Research Paper: The Comparison of the Effects of Flexible vs Rigid Ankle-foot orthoses on Balance and Walking Performance in Individuals With Multiple Sclerosis: A Crossover Study

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ABSTRACT

Objectives: Ankle-Foot orthoses are used to minimize the impact of weakness in ankle dorsiflexion muscles. The study on different orthotic types defines the optimal design, which effectively improves the users' mobility. This study investigated the potential benefits and risks of a Dictus-band (flexible orthotic), compared with a thermoplastic (fixed) ankle-foot orthosis on the mobility of individuals with Multiple Sclerosis (MS).

Methods: Fifteen subjects with MS and dorsiflexion ankle weakness volunteered in this randomized crossover study. The study participants received either a Dictus-band or a thermoplastic ankle-foot orthosis worn on the weaker leg, compared to barefoot as the control condition. Postural stability during standing, forward reach test, timed up and go test, and walking speed in the 10-meter walking test were compared between the study conditions.

Results: There were no significant differences in the postural stability and forward reach tests between study conditions (P>0.5). When the research participants used a Dictus-band, compared to the fixed ankle-foot orthosis, the time required to complete the timed up and go was significantly reduced [P<0.01; Mean±SD difference: 6.4±1.4; 95% Confidence Interval (CI): 2.7-10.2], and walking speed was increased in the 10-meter walking test (P<0.01; Mean±SD difference: 0.46±0.8; 95%CI: 0.23-0.69). There was no difference in the timed up and go and 10-meter walking test data between the barefoot and Dictus-band conditions (P>0.5). No adverse or safety events were sustained in this research.

Discussion: The present study data provided initial evidence for the lack of detrimental effects of using the Dictus-band in subjects with MS and ankle dorsiflexion deficiencies.

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Highlights

- Using Dictus-band to compensate for drop foot in Person with Multiple Sclerosis (PwMS) is a feasible, safe, and potentially effective therapeutic intervention.
- Dictus-band improves dynamic balance and walking performance, compared to a fixed thermoplastic AFO.
- The concern that Dictus-band could create balance problems for users was not supported.

Plain Language Summary

Multiple Sclerosis (MS) is a neurological condition in which the leg muscles become weak. The weak muscles cannot efficiently control the ankle motion during walking; thus, individuals with MS demonstrate a dropped foot during walking. There is some external support called orthoses, i.e., worn on the lower leg to prevent unstable foot movement. This study attempted to compare the effects of a dynamic and static orthosis on the mobility of people with MS. we also explored the potential harms and benefits of each design.

1. Introduction

Multiple Sclerosis (MS) is a neurodegenerative disease that causes a progressive disability in young adults [1]. The mobility problems are common in People with Multiple Sclerosis (PwMS) [2]. Decreased force generation and endured the dorsiflexor muscles, and the subsequent reduced mobility, are commonly noted in PwMS [3]. PwMS expressed that this reduction in walking ability significantly impacts their personal life and social participation [4]. The observed gait problems in PwMS often include a lack of foot clearance in the swing phase (drop foot) and poor foot placement at the initial contact of the stance phase [5]. This decreased ability to control ankle dorsiflexion results in abnormal, unstable, and unsafe gait patterns [5, 6]. These limitations caused by the loss of dorsiflexion in PwMS for safe and functional ambulation necessitate effective interventions [7].

An Ankle-Foot Orthosis (AFO) is the most commonly prescribed device to restore safe mobility in PwMS. AFO is also employed to minimize the impact of weakness in ankle dorsiflexion muscles [8]. AFOs have different types and are usually classified based on their structural designs [9]. Traditional orthoses, often made with a thermoplastic material, provide resistance to plantarflexion to prevent foot drop during the swing phase [9]. Thermoplastic AFOs fail to restore healthy ankle movements. This is because they impede the active plantar flexion that individuals possess and require for propulsive gait [10]. Specifically, these AFOs disrupt the active ankle plantarflexion necessary for normal gait; thus, this process results in less foot-ground contact right after initial contact. Besides, it reduces the generation of a propulsive force at a terminal stance [8]. Using a thermoplastic AFO increases the vertical ground reaction force and reduces balance during walking [11].

Dictus-band is another orthotic device for foot drop; it differs from traditional static or fixed AFOs. This is because it dynamically assists dorsiflexion movement to lift off the toes with an elastic rubber band. This device also allows a possible range of plantar flexion if the user forcefully contracts the plantar flexor muscles during walking. Active plantar flexion can be beneficial for forwarding propulsion, faster ambulation, and managing balance disturbances during walking [9]. There has been a robust theoretical justification and some evidence from a study on a similar elastic band appliance used for individuals with drop foot [12]; however, an opposite viewpoint suggests that the dynamic tension of the elastic band could unbalance the moments applied at the ankle; subsequently, it may be harmful to safe walking. Thus, per the Medical Research Council (MRC) framework for complex interventions, this exploratory study aimed to examine the possible benefits and risks of the new Dictus-band intervention. We hypothesized that using a Dictus-band in patients with drop foot could present the advantage of allowing plantar flexor muscle activation for more efficient and safe walking, rather than restricting plantar flexion with a fixed AFO. This study aimed to investigate the potential effectiveness (or harms) of a Dictus-band dynamic AFO, compared with a fixed thermoplastic AFO during walking in PwMS with drop foot. If the pilot data suggest benefits, the relevant outcomes will be applied to calcu-

late effect sizes; accordingly, it could be implemented to enable a future fully-powered clinical trial.

2. Methods

A randomized crossover trial was conducted to compare the immediate effects of two orthoses (thermoplastic AFO & Dictus-band) on gait and balance in PwMS in a single session. The study participants acted as their control (barefoot condition). Moreover, the order of control/interventions and testing conditions was randomized by drawing concealed envelopes from a hat. This study was approved by the relevant institutional review board and ethics committee. Each study participant provided a written informed consent form before testing.

Fifteen PwMS were recruited by a convenience sampling method in an outpatient clinic. The diagnosis of MS [13] was established by a neurological specialist at Alzahra Hospital, Isfahan City, Iran. The research participants were enrolled if they were functionally ambulant (walking for 20 meters) without the assistance of any device or subject; however, they demonstrated evidence of dorsiflexion weakness during walking (drop foot). They were excluded if presenting a significant cognitive impairment, a history of relapse in the last three months, remarkable musculoskeletal disorders (e.g., fracture or articular lesions in the lower limb), or medical instability (e.g., heart or respiratory problems) which impacted ambulation. None of the study participants had any experience with either of the orthotic devices used in the study.

Demographic variables and disease characteristics of the study sample were recorded. Each research participant was randomly assessed under 3 conditions; barefoot, thermoplastic AFO, and flexible Dictus-band. The thermoplastic AFOs were custom-made fabricated from a 3-mm polypropylene sheet. The orthoses extended from the calf to the toes and are contoured behind the medial and lateral malleoluses at the ankle (Figure 1.A). The Dictus-band was a prefabricated flexible orthosis, consisting of a foot cuff, leg cuff, elastic band, and hooks (Figure 1.B). The cuffs were fitted on the midfoot. Moreover, the lower leg and the interconnecting elastic band assisted the dorsiflexion of the ankle. The study participants used both orthoses bare feet in the gait lab. This measured aimed to control for the possible impact that wearing shoes could have on the assessments, compared with the barefoot condition. Each AFO had two straps to be fitted over the ankle and forefoot areas; these straps were to let the orthosis be worn on its own and without a shoe (Figure 1.A). Orthotic measurement and the fitting of both orthoses were performed by a qualified orthotic team.

The study subjects' walking performance was measured by the 10-Meter Walking Speed test (10-MWS). In the 10-MWS, the participants walk for 10m at their self-selected and safe pace [14]. The time is recorded using a stopwatch and the relevant speed (m/s) is calculated. Dynamic balance during functional mobility was assessed by the Timed Up and Go test (TUG) [15]. In the TUG, participants are requested to sit on an armchair and stand up with the word "go". Then, they walk 3m until reaching a marked line and turn and walk back toward the chair and sit down on the chair. The time to complete the TUG was recorded using a stopwatch. Standing balance was measured with the Forward Reach Test (FRT) [16] and postural stability over a force platform. The FRT measures the distance each participant can reach while leaning forward with an outstretched arm kept at shoulder level. The middle finger displacement is measured with a yardstick. The upright FRT is a well-established proxy measure to assess balance problems in PwMS [16].

Postural stability was recorded during standing on a force platform (Advanced Medical Technologies Inc., Watertown, USA) at a sampling rate of 100 Hz. The research participants were requested to put their feet on a marked area on the force platform (heels were kept together, and forefoot slightly turned out); accordingly, they were instructed to keep looking straight forward to a reference cross placed on the wall in front of them at their sight level. The study participants had to maintain a quiet standing position with arms relaxed at their side for 70s. The recorded signals were processed to calculate the Center of Pressure (CoP) over the force platform. The CoP signal was filtered using a second-degree curve with a 10Hz cut-off threshold. The first and last 5s were trimmed (60s remaining) to obtain more reliable data. The recorded CoP had two components of Anteroposterior (AP) and Mediolateral (ML) displacement. Mean Velocity (MV) was calculated to capture the CoP movement during the recording time for the AP or ML components.

All measurements were conducted in one session. In all measurements, each research participant did one trial to become familiar with the process; then, the tests were repeated 3 times, and mean values were calculated. The study participants were allowed a 2- to 5-min break between each trial to prevent fatigue.

One-way repeated-measures Analysis of Variance (ANOVA) was used to compare the outcomes measured in the 3 study conditions among the study participants. If the repeated-measures ANOVA findings test indicated a significant difference, Bonferroni posthoc test was con-

Figure 1. The Orthoses: A) Thermoplastic ankle-foot orthosis; B) Dictus-band

ducted to explore pairwise differences between the study conditions. The statistical analyses were performed using SPSS at the significance level of 0.05.

3. Results

Fifteen PwMS participated in this study; according to the Expanded Disability Status Scale (EDSS), one (6.7%) research participant reported moderate disability, one (6.7%) relatively severe disability, 8 (53.3%) a disability affecting all daily living activities, and 5 (33.3%) required assistance for walking and working. Eight study subjects experienced right-sided hemiparesis, 5 were left-sided, and 2 presented a bilateral weakness (for whom orthoses were worn on the weaker leg). The study subjects' characteristics are outlined in Table 1. All research participants completed all testing procedures. No adverse events were reported in this research.

Table 2 summaries the Mean±SD scores of the 4 tests for the 3 conditions. The ANOVA data revealed that gait speed (10-MWS) was significantly different across the study groups (Wilk's Lambda=0.32, f=13.82, P=0.001, Partial eta-squared=0.68); this finsing was significantly different between barefoot [P=0.01; 95%Confidence Interval (CI): 0.1-0.8; Cohen's d=0.72] and dictus-band (P<0.001; 95%CI: 0.23-0.69; Cohen's d=0.78) conditions, compared to the AFO condition (Table 3). Dynamic alance (TUG) analyses results revealed the same pattern; ANOVA signiified between-group differences (Wilk's Lambda=0.38, f=10.5, P<0.01*, Partial eta-squared=0.62). Moreover, pairwise comparisons reflected better scores in barefoot (P=0.002; 95%CI: 2.56-10.63; Cohen's d=0.96) and Dictus-band (P=0.001; 95%CI: 2.7-10.2; Cohen's d=0.94) conditions, compared to the AFO condition (Table 3). Balance measures (FRT & CoP parameters) indicated no significant differences between the study conditions.

4. Discussion

This study provided preliminary evidence, suggesting that using a Dictus-band to control foot drop in PwMS is safe (no adverse events & no aggravation of balance) and more effective, compared to implementing a rigid AFO (improved gait speed & dynamic balance). A major concern driving this exploratory trial was the odds of any detrimental effects that the Dictus-band could have around an increased risk of balance dysfunction during standing and walking activities. This is because it could influence the forces exerted on the ankle joint; thus, it

Table 1. Demographic characteristics of the study participants (n=15)

Characteristics	Values*
Female, No. (%)	12 (80)
Age (y)	41±9 (27-57)
Height (cm)	160±6 (145-175)
Weight (kg)	64±12 (47-84)
BMI (kg/m^{2})	25±4 (17-33)
EDSS	4±0 (3-6)
Most affected leg, No. (%) Dominant Non-dominant	 9 (60) 6 (30)

*Values are Mean±SD (minimum-maximum) unless another is indicated.

Table 2. Changes in the outcome measures across the study conditions

Outcome Measures		Mean±SD (minimum-maximum)			One-way Repeated-measures ANOVA
		Conditions			
		Barefoot	AFO	Dictus-band	
10-m walking speed (m/s)		1.58±0.67 (0.58-3.06)	1.13±0.58 (0.23-2.19)	1.59±0.6 (0.57-2.79)	Wilk's Lambda=0.32, f=13.82, P=0.001*, Partial etasquared=0.68
Timed up & go (Sec)		12.2±4.9 (4.5-23.1)	18.8±8.4 (8.5-37.4)	12.4±4.7 (7.5-23.9)	Wilk's Lambda=0.38, f=10.5, P<0.01*, Partial etasquared=0.62
Forward reach (cm)		22.1±5.9 (12-31)	20.6±6 (9.5-30)	20.8±6.6 (9.7-33)	Wilk's Lambda=.79, f=1.7, P=0.22, Partial etasquared=0.21
MV of CoP (mm/s)	AP	19.6±8.1 (11.7-38)	21.3±8.8 (12.4-40.5)	19.3±5.2 (11-28.2)	Wilk's Lambda=0.9, f=0.7, P=0.5, Partial etasquared=0.1
	ML	18.6±6.1 (9.1-31.3)	18.9±5.7 (12.2-31)	17.6±6.4 (5.4-29.3)	Wilk's Lambda=0.97, f=0.2, P=0.82, Partial etasquared=0.03

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ANOVA: Analysis of Variance; AFO: Ankle-Foot Orthosis, MV: Mean Velocity; CoP: Center of Pressure; AP: Anteroposterior; ML: Mediolateral.

* This indicates a statistically significant difference between the research groups (P<0.05).

increased the risk of falls. The collected results failed to support this concern. This is because the performance of standing balance and forward reach tests remained unchanged using either the Dictus-band or AFO conditions, compared with the barefoot condition. Furthermore, using a Dictus-band induced more improvement in the TUG (a measure of falls risk) and 10-MWS (a measure of walking performance), compared to an AFO in PwMS. The present research measurements were easily administered and can be recommended for future studies' use. We plan to investigate the longer-term and real-life (including daily living activities & social participation) effects of the Dictus-band; accordingly, this objective is aimed to be assessed in a definitive trial with an adequate statistical power extracted from this study.

The obtained results indicating postural stability and standing balance were not affected by either the thermoplastic AFO or Dictus-band. These data were in contrast to previous studies that reported the beneficial effects of

Table 3. The results of pair-wise comparisons between the study condition

Pair-wise Comparisons		10-m Walking Speed (m/s)	Timed up & Go (seconds)	Forward Reach (cm)	MV of CoP (mm/s)	
					AP	ML
Barefoot - AFO	P (95%CI)	0.01* (0.1 to 0.8)	0.002* (2.56 to 10.63)	0.33 (-0.81 to 3.55)	0.9 (-6.36 to 2.99)	1 (-3.16 to 2.53)
	MD (SE)	0.45 (0.13)	6.59 (1.48)	1.37 (0.8)	1.69 (1.72)	0.31 (1.5)
Barefoot -"Dictus-band"	P (95%CI)	1 (- 0.25 to 0.23)	1 (-1.1 to 0.8)	0.74 (-1.45 to 3.77)	0.9 (-4.92 to 5.43)	1 (-4.05 to 6.05)
	MD (SE)	0.01 (0.09)	-0.15 (0.96)	1.16 (0.96)	0.25 (1.9)	1 (1.86)
AFO - "Dictus-band"	P (95%CI)	<0.001* (0.23 to 0.69)	0.001* (2.7 to 10.2)	1 (-2.81 to 3.23)	1 (-2.93 to 6.81)	1 (-4.06 to 6.69)
	MD (SE)	0.46 (0.85)	6.4 (1.36)	021 (1.11)	1.94 (1.79)	1.31 (1.98)

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AFO: Ankle-Foot Orthosis; MV: Mean Velocity; CoP: Center of Pressure; AP: Anteroposterior; ML: Mediolateral; P: P-value; CI: Confidence Interval; M.D: Man Differences; SE: Standard Error

* This indicates a statistically significant difference between the study groups (P<0.05).

using AFOs on postural stability [17, 18]. McLoughlin et al. [17] addressed a slight increase in postural sway with a flexible ankle orthosis (an orthosis similar to Dictus-band). The clinical impact of postural sway changes is difficult to interpret; furthermore, the techniques they used to record postural stability differed from those of this study. Thus, it could explain discrepancies between the results of the two studies. Cattaneo et al. reported beneficial effects using thermoplastic AFOs to improve standing balance [18]; however, they used a clinical test (Equiscale) in which the balance performance was scored via a visual inspection of standing by an assessor. The current study used an automated measurement method to prevent assessor bias and error that could have an impact on the results.

Dynamic balance and walking performance were relatively reduced whilst wearing thermoplastic AFO; the Dictus-band provided no significant change, compared with the barefoot condition. These results were consistent with those of previous studies; they reported thermoplastic AFOs to disrupt the ankle's active RoM. Thus, this process affected walking performance and dynamic balance [12, 19]. Furthermore, insufficient ankle plantar flexion is identified as a primary contributor to reduced walking performance in PwMS [20]. In this study, the 10-MWT was used to measure walking performance. It has functional relevance since falls in PWMS mostly occur when walking short distances indoors [21]. Other studies have measured energy costs [22] or walking for a longer distance or time [17]. The longer mean time to complete the TUG test with the thermoplastic AFO could imply that the restrictions of ankle motion with orthoses can affect the user's performance in the functional components of the TUG. Raising from a chair, walking fast, and stand-to-sit requires further ankle mobility to safely transfer the body's center of mass over the foot [23, 24]. Additionally, immobilizing the ankle in a thermoplastic AFO could affect the individual's performance to complete these maneuvers within the TUG test.

The benefits of using the Dictus-band might not be limited to the outcomes signified in this research. This orthotic option is cost-effective, cosmetically acceptable, easy to wear, and applicable as a device for resistance training. Resistance training could improve the functional capabilities required for safe and efficient mobility in PwMS [25]. The Dictus-band covers a smaller area of skin. Besides, it is less likely to interfere with sensory inputs to the foot and calf than a thermoplastic AFO. Furthermore, the powerful afferent stimulus from an active plantarflexor muscle group will also be greater in the dynamic orthotic, compared to the static version. These kinds of foot and ankle sensations play an essential role in balance and mobility performance among PwMS [26].

This study had several limitations that need to be addressed. The research participants and assessors were not blinded to the study conditions; the risk of bias should be considered, although this may be less relevant with objective outcomes (e.g., automated data collection for postural sway). The study participants did not wear their shoes; using shoes with orthoses used in this study might change the obtained results. The explored participants practiced walking around in the devices for about 5 min prior to testing; however, it has been suggested that an upward of 4 weeks is required to adapt to a new AFO [27].

This study investigated the immediate effects of using a Dictus-band orthotic in PwMS. It fulfilled its objective and highlighted that preventing drop foot with Dictus-band had no detrimental effect on the balance and mobility of users. Accordingly, this result supports further studies to investigate the impact of longer-term use before progressing to definitive effectiveness. Further studies are also required to measure users' preferences and costs while comparing this orthosis with other therapeutic interventions.

5. Conclusion

The effects of a Dictus-band orthotic on the mobility of PwMS were superior to a thermoplastic AFO. This effect could potentially be because it dynamically compensates for dorsiflexion weakness without blocking the plantarflexion required for body transfer maneuvers and ambulation. However, it was similar in effect to a barefoot condition. The concern that Dictus-band may present a challenge for balance and increased the risk of falls was not supported in this study.

Ethical Considerations

Compliance with ethical guidelines

The necessary ethical approval was obtained from the Ethics Committee of Isfahan University of Medical Sciences (Registration No: IR.MUI.REC.1394.3.979). Participants provided informed consent forms before participation, per the standards of the Declaration of Helsinki.

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Authors' contributions

Conceptualization and Supervision: Ebrahim Sadeghi-Demneh, Susan Hillier; Methodology: Ebrahim Sadeghi-Demneh, Sama-Sadat Parian, Niloufar Fereshtenjad; Investigation: Sama-Sadat Parian, Niloufar Fereshtenjad; Writing – original draft: Ebrahim Sadeghi-Demneh, Susan Hillier; Writing – review & editing: All authors; Data collection: Sama-Sadat Parian, Niloufar Fereshtenejad; Data analysis: Ebrahim Sadeghi-Demneh; Funding acquisition and Resources: Ebrahim Sadeghi-Demneh.

Conflict of interest

The authors declared no conflicts of interest.

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