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Executive summary

The evidence for the effectiveness of Functional Electrical Stimulation (FES) for foot drop in Stroke and Multiple Sclerosis is limited by significant variations in the way the devices are used, patient characteristics and the outcomes measured in the trials. **FES should not therefore, be routinely funded.**

If a clinician considers that there are exceptional circumstances for a patient, then an application to the Individual Funding Requests Panel should be made.

Contents

Functional Electrical Stimulation (FES) for foot drop in Stroke and Multiple Sclerosis

1.0 Introduction

Functional electrical stimulation (FES) applies small electrical impulses directly to damaged nerves, via cutaneous electrodes adherent to the skin. It has been used to improve mobility and quality of life in service users experiencing the sequelae of upper motor neuron disease, such as stroke and multiple sclerosis (MS).

“Dropped foot” is a common consequence of the damage caused to nerve pathways following stroke or MS and results from weakness of the dorsiflexor muscles (the muscles that lift the foot at the ankle) and/or spasticity, or rigidity, of the plantarflexors (the muscles that point the foot down, or enable the foot to lift off from the ground when walking). This can lead to abnormal gait, reduced walking speed, and higher risk of falls[2] as well as influencing confidence, independence and social inclusion.

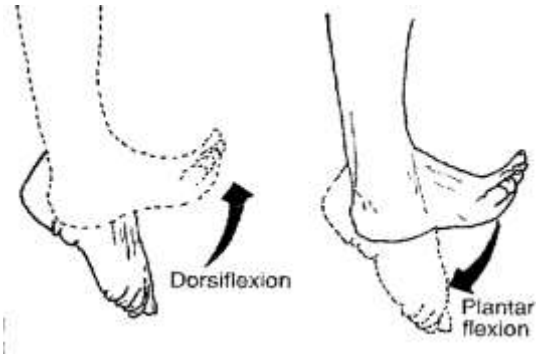

Figure 1: diagram showing dorsi and plantar flexion

Foot drop can result from a number of neurological conditions, including stroke and MS. FES stimulates the peroneal nerve and activates the dorsiflexor muscles during walking. Potentially, FES can have both an orthotic effect, by improving gait whilst in use as well as a

therapeutic effect by providing muscle re-training; a benefit that could persist after cessation of stimulation.

1.1 Background

This report has been produced in response to a request from the Clinical Policy Development Group, as the Individual Funding Request Panel for Norfolk & Waveney has received more than three funding requests for FES.

1.2 Objective

The aim of this report is to review and summarise the evidence, to inform the development of a policy for the provision of FES devices for patients experiencing foot drop following a stroke or a diagnosis of multiple sclerosis, within Norfolk.

1.3 Methods

A literature search of the OVID MEDLINE database, PubMed and google scholar was carried out in November 2013. In addition, national guidelines and commissioning policies from elsewhere in the UK were reviewed to inform the development of this paper and ensure consideration of appropriate current studies.

1.4 What is foot drop?

The International Classification of function, disability and health[1] (WHO 2001) describes foot drop as an 'impairment of body structure that may markedly influence the activities and participation of the affected individual'. 4-digit International Disease Classification Version 10 (ICD-10) code M21.3 represents acquired wrist or foot drop.

The term 'foot drop' denotes a compensatory gait, caused by damage to the common peroneal nerve or paralysis of the muscles in the anterior portion of the lower leg, resulting in

[1] www.who.int

weakness or lack of voluntary control in the ankle and foot dorsiflexors (commonly tibialis anterior). In moderate cases, the front foot drops to the floor after heel strike[5] but in severe cases, toe strike may precede heel strike, causing the toe to 'catch' on the floor during leg swing, thereby increasing the risk of falls as well as increasing the effort required to walk.

These gait abnormalities may mean the toes drag along the floor, forcing the individual to lift their leg higher when walking, which can result in chronic hip or back pain, muscle contracture,[2] loss of proprioception and poor balance.[3] In addition, individuals may experience difficulties finding comfortable, appropriate footwear.

2.0 Epidemiology

The exact prevalence of foot drop within the East of England and, indeed, the UK, is challenging to report because figures are often not formally recorded. Foot drop is caused by a variety of neurological conditions and often patients are not receiving on-going treatment, so secondary symptoms, such as foot drop, go unreported.[4]

Foot drop is, however, recognised as one of the common gait impairments associated with hemiplegia (unilateral weakness or paralysis) with an estimated 20%[5] of all stroke survivors experiencing some degree of dropped foot. The Stroke Association estimates that over 300,000[6] people are living with moderate to severe disabilities as a result of stroke.

[2] Sackley C, Disler P, Turner-Stokes L, Wade D, Brittle N and Hoppitt T 'Rehabilitation interventions for foot drop in neuromuscular disease' *The Cochrane Collaboration* database syst rev 2009
[3] www.nationalmssociety.org
[4] Horsley W, East Midlands Specialised Commissioning Group Orthotic Functional Electrical Stimulation (FES) for 'drop foot' of neurological origin (March 2012)
[5] Wade D, Wood W, Heller A, et al Walking after stroke; Measurement and recovery over the first 3 months, *Scand J Rehabil Med* 1987; 19;25-30
[6] www.stroke.org.uk

There are around 110,000 new cases of stroke in England per annum (an incidence of 2 per 1,000).[7] Approximately one third results in death. Between 50-75% of the survivors have residual functional impairment. It is estimated that between 15 - 20% of these have a drop-foot[8] meaning there could be between 5,300 and 11,100 new patients per year across the UK, presenting with drop-foot post-stroke (and potentially eligible for FES). These estimates are not robust and efforts need to be made locally to record incidence.

It was not possible to ascertain from current literature, the prevalence of foot drop associated with MS. However, there are an estimated 126,669[9] multiple sclerosis sufferers in the UK, with numbers increasing each year. A commissioning paper from West Sussex has estimated there to be a ratio of 4:1 stroke to MS. This would create a total prevalent patient UK population of 29,000.[10]

It has also been challenging to ascertain local figures, due to complications with coding and data collection. Service review at one local acute trust (Norfolk and Norwich University Hospital) identified approximately 50 patients with foot drop as a consequence of stroke or MS, over a 5 year period and a local 2009/10 business case[11] suggested a total of 100 patients per year would be eligible for FES, across the East of England.

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[7] Department of Health, Policy and Guidance: Stroke; available online at http://www.dh.gov.uk/en/Policyandguidance/healthandsocialcaretopics/stoke/index.htm

[8] Burridge, J.H, 'Does the Drop-Foot Stimulator Improve Walking?'; Kottink et al, 'The Orthotic Effect of FES'.

[9] MacKenzie S, Morant S, Bloomfield G, MacDonald T and O'Riordan J 'Incidence and prevalence of multiple scleoris in the UK 1990-2010: a descriptive study in the general practice research database' *J Neirol Neurosur Psychiatry 2013;0:1-9*

[10] West Sussex PCT: 'Functional Electrical Stimulation (FES) of the Peroneal Nerve to Improve Gait in Patients with Drop-foot due to Stroke, Incomplete Spinal Cord Injury of Multiple Sclerosis'

[11] The Anglia Stroke & Heart Network: 'Document for discussion by the Commissioning & Guidelines Group. Functional Electrical stimulation for foot drop following stroke'

3.0 Treatment modalities for foot drop in stroke and MS

Foot drop is a common condition, with potentially profound effects on disability and quality of life, yet the literature offers little direction as to treatment options and the evidence base is sparse. Broadly, treatment options include the following:

- No intervention
- Physiotherapy
- Ankle foot orthosis (AFO)
- Botulinum toxin injections
- Surgery
- FES

3.1 No intervention

Choice of treatment modality should be the result of individual patient assessment and open discussion between the patient/patient representative and the clinical team. Patients should be allowed to make informed decisions about their on-going care and receive, where appropriate, written and verbal information about the options available to them.

In terms of FES, three systematic reviews[12,13,14] report that there is inconclusive evidence about the effectiveness of FES in the treatment for drop foot, either due to the heterogeneity of the literature or equivocal results. Barrett et al[15] showed in an RCT that the FES intervention groups had a slower walking speed, no difference in effort and no difference in distance covered compared to an exercise group at 18 weeks having adjusted for

[12] Mehrholz J, Kugler J, Pohl M. Locomotor training for walking after spinal cord injury. *Cochrane Database of Systematic Reviews* 2008, Issue 2. Art. No.: CD006676. DOI: 10.1002/14651858.CD006676.pub2.
[13] Pomeroy VM, King LM, Pollock A, Baily-Hallam A, Langhorne P. Electrostimulation for promoting recovery of movement or functional ability after stroke. *Cochrane Database of Systematic Reviews* 2006, Issue 2. Art. No.: CD003241. DOI: 0.1002/14651858.CD003241.pub2
[14] Hamzaid NA, Davis GM. Health and fitness benefits of functional electrical stimulation-evoked leg exercise for spinal cord-injured individuals: a position review *Topics in Spinal Cord Injury Rehabilitation*, 2009;14(4):88-121
[15] Barrett CL, Mann GE, Taylor PN, Strike P. A randomized trial to investigate the effects of functional electrical stimulation and therapeutic exercise on walking performance for people with multiple sclerosis. *Mult Scler.* 2009;15(4):493-504

differences in baseline measures. Daly et al 2006[16] report that in the two groups they randomised (neuromuscular stimulation implanted devices and exercise group) both groups subjectively reported gains in walking endurance and functional milestones. Functional milestones, such as 'prepared dinner', 'walked outside', were reported in 11 instances in the exercise group and 53 instances in the implanted device group. Milestones of greater motor complexity were demonstrated more frequently for implanted device group.

3.2 Physiotherapy

A systematic review of interventions to improve motor recovery after stroke[17] indicates that evidence is sparse, with small or poorly designed studies. However, the reviewers conclude that motor recovery has been significant following high intensity physiotherapy, biofeedback and repetitive task training.

NICE guidance on stroke rehabilitation [18] (CG162) states the importance of early physiotherapeutic input and timely orthotic support following stroke. As such most studies exploring the benefits of FES treat it as an adjunct to rehabilitative physical therapy; indeed, this is how it would be used in clinical practice.

3.3 Ankle foot orthoses (AFO)

An AFO is a brace device, usually made of plastic, worn on the lower part of the leg and foot, with the aim of supporting the foot by holding it in a dorsiflexed position, to aid walking. There are various styles; some fixed and some kinetic but usually externally strapped to the limb and worn inside the shoe.

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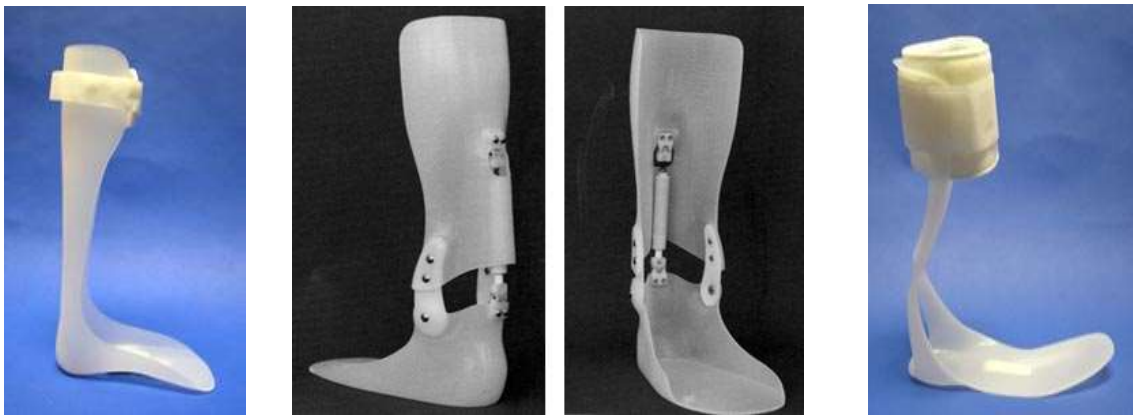
[16] Daly JJ, Roenigk K, Holcomb J et al. (2006) A randomized controlled trial of functional neuromuscular stimulation in chronic stroke subjects. Stroke 37: 172–178.

[17] Langhorne P., Coupar F., Pollock A. (2009). Motor recovery after stroke: a systematic review. Lancet Neurol. 8, 741–754.10.1016/s1474-4422(09)70150-4

[18] www.nice.org.uk

Figure 2: Ankle Foot Orthoses (AFO)



AFO has been shown to improve gait speed, six minute walking distance[19], functional mobility[20] and ankle kinematics[21] when compared with barefoot gait. Improving function in this patient cohort has been associated with increased confidence.[22] AFO is a non-invasive, simple to use, relatively cost effective[23] therapy that is generally well tolerated[24] and may be the treatment of choice in cognitively impaired subjects.

AFO therapy has some drawbacks: its use can interfere with normal ankle kinetics feedback and proprioception[25] thereby impeding stability and balance, as well as residual muscle strength and flexibility. AFOs are worn in shoes; often the shoe with the AFO must be larger in size than that of the other foot, causing aesthetic and economic considerations. Poorly

[19] Kim M, Eng J, Whittaker M 'Effects of a simple functional electric system and/or a hinged ankle-foot orthosis on walking in persons with incomplete spinal cord injury' *Archives of physical medicine and rehabilitation* vol 85 issue 10 2004 p 1718-23

[20] Tyson S, Thornton H 'The effect of a hinged AFO on hemiplegic gait: objective measures and users' opinions' *Clin Rehabil Jan 2001 vol 15 no 1 53-58*

[21] Creylman V, Muraru L, Pallari J, Vertommen H, Peeraer L 'Gait assessment during the initial fitting of customised selective laser sintering foot orthoses in subjects with foot drop' *Prosthet Orthot apr 2013, vol 37, no 2 132-138*

[22] Barrett C., Taylor P. The effects of the odstock drop foot stimulator on perceived quality of life for people with stroke and multiple sclerosis. *Neuromodulation*, 2010; 13(1):58-64.

[23] NHS Quality Improvement Scotland best practice statement 2009: 'Use of ankle foot orthoses following stroke' www.stroke.scot.nhs.uk

[24] Wit D, Buurke J, Nijlant J, Ijzerman M, Hermens H 'The effect of an AFO on walking ability in chronic stroke patients: a RCT' *Clin Rehabil* may 2004 vol 18 no 5 550-57

[25] Ring H. Treger I. Gruendlinger L. Hausdorff JM., Neuroprosthesis for footdrop compared with an ankle-foot orthosis: effects on postural control during walking. *Journal of Stroke & Cerebrovascular Diseases* 18(1):41-7, 2009 Jan.

fitting footwear can reduce comfort for the wearer and therefore further limit their motivation to remain mobile. Despite positive patient evaluation using the SIP68 mobility score, Geboers et al[26] found no improvement dorsiflexor strength during walking tests (ten meter walk with or without stairs and six minute walk with cognitive loading) using an AFO as compared to normal footwear. Improved standing balance symmetry and gait speed have been demonstrated but these responses are not reproduced in patients with long standing hemiparesis.[27]

3.4 Botulinum toxin injections

A meta-analysis exploring the effects of botulinum toxin-A, injected into spastic muscles of stroke survivors found a small, statistically significant increase in walking velocity ($p=0.018$).[28] Other large-scale studies have demonstrated reduced muscle tone but limited functional improvement[29] and this treatment is not recommended as standard treatment in current national guidance.

3.5 Surgery

Surgical treatment is not first line and should be considered as part of specialist review in refractory disease. Surgical treatment options include nerve or ligament surgery and bony fusion, for symptomatic relief.

3.6 FES

FES is the application of electrical stimulation to produce a functional movement that mimics normal voluntary movement. This stimulation is provided via skin surface or implanted

[26] Geboers JF, Wetzelear W I., Seelen HA., et al Ankle foot orthosis has limited effect on walking test parameters among patients with peripheral ankle dorsiflexors paresis *J Rehabil Med* 2002; 34;80-8).
[27] Wang R., Yen L., Lee CC., Lin PY Wang MF., Yang YR Effects of an ankle foot orthosis on balance performance in patients with hemiparesis of different durations *Clin Rehabil* 2005; 19;37-44
[28] Foley et al 'Does the treatment of spastic equinovarus deformity following stroke with botulinum toxin-A increase gait velocity?' *European Journal of Neurology* vol 17 issue 12 p1419-27 2010
[29] Ozcakir S et al 'Botulinum toxin in poststroke spasticity' *Clinical Medicine and Research* vol 5 no 2 132-8

electrodes and is triggered by a pressure sensitive footswitch worn inside the shoe.[30] In skin surface FES, electrodes placed over the nerve are connected by leads to a stimulator unit and controlled with a foot switch. Implanted FES electrodes are usually inserted into the epineurium of the peroneal nerve under general anaesthesia and operated either by leads passed through the skin or by radiofrequency waves[31].

Potential benefits of FES include prevention of disuse atrophy, increased local blood flow, and muscle re-education.[32] Frequency of stimulation, pulse width, amplitude and waveform may be selected to maximize efficacy, meaning it requires the skills of an adequately trained professional to set up the device, according to the physical response of the individual. Kottink et al[33] evaluated walking speed as the primary outcome in stroke survivors with chronic hemiplegia using an implanted FES, compared with controls (using their usual AFO). The treatment group improved walking speed by 23%.

Figure 3: FES devices

[30] Shiels J., Wilkie K., Bulley C., Smith S., Salisbury L., A mixed methods service evaluation of a pilot functional electrical stimulation clinic for the correction of dropped foot in patients with chronic stroke Primary Health Care Research & Development (2010)
[31] NICE 2009. IPG 278 Functional Electrical Stimulation for drop foot of central neurological origin. accessed at: http://www.nice.org.uk/guidance/IPG278/Guidance/pdf/English
[32] Alfieri V., Electrical stimulation for modulation of spasticity in hemiplegic and spinal cord injury subjects. *Neuromodulation* 2001; 4;85-92
[33] Kottink AI, Hermens HJ., Nene AV., et al A randomized controlled trial of an implantable 2 channel peroneal nerve stimulator on walking speed and activity in post stroke hemiplegia *Arch Phys Med Rehabil* 2007; 88; 971-978

The evidence is challenging to interpret due to the small sample size, heterogeneity of primary clinical endpoints, the subjective nature of functional improvement and the different modalities of FES that were studied. However, few adverse side effects were noted. Electrical stimulation has been associated with tingling sensations in the user, localized erythema and mild discomfort. NICE also note the anecdotal reports of FES influencing seizure threshold in patients with co-morbid epilepsy, increased spasticity and autonomic dysreflexia in patients with spinal cord injury. Further research is needed to inform a safety profile and identify a comprehensive list of medical contraindications.

4.0 National guidance

4.1 National Institute of Health and Clinical Excellence (NICE)

In January 2009, NICE issued guidance stating:

> "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." (IPG 278)[34]

The basis for this recommendation is a collection of studies demonstrating beneficial effects of FES: a meta-analysis of 71 stroke patients[35] showed significant improvements in gait speed (0.18m/sec); findings supported by a case review of 111 stroke survivors who experienced increased walking speed and reduced walking effort when compared to matched controls.[36] A randomized controlled trial of stroke survivors reported subjective functional achievements after 3 months of treatment with 'implanted' FES.[37]

NICE acknowledges the need for robust evidence base and concludes:

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[34] www.nice.org.uk

[35] Robbins SM, Houghton PE, Woodbury MG et al. (2006) The therapeutic effect of functional and transcutaneous electric stimulation on improving gait speed in stroke patients: a meta-analysis. *Archives of Physical Medicine & Rehabilitation* 87: 853–859

[36] Taylor PN, Burridge JH, Dunkerley AL et al. (1999) Clinical use of the Odstock dropped foot stimulator: its effect on the speed and effort of walking. *Archives of Physical Medicine & Rehabilitation* 80: 1577–1583

[37] Daly JJ, Roenigk K, Holcomb J et al. (2006) A randomized controlled trial of functional neuromuscular stimulation in chronic stroke subjects. *Stroke* 37: 172–178

"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"

4.2 Scottish Intercollegiate Guidelines Network (SIGN)

SIGN published guidelines in 2010[38] on the management of patients with stroke. They acknowledge that FES may present an effective intervention in a specific patient demographic although recognize the need for additional research in this area. Regarding FES they conclude that there is:

"presently insufficient high quality evidence to support or refute the use of electrostimulation to improve gait, muscle strength or functional outcomes after stroke."

And recommendation that:

"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".

4.3 Cochrane Review

A Cochrane Review (2009) highlighted the fact that most of the supporting evidence is from small and short-term trials with a notable lack of good-quality studies comparing FES with other rehabilitation methods[39].

4.4 Royal College of Physicians

The Royal College of physicians National Clinical Guidelines for Stroke [40] (2008) recommends:

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[38] Scottish Intercollegiate Guidelines Network Management of patients with stroke: Rehabilitation, prevention and management of complications, and discharge planning *A national clinical guideline.* SIGN 118 June 2010 http://www.sign.ac.uk/pdf/sign118.pdf accessed 10 August 2010

[39] Pomeroy VM *et al.* 2009. Electro stimulation for promoting recovery of movement or functional ability after stroke (Review) The Cochrane Library 2009, issue 1 accessed at: http://onlinelibrary.wiley.com/o/cochrane/clsysrev/articles/CD003241/frame.html

- Functional electrical stimulation of the arm or leg should not be used on a routine basis outside the context of clinical trials.
- Functional electrical stimulation of the leg should only be considered and used for individual patients who:
    - have footdrop impeding gait not satisfactorily controlled using ankle–foot orthoses *and*
    - have demonstrable gait improvement from its use

5.0 Effectiveness

Studies have used various protocols, devices and lengths of use of FES with a range of outcomes. Two systematic reviews demonstrate statistically significant benefits of using FES: Roche et al[41] looked at a range of different study methodologies including before and after studies, FES versus an alternative therapy and FES combined with another therapy. Heterogeneity of study design precluded a meta-analysis; possible bias is acknowledged. The authors concluded that there is an orthotic effect of FES, particularly when combined with other therapies (e.g. botulinum toxin injections or electromechanical gait training) including faster walking speed (ranges from 7% to 19% in before and after studies) and reduced physical effort (ranges from 19% to 37% in two before and after studies).

In a second systematic review, Kottink et al[42] calculated pooled estimates on walking speed and found that FES increased walking speed by 0.13 m/s or 38%. (The research team were unable to generate pooled estimates of changes in effort due to the small number of studies). Physical improvements in terms of walking distance and speed are supported by

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[40] Royal College of Physicians. National Clinical Guidelines for Stroke 3rd ed. 2008 http://www.rcplondon.ac.uk/resources/stroke-guidelines

[41] Roche A, o'Laighin G, Coote S Surface-applied functional electrical stimulation for orthotic and therapeutic treatment of drop-foot after stroke - a systematic review. *Physical Therapy Reviews*, 2009;14(2):63-80

[42] Kottink AIR, Oostendorp LJM, Buurke JH, Nene AV, Hermens HJ IJzerman MJ. The orthotic effect of functional electrical stimulation on the improvement of walking in stroke patients with a dropped foot: A systematic review. *Artificial Organs* 2004 28(6) 577-586

reported benefits in terms of quality of life measures following FES use in MS patients[43] (but there were significant selection and measurement biases in this study, including no reference to eligibility/inclusion criteria of selected patients and a lack of control group, meaning it is not clear the change was due to FES alone or the effects of additional clinical input). Esnouf et al[44] report improved satisfaction and performance with activities of daily living in patients referred for FES who met the study's inclusion criteria. This study was the only one to consider falls as an outcome measure. The FES group had fewer falls in total compared to the group assigned to exercise (5 compared to 18 in the exercise group).

Non-review studies were also appraised as part of the literature review. Most explored the impact of FES on at least one walking speed measure but each study used a different testing paradigm for the FES intervention: Ng et al[45] looked at outcomes after 4 weeks of FES use, Embrey et al[46] used 3 months of FES use plus a walking regime, Stein et al[47] used FES for 3 months alone and Kojovic et al[48] used 4 weeks plus a walking therapy. However, these studies did report overall orthotic amelioration in terms of walking speed and reduction in physiological cost index (an indication of effort of walking). Many of the studies showing a positive effect of FES were uncontrolled trials or before and after studies where the results of walking speed were presented after a period of FES use, but with no comparator group that had an alternative intervention.

[43] Barrett C., Taylor P. The effects of the odstock drop foot stimulator on perceived quality of life for people with stroke and multiple sclerosis. *Neuromodulation*, 2010; 13(1):58-64.

[44] Esnouf J, Taylor P, Mann G, Barrett C. Impact on activities of daily living using a functional electrical stimulation device to improve dropped foot in people with multiple sclerosis, measured by the Canadian Occupational Performance Measure. *Mult Scler*. 2010 Jul 2

[45] Ng M.F.W., Tong R.K.Y., Li L.S.W. A pilot study of randomized clinical controlled trial of gait training in subacute stroke patients with partial body-weight support electromechanical gait trainer and functional electrical stimulation: Six-month follow-up *Stroke*, 2008; 39(1):154-160

[46] Embrey DG, Holtz SL, Alon G, Brandsma BA, McCoy SW. Functional electrical stimulation to dorsiflexors and plantar flexors during gait to improve walking in adults with chronic hemiplegia. *Arch Phys Med Rehabil.* 2010 May;91(5):687-96

[47] Stein RB, Everaert DG, Thompson AK, Chong SL, Whittaker M, Robertson J, Kuether G. Long-term therapeutic and orthotic effects of a foot drop stimulator on walking performance in progressive and nonprogressive neurological disorders. *Neurorehabil Neural Repair.* 2010;24(2):152-67

[48] Kojović J, Djurić-Jovicić M, Dosen S, Popović MB, Popović DB. Sensor-driven four-channel stimulation of paretic leg: functional electrical walking therapy. *J Neurosci Methods*, 2009;181(1):100-5

Three systematic reviews[16,17,18] report inconclusive evidence as to the effectiveness of FES in the treatment for drop foot. A common theme is that the literature is too heterogeneous in terms of the intervention protocols used and outcomes measured to be able to provide pooled effect measures. Barrett et al[19] showed in an RCT that the FES intervention groups had a slower walking speed, no difference in effort and no difference in distance covered compared to an exercise group at 18 weeks.

5.1 FES vs AFO

Only four studies were found that compared FES directly with AFO. These were all of moderate to low quality. Ring et al[49] studied different gait parameters the same patient cohort, using FES (neuroprosthesis) compared with AFO. Whilst there was no significant difference in gait speed with the neuroprosthesis, there was a significant change in stride time, gait asymmetry and swing time variability in the FES group at eight weeks. Thus, compared with AFO, FES appeared to enhance balance control during walking and thus manage footdrop more effectively. Mesci et al support FES as a superior treatment option, showing that neuromuscular electrical stimulation produced significant improvement in most othrotic clinical parameters.[50]

Sheffler[51] used a within-patient trial design comparing outcomes of FES, AFO and no device in terms of ambulation and patient preference. Both FES and AFO improved ambulation profiles compared to having no orthotic but there was no significant difference in physical outcome measures between FES and AFO; service users did, however, state a preference for FES. These results are supported by work carried out by Swigchem et al[52], who showed

[49] Ring H, Treger I, Gruendlinger L, Hausdorff JM. Neuroprosthesis for footdrop compared with ankle-foot orthosis: effects on postural control during walking. J Stroke and Cerebro Dis. 2009 18(1) 41-47
[50] Mesci N, Ozdemir F, Kabayel DD, Tokuc B. The effects of neuromuscular electrical stimulation on clinical improvement in hemiplegic lower extremity rehabilitation in chronic stroke: a single-blind, randomised, controlled trial. *Disabil Rehabil*. 2009;31(24):2047-54
[51] Sheffler LR, Hennessey MT, Naples GG, Chae J. Peroneal nerve stimulation versus ankle foot orthosis for correction of footdrop in stroke: impact on functional ambulation. Neurorehab and neur repair. 2006 20 355-360
[52] Van Swigchem et al 'Effect of peroneal electrical stimulation versus ankle-foot orthoses in obstacle avoidance in people with stroke related foot drop' *Phy Ther* 2012 Mar;92(3):398-406

FES to be superior to AFO for obstacle avoidance in community dwelling stroke survivors; the same authors reported a single case study of a man for whom surface FES was not suitable but showed near normal gait after having FES implanted.

5.2 FES after stroke

In the UK, an estimated 150,000 people have a stroke every year[53] and survivors are left with a range of physical and cognitive morbidity. It is recognized that stroke recovery should be supported by specialist multi-disciplinary teams[54] in specialist units, focusing on holistic rehabilitation. An important part of this is intensive physiotherapy; fitness training, repetitive task training and muscle strengthening. It should be noted, that FES could be, in practice, a therapeutic adjunct in this patient population.

There is evidence to support its use even when compared as a single intervention: FES has been shown to improve Functional Independence Measurement Motor Subscores[55] using self-reported scales in chronic stroke patients using the device daily for four weeks. Improved physical function has been demonstrated following conventional rehabilitative support but the effect is increased with FES as an adjunctive technique[56] in acute stroke survivors. These results may not be reproducible in a subset of patients with chronic hemiparesis.[57] Daly et al (2011) investigated short-term follow up in stroke survivors using FES and found the treatment arm demonstrated greater clinical gains compared with controls.[58]

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[53] www.stroke.org.uk

[54] Langhorne P, Bernhardt J, Kwakkel G 'Stroke rehabilitation' *Lancet* vol 377, issue 9778 May 2011 1693-1702

[55] Mesci N, Ozdemir F, Kabayel D, Tokuc B 'The effects of neuromuscular electrical stimulation on clinical improvement in hemiplegic lower extremity rehabilitation in chronic stroke: a single-blind, randomised, controlled trial' *Disabil Rehabil* 2009;31(24):2047-54

[56] Solopova A, Tihonova D, Grishin A'Assisted led displacements and progressive loading by a tilt table combined with FES promot gait recovery in acute stroke' *Neurorehab* vol29, no1, 2011

[57]Ring H, Treger I, Gruendlinger L 'Neuroprosthesis for foot drop compared with an ankle-foot orthosis: effects on postural control during walking' *Journal of stroke and cerebrovascular disease* vol18, issue1 jan 2009 p41-7

[58] Daly J., Zimbelman J., Roenigk B, McCabe J, Rogers J., Butler K., Burdsall R., Holcomb J., Marsolais E., Ruff R., Recovery of Coordinated Gait; Randomized Controlled Stroke Trial of Functional Electrical Stimulation (FES) versus no FES, with weight supported treadmill and over ground training Neurorehabilitation and Neural Repair 25 &97) 588-596

5.3 FES in MS patients

NICE guidance on the management of MS states that "treatments aimed at improving walking should be offered" and the National Service Framework (2005) mentions that people with long-term neurological conditions should receive "timely, appropriate assistive technology/equipment". The MS Society has produced a fact sheet for its members, to raise awareness of FES as a potentially useful intervention and clearly supports FES as a means of improving function and quality of life.[59] MS is the most common neurological disease in the western world and about 75% of patients experience problems with mobility.

In a recent study, Barrett et al[60] explored the efficacy of FES in patients with secondary progressive MS and a unilateral foot drop. Performance was compared in subjects with and without stimulation. The researchers showed a statistically significant improvement in walking distance, walking speed and concluded that FES yields an orthotic effect; whereas physiotherapeutic input and exercise may promote a training effect with similar results. Barrett et al[61] further considered the effects of FES on walking performance for people with multiple sclerosis causing drop foot. The research team report a reduction in physiological cost index (PCI) but state that outcome measures may not be easily translated into clinically relevant values.

It remains uncertain whether FES offers additive functional benefits over increasing muscle strength, via exercise, to reduce the physical effort of walking with this condition.[62] Therapeutic impact should focus on the psychosocial effects as well as clinical markers of

[59] www.mssociety.org.uk

[60] Barrett C, Mann G, Taylor P, Strike P 'A randomized trial to investigate the effects of functional electrical stimulation and therapeutic exercise on walking performance for people with multiple sclerosis' *Multiple Sclerosis* 2009;15:493-504

[61] Barrett C., Taylor P. The effects of the odstock drop foot stimulator on perceived quality of life for people with stroke and multiple sclerosis. *Neuromodulation*, 2010; 13(1):58-64

[62] Newman, Dawes, van der Berg, Wade, Burridge, Izadi 'Can aerobic treadmill training reduce the effort of walking and fatigue in people with multiple sclerosis: a pilot study' *Multiple Sclerosis Journal* Jan 2007 vol13, issue 1 p113-9

physical function. The Psychosocial Impact of Assistive Devices Scale (PIADS) has been used to explore perceived quality of life after 18 weeks of FES, in stroke and MS patients. Although improvements were noted with FES use, this did not always correlate well with increase in walking parameters.[63] Benefits were greater for stroke survivors than those with progressive MS.

6.0 Safety

FES appears to be safe; there is no reported evidence of adverse long-term side effects in adults.

In a randomised controlled trial of 29 patients with chronic stroke, 14 of whom received FES, four instances of skin erythema were reported[64]. In a case series of 17 patients with implantable electrodes, 14 instances of skin erythema were reported, with one patient requiring electrode removal.[65] Two patients developed wound infection following electrode implantation in a case series of 15 patients.[66] One instance of device malfunction was reported after 10 weeks in a randomised controlled trial of 29 patients, 14 of whom had implanted electrodes.[67]

6.1 Adhesive versus implantable electrodes

No studies could be found that explored a direct comparison of FES operational modalities so it was not possible to draw conclusions as to the most appropriate means of attaching the electrodes. However, evidence exists to imply improved outcomes from both techniques.

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[63] Barrett C, Taylor P 'The effects of the odstock drop foot stimulator on perceived quality of life for people with stroke and multiple sclerosis' *Neuromodulation: technology at the neural interface'* Vol13, issue1, 58-60

[64] Daly JJ, Roenigk K, Holcomb J et al. (2006) A randomized controlled trial of functional neuromuscular stimulation in chronic stroke subjects. Stroke 37: 172–178

[65] Daly JJ, Kollar K, Debogorski AA et al. (2001) Performance of an intramuscular electrode during functional neuromuscular stimulation for gait training post stroke. Journal of Rehabilitation Research & Development 38:

[66] Burridge JH, Haugland M, Larsen B et al. (2007) Phase II trial to evaluate the ActiGait implanted drop-foot stimulator in established hemiplegia. Journal of Rehabilitation Medicine 39: 212-218

[67] Kottink AI, Hermens HJ, Nene AV et al. (2007) A randomized controlled trial of an implantable 2-channel peroneal nerve stimulator on walking speed and activity in poststroke hemiplegia. Archives of Physical Medicine & Rehabilitation 88: 971–978

A meta-analysis of three studies on skin surface-applied FES found that it increased gait speed by a mean difference of 0.18 metres /second (95% CI 0.08 to 0.28) in stroke patients (n = 36) compared with conventional therapy (n = 35). When evidence was considered from all studies (three controlled trials and two non-controlled trials) the mean effect size ranged from - 0.11 to 1.431.[68] In a case series of 140 patients[69] undergoing skin surface FES, stroke patients (n = 111) showed an increase in walking speed of 12% (0.07metres/second) and a decrease in effort of 18% (-0.16 beats/metre) (measured by a physiological cost index) when using the stimulator (orthotic effect) compared with baseline. At 4.5-month follow-up there was a 14% (0.08 metres/second) increase in walking speed and a 19% (-0.17 metres/second) reduction in effort. In patients with multiple sclerosis (n = 21) there was a 16% (0.08 metres/second) increase in walking speed and a 24% (-0.20 beats/metre) decrease in effort. However, when not using the stimulator the patients reported a 7% (-0.03 metres/second) decrease in walking speed and a 16% (0.13 beats/metre) increase in effort.

Two randomised controlled trials reported on efficacy outcomes following implantation of electrodes.[70,71] In the first trial FES was compared with conventional therapy in 29 patients. FES resulted in a 23% improvement in walking speed measured with the six-minute walking test (6MWT), compared with an improvement in the control group of 3% (p = 0.010). In the second, no significant differences in the 6 minute walk were found between the group with implanted electrodes (post-treatment mean/median walking distance 252.2 metres) and the control group[71] who received physiotherapy training (post-treatment mean/median walking distance 165.9 metres; (p = 0.184). The primary outcome measure in this study was gait component execution according to the Tinetti gait scale, a 12-point scale assessing gait

[68] Robbins SM, Houghton PE, Woodbury MG et al. (2006) The therapeutic effect of functional and transcutaneous electric stimulation on improving gait speed in stroke patients: a meta-analysis. Archives of Physical Medicine & Rehabilitation 87: 853–859

[69] Taylor PN, Burridge JH, Dunkerley AL et al. (1999) Clinical use of the Odstock dropped foot stimulator: its effect on the speed and effort of walking. Archives of Physical Medicine & Rehabilitation 80: 1577–1583

[70] Kottink AI, Hermens HJ, Nene AV et al. (2007) A randomized controlled trial of an implantable 2-channel peroneal nerve stimulator on walking speed and activity in poststroke hemiplegia. Archives of Physical Medicine & Rehabilitation 88: 971–978

[71] Daly JJ, Roenigk K, Holcomb J et al. (2006) A randomized controlled trial of functional neuromuscular stimulation in chronic stroke subjects. Stroke 37: 172–178

components such as gait initiations, walking path and trunk alignment. The FES group had a statistically significant greater gain versus the control group for gait component execution (p = 0.003; parameter estimate 2.9, 95% CI 1.2 to 4.6). Around 50% of the control group had no gains, whereas 14% of the FES group had no gains.

7.0 Cost effectiveness

A Quality Adjusted Life year (QALY) is a standard, internationally-recognised way of comparing the effect of a variety of treatments. It gives an idea of how many extra months or years of life of a reasonable quality a person might gain as a result of the suggested treatment.The NHS purchasing and supply agency (Centre for Evidence-based Purchasing, 2010) modelled the cost effectiveness of FES in stroke patients using efficacy data with physiotherapy (as a single intervention) as a comparator.[72] The report suggests that FES has an estimated cost per QALY of £19,238 (£52,337 in the first year, due to the cost of the equipment and initial consultation, followed by £10, 964[56] in subsequent years). Using an acceptable cost threshold of £30k per QALY, there is a probability of 66% that FES is cost-effective.[56] In addition, it can be made more cost-effective by carefully selecting those patients who can most benefit from FES.

A report produced for the South and West Regional Development and Evaluation Committee (using data from the National Clinical FES Centre in Salisbury) suggest a mean QALY gain of 0.065 from using FES and a mean length of FES use of 4.4-4.9 years based on clinical audit.[73] Using 2007 costs the author suggested a cost per QALY of £25,231 in the first year and £12,431 if used over 5 years. NICE (2009) states that current evidence on the safety and efficacy of FES for improving gait in drop foot of central neurological origin is adequate

[72] The Centre for Evidence based Purchasing Market review; functional electrical stimulation for drop foot of central neurological origin NHS Purchasing and Supplies Agency Feb 2010
[73] Swain ID, Taylor PN, Burridge JH, Hagan SA, Wood DE 'Report to the Development Evaluation Committee: common peroneal stimulation for the correction of foot-drop' www.salisburyfes.com 1996

to support the use of the procedure, with normal arrangements for clinical governance, consent and audit. NICE recommends further research focusing upon patient-reported outcomes including quality of life and effect upon activities of daily living.

Falls in older people, including those with stroke or multiple sclerosis represents a significant financial and social burden for UK healthcare providers. One study looking at incidence of falls in the UK, as per the Home Accident Surveillance System (HASS), Leisure Accident Surveillance System (LASS) and Hospital Episode Statistics (HES) databases in 1999 suggested that there were 647 721 A&E attendances and 204 424 admissions to hospital for fall related injuries in people aged 60 years and over. The authors correlate this number to a cost of £300 000 per 10,000 60–64 year olds, increasing to £1 500 000 in the over 75 age group.[74] Although it is not currently possible to ascertain the number of falls that may relate to.stroke and MS patients with foot drop, it is hoped that provision of FES may prevent falls in stroke and MS patients.

7.0 Local situation

Currently, FES is not routinely funded by CCGs in Norfolk and Waveney but can be considered through the Individual Funding Request (IFR) Panel route. The NHS Constitution (2009) determines that local funding decisions should be made rationally and following a consultation of relevant evidence, thereby offering patients the opportunity to gain an explanation for funding decisions and a transparent decision model. The IFR Panel has received more than three requests for funding of FES, which has prompted the development of a specific policy. In some instances, patients have purchased their own machines after a short-term trial of hospital owned equipment.

A patient survey of 17 such service users at one of the acute trusts has demonstrated positive findings in people experiencing foot drop as a result of upper motor neuron disease, in whom foot drop that had caused significant clinical problems, trips and falls. The survey participants had been selected as being appropriate for FES by the physiotherapy specialists and had undergone robust explanation and training. 90% of these patients were still using the device up to 5 years after purchase, with half using it every day. All users felt,

[74] Sciffham et al 'Incidence and costs of unintentional falls in older people' *J Epidemiol Community Health* 2003;**57**:740-744

anecdotally, that they were experiencing fewer falls and 80% felt the machine was integral to the continuation of work and/or hobbies (see appendix 1)

8.0 Conclusions

The evidence for the effectiveness of FES is limited by significant variations in the way the devices are used, the length of treatment courses, patient characteristics and the outcomes measured in the trials. However, general conclusions can be drawn.

Evidence exists to suggest FES leads to improvements in walking speed and has the potential to improve gait. However, the exact role of FES within a comprehensive rehabilitation plan remains unclear and may vary between patients.

There is limited evidence relating to effect on quality of life, impact on disability or carer perspective and there is a need for increased high quality, large scale trials in this area.

Conservative modelling of FES for foot drop of central neurological origin shows that it is likely to be cost effective.

There is local, clinical support for the development of a service to provide FES in Norfolk.

9.0 Summary

This report has reviewed a range of studies reporting the functional outcomes for people with foot drop secondary to stroke and multiple sclerosis. The studies include a range of patients; most often stroke survivors, albeit at varying time points in their recovery. The studies explore a range of primary outcomes including walking speed, physiological cost of walking and employ a variety of comparators: AFO versus FES, FES with conventional treatment versus FES alone, exercise intervention, physiotherapy or passive muscle stretching. Some FES devices use implantable electrodes, others use externally attached electrodes. This heterogeneity makes useful comparison challenging and makes it difficult to draw meaningful conclusions about recommended funding provision. Additional research is needed, in particular studies focusing on reduction in pain and discomfort, reduction in falls,

return to work and other economic parameters. Overall, however, the evidence suggests that FES is a potentially useful treatment adjunct in carefully selected patient cohorts with an impressive safety profile. This notion is supported by some of the national literature and clinical guidance: NICE includes data from randomized controlled trials in their guidance report, showing FES to be associated with increased walking speed by 23% compared with conventional therapy alone (an increase of 3%) and concludes it to be a safe, efficacious treatment option.

As the evidence for the effectiveness of Functional Electrical Stimulation (FES) for foot drop in Stroke and Multiple Sclerosis is limited by significant variations in the way the devices are used, patient characteristics and the outcomes measured in the trials, it is recommended that FES is not routinely funded.

If a clinician considers that there are exceptional circumstances for a patient, then an application to the Individual Funding Requests Panel can be made.

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APPENDIX 1

This draft policy has been developed through consultation with the following people:

Name	Designation	CCG/Acute provider
CCG clinicians		
Dr Hitesh Kumar	GP representative	NHS Great Yarmouth and Waveney CCG
Prof David Scott	Clinical Advisor	NHS Great Yarmouth and Waveney CCG
Dr Alasdair Lennox	GP representative	NHS North Norfolk CCG
Dr Brian Cole	GP representative	NHS Norwich CCG
Dr Les Cooper	GP representative	NHS South Norfolk CCG
Louise Stevens	CCG representative	NHS West Norfolk CCG
Dr Paul Williams	GP	NHS West Norfolk CCG
Dr Imran Ahmed	GP	NHS West Norfolk CCG
Dr Anthony Burgess	GP and CCG	NHS West Norfolk CCG
Dr Pallavi Devulapalli	GP	NHS West Norfolk CCG
Dr Ian Mack	Chair	NHS West Norfolk CCG
Dr Maggie Carter	Clinical Governance Lead	NHS West Norfolk CCG

CCG Colleagues		
Kathryn Griffiths	Project Management Specialist	(representing) NHS Great Yarmouth and Waveney CCG
Rachel Leeds	Planned Care Programme Manager	NHS Great Yarmouth and Waveney CCG
Ellis Layward	Commissioning Manager	NHS North Norfolk CCG
Lindsay Springall	Commissioning Manager	NHS Norwich CCG
Louise Browning	Independent Consultant	(representing) NHS South Norfolk CCG
Jan Sanders	Commissioning Manager	NHS West Norfolk CCG

Acute provider colleagues		
Tim Shayes	Business Manager	Norfolk and Norwich University Hospital NHSFT
Stephen Day	Head of Commissioning	Norfolk and Norwich University Hospital NHSFT
Dr Jeff Cochius	Consultant Neurologist	Norfolk and Norwich University Hospital NHSFT
Mr David Dick	Consultant Neurologist	Norfolk and Norwich University Hospital NHSFT
Kate Goddard	Senior Physiotherapist	Norfolk and Norwich University Hospital NHSFT
Penny Tilbury	Head of Physiotherapy	Norfolk and Norwich University Hospital NHSFT

Other providers		
Sarah Lauchlan	Senior Clinician	East Coast Community Healthcare
Tazivei Masarira	Senior Physiotherapist - Neurology	East Coast Community Healthcare
Allison Coxon	Community Neurology Team Lead	Norfolk Community Health and Care
Nina Melville	Team Lead Physiotherapist	Norfolk Community Health and care

Public Health Team		
Dr Suzy Duckworth	GPST1 Norwich	Norfolk County Council
Dr Tha Han	Consultant in Public Health	Norfolk County Council
John Ford	Public Health Registrar	Norfolk County Council
Stuart Keeble	Public Health Registrar	Norfolk County Council
Jon Cox	Public Health Registrar	Norfolk County Council
Dr Shamsher Diu	Consultant in Public Health	Norfolk County Council

Norfolk County Council
at your service

Name of document:	FES for foot drop in stroke and MS policy Appendix 2 and 3	**File location / Filename:**	/Public health/GPVTS/Suzy Duckworth/FES
Version:	Draft v4	**Date of this version:**	2014 09 08
Status:	Final draft	**Synopsis and outcomes of Equality and Diversity Impact Assessment (if required):**	
Owner:	Norfolk & Waveney CCGs	**Approved by (Committee):**	Clinical Policy Development Group of the Individual Funding Requests Panel of Norfolk & Waveney CCGs.
Produced by:	Dr Suzy Duckworth, GPST1 Norwich; Shamsher Diu	**Date ratified:**	
Relevant Public Health Programme:	Healthcare Commissioning	**Copyholders:**	Dr Shamsher Diu, in Consultant Public Health
		Next review due:	November 2017

Appendix 2 Tables reviewing evidence

Paper	Study Design & Exposure Participants (inclusion and exclusion criteria)	Intervention	Outcome Measures	Results/ Adverse Effects	Study strengths & limitations
RANDOMISED TRIALS					
Mesci at al (2009)	**Design;** Single-blind, randomised, controlled trial. **Sample size;** 40 patients with chronic stroke. MS patients were excluded as were people with other disorders of central nervous origin. **Age (mean);** Group 1 (n=20); 62.65 +/= 7.52 Group 2 (n=20); 59.10+/-8.58 (p=0.172) **Gender;** Group 1 (n=20); 12 men 8 women Group 2 (n=20);11 men 9 women (p=0.749) **Other characteristics;** **Side of hemiplegia** Group 1 (n=20); 9 right, 11 left Group 2 (n=20);9 right, 11 left (p=1.000) **Inclusion and exclusion criteria** were stated and were reasonable.	**Intervention**: • Conventional rehabilitation program for 4-weeks ± • Neuromuscular electrical stimulation (NMES) for hemiplegic foot dorsiflexor muscles for 4 weeks, 5 days a week • 20 patients in each group • FES is one of the application modes of NMES. The application here therefore was not FES so patient was in stable sitting position and not walking.	**Primary Outcome Measures**: a) Pre- and post-treatment measures of ankle dorsiflexion and b) level of spasticity **Secondary Outcome Measures:** a) Brunnstrom Stage, b) Rivermead leg and trunk score and c) Functional Independence Measurement motor (subscore; Functional Ambulation Categories)	**Results** • The NMES group showed a significantly ($p<0.05$) higher improvement than the control group in Brunnstrom Stage, Rivermead leg and trunk score and Functional Independence Measurement motor subscore. **Adverse effects** • None stated	**Strengths** • Participants were randomised (using 'n, n+1 method) into the treatment arms. • Assessment of walking was done by same assessor blinded to the treatment group. • Controlled group comparisons **Limitations** • Some results are presented as pre- and post treatment changes, not comparative • No sample size calculation.

					• Did not state whether electrodes were re positioned with every application
Ring et al (2009)	**Design** Randomised control trial **Sample size** 15 patients with prior chronic hemiparesis recruited from 2 outpatient clinics in rehabilitation centres. Patients had been recruited for a larger study designed to evaluate the effects of a neuroprosthesis on gait in patients with footdrop and the current study was based on a subset of those patients previously described who were tested with their AFO. The criterion for this particular subset was use of an AFO for at least 6 months before the initiation of the study. **Age (mean)** 52.2 +/- 3.6 years **Gender (m/f);** 11/4 **Other characteristics** • 12 patients post stroke, 3 patients post traumatic brain injury • 6 patients- right hemiparesis • 9 patients- left hemiparesis **Time since stroke** 5.9 +/- 1.5 year **Inclusion and exclusion criteria** were stated and were reasonable.	**Intervention** 4 week adaptation period during which participants increased their daily use of the neuroprosthesis. After 4 week adaptation period, gait was measured under 2 conditions in a randomized order; 1) while using the neuroprosthesis and 2) while using the AFO.	**Primary outcomes** • Gait speed and stride time (inverse of cadence) • Gait asymmetry index • Swing time variability. **Secondary outcomes** • None stated	**Results** a) After <u>4-week</u> adaptation period, there were no differences between walking with the neuroprosthesis and walking with the AFO (P > .05). b) After <u>8 weeks,</u> there was no significant difference in gait speed, whereas stride time improved from 1.48 +/- 0.21 seconds with the AFO to 1.41 +/- 0.16 seconds with the neuroprosthesis (P < .02). Swing time variability decreased from 5.3 +/- 1.6% with the AFO to 4.3 +/- 1.4% with the neuroprosthesis (P = .01). c) A gait asymmetry index improved by 15%, from 0.20 +/- 0.09 with the AFO to 0.17 +/- 0.08 with the neuroprosthesis (P < .05).	**Strengths** • Compared FES to AFO head to head • Reproducible and practical for non-research use. **Limitations** • No discussion about the eligibility of patients for FES. • No sample size calculation • RCT of 15 patients- so potentially too small

				Adverse effects None stated	
Embrey et al (2010)	**Design:** Randomized crossover trial ○ 18 randomly assigned (via coin toss) to A-B group ○ 15 to B-A group **Sample size:** 28 **Age:** 34-75 (mean +/- SD 60 +/- 10.9y **Other characteristics** **Time;** 1 to 18 years post hemiplegic incident (mean +/- SD 4.9 +/- 3.8y) **Gender: (M/F)**16/12 **Inclusion criteria;** a) Able to walk continuously at least 15 minutes 4 times a day b) Walked at least 6 months before the study c) Were medically stable without co morbidity factors (as determined by their physician) d) Were able to don FES device	**Intervention:** a) Weekly appointments (30mins) with primary investigator and another investigator b) Walking program- random assignment allowed comparison of benefits of walking with walking plus FES c) Gait MyoElectric Stimulator function electrical stimulation system- provided stimulation to the paretic dorsiflexors during initial contact, pre swing and swing.	**Primary outcome*** a) 6 minute walk test b) Emory Functional Ambulatory Profile (EFAP) c) Stroke impact scale (SIS) **All with no FES* **Secondary outcomes** a) Muscle strength b) Spasticity	**Results** • A-B group performed significantly **better** than the B-A group at 3 and 6 months for each of the primary outcomes. **Phase 1** • Patients who received treatment A (A-B) group showed improvement compared with patients who received treatment B(B-A) group on the 6 minute walk test (P=0.2), EFAP (P=0.8) and SIS (P=0.3) **Phase 2** • A-B group maintained improvement in all 3 primary outcomes	**Strengths** • High compliance with intervention • Randomisation resulted in balanced groups **Limitations** • Used a convenience sample of reasonably mobile people. • High drop out rate; no mention of intention to treat analysis. • Measurement bias; walking distance measured by non-blinded researchers • But study did have 2

	independently or with caregiver assistance e) Could follow directions for testing and treatment **Exclusion criteria:** a) Typical sEMG muscle pattern in gait for dorsiflexors and plantar flexors b) Received any orthopaedic surgery or tone reducing procedures 1 year before study c) Wore rigid ankle foot orthosis **d)** Had less than 10°of passive dorsiflexion and plantar flexion			without FES **Adverse effects** • None stated	people score so with good inter-rater reliability.
Barrett et al (2010)	**Design**: included an initial pilot element to test procedures and methods **Sample size:** 44 subjects with Secondary Progressive Multiple Sclerosis (SPMS) and dropped foot 20 to FES group and 24 in Exercise group **Age (mean)** FES (n=20); 52.1 years (SD 6.7) 40-63 years Exercise (n=24); 56.6 years (SD 9.0) 39-73 years **Gender:** FES (n=20); 15 females, 5 male Exercise (n=24); 16 female, 8 male **Other characteristics:** None stated **Inclusion criteria** a) ≥18 years of age with no upper age limit, b) had a diagnosis of secondary progressive made by neurologist and a rating in the range of 4-6.5 on the Kurtzke Expanded Disability Status Scale (EDSS).	**Intervention:** FES vs. exercise therapy, both for 18 weeks	**Primary outcome;** walking speed over 10m after 18 weeks of intervention, **Secondary outcome;** a) Physiological cost index (PCI) and b) Distance walked in 3 min.	**Results** • Exercise group showed increased walking speed and **no difference** in distance walked or PCI. **Adverse effects** • Measurement regime caused fatigue in patients	**Strengths** • Random allocation – permuted blocks – revealed after consent • Sample size calculation done **Limitations** • Study was underpowered. • Assessors not blinded. • Selection bias; participants recruited from an FES waiting list and assessed for responsiveness to FES. • Exercise group promised FES at end of trial so may have

	c) Unilateral dropped foot impairing mobility, passive range of ankle dorsiflexion to at least plantigrade, a good response to stimulation of the common peroneal nerve when assessed for trial by researchers with no previous use of FES. **Exclusion criteria:** a) subjects with cognitive or psychiatric problems that affected their ability to understand or comply with treatment, or any other neurological or orthopaedic problem that may have affected mobility or response to treatment				been more motivated to be compliant with exercises compared to general population.
Solopova et al (2011)	**Design;** Experimental study **Sample size**; 61 patients randomly assigned to 2 groups (experimental and control) +10 neurologically normal subjects **Age (mean)** 64+/-18 (38 to 82 years) **Gender (m/f)** Experimental group (n=32); 15/17 Control group (n=29); 18/11 **Other characteristics** • **Days after stroke** Experimental group (n=32); 8.2 +/-4.3 Control group (n=29); 9.3+/-4.5 • **Plegic side** (R/L) Experimental group (n=32); 10/22 Control group (n=29); 9/20 **Inclusion criteria** • Stable haemodynamics • Absence of lower limb contractures (with an Ashworth index <2 in all the lower limb muscles; on average	**Intervention;** 1. Experimental group received both conventional therapy and FES therapy +assisted leg movements + progressive limb loading (2 weeks of training, 30 min per day, 5 days per week) 2. Control group received only conventional therapy	**Primary outcome** a) MVC of knee flexors and extensors b) Stepping movements c) EMG activity during stepping like movements d) Clinical scores **Secondary outcome** None stated	**Results;** • After treatment, improvement of clinical scores, muscle forces and everyday life activity performance in both groups • But significantly higher in experimental group **Adverse effects** None stated	**Strengths** • High compliance with intervention • Pseudo random assignation to groups **Limitations** • Did not consider FES alone but rather FES therapy with assisted leg movements and progressive limb loading- generalisable results? • Did not state whether electrodes were re positioned with every application

	0.9+/- 0.6 [mean +/- SD] • Orthopaedic impairment • Significant cardiovascular impairments **Exclusion criteria** • Cardiac arrhythmia • Thrombophlebitis • Significant perceptual, cognitive or communication impairments • Diabetes Contra-indication for electrical stimulation (unstable epilepsy, cancer, skin abnormalities, pacemaker)				
Daly et al (2011)	**Design** Randomised control trial **Sample size** 53 subjects randomly allocated to; a) FES with intramuscular electrodes (FES-IM) b) No FES Both groups received 1.5 hour training sessions 4 times a week for 12 weeks of coordination exercises, body weight supported treadmill training (BWSTT), & over ground walking, provided with FES-IM or No FES **Age (mean)** FES 59 No FES 62 **Gender (M/F)** FES 15/5 No FES 17/7 **Other characteristics**	**Interventions** • Multimodal Gait Training Protocol (MGTP) versus with MGTP plus FES	**Primary outcomes** a) Gait Assessment and Intervention Tool (G.A.I.T) of coordinated movement components **Secondary outcomes** b) Manual muscle testing c) Isolated leg movements (Fugl Meyer scale), d) 6 Minute Walk Test, and e) Locomotion/Mobility subscale of the Functional Independence Measure (FIM)	**Results** • No baseline differences in subject characteristics or measurements • GAIT showed an additive advantage with FES-IM versus No FES (1.10 P=0.45, 95% CI=0.023-2.179) at the end of training. For both FES IM and No FES, a within group, pre/post treatment gain was present for all measures (P<.05) and a continued benefit from mid to post treatment (P<0.5) was present. For FES-IM, recovered coordinated gait persisted at 6	**Strengths** • Randomization done in 3 steps by 3 individuals; a) Generation of an unpredictable treatment allocation sequence b) Recording of enrolment date • Limiting bias as subject screening, enrolment decision and allocation group were conducted by different individuals • Comments on intrarater and interrater reliability of G.A.I.T. Intrarater reliability of the G.A.I.T was good (intraclass correration {ICC]= .98,

	Type of stroke (Ischaemic/haemorrhagic) FES No FES **Inclusion criteria** • Onset >6 months • First stroke • Inability to execute normal swing phase in the sagittal plane using hip, knee and ankle flexion • Hyperflexion or hyperextension of knee during stances • Passive joint range of motion of hip, knee and ankle equal to normal excursion needed for walking and • Not participating in gait rehabilitation **Exclusion criteria** • Inability to follow 2 level commands • Pacemaker • Peripheral neuropathy • Debilitating illness (e.g. cancer)			month following up but not for NO FES	p=.0001; 95% CI=0.95-0.99). Interrater reliability was also good (ICC=.83, P=.007; 95% CI =0.32-0.96), including between an experienced and an inexperienced clinician (ICC=.996; P=.001; 95% CI=0.986-0.999). • All outcome measures were assessed by a blinded examiner **Limitations** • Limited follow up (12 weeks) • Limited transferability of results Adequate sample size? ITT analysis?
MIXED METHODS ANALYSIS					
Shiels (2010)	**Design:** Mixed methods analysis (quantitative, qualitative and reflective components). <u>3 phases</u> **Phase 1**; routine data collected at initial assessment and 6 months post application between 2003-2007 **Phase 2**; qualitative exploring patients with stroke and carers experiences of the	**Intervention:** • Service evaluation of FES clinic for patients who had attended clinic for at least six months between 2003-2007	**Primary outcomes** • Gait velocity (m/s) • Cadence (steps per minute) measured during a timed 10m walk **Secondary outcomes(s)** Not stated	**Results** • **Between subgroup analysis** a) Gait velocity; statistically significant differences at baseline (P= 0.004) and at 6 months (P<0.001) with patients in **no orthotic subgroup performing faster** at	**Strengths** • Offers clarity on what a 'specialist team' comprises of i.e. specialist neurological physiotherapists **Limitations** • No information on how the primary outcomes were measured

	FES clinic (*not further considered here)* **Phase 3** reflection on service delivery model - *Phases 2 and 3 not furthered considered here* **Setting;** Lothian FES clinic **Sample Size:** 40 2 subgroups; 1. 24 patients were routinely using an AFO at initial contact with clinic (AFO subgroup) 2. 16 remaining chose not to use an orthotic device (no orthotic subgroup) **Age, years (mean /- SD):** ○ Total cohort; 60+/ - 11.37 ○ AFO[75] subgroup; 59.2+/-12.07 ○ No orthotic subgroup; 55.4 +/-9.95 **Gender:** ○ Total cohort; males/females 28/12 ○ AFO subgroup 14/10 ○ No orthotic subgroup 14/2 **Ethnicity** not stated **Diagnosis:** Stroke **Other characteristics:** • **Side of stroke** (left/right) ○ Total cohort;19/21 ○ AFO subgroup;14/10 ○ No orthotic subgroup; 5/11	• Annual reviews to monitor progress and equipment set up from 6 months onwards.		both time points. b) Cadence; no statistically significant difference between subgroups at baseline (P=0.199) but 6 months the **no orthotic group had significantly greater results** when compared to AFO group c) At 6 months, there was a statistically significant difference between subgroups (P=0.021) with patients in **no orthotic group taking more steps.** d) Both subgroups showed statistically significant improvements in ○ gait velocity (AFO group P<0.001; no orthotic P<0.005) and ○ cadence (AFO P<0.005; no orthotic P<0.01) e) Statistically significant benefit of FES application to patients in AFO group who already	• Service evaluation lacks the validity and rigour of more scientific research (National Patient Safety Agency 2009) • Limited transferability of results • Selection bias due to exclusion of patients for various reasons e.g. progressive illness, recovery of movement, died, failed to attend). • No control group • How well does 'statistically significant' translate into clinically significant'?

[75] Ankle foot orthosis

	• **Time, years since stroke to FES[76] set up** (mean+/-SD) o Total cohort;3.3 +/- 6.03 o AFO subgroup5.4 +/- 9.07 o No orthotic subgroup 2.2 +/- 1.75			had an existing orthotic device	

[76] Functional electrical stimulation

Appendix 3 FES Policies in other areas

PCT	Policy
The NHS East Midlands Specialised Commissioning Group (EMSCG) (2012)	FES using skin surface electrodes will be commissioned for patients meeting specific criteria[77]: • The patient has foot drop caused by upper level nerve damage • The patients has been assessed by a specialist in foot drop of neurological origin and all treatment options have been considered • There is evidence that foot drop has caused trips or falls, or gait issues causing significant clinical problems • The patient can walk a minimum of 10 metres independently (+/- aids) • The patient can physically manage a FES (+/- minimal assistance) • The patients cognitive ability is such that they can manage a FES independently • The patient does not have co morbidities which would affect their capacity to benefit from FES • The patient does not have any of the accepted clinical contraindications to FES • Clear FES treatment goals and expectations of benefit are outlined Other types of FES (implanted or wireless) are not commissioned
The NHS Peninsula Commissioning Priorities Group	Commissioning skin-surface FES for patients for whom AFO has proven unsuitable.[78]

[77] (see 33 above)

[78] Peninsula Commissioning Priorities Group Commissioning decision: Skin surface applied functional electrical stimulation for an orthotic effect to correct foot drop of central neurological origin. NHS Devon, NHS Plymouth, & Torbay Care Trust December 2011

NHS Hull (July 2010)	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'[79]
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[80]
NHS South Central (Oxfordshire) PCT Priorities Committee (May 2008)	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 [81]
NHS Plymouth	Not routinely funding FES
NHS North West London (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.[82]

[79] Mizon J. General commissioning policy statement: Functional electrical stimulation (FES). NHS Hull, July 2010 (document ref T09/10)

[80] NHS Bournemouth and Poole and NHS Dorset Functional electronic stimulation policy July 2009 www.dorset.nhs.uk/WS-Pan-Dorset/Downloads/NHSBP/Policies/Clinical/Functional%20Electronic%20Stimulation%20Policy.pdf

[81] South Central Priorities Committees Policy statement 9: Electrical stimulation (including functional electrical stimulation) for upper and lower limb dysfunction. May 2008 www.southamptonhealth.nhs.uk/aboutus/publications/publicationscheme/policysandprocedures/clinical policies/?assetdetesctl1625276=117171&categoryesctl1625276=1887

[82] NHS North West London, Planned procedures with a threshold policy: Functional electrical stimulation. August 2011. www.northwestlondon.nhs.uk/_uploads/documents/alldocuments/ppwt/policies/30-functional-electrical-stimulation.pdf

NHS Trafford	FES as a low priority treatment and will only consider funding 'on the grounds of clinical exceptionality'
The Milton Keynes, Oxfordshire, Berkshire East, Berkshire West and Buckinghamshire (MOOB) Priorities Committee	Funding for FES in drop foot of central origin should remain a low priority[83]

[83] South Central Priorities Committee (Milton Keynes, Oxfordshire, Berkshire East, Berkshire West and Buckinghamshire PCTs) Policy Statement 185; [MOBBB Statement No.22] Functional Electrical Stimulation in drop foot of central origin (October 2010)