight participants in the polypropylene AFO group were using medications for spasticity management at baseline, whereas in the Chignon group only 3 participants were using medications for spasticity management at baseline. Since spasticity of the lower extremity muscles can affect gait mechanics and ankle range of motion, the over the shelf group having higher spasticity might have affected the results.

Summary

Stroke is a leading cause of disability in the United States. With advancement in medical and surgical procedures, mortality rates have significantly reduced in the past few decades following stroke. The impairments, activity limitations and participation restrictions can vary extensively following stroke based on the type and location of stroke. The majority of functional recovery following stroke occurs within the first 6 months following onset. There are various approaches to rehabilitation ranging from neurophysiologic approaches to task specific approaches. One of the important goals for stroke survivors is to resume independent functional ambulation. Foot drop is a common impairment which affects safe walking in individuals recovering from stroke. AFO is a commonly prescribed device to correct foot drop to improve walking. A review of the literature shows that in the chronic stage of recovery, various types of AFOs improve gait outcomes and balance when compared to the no AFO condition. Although a majority of functional recovery occurs within 6 months following onset, very few studies have been conducted during that stage. Furthermore, most of the reported studies conducted during the subacute stage of recovery following stroke evaluated the effectiveness of the use of an AFO compared with no AFO.

There are different designs of AFOs available for clinicians to choose from. Only one reported study randomly evaluated the effectiveness of two different types of AFOs in the subacute stage. One additional case series used a double adjustable AFO design, which they claim to have promoted a typical gait pattern in 3 participants in the subacute

phase of stroke recovery. Although the case series provided descriptive results of using the double adjustable AFO, the research design is considered weak. Therefore, it is important to further investigate the effects of the double adjustable AFO design with a stronger research design on various gait parameters.

CHAPTER III

METHODS

The purpose of this study was to identify whether patients in the subacute stage of stroke, who demonstrate foot drop, would have better gait outcomes when using a custom DA AFO or an over the shelf PLS AFO. A secondary purpose was to determine whether one week of practice significantly changes gait outcomes under either of the AFO conditions when compared to baseline. This experimental study used a within subject repeated measures design. The manipulated independent variables in the study were 1) type of AFO with two levels: (a) double adjustable AFO and (b) posterior leaf spring AFO; and 2) practice time with 2 levels: (a) baseline (eg.no practice), and (b) after 1 week of practice. The dependent variables in this study were the following: gait endurance measured by 6 Minute Walk Test (6MWT), gait symmetry measured using GAITRite gait analysis system, gait velocity measured using GAITRite gait analysis system and patient report of which AFO they preferred to walk with. This chapter describes the methods used in the study including participant recruitment, a description of instruments that were used, testing procedures and data analysis techniques.

Participants

Twenty participants over the age of 18, of any gender and ethnicity, diagnosed with first time unilateral stroke resulting in hemiparesis with foot drop were recruited.

The number of participants was estimated based on previously reported studies. Using a repeated measures design, Hyun et al., (2015) found significant differences in gait endurance measured by 6MWT when using an AFO compared to using no AFO in 15 participants (Hyun et al., 2015). In another repeated measures design study by Carse et al, (2015) gait velocity and gait symmetry were found to be significantly better in eight participants when they were using an AFO compared to not using an AFO. Therefore, for our study, the potential participant number was projected as 20. Since the target population for this study was persons with stroke who were in the subacute phase of recovery, an additional inclusion criterion was that participants had to be 4 to 20 weeks post-stroke at time of entry into the study.

Participants were recruited through a sample of convenience from Baylor Institute for Rehabilitation in Frisco, Texas and from Pate Rehabilitation in Dallas, Texas. The physical therapists at these locations were given a brief description of the proposed study and were asked to screen for potential participants. If the potential participant met inclusion criteria and did not possess any of the exclusion criteria and was interested in learning about the study, the physical therapist asked the potential participant permission to be contacted by the primary investigator. If the potential participant gave permission, then the physical therapist contacted the primary investigator with the patient information. The primary investigator then met with the patient to provide more information about the study. A participant information sheet was used to assist in screening participants for inclusion and exclusion criteria (see Appendix C). Potential

participants who were not able to receive a double adjustable AFO through their insurance, who were not able to follow two-step commands, or not able to ambulate 20 feet with or without assistive device with no more than contact guard assistance, were excluded from the study. The two-step command used to assess the ability to follow the two-step command was “please stand up and walk to the door.” Additionally, participants with a diagnosis of cerebellar stroke and participants who were not ambulatory prior to stroke onset were disqualified from participation. Participants undergoing chemotherapy at the time of study initiation were also excluded.

Participants who met the inclusion criteria and possessed none of the exclusion criteria were asked to volunteer for the study. Participants who wished to participate read or were read their rights as human subjects and asked to sign the informed consent approved by the Institutional Review Boards (IRB) of both Baylor Health Care System and Texas Woman’s University prior to enrollment in this study (See Appendix D). Prior to getting the consent, each participant was assessed with the Mini Mental State Exam (Rovner & Folstein, 1987), in order to make sure the participant understood the consent as required by the Baylor Health Care System IRB. Participants scoring 21 or more, could sign the consent themselves. Otherwise, a legally authorized representative had to sign the consent. Qualified participants were scheduled for data collection on the day they received their custom Double Adjustable AFO at the location which was convenient to the participant.

Research Design

The research design for this experimental study was a 2 factor within subject repeated measures design with 2 levels of AFO conditions (PLS AFO and DA AFO), and 2 levels of practice time (baseline and after 1 week of practice).

Measurements

a) *Gait endurance* was measured using the 6MWT. Reliability and validity of the 6MWT has been previously established in patients with stroke in the subacute stage of recovery. The 6MWT was highly correlated with gait speed in a 5-meter walk test (r = .89). The test retest reliability of the 6MWT was reported using an intraclass correlation coefficient (ICC = .97) (Fulk, Echternach, Nof, & O'Sullivan, 2008). In our study, participants were asked to ambulate as far as possible in 6 minutes at a self-selected walking velocity. The distance ambulated during the six minutes was measured in feet using a measuring wheel and then converted to meters for data analysis.

b) *Gait Symmetry* was measured using the temporospatial measurements from the GAITRiteTM (CIR systems, Havertown, PA, USA, 2013) computerized gait analysis system. The GAITRite walking system used in this study was a 16 feet (488 cm) long x 3 (92 cm) feet wide portable walkway with embedded pressure sensors at 1.27 cm intervals along the length of the walkway. As the participant ambulated on the walkway, the pressure of the foot activated the sensors that record the person's steps, sampling at 1000 Hz. These measurements were then sent to a computer program that analyzes the specified temporal spatial parameters using an algorithm built into the special software.

This data was saved and exported to Microsoft Excel where the data was further analyzed (CIR systems Inc., Franklin, NJ). Previous studies support the GAITRite as a valid and reliable method of measuring temporal and spatial parameters (ICC = .99, and .93) (Bilney, Morris, & Webster, 2003; McDonough, Batavia, Chen, Kwon, & Ziai, 2001). Step symmetry was calculated using the ratio of the affected step length to the unaffected step length during self-selected velocity walk and fast-paced velocity walk, with perfect symmetry defined as 1.0.

c) *Gait velocity* in cm/sec was also assessed using the temporospatial measurements from the GAITRiteTM computerized gait analysis system for the self-selected pace walk and fast-paced walk. Gait velocity was converted from cm/sec to meter/sec for data analysis. Measures of gait velocity obtained from the GAITRite system have been shown to have excellent agreement with the 10 Meter Walk Test (Cronbach's alpha = .99) in patients with brain injury (Vartiainen, Savolainentyso, & Alaranta, 2009).

Procedures

This study is in compliance with the recommendations regarding human participants and in accordance with the ethical standards of Baylor Health Care System and Texas Woman's University Institutional Review Boards. Measures of gait endurance, gait symmetry and gait velocity were obtained from each participant during three testing sessions. All measurements were taken by only one researcher to avoid inter tester reliability issues.

On the day participants received their custom DA AFO, the first set of measurements was taken. The primary investigator collected demographic data including age, height, weight, and leg length measurements on each side. The Fugl-Meyer Lower Extremity Assessment of sensorimotor function was also administered to each participant for descriptive data (Fugl-Meyer, Jääskö, Leyman, Olsson, & Steglind, 1975). Then the gait outcomes were measured using one of the two AFO conditions in random order. Two possible orders were written on pieces of paper and an equal number of possible order selections were put in a hat. The participant selected the order of AFO condition by drawing out of the hat. Randomization without replacement was used to assure an equal number of participants in each order sequence. Once the order of AFO wearing was determined, baseline data was collected in the randomly selected order. Participants were allowed to use any type of assistive device of their choice if needed, but the same device was used for all conditions.

First, the 6MWT was administered with the participant wearing the first randomized AFO. Participants were asked to ambulate as far as possible in 6 minutes at a self-selected walking velocity through a well-lit indoor corridor. They were informed when half of the time was over, otherwise no verbal cueing or encouragement were provided. The distance ambulated was measured using a measuring wheel in feet and was converted to meters for data analysis. A seated resting break was provided before the next measurement is taken.

Next, gait symmetry and gait velocity measurements were obtained using the GAITRiteTM system. Participants were given a practice trial walk prior to beginning of the testing. Participants were asked to walk at their comfortable self-selected walking velocity along the walkway. They began walking three meters from the start of the walkway and were stopped walking two meters past the end of the walkway. The beginning and end of the walking area were clearly marked with colored tape or large objects such as cones for visibility. The verbal instruction was "Please walk from this line/cone to that line/cone at your comfortable speed safely." A second person was walking close to the participant outside of the walkway to ensure safety. Three trials of walking were completed at self-selected velocity. After a sitting break, participants were asked to walk as fast as they could safely. The verbal instruction was "Please walk from this line/cone to that line/cone as fast as you can safely." Again, three trials of walking were performed at the fast-paced velocity. The GAITRite system was able to capture both gait symmetry and gait velocity measurements with the same walk. The calculated mean of the three trials was used for data analysis. After a 10-minute seated rest break, the second AFO condition was used and measurements were repeated in the same order described above, to conclude baseline measurements.

To assess the effects of practice on the gait measures, AFO's were randomized for practice. That is, participants were randomized for which AFO they wore first for a week of walking practice before the subsequent measurements. Participants were randomized for which AFO they would wear first (the PLS or the DA AFO), by drawing out of a hat.

Again, a randomization without replacement technique was used. Then the participant was provided with the selected type of AFO to practice with for the following week using a prescribed wearing schedule (see Appendix E). After the one-week practice time, the primary investigator obtained the same measurements obtained at baseline with the participant wearing the type of AFO that was used to practice the week before. The same testing conditions and order of testing that were used at baseline were employed. Once measurements were completed, the participant was asked to wear the second type of AFO and to practice with it for one week using the same prescribed wearing schedule as before. Final measurements were taken after completion of the one-week practice using the second type of AFO with the same testing conditions and order. At the conclusion of testing, each participant was asked which AFO was preferred to use for his or her daily ambulatory needs. That information was used for descriptive analysis.

Data Analysis

Data were analyzed using the 25.0 version of SPSS for Windows (SPSS Inc., Chicago, IL). Descriptive statistics were calculated for all demographic and participant characteristic data including participant's age, height, weight, time since onset, Mini Mental State Exam Score, type of assistive device used, location of stroke, affected side and Fugl Meyer Lower Extremity Assessment score. Means and standard deviations were calculated for all dependent variables. The assumption of normality was tested for each dependent variable using the Shapiro-Wilk test.

Differences in the dependent variables between the two AFO conditions at baseline were analyzed using paired *t* tests. Differences in gait endurance between the two AFO conditions and two practice conditions were analyzed using a 2x2 repeated measures ANOVA. Differences in gait symmetry, and gait velocity between the two AFO conditions and two practice conditions were analyzed using two separate 2x2 repeated measures MANOVA. An alpha level of .05 was used to determine significance of differences. Effect size was calculated using partial eta squared for the repeated measures analyses. Descriptive statistics were also calculated for the participant's preferred AFO for daily ambulation.

CHAPTER IV

RESULTS

Gait rehabilitation is a key component in the rehabilitation of patients with stroke resulting in hemiparesis and foot drop. AFOs have been shown to be an effective intervention in the chronic stage of stroke recovery to improve various gait parameters (Tyson et al., 2013; Tyson & Kent, 2013). Although, it is reported that most of the functional improvements occur within 6 months of stroke (Kwakkel et al., 2004), the effect of early bracing with different types of AFOs on gait outcomes have not been investigated thoroughly. The purpose of this study was to identify whether patients in the subacute stage of stroke, who demonstrate foot drop, would have better gait outcomes when using a DA AFO, or a PLS AFO. A secondary purpose was to determine whether one week of practice significantly changes gait outcomes with either of the AFO conditions compared to baseline. This chapter provides a description of the subjects who participated in this study. Next, descriptive data are provided for the measures of gait endurance, gait symmetry and gait velocity. Finally, the inferential statistics of this study are reported.

Participants

The primary investigator screened a total of 26 potential participants. Three of the 26 potential participants contacted the primary investigator through the website

www.clinical trials.gov. However, because their foot drop was not related to stroke, they did not meet the inclusion criteria. After the physical therapists at the two locations (Baylor Institute for Rehabilitation, Frisco and Pate Rehabilitation, Dallas) performed the initial participant screening and informed the primary investigator, the primary investigator contacted 23 participants and consented them to participate in the study. However, only 20 participants completed the study. Two participants were severely fatigued after the first 6MWT and could not complete the rest of the measurements on the first day. One of them was also receiving chemo therapy which caused the severe fatigue. The third person dropped out of the study as he had another stroke. Out of the 20 participants who completed the study, 9 were women and 11 were men. One participant had hemorrhagic stroke while the other 19 had ischemic stroke. The location of the stroke for participants was as follows: 5 at the pons, 5 at the basal ganglia, 5 e at the middle cerebral artery, 2 at the internal capsule, 1 person at the anterior cerebral artery, and 1 person at both basal ganglia and internal capsule. Ten participants had hemiplegia and foot drop on the right side and the other 10 had left side involvement. Eight participants used a rolling walker, 6 participants used a single tip cane, 2 participants used a quad cane, 1 participant used a hemi walker and 3 participants did not use any assistive device for all testing. A summary of characteristics of subjects who completed the study can be found in Table 2.

Table 2

Description of Subjects

Characteristic	*M*	*SD*	Min	Max
Age (year)	57.5	12.0	30.0	81.0
Height (cm)	171	12	150	193
Weight (kg)	84.55	18.70	49.90	125.66
Number of days from onset	60	26	29	133
MMSE	29.2	1.0	27.0	30.0
Fugl Meyer LE Motor Score	22.5	2.98	16	27
Fugle Meyer Sensory Score	23.75	0.72	21	24

Note: N=20; MMSE = Mini Mental State Exam; LE= Lower Extremity

The assumption of normality for all dependent variables was tested using the Shapiro-Wilk test and all were found to meet the assumption. Please see Table 3 for the descriptive statistics for gait endurance, gait symmetry and gait velocity measurements at baseline and after one week of practice.

Table 3

Descriptive Statistics for Gait Endurance, Gait Symmetry and Gait Velocity at Baseline and After One-Week of Practice

	Baseline		After one-week practice	
Variable	*M*	*SD*	*M*	*SD*
6MWT DA AFO (m)	203.44	101.19	255.07	99.62
6MWT PLS AFO (m)	195.15	85.83	235.53	88.08
DA AFO SSV gait symmetry	1.16	0.27	1.12	0.19
PLS AFO SSV gait symmetry	1.18	0.36	1.10	0.24
DA AFO FPV gait symmetry	1.18	0.29	1.16	0.23
PLS AFO FPV gait symmetry	1.22	0.37	1.11	0.23
DA AFO SSV gait velocity (m/sec)	0.58	0.26	0.70	0.29
PLS AFO SSV gait velocity (m/sec)	0.58	0.26	0.66	0.27
DA AFO FPV gait velocity (m/sec)	0.80	0.38	0.95	0.36
PLS AFO FPV gait velocity (m/sec)	0.78	0.36	0.91	0.35

Note. *N*=20; 6MWT = Six Minute Walk Test; DA AFO = double adjustable AFO, PLS AFO = posterior leaf spring AFO; SSV=self-selected velocity, FPV=fast-paced velocity

Statistical Tests of Significances

In order to test the first hypothesis of difference in gait endurance, gait symmetry and gait velocity between the two AFO conditions at baseline, a paired *t*-test for each dependent variable was analyzed. No significant difference was found for gait endurance measurements at baseline measured by 6MWT between the two AFO conditions $t(19) =$

1.08, p = .293. Gait symmetry measurements were also not significant at baseline for self-selected velocity (SSV) $t(19)$ = -.41, p = .688, and fast-paced velocity (FPV) $t(19)$ = -1.16, p = .260. No significant differences were found for gait velocity at baseline between the two AFO conditions at SSV $t(19)$ = -0.02, p = .981 or FPV $t(19)$ = 0.80, p = .432.

The hypothesis of significant differences in gait endurance measurements, gait symmetry measurements and gait velocity measurements after one-week practice when using either custom DA AFO or over the shelf PLS AFO was tested using repeated measures analysis. The significance of differences in gait endurance was analyzed using a 2 x 2 repeated measures ANOVA. Since there were only two levels of the variables, the assumption of sphericity was met. The interaction between the type of AFO and practice time was not significant $F(1, 19) = 3.51$, p = .077, η_p^2= .156. However, the main effect of the type of AFO was significant $F(1, 19) = 4.58$, p = .046, η_p^2= .194 and the main effect of practice was also significant $F(1, 19) = 43.94$, $p < 0.001$, η_p^2 = .698. A significant main effect of AFO indicates that when comparing the DA AFO to PLS AFO when combining the baseline and 1-week practice time values, there is a significant difference between the AFO types. A significant main effect of practice time indicates that regardless of the AFO type, there is a significant difference between the baseline measures and the 1-week practice measures. That is, when measures of 6MWT while wearing the DA AFO and the PLS AFO are combined, there is a significant difference between baseline measures and measures taken after 1 week of wearing the AFO.

The significance of differences in gait symmetry, and gait velocity between the two AFO conditions and two practice conditions were analyzed using two separate 2 x 2 repeated measures MANOVA. For gait symmetry, the interaction effects between type of AFO and practice time were not significant at the SSV $F(1, 19)= 0.75$, $p = .397$, $\eta_p^2 = .038$ or FPV $F(1, 19) = 2.76$, $p = .113$, $\eta_p^2 = .127$. The main effect of practice on gait symmetry was not significant at either the SSV $F(1, 19) = 2.79$, $p = .111$, $\eta_p^2 = .128$ or the FPV $F(1, 19) = 3.50$, $p = .077$, $\eta_p^2 = .155$. The main effect of AFO type on gait symmetry was also not significant at either the SSV $F(1, 19) = 0.004$, $p = .950$, $\eta_p^2 = .00$ or the FPV $F(1, 19) = 0.01$, $p = .918$, $\eta_p^2 = 0.001$.

The repeated measures MANOVA for the analysis of differences in gait velocity revealed that the interaction effects between the type of AFO and practice time were not significant at the SSV $F(1, 19) = 1.69$, $p = .209$, $\eta_p^2 = .082$ or FPV $F(1, 19) = 1.24$, $p = .280$, $\eta_p^2 = .61$. However, the main effect of practice was significant for both the SSV $F(1, 19) = 14.38$, $p = .001$, $\eta_p^2 = .431$ and FPV $F(1, 19) = 23.73$, $p < .001$ $\eta_p^2 = .555$. A significant main effect of practice indicates that regardless of the AFO type, there is a significant difference between the baseline measures and the 1-week practice measures. That is, when measures of gait velocity while wearing the DA AFO and the PLS AFO are combined, there is a significant difference between baseline measures and measures taken after 1 week of wearing the AFO at both self-selected velocity and fast paced velocity. The main effect of the type of AFO was not significant for either the SSV $F(1, 19) = 1.05$, $p = .32$, $\eta_p^2 = .05$ or FPV $F(1, 19) = 3.63$, $p = .072$, $\eta_p^2 = .16$, velocities.

Since the interaction was not significant for any of the variables, simple effects analysis could not be performed. The following graphs were created to have a descriptive understanding of all the dependent variables with raw data. The differences in gait endurance measurements between the two AFOs at baseline and after 1-week of practice are shown in Figure 1. The differences in gait symmetry measurements between the two AFOs at base line and after 1-week of practice for self-selected velocity can be found in Figure 2. The differences in gait symmetry measurements between the two AFOs at baseline and after 1-week of practice for fast paced velocity can be found in Figure 3. The differences in gait velocity measurements between the two AFOs at baseline and after 1-week of practice for self-selected velocity can be observed in Figure 4. The differences in gait velocity measurements between the two AFOs at baseline and after 1-week of practice for fast paced velocity can be observed in Figure 5.

At the conclusion of the study, each participant was asked which AFO they preferred to walk with. Sixteen participants reported that they preferred the DA AFO and 4 participants reported that they preferred the PLS AFO for their daily walking needs.

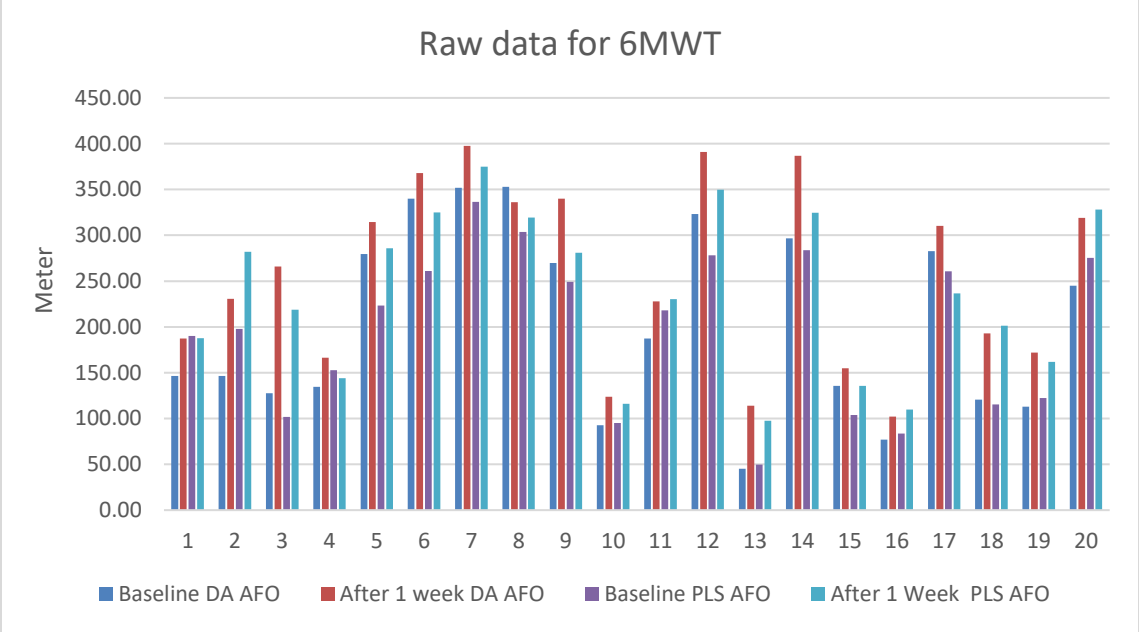

Figure 1. Gait endurance at baseline and after 1-week of practice.

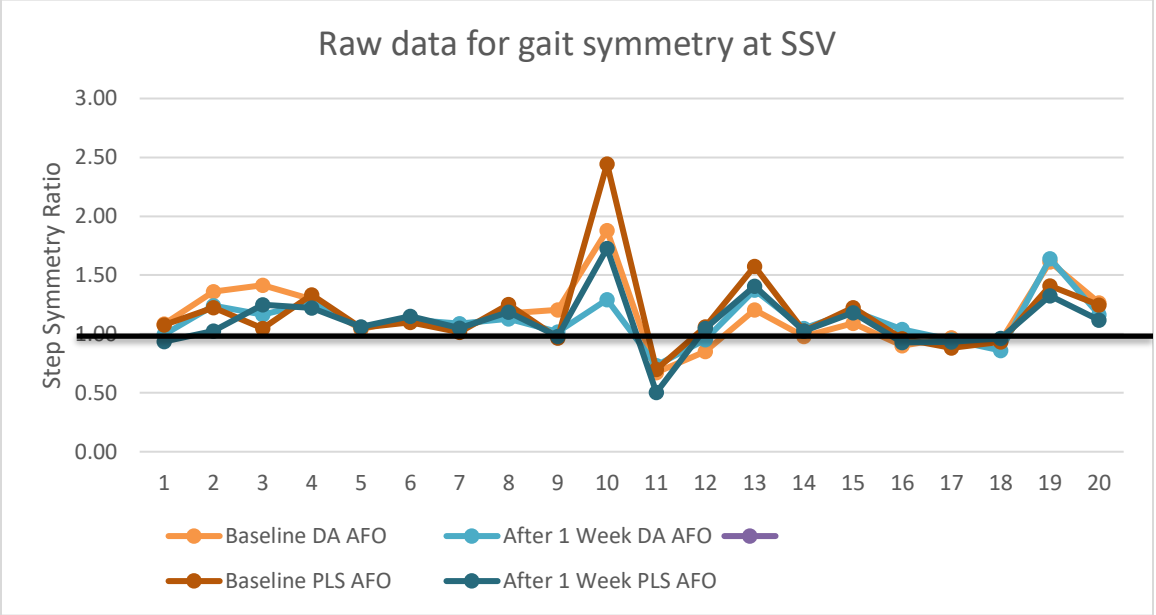

Figure 2. Gait symmetry with self-selected velocity at baseline and after 1-week of practice.

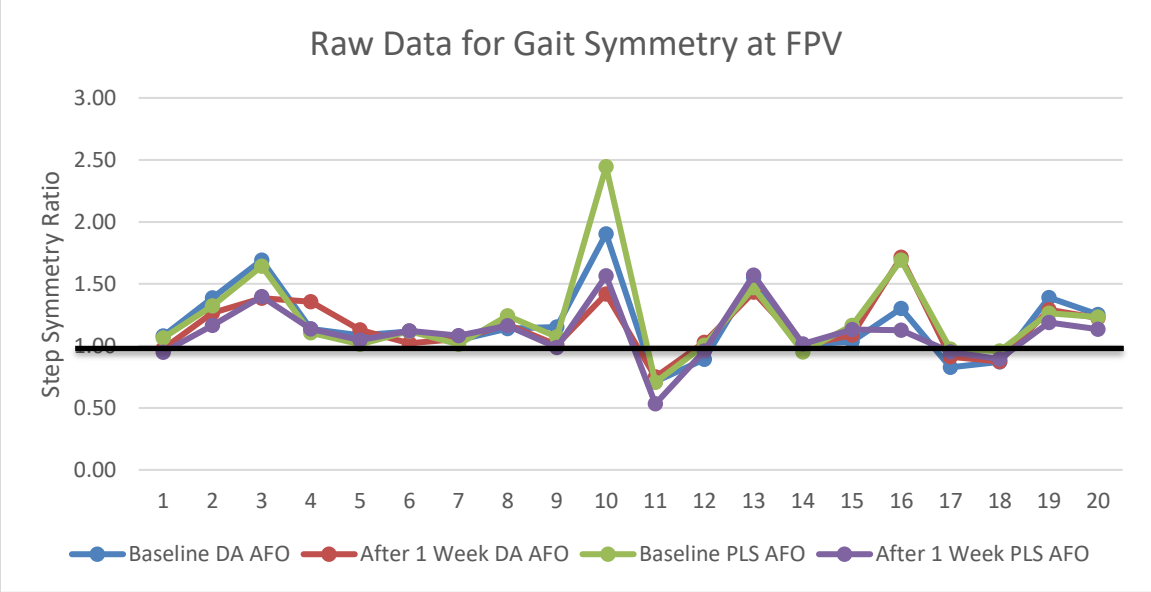

Figure 3. Gait symmetry with fast-paced velocity at baseline and after 1-week of practice

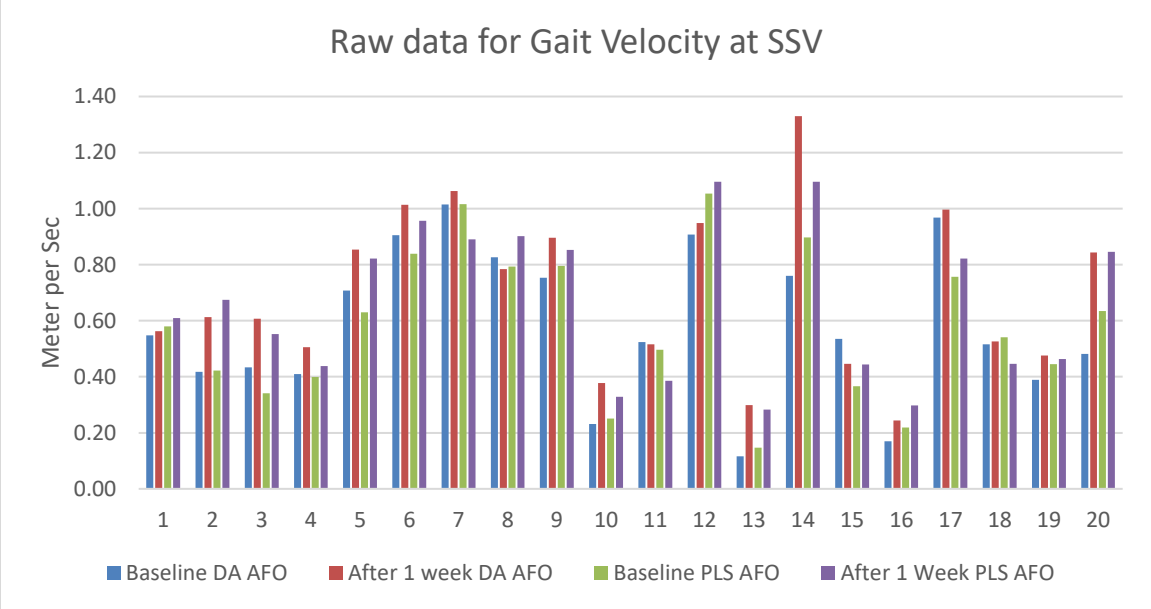

Figure 4. Gait velocity with self-selected velocity at baseline and after 1-week of practice

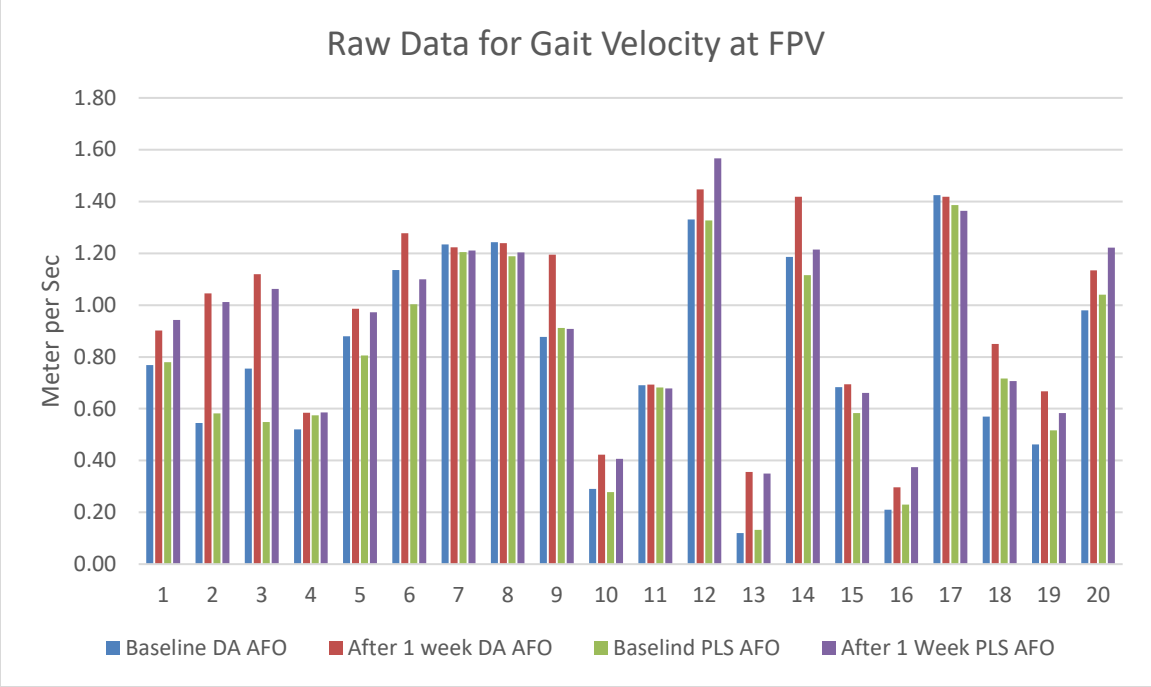

Figure 5. Gait velocity with fast-paced velocity at baseline and after 1-week of practice

Summary

Twenty participants who were in the sub-acute stage post stroke with foot drop who met the inclusion criteria and possessed none of the exclusion criteria completed this study. Demographic data for the 20 participants who completed the study were summarized.

Paired *t*-tests used to compare the differences in gait endurance, gait symmetry and gait velocity were not significant at baseline between the two AFO conditions. The 2 x 2 repeated measures ANOVA used to test the significance of difference in gait endurance between the two types of AFOs from baseline to after one week of practice revealed that there was no significant interaction between the type of AFO and practice

time. However, there was a significant difference for the main effect of AFO and for the main effect of practice. A significant main effect of AFO indicates that when comparing the DA AFO to PLS AFO when combining the baseline and 1-week practice time values, there is a significant difference between the AFO types. A significant main effect of practice time indicates that regardless of the AFO type, there is a significant difference between the baseline measures and after the 1-week practice measures. The repeated measures MANOVA used to analyze differences in gait symmetry within the group did not show statistically significant differences. Similarly, the repeated measures MANOVA used to analyze differences in gait velocity within the group did not show a statistically significant interaction between the type of AFO and practice. However, there was a significant main effect of practice for both self-select and fast paced velocity. A significant main effect of practice indicates that regardless of the type of AFO used, there was a significant difference in gait velocity after one week of practice. Charts were created for descriptive analysis. At the conclusion of the study, 16 participants reported preferring DA AFO for their walking and 4 participants preferred PLS AFO for their walking.

CHAPTER V

DISCUSSION

Difficulty in walking independently is reported as the most disabling consequence of stroke by the survivors (Pound et al., 1998). Patients with stroke resulting in hemiparesis and foot drop often have difficulty with walking due to decreased foot clearance in swing phase, and decreased weight acceptance in stance phase which results in step asymmetry, wide base of support, poor knee control and propulsion (Verma et al., 2012). An AFO is a device commonly prescribed to improve foot clearance in swing phase, initial contact and lateral stability in stance phase of gait ((Jørgensen et al., 1995; Kwakkel et al., 2004). A majority of the reported studies have looked at the effect of an AFO in the chronic phase of rehabilitation post stroke. Most of the gait recovery has been reported to occur in the subacute stage post onset of stroke. Additionally, there are a variety of designs of AFOs available for clinicians to use, but their effectiveness on gait outcomes during the subacute phase of rehabilitation have not been studied thoroughly. The purpose of this study was to identify whether patients in the subacute stage of stroke, who demonstrate foot drop, would have better gait outcomes when using a DA AFO or a PLS AFO. A secondary purpose was to determine whether one week of practice significantly changes gait outcomes under either of the AFO conditions when compared to baseline.

This chapter presents a summary of findings, followed by a discussion of the findings related to each dependent variable. The conclusion is presented next with limitations, clinical significance and recommendations for future study.

Summary of Findings

Research Question One

The first research question posed in this study was the following: Would there be a difference in gait endurance, gait symmetry and gait velocity measurements at baseline when using either a custom Double Adjustable AFO compared to an over the shelf Posterior Leaf Spring AFO in patients in the subacute stage of stroke? In order to answer this question a hypothesis was formulated. The null hypothesis is stated and the results of the study that support rejection or failure to support rejection of the hypotheses are presented.

Null hypothesis one. There would be no significant differences in gait endurance measurements, gait symmetry measurements, and gait velocity measurements at baseline, when using a custom Double Adjustable AFO (DA AFO) compared to over the shelf Posterior Leaf Spring AFO (PLS AFO) in patients in the subacute stage of stroke.

Results: Failure to reject the null hypothesis. Paired *t*-tests were performed to analyze the differences between the DA AFO and PLS AFO on measures of gait endurance, gait symmetry and gait velocity at baseline. No significant differences were

found for gait endurance measurements, gait symmetry measurements at both self-selected velocity (SSV) and fast-paced velocity (FPV) and gait velocity at SSV and FPV at baseline.

Research Question Two

The second research question posed in this study was the following: Would there be differences in gait endurance, gait symmetry and gait velocity measurements after a week of practice when using either a custom Double Adjustable AFO or an over the shelf Posterior Leaf Spring AFO in patients in the subacute stage of stroke? In order to answer this question a hypothesis was formulated. The null hypothesis is stated and the results of the study that support rejection or failure to support rejection of the hypotheses are presented.

Null hypothesis two. There would be no difference in gait endurance measurements, gait symmetry measurements and gait velocity measurements after a week of practice when using either custom Double Adjustable AFO or over the shelf Posterior Leaf Spring AFO in patients in subacute stage of stroke.

The above stated null hypothesis assesses five dependent variables: gait endurance, gait symmetry at SSV and FPV, and gait velocity at SSV and FPV. The following section reviews the results of each of these variables.

Gait Endurance. A repeated measures ANOVA revealed no significant interaction effect between the type of AFO and practice time for gait endurance.

However, the main effect of the type of AFO was significant, and the main effect of practice was also significant.

Gait Symmetry. The significance of differences in gait symmetry with self-selected velocity and fast-paced velocity walks between the two AFO conditions and two practice conditions were analyzed using a separate 2 x 2 repeated measures MANOVA. No significant interaction and no significant main effects for AFO or practice were found for both self-selected velocity and fast-paced velocity walks.

Gait Velocity. The repeated measures MANOVA analysis of differences in gait velocity revealed that the interaction effects between the type of AFO and practice time were not significant at the self-selected velocity and fast paced velocity. However, the main effect of practice was significant for both the self-selected velocity and fast-paced velocity. The main effect of the type of AFO was not significant for either the self-selected velocity or fast-paced velocity.

Results. Reject the second null hypothesis for differences in gait endurance and gait velocity measurements after one week of practice when using either the custom DA AFO or over the shelf PLS AFO in participants in subacute stage of stroke recovery. Failure to reject the second null hypothesis for differences in gait symmetry after one week of practice when using either the custom DA AFO or over the shelf PLS AFO in participants in subacute stage of stroke recovery.

The results of this study failed to reject null hypotheses 1, and null hypothesis 2 for gait symmetry. The results do support rejection of null hypothesis 2 for gait endurance and gait velocity at the self-selected velocity and fast-paced velocity. Based on these findings, the research questions can be answered as follows: Participants with stroke in the subacute stage of recovery, who had foot drop did not differ significantly in gait endurance, gait symmetry and gait velocity measurements when using DA AFO or PLS AFO at baseline. Participants with stroke in the subacute stage of recovery, who had foot drop did not have a significant interaction for gait endurance, gait symmetry and gait velocity measurements when using either DA AFO or PLS AFO after one week of practice compared to baseline.

However, there was a significant difference for the main effect of practice for gait endurance and gait velocity. That is, regardless of the AFO type, there was a significant difference between baseline measurements and measures taken after 1 week of wearing the AFO for gait endurance, and gait velocity at both self-selected velocity and fast paced velocity. There was also a significant difference for the main effect of the type of AFOs for gait endurance. That is, when comparing the DA AFO to the PLS AFO when combining the baseline and 1-week practice time values, there is a significant difference between the AFO types. There were no significant differences found for interaction or main effects for gait symmetry between the AFO types after practice.

Discussion of Sample Characteristics

Twenty participants completed this study. Fifteen participants were recruited from Baylor Institute for Rehabilitation, Frisco locations and 5 participants from Pate Rehabilitation, Dallas location. Although all participants were recruited from the Dallas metroplex area, it is assumed that these subjects do not differ from patients with stroke and foot drop during the subacute stage, in other parts of the country. That is, it is assumed that the sample of subjects in the current study is representative of the population of patients who had stroke and foot drop during the subacute stage of recovery.

The mean of the Fugl-Meyer Lower Extremity (LE) Motor subscale score was 22.5 out of the total possible score of 34. The Fugl-Meyer LE Motor subscale is reported as an appropriate measurement scale for quantifying LE motor impairment in patients with stroke (Park & Choi, 2014). In this study we used the Fugl-Myer LE Motor subscale to describe the participant's LE motor impairment which was considered moderate impairment (Duncan et al., 2000). Moderate lower extremity motor impairment along with foot drop present a clinical indication for AFO use to improve gait outcomes. In our study, nine participants had motor impairments of the hip with difficulty with flexion and or extension and 19 participants had impairments with difficulty with isolated flexion of their knee. Since the participants in the current study had moderate lower extremity motor impairments, in addition to the foot drop, this may also have affected their walking ability, during the testing.

All participants were receiving some form of physical therapy at the time of study participation. Two participants were receiving in-patient rehabilitation, one participant transitioned from in-patient rehabilitation to outpatient rehabilitation, four participants were receiving outpatient rehabilitation and 13 individuals were participating in neuro day program. Though we did not control for the type of therapy they were receiving, each participant underwent three to five days of supervised physical therapy sessions using the assigned AFO for each week along with the prescribed AFO wearing schedule, which may have also contributed to the outcomes.

Discussion of Gait Endurance

Distance walked is considered an important walking variable for individuals with stroke (Bohannon et al., 1991). The 6MWT is a common measurement used in the clinic to measure the person's ability to ambulate a distance. Walking distance has been identified as one of the predictors for community walking after stroke (Bikleveld-Uitman et al., 2013). In our study, the difference in average 6MWT score for participants wearing the DA AFO and PLS AFO at baseline was only eight meters in favor of the DA AFO, and this difference did not reach statistical significance. However, after a week of practice, the average change score for the DA AFO was 51.63 meters and 40.39 meters for the PLS AFO. Although the *p*-value was not significant for the interaction, the effect size was large. Since the *p*-value is dependent on effect size and sample size, having a small sample size might be a reason for the non-significant *p* value (Field, 2016). The Minimal Clinically Important Difference (MCID) reported for the 6MWT in adults with

pathology from a systematic review ranges from 14 meters to 30.5 meters for 7–12 weeks of intervention (Bohannon & Crouch, 2017). In our study, with just one week of practice, participants improved well above the reported upper limit of the MCID for both AFO conditions. This is confirmed with the significance for the main effect of practice. The main effect of the type of AFO was also significant, but this is not a useful finding because it simply means that there was a significant difference between the AFO types when combining the baseline and second measurements. When evaluating the difference in the change for both AFO conditions, the mean difference was in favor of DA AFO. The comparison of differences in change scores between each of the AFO conditions however, was not tested statistically since we did not have a significant interaction effect. Additionally, a majority of the participants had hip and knee impairments in addition to the foot drop according to the Fugl Meyer lower extremity motor assessment.

Only one reported study had looked at the effectiveness of different AFO designs on gait endurance, and this study was performed on patients in the chronic stage of recovery post stroke. Using a repeated measures design, Slijper et al., (2012) compared the effect of a custom made hinged AFO and an over the shelf carbon composite AFO in 12 participants with stroke in chronic stage of recovery. The researchers found a significant difference in gait endurance measured by 6MWT (p = .019) in favor of the custom hinged AFO. Interestingly in this study, the subjects owned the custom AFO for several months and were provided with the carbon AFO for a week for habituation before measurements. Therefore, the subjects had very different practice times with each of the

AFOs compared. The designs of AFOs used in our study differed from those used in the Slijper et al. (2012) study and the participants in our study had the same practice time with both type of AFOs. The only study that investigated gait endurance using the 6MWT during the subacute stage of stroke recovery evaluated the effectiveness of an AFO to not using an AFO in 15 adults using a repeated measures design (Hyun et al., 2015). This study found a significant difference in improvement on the 6MWT when using an AFO compared to not using an AFO (p = .01). Our study is different from these previously described studies in that we compared two different AFO designs used in the subacute stage of stroke recovery. Our findings for gait endurance showed no significant difference between the AFO designs on measures of 6MWT.

Discussion of Gait Symmetry

Appearance of walking is an important self-reported walking variable when assessing walking performance in individuals with stroke (Bohannon et al.,1991). The weakness resulting in hemiparesis and foot drop contributes to a relatively longer step length in the paretic or non-paretic limb which leads to asymmetrical gait in stroke survivors (Hsu, Tang, & Jan, 2003; Verma et al., 2012). In our study we evaluated gait symmetry as the ratio of step length of the affected side to step length of the unaffected side, with perfect symmetry defined as 1.0. In our study, there was not a significant interaction effect or main effect of AFO type or practice time for gait symmetry. The average gait symmetry at baseline for self-selected gait velocity for the DA AFO was 1.16 and 1.18 with the PLS AFO. The average gait symmetry for baseline measurements

for fast-paced gait velocity using the DA AFO was 1.18 and 1.22 for the PLS AFO. After a week of practice, the average gait symmetry for self-selected gait velocity for the DA AFO was 1.12 and 1.10 for the PLS AFO. With fast-paced velocity walk, after a week of practice the symmetry for the DA AFO was 1.16 and 1.11 for the PLS AFO. Some of the participants had increased step length on the affected side (paretic leg) and some participants had increased step length on the unaffected side (non-paretic leg), which could have contributed to the average near normal average symmetry. Though typical gait substitutions post stroke and hemiplegia is reported as increased step length on the paretic or affected leg, in our study some participants had longer step length on the non-paretic or affected leg. Wall & Turnbull (1986) also reported similar variation in the symmetry ratio during double support time (Wall & Turnbull, 1986). Hsu, Tang and Jan (2003) also noted symmetry variation in step length with some participants having shorter step length on the affected side. In our study, the participants used different types of assistive devices, which might have contributed to the step length differences. The individual could compensate by weight shifting to the assistive device during the swing phase of the affected leg and might have taken a shorter step on the affected leg. We tried to decrease the effect of the assistive device by using the same device used by the participant at both baseline and after one week of practice and with both types of AFOs. The location of stroke was also different for the participants and could have contributed to this variation. Additionally, all participants were receiving physical therapy sessions during the time of study. Forced use of the paretic leg is a common physical therapy

intervention, where patients are encouraged to use the paretic leg, which could have carried over during testing as well.

There is only one reported study which evaluated the symmetry ratio in the subacute stage of stroke rehabilitation. In this study Carse et al., (2015) found no significant difference in step length symmetry ratio when using an AFO compared to wearing shoes but no AFO in 8 participants (p = .082). Results of the Carse et al., (2015) study were similar to our finding of no significant difference in step length symmetry ratio, however our comparison was between two different AFO designs (DA AFO and PLS AFO).

Discussion of Gait Velocity

Gait velocity is reported as a predictive variable for community walking after stroke (Bijleveled-Uitman et al., 2013). Walking speed is considered the sixth vital sign as it has predictive capacity for falls, hospitalization and discharge placements (Fritz & Lusardi, 2009). In our study, gait velocity was assessed at both SSV and FPV using the GAITRite system. Our study revealed that the interaction effects between the type of AFO and practice time were not significant at the self-selected velocity or fast paced velocity. However, the effect size for the interaction was medium for both SSV and FPV. Since the statistical significance of a finding is dependent on effect size and sample size, having a small sample size might have affected the results. Main effect of practice was statistically significant for both the SSV and FPV with a large effect size. A significant

main effect of practice indicates that regardless of the AFO type, there is a significant difference between the baseline measures and the 1-week practice measures for gait velocity measurements.

Repetition or practice is one of the principles of neuroplasticity (Kleim & Jones, 2008) for rehabilitation after brain damage. So, this principle is further validated in our study as all participants improved with practice with both type of AFO conditions. Regardless of the design, an AFO provides improved foot clearance during swing phase, and stability of the paretic foot in stance phase, which allows the person to advance his or her leg faster safely, thus improving gait velocity. This could also be the reason for improvements observed with both types of AFOs.

The average gait velocity on the first day for SSV was 0.58 m/sec for both the DA AFO and PLS AFO. After a week of practice, the SSV improved with the DA AFO to 0.70 m/sec and with the PLS AFO to 0.66 m/sec. The reported Minimal Clinically Important Difference (MCID) for comfortable gait speed or SSV from a systematic review of adults with pathology including stroke, is 0.1 m/sec. to 0.2 m/sec (Bohannon & Glenney, 2014). The average improvement with the DA AFO with just one week of practice for SSV was 0.12 m/sec and meets the MCID. However, the SSV change with the PLS AFO was .08 m/sec and does not meet the MCID. Perry, Garrett, Gronley and Mulroy (1995) classified patients with stroke based on gait velocity into functional categories. Speed of 0.4 m/sec is classified as household ambulator, between 0.4 and 0.8 m/sec is classified as limited community ambulator and above 0.8 m/sec is considered as

full community ambulator. According to the mean scores in our study, the participants remained in the limited community ambulator category from baseline to final measurement.

The average gait velocity on the first day for FPV using the DA AFO was 0.80 m/sec and 0.78 m/sec when using the PLS AFO. After a week of practice, FPV with the DA AFO improved to 0.95 m/sec and to 0.91 m/sec with the PLS AFO. There is no reported MCID for FPV walk, but the Minimal Detectable Change (MDC_{95}) for FPV is reported to be 0.13 m/sec in the chronic stage of stroke recovery (Hiengkaew, Jitaree & Chaiyawat, 2012). The average improvement noted with the DA AFO was 0.15 m/sec and 0.13 m/sec with the PLS AFO. Therefore, improvement using both AFOs meet the reported MDC for fast walking.

We expected the DA AFO to be better than the PLS AFO for improving gait velocity, but this was not observed in our study. Since the DA AFO is a heavier device than the PLS AFO, participants' hip and knee impairments (as measured by the Fugl Meyer lower extremity motor assessment) might have contributed to the less than expected improvements in gait velocity observed with the DA AFO. Additionally, the designs of these two AFOs are very similar except for the DA AFO's ability to assist with controlled tibial advancement in midstance. We would expect that controlled tibial advancement of the paretic leg would provide improved stability in stance, in order to advance the non-paretic leg. However, we did not measure joint kinematics to evaluate this.

Pardo, Galen, Gahimer, and Goldberg (2015) evaluated the effectiveness of a custom made articulated AFO compared to a prefabricated articulated AFO and to a shoe only condition in 14 participants with stroke 2–48 months post onset. There were significant differences between the shoe only condition and each of the AFO conditions for gait velocity ($p < .05$), but no significant difference between the two AFO conditions. Participants did not have any practice with the AFO conditions. Our study findings agree with the Pardo et al. (2015) study as we did not have any significant difference between the AFO conditions before practice. But with practice, gait velocity improved significantly at both SSV and FPV for both AFOs.

Kyung Hee, et al., (2014) evaluated the fast walking speed between a hybrid custom AFO, a plastic custom AFO, and a barefoot condition in 17 patients with stroke in chronic stage of recovery. Participants were given both AFOs to practice with for 3 hours per week for two weeks. Kyung Hee, et al., (2014) found no significant difference between the AFO conditions for gait velocity ($p > .05$) but found significant differences between the barefoot condition and each type of AFO ($p < .05$). Our study finding for gait velocity was similar to this study in that we did not have a significant change between the AFO types for both walking speeds.

There are two reported studies that looked at gait velocity with different types of AFOs in two different groups of participants with stroke. de Sèze et al. (2011) compared the effect of a custom articulated AFO called Chignon AFO to an over the shelf plastic AFO in 28 participants during subacute stage of recovery. They found no significant

differences in gait speed between the AFOs at baseline ($p > .05$), at the 30 day ($p > .05$), or 90 day ($p > .05$) follow ups. The investigator also looked at the gain in gait velocity, that is the difference between wearing Chignon AFO to not wearing the AFO in one group and the difference between wearing the over the shelf plastic AFO to not wearing the AFO in the other group. de Sèze et al. (2011) reported a significant in gain with the chignon AFO when compared to no AFO ($p < .01$) at baseline, at the 30 day ($p < .01$), and at the 90 day ($p < .01$) follow ups. In another recent study Tyson et al. (2018) compared the effects of a custom bespoke AFO to an over the shelf PLS AFO in two groups of participants ($n = 129$) in the chronic stage of stroke recovery with a 6-week and 12-week follow up. Tyson et al., 2018 found no significant difference between the two AFOs for gait velocity ($p = .23$). Our study agrees with these two studies as there was no significant change in gait velocity found between the custom AFO and over the shelf PLS AFO.

Discussion of Personal Preference of AFO for Ambulation

At the conclusion of testing, each participant was asked which AFO he or she preferred to use for daily ambulatory needs. Sixteen of the participants preferred the DA AFO and 4 participants preferred the PLS AFO. The participants who preferred the DA AFO reported that they felt safer walking with the DA AFO compared to the PLS AFO. The 4 participants who preferred the PLS AFO were all females and reported ease of wearing the AFO and lighter weight of the AFO as the reasons for preferring the PLS AFO. Patient preference is an important factor because if the participant is not satisfied

with the AFO, he or she might choose not to wear it. Tyson et al., (2018) assessed long term satisfaction using the Patient Satisfaction Questionnaire in comparing the custom Bespoke AFO versus an over the shelf PLS AFO in two groups of patients in the chronic stage of stroke recovery. There was a statistically significant difference in favor of the over the shelf PLS AFO at 6 weeks follow up (p = .47), but no significant difference was found at 12 weeks follow up (p = .21). In our study, we did not use a formal assessment tool. The Patient Satisfaction Questionnaire is an outcome measure developed by Tyson and Thornton (2001) which assesses individuals' perception of the effect of an AFO in various component of gait such as ability to lift their toes, swing the leg forward, take weight through the leg, effect on their confidence, perceived safety, and speed and distance they could walk. Each component was rated on a Likert scale with responses such as much improved, a little improved, a little worse and much worse. This measure also assesses the individual's view of the AFO itself in the following areas: comfort, weight of the AFO, putting it on and taking it off, appearance, and the worthiness of wearing it (Tyson & Thornton, 2001). Although the Patient Satisfaction Questionnaire does not have any published psychometric properties, it would have been useful to use such a scale in our study to understand the participant's perception and satisfaction with both the DA AFO and PLS AFO.

Limitations

The sample size in the current study was only 20. We established the sample size based on published studies which used a repeated measures design where the AFO was

an intervention during the subacute stage of recovery following stroke. However, both of those studies compared the effects of an AFO to not wearing an AFO. Comparing gait measures between the conditions of wearing an AFO to not wearing one likely has as a larger impact (and effect size) than using two different designs of AFOs as in our study. We used differences between wearing an AFO to not wearing an AFO to estimate our needed sample size because there are no published studies using within group, repeated measures design using different AFO designs in the subacute stage of stroke recovery. Using data from the current study, it is estimated that the sample size needed would be 27 for a power of .80. Even though the statistical significance for the interactions were greater than the alpha level of .05, there was a large and medium effect size for gait endurance and with gait velocity respectively. Therefore, it is reasonable to assume that the low sample size contributed to the non-significant findings in those two variables.

Another limitation of our study is that using a repeated measures design could have been confounded by a carry-over effect. This was however, addressed by randomizing the order of testing. We believed that using the within subject design, allowed us to better control for variability of stroke manifestation than if we had used a between group design. Since the participants were in the subacute stage of recovery, we would not expect significant changes from the natural progression of stroke recovery in one week. However, the effect of practice with one type of AFO might have added to the progress made when the second type of AFO used to practice with. We attempted to address this issue by randomizing the order of wearing the AFO for practice. All of the

participants were also receiving physical therapy treatments while they were participating in this study. The variability and intensity of physical therapy treatments they were receiving might have been also another confounding factor.

Using a standardized questionnaire to assess the participants' perception and satisfaction of the AFOs would have provided more information. Most of the reported studies inquired about the participants' preference for using a particular AFO as we did in this study. Only limited studies have used a standardized questionnaire such as the Patient Satisfaction Questionnaire. Although the psychometric properties of the Patient Satisfaction Questionnaire are not reported in the literature, the questionnaire would have provided valuable information as to why participants favored one AFO over another.

The design of the DA AFO allows for dorsiflexion assist during swing phase, resistance to plantar flexion during loading response, and controlled tibial advancement during stance into dorsiflexion. The design of the PLS AFO positions the foot in dorsiflexion during swing phase and allows controlled plantar flexion at loading response with the flexibility of the plastic allowing dorsiflexion range of motion during late midstance and terminal stance. The major difference is the DA AFO's ability to provide controlled tibial advancement in stance. Controlled tibial advancement helps to decrease hyperextension of the knee when there is functional weakness of the plantarflexors. In our study, we only assessed spatiotemporal gait variables and not kinematic variables. It might have been useful to evaluate kinematic variables to assess differences between the two AFOs.

Clinical Significance

The cost of a custom DA AFO averages $1,400 and patients need to have a good insurance plan to get coverage for this device. The average cost of an over the shelf PLS AFO is about $40 and is easy to purchase without having to go through the insurance. In our study, gait endurance and gait velocity reached statistical significance regardless of the AFO used, but gait symmetry improvements did not reach statistical significance. The change score achieved with each AFO met the minimal clinically important difference for gait endurance with just one week of practice. For self-selected walking velocity, only the DA AFO met the minimal clinically important difference. Also, 16 out of the 20 participants preferred DA AFO for safe walking. Based on the findings of this study, the investigators suggest trial of a cheaper over the shelf PLS AFO initially to improve gait endurance, gait velocity and gait symmetry during the subacute stage of stroke recovery. If the clinics can store a set of different sizes of reusable over the shelf PLS AFOs, these trials can be performed without incurring a cost to the insurance. A custom DA AFO should be used only if an over the shelf AFO proves to be unsuccessful. There was no significant difference between the two types of AFOs for gait endurance, gait velocity or gait symmetry at baseline. However, with practice both gait endurance and gait velocity reached statistical significance regardless of the type of AFO used, when compared to baseline. All participants were receiving physical therapy services during the practice period. So, it is important for patients to undergo physical therapy treatments to practice the use of AFOs to make gains in gait endurance and gait velocity.

Recommendations for Future Study

For future study, we recommend repeating the current study with a larger sample size and using a validated questionnaire for participant satisfaction and preference with the type of AFO. Participant satisfaction is an important factor for proper use of the device and for patient compliance to achieve optimal gait outcomes. In our study, we only measured temporal and spatial parameters of gait. It is also important to assess the effect of AFOs on the kinematic parameters of gait to better understand the effect of these devices on gait.

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APPENDICES

APPENDIX A

Figure of a custom double adjustable AFO

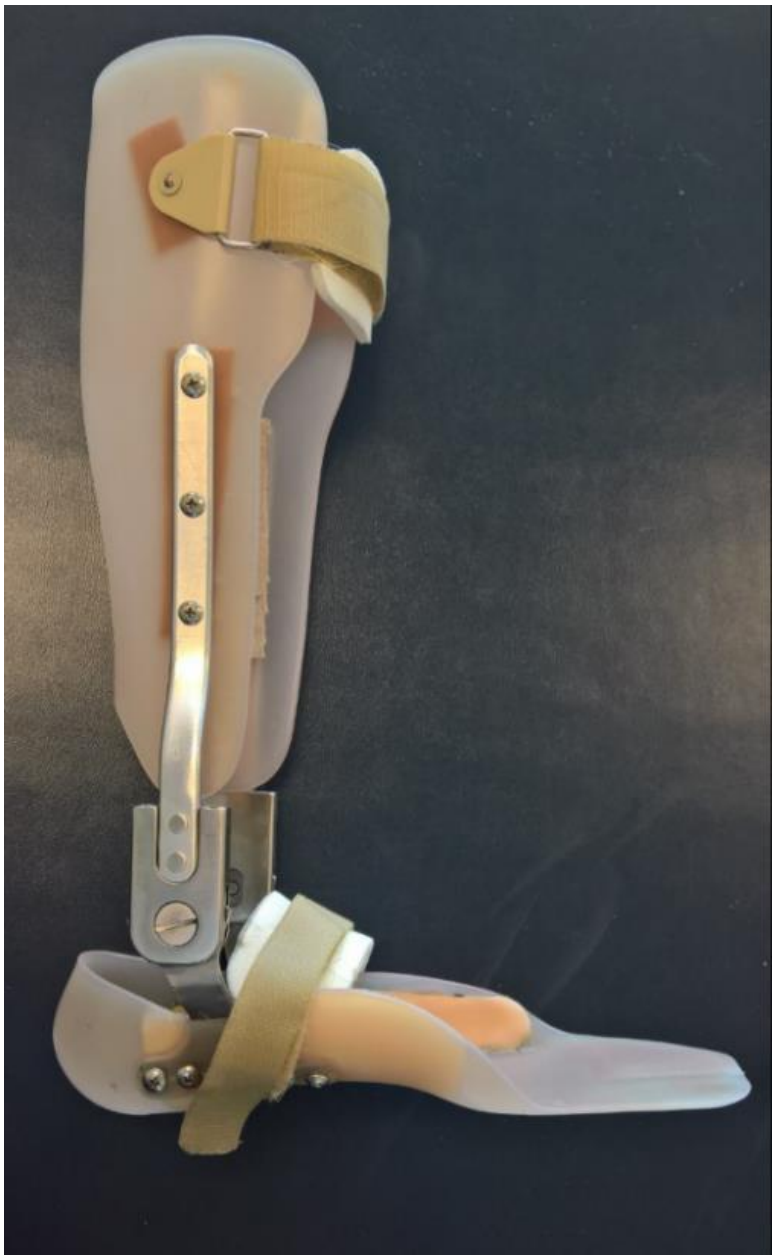

Figure 6: A custom double adjustable AFO

APPENDIX B

Figure of an over the shelf posterior leaf spring AFO

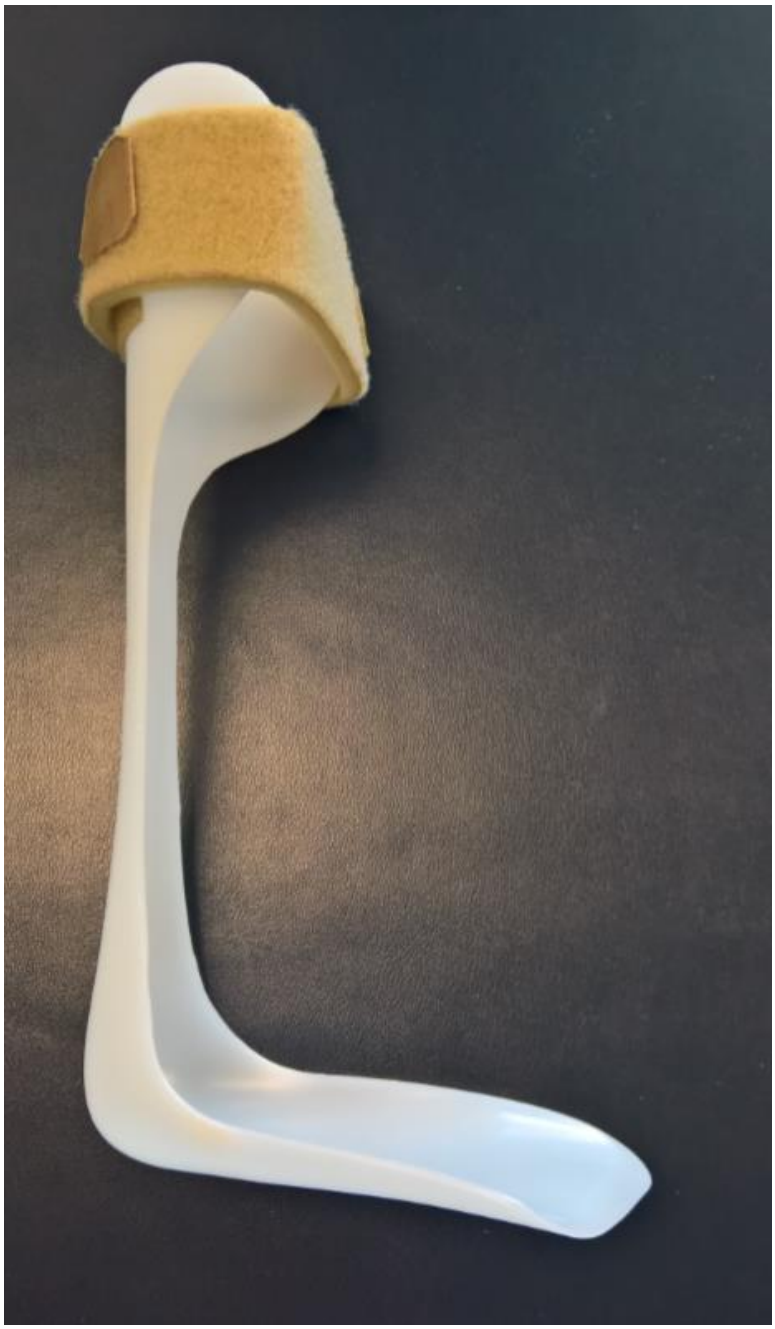

Figure 7. An over the shelf posterior leaf spring AFO

APPENDIX C

Participant Information Sheet

Participant Information Sheet

PIN: _____

Name: _____ Date of Birth ___/___/___

Gender: Female ☐ Male ☐ Height: _____cm Weight_____ kg.

Leg length R_____cm L_____cm

Address: _____

Phone Number: _____

Diagnosis: _____

Location of CVA: _____

Date of Onset: _____

Exclusion Criteria

Did the participant walk prior to stroke?	YES	NO
Can the participant walk for 20 feet?	YES	NO
Can the participant follow 2 step commands?	YES	NO
Will the participant be able to receive DA AFO?	YES	NO
Does the participant have cerebellar stroke?	YES	NO
Is the participant currently undergoing chemo?	YES	NO
Are they able to participate in this study?	YES	NO

Day 1 Measurements: Date: _____

6 MWT: DA AFO_____ (feet) PLS AFO_____(feet):

Assistive Device used: _____

GAITRite: Assistive Devices used: _____

AFO Order: testing 1) _____2) _____

AFO Order: for Practice 1) _____ 2) _____

PIN#_____

Day 2 Measurements: AFO type: _____ Date: _____

6 MWT: _____ (feet): Assistive Device used: _____

GAITRite: Assistive Devices used: _____

Day 3 Measurements: AFO type: _____ Date: _____

6 MWT: _____ (feet): Assistive Device used: _____

GAITRite: Assistive Device used: _____

Which of these two AFOs you prefer to walk with: _____

APPENDIX D

Informed Consent

BAYLOR RESEARCH INSTITUTE
BAYLOR INSTITUTE FOR REHABILITATION, FRISCO, TX
TEXAS WOMAN'S UNIVERSITY, SCHOOL OF PHYSICAL THERAPY DALLAS, TX

PARTICIPATION EXPLANATION AND CONSENT FORM

PROJECT TITLE: Effects of two different types of Ankle Foot Orthoses on gait outcomes in patients with subacute stroke.

INVESTIGATORS: Priya Karakkattil, PT MS CBIS
Elaine Trudelle_Jackson, PT PhD

TELEPHONE NUMBER: 214-689-6745

INTRODUCTION:

Before you say that you will be in this research study you need to read this form. It is important for you to understand all the information in this form. This form will tell you what the study is about and how it will be done. It will tell you about some problems that might happen during the study. It will also tell you about the good things that might happen for you during the study. When you read a paper like this to learn about a clinical trial it is called "informed consent." The people who are doing this research study are giving you very important information about the study. When you give your consent for something, it is the same as giving your permission. This consent form may contain words that you do not understand. Please talk with someone from the research staff if you have questions. Do not sign this consent form unless all your questions have been answered and you feel comfortable with the information you have read. You will be given a copy of the form to keep.

You are being asked to take part in this study because you have had a stroke and have difficulty walking because of weakness in your leg which is causing foot drop.

Why Is This Study Being Done?

The main purpose of our study is to find out whether there is a difference in your walking when using two different types of ankle foot orthoses (AFOs). The types of AFOs we are testing are a Double Adjustable AFO, or a Posterior Leaf Spring AFO. A secondary purpose is to find out whether one week of practice using these AFOs change your walking ability.

What is the Status of the Procedures or Techniques Involved in this Study?

An AFO is a type of brace which is used to help correct foot drop routinely in physical therapy. The Double Adjustable AFO and the Posterior Leaf Spring AFO are AFOs with two different designs.

IRB NUMBER: 015-286
IRB APPROVAL DATE: 12/11/201
IRB EXPIRATION DATE: 12/10/2016

Subject's Initials_____

How Many People Will Take Part In The Study?

About 20 people will take part in this study from the Dallas area.

What Is Involved In The Study?

You will be asked to allow the researcher to review your medical records and copy the information from these records into his/her research charts for this project. This information will be reviewed by the researcher and his/her staff to answer the specific question as outlined above.

The researchers in this study will meet with you 3 times during this study.

First Visit: The first time when the researcher meet with you, she will determine whether you will be able to sign this form by asking you to do a test called a Mini Mental State Examination (MMSE). If you score 21 or above you will be signing this consent. But, if you score below 21, then your legally authorized representative will be asked to sign the consent and we will retest next visit to see whether you can score 21 or more so you will be able to sign this consent at that time.
After the consent form is signed, the researcher will do a test called Fugl-Meyer Lower Extremity Assessment of sensorimotor function. This is a common test used by physical therapists for patients with stroke to find the sensation and movements in your legs. Then you will be asked to wear one of the two different types of AFOs for the rest of the measurements. You will choose the type of the AFO you are wearing by drawing the names from a hat. This is called randomization. You have an equal chance of (like the flip of a coin) of receiving the Double Adjustable AFO as you do the Posterior Leaf Spring AFO. Neither you nor the researcher will choose which type of AFO you will be walking with first. You will be wearing your shoes and the assistive device (such as cane, walker) of your choice with all measurements. After you wear the AFO, you will be asked to walk for 6 minutes at your preferred speed to assess your walking endurance. After a resting period, you will be asked to walk on the computerized carpet to measure your walking pattern 3 times at your normal speed and 3 times at a faster speed. Someone will walk beside you all the time to ensure your safety. After that you will be given the second type of AFO to wear. Then with that AFO your walking endurance and walking pattern will be measured just as the first time. After that you will be randomly assigned to practice with one of the types of AFO to practice with. You will be given an AFO wearing schedule to follow.

Second Visit: After a week of practicing with this AFO you will meet with the researcher for a second measurement. On the second day your walking endurance and walking pattern will be measured just using the type of AFO you were practicing with. Then you will be given the second type of AFO to practice with for a week along with the AFO wearing schedule to follow

Third Visit: After another week of practicing with the second AFO, you will meet with the researcher for the final measurement. At this time your walking endurance and walking pattern will be measured using the type of AFO you were practicing with. On the last day you will be

Subject's Initials_____

asked which type of AFO you will prefer for walking. All the testing procedures are approved procedures used for physical therapy evaluation and research.

How Long Will I Be In The Study?

You will be in the study for 2 weeks.

All the measurements described above will be taken on the first day using both AFOs. Then after a week of practice with one type of AFO, all measurements will be taken using that type of AFO. After practice using the second type of AFO, final measurements will be taken using the second type of AFO.
The researcher may decide to take you off the study if s/he feels that it is in your best interest, if you are not able to follow the rules of the study, if the study is stopped before it is finished or if new information becomes available that indicates it would be best for you to stop being in the study.

You can stop taking part in this study at any time. If you decide to stop taking part in the study, you should let the researcher or his/her staff know so that they can make sure you are safely taken out of the study.

What Are The Risks of The Study?

The only potential risk associated with taking part in this study is a slight chance of developing mild discomfort from walking. However, it should not be any more than what you would experience after a physical therapy session. Also there may be a chance of developing redness. You will be asked to examine your skin and if you notice any redness, you will contact the PI and your Orthotist, so adjustments can be made to the brace. If you have the redness and still keep wearing the AFO, then you will have a chance of getting skin breakdown. To avoid this, we recommend that you examine the skin as prescribed in the AFO wearing schedule. Using the AFO wearing schedule and examining the skin are typical procedures used in physical therapy clinics to avoid any skin problems.

What are the Benefits and Options of The Study?

If you agree to take part in this study, there may or may not be direct medical benefit to you. We hope that what we learn in this study will help others with your condition in the future. Your other option is to not be in the study.

What If I am Injured While Taking Part in This Study?

The people doing this research project will do everything they can to make sure you do not get hurt during the project. If you do get hurt, you should tell the researcher or his/her staff and they will help you to get necessary medical care. You or your insurance company may need to pay for

Subject's Initials_____

the medical care. Baylor Health Care System, Baylor Research Institute and Baylor Institute for Rehabilitation and Texas Woman's University have not set funds aside to pay you money if you are hurt. You have not given up any of your legal rights by signing this form.

What About Confidentiality?

You have a right to privacy. This means that all the information about you from this study will only be shown to the people working on the study. The results of this study may be published in a scientific book or journal. If this is done, your name will not be used. All information about you from this research project will be kept in a locked office or other locked area. Information that is kept on computers will be kept safe from access by people who should not see it.

The privacy law requires that Baylor Research Institute get your permission before giving any of your health information to other people. There are people who need to review your information to make sure the study is done correctly. These people may look at or copy your information while they are doing this review. When you sign this form you give permission to Baylor Research Institute to give other people information about your health as needed for the research project. These groups include people who work for Baylor Research Institute (including the Institutional Review Board), the US Food and Drug Administration, the Office for Human Research Protections and the Association for the Accreditation of Human Research Protection Programs. This also includes the following groups of people who are working with the sponsor: Texas Physcial Therapy Foundation and Texas Women's University. Even though we usually remove your name from the information, the people who get this information may be able to figure out who you are. The kinds of health information that might be given to these people include results from the measurements done by the researcher, notes from the doctor and or your physical therapists.

You do not have to give this permission and it is all right to refuse to sign this form. Your doctor will still treat you and your insurance company will still pay your medical bills (according to their policy) even if you do not give your permission for us to release this information. However, since it is important for the people listed above to have access to your information, if you do not sign this form, you cannot be in the research study.

If you give permission to Baylor Research Institute to give other people information about your health and the other people are not part of the group that must obey this law, your health information will no longer be protected by the privacy law. However, we will take all reasonable measures to protect your information from being misused.

If you change your mind and later want to withdraw your permission, you may do so. You must notify Baylor Research Institute in writing at 3310 Live Oak, Suite 501, Dallas, TX 75204. If you decide to do this, it will not apply to information that was given before you withdrew your permission and you will no longer be able to take part in the study.

You may not be allowed to look at your health information during this study. However, at a later time, you will be able to look at this information. This later time will be sometime after the study is completed.

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IRB EXPIRATION DATE: 12/10/2016

Subject's Initials_____

Unless permission is withdrawn, this permission will expire at the end of the research study.

What Are the Costs and Will I be Paid?

The only cost associated with taking part in this study is that you will be getting a Double Adjustable AFO through your insurance. However, you will receive a posterior leaf spring AFO which cost about $40 on the first measurement day. Additionally you will be given gift cards for $40 each at the second and third measurement day as payment for the time being in the study. The gift cards will be given on the second and third measurement days. Texas physical therapy foundation has awarded a grant which will allow for the researcher to provide you with this AFO and the gift cards.

What are My Rights As a Participant?

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. If you agree to take part and then decide against it, you can withdraw for any reason.

Deciding not to be in the study, or leaving the study early, will not result in any penalty or loss of benefits that you would otherwise receive.

We will tell you about any new information that may affect your health, welfare, or willingness to stay in this study.

All of the people working on the project must be careful not to carelessly harm you. If you are hurt during this project, you have the right to seek legal counsel. Nothing in this consent form takes away that right if you are hurt during this research.

Whom Do I Call If I have Questions or Problems?

If you have concerns, complaints or questions about the study or have a research-related injury, contact the Principal Investigator Priya Karakkattil at 214-862-5624. Must include phone numbers where someone can be reached 24 hours a day, seven days a week.

For concerns, complaints or questions about your rights as a research subject or if you simply wish to speak with someone who is not a part of the research staff, contact Lawrence R. Schiller, M.D., IRB Chair, at 214-820-2687.

Statement of Person Obtaining Consent:

I have explained to _____ the purpose of the research project, the procedures required and the possible risks and benefits to the best of my ability. They have been encouraged to ask questions related to taking part.

_____ _____ _____

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Subject's Initials_____

Signature of Person Obtaining Consent Date Time

Statement of Principal Investigator:

As Principal Investigator of this study, I confirm that to the best of my knowledge this subject has voluntarily agreed to take part in this study and has had an opportunity to ask questions and has received answers to these questions. If another individual was responsible for obtaining informed consent, then this individual has signed above.

_____ _____ _____

Signature of Principal Investigator Date Time

Confirmation of Consent by Research Subject:

You are making a decision about being in this research study. You will be asked to give your written consent if you want to be in the study. Giving consent is like giving permission. You should not give your permission to be in this study until you have read and understood all the pages in this form. If you cannot read, then someone can read the form to you. Make sure that all your questions about this research project have been answered before you sign this form. When you sign this form, you are giving your permission to be in the study. By signing this form, you have not given up any of your legal rights or released anyone from liability for negligence.

_____ has explained to me the purpose of the research project, the study procedures that I will have, and the possible risks and discomforts that may happen. I have read (or have been read) this consent form. I have been given a chance to ask questions about the research study and the procedures involved. I believe that I have enough information to make my decision. I have also been told my other options. To the best of my knowledge, I am not in any other medical research. Therefore, I agree to give my consent to take part as a subject in this research project.

_____ _____ _____

Signature of Subject Date Time
(or legally authorized representative)

IRB NUMBER: 015-286
IRB APPROVAL DATE: 12/11/201
IRB EXPIRATION DATE: 12/10/2016

Subject's Initials_____

APPENDIX G

AFO Wearing Schedule

AFO Wearing Schedule:

It is important to slowly and progressively increase wearing time to prevent skin breakdown. When you receive the brace, begin by wearing it for only one hour. After one hour remove the AFO and sock and check your skin for redness. Some redness may be seen on the skin and should go away within 20-30 minutes after removing the AFO. Watch to see how long the redness lasts. If redness remains after 30 minutes or if you notice any blistering or bruising please call to schedule an early return appointment.

If the skin is fine and redness has gone away by 30 minutes wait at least one hour and put the AFO back on. Alternate wearing on and off for the rest of the day making sure to check the skin condition after removal each time. For the second day alternate two hours on and one hour off. Check skin condition each time it is removed. Increase wearing time one hour each day always checking skin condition on removal.

Day One:
Wear for one hour
Take off for one hour.
Wear for one hour
Take off for one hour (Repeat)

Day Two
Wear for two hours
Take off for one hour
Wear for two hours
Take off for one hour (Repeat)

Day Three
Wear for three hours
Take off for one hour
Wear for three hours
Take off for one hour.

Day Four
Wear for four hours
Take off for one hour
Wear for four hours

Day Five, Six and Seven (if no skin issues)
Wear continuously

Come for your follow up appointment wearing your AFO