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ORIGINAL REPORT

THE LONG-TERM COST-EFFECTIVENESS OF THE USE OF FUNCTIONAL ELECTRICAL STIMULATION FOR THE CORRECTION OF DROPPED FOOT DUE TO UPPER MOTOR NEURON LESION

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Objective: **Functional Electrical Stimulation (FES) for correction of dropped foot has been shown to increase mobility, reduce the incidence of falls and to improve quality of life. This study aimed to determine how long the intervention is of benefit, and the total cost of its provision.**
Design: **Retrospective review of medical records.**
Participants: **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.**
Method: **All received common peroneal nerve stimulation, producing dorsiflexion and eversion time to the swing phase of gait using a heel switch. Device usage, 10 m walking speed and Functional Walking Category (FWC) were recorded.**
Results: **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. The average treatment cost was £3,095 per patient resulting in a mean cost per Quality Adjusted Life Years of £15,406.**
Conclusion: **FES is a practical, long-term and cost-effective treatment for correction of dropped foot.**

Key words: gait; CVA (cerebrovascular accident); multiple sclerosis; spinal cord injury; drop foot; cost analysis; electrical stimulation.

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INTRODUCTION

Functional Electrical Stimulation (FES) is a means of providing movement in paralysed muscles to assist with practical activities. FES has been shown to be a practical intervention for the correction of dropped foot, increasing walking speed (1, 2, 3, 4), reducing the effort of walking (5, 6) and incidence of falls (7), to have a positive impact on activities of daily living (7, 8, 9) and on quality of life (10, 11). Additionally the technique has also been shown to have a training effect on walking speed in stroke and other non-progressive neurological conditions (3, 12, 13).

There have been two economic evaluations of the technique. The first followed the original randomised controlled trial of the Odstock Dropped Foot Stimulator (ODFS) (1, 14, 15). Benefits to the FES users' quality of life were demonstrated by using the Index of Health-related Quality of Life (IHQL) (16). IHQL produces an index related to quality of life by relating physical disability and distress. Disability was measured by combining the results of the walking speed, Physiological Cost Index and a mobility questionnaire. Distress was demonstrated using the Hospital Anxiety and Depression scale. The derived scores were entered into the Rosser matrix and Quality Adjusted Life Years (QALY) scores derived. The control group who received physiotherapy alone had a 0.023 QALY mean gain while group that received both physiotherapy and FES achieved a 0.065 QALY mean gain, a difference of 0.042.

The second economic report was produced by the UK's Purchasing and Supply Agency in February 2010 (17) (CEP10012). It took a different approach to calculating QALY gain. Its main indicator was walking speed. The mean gain in walking speed due to FES was calculated by averaging the results from 4 published studies, 2 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 (18). 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 mean and standard deviation in the change of walking speeds it was possible to calculate the proportion of FES users who would cross these thresholds (28%) and this could be corresponded to changes in the HUI3 (Health Utility Index v 3) scale (19). 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. Twenty-two percent 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.

While these studies demonstrate that FES can be a cost effective intervention, it is not known for how long individuals may

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benefit from the technique or the total cost of treatment provision. The purpose of this study was to determine the long-term effectiveness of FES, the mean time of its use, reasons for discontinuing use and the clinical costs in providing the treatment.

METHOD

Patients with dropped foot were referred for treatment by a General Practitioner or Medical Consultant with the majority funded by the UK's National Health Service. The clinical procedure is described elsewhere (5).

Patients were first assessed for suitability of treatment by trying the device. If walking could be improved with either the Odstock Dropped Foot Stimulator (ODFS) or the 2 channel version, the Odstock 2 Channel Stimulator version 2 (O2CHSII), they were invited back to the clinic on two consecutive days to be taught how to use the device. Follow-up was provided at 6, 18 and 42 weeks and then every 6 or 12 months for as long as the device was used. Ten metre walking speed was recorded at the start of treatment and at each follow-up appointment by the treating clinician. If use of FES was discontinued, a standardised questionnaire was completed to record the reasons for discontinuing. The FES equipment was returned to the clinic at discharge.

All patients who began treatment in 1999 were identified from clinical records and their primary diagnosis, time since onset, age at start of treatment, gender, affected side, ankle-foot orthosis usage before treatment and their normal maximum walking distance recorded. The total number of clinic appointments and the date of discharge from the clinic for each patient was then determined. It was found that approximately half of patients, who discontinued FES use, stopped using FES between clinic appointments and did not return to clinic for the scheduled follow-up. In these cases the FES usage time was calculated to be the time to the last appointment plus a time equal to the period between the two previous appointments. In all other cases FES usage time was taken as the time till discharge or, if FES was still being used, the time to the date of this review. Walking speed measurements both with and without FES were recorded at each appointment (3). As this was a retrospective review of clinical records and patients had prospectively been informed that anonymised clinical data would be used for research purposes in accordance with the institution's clinical governance procedures, no ethics committee review was required for this work.

Analysis

The results were summarised using descriptive statistics. Costs were calculated by taking the mean number of clinic appointments and charging £140 for the first assessment and £300 for each subsequent clinic appointment (2012 prices). This standard hospital tariff covers all device, consumables and clinical costs. The mean cost was then divided by the mean time of FES use and then divided by the QALY gain from CEP10012. As with the CEP10012 report, no discounting was used in the economic analysis as the benefit from the intervention is concurrent with the use of the device. Walking speed both with and without FES was examined at the beginning of treatment, from 100 days onward since starting treatment and over the whole treatment period. The 100 day onward data was chosen because it was representative of the effect of the device once the user had become accustomed to the device. Walking speed changes were tested using paired Student *t*-tests (Excel).

The clinical utility of the intervention was estimated by the number of patients who crossed between functional walking categories in the first 16.5 months of treatment. This period was chosen because data was available on all the patients included in the review. The walking speed ranges for each functional category, taken from Perry et al. (18) were:

- $< 0.4 ms^{-1}$, Household walking only
- 0.4 to 0.58 ms^{-1}, Most limited community walking
- 0.59 to 0.79 ms^{-1}, Least limited community walking
- ≥ 0.8 ms^{-1}, Community walking

A criticism of this approach is that small change may be sufficient to change category if the initial walking speed is near a threshold while a large change may be insufficient to cause a change if the starting speed is further from the threshold. A second approach to calculating clinical meaningful change was put forward by Perera et al. (20) who compared changes in walking speed with changes in the Short Form 36 mobility items and a global mobility change scale in a group of elderly with a mix conditions. They calculated that the minimum meaningful change in walking speed was 0.05 ms^{-1} and 0.1 ms^{-1} for a substantial meaningful change. The number of patients who achieved these changes, averaged over the first 16.5 months was also calculated.

Four metrics were calculated. The initial orthotic effect is the change seen with FES on the first day it is used. This represents the benefit of the intervention the first day it is used. The total orthotic effect is the change with FES, at one or more follow-up assessment compared with walking without FES at the beginning of treatment. This represents the combined training effect and direct effect of the intervention. The training effect is the change in walking speed without FES at one or more follow-up assessments relative to the walking speed without FES at the beginning. The continuing orthotic effect is the change in walking speed between walking with and without FES at the same assessment at one or more of the follow-ups. This represents the effect of the intervention day to day.

Table I. *Demographic data and duration of Functional Electrical Stimulation (FES) use since 1999*

	Total *n* = 126	Stroke *n* = 62	MS *n* = 39	SCI *n* = 7	CP *n* = 3	Other *n* = 15
Age at start, years, mean (SD)	53.9 (15.6)	59.6 (15.5)	50.4 (9.1)	43.5 (14.0)	16.0 (6.4)	51.8 (15.0)
Time since onset at start, years, mean (SD)	8.6 (8.3)	4.8 (5.0)	13.5 (8.4)	6.9 (7.3)	16.0 (6.4)	11.6 (11.7)
Gender, male/female, *n*	58/68	33/29	13/25	6/1	0/3	8/7
Side of dropped foot, right/left/bilateral, *n*	63/45/16	40/22/0	17/12/10	2/2/3	0/1/2	7/7/1
AFO use at start, never used/rejected/using/missing data, *n*	34/27/51/15	19/8/28/9	12/10/14/3	2/2/1/2	0/1/2/0	2/5/4/2
Walking ability at start, m, distance, median (25–75%)	100 (50–800)	200 (50–950)	100 (35–200)	400 (200–1,600)	Insufficient data	400 (175–3,000)
Time used, years, median (25–75%)	3.6 (1.3–10.7)	3.6 (1.5–10.7)	4.0 (1.1–10.8)	1.4 (0.4–2.4)	6.7 (3.4–8.9)	3.7 (2.9–9.3)
Mean (SD)	4.9 (4.1)	5.0 (4.1)	5.1 (4.2)	1.6 (1.5)	6 (5.6)	5.8 (4.1)
[95% CI]	[4.2 to 5.6]	[4.0 to 6.0]	[3.8 to 6.4]	[0.5 to 2.7]	[–0.4 to 12.3]	[3.7 to 7.6]
Still using FES August 2010, *n* (%)	33 (26.2)	17 (27)	11 (28)	0 (0)	1 (33)	4 (27)

MS: multiple sclerosis; SCI: spinal cord injury; CP: cerebral palsy; SD: standard deviation; AFO: ankle-foot orthosis; CI: confidence interval.

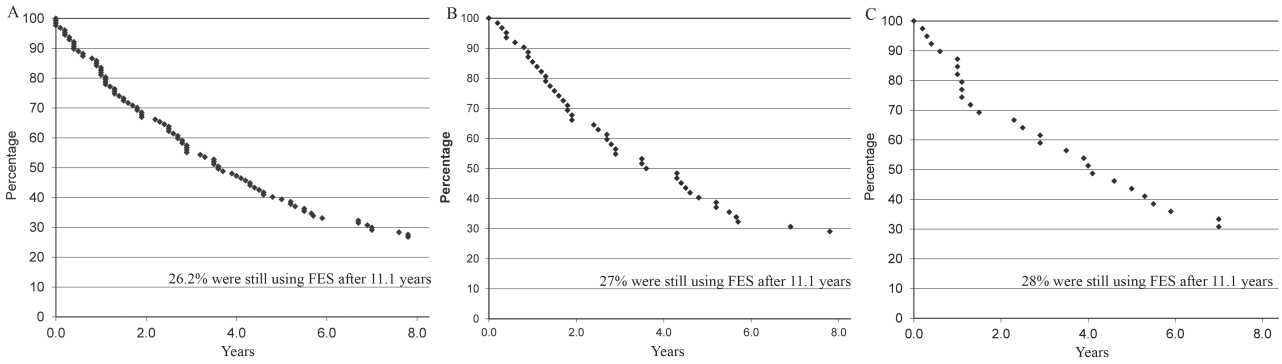

Fig. 1 A–C. The time to stopping Functional Electrical Stimulation (FES) plotted aginst the percentage of those continuing to use FES. A) In the complete group ($n=126$), B) in the stroke group ($n=62$), and C) in the multiple sclerous group ($n=39$).

RESULTS

Demographic details, the mean and median time of FES use and the number of patients still using FES is given in Table I. One hundred and twenty-six people began FES in the year 1999 (62 stroke, 39 multiple sclerosis (MS), 7 spinal cord injury (SCI), 3 cerabral palsy (CP), 15 others). In total 112 patients were followed through their entire treatment. Of those who were lost to follow-up, 12 were transferred to other clinics and 2 moved overseas. The median time of FES use was 3.6 years (mean 4.9, standard deviation (SD) 4.1, CI 4.2–5.6) with 33 people still used FES after a mean of 11.1 years. The median time of use for stroke was 3.6 years (mean 5.0, SD 4.1 CI 4.0 to 6.0) with 17 continuing and for MS 4.0 years (mean 5.1, SD 4.2, CI 3.8–6.4) with 11 continuing. The median number of appointments attended was 10.0 (mean 11.0, SD 6.6, CI 9.8–11.9). Fig. 1 A–C are 'survival plots' and show the total time of FES use for each individual plotted against the percentage of patients continuing with FES use for all patients, those with stroke and those with MS. Approximately 10% of patients discontinued FES each year. It is notable that stroke and MS have similar patterns. While, more people who had MS drop out because of deteriorating mobility, more people had further medical problems or died in the stroke group.

Table II shows the 10 m walking speed results for stroke and MS. There was insufficient data to report for the other neurological conditions. People with stroke walked 0.08 ms^{-1} faster with FES ($p<0.001$, 17%, continuing orthotic effect) and also increased their walking speed without FES by 0.11

Table II. *Walking speed in patients with stroke and multiple sclerosis*

	Stroke			Multiple sclerosis		
	Day 1 Mean (SD) [95% CI]	Whole period Mean (SD) [95% CI]	Day 100 onwards Mean (SD) [95% CI]	Day 1 Mean (SD) [95% CI]	Whole period Mean (SD) [95% CI]	Day 100 onwards Mean (SD) [95% CI]
Walking speed, ms^{-1}						
No FES	0.49 (0.31) [0.47 to 0.57]	0.63 (0.32) [0.663 to 0.599]	0.67 (0.32) [0.644 to 0.707]	0.49 (0.27) [0.400 to 0.588]	0.51 (0.27) [0.472 to 0.543]	0.51 (0.26) [0.460 to 0.549]
With FES	0.57 (0.31) [0.483 to 0.647]	0.71 (0.34) [0.678 to 0.732]	0.75 (0.34) [0.723 to 0.776]	0.55 (0.31) [0.446 to 0.652]	0.55 (0.31) [0.547 to 0.610]	0.59 (0.28) [0.543 to 0.613]
Difference, ms^{-1}						
Initial (day1) and continuing orthotic effects	0.07* (0.09) [0.047 to 0.093]	0.08* (0.09) [0.056 to 0.800]	0.08* (0.12) [0.065 to 0.088]	0.05* (0.07) [0.032 to 0.077]	0.06* (0.07) [0.067 to 0.098]	0.09* (0.11) [0.064 to 0.102]
Difference, %						
Initial (day1) and continuing orthotic effects	19.6 (24.5) [15.2 to 26.1]	17.4 (26.7) [13.0 to 19.3]	17.2 (32.3) [14.0 to 20.4]	16.2 (25.4) [7.7 to 24.7]	9.7 (36.3) [23.9 to 34.3]	29.0 (43.2) [22.3 to 35.9]
Difference from No FES Week 0						
No FES, Training effect		0.08* (0.17) [0.066 to 0.100]	0.11* (0.19) [0.086 to 0.124]		–0.05* (0.15) [–0.98 to –0.059]	–0.08* (0.17) [–0.105 to –0.052]
With FES, Total orthotic effect		0.15* (0.21) [0.130 to 0.172]	0.18* (0.23) [0.159 to 0.204]		0.02* (0.15) [-0.019 to 0.025]	0.00* (0.20) [-0.027 to 0.032]
Difference from No FES week 0, %						
No FES, Training effect		18.8 (43.3) [14.4 to 23.1]	23.8 (43.2) [19.0 to 28.6]		–3.3 (38.1) [–11.0 to -1.6]	-6.3 (38.1) [–12.4 to –0.3]
With FES, Total orthotic effect		39.1 (56.9) [33.4 to 44.6]	44 .8 (62.8) [38.1 to 51.1]		15.4 (44.5) [8.0 to 19.7]	13.8 (47.6) [6.4 to 21.3]

*Statically significant Student *t*, $p<0.0001$.
SD: standard deviation; CI: confidence interval; FES: Functional Electrical Stimulation.

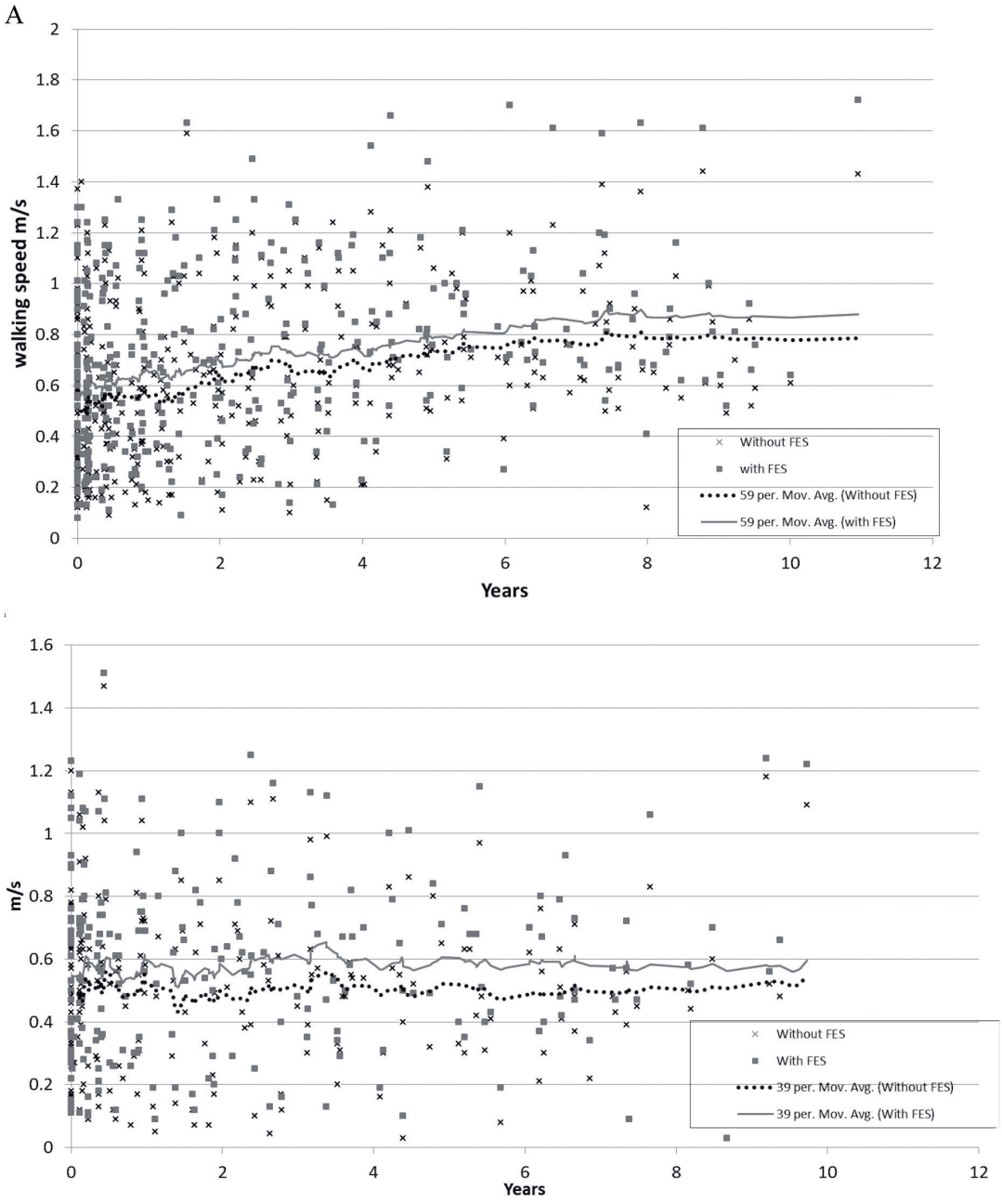

Fig. 2A–B. Walking speed with and without Functional Electrical Stimulation over 10 years, stroke. A) in stroke group ($n=62$) and B) in multiple sclerosis group ($n=39$).

ms^{-1} ($p<0.001$, 24%, training effect), resulting in an overall increase of 0.18 ms^{-1} ($p<0.001$, 45%, total orthotic effect) when compared to the start of treatment without FES. People with MS walked a mean of 0.09ms^{-1} faster throughout the 100 day onwards period with FES ($p<0.001$, 29%, continuing orthotic effect) but did not received an overall training effect. The walking speed with and without FES is plotted in Fig. 2.

Table III shows the number of patients who achieved clinical significant changes in walking speed within the first 16.5 months of FES use. Twenty two (20%) patients improved their functional walking category the first time FES was used. This increased to 42 (38%) over the next 16.5 months. Twenty-nine (26%) patients experienced a training effect sufficient to increase their functional walking category when walking without FES. While 7 people with MS improved their functional walking category walking without FES, 2 people reduced their category. In general the number of patients who changed their walking speed by 0.1ms^{-1} or more was similar to the number who changed functional walking category. However, when the patients are added who had meaningful changes between 0.05 and 0.1 ms^{-1} the proportion of patients achieving meaningful gains is greater than the number changing functional walking category.

Table III. *Clinical significant change in walking speed*

	Initial orthotic effect		Total orthotic effect		Training effect		Continuing orthotic effect	
	Reduced	Increased	Reduced	Increased	Reduced	Increased	Reduced	Increased
All (n=111), changed FWC	2	22	1	43	5	29	1	42
Speed change								
>0.1 ms^{-1}	13	27	4	57	11	34	1	26
0.05–0.01 ms^{-1}	3	22	6	19	12	18	5	34
Stroke (n=56), changed FWC	0	14	0	29	2	19	1	21
Speed change								
>0.1 ms^{-1}	1	15	4	29	4	19	4	14
0.05–0.1 ms^{-1}	5	9	0	10	3	8	0	17
MS (n=35), changed FWC	2	8	1	11	2	7	0	14
Speed change								
>0.1 ms^{-1}	3	10	1	17	3	6	1	10
0.05–0.1 ms^{-1}	0	6	0	3	7	6	0	10

The number of patients who changed Functional Walking Category (FWC) by one or more, recorded at one or more follow-up assessments in the first 16.5 months of FES use (18). The number of patients who changed their walking speed by over 0.1 ms^{-1} (substantial meaningful change) and between 0.05 and 0.1 ms (small meaningful change) (20).

Table IV shows the recorded reasons for discontinuing treatment. Twelve patients were discharged from our clinic to continue using FES supervised by other clinics. Eight transferred in the first year of treatment, one in the second year and 3 after 5 years or more. 16 patients discontinued FES use because their mobility deteriorated to a level that they could no longer benefit from using FES, 15 of who had MS. Seven patients however, discontinued because their mobility had improved, 4 of who had had a stroke. Thirteen people discontinued due to issues related to the treatment; 4 found the equipment too much bother to use, 4 found it to difficult to use, 1 had skin irritation due to the electrodes, 3 found the stimulation painful and 1 had difficulty placing electrodes. Five patients had logistical issues; 4 of whom had problems travelling to the clinic and 1, a privately funded patient, could not afford the cost. Four patients discontinued because they had insufficient benefit to their walking from the device. Four patients discontinued due to nonrelated medical problems, 2 stroke patients had further strokes and 8 people died, 7 of who had had a stroke.

Table IV. *Reasons for discontinuing treatment*

	All	Stroke	MS	SCI	CP	Other
Non-related illness	4	3			1	
Died	8	7				1
Transfer to another clinic (continuing)	12	6	6			
Moved overseas	2	2				
Not recorded	17	8	2	3	1	3
Mobility improved	7	4	1	1		1
Mobility deteriorated	17	1	15			1
Too much bother	1	1				
Skin reaction to electrodes	1					1
Difficulty using equipment	4	3	1			
Further stroke	2	2				
Problems travelling to the clinic	4	4				1
Not effective	5		2	2		1
Painful	3	2		1		
Difficulty placing electrodes	1			1		
Too much spasticity	1	1				
Cost (private patient)	1		1			

MS: multiple sclerosis; SCI: spinal cord injury; CP: cerebral palsy.

The mean cost per patient and mean cost per QALY is given in Table V. Overall the mean cost per QALY was £15,406. The willingness to pay threshold used by the National Institute for Health and Clinical Excellence (NICE) is £20,000 per QALY (discretionary to £30,000 per QALY).

No correlation was found between duration of use and initial walking speed, time since disease onset, age or maximum walking distance at start.

DISCUSSION

The metric used to identify continued device use was attendance at follow-up clinic appointments. While our records confirm that FES was continuing to be used, this does not tell us how much the devices were used in daily life. A published survey of a similar patient group has reported that FES was used every day by 53%, between 4 and 6 days a week by 15% and between 2 and 3 days a week by 23% (8). When FES was discontinued at an appointment it is likely that effective use of the FES may have already ended prior to that appointment. When FES was ended between appointments, again the exact time of stopping was often not known. There is therefore some uncertainty on the duration of use figures. Nevertheless use of the number of appointments is an accurate measure of the resources used to maintain FES use,

Table V. *1999 Total mean cost and mean cost per Quality Adjusted Life Years (QALY)*

	Stroke	All
Appointments, n, mean (SD) [95% CI]	11 (6.6) [9.3 to 12.6]	10.9 (6.2) [9.9 to 11.9]
Cost, £, mean (SD) [95% CI]	3,130 (1,830) [2,646 to 3,585]	3,095 (1,490) [2,810 to 3,379]
Time, years, mean (SD) [95% CI]	5.0 (4.1) [4.0 to 6.0]	4.9 (1.3) [4.2 to 5.6]
QALY gain (CEP10012)[a], mean	0.041	0.041
cost per QALY, £, mean	15,268	15,406

[a]See ref. 17.

SD: standard deviation; CI: confidence interval.

as only attended appointments were charged for. The results may be further skewed by the transfer of 12 patients to other clinics, particularly in the first year of treatment. This may have slightly reduced the overall figure for time used as the date of transfer was taken as the date of discharge from the clinic.

The walking speed data includes all available measurements taken in the review period. Consequently patients who continued FES have more data points than those who discontinued early and therefore the mean walking speed is biased to those who continued FES. Further, data was not recorded at all clinic appointments with data missed particularly if there was insufficient time in an appointment or if walking was too difficult or unsafe without FES. In the stroke group it is noticeable that while the absolute walking speed gradually increased over the review period (Fig. 2A), the mean difference between 'with and without' FES remained stable after the first year. This justifies the use of a QALY gain based on walking speed over a short period of time for this longer period. There was no correlation between walking speed at the start and total time of FES use. This suggests that the gradual increase in walking speed over time in the stroke group may be due to a continued training effect from FES. However, while the group would be expected to be stable because of their mean time since stroke was 4.8 years, as there was no control group, this conclusion must be made with caution.

By contrast the mean walking speed in the MS group remains remarkably constant through the review period (Fig. 2B). The progressive nature of the condition is more apparent in the clinically meaningful change data which showed that 10 patients walked slower without FES in the first 16.5 months of FES use. While an overall mean training effect in walking speed was not seen, 12 patients did achieve meaning full increase in speed, 7 of which resulted in changes of functional walking category. This suggests a dichotomised response to FES in this group, possibly related to variation in the capacity for neuroplasticity between individuals.

The average increase in walking speed with FES averaged over 100 days onwards was 0.18 ms^{-1} in the stroke group and this was the same figure used in the CEP10012 report to calculate the QALY gain. Further, 52% of patients improved the functional walking category in the first 16.5 months of FES use, significantly more than the 28% assumed in CEP10012 and this suggests the QALY gain may be underestimated. As the mean walking speed was maintained or increased over the remaining period of FES use, we believe it is valid to use the data from this study and the CEP10012 QALY gain to calculate the long-term cost benefit. There was not a similar overall increase in walking speed seen in the MS group. However, there was a continuing orthotic effect of 29% over the 100 days onward period and 40% of patients improved their functional walking category. This compares with a continuing orthotic effect of 17% and 28% of patients increasing their functional walking category in the stroke group. This suggests that while the stroke group ultimately walk faster as a result of using FES, the MS group may receive greater continuing orthotic benefit from the device, maintaining their mobility for an average of around 4 years longer than might have occurred without FES.

In conclusion, FES used to correct dropped foot is an effective long-term intervention, with a median time of usage of around 4 years. The mean treatment cost at 2012 prices was £3,095 per patient resulting in a cost per QALY of £15,406. The long-term effectiveness was demonstrated by stable increases in walking speed when FES was used over the review period. While FES users who had a stroke increased their walking speed by 45% overall, including a 24% training effect, FES users who had a MS walked 29% faster when FES was used, but with only a minority achieving a training effect. Sixty-eight percent of FES users achieved meaningful changes in walking speed with 39% improving their functional walking category.

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Paul Taylor and Ian Swain are the authors of a patent covering the ODFS device used in this study. In 2006 a spinoff company, Odstock Medical Ltd, was set up by Salisbury NHS Foundation Trust to commercially develop the device. The Trust remains the majority shareholder and receives an income from the company. Paul Taylor and Ian Swain hold a small number of 'token' shares in Odstock Medical Ltd which may have financial value in the future. Both remain employed by the Trust and are seconded part time to Odstock Medical for provision of clinical FES treatment.

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