The efficacy of Functional Electrical Stimulation in improving walking ability for people with Multiple Sclerosis

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Abstract

For the past seven years the Department has provided a clinical FES service seeing over 1000 people the majority of whom have used the Odstock Drop Foot Stimulator (ODFS) for the correction of drop foot following stroke. More recently an increasing number of people with walking difficulties due to Multiple Sclerosis, MS, have been referred and to date over 130 people have been assessed. Previous work showed that in MS the benefits to the patients were due to the orthotic effect of stimulation rather than any therapeutic or carry-over effect as is often seen in stroke patients, with the continuing orthotic effect being a 16% improvement in walking speed with a 25% decrease in the energy expenditure measured by Physiological Cost Index (PCI). The data at that time was only recorded on 21 patients followed up over a four and a half month period, however the greater number of MS patients referred over the last two years has enabled a more complete picture to be developed on the role of FES in MS, both in terms of the greater number of patients seen and in the longer period of follow up. The longest period of time that one person with MS has used the stimulator being six and a half years. One interesting fact to arise from the analysis of the larger group is that there is a subgroup who do appear to get a carry over effect similar to that seen in the stroke patients. In addition the development of a new two channel stimulator has enabled 26 people with more severe disabilities to be assisted by stimulation of a second muscle group. This can be used correct bilateral foot drop, to stimulate the gluteae to extend the hip, or the hamstrings to facilitate knee flexion.

Background

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 effects 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.

The ODFS II 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 Afoot 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 (2,3,4). After three months of use the treatment group showed a statistically significant increase in walking speed of 16% and reduction in the Physiological Cost Index (PCI) of 29% when the stimulator was used while no changes were seen in the control group (3). No significant 'carry-over' effect was seen although a trend was present. Users of the ODFS showed a continuing reduction in quadriceps spasticity which was only seen in the control group while physiotherapy continued (4). The treatment group also showed a reduction in depression score on the Hospital Anxiety and Depression index suggesting an improvement in quality of life. The trial results were presented to the South and West Regional Health Authority Development and Evaluation Committee who subsequently recommended the ODFS for use in the National Health Service.

Methods

After the ODFS is fitted the patient is seen the following day, after six weeks, after a further three months and then every six months as long as they continue to use it. Walking speed and PCI, which is an indication of the amount of effort expended, are measured at every appointment. The patients are asked to Awalk briskly@ over a 10m course with 1m at either end for acceleration and deceleration. Patients normally walk this course three times with stimulation and three times without, the order of stimulation / nonstimulation being varied to compensate for any fatigue. The mean speed and PCI for stimulated and non-stimulated walking is calculated. PCI being the change in heart rate (bt/min) / walking speed (m/min). The heart rate was measured using a Polar Heart Rate Monitor. The data in this study were obtained retrospectively from the records of these routine measurements kept in the patients notes.

In addition a questionnaire was sent to all current and former users of the ODFS, 168 and 123 respectively. A stamped addressed envelope was included to facilitate their return. The questionnaire consisted of 16 questions which sought to determine what advantages the ODFS gave; when, how and where it was used, if it made any difference to the patients use of other aids, whether the instructions, both verbal and written were satisfactory and whether the repair/advice service we were providing was responsive. Those who had stopped using the stimulator were asked why they had stopped.

Results

We have assessed 139 people with MS who have been found to be suitable for treatment, 24 of whom were bilateral. Their average age is 53.4 years SD 11.1. Of these 139 there is speed/PCI data on 112, as some patients have been assessed but have not started treatment. The reason that complete data is not available on all subjects is primarily due to the fact that some patients fatigue so rapidly that they are unable to complete all the tests. The figures presented below are only on those patient on whom complete data is available.

The longest any MS patient has been using the ODFS is over six years since commencing treatment on 29/3/94. Nine patients have used it, or a bilateral system for over three years.

Of the 139 patients only 16 have stopped treatment giving a compliance of 88%.

Recently there has been a marked increase in the number of referrals of people with MS with 77 patients, 55.4% of the total, being referred in the last two years.

Initial orthotic effect (IOE) is defined as the mean % change in speed/PCI with and without stimulation at the start of treatment.

Final orthotic effect (FOE) is defined as the mean % change in speed/PCI with and without stimulation after a period of treatment. e.g. $4\,^{1}/_{2}$ months or 3 years

Total orthotic effect (TOE) is defined as the mean % change in speed/PCI with stimulation after a period of treatment compared to that without stimulation at the start of treatment.

›Carry over- effect (COE) is defined as the mean % change in speed/PCI without stimulation after a period of treatment compared to that without stimulation at the start of treatment.

Positive values of percentage change in walking speed indicate faster walking. Positive values of percentage change in PCI indicate an increase in effort, negative values a reduction in effort

Table 1 Changes in Walking Speed and Energy Expenditure after four and a half months usage, ODFS (52 patients)
N.B. Patients who can not walk 10m without stimulation are not included.

Pre use Mean PCI No stim.	Mean PCI Stim	Mean Speed No Stim	Mean Speed Stim
1.09	1.03	0.49ms^{-1}	0.53ms^{-1}

After 4.5 months use Mean PCI No stim.	Mean PCI Stim	Mean Speed No Stim	Mean Speed Stim
1.03	0.84	0.51ms^{-1}	0.59ms^{-1}

	Speed	PCI
IOE	10%***	-11%***
FOE	5%***	-6%
TOE	16%	-20%
COE	-1%	-4%

* p<0.05, **p<0.01, ***p<0.001 paired t-test

Table 2 Changes in Walking Speed and Energy Expenditure after three years usage (6 patients, includes patients using both the ODFS and two channel stimulator).
N.B. five of the subjects walked faster with the stimulator at the start of treatment but one subject walked considerably slower. Their walking improved after using the stimulator for some time.

Pre use Mean PCI No stim.	Mean PCI Stim	Mean Speed No Stim	Mean Speed Stim
1.03	1.05	0.44ms^{-1}	0.47ms^{-1}

After 3 years use Mean PCI No stim.	Mean PCI Stim	Mean Speed No Stim	Mean Speed Stim
1.25	0.85	0.35ms^{-1}	0.47ms^{-1}

	Speed	PCI
IOE	6%	- 1%
FOE	36%	-29%
TOE	8%	-17%
COE	-10%	21%

In the 3 year follow up group the numbers were small but showed that there was a marked final orthotic effect and even after three years the majority of patients were walking faster and more efficiently with the stimulator than they were without the stimulator at the time they were referred for treatment. As the numbers are so small, statistical evaluation

Table 3 Changes in walking speed and PCI due to two channel stimulator for bilateral footdrop (10 patients)

Pre use Mean PCI No stim.	Mean PCI Stim	Mean Speed No Stim	Mean Speed Stim
1.57	1.13	0.27ms^{-1}	0.32ms^{-1}

After 4.5 months use Mean PCI No stim.	Mean PCI Stim	Mean Speed No Stim	Mean Speed Stim
1.65	1.25	0.30ms^{-1}	0.35ms^{-1}

	Speed	PCI
IOE	37%**	-25%**
FOE	40%*	-18%*
TOE	56%	-12%
COE	18%	11%

*p<0.05, **p<0.01 Wilcoxon Signed ranks test

Questionnaire

Of the current ODFS users107 replies were received from the 160 questionnaires that were sent out of which 15 had MS. Of the former users 53 replies were received from the 123 questionnaires that were sent out, only 3 of who had MS, two stopped using the stimulator because of a deterioration in their general condition and the other had an increase in their spasticity. The replies received the current users were different from the rest of the respondents, the majority of whom had a dropped foot as a result of a CVA. Amongst those with MS by far the most common reason for using the ODFS was the reduction of effort, 100% (5)

Discussion

The results on the main group of patients, i.e those who have used a stimulator for four and a half months show that electrical stimulation significantly improves both walking speed and walking efficiency. Unlike the initial work (6) it was also encouraging that some patients exhibit a ›carry over‹ effect over the four and a half month treatment period. Walking speed of >10% was seen to increase in 16 out of the 52 patients and PCI reduce by > 10% in 21 patients.

was not undertaken. Three patients were walking faster without stimulation after three years than they were initially and two were walking more efficiently.

The results obtained with the two channel bilateral foot drop stimulator (7) showed an improvement in both walking speed and PCI when using the stimulator which was statistically significant compared to the results obtained without stimulation. The readings taken after four and a half months showed no statistically significant difference compared to the initial readings, although the sample size was small.

The questionnaire showed that MS patients gave slightly different reasons for using the stimulator compared to thee majority of patients who had had a CVA, in that reduction in effort was the main reason they used it. This can be seen in the final orthotic effect after three years use when it can be seen that it did make a considerable difference to their walking. It is also noticeable that the bilateral stimulator also makes a considerable difference. Therefore it might be inferred that as people with MS become more disabled by the progressive nature of the disease that the stimulator becomes more important in preserving their mobility and hence independence. It is probably not surprising therefore that we have had such a small drop out rate from MS patients with only 16 out of 139 stopping treatment.

It was disappointing that we were not able to report on more subjects when 139 had been assessed, although we will be able to over the next few years as the recent influx of patients progress through the system.

It is always difficult with any severely disabled group to record objective data taken at set times as the variable nature if the disease often means that clinic appointment are difficult for the patients to attend especially as we see patients from all over the United Kingdom.

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