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Abstract

Purpose: The study was carried out as a randomized clinical trial to assess the effect of posterior leaf spring ankle foot orthosis (PLS-AFO) and carbon composite ankle foot orthosis (C-AFO) on functional mobility, walking speed and satisfaction among stroke survivors with hemiplegia. **Methods**: Twenty-seven ambulatory stroke survivors with hemiplegia who had completed a rehabilitation program and were already using an ankle foot orthosis (AFO) were included in the study. Subjects were randomly assigned either PLS-AFO or C-AFO and assessment was done with and without their AFOs. Functional mobility, walking speed, and satisfaction were assessed using the Timed Up and Go test, the 10-meters walking test and the Client Satisfaction with Device questionnaire, respectively. **Results:** Both types of AFO improved functional mobility. C-AFO and PLS-AFO reduced Timed Up and Go test time by 7 seconds (22.4%), and 4.4 seconds (10.5%) respectively. Self-selected walking speed increased in AFO users by 0.20 m/s (40%) and 0.10 m/s (33.3%) for C-AFO and PLS-AFO, respectively. No changes were observed during the fast-walking speed. With both AFOs, participants were satisfied in terms of weight, fit and comfort (>90%). **Conclusion:** It is concluded that both PLS-AFO and C-AFO can improve the walking ability of stroke survivors with hemiplegia. C-AFO demonstrated better self-selected walking speed and functional mobility as compared to PLS-AFO. Neither of the AFOs improved the fast-walking speed. Both AFOs provided a high level of user satisfaction.

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ABSTRACT

Purpose: The study was carried out as a randomized clinical trial to assess the effect of posterior leaf spring ankle foot orthosis (PLS-AFO) and carbon composite ankle foot orthosis (C-AFO) on functional mobility, walking speed and satisfaction among stroke survivors with hemiplegia. **Methods**: Twenty-seven ambulatory stroke survivors with hemiplegia who had completed a rehabilitation program and were already using an ankle foot orthosis (AFO) were included in the study. Subjects were randomly assigned either PLS-AFO or C-AFO and assessment was done with and without their AFOs. Functional mobility, walking speed, and satisfaction were assessed using the Timed Up and Go test, the 10-meters walking test and the Client Satisfaction with Device questionnaire, respectively. **Results:** Both types of AFO improved functional mobility. C-AFO and PLS-AFO reduced Timed Up and Go test time by 7 seconds (22.4%), and 4.4 seconds (10.5%) respectively. Self-selected walking speed increased in AFO users by 0.20 m/s (40%) and 0.10 m/s (33.3%) for C-AFO and PLS-AFO, respectively. No changes were observed during the fast-walking speed. With both AFOs, participants were satisfied in terms of weight, fit and comfort (>90%). **Conclusion:** It is concluded that both PLS-AFO and C-AFO can improve the walking ability of stroke survivors with hemiplegia. C-AFO demonstrated better self-selected walking speed and functional mobility as compared to PLS-AFO. Neither of the AFOs improved the fast-walking speed. Both AFOs provided a high level of user satisfaction.

Keywords: ankle foot orthosis, stroke rehabilitation, walking speed, gait, functional mobility

INTRODUCTION

Ankle foot orthoses (AFOs) remain the most commonly prescribed orthoses post-stroke to facilitate toe clearance in the swing phase of gait, provide medio-lateral stability at the ankle in the stance phase, and promote heel strike.[1,2] There is considerable evidence that AFOs improve gait parameters such as cadence, walking speed, gait pattern, stride length, and gait velocity in stroke survivors.[1,3] Many types of AFOs are used for rehabilitation of stroke survivors including solid AFOs, articulated AFOs, and flexible AFOs.[4,5] In spite of the extensive literature regarding the use of AFOs, randomised control trials are scarce, and the popularly prescribed AFOs are not well-studied in comparison to new types of AFOs.[6,7] Most comparisons are carried out among rigid, articulated, and flexible AFOs; however, comparison between flexible AFOs is less often reported.[1,4,6-8]

Carbon composite AFOs (C-AFOs) and posterior leaf spring AFOs (PLS-AFOs) are types of flexible AFOs often used to assist in walking in stroke survivors with hemiplegia.[1,4,9] To our knowledge, there is no published study to date that specifically compares the use of C-AFOs and PLS-AFOs in stroke survivors. Though both types of AFOs are flexible and have similar indications, there are structural and functional variations between the two. The PLS-AFOs are dynamic AFO made from a moulded thermoplastic material (polypropylene) which offer flexibility at the anatomical ankle joint. During loading response, PLS-AFO control plantarflexion of the foot (prevent foot slap), which substitutes the missing function of eccentric contraction of muscles of the anterior compartment of the leg (tibialis anterior muscles). After mid-stance, the flexibility of PLS-AFOs allows dorsiflexion that enables smooth tibial advancement over the foot. It supports the foot throughout the swing phase to prevent plantarflexion, aiding foot clearance while placing the foot in the appropriate positioning for the next initial contact.[10] PLS-AFOs are recommended for isolated dorsiflexor weakness; without spasticity or with mild spasticity.[9] C-AFOs are fabricated from layers of carbon and other fabric impregnated in resin and cured at a high temperature. C-AFOs have a spring-like effect that provides the ability to enhance energy from a loading response through mid-stance and releases the energy from the terminal stance though pre-swing.[11,12] C-AFOs provide biomechanical assistance and have similar indications as that of PLS-AFO. Additionally, because of spring action, it assists push-off during the terminal stance through pre-swing.[11,13] The use of C-AFOs in a population with neurologic gait dysfunction shows a positive trend for improvement in step length, cadence, and walking speed, and decreases the energy required to ambulate.[1,13,14] Furthermore, C-AFO designs classically have higher rates of overall satisfaction because of their modern appearance and weight but are more expensive than plastic AFOs.[14-16]

The main aim of this study was to assess the effects of PLS-AFO and C-AFO on gait, functional mobility, and satisfaction on stroke survivors with hemiplegia.

METHODS

Setting and Study Population

This study was a prospective randomized clinical trial conducted between January to September 2018 at the orthotic clinic of the Rehabilitation Hospital at King Fahad Medical City, a tertiary referral centre in Saudi Arabia. The study was approved by the institutional review board of the hospital (IRB log number 17-199). Stroke survivors who visited the orthotic clinic during the study period and met the inclusion criteria were included in the study. Patients aged > 18 years, of any stroke onset with hemiparesis, having ankle dorsiflexor weakness and ankle planter flexor spasticity on the Modified Ashworth Scale of less than 3 on the affected side were included in the study. Stroke survivors using AFOs who had completed an inpatient rehabilitation program and were able to walk more than 10 meters with or without the AFO were considered eligible participants. Those patients were who were able to follow three-step commands and were willing to participate in the intervention and provide informed consent were included in the study. Those with expressive aphasia were included if they were consistently able to follow instructions. Patients were excluded if they were medically unstable, had severe global communication problems (severe receptive dysphasia), or other medical problems that affected walking (such as in cardiovascular disease, pulmonary disease or degenerative disease of hip or knee).

Randomization and Allocation of AFOs

All eligible participants who agreed to participate signed a consent form and were given the study number before being assigned into study group, either C-AFO or PLS-AFO by using block sampling technique. A random binary coded random block of four numbers developed in MS Excel was used to allocate participants to either PLS-AFO or C-AFO, and the equipoised distribution of patients was maintained. Henceforth, it was an open-label parallel arm study, and the participants were allowed to withdraw from the study at any time.

Intervention

Two types of flexible AFOs were used in the study; PLS-AFO and C-AFO produced by Ottobock (catalogue reference number 28U9 and 28U23 respectively)**.** Fitting of the allocated AFO was done by a certified orthotist. Subjects were provided an AFO to use for seven days before reassessment and data collection. Patients were asked not to use their old AFO. Patients were not enrolled in an active physical therapy program or formal gait training during the study period.

Assessment Tools

Valid and reliable outcome measures were used; the 10-Meter Walking Test (10MWT) was used to assess walking speed.[17] The Timed Up and Go (TUG) test was used for assessment of functional mobility, and satisfaction with AFO was measured by the Client Satisfaction with the Device questionnaire, Arabic version (CSD-Ar).[3,18-20] The timing of walking speed and functional mobility were recorded using a digital iPhone 6 stopwatch function. The iPhone was checked for percentage error and deviation of data within the readings.[21]. To avoid inter-rater variability, stopwatch measurements were recorded by one person who was not involved in allocating participants to the study group.

Walking Speed

Walking speed was assessed in two conditions -- at self-selected walking speed and fast walking speed. Participants were instructed to walk 10 meters distance three times at a self-selected walking speed and fast speed if possible. The time spent to cover the middle six meters was recorded in seconds. The walking speeds of both a self-selected walking speed and a fast-walking speed were calculated by dividing the distance covered (middle six meters) by the average time.[17,22,23] Participants who felt unsafe or who were used to walk with a cane could use walking canes throughout the tests. The first walking assessments was performed while participants wore their standard shoes, without AFOs, and with or without a walking cane depending on the participant's choice. The second walking assessments was done a week later (7 days) with the same standard shoes and the provided AFO (PLS-AFO or C-AFO) with or without a walking cane depending on the patient's choice during the first test.

Functional Mobility

Functional mobility was assessed by using TUG test, based on instructions derived from Podsiadlo and Richardson.[19] Participants were timed while rising from a chair, walking three meters, turning, walking back, and sitting down again. The assessments were done without an AFO and with AFO. Patients practised once to familiarize themselves with the test before the real, timed test was performed. The first assessment was performed on participants wearing their standards shoes, without an AFO, and with or without a walking cane depending on the participant's choice. The second test was done after one week (7 days) while participants wearing the same standard shoes with the provided AFO (C-AFO) or PLS-AFO). If the walking cane was used on the first assessments, it was also used on the second assessment. A digital stopwatch from an iPhone application was used to measure time.

Satisfaction

At the end of the second walking assessments, participants were provided with a Client Satisfaction with the Device Arabic version (CSD-Ar) questionnaire, to fill out regarding the provided AFO.[20] CSD-Ar questionnaires assessed various aspects of AFO, including; fitting, weight, comfort, ease of wear, appearance, durability, pain and skin effects.[20]

Statistical Methods

The open-label parallel-arm study was designed to measure the effect of 'PLS-AFO' and 'C-AFO' in stroke patients. It was presumed that both orthosis arms were equally good, and the sample size of ten participants for each arm was sufficient to measure critical difference at 95% CI with 90% power of the study. While bearing with the 50% drop out rate, a total number of 32 patients were allocated into two arms by block sampling technique. In addition, mobility data and satisfaction survey questionnaires were tested on ten age-matched controls for measurement of least significant difference. Data were recorded on a data sheet and then entered in excel sheet.

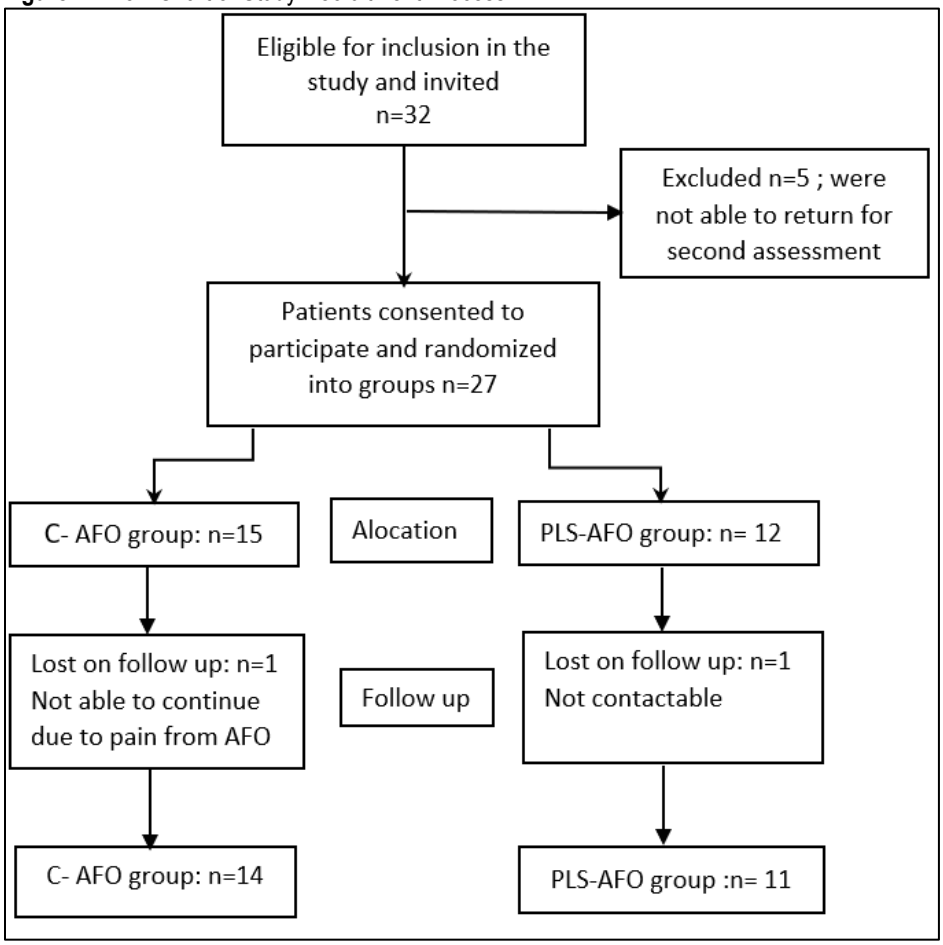
Categorical data were described as frequency percent, and the metric data was described as mean ± SD. Normality of the data was checked using the Shiprov-Wilk test and Kolmogorov-Smirnov test, which was significantly violated for all the metric variables. Intergroup comparison for the mobility effect of C-AFO versus the mobility effect of PLS-AFO was done using the Mann Whitney U test and Fisher's exact test for non-metric data. The intragroup comparison for TUG time and walking speed was done by Wilcoxon matched-pair test. All the inferences were drawn at a 95% confidence interval with the help of SPSS 25.0 statistical software.

RESULTS

Participants

A total of 32 patients were screened for eligibility within a period of nine months, out of which 5 could not return for assessment. Thereby, 27 patients completed the first assessment. One patient complained of pain and other disliked the orthosis which resulted attrition in the study. Hence the subsequent second assessment was done in 25 patients only. Details of participants workflow is shown in Figure 1. The mean follow-up for all AFOs was 7.3 ± 1.9 days; The difference was not significant in participants follow up date between the two groups.

Figure. 1. Flow Chart of Study Recruitment Process.



Demographic Characteristics

The majority of participants were males (n=23, 71.9%). Males and females were observed in each group, and the difference was not significant (P > 0.694) on gender distribution. The average duration of stroke onset was 17 months, ranging from 9 months to 36 months. Mean age of all participants was 49±12.3 (range 25 and 68) years. Detail demographic characteristics of participants are shown in Table 1.

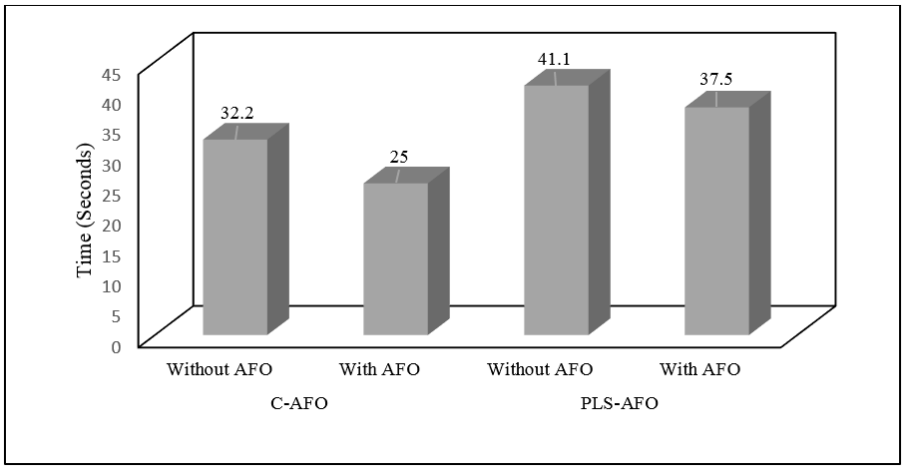
Table 1. Demographic Characteristics of Participants.

Characteristic		C-AFO (n=16)	PLS-AFO (n =16)	p-value	95% CI
Gender	Female	5 (31.25)	4 (25.00)	0.694	-0.243 - 0.373
	Male	11 (68.75)	12 (75.00)		
Age (year)	mean ± SD	47.6 ± 11.9 (30, 68)	50.8 ± 13 (25, 65)	0.518	-12.193 - 5.798
Side Affected	Left	9 (56.25)	6 (37.50)	0.288	-0.152 - 0.527
	Right	7 (43.75)	10 (62.50)		
Cause	Ischemic Stroke	9 (56.25)	12(75.00)	0.246	-0.135 - 0.510
	Haemorrhagic Stroke	7 (43.75)	4 (25.00)		
Assistive Device	None	11 (68.75)	7 (43.75)	0.154	-0.083 - 0.583
	Walking Cane	5 (31.25)	9 (56.25)		
Follow-Up (day)	mean ± SD	7.5 ± 2.3 (5, 15)	7.2 ± 1.2 (5, 9)	0.627	-1.024 - 1.624

Functional Mobility

There was no significant difference in TUG time between the C-AFO participants and PLS-AFO before application of the AFOs (p=0.0229). Similarly, with the AFOs, TUG time between C-AFO participants and PLS-AFO participants was not statistically significant (p=0.072); however, there was a significant reduction of TUG time on each group. C-AFO group TUG time was reduced by 7.0 seconds (p=0.001) while PLS-AFO group TUG time was reduced 3.4 seconds (p=0.002) when compared with TUG without AFO. Paired comparison showed that both AFO types improved functional mobility; C-AFO by 22.4% from baseline measurement, whereas PLS-AFO improved by 10.5% (Figure 2)

Figure. 2. Comparison of TUG Time in Carbon Composite Ankle Foot Orthosis (C-AFO) and Posterior Leaf Spring Ankle Foot Orthosis (PLS-AFO).



Walking Speed

There was no significant difference between the participants in both groups; C-AFO and PLS-AFO without AFO and with AFO during self-selected walking speed as well as fast walking speed (Table 2). There was significant improvement on self-selected walking speed when AFOs were applied (on follow up); C-AFO group improved walking speed by 0.20m/s (p=0.01) while PLS-AFO group improved walking speed by 0.10m/s (p=0.009). Both AFO groups improved their self-selected walking speed. The C-AFO group increased self-selected walking speed by 40% from the baseline measurement among C-AFO cases, whereas PLS-AFO group improved self-selected walking group by 33.3%. (Figure 3)

Figure. 3. Comparison of Self-Selected Walking Speed (m/s) in Carbon Composite Ankle Foot Orthosis (C-AFO) and Posterior Leaf Spring Ankle Foot Orthosis (PLS-AFO).

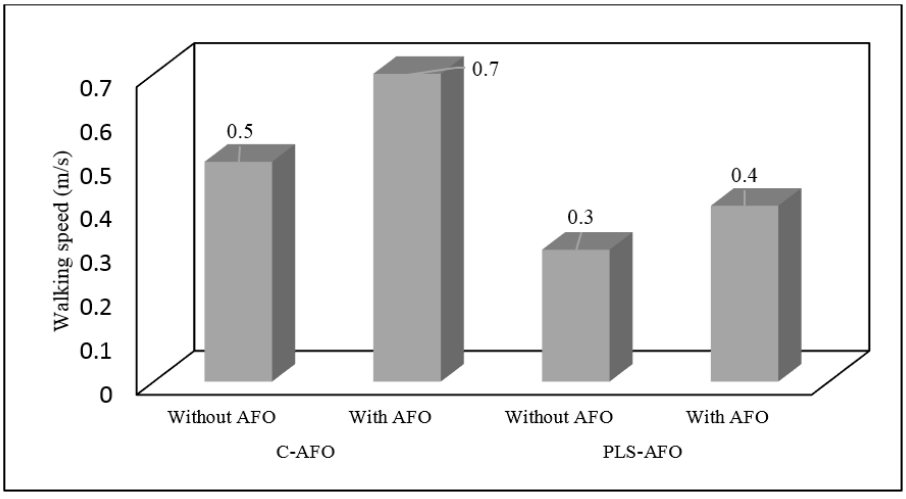


Table 2. Walking Speed with and Without Ankle Foot Orthosis (Expressed as mean ±SD).

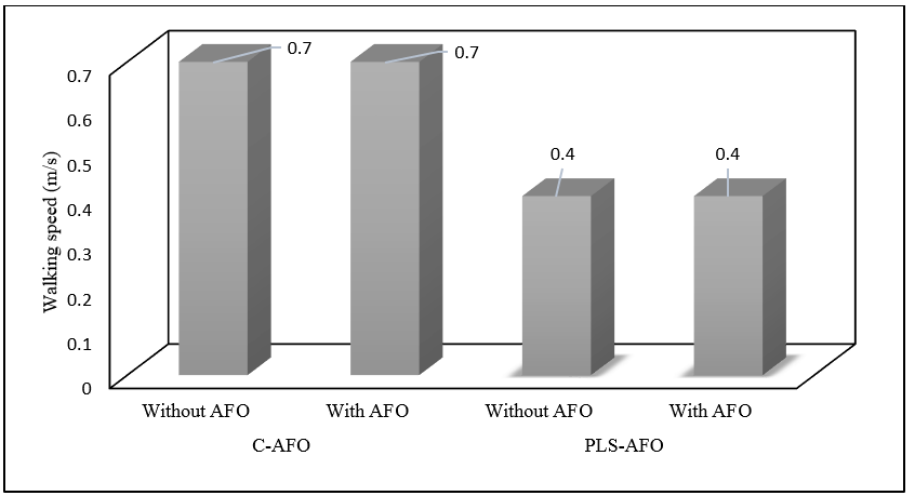
Characteristic		C-AFO (Speed m/s) (n= 14)	PLS-AFO (Speed m/s) (n=11)	p-value	95% CI
Without AFO	Self-selected walking speed	0.5 ± 0.4 (0.1, 1.2)	0.3 ± 0.2 (0.1, 0.8)	0.156	-0.072 - 0.425
	Fast walking speed	0.7 ± 0.5 (0.1, 1.7)	0.4 ± 0.3 (0.1, 1.0)	0.074	-0.030 - 0.625
With AFO	Self-selected walking speed	0.7 ± 0.4 (0.1, 1.4)	0.4 ± 0.3 (0.1, 0.9)	0.034	0.027 - 0.630
	Fast walking speed	0.7 ± 0.5 (0.1, 1.7)	0.4 ± 0.3 (0.2, 1.1)	0.113	-0.068 - 0.604

PLS-AFO: Posterior leaf spring Ankle foot orthosis, C-AFO: Carbon composite ankle foot orthosis, m/s: meter per second

Fast Walking Speed

There was no change on average fast walking speed among the C-AFO group and PLS-AFO group (Figure 4).

Figure. 4. Comparison of Fast Walking Speed (m/s) in Carbon Composite Ankle Foot Orthosis (C-AFO) and Posterior Leaf Spring Ankle Foot Orthosis (PLS-AFO).



Satisfaction

Grading was collapsed to "strongly agree" as satisfied and "disagree" as not satisfied. Participants were highly satisfied with both AFOs on most aspects. Moderate satisfaction with pain free was reported on C-AFO due to skin abrasion. Also PLS-AFO was moderate scored on durability due to its flexibility (Table 3).

Table 3. Analysis of Satisfaction with PLS-AFO and C-AFO.

	PLS-AFO (n=11)	C-AFO (n=14)	p-value (Fisher exactly test)	95% CI
My orthosis fit well.	11 (100.0%)	12 (85.7%)	0.191	-0.040 - 0.326
The weight of my orthosis is manageable.	10 (90.9%)	14 (100.0%)	1.000	-0.079 - 0.261
My orthosis is comfortable throughout the day.	10 (90.9%)	13 (92.9%)	0.859	-0.197 - 0.236
It is easy to put on my orthosis.	11 (100.0%)	13 (92.9%)	0.366	-0.063 - 0.206
My orthosis looks good.	10 (90.9%)	13 (92.9%)	0.366	-0.197 - 0.236
My orthosis looks durable.	8 (72.7%)	13 (92.9%)	0.173	-0.094 - 0.497
My skin is free of abrasion and irritation.	9 (81.8%)	12 (85.7%)	0.792	-0.254 - 0.331
My orthosis is pain-free to wear.	10 (90.9%)	10 (71.4%)	0.277	-0.097 - 0.486

DISCUSSION

The study demonstrated that stroke survivors increased their gait speed when using either PLS-AFOs or C-AFOs. The 10MWT on self-selected walking speed was the only gait parameter which was statistically significant when both AFOs were compared. When both AFOs were paired to compare the difference in gait speed without and with AFOs, the C-AFO group showed better results with AFOs. Paired statistics show that neither PLS-AFO group nor C-AFO group showed better performance at fast walking speed

when using AFO. The outcome of this study is similar to that of other studies, which reported that PLS-AFOs and C-AFOs improve walking speed among stroke survivors.[4,13] Also, since the patients were tested both without and with AFO, the results could be due to combination of test learning effect as well as AFO itself.

It is interesting to note that the TUG showed a shorter time duration for the C-AFO group, both without AFOs and with AFOs, as compared to the PLS-AFO group; however, the results were not statistically significant. TUG in this study was associated with functional mobility. PLS-AFO and C-AFO statistically improved functional mobility. This is similar to the results of another study which had reported a reduction in TUG time with AFOs.[3] C-AFOs were shown to be better in terms of functional mobility than PLS-AFOs. C-AFO participants performed quicker in TUG time by seven seconds as compared to four seconds with PLS-AFO participants. In elderly people without stroke, a different cut-off point reported in the literature varied from 12.47 seconds to 15 seconds.[24,25] However, in this study, the time required to perform TUG in both groups of patients was nearly double. The average time duration required for performing TUG in chronic stroke patients without AFOs was reported to be 22.6 seconds on average, as compared to 37.5 seconds and 25 seconds on average for C-AFO users and PLS-AFO users in this study.[26] This may be due to our study group undergoing gait adjustments with the use of orthoses. Although previous literature shows that the TUG may have less value for people who have reached good functional ability, TUG is still a suitable instrument for assessing functional progress in stroke survivors. A lower TUG score has been associated with an increase in falls post-stroke in newly discharged patients, indicating that the fall risk decreases with improvement in functional mobility.[27]

Post-stroke gait velocity can increase from three months to between 12 and 18 months after stroke, whereas the Fugl-Meyer scale and Barthel Index showed improvement up to six weeks and three months after stroke, respectively.[28,29] Walking speed has been proposed to be an outcome measure of mobility for post-stroke subjects who can walk faster than 0.33m/s.[28,29] For the 10MWT, the minimally clinically important difference is reported as 0.1 m/s.[30] In this study, during the first visit, the self-selected walking speed for 10MWT was nearly the same in both the PLS-AFO and C-AFO groups; however, the average time in the self-selected walking speed with AFO was six seconds less in C-AFO patients than it was in PLS-AFO patients. This may reflect the better adaptability of patients using C-AFOs with respect to their gait speed as compared to patients using PLS-AFOs; however, this finding was not statistically significant. The average time for 10MWT in the fast-walking speed was nearly the same for both subjects using PLS-AFOs and subjects using C-AFOs. Similarly, the average speed in the fast-walking 10MWT remained 0.7 m/s for both groups, with and without AFOs, with the PLS-AFO group having an average speed of 0.4 m/s both with and without AFOs.

It is interesting to note that both groups performed well on self-selected walking speed with and without AFOs; however, a statistically significant association was found between participants with AFO. This may be in concordance with the satisfaction expressed with both types of orthoses. It has also been previously reported that the compatibility of orthoses improves over time as patients get comfortable with them, especially regarding safety and confidence.[31]

The mean gait speed of healthy individuals is around 1.3 m/s but ranges from 0.23 to 0.73 m/s in individuals with hemiparesis.[32] Other studies report that comfortable walking speeds of healthy subjects and subjects with stroke ranged from 0.99 to 1.8 m/s and 0.13 to 0.91m/s, respectively.[26] One of the targets for improving gait is to achieve community ambulation. A 10-meter gait velocity measure is stratified into functional ambulation classes such as household ambulation (<0.4 m/s), limited community ambulation (0.4–0.8 m/s) and full community ambulation (>0.8 m/s).[33,34] Keeping these targets in view, efforts to improve gait velocity become meaningful, and acquiring a higher class of ambulation is associated with substantially better functional mobility and quality of life, especially with new strokes. Considering the above, both groups in this study fall under “limited community ambulation” without and with AFO. This may have attributed to a decreased effectiveness of AFOs in the fast waking speed as observed during the study.

Though AFOs improve the biomechanics of gait and offer long-term improvements in balance and mobility, some patients are reluctant to use AFOs due to concerns regarding weight, discomfort, poor fit, and cosmetic reasons.[31,35,36] Some clinicians are also concerned that AFOs may induce muscle disuse and delay functional recovery.[37] It is important to determine patients’ satisfaction with the use of orthoses; hence, a patient satisfaction survey was carried out among members of both groups in our study. The PLS-AFO group was highly satisfied with respect to the orthosis’s weight and ease in being put on, while the C-AFO group was highly satisfied with the orthosis’s weight. Both groups were satisfied with other aspects, including weight, fitting, donning, appearance, comfort, and level of pain. C-AFOs were rated better in durability as compared to PLS-AFOs. This may be because PLS-AFOs are more flexible than C-AFOs (though there was no statistical significance between the PLS-AFO group and the C-AFO group). Overall satisfaction with both PLS-AFO and C-AFO orthoses is higher as compared to the results of other satisfaction studies of lower limb orthoses in neurological disorder cases.[38] Generally, 35.3% of study subjects who used an AFO indicated that they walked more confidently and patients reported a 70% increase in self-confidence while using an AFO.[3,39] It is important to consider patients’ preference when prescribing an AFO. Despite the high satisfaction shown in the study, there were reports of

pain with C-AFOs due to the upright strut on the medial side; however, there was only one participant "strongly dissatisfied" with the use of a C-AFO due to pain. This suggests that design alterations may be required.

Limitations

The sample size was adequate for a clinical trial of the two types of AFOs (C-AFOs and PLS-AFOs) but not for the satisfaction survey. This affected the grading of satisfaction questionnaires; however, the study provides insight into the satisfaction of the two groups of stroke survivors. Similarly, the assessment of orthotic durability is not reliably reflective in our study since the usage duration was very short. Stroke onset was not a consideration in our study; however, future trials can compare use of two AFOs in acute or chronic stages of stroke, which may give different results. Due to the nature of the study, it was not possible to blind participants and assessor the type of AFO used. Neither PLS-AFOs nor C-AFOs resulted in any improvement in the fast-walking speeds. This might be because of the participants who were limited community ambulators. There is a need to further analyse the effects of PLS-AFOs and C-AFOs on patients with a different walking speed.

CONCLUSION

This study provides an understanding of the effects of the two types of flexible ankle foot orthoses (PLS-AFO and C-AFO) on stroke survivors which can help in selection of AFO. Though both AFOs provided high level of user satisfaction in this study, C-AFO can be preferred when the main goals are to improve functional mobility and self-selected walking speed.The findings of this study need to be further explored in future research on a larger sample size by using variable walking speeds in acute vs chronic stroke.

Conflicts of Interest and Source of Funding

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