

Priorities Forum Statement

Number	59
Subject	Use of Functional Electrical Stimulation
Date of decision	August 2015
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GUIDANCE

Recommendation

Functional Electrical Stimulation (FES) for neurological conditions will not be routinely funded due to a lack of evidence of clinical and cost effectiveness.

New funding for FES will only be considered on a case by case basis, for drop foot and only in exceptional circumstances. The requesting clinician will be required to provide significant evidence that:

- There is an unusual or unique factor about the patient's clinical circumstances and as a result the patient is likely to gain significantly more benefit from FES than standard treatment and more than might generally be expected for foot drop patients.
- There should have been a medium to long term (minimum 3 months) trial with FES and evidence of marked clinical benefit (e.g. reduction in falls) that cannot or has not been achieved with other treatments such as ankle foot orthosis
- Patient is able to manage the use of and is compliant with prescribed treatment
- The clinician will undertake 6 monthly reviews to ensure FES remains the optimum treatment.

For patients already being treated with FES, who require on-going funding for the maintenance and support of equipment, prior approval will be required. The patient will be

- Consistently using FES
- Have objectively demonstrated (using validated assessment) that the use of FES is still clinically appropriate such as a sustained improvement in gait e.g. improved walking ability and for achieving key functional outcomes ; and that this cannot be attained using alternatives such as ankle foot orthoses.

The use of FES for the purposes of assessment or in therapy is not usually funded.

The use of FES cycle is also not usually funded.

Current practice/relevant comparators

Treatment options include physiotherapy and/or an ankle-foot orthosis to align the lower leg and control the motion of the ankle and foot, providing stability and improving gait. Medical and

pharmaceutical treatments can also be considered. Surgery (usually reserved for refractory cases) includes selective tendon release of muscles.

Natural history of the disease/ prognosis, survival

FES has been proposed for a number of neurological disorders in upper limbs and lower limbs, as set out below. These are, in general, long-term conditions with a disease course specific to the underlying condition. Research focuses on use with Stroke and Multiple Sclerosis.

Explanation of drug/technology

FES is a means of producing contractions in muscles, paralysed due to central nervous system lesions, by means of electrical stimulation. Applications are found in stroke, spinal cord injury, head injury, cerebral palsy, multiple sclerosis and other neurological conditions, whether congenital or acquired. The electrical stimulation is applied either by skin surface electrodes or by implanted electrodes.

Motor dysfunction in the upper and/or lower limbs is a common complication of a number of neurological disorders. In the upper limb, it can lead to painful subluxation of the shoulder and problems with shoulder, elbow, wrist and hand movement. In the lower limb, drop-foot resulting from peroneal nerve damage causes abnormal gait, reduced walking speed and increased risk of falls.

The most common neurological condition which results in foot drop is stroke. It is also seen in incomplete spinal cord injury and brain injury. Conditions such as Multiple Sclerosis and Parkinson's disease may also result in foot drop.

Conventional approaches to treating foot drop include physiotherapy, orthotic devices such as ankle foot orthosis (AFO), 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 AFO.

Functional Electrical Stimulation (FES) has been developed as an alternative or adjunct to the above treatments. It uses a stimulator to deliver electrical pulses to the common peroneal nerve (which must be intact), thus activating the ankle dorsiflexors during the swing phase of gait and mimicking normal voluntary gait movement. In the UK, individuals are typically offered the use of a FES device with skin surface electrodes, after which they are assessed to determine if there has been any improvement in their gait.

It is important to note that not all patients with foot drop will require FES, and many may well have their condition adequately managed by more conventional physiotherapy or medical care.

Epidemiology

There is no good estimate of the numbers affected or who will require the use of FES.

Evidence of clinical and cost effectiveness

There is a large pool of published literature relating to skin-surface FES. An East Midlands Specialist Commissioning review 2011 that assessed the available literature was equivocal with regards its clinical effectiveness.

Many of the studies conducted were of poor quality by FES providers. Generalisation relating to the clinical effectiveness evidence is difficult due to inter-study heterogeneity. The methodological quality of the evidence is poor and bias cannot be ruled out. The small number of randomised controlled studies demonstrated variable results, with some in favour of FES and others demonstrating little or no difference or negative effects compared with control groups. Studies of the highest methodological quality (including two Cochrane reviews) tend to demonstrate the least benefit for FES.

The comparator for FES is of crucial importance. Much of the evidence relies upon a comparison with physiotherapy alone, whereas treatment guidelines that do recommend FES will often place it as an alternative or subsequent treatment to Ankle Foot Orthosis (AFO). In fact, of the small number of studies that do compare FES against AFO, the evidence either shows no significant difference in outcomes between the two or is at best equivocal. One study has demonstrated a clear patient preference for FES over AFO, however, patient preference alone cannot be justification for funding a new intervention in the absence of robust evidence of improved clinical outcomes.

Evidence of Cost Effectiveness

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. In addition, available cost effectiveness analyses (although yield cost per QALY which meets conventional limits on cost-effectiveness for treatments within the NHS) rely upon a number of modelling parameters which may be considered biased in favour of FES, for instance, an estimate of efficacy of 74% seems generous in light of the results of published randomised controlled trials.⁹ Further, no sensitivity analysis was performed with respect to the published economic appraisal. In addition, the cost analysis considers 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.

Other NHS Policies

A comparison of the clinical policies of various NHS commissioning organisations with respect to FES shows significant variability across organisations. There is no consistent national policy with respect to FES one way or the other. This, therefore, suggests the lack of strong evidence for or against FES.

NICE IPG 278 states that *“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.*

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

1.3 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 NICE Clinical Guidelines on the management of Multiple Sclerosis refer to FES only in the context of the management of urinary incontinence.

Intercollegiate Stroke Working Party. National Clinical Guideline for Stroke, 4th edition London: Royal College of Physicians 2012. ISBN 978-1-86016-492-7 recommends

“6.13.1 Recommendations

A Functional electrical stimulation can be used for drop foot of central neurological origin provided normal arrangements are in place for clinical governance, consent and audit.

B Therapeutic electrical stimulation for treatment of the upper and lower limbs following stroke should only be used in the context of a clinical trial

6.19.2.1 Recommendations

Any patient who has developed, or is developing, shoulder subluxation should be considered for functional electrical stimulation of the supraspinatus and deltoid muscles.”

References

1. NICE IPG 278: Functional electrical stimulation for drop foot of central neurological origin
2. NICE Clinical Guidelines on the management of Multiple Sclerosis
3. National Clinical Guideline for Stroke (4th Edition) Royal College of Physician
4. East Midlands Specialist Commissioning Functional Electrical Stimulation Review 2011
http://www.leicestercity.nhs.uk/Library/EMSCGPolicyFESEUpdated3March11_3_V1D3.pdf
5. Cambridgeshire and Peterborough CCG Policy (2013)
http://www.cambsphn.nhs.uk/Libraries/Lower_Clinical_Priority_Policies/V1_FES_DEC13_1.sflb.ashx

Human Rights and Equalities Legislation has been considered in the development of this guidance