Orthotic functional electrical stimulation for drop foot of neurological origin

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Summary

Functional electrical stimulation (FES) is a broad term encompassing skin-surface (transcutaneous) and implantable systems used both as functional training aids and long-term orthotic treatments. The latter is the primary focus of this appraisal. Orthotic FES is most often delivered via skin-surface electrodes to treat drop foot of neurological origin.

Drop foot is a term to describe a compensatory gait which patients with central neurological impairment may develop. It occurs when nerve transmissions to the ankle and dorsiflexor muscles are impaired leading to incomplete foot lift, and consequent ‘foot drop’ during normal walking. This leads to an unstable gait causing balance problems and impaired mobility.

Orthotic FES detects the normal muscle contractions or other sequelae of normal walking and triggers a series of electrical impulses which cause the necessary muscles to contract and thus restore, partially at least, a normal gait.

There is a large volume of evidence for FES in drop foot of various neurological origins although predominantly in post-stroke patients. Important differences in study parameters make generalisations difficult. Much of the evidence is of low quality; e.g. non-randomised studies, absence of control groups, short follow-up, few patients. Evidence of higher quality tends to demonstrate the least benefit for FES.

FES has been recommended as a treatment option for drop foot where ankle-foot orthoses have not worked or are not suitable. However there is scant evidence demonstrating the efficacy of FES compared with AFO.

NICE issued positive interventional procedure guidance for FES for drop foot in January 2009. Skin-surface FES for a single patient is estimated to cost about £2,600 over five years.

Compared with physiotherapy, a number of cost-effectiveness analyses have calculated a cost per QALY for FES over a five-year time horizon of less than £20,000. However these analyses are either methodologically weak or insufficient detail is provided for proper critique. A cost-effectiveness acceptability analysis indicates that skin-surface FES has a low probability of yielding a cost per QALY < £20,000, perhaps indicating the degree of uncertainty around treatment effects and costs.

There is little robust evidence to indicate the likely patient numbers for FES, and actual patient numbers may be dependent to a certain extent on local clinical preferences. The available information indicates that overall patient numbers are likely to be very low within NHS North East.
Introduction

‘Drop foot’ is the name given to a particular style of walking or gait which is often present in individuals with a neurological deficit in the central nervous system. The nature of the neurological deficit may be due to a variety of causes; common causes include stroke, multiple sclerosis, cerebral palsy and spinal or brain injuries. The neurological deficit in drop foot results in poor control of ankle and toe dorsiflexor muscles. This causes the foot to hang downwards (‘drop’) and drag along the ground during normal walking. In consequence patients tend to develop a different and less stable gait which impacts on their mobility, speed and balance. 

Treatments for drop foot include physiotherapy, orthotic devices, medical therapy, electrical stimulation of the affected nerves, and surgery. These options can be used alone or in combination with one another. First-line treatment is usually physiotherapy or the use of an ankle foot orthotic device (AFO). An AFO is a device, usually made of plastic, which is worn on the lower part of the leg and on the foot. It is used to align the lower leg correctly and control the motion of the ankle and foot, to provide stability and improve gait. Medical therapy includes orally administered drugs such as baclofen, dantrolene or tizanidine. More recently Botox® injections into the most affected muscles have been used to treat spasticity. Surgery includes selective tendon release of these muscles, selective dorsal rhizotomy and intrathecal baclofen pump. Surgery is rarely indicated and is usually reserved for the most refractory cases.

Functional electrical stimulation (FES) has been developed 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 aid whereby the benefits are noted once the FES has ceased or as an orthotic device whereby the benefits occur whilst the device is worn. 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 that are the primary focus of this report. 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.

The NHS North East Treatment Advisory Group has been requested by a member commissioning organisation to conduct an appraisal of, and issue a recommendation, for, the use of FES as a long-term orthotic intervention.
Clinical Evidence


Current evidence on the safety and efficacy (in terms of improving gait) of FES for drop foot of central neurological origin appears adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

Patient selection for implantable FES for drop foot of central neurological origin should involve a multidisciplinary team specialising in rehabilitation.

Further publication on the efficacy of FES would be useful, specifically including patient-reported outcomes, such as quality of life and activities of daily living, and these outcomes should be examined in different ethnic and socioeconomic groups.

The accompanying NICE evidence overview document included evidence up to August 2008. The evidence overview focused principally on one meta-analysis which itself included three small controlled studies and two small case series, plus three randomised controlled studies and three case series. This covered a total of 230 patients treated with FES for drop foot. 3

An additional evidence review of FES was published by the East Midlands Specialised Commissioning Group in April 2011. The focus of this review was skin-surface orthotic FES and it included 30 articles; six systematic reviews including one meta-analysis, twelve controlled trials, nine non-controlled trials, one observational study, one economic review and one case series. 1

The evidence considered within this report will be that which has not been included in either the NICE evidence overview or the EMSCG report and therefore this report should be read in conjunction with these documents.

Only two additional and relevant studies that had not already been summarised by NICE or the EMSCG were identified. 4,5

The first of these represents the largest randomised controlled study of FES, albeit utilising implantable FES electrodes as a therapeutic training aid. All patients (n = 53) were randomised to an intensive multi-modal 12-week therapeutic training programme, with one group also receiving FES (n = 26). Both groups demonstrated significant improvements in measures of gait and walking at the end of the training programme. Patients in the FES group demonstrated
numerically greater improvements in almost all outcomes compared with the non-FES group. After six months following the training programme, the FES group maintained its gait improvements whereas the non-FES patient group had worsened slightly. Surprisingly, between-group comparisons are not provided. 4

The second study was a small UK-based qualitative investigation of FES user experiences, preferences and choices relating to FES and ankle foot orthoses for foot-drop after a stroke. Nine current FES users and four partners and principal carers of current FES users, all post-stroke, were recruited from a FES clinic. The investigators appear to be predominantly FES clinic staff. FES use ranged from 1 to 4 years for all participants. Only one participant reported a preference for AFO, with the remaining 12 preferring FES. Usefully, the report lists a number of positive and negative experiences reported with both FES and AFO (summarised in appendix 1). 5
Summary of the clinical evidence

The additional evidence to that previously summarised in the reports by NICE and EMSCG is useful. The large RCT (n = 53) suffers from limited follow-up (12 weeks) and an atypical and potentially irreproducible intervention being invasive and intensive. In addition, the FES intervention was used for a short-term functional training programme, but is nonetheless informative. FES patients did indeed demonstrate greater clinical gains compared with non-FES patients, and these appeared to show some degree of durability. However, gains were generally small and of uncertain practical usefulness. 4

The evidence of user preferences is also useful but potentially biased. Participants were not randomly selected and all were existing FES users, indicating at least a degree of satisfaction with FES from the outset. In addition, the research team appear to be predominantly staff involved with delivering a FES service. 5

Taking only the highest quality evidence from randomised controlled studies and meta-analyses, the overall picture of evidence is mixed. Some studies demonstrate small but potentially clinically important benefits for FES as an orthotic intervention, whereas others indicate little or no benefit, or even detrimental effects. 1

Perhaps the greatest weakness in the evidence base for orthotic FES is that comparators, where these are available, seldom include AFO. The EMSCG report identified only four such studies and at least three of these did not demonstrate an improvement in walking speed compared with FES. This is a striking omission given that treatment guidelines generally regard FES as a subsequent treatment to AFO. It is therefore difficult to determine the incremental benefit, if any, of FES over AFO. 1

The interpretation of the whole evidence base is further compounded due to a large degree of heterogeneity in the evidence: therapeutic vs. orthotic; skin-surface vs. implant; different devices used on different settings or programmes; variation in follow-up; different end-points measured; different aetiologies (although most patients/studies are post-stroke); different application of supportive therapies such as physiotherapy or drugs. 1

The quality of much of the evidence is poor, with frequent use of before and after case series reports, or studies with short follow-up and small numbers of patients. Most studies were at moderate to high risk of bias and results must be considered cautiously. 1
Safety

The safety of FES has not been thoroughly investigated. \(^1\)\(^2\) NICE identified a relatively high rate of mild to moderate adverse effects although the majority of these tended to stem from use of FES implants. In addition, NICE identified more serious but apparently hypothetical safety concerns with FES in general. \(^2\) The EMSCG report concluded that ‘there do not appear to be significant safety issues related to the use of FES and it appears to be well tolerated and preferred [to other treatments, e.g. physiotherapy and AFO], at least in adults’. \(^1\)

Discharge rates and reasons for discharge from the FES service at the National FES Centre (UK) are described in an unpublished conference paper in a cohort of 127 FES patients with 11 years of follow-up. Patients were fitted with an Odstock® FES device in 1999. The mean time in use was 4.9 years (median 3.6 years). After 11 years, 33 patients were still using the device (26%). Of the 94 patients who were discharged from the service, 12 (9%) were recorded as having transferred to another clinic and were still using FES. Data was missing for 17 patients (13%) and 8 patients had died (6%). Of those who gave a reason for discontinuing FES (n = 47), 17 reported a deterioration in mobility, 7 improved mobility, 5 found it ineffective, 4 reported difficulty using the equipment, 4 had logistical problems attending clinic, 3 found it painful, 2 suffered further strokes, and one each had difficulty placing electrodes, reported too much spasticity, found the cost too high (non-NHS patient), found it ‘too much bother’, and experienced skin reactions to the electrodes. \(^6\)

Overall, with appropriate patient assessment, the safety of FES appears to be good with a relatively low incidence of direct adverse effects including a low incidence of skin reactions with skin-surface FES. Despite the relatively good safety profile, long term persistence with FES appears to be low, with half of patients discontinuing before four years.
Relevant guidance

Other than NICE IPG number 278, other relevant guidance and policies originating from the UK have been published.

The Royal College of Physicians, in their clinical guideline for stroke published in 2008, recommend FES for foot drop with the following constraints: 7

- [It] should not be used on a routine basis outside the context of a clinical trial
- Only where foot-drop impedes gait which is not satisfactorily controlled using AFO and patients have demonstrable gait improvement from use

The guidelines also state that FES ‘should only be prescribed by a specialist team familiar with its use and evaluation and able to confirm that it offers a specific benefit not achievable in other ways’. 7

In considering the management of gait, balance and mobility in post-stroke recovery a recent guideline issued by the Scottish Intercollegiate Guidelines Network (SIGN) recommends six different treatment strategies including AFO. A further three strategies are listed to be considered and these include FES for drop-foot. Specifically, with respect to FES for drop-foot, the guideline states ‘FES may be considered as a treatment for drop-foot, where the aim of treatment is the immediate improvement of walking speed and/or efficiency’. This recommendation is described as a grade C recommendation on a scale ranging from A (highest grade) to D (lowest grade) and relates to well conducted studies of low methodological quality. 8

The NHS East Midlands Specialised Commissioning Group (EMSCG) published a comprehensive appraisal report on FES for drop foot in 2011. An associated policy recommendation was not to fund FES outside of a clinical study. The policy recommendation was accepted but has not yet been implemented and may still subject to change. 1,9

The NHS Peninsula Commissioning Priorities Group has recently made a decision to commission skin-surface FES for patients for whom AFO has proven unsuitable. 10

A general commissioning policy was published by NHS Hull for FES for dropped foot in adults secondary to central neurological dysfunction in July 2010. The policy states that FES is ‘not routinely commissioned for dropped foot because of the limited evidence for clinical effectiveness and a lack of independent, published cost effectiveness data’. 11
The NHS Pan-Dorset Technologies Forum conducted a technology review of FES. The subsequent commissioning policy for NHS Bournemouth & Poole and NHS Dorset does not provide FES for new patients and restricts its use for existing patients only where there is a documented history of tripping, falling or gait problems and where there is a full range of joint and muscle movement and no severe spasticity or oedema. FES implants are not recommended under any circumstances.  

In May 2008 the NHS South Central Priorities Committee, covering nine PCTs, identified electrical stimulation, including FES, for upper and lower limb dysfunction as a ‘low priority’ due to a lack of evidence of clinical and cost effectiveness.  

NHS North West London published a policy for FES in August 2011. This restricted FES for drop for of central neurological origin only and stated that FES would not be funded for lower motor neurone diseases. The organisation would only consider ongoing funding if there is a documented history of tripping, falling, or gait problems, and the patient has a full range of joint and muscle movement and no severe spasticity or oedema.  

NHS Trafford has also listed FES as a low priority treatment and will only consider funding ‘on the grounds of clinical exceptionality’.
Cost analysis

Costs include VAT at 20% unless otherwise indicated.

There are a number of different skin-surface FES systems available. These have been described in detail by the NHS Purchasing and Supplies Agency in a report published by their Cost Evidence-based Purchasing team. Based on a five-year in-use period the systems range in annual cost from about £283 to £1,390 (total costs over five years range from £1,415 to £7,000). As well as the directly chargeable patient equipment some of the devices incur significant investment costs, for example clinic hardware and clinician training. These are expected to fall on service providers and are therefore not considered within this review. 16

Only one type of intra-muscular FES system is known to be in use in the UK. This costs £6,612 for assessment, surgery and hardware. Annual costs of £351 will be incurred for follow-up. Total cost over five years is therefore £8,016, with an annual cost over five years of about £1,600. Only one centre in the UK is currently able to provide this service and therefore significant additional patient transport and hotel costs may be incurred. 16

As well as hardware costs, there will be costs incurred for clinical appointments. A description of a typical clinical pathway for (NHS) FES patients would require a minimum of 10 appointments over five years, with six of these appointments occurring in the first year. 17 The department of health payment-by-results tariff specifically excludes services for rehabilitation of stroke, brain injuries, spinal cord injuries, and other neurological disorders from the tariff. 18 Information provided by the NHS North East Specialised Commissioning Team relating to locally agreed tariffs for neurological rehabilitation services with a major local provider indicate that the cost of an outpatient appointment is about £X. Some specific services are substantially more costly, ranging from about £X per outpatient appointment for spasticity to about £X for any contact relating to multiple sclerosis. 19 For the purpose of this analysis the cost will be assumed to be £120, similar to that estimated by the Centre for Evidence-based purchasing which used a value of £140 in their analysis. 20 Thus the total cost of the estimated 10 visits over five years is £1,200. It is not clear whether this number of visits would be greater or even less than that which patients might experience in the absence of FES. 17

The total cost of FES over five years is therefore estimated at about £2,600.

A number of cost analyses have been published regarding FES; all appear to have been authored by, or received contributions from, the National FES Centre (UK).
The Centre for Evidence-based Purchasing (CEP), part of the NHS Purchasing and Supply Agency, published an economic report on FES for drop foot of central neurological origin in February 2010. The report relates only to post-stroke patients and includes a robust cost-utility analysis. Of crucial importance within the analysis is the assumed ‘efficacy’ rate which is stated as 74%. This figure is not referenced and appears to be rather generous compared with the most recent evidence. A sensitivity analysis on the efficacy rate is not presented. The cost of FES appears reasonable taking into account hardware costs and clinical appointments. The base-case cost per quality-adjusted-life-year (QALY) over a five-year horizon and incremental to physiotherapy is estimated at £19,238. An assumption of five-year’s use of FES is supported by evidence from the National FES Centre regarding mean treatment durations. However the modelling of FES as an alternative to physiotherapy may not align with expected treatment pathways where FES would more likely be offered when AFO is considered unsuitable or has been unsuccessful. AFO itself would more likely follow-on from physiotherapy alone.

The same report estimates the probability of FES being cost-effective incremental to physiotherapy over five years at a threshold of £30,000 per QALY as 66%. The same probability at a threshold of £20,000 per QALY is less than 25%.

The cost-effectiveness of FES is highly sensitive to the time-horizon over which it is calculated, due in part because the majority of costs associated with FES are incurred in the first year. For example, the incremental cost per QALY compared with physiotherapy in year one is about £52,000, with each subsequent years 2 to 5 estimated at £11,000 per QALY.

An unpublished conference paper presented in 2007 provides a detailed economic assessment of a specific device, the Odstock® Dropped Foot Stimulator (ODFS™). The analysis uses a single clinical study as the basis for the economic model.

The five-year cost of treatment including hardware and clinical appointments is estimated at £2,840 which is similar to the net cost previously estimated in this report for skin-surface FES. The methodology used to calculate the cost per QALY does not appear to be sound, calculating average values as opposed to incremental values. Fortunately an alternative QALY gain is provided which has a value very similar to that for the mean gain incremental to the control group. From this, it can be assumed that the estimated cost per QALY incremental to physiotherapy over five-years is about £14,000. Again, the duration of therapy has a substantial effect on the estimated costs per QALY. In year one the incremental cost per QALY is estimated at about £40,000.
A more recent unpublished conference paper consisting of a retrospective review of patients from the National Clinical FES Centre (Salisbury, UK) is also available. The paper provides extensive audit data going back up to 11 years. The mean time for FES use is about four to five years (n = 259) with some variation depending on the underlying diagnosis, most noticeably a mean duration of less than two years in patients with spinal cord injury (n = 7). Crude cost per QALY is calculated using audit data relating to parameters of mean healthcare utilisation and clinical parameters from a single study. However, as with the earlier economic analysis, a mean QALY gain is used and not an incremental QALY relative to physiotherapy alone. This has an effect of overestimating the QALY gain and underestimating the cost per QALY. Corrected values provide crude cost per QALY incremental to physiotherapy of about £15,000 to £16,000.  

Estimating the number of patients who might require the service is complex. The hospital episodes statistics inpatient data for England 2010-11 are not specific. There were 500 admissions for ‘wrist or foot drop (acquired)’, corresponding to an estimated 25 admissions for NHS North East. A range of procedural codes relating to neurostimulation of peripheral nerves and transcutaneous nerve stimulation might reasonably apply to the use of FES as well as numerous other interventions, the sum of which comes to nearly 3,000 admissions.  

One local PCT cluster with a population of more than 600,000 has received four requests for orthotic skin-surface FES in a ≥ 19 month period. The small number of relevant admissions identified on the HES dataset combined with the experiences of a local commissioning cluster indicates that patient numbers are likely to be very low.  

Future demand has not been estimated as no reliable evidence has been identified.

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*A HES 4-character procedure and intervention codes: A70.(1, 2, 3, 4, 7, 8 and 9).*
Points to consider

For many patients considered for FES the alternative treatment would likely be an ankle-foot orthoses (AFO). Indeed, the two are not mutually exclusive and may be used in combination. There are advantages and disadvantages of each treatment modality which will vary in relative importance from patient to patient. Examples of reported negative and positive user experiences of these treatments are listed in appendix 1.

FES services are available from a limited number of centres and patients may incur additional travel for treatment. For implantable FES patients will have to undergo minimally invasive surgery under general anaesthesia at a remote treatment centre.

There is a large volume of evidence for FES, both skin-surface and implantable systems. Generalisation relating to the clinical evidence is compounded by multiple differences between studies. The methodological quality of much of the evidence is poor and bias cannot be ruled out. The small number of randomised controlled studies demonstrate variable results, with some in favour of FES and others demonstrating little or no difference or negative effects compared with control groups.

The comparator for FES is of crucial importance. Much of the evidence relies upon a comparison with physiotherapy alone, whereas treatment guidelines which do recommend FES will often place it as an alternative or subsequent treatment to AFO. The evidence base for FES for drop foot is constantly evolving. Studies of the highest methodological quality tend to demonstrate the least benefit for FES.

FES is associated with modest overall costs, requiring relatively large up-front hardware costs, some on-going hardware costs, and a significant number of clinic visits especially in the first year. Available cost effectiveness analyses consider FES compared with physiotherapy alone whereas treatment guidelines recommend FES as an alternative to AFO. It is therefore not clear what the cost-effectiveness is of FES compared with AFO. The cost for skin-surface FES is estimated at upwards of £2,600 over five years. FES implants are considerably more costly at upwards of £7,000.

The available cost analyses all yield cost per QALYs which meet conventional limits on cost-effectiveness for treatments within the NHS. However, none of the analyses is entirely independent of a leading FES system supplier and each relies upon a number of assumptions or modelling parameters which may be considered biased in favour of FES. For this reason these analyses should be interpreted cautiously. No cost effectiveness analyses comparing FES with AFO were identified.

A number of other commissioning, professional, and technology appraisal organisations have issued recommendations on the use of FES for drop foot. These are variously negative, or positive with specific restrictions attached.
References


2. NICE. Interventional procedure guidance number 278: Functional electrical stimulation for drop foot of central neurological origin. January 2009

3. NICE. Interventional procedure overview of functional electrical stimulation for drop foot of central neurological origin. April 2008


6. Taylor P. How long do dropped foot stimulator users continue to use FES and how much does it cost? An eleven and six year clinical audit. Paper presented at the International FES Society annual conference, Austria, September 2010


Author’s declaration

The author has participated in a non-promotional educational event sponsored by a manufacturer of a product used to treat various spastic conditions, although the event was not related to this product. The author has no other relevant interests to declare.
Appendix 1.

User and carer reported experiences of FES and AFO for drop foot. \(^5\)

<table>
<thead>
<tr>
<th>Positive experiences</th>
<th>Negative experiences</th>
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| **FES** (skin-surface) | • Ability to exercise ankle, increasing muscle tone/bulk  
• Greater flexibility in function  
• Faster gait with greater foot lift and less tripping  
• More normal-looking gait  
• Greater independence  
• More lightweight than AFO  
• Makes it easier to obtain shoes  
• Easy to put on  
• Possible to turn-off when stationary | • Unreliable equipment  
• Does not function in specific contexts, e.g. near water  
• Hard to put on  
• Difficulty manipulating the connecting parts  
• Complicated to wear when travelling  
• Allergic reactions to the electrode pads |
| **AFO** | • Ease of day-to-day use  
• Use is part of routine  
• Easy to put on  
• Reliable equipment  
• Useful in emergencies  
• Useful during air travel (no wires)  
• Easier to put on independently  
• Can be used near water | • Uncomfortable, cumbersome, inflexible  
• Difficult to find appropriate shoes  
• Remains in place when sitting and not needed |