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ORIGINAL RESEARCH

Effectiveness of Functional Electrical Stimulation on Walking Speed, Functional Walking Category, and Clinically Meaningful Changes for People With Multiple Sclerosis

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Abstract

Objective: To determine the effectiveness of functional electrical stimulation (FES) on drop foot in patients with multiple sclerosis (MS), using data from standard clinical practice.

Design: Case series with a consecutive sample of FES users collected between 2008 and 2013.

Setting: Specialist FES center at a district general hospital.

Participants: Patients with MS who have drop foot (N=187) (117 women, 70 men; mean age, 55y [range, 27−80y]; mean duration since diagnosis, 11.7y [range, 1−56y]). A total of 166 patients were still using FES after 20 weeks, with 153 patients completing the follow-up measures.

Interventions: FES of the common peroneal nerve (178 unilateral, 9 bilateral FES users).

Main Outcome Measures: Clinically meaningful changes (ie, >.05m/s and >0.1m/s) and functional walking category derived from 10-m walking speed.

Results: An increase in walking speed was found to be highly significant ($P<.001$), both initially where a minimum clinically meaningful change was observed (.07m/s) and after 20 weeks with a substantial clinically meaningful change (.11m/s). After 20 weeks, treatment responders displayed a 27% average improvement in their walking speed. No significant training effect was found. Overall functional walking category was maintained or improved in 95% of treatment responders.

Conclusions: FES of the dorsiflexors is a well-accepted intervention that enables clinically meaningful changes in walking speed, leading to a preserved or an increased functional walking category.

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Drop foot is a reduced ability to clear the foot above the ground during the swing phase of gait, caused by dorsiflexion and eversion weakness, creating an unstable gait and an increased risk of falls for people with multiple sclerosis (MS).[1] One potential treatment is to stimulate the peroneal nerve, to activate the dorsiflexors, using functional electrical stimulation (FES). Liberson et al[2] were the first to pioneer this method in stroke patients with drop foot. The method was later reported to generate strength increases after peroneal stimulation of people with MS.[3]

More recently, a number of studies have measured walking speed in terms of an orthotic effect, defined as the difference at any given time point between unassisted walking and walking with FES. Audit data from 21 people with MS, collected over a period of 4.5 months, showed an orthotic effect of .08m/s, with FES users increasing their walking speed by 16%.[4] The study also

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examined the physiological cost index, an indicator of the amount of effort expended while walking, and found a 24% reduction, indicating greater walking efficiency.[4] Similar findings were reported in a controlled study[5] of 12 pairs matched for age and sex, which found a lower physiological cost index and oxygen uptake when walking with FES. In contrast, a pilot study[6] of 11 patients found no significant differences in walking speed; however, the authors noted a rather small sample size. Furthermore, research from 2 other studies[7,8] provides additional support for the findings that FES significantly increases walking speed and reduces energy expenditure.

An alternative, more traditional method for treating drop foot is the use of an ankle-foot orthosis (AFO). An AFO works through supporting the ankle and limiting the range of movement. In contrast, FES seeks to restore a normal range of movement. There has been little in the way of comparison between using an AFO and FES for people with MS. Further measures from 20 of the patients who formed part of the current study have been reported elsewhere in a feasibility study.[9] The study compared the walking speeds of patients wearing an AFO, patients walking unassisted, and patients walking with FES at baseline. The analysis revealed that patients walked faster with FES compared with an AFO ($P=.03$), with a clinically meaningful change of .08m/s. No significant difference was found between walking with an AFO and unassisted walking. The results suggest that people with MS who did not optimally benefit from an AFO were able to achieve clinically meaningful faster walking speeds with FES.

In contrast to the orthotic effect, a training or therapeutic effect is defined as the change in walking speed over time, measured on both occasions when not using FES. Unlike in people with stroke,[7,8,10] most studies find little evidence for a training effect in people with MS,[4,8,11] which may be due to the associated deterioration of the myelin and the reduced capacity for neuroplasticity. Although there has been some evidence for a small training effect in people with secondary progressive MS from longitudinal data,[7] this has not been confirmed with other studies.[4,8,12]

A randomized controlled trial comparing FES users with an exercise group (n=64) found that although there was an orthotic effect for the FES group, a training effect was not shown.[12] Further qualitative data analyses including all participants from the same study (n=64) found improvements in activities of daily living and a reduced number of falls for those using FES compared with exercise.[13] The qualitative findings suggest that in contrast to walking speed, FES contributes more to improvements in activities of daily living and the safety of walking than exercise. Consistent with the findings of the qualitative data, a more recent study[14] found a reduction in the number of falls and an improvement in gait and quality of life. It would be beneficial to conduct further research, to identify the most important outcome measures to people with MS who are candidates for FES.

While walking speed is frequently reported in the literature, it has been criticized for not being representative of the impact on daily life. In an attempt to determine the impact on activities of daily living, clinically meaningful changes in walking speed from a general elderly population were derived by Perera et al.[15] Those from the sample considered a minimum change to be .05m/s and a substantial change to be 0.1m/s. A further approach to measuring the impact of walking speed on daily life is through the use of functional walking categories derived from a stroke population by Perry et al.[16] These established criteria were used in a recent study[8] that examined the long-term effectiveness of FES for 39 people with MS over a period of 11 years. The study found clinically meaningful changes in walking speed and functional walking category to be associated with using FES, indicating that FES has a meaningful impact on daily life.

The evidence indicates that FES is effective in improving walking speed in a clinically meaningful way that enables a change in functional walking category. However, the studies conducted have all had relatively small sample sizes. Therefore, the current study aimed to examine the viability of using FES on a large representative sample using standard clinical practice.

List of abbreviations:

AFO ankle-foot orthosis
FES functional electrical stimulation
MS multiple sclerosis

Methods

Participants

A total of 187 people with MS and drop foot (117 women, 70 men; mean age, 55y [range, 27−80y]; mean duration since diagnosis, 11.7y [range, 1−56y]) formed a referred sample for treatment by either general practitioners or hospital consultants, with most funded by the United Kingdom's National Health Service between 2008 and 2013. Study exclusion criteria consisted of the inability to walk 10m with the assistance of a walking aid, poorly controlled epilepsy, or fixed skeletal deformities. Those with a cardiac pacemaker, implanted defibrillator, or other active implanted device were investigated by a cardiac technician to ensure there was no interaction between devices. Other precautions included recent injury, fracture, or surgery; major skin conditions; and the proximity of cancerous tissue to the site of stimulation.

Clinical procedure

After an initial assessment to determine whether FES was a suitable treatment, patients were invited to return for 2 setup appointments. At the first appointment they were instructed how to use the FES equipment. FES was applied using 2 electrodes placed over the common peroneal nerve either at the head of the fibular or popliteal fossa and over the motor point of the tibialis anterior. Stimulation was timed to the swing phase of gait using a foot switch under the heel, causing dorsiflexion with a small degree of eversion. Patients used 1 of 4 versions of the ODFS[a] (Odstock Dropped Foot Stimulator): the ODFS III[a] (single channel), which uses an analogue interface; the ODFS Pace[a] (single channel), which uses a digital interface; the Odstock 2 Channel Stimulator II,[a] which uses an analogue interface; and the ODFS Pace XL,[a] which is a wireless version of the ODFS Pace. Nine patients used bilateral stimulation, while 178 were set up with unilateral stimulation. All devices stimulated at 40Hz using either a symmetrical or asymmetrical biphasic waveform, with current intensity up to 100mA and pulse width up to 360 microseconds. Stimulation, intensity, waveform, and timing parameters were adjusted to optimize the correction of drop foot for each individual.

On the second appointment, the patients' ability to use the equipment independently was checked, and their 10-m walking speed was measured. The first walk was used to increase temperature and range of movement in the joints, the second