CRITICALLY APPRAISED TOPIC

FOCUSED CLINICAL QUESTION

In a high-functioning 50 year old male patient diagnosed approximately 8 years prior with relapsing-remitting multiple sclerosis (RRMS) and presenting with foot-drop, does the incorporation of a functional electric stimulation (FES) device, such as Bioness, into an exercise-based physical therapy program lead to increased patient-perceived walking improvements compared to exercise-based therapy alone?

AUTHOR

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CLINICAL SCENARIO

The patient was a high-functioning middle-aged male who had been diagnosed with RRMS 8 years prior. He walked without an assistive device and walked frequently and used an elliptical machine for exercise. His symptoms included right foot-drop and fatigue towards the end of his working day as a neurologist. At the clinic where he was being treated, he was encouraged by a PT to try the Bioness L300 Plus FES device to improve his foot drop. He was somewhat resistant due to the cost and an expressed desire to do all he could without devices first. This PICO question is clinically relevant for ambulatory MS patients because FES devices, such as the Walk-Aide and Bioness systems, are often used at clinics to assist patients with various neurological gait impairments, including stroke and MS.[1–3] MS is the most common cause of neurological disability in adults worldwide, and foot-drop is a common walking impairment that results in walking difficulty and an increased risk for falls.[4] A better understanding of the efficacy of FES as an adjunct therapy would assist clinicians in educating patients and improve clinical decision-making about whether a patient would benefit from FES treatment. The answer to this clinical question could have helped address the following questions that were raised while working with this patient: How often would he have to use the Bioness FES system to see carry-over benefits for his gait, if at all possible? Could using FES during the day while walking reduce his fatigue later in the day and over time?

SUMMARY OF SEARCH

- 3 electronic databases were searched and 10 studies were identified that met the inclusion and exclusion criteria, including 1 systematic review, 2 RCTs, 2 single-group repeated measures studies, 1 two-group non-randomized study, and one case series study. One RCT and 1 single-group repeated measures study, both of moderate quality, were considered highly relevant to the clinical question and were included for further review and analysis in this paper.
- Peroneal FES appears to be an effective treatment for foot-drop in MS patients and was shown to be superior to a core stabilization exercise program. Adding a core stabilization exercise program after a period of FES use may boost FES-mediated walking improvements.
- Both studies show peroneal FES improves gait kinematics, including increased ankle angle at initial contact, and walking speed, and patient-perceived improvements may become evident after 18 weeks of FES use.

CLINICAL BOTTOM LINE

Current research suggests that FES may be more beneficial than core stabilization exercises to improve gait quality in MS patients with foot drop. Patients may benefit most from a combination of FES and exercise, although, either treatment alone may lead to walking improvements. However, patient-perceived improvements are greater with FES use. Clinicians should consider individual patient risks, preferences, and values to determine the appropriateness of integrating FES into an exercise program. An FES treatment plan should be carried out for a minimum of 18 weeks to allow for subjective patient-perceived improvements to be realized.

This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor

SEARCH STRATEGY

Terms used to guide the search strategy			
Patient/Client Group	**I**ntervention (or Assessment)	**C**omparison	**O**utcome(s)
Multiple sclerosis Foot-drop	Functional electric* stimulation Functional electrostimulation Bioness Walk-Aide	Physical therapy Physiotherapy Rehabilitation Exercis* Exercise therapy	Patient-perceived Self-perceived Patient-specific Patient-report* Gait Walk* Ambulat* "walking ability"

Final search strategy (PubMed):

1. "Multiple sclerosis" [MeSH Terms]
2. patient-perceived OR "patient perception" OR perception OR patient-specific OR "patient specific" OR "self-perception" OR "self concept" OR patient-report*
3. gait OR walk* OR "walking ability" OR ambulat*
4. "electric* stimulation" OR electrostimulation OR Bioness OR Walk-aide **(removed the term "functional")**
5. "physical therapy" OR physiotherapy OR "physical rehabilitation" OR exercis*
6. foot-drop OR "foot drop"
7. Bioness **(excluded #1)**
8. #1 AND #2 AND #3 AND #4 AND #5 **(excluded #6)**
9. #1 AND #3 AND #4 AND #5
10. #1 AND #2 AND #3 AND #5
11. #1 AND #3 AND #5 AND #6

History

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Search	Add to builder	Query	Items found	Time
#11	Add	Search **(#1 AND #3 AND #5 AND #6)**	5	15:53:47
#10	Add	Search **(#1 AND #2 AND #3 AND #5)**	40	15:53:28
#9	Add	Search **(#1 AND #3 AND #4 AND #5)**	48	15:52:53
#8	Add	Search **(#1 AND #2 AND #3 AND #4 AND #5)**	2	15:50:15
#7	Add	Search **Bioness**	7	15:49:53
#6	Add	Search **(foot-drop OR "foot drop")**	989	15:49:33
#5	Add	Search **("physical therapy" OR physiotherapy OR "physical rehabilitation" OR exercis*)**	467507	15:49:08
#4	Add	Search **("electric* stimulation" OR electrostimulation OR Bioness OR Walk-aide)**	130705	15:48:46
#3	Add	Search **(gait OR walk* OR "walking ability" OR ambulat*)**	345151	15:48:20
#2	Add	Search **(patient-perceived OR "patient perception" OR perception OR patient-specific OR "patient specific" OR "self-perception" OR "self concept" OR patient-report*)**	546018	15:47:59
#1	Add	Search **"Multiple sclerosis"[MeSH Terms]**	51003	15:46:31

Databases and Sites Searched	**Number of results**	**Limits applied, revised number of results (if applicable)**
PubMed Embase Web of Science	10 2 0	Limits not applied

INCLUSION and EXCLUSION CRITERIA

Inclusion Criteria
• Studied community-dwelling adults with Multiple sclerosis • Measured patient perception and/or walking ability at discharge • Utilized exercise-based physical therapy or functional electrical stimulation as an intervention or directly compared the two
Exclusion Criteria
Abstracts only, textbooks, conference proceedings, letters to the editor, dissertations, opinion articles (narrative reviews), non-human research, or not published in English.

RESULTS OF SEARCH

Summary of articles retrieved that met inclusion and exclusion criteria

Author (Year)	Risk of bias (quality score)*	Level of Evidence**	Relevance	Study design
Mount J et al. (2006)[5]	Downs and Black: 5/29	3	Low	Two-group, non-randomized pretest-posttest design
Scott SM et al. (2013)[6]	Downs and Black: 15/29	2b	Mod	Single-group, cross-sectional repeated measures design
Straudi S et al. (2014)[7]	PEDro: 8/11	2b	Low	Randomized controlled pilot trial
Taylor P et al. (2014)[8]	PEDro: 7/11	2b	High	Randomized crossover (feasibility) trial
Van der Linden ML et al. (2014)[9]	Downs and Black: 18/29	2b	High	Single-group repeated measures design
Coote S et al. (2015)[10]	PEDro: 8/11	2b	Mod	Randomized controlled pilot trial
Street T et al. (2015)[11]	Downs and Black: 13/29	4	Mod	Case series study
Springer S et al. (2017)[3]	AMSTAR: 5/11	2a	Mod	Systematic review of randomized and non-randomized intervention studies

** Portney & Watkins Table 16.1 (2009)

BEST EVIDENCE

The following 2 studies were identified as the 'best' evidence and selected for critical appraisal. Rationale for selecting these studies were:

- Van der Linden ML et al. (2014).[9] This study on FES as an intervention is of acceptable quality and provides Level 2b evidence, which is relatively high among the studies reviewed. Furthermore, this study is highly relevant to the clinical question because they used several patient-perceived outcome measures of gait quality as well as objective gait measurements. The MS subjects in this study all had foot-drop, were in a similar age range as the patient in the scenario, and 4 of 9 subjects were similarly diagnosed with RRMS.
- Taylor P et al. (2014).[8] This randomized crossover trial provides high quality Level 2b evidence and is highly relevant to the clinical question because it directly compared FES and exercise interventions individually and combined on gait quality in MS patients with foot-drop.

SUMMARY OF BEST EVIDENCE

(1) Description and Appraisal of A Feasibility Study to Investigate the Effect of Functional Electrical Stimulation and Physiotherapy Exercise on the Quality of Gait of People With Multiple Sclerosis by Taylor P et al., 2014[8]

Aim/Objective of the Study:
The objective was to evaluate the effect of functional electrical stimulation (FES) (for ankle dorsiflexion and hip extension), physical therapy core stability exercises, and the combination of the two as well as the effects of order of treatment on improving foot drop and gait quality in secondary progressive MS (SPMS) patients with foot drop and reduced core stability.
Study Design

[e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]

Randomized crossover with baseline feasibility study

- Randomization and blinding**:** Computer software generated random numbers for group allocation, which were held separately by an independent researcher. Participants were not blinded to treatments. Assessors utilizing the Rivermead Observational Gait Analysis (ROGA) and measuring walking speed were blinded (all participants wore FES devices), and video files were pseudo-anonymous and randomized before scoring.
- Timeline of outcome measurements and treatment crossover: Baseline measurements for all outcome measures were carried out for both groups 4 weeks prior to the 1st clinical intervention session. Afterwards, measures were taken at every 6 week clinic session, and measures were taken under conditions without FES and with FES use (peroneal stimulation alone and peroneal and gluteal stimulation combined), once the FES intervention phase was initiated.
- General crossover design:
    - Phase 1: Participants were randomly allocated to either FES or a core stability exercise program alone for a total of 12 weeks.
    - Phase 2: Treatments were combined (i.e. the FES group added exercises and the exercise group added FES) for an additional 12 weeks.
- Description of groups with timeline:

  <u>Group 1</u>
    - Phase 1: Subjects received common peroneal stimulation for the 1st 6 weeks; gluteal stimulation was added at week 6 and continued to week 12.
    - Phase 2: Week 12 marked phase 2, in which FES was continued and core stability exercises were added and progressed over 6 weekly sessions (weeks 12-18) at which point core exercises continued as a home exercise program (HEP) with 2 check-in sessions at the clinic at weeks 21 and 24.

  <u>Group 2</u>
    - Phase 1: Subjects initiated core stability exercises for 12 weeks (progressed over the same timeline as described for Group 1).
    - Phase 2: Week 12 marked phase 2, in which a core exercise HEP was continued for the duration and common peroneal stimulation was added. Gluteal stimulation was added at week 18 and continued to week 24.

- Statistical Analysis: Nonparametric methods were used because several data sets were non-normally distributed. Wilcoxon signed-rank test was used for intragroup changes; Mann–Whitney U-test was used for intergroup changes. An alpha of 0.05 was used to indicate statistical significance. Intention to treat analysis was not conducted; only participants who completed the study were included in analysis.

Setting

[e.g., locations such as hospital, community; rural; metropolitan; country]

The setting was not clearly defined but may be assumed to take place at Salisbury District Hospital and lab spaces affiliated with the corresponding authors' locations.

Participants

[N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]

- Selection: Convenience sampling was used to recruit individuals with SPMS from a waiting list of patients referred for FES for gait to the National Clinical FES Centre at the Salisbury District Hospital in the UK.
- Sample size: 28 individuals were recruited, 27 enrolled, 25 were randomized, and 20 completed the study; 24 was reported as the minimum N expected to provide an accurate estimate of treatment effect and an accurate measure of variability in outcome measures to inform a future, larger study.
    - Group 1 (FES first) N = 11. 9 subjects completed the study. 1 subject dropped out due to a decline in mobility; 1 subject dropped out because of difficulty managing the FES equipment.

- Group 2 (exercise first) N = 14. 11 completed the study. 1 subject dropped out due to a decline in mobility, another dropped out due to increased spasticity, and a 3rd subject dropped out due to unrelated health complications.

- Inclusion criteria: diagnosis of SPMS with EDSS score of 6.5 or less (i.e. requires no more than two walking aids to walk about 20m without resting); gait impaired by foot drop (i.e. reduced dorsiflexion and eversion in swing with irregular heel strike); gluteal muscle weakness; reduced motor control at the hip, pelvis, or trunk that impairs gait; no prior use of FES; and an effective response to peroneal and gluteal stimulation.
- Exclusion criteria: cognitive impairments that could reduce compliance with treatment; other medical condition that impairs gait or contraindicates treatment; or unable to walk without FES or an AFO.
- Demographics: Fischer's exact test was used to conclude there was no significant difference in age, time since MS diagnosis, or EDSS score between the groups at the start of intervention ($p = 0.56$).
  - Average age in years (SD) for Group 1: 54.6 (9.4); Group 2: 56.9 (7.8)
  - Average time since diagnosis in years (SD) for Group 1: 12.2 (8.6); Group 2: 14.5 (7.5)
  - Gender for Group 1: 4 males, 8 females; Group 2: 4 males, 10 females
  - Assistive devices (AD): Group 2 used more assistive devices while walking.
    - Group 1: 7 used no AD, 3 used 1 stick, 1 used a rollator, and 1 used assistance from another person.
    - Group 2: 4 used no AD, 1 used 1 stick, 2 used 2 sticks, 2 used a rollator, 4 used crutches, and 1 used assistance from another person.

Intervention Investigated

[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided]

Control

Core Stabilization Exercises

- Description: Subjects were taught various exercises to improve trunk and pelvis stability, lower extremity muscle flexibility and strength, and balance and control of movement in lying through standing positions. For a complete list of exercises, see Appendix A in the article by Barrett et al.[12] Exercises were individualized by choosing those most appropriate from the list for each person. Exercises were prescribed by physical therapists involved in the study.
- Dosage: Exercises were carried out at weekly clinic sessions with physical therapists during the 1st 6 weeks, and HEP was initiated at the start and continued after the 6th week as described by Barrett et al.[12] As such, a HEP was to be performed every day for 30 min, 1-2 times daily at home. All exercises were prescribed by physical therapists involved in the study. Clinic exercise session times were not provided.
- Progression: Exercises were reviewed weekly at clinic sessions and progressed over the 1st 6 weeks (by choosing more difficult exercises from the list) when appropriate. HEP was not progressed after the 6th week.

Experimental

Electrical Stimulation

- Device: An Odstock 2 Channel Stimulator II was used and timing was controlled by a pressure sensitive foot switch placed under the heel.
- Electrode placement: self-adhesive electrodes were placed over the common peroneal nerve at either the fibular head or popliteal fossa and at the Tibialis anterior muscle for foot drop. For hip extension, electrodes were placed at Gluteus maximus, and if abduction was also warranted, an electrode was also placed at the Gluteus medius.
- Parameters: Stimulation for foot-drop began at heel off and up to heel strike; stimulation for hip extension began at heel strike on the ipsilateral side and up to heel off. The current was adjusted between 20-100 mA to produce a functional muscle contraction with a pulse width was approximately 200 ms and a frequency of 40 Hz.
- While not explicitly stated, it is assumed that the researchers of the study carried out FES treatment in the clinic. Patients were assumed to have used FES at home for most of the day and during ambulation during the intervention period in accordance with the protocol from Barrett et al[12], which the authors reference for the exercise protocol. Time spent during FES treatment in the clinic was not provided, and no log of FES use at home was mentioned.

Outcome Measures

[Give details of each measure, maximum possible score and range for each measure, administered by whom, where]

1. Rivermead Observational Gait Analysis (ROGA): ROGA is a visual recording gait analysis tool that measures 20 aspects of deviations from normal patterns, each measured on a 4-point scale, where a lower scores indicates improved gait quality. A 0 indicates normal and 3 indicates severe impairment; the maximum possible score is 60.
2. Ten-meter walking speed: The measure was performed over smooth floors, and 1 m of additional distance was added to either end of the course for speed adjustment. Speed was measured concurrently with ROGA recordings. The average of 3 measurements were calculated for each treatment condition. The MCID was considered to be 0.05 m/s change, while a 0.1 m/s change was considered to be a substantial meaningful change, in accordance with that established by Perera et al.[13]
3. Multiple Sclerosis Impact Scale (MSIS-29): This 29-item self-report measure uses a physical subscale (20 items) and a psychological subscale (9 items) to assess the impact of MS. Each item is ranked on a 5-point scale from 1 (not at all) to 5 (extremely). Each subscale is summed, combined, and converted to a 0 to 100 scale, where 100 indicates greater disease impact (worse health). A change score of 8 on the physical subscale or 6 on the psychological subscale have moderate to high sensitivity for indicating meaningful patient improvement.[14]
4. Falls diary: Falls per day were recorded as well as whether FES was being used at the time of the fall. Diaries were submitted to the researchers of the study at each 6 week clinic assessment.

Main Findings

[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable. Use a table to summarize results if possible.]

Interquartile range (25–75%) is provided in parenthesis following reported medians.

Standard effect size (SES) was calculated only for Group 1 by the authors; values from week 24 with peroneal and gluteal stimulation are reported below.

ROGA Group 1

- No changes were observed without FES, however, the use of peroneal FES produced consistent significant improvement in scores, which improved further with the addition of gluteal stimulation.
- The addition of core exercises at week 12 did not produce significant score changes by week 24.
- SES: 1.03

ROGA Group 2

- ROGA scores increased (gait worsened) at weeks 12 and 24 without FES.
- FES use improved ROGA scores consistently throughout phase 2, with further improvement when gluteal stimulation was added.
- Between Groups: Group 1 scored 5.5 points lower (i.e. gait improvement) than Group 2 with peroneal stimulation alone at week 18 ($p = 0.028$).
- There was a significant difference in scores between the groups ($p = 0.044$) only at week 24 without FES, with Group 1 having a median of 6 points less (i.e. gait improvement; score of 11 (6–14.3)) than Group 2 (score 17 (14.5–20)).

Walking speed Group 1

- Speeds were significantly faster with peroneal stimulation at week 0 (0.76 m/s (0.62–1.39)) and with added gluteal stimulation at week 6 (0.83 m/s (0.63–1.29)) than week 0 without FES (0.72 m/s (0.47–1.31).
- When exercises were added at week 12, a significant increase in speed was later seen at week 18 with peroneal and gluteal stimulation (1.13 m/s (0.65–1.30)) compared to without FES (0.92 m/s (0.65–1.26)) at the same time point.
- Without use of FES, there was a significant difference in walking speed at week 24 compared to week 12, with a difference in medians of 0.24 m/s ($p = 0.047$).
- SES: 1.06

Walking Speed Group 2

- Without FES, no significant changes in walking speed occurred at any point.

- Compared to no FES at the same session, subjects walked significantly faster with the addition of gluteal stimulation at week 18 and at week 24.
- Between groups: There was no significant difference in walking speed between groups for any one condition at any time point.

MSIS-29 Group 1

- A significant decrease in the psychological score was observed at weeks 6 and 18 with mean differences of -16.1 and -14.0, respectively.
- A significant decrease in the physical score was observed at weeks 18 and 24 with mean differences of -14.1 and -14.4, respectively.
- SES physical: 0.89; SES psychological: 0.44

MSIS-29 Group 2

- No significant changes occurred until week 24 with a decrease in the physical score with a mean difference of -10.3.
- Between groups: For any one time point, no significant differences occurred for like interventions between groups.

Falls Diary Group 1

- 83% of falls over the entire trial occurred when FES was not being used.
- When the falls at baseline were adjusted to better represent a 6 week period, a significant reduction in falls was observed at all intervention stages during the trial ($p < 0.05$) (except week 18).
- No median changes occurred between the two phases.
- SES: 0.90

Falls Diary Group 2

- At week 12, a significant reduction in falls was observed ($p = 0.017$), which persisted throughout phase 2 ($p = 0.017$). During phase 2 (FES added), 78% of the falls were recorded as having occurred when FES was not used.

Original Authors' Conclusions

[Paraphrase as required. If providing a direct quote, add page number]

- Compared to a core stability exercise program, FES has a greater effect on gait quality and self-perceived mobility and quality of life in individuals with SPMS who have foot drop.
- Adding physical therapy exercises after a period of FES usage may enhance the effect on gait quality.
- The addition of gluteal stimulation may further improve gait quality compared to peroneal stimulation alone.

Critical Appraisal

Validity

PEDro Scale score: 7/11 based on eligibility criteria specified (yes); random allocation (yes); concealed allocation (yes); baseline comparison (no); group 2 used more assistive devices and had more severe walking impairment); blinding of subjects (no); blinding of therapists (no); blinding of accessors (yes); measured outcomes for >85% participants (no); intention to treat analysis (no); between group comparison (yes); point estimates and variability (yes).

- Their method of convenience sampling, selecting patients waiting to try FES, might have biased the outcomes in favor of FES treatment over exercise because subjects were already motivated to use FES, which could also potentially make their results less reproducible in studies with more representative sampling of the population.
- Following allocation, subjects in Group 2 used more assistive devices and required increased levels of assistance (e.g. crutches verses single stick) than Group 1, which may have biased results in favor of Group 1.
- Following allocation, Group 2 had 10 subjects with an EDSS score of 6 - 6.5 (increased disability) as opposed to only 2 subjects in Group 1. While the authors report there were no differences between the groups across the range of EDSS scores (4 - 6.5), a large difference exists at the more severe end of the spectrum, which could have biased the results in favor of Group 1.
- After 25 subjects were randomized to treatment arms, only 20 completed the study and were included in the analysis. No intention to treat analysis was performed to adjust for missing data,

which would have provided a more unbiased comparison between groups by controlling for dropout and the effects of crossover.

- Details regarding treatment times (e.g. length of exercise sessions in the clinic) were not included, which diminishes the reproducibility of the study. Furthermore, data regarding time spent on the daily HEP and time using FES at home was not collected. If compliance varied across the 2 groups, this could have biased the outcomes and diminished the validity of the study.
- A table of data comparing differences between groups was not included; the authors only provide occasional between group values within the text, which diminishes the quality of the results provided to the reader.
- Efforts were taken to appropriately blind the assessors when measuring gait outcomes by having all patients wear an FES device regardless of treatment/phase.
- Efforts were taken to blind researchers analysing video data for gait analysis by removing patient identifying information.
- The use of nonparametric statistical tests was appropriate given their report of non-normally distributed data sets.

Interpretation of Results

[This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.]

Results of the study showed that adding gluteal stimulation significantly improved gait quality measured by ROGA, but adding core exercises did not provide further benefit. The standard effect size of 1.03 for Group 1 for gait quality (ROGA), suggests a large treatment effect from FES treatment when peroneal and gluteal stimulation is provided. Gait quality worsened in Group 2 at weeks 12 and 24 without FES and walking speed did not change under any condition, suggesting core exercises did not improve gait, as measured by ROGA; because Group 2 participants had more severe walking disability at baseline and required more assistance than those in Group 1, these negative results could have been impacted by reduced HEP compliance by Group 2 participants because of the added difficulty of walking. Significant between group median differences occurred only at week 24 without stimulation, with Group 1 displaying more gait improvement than Group 2; significant between group differences with FES (peroneal only) only occurred at week 18, again in favor of Group 1. These between group results suggest that the order of utilizing FES prior to a core exercise program might provide the most benefit, but this conclusion would be strengthened if the results would have shown a consistent difference between groups for FES with added gluteal stimulation as well, the condition that provided the most overall benefit for gait quality.

Overall, walking speed increased with FES treatment alone, but no significant training effect was demonstrated, meaning when stimulation was removed, FES provided no significant carryover effect to participants in either group. No significant between group differences occurred regarding walking speed, suggesting the order of interventions did not influence the outcomes. While adding core exercises after a period of FES tended to increase walking speed for Group 1, the converse was not true; however, Group 2 results, which showed a smaller change in walking speed with the addition of FES, might have been impacted by participants' increased reliance on assistive devices, which could have caused this group to plateau with little improvement. Similar to ROGA results for Group 1, the standard effect size of 1.06 for walking speed for Group 1, suggests a large treatment effect from FES treatment when peroneal and gluteal stimulation is provided. Furthermore, the significant increase in walking speed without stimulation observed between the initiation and conclusion of core exercises for Group 2 suggests the benefits of exercise on walking speed might have been masked in the presence of FES.

With regard to the MSIS-29 subjective measure of the impact of MS, no significant differences occurred between the two groups, indicating the order of interventions did not influence perceived disease impact. Results for Group 1 did show significant improvements in both psychological and physical scales that were also clinically meaningful[14], with standard effect sizes of 0.89 (physical) and 0.44 (psychological), indicating a larger treatment effect on the physical scale and a moderate treatment effect on the psychological scale. Results for Group 2 showed only a significant change in the physical score at week 24 when exercises were combined with FES, which was also clinically meaningful.[14]

Both FES and core exercises resulted in decreased falls, however, FES seemed to have a dominant effect as Group 2 experienced a further significant reduction when FES was added. The majority of falls that did occur in either group happened while FES was not in use, further suggesting the effectiveness of FES in preventing falls. The standard effect size of 0.90 for Group 2 on falls reduction suggests a large treatment effect for this group when peroneal and gluteal stimulation were used.

Overall, the validity of the results are diminished by the bias that likely occurred due to group differences with regard to walking disability (use of assistive devices), and the small sample size decreases the reliability validity of the study. Importantly, the study was not powered sufficiently to produce unambiguous results.

Applicability of Study Results

[Describe the relevance and applicability of the study to your clinical question and scenario. Consider the practicality and feasibility of the intervention in your discussion of the evidence applicability.]

This study demonstrated that FES can be an effective and feasible walking treatment for patients with SPMS and foot drop by improving gait quality, subjectively lessening the disease's physical impact, and reducing falls; and adding gluteal to peroneal stimulation may enhance gait quality. Results favored FES over core stability exercises, particularly for Group 1, whose subjects had relatively less walking disability at baseline, and there was some evidence to suggest that adding core stabilization exercises after a period of FES use could further improve gait. However, there are several factors that impact the applicability of this intervention to the clinical question and patient scenario stated previously.

The subjects in this study were comparable in age, although slightly older than the 50 yr old patient in the scenario. The subjects also similarly experienced foot drop and gait abnormalities, which increases the study's relevancy to the patient scenario. However, there was a larger proportion of females in the study, the subjects were further along in their diagnosis and progression of the disease (they had a diagnosis of SPMS as opposed to RRMS). Additionally, many of the subjects used an assistive device and had increased walking disability compared to the patient in the scenario who did not use a walking aid. These differences in disability and walking characteristics reduces the applicability to the patient who is less impaired and does not use an assistive device. However, FES was shown to ameliorate foot drop effectively, and therefore FES should be considered as a viable treatment option for the patient in the scenario. In fact, Group 1 subjects, who had less disability compared to Group 2, were more responsive to FES.

Other factors that affect the practicality of FES treatment include the high cost of the device for the patient and whether insurance will reimburse for any of the cost. The patient in the scenario was a physician who may have had a sufficient salary to purchase a Bioness FES device. However, cost was still a concern for him, as it would likely be for many patients with MS who often incur exorbitant medical expenses for treatment. It may be worthwhile to allow the patient sufficient time to discuss cost with the insurer and the supplier prior to initiating a program involving FES, especially since this study did not show a significant carryover effect on gait when FES was not in use, indicating FES should be used consistently to be effective.

Lastly, patient preferences and values should be addressed. Responses to electrical stimulation will vary among individuals, and some may even consider FES to be painful. Potential for pain should be discussed with the patient prior to FES use. Other concerns include the patient's ability to use and don/doff the device The patient's value of aesthetics and how wearing the device might impact self-perceptions should be considered, especially if the individual prefers to wear shorts, skirts, or dresses. Decision aids should be provided to the patient when possible, such as specific FES brochures and materials, to increase awareness about the treatment and relay accurate risk/benefit information about the device, such as the potential for skin irritation.

Future sufficiently powered RCTs are still required to definitively argue for FES over traditional PT exercise programs to improve gait. Future studies are also needed that draw from a more representative ambulating MS patient population or stratify subjects appropriately by disability. Furthermore, while this study did incorporate the subjective measure, the MSIS-29, measures should be used that specifically emphasize the patient's perceptions of walking ability, such as the 12-item Multiple Sclerosis Walking Scale (MSWS-12)[15], as detailed and relatively nuanced objective gait quality measurements, such as those identified by ROGA, may not translate to patient-perceived perceptions. Positive patient perceptions could be critical to ensuring long-term compliance with using FES and directly impact the overall effectiveness of the treatment.

(2) Description and appraisal of Habitual Functional Electrical Stimulation Therapy Improves Gait Kinematics and Walking Performance, but Not Patient-Reported Functional Outcomes, of People with Multiple Sclerosis who Present with Foot-Drop by Van der Linden ML et al. (2014)[9]

Aim/Objective of the Study:

The objective was to evaluate the medium-term effectiveness of using FES in subjects with MS, who were newly prescribed FES, to improve foot-drop and gait kinematics, walking performance, and patient-reported outcomes.

Study Design

[e.g., systematic review, cohort, randomised controlled trial, qualitative study, grounded theory. Includes information about study characteristics such as blinding and allocation concealment. When were outcomes measured, if relevant]

Single group repeated measures design

- Measures were repeated at 4 separate clinic visits: once 4 weeks before the baseline assessment (without FES) and 3 more times under 2 conditions, with and without FES use, at baseline, 6 weeks, and 12 weeks. Regular FES use was initiated after the baseline assessment.
    - At each of the 4 visits, 3D gait analysis was carried out first without FES use followed by with FES use.
    - At the baseline and the 12 week visit, gait measures (10-meter timed walking test (10mWT) and a 2 min timed walking test (2minWT)) were utilized first without FES use and then with FES use; at the 6 week visit the order of the conditions were reversed (i.e. measures were taken with FES use first followed by without FES).
- Subjects were given a 5 min rest period between tests.
- If subjects required additional walking aids during testing, they were required to continue using the device(s) for the remaining assessments.

Data analysis and statistics:

- Training (or therapeutic) effect (i.e. carry-over) on gait and walking performance was defined, similar to that described in the previous study by Taylor et al.[8], as the measured change between the baseline assessment score without FES and 12 week assessment score without FES.
- Direct orthotic effect was calculated as the difference between the assessment with and without FES within the same assessment, which was assessed at baseline and at 6 and 12 weeks.
- Total orthotic effect was the combined training and orthotic effect, measured by the change between the week 12 assessment score with FES assistance and the baseline score without FES.
- Doubly repeated measures ANOVA was used to determine statistical significance, with regard to time and FES condition, for gait kinematics and walking performance. For within-subject analysis (time and condition), an alpha value of less than 0.05 indicated statistical significance.
- Effect size for the training effect at 12 weeks was calculated using Cohen's d; effect sizes were defined by the authors as follows: medium for values greater than 0.3 - 0.5; good for values greater than 0.5 - 0.8; and large for values greater than 0.8.
- SEM values, derived from the standard deviation at baseline, were calculated from measurements at 4 weeks prior to baseline and those at baseline. MDC values calculated from the SEM, and the number of subjects exceeding the MDC for training and orthotic effects were tracked.

Setting

[e.g., locations such as hospital, community; rural; metropolitan; country]

A gait analysis laboratory at Queen Margaret University, Edinburgh

Participants

[N, diagnosis, eligibility criteria, how recruited, type of sample (e.g., purposive, random), key demographics such as mean age, gender, duration of illness/disease, and if groups in an RCT were comparable at baseline on key demographic variables; number of dropouts if relevant, number available for follow-up]

Note: This is not a list of the inclusion and exclusion criteria. This is a description of the actual sample that participated in the study. You can find this descriptive information in the text and tables in the article.

- Convenience sampling was used to recruit participants (August 2011-April 2013) from a community National Health Service and physiotherapy service located in Edinburgh, UK.
- Eligibility criteria: individuals with a clinical diagnosis of MS, an age of 18-75 years, and who were considered by a clinical specialist physical therapist to be appropriate for FES; the specialist therapist conducted a thorough clinical exam to assess lower extremity strength and ankle range of motion.
- Exclusion criteria: Individuals considered not suitable for FES included those who did not have the strength to bend the hip and knee and lift and hold the leg against gravity in supine; those lacking ankle plantarflexion range of motion and a fixed deformity; and individuals who could not walk community distances.
- Participant numbers: Twenty-three individuals with MS were deemed suitable for FES by a physical therapist; 15 of these agreed to FES treatment and were invited to participate in the study; 11 of these continued participation to the 1st assessment, but 2 dropped out, wishing to discontinue FES; 9 of the original participants were available for follow-up and were included in the analysis of the data. No adverse events were reported.
- Participant demographics (standard deviation in parenthesis): Total N = 9; gender, male: 2, female: 7; average age: 53(9) yrs; disease type, RRMS: 4, Primary Progressive MS: 4, SPMS: 1; average

height: 1.67(0.09) m; average body mass: 24.8(2.1) kg; average BMI: 24.8(2.1) kg/m2; walking aid during testing, yes: 1, no: 8

Intervention Investigated

[Provide details of methods, who provided treatment, when and where, how many hours of treatment provided]

Control

There was no control intervention for this study as the design involved a single group with repeated measures.

Experimental

Functional Electrical Stimulation (FES)

- Device: A single channel device was used for FES, either the Odstock Drop Foot Stimulator (ODFS III) or a newer version, the Pace (Biomedical Engineering and Medical Physics, Salisbury, UK).
- Electrode placement: For common peroneal nerve stimulation, one square 50x50 mm electrode was placed at the head of the fibula and another over the Tibialis Anterior motor point, and minor adjustments were made in some subjects to elicit an optimal effect.
- Parameters: Intensity of current amplitude was set to achieve ankle dorsiflexion for foot clearance during the swing phase of gait and ranged from 20-70 mA.
- Administration: Devices were fitted to each individual and settings, which remained unchanged across assessments at each visit, were adjusted by a qualified physical therapist.
- FES was utilized in the clinic and patients were instructed to use the device with FES at home between clinic visits for the duration of the study.

Outcome Measures

[Give details of each measure, maximum possible score and range for each measure, administered by whom, where]

The authors did not indicate who administered the measures aside from the associated researcher(s).

Self-report measures were given at the end of each session, to be completed at home. Measures and the activity monitor were mailed back to the researcher in a pre-stamped envelope.

Primary outcomes: walking performance and gait kinematics

1. 3D Gait Analysis: Subjects walked barefoot for gait analysis only; the FES foot sensor was taped under the heel. An infra-red camera (Vicon Nexus 3D motion analysis system) was used to measure gait kinematics of subjects wearing reflective markers, which were attached to lower extremity and pelvic landmarks, during 6 walking trials of 5 m for each condition (with and without FES). Measurements were averaged across the trials for analysis.
2. 10 meter walk test (10mWT): subjects were instructed to walk in a straight direction towards a corridor wall for 10 meters at their preferred speed, and time was recorded with a stopwatch. An average of 2 trials was used for analysis. For this measure, same day reliability for subjects with MS who are community ambulators have been reported as between 1.7–2.7 s.[16]
3. 2 minute walk test (2minWT): subjects were instructed to walk around a 16.5 m elliptical course for 2 continuous minutes, and the distance travelled was recorded. For this measure, same day reliability for subjects with MS who are community ambulators have been reported as between 16–22 m.[16]
    - Subjects were asked to rank their rate of perceived exertion (RPE) on the Borg Scale[17]: 6 is 'no exertion at all' and 20 'maximal exertion.' The change in RPE, between the score given after the first lap and immediately after 2 minutes, was included in analysis.

Secondary outcomes: patient-reported outcomes and habitual physical activity

4. MS walking Scale (MSWS): This subjective measure has 12 items that assesses perceived performance of walking over the last 2 weeks. Items are ranked on a 5-point scale, summed, and transformed for a final score between 0-100, where lower scores indicate better walking ability. This measure has excellent reliability and has a reported MDC of 22 points.[18]
5. MS impact scale (MSIS-29): This 29-item self-report measure uses a physical subscale (20 items) and a psychological subscale (9 items) to assess the impact of MS. Each item is ranked on a 5-point scale from 1 (not at all) to 5 (extremely). Each subscale is summed, combined, and can be converted to a 0 to 100 scale, where 100 indicates greater disease impact (worse health).

- A change score of 8 on the physical subscale or 6 on the psychological subscale have moderate to high sensitivity for indicating meaningful patient improvement.[14]
- In this study, all 29 answers were added for a total range from 29-145.
- This measure has good responsiveness, with reported effect sizes of 0.82 (physical) and 0.66 (psychological).[19]

6. Fatigue Severity Scale (FSS): This measure has 9 items about fatigue experienced over the last week. Each item is ranked from 1 to 7, 1 indicates the sentence is not appropriate and 7 indicates strong agreement. The numbers from each item are added and averaged for a final score, were a higher score indicates higher impact from fatigue.
7. Step count (to measure habitual physical activity): An ActivPAL activity monitor (attached to the anterior thigh) was used to track daily step count and time spend sitting/lying, standing and walking, as well as sit-to-stand transitions. After each assessment, subjects were instructed to wear the monitor for a 7 day period before returning it to the researcher. Step counts that were averaged over at least 5 days were used for analysis. For a walking speed of 3.2 km/h on a treadmill, Standard Error of Measurement (SEM) for step count for healthy individuals has been recorded as 6 steps; SEM for self-selected overground walking by healthy individuals has been recorded as 22 steps.[20]

Main Findings

[Provide summary of mean scores/mean differences/treatment effect, 95% confidence intervals and p-values etc., where provided; you may calculate your own values if necessary/applicable. Use a table to summarize results if possible.]

Gait kinematics

- A statistically significant direct orthotic effect (FES compared to no FES use) was shown for peak dorsiflexion during swing phase (p= 0.006) and stride length (p= 0.049) of the gait cycle. FES use over the 12 week period resulted in significant improvements from baseline for stride length (p = 0.045) and walking speed (p = 0.046); however, mean ankle angle increased by 2.6° (95% CI: -1°, 4°) but failed to reach significance over the 12 week period (p= 0.082).
- The effect size for FES training effects on gait kinematics ranged from 0.22 (peak knee flexion; mean difference = 2°) to 0.78 (ankle angle at initial contact; mean difference = 3°)
- Positive results were demonstrated for the total orthotic effect size (baseline (no FES) compared to 12 weeks (with FES)) for the following: ankle angle at initial contact and peak dorsiflexion in swing (mean difference = 3.4°; ES > 1.0); stride length (mean difference = 0.12 m; ES = 0.70); walking speed (mean difference = 0.15 m/s; ES = 0.80); knee flexion in swing (ES = 0.36); and hip range of motion (ES = 0.45).

Walking performance

- Results showed significant statistically significant direct orthotic effects of FES for the 2mWT (p =0.002) and the 10WT (p = 0.006). However, performance over the 12 week period did not change significantly for either the 2mWT (p=0.209) or the 10WT (p= 0.545).
- At 12 weeks, mean training effects showed a 4.7% walk distance improvement (ES = 0.20) for the 2mWT and an 8.2% walk time improvement (ES = -0.29) for the 10WT. With regard to training effect, the authors' text reports that 5 subjects (6 subjects of 9 shown in Table 5) exceeded the MDC for the 10mWT (0.47 s) and 2 subjects (out of 8) exceeded the MDC for the 2mWT (10.7 m). Mean change in RPE over the 2mWT were not significant with regard to training effect; (-1.2 point change; 95% CI: -5.7, 3.4; ES: -0.86).
- With regard to the total orthotic effects, results showed a 12.1% improvement (ES = -0.41) for the 10WT and a 9.8% improvement (ES = 0.42) for the 2mWT. Results show 6 out of 9 subjects exceeded the MDC on the 10WT and 5 out of 8 subjects exceeded the MDC for the 2mWT. A total orthotic effect for the change in RPE over the 2mWT was -0.95.

Subjective outcome measures

- Over the 12 weeks, results show no significant change with FES use for the number of steps taken or any subjective measure with the exception of the MSWS at week 6. Compared to baseline, MSWS scores improved (i.e. scores decreased) at 6 weeks (p = 0.034) with a mean difference of 8.5 points less (4 subjects exceeded the MDC of 14 points at 6 weeks) but scores worsened at 12 weeks, returning to baseline levels (1 subject significantly worsened according to MDC values). The effect size for the FES intervention over the 12 weeks for the MSWS was -0.03. Results at 12 weeks show no subjects exceeded the MDC for either the MSIS-29 (MDC = 13) or the MSWS to show subjective improvement, but 1 subject of 9 exceeded the MDC for each in the negative direction (i.e. significantly worsened self-perception).

Original Authors' Conclusions

[Paraphrase as required. If providing a direct quote, add page number]

- Peroneal FES to treat foot-drop in MS patients may improve walking speed and ankle kinematics over a medium-term period of 12 weeks.
- This is the first FES study to measure total orthotic effects on gait kinematics in individuals with MS.
- There may be a strong total orthotic treatment effect from medium-term FES use on ankle dorsiflexion angle at initial contact during walking with FES assistance.
- Objective walking performance improvements from FES training were not positively reflected in MS patient-reported outcomes.

Critical Appraisal

Validity

[Summarize the internal and external validity of the study. Highlight key strengths and weaknesses. Comment on the overall evidence quality provided by this study.]

Down's and Black score: 18/29 based on distribution of confounders among patients clearly described (no); attempted to blind subjects (no); attempted to blind those measuring outcomes (no); compliance with intervention (unclear); randomization (no); concealment (no); adequate adjusting for confounding variables in analysis (no); no power analysis reported.

- The sample size was small (n = 9), which reduces the validity of the study.
- The walking aid for one of the subjects was not described and the authors do not provide a description of how the walking aid distributed with the outcome data. Authors also fail to report time since diagnosis, which also could have impacted the distribution of data as a confounding variable.
- No effort was clearly made to monitor participant compliance of FES use outside the clinic, which could reduce the internal validity of the study. If some of the patients in this small sample were not compliant, the significance of any training effect could be diminished.
- Subject characteristics that could have been confounding variables to walking outcomes were not adjusted for in the analysis. For example, disease type/progression and use of a walking aid could impact walking ability, yet these potential confounders were not considered in the analysis, which creates selection bias.
- Between repeated measures, a 5 minute rest (wash-out period) was provided, which may not have given subjects adequate time to recover between multiple walking performance tests and conditions and thereby diminishes the study's internal validity. Inadequate wash-out may have led to worsened performance over time as walking performance measures utilized 2-3 trials.
- Two different models of the FES devices were used. Authors did not provide details regarding differences in comfort, ease of donning/doffing, for example. Their results could be confounded if differences between devices differentially affected compliance with FES at home.
- To adjust for an effect of the order of conditions (i.e. with FES and without FES assistance) the order was reversed at week 6, which increases the study's validity by reducing bias imposed from the ordering of conditions.
- The study had good external validity, despite the small sample size, as subjects were comprised of both genders, fairly representative of the main MS disease types, and ranged in age from 34-65 yrs, and the physical therapy staff was representative of standard treatment environments.
- The outcome measures were accurate and the statistical measures were appropriate for the outcome data.

Interpretation of Results

[This is YOUR interpretation of the results taking into consideration the strengths and limitations as you discussed above. Please comment on clinical significance of effect size / study findings. Describe in your own words what the results mean.]

This study demonstrated statistically significant improvements ($p>0.05$), over a 12 week period with peroneal FES use, in stride length and walking speed in individuals with MS, suggesting that with FES, individuals were able to walk faster and take more longer strides over a medium-term intervention period.

A statistically significant ($p>0.05$) direct orthotic effect was seen for peak ankle dorsiflexion in swing phase and stride length, demonstrating immediate positive effects of peroneal FES on foot-drop as ankle dorsiflexion is required to clear the foot during swing through; and FES may provide an immediate benefit of longer strides, possibly due to better foot clearance.

After 12 weeks, the training effect resulted in a mean difference in ankle angle at initial contact of 2.6°, with a moderate effect size of 0.78, but this result was not significant because the p value was greater than 0.05

and the large (imprecise) 95% CI range of 5° (95% CI: -1°, 4°) spanned 0, which indicates the mean could have included no change. Therefore, while the angle change was not significant, possibly in part due to the small sample size, the ability of the FES treatment to carry-over (without FES assistance) in this regard was of moderate impact and indicated more normal gait kinematics with FES training. Gait analysis was conducted prior to the other walking tests, therefore, this ankle angle result was less likely to be negatively biased by any fatigue experienced from repeat measures with only a short wash 5 min wash-out period.

Moderate to large effect sizes were also reported for the total orthotic effect for dorsiflexion in swing through (2.9° mean change; ES = 1.3) and ankle angle at initial contact (3.4° mean change; ES = 1.0), with improvements even demonstrated at the knee and hip. These positive results suggest that compared to baseline without FES assistance, FES use after a medium-term FES training period produced treatment effects of the greatest magnitude by improving foot drop and reducing gait abnormalities.

FES did provide a significant direct orthotic effect on walking speed and distance covered, as p-values were less than 0.05 for the 2mWT and the 10WT. However, the results showed no statistically significant effect of time for the walking performance tests. The training effect did show modest improvements in walk distance and walk time, but the effect sizes for both measures were small, suggesting FES use over 12 weeks does not greatly impact either walking parameter when FES assistance is not provided. However, some patients during this condition did exceed the MDC, suggesting some but not all patients can make significant training improvements in walking speed and distance; however, patient characteristics, such as assistive device used, were not described for those who did exceed the MDC. Such information could have assisted in the interpretation of skewed data. Walking performance results for the total orthotic effect were more pronounced with low-moderate effect sizes and more individuals exceeding the MDC for both tests, indicating FES provided the greatest impact on walking performance after 12 weeks of training and with FES assistance.

Results from the subjective measures, all with p values greater than 0.05, demonstrated MS patients did not perceive any positive changes with respect to walking and mobility, fatigue impact, or MS disease impact on quality of life after a 12 week intervention of peroneal FES use. These negative results indicate MS patients may not perceive much value in using an FES device for walking even when objective measures demonstrate significant gains in quality of movement and speed.

Applicability of Study Results

[Describe the relevance and applicability of the study to your clinical question and scenario. Consider the practicality and feasibility of the intervention in your discussion of the evidence applicability.]

This study demonstrated that peroneal FES is a suitable and feasible walking intervention for MS patients with various disease types who have foot-drop and may provide medium-term improvements in ankle kinematics and walking speed with consistent use. Unfortunately, the objective walking gains observed in the study were not perceived to impact walking quality, fatigue levels, or quality of life. The applicability of this study to the previously stated clinical question and patient scenario are both positively and negatively impacted by several factors relating to the study and patient values.

The patient relevance is increased by the study's sampling from a community health service, as the patient in the scenario was also a community-dwelling adult. His gender, age (50s), disease type (RRMS), and level of independence (no walking aid) was well represented in the study sample. All subjects in the study similarly had foot-drop and secondary gait impairments.

As mentioned for the previous FES study, the physical therapist must also consider the risks and benefits of the intervention. While this study reported that no adverse events occurred, 2 of 11 subjects dropped out after initiating the intervention because they wished to discontinue FES use. This raises the question of why and if the subjects who dropped out perceived pain or perhaps viewed the device as inconvenient or aesthetically displeasing. No mention was made of these important personal patient preferences, but should always be considered prior to trying FES. As mentioned for the previous FES study, the practicality of FES is negatively impacted by the high cost of the device, which should be openly discussed with the patient prior to initiating the intervention. Ease of donning/doffing and the device's technical ease of use will also impact its practicality on an individual basis.

Additionally, the patient's goals must be factored into decision making about the intervention. If the patient is seeking more than a direct orthotic effect from FES and actually wants to see carry-over improvement without having to wear the device, the results from the study were less convincing, and therefore, FES may not be worth the patient's time and investment. However, if the patient does not mind consistently wearing the device when walking, then FES might be a suitable intervention, as results for the direct and total orthotic effects of FES were more convincing with significant data and strong effect sizes.

The results of this study suggest that people with MS may not perceive the positive effects of FES or may not be impacted at a scale that translates to feelings of improved quality of life, less fatigue, or improved walking ability. However, it is possible that subjective outcome measures would yield more favorable results from a larger study that adjusted for confounding demographic variables, such as the use of walking aids/impairment level, disease type, and time since diagnosis and adjusted for FES compliance outside the clinic.

SYNTHESIS AND CLINICAL IMPLICATIONS

Evidence Synthesis

There is strong evidence showing FES provides a direct orthotic effect on gait kinematics and walking speed for MS patients with foot-drop.[3] This paper analyzed 2 moderate quality intervention studies of strong Level 2b design that evaluated the direct orthotic and therapeutic effectiveness of FES for adults with MS who have foot-drop and impaired gait.[8,9] Based on the evidence, peroneal FES appears to be an efficacious medium-term intervention to improve foot clearance in MS patients with foot-drop by increasing the ankle dorsiflexion angle at initial contact during gait. FES training leads to increased walking speeds over time frames of 12 and 24 weeks, and one of the studies demonstrated reduced patient-perceived physical impact of MS and improved patient-perceived quality of life after 18 weeks of FES treatment.

The results from Taylor et al.[8] provide good evidence that FES has a greater effect on objective qualities of gait and patient perceptions at 18 and 24 weeks compared to a core stability exercise program. Furthermore, adding exercises after a medium-term training period of FES may enhance walking improvements. The study by Van der Linden et al.[9] did not demonstrate improved patient perceptions for quality of life, fatigue, or walking ability by 12 weeks. However, patient-perceived improvements were not observed until week 18 in the Taylor et al.[8] study, suggesting that patient-perceived improvements may not be realized immediately with short-term FES use.

Common limitations that affected the quality and validity of these studies were the small sample sizes, a lack of adjustment for confounding patient demographic variables, a lack of control for patient compliance with FES, and the therapists were not blinded. Both studies are highly relevant to the patient scenario presented as they adequately represent community-dwelling males in the 5th decade of life with MS and a foot-drop impairment. However, many of the subjects in these studies required an assistive device for ambulation and were more impaired with a longer disease history or more severe disease progression, as opposed to the patient in the scenario who was high-functioning, relatively recently diagnosed, and did not require a walking aid. Therefore, these results should be applied to independently ambulating MS individuals with some caution.

Clinical Implications

Patient-perceived improvements in walking or other quality of life measures may necessitate a longer-term FES treatment period of at least 18 weeks. Currently, there is limited evidence that demonstrates improved patient-perceptions from FES training. Therefore, a physical therapist who is considering FES with an MS patient should explain that it may take a few months before the patient notices improvements in function or quality of life as a result of FES. In addition to objective walking measures, subjective measures, such as the MSWS and MSIS-29, should be used to assess how the patient is responding to treatment. Poor patient perceptions of FES treatment could result in poor compliance and the patient's wasted time and money. Prior to initiating a plan for FES, the therapist should explain that there is good evidence that shows FES can improve one's movement quality and walking speed and lessen the effects of foot-drop with consistent use, and these effect may be further improved with the addition of an exercise program. The patient's beliefs and values should be strongly considered, and the therapist, for example, should discuss the patient's expectations for FES, one's ability to manage and don/doff the device, the cost/reimbursement of the device if the patient were to make a purchase, the risks and benefits (i.e. potential for pain, skin breakdown), and how wearing the device might impact the patient's self-image. Decision aids, such as educational materials and brochures for the FES device should be provided to each patient who is considering FES. If a patient is deemed appropriate for FES treatment after a thorough subjective and objective exam, the therapist should strongly consider integrating FES into the patient's treatment plan. There is no evidence to suggest FES should proceed a period of exercise; therefore, FES treatment may be initiated early on in conjunction with an individually tailored exercise program to strengthen weakened muscle groups and improve core stability.

Implications for Future Research

There is a need for future randomized controlled FES trials involving MS patients that are sufficiently powered and have larger sample sizes to study the therapeutic (carry-over) effect of FES and to compare FES medium- and long-term treatment outcomes to control groups exposed to discrete and combined alternative treatments, such as strengthening, aerobic, or balance programs. Future studies should appropriately adjust for patient demographics, such as disease type, age, and level of walking assistance in their analyses, as the MS population is generally very heterogeneous with regard to disease severity and disability. Future studies need to sufficiently monitor patient compliance with FES, which could confound results. Finally, more research is needed by future FES studies to better understand the relationship between patient reported outcomes and objective walking performance and gait quality. Hence, future RCTs should consistently incorporate subjective outcome measures into their analyses.

REFERENCES

1. Bosch PR, Harris JE, Wing K, American Congress of Rehabilitation Medicine (ACRM) Stroke Movement Interventions Subcommittee. Review of therapeutic electrical stimulation for dorsiflexion assist and orthotic substitution from the American Congress of Rehabilitation Medicine stroke movement interventions subcommittee. *Arch Phys Med Rehabil* 2014;95(2):390-396. doi:10.1016/j.apmr.2013.10.017.

2. Springer S, Vatine J-J, Wolf A, Laufer Y. The effects of dual-channel functional electrical stimulation on stance phase sagittal kinematics in patients with hemiparesis. *J Electromyogr Kinesiol* 2013;23(2):476-482. doi:10.1016/j.jelekin.2012.10.017.

3. Springer S, Khamis S. Effects of functional electrical stimulation on gait in people with multiple sclerosis - A systematic review. *Mult Scler Relat Disord* 2017;13:4-12. doi:10.1016/j.msard.2017.01.010.

4. Kingwell E, Marriott JJ, Jetté N, et al. Incidence and prevalence of multiple sclerosis in Europe: a systematic review. *BMC Neurol* 2013;13:128. doi:10.1186/1471-2377-13-128.

5. Mount J, Dacko S. Effects of dorsiflexor endurance exercises on foot drop secondary to multiple sclerosis: a pilot study. *NeuroRehabilitation* 2006;21(1):43-50.

6. Scott SM, van der Linden ML, Hooper JE, Cowan P, Mercer TH. Quantification of gait kinematics and walking ability of people with multiple sclerosis who are new users of functional electrical stimulation. *J Rehabil Med* 2013;45(4):364-369. doi:10.2340/16501977-1109.

7. Straudi S, Martinuzzi C, Pavarelli C, et al. A task-oriented circuit training in multiple sclerosis: a feasibility study. *BMC Neurol* 2014;14:124. doi:10.1186/1471-2377-14-124.

8. Taylor P, Barrett C, Mann G, Wareham W, Swain I. A feasibility study to investigate the effect of functional electrical stimulation and physiotherapy exercise on the quality of gait of people with multiple sclerosis. *Neuromodulation* 2014;17(1):75-84; discussion 84. doi:10.1111/ner.12048.

9. Van der Linden ML, Hooper JE, Cowan P, Weller BB, Mercer TH. Habitual functional electrical stimulation therapy improves gait kinematics and walking performance, but not patient-reported functional outcomes, of people with multiple sclerosis who present with foot-drop. *PLoS ONE* 2014;9(8):e103368. doi:10.1371/journal.pone.0103368.

10. Coote S, Hughes L, Rainsford G, Minogue C, Donnelly A. Pilot randomized trial of progressive resistance exercise augmented by neuromuscular electrical stimulation for people with multiple sclerosis who use walking aids. *Arch Phys Med Rehabil* 2015;96(2):197-204. doi:10.1016/j.apmr.2014.09.021.

11. Street T, Taylor P, Swain I. Effectiveness of functional electrical stimulation on walking speed, functional walking category, and clinically meaningful changes for people with multiple sclerosis. *Arch Phys Med Rehabil* 2015;96(4):667-672. doi:10.1016/j.apmr.2014.11.017.

12. Barrett CL, Mann GE, Taylor PN, Strike P. A randomized trial to investigate the effects of functional electrical stimulation and therapeutic exercise on walking performance for people with multiple sclerosis. *Mult Scler* 2009;15(4):493-504. doi:10.1177/1352458508101320.

13. Perera S, Mody SH, Woodman RC, Studenski SA. Meaningful change and responsiveness in common physical performance measures in older adults. *J Am Geriatr Soc* 2006;54(5):743-749. doi:10.1111/j.1532-5415.2006.00701.x.

14. Characteristics of the 29-item Multiple Sclerosis impact scale. Available at: http://multiplesclerosis.elsevierresource.com/articles/measurement-characteristics-and-clinical-utility-29-item-multiple-sclerosis-impact-scale. Accessed November 11, 2017.

15. Motl RW, Snook EM. Confirmation and extension of the validity of the Multiple Sclerosis Walking Scale-12 (MSWS-12). *J Neurol Sci* 2008;268(1-2):69-73. doi:10.1016/j.jns.2007.11.003.

16. Feys P, Bibby B, Romberg A, et al. Within-day variability on short and long walking tests in persons with multiple sclerosis. *J Neurol Sci* 2014;338(1-2):183-187. doi:10.1016/j.jns.2014.01.001.

17. Borg GA. Psychophysical bases of perceived exertion. *Med Sci Sports Exerc* 1982;14(5):377-381.

18. Hobart JC, Riazi A, Lamping DL, Fitzpatrick R, Thompson AJ. Measuring the impact of MS on walking ability: the 12-Item MS Walking Scale (MSWS-12). *Neurology* 2003;60(1):31-36.

19. Hobart J, Lamping D, Fitzpatrick R, Riazi A, Thompson A. The Multiple Sclerosis Impact Scale (MSIS-29): a new patient-based outcome measure. *Brain* 2001;124(Pt 5):962-973.

20. Dahlgren G, Carlsson D, Moorhead A, Häger-Ross C, McDonough SM. Test-retest reliability of step counts with the ActivPAL™ device in common daily activities. *Gait Posture* 2010;32(3):386-390. doi:10.1016/j.gaitpost.2010.06.022.