Orthotic functional electrical stimulation for drop foot of neurological origin (update)

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August 2015

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Summary

- Functional Electrical Stimulation (FES) is a broad term encompassing skin-surface and implantable systems used as both functional training aids and long term orthotic treatments.

- ‘Drop foot' refers to a particular walking gait often present in individuals with a neurological deficit of the central nervous system. It causes patients to develop a new, less stable gait which results in less mobility, speed, and balance as well as increasing the risk of falls.

- NICE states that the current evidence on the safety and efficacy of FES for drop foot appears adequate to support use of the procedure provided that normal arrangements are in place for clinical governance, consent, and audit.

- There is a large volume of evidence for FES in drop foot of various neurological origins, though much of it is of low quality (e.g. non-randomised studies, no control groups, short follow up, few patients).

- There is little evidence directly comparing FES to ankle foot orthoses. One clinical trial suggests no significant difference between them, though it is limited by several methodological flaws.

- A recent business plan suggests one-off costs of between £670 and £1750 for the cheapest, most popular devices. Ongoing consumables cost approximately £150 per year.

- There is little robust evidence to indicate how many patients per year would be likely candidates for FES, but overall patient numbers are likely to be very low within the NTAG region.
Introduction and background

‘Drop foot’ refers to a particular walking gait often present in individuals with a neurological deficit of the central nervous system. Drop foot may be present regardless of the nature or cause of neurological deficit; common causes include stroke, multiple sclerosis (MS), cerebral palsy, and spinal or brain injuries. Drop foot occurs as a result of poor control of dorsiflexor muscles in the ankle and toe, which causes the foot to hang downwards (“drop”) and drag along the ground during normal walking. As a consequence, patients tend to develop a new, less stable gait which results in less mobility, speed, and balance.\(^1,2,3\)

Available treatments for drop foot include physiotherapy, orthotic devices, medical therapy, electrical stimulation, and surgery. Any of these options can be used alone or in combination with each other. Physiotherapy or ankle foot orthotic devices (AFO) are generally considered first line treatment options. An AFO is usually made of plastic and is worn on the lower leg and foot. It is used to align the lower leg correctly and control motion, providing stability and improving gait. Medical therapy includes orally administered drugs such as baclofen, dantrolene, or tizanidine. More recently, Botox® injected into the most affected muscles has been used as a treatment for spasticity. Surgery is rarely indicated, and is reserved for the most refractory cases.\(^3\)

Functional Electrical Stimulation (FES) has been developed to help those with 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 or indirectly. Two broad types of FES exist: Implanted or skin surface. Implanted FES electrodes are usually inserted into the epineurium of the peroneal nerve under general anaesthesia whilst skin surface electrodes may be placed externally over the nerve and are connected by leads to a stimulator unit, controlled by a foot switch.\(^1\)

The main benefits of FES are twofold. Orthotic effects are immediate, and are experienced whilst the device is in place. Therapeutic effects develop over time with continued use of the device, and would be expected to occur even in the absence of the device being used (e.g. increased muscle mass due to repeated use of the device).\(^4\) Whether FES is used as an orthotic or therapeutic device is at the moment largely a local clinical decision and may be dependent on the original neurological condition.

FES devices are considered Class II Medical Devices by the MHRA. Unless custom made, they must have a CE marking.\(^5\)

In 2012, the NHS North East Treatment Advisory Group conducted an appraisal for the use of FES as a long-term orthotic intervention. This report updates that previous report, and therefore it focuses primarily on the orthotic properties of skin-surface FES devices.
Clinical Evidence

NICE published interventional procedure guidance number 278, entitled ‘Functional Electrical Stimulation for drop foot of central neurological origin’ in January 2009. This guidance states:2

Current evidence on the safety and efficacy (in terms of improving gait) of functional electrical stimulation (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 evidence overview included evidence published up to August 2008. This focused principally on one meta-analysis, which 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

The use of FES is also mentioned in the NICE guidelines for Stroke Rehabilitation6 and Multiple Sclerosis.7

An additional comprehensive evidence review of FES was published by the East Midlands Specialised Commissioning Group in April 2011 (now adopted by NHS Nottingham North & East CCG). This review focused on 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

This report will consider the evidence not included in the NICE evidence overview or the EMSCG report and which has been published since the last NETAG review in 2012. It should ideally therefore be read in conjunction with those documents.

There is a wealth of medical literature investigating FES, though much of it is of low quality. Robust randomised controlled trial (RCTS) may be difficult to design and undertake due to the nature of the intervention. Placebo interventions may be ethically difficult to justify, and the varied causes of drop foot and heterogeneous outcomes may make comparisons unreliable. Most available evidence is therefore in the form of case reports or series, which limits our ability to conclusively assess the efficacy of FES.
1. **Stroke**
   
   a. Controlled trials

   The Functional Ambulation: Standard Treatment Versus Electrical Stimulation Therapy (FASTEST) trial was a randomized, controlled, single blinded study of 197 patients in the chronic phase of stroke recovery. It is the only trial to date which has directly compared FES with AFO.

   Patients were randomized to either FES or an AFO for 30 weeks, after which time the AFO group crossed over to FES for the remaining 12 weeks. The primary outcome was gait speed, as measured in a 10 metre walk test, in both comfortable and quick speeds. Secondary outcomes included a timed up and go test as well as several validated measures of balance, motor impairment, and the stroke impact scale. Physical therapy was provided in both groups.⁸

   At the 30 week point, gait speed had significantly improved in both groups (P<0.001), though there was no significant differences found between AFO and FES (0.15± 0.14 vs 0.14 ± 0.16; p=0.78). There was also no significant difference when only severely impaired patients were analysed (0.11 ±0.14 vs 0.11±0.11, p=0.16). All secondary outcomes were significantly improved by the end of the 30 week period, though again there were no significant between-group differences.⁹

   At 42 weeks, a significant treatment difference from baseline in the FES group was described (effect size 0.84, p=0.03). The differences between the AFO and FES group at this point were not described.¹⁰

   The trial was underpowered to detect differences between the groups and excluded those with a previous inadequate response to FES, which may have somewhat skewed the results. Although this is the first trial to compare FES with AFO, it does not provide information on whether those who fail with an AFO will do better with FES.

2. **Multiple Sclerosis**
   
   a. Case series

   A 20 week case series study included 187 patients with drop foot caused by MS.¹¹ Four versions of a popular FES unit (Odstock Dropped Foot Stimulator) were used in the trial and it is unclear whether patients received concomitant physiotherapy throughout the trial.

   At the end of the study period, 166 patients were still using FES. Reasons for discontinuation included disease progression, difficulty in using the equipment, spasm, weakness and pain, psoriasis, skin irritation due to electrodes, and stimulation being too painful.
Significant improvements in walking speed (m/s) in a 10m walking test were seen with stimulation vs no stimulation both initially (FES group 0.79±0.031 vs unassisted group 0.72±0.33, p=0.001), and at 20 weeks (0.82 ± 0.34 vs 0.72±0.33, p=0.001).

3. **Hemiplegia**

a. **Case series**

Thirty six patients with drop foot caused by chronic hemiparesis were included in a case series assessing the effectiveness of a dual channel FES system (BioNess L300). Primary outcome was gait speed, which was measured at baseline and after 6 weeks, both with and without FES fitted. Patients were subdivided into three groups, depending on their ambulatory abilities: limited household ambulation (Group A), limited community ambulation (B) and functional community ambulation (C). Orthotic results by subgroup are presented below.

<table>
<thead>
<tr>
<th>Group</th>
<th>Gait speed at baseline (m/s)</th>
<th>Gait speed at 6 weeks (m/s)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No FES</td>
<td>FES</td>
</tr>
<tr>
<td>A (n=15)</td>
<td>0.30± 0.09</td>
<td>0.40±0.14 (p&lt;0.01)</td>
</tr>
<tr>
<td>B (n=15)</td>
<td>0.64±0.11</td>
<td>0.70±0.15*</td>
</tr>
<tr>
<td>C (n=6)</td>
<td>0.90±0.11</td>
<td>1.05±0.16*</td>
</tr>
<tr>
<td>Overall (n=36)</td>
<td>0.54±0.24</td>
<td>0.63±0.27 (p&lt;0.001)</td>
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</tbody>
</table>

* Table One: results from the Springer et al trial in hemiplegic patients.
* * reported as significant but p values not presented.
† Not significant
Summary of the Clinical Evidence

The additional evidence since the last NETAG appraisal continues to add to the substantial amount of published material, though it could be described as more of the same. It is, on the whole of low quality, and there have been no ‘smoking gun’ studies published which allow any robust conclusions to be made.

Comparative evidence with AFO is useful, as evidence in this area is particularly limited. Like the limited number of prior comparative studies, this one shows no significant difference between the groups. Most guidelines suggest FES as a subsequent treatment to AFO, but there is no evidence to suggest that it is superior, or that it is likely to work in those who have failed with an AFO.

The interpretation of the whole evidence base is further compounded due to a large degree of heterogeneity in the evidence: therapeutic vs orthotic effects; skin surface vs implanted; different devices; different settings or programmes; follow up variation; different end points; different aetiologies; differences in supportive therapies provided.¹

Much of the published evidence focuses on gait speed as a primary outcome measure. Improvements in gait speed in all groups in all studies were substantially higher than the minimal clinically important difference, which has been defined as 0.175m/s for patients undergoing outpatient rehabilitation.¹³ More evidence which focuses on patient-centred outcomes like quality of life is required.
Safety

The safety of FES has not been thoroughly investigated.\textsuperscript{1,2} NICE identified a relatively high rate of mild to moderate adverse effects, although the majority of these stemmed from the use of FES implants. Additionally, NICE identified some more serious safety concerns with FES in general, though these appear to be hypothetical in nature, with no reports of them occurring at this time.\textsuperscript{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 (such as physiotherapy or AFO), at least in adults.’\textsuperscript{1}

In the FASTEST trial, a total of 160 adverse events (AEs) in 59 patients were thought to be related to FES use. Mild AEs accounted for 92\% of those, with the other 8\% being rated as moderate. 18 serious AEs occurred, but they were unrelated to FES use. Half of the reported AEs were skin irritation caused by stimulation, which were all reversible. Falls relating to the device occurred on 24 occasions.\textsuperscript{10}
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 2012, recommend FES in a similar context to NICE, i.e. where normal arrangements are in place for clinical governance, consent and audit.\(^\text{14}\)

In considering the management of gait, balance and mobility in post-stroke recovery, the Scottish Intercollegiate Guidance Network (SIGN) guidance recommends six different treatment strategies including AFO. A further three strategies are listed to be considered, including 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 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.\(^\text{15}\)

SIGN also refer to FES in their 2013 guideline on brain injury rehabilitation in adults, though they do not recommend its use. They state that there is no evidence regarding its use in patients with brain injuries, and there is weak evidence that electrical stimulation may be effective for decreasing lower extremity spasticity for up to 24 hours.\(^\text{16}\)

The Guidelines and Audit Implementation Network 2014 guidelines for the rehabilitation of patients with metastatic spinal cord compression recommend FES as a component of balance, gait, and mobility re-education for patients with grade three or above bilateral leg power.\(^\text{17}\) This guidance is intended for use by physiotherapist and occupational therapists.

A number of NHS commissioning groups have issued policy decisions and recommendations. A selection of these are presented below.

<table>
<thead>
<tr>
<th>Group</th>
<th>Recommendation</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHS Nottingham North &amp; East (formerly EMSCG)</td>
<td>Skin surface FES will be commissioned for patients meeting specific criteria.</td>
<td>2012</td>
</tr>
<tr>
<td>NHS Central Lancashire</td>
<td>FES will not be commissioned for drop foot of central neurological origin unless:</td>
<td>Not dated</td>
</tr>
<tr>
<td></td>
<td>• Drop foot is impeding gait and is not satisfactorily controlled with AFO, AND</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• The patient has demonstrable functional improvement from an individual trial of FES, AND</td>
<td></td>
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<tr>
<td></td>
<td>• The intervention is recommended by a multidisciplinary team specialised in rehabilitation.</td>
<td></td>
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<tr>
<td>Hull CCG</td>
<td>FES is not routinely funded</td>
<td>2013</td>
</tr>
<tr>
<td>Bath and North East Somerset CCG</td>
<td>Criteria: only for drop foot as per NICE IPG278 and by specialist community services for adults only (over 18 years)</td>
<td>2015</td>
</tr>
<tr>
<td>East and North Hertfordshire CCG</td>
<td>FES is not routinely funded</td>
<td>2015</td>
</tr>
</tbody>
</table>
Cambridgeshire and Peterborough CCG | Considered a low priority and will not normally be funded. | 2013
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West Suffolk CCG | Considered a low priority and will not be funded | 2013
North West CSU | The patient must be being treated for foot drop which must be of central neurological origin, due to an upper motor neurone lesion i.e. one that occurs in the brain or spinal cord at or above the level of T12. This is normally but not exclusively associated with spasticity. In some cases wireless FES devices may be required | 2015
Peninsula Commissioning Priorities Group | FES delivered by skin surface electrodes may be offered by service providers under contractual provisions for physiotherapy services to patients for whom ankle foot orthoses (AFO) have not been suitable. This will include: assessment by physiotherapists trained to provide FES and AFO as part of the complete physiotherapy service offered; early assessment of benefit; ongoing easily accessible patient review; and annual audit results communicated to commissioners. | 2013
NHS Norfolk and Waveney | FES for foot drop in stroke and multiple sclerosis is not routinely funded | 2014

Table two: NHS local decisions on FES for drop foot.
Cost analysis

Costs include VAT at 20% unless otherwise indicated.

There are a number of different FES systems available. These have been described in detail by the NHS Purchasing and Supplies Agency in a report published by their Centre for Evidence-based Purchasing team in 2010. Based on a five-year-in-use period, annual costs range from about £283 to £1390. There are no fully published, more up to date cost effectiveness analyses. As well as the directly chargeable patient equipment, some of the devices incur significant investment costs (such as clinic hardware and clinician training), which are not included in this review as these are expected to fall on service providers.27

Only one type of intra-muscular FES system is known to be in use in the UK. Costs were estimated at £6,612 for assessment, surgery and hardware in 2010, with annual follow up costs of £351. Total costs over five years were therefore £8,016, with an annual cost over five years of about £1600. This service is provided in limited locations so there may be significant additional transport and hotel costs incurred.27

As well as hardware costs, there will be costs incurred for clinical appointments. The Northumberland, Tyne and Wear trust FES service describes approximately seven clinic sessions or appointments in the first year with annual reviews for patients with a successful outcome, though they do not provide an estimated cost per appointment.28 Services for rehabilitation of stroke, brain injuries, spinal cord injuries, and other neurological disorders are “unbundled” from core Healthcare Resource Groups in the National Tariff 2014/2015 and costs should be negotiated locally.29 The Centre for Evidence-based purchasing estimated a value of £140 per appointment in their 2010 analysis.27 Thus the total cost of an estimated ten appointments over five years (7 appointments in year one plus 4 annual appointments) would be roughly £1,540, though costs may have changed significantly since the CEP report. It is not clear whether this number of visits is greater or less than that which patients might experience in the absence of FES.30

A rough estimate of the total cost of skin-surface FES over five years is therefore estimated at about £3680.

A recent business plan produced by Northumberland, Tyne and Wear NHS foundation trust suggested that costs for the most popular devices range from £670 to £1750, with an approximate ongoing cost of £150 per year for sundries. Manufacturers were approached to confirm these costs, though only the manufacturers of the WalkAide responded.28

The same plan noted that the number of patients meeting the criteria for FES was small, with 17 funding requests in the 2013-2014 financial year from the North East region.
Whilst there have been several cost effectiveness analyses presented at conferences, there are no fully published, independent economic assessments in the medical literature. No cost effectiveness studies assess the costs of FES as a subsequent treatment to AFO, in line with their place in therapy according to UK guidance.
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.\(^3\) There are advantages and disadvantages of each treatment modality which will vary in relative importance from patient to patient.

- FES services are available from a limited number of centres. Additional travel and accommodation costs may be required for treatment. Skin surface FES is non-invasive, but implantable FES will require patients to undergo minimally invasive surgery under general anaesthesia at a remote treatment centre.

- There is a large volume of published evidence for FES. Generalisation relating to the available clinical evidence is limited 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 favouring FES and others demonstrating little or no difference, or even negative effects, compared to control groups.

- The comparator for FES is of crucial importance. Much of the evidence relies on comparison with physiotherapy alone, whereas treatment guidelines often place FES as an alternative or subsequent treatment to AFO. The most recent trial comparing FES to AFO found no significant difference between the two. There is no evidence which specifically assesses the efficacy of FES in patients who have failed AFO use. The evidence base for FES is constantly being added to. Studies of the highest methodological quality tend to demonstrate the least benefit for FES.

- FES is associated with modest overall costs, requiring relative large up-front hardware costs, some on-going hardware costs, and a significant number of clinic visits, especially in the first year. It is not clear what the cost effectiveness of FES compared to AFO is. The cost for skin surface FES is roughly estimated at upwards of £3680 over five years, though this estimate is based on outdated figures.

- There has been some press attention regarding FES, particularly focused around it use by a prominent celebrity and local negative decisions.\(^31\)

- A number of other commissioning, professional, and technology appraisal organisations have issued recommendations on the use of FES for drop foot. These vary from negative to positive, or positive with restrictions.
These data are confidential to the NHS and commercially sensitive, and should not be disclosed to third parties outside of NTAG.

**Author’s declaration:** The author has no relevant interests to declare.
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