Economic Justification for the Odstock Dropped Foot Stimulator (ODFS)

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Abstract

The ODFS is a mobility aid designed to correct dropped foot following stroke, multiple sclerosis, spinal cord injury and other upper motor neurone conditions. The device uses small pulses of electrical stimulation applied to the common peroneal nerve using self adhesive skin surface electrodes to elicit dorsiflexion and eversion. This is timed to the gait cycle using a pressure sensitive foot switch. The device was the subject of a randomised controlled trial with subjects who had chronic hemiplegia. The results indicated significant improvement in gait that was translated into an improvement in quality of life. The average cost per QALY was estimated to be £25,235 over one year, reducing to between £8,738 and £12,431 if the device was used for 5 years. Additional cost savings may be achieved due to reduction of hospital admissions following falls, reduced use of other assistive equipment and improved overall health status. In conclusion, the ODFS is a cost effective device for improvement of gait following upper motor neurone lesion.

Introduction

Dropped foot is a common problem in many neurological conditions including stroke, multiple sclerosis and incomplete spinal cord injury. While it is often only one of many gait deficits experienced, its role in causing falls means it is particularly debilitating to gait, reducing the ability to perform normal activities of daily living and affecting quality of life[1]. In a survey by Finlayson[2] of people who had MS, 70% reported curtailing activity due to fear of falling. Functional Electrical Stimulation (FES) uses neuromuscular stimulation to activate paralysed or weak muscles to produce movement to assist or enable function. It was first used to correct dropped foot in people with hemiplegia by Liberson[3] who used skin surface electrodes to stimulate the common peroneal nerve. When timed to the gait cycle using a switch placed under the heel, stimulation caused dorsiflexion and eversion in the swing phase.

The Odstock Dropped Foot Stimulator (ODFS)[4] is a development of Liberson's device. It is a small battery powered device about the same size as a mobile phone. While the general principle of operation is the same, improved technology allows the device to be adjusted to suit the individual characteristics of each user's gait. The clinical method has been developed enabling the device to be used with a broad spectrum of patients, delivered though a specialised outpatient service.

While the standard intervention for dropped foot is an ankle foot orthosis, FES may provide several advantages over a passive orthosis. FES is an active intervention that enables the user to make use of their own muscle power. This significantly increases the efficiency of gait. Because an active muscle contraction is produced, significant muscle training is possible, leading to strengthening and in some cases improved voluntary control.

By provision of active dorsiflexion and eversion, the foot clears the ground in the swing phase more easily. This reduces the effort of gait, reducing compensatory activities such as hip hitching and circumduction. At the end of the swing phase dorsiflexion with eversion determines that first contact occurs with a heel strike and ensures that the loading response is through the midline of the foot increasing the safety in weight bearing.[5]

Reduction in effort may lead to a reduction of associated reactions and result in a general lowering of tone. Contraction of the tibialis anterior muscle and the hamstrings via the withdrawal reflex may, by reciprocal inhibition, reduce antagonist activity leading to a more normal modulation of tone in gait. However, the direct benefit from the orthotic use of the device is that walking is easier and safer and therefore confidence will improve leading to an extension of mobility range and an overall improvement in quality of life.

Clinical Service

Patients are first seen at an assessment clinic to determine the suitability of the treatment. At the assessment, the device is tried and if an improvement in gait can be demonstrated, treatment is recommended. The patient is then asked to attend on two consecutive days. On the first day they are shown how to use the ODFS. On the second day their ability to correctly use the device is checked and additional instruction given as required. Follow up is provided 6 weeks later, 3 months after that and then after a further 6 months. Continuing follow up is then provided every 6 or 12 months depending on the individual for as long as the device is used[6].

Purpose of this report

The ODFS was the subject of a randomised controlled trial in chronic stroke[7]. The results from the trial were used to assess the impact of the ODFS on the quality of life of its users and related to the cost of treatment using QALY analysis. This was presented to the South and West Regional Health Authority's Development and Evaluation Committee who independently assessed the trial findings. They subsequently recommended the device for use in the NHS[8].

This report revisits the QALY analysis and presents up-to-date costs for 2007. Additional possible cost savings are also considered based on further trial and clinical audit data.

Method

Design

A randomised controlled trial (RCT). The treatment group received the ODFS as part of a physiotherapy programme. They were allowed unrestricted use of the device throughout the trial. The control group received physiotherapy. Both groups received 10 one hour treatment session in the first 4 weeks of the trial. Assessments were carried out prior to randomisation and starting treatment, at one month and after a further 2 months. Subjects allocated to the treatment had additional walking test with the device performed after randomisation on the first day.

Recruitment

Subjects were recruited following GP and consultant referral.

Selection Criteria

- Single CVA resulting in hemiplegia at least 6 months previously
- Unilateral dropped foot defined as the toe catching the ground or compensatory action such as hip hitching or circumduction to avoid the toe catching in the swing phase of gait
- Sufficient dorsiflexion due to electrical stimulation so a heel strike is produced
- No mental impairment, a satisfactory understanding of the device and good motivation
- No other significant medical conditions
- Ability to stand unsupported and walk a minimum of 10m (with appropriate assistive aids)
- Not hypersensitive to the sensation of electrical stimulation
- Able to stand from sitting without assistance and walk at least 50m prior to the stroke.
- Informed written consent.

Assessments

- Walking speed over 10m.
  This was performed over smooth vinyl flawing. 1m preceded and followed the 10m walkway to allow for acceleration and deceleration. Three measurements were made and an average calculated[9].
- Physiological Cost Index (PCI) over 10m[10]
  This is a measure of the effort expended while walking based on increase in heart rate related to walking speed. This was measured concurrently with walking speed.
- Mobility Questionnaire
  A 5 question multiple choice questionnaire assessing the degree of mobility
- Hospital Anxiety and Depression scale[11]
  A standardised questionnaire

Cost Benefit analysis

Benefits to the patient's quality of life are demonstrated by using the Index of Health Related Quality of Life (IHQL)[12]. IHQL produces an index related to quality of life by relating physical disability and distress. In this study disability is measured by combining the results of the walking speed, PCI and mobility questionnaire. Distress was demonstrated using the Hospital Anxiety and Depression scale. Rosser et al. produced an eight level hierarchal description to define disability ranging from no disability (D1) to unconscious (D8). Similarly, a five level hierarchal system was used to define emotional distress where E1 represented no distress and E5 represented extreme distress. From examination of this descriptive system it could be estimated that the trial subjects could be described by disability scores D2 to D6 and emotional scores E1 to E4. To allocate D scores to each trial subject, a ranked score was derived for walking speed, PCI and mobility questionnaire results as shown in table 1. The score for each index were then summed and related to a D score as shown. HAD scores were treated in the same manner to produce an E score.

To produce a score for the quality of life for each individual, the D and E value were entered into the Rosser matrix (see appendix). This score is the Quality Adjusted Life Year (QALY). This was done for values collected at the beginning and end of the trial. The difference in the two QALY scores is the QALY gain. The cost of this QALY gain is calculated by multiplying the QALY gain by the cost of the intervention and dividing by the number of years that are affected by the quality of life gain.

Table 1. Conversion system for relation of recorded outcome measures to the dimensions used in the Rosser matrix

Walking Speed (ms^{-1})										
<0.1	0.1-0.29	0.3-0.49	0.5-0.69	0.7-0.89	0.9-1.09	1.1-1.29	1.3-1.49	>1.5		
0	1	2	3	4	5	6	7	8		
PCI beats per (min / metres per min)										
>1.31	1.21-1.3	1.1-1.2	0.91-1.0	0.81-0.9	0.71-0.8	0.61-0.7	0.51-0.6	0.41-0.5	0.31-0.4	<0.3
0	1	2	3	4	5	6	7	8	9	10
Mobility Questionnaire										
<1	1-2	3-4	5-6	7-8	9-10	11-12	13-14	15-16		
0	1	2	3	4	5	6	7	8		
Total disability score (walking speed + PCI + mobility questionnaire) related to disability dimension										
<6.9	7.0-10.9	11-14.9	15-18.9	>19						
D6	D5	D4	D3	D2						
HAD										
>18	18-17	16-15	14-13	12-11	10-9	8- 7	6- 5	4 3	2-1	<1
0	1	2	3	4	5	6	7	8	9	10
HAD score related to distress dimension										
<2	3-5	6-8	>9							
E4	E3	E2	E1							

Results

Thirty two subjects were recruited to the trial. Their mean age was 56.5 years and mean time from stroke was 4 years 5 months.

Walking Speed

FES group

At the end of the trial period 13 FES subjects walked faster, 2 had no change and 1 walked more slowly when using the ODFS at the end of the trial compared with unassisted walking at the beginning. The mean increase in speed was 0.22 ms^{-1} (SD 0.09), a mean % increase of 18.1%. Increase in speed was significant (paired T test p <0.0002). However, there was no significant change in walking speed without the ODFS.

Control group

In the control group 6 subjects walked faster, 6 at the same speed and 3 more slowly. Mean increase in speed (all control subjects) = 0.03 m/s SD 0.09. mean % increase = 5.1% which was not significant (paired T test p<0.604).

There was no significant difference in walking speed between the FES group when not using the ODFS and control group at any stage. However, there was a statistical significant difference when the ODFS was used at month 3 (Mann Whitney U p=0.043).

Table 2. Walking speed mean and standard deviation

	Month 0 (ms^{-1})	Month 1 (ms^{-1})	Month 3 (ms^{-1})
FES no stim	0.64 (0.46)	0.62 (0.41)	0.63 (0.39)
FES with stim	0.68 (0.49)	0.75 (0.51)	0.77 (0.43)
Control	0.48 (0.25)	0.58 (0.25)	0.51 (0.27)
Man Whitney U test FES no stim - control	P=0.318	P=0.621	P=0.407
Mann Whitney U test FES with stim - control	P=0.228	P=0.221	P=0.043

Physiological Cost Index

FES group

At the end of the trial period 10 FES subjects had a lower PCI, 4 had no change and in 2 subjects it was higher when using the ODFS at the end of the trial compared with unassisted walking at the beginning. Mean reduction in PCI was 0.21Btm^{-1} SD 0.27 mean % reduction = 46.44% which was significant (paired T test p< 0.0067)

Control group

In the control group 5 subjects had a lower PCI, 8 no change and in 3 subjects it was higher. There was a mean of 0.02 Btm^{-1} which was not significant p<0.7101 (paired T test). There is a significant difference in change in PCI between the FES and control group p<0.0466 (student T test)

Table 3. PCI mean and standard deviation

	Month 0 (Btm^{-1})	Month 1 (Btm^{-1})	Month 3 (Btm^{-1})
FES no stim	0.80 (0.74)	0.71 (0.71)	0.76 (0.64)
FES with stim	0.59 (0.49)	0.61 (0.67)	0.54 (0.56)
Control	1.03 (0.67)	0.98 (0.74)	1.00 (0.69)
Man Whitney U test FES no stim - control	P=0.220	P=0.327	P=0.127
Mann Whitney U test FES with stim - control	P=0.0569	P=0.127	P=0.083

Btm^{-1} = heart Beats per meter

Mobility Questionnaire

Mean increase in score during the trial period in the FES group of 2.56 while the Control group increased by 0.85. Both changes were statistically significant. There was a significant difference between the change in the FES group and the change in the control group p< 0.0489 (Fisher exact probability test). No significant difference was seen at the start of the trial. (Table 4)

Table 4. Mobility questionnaire mean and standard deviation

stage	Month 0	Month 1	Month 3	mean change
FES group	11.8 (4.15)	12.6 (3.32)	14.5 (3.46)	2.56 (1.42)
Wilcoxon compared with month 0		P=0.01	P=0.01	
Control	12.3 (2.34)	13.3 (1.51)	13.3 (1.37)	0.85 (1.21)
Wilcoxon compared with month 0			no dif	P=0.025
Comparison of change between groups Fisher exact probability test				P=0.0498

Hospital Anxiety and Depression Scale

There was significant reduction in both anxiety and depression in the FES group over the three month period p<0.0028 anxiety scores and p<0.0047 depression scores (table5). No significant improvement was seen in the control group. The difference between control and FES groups showed a trend to significance p<0.0820.

Table 5. HAD mean and standard deviation

	Month 0		Month 3		Difference	
	Anxiety	**Depression**	**Anxiety**	**Depression**	**Anxiety**	**Depression**
FES	6.25 (3.20)	5.25 (2.76)	4.13 (1.81)	3.38 (2.72)	-2.00 (-2.88)	-2.13 (-1.64)
Wilcoxon					p = 0.0047	p = 0.0028
Control	5.44 (3.28)	3.78 (2.44)	3.75 (1.94)	3.11 (3.05)	-1.44 (-3.13)	-0.67 (-2.02)
Wilcoxon					p = 0.096	p = 0.441

Disbenefits

12% of subjects showed no benefit, none were made worse.

Skin irritation was a problem for one subject who was unable to continue using the stimulator. A possible cause of skin irritation is the formation of electro-chemical compounds when stimulation produces a charge imbalance. Since completion of the trial the output of the ODFS has been modified to give the option of a symmetrical biphasic output, eliminating possible charge imbalance. Additionally, improvements in electrode technology have also been made, reducing the risk of skin irritation.

The stimulation system involves wearing self adhesive electrodes on the leg, a switch in the heel of the shoe, and leads connecting these to the stimulator which is worn either in a pocket or on belt. This is an inconvenience and time is taken setting it up each day. 14 of the 16 subjects in the trial were able to set the stimulator up independently but 3 of these said they usually had help. 2 subjects were unable to set it up without help. 4 subjects said they often had difficulty finding the correct electrode positions and 4 said they found the system an encumbrance. Four subjects said the sensation of stimulation was slightly uncomfortable, none found it too uncomfortable to use.

Costs benefit

The walking speed, PCI, Mobility questionnaire and HAD results were converted to D and E scores using the ranking system shown in Table 1. The results are shown in table 6. From the Disability and Emotional distress scores a D and E score was calculated for each subject.

Example: subject 8 who was at point D4 on the Rosser Matrix at the start of the trial. Walking speed was 0.37 ms^{-1} (40% of normal walking speed) (score 2), PCI 0.98 (300% normal)(score 3) and Mobility Questionnaire score was 12 (score 6). This gives a total disability score of 11. Subject 8 could stand independently from a wheelchair and walk over 500m but always used a walking stick unless supported, only occasionally walked outside alone and not on uneven ground unless with help. At the end of the trial walking speed was 0.55 m/s (score 3), PCI was 0.33 (score 9) and Mobility score was 15 (score 8), giving a total Disability score of 15. She no longer used a stick, now walked outside regularly and was able to walk on uneven surfaces which enabled her to walk her dog in the New Forest. Point on the Rosser Matrix was therefore D3. Subject 8 has continued to use the ODFS since the end of trial 12 years ago.

D and E scores for each individual were entered into the Rosser matrix and a QALY score derived. Mean and median scores are given in table 7.

Costs

Assessments for the ODFS cost £140 and treatment sessions are charged at £300 per sessions (Odstock Medical Ltd. price 2007). This is the full economic cost and includes all consumables, maintenance and treatment. There are normally 5 treatment sessions in the first year and either 1 or 2 follow up sessions in subsequent years depending on the individual. The total cost in the first year is therefore £1640 and either £300 or £600 in subsequent years. Taking the mean QALY gain of 0.065, the cost per QALY is £25,231 if the device is used for one year. This is comfortably within the NICE cut off figure for cost effectiveness of £30,000 per QALY.

However, the ODFS is a long term mobility aid and is often used for many years. In an audit of the clinical records of 305 people who began using FES for gait assistance between January 2000 and December 2003 (116 stroke, 105 MS, 8 SCI, 6 CP and 9 other diagnosis) from the Salisbury FES clinic showed that only 22 (7%) had been discharged from the clinic by May 2007. It is therefore justifiable to look at the cost per QALY over an extended period of time. Table 8 gives costs per QALY at 1, 5 and 10 years.

Table 6. Median Disability and Emotional distress scores

Disability

	FES			Control				
	Month 0	**Month 3**	**Wilcoxon**	**Month 0**	**Month 3**	**Wilcoxon**	**MWU M0**	**MWU M3**
Speed	3	3.5	0.010	2.5	2.5	0.374	0.375	0.073
PCI	7	8	0.008	4	4	0.310	0.280	0.042
Mobility	5	6.5	0.002	5	6	0.063	0.607	0.011
Total	15	18	0.001	10.5	10.5	0.056	0.145	0.004

Emotional

	FES			Control				
	Month 0	**Month 3**	**Wilcoxon**	**Month 0**	**Month 3**	**Wilcoxon**	**MWU M0**	**MWU M3**
HAD	5.00	7.25	0.001	5	5.5	0.286	0.894	0.117

MWU = Mann Whitney U test, M0 = month 0 and M3 = month 3

Table 7. QALY Gain

	FES				Control			
	Month 0	**Month 3**	**QALY gain**	**Wilcoxon p=**	**Month 0**	**Month 3**	**QALY gain**	**Wilcoxon p=**
Mean	0.856	0.921	0.065		0.825	0.848	0.023	
(sd)	(0.094)	(0.065)	(0.058)		(0.089)	(0.086)	(0.047)	
Median	0.874	0.950	0.041	0.001	0.833	0.855	0.024	0.062
Difference between groups Mann Whitney U p=					0.336	0.017	0.073	

Table 8. Mean, median, 25th and 75th percentile cost per QALY

	QALY	1 year***	5 year*	5 year**	10 year*	10 year**
Actual cost		£1640	£4040	£2840	£7040	£4340
Mean	0.065	£25230	£12431	£8738	£10830	£6676
Median	0.041	£40000	£19707	£13854	£17170	£10585
0.75%	0.0975	£16821	£8287	£5826	£7221	£4451
0.25%	0.0225	£73708	£36298	£25517	£31626	£19497

* 2 follow up appointments at £300 per appointment a year

** 1 follow up appointment at £300 a year

*** 5 appointments at £300 plus an assessment appointment at £140 in the first year

Are the effect seen in the RCT also obtained outside the research setting?

Following the trial of the ODFS and the recommendations of the South and West Regional Health Authority's Development and Evaluation Committee, a clinical service for provision of the device was established. In order to monitor the service, measurement of walking speed and PCI were continued. Clinical audit of these results over the first 18 weeks of treatment for a group of 111 chronic stroke users of the device confirmed the results of the RCT. Walking speed was increased by an average of 27% while PCI fell by 31% when the device was used at 18 weeks compared with unassisted walking at the start of treatment[4]. Similar effects were also recorded for ODFS users with a dropped foot due to multiple sclerosis or spinal cord injury. In a second audit it was shown that the improvement seen by stroke ODFS users at 18 weeks was maintained over a 3 and a half year period[13].

Cost savings to the NHS

While QALY analysis justifies the costs of treatment in its own right use of the ODFS may result in direct savings to the NHS.

Reduction in falls

In a second RCT of the ODFS in a group of 56 people who had secondary progressive multiple sclerosis, ODFS users reported 72% fewer falls than a control group who received physiotherapy, over an 18 week period[14]. 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[15]. 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 16% between 2002 and 2007 the annual saving would be €381 (£254) or €1914 (£1275) over 5 years at 2007 prices. From an individual perspective, the mean time between injury would increase from 2.15 years to over 7 years.

Reduction in use of other assistive devices

In a questionnaire completed by 107 ODFS users (74% stroke, 14%MS, 5% head injury, 4% spinal cord injury and 3% cerebral palsy) changes in requirements for other assistive devices were reported[16]. Of those who used each aid before starting treatment with the ODFS,18% stopped using wheel chairs, 25% stopped using a walking frame, 29% stopped using crutches and 56% stopped using an AFO. The mean time of ODFS use 19.5 months.

Impact of the ODFS on health.

In the same questionnaire, 71% of ODFS users reported that they were able to walk further when the ODFS was used. Additionally, 33% of users reported that they used the device to help keep them fit. It is known that electrical stimulation promotes blood circulation in the lower limb[17]. While an AFO may restrict the natural venous pump action caused by repetitive reciprocal movement in the lower leg, this action is promoted by FES because the range of ankle movement is returned to normal. This may reduce the risk of developing complications such as deep vein thrombosis and pressure sores. The increased overall activity provided by the ODFS may positively impact on cardiovascular fitness and reduce the risk of osteoporosis.

The questionnaire also asked how the ODFS was used. 70% used the ODFS for shopping and trips out. 57% used the ODFS for social events and 19% for work. 79% reported that their confidence was increased when walking with the ODFS and 52% reported that their independence was increased. It is therefore clear that the device is instrumental in promoting social integration. Taken together with the improvement in HAD scores reported in the trial it can be concluded that the ODFS has a positive impact on mental well being that may reduce the demand for mental health interventions.

Economic benefit to the wider community.

As previously mentioned, the questionnaire reported that 19% of ODFS users used the device at work. Anecdotally it is reported in the clinic that the ODFS has aided return to work in the case of stroke and spinal cord patients. Reports have also indicated that the device helps people with MS continue at work when progression of their disease may otherwise have resulted in premature retirement. Because the effort of walking is reduced and walking range increased, ODFS users are better able to interact with able bodied colleagues in the work place. Because the ODFS may enable access where wheelchair access is not possible, fewer adaptations may be required.

39% of ODFS users reported that they needed assistance from another person while walking before they

received the device. After starting to use the ODFS, 46% reported that they required less assistance while 17% no-longer required assistance. This increase in independence reduces the burden on carers and family members.

Conclusion

It has been demonstrated that the functional benefit from use of the ODFS has a significant benefit on quality of life, resulting in a mean QALY gain of 0.065. Using 2007 treatment costs (£1640 in the first year and between £300 and £600 per year in subsequent years) the average cost per QALY after one year of treatment is £25,235. This is well within the NICE benchmark for cost effectiveness of £30,000 per QALY. However, the ODFS is a long term mobility aid suggesting that cost per QALY over 5 years of between £8,738 and £12,431 is more representative. In addition to the QALY gain there may significant cost savings to the NHS from prevention of injury due to falls, improved health due to increased fitness and reduction in use of other aids Finally, the greater social integration promoted by the device allows greater participation in society and in some cases supports employment.

Supplier

The Odstock Dropped Foot Stimulator is CE marked and FDA approved and is supplied by Odstock Medical Limited, The National Clinical FES Centre, Salisbury District Hospital, Salisbury, Wiltshire, SP2 8BJ, UK. Odstock Medical, which was England's first NHS owed company, also provides a clinical FES service to the NHS.

References

1. Kesselring, J, Neurorehabilitation in Multiple Sclerosis- what is the evidence base? Journal of Neurology 2004; 251, (4); 25-29.

2. Finlayson M. Studies examine aging with MS with help of NARCOMS Registrants. MSQR online. 15/08/2006. United Spinal Association and the CMSC/Nprth American Research Committee.

3. Liberson, WT; Holmquest, HJ; Scot, D; et al (1961) Functional electrotherapy: Stimulation of the peroneal nerve synchronized with the swing phase of gait of hemiplegic patients. *Archives of Physical Medicine and Rehabilitation, 42:101-105.*

4. Taylor PN, Burridge JH, Wood DE, Norton J, Dunkerley A, Singleton C, Swain ID. Clinical use of the Odstock Drop Foot Stimulator - its effect on the speed and effort of walking. *Archives of Physical Medicine and Rehabilitation,* 80: 1577-1583, 1999.

5. Granat MH, Maxwell DJ, Ferguson ACB, Lees KR and Barbenel JC, Peroneal Stimulation. Evaluation for the correction of spastic drop foot in hemiplegia. Archives of Physical Medicine and Rehabilitation 1996; 77; 19-24

6. Taylor PN. The use of electrical stimulation for correction of dropped foot in subjects with upper motor neuron lesions. *Advances in Clinical Neuroscience and Rehabilitation,* 2(1): 16-18, 2002.

7. 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. *Clin Rehabil* 11. 201-210.

8. DEC report. See www.salisburyfes.com

9. Wade D, Wood V, Hellar A, Maggs J, Langton-Hewer R. Walking after stroke. Scandinavian Journal of Rehabilitation Medicine. 1987. 19(1). 25-30

10. Bailey M, Ratcliffe C. Reliability of Physiological Cost Index in walking normal subjects using steady-state and non-steady-state and post-exercise. Physiotherapy. 1995. 81(10). 618-623.

11. Zigmond AS and Snaith RP. The Hospital Anxiety and Depression scale. Acct Psychiatric Scandinavia 1983; 67; 361-70.

12. Rosser R, Cottee M, Rabin R, Selai C. Index of health-related quality of life. in Hopkins A, Measures of quality of life, (1992) Royal College of Physicians.

13. Swain ID, Taylor PN. The clinical use of functional electrical stimulation in neurological rehabilitation. *In:* Horizons in Medicine 16 – Updates on major clinical advances. Ed. Franklyn J. Pub. Royal College of Physicians, ISBN 1-86016-233-9, London, pp. 315-322, 2004.

14. Mann GE, Jolley CJ, Taylor PN. An investigation into the effect of functional electrical stimulation on mobility and quality of life in patients with Multiple Sclerosis. *10th Annual Conference of the International FES Society*, pp. 309-311, Montreal, Canada, July 2005

15. Nurmi I, Lüthje P. Incidence and costs of falls and fall injuries among elderly in institutional care. Scand J Prim Health Care. 2002 Jun;20(2):118-22.

16. Taylor PN, Burridge JH, Dunkerley AL, Lamb A, Wood DE, Norton JA, Swain ID. (1999) Patient's Perceptions of the Odstock Dropped Foot Stimulator (ODFS). *Clin. Rehabil* 13: 333-340.

17. Taylor PN, Ewins DJ, Fox B, Grundy D, Swain ID. Limb blood flow, cardiac output and quadriceps muscle bulk following spinal cord injury and the effects of training for the Odstock Functional Electrical Standing System. Paraplegia 31 (1993) 303-310

Appendix 1

Economic justification of the STIMuSTEP implanted Dropped foot stimulator.

The STIMuSTEP provides the same function as the ODFS but the stimulus is delivered through implanted electrodes. This has several advantages. Firstly the task of correctly placing the self adhesive skin surface electrodes is removed from the patient. This means consistent results are produced from the device. It is also more convenient for the device user. Secondly, some users of external skin electrodes are affected by skin irritation. This risk is completely removed by the use of implanted electrodes. Finally, the sensation of the electrical stimulation is reduced because the skin is no longer stimulated. These advantages mean that the STIMuSTEP requires less clinical follow up and there are reduced consumable costs.

The device was tested in a series of case studies[16]. Overall, the clinical effect of the device was found to be comparable to the ODFS but with the advantages outlined above[18]. While full QALY analysis has not been carried out for the STIMuSTEP it is reasonable to assume that its impact of quality of life is as least as good as the ODFS allowing the same QALY gain to be used.

Costs (2007)

The costs of the STIMuSTEP in the first year are £7,187. This includes 6 months use of the ODFS to test for the suitability of the implant before receiving the device. The price also includes the cost of the device, the surgical costs, follow up and a contingency against the cost of corrective surgery if required. The cost of follow up in subsequent years is £351. The cost per QALY is shown in table 9. It can be seen that the mean cost per QALY at 5 years is £26,434, comfortably within the NICE limit of £30,000 per QALY. As the STIMuSTEP is a long term Mobility aid, this is an acceptable time scale over which to demonstrate cost effectiveness. Because the suitability for the implant is tested before implantation using the ODFS, poor responders can be excluded from the procedure. This means it is reasonable to assume that QALY gain will be in the upper 50 percentile of the range. As with the ODFS there are likely to be consequential cost savings to the NHS due to reduced risk of injury due to falls, improved overall heath status and reduced use of other assistive aids.

Table 9. Mean, median, 25th and 75th percentile cost per QALY for the STIMuSTEP implanted Dropped Foot Stimulator

	QALY	1 year	5 year	10 year
Actual cost		**£7,187**	**£8,591**	**£10,346**
Mean	0.065	£110,569	£26,434	£15,917
Median	0.041	£175,293	£41,907	£25,234
0.75	0.0975	£73,713	£17,623	£10,611
0.25	0.0225	£319,422	£76,364	£45,982

Conclusion

The STIMuSTEP is a cost effective long term mobility aid for the correction of dropped foot.

References

18. Taylor PN, Mann GE, Wood DE, Hobby J. Pilot study to evaluate the safety and efficacy of an implanted dropped foot stimulator (IMPULSE). *8th Annual Conference of the International FES Society*, pp. 168-172, Queensland, Australia, July 2003

Appendix 2

Index of Health Related Quality of Life (IHQL)

The IHQL provides a broad and sensitive measure of social, psychological and physical functioning and is designed to be applicable across all diagnostic groups. It is therefore possible to derive an assessment of health status on a single scale. The IHQL is derived from the original 2 dimensional Rosser index based on the dimensions of disability and distress. However, the dimension of distress has been split into physical (pain) and emotional distress to make a 3 dimensional index.

Dimensions

Disability

D1 No physical disability.

D2 Slight Social disability, e.g. slight cold. No limitations with physical ability, self-care or mobility, but some role functions slightly impaired by social disability.

D3 Slight physical disability. Able to get around the house and community but unable to perform heavy physical tasks. Role functions slightly limited by physical disability. Able to perform all self care activities.

D4 Able to get around the house and do light lighter physical work. Some difficulty getting around the community due to weakness or physical limitations. Can perform all self-care activities. Ability to perform role functions limited.

D5 Difficulty in getting around the house. Can only go out with assistance. Major physical limitations; e.g. can only do light work. Can perform most self care activities but needs help getting in and out of the bath. Limited abilities to perform role functions.

D6 Confined to a chair therefore can only get out with assistance. Can only do the lightest of tasks, e.g. switch on the TV. Can feed self but needs help with all other self-care activities. Very limited ability to perform role functions.

D7 Confined to bed. Needs help with all self-care activities. Minimal ability to perform role functions.

D8 Unconscious

Discomfort (pain)

P1 No Pain

P2 Slight pain (a) occasional
(b) frequently (c) almost all the time.

P3 Moderate pain (a) occasional
(b) frequently (c) almost all the time.

P4 Severe pain (a) occasional
(b) frequently (c) almost all the time.

P5 Agonising pain (a) occasional
(b) frequently (c) almost all the time.

Distress (emotional)

E1 No distress. Very happy and relaxed almost all the time.

E2 Slight distress. Happy and relaxed most of the time, but anxious and depressed some of the time.

E3 Moderate distress. Anxious and depressed most of the time, but happy and relaxed some of the time.

E4 Severe distress. Very anxious and depressed almost all the time.

E5 Extremely depressed. Actively suicidal.

	E1	E2	E3	E4	E5
D1	1.000	0.970	0.894	0.791	0.643
D2	0.990	0.960	0.884	0.781	0.632
D3	0.971	0.940	0.864	0.762	0.614
D4	0.946	0.917	0.840	0.738	0.590
D5	0.917	0.887	0.811	0.710	0.561
D6	0.885	0.855	0.780	0.678	0.530
D7	0.838	0.804	0.729	0.628	0.481

Rosser matrix for the first level of the pain dimensions. As the patient group that used the ODFS are known to not have significant pain resultant from stroke, no assessment of pain was made and therefore only the first pain dimension shown above was used.

Appendix 3
Summary of the evidence for the cost effectiveness of the ODFS July 2010

Since publication of "Economic Justification for the Odstock Dropped Foot Stimulator (ODFS)" a second report has been produced on the cost effectiveness of FES for correction of dropped foot. Additionally, further publications on the clinical effectiveness of FES have also been produced. The potential cost savings due to reduced falls has also been recalculated to reflect 2010 exchange rate and inflation. This evidence is summarised here.

PASA report.

The second economic report was produced by the Purchasing and Supply Agency in February 2010[3]. 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 is almost identical to the QALY gain of 0.042 calculated in the earlier study. A cost per QALY was found at 1 year of £52,336 and at 5 years of £19,238.

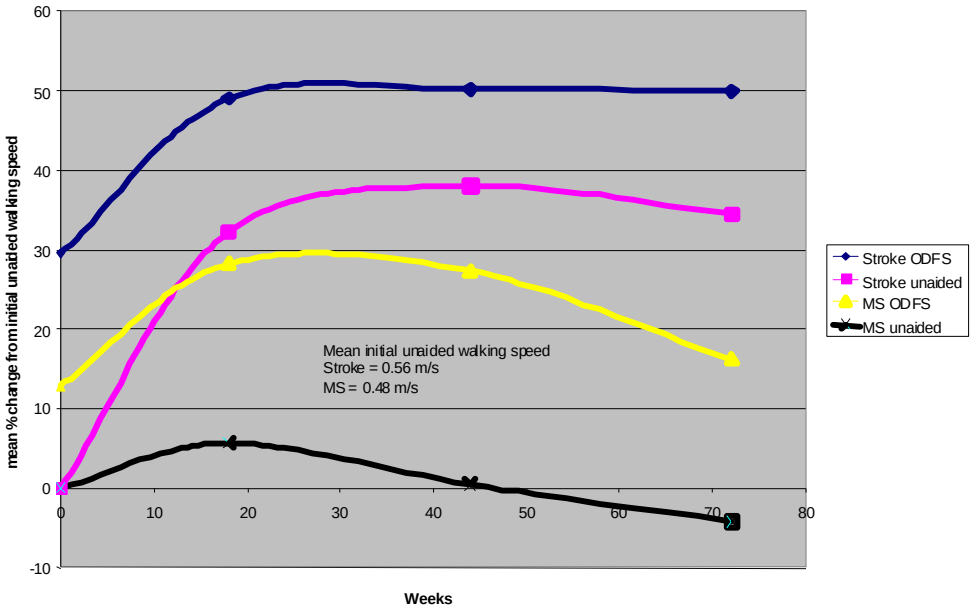
Cost effectiveness of the ODFS for people with a dropped foot due to multiple sclerosis.

The two studies produced comparable results using two different techniques and both support the proposition that the FES for dropped foot is a cost effective intervention. However both studies used data that was derived from trials of FES with people who had a dropped foot due to stroke. Can the results be applied to people who have a dropped foot due to multiple sclerosis?

While no equivalent study has bean performed for the MS group there is some data available that allows comparisons between stroke and MS. Figure 1 shows the effect on walking speed of ODFS use for 1 group who have a dropped foot due to stroke and a second group who have a dropped foot due to multiple sclerosis, over a 72 week period[4]. The gragh shows mean percentage change in walking speed normalised to walking without FES at the beging of treatment. It can be seen that the responce to the the device is different between the groups.

While the Stroke group show a significant increase in walking speed without FES after 18 weeks of device use, the MS group do not. The walking speed of the MS group is shown to reduce gradually over

Figure 1
Mean % change in walking speed for stroke (n=27) and MS (n=20) ODFS users



the 72 weeks and this is likely to be contributable to the progressive nature of MS. However, the lack of training effect at 18 weeks is still a surprise and suggests that there is difference the capacity for neuroplastic relearning between the two groups. This finding has also been reported in three other studies[5, 6, 7]. However, the direct benefit received from the device at any one time, represented by the difference between the lines for walking speed change with and without FES for the two groups is still comparable and in fact greater for the MS group than the Stroke group.

This difference in response to FES and the general progression of MS means that a MS FES user is less likely to increase their walking speed sufficiently to cross thresholds set by Perry and this would have the effect of reducing the initial QALY gain. However, there is a significant orthotic gain from the device and it can be seen that walking speed with the device at 72 weeks is still higher than initial walking speed unaided at the start of treatment. This indicates that FES users will take longer to pass the Perry thresholds as mobility declines resulting in preservation of quality of life.

The Purchasing and Supply Agency report took data on skin irritation due to electrodes from the 1998 clinical rehab paper on patient's perceptions of use of the ODFS[8]. The figure of 22% is relatively high and not in line with more recent clinical audit data that gave a prevalence of skin irritation. Since 1998 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[9]. In that time 585 individual patients were seen in the clinic. 13 cases of irritation were reported. An appeal for honesty to the clinicians working in the clinic indicated some under reporting, estimated to be about 25%. This therefore results in prevalence in the clinic of between 3 and 4 %. However, 8 cases were reoccurrence and 5 first time cases, 3 of whom developing skin reaction in the first 6 months and the other 2 between 12 and 18 months of ODFS use. This means the prevalence of new cases was around 1 to 1.5%. There were no cases of discontinued treatment due to skin irritation in this period. Further, in the randomised controlled trial of the ODFS with people who have secondary progressive MS, there were no reports of skin irritation in the period of the trial[5]. These results suggest that the dis-benefit effect of skin irritation has been significantly exaggerated in the Purchasing and Supply Agency report, resulting in a smaller QALY gain than might otherwise have been expected.

The main outcome measure used to indicate the effect of FES for dropped foot has traditionally been walking speed. It has been seen as a proxy measure for change in gait quality. However, Barrett and Taylor described a study that measured the effect of the ODFS use on quality of life measured using the Psychosocial Impact of Assistive Devices scale (PIADS) in a group of 20 people who had MS and 21 who had had a stroke[10]. 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 Faurier's Analyses (*F*-tests). A similar effect on walking speed was seen as previously shown in published papers. However, it was found that there was no correlation between change in walking speed and the quality of life measure. This indicates that walking speed while indicating an overall improvement in gait does not necessarily reflect the perceived benefit to the user of FES. The subjective benefits of the device reflected by the PIADS scores, such as increasing confidence during walking, reducing falls, and increasing social participation, may be of more importance to ODFS users than more routinely used objective measures. This may account for the low drop-out rate of 8.7% after a maximum of two years of ODFS use seen in this study. This value is much smaller than the average assistive device abandonment rate of 29.3% reported by Scherer[14], and is very similar to previously reported values of 8% reported by Taylor et al. in 2004[15].

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[11]. 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[12]. 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%[6].

A study by Esnouf et al, examined the effect of using the ODFS on activities of daily living (ADL) measured using the Canadian Outcome Performance Measure (COMP)[13]. In this randomized controlled trial, a group of 63 people who had a dropped foot due to secondary progressive MS were randomly assigned to a group that received the ODFS and another that received physiotherapy exercise over an 18 week period. At the end of the study it was found that there was no significant effect of ADL in the group who received physiotherapy while significant improvements in ADL were seen in the ODFS group. 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, recorded using a falls diary. No published data on the incidence of falls requiring medical treatment for people with MS could be found. However, data does exist for a general elderly population. Nurmi and Luthje (2002) performed an audit of falls amongst the elderly in institutional care[15]. They reported an incidence of falls of 1398 falls per 1000 person years and that one third of falls resulted in injury. The average cost per injury was €944. The average cost per fall per year was therefore €440. If falls that resulted in injury were reduced by the same proportion as in the ODFS trial, there would be an annual saving of €329 or €1650 over five years. Allowing for an inflation rate of 27% (retail price index) between 2002 and 2010 the annual saving would be €418 (£349) or €2099 (£1755) over 5 years at 2010 prices (exchange rate 14th July 2010). From an individual perspective, the mean time between injuries would increase from 2.15 years to over 7 years.

Conclusion

Two independent studies have examined the QALY gain due to use of FES for correction of dropped foot and have derived almost identical QALY values, both indicating that the intervention is cost effective. While

overall increase in walking speed is less in MS users of the ODFS, it has been demonstrated that use of the device delays the effective decline in walking speed and therefore progression bellow the Perry indicator thresholds. It can therefore be surmised that there is a likely QALY gain over the period the device is used. Additional data demonstrates that the ODFS positively impacts of activities of daily living, the effort of walking and quality of life and that the change in quality of life is similar to ODFS users who have a stroke. Finally the recorded significant reduction of falls may lead to additional cost savings to the health service due to reduction in the incidence of injuries.

Reference

1. Swain ID, Taylor PN, Burridge JH, Hagan SA, Wood DE. Report to the development evaluation committee Common peroneal stimulation for the correction of drop-foot (1996) http://www.salisburyfes.com/dec.htm

2. Taylor P, Mann G, Jolley C, Swain I. Economic Justification for the Odstock Dropped Foot Stimulator (ODFS). ISPO meeting 3rd Nov 2007

3. Economic Report. Functional Electrical Stimulation for dropped foot of central neurological origin. CEP10012. Published by the NHS Purchasing and Supply Agency Feb 2010 www.dh.gov.uk/cep

4. Taylor PN. The use of electrical stimulation for correction of dropped foot in subjects with upper motor neuron lesions. *Advances in Clinical Neuroscience and Rehabilitation,* 2(1): 16-18, 2002.

5. CL Barrett, GE Mann, PN Taylor and P Strike. A randomized trial to investigate the effects of functional electrical stimulation and therapeutic exercise on walking performance for people with multiple sclerosis. Mult Scler. 2009 Apr;15(4):493-504

6. Taylor PN, Burridge JH, Wood DE, Norton J, Dunkerley A, Singleton C, Swain ID. Clinical use of the Odstock Drop Foot Stimulator - its effect on the speed and effort of walking. *Archives of Physical Medicine and Rehabilitation,* 80: 1577-1583, 1999.

7. Stein RB, Everaert DG, Thompson AK, Chong SL, Whittaker M, Robertson J, Kuether G. Long-term therapeutic and orthotic effects of a foot drop stimulator on walking performance in progressive and nonprogressive neurological disorders. Neurorehabil Neural Repair. 2010 Feb;24(2):152-67. Epub 2009 Oct 21.

8. Taylor PN, Burridge JH, Wood DE, Norton J, Dunkerley A, Singleton, C, Swain ID. Patient perceptions of the Odstock Drop Foot Stimulator. *Clinical Rehabilitation,* 13: 333-340, 1999

9. Salisbury FES Newsletter Summer 2006, available at http://www.salisburyfes.com/summer2006.htm#7

10. Barrett CL, Taylor PN. The effects of the Odstock Drop Foot Stimulator on Perceived Quality of Life for People with Stroke and Multiple Sclerosis. Neuromodulation 2010 13, 1, pp: 58-64

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

12. Taylor P, Johnson M, Mann G, Swain I. Patterns of use and users' perceptions of the Odstock Dropped Foot Stimulator following stroke and multiple sclerosis. *9th Annual Conference of the International FES Society and 2nd FESnet Conference*, (ISBN 1-85899-191-9), pp. 296-298, Bournemouth, UK, September 2004

13. JE Esnouf, PN Taylor, GE Mann, CL Barrett. Impact on falls and activities of daily living of use of a Functional Electrical Stimulation (FES) device for correction dropped foot in people with multiple sclerosis. Mult Scler accepted for publication 10th feb 2010

14. Scherer MJ. Outcomes of assistive technology use on quality of life. *Disabil Rehabil* 1996;18:439–448.

15. Taylor P, Johnson M, Mann G, Swain I. Patterns of use and users' perceptions of the Odstock Dropped Foot Stimulator following stroke and multiple sclerosis. *9th Annual Conference of the International FES Society and 2nd FESnet Conference*, (ISBN 1-85899-191-9), pp. 296-298, Bournemouth, UK, September 2004