# The Case for the Odstock Dropped Foot Stimulator (ODFS®)

A summary of the published evidence for the Odstock Dropped Foot Stimulator

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May 2015

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The Case for the Odstock Dropped Foot Stimulator (ODFS®)

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Introduction

Dropped foot is a common problem resulting from a range of neurological conditions, in particular multiple sclerosis (MS) and stroke. It is characterised by a deficit in dorsiflexion and eversion in the swing phase of gait, leading to the foot catching on the ground as it is brought forward which can lead to 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 an ankle foot orthosis (AFO), a splint that fits within the shoe, rigidly or semi-rigidly fixing the ankle. While AFOs can be effective, there is little published evidence to support their effectiveness or cost utility. Many people reject AFOs because they can be uncomfortable, heavy, restricting of voluntary movement or sometimes ineffective, leading to a high rate of abandonment. 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 study investigating the use of FES for the correction of dropped foot in MS, only 23% of participants were current AFO users at the start of the trial, 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 effected 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. Co-currently with the motor stimulation sensory Ia afferent nerve fibres are also excited and may, through reciprocal inhibition, inhibit spasticity in the antagonist muscle and hence enable a greater range of motion. 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®) in the 1990’s.

The clinical purpose of FES for the correction of dropped foot

The intervention is intended to provide a practical assistive device enabling 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.

By convention, the effects on the user are described in two ways. The orthotic effect is the direct effect of using the FES when the device is used (FES switched on). The second effect is the training or therapeutic effect and relates to changes in walking ability when not using FES (FES switched off) that can be attributed to using FES for a
period of time. This is sometimes also referred to as carry-over effect, which is the short term improvement in walking immediately following use of FES.

The ODFS has the following practical orthotic 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 in stance improving the safety of weight bearing.
- 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 orthotic effect of using the device as an orthosis there can also be therapeutic effects.

- Most FES users 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.

While the therapeutic effects of FES are of benefit to many FES users, the primary use of the device is as an orthosis, providing practical and effective gait assistance in everyday life.

This review

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 (2014), around 20,000 ODFS units have been produced and the ODFS has been the subject of multiple clinical investigations. There are over fifty published peer reviewed journal articles relating to the ODFS® and many additional reports, articles and abstracts. A summary of the primary clinical trials, case series and retrospective studies relating to the ODFS are presented here. While there is a growing body of literature relating to other FES devices, this is not included in this review except where directly relevant.

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. Measurements of walking speed over a distance of 10 metres 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 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 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.

Wright et al. compared the use of FES or AFO on the gait of 22 participants who were in the recovery stage following a stroke within the last 6 months\(^6\). They were randomly assigned to use either an Orthomerica Supra-Lite AFO or an Odstock Dropped Foot Stimulator (ODFS®) to manage their dropped foot and followed over a 24 week period. Both groups demonstrated significant improvements in walking speed and physiological cost index (t-test, \(p<0.05\)). Both groups showed significantly increased endurance in their walking range (t-test, \(p<0.05\)). This general recovery was also demonstrated by significant improvements in the Rivermead Mobility Index (t-test, \(p<0.05\)). No significant changes in spasticity were observed measured using the Ashworth scale. No significant differences between the groups were observed by ANCOVA on any of these measurements. However, further analysis of the original data examining the change in walking speed over the first 12 weeks, the period that common peroneal stimulation alone was used, showed that the FES improved unassisted walking speed by a mean of 0.14ms\(^{-1}\) compared with an increase of 0.09 ms\(^{-1}\) in the AFO group a statistically significant difference (\(p =0.004\)) shown using a Mann Whitney U test, suggesting that FES had a better training effect than AFO use. This study can be criticised for the relatively small sample size in a population that was changing through natural recovery.

In an RCT, Johnson et al. investigated 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\(^7\). 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 (\(P_{-0.020}\)) 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.

Sheffler et al. performed a randomised controlled trial to investigate the effect on neuroplasticity by comparing the training effect between AFO (ankle foot orthosis) and FES users\(^8,9\). 110 stroke survivors were randomly allocated to either a group who use the ODFS or a group who used a custom made AFO. Subjects were treated for 12 weeks and followed up for 6 months post treatment. Both groups received 2 sessions per week of physiotherapy gait training over the first 5 weeks of the study reducing to 1 session a week in the following weeks. After the intervention period the participants returned to using an AFO if they had used one prior to the study. The principal outcome measure was the Fugl-Meyer Assessment (FMA), an impairment level test designed to detect change in motor function. Secondary measures were the modified Emory Functional Ambulation Profile (a test that derives a score based on measurement of walking speed in 5 different scenarios) recorded without FES (training effect only) and the Stroke Specific Quality of Life (SSQOL) scale. Overall there was no significant change in FMA in either group over the course of the study. However, significant improvements in both mEFAP and SSQOL both at 12 and 24 weeks were seen in both groups. The improvement in walking speed (mEFAP) is consistent with the previous RCTs and suggests that there was a reduction in impairment that the FMA was insufficiently sensitive to measure. Only one of the 16 items in the lower limb section of the FMA relates to ankle
dorsiflexion and the three level scoring system allows only fully (2) partial (1) or absent (0) for each tested movement. It was noted that participants in the FES group who had no active dorsiflexion prior to treatment had some active movement after the intervention. This was not seen in the AFO group. The study concluded that there was no evidence of a motor relearning effect on lower limb motor impairment in either FES or AFO groups. However, both the FES and usual-care groups demonstrated significant improvements in functional mobility and quality of life during the treatment period, which were maintained at 6-month follow-up. The study design can also be criticised for being somewhat removed from standard clinical practice as participants received considerably more physiotherapy gait training than is common.

Two small RCTs have investigated the feasibility of using the ODFS® in early gait training following stroke. While neither was adequately powered to give statistically meaningful between group results, both demonstrated that it was feasible to use FES in sub-acute stroke. In the study by Wilkinson et al. both FES and control groups showed significant improvements (FES turned off) in 10m walking speed, 6 minute walking distance, Rivermead Mobility Index and Canadian Occupational Performance Measure with no difference between groups. The FES group had improved Rivermead Observational Gait Analysis scores, a measure of the quality of gait indicating fewer deviations from normal gait which was not seen in the control group. The FES group walked faster when FES was used. For an adequately powered study 125 participants would be required.

**Multiple Sclerosis**

A randomised controlled clinical trial was conducted with people who have a dropped foot due to secondary progressive multiple sclerosis (SPMS). 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.

While the above trial showed that FES had a beneficial orthotic effect in terms of improved walking speed and reduced incidence of falls, physiotherapy exercises were demonstrated to have a beneficial training effect, while FES did not have this effect. It is common in MS that dropped foot does not present in isolation but is often associated with more proximal weakness in the hip, lower back, and abdominal muscles. The authors suggested that an improved effect may be obtained if FES for dropped foot was combined with core stability exercises. This was tested in a following study where twenty-eight people with secondary progressive multiple sclerosis and unilateral dropped foot participated in a randomized crossover trial. Group1 received FES for correction of dropped foot for six weeks with the addition of hip extension for a further six weeks. In weeks 12–18, FES was continued with the addition of eight sessions of core stability physiotherapy with home-based
exercise. FES and home-based exercise were continued until weeks 19–24. Group 2 received the same physiotherapy intervention over the first 12 weeks, adding FES in the second 12 weeks. It was found that FES for dropped foot correction alone improved walking speed and Rivermead Observational Gait Analysis (ROGA) score, whereas physiotherapy had no effect. Adding gluteal stimulation further improved ROGA score. Both interventions reduced falls (72% for FES alone), but adding FES to physiotherapy reduced them further. FES had greater impact on the Multiple Sclerosis Impact Scale (MSIS-29), indicating improved quality of life. The change in MSIS-29 was equivalent to 1 point fall in EDSS score, suggesting mobility may be returned to the level experienced by a participant on average 3 to 4 years earlier. The study concluded that adding gluteal stimulation to common peroneal stimulation was feasible and that FES for dropped foot can improve mobility and quality of life and reduce falls. Adding gluteal stimulation further improved gait quality. Adding physiotherapy may have enhanced the effect of FES, but FES had the dominant effect.

Case series and prospective audit 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 prospective audit study reported on 151 patients with a dropped foot who had been using the device for 18 weeks. 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-metre distance, as measured by the Physiological 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<0.01) and a 31% reduction in PCI (p<0.01) 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<0.01) in walking speed and a 19% reduction in PCI (p<0.01) compared to their baseline measures without stimulation. These results suggest some carryover effect of stimulation. A smaller subset of multiple sclerosis patients had a similar orthotic benefit but demonstrated no carry-over effect of stimulation. 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. As the ODFS® users were an average of 5.4 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 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 adding gluteal stimulation further improved gait quality. Both groups had an average increase of 27% (p<0.01) in walking speed indicating the effort used in walking, was reduced by 24%.

A number of smaller studies have supported the findings of the larger study. 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 113 people who have had a stroke walking speed increased over the first 18 weeks of FES use and then was maintained at that level over the next 12 months. In a group of 41 MS users, walking speed also increased over the first 18 weeks of FES use. While overall walking speed declined over the next 12 months, the difference between speed with and without was maintained.
indicating continued orthotic benefit from FES (Figure 1). A sub group of 44 people with a dropped foot due to stroke were followed over an extended period. It was demonstrated that the improvement in walking speed due to FES was maintained 42 months after first using the device\textsuperscript{14}.

A recently published study by Street et al. also examined the effect of FES use on FWC and clinically meaningful changes in walking speed for people with multiple sclerosis (pwMS) who have dropped foot\textsuperscript{16}. Perry et al. related walking speed to functional independence defining people with a walking speed of less than 0.4ms\textsuperscript{-1} as household walkers, between 0.4 and 0.58 ms\textsuperscript{-1} as most restricted community walkers, between 0.58 and 0.8 ms\textsuperscript{-1} as least limited community walkers and over 0.8ms\textsuperscript{-1} as non-limited community walkers.\textsuperscript{49} This case series used a consecutive sample of patients collected between 2008 and 2013 at Salisbury District Hospital. One hundred and eighty seven (117 females, 70 males, mean number of years since diagnosis 11.7, median 9, range 1 - 56 years, age range 27-80, average 55 years) pwMS with dropped foot received FES of the common peroneal nerve (178 unilateral, 9 bilateral patients). One hundred and sixty-six pwMS (89\%) continued to use FES after 20 weeks with 153 pwMS completing the follow up measures. A minimal clinical meaningful change was defined as a change in walking speed of between ≥0.05 and 0.1ms\textsuperscript{-1} and a substantial meaningful change defined as 0.1ms\textsuperscript{-1} or greater.\textsuperscript{50} The study found that walking speed was increased by a mean of 0.07ms\textsuperscript{-1} (p<0.001) on the first day FES was used increasing to 0.11ms\textsuperscript{-1} (p<0.001) after 20 weeks, which is a mean average increase of 27\% and a substantial clinically meaningful change. 71\% of pwMS achieved a clinical meaningful change in walking speed at 20 weeks. Overall 90 pwMS were in the lower groups for FWC at the start of treatment with 49 (54\%) improving their FWC after 20 weeks while 8 (5\%) pwMS experienced a decline in FWC. While no overall significant training effect was found, 31\% did experience an increase in walking speed and 38\% a decline. The number of pwMS who achieved a meaningful change in walking speed is summarized in figure 2. The authors concluded that despite the likely deterioration in walking performance over the study period due to the progression of MS, FES is highly effective as an orthotic aid for improving or maintaining mobility.
In the same clinical audit, 67 people with multiple sclerosis (pwMS) were asked about their use of an AFO immediately prior to starting FES use\(^{26,42}\). Twenty five were using AFOs while 27 had used and rejected AFOs and 15 had never used an AFO. Walking speed was measured, both with and without the AFO and FES at the beginning of treatment for 20 of the 25 who were using an AFO\(^{27}\). No significant difference was found in walking speed between wearing an AFO and walking unassisted. However, walking was 0.08 ms\(^{-1}\) (\(p<0.001\)) faster with FES. It is likely that in the majority of cases the motivation for referral for FES was to improve walking more effectively than had been possible using a splint. Hence while this may result in selection bias in this data, it also indicates that there is a significant number of people with dropped foot who are dissatisfied with the gait assistance provided by AFOs.

Singleton and Street used a similar approach to one used in the above study to analyse data collected from the West Midlands Rehabilitation Centre\(^{51}\). 257 pwMS who used FES were followed over the first 6 months of their use of FES. A statistically significant orthotic effect in walking speed was found at base line, 0.08ms\(^{-1}\) (\(p<0.001\)) and at six months, 0.09ms\(^{-1}\) (\(p<0.001\)). No overall training effect was found (0.01ms\(^{-1}\) \(p=0.43\)). 58% achieved a clinically meaningful change in walking speed when walking with FES at six months and 32% walked faster without FES, experiencing a training effect. However, 29% had a reduced walking speed without FES.

**Long term prospective audit data**

The long term use of FES was examined in a study by Taylor et al (2013)\(^{15}\). The study aimed to determine how long the intervention is of benefit and the total cost of its provision. From a retrospective review of medical records one hundred and twenty-six people with spastic dropped foot (62 stroke, 39 multiple sclerosis, 7 spinal cord injury, 3 cerebral palsy, 15 others) who began treatment in the year 1999, were followed for the duration of the FES use. Device usage, reasons for discontinuing treatment, 10 m walking speed and Functional Walking Category (FWC) were recorded. The median time of FES use was 3.6 years (mean 4.9, standard deviation 4.1, 95% confidence interval 4.2–5.6) with 33 people still using FES after a mean of 11.1 years. People with stroke walked a mean of 45% faster overall, including a 24% training effect with 52% improving their FWC. People with multiple sclerosis did not receive a consistent training effect but walked 29% faster when FES was used with 40% increasing their FWC.
Singleton and Street also conducted a long term audit on a cohort of 50 FES users who were followed for 4 years\textsuperscript{14}. The mean orthotic effect at set up was 0.10ms\textsuperscript{-1} (p<0.001) and at 4 years was 0.12ms\textsuperscript{-1} (p<0.001) indicating that the benefit from FES had been maintained. However, unassisted walking declined over the period from 0.59 ms\textsuperscript{-1} to 0.40ms\textsuperscript{-1} p<0.001 due to the progression of MS. Walking speed with FES at 4 years was 0.56ms\textsuperscript{-1} and not statistically different from unassisted walking speed at the start of FES use (p=0.38). The finding was similar to that found by Taylor et al. in their 10 year audit of ODFS\textsuperscript{®} users and indicates, in terms of walking speed, FES had provided a means of achieving the mobility experienced before 4 years of deterioration due to the progression of MS, therefore adding 4 years of improved mobility to their lives\textsuperscript{15}.

Quality of Life

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 device related 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\textsuperscript{17}. 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 Fourier’s Analyses (F-tests). A similar effect on walking speed was seen as previously shown in published papers\textsuperscript{12, 13, 14, 15}. 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\textsuperscript{18}. Study participants completed a 7 item questionnaire about their perception of the effect of the ODFS\textsuperscript{®}. 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.

Recent research on 4516 people with multiple sclerosis using the EQ5D has found a large gap between quality of life for people with multiple sclerosis (mean health state score 59.7 ± 22.4) and the general population (86).\textsuperscript{33} Twenty-seven (mean age 53, range 44-70) people with multiple sclerosis completed the EQ5D-5L questionnaire at baseline and after 18 weeks of using FES.\textsuperscript{33} A significant improvement in quality of life was found between baseline (51.0 ± 22.3) and after using FES for 18 weeks (58.4 ± 22) (p=0.02) and an improvement of 15 points on the VAS was also found (p<0.05). The study suggests that pwMS who have mobility problems have a reduced quality of life compared to the general cohort of pwMS, which includes a wider range of disease progression and that FES improves their quality of life.

The effect of FES on the quality of walking: gait kinematics

Scott et al investigated the kinematic effect of FES in 12 pwMS with relapsing remitting multiple sclerosis who were new users of functional electrical stimulation\textsuperscript{20}. Gait kinematics were recorded using 3D gait analysis. Walking ability was assessed through the 10-metre and the 6-minute walk tests. All assessments were performed with and without the assistance of functional electrical stimulation. Ankle dorsiflexion at initial contact (p=0.026) increased by 5.9º reducing the risk of the toe dragging on the ground. Knee flexion was also increased at initial contact by 2.4º (p=0.044) reducing knee hyperextension and hence helping to protect the knee joint. The peak knee flexion during swing increase by 8.9º (p = 0.011) increasing ground clearance through swing, again reducing the risk of the toe catching the ground. The increased peak dorsiflexion in swing of nearly 4 degrees during functional electrical stimulation assisted walking approached significance (p=0.069). The 10-m walk time was significantly improved by functional electrical stimulation (p=0.004) but the 6 min walk test was not. It was
concluded that the acute application of functional electrical stimulation resulted in an orthotic effect through a change in ankle and knee kinematics and increased walking speed over a short distance in people with multiple sclerosis who experience foot drop.

A study by van der Linden et al. compared the gait characteristics of people with Multiple Sclerosis (pwMS) to those of healthy controls walking at the same average speed and assessed the effects of the acute application of FES for dropped foot correction. Twenty-two pwMS (mean age 49 years), who were new FES users, and 11 age matched healthy controls participated. Three dimensional gait kinematics were assessed whilst pwMS and healthy controls walked at self-selected walking speeds (SSWS). Healthy controls also walked at the average walking speed of the pwMS group and pwMS also walked using FES. Compared to healthy controls walking at their SSWS, pwMS walked slower and showed differences in nearly all gait characteristics \( p<0.001 \). Compared to healthy controls walking at the same average speed, pwMS still exhibited significantly shorter stride length \( p=0.007 \), reduced dorsiflexion at initial contact \( p=0.002 \), reduced plantar flexion at terminal stance \( p=0.008 \) and reduced knee flexion in swing \( p=0.002 \). However, no significant differences were seen between groups in double support duration \( p=0.617 \), or hip range of motion \( p=0.291 \). Acute application of FES resulted in a shift towards more normal gait characteristics, except for plantar flexion at terminal stance which decreased. In conclusion, compared to healthy controls, pwMS exhibit impairment of several characteristics that appear to be independent of the slower walking speed of pwMS. The acute application of FES improved most impaired gait kinematics.

In a second study by van der Linden et al nine pwMS were assessed on four occasions; four weeks before baseline, at baseline and after six weeks and twelve weeks of ODFS use. Joint kinematics and performance on the 10 meter and 2 minute walk tests (10MWT, 2 minWT) were assessed with and without FES. Participants also completed the MS walking Scale (MSWS10), MS impact scale (MSIS29), Fatigue Severity Score (FSS) and wore an activity monitor for seven days after each assessment. Compared to unassisted walking, FES resulted in statistically significant improvements in peak dorsiflexion in swing \( p = 0.006 \), 10MWT \( p = 0.006 \) and 2 minWT \( p = 0.002 \). Effect sizes for the training effect, defined as the change from unassisted walking at baseline to that at 12 weeks, indicated improved ankle angle at initial contact \( 2.6^\circ, 95\% \text{ CI } 21^\circ \text{ to } 4^\circ, d = 0.78 \), and a decrease in perceived exertion over the 2 min walking tests \( 21.2 \text{ points, } 95\% \text{ CI } 25.7 \text{ to } 3.4, d=-20.86 \). Five participants exceeded the Minimally Detectable Change (MDC) for a training effect on the 10mWT, but only two did so for the 2 minWT. While the MSWS12 improved at 6 weeks, no effect of the use of FES were found for MSWS, MSIS29, FSS or step count at 12 weeks.

Shefler et al. investigated the training effect of FES use on the kinematic parameters of gait in a group of 110 stroke survivors who used the ODFS or an AFO for a period of 12 weeks. Both groups received physiotherapy. Kinematic gait analysis was performed at the beginning and end of treatment and 12 and 24 weeks after the intervention was removed. All measurements were taken without FES. Both groups demonstrated a significant improvement in cadence, stride length, walking speed which were found to be associated with increased peak hip and ankle push off power at terminal stance and increased hip flexion at heel strike. Improvements were maintained at follow up. The study indicates that gait training with either FES or AFO is effective at improving the kinematic parameters of gait in chronic stroke.

**Parkinson’s Disease**

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 metre 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 (72% fewer) and episodes of freezing occurred during the treatment period. The number of falls returned to pre-treatment levels when treatment was stopped.

In a second observational study in Parkinson’s disease, Popa and Taylor investigated the effect of combined upper and lower limb Functional Electrical Stimulation (FES) to improve hand function and gait. \(^{23}\) Eleven people with Parkinson’s and Hoehn and Yahr score 2-3 used FES to assist dorsiflexion while walking and hand opening or fine hand movements for 2 weeks. The outcome measures were; the 9-Hole Peg Test, the box and block test, 10m Walking Test, the Tinetti Balance scale, the Modified Parkinson’s Disease Quality of Life questionnaire (PDQL), SPES/SCOPA scale (Short Parkinson’s Evaluation Scale/Scales for Outcomes in Parkinson’s disease) and adherence to treatment. All tests were carried out without FES. Nine participants completed the protocol with two dropping out of the study due to difficulty in using the equipment. A mean increase in walking speed of 0.29ms\(^{-1}\) (p = 0.002), step length of 0.09 m (p=0.007) and cadence of 19.8 steps min\(^{-1}\) (p = 0.045) were recorded using the 10m walking test. There was an improvement in balance demonstrated by an increased by 2.9 (p = 0.006 in the Tinetti Balance score. There was an increase in the number of blocks moved in the Box and Block Test of 5.1 (p=0.025) indicating a clinically meaningful change in hand function. A significant change in the Parkinson’s symptoms score of the PDQL of 4.9 (p = 0.013) and a reduction in the SPES/SCOPA score of -5.7 (p=0.005) indicating a reduction in the impact of Parkinson’s. Overall it was concluded that FES produced significant improvements in gait and upper limb function after a relatively short treatment period, indicating that FES may be a practical therapeutic intervention for bradykinesia.

**Incomplete Spinal Cord Injury**

Two case series studies from independent centres have reported the effect of using the ODFS with people who have incomplete spinal cord injury (ISCI) and found similar effects for the orthotic and training effects of FES. Taylor et al. followed a group of 8 people with ISCI over 18 weeks of FES use. \(^{12}\) A substantial clinical increase in walking speed was achieved with FES at week 18 in comparison to walking without FES at the beginning of treatment, 0.1ms\(^{-1}\) (p < 0.05), an increase of 19%. There was also a trend towards a significant training effect of 0.06ms\(^{-1}\) (p= 0.09), an increase of 12%. The second case series study was performed by Street and Singleton. 22 people with ISCI were followed over 6 months of FES use. The orthotic effect on walking speed at 6 months was found to be 0.12ms\(^{-1}\) (p=0.004), a mean change of 18%. A training effect of 12% or 0.08ms\(^{-1}\) (p=0.04) was also found.

**FES users’ experience**

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. \(^{24}\) The questionnaire was returned by 64% of devices users. The mean time of use was 19.5 months. The mean time since CVA was 5.5 years while for those who had MS the mean time since diagnosis was 12½ 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.

A second questionnaire survey was sent to 286 FES users from which 211 replies were received. The survey found similar results to the above study for how and why the ODFS was use\textsuperscript{25}. Additionally questions were asked about the users attitudes to FES use. The questionaire gave a series of statements and the respondent was asked if they agreed or disagreed with the statement. 92% of CVA and 98% of MS were glad that they had the ODFS and 91% of CVA and 90% of MS would recommend it to another person. 70% of CVA and 73% of MS agreed that its use increased their independence and 85% of CVA and 83% of MS agreed that they were more confident when using the ODFS. 69% of CVA and 71% of MS agreed that it improved their quality of life.

In a study by Malone et al., structured interviews were conducted with 12 users of the ODFS, six were people with MS and 6 had experienced a stroke\textsuperscript{26}. Their partners / carers were also interviewed. They were asked to describe their 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.

A second qualitative study, Bulley et al. also explored the experiences, preferences and choices relating to the use of functional electrical stimulation (FES) for foot-drop and compared it with the experience of ankle foot orthoses (AFOs) by people who have suffered a stroke and their carers\textsuperscript{27, 28}. Semi-structured interviews were used to explore individual experiences using interpretative Phenomenological Analysis (IPA). Nine participants who had used both FES and several types of AFO were recruited from a single FES clinic. Participants described experiences, preferences and choices relating to AFO and FES use. All but one person expressed a preference for FES, relating FES use to being able to move the ankle more freely; walk more normally, safely and independently; and experience greater comfort. Several people used AFOs when the FES equipment failed, when travelling and near water. One person rationed their use of FES on a daily basis due to allergic reactions.

The above studies have frequently found that the safety of gait is an important factor in why people chose to use FES. To explore this further, Street et al. used the Falls Efficacy Scale- International (FES-I) to explore the effect on fear of falling\textsuperscript{29}. The FES-I asks how concerned a person is about falling in 16 different activities/situations and asks to rate their concern on a 4 point scale where 1 = not concerned and 4 = very concerned. If an activity is not done by the person, for example if someone else does their shopping for them, they are asked to imagine how concerned they would be if they did that activity. As an addition to the questionnaire, they were asked to say if they did participate in each activity on the FES-I and rate their participation on a 4 point scale where 1 = regularly, 2 = sometimes, 3 occasionally and 4 = never. The responses to each question were summed (range 16 to 64) and the change in the 2 scores calculated. 31 pwMS complete the questionnaires before starting FES and after 18 weeks of FES use. The median reduction in FES-I score was 6, IQR 1-10 ($p<0.001$) indicating a reduced fear of falling. The participation score also fell by 4.5, IQR 1-9 ($p<0.001$) indicating that FES lead to an increase in participation in activities of daily living. The activities that were most commonly improved by FES were cleaning the house, walking around the neighbourhood, using stairs, shopping, answering the telephone and visiting friends or relatives.

Street et al. examined the effect of FES on patients centres outcome measures using the Goal Attainment Scale (GAS) and perceived level of effort using the Borg scale\textsuperscript{42, + unpublished data}. 56 pwMS and 21 stroke survivors used the ODFS Pace for a period of 18 weeks. Three GAS goals were set at the start of FES use through discussion between the treating clinician and the FES user. The achievement of the goals was reassessed at the second follow up clinic appointment; 18 week after FES was started. Stroke survivors achieved or exceeded 86% of their chosen goal. The most frequently chosen goal areas were...
Increasing walking distance (n=15), reduced fear of falling (n=11), increased level of independence (n=6), improved quality of walking (n=5) and reduced effort of walking (n=4). In the MS group, 67% of goals were achieved or exceeded. The most frequently chosen goal areas for pwMS were increasing walking distance (n=37), improvement in social / functional activities (n=24), reduced fear of falling (n=18), increased level of confidence while walking (n=18) and reduced effort of walking (n=18). The Borg rate of perceived effort scale consist of an 11 point scale were 0 indicates complete rest, 1 very easy, 2 easy, 3 moderate, 4 somewhat hard, 5 hard, 7 very hard and 10 extremely hard. The test is administered at the same time as the 10m walking test with the FES user asked to rate the effort of walking after each 10m walk. The median score reduced from 4 (IQR 3 to 5) to 3 (IQR 2 to 3) when FES was first used. The reduction in effort was maintained at 18 weeks. The perception of reduced effort while walking is in line with the observation of reduced oxygen consumption and physiological cost index both reduce when FES is used.

Singleton and Street used Visual Analogue Scales (VAS) with a range of 0 to 10 to assess the perceived impact of FES on various aspects of walking and quality of life. 50 pwMS who used FES for 4 years recorded VAS outcome measures at set up and each follow up clinic appointment. In all but two cases the VAS score change recorded at 6 months was maintained at 4 years. The perceived frequency of trips and falls changed from a VAS of 8 to 2, confidence while walking from a VAS of 4 to 8, the effort of walking from a VAS 8 to 5 and quality of life from a VAS of 7 to 8. The other two VAS assessments continued to improve between 6 months and 4 years. The Perceived level of Spasticity VAS reduced from 7 to 5 at six months and reduced further to 3 at 4 years. The level of perceived pain reduced from 5 to 3 at six months and reduced to 1 at 4 years. The study indicates that the perceived benefit from FES is maintained throughout its use, despite the progressive nature of MS.

**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 on some occasion 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 developed 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 survey respondents 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. In the 10 year audit of 126 FES users, only 1 person discontinued due to skin irritation.

Cost effectiveness

There are 4 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. 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 £19,821 for one year’s FES use and £10,037 over 5 years. In 2007 the report was re-examined and costs per QALY calculated for current prices. This gave a cost per QALY of £39,047 at one year and between £13,524 and £19,237 at five years depending on the number of follow up clinic appointments received. 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 that 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). 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 the difference in walking speed recorded with and without FES and VAS assessments of the impact of FES on various aspects of walking and quality of life showing it they maintained over the whole period that FES was used for.

A further economic report was produced by the Purchasing and Supply Agency in February 2010. 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⁻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⁻¹ and for becoming a functionally independent walker was 0.80 ms⁻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 which examined data on skin irritation due to electrodes from the 1999 clinical rehab paper on patient’s perceptions of use of the ODFS may have been exaggerated. 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. 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. 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.

The latest study to examine the cost–utility of FES used the EQ-5D-5L questionnaire, the standard health economics instrument, to estimate the health utility index from using the ODFS® Pace. Twenty-seven pwMS completed the questionnaire before beginning FES and again after 20 weeks use. The study showed a QALY gain of 0.074 (p=0.02). A follow-up study from the 1999 audit extended the follow up period to 15 years and provided an updated mean FES use time of 5.5 years for pwMS with a mean number of clinic sessions of 11.7 per person, giving a total mean cost for the whole treatment period of £3,348. Using the EQ-5L-SD derived QALY figure, a cost per QALY of £8,226 can be calculated.

Possible cost savings to the NHS due to reduction in falls

Two studies have shown a 72% reduction in the incidence of falls when FES has been used. 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 44% (retail price index) between 2002 and 2014 the annual saving would be €474 (£374) or €2376 (£1877) over 5 years at 2014 prices. 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 (IPG) 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,
• The results of the procedure are monitored.

Scottish Interventional Guidance Network

The Scottish Interventional Guidance Network (SIGN 118) report (2010); Management of patients with stroke: Rehabilitation, prevention and management of complications, and discharge planning. A national clinical guideline\textsuperscript{38,39}, 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,”

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“There is evidence, mainly from uncontrolled observational studies, to support the use of surface-applied FES for the orthotic improvement of walking speed and reduction in walking effort in patients with dropped foot. Patient acceptability of their treatment appears to be high. There are few major safety concerns.”


Functional electrical stimulation can be used for drop foot of central neurological origin provided normal arrangements are in place for clinical governance, consent and audit\textsuperscript{40}.


This standard aligns itself with the IPG278 NICE guidelines\textsuperscript{41}.

Conclusions

A review of the published evidence relating to the Odstock Dropped Foot Stimulator (ODFS\textsuperscript{®}) demonstrates that the device is an effective orthosis for people with dropped foot due to an upper motor neurone lesion. This is shown by clinically meaningful increases in walking speed leading to improvements in functional walking category and hence indicating a positive impact on quality of life. This improvement in walking speed was also seen relative to walking with AFOs. FES users experience a reduction in the effort of walking indicated by a reduction of the physiological cost index and oxygen consumption while walking. For people who have a stroke, a training effect in these parameters is also observed and this is also observed for 31\% of pwMS. For pwMS, FES can provide approximately 4 years extra mobility in the context of a progressive condition. Kinematic analysis shows that FES causes improvements in ankle knee and hip movement improving efficiency, reducing knee hyperextension and enabling greater ground clearance. Three studies have reported that FES use leads to a 72\% reduction in falls.

The device is well accepted with a mean time of use as an orthosis of 4.9 years for stroke and 5.5 years for MS. 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, that they can walk further and that they experience less pain and spasticity. Improvements in activities of daily living and quality of life are also demonstrated. Partners of ODFS\textsuperscript{®} 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. Four cost/utility 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.
Cited references


19. L Paul, D Rafferty, S Young, L Miller, P Mattison and A McFadyen. The effect of functional electrical stimulation on the physiological cost of gait in people with multiple sclerosis Mult Scler 2008; 14; 954 originally published online Jun 23, 2008; http://msj.sagepub.com/cgi/content/abstract/14/7/95


33. Street T, Taylor P, Swain I. Quality of Life following the use of Functional Electrical Stimulation for Multiple Sclerosis. International FES Society UK and Ireland chapter scientific meeting, Sheffield, UK 8th-9th May 2015


44. Wilkinson IA, Burridge J, Strike P, Taylor P. A randomised controlled trial of integrated electrical stimulation and physiotherapy to improve mobility for people less than 6 months post stroke. Disabil Rehabil Assist Technol, Early Online: 1–7, 2014 Informa UK Ltd. DOI: 10.3109/17483107.2014.917125


51. Singleton C and Street T. The effect of dropped foot stimulation on walking speed for People with Multiple Sclerosis – a longitudinal study. International FES Society UK and Ireland chapter scientific meeting, Sheffield, UK 8th-9th May 2015


Other references relating to the ODFS®


18. Linda Miller, Danny Rafferty, Lorna Paul, and Paul Mattison A comparison of the orthotic effect of the Odstock Dropped Foot Stimulator and the Walkaide functional electrical stimulation systems on energy cost and speed of walking in Multiple Sclerosis. 2015 Disabil Rehabil Assist Technol, Early Online. ISSN 1748-3107 print/ISSN 1748-3115 online, DOI: 10.3109/17483107.2014.898340
Review articles featuring the ODFS®


