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Clinical Efficacy of Different Ankle Foot Orthosis Design in Subjects with Foot Drop after Stroke: A Review and Comparison

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Abstract— Ankle foot orthoses (AFOs) are usually used for patients with hemiplegic foot drop after stroke to provide support in walking. While the literature provides important information on the beneficial effect of the AFOs, there is still a need for more data describing the impact of different designs of AFOs on gait of subjects during rehabilitation phase after stroke. The aim of this study was to compare the clinical efficacy of two designs of AFOs (Solid and Hinged) on specific gait parameters, kinematics and kinetics during gait by subjects with hemiplegic foot drop after stroke. Thirty subjects with hemiplegic foot drop after stroke participated in this study. Comparison of gait pattern was performed in barefoot, solid and hinged AFO walking conditions. Temporal-spatial, kinematic and kinetic data were collected using force platform (version BTS P-6000, Italy) and six high definition optoelectronic cameras with reflective markers (BTS SMART-DX 6000, Italy) in gait and motion analysis lab. Though subjects walked faster, with a higher cadence and step lengths, when using solid AFO as compared to hinged AFO, the difference was non-significant ($P > 0.05$). Significant difference was observed between gait parameters, kinematics and kinetics of either ankle foot orthosiss compared to barefoot ($P < 0.05$). Significant difference was observed between two AFOs in mean increase in dorsiflexion at initial contact, peak ankle dorsiflexion during stance, ankle power at push off and peak vertical ground reaction. These findings suggest that, compared to barefoot an AFO yields better gait and thus more effectively manage footdrop, however difference between uses of its variants has almost no impact. Further research to explore the potential utility of these designs of AFOs is indicated.

Keywords *— Ankle Foot Orthosis; Foot Drop; Gait; Kinematics; Kinetics; Stroke*

1. Introduction

Stroke is a clinical syndrome characterised by cluster of signs and symptoms due to occlusion of artery supplying a particular region of brain [1]. It is the second leading cause of death and third leading cause of disability globally [2] with increasing prevalence and incidence in India. There has been significant increase in stroke burden in the world over the last two and half decades especially in developing countries like India [3, 4].

Hemiplegia following stroke is characterized by typical posturing with flexor tone predominating in upper extremity and extensor tone in lower extremity [5]. The hemiplegic subjects walk with circumduction gait due to weakness of distal muscles (foot drop) and extensor hypertonia in lower limb [6]. Foot drop is the most common gait abnormality in hemiplegic stroke and is manifested by an inability to actively dorsiflex foot during swing phase (Fig.1). This leads to compensatory movement patterns, slowed gait velocity, limited functional mobility, and increased risk of falls [7, 8, 9]. Active rehabilitation comprising of neurodevelopmental techniques, muscle strengthening, treadmill training, intensive mobility exercises and bracing have been shown to improve the speed and efficiency of walking in patients with hemiplegic stroke [10]. One method often employed to treat foot drop is the use of an ankle foot orthosis (AFO). AFOs have been shown to provide many benefits for improving hemiparetic gait, including increased gait velocity [11], a more symmetrical gait pattern, improved foot clearance during swing [12, 13, 14], and decreased energy expenditure [9].

Fig. 1: Hemiplegic Foot drop (Left) with compensatory movements

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Although the use of AFOs in the rehabilitation of stroke patients is common, a variety of different types of AFOs can be used and few studies have looked at their potentially distinct effects on gait [15]. Many studies have evaluated the effects of AFO in stroke subjects (AFO vs. Barefoot). Some authors did comparisons of different types of AFOs with the footwear or barefoot walking but there is still a need of further study.

The hypothesis was that joint kinematics, kinetics and temporal-spatial gait parameters would all be improved when walking with AFOs which either blocked sagittal plane ankle motion, or only allowed ankle dorsi flexion, when compared to a barefoot condition.

2. Literature Survey

A systematic literature review was conducted to justify the need of the study. Moreover the technological and clinical aspects of stroke rehabilitation using AFOs were studied and presented in Table1.

Table 1: Literature Review

Study	Type of AFO	Subjects (N)	Outcome Measure	Parameters	Findings
Sankaranarayan et al. (2016) [16]	SAFO	21	6-minute walk test, 10-meter walk test, FIM	Distance Covered, Gait Speed	Significant improvement in gait parameters in only one-third subjects
Andrea Pavlik (2008) [17]	SAFO and HAFO	4	10-m paper walkway, TUG test	Gait Speed, Step length, Stride length	Significant improvement in walking speed, step and stride lengths
Farmani et al. (2016) [18]	SAFO with rocker bar	15	10-m paper walkway, TUG test	Gait Speed	Higher gait speed and less time in TUG ($P<0.05$)
Bulley et al. (2011) [19]	SAFO, PLS-AFO and FES	9	Semi-structured interviews exploring individual experiences		Positive and negative experiences of both FES and AFO
Kluding et al. (2013) [20]	SAFO, HAFO and FES	197	6-minute walk test, 10-meter walk test, TUG test, Balance Test	Gait Speed, Other functional outcomes	Either FES or AFO yielded clinically and statistically significant
Sheffler et al. (2012) [21]	HAFO and FES	12	Spatiotemporal, kinematic, and kinetic parameters through Gait Analysis	Stride length, Cadence, Gait Speed, Peak hip, knee and Ankle Power generation	Stride length was improved with both while gait speed improved with FES, Dorsiflexion status interaction effect favored the AFO.
Ring et al. (2009) [22]	Standard AFO Vs. Neuroprosthesis	15	6-minute walk while wearing force-sensitive insoles	Gait Speed, Stride Time, Swing asymmetry	No significant difference in gait speed. Stride time, gait symmetry index improved in both.
Nolan et al. (2010) [23]	Dynamic AFO	1	Spatiotemporal and Kinematic parameters through gait analysis	Gait speed, Cadence, Step length, Stride length, Step width	Dynamic AFO improved temporal-spatial parameters and gait velocity.
Tyson & Thornton (2001) [24]	HAFO	25	Paper Walk way, Face-to-face questionnaire	Stride length, Step length, Symmetry, Cadence and Speed	HAFO improved functional mobility, stride length, cadence and velocity, but not step length or symmetry.
Rao et al. (2008) [25]	AFO (Type not mentioned)	40	GAITRite system	Gait Speed, Cadence, Step, and stride length	AFO improves gait velocity, cadence, step, and stride length
Hwang et al. (2012) [26]	Dual AFO	15	GAITRite system	Step time, Swing time, Single support time, Speed, Stride Length	Affected/non-affected stride length, velocity increased significantly.
Shin et al. (2017) [27]	Standard AFO Vs. New multi joint AFO	15	10-meter walk test, functional reaching test and TUG test		Significant differences in the orthosis using posterior joint-stop function.
Dogan et al. (2010) [28]	HAFO	51	Ashburn walking and stair test, TUG test, the	Walking Time, Stair climbing time,	Improvements in gait speed, balance and mobility with AFO

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			Berg Balance Scale and the mobility subscale of the stroke rehab.	Berg Balance score, Gait speed	use. No statistically significant difference between the durations of stair climbing with or without AFO
Zollo et al. (2015) [29]	SAFO Vs. Dynamic AFO	10	Biomechanical gait analysis	Spatio-temporal, kinematic and EMG feature	No significant differences in spatio-temporal parameters. SAFO increased co-contraction of some muscles involved in the gait.
Rao et al. (2014) [30]	Off-the-shelf carbon AFO and custom plastic AFO	30	GAITRite electronic walkway	Gait Speed, Cadence, Stride length, and step length	No significant difference in gait parameters between AFOs but improved compared to no AFO.
Lewallen et al., (2010) [15]	HAFO, SAFO, PLS AFO	13	GAITRite system	Step length, Single support time, and speed	Compromised gait with SAFO gait for speed, step length, and single support time.
Gok et al. (2003) [13]	Seattle-type polypropylene AFO and metallic AFO	12	Vicon 370 Motion Analysis System	Spatio-temporal, kinematic and kinetic parameters	Both orthoses had similar positive effects No significant difference between orthosis.

Abbreviations: FIM; Functional Independence Measure, TUG: timed "Up and Go", SAFO: Solid Ankle Foot Orthosis, HAFO: Hinged Ankle Foot Orthosis, DAFO: Dynamic Ankle Foot Orthosis, PLS AFO: Posterior Leaf Spring Ankle Foot Orthosis.

The following gaps were identified in the literature.

- Though HAFO compared to SAFO had some better effects on gait of stroke subjects, author has suggested for more investigations (Aliyeh Daryabor, 2018) [36]
- There is a need to examine long term effects and cost-effectiveness of prescribing variants of AFO in stroke subjects. (Noel Rao et al, 2014) [30]
- Future studies are encouraged for well-designed clinical trials to establish evidence of AFO use on gait in stroke. (Ferreira et al, 2013) [33]
- There is controversy in the results of these studies and conflicting outcome measures.

Therefore the aim of this study was to evaluate and compare the efficacy of two most commonly used plastic AFOs (Solid and Hinged) on the subjects with hemiplegic foot drop due to stroke.

3. Method

3.1 Participants

Thirty subjects with hemiplegia secondary to stroke were selected from our Institute. Seventeen subjects had right and thirteen subjects had left cerebral lesions. The inclusion criteria are subjects with either sex with first stroke with foot drop, age range- 18 to 60 years, at least 6 weeks post-stroke but not more than 1 year duration, should have an ability to walk and understand and follow command. Subjects having visual impairment, unstable angina, global aphasia, co-ordination problem and using any assistive device during ambulation were excluded. The study protocol was approved by the Institutional Review Board. Signed informed consent was obtained from each of the subjects after explanation of the test procedures and rights of subjects.

3.2 Ankle Foot Orthosis

Fig. 2: SAFO (left) and HAFO (right)

The solid AFO (Fig.2) was fabricated with trim lines anterior to the malleoli to prevent ankle dorsiflexion and plantar flexion; the hinged AFO (Fig.2) was fabricated with simple hinge that blocks plantar flexion beyond 90 degrees and allowing free dorsiflexion. The proximal trim lines of both AFOs ended 1 centimetre distal to the neck of the fibula and distal extension is with complete foot plate up to tip of toes. Each AFO had two straps: a two-inch strap at the proximal calf region and a one-inch strap at the instep.

3.3 Study Tools and Instrumentation

All temporal-spatial, kinematic and kinetic data were collected using force platform (version BTS P-6000, Italy) and six high definition optoelectronic cameras with reflective markers (BTS SMART-DX 6000, Italy) in gait and motion analysis lab (Fig.3). The sampling rate of force platform is 1000 Hz and maximum acquisition sampling

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frequency of the optoelectronic cameras is 2000 fps. A Helen Hayes model was applied concurrently to track motion of the lower limbs and pelvis through 15 markers placed at different bony landmarks. The obtained data was processed using BTS Smart Analyser and Matlab, including filtering of marker trajectories with a 4th order low-pass Butterworth filter.

Fig. 3: Gait and Motion Analysis Lab Setup

3.4 Procedure and Protocol

After detailed assessment and evaluation, the subjects were randomly divided into two groups. Group A consisting of 15 subjects who used SAFO and 15 subjects using HAFO belong to Group B. Fitting and alignment of AFOs was established by certified Orthotist. Gait training was given to these subjects after fitment of orthosis for few days to gain stability and achieve normal walking. Pertinent demographic and anthropometric data was collected before test. The subjects were psychologically normal with no anxiety, stress, fear etc. Practice trials were performed by each subject until they could consistently and naturally contact both of the force plates. They were taught to walk with their own self-selected walking speed. Each subject walked along walkway with two force plate embedded on floor for each of the two orthotic conditions wearing shoes. Reflective markers were placed on specific anatomic landmarks such as pelvis, hip, knee, ankle and foot following standard protocol. The temporal-spatial (Cadence, Step length, Stride length and Velocity) with kinematic and kinetic data were recorded and compared between two orthotic conditions. To maintain consistency in fit of orthoses and data recording, same investigator was recruited who followed similar protocol and procedure throughout the study.

3.5 Data analysis

Each of the four dependent variables such as Cadence, Step length, Stride length and Velocity, were statistically analysed employing two orthotic conditions (SAFO and HAFO) through unpaired t-test. Statistical Package for the Social Sciences (SPSS) v.20 and MS-Excel was used for the statistical analysis. Probability level of α=0.05 was accepted as indicative of a statistically significant difference in the individual comparisons.

4. Results

A total number of 30 participants having hemiplegic foot drop were selected for the study with the age range from 20-60 years. There were 18 male and 12 female participants. Half of the patients were fitted with SAFO and rest of the patients was fitted with HAFO. No drop outs were there in the study. The demographic data are represented in Table 2.

Table 2: Demographic data

Sl. No	Orthosis	Age (Mean ± SD)	Sex	No (N)	Weight (kg)	Height (cm)	Mean time since Stroke
1	SAFO	46.33± 9.59	M=10, F=5	15	65.37	174.5	125 days
2	HAFO	47.13± 7.53	M=8, F=7	15	68.48	176.3	137 days

The mean of step length, cadence and velocity in SAFO was found to be slightly higher than HAFO for our subjects with hemiplegic foot drop. However, none of the parameter showed any statistical significant difference between SAFO and HAFO ($p>0.05$). The results of spatio-temporal gait parameters are presented in Table 3.

Table 3: Comparison of gait parameters

Parameter	Barefoot (A)	SAFO (B)	HAFO (C)	P value (A-B)	P value (A-C)	P value (B-C)
Step length (m)	0.24± 0.05	0.34± 0.08	0.26± 0.08	0.02	0.04	0.26
Stride length (m)	0.52± 0.19	0.59± 0.24	0.60± 0.22	0.007	0.008	0.97
Cadence (steps/min)	58.17± 18.45	61.72± 20.29	61.07± 11.44	0.003	0.007	0.96
Velocity (m/s)	0.27± 0.15	0.35± 0.23	0.3± 0.18	0.03	0.04	0.77

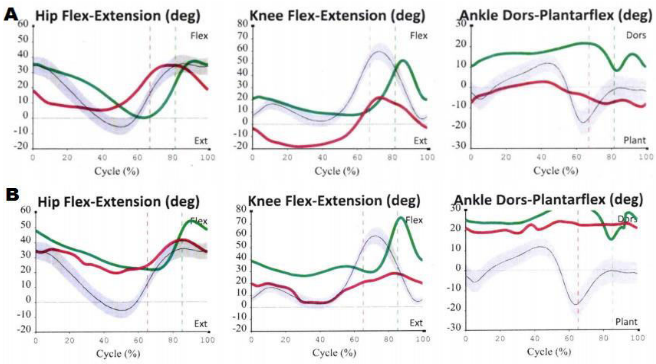

Fig.4: Kinematics of Hip, Knee and Ankle joints, A: Hinged AFO and B: Solid AFO (Red line indicates affected side and green line for normal side)

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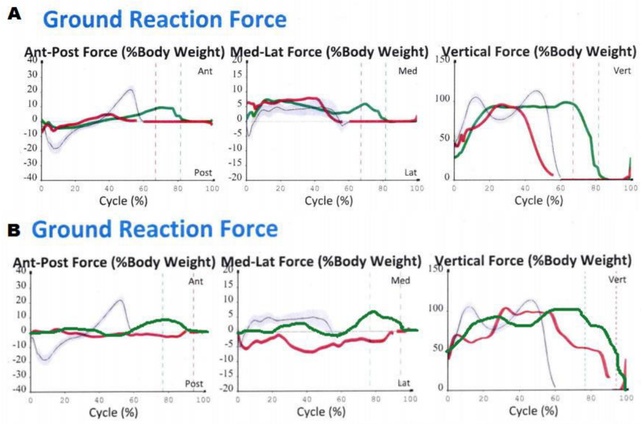

Fig.5: Kinetics (Ground Reaction force) comparison, A: Hinged AFO and B: Solid AFO (Red line indicates affected side and green line for normal side)

5. Discussions

The aim of this study was to compare the clinical efficacy of AFOs (Solid and Hinged) on specific gait parameters, kinematics and kinetics during gait by subjects with hemiplegic foot drop after stroke. It has been reported that the walking speed which is reduced in stroke [31] can be improved with AFO [11]. The use of AFO has beneficial effects in terms of improving functional mobility, quality of gait and decreasing the rate of falls in these subjects [32, 33]. Thus stroke individuals provided with an AFO improved gait parameters such as cadence, stride length, and gait velocity [13, 34]. Luiz et al [33] aimed to analyse the effect of an AFO on gait variables (velocity and cadence) of stroke patients. While results suggest improvement in gait velocity with AFO, its impact on cadence remains inconclusive. They suggested for further well-designed randomized, controlled, clinical trials to establish better scientific evidence for the effects of AFO usage on gait variables of stroke patients. The literature support on the use of different types of AFO to improve ambulation of stroke individuals is limited.

5.1 Temporal-spatial gait parameters

In this study comparison between two most common variants of AFO was performed to check the clinical efficacy in stroke subjects. AFO use considerably improves gait velocity, cadence, step, and stride length of individuals with hemiplegia due to stroke. The results of the current study demonstrated that the use of solid AFO (0.34±0.08) resulted in slight increase step length compared to HAFO (0.26±0.08), however they did not show any statistical difference ($p>0.05$). Stride length, cadence and velocity of both orthotic conditions were almost similar and statistically non-significant. These results are similar to those found by Lewallen et al. [15] where no significant difference among gait parameters was found. The study of Hesse et al. [35] found that subjects wearing a solid AFO showed improved gait when compared to barefoot and shoes-only conditions.

A study by Daryabor et al [36] showed a direct comparison of solid and hinged AFO. He found that all types of AFOs had positive effects on ankle kinematic in the first rocker and swing phases, but not on knee kinematics in the swing phase, hip kinematics or the third rocker function. The authors found that the articulated passive AFO compared with the non-articulated passive AFO had better effects on some aspects of the gait of patients with hemiplegia following stroke and suggested that more investigations are needed in this regard though. Zollo et al [29] did the biomechanical gait analysis on hemiparetic subjects with foot drop syndrome under 3 conditions with randomized sequences: 1) without AFO; 2) wearing a solid AFO; 3) wearing a dynamic AFO.

Significant changes in spatio-temporal, kinematic and electromyographic features of gait were investigated. The outcome of gait analysis shows that there are no significant differences among the solid and the dynamic AFO on the spatio-temporal parameters. Both SAFO and HAFO reduced range of the ankle motions compared to barefoot. They also reduced the asymmetry between the paretic and the contralateral limb in terms of ankle angle at initial contact and hip flexion. The solid AFO generally led to an increase of the co-contraction of the couples of muscles involved in the gait. This indicates that AFOs can limit foot-drop and improve balance in stroke population. Main difference between AFOs was probably related to muscular activity. Noel Rao et al [30] compared the effects of two types of AFO on gait of patients with stroke and evaluated their preference in using each AFO type design. Thirty individuals with acute hemi paretic CVA were tested without an AFO, with an off-the-shelf carbon AFO (C-AFO), and with a custom plastic AFO (P-AFO) in random order at the time of initial orthotic fitting. Both types of AFO significantly improved gait velocity, cadence, step length, and stride length in patients with acute stroke.

5.2 Kinematics

Ankle kinematics demonstrated an increase in dorsiflexion at initial foot contact and increase in peak ankle dorsiflexion during stance and swing phase with either AFO. An increase in peak dorsiflexion in swing phase and increased peak dorsiflexion at toe-off was observed. These results were similar to studies conducted by earlier researchers [37, 38, 39, 40]. In knee kinematics, an increase in knee flexion at initial response and an increase in peak knee flexion at loading response with an AFO were observed. However, there is no effect on peak knee flexion in swing phase. The preference results are similar to those found by earlier researchers [38].

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Few studies have evaluated the impact of an AFO on hip kinematics. In terms of peak hip flexion at initial contact, AFO has found no effect which was reiterated when the effect of an AFO on peak hip extension during stance phase was examined. Significant differences were observed for ankle kinematics while knee and hip motions did not show any significant statistics while comparing SAFO and HAFO (Fig.4).

5.3 Kinetics

The peak of vertical component of ground reaction force reached maximum in SAFO (100% body weight) compared to 90% bodyweight in HAFO (Fig.5). There was no significant difference between these two orthosis with respect to medio-lateral component of ground reaction force. A trend towards significance in ankle power at push-off between SAFO and HAFO in the group as a whole is notable because of a clinical concern that inhibition of ankle movement by an SAFO may enhance weight-bearing stability in hemiparesis but at the cost of loss of ankle power necessary for optimal walking speeds and forward gait progression. Prior studies [21] have found that an AFO decreases ankle power during both treadmill ambulation and stair locomotion. HAFO diminished ankle power to a lesser degree than a SAFO.

A possible explanation for greater ankle power at push-off of the SAFO relative to the HAFO is that repetitive dorsiflexion restriction with the SAFO during ambulation may facilitate reciprocal strengthening or functioning of the gastro-soleus complex. Two studies [8, 35] involving 35 participants showed an increase in the length of centre of pressure excursion under the affected foot during stance with the ankle-foot orthosis ($P < 0.0001$). Other trials [39, 41, 42] involving 99 participants measured aspects of the kinetics but there were no common parameters that could be pooled. All reported a significantly positive effect with an AFO except Yamamoto et al. [42] who had reported mixed results in only 10 patients.

6. Conclusion

An AFO can improve the temporal-spatial gait parameters, ankle and knee kinematics and kinetics of walking in stroke subjects with foot drop. AFO use significantly improves velocity, cadence, step length and stride length in patients with acute and chronic stroke. There was no significant difference in temporal-spatial parameters and kinematics of gait observed between SAFO and HAFO, though significant difference was noticed with respect to kinetics. This outcome should be taken into consideration while prescribing AFOs. Further study is needed to examine the longer-term effects and the cost-effectiveness of prescribing different types of AFO for people with stroke.

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