

Texas Woman's University

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

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Introduction

Stroke is a leading cause of death and disability in the world today. About 795,000 people are diagnosed with stroke yearly in the United States. The annual cost of stroke from medical services and disability in our nation is \$ 38.6 billion dollars. With the advancement in acute stroke management, the death rate has fallen in the last decade (Executive summary: Heart disease and stroke statistics--2012 update.2012) but 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). 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. Therefore gait rehabilitation is an important aspect of neurorehabilitation with focus on attaining the most functional and symmetrical gait to prevent falls from faulty gait mechanics, and to prevent sedentary life styles and associated comorbidities (Hesse, 2003). 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, H, 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; Slijper, Danielsson, & Willén, 2012). Systematic analyses have shown that use of various types of ankle foot orthoses improve walking impairments and balance, reduce energy costs, and improve 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 the 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.

Three reported studies have investigated the effects of using an AFO compared to not using an AFO within 6 months following onset of stroke. Rao et al found that the use of an AFO significantly improved gait velocity, cadence and step length on the affected and unaffected side (Rao et al., 2008). Hyun et al. found that using an AFO significantly improved VO₂ peak and 6 minute walk test scores (Hyun, Kim, Han, & Kim, 2014). Carse et al showed significant improvement in walking velocity, average step length and cadence with use of AFO. (Carse, Bowers, Meadows, & Rowe, 2014).

There is only one reported study which looked at the effects of using two different types of AFOs during the subacute stage of stroke, less than 6 months following 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. Results of this study showed that gait speed and knee and ankle control were significantly higher in the Chignon AFO group compared to the polypropylene AFO group. Additionally, participants in the Chignon AFO group had significantly lower spasticity than those in the polypropylene AFO group (de Sèze et al., 2011).

In a recent 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 (McCain et al., 2012). The authors suggested that the design of the Double Adjustable 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. 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, Sadeghi-Demneh, & Nester, 2013; Tyson & Kent, 2013). Although, the majority of gait improvements occur within six months of stroke (Kwakkel, Kollen, & Lindeman, 2004), the effect of early bracing with different types of AFOs on gait outcomes has not been investigated thoroughly.

Purpose of the study:

The purpose of this study will be to identify whether patients in the subacute stage of stroke, who demonstrate foot drop, will have better gait outcomes when using a Double Adjustable AFO, or a Posterior Leaf Spring AFO. A secondary purpose will be to determine whether one week of practice significantly changes gait outcomes with either of the AFO conditions.

Research Hypotheses

The research hypotheses of this study are as follows:

1. There will be a difference in gait endurance measurements, gait symmetry measurements and gait velocity measurements at baseline when using custom Double Adjustable AFO compared to a PLS AFO in patients in subacute stage of stroke.
2. There will be a difference in gait endurance measurements, gait symmetry measurements and gait velocity measurements after one week of practice when using custom Double Adjustable AFO compared to a PLS AFO in patients in subacute stage of stroke.
3. After a week of practice, there will be a difference in gait endurance measurements, gait symmetry measurements and gait velocity measurements compared to baseline measurements, when using either custom Double Adjustable AFO or a PLS AFO in patients in subacute stage of stroke.

Significance of Study

An important goal of stroke rehabilitation is to improve gait outcomes (Hesse, 2003). An AFO is commonly prescribed as an adaptive strategy to compensate for foot drop; however the gait outcomes have not been thoroughly investigated following the use of AFOs in the subacute stroke population. Additionally, high variability of stroke manifestation makes it difficult to compare two groups of patients affected by stroke using different AFO designs. This study uses 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 will provide valuable information about the effects of early bracing to address gait impairments in the subacute stroke population.

Stroke is one of the neurological diseases associated with increased falls resulting in injury in the elderly (Eng et al., 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 the 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 is not specifically looking at falls as an outcome, it is reasonable to infer that improving gait outcomes could potentially decrease the fall risk.

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. (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). Gait velocity has been identified as a factor which predicts independent community ambulation in stroke survivors (Rosa, Marques, Demain, & Metcalf, 2014). Gait speed and gait endurance are also identified as predictors for community ambulation after stroke (Bijleveld-Uitman, van, & Kwakkel, 2013). Although my study is 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 AFO will impact a stroke survivor's ability to improve participation in the community and to decrease caregiver dependency.

Methodology

Experimental design:

The research design for this experimental study will be a 2 factor within subject repeated measures 2x 2 design. The manipulated independent variables in the study will be 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, and (b) after 1 week of practice. The dependent variables in this study are 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.

Participants

Twenty participants over the age of 18, of any gender and ethnicity, diagnosed with first time unilateral stroke, 4 - 20 weeks post-stroke onset, resulting in hemiparesis with foot drop will be recruited. The number of participants was estimated based on previously reported studies. Hyun et al found significant differences in gait endurance measured by 6MWT when using AFO compared to using no AFO with 15 participants in a similar study (Hyun, Kim, Han, & Kim, 2014). In another study by Carse et al, gait velocity and gait symmetry were found to be significantly better with 8 participants (Carse, Bowers, Meadows, & Rowe, 2014). Therefore, for our study, the potential participant number was projected as 20.

Participants will be recruited through a sample of convenience from Baylor Institute of Rehabilitation locations and through word of mouth. The physical therapists at these locations will be given a brief description of the proposed study and will be asked to screen for potential participants. Potential participants who are not able to receive a double adjustable AFO through their insurance, who are not able to follow two steps commands or not able to ambulate 20 feet with or without assistive device with a minimum level of assistance of contact guard assistance will be excluded from the study. Participant will also be excluded from the study if the person is undergoing chemotherapy at the time of research. The two step command used to assess will be “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 will be disqualified from participation. If the potential participant meets inclusion criteria, and does not possess any of the exclusion criteria and is interested in learning about the study, the physical therapist will ask the potential participant permission to be contacted by the primary investigator. Participants who meet the inclusion criteria and possess none of the exclusion criteria will be asked to volunteer for the study. Each participant will read or be read their rights as human subjects and asked to sign the informed consent approved by the Institutional Review Boards of both Baylor Health Care System and Texas Woman's University prior to enrollment in this study. A Mini Mental State Examination (MMSE) will be performed to determine whether the participant has the cognitive ability to sign the informed consent. If the participant scores below 21, then a legally authorized representative will be asked to sign the consent. For a person who scored below 21, MMSE will be assessed at subsequent visits to determine whether they are able to sign the consent and when they reach the cut off score of 21, each participant will be given consent to sign by themselves at that time. MMSE will be administrated by the primary investigator who is a licensed PT who will be trained to administer this test. Participants will be scheduled to do data collection on the day they receive their custom double adjustable AFO at Baylor Institute for Rehabilitation, Frisco location.

Instrumentation/Measurements

a) Gait endurance will be measured using the Six Minute Walk Test (6MWT).

Participants will be asked to ambulate as far as possible in 6 minutes at a self-selected walking velocity through a well-lit indoor corridor. Participants will be informed when half of the time is over, otherwise no verbal cueing or encouragement will be provided. A gait belt will be used to ensure patient safety. If the participant needs to sit during the testing, that will be allowed.

However the timer will not be stopped for sitting rest breaks. The primary investigator will walk beside the patient, without influencing the speed of ambulation to ensure safety. The distance ambulated during the six minutes will be measured in feet using a measuring wheel and then converted to meters for data analysis.

b) Gait Symmetry will be measured using the temporospatial measurements from the GAITRite™ (CIR systems, Havertown, PA, USA) computerized gait analysis system. The GAITRite walking system used in this study is a 16 feet long x 3 feet wide portable walkway with embedded pressure sensors at 1.27 cm intervals along the length of the walkway. As the participant ambulates on the walkway, the pressure of the foot activates the sensors that record the person's steps. The data will be sampled at 1000 Hz. These measurements are then sent to a computer program that analyzes the specified temporal spatial parameters using the algorithm built into the special software. This data can be saved and exported to Microsoft Excel where the data can be further analyzed (*GAITRite electronic walkway technical reference, revision L. 2013.*) Step symmetry will be 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 will also be assessed using the temporospatial measurements of the self-selected pace walk and fast paced walk from the GAITRite™ computerized gait analysis system.

Procedures:

All measurements will be obtained from each participant during three testing sessions and by only one researcher to avoid inter tester reliability issues. On the first measurement day, participants receive their custom DA AFO. The primary investigator will collect demographic

data including age, height, weight, leg length measurements on each side, and Fugl-Meyer Lower Extremity Assessment of sensorimotor function. Then the gait outcomes will be measured using one of the two AFO conditions in random order. Two possible orders will be written on piece of paper and an equal number of possible order selections will be put in a hat. The participant will select the order of AFO condition by drawing out of a hat. Randomization without replacement will be used. Once the order of AFO wearing has been determined, data will be collected in the randomly selected order. Participants will be allowed to use any type of assistive device of their choice, but the same device will be used for all conditions.

First, the 6MWT will be administered with the participant wearing the first randomized AFO. Participants will be asked to ambulate as far as possible in 6 minutes at a self-selected walking velocity through a well-lit indoor corridor. A five minute seated resting will be provided before the next measurement is taken. Next, gait symmetry and gait velocity measurements will be obtained using the GAITRite system. Participants will be given a practice trial walk prior to beginning of the testing. Participants will be asked to walk at their comfortable self-selected walking velocity along the walkway. They will begin walking three meters from the start of the walkway and will stop walking two meters past the end of the walkway. The beginning and end of the walking area will be marked with red tape for visibility. The verbal instruction will be “Please walk from this red line to that red line at your comfortable speed safely”. A second personnel will be walking close to the participant outside of the walkway to ensure safety. After a five minute sitting break, participant will be asked to walk as fast as they can safely. The verbal instruction will be “Please walk from this red line to that red line as fast as you can safely”. The GAITRite system will be able to capture both gait symmetry and gait velocity measurements with the same walk. Three trials will be performed of the self-selected velocity walk and fast

paced velocity walk. The calculated mean of the three trials will be used for data analysis. After a 10 minute seated rest break, the second AFO condition will be used and measurements will be repeated in the same order described above.

To assess the effects of practice on the gait measures, AFO's will be randomized for practice. Participants will be randomized for which AFO they will wear first (the PLS or the DA AFO), by drawing out of a hat. Again randomization without replacement technique will be used. Then the participant will be provided with the selected type of AFO to practice with for the following week using a prescribed wearing schedule. At the end of the one-week practice time, the primary investigator will obtain 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 will be employed. Once measurements are completed, the participant will be provided with the second type of AFO and will be asked to wear for one week using the same prescribed wearing schedule as before. Final measurements will be taken after completion of the one-week practice using the second type of AFO with the same testing conditions and orders. At the conclusion of testing each participant will be asked which AFO they will prefer to use for their daily ambulatory needs for descriptive analysis. All data collected will be de-identified and stored in the Primary Investigator's secure personal computer. Any documents used such as Participant information sheet will be securely locked in a cabinet at Texas Woman's University where only the Primary investigator will have access.

Data Analysis

The following statistics will be calculated using SPSS for Windows. Descriptive statistics will be calculated for all demographic data including age, height, weight, time since onset Fugl Meyer lower extremity assessment score and AFO preference.

Differences in gait endurance will be analyzed using a 2x2 repeated measures ANOVA. Differences in gait symmetry, and gait velocity between the two AFO conditions and two practice conditions will be analyzed using two separate 2x2 repeated measures MANOVA. If assumption of sphericity is not met, Greenhouse-Geisser statistic will be used. An alpha level of .05 will be used to determine significance of differences, with a Bonferroni correction applied as needed to protect against Type I error.

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