Effects of Custom-Molded and Prefabricated Hinged Ankle-Foot Orthoses on Gait Parameters and Functional Mobility in Adults with Hemiplegia: A Preliminary Report

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ABSTRACT

Introduction: Hinged ankle-foot orthoses (AFOs) have been shown to improve gait and functional mobility in both adult and pediatric populations with neurological disorders. Hinged AFOs provided to clients can either be prefabricated or custom-made. To date, there have been no studies comparing a custom-made articulated AFO (C-AFO) with a prefabricated articulated AFO (P-AFO) and the effects that they have on gait and functional mobility in individuals with hemiplegia after a stroke.

Materials and Methods: The purpose of this study was to determine if there were any differences in the gait and functional mobility parameters of patients with hemiplegia when wearing the C-AFO or the P-AFO and also to determine if there was a difference in the braced versus not-braced conditions. Fourteen participants with hemiplegia completed tests that assessed spatiotemporal gait parameters using the GAITRite walkway. In addition, participants completed tests to assess weight-bearing symmetry during sit-to-stand (using the Balance Master), stepping capabilities using the maximal step length (MSL) test, and functional mobility using the timed up and go test (TUG). Data were analyzed using a repeated measures analysis of variance with Bonferroni adjustments for multiple comparisons.

Results: There were no significant differences ($P > 0.05$) between the two braced conditions for the gait parameters, the TUG, the sit-to-stand symmetry, and the MSL. There were significant differences between the braced (C-AFO or P-AFO) and the shoes-only conditions for the gait parameters (gait speed, stride length, step length, and gait symmetry of the uninvolved leg) and for the functional mobility assessments (TUG and MSL-involved leg).

Conclusions: This preliminary study has shown that there was no significant difference in any of the gait or functional mobility parameters when wearing the C-AFO or the P-AFO, provided that the P-AFO provides optimal support and fits the individual's anatomical dimensions well. Significant differences in both gait and functional mobility measures were observed between the shoes-only and braced conditions. The results of this study also demonstrated that wearing a hinged AFO does contribute to a better gait and functional mobility in people who have had a stroke. (*J Prosthet Orthot*. 2015;27:33–38.)

KEY INDEXING TERMS: stroke, hinged ankle-foot orthosis, gait, balance

Stroke is a leading cause of serious long-term disability in the United States. The US Centers for Disease Control and Prevention estimates that approximately 795,000 individuals in the United States have a stroke every year, with a nationwide cost related to stroke estimated at $36.5 billion every year.[1] This cost estimate includes health care costs associated with rehabilitation including physical therapy and orthotic interventions. Given the greater costs involved in restoring mobility and function in individuals after stroke, there is always a need for cost savings and efficiencies so that the economic burden both on the individual and health care system can be reduced. The primary goal for an individual who has experienced a stroke is to restore his/her ability to walk and perform functional tasks independently.[2,3] This is achieved through rehabilitation, which includes physical therapy[4] combined with relevant orthotic interventions targeted at correcting the impaired biomechanics that underpin movement impairments. The common gait and balance impairments that are observed in individuals who have experienced a stroke can be due to a combination of muscle weakness, spasticity, and impaired processing of somatosensory input. More specifically, individuals who have experienced a stroke have difficulty walking because of inadequate foot clearance on the hemiplegic side. Clinicians often prescribe an ankle-foot orthosis (AFO) to provide an external support to the foot and ankle and potentially improve its biomechanical alignment. The external support provided by the AFO during walking translates into an improvement in the patient's ability to achieve a heel strike at initial contact during the stance phase of the gait cycle and to limit excessive plantarflexion during the swing phase of the gait cycle, thereby restoring the patient's gait closer to a pattern that is observed in healthy individuals.[5]

There is a wide variety of AFOs from which therapists choose,[6] and the literature supports the use of AFOs as an effective orthotic intervention in improving the gait pattern of

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patients with hemiplegia, in both pediatric and adult populations.[7–19] For pediatric populations, both solid-ankle AFOs and hinged AFOs have been found to be effective orthotic interventions for gait training.[7–13] Buckon et al.[19] found that the greatest improvements in functional mobility in children with spastic hemiplegia were observed with a hinged or a posterior leaf spring AFO (when compared with a solid-ankle AFO). Most of the studies looking at the efficacy of hinged AFOs in patients with hemiplegia have been performed in a pediatric population. There are few studies that have been performed using adults with hemiplegia resulting from a stroke. In adult patients with stroke, there is some evidence that hinged AFOs can improve the gait pattern[14,20] and that hinged AFOs are more beneficial than solid-ankle AFOs.[15] In a recent study of individuals with stroke,[21] the effects of an AFO (hinged or solid-ankle) were studied based on outcome measures that recorded weight-bearing asymmetry/balance and efficacy during functional mobility tasks. They found that the AFOs had little or no effect on weight-bearing asymmetry and balance, but that there was a significant difference for functional mobility scores in favor of the AFO (compared with wearing no brace). Nolan et al.[22] determined that the use of an AFO improves functional mobility for individuals after stroke, specifically for those who had a slower gait velocity.

Previous studies have shown that articulated AFOs are more effective at improving mobility than solid-ankle AFOs,[14] specifically for functional tasks such as sit-to-stand and stair climbing. This is likely due to the minimal dorsiflexion of the ankle permitted by the solid-ankle AFO while the patient attempts to perform sit-to-stand and stair climbing tasks. When wearing a hinged AFO, it is possible to achieve the forward excursion of the tibia over the foot (dorsiflexion), which is necessary for sit-to-stand and stair climbing.

Clinicians usually have the option of recommending a custom-made articulated AFO (C-AFO) or a prefabricated hinged AFO (P-AFO) for their patients. There are several key factors that need to be considered in making the orthosis selection: the type of AFO and the condition of the patient's biomechanical (range of motion), neurological impairments (muscle strength, spasticity, and sensory deficits), and integrity of their integumentary systems (skin status). Until recently, if the best choice for the patient was a hinged AFO, the only option was a C-AFO. More recently, there is the option of a P-AFO (Orthomerica, Newport Beach, CA, USA). These are available in sizes ranging from small to extra-extra large and are approximately 10% ($150) of the cost of a C-AFO. A C-AFO may be the most preferred option because of its better fit and alignment based on the patient's individual anatomical parameters. However, if a P-AFO provides similar support that results in good biomechanical alignment, as determined by the clinicians and the orthotist, it may serve as a low-cost option during gait reeducation and rehabilitation. Although the biomechanical alignment and fit of a P-AFO can be assessed by a clinician and orthotist visually, it is still unclear if the P-AFO may in any way negatively influence the patient's gait parameters or functional mobility, thereby influencing the recovery process and also exposing the patient to a greater risk of falls. To date, there have been no studies comparing the effect of a C-AFO and a P-AFO on a patient's gait and functional mobility.

The purpose of this study was to assess if there were any differences in the observed gait parameters (spatiotemporal parameters) and functional mobility in patients with hemiplegia while wearing a C-AFO, a P-AFO, or no AFO at all. It was hypothesized that there would be no significant differences between the two hinged AFOs, and that there would be no significant differences between the braced (C-AFO and P-AFO) and the shoes-only conditions in gait and functional mobility measures.

METHODS

PARTICIPANTS

The study included a total of 14 participants (64% male) with hemiplegia (57% right hemiplegia) who were recruited by outpatient physical therapy staff at the Rehabilitation Institute of Michigan and by personnel at a local orthotics company. Inclusion criteria for subject selection were as follows: aged 18 years or older, hemiplegia subsequent to a stroke, ability to bear weight and step with the impaired leg, ability to achieve a neutral ankle (at least 0 degrees of dorsiflexion) with passive or active range of motion, and current use of a C-AFO. Exclusion criteria were as follows: inability to ambulate without physical assistance, significant cardiovascular health issues, and history of a previous stroke. Eligible individuals provided written informed consent to participate in the study. The study protocol was approved by the institutional review boards of Wayne State University, Detroit Medical Center, and the University of Indianapolis.

Characteristics for the sample included the mean ± SEM for age (55.7 ± 4.3 years; range, 31–89 years), height (1.7 ± 0.03 m), weight (86.7 ± 3.3 kg), and body mass index (BMI) (29.1 ± 1.5 kg/m^2). The mean number of months since the onset of the stroke was 13.5 ± 3.3 (range, 2–48 months). Eight of the 14 subjects were within 1 year of the onset of their stroke. Self-reported health status was rated as excellent (n = 1), very good (n = 3), good (n = 8), fair (n = 1), and poor (n = 1). Nine (64%) of the 14 subjects stated that they wear their brace all day, with the remainder using it primarily for community mobility. Ten of the 14 subjects used an assistive device for gait, yet all 14 subjects chose to do the testing without their assistive device.

Using the clinically valid cut points of 0.6 and 1.0 m/s for gait velocity, participants were categorized as slow, intermediate, and fast walkers (slow, <0.6 m/s; intermediate, 0.67–1.0 m/s; fast, >1.0 m/s).[23] For the shoes-only condition, 7 participants were classified as slow walkers, 5 as intermediate, and 2 as fast. Six of the 14 participants improved their gait speed category by wearing a hinged AFO.

STUDY DESIGN

The study utilized a repeated measures design. Each participant was assessed under three conditions: wearing their own C-AFO, wearing the P-AFO that had the best fit and provided the best biomechanical alignment, and with no AFO. Randomization of order of the three test conditions was obtained using a table of random numbers, thereby addressing any potential variability introduced by presence of fatigue or accommodation to walking during testing. Before the implementation of the gait/functional mobility assessments, the participants' height, weight, age, leg length, medical history, state of health, and assistive device and C-AFO use were recorded.

Participants were assessed in a series of gait and functional mobility tests. The order of testing of outcome measures was sit-to-stand on a force plate, maximal step length (MSL) test, gait on an instrumented walkway, and the timed up and go test (TUG). Once the subject had completed all of the tests for one condition (e.g., wearing the C-AFO), they would then change braces for the next testing condition.

Once all of the mobility assessments were completed for all three conditions, the research participant was asked to complete a brief questionnaire regarding his/her impressions about the two types of AFOs.

PROCEDURES

The research participants were asked to bring their C-AFO on the day of the data collection (the entire assessment was completed on one day, lasting from 45 to 90 minutes, depending on the participant's endurance level). All C-AFOs were made and fitted by a certified orthotist. Each research participant used the P-AFO that provided the best fit and matched his/her shank, ankle, and foot dimensions. An orthotics manufacturer (Orthomerica, Newport Beach, CA, USA) provided the various sizes of P-AFOs, with the correct fit determined by the principal investigator (and based on patient comfort). The participants used their own footwear, primarily a comfortable athletic or walking shoe for testing in all three conditions (C-AFO, P-AFO, and no-AFO).

During the testing of the gait parameters, those research participants who needed an assistive device were instructed to use that device as necessary. All participants tolerated wearing both of the hinged AFOs (custom-made or prefabricated) for all of the testing.

SPATIOTEMPORAL GAIT PARAMETERS

Stride length, step length, gait symmetry, and gait speed were assessed using the GAITRite (CIR Systems Inc, Sparta, NJ, USA). The GAITRite walkway has demonstrated excellent reliability (intraclass correlation coefficients [ICCs], between 0.82 and 0.92) in assessing temporospatial gait parameters in healthy young and older adults.[24] Stride length was measured as the line of progression between the initial contact points of two consecutive footprints of the same foot. Step length was measured as the line of progression from the heel center of the current footprint to the heel center of the previous footprint of the opposite foot. Both stride length and step length were measured in centimeters. Stance time percentage (for both legs) was calculated as stance time divided by the sum of stance and swing times multiplied by 100. Using this ratio provides a clearer picture of how much time is spent on the hemiplegic limb during gait.

FUNCTIONAL MOBILITY ASSESSMENTS

The MSL is a test of stepping capabilities and clinical balance that correlates with several balance and functional mobility measures in healthy and impaired adults (e.g., unipedal stance, tandem stance, TUG, performance-oriented mobility assessment, and the six-minute walk test).[25–27] Test-retest reliability values were found to be high (ICC $>$ 0.9) for the MSL in healthy women.[27] Participants stood adjacent to a yardstick on the floor with their feet together and their arms crossed. They stepped forward maximally with one leg and then returned to the starting position. Participants chose which foot would be the stepping foot (they were allowed one trial with each leg to decide which leg they preferred). The participants then performed three trials with their chosen leg (7 of the 14 subjects chose their involved leg). The MSL was recorded as the mean of these three trials.

A fixed dual force plate system measured the vertical forces exerted by a subject during dynamic activities and was used to assess the left/right symmetry of weight bearing during the performance of sit-to-stand (Balance Master; NeuroCom International Inc, Clackamas, OR, USA). Previous studies that used a force platform to assess patients with a stroke determined that the test-retest reliability is greatest for dynamic movements (ICC = 0.84 for standing weight shifts)[28] and that performance on sit-to-stand can identify fall risk.[29] The percentage of weight bearing on each foot during sit-to-stand was recorded. The subject sat on a box (41-cm tall) and stood on command, with heels an equal distance from the box and both feet an equal distance from midline. The mean of three trials was recorded as the percentage of weight on the involved and the uninvolved leg during the sit-to-stand movement.

The TUG has been shown to be a reliable measure of functional mobility and dynamic balance in older adults (ICC $>$ 0.90 for both interrater and intrarater reliability)[30–32] and in people with stroke (ICC $>$ 0.95)[33] Results from the TUG have been found to differentiate patients with stroke from a sample of healthy elderly subjects.[33] Participants stood from a chair with armrests, walked 3 meters at their self-determined safe walking speed, turned around, returned to the chair, and sat down. The time for the TUG was recorded (using a stopwatch) from the command "go" to the moment when the subject sat down again. The TUG was recorded as the mean time (in seconds) of three trials.

DATA ANALYSIS

The Statistical Package for the Social Sciences version 17 (SPSS Inc, Chicago, IL, USA) was used for all data analysis. The Kolmogorov-Smirnov test was used to confirm that each of the outcome variables was normally distributed. Because all variables in the study were normally distributed, parametric statistics were used to analyze the data. Repeated measures analysis of variance (ANOVA) was used to determine if there was a significant within-subjects effect for each of the gait (gait speed, stride length, step length, and gait symmetry) and functional mobility (TUG, MSL, and sit-to-stand symmetry) measures assessed under the three conditions used in this study (no AFO, C-AFO, P-AFO). Post hoc pairwise comparisons with Bonferroni adjustments for multiple comparisons were conducted when ANOVAs revealed significant within-subject effects. Statistical significance was set at $P < 0.05$.

RESULTS

There were significant within-subject effects for gait speed, stride length, step length, stance time percentage (uninvolved), TUG, and MSL-involved. Post hoc analyses showed significant differences between the braced (C-AFO or P-AFO) and the shoes-only conditions for the gait parameters (gait speed, stride length, step length, and stance time percentage [uninvolved]) and for the functional mobility assessments (TUG and MSL-involved). Post hoc analyses showed that there were no significant differences ($P > 0.05$) between the two braced conditions (C-AFO vs. P-AFO) for gait speed, stride length, and step length on the involved and uninvolved legs and stance time percentage of the uninvolved leg. Post hoc analyses also showed that there were no significant differences ($P > 0.05$) between the two braced conditions (C-AFO vs. P-AFO) for the TUG and MSL-involved. There were no significant within-subject effects for stance time percentage (involved), sit-to-stand symmetry (involved), and MSL-uninvolved (Table 1).

DISCUSSION

To the best of our knowledge, this is the first study that has investigated the effects of two types of hinged AFOs (custom-made and prefabricated) alongside a shoes-only condition on an individual's gait parameters and functional mobility measures after he/she had experienced a stroke. The purpose of this study was to assess if there were any differences in gait and functional mobility for patients with hemiplegia in three different conditions: wearing the C-AFO, the P-AFO, or no AFO. The hypothesis that there would be no significant differences in gait or functional mobility between the two types of hinged AFO was supported by these results. Therefore, the findings of this preliminary pilot study may indicate that wearing a P-AFO is as effective as wearing a C-AFO in improving the spatiotemporal gait parameters of the individual or his/her functional mobility measures. However, the clinicians and/or the orthotist must first ensure that the P-AFO provides optimal support to achieve the necessary biomechanical alignment and the patient feels comfortable while wearing a P-AFO. Optimal support can be achieved by ensuring that the P-AFO fits well with the anatomical dimensions of each individual patient. The aforementioned requirements were strictly adhered to in this study, and therefore the results of this preliminary study may not hold true if the aforementioned requirements are not met in clinical practice or in future studies.

There were significant differences between the braced and the shoes-only conditions for the majority of gait and functional mobility parameters. Wearing a brace allowed participants to increase gait speed, stride length, step length, and performance on the TUG. Previous studies have shown the benefits of wearing an AFO for participants who have had a stroke.[14,21] These findings are in line with the current results, further supporting the position that wearing an AFO improves gait and functional mobility in people who have had a stroke.

The results of this preliminary study may have some important implications for clinicians who recommend hinged AFOs for their clients with hemiplegia. The findings that there were no significant differences in gait and functional mobility parameters when wearing the C-AFO versus the P-AFO offer the possibility of the use of P-AFOs when some of the previously mentioned considerations are met to obtain a good fit

Table 1. Gait and functional mobility results for 14 adults with stroke

	No AFO	C-AFO	P-AFO
Gait speed, m/s	0.53 ± 0.07 (0.14–0.89)	0.66 ± 0.08 (0.17–1.15)*	0.63 ± 0.07 (0.2–0.97)*
Stride length (involved), cm	83.44 ± 6.68 (52.24–125.52)	96.12 ± 7.19 (56.36–145.70)*	94.15 ± 6.04 (63.84–127.65)*
Stride length (uninvolved), cm	83.26 ± 6.76 (51.31–124.91)	96.32 ± 7.05 (60.61–145.74)*	94.09 ± 5.97 (64.88–129.51)*
Step length (involved), cm	44.13 ± 3.59 (27.83–65.62)	50.05 ± 3.34 (36.62–71.65)*	48.82 ± 3.05 (34.28–63.81)*
Step length (uninvolved), cm	38.73 ± 3.59 (17.00–60.01)	45.53 ± 4.13 (18.77–73.99)*	44.52 ± 3.33 (24.72–64.08)*
Stance time (involved), %	59.87 ± 1.26 (53.43–67.17)	61.42 ± 1.18 (54.17–68.07)	61.42 ± 0.96 (55.60–68.33)
Stance time (uninvolved),%	74.09 ± 1.99 (66.03–86.10)	71.68 ± 1.84 (63.37–86.37)*	72.12 ± 1.87 (64.10–81.83)
TUG, seconds	23.74 ± 3.88 (12.05–53.21)	19.69 ± 3.33 (9.08–47.27)*	19.99 ± 3.15 (10.93–46.32)*
STS symmetry (involved), % weight	35.44 ± 3.66 (7.00–58.67)	31.00 ± 3.46 (2.67–46.00)	34.20 ± 3.25 (15.67–55.00)
MSL (involved), in	17.93 ± 1.89 (12.00–27.83)	20.60 ± 2.45 (10.33–32.17)*	20.31 ± 2.01 (9.75–29.50)
MSL (uninvolved), in	24.53 ± 2.94 (17.17–34.50)	24.64 ± 3.10 (16.17–34.50)	25.52 ± 2.66 (17.17–33.80)

Values are presented as mean ± SEM. Numbers in parentheses are the range of values.
There were no significant differences between the C-AFO and P-AFO conditions ($P > 0.05$) for all of the gait and functional mobility measures.
*$P < 0.05$ for no-AFO condition versus C-AFO or P-AFO.
AFO, ankle foot orthosis; STS, sit-to-stand; TUG, timed up and go; MSL, maximal step length.

and comfort for the patients. Clinicians are always striving to provide the best quality of care for their clients, but they also need to be mindful of the economic implications (both to the client and to the health care system). There are many clients who will have to pay out of pocket for medical equipment, and the significant cost difference between the C-AFO and the P-AFO can be a critical factor in the decision-making process.

It is important to note that there are certain subjects who would not be appropriate for the P-AFO such as subjects with sensory loss in the involved leg, subjects with diabetes mellitus, and subjects with significant anthropometric differences from the "standard" size. For example, if a subject is short in stature but wide in girth, he/she would need the large or extra-large P-AFO to fit the width of the calf. Unfortunately, the large or extra-large might be too long for his/her leg, resulting in the top of the P-AFO rubbing against the popliteal fossa. Therefore, it is important to realize that fitting a P-AFO correctly would not be possible for certain people, and in these circumstances, the cost should not be the factor that guides the clinical decision making. Although we did not test any of the above as part of this investigation, we believe a future study could examine the fitting of P-AFOs in greater detail.

Although the order of testing conditions (no brace, C-AFO, and P-AFO) was random, the order of performing the outcome measures was not random (for each of the three condition, the participants were tested on the Balance Master, the MSL test, the GAITRite walkway, and then the TUG). This fixed ordering of the tests may have had an effect on the results because fatigue may have played a role during these tests. Ng and Hui-Chan[33] determined that subjects with chronic stroke (at least one year after stroke) performed the TUG in 22.6 ± 8.6 seconds. There were 8 participants in this current study that were at least one year after stroke. These participants achieved an average TUG score of 23.21 seconds (no AFO), 20.82 seconds (C-AFO), and 20.73 seconds (P-AFO). This close agreement of our data to previously published data may suggest that the order of testing had not influenced the TUG scores for this sample of participants.

Overall, the questionnaire revealed that the participants rated the C-AFO more favorably compared with the P-AFO in questions relating to ease of donning/doffing, balance, gait, comfort, and cosmetic appearance. However, it should be noted that the participants were already accustomed to walking with the C-AFO but had used the P-AFO for the first time on the day of testing. Therefore, these findings must be interpreted with caution. Moreover, this is a limitation of this study and a future study can perhaps investigate the perception of the participant in greater detail.

Another limitation of this study is the relatively low sample size. Recruitment of subjects for this study was challenging for the following reasons: the specificity of the inclusion criteria (participants with hemiplegia who wear a C-AFO) and the lack of compensation for subjects who volunteered their time in performing this test. The specificity of the inclusion criteria also leads to another limitation, namely, the generalizability of the study. These results can only be applied to people with stroke, not to all AFO users. One final limitation is that the P-AFOs were not modified to improve the fit and comfort for the participants. By making the participants wear the unmodified P-AFO, the results were not as close to the clinical reality of the therapist being able to adjust the P-AFO. Future research will be required to determine the generalizability of the results among all AFO users with a multiplicity of diagnoses, as well as the long-term positive/negative effects of wearing P-AFOs. Therefore, a larger study is definitely warranted before the full effects of a P-AFO on gait parameters and functional mobility measures are fully understood. There is also a paucity of research on how the kinematics of lower-limb movement is affected when a patient walks with a P-AFO as opposed to a C-AFO.

CONCLUSIONS

This is the first report to compare a custom articulated to a noncustom articulated AFO in individuals with stroke and study their effects on that individual's spatiotemporal gait parameters and functional mobility measures. Although the C-AFO is designed to provide the best fit and comfort because it is designed to match each individual patient's anatomical parameters, the gait parameters and functional mobility measures with the C-AFO were not significantly different from the P-AFO. These preliminary findings suggest that a P-AFO may help in providing good support and biomechanical alignment in helping the individual achieve a better gait pattern, provided it is fitted to optimally match the individual's anatomical dimensions. The findings of this study may only be applicable in patients where the P-AFO fitting is deemed optimal by a clinician and/or orthotist. Furthermore, larger studies are needed to fully understand the effect of the P-AFO on the kinematics and kinetics of lower-limb movement during walking.

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