Introduction

Dropped foot is a common problem resulting from a range of neurological conditions, in particular multiple sclerosis (MS) and stroke. It is characterised as a deficit in dorsiflexion and eversion in the swing phase of gait, leading to foot catching on the ground as it is brought forward or energy wasting compensatory movements to avoid the foot catching. Additionally, poor placement of the foot on the ground at initial contact often places the ankle in an unstable position. The combined effect reduces the safety of walking, increasing falls or resulting in behaviour to avoid falls that restrict mobility and participation. In a survey by Peterson of people who had MS, 63% reported that they had a fear of falling and of these 83% reported curtailing activity due to this fear. The established intervention for dropped foot is the ankle-foot orthosis (AFO), a splint that fits within the shoe, rigidly or semi-rigidly fixing the ankle. While AFOs can be very effective, many patients reject them because they are sometimes uncomfortable, heavy and restricting. Clinicians are sometimes reluctant to issue AFOs because it is believed that the restriction of movement may discourage recovery of function and lead to increased spasticity and soft tissue shortening. In a recent trial of dropped foot intervention only 23% of participants were current AFO users, 30% had rejected AFOs and 47% had never used an AFO.

Functional Electrical Stimulation (FES) is a means of producing useful movement in paralysed muscles. Small electrical pulses are applied to the nerves that supply the affected muscles using self adhesive electrodes placed on the skin. The stimulus induces a nerve impulse that is propagated to the muscle causing the muscle to contract in a manner very similar to a natural contraction. Stimulation of the Ia afferent nerve fibres may, through reciprocal inhibition, inhibit spasticity in the antagonist muscle. For correction of dropped foot the common peroneal nerve is stimulated at its most superficial point, just below the head of the fibula bone. The resulting contraction of the anterior tibialis, toe extensors and peroneus muscles produce dorsiflexion with some eversion. When this is timed to gait cycle using a low profile pressure switch placed in the shoe under the heel, the foot is lifted through the swing phase, correcting the dropped foot. The technique was first used by Liberson who noted that there was both an orthotic effect assisting mobility and a training effect resulting in improved gait after using FES. While initial experience was promising the technique did not achieve significant use in the UK until introduction of the Odstock Dropped Foot Stimulator (ODFS).

Clinical purpose of the use of FES for the correction of dropped foot

The intervention is intended to be a practical assistive device to assist daily mobility for people who have dropped foot due to upper motor neurone neurological conditions. Specifically, electrical stimulation of the common peroneal nerve causes dorsiflexion and eversion of the foot through the swing phase of gait. This has the following practical effects:

- The foot is prevented from catching the ground as it is brought forward. This improves the safety of gait.
- The foot contacts the ground at the end of the swing phase with the heel and with slight eversion. This ensures weight bearing through the centre or slightly medially to the centre line of the foot leading to greater ankle stability. This improves the safety of weight bearing in the stance phase of gait.
- Walking speed is increased
- The effort of walking is reduced.
- The walking range (distance) is increased
- The above affects lead to a greater confidence when walking, greater independence and participation and an overall improvement in quality of life.
In addition to the direct affect of using the device as an orthosis there can also be therapeutic effects.

- Most patients with dropped foot due to stroke and spinal cord injury and 1/3 of people with MS improve their walking without the device after using the device for several months.
- The effect of electrical stimulation on improving muscle strength, fatigue resistance, muscle bulk, local blood supply and skin condition are well established.

When reviewing the literature to support or otherwise the clinical use of FES for correction of dropped foot, the above aims of the intervention should be focused on and studies that review different interventions with different aims excluded from the review. In particular it is important not to confuse therapeutic and orthotic effects of FES.

Early clinical evaluation of Functional Electrical Stimulation (FES) for correction of dropped foot due to an upper motor neuron lesion was first evaluated by Liberson. Salisbury District Hospital developed the Odstock Dropped Foot Stimulator (ODFS) based upon the device first used and described by Liberson. To date (2010), over 10,000 ODFS units have been produced and the ODFS has been the subject of multiple clinical investigations. There are over twenty-five published peer reviewed journal articles relating to the ODFS and many additional reports, articles and abstracts. A summary of the primary clinical, case series and retrospective studies are presented here.

Randomized Controlled Clinical Trials of the ODFS

Stroke
A randomized controlled clinical trial was conducted to evaluate the effect of the Odstock Dropped Foot Stimulator (ODFS) on effort and speed of walking in hemiplegic patients with dropped foot. Thirty-two chronic post-stroke (>6 months) subjects were randomized to either a treatment group receiving stimulation with the ODFS and concurrent physical therapy or a control group receiving physical therapy alone. During the first month of the trial, all subjects received 10 sessions of physical therapy. Each session was approximately one hour. Evaluations of walking speed over a distance of 10 meters were collected at baseline, 4 weeks, and 12 weeks following the initial device set-up. Comparisons were made between mean walking speed at baseline and mean walking speed at the conclusion of the study for each group. At 12-weeks follow-up, a mean increase in walking speed of 20.5% was observed for the treatment group (when the stimulator was in use) and 5.2% in the control group. The Physiological Cost Index (PCI), a measure of walking efficiency, was also evaluated in this study. Improvement was also demonstrated via a reduction in PCI at the conclusion of the study compared to baseline. The treatment group had a 24.9% reduction of PCI (when the stimulator was in use) whereas the control group had a 1% reduction. During the course of this trial, no significant carryover effect of stimulation with the ODFS device was observed since there were no significant improvements in walking speed in the treatment group without the use of stimulation.

In an RCT, Johnson et al. investigate the effect of combined botulinum toxin type A (BTX) with functional electric stimulation (FES) treatment on spastic drop foot in stroke and compared it with a control group receiving physiotherapy. 21 ambulant adults who were within 1 year of stroke with a spastic drop foot were randomly assigned to the two groups. 18 research volunteers completed the study. The treatment group received BTX injections (Dysport) on 1 occasion into the medial and lateral heads of the gastrocnemius (200U each) and tibialis posterior (400U each) muscles and FES, used on a daily basis for 16 weeks to assist walking. Both groups continued with physiotherapy at the same rate. Outcome measures were walking speed over 10m, Physiological Cost Index (PCI) and Rivermead Motor Assessment (RMA). It was shown that walking speed increased over 12 weeks in both control (P=.020) and treatment groups (without stimulation, P=.004; with stimulation, P=.042). The baseline corrected (analysis of covariance) increase in mean walking speed at 12 weeks, relative to controls, was .04m/s (95% confidence interval [CI], .003–.090) without stimulation, and .09m/s (95% CI, .031–.150) with stimulation. Statistically significant improvements in PCI and RMA were found in the treatment group but were not seen in the control group. It was concluded that the combined treatment effectively improved walking and function. BTX is a useful adjunct to FES where high calf tone may reduce effective range of movement.
Multiple Sclerosis
A randomised controlled clinical trial was conducted with people who have a dropped foot due to secondary progressive multiple sclerosis (SPMS)\(^4,\,5\). A group of 54 people with SPMS were randomly allocated to a treatment group who received the ODFS for daily use to correct dropped foot or a control group who received a home based self administered, physiotherapy exercise programme. Both groups used the intervention for 18 weeks and attended the clinic for follow up support and assessment once every 6 weeks. Uses of the ODFS walked faster at each assessment after week 0 when the device was used, measured over 10m (percentage mean difference at 18 weeks of 10 %\( p = 0.001\)). However, there was no training effect from the device. The physiotherapy group did show a training effect over 18 weeks (percentage mean difference at 18 weeks of 13 %\( p = 0.001\)). Walking distance over 3 minutes was also consistently greater when the device was used (percentage mean difference at 18 weeks of 12 %\( p = 0.004\)) but again no training effect was seen. In the control group a training effect was seen over 18 weeks (percentage mean difference at 18 weeks of 15 %\( p = 0.005\)) but this was less than the overall benefit seen by the FES walkers who were able to walk 25% further in 3 minutes when FES was used at the end of the trial compared to the beginning unaided. The effect of using the ODFS on activities of daily living (ADL) measured using the Canadian Outcome Performance Measure (COMP). At the end of the study it was found that there was no significant effect of ADL in the group who received physiotherapy (Median change = 0 for performance and 0 for satisfaction) while significant improvements in ADL were seen in the ODFS group (Median change = 1.1 for performance \(p=0.038\) and 1.7 for satisfaction \(p=0.001\)). Significant improvements seen were a reduction of tripping and falls and an increase in the distance that could be walked. In the same study the ODFS users also reported 72% fewer falls than a control group (\(p=0.035\)), recorded using a falls diary.

Case series and Retrospective Data
Outcome measures used in the original RCT continued to be collected after the ODFS was introduced into clinical service at Salisbury District Hospital in 1996. A retrospective study reported on 151 patients with a dropped foot who had been using the device for 18 weeks\(^6\). All subjects had a dropped foot resulting from an upper motor neuron lesion, including stroke, MS, or incomplete spinal cord injury. Changes in walking speed and walking effort over a 10-meter distance, as measured by Physiologic Cost Index (PCI), were reviewed and collected from patient charts. Comparisons were made between the walking speed and PCI at the initial device set-up and after the device had been in use for 4.5 months (both with and without stimulation). In a subset of 111 stroke patients, a mean increase in walking speed of 27% (\(p<.01\)) and a 31% reduction in PCI (\(p<.01\)) was observed with the ODFS stimulator in use. These results were based upon a comparison of baseline data without stimulation against 4.5 month follow-up data using the ODFS device. Without stimulation at the 4.5 month follow-up visit, stroke subjects had 14% increase (\(p<.01\)) in walking speed and a 19% reduction in PCI (\(p<.01\)) compared to their baseline measures without stimulation. These results suggest some carryover effect of stimulation. A smaller subset of multiple sclerosis patients had similar orthotic benefit but demonstrated no carry-over effect of stimulation. A small population of SCI patients showed some orthotic benefit and a trend towards carry over affect.

In a subgroup of 27 ODFS users who had had a stroke, walking speed both with and without the device was observed to improve over the first 18 weeks and thereafter remain unchanged\(^7\). As the ODFS users were an average of 5.4(sd ±10.7) years post stroke this supports the hypothesis that the carryover observed was due to use of the stimulator rather than natural recovery following the stroke. In a group of 78 MS subjects, users walked 20% faster when using the device. Although no overall carryover effect was observed, one third showed an improvement in unaided walking speed of more than 10%. In a subgroup of 20 MS users, this improved walking speed with the device was shown to also peak at 18 weeks with no significant change from initial values after that time. 18 MS users of the bilateral dropped foot stimulator showed a 48% increase in walking speed at 18 weeks but again no significant carryover effect although a strong trend was observed. In an audit study by Swain and Taylor 2004 it was shown that in a cohort of 44 people with a dropped foot due to stroke that the improvement in walking speed due to FES was maintained 42 months after first using the device\(^8\).
The main outcome measure used to indicate the effect of FES for dropped foot has traditionally been walking speed. It has been seen as a proxy measure for change in gait quality. However, Barrett and Taylor described a study that measured the effect of the ODFS use on quality of life measured using the Psychosocial Impact of Assistive Devices Scale (PIADS) in a group of 20 people who had MS and 21 who had had a stroke. The PIADS score was taken after 18 weeks of ODFS use. Additionally, walking speed was measured both at the beginning of treatment and at 18 weeks. A statistically significant improvement was recorded in PIADS score in both MS and stroke groups with no statistically significant difference between the groups tested using Fauirier’s Analyses. A similar effect on walking speed was seen as previously shown in published papers. However, it was found that there was no correlation between change in walking speed and the quality of life measure. This indicates that walking speed while indicating an overall improvement in gait does not necessarily reflect the perceived benefit to the user of FES. In a study by Burridge et al. it was shown that the improvement in walking speed and PCI was greater when walking with FES over uneven ground than over smooth surfaces. Study participants completed a 7 question questionnaire about their perception of the effect of the ODFS. It was found that there was a significant correlation between the reduction in PCI when walking on uneven surfaces and the perception score, with a weaker association when walking over smooth surfaces. No relationship was found between change in speed and perception score.

In a study published in 2008 Paul et al measured the oxygen consumption of 12 people with MS while walking with and without the ODFS. It was found that the oxygen consumption fell from 0.46 mL min$^{-1}$ kg$^{-1}$ m$^{-1}$ to 0.41 mL min$^{-1}$ kg$^{-1}$ m$^{-1}$ indicating a statistically significant increase in gait efficiency when the ODFS was used. This result is in line with a questionnaire survey of 43 ODFS users who had MS, 88% of whom reported that walking was less effort when walking with the ODFS. It is also in line with the 1999 audit paper that showed that the physiological cost index, an index derived from the change in heart rate and walking speed indicating the effort used in walking, was reduced by 24%.

Mann et al. investigated the use of the ODFS for prevention of freezing of gait in Parkinson’s Disease. Seven subjects with idiopathic Parkinson’s Disease received single channel electrical stimulation for 8 weeks to the common peroneal nerve to improve heel strike and provide sensory stimulus during the swing phase of gait. Stride length, time and number of steps to complete a 20 meter walk and distance completed in 3 minutes were assessed. Episodes of freezing and incidence of falls were recorded. Walking tests showed an immediate orthotic effect on distance and average stride length at some
assessments during the treatment period but not on number of steps and walking speed. A training effect was observed for all parameters of gait measured. Fewer falls and episodes of freezing occurred during the treatment period. The number of falls returned to pre treatment levels when treatment was stopped.

There is also published literature on the patient’s experience of using FES. Taylor et al. (1999) reported the results of a questionnaire survey sent out to 291 users of the FES service in Salisbury. The questionnaire was returned by 64% of devices users. The mean time of use was 19.5 months. The mean time since CVA was 5 ½ years while for those who had MS the mean time since diagnosis was 12 ½ years. The most commonly reported reasons for using the device were:

- Increased confidence while walking 78.5%
- Reduced effort of walking 77.6%
- Increased walking distance 70.1%
- Reduced risk of tripping while walking 69.2%
- Increased walking speed 61.7%
- Increased independence 51.4%

Of those who used a wheelchair prior to using FES, 32% had reduced their use of the chair while 18% had stopped using it altogether. Of those who required assistance from a carer while walking 46% had reduced their requirement for assistance while 14% no longer required assistance.

In a study by Malone et al. conducted structured interviews with 12 users of the ODFS, six who had MS and 6 who had had a stroke, and their partners / carers. They were asked to describe there lives before and after receiving FES. The users reported that the ODFS had changed their lives. The users were more socially confident with the device, as it reduced the risk of tripping and / or falling. Partners felt more confident leaving the ODFS user alone at home. Overall, the participants wished more people were aware of the device and able to get access to it.

In a long term audit of all 126 patients who began treatment for dropped foot at Salisbury District Hospital in 1999 the average total time the device was used for was 4.9 years (stroke 5.0, MS 5.1 years, SCI 1.6, CP 6.0 years). 26% of the patients were continuing to use the device in August 2010.

**Adverse Effects and Summary**

Only minor adverse effects have been reported from use of the ODFS system, and they are common adverse effects associated with any powered muscle stimulator. In a survey of 107 device users, 22% had experienced some skin irritation from electrodes at some time over an average of 19.5 months. However, these problems had been overcome enabling continued use of the device. Since the survey the Salisbury clinic has changed the type of electrodes used and reduced the maximum period for which electrodes are used for. In a six month period from June 2005 every occurrence of skin irritation occurring in the Salisbury FES clinic was recorded. In that time 585 individual patients were seen in the clinic. 13 cases of irritation were reported. An appeal for honesty to the clinicians working in the clinic indicated some under reporting, estimated to be about 25%. This therefore results in prevalence in the clinic of between 3 and 4 %. However, 8 cases were reoccurrence and 5 first time cases, 3 of whom developing skin reaction in the first 6 months and the other 2 between 12 and 18 months of ODFS use. This means the prevalence of new cases was around 1 to 1.5%. There were no cases of discontinued treatment due to skin irritation in this period. Further, in the randomised controlled trial of the ODFS with people who have secondary progressive MS, there were no reports of skin irritation in the period of the 18 week trial.

Out of a survey of 56 people who had discontinued use of the ODFS, three (3) discontinued due to skin irritation. Five out of the 56 discontinued use of the device due to increased spasticity. While the overwhelming majority tolerated the sensation of stimulation well, one (1) out of the 56 discontinued because they found the sensation to be painful. Other reasons for discontinuation were due to convenience and functional issues not associated with adverse effects. The most commonly cited reason for discontinuation was improvement in mobility such that the device was no longer required.
Cost effectiveness

There are 2 reports that estimate the QALY gain associated with use of FES.

The first report was from the Development and Evaluation Committee of the South and West Regional Health authority 1996\textsuperscript{15, 16}. It was this report that was submitted to the NHS to justify the establishment of the first clinical service for FES drop foot. The report was reviewed and accepted by the Health Authority and is available at http://www.salisburyfes.com/dec.htm. The report used data from the randomised controlled trial of the ODFS performed between 1993 and 1995 with 32 people who had had a stroke. The trial compared the effect of using the device with a standard treatment consisting of physiotherapy. The QALY gain was calculated using a combination of data including change in walking speed and physiological cost index, change in Hospital Anxiety and Depression Index (HAD) and change in a mobility score derived from a custom designed questionnaire closely aligned with the Health Related Quality of Life (IHQL). After 12 weeks of intervention it was calculated that the FES group received a QALY gain of 0.065 while the physiotherapy group had a gain of 0.023, a difference of 0.042. At 1996 prices this gave a cost per QALY of £10,037 over 5 years. In 2007 the report was re-examined and costs per QALY calculated for current prices\textsuperscript{16}. This gave a cost per QALY of £39,047 at one year and between £13,524 and £19,237 at five years. However, this analysis assumes that a comparison is made with an individual who receives physiotherapy. In clinical practice the ODFS is used as a long term aid while physiotherapy is rarely received for more than a few weeks. It may therefore be fair to attribute the whole of the QALY gain seen by FES users rather than the difference between FES and Physiotherapy interventions. This gives a cost per QALY gain of £25,230 at 1 year and between £8,738 and £12,431 at 5 years.

From an audit of patients who began FES use in 1999, it is now known that the average length of time FES was used for was 4.9 years and that the average cost per patient was £2,965 (based on an average of 10.9 hospital appointments per patient)\textsuperscript{17}. It can therefore be calculated that for this cohort of 127 patients and assuming the same QALY gain calculated above, the mean cost per QALY was £9,658, well within the willingness to pay threshold of £30,000 used by NICE. It is not appropriate to apply discounting to the QALY gain as FES is a continuing intervention. This is supported by records of walking speed that demonstrated speed maintained or increased over a time of 3 and half years.

The second economic report was produced by the Purchasing and Supply Agency in February 2010\textsuperscript{18}. It took a different approach to calculating QALY gain. Its main indicator of effect was walking speed. The mean gain in walking speed due to FES was calculated by averaging the results from four published studies, two of which used the ODFS. It was found that the mean increase in walking speed was 0.18 ms\textsuperscript{-1}. The change in walking speed was compared to Perry’s criteria for mobility based on walking speed. Perry calculated that the mean threshold for becoming a moderate community walker was 0.58 ms\textsuperscript{-1} and for becoming a functionally independent walker was 0.80 ms\textsuperscript{-1}. By examining the range of walking speeds it was possible to calculate the proportion of FES users who would cross these thresholds and this could be corresponded to changes in the HUI3 (Health Utility Index v3) scale. The other input to the model was the number of FES users who received dis-benefit due to skin reaction to the electrodes. This was the only reported adverse effect of FES. 22% of FES users were reported as having minor skin irritation while 3% received a major skin reaction sufficient to cause discontinued use of FES. Using this technique an overall QALY gain of 0.041 was calculated. This compares with a QALY gain of 0.042 in the earlier study. A cost per QALY was found at 1 year of £52,336 and at 5 years of £19,238.

The Purchasing and Supply Agency report took data on skin irritation due to electrodes from the 1999 clinical rehab paper on patient’s perceptions of use of the ODFS\textsuperscript{12}. As described above in the section on adverse effects, the types of electrodes used and clinical procedures have since been improved since 1999 and this means the prevalence of new cases in the clinic significantly reduced to around 1 to 1.5%. Further, in the randomised controlled trial of the ODFS with people who have secondary progressive MS, there were no reports of skin irritation in the period of the trial\textsuperscript{4}. Also, in the audit of patients who began use of FES in 1999, only one FES user discontinued FES due to skin reactions in the whole 10 year follow up period\textsuperscript{17}. These results suggest that the dis-benefit effect of skin irritation has been
significantly exaggerated in the Purchasing and Supply Agency report, resulting in a smaller QALY gain than might otherwise have been expected.

Possible cost savings to the NHS due to reduction in falls

In the study by Esnouf et al. it was demonstrated that ODFS users experienced 72% fewer falls than the control group, recorded using a falls diary. No published data on the incidence of falls requiring medical treatment for people with MS could be found. However, data does exist for a general elderly population. Nurmi and Luthje (2002) performed an audit of falls amongst the elderly in institutional care. They reported an incidence of falls of 1398 falls per 1000 person years and that one third of falls resulted in injury. The average cost per injury was €944. The average cost per fall per year was therefore €440. If falls that resulted in injury were reduced by the same proportion as in the ODFS trial, there would be an annual saving of €329 or €1650 over five years. Allowing for an inflation rate of 27% (retail price index) between 2002 and 2010 the annual saving would be €418 (£349) or €2099 (£1755) over 5 years at 2010 prices (exchange rate 14th July 2010). From an individual perspective, the mean time between injuries would increase from 2.15 years to over 7 years.

National Guidelines

NICE IPG278 (2009)

The Interventional procedure Guidelines number 278 produced by the National Institute for health and Clinical Excellence states:

1.1 Current evidence on the safety and efficacy (in terms of improving gait) of functional electrical stimulation (FES) for drop foot of central neurological origin appears adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

In the public information document that accompanies IPG278 summarises the guidelines as follows:

This procedure can be offered routinely as a treatment option for people with drop foot caused by damage to the brain or spinal cord, provided that doctors are sure that:

• the patient understands what is involved and agrees to the treatment,

and

• the results of the procedure are monitored.

Scottish Interventional Guidance Network (SIGN 118)

The Scottish Interventional Guidance Network report (2010); Management of patients with stroke: Rehabilitation, prevention and management of complications, and discharge planning. A national clinical guideline, concludes:

“Functional electrical simulation may be considered as a treatment for drop-foot, where the aim of treatment is the immediate improvement of walking speed and/or efficiency, ”
Conclusion

A review of the published evidence relating to the Odstock Dropped Foot Stimulator (ODFS) demonstrates that the device is an effective orthosis for people with dropped foot due to an upper motor neurone lesion. This is shown by increases in walking speed and reduction in the effort of walking indicated by a reduction of the physiological cost index. For people who have a stroke a training effect in these parameters is also seen. Use of the device is reported as leading to a 72% reduction in falls. The device is well accepted with a mean time of use as an orthosis of 4.9 years. Users of the device report that their walking is less effort, that they are less likely to trip and fall, that they feel more confident while walking and that they can walk further. Improvements in activities of daily living and quality of life are also demonstrated. Partners of ODFS users report that they are less concerned for the safety of their FES using partners when left alone, resulting in an improvement in their own independence. Two independent cost benefit studies indicate that the device is cost effective within the terms used by the NHS. Finally, use of the device is supported by national guidelines.

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