Original Research

Objective Assessment of Functional Ambulation in Adults with Hemiplegia using Ankle Foot Orthotics after Stroke

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Objective: To objectively evaluate the effect of ankle foot orthotics (AFOs) on functional ambulation in individuals with hemiplegia secondary to stroke using quantifiable outcome measures.
Design: With-without repeated measures design.
Setting: Rehabilitation research center.
Participants: Eighteen adults with stroke-related hemiplegia 6 months using a prescribed AFO.
Interventions: Not applicable.
Main Outcome Measurements: The distance (m) and velocity (m/s) during the 6-Minute Walk Test (6MWT) and total time (s) and velocity (m/s) during the 25-ft walk (25ftW). Secondary analysis evaluated the 6MWT and 25ftW grouped by the time component of the Ambulatory Index (AI).
Results: Distance walked during the 6MWT was significantly greater with AFO (228.54 ± 103.93) than without AFO (197.49 ± 104.13), $P = .002$. Time to complete the 25ftW was significantly greater without AFO (21.22 ± 20.57) than with AFO (15.49 ± 14.65), $P = .010$. There was a significant difference in average velocity between the 25ftW and 6MWT during the with AFO condition, $P = .010$. Secondary analysis grouped by the AI time showed that as level of function decreases, brace effect on functional ambulation increases (Group 3: 25ftW with AFO, $P = .040$).
Conclusions: AFO usage in hemiplegic stroke patients improves functional ambulation, particularly in individuals with a slower gait velocity. The 25ftW, with and without AFO, may be useful to the patient and clinician when determining the importance of brace utilization. Speed modulation was improved when the AFO was added to the paretic limb, and AI grouping indicated that the AFO was more beneficial in people with a slower gait velocity (>20 seconds for the 25ftW). A more definitive study is needed to more completely address this issue. As an exploratory study, the feasibility of different walking assessments was determined so that future studies can validate which objective measures can be used and easily implemented in clinical settings.

INTRODUCTION

Stroke is the leading cause of serious long-term disability in the United States; more than 1 million Americans experience functional limitations in activities of daily living as a result of stroke [1]. Addressing deficits in mobility after stroke is extremely important to the patient with hemiplegia and is often one of the first physical impairments to be addressed in the early stages of rehabilitation [2,3]. Patient goals for rehabilitation after stroke are primarily functional in nature and regaining the ability to walk is a key objective [4,5]. Assistive technology devices such as ankle foot orthotics (AFOs) can be incredibly useful in accommodating the limitations in mobility that result from stroke [3]. AFOs serve to assist, control, and maintain the desired position of the ankle and foot during walking, potentially leading to improved functional ambulation [6]. Functional ambulation includes the extent to which an individual is capable and willing to move around in their environment [7]. Previous research has attempted to group or define

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Disclosure: 7A, Innovative Neurotronics; 8A, NIDRR Switzer Grant and NIDRR TBI Model Systems

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Disclosure: nothing to disclose

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Disclosure: 8A, NIDRR TBI Model Systems

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Disclosure: 2A, Allergan; 7A, Allergan; 8A, NIDRR TBI Model Systems

Disclosure Key can be found on the Table of Contents and at www.pmrjournal.org

The contents of this publication were developed under a grant from the Department of Education, NIDRR grant number H133P020012. However, those contents do not necessarily represent the policy of the Department of Education, and you should not assume endorsement by the Federal Government.

Supported by the Department of Education National Institute on Disability and Rehabilitation Research (grant no. H133P020012), New Balance Athletic Shoe, Inc, and Kessler Foundation.

Submitted for publication January 21, 2009; accepted April 28.

PM&R
1934-1482/09/$36.00
Printed in U.S.A.

Vol. 1, 524-529, June 2009
DOI: 10.1016/j.pmrj.2009.04.011

changes in functional walking after stroke, but has not specifically identified how an AFO changes functional ambulation [8,9]. Improvements in mobility from AFOs have been demonstrated in outcome variables such as velocity, stride length, and gait patterns, but the functional significance of these improvements has rarely been considered [9]. Research efforts have focused on neuromuscular and biomechanical changes in acute stroke without considering their relationship to function [9].

It is important for clinicians to use measures capable of detecting changes in functional mobility that reflect safe and practical real life function [10]. Previous research in this area suggests that individuals must negotiate a distance between 332 and 360 m to access goods and services in the community [11,12]. Walking distance is therefore a key indicator of functional ambulation [13]. Gait velocity is also an important reliable measure of functional ambulation after stroke because safe navigation of community crosswalks mandates that an individual be able to complete a prescribed distance in a defined period [10,11]. Average crosswalks in commercial areas require a walking velocity of 1.31 m/s to successfully cross the intersection [12]. Crosswalks in commercial areas range in length from 22 to 34 m, and provide approximately 20.5 seconds on average to walk from curb to curb [12]. In residential areas, crosswalks are considerably shorter and range from 8 to 16 m [12]. Successful community ambulation after stroke requires walking a long enough distance and sufficient gait velocity to cross streets in a timely manner and to access goods and services.

Measures of walking distance (6-Minute Walk Test; 6MWT) and velocity (25-ft Walk; 25ftW) have been validated as objective outcome measures by researchers and clinicians to evaluate functional ambulation after stroke [4]. The 6MWT is one measure frequently used to evaluate walking distance among individuals after stroke. This measure demonstrates a high degree of reliability and is correlated to other measures of walking ability and function. The ease of administration, interpretation, and low cost make these functional ambulation tests very practical for clinical use. The ability to quantify these outcomes makes them intrinsically more objective and sensitive [14,15]. Therefore, measurements of functional ambulation are critical to identify improvements in mobility after stroke. Previous work has not adequately addressed the relationship between AFO utilization and changes in functional ambulation after stroke. The purpose of this investigation was to address this issue by objectively evaluating the effect of AFOs on functional ambulation in individuals with hemiplegia secondary to stroke by using quantifiable outcome measures.

METHODS

Participants

Individuals with hemiplegia secondary to cerebrovascular incident with symptoms lasting more than 6 months were recruited for participation. All participants had been prescribed an AFO for functional ambulation by their treating physician. Other inclusion criteria included: 1) uninvolved lower limb had no history of injury or pathology; 2) must be able to walk independently or with supervision for 25 ft, both with and without AFO; and 3) must wear an AFO when walking at least 50% of the time. Individuals with significant orthopedic, neuromuscular, or neurological pathologies or history that would interfere with walking or limit the range of motion of the legs were excluded from the study.

Procedures

Participant mobility was evaluated by research personnel and the study physician using the Ambulation Index (AI), an ordinal rating scale designed to assess independent mobility by evaluating the time and degree of assistance required to walk 25 ft. The scale typically ranges from 0 (asymptomatic and fully active) to 10 (bedridden) [16].

Functional ambulation was measured using the 6MWT and timed 25ftW with (+AFO) and without (-AFO) an AFO. Participants completed one 6MWT and one timed 25ftW in each test condition, with the order being randomly assigned. All participants received standardized instruction in the performance of the walking tests. For the 6MWT, participants were instructed to walk as far as possible, safely, and at their self-selected comfortable pace for 6 minutes. The distance covered every 30 seconds during the 6MWT was recorded to the nearest inch using a measuring wheel. Per convention, all data were converted to the metric system before analysis. For the 25ftW, participants were instructed to walk as fast as possible and safely for 25 ft. The time to walk 25 ft was recorded to the nearest 100th of a second. During all walking tests, participants were allowed to stop and rest if necessary but time kept running. Members of the study team provided supervision and noncontact guarding during all walking trials for safety. All procedures performed in this investigation were approved by the Human Subject Review Board and informed consent was obtained before study participation.

Outcome Measures

The total distance (m) and velocity (m/s) during the 6MWT and total time (s) and velocity (m/s) during the 25ftW were the primary variables of interest. The selected walking tests are

Table 1. *Participant characteristics*

	Age (y)	Height (in)	Weight (kg)	Time Since Stroke (mo)
Mean ± SD	53.44 ± 11.50	67.64 ± 4.78	190.03 ± 44.06	54.89 ± 36.98

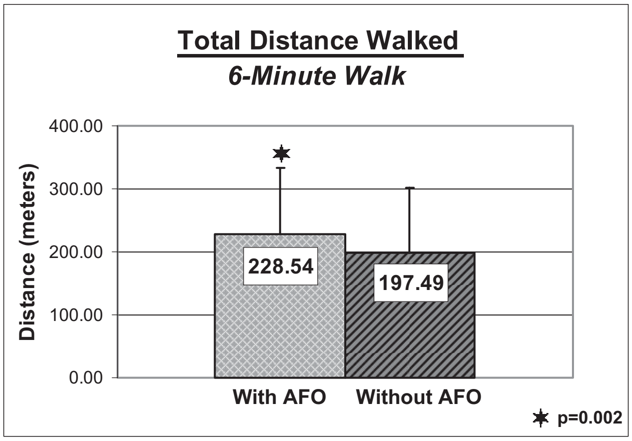

Figure 1. Total distance walked (m) with AFO and without AFO during the 6-minute walk test.

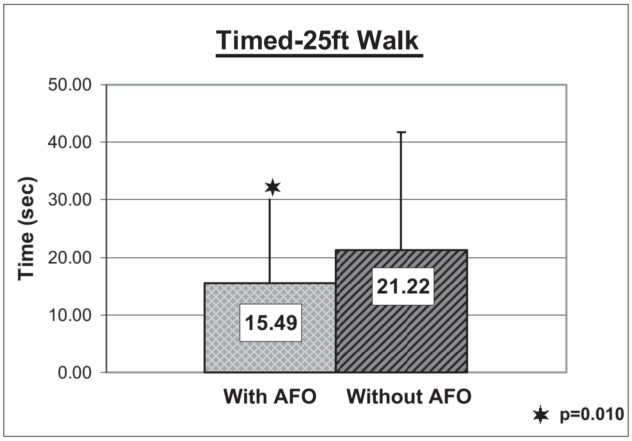

Figure 3. Time (s) to complete the 25-foot walk (25ftW) with AFO and without an AFO.

quantitative functional mobility performance tests. The time component of AI scores was used to group participants by mobility. Demographic information including age, gender, time since stroke, location, and type of stroke was collected and verified with medical records. Data from all assessments will be represented as mean ± standard deviation.

Data Analysis

Demographic data were analyzed using descriptive statistics in SPSS version 16.0. Paired sample *t*-tests were performed to determine if there was a significant difference in the total distance walked during the 6MWT and time to complete the 25ftW between the two conditions, with AFO and without AFO. Velocity during the 6MWT and 25ftW were calculated and analyzed using paired sample *t*-tests to determine if there were significant differences in velocity between the 2 walking tests with and without AFO. Velocity difference scores for the 6MWT and 25ftW were also calculated for each condition and analyzed using a paired sample *t*-test.

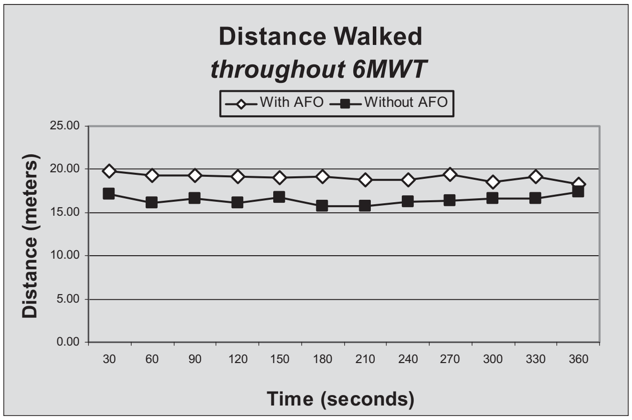

Figure 2. Total distance walked (m) with AFO and without an AFO throughout the 6-minute walk test (6MWT).

Secondary analysis evaluated functional performance on the 6MWT and 25ftW as grouped by the time component of the AI. Grouped walking trials were analyzed for AFO effect and AI group by AFO interaction using repeated measures analysis of variance. Paired sample *t*-tests were used to compare differences within AI groups between the 2 conditions.

RESULTS

Twenty participants agreed to participant in the study. Data from 18 participants (14 men and 4 women) were available for analysis because the 6MWT was not successfully completed by 2 participants in the without AFO condition. Of the patients who were included in the analysis, 9 participants were affected on the right side and 9 were affected on the left. Sixteen participants used a rigid plastic brace, one participant used a hinge brace, and the other participant used a dynamic brace. A detailed description of patient characteristics can be found in Table 1.

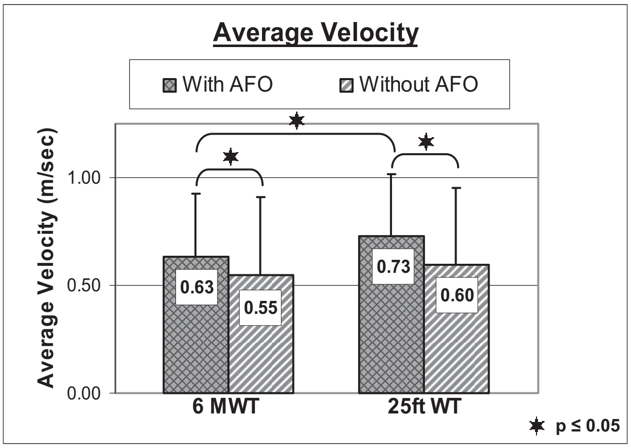

Figure 4. Average velocity (m/s) during functional ambulation outcome measures with AFO and without AFO.

Table 2. *Functional ambulation outcome measures (6MWT distance and 25ftW time) grouped by AI time component with AFO and without AFO*

	6MWT Distance (m)			25ftW Time (s)		
Mean ± SD	**With AFO**	**Without AFO**	***P* Value**	**With AFO**	**Without AFO**	***P* Value**
Group 1	338.41 ± 66.60	319.18 ± 44.06	.223	7.02 ± 1.67	7.60 ± 1.54	.087
Group 2	229.16 ± 65.24	195.86 ± 61.45	.069	11.46 ± 3.00	14.60 ± 4.55	.037
Group 3	117.66 ± 59.72	78.40 ± 35.87	.041	30.40 ± 22.20	45.42 ± 26.62	.040

6MWT = 6-minute walk test; 25ftW = 25-foot walk; AI = Ambulation Index; AFO = ankle foot orthotic.

Total distance walked during the 6MWT was significantly greater with AFO (228.54 m ± 103.93) than total distance walked without AFO (197.49 m ± 104.13), t(17) = -3.69, *P* = .002 (Figure 1). Distance walked every 30-second interval throughout the 6MWT was consistently greater in the with AFO condition except for during the last 30 seconds of the trial (Figure 2). Time to complete the 25ftW (Figure 3) was significantly greater without AFO (21.22 seconds ± 20.57) than time to complete the 25ftW with AFO (15.49 seconds ± 14.65), t(17) = -2.89, *P* = .010.

Average velocity was evaluated using paired sample *t*-tests during the 25ftW and 6MWT. There was a significant difference in average velocity between the 25ftW and 6MWT during the with AFO condition, t(17) = 2.901, *P* = .010 (Figure 4). In the without AFO condition, average velocity during 25ftW and 6MWT were not statistically different, t(17) = 1.57, *P* = .136. Velocity difference scores between 6MWT and 25ftW were evaluated for both conditions using a paired sample *t*-test. The velocity difference within the AFO condition was significantly greater than the difference within the without AFO condition, t(17) = 2.38, *P* = .030.

The distribution of AI scores, which typically ranges from 0 to 10, was limited to 0-5 by the study's inclusion criteria, as shown in Table 3. The sample was grouped according to the time classifications provided in the AI during the 25ftW performance without AFO (Figures 5, 6): Group 1 completed the 25ftW in less than 10 seconds (AI score = 1 and 2); Group 2 completed the 25ftW in 10-20 seconds (AI score = 3 and 4); Group 3 completed the 25ftW in more than 20 seconds (AI score = 5). When examining the distance walked during the 6MWT across AI groups, there was an overall significant effect for AFO condition, F(1,16) = -11.68, *P* = .004, with no group by AFO condition interaction, F(2,15) = 0.39, *P* = .682 (Figure 6). During the 25ftW, there was an overall significant effect for AFO condition, F(1,16) = 17.13, *P* = .001. In addition, there was a significant interaction between AI group and AFO condition, F(2,15) = 7.91, *P* = .005 (Figure 5). In AI Group 1, there was no significant effect for AFO condition for the time to complete 25ftW (Table 2). During the 25ftW in Group 2 and 3, the time to complete the 25ftW significantly decreased when wearing the AFO, Group 2 t(7) = -2.57, *P* = .037 and Group 3 t(4) = -3.00, *P* = .040.

DISCUSSION

This study demonstrated AFOs improve functional ambulation in individuals with stroke; this was demonstrated in both the improved distance (6MWT) and increased velocity (25ftW). This study is the first to demonstrate the consistency of this finding during the 6MWT, as the measured distance walked every 30 seconds was consistently higher when wearing a brace. This has important functional implications in the community because increased distance and

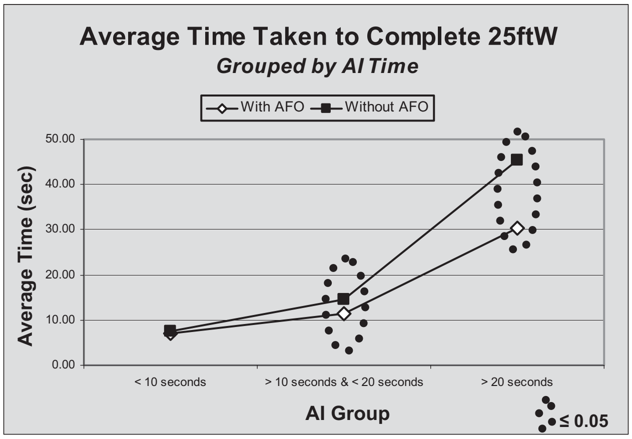

Figure 5. Time (s) to complete the 25-foot walk (25ftW) grouped by Ambulation Index (AI) time with AFO and without an AFO.

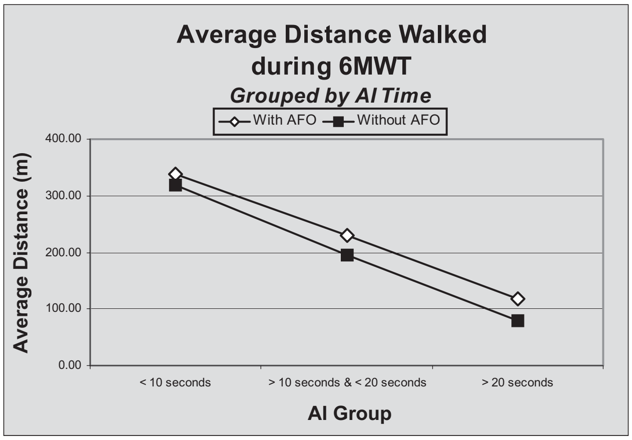

Figure 6. Average distance walked (m) during 6-minute walk test (6MWT) grouped by Ambulation Index (AI) time with AFO and without an AFO.

Table 3. *Ambulation Index assessment and time classifications*

AI Score	AI Criteria (16)	Number of Participants in AI Group	Groups Created by AI Time Component	Number of Participants in AI Time Group
0	Asymptomatic: fully active	0	—	—
1	Walks normally, but reports fatigue that interferes with athletic or other demanding activities	1	Group 1: walk 25 ft in 10 s or less	5
2	Abnormal gait or episodic imbalance; gait disorder is noticed by family and friends; able to walk 25 ft (8 m) in 10 s or less	4		
3	Walks independently; able to walk 25 ft in 20 s or less	7	Group 2: walk 25 ft in 20 s or less	8
4	Requires unilateral support (cane or single crutch) to walk; walks 25 ft in 20 s or less	1		
5	Requires bilateral support (canes, crutches, or walker) and walks 25 ft in 25 s or less; *or* requires unilateral support but needs more than 20 s to walk 25 ft	5	Group 3: walk 25 ft in more than 20 s	5

AI = Ambulation Index.

velocity over extended periods suggests greater walking efficiency and endurance. When individuals don their brace and are consistently able to walk a further distance in the community, they will have more access to goods and services, potentially encouraging greater activity and community involvement [12].

Data analysis also established that AFO implementation to the paretic limb provides individuals with the ability to modulate gait speed. Before donning the AFO, self-selected walking speed during the 6MWT and fastest walking speed during the 25ftW were not statistically different. Conversely, with the AFO participants were able to increase their walking velocity during the 25ftW above the level demonstrated during the 6MWT. The ability to generate a statistically greater velocity while wearing the brace may increase safety by providing the ability to modulate speed while negotiating community obstacles and hazards. The functional ability to increase speed in the community is essential for negotiating obstacles and safely crossing community streets [11]. The ability to modulate speed with the addition of the AFO is a significant improvement in functional ambulation. Previous research found that individuals who were more reliant on physical assistance or assistive devices other than AFOs during walking were less capable of changing gait speed [17]. This study suggests an AFO may enable individuals to improve functional ambulation by increasing gait velocity and walking distance more efficiently than canes, walkers, or physical assistance and this possibility should be investigated in future research.

It is important to note that the fastest gait velocity attained throughout all walking trials was on average 0.70 m/s. Normal, healthy, self-selected walking velocity is 1.48 m/sec for men and 1.23 m/s for women compared with mean self-selected velocity of higher functioning individuals after stroke on average 0.80 m/s [8,18]. The fastest velocity that could be generated was still at a lower level than that and the target goals for the populations, which indicates that functional ambulation goals after stroke should be based on higher functioning stroke survivors and not healthy controls [19]. It should be noted that this represents a functional compromise; a decreased gait velocity may be adequate for basic activities of daily living, but may not be sufficient for crossing wide streets in the allotted amount of time [8].

When participants were grouped by the AI time component, it was shown that higher functioning individuals walked further during 6MWT and faster during 25ftW (Figures 4, 5). Data analysis for the 25ftW showed that as level of function according to AI decreases brace effect on time to complete the 25ftW increases. The 25ftW was more sensitive to impairment levels based on the AI time variable in the sample because the AI assessment is established by speed performance during a timed 25ftW. The interaction of AI time classifications on brace condition did not carry over when considering effect of AFO during the 6MWT as an outcome measure for functional community mobility. It is important to note that this classification was derived through secondary analysis; the lack of significance might well be due to the limited sample size by group. Future studies with a larger sample size and equal numbers of participants in each impairment category may be necessary to indicate further correlations between AI time classifications and functional mobility as assessed by both 25ftW and 6MWT.

Many patients are resistant to wearing their AFOs and often ask their physician whether they must wear the brace. This may be especially true with the population evaluated in this study who can manage to walk without their brace. Although no definitive comments can be made on safety from this study, safety with regards to modulating speed is certainly associated with brace wear. Speed modulation is necessary for those walking in the community where crosswalks and traffic are persistent. The simplicity and ease of implementation of the 25ftW makes it a candidate to be of great utility in facilitating the physician's decision-making process. The ability to demonstrate speed modulation would support a brace's utility, which also supports the clinical decision to prescribe a brace and encourage patient compliance.

A potential limitation of this study is that the time between 6MWT tests with and without AFO was not standardized for each patient. Testing was arranged around the time constraints of the participant and members of the research team, similar to previous studies conducting timed walking tests [10]. Adequate rest was provided between trials if measures were collected on the same day to minimize any affects of fatigue.

An additional possible limitation is that brace type was not standardized for each patient in this investigation. The hinge brace and the dynamic AFO had a similar effect to the rest of the sample when difference scores were evaluated during preliminary data analysis. It is possible that different AFOs could potentially provide a biomechanical advantage and AFO type should be evaluated in future research.

Another potential limitation of the current study is that the inclusion and exclusion criteria of the study created a sample of stroke patients that are classified as higher functioning according to AI—although previous research has found that patients who receive an AFO at entry to or discharge from rehabilitation are more functionally impaired than those patients that do not receive an AFO [20]. This study suggests that higher functioning patients may benefit from the use of an AFO to increase and improve community ambulation.

CONCLUSION

This study demonstrates that AFO usage in hemiplegic stroke patients improves functional ambulation particularly in individuals with a slower gait velocity. It provides evidence that the 25ftW, with and without the AFO, may provide information that is useful to the patient and clinician regarding the importance of brace utilization. In the study population, the ability to modulate speed was improved when the AFO was added to the paretic limb. A more definitive study will be needed to more completely address this issue. As an exploratory study, the feasibility of different walking assessments was determined so that future studies can validate which objective measures can be used and easily implemented in clinical settings. The outcomes of these walking tests are clinically relevant in appropriating quality care and prioritizing functional improvements in the stroke population. The results of this study also agree with previous findings that gait velocity is a more reliable and sensitive measure in individuals who require more assistance during walking [17]. It is clear that the brace improves velocity, but functional mobility will be greatly affected by an individual's endurance. It would be helpful to collect physiological cost index values for walking trials and daily measures of walking which can evaluate the element of endurance in community mobility. Future research with a larger sample size is necessary to more comprehensively understand the affect of an AFO on functional ambulation and the relevance of AI on community mobility.

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