An Investigation into the Effect of Functional Electrical Stimulation on Mobility and Quality of Life in Patients with Multiple Sclerosis

G.E.Mann , C.L. Jolley and P.N. Taylor

Department of Medical Physics and Biomedical Engineering Salisbury District Hospital
Salisbury, Wiltshire SP2 8B email. g.mann@mpbe-sdh.demon.co.uk

Abstract

54 subjects with secondary progressive Multiple Sclerosis (MS) were randomly assigned to an FES group to correct dropped foot or a group which received exercise to improve gait .The study period was 18 weeks The primary outcome measure was 10 metre walking speed with secondary measures of walking speed, distance and effort over 3 minutes, quality of life measures and number of falls. The FES group showed an orthotic benefit on 10 metre walking speed but no lasting training effect. The exercise group showed a training effect over the whole study period. A similar pattern of improvement was shown in both groups in distance walked in 3 minutes but with a greater degree of benefit. There was a significant reduction in number of falls in both groups over the study period with a significantly greater reduction in the FES group. This study has shown that FES provides an effective orthosis in people with MS and has a significant role in preventing falls. Exercise has also been shown to be beneficial in providing a training effect Further work should investigate the combination of FES combined with exercise to achieve an optimum and longer lasting effect of therapy.

1. INTRODUCTION

About 85,000 people in the UK have Multiple Sclerosis (MS) a condition which is the greatest cause of disability in young adults.
The effects of MS frequently lead to disordered motor control as a result of spasticity, weakness and poor coordination.[1] Loss of selective movement frequently results in dropped foot and instability and weakness at the hip and knee. There has been little research to date into the effects of FES on gait in Multiple Sclerosis. One study reported increased muscle strength and reduction in calf tone in a limited case series of subjects with MS who had used electrical stimulation [2] A questionnaire survey found that stimulation was well accepted despite some problems with electrode placement and with use of the stimulator away from the clinic.[3] A retrospective audit of people with MS showed a mean increase in walking speed and a reduction in effort of walking after using FES for 18 weeks.[4]The Odstock Dropped Foot Stimulator (ODFS) is a single channel foot switch controlled neuromuscular stimulator used to correct dropped foot during walking. Stimulation is applied to the common peroneal nerve, using surface electrodes, to elicit dorsiflexion and eversion of the ankle to aid foot clearance during the swing phase of walking.[5]

1.1 Study Hypothesis

This study proposed that the use of stimulation of the common peroneal nerve to correct dropped foot in people with MS can provide an effective orthosis to improve mobility and quality of life.

2. METHODS

Subjects with secondary progressive MS were recruited to the study. Following recruitment they were randomly assigned to stimulation and exercise groups. Inclusion criteria were - a rating of 4-7 on the Kurtze Expanded Disability Status Scale (EDSS), dropped foot impairing mobility, no previous use of FES and an effective response to common peroneal nerve stimulation. The FES group received common peroneal nerve stimulation to correct dropped foot using the Odstock Dropped Foot Stimulator. The exercise group was given exercises to improve gait, appropriate to the individual subject. Both stimulation and exercise programmes continued for a period of 18 weeks. Assessments were carried out at the beginning of treatment week 0, week 6, week 12 and at the end of treatment week 18.The

primary outcome measure was walking speed over 10 metres. Other outcome measures included physiological cost index (PCI) over 10 metres, and walking distance, speed and PCI over 3 minutes. In the latter test subjects were required to perform two walks at weeks 6, 12 and 18 but were allowed to stop if too fatigued to complete them. In the treatment group these walks were with and without stimulation and in the exercise group an unstimulated walk at the beginning and end of the assessment. Each subject kept a falls diary for the duration of the study. A number of quality of life assessments were made. These were the Hospital Anxiety and Depression Scale (HAD), the Multiple Sclerosis Impact Scale (MSIS-29).and the Multiple Sclerosis Walking Scale (MSWS-12).

3. RESULTS

64 subjects (aged 18 years and above) with secondary progressive MS were recruited to the study. Of these 10 dropped out. The 6 minute walking test proved to be too demanding for the first 11 subjects and was changed to a 3 minute test for the remaining 43 subjects. Data are therefore presented for 43 subjects for walking tests and for 54 subjects for falls.

In the walking test group 20 subjects received FES – 13 female and 7 male, mean age 51.7 years (sd 8.0) range 31-63 years, mean time since diagnosis 13.6 years (sd8.4) range 5-32 years. 23 subjects received exercises - 16 females and 7 males, mean age 56.9 years (sd 9.1) range 39-71 years, mean time since diagnosis 17.8 years (sd 8.4), range 6 to 29 years. In the falls group 26 subjects received FES - 16 female and 10 male, mean age 52.4 years (sd 8.5) range 31-71 years, mean time since diagnosis 12.5 years (sd 8.2) range 3-32 years. 28 subjects received exercises - 20 females and8 males, mean age 57.5 years (sd 8.5) range 39-71 years, mean time since diagnosis of 18.0 years (sd 8.5), range 6 to 28 years.

The 10 metre walking speed test demonstrated a small orthotic benefit of FES at each assessment but no carry over effect into improved walking speed without stimulation The exercise group showed a carry over effect between the beginning and end of the study (Table1& Fig1).

Week	Fes n.stim ms^{-1}	Fes stim ms^{-1}	Wilcoxon	Exercise (mean of 2 walks)
0	0.76	0.82	p= 0.98	0.65
6	0.78	0.81	p=0.004	0.70
12	0.76	0.80	p=0.0003	0.76
18	0.75	0.78	p=0.008	0.78
no stim. weeks 0-18	Wilcoxon FES p=0.097		Wilcoxon Exercise p=0.0002	

Table1: 10 metre median walking speeds in m/sec

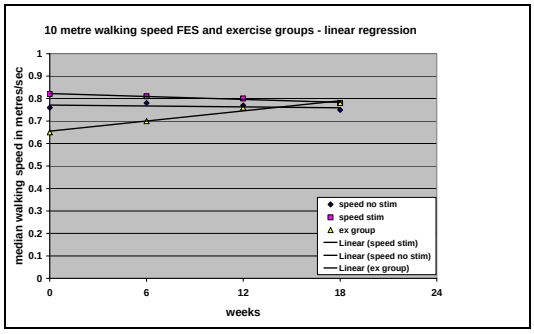

Fig.1 Graph of median 10 metre walking speed

Walking distance in 3 minutes showed a greater degree of orthotic benefit in the FES group than for speed over 10 metres and also a carry over effect at the end of the study in the exercise group (Table2 & Fig.2).

Wk	Fes no st.	Fes stim		Exs. walk1	Exs walk2	
0	108.6	n/a	p= n/a	86.8	n/a	p= n/a
6	110.5	127.0	p= 0.01	109	120.3	p= 0.45
12	119.0	125.3	p= 0.003	108	124	p= 0.07
18	116.5	127.8	p= 0.004	109	127	p= 0.22
Wilcoxon no stim week 0-18		FES p=0.33		Exercise p=0.01		

Table2: Median Distance walked in 3 mins. in metres. p values are for Wilcoxon signed ranks test.

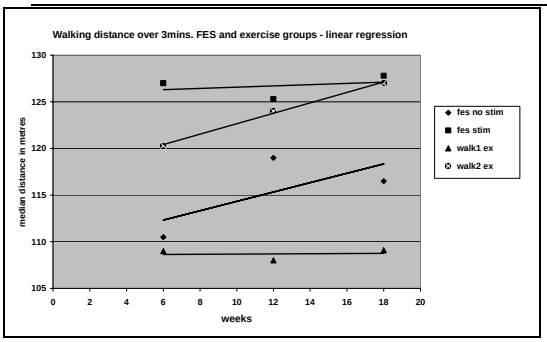

Fig.2 Graph of median distances walked in 3 mins.

Both groups reduced the total number of falls experienced between each 6 week assessment period (Fig.3), which was significant at the end of the study. The total number of falls over the study period was significantly less in the FES than the exercise group (Table 3).

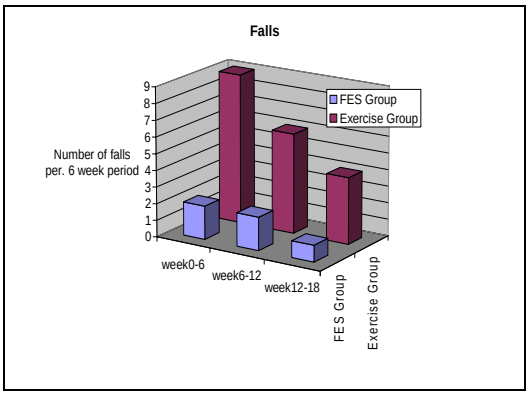

Fig.3: Total number of falls between 6 week assessments for FES and exercise groups.

Total falls weeks 0-6 compared to weeks 12-18		Difference in total falls between the 2 groups weeks 12-18
FES group Wilcoxon p= 0.013	Ex. group Wilcoxon p= 0.007	Mann Whitney U p= 0.036

Table 3: Number of falls in 1st 6 weeks compared to final 6 weeks and difference in total falls between the 2 groups weeks 12-18.

The quality of life assessments were completed but require greater discussion than allowed by the scope of this abstract.

4.DISCUSSION AND CONCLUSIONS

The greatest orthotic benefit of FES was demonstrated in walking distance over 3 minutes. This is probably more clinically relevant for people with MS than walking speed over 10 metres which showed a smaller beneficial effect. This may indicate that the 10 metre test was not the most appropriate measure to use when testing the effect of FES on walking in people with MS. In this study there was no significant training effect of FES on unstimulated walking but exercise was shown to have a significant training effect on both walking speed and distance and therefore should be considered as an essential part of any treatment programme with emphasis on the appropriate targeting of that exercise as was done in this study. The role of FES in significantly reducing falls in this subject group is particularly important in view of the economic implications of falls in healthcare.

This study shows that FES provides an effective means of correcting dropped foot in people with MS and has a significant role in preventing falls. The role of exercise has also been shown to be beneficial particularly in the training effect it provides. Importantly subjects gain autonomy and control in improving their mobility. The results of this study indicate that further work should investigate the combination of FES as an orthosis combined with exercise in order to achieve an optimum effect of therapy.

5.References

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