

Buyers' guide

Functional electrical stimulation for drop foot of central neurological origin

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- Introduction 3
- Technical considerations..... 8
- Operational considerations..... 13
- Economic considerations 24
- Purchasing..... 26
- Acknowledgements 28
- Glossary..... 30
- References..... 32
- Appendix 1: EU procurement procedure 36
- Appendix 2: Literature review methods 39
- Author and report information..... 43

CEP buyers' guides are intended to provide prospective purchasers of healthcare products on the UK market with general guidance on the technical, operational, and economic considerations to be taken into account in selecting the most appropriate product where a range of similar products exists. They do not include product-specific information, which is published separately via market reviews (which contain product specifications only) or evaluation reports (which contain additional technical and / or user evaluation data). Readers are encouraged to check CEP's web site for updates.

Scope

This buyers' guide is restricted to the application of functional electrical stimulation (FES) for drop foot of central neurological origin, although other potential uses of FES are discussed briefly. The guide summarises the clinical evidence, and the operational, technical and economic considerations which impact on purchasing decisions and the provision of FES services in the UK.

It should be noted that individual FES systems will not necessarily offer all of the capabilities mentioned in this guide. Device-specific information is provided in CEP's associated market review [1].

Background

Functional electrical stimulation (FES) is the application of electrical stimulation to nerves in order to produce muscle contractions. It is used to treat the effects of upper motor neurone lesions resulting from conditions such as stroke, cerebral palsy, multiple sclerosis or spinal cord injury. The stimulation may be from electrodes on the skin surface, or from implanted electrodes placed directly around the nerves.

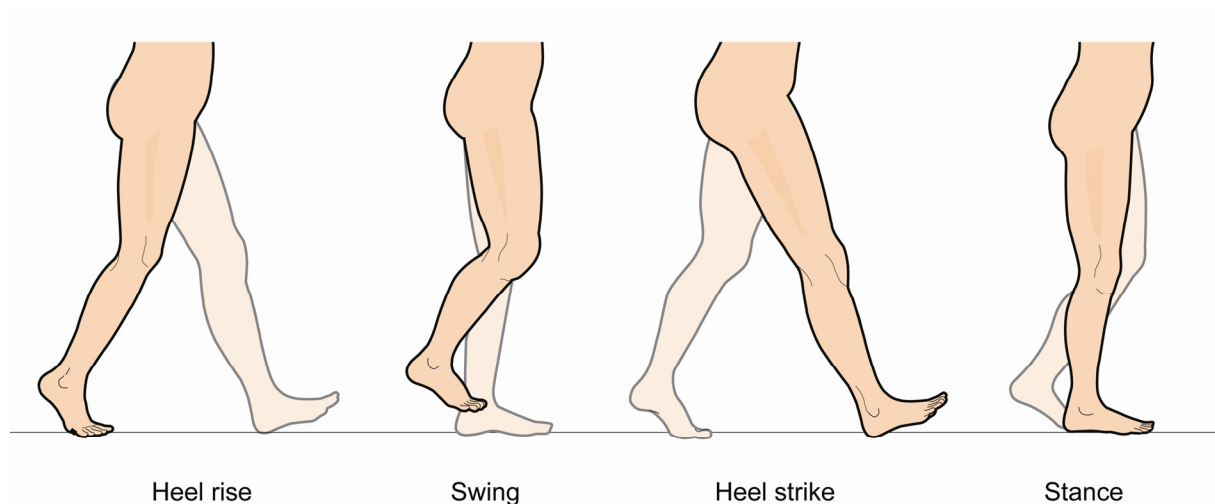
FES is not normally suitable for patients with lower motor neurone lesions, such as polio or motor neurone disease.

Drop foot is the inability to lift the foot and toes during walking. Central neurological origin means that the drop foot is due to damage to the central nervous system, such as might arise from stroke, cerebral palsy, multiple sclerosis, spinal cord injury, or other less well known conditions such as familial spastic paraparesis. [2].

During normal walking, the legs alternately move forwards (swing phase) or stand supporting the body (stance phase). There is a brief overlap of stance phases where both legs are supporting the body (figure 1). During each step, the heel leaves the ground first, followed by the rest of the foot. The leg then swings forward with a bent knee and flexed foot. At the end of the step the knee is straightened and the heel

touches the ground (heel strike). The rest of the foot is then gradually lowered to the ground and the leg and body come forwards until they are above the foot.

Figure 1. Typical gait cycle showing heel rise and heel strike



Drop foot means that the foot does not flex sufficiently during walking, and the toe tends to drag on the floor. The resulting difficulties in walking, such as slowness, tripping and tiredness [3-5], lead to a reduction in mobility and independence. NICE [6] states that *'the ability to negotiate the environment independently is fundamental to all aspects of daily life and almost all aspects of social participation are dependent upon adequate mobility. Limitation in mobility is one of the prime determinants of the amount (time and number of people) of 'care needs', whether given by family or paid carers'*.

Current treatment options for drop foot, other than FES, are primarily physiotherapy and the use of an ankle-foot orthosis (AFO). An AFO is a passive device that is worn on the lower leg and foot to improve gait and control the motion of the foot. There are many different designs of AFO available, with varying amounts of flexibility. AFOs will support the foot and ankle, but will not activate the users own muscles to enhance walking. Additionally medical therapy (such as baclofen and botulinum) or surgery may sometimes be used.

FES can be used for many purposes. It is used as both a physiotherapy tool during sessions to exercise muscle and improve function, and as a rehabilitation aide to be used in daily activities. Its use is not confined to drop foot, FES may be used on many areas of the upper and lower limbs. Examples include improving stability when standing, reducing hand spasticity and improving hand function.

FES has been provided in the UK for fifteen years [7] and its use for drop foot has been known for longer [8]. Despite this its use is not very widespread and many people cannot access FES without travelling large distances, or are unaware of the service, or cannot obtain funding. There are many potential users that could benefit from increased levels of service provision in a greater number of locations.

How FES works

FES requires that there are functional nerves in the limb (peripheral nerves), since it is the nerve that is stimulated. To stimulate the muscle directly would require a much higher current. The nerve stimulation then causes muscle contraction, in the same way as for a normally functioning limb. The nerve may either be stimulated through the skin by a surface electrode, or directly by an implanted electrode.

The stimulation intensity required will vary depending on the electrical resistance between the electrode and the nerve, amongst other factors. This varies with the type of electrode used and the tissue through which the stimulus passes. Skin has high resistance and must be clean and have good contact with the electrode. Gel is normally used and may be an integral part of the electrode. Fat also has a high resistance and larger patients will require higher intensity of stimulation, as will patients with oedema (fluid retention causing swelling in limbs) where there is a lot of tissue between the electrodes and the nerves. Implanted electrodes use a much lower intensity since they are in direct contact with the nerves to be stimulated.

A sensor detects a trigger event in the walking pattern, such as the heel leaving the ground (heel rise). This starts stimulation of the nerves and results in muscle contractions. Stimulation is stopped by a second trigger event, such as the return of the heel to the ground at the end of the step (heel strike).

The clinician is able to customise the stimulation to suit the user. The user can control some basic functions such as stimulation intensity. The intensity of stimulation required may vary throughout the day (eg due to tiredness).

National guidance

NICE published guidance on FES in 2009 [9], indicating that the procedure is sufficiently safe and effective to be routinely offered as a treatment option provided that the patient understands what is involved and agrees to the treatment, and the results of the procedure are monitored.

Where electrodes are to be implanted a healthcare team including rehabilitation specialists should be involved in deciding which patients should have the procedure [2].

In 2005 NICE guidance on the management of multiple sclerosis [6] emphasised the importance of mobility and independence, stating that *'Physiotherapy treatments aimed at improving walking should be offered to a person with MS who is, or could be, walking'*.

The government's *National Stroke Strategy* [10] states that *'Long-term assistance, review and rehabilitation are essential if people are to lead autonomous lives and overcome physical, psychological and attitudinal barriers and to engage and participate in community activities.'* It mentions FES as a new technology with which service providers need to keep pace.

The *National Service Framework (NSF) for long term conditions* [11] includes a quality requirement, QR7: *'People with long term neurological conditions are to receive timely, appropriate assistive technology/equipment and adaptations to accommodation to support them to live independently, help them with their care, maintain their health and improve their quality of life'*.

The Multiple Sclerosis Society has published guidance [12] for patients on how to access FES treatment. It explains what FES is, summarises the evidence for its use, and includes several case studies.

All medical devices should be CE marked, and British standard *BS EN 60601-2-10:2001 Part 2.10: Particular requirements for the safety of nerve and muscle stimulators* [13] sets out standards for FES devices.

Literature review

We reviewed published literature, using the methods described in appendix 2, to identify significant studies published since the NICE evidence review [9]. Particular consideration was given to the following technical factors:

- comparison of implanted with surface electrodes
- comparison of heel switches with alternatives such as accelerometers or tilt sensors
- comparison of wired with wireless systems
- the importance of flexibility in electrode positioning.

We found no studies that directly addressed these concerns. There were several papers that gave background information and these are referenced as appropriate. We found no major study results published since the NICE evidence review [9]. However, there was one literature review [14].

There is no conclusive evidence on the relative performance of different FES systems, and many of the decisions to be made in choosing equipment are likely to be based largely on user preference and clinical judgement.

FES devices consist of the following components:

- stimulating unit -- providing a pulsed electrical signal
- clinician control – enabling the device parameters to be set for the user
- user control – normally controlling the intensity and on/off switch
- sensor -- to detect gait events
- electrodes – the point at which the signal is applied to the patient.

These components may all be contained within one physical unit, or in several separate devices. For separate components, communication may be wireless or wired.

Stimulation parameters

Waveform

FES provides stimulation, in the form of a rapidly pulsed electrical current, for the duration of the swing phase in the affected leg. The waveform used in FES stimulators is normally charge balanced, meaning that there is no net flow of current between electrodes. The pulses may be symmetrical or asymmetrical (figure 2) and this may be fixed by the manufacturer or variable by the clinician. Asymmetrical waveforms are more commonly used [15]. They produce a stronger stimulation and the positions of the active and neutral electrodes can be interchanged to alter muscle responses. Some users report that symmetrical waveforms minimise skin reaction and are more comfortable[16].

Figure 2. Typical FES waveforms [16]

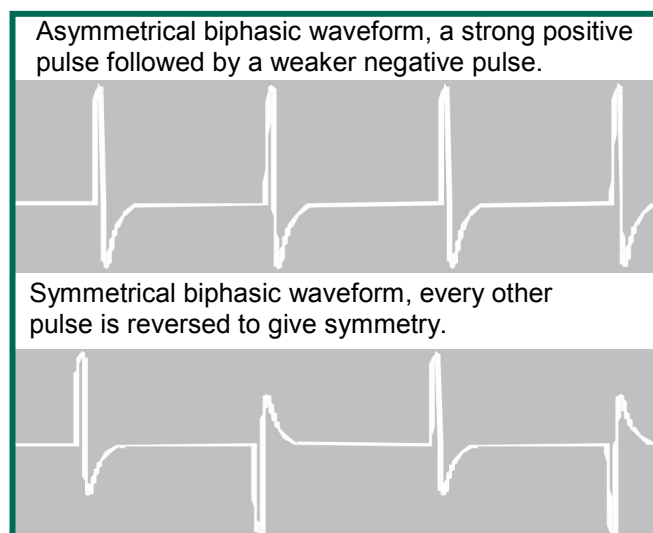
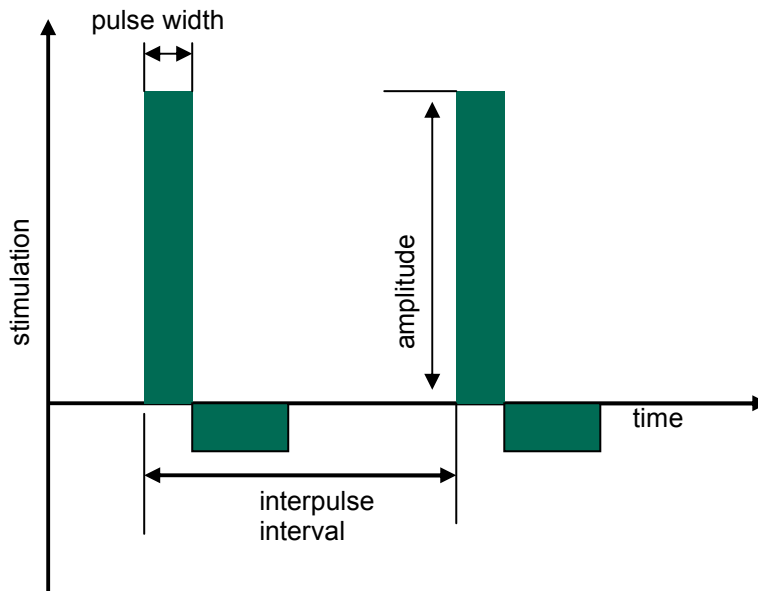


Figure 3. diagram to illustrate pulse width, amplitude and interpulse interval



Amplitude, frequency and pulse width

These three parameters (figure 3) can be used to vary the muscle contraction strength. Contraction strength will also be dependent on many other factors such as limb size, oedema and placement of electrodes.

Pulse width is the length of time that the pulses last. Interpulse interval is the time from the start of one pulse, to the start of the next, and the inverse of frequency ($1/\text{frequency}$). Amplitude is the strength or magnitude of the current applied in the pulse. All stimulators allow the user to adjust the stimulation level. In some cases it is the pulse width that is adjusted, in others the amplitude. The increase in stimulation experienced is similar by either method.

The frequency of the current is also important. If it is too low then the muscle twitches visibly, if it is very high the muscle fatigues rapidly. A frequency of around 40 Hz (40 pulses per second) is usually used to give a sustained contraction without tiring the user too quickly. It can usually be adjusted by the clinician if required.

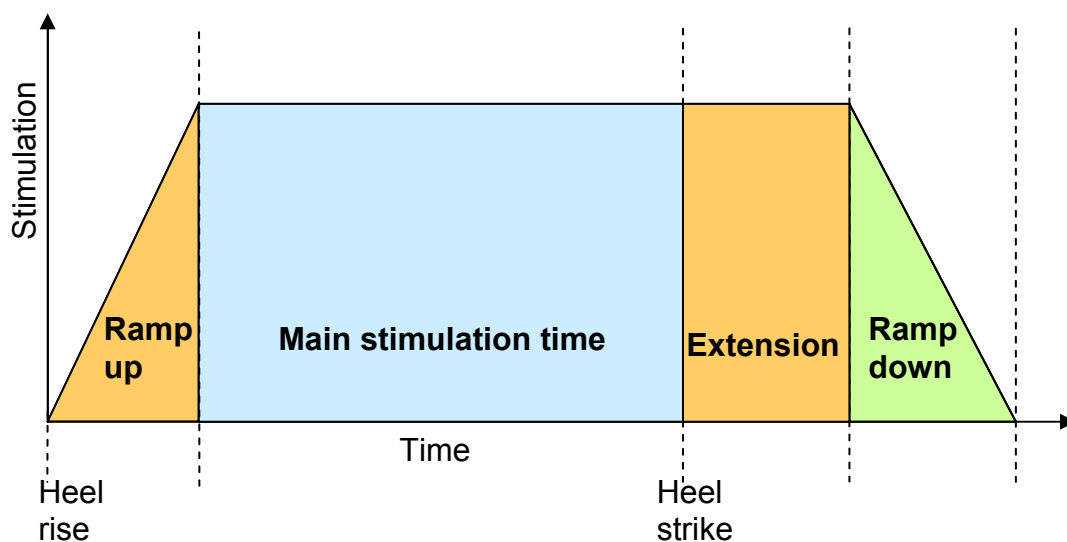
Ramp up, ramp down and extension

Ramp up and ramp down are the gradual rise or fall of stimulation intensity (figure 4). Extension is the continuation of the stimulation after heel strike. The duration of these parameters is normally determined by the clinician during set up. Alternatively the extension duration may be fixed as a percentage of the stride time, as measured by the stimulator. Where a percentage is used the extension times will be shorter when gait is faster.

Some ramping is desirable for comfortable stimulation. Shorter ramp times (up and down) will suit faster walkers. Longer ramp up times may be useful to reduce calf stretch reflexes and avoid muscle spasms that can be triggered by rapid stretching.

Extension is used to gently lower the foot to the floor at the end of the step. This avoids foot slap, where the foot rapidly falls down to the ground after heel strike. Stability may also be improved at the end of the step by using extension and ramp down

Figure 4. diagram to illustrate typical FES stimulation pattern



Changes in stimulation level

Most devices follow the pattern shown in figure 4. Some devices allow programming for stimulation level to be increased or decreased at different points in the stride.

Delay

Delay is the time from the trigger to the start of stimulation. For a standard drop foot set-up this would be zero. Where alternative muscle groups are stimulated, a delay may be required.

Max time

This is the maximum time that stimulation will continue. It is also known as the time out period. If the end trigger is not sensed, stimulation will stop after a set duration. An option to allow stimulation to continue indefinitely can also be useful, for instance if stimulation is to be used for muscles used for standing.

Wait time

This is the time that must elapse after one stimulus ends and before the next commences. It is intended to ensure that there is sufficient time allowed for each step to be completed by preventing unintentional stimulation during stance.

Sensors

Sensors commonly used include on/off foot switches, force sensing resistors, and tilt sensors or accelerometers. The type used is largely dependent on the trigger chosen.

Foot switches and force sensing resistors are commonly used on the heel and detect the heel rise and heel strike. They are normally placed under an inner sole in the shoe and require that a shoe is worn. A foot switch will normally start stimulation when pressure is removed, and stop stimulation when pressure is replaced. It does not measure the amount of pressure applied.

A force sensing resistor measures the pressure applied. This enables the stimulator to calculate further information about the user's gait. Calculations may include adjustments to the pressure required for triggering when walking on softer ground, or differentiating between inadvertent foot strikes and genuine steps.

Tilt sensors are normally a form of accelerometer. They measure tilt, or angular displacement, using the action of gravity on the sensor. The method varies with the sensor design used. Sensors are typically placed on the leg, and may be contained in a single device [17]

Tilt sensors require some processing of the data by the stimulator device, in order to recognise the correct part of gait in which to activate stimulation. This may involve collecting data while the user is walking and using software to analyse this and set a trigger threshold.

There are no clinical trials comparing the effectiveness of different sorts of sensors, although several papers describe the use of each [7,17].

Some papers describe tilt sensors placed on the trunk [18] and also complex systems of tilt sensors on various parts of the leg [19-21]. Research has been done using both sensory nerve signals and muscle activation, or electromyography (EMG), to detect trigger events [22,23]. At present this is not used in any stimulators available in the UK.

Power

All FES devices require battery power. There is a choice between disposable or reusable standard batteries or a custom rechargeable power pack. Reusable batteries will not last as long as a disposable battery before they need recharging. However, rechargeable batteries for all stimulators currently on the market allow at least 12 hours use (allowing overnight charging) and may not need charging for several weeks.

To treat drop foot the peroneal nerve is normally stimulated. The standard positions for surface electrodes are on the lower leg (figure 5). Placement is adjusted to give the required movement of the foot.

The main considerations are summarised in table1.

Triggering

Triggering is how the system recognises that it is the right time in the gait cycle to apply stimulation. This is normally a choice between heel rise/strike and the angle of the leg. The choice is dependent on the user's gait characteristics and preferences that affect the choice of FES system.

Heel rise and heel strike on the affected foot can be used where there is good contact between the heel and ground during stance, and where the heel is the first part of the foot to leave the ground, and the first to return to the ground. This is the case during normal gait, but may not be the case in all FES users. This is a commonly used triggering method [24]. Triggering may also be from the non-stimulated limb, if this foot has a more readily detected heel rise and strike. In this case stimulation starts on heel strike, after some delay.

Tilt sensors, to detect the angle of the lower leg, can be used when there is sufficient flexion of the leg during gait. Where the leg remains very straight during walking the triggering may be ineffective. One advantage of tilt sensors is that they do not require a component in the shoe. This means that the stimulator may be used without shoes, and eliminates the need for wires or other means of communication between the foot and the stimulator.

The trigger methods available depend on the FES system selected.

Ease of use

This is very important since many users may also have restricted upper limb mobility. Many users who have had strokes will need to set up the equipment with only one hand. They may also be elderly with reduced dexterity and poor eyesight. If setting up the device is too difficult then people may cease to use it {Taylor 79 /id; Taylor, 1999 156 /id}.

Figure 5. Peroneal nerve and electrode positions for drop foot FES

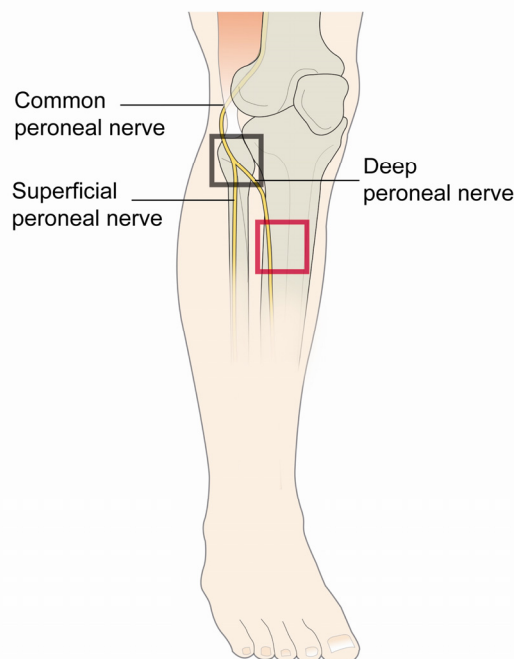


Table 1. Summary of main operational considerations

Communication	Wires <ul style="list-style-type: none"> • low cost • fiddly to set up • trailing wires visible. 	Wireless <ul style="list-style-type: none"> • easy to set up • no visible wires • remote units must be powered. 	Single location <ul style="list-style-type: none"> • simple to set up • may limit other options.
Sensor	Tilt on leg <ul style="list-style-type: none"> • no shoes needed • need sufficient leg flexion • sensor included in device • walking trials and data analysis to set trigger. 	Foot switch <ul style="list-style-type: none"> • shoes required • simple, low cost • separate sensor required. 	Force sensor on foot <ul style="list-style-type: none"> • shoes required • enables variable trigger activation threshold • separate sensor required • device must calculate trigger activation threshold.
Electrode positioning	Implant <ul style="list-style-type: none"> • permanent positioning • surgery required. 	Cuff <ul style="list-style-type: none"> • electrode position fixed on cuff • cuff must be correctly orientated on leg • may be bulky for some trousers etc • cuff pressure may improve electrode contact. 	By user <ul style="list-style-type: none"> • user must be trained • relies on user skill • flexible placement, allowing clinician to utilise alternative electrode positions, or stimulate other muscle groups.
Clinician features	Clinician unit <ul style="list-style-type: none"> • additional unit required • store user data. 	Stimulator unit (analogue) <ul style="list-style-type: none"> • adjust parameters directly • can seem complicated when unfamiliar • no recording of data. 	Stimulator unit (digital) <ul style="list-style-type: none"> • scroll through menus to set up • data stored on patient unit. Recorded in notes by clinician..

Electrode positioning

Correct electrode positioning is critical to get the desired foot movement. There are three approaches:

- implant the electrodes, placement is then permanent and fixed
- place the electrodes on a cuff that fits around the calf. The electrodes are fixed on the cuff and then if the cuff can be replaced in the same position on the leg then electrode position will be correct. Cuff positioning can be made simpler by shaping it, for instance with a curved section that fits around the patella (knee cap). The chosen electrode positions must fit within the cuff, meaning that alternative stimulation sites cannot be used. Good contact between skin and electrode is important, and it is possible that use of the cuff improves this contact.
- train the user to place the electrode in the correct position. This is reinforced during the frequent check up appointments (common when first using FES), by photos, diagrams and marking the electrode position on the leg during the initial fitting. This method allows clinicians to use alternative electrode positions, and also to stimulate different muscle groups.

All of these methods have been used successfully and the choice will often depend on the preferences, or needs, of the user as well as the other characteristics of the chosen system.

Location

The user control and stimulation units may be placed on the leg, on a waistband or in a pocket. Where the device contains a tilt sensor it is normally placed on the leg.

Placement on a waistband or pocket allows the user to adjust the intensity and switch the unit on or off whilst standing, but requires additional units and either wires or wireless technology for communication.

Where the controls and stimulation unit are on the leg the user must sit down to adjust the controls. This removes the need for communication between units since they may be housed in the same device. The device may be bulky for wearing under some clothes.

Communication between system components

There are three approaches commonly used:

- wired connections, requiring the user to connect wires at each use. Wires are visible if shorts or skirts are worn
- wireless communications, requiring power for all communicating units
- integration of all components, avoiding the need for remote communication.

Controls

These should be clearly visible and easy to operate with reduced dexterity. Controls may be push buttons with light emitting diode (LED) displays or dials with printed values.

Unintentional activation

When sitting or standing, accidental triggering of the device is undesirable. This can be avoided by the user putting the device on pause, or by the device recognising the difference between an intended step and an inadvertent footstrike. After pausing, the units should retain the previous settings.

Standby and sleep modes

These modes are designed to save energy and avoid unintentional stimulation. If the unit is not used for some time, it may go into standby, and this may be followed with a sleep mode or switching off. The user needs to be aware how the unit reactivates and if the intensity settings will remain the same, or reset to initial levels. In the morning, or when rested, users may require lower settings.

Battery changes

Users must be able to recharge or change batteries as needed. Clinicians or technicians may be required for some additional infrequent battery changes.

Implanted or surface electrodes

The vast majority of FES users in the UK at present use surface electrodes. Implanted electrode systems require surgery, have a relatively high cost and are normally only recommended for people with an established use of FES. They have advantages for users who cannot tolerate surface electrodes because of skin sensitivity or who have difficulty in correctly placing electrodes. They may also be

desirable for long term, frequent users of FES due to minimising the amount of equipment and set up time..

Flexibility

Drop foot is one of the most common uses of FES and the starting point for many new services. However there are many other potential uses of FES and this should be considered when starting a service and purchasing equipment.

Consumables

Surface electrodes need replacing regularly. Other items such as foot switches may also need replacing occasionally. The price and expected life of these must be included in the equipment cost. Some devices require that electrodes are purchased from the device manufacturer.

Clinician training

Clinician skill, experience and knowledge are very important factors in FES being effective for the user. Training at present is only offered by device suppliers. The available training should be part of the purchase decision. This may include the training in FES or may be restricted to how to use the product, assuming staff have an understanding of FES techniques. Training may also be required for new members of staff at a later date, or to update or refresh current staff.

Where implanted electrodes are used it is essential that surgeons are appropriately trained in implanting the device. Manufacturers' recommendations for training should be followed and the cost of this training (including surgical staff hours) should be included when considering the device.

Maintenance

The only routine maintenance required is generally basic cleaning, charging and replacing batteries and replacing consumable items. This can be completed by the user.

Users may depend on the device for mobility so there should be some means of replacing a faulty device during repair or ensuring that repair is rapid.

Purchase decisions should take into account the support available if a device is faulty, including the charges, time taken for repairs, and the availability of replacement devices.

Exercise mode

This allows the user to exercise muscles while seated. This may increase muscle strength, range of movement and tolerance of the stimulation sensation. It may also reduce oedema, spasticity and pain. The exercise mode might be used to enable someone to start using FES for functional movement, to increase the length of time they use FES, or to alleviate other symptoms.

The FES device applies a regular on/off cycle of stimulation for a set amount of time. The stimulation parameters may be adjustable to different levels during exercise than for walking.

Clinician features

Clinicians need to be able to adjust the device parameters to suit the user. They may also want to record these parameters and monitor the amount of use that is made of the device over time.

Parameter adjustment may be made directly on the main stimulation unit or via an additional clinician unit such as a PC or a dedicated personal digital assistant (PDA). Where a clinician unit is used there is the possibility to store user data centrally, uploading stimulator parameters to the patient device and downloading usage data. If programming is on the main stimulation unit these data will have to be manually recorded from the unit if a record is required. However, no additional clinician unit need be purchased.

Setting up a FES service

Small FES services are starting up in many locations. Patients are treated on an individual basis and reports are sent to local health boards to request funding. As the number of patients increases, a fully funded FES service may become a more cost-effective option.

In order to set up a FES service, a valid business case should be produced. The business case outlines the reasons for the new service, considers the options compared with existing arrangements, describes the expected benefits, costs and timescales for implementation, and how the changes in service will be evaluated.

Calculating patient numbers

It is important to predict the number of patients that will be using the new service. Patients with neurological conditions such as stroke, spinal cord injury, cerebral palsy and MS among others, can be considered appropriate candidates. FES can be used

to stimulate the nerves on upper and lower limbs, improving limb function, circulation and mobility and so is also suitable for a number of disabilities other than drop foot.

The number of expected patients can be estimated by different methods. Existing services have either used:

- the number of referrals previously received per month in addition to the number of patients currently treated to estimate the number of future patients
- population catchment areas to determine potential patient numbers, although this typically gives a higher number of patients than would actually be seen. (One estimate is that approximately 0.1-0.2% of the total UK population may benefit from FES [27].)

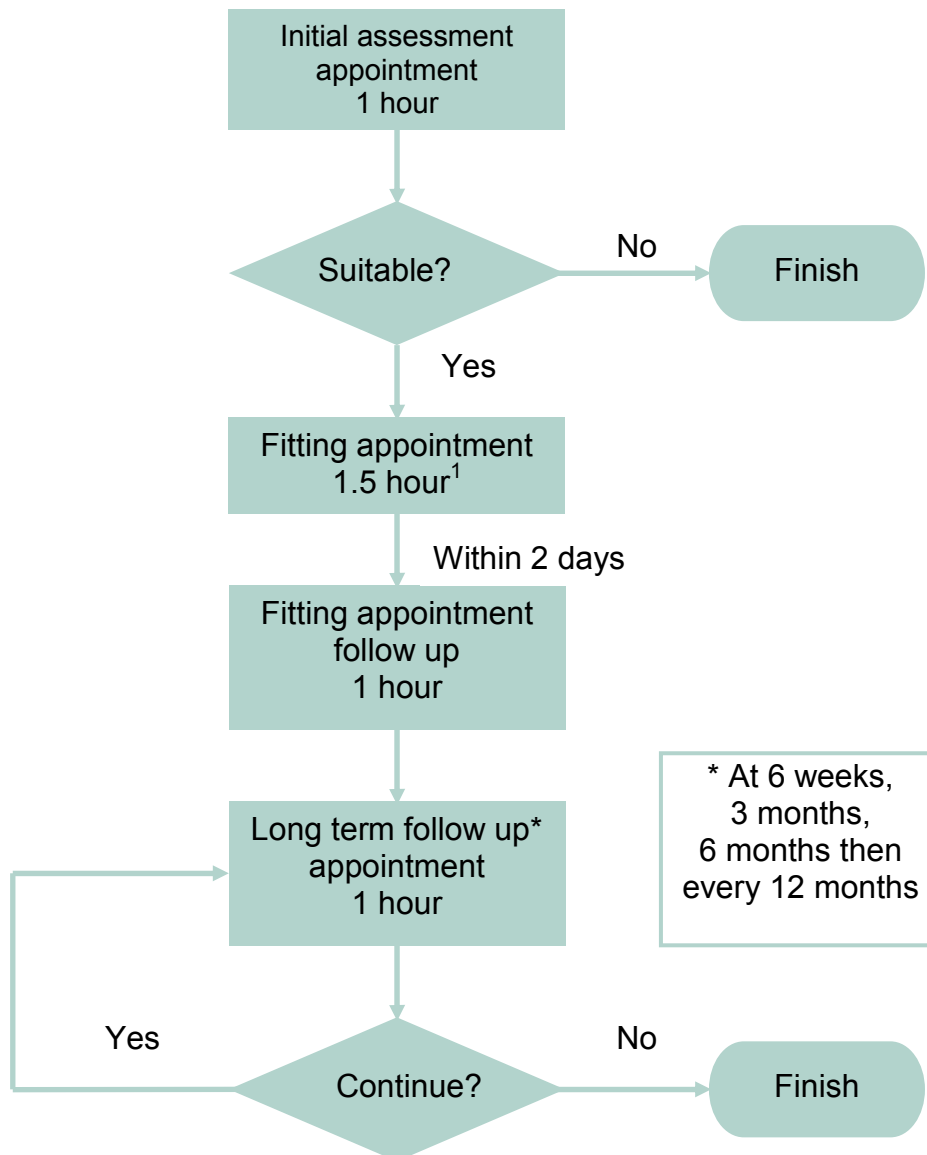
Patients deemed suitable for FES typically require treatment until there is either a deterioration of their condition (eg MS), or an improvement of their condition (eg stroke) so that they no longer require FES.

Clinical pathway

A typical clinical pathway for a patient who has been referred for FES using surface electrodes is shown in figure 6. The pathway may vary considerably between clinics and for different devices. The patient attends an initial assessment to see if a FES device is suitable. This would usually last one hour. If suitable, the patient attends a clinic to have the device fitted at a subsequent appointment. The fitting appointment can last up to an hour and a half. After their initial fitting, patients will be required to return to the clinic within a short period of time, typically the next day, to assess if they have managed to fit the electrodes correctly and can use the device confidently. If the assessor is satisfied that the patient is able to correctly fit the electrodes, they are then seen at 3 months, 6 months, and then annually until the patient ceases treatment. Telephone support is sometimes available, and some assessments can be made over the phone if the patient is in a remote location. Appointments after the fitting appointment usually last one hour. Telephone support can be important in addition to appointments, allowing problems to be identified and addressed rapidly.

The clinical pathway for systems using implanted electrodes would be different from that shown in figure 6, although typically the patient would have been fitted with a surface electrode system prior to consideration for implanted electrodes

Figure 6. Typical clinical pathway for FES patients



Staff

FES clinics are usually staffed by physiotherapists, clinical scientists, or both, with administrative support for patient appointments and ordering of equipment. A patient would typically need to be seen for six and a half hours of appointment time in the first year of treatment, and if there are no problems, one hour in subsequent years. The number of staff required to service the clinic would depend on the number of patients. One full time clinician would typically manage 130² patients in a year.

¹Fitting and follow up appointments may be longer if more than one channel is being set up

²In a survey of 10 FES services for this report, the number of patients seen by one whole time equivalent clinician ranges from 116 to 223, with a median of 130.

Training

Staff should receive training from each of the manufacturers whose devices they will be fitting. If there are any new devices or upgrades of existing devices then further training should be sought. In addition to training, experience is important in achieving a good stimulation result. Ideally staff should be setting up devices and training patients in their use on a regular basis. Staff who do not fit devices on a regular basis should receive a refresher course.

Accommodation

Ideally, a large room is used that would fit a 10m walkway with space at each end and each side. This would allow cameras to be set up with sufficient field of view to record the patient's gait from the front and from the side. It is also advisable to allow some extra length before the walkway for gait to stabilise before measurements. A well lit room with blackout blinds on the windows will ensure consistent lighting levels for video recording and patient privacy. The walking area should be clearly marked with enough room for patients to use walking aids unhindered.

Recording a patient using a video camera is not essential in setting up a FES service but can be a valuable tool in assessing a patient's gait and progress. There should also be space for a desk, computers, equipment and stationary storage and an examination area with seating for the patients and clinicians. A small waiting area for patients is also needed.

Equipment

A basic FES clinic can be run with very little equipment. The FES devices should be available at the clinic for the patient to try during assessment. Some clinics stock additional devices ready to give to patients immediately whilst other clinics order devices as required. Most clinics have a supply of consumables such as electrodes, footswitches and footswitch leads.

In addition to the devices and consumables, the equipment required to run a clinic would ideally include: a video camera to record a patient's gait, a digital camera to record the position of the electrodes on the patient's leg, a stop watch and heart rate monitor to record outcome measures, a computer for the administration of patient appointments and a separate computer for the clinician to record patient data at each appointment with software to analyse the video footage of the patient's gait.

Measuring treatment outcome

Current FES service providers stated that they measured patient benefits using:

- video footage of the patient walking, filmed simultaneously from the front, rear, and side. Patients are filmed before and after the FES device has been fitted and at all of their follow up appointments. Walking speed and improvement in gait are assessed
- walking speed, calculated by timing the patient over a known distance using a stopwatch
- physiological cost index (PCI) to measure the effort of walking before and after treatment. PCI is calculated from the patient's heart rate during a walk over a set distance
- clinical examinations before and after the device has been fitted, including assessments of muscle strength, spasticity and range of movement to record any improvements
- goal attainment scores, set by the patient and the clinician and assessed at each appointment
- questionnaires designed to assess changes in quality of life.

Staff questionnaires may also be of value in assessing the performance of a FES service and determining how it might be improved.

Guidance on calculating FES service costs

Table 2 outlines the main costs of setting up a FES service. There may be other local costs which have not been identified here.

Table 2 Guidance on calculating FES service costs

Capital costs	
<ul style="list-style-type: none"> • Clinician equipment 	FES device programmer (if applicable) Walking aids Couch, goniometer, stopwatch Video camera and /or digital camera Blackout blinds
<ul style="list-style-type: none"> • Assessment equipment 	Range of FES devices for fitting to patient
<ul style="list-style-type: none"> • Training 	Each member of staff requires training prior to fitting FES devices
Operating costs	
<ul style="list-style-type: none"> • Accommodation 	Rent
<ul style="list-style-type: none"> • Utilities 	Electricity, gas, water
<ul style="list-style-type: none"> • Consumables 	Heel switches, electrodes, leads, batteries, stationary
<ul style="list-style-type: none"> • Clinician staff (physiotherapist and / or clinical scientist) 	Allow a minimum of five and a half hours clinic time per patient in their first year and one hour in subsequent years
<ul style="list-style-type: none"> • Training 	New members of staff will requires the initial training for any devices they will fit
<ul style="list-style-type: none"> • Administration staff 	Management of FES service, day to day running of clinic, patient notes

Published evidence on cost-effectiveness

Following a systematic search of recognised electronic databases in November 2009 we found a single cost utility study using 1996 data [28]. This study looked at the Odstock Dropped Foot Stimulator (ODFS), an external device with surface stimulators as used for drop foot following stroke. Results suggested that there was a 0.065 QALY gain with FES versus 0.023 with physiotherapy, at a cost per QALY of £10,037 with five years continuous use. These calculations were based on a cost of £166 per use (including the cost of building and maintaining the stimulator and the supply of consumables) and a mean cost per year of £431.60 for use over five years).

New economic model

A new model for estimating the cost effectiveness of the ODFS when used for stroke patients using 2009 cost data was developed. The cost-utility model takes a payer perspective (NHS) and reports outcomes as cost per quality adjusted life years (QALYs). Costs and outcomes were not discounted. Both a one year and a five year time horizon were used for the model. Full details are given in the CEP economic report [29].

Cost inputs to the model

Costs are based on an assessment appointment costing £140, and on a clinic model in which the cost of the FES device are incorporated in the ongoing clinic charges. Each ongoing clinic appointment has been estimated at £300. The model includes an assumption that patients all have five clinic visits in the first year, and between one and two in the second and subsequent years. In the base case it is assumed that 50% of patients have two clinic visits in each ongoing year, and 50% will have one clinic visit each year. Other charging arrangements can be used in the model to test how different cost structures affect incremental cost-effectiveness.

Other inputs to the model

Utility is estimated from studies reporting quality of life measures associated with functional improvements after stroke. Walking speed is the outcome measure from the effectiveness literature used to derive utility. The model was limited by the availability of suitable data, There may be other aspects of quality of life that are improved by the ODFS for which there is no research data. More research is needed in this area.

Summary of results

The conservative base case suggests that FES has cost per QALY in the region of £19,238. In this model the cost per QALY in the first year is in the region of £52,337 and in each subsequent year in the region of £10,964.

Sensitivity analysis undertaken on the static model demonstrated that the model was sensitive to changes in time horizon, and assumptions regarding any gain in health utility. Costs for alternative stimulators can be input into an interactive version of the model to test the effects of varying these inputs on the incremental cost effectiveness ratios.

Discussion

Conservative modelling of functional electrical stimulation using the ODFS for drop foot due to stroke shows that it is likely to be cost effective compared to no treatment. There is significant potential to organise services to optimise that cost-effectiveness. Selected patients should be able to commit to long term treatment

Purchasing procedures

The Trust Operational Purchasing Procedures Manual provides details of the procurement process [30].

European Union procurement rules apply to public bodies, including the NHS, for all contracts worth more than £90,319 (from January 1st 2008) [31] (appendix 2). The purpose of these rules is to open up the public procurement market and ensure the free movement of goods and services within the EU. In the majority of cases, a competition is required and decisions should be based on best value.

NHS Supply Chain (www.supplychain.nhs.uk), a ten year contract operated by DHL on behalf of the NHS Business Services Authority, offers OJEU compliant national contracts or framework agreements for a range of products, goods and services. Use of these agreements is not compulsory and NHS organisations may opt to follow local procedures.

Sustainable procurement

The UK Government launched its current strategy for sustainable development, *Securing the Future* [32] in March 2005. The strategy describes four priorities in progressing sustainable development:

- sustainable production and consumption – working towards achieving more with less
- natural resource protection and environmental enhancement – protecting the natural resources and habitats upon which we depend
- sustainable communities – creating places where people want to live and work, now and in the future
- climate change and energy – confronting a significant global threat.

The strategy highlights the key role of public procurement in delivering sustainability.

Production and packaging

FES devices are generally made from all new materials. Most elements of an FES device are designed to be used for several years, minimising the impact of production and packaging. More complex devices require more components and hence increased production, packaging and transport impact would be expected.

Reconditioning

FES devices may state that they may not be used for more than one patient.

Some items such as stimulator units and control units may be reconditioned and reused for several patients, if allowed by the manufacturer. Some simpler devices may also be appropriate for reuse in developing health economies. The ability to directly adjust the device and reducing the number of peripheral items will assist this. Consumables and cuffs are single-patient use.

Use

Power consumption is low for all devices, and this may be further reduced where there is the option of standby or sleep modes. Devices with wireless communication, or additional units for programming require power for the accessory units, increasing the overall power consumption. Use of reusable batteries, where allowed by the device manufacturer, will minimise the impact of the power supply.

All batteries must be disposed of in accordance to the Batteries Directive that came into force in September 2008 [33]. Disposable batteries cannot be sent to landfill. Most users will need to take batteries to a local recycling centre. Using rechargeable batteries minimises the number of waste batteries.

End-of-life disposal

Consideration should be given to the likely financial and environmental costs of disposal at the end of the product's life. Where appropriate, suppliers of equipment placed on the market after the 13th August 2005 should be able to demonstrate compliance with the UK Waste Electrical and Electronic Equipment (WEEE) regulations (2006) [34]. The WEEE regulations place responsibility for financing the cost of collection and disposal on the producer. Electrical and electronic equipment is exempt from the WEEE regulations where it is deemed to be contaminated at the point at which the equipment is scheduled for disposal by the final user. However, if it is subsequently decontaminated such that it no longer poses an infection risk, it is again covered by the WEEE regulations, and there may be potential to dispose of the unit through the normal WEEE recovery channels.

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accelerometer	A device that measures acceleration. This may be due to gravity or movement.
AFO	Ankle foot orthosis, a device, usually made of plastic, which is worn on the lower part of the leg and on the foot. It is used to align the lower leg correctly and control the motion of the ankle and foot, to provide stability and improve gait [5].
amplitude	The amount of current applied.
charge balanced	No net flow of electrical current across the patient.
Discounting	The process used in cost analyses to mathematically reduce future costs and/or benefits/outcomes to their present value. These adjustments reflect that given levels of costs and benefits occurring in the future usually have less value in the present than the same levels of costs and benefits realised in the present.
electrode	Device used to apply electric current to nerves, either directly or through the skin.
extension	Continuation of stimulation for some time after the trigger to end stimulation.
frequency	Number of pulses per second, measured in Hertz (Hz)
gait	Manner or style of walking
heel rise	The moment that the heel leaves the ground at the start of the swing phase.
heel strike	The moment that the heel touches the ground at the end of the swing phase.
oedema	Fluid retention that causes swelling in limbs
pulse rate	See frequency
pulse width	Time that a pulse lasts. This is not the total time that stimulation lasts in the gait cycle.
quality adjusted life year (QALY)	A unit of health care outcomes that adjusts gains (or losses) in years of life subsequent to a health care intervention by the quality of life during those years. QALYs can provide a common unit for comparing cost-utility across different interventions and health problems.
ramp down	Gradual decrease of intensity level at the start of stimulation.

ramp up	Gradual increase of intensity level at the start of stimulation.
tilt sensor	This is normally an accelerometer used to give information on the inclination of the sensor from vertical.
trigger	The signal that starts or stops stimulation
trigger threshold	The value of the signal that is needed for the trigger to function.
utility	The relative desirability or preference (usually from the perspective of a patient) for a specific health outcome or level of health status.

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Lease options

National frameworks are in place for operating leases to help the NHS procure leases more cost efficiently and effectively. Further details are available from the PASA website [35].

EU procedures

The Public Sector Directive (2004/18/EC) has been transposed into UK law via the following statutory instruments:

- the Public Contracts Regulations SI 2006 No.5 (the regulations)
- the Utilities Contracts Regulations SI 2006 No. 6 (not relevant to this guide).

The regulations apply to contracts worth more than £90,319 (from January 1st 2008) [31] over their whole life, and specify the procedures to be followed for public sector contracting, including adherence to strict timetables, requirements for advertising, invitation to tender and the award of contract. Organisations undertaking a procurement exercise covered by the regulations must give all suppliers an equal opportunity to express an interest in tendering for the contract by placing a contract notice in the Official Journal of the European Union (OJEU).

At all stages of the procurement process, the purchaser must be demonstrably fair, as any decision made can be challenged by the unsuccessful suppliers.

Establishing a procurement strategy

To achieve a successful outcome, decisions need to be made on:

- whether an existing contract/agreement can be used
- the need to consider sustainable development issues
- whether EU directives apply
- the type and form of contract
- sourcing potential suppliers
- duration of contract and opportunity to review/extend
- payment schedules
- how to minimise any risks with the chosen strategy, including supplier appraisal and evaluation/clarification of suppliers' bids.

Preparing a business case

A business case should be drafted and approved before conducting any procurement exercise. Further guidance on preparing business cases is available from the Office of Government Commerce [36] and an illustrative example is provided in the *NHS PASA Operational Purchasing Procedures Manual*, Procedure 1-01 [37].

The EU tendering exercise

EU procurements usually take between 4 and 6 months to complete. This needs to be taken into account in the planning stages. The length of the exercise depends on the chosen procedure (open or restricted). Further information is available from the Department of Health [38].

The procurement panel

A multidisciplinary team should be selected to guide the purchase. Representatives from clinical, user, technical, estates and financial areas should be considered.

Identifying potential suppliers

Criteria for supplier selection must be established. A pre-qualification questionnaire, seeking background information (eg on the skills and experience of the service engineers) may be employed as an initial screen to exclude unsuitable suppliers.

Evaluation criteria

Performance specifications should be derived from local operational requirements, and agreed by the procurement panel. They will form the basis for assessing the adequacy of suppliers' technical specifications, provided in response to the technical specification questionnaire.

It is important to have agreed on the performance specifications of the product as they will be used in the adjudication against company specifications.

Requests for features which are supplier-specific are not permitted under the regulations. Very specific features which are not supported by operational requirements are also not allowed.

Award of contract

Following award of the contract to the successful supplier; unsuccessful suppliers may need to be debriefed. This is at the supplier's request.

Buyers must be aware of the 'Alcatel' procedure (see the *Trust Operational Purchasing Procedures Manual* [30], Procedure No.T-08, section 6 - *Mandatory Standstill Period*).

For more information on procurement please refer to the Department of Health Website [39].

Introduction

The recent NICE interventional procedure guidance “Functional electrical stimulation for drop foot of central neurological origin” undertook a comprehensive systematic literature review to consider the efficacy and safety of FES in this context. The search strategy for NICE was used as the basis for the search strategy

Research question

A research question was defined according to the “population, intervention, comparison, outcome” (PICO) structure, described by the University of Oxford’s Centre for Evidence-based Medicine [41] as shown in the table 3 below.

Table 3. Research question

Population	Intervention	Comparison	Outcomes
Patients with drop foot of central neurological origin	Functional electrical stimulation (implanted or surface electrodes)	1. tilt sensors vs foot sensors 2. wires vs wireless technology 3. implanted vs surface electrodes 4. standard drop foot electrode position vs other positions	Clinical studies: <ul style="list-style-type: none"> • walking speed • quality of life measures • Physiological cost index (PCI) • Patient satisfaction • Complications • Continued use of device • Gait analysis Simulation studies Technical studies

Literature search strategy

The section below shows the search strategies that were run on the MEDLINE database (1950-present)

Implanted vs surface electrodes:

- 1 exp electric stimulation therapy/ (30702)
- 2 exp electric stimulation/ (109176)
- 3 ((function\$ or neuromuscul\$ or peripheral\$ or transcutan\$ or electric\$) adj3 stimulat\$).tw. (57685)
- 4 (FES or TENS or NMES or FNS).tw. (7520)
- 5 or/1-4 (168985)
- 6 gait/ (12793)
- 7 exp gait disorders, neurologic/ (2260)
- 8 gait\$.tw. (17545)
- 9 (foot adj3 drop\$).tw. (635)
- 10 (foot adj3 spastic\$).tw. (130)
- 11 or/6-10 (24021)
- 12 exp electrodes/ (61242)
- 13 (electrode\$ adj3 (implant\$ or external\$ or internal\$)).tw. (6513)
- 14 or/12-13 (64971)
- 15 5 and 11 and 14 (151)
- 16 Animals/ (4526199)
- 17 Humans/ (11087380)
- 18 16 not (16 and 17) (3377684)
- 19 15 not 18 (135)

tilt vs foot switch:

- 1 – 11 as above
- 12 ((foot\$ or heel\$) adj3 (sensor\$ or switch\$ or trig\$)).tw. (283)
- 13 (tilt\$ adj3 (sensor\$ or switch\$ or trig\$)).tw. (47)
- 14 or/12-13 (328)
- 15 Animals/ (4526199)
- 16 Humans/ (11087380)
- 17 15 not (15 and 16) (3377684)
- 18 (accel\$ or gyro\$.mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier] (119587)
- 19 14 or 18 (119884)
- 20 5 and 11 and 19 (54)
- 21 20 not 17 (49)

Electrode position

- 1 – 11 as above
- 12 5 and 11 (868)
- 13 exp electrodes/ or exp electrodes, implanted/ (61242)
- 14 electrode\$.mp. (85096)
- 15 (placement or position or location or site).mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier] (866247)
- 16 13 or 14 (104277)
- 17 15 and 16 (11950)
- 18 Animals/ (4526199)
- 19 Humans/ (11087380)
- 20 18 not (18 and 19) (3377684)
- 21 12 and 17 (37)
- 22 21 not 20 (34)

wire vs wireless

- 1-11 as
- 12 5 and 11 (617)
- 13 Animals/ (1909528)
- 14 Humans/ (5178019)
- 15 13 not (13 and 14) (1268056)
- 16 exp Telemetry/ (3003)
- 17 (wireless\$ or radio\$ or telemetr\$).mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier] (367717)
- 18 16 or 17 (367717)
- 19 6 and 12 and 18 (6)
- 20 19 not 15 (6)

In addition, searches were run on Web of Science, CINAHL, EMBASE, and Medline In-Process. A request was also made for stakeholder organisations to identify unpublished studies. These methods identified 212 studies that might be of interest.

Study eligibility criteria

Studies that compared FES devices, or aspects of FES devices could be included. These were restricted to English language and human subjects.

16 papers were identified for further scrutiny. The studies were summarised in a standard format and any relevant studies were assessed for quality..

Results

Although there are many case studies, and some trials that look at FES, these tend to look at the efficacy of FES treatment, using one particular FES device. There were no studies found that directly compared FES devices, or aspects of FES devices.

Conclusions drawn from the evidence

There is an inadequate volume of high quality evidence comparing different FES devices. There is no study that compares any of the devices currently marketed in the UK.

Buyers' guide: Functional electrical stimulation for drop foot of central neurological origin

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About CEP

The Centre for Evidence-based Purchasing (CEP) is part of the Policy and Innovation Directorate of the NHS Purchasing and Supply Agency. We underpin purchasing decisions by providing objective evidence to support the uptake of useful, safe and innovative products and related procedures in health and social care.

We are here to help you make informed purchasing decisions by gathering evidence globally to support the use of innovative technologies, assess value and cost effectiveness of products, and develop nationally agreed protocols.

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