**What is an evidence note**

Evidence notes are rapid reviews of published secondary clinical and cost-effectiveness evidence on health technologies under consideration by decision makers within NHSScotland. They are intended to provide information quickly to support time-sensitive decisions and are produced in an approximately 3 month period. Evidence notes are not comprehensive systematic reviews. They are based on the best evidence that Healthcare Improvement Scotland could identify and retrieve within the time available. The reports are subject to peer review. Evidence notes do not make recommendations for NHSScotland.

**Literature search**

A systematic search of secondary literature sources was carried out between the 19th and 25th May 2011. Key online resources were searched for policy documents, reviews, evidence based summaries and economic studies.

As very little evidence was located in the secondary literature, the primary literature was searched between the 22nd and 24th August 2011 using the following databases:

- Medline (OVID SP)
- Medline in process (OVID SP)
- Central (Wiley)
- Cinahl (EbscoHost)
- Embase (OVID SP)
- Web of Knowledge

A full list of resources searched and primary literature search strategies are available on request.

**Key points**

- **Dropped foot** is the inability to lift the foot from the ground during the swing phase of gait. This condition is present in around 20% of patients surviving a stroke. It is also associated with multiple sclerosis (MS) and other neurological conditions.

- A body of evidence, based largely on uncontrolled observational studies in patients with stroke with dropped foot and patients with multiple sclerosis with dropped foot, using heterogeneous outcome measures, indicates that functional electrical stimulation (FES) (mainly using surface electrodes) is associated with improved walking speed and reduced walking effort.

- There are preliminary findings of a therapeutic effect of FES use in patients in the chronic phase of stroke rehabilitation. Three large randomised controlled trials are underway in chronic stroke patients which may provide data on comparison with the ankle foot orthosis.

- There are few safety concerns around the use of surface-applied FES and patient acceptability appears to be high, however the use of implanted electrodes may be associated with more serious adverse events.

- A recent UK economic model showed FES in addition to usual physiotherapy care to be cost effective compared with usual physiotherapy care alone in patients who have suffered a stroke (conservative base case cost per QALY of approximately £19,239). No cost effectiveness evidence was identified for other patient groups.
Introduction

This evidence note summarises the published evidence on the clinical and cost effectiveness of functional electrical stimulation for the treatment of dropped foot in patients with neurological conditions such as stroke or multiple sclerosis. Both orthotic and therapeutic outcomes are considered.

Health technology description

Dropped foot is defined as the inability to activate the ankle dorsiflexors, and lift the foot from the ground during the swing phase of gait. Other terms used to describe this condition are ‘floppy foot drop’ and ‘foot drop’. This condition results from a neurological deficit.

FES 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. Electrical stimulation can be delivered through the skin surface (surface-applied) or via surgically implanted electrodes. Commonly, an insole containing a pressure-sensitive foot switch is placed inside the shoe under the foot of the affected leg. The most commonly studied FES devices are the Odstock Dropped Foot Stimulator (ODFS) (Odstock Medical Ltd, Salisbury, Wiltshire, UK), NESS L300 (NESS) (Bioness Inc, Valencia, CA), and WalkAide (WA) (Innovative Neurotronics, Austin TX).

The most appropriate comparator device is the ankle foot orthosis (AFO).

According to the literature produced by the manufacturer of the ODFS device, potential users of FES devices are assessed for their suitability for treatment by appropriately trained professionals, such as physiotherapists, orthotists or biomedical engineers. Suitability is based on an assessment of range of movement, muscle tone, skin condition, impairments of gait, functional ability and cognition. In the United Kingdom (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.

Epidemiology

Dropped foot can result from a number of neurological conditions, the most common of these is stroke. It is also seen in incomplete spinal cord injury and brain injury. Conditions such as MS, Parkinson’s disease, cerebral palsy or hereditary spastic paraparesis may also result in dropped foot.

Some orthopaedic conditions in which muscles are disused or weak may warrant the use of FES for dropped foot correction as long as the peroneal nerve is intact and if the condition does not stem from problems in the lumbar region of the back.

Due to the range of neurological disorders that lead to upper neurone lesions, and variability in the symptoms, the prevalence and incidence of dropped foot is difficult to estimate. For stroke, a conservative estimate is that 20% of survivors have dropped foot.

In 2009-2010, an estimated 670 (95% confidence interval (CI) 447 to 893) patients in Scotland consulted a general practitioner or practice nurse regarding dropped foot, corresponding to a rate per 1,000 population of 0.12 (95% CI 0.08 to 0.16). These data are based on 60 practice team information practices that submitted complete general practice and practice nurse data to the Information Statistics Division (ISD) (D Scott, Information Analyst, ISD. Personal communication, 13 Jul 2011).

Safety and contraindications

Skin irritation is reported as an adverse effect of surface-applied FES. A 6-month prospective audit of 585 individual patients estimated the prevalence of skin irritation at 1 to 1.5%.

National Institute for Health and Clinical Excellence (NICE) specialist advisors outlined anecdotal adverse events including an increase in seizure incidence among patients with epilepsy, autonomic dysreflexia in patients with spinal cord injuries, problems with computed tomography or magnetic resonance imaging scanning with implanted electrodes, increases in spasticity or spasms, infection when using implanted systems, and skin intolerance. Theoretical risks included muscle fibrillation,
problems caused by faulty equipment, or problems when treating pregnant women or patients who have a pacemaker.

Other considerations which would exclude individuals from using FES include lower motor neurone conditions, uncontrolled epilepsy, exposed orthopaedic metal work such as external fixators around the lower leg, nerve damage resulting from a slipped vertebrae disc, or nerve damage sustained through a traumatic incident or knee or hip surgery. Diabetes can also be a contraindication for implanted FES due to the risk of infection (Dr P Taylor, Consultant Biomedical Engineer, Salisbury District Hospital. Personal communication, 22 Aug 2008).

Clinical effectiveness

The most commonly used outcomes in studies of FES for treatment of dropped foot are those associated with parameters of walking performance including speed, stride length, cadence and duration of activity. These are often combined over different walking surfaces and distances and into indices of gait performance. The effort required for walking is often examined using the physiological cost index (PCI). This gait efficiency measure is based on heart rate monitoring and expressed in heart beats per metre travelled as a proxy for oxygen consumption. Frequency of falls, gait symmetry and quality of life are also reported measures.

Some studies employ functional measures to assess the effect of any improved mobility on activities of daily living. In a small questionnaire study (n=41), there were benefits of FES on perceived quality of life in patients with stroke and with MS which were not directly correlated with effects on gait. This indicates the complexity of selecting appropriate outcomes for assessment of such devices. Orthotic effects, where outcomes are measured with the device operating, are distinct from therapeutic effects where outcomes are assessed without the device in operation to measure any ‘carry over’ effect following a period of use of FES.

Stroke

A well-conducted systematic review of surface-applied FES for treatment of dropped foot after stroke included 30 studies published from January 1990 until June 2008. There were several different study types and durations and a wide range of comparators. Patient groups varied with respect to time since stroke onset, although most patients were in the chronic stage of stroke recovery as opposed to being in the acute or sub-acute phase. Over 30 outcome measures were identified and studies were generally short term (up to 3 months). The review considered both orthotic and therapeutic outcomes. The quality of studies was poor with most having moderate or high risk of bias.

Three studies were identified comparing FES to conventional physiotherapy interventions of the same duration, with the comparison therapy either applied as a baseline intervention or, in one study, delivered to a separate control group. In the small study (n=19) which had a separate control group, FES was associated with therapeutic gains in walking speed (36.36% increase, compared with 1.32% decrease for the control group), cadence and time, following training with the device of up to 60 minutes twice a day for 3 months, when compared with a group undertaking a home exercise programme (Alon and Ring, 2003).

Four studies examined the use of FES as an adjunct to physiotherapy. Although benefits to walking speed were observed, there was uncertainty as to whether this was due to the addition of FES or due to greater rehabilitation intensity.

A small crossover trial in 14 stroke patients who had previously used an AFO compared the orthotic use of FES with the AFO. There was no significant difference in outcomes on the modified Emory Functional Ambulation Profile (mEFAP) between FES and AFO, but 12 of the 14 participants preferred FES. The authors noted the lack of an extended training period with FES which may have introduced bias against the device in this patient group (Sheffler, 2006).

Nine studies used before-and-after methodology. The majority were very small, typically with fewer than 50 participants. The largest study (n=151, of which 111 had had a stroke) found statistically significant orthotic
improvements in walking speed (27% increase) and PCI (31% decrease) with some short-term carry over (therapeutic effect) (Taylor, 1999).

Two of the studies incorporated into the review compared surface-applied FES with implanted devices. Both were considered to be at high risk of bias so no conclusions about the comparative efficacy of implanted versus skin surface application could be reached. Overall, the review concluded that surface-applied FES is associated with a positive orthotic effect, particularly on gait speed and PCI, but that there is less evidence to support a therapeutic effect.

A number of studies published subsequent to the systematic review were identified. A few of these, which provided useful additional findings covering long-term outcomes, combined orthotic and therapeutic effects on walking speed, postural outcomes and the use of implantable devices. These are outlined here.

An uncontrolled study comparing long-term FES use in different patient groups with progressive and non-progressive disorders reported combined orthotic and therapeutic benefits to figure-of-eight walking speed (37.8% increase) and PCI (18.2% decrease) in patients with non-progressive disorders (n=41, of which 26 had had a stroke) at 11 months follow up. This study found that the benefits on 10 metre walk speed underestimated the increases on the longer figure-of-eight test11. This is in agreement with a small study which found 23.8% increase in therapeutic gait velocity after 1 year of FES use in 16 patients with chronic stroke12.

An overview of studies examining effect of FES on walking speed found that, across studies, the combined orthotic and therapeutic benefit ranged from 18% to 34% in patients with stroke11.

One small study (n=15) examined the use of FES compared to AFO in a single patient group and found that gait stability and symmetry (average stride time, swing time variability, non-paretic leg and swing asymmetry) were better when FES was used at 8 weeks. There was no difference in walking speed between the two orthoses13.

An RCT of FES delivered to stroke patients (n=29) via surgically implanted electrodes compared with conventional therapy reported orthotic benefits on walking speed, with a 23% improvement in the FES group compared to 3% improvement in controls on the 6-minute walking test, following 26 weeks of use14. No therapeutic benefit was measured in this study time frame15.

Multiple sclerosis

Three studies of FES, specifically in patients with MS, were identified.

An RCT (n=44) compared FES over an 18-week period with the same duration of home exercise and found that whilst FES showed no benefit on this primary outcome in patients with secondary progressive MS, the exercise programme was effective at improving unassisted walking speed (therapeutic effect) over 10 metres16. A client-centred outcome measure was also used17. This incorporated factors identified by patients and related to their individual activities, such as fear of tripping, being able to walk a distance and negotiating steps and kerbs. After 18 weeks, there were greater improvements in performance and satisfaction in the FES group than in the exercise group. There were fewer falls recorded in the FES group, although interpretation of this is not clear due to activity levels not being recorded17.

Measurements in a small paired cohort study (n=24) found that the physiological cost of walking was higher in patients with MS compared with healthy controls and that this was reduced through use of FES. The patients in this study used walking supports and were established users of the FES device. FES also improved orthotic walking speed18.

A small pilot study found no benefit for FES on a timed 25 foot walk in a convenience sample of patients mainly with the relapsing remitting form of MS, although 10 of the 11 participants preferred walking with the stimulator than without19.

Other patient groups

A longitudinal study comparing FES use in patients with dropped foot associated with
non-progressive disorders (including stroke, spinal cord injury, surgical complications, head injury and cerebral palsy) and patients with progressive disorders (primarily MS and one case of familial spastic paraparesis) found that both groups had orthotic benefit up to 11 months but the therapeutic effect increased throughout the 11 month follow-up period in non-progressive disorders but only for 3 months in progressive disorders11.

Patient preference

Acceptability of FES to patients appears to be high, with low drop-out rates in most trials. A recent study noted that patients used the stimulator on 80% of the days documented and suggested that high usage may be due to the reduced effort of walking11.

A qualitative study exploring patient preferences related to choice of AFO or FES found that there was a preference for FES as the primary tool to manage dropped foot due to benefits of faster walking, less abnormal gait appearance and fitting of footwear, although this was commonly supplemented by AFO in specific situations where reliability, safety (around air travel or water) and ease of use were paramount20. A systematic review identified 11 papers examining patient perspectives on FES use. The most common positive response for FES treatment was the decreased effort associated with its use and the most common negative response was around problems in setting up the device6. One of the themes emerging from an evaluation of an FES service in Scotland was that application of the device was easy to learn with the support provided by staff21.

National guidance

The Scottish Intercollegiate Guidelines Network (SIGN) guideline for the management of stroke recommends considering FES for dropped foot ‘where the aim of treatment is the immediate improvement of walking speed and/or efficiency’22.

Current NICE guidance concludes that the evidence on safety and efficacy, in terms of improving gait, appears adequate to support the use of FES for dropped foot of central neurological origin8. They recommend a multidisciplinary rehabilitation team is in place to select patients for implantable FES, and highlight the need for further research focusing on patient-reported outcomes and the use of varied ethnic and socioeconomic samples. They note that interpretation of the evidence is difficult given the number of different FES devices and the differing methods of use (eg implanted versus surface-applied FES).

The Royal College of Physicians national clinical guideline for stroke also recommends the use of FES in patients who have not seen satisfactory control of dropped foot with an AFO and demonstrate gait improvement when using FES23.

Cost effectiveness

An economic report by the Centre for Evidence-based Purchasing investigated the effectiveness and cost effectiveness of FES for dropped foot due to central nervous system lesions24. The authors identified only one cost-utility study. This was from 199625 and reported a 0.065 quality-adjusted life year (QALY) gain with FES compared to 0.023 with physiotherapy, at a cost per QALY of £10,037 with 5 years of continuous use.

A new cost-utility model was developed comparing FES to usual physiotherapy care without the use of FES in the rehabilitation of patients with dropped foot following stroke. Within the model, FES is an additional therapy, as rehabilitation with usual care continues. Since usual physiotherapy care applies to all patients, the costs and utilities associated with physiotherapy were not included in the model. An outpatient clinic-based setting was assumed. A National Health Service (NHS) perspective was adopted and the model used both 1 and 5-year time horizons. The stochastic model included a base-case analysis and a Monte Carlo simulation varying each of the inputs. Benefits were expressed as QALYs and quality of life (QoL) gains assessed using the Health Utility Index 3 (HUI3). Clinical effectiveness literature informed assumptions regarding QoL gains around increased walking speed and functional independent walking. An increase in walking speed to >0.8 m/s, which equates to functional independent walking, was assumed to be
equivalent to an increase in QoL of one grade on the HUI3 ambulation attribute. An increase in walking speed to >0.58 m/s, which equates to an ability to perform moderate community activity, was assumed to be equivalent to an increase in QoL of one half of a grade on the HUI3 ambulation attribute. The model then calculated the increase in QoL based on the weighted average gain in each functional group observed in four studies. Decrements to utility were included for minor and major skin reactions.

Costs included assessment appointments, and ongoing clinic charges that incorporated the device cost. Five clinic visits in the first year and either one per year (50% of patients) or two per year (for 50% of patients) for each of the following years was assumed and 2009 costs were used.

Discounting was not applied because the orthotic effects of FES only occur while a patient is using the device, thus costs and benefits are accrued within the same timeframe. Within the clinical effectiveness section of this evidence note, it is reported that FES may be associated with therapeutic gains. Current accepted practice in economic evaluation is to apply an annual discount rate of 3.5% to both costs and health effects to discount these to a present value. The model is extremely conservative in incorporating the effects of minor and major skin reactions.

The results derived from the model show a conservative base-case cost per QALY of approximately £11,239, with a 66% likelihood of FES being cost effective at £30,000 per QALY. The cost per QALY in the first year is approximately £52,337 and in each following year £10,964. The higher costs at the onset of treatment are due to more clinic visits.

Sensitivity analysis showed that the cost effectiveness of FES is sensitive to the time horizon adopted, clinic costs and utility gains.

The authors commented that the model attempts to reflect costs in a typical NHS service. However, the model will be highly sensitive to the use of different FES devices, service models and health conditions. The model is suitable for use with different client groups but it should be adjusted for the improvement in walking speed for any given group.

The Centre for Evidence-based Purchasing estimate that device costs range from £1,415 to £7,000 for a 5-year period of use. This does not include investment costs such as clinic hardware and clinician training.

**Ongoing clinical trials**

Three ongoing trials were identified.


**Conclusion**

There is evidence, mainly from uncontrolled observational studies, to support the use of surface-applied FES for the orthotic improvement of walking speed and reduction in walking effort in patients with dropped foot. Patient acceptability of their treatment appears to be high. There are few major safety concerns. Publication of ongoing large RCTs will provide more robust evidence for practice, particularly in the comparison of FES with AFO.

**Equality and diversity**

Healthcare Improvement Scotland is committed to equality and diversity in respect of the nine equality groups defined by age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion, sex, and sexual orientation.

The evidence note process has been assessed and no adverse impact across any of these groups is expected. The completed equality and diversity checklist is available on www.healthcareimprovementscotland.org
About evidence notes

For further information about the evidence note process, see www.healthcareimprovementscotland.org

To propose a topic for an evidence note, email evidencenotes.hcis@nhs.net

References can be accessed via the internet (where addresses are provided), via the NHS Knowledge Network http://www.knowledge.scot.nhs.uk or by contacting your local library and information service.

Acknowledgements

Healthcare Improvement Scotland would like to acknowledge the helpful contribution of the following, who gave advice on the content of this evidence note:

- Linda Renfrew, Consultant Physiotherapist in MS, NHS Ayrshire & Arran
- Lisa Salisbury, Research Fellow, Centre for Integrated Healthcare Research, University of Edinburgh
- Jane Sheils, Specialist Physiotherapist, NHS Lothian
- Mark Smith, Consultant Physiotherapist, NHS Lothian
- Paul Taylor, Consultant Clinical Engineer, The National Clinical FES Centre, Salisbury NHS Foundation Trust
- Katie Wilkie, Specialist Physiotherapist, NHS Lothian

Healthcare Improvement Scotland development team

- Lorna Thompson, Author/Health Services Researcher
- Jenny Harbour, Information Scientist
- Emma Riches, Medical Writer
- Doreen Pedlar, Project Co-ordinator
- Marina Tudor, Team Support Administrator

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ISBN 1-84404-940-X

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References continued


References continued


