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A comparison of the initial orthotic effects of functional electrical stimulation and ankle-foot orthoses on the speed and oxygen cost of gait in multiple sclerosis

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Abstract

Background: Foot drop affects walking in people with multiple sclerosis (pwMS). This study compares the initial orthotic effects of two treatments for foot drop: ankle-foot orthoses (AFO) and functional electrical stimulation (FES), on the speed and oxygen cost of walking in MS.

Method and materials: Seventy-eight pwMS were randomised to receive AFO or FES (ODFS PACE (OML, Salisbury, UK)). Participants completed the 25-ft walk test (25ftWT) and 5-min self-selected walk test (5minSSWT), from which oxygen cost was determined, with and without their device. Between-, within- and sub-group analyses (based on baseline walking speed of <0.8 m/s (slow) or ≥ 0.8 m/s (fast)) were undertaken.

Results: No significant differences between baseline measures were observed. The AFO group walked significantly slower than the FES group (5minSSWT, $p = 0.037$, 0.11 m/s). The AFO group walked significantly slower with than without AFO (25ftWT, $p = 0.037$), particularly in the fast-walking group ($p = 0.011$). The slow-walking FES group walked significantly faster with FES than without (25ftWT; $p = 0.029$, 5minSSWT; $p = 0.037$). There were no differences in the fast-walking FES group or in the oxygen cost for either device.

Conclusion: AFO reduced walking speed, particularly in fast walkers. FES increased walking speed in slow, but not fast walkers.

Keywords

Ankle-foot orthosis, electrical stimulation, neurorehabilitation, orthotics, walking velocity

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Introduction

Multiple sclerosis (MS) is the most common neurological condition resulting in physical disability of the working age population in the UK.[1] Mobility deteriorates over time in people with MS (pwMS), and changes in gait are the most observable contributor to disability, with only around 50% of pwMS remaining ambulatory without assistance 15 years from disease onset.[2,3] Foot drop is a commonly observed gait problem in pwMS. It presents as reduced dorsiflexion at heel strike and toe clearance during the swing phase of walking.[4] The consequences of foot drop for pwMS may include: reduced walking speed, higher levels of fatigue and an increased effort of walking in comparison to healthy controls.[3–6] Foot drop may also impact on work and leisure activities and contributes to a reduced quality of life in pwMS.[7–9]

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Conventionally, foot drop has been treated using ankle-foot orthoses (AFO). AFO, worn on the lower leg and foot, are designed primarily to prevent excessive ankle plantarflexion where there is a loss of, or weak, dorsiflexion and eversion, by supporting the foot in a neutral position. An alternative treatment for foot drop, functional electrical stimulation (FES) was first developed by Liberson et al.[10] and is usually delivered via skin surface electrodes which stimulate the common peroneal nerve.[10] The resulting contraction of anterior tibialis during the swing phase of gait, which is triggered by either a foot switch or tilt mechanism, augments ankle dorsiflexion and assists foot drop impairment.

The effects of FES and AFO on walking speed, a commonly evaluated outcome in both AFO and FES studies, are described in terms of orthotic and therapeutic effects. A therapeutic effect is described as the change in a relevant variable (e.g. walking speed) measured over time without the device on. An orthotic effect is the change in the variable with the device compared to without, which is observed at any given time. The change seen on the first day of its use is described as the initial orthotic effect and is the most commonly reported effect in FES literature.[11] Although neither device are intended to be used on a one off basis, and initial effects are likely to be compensatory in nature, it is still important to cognisant of these initial orthotic effects. This will allow clinicians to understand how these devices affect walking initially in pwMS, which may impact on patient compliance over the longer term.

There have been only four small studies to date investigating the impact of AFOs in pwMS, which report mixed effects on walking speed and balance.[12–15] A recent systematic review and meta-analysis found clinically meaningful orthotic effects of FES on gait speed in pwMS; however, analysis was primarily based on non-randomised trials of low methodological quality.[11] Previous FES studies have also evaluated the impact of FES on the oxygen cost of walking,[16–21] which is a valid physiological marker of locomotor impairment in pwMS.[22] There is only one case series study ($n = 4$) which has compared the ongoing orthotic effect of AFOs and FES for foot drop in MS and reports variable effects.[14]

A gait speed of 0.8 m/s has been identified as the speed at which pwMS need to walk in order to achieve successful community ambulation.[5] Miller et al. previously noted a differential effect of FES which was dependant on self-selected walking speed. With FES, improvements were noted in pwMS who walked at walking speeds of < 0.8 m/s, but not > 0.8 m/s.[20] Further investigation of the potential impact of self-selected walking speed on the effect of FES and AFO is required and will help inform the clinical prescription of such devices.

The aim of this study was to compare the initial orthotic effect of AFO and FES on the speed (in both short and long walking tests) and oxygen cost of walking in pwMS with persistent foot drop and investigate the impact of walking speed on the effect of these devices.

Methods

A randomised trial was conducted to compare the effects of AFO and FES in pwMS. This paper presents the initial orthotic effects of the two devices on the speed and energy cost of gait. Neither the assessor nor the participants were blind to the group allocation.

Participants

The sample size for this study was estimated based on the data from the 5-min self-selected walk test (5minSSWT) previously collected in FES studies by our group.[6,19,20] At a power of 90% and a 5% level of significance a minimum of 37 participants in each group would be required in order to detect a change of at least 75% of 1 standard deviation value (0.16 m/s). Allowing for an estimated 15% attrition rate, a total of 84 participants were recruited.

Ethical approval for the study was granted by the West of Scotland Research Ethics Committee and NHS Ayrshire, and Arran Research and Development department sponsored the study. Convenience sampling was used to recruit 84 participants across seven NHS health board sites in Scotland (Ayrshire and Arran, Dumfries and Galloway, Greater Glasgow and Clyde, Fife, Lanarkshire, Lothian and Tayside). MS clinicians identified potential participants via their current caseloads and invited them to attend for screening. Participants who met the inclusion and exclusion criteria and gave informed written consent were enrolled in the study. Participants were included if they had: a clinical diagnosis of MS which was stable (no change in disability over previous three months), persistent foot drop which was observable during a 5-min walk test and no changes in medication or rehabilitation over the previous three months. Participants were excluded if they had: previously used AFO or FES for foot drop, another neurological condition which could present with foot drop, another condition significantly impacting on gait, moderate to severe cognitive impairment (scored < 26 Montreal Cognitive Assessment test), marked proximal weakness, moderate to marked instability (foot or knee) in stance, other significant MS impairments impacting on gait or contraindications to using FES.

Enrolled participants were randomly allocated (1:1) to receive either FES or AFO. A computer-generated randomization scheme was created by the study statistician (AKM), and the group allocation was placed in consecutive numbered sealed opaque envelopes and issued to participants by the research physiotherapists (AL, RH) following consent.

Procedures

Demographics relating to age, gender, MS type, time since diagnosis and disability were collected at the screening visit. A neurological examination and assessment of the Expanded Disability Status Scale (EDSS) was undertaken by an unblinded assessor trained in the Neurostatus Scoring System https://neurostatus.net/index.php.[23]

Participants in the AFO group were assessed, and fitted two weeks later by an orthotist, with a custom-made solid AFO according to the recommendations made by the Best Practice Statement for AFO following stroke,[24] as there are no current specific recommendations for MS. All AFOs were made using 4.5 mm polypropylene with trim lines anterior to the malleoli. Reinforcements were added to the ankle section to increase stiffness if required. The angle of the AFO was inclined forward so that the tibia sat approximately 10° to the vertical to optimise kinetics and kinematics at the knee and hip. The AFOs were individually 'tuned' by the addition or removal of small heel wedges, in order to optimise gait for each individual participant. Tuning AFOs has been found to positively impact on knee hyperextension in stroke.[25] Participants in the FES group were set up and fitted by a physiotherapist trained and experienced in FES use. The Odstock Dropped Foot Stimulator (ODFS) PACE (OML, Salisbury) device was used. All units had a wired heel switch and applied a 40 Hz stimulation frequency. Electrode position, pulse width and ramping parameters were adjusted to suit each participant by a research assistant, a physiotherapist trained in FES (AL). The intensity of the current amplitude ranged from 17 to 72 mA which was determined at the FES fitting appointment/assessment visit as the amplitude was both comfortable for the patient and achieved adequate clearance of the foot during the swing phase of gait.

Assessments were undertaken by the same research assistant (RH). The primary outcome measure for this study was the 5minSSWT. All participants walked with and without their respective devices for each walk test (described below). The order of testing was randomised between participants. All odd numbered participants in each group undertook the walking tests with their device first, and all even numbered participants walked without their device first.

5-min self-selected walk test. Participants walked for 5 min on a level floor at their self-selected walking speed around a 9.5 m elliptical course, resulting in a 10 -m shuttle length. The total distance walked was recorded to allow a calculation of mean walking speed (m/s) over the 5 min. Participants walked on two occasions, with and without their device and rested for 20 min between each test. This protocol has been used previously in FES research by our group.[6,19,20]

Oxygen cost of walking. The COSMED K4b2 (Cosmed, Rome, Italy) gas analysis system, facemask (Hans Rudolph Inc., Kansas City, MO, USA) and Polar heart-rate monitor (Polar, Finland) were fitted to participants. The COSMED system was calibrated prior to assessment according to the manufacturer's instructions. All participants rested in a seated position for 5 min prior to the test in order to estimate resting metabolism. Oxygen uptake per kilogram body weight ($mL\,min^{-1}\,kg^{-1}$) was recorded and the oxygen cost per unit distance walked ($mL\,min^{-1}\,kg^{-1}\,m^{-1}$) was calculated using data between min 3 and 4 of the 5minSSWT when a steady state was achieved. The COSMED system has good test–retest reliability,[26] is a valid measure for oxygen uptake in healthy adults[27] and has been found to correlate with disability, fatigue, walking speed and cadence in pwMS.[28]

25 foot walk test. The 25ftWT has been validated in MS as one of the three components of the Multiple Sclerosis Functional Composite Score.[29] The participant was instructed to walk along a clearly marked 25 ft course as quickly and as safely as possible. This was repeated twice walking with and then without the device. The mean time of the two walks was used to calculate the gait speed in m/s. Motl et al. found the 25ftWT to be highly reliable, valid and responsive measure which captures clinically meaningful change in walking in MS.[30]

Data analysis

Descriptive statistics for demographic data are presented as means and standard deviations unless otherwise indicated. Where data were normally distributed, paired t-tests were used to explore initial orthotic effects for each of the devices with respect to the 5minSSWT, 25ftWT and oxygen cost of walking. Two sample t-tests were used to explore between-group comparisons. Participants in each group were also split into two groups by applying the variable of baseline gait speed (5minSSWT without device), using 0.8 m/s as cut-off

point, which defines walking speed required for community ambulation in pwMS.[5] Analysis for the sub-groups was undertaken as for complete groups. Significance was assumed when $p < 0.05$, and all analyses were performed on SPSS v24.

Results

A total of 192 pwMS were issued with the patient information sheet, and 97 attended for screening. Eighty-four participants met the criteria for inclusion following screening and consented to participate in the study between September 2014 and January 2017 (Figure 1). Six participants withdrew from the study between the screening and assessment visit, five from the AFO group and one from the FES, leaving 78 participants completing the assessment.

There were no significant differences between the groups except for gender, where there was a significantly greater percentage of males (n = 19 (51.6%)) in the AFO group in comparison to the FES group (n = 9 (22%)) ($p = 0.014$) (Table 1).

Between-group differences

There were no significant between-group differences for any of the baseline measures which included the speed (5minSSWT and 25ftWT) and oxygen cost of walking without the device. There were no significant differences for the 25ftWT or oxygen cost of walking with the device. There were, however, between-group differences walking with the device for the 5minSSWT, with the AFO group walking significantly slower ($p = 0.043$) than the FES group (Table 2). There were no between-group differences found with or without the AFO or FES for any of the walking tests in the slow (<0.8 m/s) or fast (>0.8 m/s) walking sub-groups.

Within-group differences

Participants in the AFO group walked slower with the AFO than without, which was significant for the 25ftWT ($p = 0.037$) but not the 5minSSWT (Table 3). There were no significant differences walking with FES for any of the outcome measures, although there was a small non-significant increase in walking speed observed for the 25ftWT (Table 3).

Sub-group analysis

Participants in the slow walking group walked significantly faster with FES in comparison to without for both the 25ftWT ($p = 0.029$) and 5minSSWT ($p = 0.037$). This effect, however was not seen with AFOs. Participants in the fast walking group, walked significantly slower with an AFO than without for the

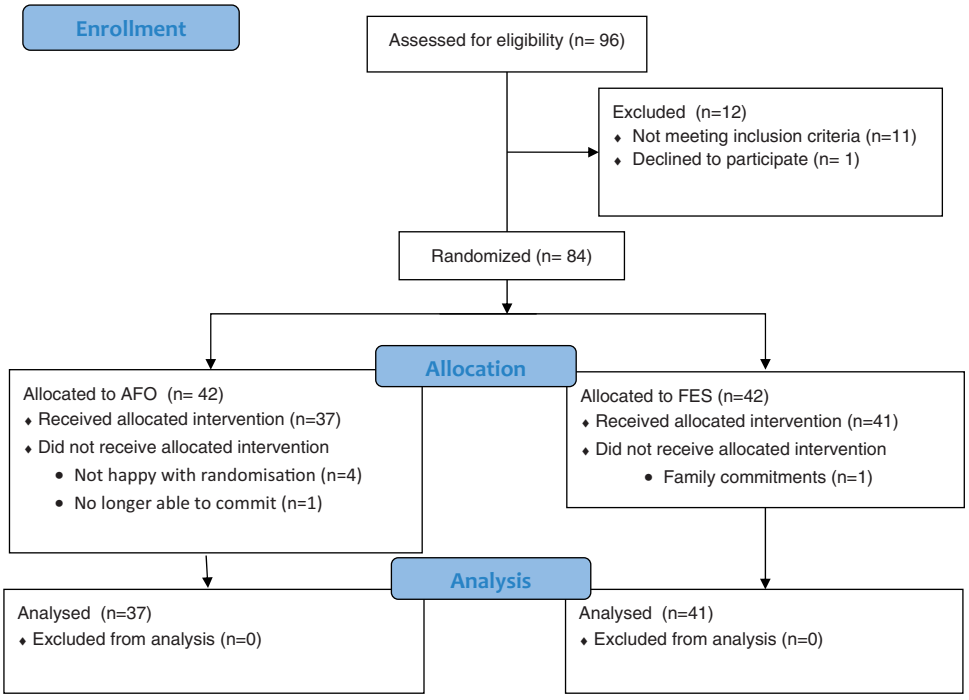

Figure 1. Consort diagram.
AFO: ankle foot orthoses; FES: functional electrical stimulation.

Table 1. Mean, standard deviations and between-group differences for demographic data.

	AFO	FES	*p*
n	37	41	
Age (yrs)			0.657[a]
Mean	51.6	50.5	
sd	11.3	10.2	
Gender,			0.014[b,c]
%Male	19 (51.4)	9 (22.0)	
Type of MS (%)			0.635[b]
Benign	0	1 (2.4)	
PP	7 (18.9)	6 (14.6)	
SP	10 (27.0)	8 (19.5)	
RR	16 (43.2)	18 (43.9)	
Unknown	4 (10.8)	8 (19.5)	
Time since diagnosis [yrs]			0.249[d]
Mean	10.4	7.6	
sd	10.4	8.5	
		6	
EDSS			0.113[d]
Mean	5.3	4.8	
sd	1.3	1.4	
Height (m)			0.214[d]
Mean	1.7	1.7	
sd	0.12	0.11	
Weight (kg)			0.207[d]
Mean	84.6	78.7	
sd	22.7	18.2	
BMI			0.603[d]
Mean	29.5	28.6	
sd	6.8	6.6	

yrs: years; sd: standard deviation; PP: primary progressive; SP: secondary progressive; RR: relapsing remitting; EDSS: Extended Disability Status Score; m: meters; kg: kilograms; BMI: body mass index; MS: multiple sclerosis; AFO: ankle foot orthoses; FES: functional electrical stimulation.
[a]t-test.
[b]Chi-square.
[c]Statistically significant.
[d]Mann-Whitney.

25ftWT ($p = 0.011$). There were no differences observed in any of the other walking outcomes when walking with either AFOs or FES in the fast-walking group. There were no differences in oxygen cost in any of the sub-groups (Table 4).

Discussion

This randomised trial is the first to compare the initial orthotic effects of AFO and FES for the treatment of foot drop in pwMS. AFO reduced walking speed in the short walking test, and this was most noticeable in fast walkers, whose baseline walking speeds were > 0.8m/s. Clinician-setup FES increased walking speed in slow walkers, who walked at speeds of <0.8 m/s. There was no difference in the oxygen cost of walking with either device. The results from this study may indicate that pwMS who walk at speeds of <0.08 m/s gain positive initial orthotic effects from FES, but not AFOs, thus giving clinicians some insight into how these devices affect walking following an initial set up. These results may help inform clinical decision making and patient understanding, thus going some way to support patient compliance of these devices. Further investigation, however, is required to understand the possible mechanisms involved.

There has only been one study, a case series (n = 4), which has compared AFO with FES in pwMS.[14] Sheffler et al.[14] noted variable effects of both devices and found that the participant with the fastest baseline walking speed (1.01 m/s) walked significantly slower with AFO but not with FES. These results concur with those observed in the current study. Only four studies to date have investigated the effect of AFOs on the speed of walking in MS and all have small sample sizes.[12–15] Of these, only one study (n = 14) investigated the initial orthotic effect and found that participants walked 14.3–72% slower in the 10 mWT with an AFO.[12] This effect, although much smaller in the current study (1.3 (slow walkers) – 8.1% (fast walkers)), suggests that AFOs have a negative initial orthotic effect in faster walkers over short distances. The AFOs used in the current study were rigid and were therefore perhaps more likely than the FES to have an immediate impact on gait biomechanics, thus resulting in an initial reduction in walking speed. It is feasible that pwMS will accommodate to AFO use over time. Two previous non-randomised trials investigating the ongoing orthotic effect of AFOs on the 25ftWT[13] in MS and the 6minWT[15] in stroke and MS did find small non-significant increases in walking speed, which supports this explanation. Further investigation particularly examining the impact of AFO on the kinetic and kinematic aspects of gait is needed to understand the possible mechanisms involved.

This study found no initial orthotic effect with FES for either short or long walking tests in MS. This is in contrast with a recent systematic review and meta-analyses of FES, where 9 of the 15 studies reviewed reported significant initial orthotic effects on combined short walking tests.[11] Meta-analyses revealed a significant initial orthotic effect ($t = 2.14$, $p = 0.016$), with a mean increase in walking speed of 0.05 m/s (7.1%).[11] This increase is larger than that observed in the current study for the 25ftWT which was 0.03 m/s (3.4%) overall, 0.05 m/s (6.5%) for the slow walkers and no change for the fast walkers. Differences in the mean baseline

Table 2. Between-group comparisons for the initial orthotic effect of AFO and FES on the 25ftWT (m/s), 5minSSWT (m/s) and the oxygen cost of walking (ml/min/kg/m).

Outcome measure	AFO Mean (sd)	FES Mean (sd)	Mean difference (se)	*p*
25ftWT (without)	0.87 (0.34)	0.94 (0.34)	−0.07 (0.08)	0.366
25ftWT (with)	0.84 (0.30)	0.97 (0.33)	−0.13 (0.07)	0.074
5minSSWT (without)	0.66 (0.21)	0.74 (0.27)	−0.08 (0.05)	0.114
5minSSWT (with)	0.63 (0.21)	0.74 (0.26)	−0.11 (0.05)	0.043[a]
Oxygen cost (without)	0.33 (0.16)	0.29 (0.14)	0.05 (0.04)	0.205
Oxygen cost (with)	0.31 (0.13)	0.29 (0.13)	0.03 (0.03)	0.428

25ftWT: 25 foot walk test; 5minSSWT: 5-min self-selected walk test; AFO: ankle foot orthoses; FES: functional electrical stimulation; sd: standard deviation; se: standard error.
[a]Statistically significant.

Table 3. Initial orthotic effect for the AFO and FES groups presenting the mean, standard deviations and within-group differences for the 25ftWT (m/s), 5minSSWT (m/s) and oxygen cost of walking (ml/min/kg/m) for all participants.

Outcome measure	Without device Mean (sd)	With device Mean (sd)	Mean difference (sd)	*p*
AFO (n = 37)				
25ftWT	0.87 (0.34)	0.84 (0.30)	−0.03 (0.09)	0.037[a]
5minSSWT	0.66 (0.21)	0.63 (0.21)	−0.03 (0.09)	0.126
Oxygen cost	0.33 (0.16)	0.31 (0.13)	−0.02 (0.07)	0.487
FES (n = 41)				
25ftWT	0.94 (0.34)	0.97 (0.33)	0.03 (0.11)	0.108
5minSSWT	0.74 (0.27)	0.74 (0.26)	0 (0.18)	0.986
Oxygen cost	0.29 (0.14)	0.29 (0.13)	0 (0.09)	0.835

AFO: ankle foot orthoses; 25ftWT: 25 foot walk test; 5minSSWT: 5-min self-selected walk test; FES: functional electrical stimulation; sd: standard deviation.
[a]Statistically significant.

Table 4. Initial orthotic effect of AFO and FES for sub-groups of participants who walked < 0.8 m/s and ≥ 0.8 m/s (mean 5minSSWT without FES).

	Without device Mean (sd)	With device Mean (sd)	Mean difference (sd)	*p*
AFO slow walking group < 0.8 m/s (n = 28)				
25ftWT	0.76 (0.27)	0.75 (0.26)	−0.01 (0.08)	0.512
5minSSWT	0.56 (0.15)	0.55 (0.16)	−0.01 (0.09)	0.322
Oxygen cost	0.37 (0.18)	0.35 (0.14)	−0.02 (0.08)	0.524
AFO fast walking group ≥ 0.8 m/s (n = 9)				
25ftWT	1.23 (0.28)	1.13 (0.22)	−0.10 (0.09)	0.011[a]
5minSSWT	0.94 (0.09)	0.89 (0.13)	−0.05 (0.11)	0.238
Oxygen cost	0.23 (0.05)	0.22 (0.04)	−0.01 (0.04)	0.792
FES slow walking group < 0.8 m/s (n = 25)				
25ftWT	0.77 (0.28)	0.82 (0.29)	0.05 (0.10)	0.029[a]
5minSSWT	0.57 (0.16)	0.62 (0.18)	0.05 (0.11)	0.037[a]
Oxygen cost	0.34 (0.15)	0.32 (0.13)	−0.02 (0.05)	0.101
FES fast walking group ≥ 0.8 m/s (n = 16)				
25ftWT	1.21 (0.21)	1.21 (0.22)	0.00 (0.11)	0.874
5minSSWT	1.00 (0.17)	0.93 (0.25)	−0.07 (0.25)	0.251
Oxygen cost	0.21 (0.05)	0.23 (0.11)	0.02 (0.12)	0.532

AFO: ankle foot orthoses; 25ftWT: 25 foot walk test; 5minSSWT: 5-min self-selected walk test; FES: functional electrical stimulation; sd: standard deviation.
[a]Statistically significant.

walking speed may be one factor which could account for the variances between the studies. Participants in the current study walked faster (0.94 ± 0.34 m/s (25ftWT)) in comparison to participants in the systematic review (0.69 ± 0.03 m/s (combined short walk tests)).[11] All but one of the studies reviewed by Miller et al.,[11] however, were from non-RCT sources which may also have resulted in an overestimation of their findings and account for the differences observed.

The results from the 5minSSWT were similar to those seen by Miller et al.,[11] who reported a small non-significant increase in walking speed with FES (0.02 m/s (3.3%) on combined long walking tests. Although there was no overall effect noted in the current study, a significant increase in walking speed was observed with FES in the slow walking group for the 5minSSWT (0.05 m/s, 8.8%, $p = 0.037$). A previous study by Miller et al.[20] reported a significant increase ($p = 0.005$) in walking speed in the 5minSSWT in pwMS walking at speeds of < 0.8 m/s, but not > 0.8 m/s with FES. Participants in the slow walking sub-group in the current study had a mean baseline walking speed (0.77 ± 0.28 m/s (25ftWT)) which was closer to that reported by Miller et al.[11] The results from the current study therefore concur with those found by Miller et al.[20] and may be an indication that FES has a positive initial orthotic effect on walking speed in both short and long walking tests in pwMS who walk slower but not faster than 0.08 m/s; however, further investigation is required. Due to the small numbers of studies which have previously investigated the impact of AFO on walking speed in pwMS, there are no systematic reviews or meta-analyses available for similar comparisons.

Although this study reports statistically significant changes with FES, it is important to consider the clinical significance of the changes observed. Paltamaa et al. reported the minimally clinically important difference (MCID) for gait speed to be between 0.08 and 0.14 m/s in pwMS.[31] The only change observed within this range in the current study was a reduction in walking speed of 0.1 m/s, with AFO, in the fast walking group of nine participants. These changes therefore would need to be verified by larger sample sizes.

The current study found no significant differences in oxygen cost when walking with either device. This result is perhaps expected given the very small changes observed in walking speed. Bregmen et al.[15] reported a 12.1% reduction in the oxygen cost of walking with AFO and Paul et al.[6] and Miller et al.[19] reported a 5.6% and 12% ($p = 0.017$) reduction, respectively, with FES; however, these studies reported ongoing not initial orthotic effects.

This study has a number of limitations. There were significant gender differences between the groups, with the AFO group recruiting a greater percentage of males compared to females. Although any gender effects are unlikely, it is unknown whether it may impact on the initial orthotic effect of either device.

This study was a multi-centre study, recruiting from seven sites and involved three different orthotists. Every attempt to standardise AFO prescription was made; however, variations between sites were observed which may have impacted the results. Further sub-group analysis found no impact of orthotic prescription on either the short or long walking tests. Condie et al. suggest that the function of AFOs may vary depending on its fabrication.[32] It is imperative therefore that future studies should provide a clear description of AFO prescription and assure standardisation. AFO prescription for this study followed evidence-based recommendations from the best practice statement for stroke,[24] as there are no guidelines for MS. It may be that the prescription recommended for stroke is not appropriate for pwMS, and this may have influenced the results. Further investigation is required to determine the most efficient AFO prescription for pwMS.

The 6-min Walk Test is a highly reliable (ICC: 0.95–0.99)[33] and responsive longer walking test commonly used in MS.[31] The validity, however, of the 5minSSWT used in this study has not been previously tested. Although walking distances undertaken were similar, there are differences in the pace, length of track and equipment used (the 5minSSWT was undertaken wearing a COSMED gas analyser), which may influence the results, and thus the validity and reliability of the 5minSSWT cannot be assumed.

The results presented from the sub-group analysis must be treated with caution as sample sizes were small and uneven across sub-groups.

Finally, it must be acknowledged that as the results presented in this study are impairment based and specific to pwMS, the results as they stand add little to the evidence base with regard to enhancing our understanding of the mechanisms of action or indeed the likely impact of the devices on aspects of activity, participation and quality of life.

Conclusion

This study, the first randomised trial comparing the initial orthotic effect of AFO and FES for foot drop in pwMS, found that pwMS with foot drop, who were issued with AFOs initially, walked slower over longer distances in comparison to those issued with FES when walking with their devices. In addition, pwMS walked slower with AFOs in comparison to without over short distances and this was particularly noticeable in those who walked faster. When FES was issued, there were no differences in walking speed, except in those who walked slowly where there was an increase in walking

speed walking with FES in both short and longer walking distances compared to without.

This study only describes the initial journey of these two devices which are usually prescribed for a minimum of months and often used for many years. These results, however allow clinicians to compare the initial orthotic effects of AFO and FES on walking speed, which will help inform clinical decision making and prescription. This will also support patient compliance over the longer term.

Further investigation of the ongoing orthotic and therapeutic effects is needed to inform our understanding of how these devices impact on the speed and energy cost of walking over time. Future research should also focus on a range of activity, participation and gait kinematic outcomes which will provide valuable information and help understand the possible mechanisms involved, allowing clinicians and pwMS to make informed evidence-based decisions.

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Declaration of conflicting interests

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LM.

Contributorship

LM researched literature and conceived the study. LP, DR, PM, RB, OM and AKM were involved in the protocol development and gaining ethical approval. LM, AL and RH were involved in patient recruitment, data collection and study management. AKM, DR and LM were involved in data analysis. LM wrote the first draft of the manuscript. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

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