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The effects of dynamic ankle-foot orthoses in chronic stroke patients at three-month follow-up: a randomized controlled trial

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Abstract

Objective: To investigate the short- and long-term effects of dynamic ankle foot orthoses on functional ambulation activities in chronic hemiparetic patients.
Design: Randomized controlled trial.
Setting: University's neurological rehabilitation outpatient clinic and orthotics department.
Subjects: Twenty-eight chronic hemiparetic patients of level 3–5 according to Functional Ambulation Classification and with a maximum spasticity level of 3 according to Modified Ashworth Scale, were randomly assigned to the study and control groups.
Interventions: The control group ($n = 14$) was assessed with tennis shoes whereas the study group ($n = 14$) was assessed initially with tennis shoes and after three months with dynamic ankle foot orthosis.
Measures: Functional Reach, Timed Up and Go, Timed Up Stairs, Timed Down Stairs, gait velocity and Physiological Cost Index.
Results: In the initial assessment no difference was found between the groups for any of the measured parameters ($P > 0.05$). After three months, intergroup comparisons while the patients in the study group were wearing dynamic ankle-foot orthosis showed a significant difference in favour of the study group for Timed Up Stairs 12.00 (10.21) seconds study versus 15.00 (7.29) seconds control group; for gait velocity 0.99 (0.45) m/s study versus 0.72 (0.20) m/s control group and for Physiological Cost Index 0.12 (0.06) beats/min study versus 0.28 (0.13) beats/min control group ($P < 0.05$). No difference was found between the groups for Functional Reach, Timed Up and Go, Timed Down Stairs ($P > 0.05$).
Conclusion: Chronic hemiparetic patients may benefit from using dynamic ankle-foot orthosis.

Keywords

Dynamic ankle-foot orthosis, stroke, functional ambulation activities

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Introduction

After stroke, around 80% of patients regain walking function within 11 weeks although there is residual hemiparesis.[1] Ankle-foot orthosis are frequently prescribed to improve the gait pattern of hemiparetic patients.[2] An ankle-foot orthosis is generally prescribed to provide mediolateral stability at the ankle in stance phase, facilitate toe clearance in swing phase and promote heel strike.[3] In hemiparetic patients spatiotemporal parameters are significantly different from those of healthy individuals; gait is characterized by asymmetry in weight bearing, reduced speed, as compared to age-matched healthy adults, increased mechanical energetic cost and problems with trunk–limb, interlimb, and intralimb coordination.[4–9]

Dynamic ankle-foot orthoses are ankle-foot orthoses with specific characteristics. A dynamic ankle-foot orthosis was first described by Hylton in 1989 as a very thin, flexible supramalleolar orthosis with a custom contoured soleplate to include support and stabilization to the dynamic arches of the foot.[10] Although Hylton called it a 'supramalleoler orthosis' because it was designed to be somewhat shorter than an ankle-foot orthosis, it actually limits excessive plantar flexion and controls the talocrural ankle joint and therefore can be considered to be an ankle-foot orthosis. It is called a dynamic ankle-foot orthosis because it allows graded amounts of ankle eversion, inversion, plantarflexion and dorsiflexion.

Dynamic ankle-foot orthoses are designed based on the concept that the most important aspect of tone-inhibiting orthosis is obtaining neutral alignment of the ankle and foot. This device provides a supportive total contact exoskeleton that maintains neutral forefoot and subtalar joint.[11] Although the dynamic ankle-foot orthosis is used primarily in the paediatric population,[12–16] the tone-inhibiting properties of this orthosis or any other orthosis that claims to have such characteristics have not been substantiated. In fact, two recent studies carried out on adult stroke patients and published in 2010 have demonstrated that a dynamic foot orthosis had no significant effect on soleus reflex excitability, suggesting that these tone-reducing orthotic devices have no significant neurophysiologic effect on spasticity.[17,18]

Dieli investigated the effect of dynamic ankle-foot orthosis on three hemiparetic adults and published the result in 1997.[19] Mueller published a single-subject study on the effect of a tone-inhibiting dynamic ankle-foot orthosis on the foot loading pattern of a hemiplegic adult.[11] Diamond and Ottenbacher have published a single-subject study on the effects of a tone inhibiting dynamic ankle-foot orthosis on the walking speed, step length and cadance of a hemiparetic patient.[20] However, to our knowledge there is no randomized controlled study in the literature related to the effect of dynamic ankle-foot orthosis on functional ambulation activities in hemiparetic adults.

With this study we aimed to investigate the effect of dynamic ankle-foot orthosis on functional ambulation activities such as Functional Reach, Timed Up and Go, Timed Up Stairs, Timed Down Stairs, gait velocity and Physiological Cost Index in chronic stroke patients with hemiparesis.

Methods

Patients who had received neurophysiologic therapy and were now followed up with home exercise programmes at bimonthly or monthly sessions at the University's neurological rehabilitation outpatient clinic were assessed for eligibility. Patients were considered eligible if they met the following inclusion and exclusion criteria.

Subjects were included if they:

- were at a cognitive level to understand the aim of the study, to give informed consent, to understand and follow the directions of the testing protocols;
- were at level 3–5 according to Functional Ambulation Classification;[21,22]

- were not wearing ankle-foot orthosis because although their gait performance was not good, their foot clearance during the swing phase of gait did not compromise their safety;
- were post-stroke patients of at least six months duration;
- had a maximum spasticity level of 3 according to the Modified Ashworth Scale;[23]
- had a range of passive dorsiflexion up to at least 90 degrees;
- were above 18 years of age.

Subjects were excluded if they:

- had comorbidities, orthopaedic or postural problems that could confound the outcomes;
- had used a dynamic ankle-foot orthosis before.

The university ethical review board gave ethical consent to the study and the subjects of the study gave informed consent. Subjects underwent block randomization. The participants were assigned to interventions by concealed block randomization carried out by a colleague unaware of the nature of the study. It was not possible to blind the patients or therapist to the treatment because of the nature of the intervention.

The study and control groups were assessed by means of the same tests initially with tennis shoes only at the time of randomization. The subjects of the study group were given a dynamic ankle-foot orthosis which was fabricated at the University's orthotics department by a physiotherapist who was experienced in fabricating ankle-foot orthoses, dynamic ankle-foot orthoses and dynamic foot orthoses for patients with neurological problems. Fabrication time was 2–3 days on average. Dynamic ankle-foot orthoses were worn inside tennis shoes. The control group wore only tennis shoes. After three months the study group was assessed while wearing dynamic ankle-foot orthoses in tennis shoes and the control group with tennis shoes only.

All subjects were assessed for Functional Reach, Timed Up and Go Test, Timed Up Stairs, Timed Down Stairs, gait velocity and Physiological Cost Index. Functional Reach test assesses limits of stability by measuring the maximum distance an individual can reach forward while standing in a fixed position. A 122-cm ruler was fastened to the wall with tape at the height of the subject's acromium. The rater told the subject to make a fist and raise the non-paretic arm to 90 degrees of shoulder flexion. An initial measurement was recorded at the position of the subject's third metacarpal. The rater then asked the subject to reach as far forward as possible, keeping the fist parallel and level with the ruler, and without taking a step or touching the wall. The second measurement was again recorded at the position of the subjects' third metacarpal.[24,25]

The Timed Up and Go assesses many of the components of basic mobility, including balance, transfers, walking and turning while walking. The time (in seconds) that it took for an individual to stand from a sitting position, walk 3 metres, turn, walk back to the chair and sit down was recorded.[26]

For Timed Up Stairs, the subject was asked to stand 30 cm from the bottom of a 10-step flight of stairs (16 cm step height). Subjects were instructed to 'Quickly, but safely go up steps'. The time (in seconds) it took to go up 10 steps from the 'go' cue until the second foot reached the top step (landing) was recorded.

For Timed Down Stairs, the time (in seconds) it took to go down 10 steps from the top landing with the 'go' cue until the second foot returned to the bottom landing was recorded. All subjects were allowed to use handrails and choose any method of traversing the stairs such as using a step-to or foot-over foot pattern. However, all subjects faced in the direction of the movement (faced up and down stairs, not to the side) as they traversed the steps. Shorter times indicated better functional ability.

Velocity was measured by calculating the time it took to walk 100 metres. Walking velocity was measured with a manual chronometer as the patient walked along a long corridor which was marked for 110 m. The first and final 5 m were discarded so that only walking velocity in the middle 100 m was measured. We recorded self-selected walking velocity.

The Physiological Cost Index, which reflects the increased heart rate required for walking and is expressed as heartbeats per metre, was calculated by dividing the difference ($HR_{walking} - HR_{baseline}$) by walking speed.[27,28] We collected participants' resting and walking heart rate using a polar heart rate monitor. Participants walked at their preferred speed for 100 m.

Statistical analysis

Comparisons between the control and study groups were made using Mann–Whitney U-test. According to power calculations a total of 20 patients were needed for a clinical trial with a study and control group with 85% power and $\alpha = 0.05$. A P-value <0.05 was considered significant. The primary outcome used for the power calculation was the Timed Up and Go Test and calculation was based on between-group comparisons. Effect size (Cohen's d) value was calculated by assessing the values derived from intergroup comparisons at three months. Values between 0.2 and 0.5 were accepted as small, 0.5–0.8 as medium and over 0.8 as large effect sizes.[29,30]

Results

Fifty-four patients were assessed for eligibility. Twenty-two of these were excluded; 17 because they did not meet inclusion criteria and five because they declined to participate. Thirty-two patients underwent randomization. As seen in the flow diagram (Figure 1), 16 subjects were allocated to each group. The study was completed on 28 subjects because one subject in the control group and one in the study group withdrew from the study for no given reason soon after randomization. One subject from the study group was lost to follow-up because he moved house and one subject in the control group died.

The demographic characteristics of the subjects are given in Table 1. The initial and third-month assessment results of the groups for Functional Reach, Timed Up and Go, Timed Up Stairs, Timed Down Stairs, gait velocity and Physiological Cost Index are given in Table 2. At the initial assessment no difference was found between the groups for any of the measured parameters ($P > 0.05$). This result showed that the groups were homogeneous. Intergroup comparisons for the third month while the patients in the study group were wearing dynamic ankle-foot orthoses in their tennis shoes and the patients in the control group were wearing only tennis shoes, showed no difference between the groups for Functional Reach, Timed Up and Go Test, Timed Down Stairs ($P > 0.05$). The results of Timed Up Stairs, gait velocity and Physiological Cost Index were significantly different in favour of the study group ($P < 0.05$).

Discussion

The present study shows that in chronic hemiparetic patients, wearing dynamic ankle-foot orthosis may lead to improvements in gait velocity and Physiological Cost Index but their effect on functional ambulation activities is inconclusive.

Although the effect of using ankle-foot orthoses in hemiparetic patients has been widely investigated from many aspects the results cannot be generalized for dynamic ankle-foot orthoses.

The dynamic ankle-foot orthosis has several unique features. First, it allows graded foot motion within the orthosis so normal balance reactions involving proximal musculature can occur. Second, by providing support for the foot's natural arches, weight is more equally distributed throughout the foot. This stimulation of foot reflexes better approximates normal function. Third, dynamic ankle-foot orthoses provide secure medial-lateral stability and

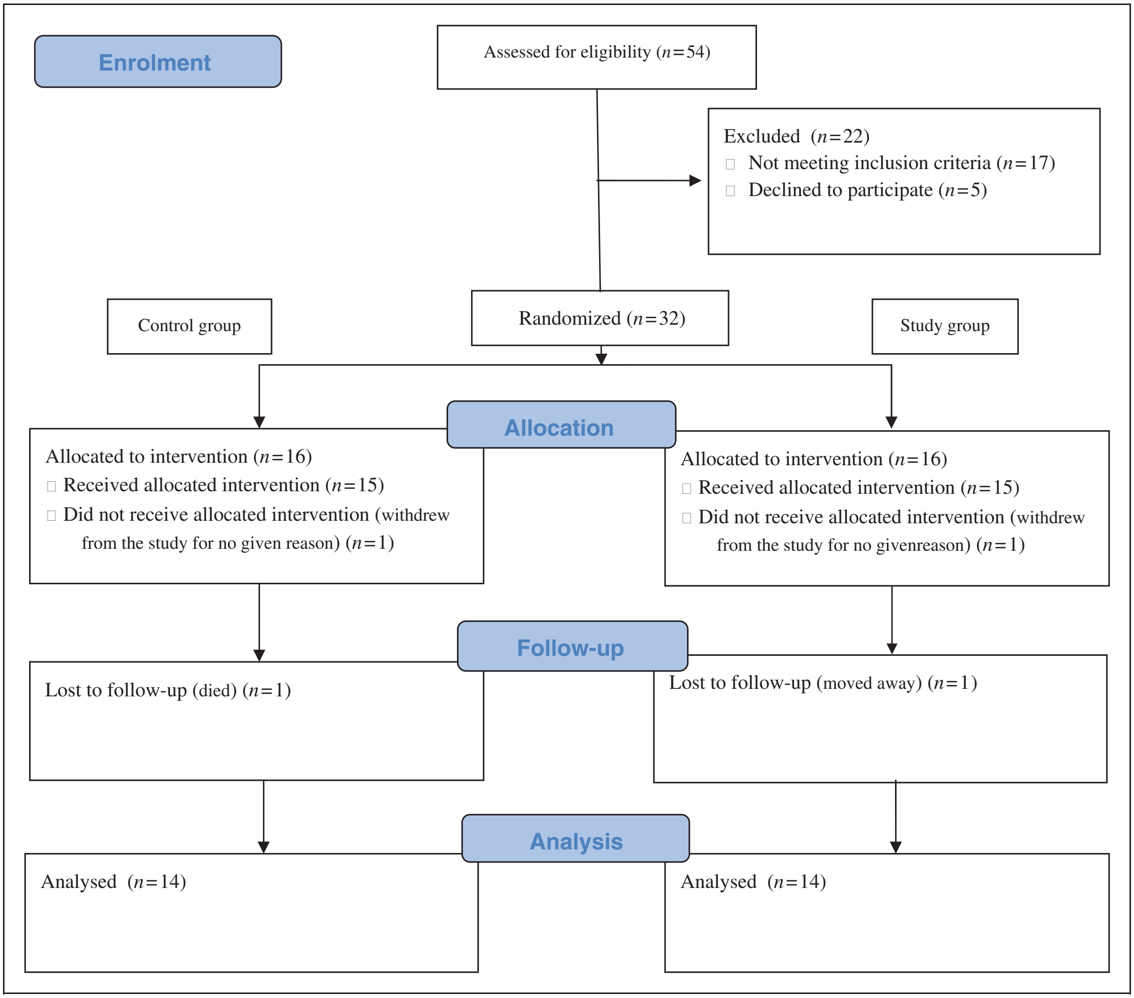

Figure 1. Flow diagram of the study.

midline positioning, resulting in improved grading of ankle plantar and dorsiflexion.[11]

Although there are case studies, there is no systematic review related to the effect of dynamic ankle foot orthosis on stroke patients.

Gait speed is a quick and easy measure of walking disability that has been recommended as an outcome measure in stroke rehabilitation.[31] Patients with stroke between the ages of 65 and 80 have been shown to walk slower (0.23–0.78 m/s) than age-matched healthy adults (0.81–1.51 m/s).[32] As seen in Table 2, our patients walked faster initially (0.84 m/s for the study and 0.65 m/s for the control group) and in the assessments after three months (0.99 m/s for the study and 0.72 m/s for the control group). This may be because the patients in our study were younger.

Various studies in the literature have shown that the gait velocity of hemiparetic patients increases when wear an ankle-foot orthosis on the affected extremity.[6,20,33–35] However, in two placebo-controlled randomized clinical trials carried out by Beckerman et al. the changes in comfortable and maximal safe walking speed were

Table 1. The demographic characteristic of the patients

Characteristics	Study group ($n=14$)	Control group ($n=14$)
Age (year) mean (SD)	42.50 (14.89)	50.64 (9.22)
Sex, n (%) men/women	11 (78.6)/3 (21.4)	7 (50)/7 (50)
Height (cm) mean (SD)	173 (10.63)	166.5 (10.62)
Weight (kg) mean (SD)	75.43 (9.48)	73.43 (16.04)
Side of hemiplegia, n (%), right/left	5 (35.7)/9 (64.3)	4 (28.6)/10 (71.4)
Duration of stroke (month) mean (SD)	30.21 (13.84)	25.36 (13.44)
Use of cane during walking, n (%), use/not use	3 (21.6)/11 (78.4)	6 (42.9)/8 (57.1)
Functional Ambulation Classification, n (%)		
3	2 (14.3)	2 (14.3)
4	8 (57.1)	11 (78.6)
5	4 (28.6)	1 (7.1)
Type of stroke, n (%)		
Ischaemic	3 (21.6)	1 (7.1)
Haemorrhagic	11 (78.4)	13 (92.9)

neither clinically nor statistically significant when using an ankle-foot orthosis in 5 degrees dorsiflexion.[36,37] Ibuki et al. claimed that the time and cost associated with fabricating and fitting a tone-reducing ankle-foot orthosis over standard ankle-foot orthosis designs may not be justified since no significant neurophysiologic effect could be demonstrated. However, they acknowledged that testing while the subjects were walking might bring about different results.[17,18]

Only two studies have compared dynamic ankle-foot orthosis with barefoot condition and prefabricated plastic ankle-foot orthosis usage.[19,20] In a single-case design study carried out in 1990 by Diamond and Ottenbacher, walking speed and average step length increased with a plastic ankle-foot orthosis and increased further with a tone-inhibiting dynamic ankle-foot orthosis, reaching an average 0.94 m/s with the dynamic ankle-foot orthosis from an average of 0.77 while barefoot.[20] In another study on three hemiplegic patients, the highest walking speed was attained with the dynamic ankle-foot orthosis: a 0.12 m/s increase was obtained with a dynamic ankle-foot orthosis when compared with walking barefoot.[19]

Our study is congruous with former studies in that wearing a dynamic ankle-foot orthosis increased gait velocity. A significant increase in gait velocity was also seen in our control group patients at the third month assessment; however, when the groups were compared for increase in gait velocity the increase in the study group was higher, with an effect size of 0.79, as seen in Table 2.

As for energy cost of walking, since gait deviation is a common symptom of stroke the asymmetric gait pattern increases muscular effort and consequently energy expenditure is increased. Therefore, clinically available information on energy cost is important for the evaluation of exercise interventions and testing of orthoses or walking aids.

The Physiological Cost Index is widely used in the clinic.[27,38] The results of our study showed a significant decrease in Physiological Cost Index when dynamic ankle-foot orthoses were compared with shoes only condition ($P<0.05$), and had an effect size of 1.61 which is considered a large effect size. This is consistent with previous studies.[1,6]

Commonly used performance tests such as Timed Up and Go, Timed Up and Down

Table 2. Comparison of the groups initially and at the third month for Functional Reach, Timed Up and Go, Timed Up Stairs, Timed Down Stairs, gait velocity and Physiological Cost Index

	Initial assessment				Third month assessment				
	Study group ($n=14$) S Mean (SD)	Control group ($n=14$) S Mean (SD)	z	*P*-value	Study group ($n=14$) DAFO+S Mean (SD)	Control group ($n=14$) S Mean (SD)	z	*P*-value	Effect size Cohen's *d*
FR (cm)	28.50 (8.48)	27.11 (5.41)	−1.150	0.250	33.43 (9.59)	28.46 (4.40)	−1.846	0.065	0.68
TUG (seconds)	16.57 (10.01)	22.50 (13.53)	−1.865	0.062	14.79 (10.36)	19.07 (8.19)	−1.843	0.065	0.47
TDS (seconds)	15.29 (12.72)	18.00 (10.38)	−1.176	0.240	13.29 (11.21)	15.36 (8.37)	−1.567	0.117	0.21
TUS (seconds)	13.64 (12.59)	18.93 (15.99)	−1.914	0.056	12.00 (10.21)	15.00 (7.29)	−2.058	0.040*	0.34+
Gait velocity (m/s)	0.84 (0.40)	0.65 (0.19)	−1.310	0.190	0.99 (0.45)	0.72 (0.20)	−3.383	0.001*	0.79++
PCI (beats/min)	0.19 (0.10)	0.31 (0.23)	−1.316	0.188	0.12 (0.06)	0.28 (0.13)	−3.383	0.001*	1.61+++

FR, Functional Reach; TUG, Timed Up and Go Test; TUS, Timed Up Stairs; TDS, Timed Down Stairs; PCI, Physiological Cost Index; S, tennis shoes; DAFO, dynamic ankle foot orthosis; S, tennis shoes.

*$P < 0.05$; + small effect size; ++ medium effect size; +++ large effect size.

Stairs and Functional Reach have been shown to be highly reliable and are recommended to evaluate improvements in various aspects of performance in individuals with chronic mild to moderate hemiparesis after stroke.[3,39–41] In the present study there was no favourable affect of wearing a dynamic ankle-foot orthosis for Timed Up and Go, Functional Reach and Timed Down Stairs. The only difference in favour of the study group was seen for Timed Up Stairs; the difference was only 3 seconds and had an effect size of 0.34, which is considered a small effect size. The favourable results obtained for gait velocity and Physiological Cost Index were not reflected in these performance tests.

There were some limitations noted. Following randomized allocation, the outcome assessor knew which group the patient was in. This was mainly because of the nature of the study: an assessor familiar with orthoses and orthotic rehabilitation will always know whether a patient is wearing an orthosis or not, even if it is concealed under trousers and in shoes. Nevertheless, the assessor will not be able to differentiate between the orthoses if they are concealed, so it would be possible to blind the assessor to whether the subjects were wearing ankle-foot orthoses or dynamic ankle-foot orthoses.

The manufacture of a dynamic ankle-foot orthosis requires more expertise and is much more time consuming than that for an ankle-foot orthosis. Although the results of this controlled randomized study have shown that dynamic ankle-foot orthoses are effective in enhancing gait and balance in hemiparetic subjects when compared with the shoes-only condition, they may not be more effective than a well-constructed ankle-foot orthosis. To recommend dynamic ankle-foot orthosis usage in hemiparetic subjects requires comparative studies between ankle-foot orthoses and dynamic ankle-foot orthoses. Such studies will also enable the assessor and patients to be blinded to the treatment alternative, consequently controlling bias.

Another limitation is the relatively small number of patients. Although there were four losses this may not be considered an important limitation since two losses were inevitable and two were at the very beginning of the study.

Clinical messages

- Using dynamic ankle-foot orthoses for hemiparetic patients with motor deficits of the leg may be beneficial in improving gait velocity and decreasing the physiological cost of walking.
- Future randomized controlled double-blind studies comparing the efficacy of dynamic ankle-foot orthoses with ankle-foot orthoses are warranted.

Authors' contributions

SE made substantial contributions to conception and design, worked in all stages of data collection, performed the statistical analysis, drafting and revising of the manuscript. FU made substantial contributions to conception and design was involved in drafting and revising the manuscript. IES worked in the stages of data collection and analysis. YY worked in analysis and interpretation of data, revised the manuscript for content. All authors read and approved the final manuscript.

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Competing interests

The author(s) declared that they have no competing interest.

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