Research Paper: Comparing the Effects of Functional Electrical Stimulation With and Without Ankle-foot Orthosis on the Balance and Walking Ability of Patients With Multiple Sclerosis

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ABSTRACT

Objectives: Multiple Sclerosis (MS) is an autoimmune disease of the central nervous system that is the second leading cause of nerve failure in young adults. One of the clinical manifestations of MS is impaired balance and gait. Ankle-foot Orthosis (AFO) and Functional Electrical Stimulation (FES) are the most common rehabilitation interventions to improve the patients' gait and balance. This study aimed to evaluate and compare the effect of using an FES system and an AFO equipped with FES on the gait and balance of patients with MS.

Methods: This research was a cross-sectional study. The patients were included in the study who were diagnosed with MS, had a score of lower than five on the expanded disability status scale, had a history of drop foot for at least three months, aged 20-50 years, and prescribed an AFO or FES, or both. The participants were asked to wear the FES system to evaluate their balance and ability to walk using the Balance Evaluation Systems Test (BESTest). Then, the participants were asked to wear an AFO equipped with FES, and their balance and ability to walk were assessed again.

Results: The AFO equipped with FES provides more gait stability than FES alone condition ($P<0.05$). The ability of patients to use the FES alone was greater than using the AFO equipped with FES ($P<0.05$).

Discussion: The study results showed that the walking ability of MS patients using an FES system is greater than that of AFO equipped with FES. This outcome can be due to the difficulty and limiting effect of using an orthosis on their performance. However, the patient's postural response during stepping back and forth in the condition of AFO equipped with the FES system was better than the FES system alone.

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Highlights

- During stepping back and forth, AFO equipped with FES provides more support than the FES alone.
- The ability of patients to use the FES alone was greater than using the AFO equipped with FES.
- Stability in walking while using AFO equipped with FES was significantly better than the FES alone.

Plain Language Summary

Multiple Sclerosis (MS) is an autoimmune disease of the central nervous system that is the second leading cause of nerve failure in young people. More than 2.5 million people are living with MS worldwide. One of debilitating symptoms of MS is balance and gait disturbance, which interferes with moving a person from one place to another, compromising the standing balance and functional activities such as walking and activity of daily living. For MS patients with drop foot, the use of functional electrical stimulation (FES) systems and ankle foot orthosis (AFO) are commonly recommended. The aim of this study was to compare the effect of FES and AFO equipped with FES on balance and walking ability of patients with MS. We found that in comparison between the FES system and the AFO equipped with FES, the FES alone was more successful regarding the ability of people with MS to walk. The reason can be the limitation resulting from AFO in the ankle area; this orthosis minimizes the ankle and foot motion by maintaining the position of the ankle joint at an upright angle, preventing the rocking motion of the toe, and also creating restrictions for foot rotation, and this will adversely affect the ability of people to walk. In contrast, the AFO equipped with FES had better results in tests in which the balance of individuals was measured. The AFO could create the feeling in the patient as an external supporter and prevented the foot from slipping and shaking and induced a greater sense of balance in the patients.

1. Introduction

Multiple Sclerosis (MS) is an autoimmune disease of the central nervous system that is the second leading cause of nerve failure in young people [1]. The incidence of MS in young women is about 1.5 to 3 times higher than in men [2]. MS-related disability is most common among patients of 20 and 30 years old [3]. More than 2.5 million people are living with MS worldwide [4, 5]. According to the latest statistics, about 70000 patients with MS have been reported in Iran, of which 72% are young women and girls and 28% are young and active men. Iran is among the top 10 countries in the world in terms of MS [3].

The above statistics clearly show the importance of addressing the outcomes of MS. Because MS affects different areas of the nervous system, it can have different consequences. Destruction of the myelin sheath of nerves in any area of the brain may cause specific symptoms {Fjeldstad, 2009 #15;Kamalian Lari, 2018 #22} [6, 7]. One of these debilitating symptoms is balance and gait disturbance, which interferes with moving a person from one place to another, compromising the standing balance and functional activities such as walking and activity of daily living [6-8]. All of these factors cause patients to lose their balance and walking ability. Patients with MS cannot participate in society and perform social activities [6, 7].

In MS, one of the most commonly involved nerves is the deep peroneal nerve, which innervates the anterior leg muscles [6, 7]. These muscles are responsible for dorsiflexion and inversion of the foot. Moreover, with these nerves' involvement, dorsiflexion of the foot is destroyed, resulting in poor foot clearance, increasing the risk of trips and falls, and affect the patients' health-related quality of life [6, 7].

The most common treatments for patients with MS include medication, orthotic interventions [9], physiotherapy [10], and occupational therapy [8]. The purpose of prescribing these interventions is to help the person's function, balance, and gait, as well as protect and maintain bones and joints against injury [11]. It has previously been observed that orthotic treatments such as Ankle-foot Orthosis (AFO) and Functional Electrical Stimulation (FES) systems have positive effects on functional ambulation [12], walking ability [13], balance [14], and kinetic and kinematic parameters of walking [15] in individuals with a neuromuscular condition. FES provides short and burst electrical pulses that are applied to the common peroneal nerve to cause pretibial compartment muscles contraction [16]. FES used for foot drop has a positive initial and ongoing effect on gait speed in short walking tests [17]. AFO also maintains the ankle joint in the neutral position, prevents the toe from hitting the ground, and improves the swing phase clearance of the lower limb [18].

Previous studies showed that the compliance rate of AFO in patients with MS is low. Weight, appearance, or failure to meet patients' needs are the important reasons for not using this orthosis [4, 14, 19]. So far, too little attention has been paid to compare the effect of AFO and FES in patients with MS who had drop foot. In the United Kingdom, Renfrew et al. [20] found out that the effect of FES on gait speed of patients with MS is comparable with AFO. In this study, the number of patients who discontinued using AFO was higher than FES during the study.

Although AFO is the most common care in Iran, few studies have evaluated its effect on the gait parameters of patients with MS [14, 15]. However, there is much less information about the effects of AFO in combination with FES in patients with MS. Therefore, the present study aimed to compare the effect of FES and AFO equipped with FES on the balance and walking ability of patients with MS.

2. Materials and Methods

This research was a cross-sectional study on MS patients with drop feet from February 2020 to August 2020. The study protocol was approved by the Ethics Committee of Iran University of Medical Sciences (IRCT1398.1363).

The inclusion criteria were as follows: MS patients with a history of drop foot for at least three months [21], age between 20 and 50 years, the experience of using an AFO or FES or both, no history of surgery, trauma, and fracture in lower limbs, no improper posture such as kyphosis and scoliosis, no infection and inflammation of the skin in the ankle area and a score of less than five on the Expanded Disability Status Scale (EDSS). The EDSS is a method of measuring disability in MS and tracking changes in the level of disability over time. It is commonly used in the evaluation of patients with MS. This measure ranges from 0 to 10 with 0.5 unit increments that a higher score describes a higher level of disability. A score of 5 to 9.5 in EDSS indicates a movement disorder [4, 19].

The sample size was calculated using G-Power software. In a previous analysis for the Wilcoxon signed-rank test by considering an α value of 0.05, the effect size of 0.5, and the minimum power of 0.8, a total of 28 cases was obtained. We included 30 patients with MS. All participants signed a written consent form.

Study interventions

The participants were fitted a prefabricated polypropylene AFO with a thickness of 3 mm (Figure 1). The trim lines of the orthosis were posterior to the malleoli, and the angle of the shank section inclined forward about 10 degrees.

The participants were also fitted with an FES system (model T-102 of Tiwan company) (https://tiwan.ir). The output frequency of this system is between 10 and 50 Hz and has two interchangeable surface electrodes. The electrodes are located in the lower outer corner of the popliteal cavity outside the leg and on the common peroneal nerve (Figure 2). This device is used to stimulate the muscle by short pulses and a series of electrical contractions. If these electrical pulses are applied to the motor nerves, it causes action potential and muscle contracts [16].

Data collection

The personal and clinical characteristics of included patients (age, sex, educational level, time since involvement with MS) were recorded. Information about patients' gait and balance while using orthosis was obtained using the Balance Evaluation Systems Test (BES Test), developed by Horak et al. [22]. This test allows the therapist to identify the disorder's area properly. The BESTest consists of 27 items in six sections of biomechanical constraints, stability constraints/verticality, transitions/anticipatory, reactive, sensory orientation, and gait stability. Each item's score ranges from zero to three, with a higher score indicating a higher level of balance. The BESTest total score ranges from 0 (lack of balance and ability to walk) to 81 (maximum balance and ability to walk) [23].

Study protocol

At first, the orthotist explained all steps of the test to the participants and asked them to wear shorts or fold their pants up to the knee so that it does not interfere with walking and balance; then, by using an alcohol pad, the electrodes were cleaned from grease and moistened with distilled water so that the desired electric current flows well. With several trials and errors, the best location of the electrodes was obtained. The orthosis was connected to the T109 calibrator using Bluetooth, and its frequency was adjusted according to the patient's needs using Tiwan's software. In the first stage, the participants were

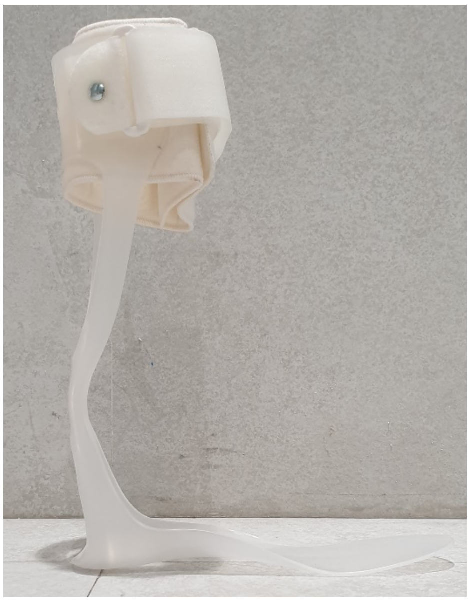

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Figure 1. Plastic ankle-foot orthosis

asked to wear the FES alone. In this condition, all items of the BESTest were applied, and the score of each test was recorded. After considering a washout time of 20 minutes, all tests were repeated with the patient wearing an AFO equipped with FES. To familiarize patients with orthosis before the test, we asked each patient to walk with that orthosis for 5 minutes.

Statistical analysis

The data normality was checked using the Shapiro-Wilk test. Results showed that in the biomechanical constraints, stability constraints, predictive changes, and sensory integrity of the BESTest, the data distribution was overly skewed (P<0.05). Therefore, the Wilcoxon signed-rank test was used to compare the mean values of BESTest between the two conditions. Regarding gait stability and reactive postural responses sections, the data distribution was normal, and therefore, the paired sample t-test was used to assess the mean scores of BESTest. For all tests, P <0.05 was considered statistically significant. Statistical analysis of the present study was performed using SPSS v. 20.

3. Results

A total of 17 women Mean±SD age: 39.35±8.16 years and 13 men Mean±SD age: 35.76±8.85 years were included in the study. Of these, 6 had a diploma, and 24 had a university degree. Analytical statistics related to gait stability and reactive postural responses, biomechanical constraints, stability constraints, predictive state change, and sensory integrity are depicted in Tables 1, 2, and 3.

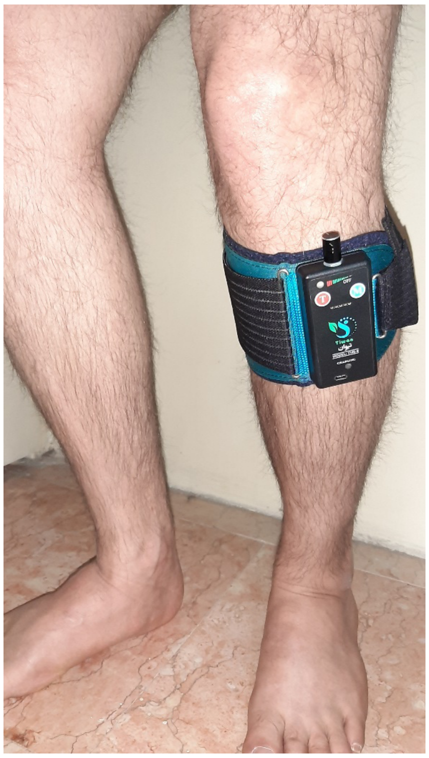

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Figure 2. Functional electrical stimulation system

According to Table 1, in the field of “change of predictive states” of the questionnaire (items 16 and 17), which are related to the conditions of stepping back and forth, AFO equipped with FES provides more stability than the FES system (P<0.05). Also, in the “stability in walking” section, items of 21, 23, 24, and 27, by which the ability of patients while walking on flat surfaces, walking with the head rotated on the horizon, walking with axial rotation and timed rise and fall are examined with dual activity, respectively. There was a significant difference between AFO conditions equipped with electrical stimulation and electrical stimulation system alone (P=0.035). That is, the ability of patients to use the electrical stimulation system alone was greater than using the ankle-foot orthosis equipped with electrical stimulation.

There was no significant difference in other variables. The results of the Wilcoxon signed-rank test showed that in the areas of reactive positional responses, biomechanical constraints, stability constraints, and sensory integration between the conditions of use of AFO equipped with FES and FES alone, no significant difference was seen.

4. Discussion

This study aimed to compare the effect of FES and AFO equipped with FES on the balance and walking ability of patients with MS. Our results showed that in comparison

Table 1. Comparing the results of BESTest between Ankle-Foot Orthosis (AFO) with Functional Electrical Stimulation (FES) and FES alone conditions

Sections	Mean±SD		P
	AFO With FES	FES	
Biomechanical constraints	8.60±1.35	8.83±1.31	0.13
Stability limits	3.93±1.17	3.93±1.46	0.85
Reactive postural response	3.50±3.83	5.16±3.63	0.21
Sensory orientation	2.80±1.12	2.66±1.06	0.67
Transitions–Anticipatory postural adjustment	4.90±2.68	5.16±2.75	0.30
Stability in gait	8.06±3.85	9.26±3.32	0.03
Total	33.80±12.46	35.06±11.33	0.14

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between the FES system alone and the AFO equipped with FES, the FES system alone was more successful in tests that measured the ability of people to walk. In contrast, the AFO equipped with FES had better results in tests in which the balance of individuals was measured.

In the walking stability domain of the BESTest, there was a significant difference between using the FES system alone and AFO equipped with FES in tests related to smooth walking, walking with horizontal rotation of the head, walking with axial rotation, and getting up and going on time with dual activity. The FES system alone had a significant effect on walking compared to the integration of an FES system with an AFO. The reason can be the limitation resulting from AFO in the ankle area; this orthosis minimizes the ankle and foot motion by maintaining the position of the ankle joint at an upright angle, preventing the rocking motion of the toe, and also creating restrictions for foot rotation, and this will adversely affect the ability of people to walk [24]. This finding is consistent with the relevant theoretical foundations because the FES system causes the anterior leg muscles to contract and facilitates the foot's dorsiflexion by applying electrical pulses to the peroneal nerve [25]. These results reflect those of Khurana et al. [26], who also found that the exertion levels of patients were lower while using the FES system than the AFO condition. Besides, there are similarities between our results and Renfrew et al. [20], who compared the effects of FES and AFO on the walking ability of patients with MS. Analysis of the findings showed that the ability to move was significantly lower in the patients who used AFO than the FES [20]. Sheffler et

Table 2. Comparing the results of stability in gait items of the BESTest between Ankle-Foot Orthosis (AFO) with Functional Electrical Stimulation (FES) and FES alone conditions

Items	Mean±SD		P
	AFO With FES	FES	
21 (Gait–level surface)	1.36±0.76	1.63±0.61	0.03
22 (Change in gait speed)	1.36±0.71	1.60±0.77	0.16
23 (Walk with head turns–horizontal)	0.96±0.76	1.03±0.71	0.001
24 (Walk with pivot turns)	1.40±0.81	1.46±0.68	0.04
25 (Step over obstacles)	1.13±0.50	1.20±0.84	1.00
26 (Timed "Get UP & GO")	1.03±0.80	1.10±0.75	0.80
27 (Timed "Get Up & Go" with dual task)	1.20±0.84	0.93±0.82	0.02

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Table 3. Comparing the results of reactive postural response items of the BESTest between Ankle-Foot Orthosis (AFO) with Functional Electrical Stimulation (FES) and FES alone conditions

Items	Mean±SD		P
	AFO With FES	FES	
14 (In place response-forward)	1.10±0.75	1.23±1.00	0.43
15 (In place response-backward)	0.86±0.73	0.86±0.77	0.25
16 (Compensatory stepping correction-forward)	1.13±0.81	1.16±0.83	0.05
17 (Compensatory stepping correction-backward)	1.10±0.80	1.00±0.74	0.03
18 (Compensatory stepping correction-lateral)	1.16±0.83	1.10±0.84	1.00

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al. [18] compared the effect of using and not using ankle orthoses on walking speed and functional mobility at a distance of 25 m in 15 patients with MS. According to the study results, there was no statistically significant improvement in walking speed, and no functional displacement was observed using the ankle-foot orthosis. Linda Miller et al. reviewed previous studies and examined the effect of using an FES system on short-distance and long-distance walking speeds in patients with MS with ankle prolapse. The results showed that the use of FES had a significant effect on patients' walking speed over short distances, and the average increase in patients' walking speed was reported to be 0.05 m/s [17].

In the tests related to the use of the FES system alone, in the stage between toe-off and heel-strike, instability and tremor of the foot and ankle were evident in all participants, so that sometimes this tremor affected the alignment of the foot. However, AFO provided the necessary stability for the ankle area, compensating for the tremor and instability and somewhat correcting the gait direction of people. Nevertheless, the integration of the AFO with the FES system lacked a significant effect on maintaining the overall balance of the body to perform better balance tests but maintaining the angle of the foot and ankle and the indirect effect of this orthosis on the knee that prevents the tibia progression could provide more stability for the person [27]. The orthosis could also create the feeling in the patient that an external supporter prevented the foot from slipping and shaking and induced a greater sense of balance in the patient. These results corroborate the findings of a previous systematic review of the literature that found the AFOs allow controlled movement of the foot in the sagittal plane, which seemed to facilitate both static and dynamic balance in the studied cohorts [28].

As observed in the test related to compensatory stepping correction by stepping forward and backward, there is a significant difference between the FES system and the AFO equipped with the FES system. The use of AFO provided the necessary stability for the ankle area and better maintained the balance of the participants. It is worth noting that maintaining balance for patients with MS is considered an essential and vital category and affects people's self-confidence and self-esteem, which is in line with previous study results [29]. A study that points to the importance of maintaining balance in patients with MS is by Cameron et al. in 2010 that examined previous studies on the causes of falls due to the inability to maintain balance in MS and realized that the effect of the disease on gait parameters includes speed, stride length, and joint movements [30]. Therefore, maintaining and controlling extra and dysfunctional joint movements due to nerve damage in MS can increase the patients' stability to some extent. In 2020, Keyvani Hafshejani et al. [15] developed kinetic and kinematic indices in 4 patients with MS by making a new joint ankle orthosis that can be adapted to the walking problems of MS patients. The results showed that walking speed and sagittal range of motion improved with the use of the new orthosis.

In other aspects, such as biomechanical limitations, reactive postural responses, and sensory integration, there was no significant difference between the two interventions, and the ability of individuals can be considered equal using both methods. For patients with MS, the prescription of orthosis should be according to the patient's preference and satisfaction [31]. Consistent with the present results, previous systematic review studies have demonstrated that the choice between AFO and FES ultimately depends on the individual's admission, physician prescription, and clinical examination [32].

MS causes fatigue in patients; thus, conducting the tests had limitations. Performing tests in short intervals caused fatigue, and sometimes participants left the test, and in contrast, applying rest time to participants between tests increased the total test-taking time. Furthermore, we used a prefabricated AFO. Further research should be undertaken to compare the effect of prefabricated AFO with a custom-made design on the balance and stability of walking in patients diagnosed with MS. The lack of cooperation of some participants due to the coronavirus disease situation and the difficulty of performing tests using masks, gloves, and shields can be considered other limitations in this study.

5. Conclusion

The walking ability of MS patients using an FES system is greater than that of AFO equipped with FES, which can be due to the difficulty and limiting effect of an orthosis on their performance. However, the patient's postural response during stepping back and forth in the condition of AFO equipped with the FES system was better than the FES system alone.

Ethical Considerations

Compliance with ethical guidelines

The patients signed the written informed consent form to participate in the study and approved the images for publication.

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Authors' contributions

All authors equally contributed to preparing this article.

Conflict of interest

The authors declared no conflict of interest.

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