



Commissioning Policy (P036V2)

Orthotic Functional Electrical Stimulation (FES) for 'foot drop' of neurological origin

Although Primary Care Trusts (PCTs) and East Midlands Specialised Commissioning Group (EMSCG) were abolished at the end of March 2013 with the formation of 5 Nottinghamshire County wide clinical Commissioning Groups (CCGs) policies that were in place prior to 1 April 2013 remain in place to ensure a consistent approach.

The NHS Nottingham North & East Clinical Commissioning Group have adopted this policy, in its existing form, at a meeting of its Governing Body on 20 August 2013.

This policy sets the overall parameters within which care will be delivered.



Orthotic Functional Electrical Stimulation (FES) for ‘foot drop’ of neurological origin

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Summary

Functional Electrical Stimulation, the (FES) is an electronic device designed to improve walking for people who have a dropped foot due to neurological damage.

A dropped foot is when you are not able to lift the foot whilst walking and means that the foot is dragged forward or swung out to the side. It is a common problem in conditions such as Multiple Sclerosis (MS). *

Based on the evidence of clinical and cost effectiveness provided in this document, FES using skin surface electrodes will be commissioned for patients meeting specific criteria. Other types of FES (implanted or wireless) are not commissioned. Providers of FES services should seek prior approval from the commissioners for each patient they consider suitable.

* Taken from NHS The Walton Centre Patient Information leaflet.

**East Midlands Specialised Commissioning Group
Orthotic Functional Electrical Stimulation (FES) for 'drop foot'
of neurological origin**

i. Version Control Sheet

Version	Section/Para/ Appendix	Version/Description of Amendments	Date	Author/Amended by
1		Draft v 1	3 Sept 2010	Elizabeth Orton & Linda Ward
2		Draft v 2 Following further engagement with providers re cost effectiveness. Recommendations changed from v1	9 March 2012	Elizabeth Orton, Linda Ward & Peter Jackson
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East Midlands Specialised Commissioning Group

Orthotic Functional Electrical Stimulation (FES) for 'drop foot' of neurological origin

ii. Policy Statement

Equality statement The EMSCG is committed to ensuring equality of access and non-discrimination.

Background Functional Electrical Stimulation (FES) has been designed to help people with neurological lesions, including drop foot, to move more easily. It works by producing muscle contractions that mimic normal voluntary gait movement by applying electrical pulses to nerves either directly (if implanted) or across the skin (if externally placed).

Statement Based on the evidence of clinical and cost effectiveness provided in this document, FES using skin surface electrodes will be commissioned for patients meeting specific criteria:

- The patient has foot drop caused by upper level nerve damage
- The patient has been assessed by a specialist in foot drop of neurological origin and all treatment options have been considered
- There is evidence that foot drop has caused trips or falls, or gait issues causing significant clinical problems
- The patient can walk a minimum of 10 metres independently (+/- aids)
- The patient can physically manage a FES (+/- minimal assistance)
- The patient's cognitive ability is such that they can manage a FES independently
- The patient does not have co morbidities which would affect their capacity to benefit from FES
- The patient does not have any of the accepted clinical contraindications to FES
- Clear FES treatment goals and expectations of benefit are outlined

Other types of FES (implanted or wireless) are not commissioned.

This policy will be reviewed periodically in the light of further research, follow up data on outcome (including quality of life measures), duration of FES use and the maintenance of provider costs within an acceptable cost-effectiveness threshold.

Providers of FES services should seek prior approval from

the commissioners for new patients that they consider suitable. A prior approval form is available to accompany this policy.

For patients already being treated, who require funding for maintenance and support, prior approval will be required and the following criteria apply:

The patient will have objectively demonstrated (using validated tools) that the use of FES is still clinically appropriate. Including:

- Evidence of foot drop which impedes gait that meets the criteria in this policy
- Documented improvement in clinical parameters from its use

Responsibilities	Each primary care trust to adopt these criteria, and incorporate them into Service Level Agreements and contracts with providers as appropriate.
Training	No known training issues.
Dissemination	To all member PCTs and relevant provider Trusts. It will also be placed on the EMSCG website http://www.emscg.nhs.uk
Resource implication	<p>Prevalence estimates show that up to 292 patients in the East Midlands may meet the policy criteria.</p> <p>Price benchmarking with three providers has resulted in significant reductions in costs at the two existing services (Sheffield Teaching Hospital (STH) and Birmingham Community Healthcare). Derby NHSFT is a new service for 2012/13.</p> <p>Local provider engagement has established that this service can be offered to selected patients at a conservative cost-effectiveness threshold consistent with the weak clinical effectiveness evidence.</p>

East Midlands Specialised Commissioning Group

Orthotic Functional Electrical Stimulation (FES) for 'drop foot' of neurological origin

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1. Introduction

1.1 The medical condition

Motor neurone lesions caused by multiple sclerosis, stroke, cerebral palsy or spinal cord injury have a range of physical consequences. These include muscle weakness, joint instability, arm flexion and leg extension hypertonicity, or hypotonicity, exaggerated reflexes and an extensor plantar response. Physically these may translate into a range of symptoms including bladder dysfunction, pain, fatigue and problems with gait such as foot drop.

Foot drop is one of the most common manifestation of upper motor neurone lesions and results from weakness or lack of voluntary control in the ankle and foot dorsiflexors, causing the toes to drag and the foot to then drop during the normal gait pattern. This is likely to increase the risk of falls as well as the effort required to walk.

Conventional approaches to treating foot drop include physiotherapy and ankle-foot orthosis (AFO) and the evidence of the clinical and cost effectiveness of functional electrical stimulation (FES) as an alternative, has been considered here.

1.2 Functional Electrical Stimulation (FES)

Functional Electrical Stimulation (FES) has been designed to help people with neurological lesions, including drop foot, to move more easily. It works by producing muscle contractions that mimic normal voluntary gait movement by applying electrical pulses to nerves either directly (if implanted) or across the skin (if externally placed). It has been tested as a therapeutic intervention/treatment whereby the benefits persist once the FES has ceased or as an orthotic device whereby the benefits occur whilst the device is used. Whether FES is used as a therapeutic or orthotic device is at the moment largely a local clinical decision and depends upon the neurological condition. It is the orthotic properties of the device in the management of foot drop that are the focus of this policy.

Implanted FES electrodes are usually inserted into the epineurium of the peroneal nerve under general anaesthesia. Electrodes may be percutaneous (passed through the skin and connected to an external pulse generator) or fully implanted and operated by radiofrequency waves. Alternatively, skin surface electrodes may be placed over the nerve and connected by leads to a stimulator unit, controlled by a foot switch. It is the external skin-surface FES that is the focus of this policy.

2. Existing clinical guidance documents

The evidence for efficacy and safety of FES has been reviewed by NICE in IPG278 (2009) which states that the efficacy (improving gait) and safety of functional electrical stimulation (FES) for foot drop of central neurological origin appears adequate to support its use under normal clinical governance and audit arrangements.

However, the reviewers highlighted significant variation in: how the procedure is carried out; patient characteristics in the studies; the comparators used. Few studies reported absolute numbers and there is limited evidence about Quality of Life (QoL)

and the impact of the procedure on disability. They indicated that there are a number of ongoing trials comparing FES with AFO (see refs).

The Scottish Intercollegiate Guidelines Network (SIGN 2010) has published guidelines on the management of patients with stroke. Regarding FES they conclude that there is

“...presently insufficient high quality evidence to support or refute the use of electrostimulation to improve gait, muscle strength or functional outcomes after stroke ...”

“Electrostimulation may be an effective intervention for some patients, with specific problems, when delivered in a specific way, although there is presently insufficient evidence to determine which selected patients may benefit.”

“Functional Electrical Stimulation may be considered as a treatment for drop-foot, where the aim of treatment is the immediate improvement of walking speed and/or efficiency. (Evidence grade C)”

The Royal College of physicians National Clinical Guidelines for Stroke (2008) recommends

- Functional electrical stimulation of the arm or leg should not be used on a routine basis outside the context of clinical trials.
- Functional electrical stimulation of the leg should only be considered and used for individual patients who:
 - have footdrop impeding gait not satisfactorily controlled using ankle-foot orthoses *and*
 - have demonstrable gait improvement from its use

The Royal College of Physicians National Guidelines for MS (RCP, 2004), also emphasise the need to implement a proactive and preventative approach at an early stage.

Both the NICE guidelines for MS (NICE 2003) and National Service Framework for Long Term Conditions (Department of Health 2007) encourage the utilisation of any modalities that improve patient mobility and social access and suggest that technology should be embraced in the clinical setting.

There is currently no East Midlands wide commissioning policy for FES. Derbyshire County have a local policy, which is under review, that this is not routinely commissioned. Ongoing research and development in the area of FES is acknowledged and will inform future reviews and clinical guidelines.

3. Epidemiology

Estimates of the prevalence and incidence of foot drop in the UK caused by neurological deficits are difficult to find due to the range of neurological disorders causing upper neurone lesions and variability in the symptoms, often not reported.

The Multiple Sclerosis Society (2009) reports an estimate of 100,000 for the number of people in the UK with MS. The Stroke Association estimates that over 300,000 people are living with moderate to severe disabilities as a result of stroke. If only 1%

of these people seek FES as a treatment option there are potentially 4000 people in the UK at any one time that may do so.

The population of the East Midlands represents approximately 7.3% of the total UK population (ONS figures below) so the demand for FES in the East Midlands could be from 292 patients at any one time. East Midlands data from 2009/10 show that 65 requests could be received annually.

East Midlands population estimate [ONS mid-2009]:
UK Pop 61.7 million, EM Pop 4.5 million. EM = 7.3% of UK population

4. Aim and Objectives

This policy assesses the evidence of clinical and cost effectiveness of Functional Electrical Stimulation (FES) for people with upper motor neurone deficits, causing drop foot and impacting on gait, risk of falls and walking ability. The policy assesses evidence for FES used as an orthotic device and assesses external skin surface electrodes only. The policy is not addressing the therapeutic use of FES as part of a battery of treatments, often used in physiotherapy departments.

The systematic review for this policy updates the literature review undertaken for NICE IPG278 up to August 2008.

5. Clinical effectiveness evidence

[See appendix 1 for details of the methodology for this review]

In total, 30 published articles were reviewed relating to the orthotic effect of FES including 6 systematic reviews (1 meta-analysis), 12 controlled (\pm randomised) trials, 9 uncontrolled or before and after trials, 1 observational study, 1 economic review, and 1 case series.

.The studies were heterogeneous in their patient groups, use of FES technology, comparators and outcome measures, as well as in their conclusions. Tables 1 and 2 summarise the quality and design of the studies reviewed and Table 3 shows studies that were excluded from the clinical effectiveness analysis.

5.1 Studies that demonstrate an orthotic effect of FES

Studies have used various protocols, devices and lengths of use of FES with a range of outcomes, both positive and negative. There were 15 studies that reported a positive orthotic effect of FES on the treatment of drop foot, including two systematic reviews.

In one review, Roche et al. looked at a range of different study methodologies including before and after studies, FES versus an alternative therapy and FES combined with another therapy but were unable to pool any outcome measures in a meta-analysis due to the heterogeneity of study designs. Most studies were at moderate or high risk of bias and no 'grey literature' was included in the search protocols. The authors concluded that there is an orthotic effect of FES, particularly when combined with other therapies (e.g. botulinum toxin injections or electromechanical gait training) and this includes faster walking speed (ranges from 7% to 19% in before and after studies) and lower effort (ranges from 19% to 37% in two before and after studies). However the review does not explicitly state how the

outcomes measured might impact quality of life or what the clinical significance of the observed increases in walking speed and decreases in physiological cost might be.

In a second systematic review Kottink (2004) did calculate pooled estimates on walking speed and found that FES increased walking speed by 0.13 m/s or 38% however they were not able to generate pooled estimates of changes in effort due to the small number of included studies.

Barrett et al. (2010) reported improved quality of life measures following FES use in MS patients but there were significant selection and measurement biases in this study. For example, there was no discussion of the eligibility of patients for FES, criteria for inclusion in the study or whether data was collected from patients that withdrew from FES use. In addition, there was no control group so it is not clear if the improved quality of life was due to FES alone or the fact that patients had additional clinical input.

Esnouf et al. (2010) reported improved satisfaction and performance with activities of daily living in patients referred for FES who met the studies inclusion criteria. In addition, this study was the only one to consider falls as an outcome measure. The FES group had fewer falls in total compared to the group assigned to exercise (5 compared to 18 in the exercise group).

Of the non-review studies, all except Esnouf (and possibly Mesci) included at least one walking speed measure but each study used a different testing paradigm for the FES intervention. For example, Ng et al looked at outcomes after 4 weeks of FES use, Embrey et al used 3 months of FES use plus a walking regime, Stein et al used FES for 3 months alone and Kojovic et al used 4 weeks plus a walking therapy. However, these studies did report an orthotic effect of FES on walking speed. Several studies reported a reduction in physiological cost index (an indication of effort of walking). Many of the studies showing a positive effect of FES were uncontrolled trials or before and after studies where the results of walking speed were presented after a period of FES use, but with no comparator group that had an alternative intervention. Overall these data suggest that FES can increase walking speed but from the literature we have reviewed it is not possible to say if this is significantly advantageous over other orthoses.

5.2 Studies that demonstrate equivocal or negative results for the orthotic effect of FES

Three high quality and one lower quality systematic reviews (Mehrholtz, 2008; Pomeroy, 2009; Hamzaid and Davis, 2009; Seifar, 2009) report that there is inconclusive evidence about the effectiveness of FES in the treatment for drop foot. A common theme is that the literature is too heterogeneous in terms of the intervention protocols used and outcomes measured to be able to provide pooled effect measures.

Barrett et al showed in an RCT that the FES intervention groups had a slower walking speed, no difference in effort and no difference in distance covered compared to an exercise group at 18 weeks having adjusted for differences in baseline measures.

In a study of children with cerebral palsy, (Van der Linden, 2008) showed slower walking speed but a significant improvement in gait kinematics with FES switched on (orthotic effect).

5.3 Studies that directly compare FES and AFO

Only 4 studies were found that compared FES directly with AFO. These were all of moderate to low quality. Ring et al., studied different gait parameters within the same patients using FES and when using an AFO. They found no difference in walking speed between the two orthoses at 4 and 8 weeks and no difference in gait stability and symmetry at 4 weeks but these improved in the FES group at 8 weeks.

Sheffler et al., 2006 again used a within-patient trial design comparing outcomes of FES, AFO and no device in terms of ambulation and patient preference. Both FES and AFO improved ambulation profiles compared to no orthotic but there was no difference between FES and AFO. Patients did however prefer FES.

Again van Swigchem et al., 2010 showed that compared to AFO FES did not result in an increase in walking speed or activity level but again patients preferred it and the same authors reported a single case study of a man for whom surface FES was not suitable but showed near normal gait after having FES implanted.

5.4 Summary of effectiveness evidence

Overall the literature reviewed was heterogeneous in nature making robust conclusions difficult to make. A significant number of studies did however suggest that FES can have a beneficial orthotic effect for some patients in terms of walking speed and reduced effort. However, a systematic and direct comparison of the benefits of FES compared to AFO was not possible as many studies used exercise or physiotherapy as the comparator group, rather than AFO and we did not review the evidence of effectiveness of AFO. Studies that did compare FES and AFO were generally of poor quality. They did not suggest superiority of either FES or AFO clinically but generally patients showed a preference for FES. There were too few published studies on the effect on falls and quality of life to draw firm conclusions regarding the benefits of FES. There are some RCTs in progress that may provide further evidence in this regard and this policy should be reviewed when these studies are published.

6. Safety

There does not appear to be significant safety issues related to the use of FES and it appears to be well tolerated and preferred, at least in adults.

7. Cost-effectiveness:

One economic evaluation (Centre for Evidence-based Purchasing, 2010) modelled the cost effectiveness of FES in stroke patients using efficacy data with physiotherapy as a comparator. The use of AFO and FES in other populations was not therefore included in the model.

The base case analysis, updated to 2009 figures, suggested an average ICER over a 5 year time horizon of £19,239. For year one the ICER was £52,337 and £10,964 for each subsequent year. The high up-front costs of equipment and consultations accounted for the skew towards earlier high costs.

The report concluded that, at a threshold willingness to pay of £30k, there is a probability of 66% that FES is cost-effective. From the same data, at a lower threshold willingness to pay of £20k, the probability that FES is cost effective falls to 20%. See Fig 1.

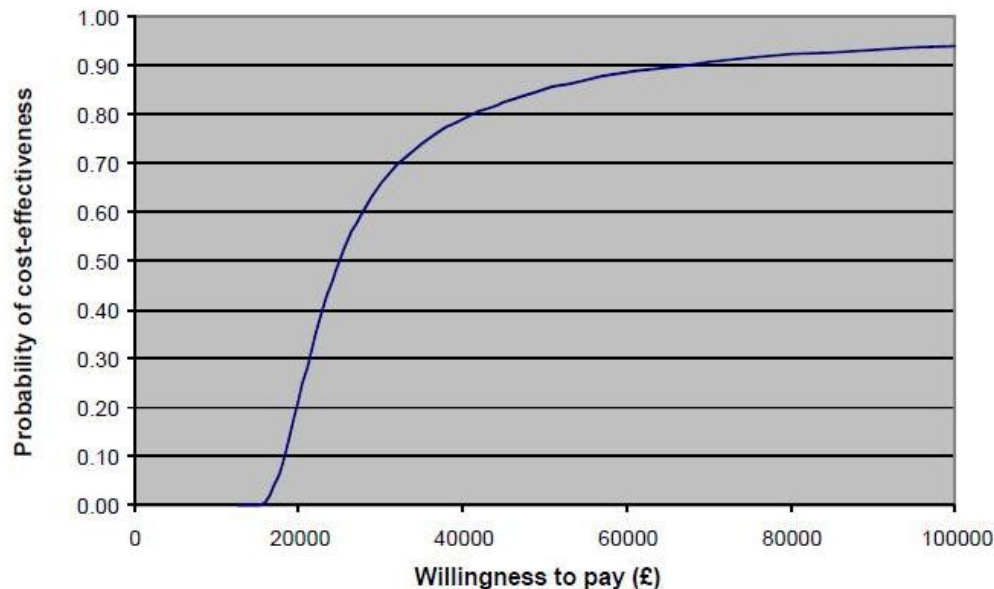


Fig 1. Overall (5 year) cost-effectiveness acceptability. CEP, 2010. p19.

The model is sensitive to gains in health utility (acknowledged as a weak area in the literature) and patient selection, requiring long term commitment to achieve cost effectiveness within accepted parameters for the NHS.

Given the lack of cost effectiveness data, further information was requested from the UK Salisbury team directly (P Taylor *personal communication*). Unpublished data from this group suggested a mean QALY gain of 0.065 from using FES and a mean length of FES use of 4.4-4.9 years based on clinical audit. Using 2007 costs the author suggested a cost per quality adjusted life year of £25,231 in the first year and £12,431 if used over 5 years. However, there was no mention of discounting or sensitivity analysis.

7.1 Summary of cost-effectiveness evidence

A critical analysis of the cost effectiveness data available identified a number of issues:

- Equivocal evidence about a significant effect of FES on quality of life
- Lack of robust evidence as to the persistence of FES effects over time and duration of patient use of FES
- Variability in costs from local providers

All of these are key drivers of cost effectiveness calculations and should be addressed in the policy.

8. Commissioning policy

Based on the evidence of clinical and cost effectiveness provided in this document, FES using skin surface electrodes will be commissioned for patients meeting specific criteria:

- The patient has foot drop caused by upper level nerve damage
- The patient has been assessed by a specialist in foot drop of neurological origin and all treatment options have been considered
- There is evidence that foot drop has caused trips or falls, or gait issues causing significant clinical problems
- The patient can walk a minimum of 10 metres independently (+/- aids)
- The patient can physically manage a FES (+/- minimal assistance)
- The patient's cognitive ability is such that they can manage a FES independently
- The patient does not have co morbidities which would affect their capacity to benefit from FES
- The patient does not have any of the accepted clinical contraindications to FES
- Clear FES treatment goals and expectations of benefit are outlined

Other types of FES (implanted or wireless) are not commissioned.

Strength of the recommendation: Weak; Further research evidence on clinical and cost effectiveness may change the conclusions of this review

This policy will be reviewed periodically in the light of further research, follow up data on outcome (including quality of life measures), duration of FES use and the maintenance of provider costs within an acceptable cost-effectiveness threshold.

9. Patient pathway

Providers of FES services should seek prior approval from the commissioners for new patients that they consider suitable. A prior approval form is available to accompany this policy.

For patients already being treated, who require funding for maintenance and support, prior approval will be required and the following criteria apply:

The patient will have objectively demonstrated (using validated tools) that the use of FES is still clinically appropriate. Including:

- Evidence of foot drop which impedes gait that meets the criteria in this policy
- Documented improvement in clinical parameters from its use

10. Designation

Contractual arrangements with services offering FES to East Midlands patients will be revised to include funding by prior approval only.

11. Date of Review

April 2013 unless significant clinical research results prior to this require an earlier review.

12. Quality of the evidence

Table 1 Evidence of the effectiveness of FES as an orthotic device

Quality (Level of evidence)	Study id	Presents positive results for FES	Quality score using SIGN scoring	Study id	Presents equivocal or negative results for FES	Quality score using SIGN scoring
Level 1	FES032 RCT	Ng et al. 2008	1+	FES027 Systematic review	Mehrholz et al., 2008	1+
	FES033 Randomised crossover trial	Embrey et al. 2010	1+	FES046 Economic report	CEP 2010	1+
	FES023 Meta-analysis	Kottink et al., 2004	1+	FES036 RCT	Barrett et al., 2009	1+
	FES030 Systematic review	Roche et al. 2009	1-	FES031 Systematic review	Pomeroy et al., 2009	1+
	FES034 RCT	Esnouf et al. 2010	1-	FES037 RCT	Kottink et al., 2008	1+
	FES035 RCT	Kojovic et al. 2009	1-	FES045 Controlled trial	Sabut et al., 2010	1+
	FES003 RCT	BurrIDGE et al., 1997	1-	FES044 RCT	Mesci et al. 2009	1-
				FES029 Systematic review	Hamzaid and Davis 2009	1-
				FES038 RCT	Van der Linden 2008	1-
			FES039 RCT	Tanovic 2009	1-	
Level 2	FES040 Uncontrolled trial	Stein et al. 2009	2+	FES028 Systematic review	Seifart et al., 2009	2++
	FES008 Uncontrolled trial	Taylor et al., 1999	2+			
	FES041 Uncontrolled trial	Barrett et al. 2010	2+			
	FES042 Case-control	Paul et al. 2008	2+			
	FES026 Crossover trial	Van Swigchem et al., 2010	2+			
	FES008 Uncontrolled trial	Taylor et al., 1999	2+			

	FES019 Uncontrolled trial	Sheffler et al., 2009	2+			
	FES025 Uncontrolled trial	Laufer et al., 2009	2+			
	FES 043 Uncontrolled trial	Seifart et al., 2010	2+			

Table 2 Studies that compare FES and AFO as orthotic devices

Author	Study id	Quality	Design and comparison groups	Outcome measures	Result
Ring et al., 2009	FES020 Uncontrolled trial	Level 2+	Within patient trial – compared outcomes when using FES and when using AFO	6 min walk speed Average stride time Swing time variability Swing asymmetry	No difference in walking speed when using FES or AFO at 4 or 8 weeks. No difference in gait stability and symmetry at 4 weeks but improved in FES group at 8 weeks.
Sheffler et al., 2006	FES024 Uncontrolled trial	Level 2+	Within patient trial comparing outcomes when using AFO, FES or no device	Modified memory functional ambulation profile. Patient preference	Both FES and AFO improved mEFAP but there was no difference between FES and AFO Patients preferred FES
Van Swigchem et al., 2010	FES026 Crossover trial	Level 2+	Within patient trial comparing outcomes before (with AFO) and after (with FES or AFO)	Walking speed Activity level (number of steps per day) Patient satisfaction	No difference in walking speed or activity level Patients more satisfied with FES because of effort, stability of walking, quality of gait pattern, walking distance, comfort and appearance
Van Swigchem	FES021 Single case report	Level 3	Single case report of implanted FES	Gait pattern	Gait pattern was near normal with the use of FES but note this was an implanted device.

Table 3 Literature review, excluded studies

Study id	Citation	Reason for non-inclusion
FES001	Sabut et al., 32nd annual international conference of the IEEE EMBS, 2010	Reports therapeutic effects only
FES002	Shawn et al., Arch Phys Med Rehabil V87, 2006	Reports therapeutic effects only
FES004	Bogataj et al., Physical Therapy v75, 1995	The therapeutic results were reported in FES002 also included in FES023
FES005	Alon and Ring J Stroke and Cereb Dis v12, 2003	The therapeutic results were reported in FES002
FES006	Kottink et al Arch of Phys Medicine V88, 2007	Reports results of implantable electrodes only
FES007	Daly et al., J Rehab res and dev v38, 2001	Reports results of implantable electrodes only
FES009	Daly et al., Stroke V37 2006	Reports results of implantable electrodes only
FES010	Burrige et al., J Rehab Med V39 2007	Reports results of implantable electrodes only
FES012	Kottink et al Artificial organs, 2010	Quality of life but Implantable electrodes
FES013	Jolley and Taylor, Proc phys res soc, 2007 (abstract)	Quality of life for OSDFS, not clinical effect.

FES014	Leung and Moseley, Physiotherapy, 2003	effectiveness of non-FES orthotic
FES015	Geboers et al., Arch Phys Med Rehabil v83, 2002	effectiveness of non-FES orthotic
FES016	Sheffler and Chae, Muscle and nerve, 2007	Review article
FES017	Weinshenker et al., Brain v112, 1989	Review article, non-FES
FES022	Sabut et al., J Electromyogrph and Kines v20, 2010	Same study as 001

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Included studies

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NCT00148343 Functional Electrical Stimulation for Footdrop in Hemiparesis. Status: Active, not recruiting. Study start July 2005

NCT01138995 Clinical Study of the L300 Versus Ankle-foot Orthosis (AFO) on Post-Stroke Subjects With Foot Drop. Status: Recruiting. Study start May 2010

14. Glossary

Word/Abbreviation	Meaning
Ankle foot orthosis	A brace used to stretch the Achilles tendon worn on the lower leg and foot to support the ankle, hold the foot and ankle in the correct position and correct foot drop. It is a thin, light plastic material (www.scope.org.uk).
Cerebral Palsy	The term used to describe a group of conditions characterised by varying degrees of paralysis and originating in infancy or early childhood. In some 80 per cent of cases this takes the form of spastic paralysis (muscle stiffness). (Blacks Medical Dictionary, 42 nd Ed,).
Commissioning	Commissioning in the NHS is the process of ensuring that the health and care services provided effectively meet the needs of the population. It is a complex process with responsibilities ranging from assessing population needs, prioritising health outcomes, procuring products and services, and managing service providers. (Taken from www.dh.gov.uk).
East Midlands Specialised Commissioning Group (EMSCG).	Specialised Commissioning is the means by which Primary Care Trusts (PCTs) work together to plan, buy and manage services which treat patients with rare conditions. (Taken from www.emscg.nhs.uk) For the East Midlands this is the East Midlands Specialised Commissioning Group.
Economic evaluation	An economic evaluation is used to assess the cost effectiveness of healthcare <i>interventions</i> (that is, to compare the costs and benefits of a healthcare intervention to assess whether it is worth doing). The aim of an economic evaluation is to maximise the level of benefits - health effects - relative to the resources available. (www.nice.org.uk).
Extensor plantar response	An abnormal reflex of the big toe (http://www.online-medical-dictionary.org/).
Gait	The way in which an individual walks. (Blacks Medical Dictionary, 42 nd Edition).
Health utility	In the analysis of health outcomes, utility is a number between 0 and 1 that is assigned to a state of health or an outcome. Perfect health has a value of 1. Death has a value of 0. (www.medicinenet.com).
Heterogenous	The term is used in <i>meta-analyses</i> and <i>systematic reviews</i> to describe when the results of a test or treatment (or estimates of its effect) differ significantly in different studies. Such differences may occur as a result of differences in the <i>populations</i> studied, the outcome measures used or because of different definitions of the <i>variables</i> involved. It is the opposite of <i>homogeneity</i> . (www.nice.org.uk).
Hypertonicity	Increased tension in the muscles.
Meta analysis	A method often used in <i>systematic reviews</i> . Results from several studies of the same test or treatment are combined to estimate the overall effect of the treatment. (www.nice.org.uk).
Multiple Sclerosis (MS).	Multiple Sclerosis (MS) is a condition of the central nervous system (www.mssociety.org.uk).
National Institute for Health and Clinical Excellence (NICE).	NICE is an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health. (NICE, 2009).
Orthotic device	A support, brace, or splint used to support, align, prevent, or correct the function of movable parts of the body (www.medicinenet.com).
Physiological	Science of the normal function of living things. (Collins English Dictionary, 1994).
Physiotherapy	Treatment of disease or injury by physical means such as massage, rather than by drugs. (Collins English Dictionary, 1994).
Quality Adjusted Life Year (QALY).	A measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is

	<p>equal to 1 year of life in perfect health.</p> <p>QALYS are calculated by estimating the years of life remaining for a patient following a particular treatment or <i>intervention</i> and weighting each year with a quality of life score (on a zero to one scale). It is often measured in terms of the person's ability to perform the activities of daily life, freedom from pain and mental disturbance. (www.nice.org.uk).</p>
Quality of Life (QoL)	A subjective assessment of one's emotional and physical well-being. (http://medical-dictionary.thefreedictionary.com).
Randomised controlled trial (RCT).	A study in which a number of similar people are randomly assigned to two (or more) groups to test a specific drug or treatment. One group (the experimental group) receives the treatment being tested, the other (the comparison or <i>control group</i>) receives an alternative treatment, a dummy treatment (<i>placebo</i>) or no treatment at all. The groups are followed up to see how effective the <i>experimental treatment</i> was. <i>Outcomes</i> are measured at specific times and any difference in response between the groups is assessed statistically. This method is also used to reduce <i>bias</i> . (NICE, 2010).
Scottish Intercollegiate Guidelines Network (SIGN).	SIGN develops national evidence based clinical practice guidelines for NHS Scotland. (www.sign.ac.uk).
Spinal cord injury	A spinal cord injury usually begins with a sudden, traumatic blow to the spine that fractures or dislocates vertebrae. The damage begins at the moment of injury when displaced bone fragments, disc material, or <i>ligaments</i> bruise or tear into spinal cord tissue. Most injuries to the spinal cord don't completely sever it. Instead, an injury is more likely to cause fractures and compression of the vertebrae, which then crush and destroy the <i>axons</i> , extensions of nerve cells that carry signals up and down the spinal cord between the brain and the rest of the body. An injury to the spinal cord can damage a few, many, or almost all of these axons. Some injuries will allow almost complete recovery. Others will result in complete paralysis (http://www.ninds.nih.gov/disorders/sci/sci.htm).
Stroke	For your brain to function, it needs a constant blood supply, which provides vital nutrients and oxygen to the brain cells. A stroke happens when the blood supply to part of the brain is cut off and brain cells are damaged or die. (www.stroke.org.uk).
Study methodologies	Describes how research is done, including how information is collected and analysed, and why a particular method has been chosen. The overall approach taken by a research project: for example, the study could be a <i>randomised controlled trial</i> of 200 people over 1 year. (www.nice.org.uk).
Systematic review	A review in which evidence from scientific studies has been identified, appraised and synthesised in a methodical way according to predetermined criteria. It may include a <i>meta-analysis</i> . (www.nice.org.uk).
Therapeutic intervention	Intervention with the aim of treating a disease.

Appendix 1. Search strategy and evidence tables

Question(s)	
<p>What is the evidence of clinical and cost effectiveness of Functional Electrical Stimulation (FES) for people with upper motor neurone deficits, causing drop foot and impacting on gait and walking ability?</p> <p>This search updates the searches done in support of NICE IPG278 (to August 2008)</p>	
Search strategy	
P – Population / Problem	Upper motor neurone deficits (in multiple sclerosis, stroke, cerebral palsy, spinal cord injury etc) causing dropped foot / dropping foot and gait abnormalities
I – Intervention or exposure	Orthotic effect (effect whilst the device is switched on) of Functional Electrical stimulation (FES) / Electrical stimulation therapy / Functional neurostimulation (FNS) / peroneal stimulation / functional electrostimulation of the lower limb and foot. Administered via the skin surface.
C – Comparison	No treatment, therapeutic exercise, physiotherapy, ankle-foot orthoses, medical therapy, surgery (selective tendon release)
O – Outcomes	<p><i>Critical to decision-making:</i> Functional outcomes for gait (e.g. reduced circumduction), reduction in falls, improved walking speed, and reduction of effort required.</p> <p>Safety. Cost effectiveness. Characteristics of those who gain most benefit from FES.</p> <p><i>Important to decision-making:</i> Wider impacts of FES e.g. improved ADL and QoL</p>

Assumptions / limits applied to search

This evidence review does not include studies investigating FES for muscle disuse atrophy or for neurological deficit in the upper body. Research articles published between 1990 and February 2011 were identified.

The focus of the search was for:

- Studies comparing FES (skin surface only) to an alternative treatment option
- Higher level studies including a comparator group
- Functional outcomes (walking speed, effort etc) and other benefits of FES
- Cost benefit studies

Studies excluded were: Narrative reviews, case series / case reports and clinical studies with no clear outcomes reported, comparisons of different FES approaches / technologies. No language restrictions were applied

Methodology

Searches were carried out in the resources listed below using the criteria / limits above. Where available full text articles were obtained and appraised for study quality. A quality score was assigned using the SIGN levels of evidence. The results are presented in the evidence tables below. Interpretation of the evidence was made using the GRADE methodology for assessing the quality of the evidence and the strength of recommendation. The SIGN and GRADE tools are outlined at the end of appendix 1.

Resources searched

Evidence-based summaries	NICE & SIGN	NHS Evidence	Cochrane	Specialist Libraries	NIHR HTA
Bibliographic databases	Medline, Pre-Medline & Embase	AMED CINAHL & BNI	PsycINFO	HMIC & Health Business Elite	

Other web-based resources	TRIP	www.controlled-trials.com			
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Searched by

Linda Ward, Clinical Review & Effectiveness Specialist, East Midlands Specialised Commissioning Group
Elizabeth Orton, Specialty Registrar in Public Health, NHS Derbyshire County

Evidence tables [See below for SIGN Levels of Evidence**]

Author, year	Study design & objective	Study detail <i>e.g. Population, Incl & Excl criteria, Sample size Intervention (I) & Control (C) Time to follow-up, Outcome & significance</i>	Comments & confidence in results based on study design ± study limitations
LEVEL 1: Meta-analyses, systematic reviews of RCTs, RCTs			
FES046 Centre for Evidence based Purchasing 2010 1+	Economic report with systematic review methodology	<p>Search period: up to November 2009</p> <p>Studies: Studies of effectiveness, economic evaluations and utility and quality of life scores</p> <p>Population: People with drop foot due to central nervous system lesions</p> <p>Evaluation: Appraised for relevance including UK setting; validity of research design; validity of research conduct</p> <p>Results: One guidance document, one systematic review and 8</p>	<p>Strengths: Clear and thorough methodology for the literature review</p> <p>Sensitivity analysis of the model</p> <p>Limitations:</p> <p>The comparator used in the model was standard physiotherapy treatment. Use of ankle-foot orthoses (AFO) was not included in the model.</p> <p>Based on studies in stroke, the results may not</p>

Author, year	Study design & objective	Study detail <i>e.g. Population, Incl & Excl criteria, Sample size Intervention (I) & Control (C) Time to follow-up, Outcome & significance</i>	Comments & confidence in results based on study design ± study limitations
		<p>further studies</p> <p>Clinical efficacy: In addition to those reported by NICE (for IPG278) eight additional studies were identified: two included in this review (Barrett 2009, Kottink 2008); five studies focused on therapeutic rather than orthotic use of FES; One was a case series</p> <p>Results: The authors commented on the variability in the study parameters “making overall conclusions of efficacy difficult”.</p> <p>Cost effectiveness: A model was developed of the likely benefits, disadvantages and costs of FES when used to treat drop foot following stroke. One cost utility analysis for stroke patients from 1996 was identified with which to generate estimates of QALY gain. Estimates of efficacy were developed from the published literature. One year and 5 year time horizons were used and a payer (NHS) perspective.</p> <p>Results: The base case analysis, updated to 2009 figures, suggested an average ICER over a 5 year time horizon of £19,239. For year one the ICER was £52,337 and £10,964 for each subsequent year. The high up-front costs of equipment and consultations accounted for the skew towards earlier high costs.</p> <p>The report concluded that there is a probability of 66% that FES is cost-effective at a willingness to pay of 30,000 but is only</p>	<p>be applicable for other patient groups with upper neurological deficit and drop foot</p> <p>Given the acknowledged low level of evidence to support FES it is not clear whether the model developed can accurately predict cost effectiveness.</p> <p>The base case for the model used 1996 QoL data from The National Clinical FES Centre. The authors of the report acknowledge that evidence of quality of life gains is not widely available in the literature and may not therefore be considered robust enough upon which to make funding decisions.</p> <p>Sensitivity to gains in health utility (acknowledged as a weak area in the literature) and patient selection (requiring long term commitment to achieve cost effectiveness within accepted parameters for the NHS)</p> <p>Likelihood of being cost effective is quoted at 66% at 30,000 wtp but NICE threshold is nominally 20,000 (although the duration over which this is calculated is not clear – i.e. is this the mean cost per QALY)</p>

Author, year	Study design & objective	Study detail <i>e.g. Population, Incl & Excl criteria, Sample size Intervention (I) & Control (C) Time to follow-up, Outcome & significance</i>	Comments & confidence in results based on study design ± study limitations
		<p>about 20% likely at 20,000 – the current NICE cost/QALY threshold.</p> <p>The model is sensitive to length of treatment, gains in health utility and patient selection</p>	
<p>FES027 Mehrholz et al 2008 1+</p>	<p>Cochrane review</p>	<p>Search period: up to 2007.</p> <p>Studies: 4 RCTs of 222 patients.</p> <p>Population: Spinal cord injury patients</p> <p>Intervention: Effect of locomotor training (inc FES) on walking function compared to any other exercise with the goal of improving walking function after spinal cord injury, or to a no-treatment control group.</p> <p>Primary Outcome Measure: speed of walking and walking capacity</p> <p>Secondary Outcome Measure: Level of independence, safety, dropout rate</p> <p>Results – Overall inconclusive. For the FES study there was no increase in walking speed (difference 0.13m/s (-0.03-0.28)), no increased risk of having an adverse incident (risk 0.00 (-0.16-0.16)) and no increased risk of dropping out of the study (risk</p>	<p>Strengths: comprehensive search strategy including grey literature</p> <p>Contacted authors for further details</p> <p>Included RCTs</p> <p>2 independent people searched literature and reviewed papers for inclusion.</p> <p>Used PEDro scale to score quality of trials.</p> <p>Limitations:</p> <p>No sensitivity analysis because of too few studies included.</p> <p>Only 1 study included FES – this was in 4 weeks of therapy sessions.</p>

Author, year	Study design & objective	Study detail <i>e.g. Population, Incl & Excl criteria, Sample size Intervention (I) & Control (C) Time to follow-up, Outcome & significance</i>	Comments & confidence in results based on study design ± study limitations
		0.00 (-0.16-0.16)..	
<p>FES031</p> <p>Pomeroy et al., 2006 Edited and assessed as up to date 2009</p> <p>1+</p>	<p>Cochrane Review</p>	<p>Search period:</p> <p>Studies: 24 Trials and 888 participants.</p> <p>Population: Adults with stroke – at any time after stroke</p> <p>Interventions:</p> <ol style="list-style-type: none"> 1) Electrostimulation vs no treatment 2) Electrostimulation vs placebo electrostimulation 3) Electrostimulation vs conventional physical therapy 4) Different types of electrostimulation e.g. TENS and FES <p>Primary Outcome Measures: those measured at the end of the trial (no follow up)</p> <p>Functional motor ability, ability to undertake activities of daily living (ADL)</p> <p>Secondary Outcome Measures: e.g. muscle function and muscle tone.</p> <p>Results: insufficient evidence to inform clinical use of</p>	<p>Strengths:</p> <p>Included controlled trials with randomisation or quasi-randomisation.</p> <p>Searched grey literature and contacted authors for further details</p> <p>Two authors involved in selection of studies for inclusion</p> <p>Quality scored including risk of bias.</p> <p>Limitations:</p> <p>Not all studies were of FES, some were acupuncture and some were TENS and not all were of lower limb function – at least 5 were not.</p>

Author, year	Study design & objective	Study detail <i>e.g. Population, Incl & Excl criteria, Sample size Intervention (I) & Control (C) Time to follow-up, Outcome & significance</i>	Comments & confidence in results based on study design ± study limitations
		<p>electrostimulation for neuromuscular re-training</p> <ol style="list-style-type: none"> 1) Electrostimulation vs no treatment Only differences were for motor reaction time, isometric torque, range of movement, functional motor ability in favour of electrostimulation – but these were from one trial 2) Electrostimulation vs placebo electrostimulation Muscle function measures in favour of electrostimulation but from one trial only. 3) Electrostimulation vs conventional physical therapy Motor impairment improved in favour of electrostimulation. <p>Acceptability of electrostimulation 53 people withdrew - 9 were due to pain, discomfort or adverse events.</p>	
<p>FES036 Barrett et al., 2009 1+</p>	<p>RCT</p>	<p>Population: (Adults) 44 people with Secondary Progressive Multiple Sclerosis and dropped foot; 20 in the FES group</p> <p>Intervention: FES vs exercise therapy, both for 18 weeks</p> <p>Primary Outcome Measure: walking speed over 10 m</p> <p>Secondary Outcome Measure: Physiological cost index - PCI</p>	<p>Strengths</p> <p>Random allocation – permuted blocks – revealed after consent</p> <p>Sample size calculation</p>

Author, year	Study design & objective	Study detail <i>e.g. Population, Incl & Excl criteria, Sample size Intervention (I) & Control (C) Time to follow-up, Outcome & significance</i>	Comments & confidence in results based on study design ± study limitations
		<p>(effort), Distance walked</p> <p>Results: Exercise group showed increased walking speed and no difference in distance walked or PCI.</p> <p>Measurement regime caused fatigue in patients</p>	<p>Limitations</p> <p>Study was underpowered.</p> <p>Assessors not blinded</p> <p>Participants recruited from an FES waiting list and assessed for responsiveness to FES – selection bias.</p> <p>Didn't use intention to treat analysis – drop outs excluded from analysis.</p> <p>Exercise group promised FES at end of trial so may have been more motivated to be compliant with exercises compared to general population.</p>
<p>FES032</p> <p>Ng et al., 2008</p> <p>1+</p>	<p>RCT</p>	<p>Population: 54 people within 6 months of stroke onset</p> <p>Intervention: 4 weeks of over ground gate training vs electro-mechanical gate training with and without FES – 6 month follow up</p> <p>Primary Outcome Measure: General mobility (Elderly Mobility Scale), Balance (Berg Balance Scale), Functional Independence measure, Barthel Index, Motricity Index leg subscale, Ambulatory ability (Functional Ambulatory Category) and 5-meter walking</p>	<p>Strengths</p> <p>Used intention to treat analysis. Those who dropped out were assigned first assessed scores.</p> <p>Randomisation – computer generated and assigned before baseline measurements taken.</p> <p>Limitations:</p>

Author, year	Study design & objective	Study detail <i>e.g. Population, Incl & Excl criteria, Sample size Intervention (I) & Control (C) Time to follow-up, Outcome & significance</i>	Comments & confidence in results based on study design ± study limitations
		<p>speed test.</p> <p>Secondary Outcome Measure</p> <p>Results: EMGT and EMGT+FES showed improvements in EMS, FAC and walking speed test scores over conventional gate training. P values but no confidence intervals were provided.</p>	<p>Restriction criteria – within 6 w of stroke and needed to stand up – reduce generalisability? 380 screened and 54 eligible.</p> <p>No sample size calculation</p>
<p>FES037</p> <p>Kottink et al., 2008</p> <p>1+</p>	<p>RCT</p>	<p>Population: 29 people with chronic stroke (mean time from stroke 7.3 years) and foot drop.</p> <p>Intervention: Implanted FES vs usual walking devices for 26 weeks.</p> <p>Primary Outcome Measure: Walking speed without FES and RMSmax of the tibialis anterior muscle</p> <p>Secondary Outcome Measure: RMSmax of the peroneus longus, gastrocnemius and soleus muscles</p> <p>Results: No (therapeutic) change in walking speed with FES turned off. There was a higher RMSmax of the TA muscle with extended knee and the GS muscle with both flexed and extended knees. May not be functionally significant</p>	<p>Strengths:</p> <p>Baseline assessments before randomisation.</p> <p>Limitations:</p> <p>Didn't explain how they dealt with drop outs – no mention of intention to treat analysis.</p>
<p>FES033</p>	<p>Randomised crossover</p>	<p>Population: 28 Adults with hemiplegia and mean time post</p>	<p>Strengths:</p>

Author, year	Study design & objective	Study detail <i>e.g. Population, Incl & Excl criteria, Sample size Intervention (I) & Control (C) Time to follow-up, Outcome & significance</i>	Comments & confidence in results based on study design ± study limitations
Embrey et al., 2010 1+	trial	<p>incident 4.9 years (not all stroke).</p> <p>Intervention:</p> <p>A) 3 months of wearing FES for 6-8h/day, 7d/wk, plus walking 1h/day 6d/wk</p> <p>B) B) 3 months of walking 1h/d, 6d/wk</p> <p>N= 15 A-B and N=13 B-A. Crossover at 3 months.</p> <p>NB FES was a novel system with a different stimulation regime to other studies included in this review.</p> <p>Primary Outcome Measure: 6 minute walk test, Emory Functional Ambulatory Profile and Stroke Impact Scale (all with no FES)</p> <p>Secondary Outcome Measure: Muscle strength and spasticity</p> <p>Results: A-B group performed significantly better than the B-A group at 3 and 6 months for each of the primary outcomes.</p>	<p>High compliance with intervention</p> <p>Randomisation resulted in balanced groups</p> <p>Limitations:</p> <p>Used a convenience sample of reasonably mobile people.</p> <p>High drop out – underpowered and no mention of intention to treat analysis.</p> <p>All had weekly appointments (realistic given usual practice in UK?)</p> <p>Walking distance measured by non-blinded researchers – measurement bias? But did have 2 people score this with good inter-rater reliability.</p> <p>No mention of intention to treat analysis</p>
FES045 Sabut et al 2010	Controlled trial	<p>Population: 30 hemiparetic patients with spastic foot drop at least 3 months post stroke. Exclusions included people with allergies, ankle dorsiflexion, medical complications and implanted devices.</p>	<p>Strengths:</p> <p>Allocation to treatment groups on an alternating basis</p>

Author, year	Study design & objective	Study detail <i>e.g. Population, Incl & Excl criteria, Sample size Intervention (I) & Control (C) Time to follow-up, Outcome & significance</i>	Comments & confidence in results based on study design ± study limitations
1+		<p>Intervention: Conventional stroke rehabilitation programme (60 minutes/day, 5 days/week for 12 weeks) ± FES for 30 minutes during the session.</p> <p>Primary Outcome Measure: Walking speed (10m walkway)</p> <p>Secondary Outcome Measure: Other gait parameters (cadence, step length); physiological cost index; ankle range of motion; spasticity of calf muscle; Fugl-Meyer scores; capacity of muscle output (RMS(max))</p> <p>Results:</p> <p>Within group: FES group had 26.3% improvement in walking speed (p<0.001); Control group had 11.5% improvement (p<0.01).</p> <p>Between group: Comparison between FES and Control group showed no statistical difference between the groups in terms of speed, cadence, step length, stride length or PCI.</p>	<p>Person assessing the walking was blinded to the treatment group</p> <p>Limitations:</p> <p>Some patients took the device home – and may have therefore had more exposure than 30 mins/day.</p> <p>No sample size calculation</p>
FES044 Mesci 2009 1+	RCT	<p>Population: 40 patients with chronic stroke. MS patients were excluded as were people with other disorders of central nervous origin.</p> <p>Intervention: Conventional rehabilitation program for 4-weeks ± Neuromuscular electrical stimulation (NMES) for hemiplegic foot dorsiflexor muscles for 4 weeks, 5 days a week. 20 patients on</p>	<p>Strengths:</p> <p>Participants were randomised into the treatment arms.</p> <p>Assessment of walking was done by an assessor</p>

Author, year	Study design & objective	Study detail <i>e.g. Population, Incl & Excl criteria, Sample size Intervention (I) & Control (C) Time to follow-up, Outcome & significance</i>	Comments & confidence in results based on study design ± study limitations
		<p>each group</p> <p>Primary Outcome Measures: Pre- and post-treatment measures of ankle dorsiflexion and level of spasticity</p> <p>Secondary Outcome Measures: Brunnstrom Stage, Rivermead leg and trunk score and Functional Independence Measurement motor subscore; Functional Ambulation Categories</p> <p>Results:</p> <p>Within group: Increased ankle dorsiflexion and decreased level of spasticity were significant in the treatment group ($p < 0.05$) but not in the control group. The NMES group showed a significantly ($p < 0.05$) higher improvement than the control group in Brunnstrom Stage, Rivermead leg and trunk score and Functional Independence Measurement motor subscore.</p> <p>Between group: No significant between group differences were found</p>	<p>blinded to the treatment group.</p> <p>Controlled group comparisons</p> <p>Limitations:</p> <p>Some results are presented as pre-and post treatment changes, not comparative</p> <p>No sample size calculation.</p>
<p>FES023</p> <p>Kottink et al., 2004</p> <p>1+</p>	<p>Meta-analysis</p>	<p>Search period: 1966-2003</p> <p>Studies: 8 studies included and three conference proceedings</p> <p>Population: Stroke patients with dropped foot</p> <p>Interventions: FES of peroneal nerve, surface or implanted,</p>	<p>Strengths:</p> <p>2 assessors with 16 criteria to measure against. Scores ranged from 9-18 out of 19, most were at the upper end of this range. Had a third rater to resolve disagreements.</p>

Author, year	Study design & objective	Study detail <i>e.g. Population, Incl & Excl criteria, Sample size Intervention (I) & Control (C) Time to follow-up, Outcome & significance</i>	Comments & confidence in results based on study design ± study limitations
		<p>comparative trials, orthotic and therapeutic measures.</p> <p>Primary Outcome Measures: Walking speed and PCI</p> <p>Results: 6 studies were used for the pooled estimate on walking speed. FES increases walking speed by 0.13 m/s (0.07-0.3) or 38% (22.18-53.8%). Only 2 studies measured PCI so there was no pooled estimate. One study showed no change in effort with time but a reduction with FES switched on and the other study showed a reduction of effort also with FES switched on.</p>	<p>English and Dutch language. Included conference abstracts. Searched standard databases</p> <p>Limitations:</p> <p>No mention of how many people extracted the data.</p> <p>No sensitivity analysis.</p>
<p>FES030</p> <p>Roche et al 2009</p> <p>1-</p>	<p>Systematic Review</p>	<p>Search period 1990-2008.</p> <p>Studies: 31 Studies included; before and after, FES vs intervention and FES combined with another intervention.</p> <p>Population: stroke patients</p> <p>Intervention: Surface electrodes stimulating the lower limb/common peroneal nerve or tibialis anterior muscle.</p> <p>Primary Outcome Measure: Therapeutic and orthotic effects; speed of walking and effort</p> <p>Results – FES can have a positive orthotic effect particularly for gait speed and effort in chronic post-stroke patients. No meta-analysis.</p>	<p>Strengths:</p> <p>Exclusion of articles was done by 2 people independently.</p> <p>Used Cochrane methodology to review quality.</p> <p>Limitations:</p> <p>Only English-language articles</p> <p>No grey literature</p> <p>No meta-analyses</p> <p>Overall the studies were rated as at risk of bias. Only 1 study had low risk of bias, 12 moderate</p>

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		Therapeutic effects are less clear Some evidence of benefit for combined physical therapy and FES.	risk 5 mod-high and 11 were high risk. No sensitivity analysis
FES029 Hamzaid and Davis 2009 1-	Systematic Review	<p>Search Period: up to July 2008</p> <p>Studies: 33 included. One RCT and 32 controlled studies (quasi-experimental research)</p> <p>Population: neurologically disabled people</p> <p>Primary Outcome Measure: Health and fitness with 6 domains</p> <p>Secondary Outcome Measure:</p> <p>Results: Some positive outcomes were identified across multiple domains of health and fitness but overall inconclusive due to range of methodologies used.</p>	<p>Strengths</p> <p>Range of sources including grey literature, more than one author reviewed titles for inclusion.</p> <p>Limitations</p> <p>No strength of association measures with confidence intervals were given.</p> <p>No sensitivity analysis described</p>
FES038 Van der Linden et al., 2008 1-	RCT	<p>Population: (children) 14 people with cerebral palsy and dropped foot;</p> <p>Intervention: combined 2 weeks of neuromuscular stimulation followed by 8 weeks of FES vs FES plus physiotherapy as usual. FES applied to dorsiflexors (n= 5 tr and 5 con) or the</p>	<p>Strengths:</p> <p>Consent before allocation.</p> <p>Researcher who measured range of motion and performed data analysis was blind to allocation.</p>

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		<p>quadriceps (2 tr and 2 con).</p> <p>Primary Outcome Measure: Gait kinematics (passive dorsiflexion) when FES was switched off, Functional Assessment Questionnaire.</p> <p>Secondary Outcome Measure: orthotic effect of FES in control and treated children.</p> <p>Results: No significant therapeutic change in gait kinematics.</p> <p>Significant orthotic effect of gait kinematics but children walked slower with FES on.</p> <p>Children did not tolerate level of stimulation to quadriceps</p> <p>Parents reported that FES resulted in skin problems, embarrassment and was impractical.</p>	<p>Limitations</p> <p>Underpowered – needed 33 in each group and only had 7.</p> <p>Randomisation was only done on a pair wise level. Pairs were matched for attributes first and then allocated.</p> <p>Didn't use intention to treat analysis</p>
FES034 Esnouf et al., 1-	RCT	<p>Population: 64 People with secondary progressive Multiple Sclerosis with unilateral dropped foot</p> <p>Intervention: FES vs physical therapy for 18 weeks</p> <p>Primary Outcome Measure: Satisfaction and performance scores for Activities of Daily Living (ADL) using the Canadian</p>	<p>Strengths</p> <p>Random allocation – permuted blocks – revealed after consent</p> <p>Limitations</p>

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		<p>Occupational Performance Measure (COMP) and falls diary</p> <p>Secondary Outcome Measure: Falls – documented in a diary</p> <p>Results: Improvements in performance and satisfaction scores were significantly higher in the FES group compared to the controls. FES also assessed as effective at reducing falls.</p>	<p>They suggest that the study was underpowered.</p> <p>Participants recruited from an FES waiting list and assessed for responsiveness to FES – selection bias.</p> <p>No mention of intention to treat analysis.</p> <p>Exercise group promised FES at end of trial – recall bias using the diaries? Don't know if the exercise group were more active and therefore had more falls.</p>
<p>FES039 Tanovic 2009 1-</p>	<p>Randomised prospective clinical comparative study</p>	<p>Population: Adult patients with hemiparesis due to stroke, diagnosed within 3 months of the trial.</p> <p>Intervention: Kinesiotherapy vs kinesiotherapy plus FES for 5x15 minute sessions/week.</p> <p>n=40 in each, with further subdivisions in each of 20 patients with deep hemiparesis and 20 patients with light hemiparesis.</p> <p>Primary Outcome Measures: RAP index and BI index (both are walk function rehabilitation indices but no detail of how these are measured).</p> <p>Secondary Outcome Measures:</p>	<p>Strengths</p> <p>Balanced groups at baseline.</p> <p>Limitations:</p> <p>All existing patients at the institution and were not randomised.</p> <p>No mention of how they were randomised</p> <p>Not clear how long the FES stimulation was</p> <p>Not clear how the BI and RAP scores are</p>

Author, year	Study design & objective	Study detail <i>e.g. Population, Incl & Excl criteria, Sample size Intervention (I) & Control (C) Time to follow-up, Outcome & significance</i>	Comments & confidence in results based on study design ± study limitations
		<p>Results: BI index no difference between controls and intervention group at 4 weeks (deep and light) or at 8 weeks (deep) but there was a difference at 8 weeks for light hemiparesis ($p < 0.05$).</p> <p>RAP index was no different at 4 weeks for deep or light but was different at 8 weeks for both.</p> <p>Conclude that therapy for more than 4 weeks is needed</p>	<p>calculated or what they contain</p> <p>No power calculation and study size estimation.</p> <p>No blinding, no data on compliance, no data on drop outs or intention to treat.</p> <p>?correct statistical test?</p>
<p>FES035</p> <p>Kojovic et al., 2009</p> <p>1-</p>	<p>RCT</p>	<p>Population: 13 acute stroke patients recruited from the stroke clinic within 8 weeks of stroke.</p> <p>Intervention: Functional Electrical Therapy (FET) plus standard therapy and 45 min walking for 5 days/week over 4 weeks vs standard therapy and walking only</p> <p>Primary Outcome Measure: Fugl-Meyer (FM) test, Barthel Index (BI), mean walking velocity over 6m and physiological cost index (PCI)</p> <p>Secondary Outcome Measure:</p> <p>Results: Better FM, BI, walking velocity and PCI at 4 weeks in the FET vs control group</p> <p>NB FET treatment stimulated quadriceps, hamstrings as well as</p>	<p>Strengths:</p> <p>computer generated randomisation before baseline measurements taken.</p> <p>Similar baseline characteristics of the groups</p> <p>No drop outs</p> <p>Limitations:</p> <p>Small study (n=7 and 6 in each group)</p> <p>No blinding or sample size calculation. Power was estimated at 70%</p>

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		lower leg, so different to other studies.	
FES003 Burrige et al., 2007 1-	RCT	<p>Population: 32 chronic stroke patients referred for FES treatment.</p> <p>Intervention: Surface electrodes, not clear how much the patients used it or what the compliance was, had 10 sessions of physio.</p> <p>Primary outcome: Effect of FES and physio vs physio on walking speed and PCI (effort) at 12-13 weeks.</p> <p>Results: In the intervention group Speed goes from 0.68 m/s to 0.77 m/s and effort goes from 0.59 beats per min per m/min to 0.54. In the control group Speed goes from 0.48 m/s to 0.51 m/s and effort goes from 1.03 beats/min per m/min to 1.00</p> <p>statistical increase in speed with FES on p=0.0438, no statistical change in effort with FES on p=0.0830</p>	<p>Strengths:</p> <p>Good sequence generation and allocation concealment</p> <p>Limitations:</p> <p>Doesn't say how many people were approached in outpatient clinic, only that 33 consented. All had been referred for FES so were expecting it.</p> <p>randomisation didn't work effectively as there were differences between the control and intervention groups at baseline. No sample size calculation is reported.</p>
LEVEL 2: Systematic reviews of case control or cohort studies, case control or cohort studies			
FES028	Systematic	Search period: Up to Dec 2006.	Strengths:

Author, year	Study design & objective	Study detail <i>e.g. Population, Incl & Excl criteria, Sample size Intervention (I) & Control (C) Time to follow-up, Outcome & significance</i>	Comments & confidence in results based on study design ± study limitations
Seifart et al 2009 2++	review	<p>Studies: 5 studies included; before and after, FES vs intervention and FES combined with another intervention.</p> <p>Population: children with cerebral palsy</p> <p>Intervention: Surface or percutaneous electrodes applied to the leg muscles(s). 3 were case reports, 1 single subject and 1 crossover design.</p> <p>Primary Outcome Measure: Therapeutic effects – walking speed</p> <p>Secondary Outcome Measure:</p> <p>Results – Results were inconclusive</p>	<p>2 reviewers excluded low quality studies using a standardised scoring mechanism.</p> <p>Grey literature searched for a limited number of conferences.</p> <p>Limitations:</p> <p>Only English and ‘locally obtainable’ studies included.</p> <p>Small number of studies were included and were of low quality – Scored level 2c (n=2) and 4 (n=3)</p> <p>No sensitivity analysis</p>
FES040 Stein et al., 2009 2+	Uncontrolled trial	<p>Population: people with nonprogressive (e.g. stroke) or progressive (e.g. multiple sclerosis) disorders.</p> <p>Intervention: FES for 3-12 months in the community</p> <p>Primary Outcome Measure: 10 m Walking speed and 8 m figure 8 test and physiological cost index (PCI). Tested with FES on and off and at baseline and end of study.</p> <p>Result: both groups had an orthotic effect with FES (increased</p>	<p>Strengths:</p> <p>Reproducible and practical for non-research use.</p> <p>Limitations:</p> <p>No alternative intervention. It is possible that a new therapeutic input by itself improved gait measures.</p>

Author, year	Study design & objective	Study detail <i>e.g. Population, Incl & Excl criteria, Sample size Intervention (I) & Control (C) Time to follow-up, Outcome & significance</i>	Comments & confidence in results based on study design ± study limitations
		walking speed and reduced PCI). A therapeutic benefit was only found at 11 months for the non-progressive group and at 3 months for the progressive group.	
FES018 Hausdorff and Ring, 2008 2+	Uncontrolled trial	<p>Population: 24 patients with chronic hemiparesis recruited in an outpatients clinic. 17 had used an AFO before the study.</p> <p>Intervention: Gradual increase in using FES during a 4 week adaption period</p> <p>Primary Outcome Measures: PCI, Falls, Gait Asymmetry, Gait rhythmicity using 6 min walk, and others measured in a 50 m walkway at 4 weeks and 8 weeks.</p> <p>Results: all gait measures improved over time compared to baseline of no prosthesis. 24 falls in 8 weeks before the study (recall) and 2 falls during the study.</p>	<p>Strengths:</p> <p>One of the few studies to try to measure falls, but it does not compare falls with FES vs usual orthotic/walking aid and does not give an indication of the severity of the falls outcome.</p> <p>Limitations:</p> <p>No control group, doesn't compare FES with AFO use or usual aids.</p> <p>Recruitment biases – not clear how many people were approached for the study.</p>
FES041 Barrett et al., 2010	Uncontrolled trial	<p>Cohort: 21 People with Stroke and 20 people with Multiple Sclerosis who have been fitted with FES for 18 weeks.</p> <p>Intervention: FES</p> <p>Primary Outcome Measure: Quality of Life (as measured by the</p>	<p>Strengths:</p> <p>Limitations:</p> <p>No control group so don't know if improved quality of life is due to additional therapeutic</p>

Author, year	Study design & objective	Study detail <i>e.g. Population, Incl & Excl criteria, Sample size Intervention (I) & Control (C) Time to follow-up, Outcome & significance</i>	Comments & confidence in results based on study design ± study limitations
2+		<p>Psychosocial Impact of Assistive Devices Scale) and walking speed with and without stimulation after 18 weeks</p> <p>Secondary Outcome Measure:</p> <p>Results: FES has a beneficial effect on perceived QOL for people with stroke and MS but this is not correlated with measures of gait.</p> <p>Stroke, orthotic effect of FES at 0 and 18 weeks.</p> <p>MS, orthotic effect of FES at 18 weeks.</p> <p>NB the protocol for measuring walking speed was changed from previous studies showing no effect of FES vs exercise (above) and needs to be validated in controlled trials.</p>	<p>input.</p> <p>No discussion about the eligibility of patients for FES.</p>
<p>FES042</p> <p>Paul et al., 2008</p> <p>2+</p>	Case-control	<p>Cases: 12 people with Multiple Sclerosis with no co-morbidities that would restrict gait and have used FES for 6 months or more. Mostly secondary progressive MS.</p> <p>Controls: 12 healthy controls matched on age and gender.</p> <p>Intervention: Wearing FES</p> <p>Primary Outcome Measure: Walking speed and Physiological cost of gait</p>	<p>Strengths:</p> <p>Limitations:</p> <p>Controls and cases from different populations. Controls were from University employees and Cases were from an MS clinic.</p> <p>The clinical significance of this increase was not clear.</p>

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		Result: Wearing FES resulted in increased walking speed and reduced physiological cost of gait in people with MS and in controls.	
FES026 Van Swigchem et al., 2010 2+	Crossover trial	<p>Population: 26 community dwelling chronic stroke patients.</p> <p>Intervention: Their ankle-foot orthosis was replaced by FES and outcome measured at 2 and 8 weeks</p> <p>Primary Outcome Measure: 10m walking speed, level of activity, patient satisfaction</p> <p>Result: FES did not increase walking speed or activity but patients were more satisfied with FES (e.g. comfort, appearance, quality of gait, stability)</p> <p>One patient had allergic reaction to the electrodes and 3 others had skin irritations. Some minor complaints also.</p>	<p>Strengths: Reproducible and practical for non-research use.</p> <p>Limitations: No study size/power calculation undertaken. No alternative therapy group. New intervention of any type may have increased satisfaction. Measurement bias of the questionnaire – patient self reporting on a new device they haven't previously used – novelty? Questionnaire not validated.</p>
FES008 Taylor et al., 1999 2+	Uncontrolled trial	<p>Population: 151 patients with upper motor neuron lesion (stroke, MS and SCI) referred by consultant or GP and assessed for suitability in clinic.</p> <p>Intervention: patients wore at home and were followed up fter</p>	<p>Strengths Reproducible and practical for non-research use.</p> <p>Limitations There is no comparator group, baseline</p>

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		<p>6wks, 3m and then every 6 m</p> <p>Primary Outcome Measures: changes in walking speed and PCI</p> <p>Result: Immediate orthotic effect - Stroke: 12% increase in walking speed, 18% decrease in effort. MS: 5% increase in walking speed and 12% decrease in effort. SCI patients: 8% increase walking speed and a non significant 11% decrease in effort.</p> <p>Immediate orthotic effect shows significant increase in walking speed for all (5%-12%) and a decrease in effort for stroke and MS (18% and 12%)but not SCI</p>	<p>measurements were made without patients usual orthotic.</p> <p>Don't know what the walking speed and effort was at baseline with the usual AFO/device if there was one</p>
<p>FES019</p> <p>Sheffler et al., 2009</p> <p>2+</p>	<p>Uncontrolled trial</p>	<p>Participants: 11 MS patients recruited from an outpatients department, diagnosed for more than 6 months.</p> <p>Intervention: surface FES. Patients offered 2 days of gait training with the device then used at home for up to 8 hours/day for 4 weeks.</p> <p>Outcome measures: timed foot walk and elements of the modified Emory Functional Ambulation Profile, measured with and without FES.</p> <p>Results: FES improved Stair performance but no other</p>	<p>Strengths</p> <p>Reproducible and practical for non-research use.</p> <p>Limitations</p> <p>No AFO comparison or control group.</p>

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		measures of the mEFAP.	
FES025 Laufer et al., 2009 2+	Uncontrolled trial	<p>Participants: 16 patients with chronic hemiparesis</p> <p>Intervention: FES followed up after 2 months</p> <p>Outcome measures: gait velocity, and measures of gait stability.</p> <p>Results: increase in gait speed from 0.67 m/s to 0.86 m/s</p>	<p>Strengths</p> <p>Reproducible and practical for non-research use.</p> <p>Limitations</p> <p>No AFO comparison or control group.</p>
LEVEL 3: Non-analytic studies e.g. case reports, case series			
FES043 Seifart et al., 2010 3	Uncontrolled trial/case series	<p>Participants: 5 children with cerebral palsy</p> <p>Intervention: Botulinium injection followed by 4 week FES home programme.</p> <p>Outcome measures: Walking speed and muscle strength</p> <p>Results</p>	<p>Strengths:</p> <p>One of the very few studies of cerebral palsy.</p> <p>Limitations:</p> <p>Only 3 subjects followed the protocol.</p> <p>No comparator/control group</p>

Author, year	Study design & objective	Study detail <i>e.g. Population, Incl & Excl criteria, Sample size Intervention (I) & Control (C) Time to follow-up, Outcome & significance</i>	Comments & confidence in results based on study design ± study limitations
FES021 Van Swigchem, 2011 3	Case report	<p>Participant: 1 adult – stroke chronic phase.</p> <p>Intervention: implanted FES</p> <p>Outcome measures: gait pattern</p> <p>Results: report near normal gait patterns after implantation</p>	<p>Strengths:</p> <p>Limitations</p> <p>Single case – surface FES was not suitable.</p>

Criteria for evaluating the quality of the evidence and strength of recommendation using the GRADE methodology*:		
*GRADE Working Group publications, 2008. http://www.gradeworkinggroup.org/publications/index.htm Accessed 26/11/09		
Quality of evidence: definitions Evaluation of quality of the evidence should consider the study design ± study limitations	High quality	Further research is very unlikely to change our confidence in the estimate of effect
	Moderate quality	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
	Low quality	Further research is <i>very</i> likely to have an important impact on our confidence in the estimate of effect and <i>is likely to</i> change the estimate
	Very low quality	Any estimate of effect is very uncertain

Factors affecting the strength of recommendation: Strong or Weak	Quality of the evidence on clinical effectiveness
	Uncertainty about the balance between desirable and undesirable effects
	Uncertainty or variability in values and preferences [e.g. QoL]
	Uncertainty about whether the intervention represents a wise use of resources
<p>GRADE classifies recommendations as strong or weak Strong recommendations mean that most informed patients would choose the recommended management and that clinicians can structure their interactions with patients accordingly Weak recommendations mean that patients' choices will vary according to their values and preferences, and clinicians must ensure that patients' care is in keeping with their values and preferences Strength of recommendation is determined by the balance between desirable and undesirable consequences of alternative management strategies, quality of evidence, variability in values and preferences, and resource use.</p> <p>The strength of a recommendation reflects the extent to which we can be confident that desirable effects of an intervention outweigh undesirable effects</p>	

Quality assessment of studies	
<p>**Evidence levels are taken from the SIGN Guideline Developer's Handbook, http://www.sign.ac.uk/guidelines/fulltext/50/annexb.html [accessed 19.06.2009].</p> <p>The level of evidence indicated for each study has been adapted to allow broad categorisation of each reference according to the research methodology used. NB. Studies with a level of evidence '-' should not be used as a basis for making a recommendation.</p>	
Level of Evidence 1++	High quality meta-analyses, systematic reviews of RCTs; RCTs with a very low risk of bias
Level of Evidence 1+	Well-conducted meta-analyses, systematic reviews; RCTs with a low risk of bias

Level of Evidence 1-	Meta-analyses, systematic reviews; RCTs with a high risk of bias
Level of Evidence 2++	High quality systematic reviews of case control or cohort or studies; High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
Level of Evidence 2+	Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
Level of Evidence 2-	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
Level of Evidence 3	Non-analytic studies e.g. case reports, case series
Level of Evidence 4	Expert opinion, formal consensus