

Clinical use of FES to improve walking in people with Multiple Sclerosis

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Introduction

Multiple Sclerosis, MS, is a chronic disease of unknown cause which affects the central nervous system and is characterised by demyelination of nerve fibres in the brain and spinal cord. It affects over 85,000 people in the UK and between 250-350,000 people in the United States. It is five times more common in temperate climates than in tropical regions (1). It is an unpredictable disease making prognosis difficult and symptoms can range from relatively benign to devastating, as communication between the brain and the peripheral nervous system is disrupted. As MS affects the central nervous system it can cause muscular weakness, reduced sensation, spasticity, fatigue and ataxia in addition to pain, balance problems, bladder, bowel and sexual dysfunction, speech and visual disturbances and altered mental state.

The disease progression is variable and usually follows one of several patterns. Most common is relapsing-remitting (RR) which is a series of attacks followed by complete or partial remission only to reoccur after a period of stability. Primary-progressive (PP) is characterised by a steady decline with no distinct remissions. Secondary-progressive (SP) begins with a relapsing-remitting course followed by a later primary progressive course. Rarely patients may have a progressive-relapsing (PR) course in which the disease takes a progressive path followed by acute episodes. In addition 20% of the MS population have a benign form of the disease which shows little or no progression after the initial attack. As a result of this variability of symptoms and progression any clinical trials in MS are notoriously difficult.

Most people with MS experience muscle weakness in their extremities and difficulty with coordination at some time during the course of their disease which may be severe enough to affect walking (1). Foot drop is one of these effects and may occur either unilaterally or bilaterally. It may be characterised by an isolated weakness of the foot dorsiflexors but it is more usual for other movements to be affected as well, commonly reduced knee flexion. Spasticity may also be a factor which contributes to difficulty in mobility.

Design

The ODFS III is a single channel, foot switch triggered stimulator designed to elicit dorsiflexion of the foot by stimulation of the common peroneal nerve, (max. amplitude 100mA, 350µs pulse, 40 pps). Skin-surface electrodes are placed, typically, over the common peroneal nerve as it passes over the head of the fibula bone and the motor point of tibialis anterior. The rise and fall of the stimulation envelope and extension after heel strike can be adjusted to prevent a stretch reflex in the calf muscles and to prevent "foot flap" due to the premature ending of dorsiflexion. The ODFS was the subject of a randomised controlled trial in which 32 stroke patients who had had a stroke for in excess of 6 months were allocated to a treatment group who used the device and received 12 sessions of physiotherapy and a control group who only received physiotherapy (2). Since that time it has been widely used for a variety of neurological conditions (3) and has been recognised by the Development and Evaluation Committee of the South West Regional Health Authority and the Royal College of Physicians of England in their Guidelines on Stroke. There is also a two channel version which can be used for either bilateral common peroneal nerve stimulation or stimulation of one common peroneal nerve and a separate muscle group (4). In the two channel stimulator only one foot switch is required to control both channels with the relative timing being adjusted when the system is first fitted. Therefore the system can be used in swing

phase to stimulate hamstrings to achieve greater knee flexion, or in stance phase to stimulate gluteae to improve hip extension or quadriceps to improve knee stability. Both single and two channel stimulators are CE marked and are available for purchase from the Department of Medial Physics and Biomedical Engineering in Salisbury.

Clinical Service

The clinical service has been described in detail in previous publications.(5) The basic philosophy behind the approach in Salisbury is that it is a clinical service and not merely the provision of technology. As such, patients are under constant clinical review for as long as they use the equipment. To date we have seen 311 people with MS in Salisbury making them the second largest diagnostic group after CVA, although at present they represent the majority of new referrals. Out of these 311 only 29 (9%) have stopped using the systems. Below is a breakdown of the people with MS referred over the past ten years.

Average age	49.1 years	range 31-89
Average time used	30.0 months	range 1-114 months
Average time used if stopped	20.8 months	range 4-56 months
Male	109	
Female	202	
Never used AFO	158	
Using AFO prior to FES	83	
Rejected AFO	78	
ODFS only	225	
2 Channel system	102	
Bilateral dropfoot	46	
Dropfoot and hamstrings	41	
Dropfoot and gluteae	11	
Dropfoot and calf	1	
Dropfoot and quadriceps	3	

Of the 41 who started in 1999, 41 were still using the system 1 year later (87%)

Of the 29 who started in 2000, 29 were still using the system 1 year later (100%)

Of the 58 who started in 2001, 55 were still using the system 1 year later (95%)

Of the 134 who started FES between 1999 and 2001, 125 were still using the system 1 year later (93%)

Reasons the 29 people stopped

No reason 5, lost to follow up 1, Mobility deteriorated 2, Mobility improved 1, Skin problems 1, Insufficient benefit 3, Too difficult 1, Too much bother 5, Too painful 1, Other 8

Results

The results presented below are calculated using those subjects for whom we have complete data. Therefore people who could only walk the set 10m course when using the stimulator are not included. Comparisons were made using the Wilcoxon Signed Ranks test. In all results orthotic gain is defined as the difference between the walking performance (speed or PCI) with and without the stimulator at any given session. Carryover is defined as the difference between walking performance without stimulation when compared to walking performance without stimulation at the initial session. Total orthotic effect is defined as the walking performance with stimulation compared to walking performance without stimulation at the initial session.

Unilateral dropped foot at 18 weeks n=78

PCI			Speed		
Orthotic Gain	Carryover	Total Orthotic Effect	Orthotic Gain	Carryover	Total Orthotic Effect
-12.3% p<0.01	8.4% NS	-7.1% p<0.01	19.3% p<0.01	2.3% NS	20% p<0.01

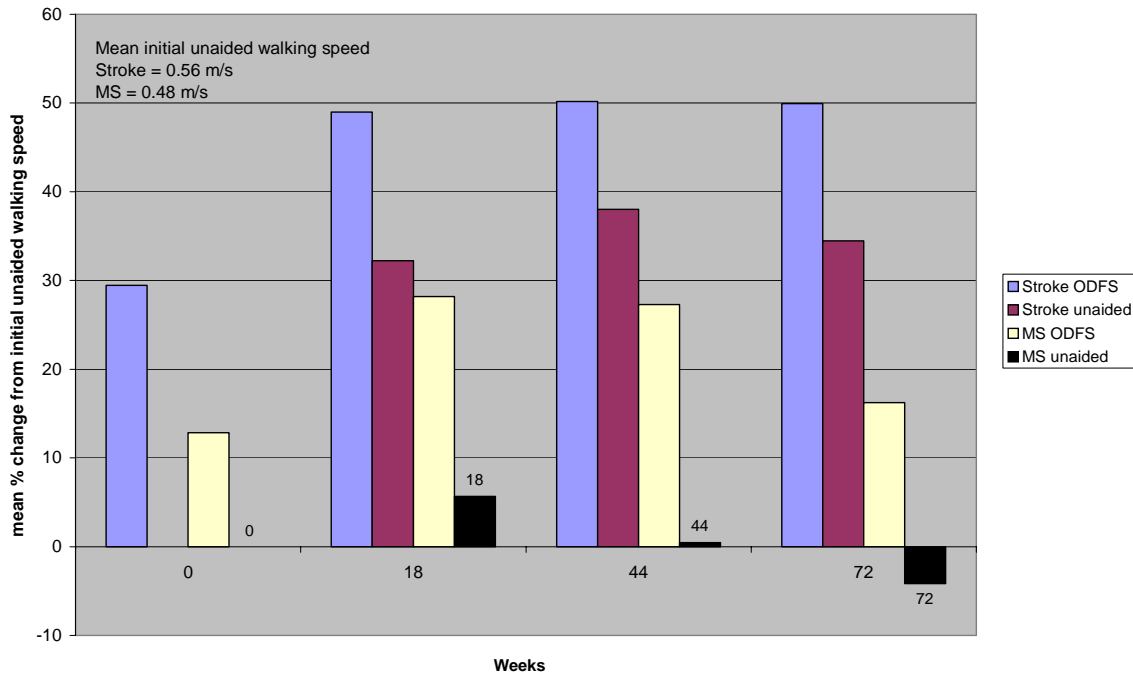
Unilateral dropped foot at 72 weeks n=20

PCI			Speed		
Orthotic Gain	Carryover	Total Orthotic Effect	Orthotic Gain	Carryover	Total Orthotic Effect
-20.2% p<0.01	29.4% p<0.05	-0.4% NS	24.7% p<0.01	-4.2% NS	16.2% p<0.01

Two Channel dropped foot system at 18 weeks

PCI			Speed		
Orthotic Gain	Carryover	Total Orthotic Effect	Orthotic Gain	Carryover	Total Orthotic Effect
-19.6% p<0.01	6.0% NS	-16.6% p<0.05	35.6% p<0.01	12.6% NS	47.7% p<0.01

Mean % change in walking speed for stroke (n=27) and MS (n=20) ODFS users



The above graph shows the mean percentage change in walking speed relative to walking without the ODFS at the first assessment for two groups of patients with MS or chronic Stroke. The stroke group shows a significant rise in walking speed both with and without the ODFS over the first 18 weeks of use, which then stabilises at this level. While there is an improvement in the performance when walking with the device for those who had MS, there is little change in walking speed when not using the device.

Conclusion

This paper describes the successful implementation of a clinical service model for provision of FES device to improve walking function in people with MS. Compliance with treatment was high indicating that the device addressed a clinical need and that it was well accepted by its users. Users of the device walked faster and with less effort and often reported that its use extend their walking range, helping to combat the fatigue often experienced by people with MS. For those with bilateral dropped foot, the wheelchair could be discarded for short transfers such as from car to office or home and access was often made possible where a wheelchair could not be used, for example, ascending and descending stairs. These results suggest that correction of dropped foot using electrical stimulation can help to maintain mobility leading to prolonged independence and quality of life.

Acknowledgements

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Suppliers

The Odstock Dropped Foot Stimulator, Odstock 2 Channel Stimulator and Microstim 2 are CE marked and available to clinicians who have attended a training course in their use from the Department of Medical Physics

and Biomedical Engineering, Salisbury District Hospital, Salisbury, Wiltshire, SP2 8BJ.
(www.salisburyfes.com)

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