How long do Dropped foot stimulator users continue to use FES and how much does it cost? An eleven and six year clinical audit.

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Purpose of audit

To determine the mean time of FES use to assist walking and clinical costs in providing this treatment for patients attending for dropped foot correction at the Nation Clinical FES Centre in Salisbury.

Method

From the FES database all patients who began FES use in 1999 and 2004 were identified together with diagnosis, time since onset, age at start of treatment, gender, and effected side. Patients either used the Odstock Dropped Foot Stimulator (ODFS) or the 2 channel version, the Odstock 2 Channel Stimulator version 2 (O2CHSII). The list of names was then cross referenced with the clinic database and the date of the last clinic appointment, the total number of clinic appointments and the date of discharge from the clinic determined. It was found that the time from the last appointment till discharge varied considerably. This is because if a patient does not attend clinic for follow up, it can be some time before they are formally discharged from the clinic, while it is likely that FES use is discontinued earlier. For this reason where the gap between the last appointment and discharge date appeared unreasonably long, the time was reduced to be equal to the period between the two previous appointments.

Analysis

The results were summaries using descriptive statistics. Survival plots were produced indicating the total time of FES use for each individual plotted against the percentage of patients continuing with FES use. 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. These are OML standard tariff. The mean cost was then divided by the mean time of FES use and then divided by the QALY gain calculated in the original ODFS trial to give the mean cost per QALY^{1, 2}.

Results

Demographic details, the mean and median time of FES use and the number of patients still using FES is given in table 1 for those starting in 1999 and in table 2 for those who started in 2004. In 1999 the mean time till stopping FES use was 4.9 years with 26.2% of patients still using FES for walking after a mean of 11.1 years. In 2004 the mean time of FES use was 4.4 years with 57% continuing to use FES an average of 6.2 years later.

Table 3 tabulates the recorded reasons for discontinuing treatment (1999 cohort only). 12 patients were discharged from the clinic to continue FES supervised by other clinics. Eight transferred in the first year of treatment, one at 2.4 years and 3 after 5 years or more. It is not known how long they continued FES but it is likely this has reduced slightly the overall mean time of FES use. 16 patients discontinued because their mobility deteriorated so could no longer benefit from using FES, 15 of whom 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 to much bother to use, 4 found it to difficult to use, 1 had skin irritation to the electrodes, 3 found the stimulation painful and 1 had difficulty placing electrodes. Five patients had logistical issues; 4 of whom had problem 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 none related medical problems, 2 stroke patients had further strokes and 8 people died, 7 of whom had had a stroke.

The mean costs per patient and mean cost per QALY is given in tables 4 and 5 for 1999 and 2004. The value for QALY gain is taken from the cost analysis study done following the randomised control trial of the ODFS. The cost per QALY is calculated for CVA patients separately as the QALY gain relates to a trial with stroke patient only. However, as clinically patients with dropped foot due to other causes respond to FES in a similar way as stroke, the cost per QALY for the whole group is also calculated, assuming the same QALY value. Overall the mean cost per QALY was £9,658 for those who began in 1999 and £10,474 for those who started in 2004. The cost per QALY will fall as 2004 patients continue to use FES, because initial costs in the first year (£1,640) are higher then the cost of maintaining FES use (£300 - £600 per year). The willingness to pay threshold used by NICE is £30,000 so FES is comfortably within this threshold.

Figures 1 to 6 shows survival plots for all patients and separately for CVA and MS for both 1999 and 2004. It is notable that CVA and MS have similar patterns. While, in the 1999 cohort, more people who had MS drop out because of deteriorating mobility, more people had further medical problems or died in the stroke group. A smaller proportion of FES users discontinue within the first 2 years of treatment in the 2004 cohort (22%) compared with the 1999 group (35%) although 8 FES users were transferred to other clinics in the first year in the 1999 group and are likely to have continued using FES longer. Approximately 10% of the 2004 cohort, discontinue FES each year.

Conclusion

FES used to correct dropped foot is a cost effective long term intervention, with a mean time of usage of around 5 years. Using QALY gain figures from the original Odstock Dropped Foot Stimulator trial and average treatment costs of £3,095, the cost per QALY is £9,658.

References

- 1. Burridge J, Taylor P, Hagan S, Wood D, Swain I. (1997) The effects of common peroneal nerve stimulation on the effort and speed of walking: A randomised controlled clinical trial with chronic hemiplegic patients. *Clint Rehabil* 11. 201-210.
- Taylor P, Mann G, Jolley C, Swain I. Economic Justification for the Odstock Dropped Foot Stimulator (ODFS). ISPO meeting 3rd Nov 2007

Started FES in 1999	Number	Mean age (SD) years	Mean time since onset (SD) years	Gender	Side of dropped foot	Mean time used FES (SD) years	Median time used (inter-quartile range) years	Number still using FES August 2010
Total	127	53.9	8.6	Male 58	Right 63	4.9	3.6	33
		(15.6)	(8.3)	Female 68	Left 45	(4.1)	(1.3 – 10.7)	(26.2%)
					Bilateral 16			
CVA	62	59.6	4.8	Male 33	Right 40	5.0	3.6	17
		(15.5)	(5.0)	Female 29	Left 22	(4.1)	(1.5 – 10.7)	(27%)
MS	39	50.4	13.5	Male 13	Right 17	5.1	4.0	11
		(9.1)	(8.4)	Female 25	Left 12	(4.2)	(1.1 – 10.8)	(28%)
					Bilateral 9			
SCI	7	43.5	6.9	Male 6	Right 2	1.6	1.4	0
		(14.0)	(7.3)	Female 1	Left 2	(1.5)	(0.4 – 2.4)	(0%)
					Bilateral 3			
СР	3	16.0	16.0	Male 0	Right 0	6	6.7	1
		(6.4)	(6.4)	Female 3	Left 1	(5.6)	(3.4 – 8.9)	(33%)
					Bilateral 2			
Other	15	51.8	11.6	Male 8	Right 7	5.8	3.7	4
		(15.0)	(11.7)	Female 7	Left 7	(4.1)	(2.9 – 9.3)	(27%)
					Bilateral 1			

Table 1. Results for patients who began FES use in 1999

Started FES in 2004	Number	Mean age (SD) years	Mean time since onset (SD) years	Gender	Side of dropped foot	Mean time used FES (SD) years	Median time used (inter- quartile range) years	Number still using FES August 2010
Total	132	53.5 (13.2)	8.6 (7.9)	Male 63 Female 69	Right 67 Left 50 Bilateral 11	4.4 (2.3)	5.8 (2.2 – 6.2)	75 (57%)
					Not recorded 4			
CVA	35	58.2 (15.0)	4.7 (3.6)	Male 33 Female 12	Right 21 Left 12 Not Recorded 2	5.3 (1.1)	5.8 (4.4 - 6.2)	25 (71%)
MS	69	53.7 (10.2)	12.3 (9.4)	Male 22 Female 47	Right 32 Left 28 Bilateral 8 Not Recorded 1	4.2 (2.4)	5.1 (2.0 – 6.2)	35 (51%)
тві	5	39.6 (10.9)	9.3 (9.7)	Male 4 Female 1	Right 2 Left 3	4.9 (1.5)	5.7 (3.7 - 6.2)	3 (60%)
FSP	7	57.5 (10.0)	9.5 (1.5)	Male 4 Female 3	Right 2 Left 2 Bilateral 3	5.3 (1.1)	5.8 (4.4 – 6.2)	6 (86%)
Other	16	44.9 (16.3)	3.0 (1.4)	Male 9 Female 7	Right 10 Left 5 Not Recorded 1	5.1 (2.1)	5.9 (5.7 – 6.2)	12 (75%)

Table 2 Results for Patients who began FES use in 2004

Table 31999 cohort. Reasons for discontinuing treatment

	Non related Illness	Died	Transfer to another clinic (continuing)	Moved overseas	Not recorded	Mobility improved	Mobility deteriorated	To much bother	Skin reaction to electrodes
All	4	8	12	2	17	7	17	1	1
CVA	3	7	6	2	8	4	1	1	
MS			6		2	1	15		
SCI					3	1			
СР	1				1				
Other		1			3	1	1		1

	Difficulty using equipment	Further CVA	Problems travelling to the clinic	Not effective	Painful	Difficulty placing electrodes	To much spasticity	Cost (private patient)
All	4	2	4	5	3	1	1	1
CVA	3	2	4		2		1	
MS	1			2				1
SCI				2	1	1		
СР								
Other			1	1				

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	Mean number of appointments (SD)	Mean Cost (SD)	Mean Time (SD) Years	Mean QALY gain	Mean Cost per QALY
CVA	11	£3130	5.0	0.065	£9,587
	(6.6)	(£1830)	(4.1)		
All	10.9	£3095	4.9	0.065	£9,658
	(6.2)	(£1490)	(1.3)		

Table 4.	1999 Total Mean Cost and Mean Cost per QALY
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2004 Total Mean Cost and Mean Cost per QALY Table 5.

	Mean number of appointments (SD)	Mean Cost (SD)	Mean Time (SD) Years	Mean QALY gain	Mean Cost per QALY
CVA	10.6	£3,020	4.1	0.065	£11,296
	(4.2)	(£1,107)	(2.3)		
All	10.4	£2,965	4.4	0.065	£10,474
	(4.4)	(£1,170)	(2.3)		

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Figure 1 1999 - 2010 All patients

Estimated total time of FES use for all patients who began using FES in 1999 n = 127



Figure 2 1999 - 2010 CVA

Estimate total time of FES use for all Stroke Patients who began FES use in 1999 n=62



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Figure 3 1999 - 2010 MS





Figure 4 2004 – 2010 All Patients

Estimated total time of FES use for all patients who started using FES in 2004 n=132



Figure 5 2004 – 2010 CVA



Estimated total time of FES use for all stroke patients who began using FES in 2004 n=35

Figure 6 2004 - 2010 MS

Estimated total time of FES use for all patients with MS who started in 2004 n=69

