Economic report

Functional electrical stimulation for drop foot of central neurological origin

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Contents

This report examines the effectiveness and cost effectiveness of functional electrical stimulation (FES) as a treatment for drop foot due to central nervous system lesions such as stroke, spinal cord injury and multiple sclerosis (MS). FES involves the application of electrical impulses to the common peroneal nerve either via externally placed electrodes, positioned by the patient on the skin surface, or via surgically implanted electrodes.

In November 2009 we searched electronic databases and guideline portals for guidance, systematic reviews, randomised controlled trials and economic studies of FES. One guidance document, one systematic review and eight additional studies were found. We extracted data from relevant studies, appraised the results and compared the effectiveness of FES as reported across studies. A glossary of health economic terms used in this report is provided in appendix 3.

The review found few high quality studies reporting functional outcomes for people with drop foot of central nervous system origin treated with FES. A meta-analysis of studies including a non-randomised study estimated increased gait speed in people using FES for drop foot following stroke and reported that in a fixed effect model gait speed was significantly increased by 0.18 m/s compared with conventional treatments. This estimate was used as the basis for calculating a quality of life improvement for the economic model.

A single cost utility study using data from 1996 was found. Results suggested that there was a 0.065 QALY gain with FES versus 0.023 with physiotherapy, at a cost per QALY of £10,037 with five years continuous use (based on £166 per use and £431.60 for use over five years).

We developed a new economic model based on 2009 cost data. The cost-utility model takes a payer perspective (NHS) and reports outcomes as cost per quality adjusted life years (QALYs). Costs and outcomes were not discounted as the orthotic effects of FES only occur while a patient is using the device and costs and benefits are accrued within the same timeframe. Both a one year and a five year time horizon were used for the model.

The conservative base case suggests that FES has cost per QALY in the region of £19,238. In this model the cost per QALY in the first year is in the region of £52,337 and in each subsequent year in the region of £10,964.

Sensitivity analysis undertaken on the static model demonstrated that the model was sensitive to changes in time horizon, and assumptions regarding any gain in health utility.

A cost-effectiveness plane and cost-effective acceptability curve were generated using a Monte Carlo simulation with 10,000 iterations of the model. This showed that with expected variation to the inputs, at a willingness-to-pay threshold of £30,000 per incremental QALY, this model estimates the probability that FES is cost-effective to be 0.66 or 66%.

The model's costs reflect a typical NHS FES service, but may vary with the introduction of new service models and new FES devices, the wireless devices for example are more expensive than the wired device that has been costed here. The high costs in the first year reflect the higher number of appointments in the first year. The quality of life gains from FES in this model are based entirely on walking speed, there may be other quality of life improvements that are not captured in this model.

The economic model underpinning this report is based on the published efficacy of FES in treatment of stroke patients and on the reported costs of the wired Odstock Dropped Foot Stimulator (ODFSII). The model may be applicable to MS patients too, but the efficacy estimates in the model, particularly the incremental improvements in walking speed, should ideally be studied in a MS population first. It is reasonable to make the assumption that the QALY gain would be essentially the same for any of the wired dropped foot devices on the market and may be higher for implantable devices. The ICER (the cost per QALY) will be different, depending on the device used, its cost and the condition being treated.

Conservative modelling of functional electrical stimulation for drop foot of central neurological origin shows that it is likely to be cost effective. There is significant potential to organise services to optimise that cost-effectiveness.

Background

Functional electrical stimulation (FES) is a treatment for paralysis due to central nervous system lesions such as stroke, spinal cord injury and MS. It involves the application of electrical impulses to the common peroneal nerve either via externally placed electrodes, positioned by the patient on the skin surface, or via surgically implanted electrodes. Frequency of stimulation, pulse width, amplitude and waveform may be selected in order to maximise efficacy. Such an intervention can produce contraction in the dorsiflexor muscles to prevent drop foot during walking [1]. First-line interventions currently used in practice to treat drop foot are physiotherapy and ankle-foot orthosis. Pharmacological treatments include baclofen, dantrolene and botulinum toxin; surgery is rarely indicated.

The Odstock Dropped Foot Stimulator (ODFS) was originally developed by Odstock Medical Limited (OML) in 1989-95, with funding provided by the Medical Devices Agency in the Department of Health. The national clinical FES service, based in Salisbury District Hospital, Wiltshire, commenced in 1995, following completion of the first randomised controlled trial comparing the device with physiotherapy in 32 subjects [2]. As of 2006, 2,100 people were reported by Odstock to have been treated using FES, 54% of whom had suffered stroke, 25% MS, 8% spinal cord injury and 13% a variety of other neurological conditions. Typically, 40 patients are treated by the service each week, four of whom are new referrals [1].

People eligible for the treatment are required to have drop foot due to an upper motor neurone lesion, and to be able to walk assisted for at least several metres. All eligible patients may currently be referred to the service by their GP or consultant, at which point FES funding may need to be applied for before an appointment is made, FES will then be tried and, if suitable, follow-up appointments arranged to instruct on use of the device. The service may still be limited on a nationwide scale due to lack of local availability; however, training courses provided by the national clinical FES service to physiotherapists have now allowed provision of a variety of FES devices at centres across the UK. To date, there are said to have been more than 1000 OML systems placed outside of Salisbury. It is reported that in some cases NHS funding may not be possible as local funding may be capped [1]. Manufacturers of the devices also supply training.

FES was first recommended in selected patients by the Royal College of Physicians' national clinical guidelines on stroke [2,3]. In early 2009, NICE [4] advised that there was adequate evidence on the safety and efficacy of FES for drop foot of central neurological origin to support its use with normal arrangements for clinical governance, consent and audit. NICE based this recommendation primarily on the findings of a 2006 meta-analysis of use of FES to improve gait in stroke patients [5], supported by data from further RCTs and a case series [1].

FES is increasingly being used in the treatment plans of people with foot drop due to multiple sclerosis. This report has a focus on stroke and uses costing for the wired device sold by OML. Studies into the effects of FES in a MS population and comparative research with alternative devices are underway and a timely revision of this document is advised when this data becomes available.

Report objective

This economic report aims to evaluate the clinical and cost effectiveness of FES when compared with alternative treatments of orthoses, physical rehabilitation or medical treatments. Data is extracted from relevant sources including all relevant systematic reviews and randomised controlled trials. Eligible reviews and studies have specified the use of FES in people with drop foot of central neurological origin. The majority of studies concern stroke patients. Only studies which have specified the use of FES for drop foot have been considered.

The economic model underpinning this report is based on the published efficacy of FES in treatment of stroke patients and on the reported costs of the wired ODFSII. It may be applicable to MS patients too, but the efficacy estimates in the model, particularly the incremental improvements in walking speed, should ideally be studied in a MS population first. It is reasonable to make the assumption that the QALY gain would be essentially the same for any of the dropped foot devices on the market for stroke but the cost per QALY will be different, depending on the device used and the condition being treated.

Methods

Search strategy

The main search was conducted on the 18th November 2009.

Search strategies (see appendix 2), including key words and sensitivity/specificity filters, were focused on finding studies of effectiveness, economic evaluations and utility and quality of life scores for people with drop foot arising from stroke. The databases listed in table 1 were initially searched for systematic reviews, randomised controlled trials and cost-effectiveness studies. Studies in languages other than English were not included. All references were stored in Reference Manager.

Table 1. Databases searched

Electronic sources	Medline (1950 to date)
	Embase (1988 to date)
	Cochrane Library, including Cochrane Central, Cochrane Database of Systematic Reviews
	CRD databases including Health Technology Assessment Databases, NHS Economic Evaluation Database, Database of Abstracts of Reviews of Effectiveness
Guidelines	NELH Guidelines finder
	National Guidelines Clearing House (USA)

Critical appraisal

All studies found in the search were critically appraised and assessed for:

- relevance to the research questions, including their UK setting

- validity of research design. Study designs that minimise many forms of bias, (including selection, recall, researcher, participant, funding, and publication biases) and confounding errors arising from omitted variables; designs that are powerful enough to detect any significant effect; and designs that include valid populations and outcome measures. We considered observational studies for questions of safety, including case series. Economic evaluations were assessed according to methods described by Drummond 2005 [6] and considered reliable if underlying effectiveness estimates were sourced from randomised controlled trials or systematic reviews

- validity of research conduct. Studies that appear to be relevant and appropriately designed can still be carried out, analysed or reported in a way that compromises their reliability. Conflicts of interests are reported where these are declared.

Study comparison and synthesis

Study results are reported in evidence tables allowing comparisons across the studies which have been appraised. A senior reviewer assessed whether effectiveness could be determined from well-conducted randomised controlled trials and systematic reviews of their findings. Consideration was given to evidence from less reliable sources, such as less well-conducted randomised controlled trials and systematic reviews, or non-randomised studies, including observational studies, where there were gaps in the high level evidence.

Results of evidence review

Clinical efficacy

The systematic review and meta-analysis conducted by Robbins et al [5] in 2006 aimed to investigate the effect of FES on improving gait post-stroke (drop foot not specified). In the meta-analysis of three studies FES significantly increased gait speed by 0.18 m/s compared with conventional treatments (95% confidence interval 0.08 to 0.28; fixed effects model; data from one RCT, one crossover RCT and one non-randomised trial; n=71). Effect sizes of all five FES studies ranged from -0.11 to 1.43.

The NICE review [7] included these trials and two later RCTs that assessed implanted electrodes. In one RCT [8] walking speed improved by 23% in the FES treatment group versus 3% in those treated conventionally (p=0.010). In the second RCT [9] FES significantly improved gain in gait component execution (assessed by the Tinetti gait scale - a validated 12 point scale for assessing fall risk) compared with physiotherapy (parameter estimate 2.9, 95%CI 1.2 to 4.6; p=0.003; n=32). Erythema, skin redness, has been the most notable adverse effect in case series for implanted electrodes.

Our search identified eight additional studies published after the date of the NICE review (appendix 1). In seven of these studies patients were specified to be post-stroke or to have chronic hemiparesis as a result of stroke or an upper motor neurone lesion (two within 6 months of stroke, four post 6 months, and one unspecified time interval). Two of the studies did not specify that patients had drop foot. The smallest study was a case series involving 15 participants; the six remaining RCTs had sample sizes ranging from 23 to 40. Comparators were variable: passive movements (Bobath technique), physiotherapy-assisted stretching, ankle-thigh adhesive taping, home exercise programme, or no intervention in combination with ankle-foot orthoses or rehabilitation exercises. Studies varied in whether the comparator treatment was also used in conjunction with FES. The treatment period ranged from five daily sessions to four weeks of treatment. One study used implantable electrodes; all others used different FES devices.

Individual studies specified different primary outcomes and had variable results, making overall conclusions on efficacy difficult. Both of the two largest RCTs found that FES significantly improved ankle range of movement and dorsiflexion strength during treatment, but these improvements were limited to the time of the intervention. The study by Mesci et al [10] followed patients post treatment and found no differences between the intervention and control groups at the end of the study. Reflecting the findings of the Robbins et al [5] systematic review, one RCT and one case series found that FES significantly improved stride time and gait asymmetry. The one study by Kottink et al [8] involving implantable electrodes found improvement in maximum contraction of leg muscles. Improvement was limited to when the stimulator was switched on. One study found no differences between FES and conventional rehabilitation for any outcome, and another study found that FES was equivalent to ankle-thigh taping for improving range of movement. Only the case series considered patient preference, and this was in favour of FES rather than ankle-foot orthosis.

One RCT [11] involved 18 weeks of FES compared with a home exercise programme in 44 people with secondary progressive MS. There was no difference in any outcome at study end.

Economic evaluations of FES

Our search identified only one economic evaluation on the use of FES for drop foot [2]. The cost utility analysis was part of a report to the South and West Regional Development and Evaluation Committee by the researchers who performed an RCT of the ODFS, some of whom worked at the National Clinical FES Centre in Salisbury. It was published in 1996 and uses 1996 estimates of cost. Their estimates were 0.065 QALY gain with use of the ODFS versus 0.023 with physiotherapy, at a cost per QALY of £10,037 with five years continuous use (based on £166 per use and £431.60 for use over five years).

National guidance

2009 NICE guidance [7] states that current evidence on the safety and efficacy of functional electrical stimulation (FES) for improving gait in drop foot of central neurological origin is adequate to support the use of this procedure, with normal arrangements for clinical governance, consent and audit. It is recommended that patient selection for implantable FES should involve a multidisciplinary team specialising in rehabilitation. NICE recommends further research focusing upon patient-reported outcomes including quality of life and effect upon activities of daily living.

Discussion

The available evidence on the use of functional electrical stimulation to treat drop foot of central neurological origin comes mainly from small studies conducted on people with stroke, this makes overall conclusions on efficacy less firm and extrapolation of the results to other diseases difficult. There are considerable differences between conducted trials, which have used different devices and comparators (including differences in frequency of stimulation and other parameters), assessed different primary outcomes in differing populations, and found variable results. Many studies have also been limited by small sample size, loss to follow-up, and a lack of blinding.

There is some systematic review evidence that FES may improve gait speed and gait execution, and a few studies have found FES to improve range of movement at the ankle. However, several studies found no significant improvement with FES compared with conventional treatments.

Most studies were limited by only a short intervention period, with a lack of follow-up after treatment. However, studies which did provide post-treatment follow-up demonstrated that improvement was restricted to the time of use with a lack of improvement compared with baseline with discontinued use, or when the stimulator was not switched on. The short duration of efficacy studies has implications for economic models, which will usually consider cost over a one to five year treatment period. In addition, an important omission of studies is a lack of data on quality of life and patient-reported outcomes, such as satisfaction and improvement in activities of daily living. Studies have also been too small and of too short a duration to provide reliable safety data. Further research involving the different FES devices, both external and implantable, used in variable patient populations, will be needed on these outcomes to inform more reliably on the efficacy and safety of FES.

Objectives

The objective of this economic analysis was to develop a model of the likely benefits, disadvantages, and costs of FES when used to treat drop foot following stroke (no studies of drop foot due to other central neurological causes were suitable). The model comprises two elements:

1. a base case analysis derived from a conservative static model

2. a stochastic model (Monte Carlo simulation) using 10,000 iterations of the model, varying each of the inputs and generating a cost-effectiveness plane and cost-effective acceptability curve.

An interactive tool, in which the user can vary the assumptions made and examine their impact on the cost per QALY, is available as a separate Excel spreadsheet.

Methods

A model was developed to assess the cost-effectiveness of FES compared to usual care without FES in the rehabilitation of patients with drop foot following stroke. The model was built to capture the current clinical pathway. The base case is designed as a conservative estimate of cost-effectiveness. It forms the basis for a stochastic model which incorporates a measure of uncertainty for each parameter, then randomly selects from the distribution of each parameter to illustrate the overall impact of that uncertainty. In so doing, even though it is built on the conservative base case, it gives a reasonable estimate of the actual cost-effectiveness of FES for stroke patients.

Model structure

The structure of the model (figure 1) shows the flow of patients into various health states and the transitions between them,

Comparators

The comparator for this model was usual physiotherapy care without the use of FES. In this model FES is an additional therapy, meaning that rehabilitation continues as usual care. The costs and utilities gained from physiotherapy apply to all patients and therefore have not been included in the analysis.

Figure 1. Model structure
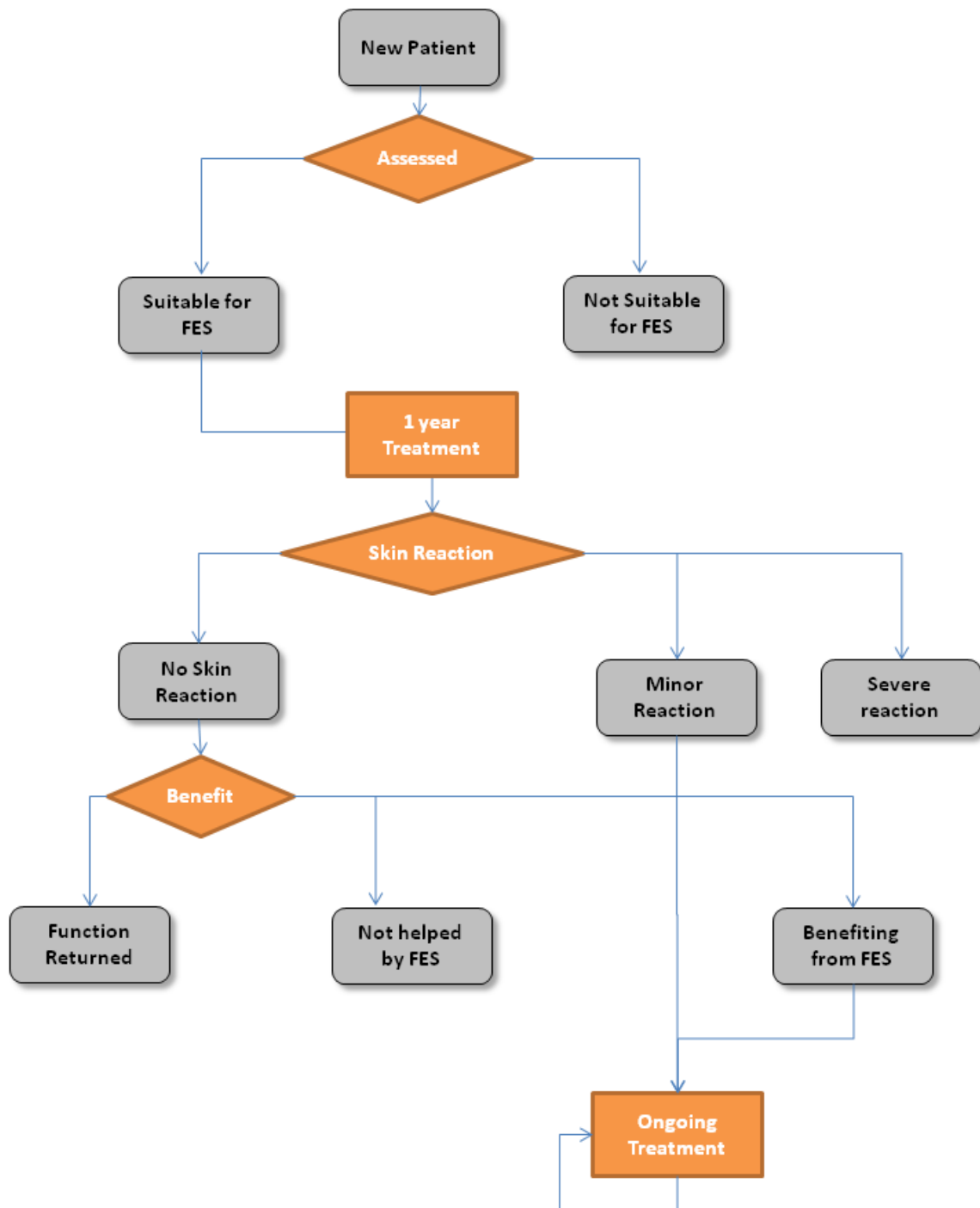
Cost data and assumptions

Costs are based on an assessment appointment costing £140, and on a clinic model in which the cost of the FES device are incorporated in the ongoing clinic charges. Each ongoing clinic appointment has been estimated at £300,with the assumption that patients all have five clinic visits in the first year, and between one and two in the second and subsequent years [12]. In the base case it is assumed that 50% of patients have two clinic visits in each ongoing year, and 50% will have one clinic visit each year.

Inputs to the base case are presented in table 2.

Discounting

Because the orthotic effects of FES only occur while a patient is using the device, within this model costs and benefits are accrued within the same timeframe. Discounting is therefore irrelevant and has been ignored.

Quality of life modelling

There are no published studies that specifically assess the quality of life (QoL) of patients using FES. This model was therefore built using a number of different sources, including data published on stroke quality of life [13-18], health states deduced from studies using FES [5,8-10,19-27], health states deduced from eligibility criteria to treatment with FES [19,21,24,25] and hypothetical measurable utility gains that might be recorded using a standard generic instrument [14,28,29].

Effect of eligibility for FES

The responsiveness of generic QoL measures suggests that European Quality of Life-5 Dimensions (EQ-5D), Health Utility Index Mark 2 and 3 (HUI2 and HUI3) strongly correlate with clinical scoring measures and that the Short Form-6 Dimensions (SF-6D), HUI3 and EQ-5D where most responsive to changes in patients condition [14]. The eligibility criteria for FES are reasonably consistent between studies [8,19,21,26]. Due to the criteria for eligibility for FES, especially criteria such as *'Ability to stand unsupported and to walk 10m without the aid of another person'*, mean that EQ-5D and HUI2 do not allow for the possibility of FES improving the QoL utility scores.

HU13 is an acceptable scale for modelling increased health utility in patients with stroke using FES.
Those patients whose functional ability improved significantly using FES might conceivably improve by one grade on the ambulation attribute of the HUI3 scale.

Quality of life baseline score

The model's QoL baseline score was estimated using data from a number of sources [13,15-18,29]. However, QoL gains are imputed, and are therefore absolute rather than relative; the baseline assumption has no impact on the cost per QALY estimate.

QALY analysis is based on the original data reported in two studies of the ODFS [19,30].

Effectiveness outcome data and assumptions

Measured walking speed

Perry et al [29] classified the functional ability of patients with a stroke by their walking speed. For the group of patients eligible to use FES there are two important functional speeds [28] - 0.58 m/s which equates to an ability to perform moderate community activity, and 0.8 m/s which equates to functional independent walking [29].

We have assumed that patients who through the use of FES are able to increase their walking speed to >0.8 m/s are equivalent to the patients who have a measurable increase in QoL as measured by improvement of one grade on the ambulation attribute of the HUI3 scale.

Functional independent walking

HUI3 is a very coarse instrument for assessing improved utility. This means that the above assumption is likely to grossly underestimate the utilities gained through use of FES. Increasing walking speed to above 0.58m/s is another key milestone that may or may not cause patients to improve by one grade on the HUI3 Ambulation attribute. It seems reasonable and still a conservative approach to estimate that the utilities gained through crossing this milestone are equal to half that of crossing to functional independence. This will still underestimate utilities attributable to FES as patients who improve, but do not cross the functional thresholds, will not be classified as achieving any gain.

We have assumed that patients who through the use of FES are able to increase their walking speed to >0.58 m/s are equivalent to the patients who have an increase in QoL equivalent to one half of a grade on the ambulation attribute of the HUI3 scale.

Increase in quality of life

Four papers were used to model the effects according to the assumptions above [19,21,24,25]. The quoted mean and standard deviation of the walking speeds were used to calculate the proportion of the treatment group above each of the functional speeds 0.58 m/s and 0.8 m/s, at baseline and when stabilised using FES.

The increase in the proportion in each functional group, in each of the four studies [19,21,24,25], was weighted by the sample size in each study to calculate a weighted average for the gain in each functional group. This value was then used for the base case.

Minor skin reactions

There are a group of patients who suffer minor skin reactions to the use of the FES electrodes [20,31]. As they elect to continue using the equipment it is assumed that their loss of utility from the distress caused is less than the utility gained. In the base case it is assumed that each person benefiting from FES and suffering a minor skin reaction was one of those who crossed a walking speed threshold. This is an extremely conservative estimate, as the model does not fully account for possible benefits but fully accounts for possible harm. Minor skin reactions are assumed to cause enough distress to cause a loss of one grade on the pain attribute of the HUI3 scale.

Major skin reactions

Some patients suffer such severe reactions to the use of the electrodes that they stop using FES [20,32]. It is assumed that major skin reactions are sufficiently distressing to cause a loss of two grades on the pain attribute of the HUI3 scale, and that any patient suffering this level of distress would cease to use FES. It is also assumed that these skin reactions become apparent at the end of the first year. This is a conservative assumption as this group of patients will incur a full year of costs and derive no utility from that year.

Table 2. Inputs to the model

	Categories	Base case values
General	Suitable for FES	85%
	Not suitable for FES	15%
Skin reaction	No skin reaction	75%
	Minor skin reaction	22%
	Severe skin reaction	3%
Effectiveness	Benefit	74%
	Return of function	18%
	No benefit	8%
Costs (£)	Initial assessment	£140
	Year 1 treatment	£1500
	Ongoing treatment	£450 pa
Quality of life	Baseline	0.75
	Benefiting	0.92823
	Minor skin reaction	0.81855

Four additional variables were included in the model to take account of reported current practice (table 3). Not all patients can be expected to gain a measurable QoL benefit from FES. The therapeutic effectiveness of FES (ie the percentage of physical function returned to the patient was assumed to be zero for the base case analysis. Therapeutic effect has been demonstrated in uncontrolled studies not RCTs [24,33]. The impact of accepting any reasonable estimate of therapeutic effect can be varied in sensitivity analysis. Some stroke patients will require more than two clinic visits in the ongoing years. The average duration of FES treatment was assumed to be 5 years for the base case analysis.

Table 3. Additional variables

	Variable	Base case values
1.	Percentage of people gaining a measurable QoL benefit	28%
2.	Therapeutic effect of FES	none
3.	Proportion requiring 2 clinic visits in each ongoing year	50%
4.	Mean number of years of FES treatment	5

Stochastic model

A stochastic model with Monte Carlo simulation using 10,000 iterations of the model was developed. This model varied each of the inputs within their expected distributions and a cost-effectiveness plane and cost-effective acceptability curve was generated.

In the stochastic model it is assumed that the patients who have minor skin reactions and continue to use FES gain at least enough utility from FES to counteract the disutility from the skin reaction.

Base case analysis

The conservative base case presents the comparison of costs and outcomes expected using FES for drop foot following stroke (table 4). These suggest that FES has a cost per QALY in the region of £19,238. In this model the cost per QALY in the first year is in the region of £52,337 and in each subsequent year in the region of £10,964.

Table 4. Base case results for a cohort of 100 patients

		Number of patients	Costs	Total costs
Cohort costs	Assessed	100	£140	£14,000
	Year one	85	£1500	£127,500
	Ongoing/subsequent years	65.875	£450	£29,644
		Number of patients	**QALY gain**	**Total gain**
Cohort benefits	Assessed	100	0	0
	Year one	65.875	0.041	2.703651018
	Ongoing/subsequent years	65.875	0.041	2.703651018
		Cost/QALY		
Incremental cost effectiveness ratio (ICER)	Year one	£52,336.64		
	Subsequent years	£10,964.34		
	5 year mean	£19,238.80		

The cost per QALY is higher in the first year compared with subsequent years because patients need more clinic visits in the first year, so the first year of utilities are gained at a high cost. The number of visits and therefore the annual cost reduces in year two onwards for patients that continue treatment. This suggests that with careful patient selection and identification of patients who are committed to using FES long-term, the cost per QALY in practice might be close to the five year mean of £19,238.

Sensitivity analysis

The sensitivity analysis (table 5) shows that:

1. the cost-effectiveness of FES is moderately influenced by the design of the clinical pathways that patients follow

2. the cost-effectiveness of FES is significantly affected by how long patients continue to benefit from treatment. For example, compared with the base case ICER of £19,171 over 5 years of treatment, FES provided for two years suggests a mean ICER of about £31,539 whereas if FES is provided for ten years the ICER falls to £15,049

3. the cost-effectiveness of FES is significantly influenced by gains in health utility, the area where the literature is weakest. For example, the ICER for FES rises if a therapeutic effect is modelled. If 50% of FES users regained function, the analysis would suggest an ICER of £17,827.

Table 5. Sensitivity analysis

	Base case	Sensitivity analysis	Mean ICER (£/QALY)
Base case	N/A	N/A	£19,171
General			
Time horizon	5 years	2 years	£31,539
	5 years	10 years	£15,049
Effectiveness			
Return of function	No therapeutic effect of FES	25% of function returned	£18,475
		50% of function returned	£17,827
		75% of function returned	£17,224
Costs			
Initial assessment	£140	£280	£20,203
Clinic cost	£300	£500	£32,296
Health-state utility			
QoL gain	0.0499	(high gain) 0.0639	£14,307
		(low gain) 0.0359	£29,044

Stochastic model

At a willingness-to-pay threshold of £30,000 per incremental QALY, this model estimates the probability that FES is cost-effective to be 0.66 or 66% (figure 2).

Figure 2. Overall (5 year) cost-effectiveness acceptability
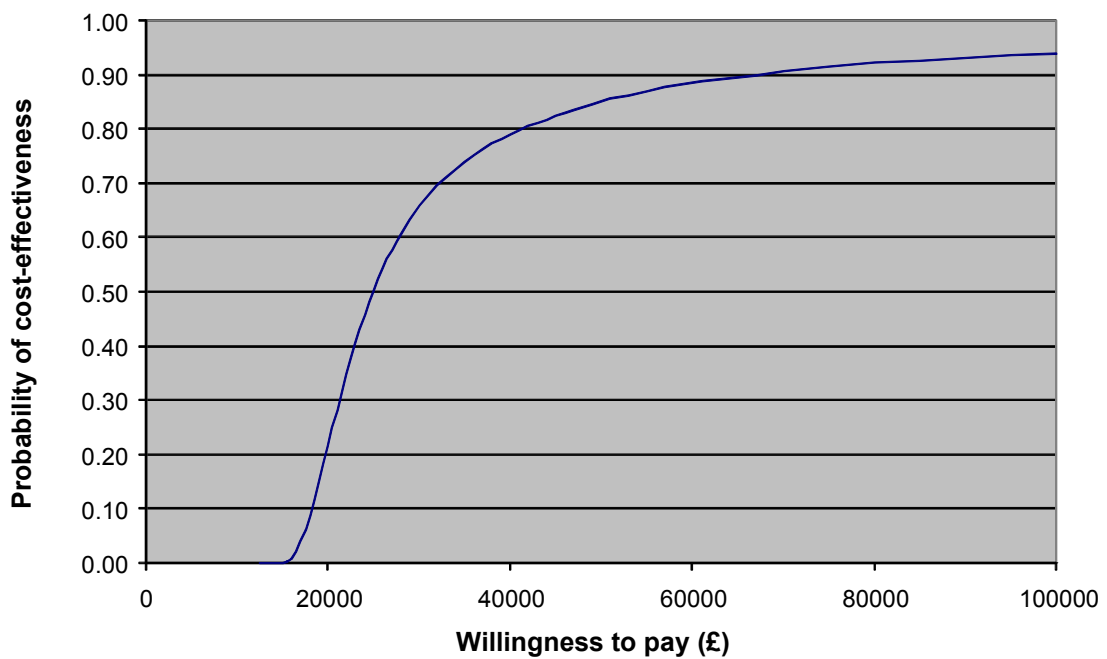
Discussion

We found one systematic review, one NICE review and eight additional studies. The evidence for effectiveness of FES is limited by significant variations in the way the devices are used, the length of treatment courses, patient characteristics and the outcomes measured in the trials. This restricts direct comparison of the data and allows only general conclusions to be drawn.

Trials have shown an improvement in walking speed, although this may be a physiological outcome unrelated to functional improvement. It does indicate that, at least in trials, FES has the potential to improve gait. No trials were found that reported carry-over effects when the devices were removed, and although promoted as useful for rehabilitation, the exact role of the devices in a comprehensive rehabilitation plan may vary between patients. Specialists invited to comment on the NICE guidance [7] thought that patient selection and treatment application were important in the application of this technology. Not all patients with spasticity of the foot will benefit from FES. They comment that treatment will need to be long term in many cases.

There is limited evidence about quality of life and the impact of the procedure on disability, either from the patients' perspective or that of carers and family members.

We found one cost utility study [2] based on the Odstock Drop Foot Stimulator, published online using data from 1996. A new model was developed to take account of current costs and pattern of use.

Conservative modelling of functional electrical stimulation for drop foot of central neurological origin shows that it is likely to be cost effective. There is significant potential to organise services to optimise that cost-effectiveness.

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1. Functional Electrical Stimulation (FES). Research, Development and Clinical Service [Internet] Salisbury: National Clinical FES Centre; 2009 [updated 2009; cited 2010 Jan 15]. Available from: http://www.salisburyfes.com/

2. 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. South and West Regional Development and Evaluation Committee; 1996. Available from: http://www.salisburyfes.com/dec.htm.

3. Intercollegiate Working Party for Stroke. National clinical guidelines for stroke. London: Royal College of Physicians; 2000.

4. NICE. Functional electrical stimulation for drop foot of central neurological origin. London: National Institute for Health and Clinical Excellence; 2009. Available from: http://www.nice.org.uk/nicemedia/pdf/IPG278Guidance.pdf.

5. Robbins SM, Houghton PE, Woodbury MG, Brown JL. The therapeutic effect of functional and transcutaneous electric stimulation on improving gait speed in stroke patients: a meta-analysis. Arch Phys Med Rehabil. 2006;87(6):853-9.

6. Drummond MF, Sculpher MJ, Torrance GW, O'Brein BJ, Stoddart GL. Methods for the Economic Evaluation of Health Care Programmes. 3 ed. New York: Oxford University Press; 2005.

7. NICE. Interventional procedure overview of functional electrical stimulation for drop foot of central neurological origin. London: National Institute for Health and Clinical Excellence; 2008. Available from: http://www.nice.org.uk/nicemedia/pdf/657_FES_overview_post%20IPAC%20II%20190109.pdf.

8. Kottink AI, Hermens HJ, Nene AV, Tenniglo MJ, van der Aa HE, Buschman HP, et al. A randomized controlled trial of an implantable 2-channel peroneal nerve stimulator on walking speed and activity in poststroke hemiplegia. Arch Phys Med Rehabil. 2007;88(8):971-8.

9. Daly JJ, Roenigk K, Holcomb J, Rogers JM, Butler K, Gansen J, et al. A randomized controlled trial of functional neuromuscular stimulation in chronic stroke subjects. Stroke. 2006;37(1):172-8.

10. Mesci N, Ozdemir F, Kabayel DD, Tokuc B. The effects of neuromuscular electrical stimulation on clinical improvement in hemiplegic lower extremity rehabilitation in chronic stroke: A single-blind, randomised, controlled trial. Disabil Rehabil. 2009;31(24):2047-54.

11. Barrett CL, Mann GE, Taylor PN, Strike P. 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;15(4):493-504.

12. National Clinical FES Centre. Submission to CEDAR regarding Functional Functional Electrical Stimulation. Salisbury: National Clinical FES Centre; 2009.

13. Haacke C, Althaus A, Spottke A, Siebert U, Back T, Dodel R. Long-term outcome after stroke: evaluating health-related quality of life using utility measurements. Stroke. 2006;37(1):193-8.

14. Pickard AS, Johnson JA, Feeny DH. Responsiveness of generic health-related quality of life measures in stroke. Qual Life Res. 2005;14(1):207-19.

15. Tengs TO, Yu M, Luistro E. Health-related quality of life after stroke a comprehensive review. Stroke. 2001;32(4):964-72.

16. Tengs TO, Lin TH. A meta-analysis of quality-of-life estimates for stroke. Pharmacoeconomics. 2003;21(3):191-200.

17. Tseng MC, Lin HJ. Health-related quality of life after stroke: review of the literature and implications for future research. Acta Neurol Taiwan. 2007;16(1):7-12.

18. Xie J, Wu EQ, Zheng ZJ, Croft JB, Greenlund KJ, Mensah GA, et al. Impact of stroke on health-related quality of life in the noninstitutionalized population in the United States. Stroke. 2006;37(10):2567-72.

19. Burridge JH, Taylor PN, Hagan SA, Wood DE, Swain ID. The effects of common peroneal stimulation on the effort and speed of walking: a randomized controlled trial with chronic hemiplegic patients. Clin Rehabil. 1997;11(3):201-10.

20. Daly JJ, Kollar K, Debogorski AA, Strasshofer B, Marsolais EB, Scheiner A, et al. Performance of an intramuscular electrode during functional neuromuscular stimulation for gait training post stroke. J Rehabil Res Dev. 2001;38(5):513-26.

21. Hausdorff JM, Ring H. Effects of a new radio frequency-controlled neuroprosthesis on gait symmetry and rhythmicity in patients with chronic hemiparesis. Am J Phys Med Rehabil. 2008;87(1):4-13.

22. Kottink AI, Hermens HJ, Nene AV, Tenniglo MJ, Groothuis-Oudshoorn CG, IJzerman MJ. Therapeutic effect of an implantable peroneal nerve stimulator in subjects with chronic stroke and footdrop: a randomized controlled trial. Phys Ther. 2008;88(4):437-48.

23. Ring H, Treger I, Gruendlinger L, Hausdorff JM. Neuroprosthesis for footdrop compared with an ankle-foot orthosis: effects on postural control during walking. J STROKE CEREBROVASC DIS. 2009;18(1):41-7.

24. Taylor PN, Burridge JH, Dunkerley AL, Wood DE, Norton JA, Singleton C, et al. Clinical use of the Odstock dropped foot stimulator: its effect on the speed and effort of walking. Arch Phys Med Rehabil. 1999;80(12):1577-83.

25. Waters RL, McNeal D, Perry J. Experimental correction of footdrop by electrical stimulation of the peroneal nerve. J Bone Joint Surg Am. 1975;57(8):1047-54.

26. Yavuzer G, Geler-Kulcu D, Sonel-Tur B, Kutlay S, Ergin S, Stam HJ. Neuromuscular electric stimulation effect on lower-extremity motor recovery and gait kinematics of patients with stroke: a randomized controlled trial. Arch Phys Med Rehabil. 2006;87(4):536-40.

27. Yavuzer G, Oken O, Atay MB, Stam HJ. Effect of Sensory-Amplitude Electric Stimulation on Motor Recovery and Gait Kinematics After Stroke: A Randomized Controlled Study. Archives of Physical Medicine and Rehabilitation. 2007;88(6):710-4.

28. Cunha IT, Lim PA, Henson H, Monga T, Qureshy H, Protas EJ. Performance-based gait tests for acute stroke patients. Am J Phys Med Rehabil. 2002;81(11):848-56.

29. Perry J, Garrett M, Gronley JK, Mulroy SJ. Classification of walking handicap in the stroke population. Stroke. 1995;26(6):982-9.

30. Burridge J, Wood D, Taylor P, Swain I, Hagan S. The effect of common peroneal nerve stimulation on quadriceps spasticity in hemiplegia. Physiotherapy. 1997;83(2):82-9.

31. Taylor PN, Burridge JH, Dunkerley AL, Lamb A, Wood DE, Norton JA, et al. Patients' perceptions of the Odstock Dropped Foot Stimulator (ODFS). Clin Rehabil. 1999;13(5):439-46.

32. Taylor PN, Johnson M, Mann GE, Swain ID. Patterns of use and users perceptions of the Odstock Dropped Fott Stimulator following stroke and multiple sclerosis. 9th Annual Conference of the International FES Society; 2004; Bournemouth. 2004.

33. Swain ID, Taylor PN. The clinical use of functional electrical stimulation in neurological rehabilitation. In: Franklyn J, editor. Horizons in Medicine 16 - Updates on major clinical advances. London: Royal College of Physicians; 2004. p. 315-322.

34. Bakhtiary AH, Fatemy E. Does electrical stimulation reduce spasticity after stroke? A randomized controlled study. Clin Rehabil. 2008;22(5):418-25.

35. Baricich A, Carda S, Bertoni M, Maderna L, Cisari C. A single-blinded, randomized pilot study of botulinum toxin type A combined with non-pharmacological treatment for spastic foot. J Rehabil Med. 2008;40(10):870-2.

Table 6. Retrieved studies on FES for drop foot after stroke

Study details	Population	Intervention and comparator	Outcomes	Results	Notes
Bakhtiary et al 2008 [34] RCT (blinding unclear) Location: Rehabilitation clinic of Semnan University of Medical Sciences	40 stroke patients with drop foot. Age: 42-65 years.	9 minutes FES (supramaximal stimulation current including 100Hz pulse every 6secs) plus 15 minutes inhibitory Bobath techniques (passive ankle movements) vs Bobath techniques only, administered over 20 daily sessions.	Ankle joint dorsiflexion range of movement (ROM), dorsiflexion strength, plantarflexion muscle tone, soleus muscle H-reflex (not specified which is the primary outcome).	Combination therapy significantly improved range of movement (mean change 11.4degrees vs. 6.1degrees; p=0.001) and dorsiflexion strength (mean change in strength grade [0-5] 0.7 vs. 0.4; p=0.04). There was no effect upon H-reflex.	

Study details	Population	Intervention and comparator	Outcomes	Results	Notes
Baricich et al 2008 [35] Single-blind RCT (assessors)

Location: Italy | 23 chronic hemiplegic patients with spastic equinovarus foot at least 6 months post stroke. | 3 treatment groups: FES (5-Hz, rectangular biphasic balanced current of the 30 min twice daily over 5 daily sessions; followed by 20mins calf muscle stretching); adhesive taping to the ankle and thigh (maintained for 5 days to stretch the muscles); and stretching (30mins physiotherapist-assisted stretching, twice daily for 7 days). | Modified Ashworth Scale; passive range of motion at the ankle; measurement of muscle action potential at the gastrocnemius medialis; and measurement of maximum ankle dorsiflexion angle in stance using gait analysis (not specified which is the primary outcome). Assessment 10, 20 and 90 days post-injection. | FES improved MAS score on the day of treatment. At 90 days both FES and taping improved all measures. Stretching was least effective. | Botulinum toxin type A injections were given to the medial and lateral gastrocnemius prior to the interventions where indicated by spastic grade and muscle size. The aim of the RCT was to investigate the effects of this in combination with various treatments and results have limited implication for isolated use of FES. |

Study details	Population	Intervention and comparator	Outcomes	Results	Notes
Barret et al 2009 [11] Unblinded RCT (concealed allocation) Location: National FES Clinic, Salisbury, UK	44 adults with secondary progressive MS and predominantly unilateral drop foot and good response to stimulation of the common peroneal nerve. Exclusion: cognitive, other neurological or orthopaedic impairment.	FES (ODFS single channel fixed frequency of 40Hz with adjusted amplitude and pulse width) vs home exercise programme, daily for an 18 week period.	Primary outcome: self-selected walking speed over 10 metres at 18 weeks. Secondary outcomes: physiological cost index (PCI) and distance walked in 3 minutes.	At study end, FES made no significant change to any outcome. Exercise significantly increased walking speed and distance walked. Within the FES group, stimulation improved walking speed and distance walked compared with no stimulation, with no effect on PCI.	53 patients were enrolled into the study and 9 dropped out. Results were not based on intention-to-treat.

Study details	Population	Intervention and comparator	Outcomes	Results	Notes
Hausdorff 2008 [21] Randomised crossover trial Location: Israel	24 patients with chronic hemiparesis (>6months) and drop foot. Inclusions: UMN deficit (not specified stroke); normal passive range of ankle movement; able to walk unassisted (with a cane) 10m; no cognitive impairment; muscle spacticity of no more than 4 on the Ashworth Scale. Mean age 54.0; hemiparesis for mean 5.8 years; 83.3% male.	FES (NESS L300) or no-FES. Patients walked with for 6mins while wearing force-sensitive insoles, once with and once without FES. 4-week adaptation period was given prior to study start in which they used the FES for increasing daily periods.	Temporal gait parameters, velocity and PCI. Assessments after 4 and 8 weeks of use.	FES significantly improved gait asymmetry index by 28% immediately and by 45% at 8 weeks. Stride time variability significantly decreased by 23% immediately and by 33% at 8 weeks. Walking speed significantly improved by 17% immediately and by 34% at 8 weeks.	Patients not followed up without use of the FES.

Study details	Population	Intervention and comparator	Outcomes	Results	Notes
Mesci 2009 [10] Single blind RCT (assessors) Location: Turkey	40 patients with chronic stroke. Inclusion: hemiplegia/hemiparesis due to first stroke ≥3 months previously; passive range of movement at the ankle; spasticity <4 on Modified Ashworth Scale. Exclusions: cognitive impairment; LMN or peripheral neural lesions; other CNS disorders; serious cardiac disease; skin or circulatory disorders; prior use of FES. Average patient age 60.9 years.	Inpatient FES (Swiss Complex II device; biphasic 50Hz frequency, 400µsn pulse width) or no FES, 5 days a week for 4 weeks (total 20 sessions; each FES session 20 mins). Both groups received a conventional rehabilitation exercise programme.	Ankle range of movement, spasticity Modified Ashworth Scale (MAS), neurophysiological improvement on the Brunnstrom Stage (BS), Rivermead Motor Assessment Scale, Functional Independence Measurement (FIM), Functional Ambulation Categories (FAC). Primary outcome not specified.	There were no differences between intervention and control groups for any parameter post-treatment. FES significantly improved ankle dorsiflexion ROM and MAS compared with pre-treatment levels (p<0.05). Neither of these measures differed pre- and post-treatment in the control group. Both groups showed improvement in BS, FIM, FAC and Rivermead motor scores.	Pre-treatment differences in ankle dorsiflexion ROM and MAS.

Study details	Population	Intervention and comparator	Outcomes	Results	Notes
Kottink, 2008 [22] Unblinded RCT Setting: The Netherlands	29 patients with hemiplegia and drop foot for >6 months duration as a result of stroke. Exclusions: limited passive dorsiflexion of the ankle, other significant neurological or medical comorbidity, and any contraindications to surgery.	Two-channel implantable FES vs continued use of a conventional walking device (ankle-foot orthosis, orthopaedic device or none).	Maximum root mean square (RMSmax) of tibealis anterior, peroneus longus, medial gastrocnemius, and soleus muscles during maximum contraction; and activity of the TA muscle during swing phase of gait (RMSswing).	FES increased RMSmax of the TA with extended knee, and the GS muscle with extended and flexed knee. There was no change in the control group. When the stimulator was not switched on there was no improvement in walking speed.	

Study details	Population	Intervention and comparator	Outcomes	Results	Notes
Ring, 2009 [23] Case series Setting: Israel	15 patients with chronic hemiparesis (>6 months) and drop foot as a result of stroke or brain injury (12 post stroke; 3 post brain injury). Inclusions: regular use of ankle-foot orthosis; normal passive range of ankle movement; able to walk 10m unassisted (or with a cane); no cognitive impairment; no significant comorbidity. Mean age 52.2 years.	FES (stimulation and gait parameters individualised). 4 week adaptation period using the FES for increasing daily periods while continuing to use their AFO. FES alone was encouraged during the following 4 weeks.	Self-selected 6MWT, gait asymmetry test and swing time variability. Assessments at 8 weeks.	FES significantly improved stride time (p<0.02), swing time variability (p=0.01) and gait asymmetry (p<0.05). No significant difference between FES and AFO in gait speed. Patient preference was for FES rather than AFO.	All patients included had previously been tested with their plastic AFO and had been using it for at least 6 months.

Study details	Population	Intervention and comparator	Outcomes	Results	Notes
Yauzer, 2007 [27] Double blind RCT Setting: University hospital, The Netherlands	30 consecutive inpatients (rehab) within 6 months of stroke. Inclusions: Brunnstrom score 1-3; no cognitive impairment; able to stand and walk with/without assistance; no contraindications to FES. Mean age 63.2 years.	FES (Sonopuls 992; biphasic stimulation; 35Hz, pulse width 240μs, variable amplitude) vs no FES. All patients received conventional stroke rehabilitation for 2-5 hours, 5 days a week for 4 weeks. Intervention group received an additional 30mins FES without muscle contraction (5 days for 4 weeks). Placebo group received an identical device with no stimulation.	Brunnstrom scale motor recovery, time distance and gait kinematics assessed at baseline and 4 weeks.	No significant differences between groups. Both FES and control groups demonstrated improvement in Brunnstrom stage, ankle dorsiflexion and gait kinematics.	

Search terms used

Note: These search strategies were crossed with methodological filters to retrieve systematic reviews, evidence-based reviews, guidelines, economic evaluations and studies describing utilities and quality of life for people with stroke.

MEDLINE + EMBASE (RCT + SR search)

21   (Functional electric* stimul* or Functional electric* therap* or FES or Odstock dropped foot stimul* or ODFS or Odstock).mp.

22   (neuromuscular* stimul* or Electric* stimul* or electrostimul* or electrotherap* or tens or transcutaneous nerve stimulation or electric nerve stimulation).mp.

23   exp Electric Stimulation Therapy/ or exp Transcutaneous Electric Nerve Stimulation/

24   ((Drop foot or foot drop or dropfoot or footdrop or dropped foot or gait or dorsiflexion or flexion or motor ability or neuromuscular re-training or muscular re-training or functional ability or (foot or feet or ankle*)) and (movement* or flexi* or extension or control or retraining or re-training or functional ability or torque or strength* or force)).mp.

25   Gait Disorders, Neurologic

26   21 or ((22 or 23) and (24 or 25))

CRD (all three databases)

#1   (Functional AND electric* AND stimul* OR Functional AND electric* AND therap* OR FES OR Odstock AND dropped AND foot AND stimul* OR ODFS OR Odstock)

#2   neuromuscular* AND stimul* OR Electric* AND stimul* OR electrostimul* OR electrotherap* OR tens OR transcutaneous AND nerve AND stimulation OR electric AND nerve AND stimulation

#3   Drop AND foot OR foot AND drop OR dropfoot OR footdrop OR dropped AND foot OR gait OR dorsiflexion OR flexion OR motor AND ability OR neuromuscular AND re-training OR muscular AND re-training OR functional AND ability

#4   MeSH Electric Stimulation Therapy EXPLODE 1 2

#5   MeSH Transcutaneous Electric Nerve Stimulation EXPLODE 1 2 3

#6   MeSH Gait Disorders, Neurologic EXPLODE 1 2

#7   #2 or #4 or #5

#8   #3 or #6

#9   #7 and #8

#10   #1 or #9

Search results

Databases and sites searched	Dates searched	Number of hits
MEDLINE – systematic reviews filter	1950-date	39
EMBASE – systematic reviews filter	1988-date	94
MEDLINE – RCTs filter	1950-date	412
EMBASE – RCTs filter	1988-date	486
MEDLINE – economics filter	1950-date	38
EMBASE – economics filter	1988-date	83
Cochrane CENTRAL	No date restrictions	497
CRD – DARE + HTA + EED	No date restrictions	82
Total number after de-duplication		**1152**
Total number after first appraisal		**120**

Glossary

Base case analysis: is the first analysis of an economic model against which any variations to the inputs are compared to in sensitivity analysis. It is usually the analysis which compares the addition of a new technology to current care in terms of changes in costs and outcomes of treatment

Conservative model: an approach to modeling that assumes minimal values for inputs where there is doubt

Cost effective acceptability curve (CEAC): a graphical way of summarising the information on uncertainty in cost-effectiveness analysis

Cost effectiveness: value for money. A specific health care treatment is said to be 'cost-effective' if it gives a greater health gain than could be achieved by using the resources in other ways

Cost effectiveness plane: a graphical way of demonstrating the results of cost effectiveness analysis. It directly shows the ICER of the new compared with the old treatment option and on the x and y axis (respectively) the additional effect and cost of the new treatment

Discounting: the annual rate at which future values (costs or benefits) are diminished to make them comparable to values in the present. These adjustments reflect that given levels of costs and benefits occurring in the future usually have less value in the present than the same levels of costs and benefits realised in the present.

Dorsiflexor muscles: the muscles on the front and side of the leg that bend the foot up when walking

Fixed effect model: gives a summary estimate of the magnitude of effect in a meta-analysis. It takes into account within-study variation but not between-study variation and hence is usually not used if there is significant heterogeneity (differences between the studies)

Incremental cost-effectiveness ratio (ICER): The difference in costs between one intervention and an alternative, divided by the difference in outcomes

Monte Carlo simulation: an analytical technique for solving a problem by performing a large number of trail runs, called simulations, and inferring a solution

from the collective results of the trial runs. The method calculates the probability distribution of possible outcomes

Peroneal nerve: the nerve supplying the muscles lifting the foot and activated by FES during walking

Quality Adjusted Life Year (QALY): a measure of the benefit of health care combining the impact of an intervention on both expected length of life and quality of life. QALYs can provide a common unit for comparing cost-utility across different interventions and health problems

Static model: an economic model that has no explicit time dimension. A static model abstracts from the process by which equilibrium or an optimum might be reached only over time

Stochastic model: a random model arising from a process that generates different values, each with some probability. Contrasts with a deterministic model

Time Horizon: the time period over which the costs and benefits of health outcomes are considered

Utility: a measure of the value that individuals attach to different health outcomes. These are often used in calculating QALYs to weight periods of time in different health states

Willingness to pay threshold: the threshold below which an individual, group or society choose to pay, along with a change in policy, without being made worse off. Willingness to pay is therefore a monetary measure of the benefit to them of the policy change

**Economic report:
Functional electrical
stimulation for drop foot of
central neurological origin**

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