NICE advice

ODFS Pace and Pace XL functional electrical stimulation devices for treating drop foot

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Summary

The Odstock Dropped Foot Stimulator (ODFS) Pace and Pace XL devices are functional electrical stimulators indicated for treating drop foot relating to neurological conditions. They can be used as an alternative or adjunct to orthotic devices or other walking aids, or to provide a longer term therapeutic effect. Relevant evidence includes 3 randomised control trials (RCTs; 5 papers), and 1 case series. In people with multiple sclerosis, 1 RCT reported a significant improvement in activities of daily living and a reduction in the number of falls compared with exercise therapy, whereas the other reported an improved walking performance while using the device but no benefit once people stopped using it. A case series found significant improvements in outcome measures for assisted walking (with the ODFS device) compared with unassisted walking.

Three papers reported studies involving people with a history of stroke. Two of the papers from a single trial reported no significant difference in training effect outcomes between the ODFS and standard care (physical therapy) groups. A further paper reported a

significant improvement in walking speed with the ODFS compared with standard care (physiotherapy), but a non-significant improvement in physiological cost index (effort involved in walking) and no lasting effect without the device.

The ODFS Pace and Pace XL stimulators cost £670 and £995 respectively (excluding VAT), and are used for an average of 5 years. The total treatment costs are £3,320 and £4,325 per patient over 5 years respectively, including consumables. All costs are excluding VAT.

Product summary and likely place in therapy	Effectiveness and safety
• The Odstock Dropped Foot Stimulator (ODFS) Pace and Pace XL are portable functional electrical stimulation (FES) devices, which are used to help people with drop foot walk. • The ODFS devices are used as part of an integrated rehabilitation system as an alternative, or in addition to, a foot orthosis or other walking aid for everyday use, or as a therapeutic intervention during physiotherapy sessions.	• The evidence in this briefing is of mixed quality and comes from 6 reports including a total of 545 patients. • Two papers (from a single trial) reported different outcome measures for people with multiple sclerosis. One paper (n=53) reported a significant improvement in activities of daily living and a reduction in the number of falls for people in the intervention group compared with exercise therapy, whereas the other reported an improved walking performance while using the device but no benefit once people stopped using it (n=44). • Two of the papers, from a single trial on people with a history of stroke, reported no significant difference in training effect outcomes between the ODFS and standard care (physical therapy) groups (n=84 in both papers). • One further paper on people with a history of stroke reported a significant improvement in walking speed with the ODFS compared with standard care (physiotherapy), but a non-significant improvement in physiological cost index (a measure of the effort involved in walking) and no training effect (after stopping use of the device; n=32).

	• One case series on people with multiple sclerosis reported significant improvements in assisted walking with the ODFS device compared with unassisted walking (n=153).
Technical and patient factors • The devices consist of a stimulator, self-adhesive electrodes that attach to the leg and a footswitch, which is placed under the foot in the user's shoe. • As a user walks, a change in pressure on the footswitch activates the stimulator to apply a small electrical pulse via the electrodes. This causes the leg muscles to contract, which lifts the foot and stabilises the ankle. This aids walking in people with drop foot. • ODFS may have an orthotic or therapeutic effect, which is the impact on the user's ability to walk with and without the device respectively.	**Cost and resource use** • The ODFS Pace and Pace XL stimulators cost £670 and £995 respectively, excluding VAT. • Per patient costs are determined by tariff payments, which cover all equipment, consumables and staff time costs. At the National Clinical FES Centre, first appointments cost £140, with each subsequent appointment costing £300. • Total treatment costs over 5 years are estimated to be £3,320 and £4,325 for the Pace and Pace XL devices respectively. All costs are excluding VAT.

Introduction

Drop foot, also known as foot drop or dropped foot, is a symptom of a medical condition that makes it difficult to lift the front of the foot and the toes. Drop foot can be caused by conditions that lead to muscle weakness (for example, muscular dystrophy), peripheral nerve disorders (for example, neuropathy) or disorders of the central nervous system (NHS Choices 2014). Central nervous system disorders can be categorised into lower or upper motor neurone lesions, depending on the place within the neural pathway that has

been damaged. The NICE guidance on functional electrical stimulation for drop foot of central neurological origin notes that upper motor neurone lesions often result from conditions such as stroke, multiple sclerosis, cerebral palsy or spinal cord injury. Depending on the cause, drop foot may affect one or both legs, and can either be temporary or permanent (NHS Choices 2014).

Drop foot lessens ankle stability and causes the person to drag their foot during walking, which is very tiring. This reduces mobility and may limit everyday activities, including going to work. People with drop foot may need walking aids or wheelchairs to keep mobile. It also increases the risk of trips and falls, which can lead to the person needing formal care and even hospital admission (Wilkinson et al. 2014). So, the treatment of drop foot is important to ensure people can remain mobile and live independently.

Drop foot is commonly a secondary and unreported symptom of a medical condition, so the prevalence is difficult to estimate. Over 65% of people with multiple sclerosis (about 57,000 people living with the condition in England) experience some mobility problems (Jones et al. 2013; Multiple Sclerosis Society 2016) and about 72% of people surviving stroke (approximately 707,000 people in England) are affected by leg weakness (Lawrence et al. 2001; Stroke Association 2016), which may lead to drop foot.

Technology overview

This briefing describes the regulated use of the technology for the indication specified, in the setting described, and with any other specific equipment referred to. It is the responsibility of health care professionals to check the regulatory status of any intended use of the technology in other indications and settings.

About the technology

CE marking

Odstock Medical first received a Class IIa medical device CE mark for the Odstock Dropped Foot Stimulator (ODFS) Pace in November 2008. This certification was amended in April 2012 to add the ODFS Pace XL device.

Description

The ODFS is a portable functional electrical stimulation (FES) device that is designed to correct drop foot in people with upper motor neurone conditions (for example, stroke, multiple sclerosis and spinal cord injury). Two versions of the device are available, the ODFS Pace and the ODFS Pace XL. Both devices share a similar design, with the major difference being that the Pace XL device is wirelessly activated.

The device consists of:

- a battery-operated stimulator, with dimensions of 72 mm × 62 mm × 26 mm and a weight of 119 g (including the battery)
- a pair of self-adhesive electrodes
- an electrode lead that connects the stimulator to the electrodes
- a footswitch, that activates the stimulator, and a footswitch lead, which is not needed for the Pace XL.

During use, the electrodes are externally attached to the lower leg; 1 on the outside of the leg below the knee and 1 on the shin. The footswitch is placed inside the user's shoe so that it is under the foot, and is connected to the stimulator using the footswitch lead for the Pace device, or wirelessly in the case of the Pace XL device. The stimulator is commonly attached to the user's belt by a clip or in an accessory pouch, and the electrodes, electrode lead and footswitch lead are worn under clothing.

A change in pressure on the footswitch as the user walks activates the stimulator. The stimulator then sends a small pulse of electricity through the electrodes to the common peroneal nerve in the leg, causing contraction of the inactive muscles. This causes the foot to lift (dorsiflexion) and turn out slightly (eversion), and also stabilises the ankle as the foot is returned to the floor, all of which aid walking. The ODFS Pace and Pace XL include an activity logger that allows the user to view information, such as the total number of steps or total time spent walking since the logger was last reset. These activities are automatically recorded by the stimulator. The ODFS Pace and Pace XL also have an exercise mode to stimulate muscles independent of walking. This can be used to increase muscle strength and control spasticity.

The ODFS devices are powered by 1 standard 9V battery. Two rechargeable lithium polymer batteries and a battery charger are provided with the Pace XL. The battery needs

to be recharged every 1 to 2 days depending on usage and should last for 3 to 6 years. The Pace device can be operated with a non-rechargeable battery, however the manufacturer can provide a rechargeable battery with the device. This must be paid for by the user.

People with 2 drop feet (bilateral drop foot) can also be treated using 2 Pace or Pace XL devices, although Odstock also distribute a 2 channel stimulator which can be used for this purpose. This briefing focuses on using the ODFS Pace devices to manage unilateral drop foot.

FES devices, including the ODFS Pace device, are not indicated for people with lower motor neurone lesions resulting from peripheral nerve injuries or for prolapsed intervertebral discs in the lumbar region of the spine. The ODFS Pace devices should not be used by people with an implanted electronic device, such as a cardiac pacemaker or implanted defibrillator, unless investigations by the NHS clinical team have shown no interactions between the devices.

The manufacturer states that the ODFS Pace device was first developed in 2007. Earlier versions of the Odstock FES were analogue devices (in terms of adjusting the settings of the stimulator). These devices are no longer being produced, and those in use are being replaced by the digital Pace devices as they wear out.

Setting and intended use

Treatment for drop foot is part of an integrated rehabilitation programme, which aims to increase user mobility and to reduce the risk of injury through falling. In current NHS practice, a person is usually referred to a FES clinic by their GP or a consultant in neuro-rehabilitation. If assessed as suitable for the ODFS Pace, the devices must be provided to the user by a suitably trained healthcare professional, usually a physiotherapist. A detailed user manual explains how the device should be set up and operated.

The main purpose of the ODFS Pace and ODFS Pace XL devices is to have an orthotic effect on users, which is the direct effect on the user's ability to walk while the device is being worn. Additionally, the device may have a training effect, also referred to as a therapeutic effect, which is the impact of the device on mobility when it is not being worn.

The devices are portable so they can be used in several settings, including independent

use by people at home and during physiotherapy sessions. The device is suitable for wearing all day, and should be kept dry. The length of time the device is worn each day will depend on several factors, such as the preferences of the wearer and the severity of the condition. Some users will wear the device throughout their waking hours, whilst others may only use it for specific activities.

The devices are approved for use in both children and adults.

Current NHS options

NICE interventional procedures guidance on functional electrical stimulation for drop foot of central neurological origin states that current evidence on the safety and efficacy (in terms of improving gait) appears adequate to support using this procedure provided that normal arrangements are in place for clinical governance, consent and audit. It also notes that other treatment options include physiotherapy to strengthen the affected muscles, or an ankle-foot orthosis (or brace) device to provide ankle stability and improve gait by aligning the lower leg and controlling motion. Ankle-foot orthosis devices do not stimulate the muscles in any way (Dale et al. 2010). Less commonly, relaxant drugs or botulinum toxin type A injections may be used. Surgery may be considered for people whose walking is not improved by these approaches, either by transferring tendons to the affected area to pull the ankle upwards (dorsiflexion) or fusing the ankle or foot bones to increase stability (NHS Choices 2014). Treatment for drop foot often includes multiple interventions, provided as part of an integrated rehabilitation system.

NICE is aware of the following CE-marked devices that appear to fulfil a similar function to the ODFS Pace and ODFS Pace XL devices:

- L300 Foot Drop System (Bioness)
- Walkaide (Innovative Neurotronics)
- MyGait (Ottobock).

Costs and use of the technology

An ODFS Pace kit costs £670 and includes the stimulator, 1 electrode lead, 1 foot switch lead, 2 foot switches and 1 pack (2 pairs) of electrodes. Additional ODFS Pace consumables are the foot switch (£24.98), foot switch lead (£12.57) and rechargeable

nickel-metal hydride batteries with charger (£16).

An ODFS Pace XL kit costs £995 and includes the stimulator, 1 electrode lead, 1 back-up wired footswitch, 1 wireless footswitch module and wireless insole, 1 pack (2 pairs) of electrodes and rechargeable batteries with charger. Additional ODFS PACE XL consumables are the wireless foot switch module (£130), wireless foot switch insole (£40), rechargeable lithium polymer batteries (£20) and battery charger (£30).

Additional consumables for both the ODFS Pace and Pace XL are the electrodes (£10.25 per pack) and electrode lead (£4.27).

All costs are excluding VAT.

The manufacturer states that there are no maintenance costs for the stimulator, which has an anticipated lifespan of approximately 5 years. The manufacturer estimates that each person will need 6 to 9 packs of electrodes, 1 electrode lead, 1 foot switch, and 1 foot switch lead per year. The manufacturer also notes that people use the device for an average of 5 years, at which point they stop using it. The device stimulator can be reused by another person, if it is in a suitable condition. Over 5 years, the cost of the ODFS Pace and Pace XL is £3,320 and £4,325 respectively, excluding VAT, once consumables have been added.

Likely place in therapy

The ODFS is likely to be used as part of an integrated rehabilitation programme instead of, or in addition to, an ankle-foot orthosis or other walking aid.

Specialist commentator comments

One commentator noted that people with drop foot are fearful of trips and falls and so often limit their daily activities, including social activities. This can impact on whole families and place a great burden on the carer. Increased mobility can reduce this burden. A second commentator noted that carers often report that they are less concerned over patient safety when the ODFS is being used, and feel the devices result in greater independence.

One commentator stated that, in their experience, both clinicians and users are happy with

the results of the ODFS. This is because it leads to clinically meaningful increases in walking speed, which improves functional walking capacity, and has a positive impact on the person's quality of life. Users also report a number of positive outcomes when using the devices, including less effort when walking, the ability to walk further, reduced risk of trips or falls, greater confidence when walking and less pain. A second commentator noted that the ODFS can increase muscle strength, range of movement and memory of movement, reducing spasticity effects. They also stated that the effect of the ODFS can make the leg feel lighter. These factors can allow users to stay in employment for longer as a result of improved mobility.

Two commentators considered the ODFS devices to be suitable for people with long-term conditions, particularly multiple sclerosis, because they can allow them to keep active for longer. One commentator added that in their experience, using the ODFS can provide about 4 years of extra mobility for people with multiple sclerosis.

One commentator remarked that the ODFS is beneficial compared with orthotic devices because it is not a passive support, but rather stimulates muscle activity. A second commentator added that the ODFS is more appropriate for certain people and whether the device is suitable can be determined by analysing several factors before treatment. These include: pre-morbid status, co-morbidities, degree of spasticity, muscle weakness and sensory impairment. One of these commentators also highlighted that some users benefit from a combination of FES and orthotic devices used together. They also noted that the ODFS is lighter than orthotic devices, with users often preferring the freedom of movement associated with its use. The commentator added that the Pace and Pace XL devices have improved comfort and ease of use, compared with the analogue versions of the device. A third commentator noted an advantage of the Pace and Pace XL devices is the exercise mode feature, which may be used to support rehabilitation programmes when the user is at home.

One commentator highlighted the benefits of the ODFS in rehabilitation for children with cerebral palsy, because new learning is encouraged by activating muscles using electrical impulses. They added that re-learning can happen in people after stroke, who may also benefit from maintaining muscle physiology, which can enhance rehabilitation because muscle activity reduces muscle wasting.

Two commentators noted that implanted FES devices are significantly more expensive than external devices, but may be recommended for people who would struggle to consistently fit external electrodes, such as those with poor upper limb dexterity, those

with cognitive difficulties, and people with skin conditions. (Please note, ODFS devices are external only, and implanted devices are outside the scope of this briefing.) A third commentator added that although implanted devices remove the risk of electrodes being incorrectly placed, they can cause local infection and bleeding.

Two commentators stated that in their experience maintenance is needed for the device, particularly if it is used daily, and there is a cost associated with these repairs. One of them added that a 5-year lifespan for the stimulator is realistic, if repairs are carried out. One commentator also noted that in their experience at least 12 pairs of electrodes (6 packs) are needed annually, and more than 1 electrode lead and footswitch lead is sometimes needed.

One commentator remarked that in their experience, appointment frequency and the overall cost of care will vary depending on the local population, and may be significantly different from the National FES Clinical Centre standard.

Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to:

- Promote race and disability equality and equality of opportunity between men and women.
- Eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

The ODFS may help people with a disability to improve their mobility and so carry out more everyday activities. Disability is a protected characteristic under the Equality Act 2010.

Drop foot is a common secondary outcome for people with neurological conditions, in particular stroke and multiple sclerosis. The risk of stroke is greater in men and people of African and Caribbean family origin, and also increases with age (Wang et al. 2013). Women are at a greater risk of multiple sclerosis, with the condition most likely to affect people aged 40 to 60 years (Mackenzie et al. 2014). Age, sex and race are protected

characteristics under the Equality Act 2010.

Patient and carer perspective

The Multiple Sclerosis (MS) Trust gave the following patient perspectives:

- People with MS typically have many other symptoms that they are dealing with and, because of the progressive nature of the disease, have different needs to people who have had a stroke.
- The ODFS Pace is a practical addition to physiotherapy, it is simple and easy to use, and can generally be managed independently by the person with MS.
- Although the effects of a FES are unlikely to be permanent, it can allow people with MS to stay active, independent, in work, engaged in leisure activities, and with reduced dependence on either formal or informal carers. A FES can make the difference between a person being mobile, and the need for permanent use of a wheelchair. They stated that independence and mobility is crucial in helping people to stay in control of their condition and their life.
- A FES can reduce the risk of trips and falls, which can result in injury, time off work, loss of income and increased healthcare costs. It can increase both walking speed and distance, which helps people do important daily tasks. It can reduce effort when walking, which in turn reduces fatigue, 1 of the major factors contributing to people leaving employment. Further advantages include improvements in breathing, muscle tone, balance, posture and gut motility, all of which happen because users can keep standing and walking.
- They regularly hear from people with MS about the critical importance that a FES makes to their walking, and about the frustration felt by those who have been unable to get a FES, and now face loss of independent mobility as a consequence.
- They noted that there is a therapeutic window in which a FES can be used in people with MS, and that the Expanded Disability Scale Score can be used to determine this. A score in the range of 4–6 would mean that the device could be considered for the person; a score below this indicates a sufficient level of mobility and a score above means that the person is too severely disabled. They estimated that a FES would be suitable for and benefit about 5% people with MS.

The Stroke Association gave the following patient perspectives:

- Drop foot can be a very life-limiting condition that affects people's confidence and makes it difficult to return to work. Also, people with drop foot often report feeling that it is something that they just have to put up with.
- Stroke survivors have described how FES devices can have a positive impact on their lives, helping them to overcome the consequences of the condition and recover.
- Problems with the ODFS devices have been reported, but they are usually minor, and often relate to cosmetic concerns with the devices.
- They remarked that people of African, Caribbean and South Asian family origin tend to have strokes at a younger age and, so they may have a greater need for FES devices to aid rehabilitation at a younger age. Also, people in economically deprived areas are twice as likely to have a stroke, making them more likely to benefit from a FES device.
- FES clinics do not exist in all areas and, so people in these areas must be referred to a clinic in a neighbouring area or to the National Clinical FES Centre in Salisbury.

Evidence review

Clinical and technical evidence

Regulatory bodies

A search of the Medicines and Healthcare Products Regulatory Agency website revealed no manufacturer Field Safety Notices or Medical Device Alerts for this device. No reports of adverse events were identified from a search of the US Food and Drug Administration (FDA) database: Manufacturer and User Device Facility Experience (MAUDE).

Clinical evidence

Forty-two relevant studies were identified of which 6 represented the best quality evidence (based on study design, number of patients and relevant outcome measures) and are summarised in this briefing (see search strategy and evidence selection section for more detail). This includes 5 papers reporting results from 3 randomised controlled trials (RCTs) and 1 case series. For all 5 studies reporting data from the RCTs (Barrett et al. 2009; Esnouf et al. 2010; Sheffler et al. 2013; Sheffler et al. 2015; Burridge et al. 1997), the

evidence presented was based on the analogue versions of the Odstock Dropped Foot Stimulator (ODFS), whereas the case series incorporated a range of ODFS devices (including the Pace and Pace XL) without separating the results by device type (Street et al. 2015). Two of the papers were based on a single RCT, which included people with multiple sclerosis (MS; Barrett et al. 2009; Esnouf et al. 2010) and 2 of the papers were based on a single RCT that included people who had survived a stroke (Sheffler et al. 2013; Sheffler et al. 2015). When 2 papers were based on the same trial, each paper reported different outcome measures. The 3 RCTS and 1 case series all compared the ODFS with either usual care, exercise, ankle-foot orthosis (AFO), or exercise and AFO.

Barrett et al. (2009) carried out an RCT to investigate the effects of the ODFS on gait compared with exercise therapy for people with secondary progressive multiple sclerosis (SPMS). Eligible people, aged 18 years or older who had a diagnosis of SPMS, a predominately unilateral drop foot and no previous use of functional electrical stimulation (FES), were recruited from the UK National Clinical FES Centre. The study design included a pilot element to test procedures; the data from these patients were excluded from the analysis. Patients were randomised into 2 groups. In the intervention group (n=20), patients used the ODFS to treat drop foot. After the training period, people were encouraged to use the device most of the day and to switch it on and off as needed. In the comparator group (n=24), patients had a programme of simple physiotherapy exercises to carry out at home. Outcomes included walking speed over 10 metres, physiological cost index (an indicator of the effort involved in walking) over 10 metres and distance walked in 3 minutes. These were assessed at weeks 6, 12 and 18. The intervention group did the tests with the ODFS switched on (with stimulation) and switched off (without stimulation). Treatment was over 18 weeks and people were not followed up after the intervention period. No significant improvement in unassisted walking speed over 10 metres or unassisted distance walked in 3 minutes (that is, the training effect) was seen over the 18 week treatment period in the intervention group with the ODFS switched off compared with baseline values. The exercise group showed significant improvement in both walking speed (p=0.001) and walking distance (p=0.005) compared with baseline values over the same period, but only the walking speed was statistically significantly improved compared with the ODFS group (mean difference between groups 0.081 metres per second; 95% confidence interval [CI] 0.01 to 0.15; p=0.028). This suggests that home exercise is a more effective means of improving unassisted walking performance compared with ODFS in people with SPMS. An orthotic effect was seen with ODFS. At each assessment stage of the study (6, 12, and 18 weeks), there were statistically significant improvements in both the 10 metre walking speed and distance walked in 3 minutes in the ODFS group with stimulation compared with ODFS without stimulation (baseline to week 18: walking speed

p=0.001; distance p=0.004). There was no indication that ODFS had significant training or orthotic effects on energy expenditure. The summary and results are shown in table 2 and table 3.

Esnouf et al. (2010) reported on the same RCT as Barrett et al. (2009) to determine if the ODFS improved activities of daily living in people with SPMS. The inclusion criteria were the same as those stated above. The number of patients is slightly greater than in Barrett et al. (2009) because this study included the people who took part in the pilot study. People were randomised to 2 groups. In the intervention group (n=26), the ODFS was provided for daily use. In the comparator group (n=27), the physiotherapist assigned patients exercises to complete once or twice daily at home. In the comparator group, ankle-foot orthosis use was continued if the patient already used one but no new orthoses were issued. Treatment sessions with the physiotherapist for both groups were carried out at baseline and in weeks 6, 12 and 18. Both groups had their allocated treatment and were followed up over 18 weeks. Their Canadian Occupational Performance Measure (COPM), which is used to assess activities of daily living, was rated at baseline and 18 weeks, and patients completed a 'falls diary' throughout. The results showed that improvements in COPM performance and satisfaction scores were greater in the intervention group than the comparator group (COPM performance – difference in intergroup change: 1.1, p=0.038; COPM satisfaction – difference in intergroup change: 1.7, p=0.007). The results also showed a significantly lower median number of falls in the intervention group (intergroup comparison: median difference between groups: 13; 18 in comparator group; 5 in intervention group; p=0.036). COPM results for climbing stairs, balance, and steps and kerbs were included in the paper but p-values between groups were not reported because they were not statistically significant. There were significant improvements within the intervention group for COPM tripping performance scores (3.5; p<0.05) and tripping satisfaction scores (4.5; p<0.05). There was also a significant improvement between groups (difference in improvement score 4.5; p<0.05). Improvement scores were also significant for walking distance satisfaction scores both within the intervention group (5.5; p<0.05) and between groups (difference in improvement score 2.5, p<0.05). The summary and results are shown in table 4 and table 5.

Sheffler et al. (2013) did an RCT to compare the motor relearning effect of the ODFS compared with usual care on lower limb motor impairment, activity limitation, and quality of life among chronic ischaemic, lacunar or haemorrhagic stroke survivors. Eligible people were aged over 18 years and had a stroke at least 12 weeks before the start of the study. Patients were randomised into 2 groups. In the intervention group (n=39), patients were trained to use the ODFS for home and community mobility, and used an assistive device as

needed. Sheffler (2015) reported that these devices could include a cane, quad cane or walker. These people had regular training, which consisted of 1-hour sessions twice a week in the first 5 weeks and 3 times a week in the following 7 weeks. In the comparator group (n=45), standard physical therapy interventions were used. Forty-eight people were treated with an ankle-foot orthosis and 8 had no device at the start of the study. Some patients dropped out at each time point. People were treated for 12 weeks and followed up for a further 24 weeks post-treatment. Assessments were carried out at baseline, 12, 24 and 36 weeks. Outcomes were assessed using the lower extremity portion of the Fugl-Meyer (FM) Assessment (motor impairment), the Modified Emory Functional Ambulation Profile (mEFAP) measured without a device (functional ambulation), and the Stroke Specific Quality of Life (SSQOL) scale in which 12 outcomes are rated on a scale of 1 to 5. There was no significant intervention group main effect (a main effect is the effect of an independent variable upon a dependent variable) or intervention group by time interaction effect (which measures if the difference between the intervention and comparator group changed differently over time) for motor impairment (FM; p=0.797, p=0.321 respectively), functional ambulation (mEFAP; p=0.968, p>0.999 respectively), or SSQOL (p=0.360, p=0.627 respectively) on raw scores. For motor impairment (FM), time effect was significant (p=0.007), but no significant changes were seen from baseline to each time point (p>0.05). The model parameter estimates for time effect during treatment were not significant (difference 0.525; −0.345 to 1.396; p=0.238). For functional ambulation (mEFAP), time effect was significant (p<0.001). The model parameter estimates for time effect during treatment were significantly lower than at baseline (difference −13.864; −21.256 to −6.473; p<0.001). For SSQOL, time effect was significant (p<0.001). The model parameter estimates for time effect during treatment were significantly higher than at baseline (difference 9.910; 3.724 to 16.096; p=0.002). The summary and results are shown in table 6 and table 7.

Sheffler et al. (2015) reported on the same RCT as Sheffler et al. (2013) to compare mechanisms for functional improvement between the ODFS compared with usual care using quantitative gait analysis. The inclusion and exclusion criteria, and the randomisation of patients into 2 groups were the same as stated in Sheffler et al (2013; table 6 and table 7). In the intervention group (n=39), patients were trained to use the ODFS for home and community mobility, with an assistive device (such as a straight cane, quad cane, or walker) as needed. In the comparator group (n=45), standard physical therapy interventions were used. Patients were treated for 12 weeks and followed up for 6 months post-treatment and were assessed at baseline, 12, 24 and 36 weeks. There were 13 main study outcomes, classed as spatiotemporal (including speed and length of gait), kinematic (analysis of 3-dimensional movement including joint angles) and kinetic (forces involved in

the production of movement) parameters of gait, all assessed with quantitative gait analysis. Activity level was also assessed. The main effects that were statistically significant in the intervention group compared with the comparator group were cadence ($p<0.001$) and peak hip power ($p=0.003$). The differences between the intervention and comparator group were not statistically significant for all other main effect outcome measures (see table 9 for full results). Time effect at final follow-up was significant for cadence ($p<0.0001$), stride length ($p=0.0003$), walking speed ($p<0.0001$), anterior-posterior ground reaction force ($p=0.032$), peak hip power (pre-swing; $p<0.0001$) and peak ankle power ($p=0.003$). Time effect was not significant for peak ankle flex swing ($p=0.058$). For activity level, there was no significant time effect or intervention by time effect (a measure of whether the effects of an intervention are sustained over time) for average time standing per day, average time walking per day, or average number of steps per day. The study is summarised in table 8.

Burridge et al. (1997) carried out an RCT to measure the effect of the ODFS on the effort and speed of walking compared with physiotherapy for people who have had a stroke. Eligible people were those who had a stroke causing a hemiplegia at least 6 months ago, had the ability to stand from sitting without help and could walk a minimum of 50 metres independently before the stroke. Patients were recruited from the UK National Clinical FES Centre and randomised into 2 groups. In the intervention group (n=15), patients had the ODFS and a course of physiotherapy sessions. In the comparator group (n=16), patients only had the course of physiotherapy. All patients had the same therapy contact time (10 1-hour physiotherapy sessions in the first month of the trial), but patients in the treatment group spent some of this time on training and adjusting the ODFS. Outcomes included walking speed over 10 metres and physiological cost index over 10 metres, assessed at baseline, week 4 and week 12. A training effect was not seen in the treatment group, because there was no significant difference between the treatment group without stimulation compared with the comparator group at any time point on either measure. An orthotic effect was seen on some outcome measures at certain time points. When comparing the treatment group when having stimulation with the comparator group, results were significant for 10-metre walking speed (minutes/second) at week 12 (95% CI −0.460 to 0.001; $p=0.044$). No other results comparing the treatment group when having stimulation with the comparator group were significant at any other time point for either measure. The treatment group when having stimulation at baseline, week 4 and week 12 was also compared with the treatment group without stimulation at baseline. Results were significant for walking speed at week 12 (percentage change 20.50; 95% CI 0.060 to 0.210; $p=0.004$), physiological cost index at week 0 (percentage change −20.68; 95% CI 0.040 to 0.325; $p=0.010$) and physiological cost index at week 12 (percentage change −24.87; 95%

CI 0.040 to 0.430; p=0.008). The summary and results are shown in table 10 and table 11.

Street et al. (2015) carried out a case series study with data collected between 2008 and 2013. The objective of the study was to determine the effectiveness of FES on drop foot in people with MS. The study collected data on patients during standard clinical care (n=153) from a UK-based specialist FES centre, using 1 of 4 different versions of the ODFS (ODFS III, ODFS Pace, Odstock 2 channel Stimulator II and Pace XL). Patients for whom FES was suitable had 1 appointment to teach them how to use the FES. Baseline measurements were taken at a second appointment. After a 10-metre walk to increase muscle temperature and range of movement, they did 2 further 10-metre walks to measure the speed of unassisted walking and the effect of FES respectively. These measurements were taken again at a median of 20 weeks (interquartile range 16–24 weeks). The difference between the second and third walk defined the orthotic effect and the difference in walking speed over time when not using FES defined the training effect. For 10-metre walking speed, the results showed a main effect for stimulation compared with no stimulation ($F_{1,152}$ 91.88; p<0.001) and an interaction effect between stimulation over time ($F_{1,152}$ 9.79; p=0.002). When comparing unassisted walking with assisted (FES) walking, there was a significant improvement for initial orthotic effect (mean difference 0.07±0.11; 95% CI 0.05 to 0.08; p=0.001), continuing orthotic effect (mean difference 0.11±0.16; 95% CI 0.08 to 0.13; p=0.001) and total orthotic effect (mean difference 0.10±0.22; 95% CI 0.07 to 0.14; p=0.001). The training effect was not significant (mean difference 0.00±0.26; 95% CI −0.04 to 0.03; p=0.53.). Functional walking category lasted or improved in 95% of people who responded to treatment. The summary and results are shown in table 12 and table 13.

Several older studies, using the analogue version of the ODFS, are presented in the NICE guidance on functional electrical stimulation for drop foot of central neurological origin.

Recent and ongoing studies

One ongoing or in-development trial on the ODFS for multiple sclerosis was identified in the preparation of this briefing.

- Walking with FES or AFO in people with MS with foot drop (NCT01977287). The expected primary completion date for the study is March 2016.

Costs and resource consequences

The process of getting a device involves several appointments. A person is first assessed at a specialist FES clinic to decide whether a FES is appropriate for them. If it is thought to be appropriate, 2 further appointments are needed for fitting the device and setting up a training programme. Follow-up appointments are also necessary for tracking progress. The time between appointments is dependent on the person, but they are more frequent to begin with (for example, at 6 weeks and 3 months after the device has been fitted and every 6 or 12 months thereafter). Each appointment lasts about 1 hour, although this may be longer for those with complex care needs.

Total costs for ODFS usage are based upon the tariff payment that providers receive for the care they give. This tariff payment includes all equipment costs, consumable costs (excluding the costs of batteries for the Pace devices) and staff time. The manufacturer advises that NHS tariff payments are £140 for the first appointment and £300 for each subsequent appointment, offered at the National Clinical FES Centre in Salisbury and at 8 specialist FES centres throughout England. The manufacturer states there will be 6 appointments in year 1, including 1 initial assessment and an average of 1.4 appointments in each subsequent year. Over a 5 year period, this equates to a total cost of £3,320 for the Pace device and £4,325 for the Pace XL device, excluding VAT.

The registered healthcare professional providing the device (typically a physiotherapist) must have completed a 1-day training course. This course costs £229 per person, excluding VAT. Discounts are available if several staff are trained together at the same location.

The average cost of a physiotherapy visit, as an outpatient appointment, is £46 (Department of Health 2014). The average annual cost of a standard ankle-foot orthosis is £123 per patient.

The ODFS devices are in use in the NHS; the manufacturer estimates that 10,000 to 15,000 people have already used them. The ODFS devices are supplied by specialist FES clinics, sometimes after an effective use of resources-type application process. More widespread use of the devices is not expected to change service delivery, if limited to these clinics. However, if the service is expanded so that it is used outside these clinics then additional equipment and staff training may be needed. More widespread use may help savings if it reduces the number of falls, compared with physiotherapy and ankle orthoses alone.

As noted in the introduction, people who have had a stroke or those with multiple sclerosis may struggle with everyday activities because of secondary conditions such as drop foot. The NICE guideline on stroke notes informal care costs of £2.4 billion and costs of £1.8 billion resulting from lost productivity and disability. Similarly, a 2008 survey of 4,000 members of the Multiple Sclerosis Society of Great Britain and Northern Ireland found that over a 6-month period the mean costs for informal care and lost employment were £6,019 and £4,240 respectively (McCrone et al. 2008).

Health economic evaluations

Two papers and 1 report were identified that reported economic evaluations of the ODFS. Taylor et al. (2007) reported on a cost–utility analysis of the ODFS in people with stroke, based on efficacy data presented by Burridge et al. (1997). The Centre for Evidence-based Purchasing (CEP) produced an economic report that analysed the cost effectiveness of FES compared with physiotherapy for drop foot of central neurological origin, based on a cost–utility model using a Monte Carlo simulation (Taft et al. 2010). Taylor et al. (2013) reported on a cost-utility analysis of FES for drop foot caused by upper motor neuron lesions, using quality adjusted life-years (QALY) data from the CEP report and retrospectively collected resource use data.

Taylor et al. (2007) reported a mean QALY gain of 0.065 with the ODFS (between month 0 and month 3) compared with physiotherapy, equating to a cost per QALY of £25,231 for 1 year's use and between £6,676 and £10,830 over 10 years. An incremental cost-effectiveness ratio (ICER) comparing ODFS and physiotherapy was not presented. The CEP report suggested that FES has a cost per QALY of £52,337 in the first year, and £19,239 after 5 years. Using a 5-year time horizon and at a 'willingness-to-pay threshold' of £30,000 per incremental QALY, FES was cost-effective in 66% of model iterations (Taft et al. 2010). Taylor et al. (2013) reported a mean QALY gain of 0.041 and a cost per QALY of £15,406 for all users over 4.9 years. Sub-group analysis was also done for people with stroke and a cost per QALY of £15,268 over 5 years was reported. Again, an ICER for FES compared with physiotherapy or any other comparator was not presented.

Both the papers and the report share some limitations. First, an ICER for the ODFS or FES compared with a relevant comparator (for example physiotherapy) was not accurately determined in any of the three studies, however Taylor et al. (2007) calculated cost per QALY using physiotherapy as the comparator. In both Taylor et al. (2007) and Taylor et al. (2013), results were presented as cost per QALY. This output should not be compared with a NICE cost-effectiveness threshold and is not meaningful in assessing the cost

effectiveness of the ODFS or FES. Within the CEP report (Taft et al. 2010), it could not be determined if the ICER was accurately estimated based on the information presented. This is because the utility score for physiotherapy was not explicitly reported. Second, neither costs nor QALYs were discounted, despite a 5- or 10-year time horizon being adopted. Thirdly, QALY gain was not based on a survey of patients using a standardised instrument, such as the EQ-5D, which brings into question the reliability of the estimates used. Finally, both the CEP report (Taft et al. 2010) and Taylor et al. (2013) reported on FES devices in general, although ODFS was used most often. The results presented are therefore based on efficacy data not completely related to the ODFS, limiting the applicability of the results. Given these limitations, the results of all 3 studies should be used with caution.

Strengths and limitations of the evidence

The 5 RCT studies were evaluated using the RCT QA checklist recommended by the NICE guidelines manual: appendices B–I. When 2 separate papers reported on a single trial, the risk of bias was assessed purely on the information reported in the individual paper. A summary is reported in table 1.

All included studies report outcomes based on analogue versions of the Odstock Dropped Foot Stimulator (ODFS) devices. The manufacturer states that the ODFS Pace and Pace XL devices are equivalent to these analogue versions, in terms of the effect on walking ability. Therefore, the efficacy data recorded using analogue devices should be generalisable to the Pace and Pace XL devices.

Table 1: Levels of bias in the 4 RCTs

Risk of bias	Barrett et al. (2009)	Esnouf et al. (2010)	Sheffler et al. (2013)	Sheffler et al. (2015)	Burridge et al. (1997)
Selection bias	Low risk	Low risk	Low risk	Low risk	Unclear risk
Performance bias	High risk	High risk	Unclear risk	Unclear risk	Unclear risk
Attrition bias	High risk	High risk	Unclear risk	Unclear risk	Low risk
Detection bias	Low risk	Low risk	Low risk	High risk	Low risk

The risk of selection bias in Burridge et al (1997) was unclear. The study reported a suitable method of randomisation, but did not carry out any analysis on the baseline characteristics. The authors did note that patients in the comparator group walked more slowly and with more effort than those in the treatment group. Although they stated that this may bias against the FES, this difference between groups was not significant at baseline. Also, a reason for exclusion from starting the trial was 'no observed improvement in walking with stimulation'. In practice, patients are assessed to determine if treatment with the ODFS is suitable for them. The paper does not give any detail on the definition of 'observed improvement' and so it is unclear if this is reflective of standard practice or if this is a bias.

Four studies (Barrett et al. 2009; Esnouf et al. 2010; Sheffler et al. 2013; Sheffler et al. 2015) were rated as having a low risk of selection bias. All studies included a suitable method of randomisation and adequate concealment of allocation. Sheffler et al. (2013) and Sheffler et al. (2015) reported no statistically significant differences in baseline characteristics and adjusted the statistical analysis for potential confounders. Barrett et al. (2009) stated that there were small but noticeable differences in age and time since diagnosis between the intervention and comparator groups. These were used as covariates in the analysis of covariance (ANCOVA), which showed that these had no significant effects on response variables at 18 weeks. This also applies to Esnouf et al. (2010), which reports the same study. Esnouf et al. reported that a greater proportion of patients in the comparator group used ankle-foot orthoses or had rejected an orthosis before starting the study, suggesting that they may have been more vulnerable to falls. This was not tested for statistical significance.

The risk of performance bias in Esnouf et al. (2010), Sheffler et al. (2013), Sheffler et al. (2015) and Burridge et al. (1997) was unclear. Esnouf et al. (2010) and Sheffler et al. (2013) did not explicitly state if the people in both groups had the same care other than the intervention. Sheffler et al. (2015) and Burridge et al. (1997) stated that both groups had the same number of therapy hours and that the content of therapy sessions was standardised across treatment groups. This controls for differences between intervention and comparator groups, but it does not necessarily reflect standard practice in which people may have fewer hours of care, so it may lack external validity. In Esnouf et al. (2010), Sheffler et al. (2013) and Sheffler et al. (2015), patients within the comparison group had different care. Some patients had an ankle-foot orthosis and others did not. It is not clear if this is a bias or if it accurately reflects standard practice. However, it is possible that some baseline measures differ between people with and without an orthosis. Sheffler et al. (2013) and Sheffler et al. (2015) reported that people were trained to use their ODFS

devices for mobility, with use of assistive devices as needed. Burridge et al. (1997) also reported that some patients used a walking aid during assessment. It is not clear if both groups used assistive devices.

The risk of performance bias in Barrett et al. (2009) was rated as high. The paper reports that the intervention and comparator groups had the same number and timing of follow-up appointments, but the clinical assessors were not blinded to the interventions. All interventions were given by the researchers conducting the trial.

Patients and individuals giving care were not blinded to treatment allocation in any of the studies because this was not possible for the intervention.

It was unclear if there was attrition bias in Esnouf et al. (2010), Sheffler et al. (2013) and Sheffler et al. (2015). The papers did not report if there were any differences between those who completed treatment and those who did not. These studies had a relatively high number of people withdrawing from or not completing the studies and in each study, slightly more people in the intervention group withdrew from or did not complete the study. The authors of Sheffler et al. (2013) and Sheffler et al. (2015) state that this may have compromised internal validity.

Barrett et al. (2009) has a high risk of attrition bias. The study also had a relatively high number of people withdrawing from or not completing the studies, which was higher in the intervention group. The paper reported that some of the reasons for dropout were related to the intervention. The authors stated that patients dropped out so early in the trial that minimal information would have been gained by completing an intention-to-treat analysis. The authors also stated that it is likely that the comparator group had fewer dropouts and that people followed their exercise regime closely with positive results partly because they knew that they would get a FES at the end of the trial, which is not reflective of real practice.

Burridge et al. (1997) was rated as having a low risk of attrition bias. Nobody withdrew from this study, although 1 patient from the FES group was excluded because the outcome data meant the patient was considered to be an outlier; this patient walked much more slowly than all other patients, resulting in an improvement that was considered to be non-comparable. Although the outcome data was comparable for the 2 groups, the trial has limited external validity. Some patients were self-referred from an advert in a newspaper and some were selected by treating physiotherapists as suitable for the trial. The authors acknowledge that this was a sample of particularly 'enthusiastic, compliant

and apparently suitable patients'. Also, the authors point out that it is likely that the comparator group had fewer dropouts partly because of the incentive that they would get FES after the trial and that if they withdrew from the trial they would not have the 10 physiotherapy sessions, which is not reflective of real practice.

Four studies were rated as having low risk of detection bias (Barrett et al. 2009; Esnouf et al. 2010; Sheffler et al. 2013; Burridge et al. 1997). All studies had an appropriate follow-up for the outcomes identified, although longer follow-ups would have been informative. Sheffler et al. (2013) and Sheffler et al. (2015) followed patients after the treatment period. All studies clearly defined the outcomes and also used valid and reliable methods to determine the outcomes. Barrett et al. (2009) and Burridge et al. (1997) did not blind investigators to the patients' exposure to the intervention because this is not possible when measuring the orthotic effect. However, all measures were objective and so unlikely to be influenced by detection bias. Esnouf et al. (2010) used a standardised instrument to determine the primary outcome measure. This measure is subjective but investigators were blinded to patients' exposure to the intervention. Esnouf et al. (2010) also collected data on the number of falls as a secondary outcome from a diary kept by the patient. It is not possible to know if the diary was accurately completed. Also, the proportion of time spent walking with the ODFS or ankle-foot orthosis was not recorded, so the fall data are difficult to interpret. Sheffler et al. (2013) also used validated instruments, but they state that the Fugl-Meyer assessment may not be sensitive enough to detect clinically important changes in motor impairment.

Sheffler et al. (2015) has a high risk of detection bias. The outcomes were clearly defined and all but 1 (activity level) were measured using quantitative gait analysis (QGA). When having QGA, patients used no FES device or assistive device (cane, quad cane or walker) and the authors stated that the effect of this on the data is unknown. When patients have QGA, markers are stuck to the skin. The authors stated that there may be some bias from the inconsistent placement of markers between assessments. Finally, patient activity was measured using an activity logger for 3 consecutive days after each follow-up. The average total steps per day on these 3 days was used as a proxy for overall activity level.

The study by Street et al. (2015) was assessed using the CASP cohort studies checklist (CASP UK 2013). The study design ranks less highly in the hierarchy of evidence than an experimental study because there is no comparator group. The study recruited the cohort in an acceptable way using eligibility criteria, but no calculation was used to determine sample size. The study used data from standard clinical practice and patients were included based on GP and consultant referral data suggesting the sample is generalisable.

Walking speed is an objective measure, which is unlikely to be biased. The functional walking category measure may be subject to some bias because a small change in walking speed may be enough to change a category. A larger change may not alter the category if the initial walking speed was near the lower threshold. The authors report that the clinically meaningful change in walking speed that they defined may not apply to this population. The value for a clinically meaningful change was derived from an elderly population of stroke survivors. This cohort was younger and had more profound disability specific to MS. The authors state that this suggests that a threshold for a clinically meaningful change may be overestimated in a population with more severe disability. The study authors took into account a previously seen confounding factor, which is the carry-over effect of using FES immediately before unassisted walking, and adjusted the study design to measure the unassisted walk first. No subgroup analysis was carried out on baseline characteristics, such as those who used ankle-foot orthoses at the start of the study, and there is no reporting of the severity or type of MS. Also, 4 different ODFS devices were used and analysis is not reported by device type. Follow-up ranged from 16 to 24 weeks, meaning that not all patients were followed up for the same amount of time. People who were discharged from treatment for various reasons were not included in the analysis, which may bias the results in favour of FES. Extra analyses reported floor and ceiling effects (data values at the minimum or maximum scores that the test allows for) of the functional walking category, although the conclusion of this analysis is not reported. Finally, the results for training effect (defined as unassisted walking over time) were not reported clearly in the paper and were listed in a table under 'FES walk'.

Relevance to NICE guidance programmes

NICE has issued the following guidance:

- Functional electrical stimulation for drop foot of central neurological origin (2009) NICE interventional procedure guideline 278
- Multiple sclerosis in adults: management (2014) NICE guideline CG186
- Selective dorsal rhizotomy for spasticity in cerebral palsy (2010) NICE interventional procedure guidance 373
- Spasticity in under 19s: management (2012) NICE guideline CG145
- Stroke and transient ischaemic attack in over 16s: diagnosis and initial management (2008) NICE guideline CG68

- Stroke rehabilitation in adults (2013) NICE guideline CG162

NICE guidance on cerebral palsy is in development and is expected to be published in January 2017.

NICE guidance on spasticity (after stroke) – botulinum toxin type A is in development and the publication date is to be confirmed.

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Appendix

Contents

Data tables

Table 2 Overview of the Barrett et al. (2009) study

Study component	Description
Objectives/ hypotheses	To assess the effects of single channel common peroneal nerve stimulation (FES using the ODFS) on objective aspects of gait compared with exercise therapy for people with secondary progressive multiple sclerosis.
Study design	Randomised controlled trial.
Setting	Patients recruited from the waiting list for FES treatment at the FES clinic where the trial was conducted after being referred by either their GP or a consultant.
Inclusion/ exclusion criteria	All patients were aged 18 years or over, with a diagnosis of SPMS and a rating of 4.5 to 6 on the EDSS. Patients also had to meet several criteria, including: predominantly unilateral dropped foot, a passive range of ankle dorsiflexion, response to common peroneal nerve stimulation and no previous use of FES. Patients were excluded if they had cognitive or psychiatric problems that affected their ability to understand or keep to treatment, or any other condition that may affect mobility or response to treatment.
Primary outcomes	The primary outcome variable was walking speed over 10 metres. Secondary outcome measures were PCI and distance walked in 3 minutes.
Statistical methods	Included: summary descriptive measures, Anderson-Darling test of normal distribution assumption and basic tests for equality of means or mean changes using standard independent sample or paired sample tests. ANCOVA was done on outcomes at 18 weeks, with baseline measures as covariates, after assessment of data conformity to ANCOVA assumptions.

Patients included	A total of 64 patients were recruited. The first 11 were used to pilot the trial protocol. Data produced from these pilot study patients were excluded in the analysis. Fifty three patients were recruited for the main trial. Number analysed: FES=20, exercise=24.
Results	The comparator group showed a statistically significant increase in 10 metre walking speed relative to the intervention group, who showed no significant change in walking performance without stimulation. There were no differences between the intervention group and comparator group in distance walked. At each stage of the trial, the intervention group performed to a statistically significantly higher level with FES than without for the same outcome measures.
Conclusions	Exercise may provide a greater training effect on walking speed and endurance than FES for people with SPMS. FES using the ODFS may provide an orthotic benefit when the outcome is measured using the same parameters.
Abbreviations: ANCOVA, analysis of covariance test; EDSS, Kurtzke Expanded Disability Status Scale; FES, functional electrical stimulation; PCI, physiological cost index; SPMS, secondary progressive multiple sclerosis.	

Table 3 Summary of results of the Barrett et al. (2009) study

	Intervention group: ODFS without stimulation	**Comparator group: exercise**	**Analysis**
Randomised	n=26	n=27	
Efficacy	n=20	n=24	
Primary outcomes			
Mean walking speed over 10 metres (metres/ second)	0.74±0.026	0.82±0.024	Difference: 0.081 (95% CI 0.01 to 0.15; p=0.028)

Walking speed over 10 metres (metres/second; mean±SD)	Week 0: 0.79±0.31 Week 6: 0.83±0.35 Week 12: 0.82±0.33 Week 18: 0.80±0.38 Change: p=0.592	Week 0: 0.68±0.28 Week 6: 0.72±0.27 Week 12: 0.72±0.27 Week 18: 0.77±0.29 Change: p=0.001	NR
Selected secondary outcomes			
PCI recorded over 10 metres (beats per minute/metres per minute, ANCOVA adjusted mean±SE)	0.69±0.041	0.70±0.037	Difference: 0.01 (95% CI −0.01 to 0.15; p=0.81)
PCI recorded over 10 metres (beats per minute/metres per minute, mean±SD)	Week 0: 0.7±81.18 Week 6: 0.75±1.15 Week 12: 0.68±0.96 Week 18:0.74±1.12 Change: p=0.48	Week 0: 0.68±0.52 Week 6: 0.60±0.47 Week 12: 0.61±0.49 Week 18: 0.66±0.54 Change: p=0.53	NR
Distance walked in 3 minutes (metres, ANCOVA adjusted mean±SE)	124±8.5	112±7.9	Difference: 11 (95% CI −0.01 to 0.13; p=0.334)
Distance walked in 3 minutes (metres, mean±SD)	Week 0: n/a Week 6: 122±56 Week 12: 124±51 Week 18: 125±55 Change: p=0.34	Week 0: 97±44 Week 6: 106±46 Week 12: 111±43 Week 18: 113±46 Change: p=0.005	NR

	Intervention group: ODFS with stimulation (n=20)	Intervention group: ODFS without stimulation (n=20)	Analysis
Walking speed over 10 metres (metres/second, mean±SD)	Week 0: 0.79±0.31 Week 6: 0.83±0.35 Week 12: 0.82±0.33 Week 18: 0.80±0.35 Change: p=0.592	Week 0: 0.79±0.35 Week 6: 0.78±0.35 Week 12: 0.77±0.34 Week 18: 0.73±0.35 Change: p=0.155	Difference: Week 0: p>0.50 Week 6: p=0.001 Week 12: p=0.001 Week 18: p=0.001
PCI over 10 metres (beats per minute/metres per minute, mean±SD)	Week 0: 0.78±1.18 Week 6: 0.75±1.15 Week 12: 0.68±0.96 Week 18: 0.74±1.12 Change: p=0.48	Week 0: 0.68±0.77 Week 6: 0.92±1.66 Week 12: 0.73±0.97 Week 18: 0.82±1.17 Change: p=0.35	Difference: Week 0: p=0.35 Week 6: p=0.17 Week 12: p=0.08 Week 18: p=0.38
Distance walked in 3 minutes (metres, mean±SD)	Week 0: n/a Week 6: 122±56 Week 12: 124±51 Week 18: 125±55 Change: p=0.34	Week 0: 99±42 Week 6: 112±51 Week 12: 111±53 Week 18: 112±50 Change: p=0.24	Difference: Week 0: p=n/a Week 6: p=0.010 Week 12: p=0.003 Week 18: p=0.004
Abbreviations: ANCOVA, analysis of covariance test; CI, confidence interval; FES, functional electrical stimulation; n/a, not applicable; NR, not reported; PCI, physiological cost index; SD, standard deviation; SE, standard error.			

Table 4 Overview of the Esnouf et al. (2010) study

Study component	Description

Objectives/ hypotheses	To determine if the Odstock Dropped Foot Stimulator improved activities of daily living for people with multiple sclerosis compared with physiotherapy exercises.
Study design	Randomised controlled trial.
Setting	Patients referred to the National Clinical FES Centre, UK.
Inclusion/ exclusion criteria	All people in the study had secondary progressive MS, with dropped foot that impaired mobility. Other inclusion criteria included: no previous use of FES, rating of 4–6.5 on the Kurtzke Expanded Disability Status Scale, and an effective response to common peroneal nerve stimulation.
Primary outcomes	Outcome measures were COPM scores and number of falls.
Statistical methods	The Wilcoxon Signed Rank test and Mann–Whitney U-test used to test for intragroup and intergroup statistically significant differences, respectively (indicated by a p-value of less than 0.05).
Patients included	64 people with unilateral dropped foot due to secondary progressive multiple sclerosis. Results of 53 research volunteers are reported. Intervention group: n=26, comparator group: n=27.
Results	Improvements in performance and satisfaction scores were greater in the intervention group than the comparator group ($p<0.05$). The median number of falls over the study period was 5 in the intervention group and 18 in the comparator group ($p=0.036$).
Conclusions	The study shows that people with multiple sclerosis using the ODFS increased their COPM performance and satisfaction scores of their identified problems with activities of daily living more than those in a comparator group, who had physiotherapy exercises. The ODFS users also had fewer falls.
Abbreviations: COPM, Canadian Occupational Performance Measure; FES, functional electrical stimulation; MS, multiple sclerosis; ODFS, Odstock Dropped Foot Stimulator.	

Table 5 Summary of results of the Esnouf et al. (2010) study

	Intervention group: FES	Comparator group: Exercise	Analysis
Randomised	n=32	n=32	
Efficacy	n=26	n=27	
Primary outcomes			
COPM Performance score Median (IQR)	Month 0: 3.5 (2.7 to 4.0) Month 3: 4.8 (4.2 to 5.6) Change: 1.1 (0.1 to 2.0); p=0.0002	Month 0: 3.4 (3.0 to 4.2) Month 3: 3.8 (3.2 to 5.0) Change: 0.0 (0.0 to 0.9); p=0.0553	Between-group comparison Month 0: p=0.574 Month 3: p=0.089 Change: p=0.038
COPM Satisfaction score Median (IQR)	Month 0: 2.2 (1.4 to 3) Month 3:4.0 (2.9 to 5.5) Change: 1.7 (0.3 to 2.7); p=0.0001	Month 0: 2.6 (1.8 to 3.0) Month 3: 2.4 (1.6 to 4.0) Change: 0.0 (0.0 to 1.0); p=0.0437	Between-group comparison Month 0: p=0.515 Month 3: p=0.027 Change: p=0.007
Selected secondary outcomes			
Falls (median number over study period)	5	18	Between-group comparison p=0.036
COPM results for tripping Median improvement (IQR)	Performance: 3.5[a] (1.25 to 3.5) Satisfaction: 4.5[ab] (3.25 to 5.75)	Performance: 0 (0.0 to 0.0) Satisfaction 0.0 (0.0 to 0.0)	Between-groups (difference in improvement score for satisfaction) 4.5; p<0.05

COPM results for walking a distance Median improvement (IQR)	Performance: 1.0 (0.75 to 3.0) Satisfaction: 5.5[ab] (4.0 to 7.0)	Performance: 0.5 (0.0 to 1.75) Satisfaction: 3.0[a] (0.0 to 2.75)	Between groups (difference in improvement score for satisfaction) 2.5, p<0.05
Abbreviations: COPM, Canadian Occupational Performance Measure; IQR, interquartile range. [a]Statistically significant within-group difference (Wilcoxon signed rank test p<0.05). [b]Statistically significant between-group difference (Mann–Whitney U-test p<0.05).			

Table 6 Overview of the Sheffler et al. (2013) study

Study component	Description
Objectives/ hypotheses	To compare the motor relearning effect of a surface PNS (the ODFS) compared with usual care on lower limb motor impairment, activity limitation, and quality of life among chronic stroke survivors.
Study design	Single-blinded randomised controlled trial.
Setting	Stroke rehabilitation outpatient program within a multihospital academic medical centre.
Inclusion/ exclusion criteria	Patients were recruited from a stroke rehabilitation outpatient programme, with inclusion criteria of age at least 18 years, at least 12 weeks post-stroke with unilateral hemiparesis, and ankle dorsiflexion strength of 4/5 or less on the Medical Research Council scale. A large number of exclusion criteria were also applied, including lower extremity oedema, skin breakdown, serious cardiac arrhythmias, pacemakers or other implanted electronic systems, pregnancy, or uncontrolled seizure disorder.
Primary outcomes	Lower extremity portion of the FM Assessment (motor impairment), the mEFAP measured without a device (functional ambulation), and the SSQOL scale.

Statistical methods	Intention-to-treat analysis done. Baseline characteristics evaluated using Wilcoxon rank sum test or Fisher's exact test. All outcome measures modelled using a linear mixed effects approach. Differences between treatment groups tested at each discrete time point using the nonparametric Wilcoxon rank sum test with Bonferroni's correction.
Patients included	110 chronic stroke survivors (at least 12 weeks post-stroke) with unilateral hemiparesis and dorsiflexion strength of 4/5 or less on the Medical Research Council scale. After dropout and exclusions: PNS=54, control=56.
Results	There was no significant treatment group main effect or treatment group by time interaction effect on FM, mEFAP, or SSQOL raw scores ($p>0.05$). When comparing average change scores from baseline (T1) to end of treatment (T2, 12 weeks), and at 12 weeks (T3) and 24 weeks (T4) after the end of treatment, significant differences were noted only for the mEFAP and SSQOL scores. The change in the average scores for both mEFAP and SSQOL happened between T1 and T2, followed by relative stability afterwards.
Conclusions	No evidence of a motor relearning effect in either the PNS or comparator groups, but both PNS and comparator groups showed significant improvements in functional mobility and quality of life during the treatment period, with the effect maintained at 6-month follow-up. There were no significant treatment group differences at any time point.
Abbreviations: FM, Fugl-Meyer; mEFAP, modified Emory functional ambulation profile; ODFS, Odstock Dropped Foot Stimulator; PNS, peroneal nerve stimulation; SSQOL, stroke specific quality of life.	

Table 7 Summary of results of the Sheffler et al. (2013) study

	Intervention group: PNS	**Comparator group: UC**	**Analysis**
Randomised	n=54	n=56	
Efficacy	n=39	n=45	

Primary outcome: FM Assessment	NR (shown in plots)	NR (shown in plots)	No significant treatment group main effect (p=0.797) or treatment group by time interaction effect (p=0.321) on raw scores. Time effect was significant (p=0.007) but no significant changes were seen from baseline to each time point (p>0.05). Model parameter estimates for time effect during treatment: Difference 0.525 (95% CI −0.345 to 1.396; p=0.238).
Selected secondary outcomes			
mEFAP	NR (shown in plots)	NR (shown in plots)	No significant treatment group main effect (p=0.968) or treatment group by time interaction effect (p>0.999) on raw scores. Time effect was significant (p<0.001). Model parameter estimates of time effect at T2, T3 and T4 were all significantly lower than at baseline. Model parameter estimates for time effect during treatment: Difference −13.864 (−21.256 to −6.473; p=<0.001).
SSQOL	NR (shown in plots)	NR (shown in plots)	No significant treatment group main effect (p=0.360) or treatment group by time interaction effect (p=0.627) on raw scores. Time effect was significant (p<0.001). Model parameter estimates of time effect at T2, T3 and T4 were all significantly higher than at baseline. Model parameter estimates for time effect during treatment: Difference 9.910 (3.724 to 16.096; p=0.002).
Abbreviations: CI, confidence interval; FM, Fugl-Meyer; mEFAP, modified Emory functional ambulation profile; NR, not reported; PNS, peroneal nerve stimulation; SSQOL, stroke specific quality of life; t1, timepoint 1 (baseline); t2, timepoint 2 (end of device usage period); t3, timepoint 3 (12 weeks post-treatment); t4, timepoint 4 (24 weeks post-treatment); UC, usual care.			

Table 8 Overview of the Sheffler et al. (2015) study

Study component	Description
Objectives/ hypotheses	The objective of this study was to evaluate possible mechanisms for functional improvement and compare ambulation training with surface peroneal nerve stimulation (using the ODFS) compared with usual care via quantitative gait analysis.
Study design	Randomised controlled trial.
Setting	Patients were recruited from an academic medical centre.
Inclusion/ exclusion criteria	Inclusion criteria age at least 18 years, at least 12 weeks post-stroke with unilateral hemiparesis, ankle dorsiflexion strength of 4/5 or less on the Medical Research Council scale, and an effective response to common peroneal nerve stimulation. A large number of exclusion criteria were also applied, including lower extremity oedema, skin breakdown, serious cardiac arrhythmias, pacemakers or other implanted electronic systems; pregnancy, or uncontrolled seizure disorder.
Primary outcomes	Spatiotemporal (cadence, double support duration, stride length, walking speed), kinematic (peak hip flex swing, peak knee flex swing, peak ankle DF swing, ankle DF at IC, peak ankle abduction swing, peak ankle exterior rotation swing) and kinetic parameters (AP GRF, peak hip power pre-swing, peak ankle power at push off) of gait. People were assessed while not wearing the ODFS.
Statistical methods	Intention-to-treat analysis done. A linear mixed-effects model was used to evaluate the mean change in outcome measure within the treatment group. Bonferroni correction was used to control the family-wise error rate and report the authors' adjusted p values.
Patients included	110 chronic stroke survivors (at least 12 weeks post-stroke) with unilateral hemiparesis (PNS=54, UC=56).

Results	Cadence, stride length, walking speed, anterior-posterior ground reaction force, peak hip power in pre-swing, and peak ankle power at push-off all significantly improved with respect to time. However peak ankle dorsiflexion in swing worsened. In general, the greatest change for all parameters happened during the treatment period. There were no statistically significant effects of the treatment on any of the spatiotemporal, kinematic, or kinetic parameters.
Conclusions	Gait training with PNS and UC was associated with improvements in peak hip power in pre-swing and peak ankle power at push-off, which may have resulted in improved cadence, stride length, and walking speed; but there were no differences between groups. Both groups also had a decrease in peak ankle dorsiflexion in swing, although the clinical implications of this finding are unclear.
Abbreviations: AP GRF, anterior-posterior ground reaction force; DF, dorsiflexion; IC, initial contact; PNS, peroneal nerve stimulation; UC, usual care.	

Table 9 Summary of results of the Sheffler et al. (2015) study

	Intervention group	**Comparator group**	**Analysis**
Randomised	54	56	
Efficacy	39	45	Assumed same as Sheffler 2013 study see table 7.
Primary outcome: Cadence (steps/minute, mean±SD)	t1: 65.0±22.0 t2: 67.4±21.5 t3: 69.3±26.4 t4: 70.8±26.8	t1: 66.7±22.7 t2: 72.6±22.6 t3: 72.0±23.2 t4: 73.7±22.7	Treatment group main effect p<0.001 Treatment group × time effect p>0.999 Time effect at t4 p<0.0001
Selected secondary outcomes			

Double support (seconds, mean±SD)	t1: 1.14±0.76 t2: 1.05±0.75 t3: 1.08±0.87 t4: 1.02±0.77	t1: 1.15±0.87 t2: 0.92±0.72 t3: 0.97±0.74 t4: 0.91±0.68	Treatment group main effect p>0.999 Treatment group × time effect p>0.999
Stride length (metres, mean±SD)	t1: 0.62±0.24 t2: 0.68±0.27 t3: 0.71±0.28 t4: 0.71±0.28	t1: 0.67±0.24 t2: 0.74±0.22 t3: 0.72±0.24 t4: 0.73±0.2)	Treatment group main effect p=0.998 Treatment group × time effect p>0.999 Time effect at t4 p=0.0003
Walking speed (metres/ second, mean±SD)	t1: 0.35±0.20 t2: 0.40±0.25 t3: 0.44±0.28 t4: 0.44±0.28	t1: 0.40±0.24 t2: 0.47±0.24 t3: 0.46±0.25 t4: 0.47±0.24	Treatment group main effect p>0.999 Treatment group × time effect p>0.999 Time effect at t4 p<0.0001
Peak hip flex swing (degrees, mean±SD)	t1: 32.5±8.0 t2: 33.2±11.3 t3: 32.8±9.6 t4: 34.5±10.1	t1: 35.3±9.3 t2: 35.1±9.4 t3: 36.2±9.2 t4: 35.4±8.6	Treatment group main effect p=0.350 Treatment group × time effect p>0.999

Peak knee flex swing (degrees, mean±SD)	t1: 25.1±13.1 t2: 27.6±14.1 t3: 27.8±15.9 t4: 29.6±16.4	t1: 30.5±15.1 t2: 31.3±16.6 t3: 31.6±17.0 t4: 31.3±15.5	Treatment group main effect p=>0.999 Treatment group × time effect p=>0.999
Peak ankle flex swing (degrees, mean±SD)	t1: 2.1±7.7 t2: 1.0±8.5 t3: 1.8±8.5 t4: 1.1±8.5	t1: 2.6±6.7 t2: −0.3±7.9 t3: −1.2±10.2 t4: 0.1±8.8	Treatment group main effect p=0.293 Treatment group × time effect p>0.999 Time effect at t4 p= 0.058
Ankle DF at IC (degree mean±SD)	t1: −7.3±9.4 t2: −6.9±9.3 t3: −5.9±8.0 t4: −6.8±8.4	t1: −5.9±8.1 t2: −8.2±10.2 t3: −9.3±11.4 t4: −6.7±9.4	Treatment group main effect p>0.999 Treatment group × time effect p=0.181
Peak ankle abduction swing, (degrees, mean±SD)	t1: −4.1±6.2 t2: −3.8±4.5 t3: −3.8±4.5 t4: −4.2±5.3	t1: −7.5±17.6 t2: −6.1±7.7 t3: −6.0±6.0 t4: −4.7±4.9	Treatment group main effect p=0.464 Treatment group × time effect p=0.999
Peak ankle external rotation swing (degrees, mean±SD)	t1: 0.1±18.0 t2: 1.6±19.3 t3: −0.8±16.5 t4: 1.2±20.3	t1: 4.4±20.1 t2: 3.4±17.8 t3: 4.7±19.9 t4: 0.8±17.9	Treatment group main effect p>0.999 Treatment group × time effect p>0.999

AP GRF (Nm, mean±SD)	t1: 0.51±0.28 t2: 0.60±0.29 t3: 0.64±0.38 t4: 0.74±0.56	t1: 0.55±0.30 t2: 0.69±0.33 t3: 0.64±0.27 t4: 0.67±0.31	Treatment group main effect p>0.999 Treatment group × time effect p>0.999 Time effect at t4 p=0.032
Peak hip power in pre-swing (W/kg, mean±SD)	t1: 0.30±0.21 t2: 0.45±0.43 t3: 0.48±0.41 t4: 0.53±0.52	t1: 0.38±0.31 t2: 0.50±0.44 t3: 0.53±0.48 t4: 0.59±0.61	Treatment group main effect p=0.003 Treatment group × time effect p>0.999 Time effect at t4 p<0.0001
Peak ankle power at push-off (W/kg mean±SD)	t1: 0.42±0.41 t2: 0.54±0.49 t3: 0.56±0.54 t4: 0.62±0.63	t1: 0.51±0.58 t2: 0.66±0.65 t3: 0.64±0.64 t4: 0.64±0.64	Treatment group main effect p>0.999 Treatment group × time effect p>0.999 Time effect at t4 p=0.003
Average time standing/day (minutes, mean±SD)	t1: 153.5±87.2 t2: 170.6±78.6 t3: 156.4±79.2 t4: 173.2±115.2	t1: 127.3±75.5 t2: 127.1±71.7 t3: 138.1±91.5 t4: 157.5±115.5	Time effect: $F_{3,151}$ 1.05; p>0.999 Treatment group × time effect: $F_{3,151}$ 0.57, p>0.999

Average time walking/day (minutes, mean±SD)	t1: 67.8±58.6 t2: 67.3±58.5 t3: 77.5±56.1 t4: 71.8±54.1	t1: 65.9±53.6 t2: 67.5±48.2 t3: 71.1±46.8 t4: 78.8±50.7	Time effect: $F_{3,148}$ 0.54, p>0.999 Treatment group × time effect: $F_{3,148}$ 1.13, p>0.999
Average number of steps/day (mean±SD)	t1: 3223±3134 t2: 3383±3470 t3: 3991±3397 t4: 3738±3211	t1: 3270±2947 t2: 3555±2951 t3: 3734±2820 t4: 4038±2848	Time effect: $F_{3,153}$ 0.78, p>0.999 Treatment group × time effect: $F_{3,153}$ 0.78, p>0.999
Abbreviations: AP GRF, anterior-posterior ground reaction force; DF, dorsiflexion; $F_{x, y}$, degrees of freedom with $_x$ representing the number of treatment arms minus 1 and $_y$ representing the residual error; IC, initial contact; Nm, newton per kilogram; SD, standard deviation; t1, timepoint 1 (baseline); t2, timepoint 2 (end of device usage period); t3, timepoint 3 (12 weeks post-treatment); t4, timepoint 4 (24 weeks post-treatment); W, watt.			

Table 10 Overview of the Burridge et al. (1997) study

Study component	Description
Objectives/ hypotheses	To measure the effect of the ODFS on the effort and speed of walking.
Intervention/ comparator	Intervention: OFDS and physiotherapy Comparator: Physiotherapy alone
Study design	Randomised controlled trial.

Setting	Specialist UK-based FES centre
Inclusion/ exclusion criteria	Inclusion criteria were: stroke causing a hemiplegia for at least 6 months; ability to stand from sitting without help; and walk a minimum of 50 metres independently before to stroke. Exclusion criteria were: bilateral dropped foot, discomfort with stimulation; mental impairment; severe expressive and receptive dysphagia; unable to walk 10 metres; unable to elicit functional ankle dorsiflexion; unable to attend physiotherapy sessions; no improvement seen in walking with stimulation.
Primary outcomes	Changes in walking speed measured over 10 metres and effort of walking measured by PCI.
Statistical methods	Non-parametric statistical tests were used. Wilcoxon signed ranks test was used to determine significance of differences within each group and Mann–Whitney test for differences between groups. Categorical variables were correlated using the chi-square test and relationships between quantitative variables using Spearman's p.
Patients included	32 hemiplegic patients who had a single stroke at least 6 months before the start of the trial.
Results	Mean increase in walking speed between the start and end of the trial was 20.5% in the FES group with stimulation, and 5.2% in the control group. There was a reduction of 24.9% in PCI in the FES group with stimulation, and 1% in the control group. There was no improvement in these parameters in the FES group when the stimulator was not used. When the FES group was compared with the control group, there was a statistically significant improvement in walking speed at week 12, but not at week 4, and no statistically significant improvements in PCI at any time point.
Conclusions	Walking was statistically significantly improved when the ODFS was worn but no 'carry-over' (training effect) was seen. Physiotherapy alone did not improve walking.
Abbreviations: FES, functional electrical stimulation; m, metres; ODFS, Odstock Dropped Foot Stimulator; PCI, physiological cost index.	

Table 11 Summary of results of the Burridge et al. (1997) study

	FES	Control	Analysis
Randomised	n=16	n=16	n=32
Efficacy	n=15	n=16	n=31 (1 patient from the FES group excluded from analysis)
Primary outcome: 10-m walking speed (metres/second, mean±SD)	FES without stimulation Week 0: 0.64±0.46 Week 4: 0.62±0.41 Week 12: 0.63±0.39 FES with stimulation: Week 0: 0.68±0.49 Week 4: 0.75±0.51 Week 12: 0.77±0.43	Control Week 0: 0.48±0.25 Week 4: 0.51±0.25 Week 12: 0.51±0.27	FES without stimulation vs control Week 0: p=0.318 (95% CI −0.130 to 0.360) Week 4: p=0.621 (95% CI −0.170 to 0.280) Week 12: p=0.407 (95% CI −0.120 to 0.320) FES with stimulation vs control Week 0: p=0.228 (95% CI −0.380, to 0.100) Week 4: p=0.221 (95% CI −0.400, to 0.900) Week 12: p=0.044 (95% CI −0.460 to 0.001)[a]

Changes in 10-m walking speed (metres/second, mean±SD)	FES without stimulation Week 4 vs Week 0: 0.06±0.21 Week 12 vs Week 0: 0.01±0.15	Control Week 4 vs Week 0: 0.03±0.08 Week 12 vs Week 0: 0.03±0.10	FES without stimulation Week 4 vs Week 0: % change 1.2, p=0.551 (95% CI −0.130 to 0.045) Week 12 vs Week 0: % change 0.12, p=1.00 (95% CI −0.085 to 0.075) Control Week 4 vs Week 0: % change 5.21, p=0.255 (95% CI −0.0200 to 0.065) Week 12 vs Week 0: % change 5.21, p=0.379 (95% CI −0.030 to 0.080) FES group with stimulation week 0 vs FES group without stimulation week 0 Mean=0.04±0.11, % change 6.1, p=0.187 (95% CI −0.020 to 0.100) FES group with stimulation week 4 vs FES group without stimulation week 0 Mean=0.11±0.24, % change 17.61, p=0.205 (95% CI −0.020 to 0.195) FES group with stimulation week 12 vs FES group without stimulation week 0 Mean=0.13±0.13, % change 20.50, p=0.004 (95% CI 0.060 to 0.210)
Selected secondary outcomes			

PCI (beats per minute/ metre per minute, mean±SD)	FES without stimulation Week 0: 0.80±0.74 Week 4: 0.71±0.71 Week 12: 0.76±0.64 FES with stimulation: Week 0: 0.59±0.49 Week 4: 0.61±0.67 Week 12: 0.54±0.56	Control Week 0: 1.03±0.67 Week 4: 0.98±0.74 Week 12: 1.00±0.69	FES without stimulation vs control Week 0: p=0.220 (95% CI −0.141 to 0.052) Week 4: p=0.327 (95% CI −0.179 to 0.620) Week 12: p=0.127 (95% CI −0.080 to 0.770) FES with stimulation vs control Week 0: p=0.057 (95% CI −0.010 to 0.640) Week 4: p=0.127 (95% CI −0.080 to 0.770) Week 12: p 0.083 (95% CI −0.020 to 0.749)

Changes in PCI (beats per minute/metreper minute, mean±SD)	FES without stimulation Week 4 vs Week 0: −0.09±0.05 Week 12 vs Week 0: −0.04±0.12	Control Week 4 vs Week 0: −0.05±0.27 Week 12 vs Week 0: −0.03±0.20	FES without stimulation Week 4 vs Week 0: % change −5.62, p=0.335 (95% CI −0.085 to 0.255) Week 12 vs Week 0: % change −11.83, p=0.670 (95% CI −0.105 to 0.2245) Control Week 4 vs Week 0: % change −5.80, p=0.148 (95% CI −0.065 to 0.160) Week 12 vs Week 0: % change −3.90, p=0.469 (95% CI −0.060 to 0.120) FES with stimulation week 0 vs FES without stimulation week 0 Mean −0.20±0.32, % change −20.68, p=0.010 (95% CI 0.040 to 0.325) FES with stimulation week 4 vs FES without stimulation week 0 Mean −0.18±0.44, % change −20.49, p=0.094 (95% CI −0.025 to 0.380) FES with stimulation week 12 vs FES without stimulation week 0 Mean −0.26±0.37, % change −24.87, p=0.008 (95% CI 0.040 to 0.430)

Abbreviations: FES, functional electrical stimulation; m/s, metres per second; m, metre; min, minute; PCI, physiological cost index; vs, versus.

[a]Results may be reported incorrectly because the p value is <0.05 but the 95% CI spans zero.

Table 12 Overview of the Street et al. (2015) study

Study component	Description
Objectives/ hypotheses	To determine the effectiveness of FES on drop foot in patients with MS, using data from standard clinical practice.
Study design	Case series with data collected between 2008 and 2013.
Setting	UK-based specialist FES centre.
Inclusion/ exclusion criteria	Study exclusion criteria were: inability to walk 10 metres with the assistance of a walking aid; poorly controlled epilepsy; or fixed skeletal deformities. Other precautions included recent injury, fracture, or surgery; major skin conditions; and cancerous tissue near the site of stimulation.
Primary outcomes	Clinically meaningful changes in functional walking category and walking speed over 10 metres.
Statistical methods	A repeated-measures analysis of variance was used to analyse the walking speed over 10 metres. Planned comparisons were done using paired t tests.
Patients included	166 people with MS.
Results	An increase in walking speed was found to be significant both initially and after 20 weeks with a substantial clinically meaningful change. No significant training effect was found. Functional walking category lasted or improved in 95% of people responding to treatment.
Conclusions	FES is a well-accepted intervention that aids clinically meaningful changes in walking speed, leading to a preserved or increased functional walking category.

Abbreviations: FES; functional electrical stimulation. MS; multiple sclerosis.

Table 13 Summary of results of the Street et al. (2015) study

	Unassisted walk	FES walk	Analysis
Efficacy	-	-	n=153
Primary outcome: walking speed over 10 metres (m/s)	-	-	Main effect for stimulation vs no stimulation ($F_{1,152}$ 91.88, p<0.001). Interaction effect between stimulation over time ($F_{1,152}$ 9.79, p=0.002).
Selected secondary outcomes			
Initial orthotic effect (metres/second, mean±SD)	0.72±0.33	0.79±0.31	Mean difference: 0.07± 0.11[a], p=0.001 (95% CI 0.05 to 0.08)
Continuing orthotic effect (metres/second, mean±SD)	0.72±0.35	0.82±0.34	Mean difference: 0.11±0.16[b], p=0.001 (95% CI 0.08 to 0.13)
Total orthotic effect (metres/second, mean±SD)	0.72±0.33	0.82±0.34	Mean difference: 0.10±0.22[b], p=0.001 (95% CI 0.07 to 0.14)
Training effect (metres/second, mean±SD)	0.72±0.33	0.72±0.35	Mean difference: 0.00±0.26, p=0.53 (95% CI -0.04 to 0.03)

Abbreviations: CI, confidence interval; m/s, metres/second; SD, standard deviation; vs, versus.

[a]Minimal meaningful change.

[b]Substantial meaningful change.

Search strategy and evidence selection

Search strategy

Search strategy

The search strategy was designed to identify evidence on the clinical and cost effectiveness of the ODFS Pace functional electrical stimulation (FES) device for use in patients with drop foot.

The strategy was developed for MEDLINE (Ovid interface). The strategy was devised using a combination of subject indexing terms and free text search terms in the title, abstract and keyword heading word fields. The search terms were identified through discussion within the research team, scanning background literature, browsing database thesauri and use of the PubMed PubReMiner tool. The strategy reflected the nature of the MIB assessments as rapid evidence reviews, with a relatively pragmatic, focused search approach being used.

The main structure of the search strategy comprised two concepts:

1) dropped foot

2) ODFS Pace FES device.

The search concepts were combined as follows: dropped foot AND ODFS Pace FES device.

Terms for the ODFS Pace FES device concept were based on the key action of the device – functional electrical stimulation of the common peroneal nerve. The strategy also included 3 stand-alone search lines on the manufacturer and device names (lines 18–20).

The strategy excluded animal studies using a standard algorithm. Non-English language publications were also excluded from the search results. No date limit was applied to the

strategy.

The MEDLINE strategy was translated appropriately for the other databases searched. The PubMed search was limited to records that were not fully indexed on MEDLINE. Conference-related records were excluded from the Embase search.

The following databases were searched:

- Cochrane Central Register of Controlled Trials (Cochrane Library, Wiley)
- Cochrane Database of Systematic Reviews (Cochrane Library, Wiley)
- Database of Abstracts of Reviews of Effects (Cochrane Library, Wiley)
- Embase (Ovid SP)
- Health Technology Assessment Database (Cochrane Library, Wiley)
- MEDLINE and MEDLINE in Process (Ovid SP)
- NHS Economic Evaluation Database (Cochrane Library, Wiley)
- PubMed.

Evidence selection

A total of 972 records were retrieved from the literature search. After de-duplication, 590 records remained. The title and abstracts of all 590 records were screened independently by 2 reviewers, against the following inclusion and exclusion criteria:

Inclusion criteria:

- use of the Odstock functional electrical stimulator
- patients with drop foot
- comparators are physiotherapy or mechanical devices
- useful outcomes listed.

Exclusion criteria:

- low number of patients (that is, <10)
- non-English language studies
- conference abstracts
- review protocols
- non-comparative studies.

Disagreements between the 2 reviewers were resolved through discussion, and, where necessary, through consultation with a third reviewer. This first sift excluded 548 papers. A further 10 papers were not retrieved because they were deemed not to be relevant, high quality studies based on the abstracts. Full records were retrieved for the remaining 32 papers. A list of the papers that were not retrieved is provided below:

- Bosch PR, Harris JE, Wing K et al. (2014) Review of therapeutic electrical stimulation for dorsiflexion assist and orthotic substitution from the American Congress of Rehabilitation Medicine stroke movement interventions subcommittee. 95: 390–6
- Dunning K, O'Dell MW, Kluding P et al. (2015) Peroneal stimulation for foot drop after stroke: A systematic review. American Journal of Physical Medicine and Rehabilitation 94: 649–64
- Granat MH, Maxwell DJ, Ferguson AC et al. (1996) Peroneal stimulator; evaluation for the correction of spastic drop foot in hemiplegia. Archives of Physical Medicine and Rehabilitation 77: 19–24
- Hayes Inc. (2011) Functional Electrical Stimulation (FES) for treatment of foot drop in multiple sclerosis patients. Healthcare Technology Brief Publication
- Lairamore CI, Garrison MK, Bourgeon L et al. (2014) Effects of functional electrical stimulation on gait recovery post-neurological injury during inpatient rehabilitation. Perceptual and Motor Skills 119: 591–608
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The second sift was done against the same inclusion and exclusion criteria. Again, disagreements between the 2 reviewers were resolved through discussion and consultation with the third reviewer. A total of 21 papers were excluded for the following reasons:

- intervention not relevant (n=19)
- record was a presentation (n=1)
- record was a duplicate (n=1).

Of the remaining 11 studies, 6 representing the best quality evidence, which included all relevant outcomes to the treatment, were selected.

All papers were assessed for methodological quality using the checklists provided within the NICE guidelines manual: appendices B-I.

About this briefing

Medtech innovation briefings summarise the published evidence and information available for individual medical technologies. The briefings provide information to aid local decision-making by clinicians, managers and procurement professionals.

Medtech innovation briefings aim to present information and critically review the strengths and weaknesses of the relevant evidence, but contain no recommendations and **are not formal NICE guidance**.

Development of this briefing

This briefing was developed for NICE by Newcastle and York External Assessment Centre. The interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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Specialist commentators

The following specialist commentators provided comments on a draft of this briefing:

- Dr Bhaskar Basu, Consultant in Rehabilitation Medicine, University Hospital of South Manchester NHS Foundation Trust
- Mrs Christine Singleton, Clinical Specialist, Birmingham Community Healthcare NHS Trust
- Dr Lloyd Bradley, Consultant in Rehabilitation Medicine, West Sussex Hospitals NHS Trust
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Declarations of interest

- Christine Singleton has received remuneration from Odstock Medical Limited for teaching on training courses relating to functional electrical stimulators for drop foot.

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