Functional Electrical Stimulation (FES)
Clinical Service at the National Clinical FES Centre
Salisbury District Hospital & OML Clinics

An introduction to Functional Electrical Stimulation for the upper and lower limb – referral criteria and clinical pathway

FES & the correction of Dropped Foot and other gait problems

- Dropped foot is the inability to lift the foot as the leg swings forward when walking. It is caused by weakness in the muscles that lift the foot and/or excessive activity (spasticity) in the antagonist muscles.

- Dropped foot increases the risk of falls, reduces mobility and participation.

- Functional Electrical Stimulation (FES) is the production of functional movement in paralysed muscles by the application of small pulses of electrical current to the nerves that supply them.

- The Odstock Dropped Foot Stimulator (ODFS®) stimulates the common peroneal nerve using self adhesive skin electrodes mounted on the lower leg. Stimulation is timed to the walking cycle by using a pressure switch placed in the shoe under the heel. Stimulation begins when the heel is lifted from the ground and ends just after heel strike. Stimulation causes the foot to lift and stabilises the ankle when it is returned to the ground.

- The ODFS® is primarily used as a long-term orthosis. However, therapeutic training benefit has been demonstrated in people who have a dropped foot due to stroke, spinal cord injury, Parkinson's and some people with MS.

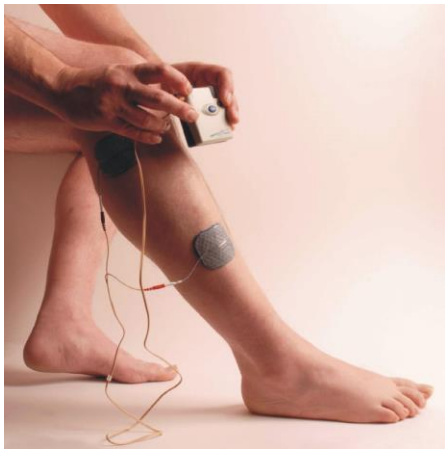
- The main effects of the ODFS® are:

    - Increased safety due to reduced tripping and increased stability in stance
    - Increased walking speed and range
    - Reduced effort of walking
    - Greater confidence and independence

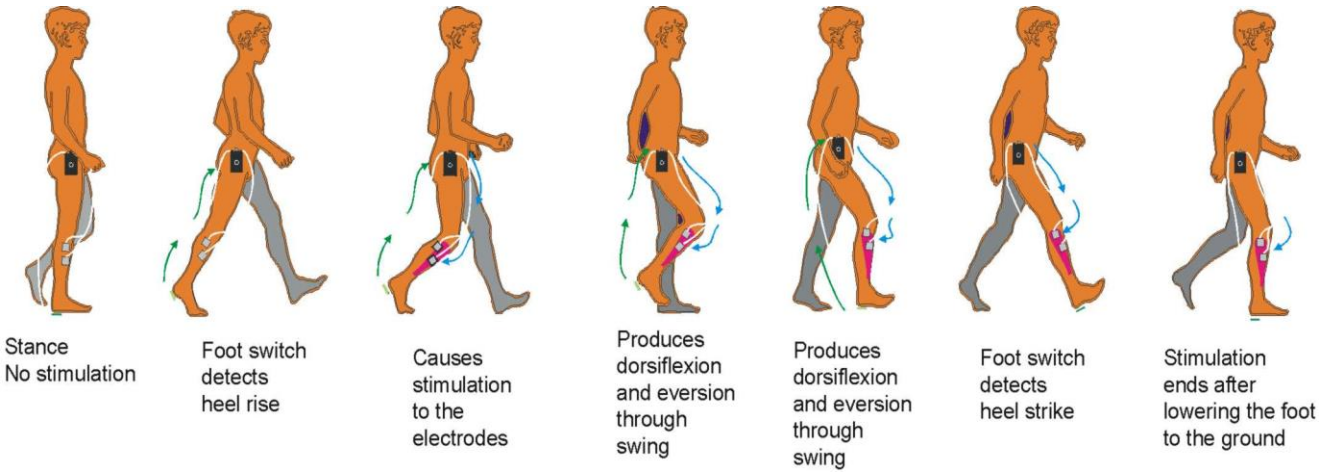
- The ODFS® is a practical device with adherence to treatment at one year of 86%.

- FES can be used to assist in any neurological condition resultant from an upper motor-neuron lesion. This includes stroke, MS, SCI, TBI, CP, HSP and Parkinson's Disease.

Operation of the ODFS® Pace



Self-adhesive electrodes are placed on the skin over the common peroneal nerve at its most superficial point, over the head of fibula. Stimulation causes dorsiflexion and eversion. By choosing electrode positions and stimulation parameters knee and hip flexion can be improved, further assisting gait. The stimulation is timed using a foot switch placed in the shoe. Stimulation begins when weight is taken from the switch and ends just after heel contact, lowering the foot to the ground. Stimulation feels like pins and needles. Most people quickly become used to the sensation. The foot switch can be easily moved from shoe to shoe enabling any footwear to be used.



The most important factors in successful use of the ODFS® are:

- Appropriately trained clinical staff
- Thorough patient training in the use of FES
- Regular planned follow up to ensure continued benefit from FES
- Prompt response to any problems

Development of the ODFS® Pace

- The Odstock Dropped Foot Stimulator (ODFS®) Pace was developed at Salisbury District Hospital under funding from the Department of Health.

- The Device was evaluated for dropped foot in chronic stroke in a randomised controlled trial (RCT)[1, 2]. Additional case series data was collected from patients with MS and incomplete spinal cord injury[3]. The trial demonstrated:

    - Increased walking speed when the ODFS® Pace is used
    - Reduced walking effort
    - Reduced spasticity
    - Increased quality of life
    - Significant cost utility gain (cost-effectiveness - QALY analysis)

- The clinical service modal and evidence for the ODFS® Pace were presented to the Development and Evaluation Committee of the South and West Regional Health Authority who subsequently recommended the treatment for use in the NHS for patients with dropped foot due to upper motor neurone lesions[4, 5]

- Audit of the clinical service confirms the results of the RCT and demonstrates a training effect from using the ODFS® and a high level of treatment adherence (86% at one year)[6, 7, 8, 9]. The main reasons patients choose to continue to use the ODFS® are:[10]

    - Reduced effort of walking
    - Increased confidence when walking
    - Reduced trips and falls

- An RCT of the use of the device with secondary progressive MS demonstrated increased walking speed with the device, 72% reduction in falls and a significant positive impact on activities of daily living in comparison to a group that received physiotherapy[11, 12].

- An audit of 186 users of the ODFS® Pace who had MS showed that FES improves functional ambulation category[15].

- The ODFS® Pace has been demonstrated to be a clinically and cost-effective long term assistive device with an average use of 5 years[16, 17,] and cost-effective relative to AFOs[18].

- Studies using the ODFS® Pace with people who exhibited freezing of gait due to Parkinson's disease indicated that the device may have a significant training effect, reducing bradikinesia[13, 19].

- Many Thousands of patients have received treatment for dropped foot using FES from OML since the service began. Over 20,000 have received treatment elsewhere in the UK.

- FES is recommended for dropped foot in the NICE guidelines IPG278[15,.20]. It is also recommended in NICE[21] and RCP[22] stroke guidelines, NICE guidelines for MS[23], CP[24] and traumatic injury[25]. FES clinical practice is recommended in ACPIN[26] and ANPT guidelines[27].

Referral criteria

Cause and functional deficit:

- Neurological deficit due to an upper motor neurone lesion. An upper motor neurone lesion is defined as one that occurs in the brain or spinal cord at or above the level of T12. This is normally but not exclusively associated with spasticity.

- Upper motor neurone lesion resulting in dropped foot occur in conditions such as stroke, multiple sclerosis, incomplete spinal cord injury at T12 or above, cerebral palsy, familial/hereditary spastic paraparesis, head injury and Parkinson's disease.

Nature of functional deficit:

- Dropped foot defined as a deficit of dorsiflexion and/or eversion of the ankle. While this will be frequently associated with lack of heel strike, FES can be successfully used to correct inversion at first contact to significantly improve the stability of the ankle in the stance phase, improving the safety of gait.

- A dropped foot can be unilateral or bilateral.

- In addition to drop foot, deficits in knee flexion or extension, hip extension, flexion and abduction and push off at terminal stance can be addressed. FES can be used to strengthen and/or control other muscles used in gait such as hamstrings, quadriceps, gluteal and calf muscles.

Functional ability:

- Able to passively achieve a neutral (or near neutral) angle of the ankle. A resistance due to spasticity of the calf muscles can be overcome, but fixed contracture preventing plantagrade is a contraindication.

- Able to obtain standing from sitting unaided. Use of aids such as sticks, frame or crutches is acceptable. In supervised gait re-education, less ability may be acceptable.

- Able to walk a minimum distance of about 5-10m. Use of aids such as ankle foot orthosis (AFO), sticks, frame or crutches is acceptable. In supervised gait re-education, less mobility may be acceptable.

- There is no maximum walking distance limit. FES devices have been successfully used in cases where a dropped foot only becomes a significant problem when the device user is tired or when the deficit is relatively mild.

- A reasonable exercise tolerance is required for treatment sessions. However, FES often reduces the effort of walking therefore poor exercise tolerance is only an exclusion criteria in extreme cases.

Motivation, understanding and independence:

- Able to understand the aims of the treatment and be motivated to comply with treatment protocols. Where appropriate, carer support can assist in using the equipment.

- Where patients live alone and do not have carer assistance, they must be able to place electrodes and operate the equipment independently. If family or carer support is present, less independence is required.

Precautions:

- Poor skin condition is a contraindication as sores or irritation prevents the use of self-adhesive electrodes.

- Poorly controlled epilepsy. Where epilepsy is controlled by drugs or there has been no fits experienced for a reasonable period (approx. 3 months), FES can be used.

- A history of significant autonomic dysreflexia in incomplete spinal cord injury above T6.

- The effect of FES on the unborn child in pregnancy is not known.

- Active medical implants such as cardiac pacemakers or other devices must be treated with caution and information sought from the device supplier about the use of electrical stimulation in their presence. An additional clinical test may be required to determine the safety of FES. For some devices this can be arranged in Salisbury.

- Patients with a cancerous tumour in the area of the electrical stimulation should be excluded as increased local blood flow may increase tumour growth.

- Patients with exposed orthopaedic metal work in the area of electrical stimulation should be avoided.

While the majority of our patients fit the above criteria, patients outside these criteria can be considered. Please contact the team for more information.

Clinical Pathway

All referrals for NHS treatment are made by the patient's GP, Medical Consultant or HCP to Prof Paul Taylor, Clinical Director, Odstock Medical Limited, National Clinical FES Centre, Salisbury District Hospital, Salisbury, Wiltshire, SP2 8BJ, UK. Self-referrals are also accepted for privately funded treatment and a self-referral form is available on the OML website. The referral letter is reviewed by Prof. Taylor, or in his absence by experienced clinical staff at the National FES Centre. FES might be a suitable treatment an appointment is made for an initial assessment in Salisbury or at one of OML's clinics. Sometimes further details are requested from the referring Clinician.

At the initial assessment clinic, the above referral criteria are checked. An additional acceptance criterion is the ability to tolerate the sensation of electrical stimulation. A FES device is tried and in most cases an improvement in gait is immediately apparent. Following discussion with the patient a decision whether to proceed with treatment is made. In some cases, the Clinician may judge that a period of electrical stimulation training is required in order to strengthen muscles, reduce spasticity or to accustom the patient to the sensation of electrical stimulation before FES is used for walking. Stimulation exercises may be started at this appointment if time permits. Otherwise, exercises will be set up at another appointment.

The ODFS® Pace is fitted over two clinic sessions, usually within one week. On the first day the user is taught how to apply the device and on the second day their ability to do so is assessed and further training given if necessary. Use of the stimulator is increased gradually over 2 to 3 weeks until it can be used all day. Follow up is made at 6 weeks, 18 weeks and 44 weeks from first use and then every 6 months or yearly depending on the patient's condition, for as long as the device is used. If users experience problems, they are encouraged to contact the clinic for advice or equipment repaired. Extra clinic sessions can be arranged if necessary.

In the case of more complex movement problems where more than one muscle group are stimulated, treatment is often started with a single channel ODFS® Pace and the second channel introduced at the 6 or 18 week follow up assessment, once the user has become accustomed to FES.

Functional Electrical Stimulation (FES) for the upper limb rehabilitation

FES treatment is provided for upper limb neurological problems resulting from conditions such as stroke, brain injury, spinal cord injury or cerebral palsy. Referrals are accepted for three main categories of upper limb treatment.

Subluxation of the shoulder

- The main aim is to reduce pain associated with shoulder subluxation.
- The three compartments of the deltoid muscle plus the supraspinatus muscle are stimulated causing the humerus to elevate into the glenoid humeral socket.

- The treatment may need to be continued long term to maintain reduction of pain unless functional movement improves.

FES Exercise to improve hand and arm function

Stroke and Cerebral Palsy:
- Patients should have some functional ability, typically being able to produce a grip but may not be able to release, or reduced ability to extend the elbow.
- Main treatment aim is to increase the strength of the extensor muscles while reducing the spasticity in the flexor muscles.
- Repetition of exercises may lead to neuroplastic changes resulting in improved function.

Spinal cord injury:
- Patients should have some functional ability, typically a weak tenodesis grasp in C6 tetraplegia or general weakness in incomplete C5/6/7 tetraplegia.
- The main treatment aim is to increase the strength and therefore function of the effected muscles.

Non-functional group:
- FES can be used to relieve spasticity with the aim of loosening an over tight grip or elbow flexion.
- The main treatment aim is to reduce pain associated with spasticity, assist with hygiene by enabling better hygiene or assist other activities of daily living such as dressing.

Motivation, understanding, independence and precautions:
Cardiac pacemaker users should not use FES in the hand arm or torso. The other precautions are the same requirements as for the lower limb applications of FES.

Clinical Procedure for Upper limb FES
The referral and assessment process are the same as for lower limb applications.

In most cases upper limb treatment is limited to a 6-month period. In that time the patient will be seen for five, 1-hour appointments. At the first appointment an electrical stimulation exercise programme for the patient to perform at home will be devised. Where appropriate, additional physiotherapy exercises may also be given. Follow up is provided at 2, 8, 16 and 24 weeks. At each session, the exercises are reviewed and progressed. Where appropriate, functional measures will be made to record progress.

In some cases it is beneficial to continue treatment over a longer period. This reviewed at the week 24 appointment and a recommendation made to the referring clinician.

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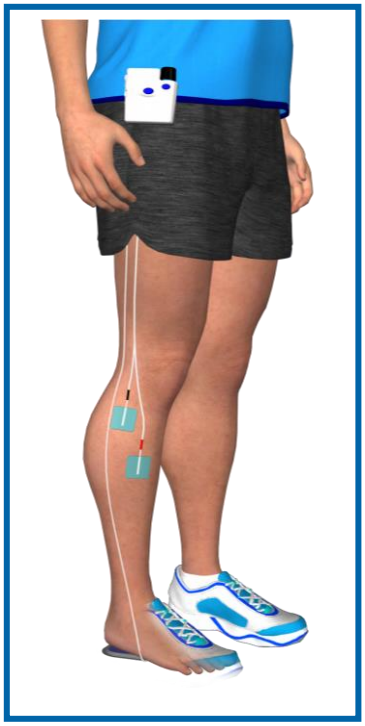
OML | Leading FES Rehabilitation

FES user…

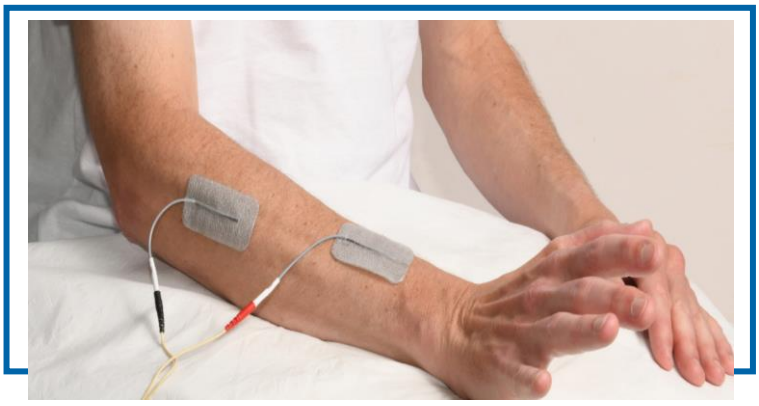
"It changed my life. One minute I was struggling around with a walking stick and the next I could walk without it. It gave me the confidence and I'm no longer dependent on other people – I can just go."

The ODFS® Pace is a Functional Electrical Stimulation (FES) device used to improve walking for people who have neurological conditions such as stroke. Dropped foot is the difficulty in lifting the foot and instability of the ankle while walking. By activating the muscles that control the foot, walking is made easier, safer and faster. Falls are reduced and FES users report that they walk with much greater confidence. FES helps to retrain muscles leasing to improved walking after FES is used. FES can also be used to improve knee and hip movements.



FES and ODFS® Pace are recommended by NICE* for use in the NHS.

FES can also help hand and arm movement, help control spasticity and control the pain of subluxed shoulders.



FES is also avilable at other independent clinics. Contact OML for details

*NICE IPG278 & MIB65