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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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[1] 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[48, 67]. 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[2].

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[3] 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[3]. Salisbury District Hospital developed the Odstock Dropped Foot Stimulator (ODFS®) based upon the device first used and described by Liberson. To date (2017), 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.

Study weighting method

The selected studies were rated using the following methods. First they were scored using the van Tuldar assessment method[61]. This method is primarily intended to rate randomised control trials (RCTs). Hence the van Tuldar score is almost always higher for RCTs than for case-series or post-market clinical follow-up. This can give an impression that the latter studies are of poorer quality than the RCTs and hence should be considered less important. However, this fails to take into account that the studies are designed for different purposes and provide different information. It is increasingly accepted that the once afforded status of RCT's as the "gold standard" is limited by the context of the reserach[62, 63, 64, 65]. RCTs, in an effort to control confounding variables to ensure scientific rigour, can sometimes be performed in an artificial environment, perhaps providing considerably more clinical input than would be available in standard clinical practice or use a comparator that is not standard care. This can limit their relevance to standard clinical practice. Well-designed post market clinical follow-up studies can often provide much more realistic information, reporting the "real life" effect, and hence can be considered more ecologically valid. This is particularly the case where the underlying condition is either stable (stroke, spinal cord injury, cerebral palsy) or declining (multiple sclerosis, Parkinson's Disease or hereditary spastic paraparesis) enabling the assumption that any treatment effect observed is very likely to be due to the intervention and not spontaneous recovery. To address these concerns the studies were therefore given an ecological validity score 1 to 4, where 1 indicated a laboratory based design, 2 indicated a clinical procedure substantially modified by experimental design and / or nonstandard care comparator, 3 indicated standard clinical practice with some modification by experimental design and 4 indicated a standard clinical practice. To address the issue that evidence is not available for various aspects of the clinical effect of FES from the ODFS Pace, a relevance score was also devised as follows: ODFS Pace 5, ODFSIII 4, Other footswitch controlled dropped foot stimulators 3, Tilt sensor controlled dropped foot stimulators 2, Other dropped foot stimulator 1. Where sufficient evidence is available directly from ODFS devices alone, only this evidence is provided. Where there is insufficient evidence from ODFS devices, evidence from similar devices is presented. The assessment form is presented below.

Table 18 Study assessment form

Ref no.	**Study**

Van Tuldar Criteria	**Yes =1 No =0**
1. Were the eligibility criteria specified?	
2. Was a method of randomization performed?	
3. Was treatment allocation concealed?	
4. Were prognostic indicators similar for groups at baseline?	
5. Were the index and control interventions explicitly described?	
6. Was the care provider blinded to the intervention?	
7. Were co-interventions avoided or comparable?	
8. Was the compliance reported in all groups?	
9. Was the patient blinded to the intervention?	
10. Was the outcome assessor blinded to the intervention?	
11. Were the outcome measures relevant?	
12. Were adverse effects described?	
13. Was the withdrawal/dropout rate described?	
14. Was a short-term follow-up measurement performed? (<1year)	
15. Was a long-term follow-up measurement performed? (>1year)	
16. Was timing comparable for outcome assessment in both groups?	
17. Was the sample size for each group described?	
18. Did the analysis include an intention to treat analysis?	
19. Was the variability given for primary outcome measures?	
Total	
Relevance score: ODFS Pace 5, ODFSIII 4, Footswitch controlled DFS 3, Tilt sensor controlled FES 2, Other dropped foot stimulator 1	
Ecological validity score. 1. Lab based design 2. Clinical procedure substantially modified by experimental design and / or nonstandard care comparator 3. Standard clinical practice with some modification by experimental design 4. Standard clinical practice.	
Size **(**total n)	
Condition	
Design (RCT, Case series, Case-control, PMCF)	

The following table summarises the scoring of the studied used in this review. Additionally the study size, design and main findings are also presented. Main findings are presented as orthotic effects (OE) where outcome measures are recorded while using the device and therapeutic effects (TE) where outcome measures are recorded without FES being used. The latter indicates the training effect from FES.

Table 19 Summary of reviewed studies scores

Ref No.	1st Author + date	Van Tuldar score	Relevance score	Ecological validity score	Number of participants	Condition	Design	Main findings
1*	Esnouf 2010	13	4	3	54	MS	RCT	OE-TE 72% fewer falls, improved ADL
3	Liberson 1961	6	3	1	7	CVA	CS	Improved muscle activity TE
4*	Burridge 1997	11	4	3	32	CVA	RCT	Increased OE speed, reduced PCI
5*	Burridge 1997	11	4	3	32	CVA	RCT	Reduced TE Quadriceps spasticity
6*	Wright 2004	12	3	3	22	CVA acute	RCT	Faster improvement in TE speed. Same as AFO for OE
7*	Johnson 2004	13	4	3	21	CVA	RCT	Improved TE + OE speed, PCI and Rivermead motor assessment
8+	Sheffler 2013	13	4	2	110	CVA acute	RCT	Improved TE mEFAP, SSQOL improved but no dif with AFO. No effects on FMA
9+	Sheffler 2015	13	4	2	110	CVA acute	RCT	TE improved speed, cadence, stride length, hip and ankle power and hip flexion. No dif with AFO group
10*	Barrett 2009	10	4	3	53	MS	RCT	OE speed and distance, no TE Control group had TE
11*	Taylor 2013	12	3	2	28	MS	RCT	FES TE and OE improvements in ROGA, Speed and MSIS29 Compared to Exercise
12*	Taylor 1999	8	4	4	160	CVA, MS, SCI	PMCF	TE and OE increase in Speed and PCI
13*	Taylor 2002	5	4	4	47	CVA, MS	PMCF	OE speed maintained long term both groups, TE speed CVA only. FES cost-effective
14*	Swain 2004	7	4	4	158	CVA, MS	PMCF	OE speed maintained long term both groups, TE speed CVA only
15*	Taylor 2013	10	4	4	127	CVA, MS, SCI	PMCF	Mean time of FES use 4.9years. FES cost effective.
16*	Street 2015	8	5	4	187	MS	PMCF	OE speed increase

17*	Barrett 2010	8	4	4	41	CVA, MS	PMCF	Improved QoL
18*	Burridge 2007	6	4	4	20	CVA, MS	PMCF	OE Increased reduction of effort walking on uneven surfaces
19+	Paul 2008	6	4	3	12	MS	PMCF	OE Reduce O^2 consumption with FES
20+	Scott 2013	7	4	1	12	MS	CS	OE Improved dorsiflexion and knee flexion. Reduce knee hyperextension. Increased speed
21+	Van Der Linden 2014	6	4	1	22	MS	CS-C	OE FES improved gait kinematics, except push off
22*	Mann 2008	8	4	2	10	PD	CS	TE+OE FES improved speed, step length, distance and freezing. OE only reduced falls
23*	Popa 2013	9	5	3	11	PD	CS	TE Increase speed, step length and QoL. Reduced PD symptoms.
24*	Taylor 1999	9	4	4	121	CVA, MS, SCI	PMCF	FES improved confidence, reduces falls and effort. Device used full time by 50%, and part tome by remainder.
25*	Taylor 2004	8	4	4	211	MS, CVA	PMCF	FES improves, Independence, confidence and QoL, and reduces effort.
26*	Malone 2002	5	4	4	12	CVA, MS	PMCF	FES has a big impact on device users and their carers.
27+	Bully 2001	7	4	4	9	CVA	PMCF	8/9 users preferred FES to AFO. Ankle freer, walking more normal, safer and more independent. FES more comfortable.
28+	Wilkie 2011	5	4	4	13	CVA	PMCF	See ref 27.
29*	Street 2015	7	5	4	31	MS	PMCF	FES users less concerned about falling and achieved more ADL
31*	Swain 1996	12	4	4	32	CVA	RCT	FES is cost effective.
32*	Taylor 2007	12	4	4	32	CVA	RCT	FES cost effective over 5 years
33*	Street 2015	6	5	4	27	MS	PMCF	EQ-5D-5L value for QALY gain = 0.114
42*	Street 2014	5	5	4	40	MS	PMCF	Improved walking speed with FES compared to AFO.
43*	Salisbury 2013	12	4	3	16	CVA acute	RCT	FES is feasible with sub-acute stroke patients.

44*	Wilkinson 2014	13	4	3	20	CVA acute	RCT	FES is feasible with sub-acute stroke patients. OE speed increase.
45*	Van der Linden 2014	8	4	3	9	MS	CS	FES improved OE kinematics.
47*	Taylor 2014	10	4	4	39	MS	PMCF	Mean FES use 5.5 years and cost effective
51+	Singleton 2015	5	5	4	257	MS	PMCF	OE speed at 18 weeks and 4 years. No TE
52	Khurana 2013	4	1	1	20	MS	RCT	FES OE reduces energy expenditure compared to AFO.
54 *	Taylor 2017	5	5	4	71	MS, CVA	PMCF	EQ-5D-5L value for QALY gain = 0.114. FES V cost effective
55*	Durham 2004	9	4	3	12	CP	CS	OE improved gait kinematics.
56	Bailes 2016	8	3	2	12	CP	CS	OE improved speed and 6m distance. TE improvement in obstacle avoidance.
57	Pool 2016	13	2	3	32	CP	RCT	OE on dorsiflexion, stance time and step length.
58	Pool 2016	13	2	3	32	CP	RCT	Improved ADL with FES use
59	El-Shamy 2016	9	2	3	34	CP	RCT	OE improved general gait parameters
60+	Marsden 2012	6	4	4	11	HSP	CS-C	OE improved speed, ground clearance and dorsiflexion.
66+	Juckes 2019	10	5	4	82	MS	CS-C	Improved speed, PIADS, EQ-5D-5L cost effective.
67+	Renfrew 2019	15	5	3	85	MS	RCT	Comparison with AFO, both groups improved speed but AFO group did not achieve MCID. FES had improved PIADS and cost effectiveness poor AFO adherence
68*	Taylor 2020	15	5	3	64	PD	RCT	Comparison with normal care. TE bradykinesia / walking speed.

Abbreviations

CS case series, CS-C case series with matched (non-randomised) control group, CP cerebral palsy, CVA cerebral vascular accident (stroke), HSP hereditary spastic paraparesis, MS multiple sclerosis, OE orthotic effect, PD Parkinson's disease, PMCF post market clinical follow-up (study using prospective data from standard clinical practice) RCT randomised controlled trial, TE training effect. *Study from Salisbury, +Study using equipment and techniques developed in Salisbury

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[4, 5]. 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 $0.14 ms^{-1}$ 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*_.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[43, 44]. 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)[2, 10]. 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[11]. 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.

Post Market follow up

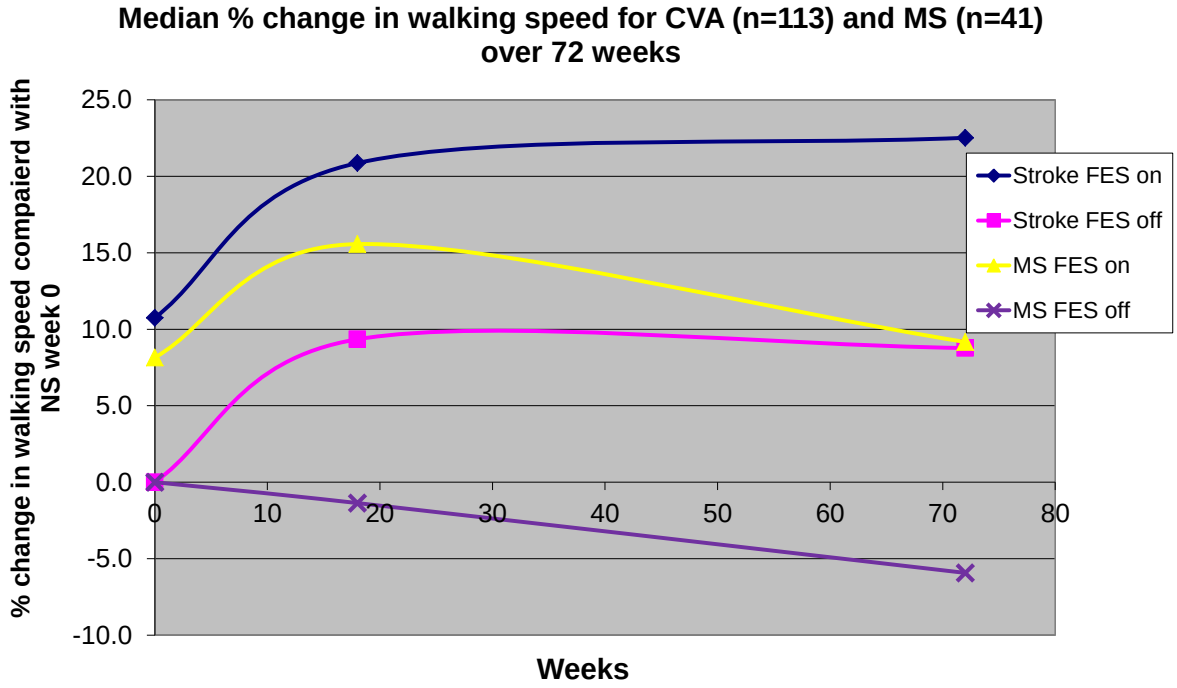
Case series data

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[12]. 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 ($p<0.0l$) 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 ($p<0.0l$) in walking speed and a 19% reduction in PCI ($p<0.0l$) 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[7]. 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®[19]. 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®11. 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%[12].

A number of smaller studies have supported the findings of the larger study[12]. 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%[13]. 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[14]. 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[14].

Figure 1



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[16]. Perry et al. related walking speed to functional independence defining people with a walking speed of less than 0.4ms^{-1} as household walkers, between 0.4 and 0.58 ms^{-1} as most restricted community walkers, between 0.58 and 0.8 ms^{-1} as least limited community walkers and over 0.8ms^{-1} as non-limited community walkers[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^{-1} and a substantial meaningful change defined as 0.1ms^{-1} or greater[50]. The study found that walking speed was increased by a mean of 0.07ms^{-1} (p<0.001), on the first day FES was used increasing to 0.11ms^{-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.

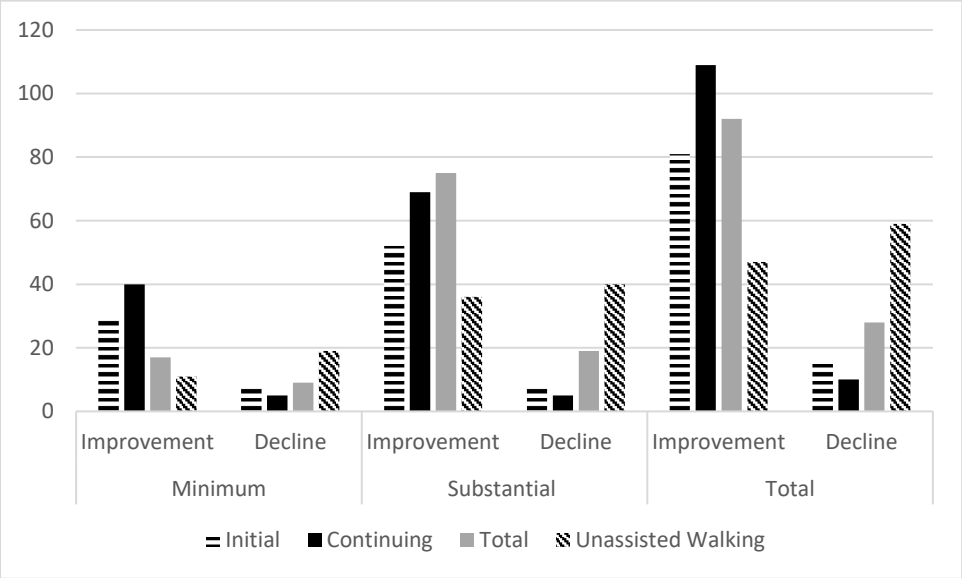


Figure 2

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[51]. The mean orthotic effect at set up was 0.10ms-1 ($p<0.001$) and at 4 years was 0.12ms-1 ($p<0.001$) indicating that the benefit from FES had been maintained. However, unassisted walking declined over the period from 0.59 ms-1 to 0.40ms-1 $p<0.001$ due to the progression of MS. Walking speed with FES at 4 years was 0.56ms-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® 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.

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[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[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[18]. Study participants completed a 7 item 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.

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).[53] 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. [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 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[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[21]. 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[45]. Joint kinematics and performance on the 10 meter and 2 minute walk tests (10WT, 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 (2.6º, 95% CI 21º to 4º, d = 0.78), and a decrease in perceived exertion over the 2 min walking tests (21.2 points, 95% CI 25.7 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 effects 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[9]. 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[22]. 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.

In a small RCT by Taylor et al., 64 pwPD were randomly allocated 1:1 to receive either usual care or FES with usual care for 18 weeks, followed by 4 weeks of FES withdrawal[68]. Outcome

measures were recorded by blinded assessors at baseline, weeks 6, 18 and 22, while intervention participants were not wearing the FES device; assessments were made in the 'on' phase of PD (when medication is effective) and at the same time in relation to the participants' daily medication schedule. Blinding of assessors was maintained for 80% of participants. The mean between-group difference in walking speed was 0.14ms^{-1} (95% CI: 0.03 to 0.26) at week 18 in favour of the treatment group, which was slightly reduced at week 22, 0.10ms^{-1} (95% CI: -0.05 to 0.25). There was a clinically meaningful difference in the Unified Parkinson's Disease Rating Scale (UPDRS) motor score of -3.65 (95% CI: -4.35 to 0.54) at week 18 in favour of the treatment group, which was lost at week 22 (mean difference -0.91 (95% CI: -2.19 to 2.26).

Twenty-five participants in the functional electrical stimulation group completed the "change questionnaire" at week 18. This purpose designed questionnaire assessed participants opinion of what aspects of PD had changed since using FES. The most frequently identified factor moderately or considerable improved was walking speed (n=11 participants). The opinion on what was the most important factor was split across 9 factors, the most frequently identified being confidence that walks can be completed. Discussion held with a group of participants confirmed that confidence was the most important factor. Confidence is not well aligned with the outcome measures used in the study. However, change in self-reported confidence was found to be strongly correlated with self-reported change in walking speed r_s=0.874, which also correlated with self-reported change in overall walking ability r_s= 0.904, indicating that walking speed is an appropriate surrogate measure. Qualitative data from participant interviews suggested increased speed was often associated with an increase in confidence in mobility and a reduced fear of falling. This appeared to have an impact on participation in activities of daily living, social events and perceived confidence when engaging in these activities. The FES group experienced fewer falls that resulted in an injury than the normal care group.

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.

Neurodevelopmental Disorders and FES

There is less research for the use of FES for the lower limb in neurodevelopmental disorders, however the available research has been largely supportive of the effectiveness, acceptability and safety of using FES with neurodevelopmental disorders such as cerebral palsy (CP) and Hereditary and spontaneous spastic paraparesis (HSP).

Cerebral Palsy

The term cerebral palsy (CP) is used to describe a group of disorders caused by non-progressive brain damage. CP is often accompanied by secondary musculoskeletal impairments which are characterised by a combination of gastrocnemius muscle spasticity, contracture, ankle dorsiflexion, weakness and poor ankle selective motor control. There are few studies that have been conducted on the effectiveness of FES for the lower limb in CP. One of the first studies examined the effect of FES applied to the anterior tibial muscles in a group of 10 children with CP who walked with a toe stepping gait (mean age 9.1 years). The main outcome measure was heel-toe interval measured using gait analysis. Outcome measures were taken at set-up, after three months of using the device and three months after discontinuing. A significant benefit in heel-toe interval and immediate significant orthotic effect in walking speed was found at set-up. No training or therapeutic effect was found. The sample size for the study was small and the design did not allow comparison with alternative treatments. No adverse events or other complications were reported from the study. The study suggests that the ODFS® III is effective for children with CP and provides support for further work. (Durham et al., 2004, physiotherapy)

The study by Durham et al., 2004 conducted using the ODFS® III can be used to support the acceptability of using the device with CP, however, due to the lack of studies examining the ODFS® III, further studies using other commercially available devices are included here to further assess effectiveness, acceptability and any residual risks associated with the device. The *Ness L300* works in a very similar way to the ODFS® Pace using a footswitch to trigger stimulation timed to the swing phase of the gait. A recent case series including 11 children with CP (mean age 9 years 11 months) required participants to use the device during an accommodation period of 4 weeks followed by 12 weeks of treatment. Interestingly, no significant initial orthotic effect was found in this study but a total orthotic effect was found for walking speed, six minute walk test. A significant therapeutic or training effect was only found on a Standardized Walking Obstacle Course (SWOC). The authors suggest that children with CP should be provided with a period of time to accommodate to using FES before deciding on the long term benefits (Bailes et al., 2016). Although there are a lack of studies conducted with CP using an ODFS® III or ODFS® Pace, there have been some recent randomised controlled trials examining the effectiveness of FES with this population using the *Walkaide* FES system. Electrical stimulation from the *Walkaide* FES device is triggered using a tilt sensor rather than a footswitch which the ODFS® Pace uses, therefore the results from these studies should be interpreted with caution.

One randomised controlled trial (Pool et al., 2015) included 32 children with CP (average age 10 yrs 3 months). The intervention group received eight weeks of daily FES with the *Walkaide system* (four hours per day, six days per week), while the control received standard care. The participants were assessed at baseline and after eight weeks of treatment followed by six weeks

of follow-up without FES. The treatment group had an increased ankle angle at initial contact (mean difference 11.9°, 95 % CI 6.8° to 17.1°; $p < 0.001$; $d = 0.6$), increased ankle angle in maximum dorsiflexion in swing (mean difference 8.1°, 95 % CI 1.8 to 14.4°; $p = 0.007$; $d = 0.4$), increased normalized time in stance (mean difference 0.27, 95 % CI 0.05 to 0.49; $p = 0.011$; $d = 0.4$) and increased normalized step length on the affected side (mean difference 0.06, 95 % CI 0.003 to 0.126; $p = 0.035$; $d = 0.4$) post treatment compared to the control group while using FES. No significant therapeutic effect was found for any of the above measures apart from a borderline significant effect for increased normalized time in stance (mean difference 0.23, 95 % CI − 0.001 to 0.47; $p = 0.050$; $d = 0.4$). Potentially, the study intervention period of eight weeks was too short to see the full benefits of FES. Further randomised controlled trials should consider providing a period of several weeks as the case series by Bailes et al., (2016) suggests to accommodate to using the device and have a longer intervention period. In terms of risk there were no reported unintended effects or adverse events from using the device in this study.

Another recent randomised controlled trial (n=34) examined the effects of FES on gait pattern and energy expenditure over a period of three months. The intervention group received functional electrical stimulation for two hours a day three days a week, while the control group participated in physiotherapy for the duration of the study. The Gaitrite system was used to evaluate gait parameters and an indirect calorimeter was used to assess energy expenditure. Researchers found an overall significant improvement in gait parameters ($p<0.005$) (El Shamy e and Abdelaal, 2016, abstract only accessed 12/04/2017, full text requested).

There has also been some qualitative work using the Canadian Occupational Performance Measure (COPM) examining whether FES is effective in improving self-perceptions of individually identified mobility performance problems. The study included 32 children with CP (average age: 10 years, 8 months). Participants were randomly assigned to the intervention group which consisted of daily FES, or the control which was standard care. After eight weeks of intervention or control, participants were again assessed after a six week follow-up during which they received no treatment. The results found significantly higher performance scores (mean difference 1.6, 95 % CI 0.1 to 3.2, p = 0.034) and satisfaction scores post treatment (mean difference 2.4, 95 % CI 0.5 to 4.2, p = 0.004) compared to the control group. However no significant difference was found between groups after the six week follow up for performance but there was a small but significant difference for satisfaction (mean difference 1.9, 95 % CI 0.1 to 3.8, p = 0.03). In terms of risk, there were no reported adverse effects from using the FES device in this study. The study suggests that FES is useful for improving self-perceptions of individually identified mobility performance problems.

Familial Spastic Paraplegia

HSP is a heterogeneous degenerative condition associated with a dying back axonal degeneration affecting the corticospinal tracts, dorsal columns and spinocerebellar tracts. HSP is characterised by weakness, spasticity and stiffness predominantly experienced in the lower limbs which result in difficulties with walking and balance. Similarly to other causes of foot drop people with HSP are at a greater risk of tripping and falling due to impaired dorsiflexion. There is only one study which has examined the effectiveness of FES in people with HSP which compared 11 long term users (average 2.6 years +/-1.6) of FES with healthy controls (n=11). Researchers examined ankle muscle strength, stiffness and walking speed along with lower limb kinematics. FES resulted in a small but significant increase in walking speed ($p<0.05$), a

significant difference was also found for improved toe clearance and maximal dorsiflexion. The study design was limited in only examining the orthotic effect following the use of FES in a group of people with HSP who had used FES in the past. Therefore, the study design did not allow the examination of a training or therapeutic effect and the size of the orthotic effect may have been masked by not using a true baseline. The study was also potentially underpowered due to the small sample size (Marsden et al., 2012). In terms of risk the study did not report on any adverse events or complications following the use of FES.

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 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.

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[25]. Additionally questions were asked about the users attitudes to FES use. The questionnaire 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[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[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[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[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 gaol 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 compete 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[19, 52] and physiological cost index[4, 12] 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[51]. 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[24]. 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[30]. 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[10].

Out of a survey of 56 people who had discontinued use of the ODFS®, three (3) discontinued due to skin irritation[24]. 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[15].

Cost effectiveness

There are 6 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[31, 32]. 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[32]. 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)[15]. 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[15, 51].

A further economic report was produced by the Purchasing and Supply Agency in February 2010[34]. 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[24]. 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[10]. 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[15]. 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.

Street et al. examined the cost – utility of FES using the EQ-5D-5L questionnaire, the standard health economics instrument, to estimate the health utility index from using the ODFS® Pace[33]. 45 pwMS and 27 pwCVA completed the questionnaire before beginning FES and again after 20 weeks use. The study showed a QALY gain of 0.114 (p=0.02) in both groups. Justified by the observation that the mean increase in walking speed due to FES remains steady throughout the time FES was used, the QALY gain was extrapolated over 4.9 years giving a total gain of 0.542 after discounting at 3% per year. From the long term audit the mean cost was £3095, giving a mean cost per QALY of £5,705.

In a similar study design, Juckes et al. recorded the walking speed, EQ-5D-5L and PIADS of 82 consecutive pwMS who received the ODFS Pace over 6 months[66]. An increase in walking speed from 0.670m/s without FES at the start of treatment to 0.768m/s with FES at 6 months was fund ($p<0.001$). The Utility index changed from 0.486 to 0.596 ($p<0.001$) over the same period giving a QALY gain of 0.110 and an estimated cost per QALY over 5 years of £6137. Statistically significant changes were also recorded in all 3 domains of the PIADS indicating improved devise related quality of life.

Renfrew et al. compared the effect of using the ODFS Pace with a custom moulded ankle foot orthosis[67]. 85 pwMS who had not used either FES or AFO for dropped foot correction were randomly allocated to each group and used the interventions for 12 months. While both interventions improved walking speed over 12 months twice as many participants in the AFO group (21) discontinued the intervention than the FES group (11), primarily due to discomfort from wearing the AFO. FES users reported higher PIADS score indicating a greater device related quality of life ($p=0.001$). Despite higher costs for the FES group, because of a greater QALY gain, there was an incremental cost-effectiveness ratio of £14,285, modelled over 2 years, indicating the FES gave better value for money than an AFO.

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[2, 10]. 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[35]. 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

(exchange rate 14th July 2014). 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[36] 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[37] 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

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[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,"

Evidence Note 46 - The use of functional electrical stimulation (FES) in adults with dropped foot. Quality Improvement

> "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."

Intercollegiate working party for stroke, (2012) National clinical guidelines for stroke London, Royal College of Physicians 4th edition

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[40].

Multiple sclerosis: Management of multiple sclerosis in primary and secondary care. CG186 (2014)

This standard aligns itself with the IPG278 NICE guidelines[41].

Cerebral palsy in adults NICE guideline [NG119]

The guidelines recommends consideration of a referral to an FES service for mobility[70]

Paediatric FES Guidance (Association of Chartered Paediatric Physiotherapists Chartered Society of Physiotherapy)

Guidance in the use of FES to assist walking and other activities in children, predominantly with cerebral palsy[71].

ACPIN Clinical Practice Guidelines

Evidence Based Clinical Practice Guidelines for the use of Functional Electric Stimulation to improve mobility in adults with lower limb impairment due to an upper motor neuron lesion[76].

USA

Academy of Neurologic Physical Therapy A Clinical Practice Guideline for the Use of Ankle-Foot Orthoses and Functional Electrical Stimulation Post-Stroke

These guidelines summarise the evidence for AFO and FES in a series of domains: Quality of Life, Gait Speed, Other Mobility, Dynamic Balance, Walking Endurance, Plantarflexor Spasticity, Muscle Activation and Gait Kinematics. While the guidelines conclude that there is strong evidence for both class of device, FES my have a greater therapeutic effect[69].

Canada

FES for dropped foot[72]

Foot drop stimulators for foot drop: A review of clinical-, cost-effectiveness and guidelines:- In people with foot drop caused by stroke, functional electrical stimulators (FES) seems to lead to the same functional outcome (walking speed) and Body Functions & Structures outcomes compared to ankle and foot orthosis (AFO), and the combination of FES and rehabilitation seems to improve walking speed compared to rehabilitation alone. FES may significantly reduce the perceived exertion compared to AFO in those with multiple sclerosis-related foot drop.

Other Canadian guidelines[73, 74, 75]

Conclusions

A review of the published evidence relating to the Odstock Dropped Foot Stimulator (ODFS®) indicates 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.

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 significant training effect is also observed. 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® 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. Finally, use of the device is supported by national guidelines.

The ODFS is a clinically and cost effective long-term assistive device for people with dropped foot due to upper motor-neurone lesions.

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