

PARTIALLY EXCLUDED POLICY – PE101
THE INITIAL AND CONTINUED USE OF FUNCTIONAL ELECTRICAL STIMULATION FOR DROP
FOOT OF CENTRAL NEUROLOGICAL ORIGIN

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1. Policy summary

1.1 Functional electrical stimulation (FES) for the treatment of drop foot in patients with central neurological conditions is considered a low priority procedure and should not be commissioned. This applies to both new patients to FES and those requiring ongoing treatment beyond the life-expectancy of the device. This policy covers both adult and paediatric patients.

2. Background to the condition and treatment

2.1 Drop foot is defined as the inability to activate the ankle dorsiflexors and lift the foot from the ground during the swing phase of gait. It can be caused by lower or upper motor neuron lesions. It results in weakness or lack of voluntary control of the ankle and foot dorsiflexors, causing the toes to drag and the foot to drop during the normal swing phase of gait. Drop foot can increase the risk of falls as well as the effort required to walk.

2.2 The most common neurological condition which results in foot drop is stroke. Drop foot occurs in central neurological conditions, such as Multiple Sclerosis, Stroke, Hereditary Spastic Paraparesis, Parkinson's, Cerebral Palsy, Brain injury and Spinal Cord Injury.

2.3 Conventional approaches to treating foot drop include physiotherapy, orthotic devices such as ankle foot orthosis (AFO), electrical stimulation of the affected nerves, medication and surgery, such as ankle fusion or a tendon transfer procedure. These options can be used alone or in combination with one another. First-line treatment is usually physiotherapy or the use of an AFO.

2.4 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.¹ 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.

2.5 The prevalence of foot drop in Suffolk is difficult to assess. Synthetic estimates derived from a study of Scottish general practices suggest that, were the same rate to apply to Suffolk, there would be 80 – 100 people consulting primary care for foot drop each year.² 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.

3. Rationale behind policy decision

3.1 Evidence of clinical effectiveness

- a) NICE have recently published a Medtech innovation briefing in March 2016: ODFS Pace and Pace XL Functional electrical stimulation devices for treating foot drop.³ The briefing looked at 5 papers from 3 Randomised control trials and one case series. A single RCT reported decreased falls and an improvement in activities of daily living. Barrett *et al* showed an improvement in walking speed and walking distance in the exercise group as opposed to the FES group.⁴ The same RCT published in a different paper that FES improved the quality of life.⁵
- b) There is a large pool of published literature relating to skin-surface FES. Two 2012 reviews (from the Midlands and East specialized commissioning group and the North-east treatment advisory group) that assessed the available literature were equivocal with regards its clinical effectiveness^{6,7} Many of the studies conducted were of poor quality. 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 FES⁸ and others demonstrating little or no difference or negative effects compared with control groups.⁹ Studies of the highest methodological quality (including two Cochrane reviews) tend to demonstrate the least benefit for FES.^{Error!}
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- c) 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 AFO. In fact, of the small number of studies that does 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.
- d) An updated literature search since the previous policy draft revealed a single systematic review that compared FES to AFO which showed patient preference for FES and a decreased physiological cost index but no change in functional mobility and gait speed.¹⁰ Further systematic review were of poorer quality as they did not compare FES to AFO or did not look at good quality functional outcomes.^{11,12} Four RCTs (5 papers) which compared AFO to FES found overall equivalent gains with no significant difference to gait and mobility.¹²⁻¹⁷ One study did show a patient preference for FES.¹⁶ The data on long term use of FES is very limited with the majority of trials evaluating treatment over 6-30 weeks¹⁰ and in a long-term follow-up RCT, Bethoux *et al* evaluated effectiveness compared to an AFO over 12 months.¹³ There is little or no data on the continued use of the device after for prolonged treatments.

3.2 Evidence of cost effectiveness

- a) 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.¹⁸ 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.

- b) An additional publication showed that the cost per QALY as of 2012 costs £15,406 however this paper looked retrospectively at patients treated with FES and did not compare costs of alternative treatment options.¹⁹

3.3 Other NHS policies

- a) 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.
- b) In the absence of robust evidence from high quality research and considering the NHS policies elsewhere, FES for foot drop in neurological conditions is considered as low priority procedure and not routinely funded. In the case of exceptional circumstances, a clinician may submit an individual funding request to the panel for consideration.
- c) The CCG operates a panel of GPs, managers and public health experts to consider requests from doctors on a case by case basis. As part of the policy we have produced guidance to help the panel consider these requests. This guidance reflects any national guidance and the current literary evidence to ensure that the patient with a clinical need (ability to benefit from the procedure) is considered.

4. References

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