Salisbury FES Newsletter
Autumn 2003

Editorial

The FES (Functional Electrical Stimulation) Newsletter is a biannual publication with the purpose of promoting the clinical use of FES. It is distributed chiefly to clinicians who have attended the Salisbury introductory FES course but also those who have an interest in the field or those we hope may be interested. FES is a means of producing functional movement in paralysed muscles by the application of electrical impulses to the nerves of those muscles. FES is increasingly used in neurological rehabilitation to improve mobility and upper limb function. The most common use is for the correction of dropped foot in hemiplegic gait, an intervention now recommended by the Royal College of Physicians in their publication "National clinical guidelines on stroke".

Next September (6^{th} – 9^{th}) the Salisbury FES team will be hosting the annual meeting of the international FES society (IFESS). This is the first time the conference has come to the UK and is expected to attract 400 or more delegates from all over the world. As there is nowhere big enough to hold such a large meeting in Salisbury, the meeting will take place at the Bournemouth international Centre, which is on the sea front, right next to the pear. We plan to have a strong clinical content in the conference as well as reports on the latest technology and implanted techniques. The first call for papers will be out soon. This is defiantly a date for your diary.

Before IFESS is our own annual **FES User Day** on the 5^{th} December and will this year at City Hospital, Birmingham. For the first time this meeting will be co-sponsored by FESnet, the national network for all those interested in FES. As usual there will be reports on the latest developments in clinical FES, case studies and a problem solving workshop. These meetings are a good opportunity to swap experience and meet up with others working in the field. We welcome presentations on any aspect of clinical FES. Please return the form at the end of this newsletter. While you do not have to offer a presentation to come we particularly welcome case studies and reports of clinical experience with FES from all practitioners in the field.

Increasingly we are contacted by people seeking FES treatment and asking if they can obtain it in their area. The Data Protection Act dose not allow us to give out details of the clinicians on our database who have done the FES course and in any case many clinicians may not be in a position to offer treatment. For this reason we are trying to compile a list of clinicians or centres who are able to provide a service (either NHS or private). We would be most grateful if you could complete and return the form at the back of the newsletter.

Thanks to all who have contributed to this newsletter. As always we welcome your feedback and we are pleased to hand on any "good ideas", reports, meeting reviews or adverts that you have through this newsletter. Next addition will be put together in January so please send copy by then. This and all back issues of the Salisbury FES Newsletter are on our web page www.salisburyfes.com

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Clinical service for provision of the ODFS for chronic stroke, MS, incomplete SCI and other stable neurological conditions

Referral

Patients are only seen following referral by their GP or Medical Consultant. Referrals are reviewed to check the patient's suitability for treatment and it is not uncommon for it to be necessary to seek further information from the referring doctor to clarify the patient's condition or diagnosis. A common inappropriate referral is where patients have a dropped foot due to a peripheral nerve lesion such as sciatic nerve damage following knee or hip surgery. This leads to a lower motor neurone lesion and it is not possible to excite the muscle using the electrical stimulation techniques we have available.

Assessment

Patients are first seen at an assessment clinic. Subjects are suitable for treatment if they have a dropped foot due to an upper motor neurone lesion and are able to walk at least a few metres with appropriate aids or assistance. The patient is given a physical examination including estimates of active and passive joint range, spasticity (Ashworth) and muscle strength about the hip, knee and ankle. A description of their gait is recorded and a provisional treatment plan made. The following are contraindications; fixed contractures of the ankle, poorly controlled epilepsy (there is some anecdotal evidence of symptoms being exacerbated by electrical stimulation) and poor skin condition in the area of the electrodes. The effect of the stimulation is not known in pregnancy and pacemaker users are assessed by a cardiologist to ensure the ODFS does not interfere with the pacemaker. Patients must be sufficiently cognitively aware to understand the operation and purpose of the device and have sufficient motivation to use it. Where a patient is not capable of donning and doffing the device independently, it can still be used if they have assistance at home from a carer. The stimulator is tried and if gait can be improved, the patient is recommended for treatment.

It is not uncommon for the response to common peroneal stimulation to be a little weak or for increased calf tone to prevent a good range of movement. In such cases it can be useful to use an exercise stimulator for a period of a month or 6 weeks before starting to use the ODFS. We use the Microstim 2 stimulator because it has a very slow and gentle ramp. This makes the stimulation more comfortable and the gradual change in dorsiflexion produced is slow enough to avoid the production of a stretch reflex in the calf muscles. Electrodes are placed in the same positions as for the ODFS. Treatment times begin with just 10 minuets a day increasing over the 6 week period to about 2 periods of thirty minutes. A reduction in calf tone in response to stimulation is commonly seen but it is also not uncommon to see a carry over effect leading to reduced calf tone while walking, even before the ODFS is used.

Where patients are very sensitive to the sensation the same procedure is followed. The stimulation level can be started at a low amplitude and increased a little each day until a good movement is produced. Using larger electrodes can also reduce the sensation a little as the density of current is reduced. We often find that many patients find the Platinum Blue Pals hypo-allergesic 50 x 50 mm electrodes more comfortable than other electrodes and increasingly we are using these electrodes with most patients unless they have small legs and therefore require smaller electrodes. Another advantage of larger electrodes is that finding the correct positions can be a bit easier. However, if electrodes are too large, it can be difficult to avoid stimulation of other muscle groups. As with the ODFS we use a 40Hz stimulus with an intermittent pattern (mode 6 on the old Microstim 2, mode 0 on the new Microstim 2V2). These exercises are set up at the first assessment clinic.

Setting up the ODFS

The ODFS is fitted over two clinic sessions on consecutive days. On the first day the user is taught how to apply the device while on the second day their ability to do so is assessed and further training given if necessary. Patient education is key to successful use of the ODFS and it is worth spending a lot of time to make sure they understand the device and what is trying to be achieved. If appropriate, carers are also instructed in its use. We usually mark the electrode positions with an indelible felt tip pen, colour coded for the red and black lead. (The ink fades after about three days) The patient is given an instruction manual and taken through the main points of the manual, in particular the section on skin and electrode care and precautions. The electrode positions are marked on a diagram of the leg and sometimes digital photographs are also taken and given to the patient to help them find electrode positions. We ask the patient (and / or carer) to read the manual and come back to the second appointment with any questions that they may have.

At the second appointment we measure walking speed and physiological cost index (PCI) over 10m both with and without the ODFS. Generally 3 walks with and 3 walks without the ODFS are recorded and the order of walks randomised to compensate for fatigue. If a patient is unable to complete 3 walks, fewer walks are done. This is used as a record of the patient's progress and is reported back to the referring Doctor. Patients receive a copy of all correspondence about their treatment. The ODFS settings and accessories are recorded in the patient notes and this information used for sending out spares if required. Finally the patient is given spare electrodes and a spare foot switch.

Follow up

Follow up is made at 6 weeks, 18 weeks, 45 weeks and 72 weeks from first use and then yearly for as long as the device is used. If users experience problems they are encouraged to contact the clinic so advice can be given, equipment repaired or extra clinic sessions arranged if necessary. Many problems can be solved with telephone advice and we make it clear that we prefer people to phone as soon as they have a problem rather wait to the next appointment. We try to solve technical problems by sending out spare equipment by next post. Our technical staff are also trained in the clinical application of the ODFS and this aids them in understanding patient queries. However, we encourage patients from other clinics to contact the clinic where they received their ODFS, as it is that clinic' s responsibility to provide continuing follow up care.

At follow up clinics the patients use of the stimulator is checked. Sometimes the stimulator settings need adjusting, particularly if their gait has changed; for example, it may be necessary to reduce the rising edge ramp if their gait is significantly faster. Skin condition is always checked and advice on skin and electrode care re-emphasised if needed. Any changes in gait are noted, in particular, changes in spasticity, which might indicate a problem. The walking speed and PCI tests are repeated and changes fed back to the patient to give them an indication of their progress. The patient is given enough electrodes to last them to their next appointment.

Conclusion

We have been using this clinical model for eight years and it has proved to be successful. This is reflected in the compliance rate for the ODFS, which is 92% at 18 weeks and 86% after 1 year. This is high for any orthotic aid. We believe the key has been to provide a high level of patient and carer education at the start of treatment, re-enforced with continuing follow up. This is supported by rapid response to problems and good technical back up.

Paul Taylor

PDF Down loads from the web

We now have equipment order forms, VAT exemption forms, price lists and case study assessment forms available on our web page in down loadable PDF format. This means they can easily be printed out and used. Is there anything ells we could put up there? Please let us know. Our web page is www.salisburyfes.com.

Early use of FES to shoulders in tetraplegia

In this unit, along with all other spinal units, we have an increasing number of tetraplegic patients being admitted. Whereas before they used to come to us for rehabilitation several months post SCI, nowadays, with better and earlier fixation being used, we are receiving them only a week or two after their 'accident'.

Wherever possible we now routinely use FES on their shoulders and arms right from admission. Although we do not have a large enough throughput of patients to prove that it is helpful, our observations over the last five years have been that the patents that receive regular FES:

- Have little or no shoulder pain when they start using their upper limbs functionally, i.e. transfers, pushing wheelchair and exercising.
- Do not appear to lose much muscle bulk around the shoulder girdle as untreated patients.
- Seem to have fewer problems with maintaining ROM in upper limb joints.
- Can hold their heads up in a better position for longer when they start sitting and are less afraid of trying to move their head / neck.
- Have less pain and swelling in forearms and hands
- Enjoy the feeling of their muscles moving, particularly if they cannot do it for themselves.

It can be argued that this is a rather time-consuming treatment, particularly where therapists are in short supply. We have found that friends and relatives are more than happy to learn accurate electrode placement and once they have got the hang of it, the therapists can act in a supervisory and observational role.

We use Salisbury 4 Channel Muscle Stimulators and 5am or smaller reusable electrodes, depending on which muscles are being worked.

The muscles which are routinely stimulated are deltoid and upper trapezius / suraspinatus, rhomboids, triceps (not always possible due to denervation), wrist extensors and flexors and lumbricals. Other muscles of the hand and wrist can be picked up, but this is more often done during a hand session with our Occupational Therapist.

It is difficult to prove that early use of FRES makes a difference to the standard and rate of recovery because, of course, it is being used in conjunction with all other treatments. However, experience and observation indicate that patients who receive it develop fewer shoulder problems, particularly pain, and therefore more able / willing to participate in upper limb activities.

Reference: For an overview of upper limb stimulation techniques, please see the winter 2002 addition of the FES Newsletter, available on our web page www.salisburyfes.com

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Case study
Stimulation of triceps to assist sit to stand

A patient with secondary progressive multiple sclerosis was referred to our clinic for an assessment for the use of FES for gait assistance. The patient was 51 years old and she had first been diagnosed with MS thirty years ago. Unfortunately on assessment her gait was found to be very poor, dominated by proximal weakness. It was not possible to use FES to improve her gait. It was noted that she had significant difficulty in gaining standing from sitting. In particular she was not able straighten her left arm when attempting to push up from the armrest of her wheel chair. The strength in her legs was insufficient to push her body upright without assistance from her arms. By experimentation it was found that by stimulating the triceps while attempting to obtain standing, it was possible to straighten the left arm, significantly assisting lifting. A Microstim 2V2 was set up and patient asked to exercise twice daily starting with a period of 10 minutes building up to 30 minutes over six weeks. Mode 0 on the Microstim 2V2 was used which gave stimulation at 40 Hz and an intermittent output with a long ramp of 6 seconds. The patient was instructed to use the device functionally, timing rising from the chair as the stimulation came on.

The patient was followed up six weeks later. She reported that she had found the device useful, in particular in assisting transfers on and off the toilet and also transferring into the standing frame. However, some problems were experienced. The wires and stimulator box got in the way while transferring. This was overcome by mounting the stimulator on the upper arm, held in position using Tubi-Grip and replacing the wires with shorter ones. She had also experienced some neck pain. The patient had a history of mild neck pain and this was associated with a scoliosis of the spine due to weakness of the trunk. Initially the triceps exercises had been done without the upper limb being supported. This may have coursed abnormal loading on the cervical spine. The patient was advised to exercise with the arm in a functional position to assist sit to stand. While triceps strength had improved it was still insufficient to straighten the arm while wait bearing without FES assistance. It was also found that the rising ramp of the stimulation was a bit slow requiring the user to wait some time before attempting standing. The stimulation then remained at its full intensity for quite a short time. For these reasons, the stimulation mode was changed to mode 7, which has a 2 second ramp and 8 second on time. Overall the device was well accepted and it is planned to continue its use.

Carol Mcfadden and Ian Swain
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Case Study
Dropped Foot

Past medical history
A 60 year old school secretary Mrs. B. reported a history of headaches, gait ataxia and swallowing problems in 1999. She was diagnosed with a right petro-clival meningioma which extended into the middle cranial fossa. This was excised in two stages in February 1999 and a right frontal ventricular peritoneal shunt inserted to relieve the symptoms of hydrocephalus. She sustained a post operative brain stem CVA, followed by occasional epileptic seizures which were not controlled by medication at that stage. In March 2001 she underwent successful stereotactic radiosurgery to remove the residue of the meningioma.

Social history
Lives with her husband in a house – needs to manage stairs

Signs and symptoms at that time were:
Dense right facial weakness and profound deafness on that side
Reduced sensation of the right side of the face
Evidence of a healing right corneal ulcer and right sided cataract
Right pupil unreactive to light
Protrusion of the tongue to the right
Left spastic paraparesis, greater in the upper than lower limb

Medication
Epanutin
Hypromellose eye drops
Diazepam

Referral for FES
In July 2002 Mrs. B. was referred to Salisbury for assessment for FES after reading about it in a patient stroke journal.

Initial Assessment
Mrs. B. was found to have good control at both left hip and knee, and inversion and plantaflexion of the foot with no active dorsiflexion. She walked with exaggerated hip and knee flexion, compensating for the lack of dorsiflexion at the foot. There was some ankle swelling and calf spasticity – grade 2 on the Modified Ashworth Scale (MAS). She responded well to stimulation of the common peroneal nerve with good correction of dorsiflexion and eversion.

FES Treatment
At her first appointment she was set up with a Microstim 2 exercise stimulator to reduce calf spasticity and increase range of movement at the ankle and an Odstock Dropped Foot Stimulator (ODFS) to aid walking. The popliteal fossa electrode position was found to be the most effective at correcting the plantaflexion and particularly the inversion of the foot. Blue pals electrodes were used for comfort, stimulation was triggered on heel rise and the asymmetrical biphasic waveform set. The tests of walking speed and physiological cost index (PCI) with stimulation at the first assessment showed slightly reduced speed and increased effort (see table).

At her follow up appointment 6 weeks later Mrs. B. was managing well with both stimulators. She felt that the spasticity in her calf had reduced and that she was walking better. We were able to change her electrodes to the standard position and still achieve adequate eversion. Her test results had improved (see table).

Three months later Mrs. B. was having problems with intermittent functioning of the ODFS. Her husband was finding it difficult to position the electrodes to gain optimum correction of inversion. This caused her to land on the lateral border of her foot, making her unstable and increasing her anxiety. The frustration with her husband at not being able to find the correct electrode positions fuelled her anxiety, and fear of the foot inverting increased her spasticity level further, thus compounding the problem. However, tests of walking speed and PCI showed significant improvements in that Mrs. B. had increased her unstimulated walking speed by 22% and reduced her PCI by 13.8% since she began FES treatment (see table). Some time was spent locating and marking effective electrode positions for Mrs. B. and explaining the effect of anxiety and frustration on spasticity. She now has the electrode positions marked with tattoos!

Mrs B. had a follow up appointment 6 months later in July 2003. Her walking tests showed a small increase in speed of 3% with stimulation and a reduction of 15% in PCI. Remarkably her unstimulated walking speed had improved by 44% in 10 months and the effort reduced by 13% (see table).The ankle swelling had resolved and calf tone reduced to MAS 1. However, the stimulation was causing her to walk with an exaggerated flexor withdrawal reflex (hip flexion and external rotation, knee flexion and dorsiflexion and eversion of the foot). The stimulation intensity was therefore lowered to reduce this effect. This worked well at the time and walking tests were completed successfully.

Two weeks later Mr. B. telephoned to say that the system was not working reliably and that they were again experiencing problems with excessive inversion of the foot. This was not solved by turning the intensity back up to its original level. He had checked all parts of the system for faults, including the footswitch and all seemed to be functioning well. A completely new system was sent to Mr. and Mrs. B. but this was not successful either. It was therefore necessary for them to attend a further clinic appointment as they were becoming very frustrated and losing confidence in the device. At this appointment Mrs. B. complained of a sharp pain in her left lower leg on stimulation radiating from the head of the fibula to the dorsum of her foot. She said that she had had this pain for some weeks but that it had worsened in the past 2 weeks. It was apparent that the pain was contributing to an increase in spastic patterning in the leg and that it may have been the cause of the excessive flexor withdrawal reflex response seen at the previous appointment. The waveform was changed to symmetrical biphasic to reduce to sensory response and was instantly more comfortable. A straight lift of the foot was achieved with adequate eversion. There was a consistent heel strike indicating that the footswitch was being successfully triggered at each step.
The system is continuing to work well for Mrs. B. and she is once again confident in it. She will continue to be reviewed every 6 months.

Mrs. B. - Walking test results for first 6 months FES treatment

Week	No Stim. Walking speed m/s	With Stim. Walking speed m/s	No Stim. PCI	With Stim. PCI	% change walking speed	% change PCI	% change No Stim. walking speed	% change No Stim. PCI
0	0.27	0.26	1.6	1.73	-4	+8	-	-
6	0.31	0.34	1.52	1.44	+10	-5	+15	-6
18	0.33	0.36	1.38	1.19	+10	-14	+ 22	- 13
44	0.39	0.40	1.42	1.21	+ 3	- 15	+ 44	- 13

Comments

This case study highlights a number of important factors in treatment with FES.

- The need for thorough explanation of electrode positioning, of the desired movement and of the fact that there are factors such as anxiety and frustration that can contribute to difficulty in reproducing the movement achieved by the clinician.
- The importance of explanation and reassurance for the patient as to why they may be having problems.
- Although regular review in the clinic is important, patients must feel that they have access by telephone to a clinician to whom they can report problems and from whom they can receive advice and reassurance. This is essential if they are not to lose heart and give up.
- It is important to be in possession of all the facts. The issue of pain down the leg on stimulation had not been highlighted because Mrs. B. had felt that she should have to bear it and not make a fuss. We do not know why she developed an increased sensitivity to the sensation of the stimulation. It may have been due to reduced spasticity and swelling in the lower leg, but reducing the intensity did not resolve it. We were able to reduce the discomfort by using the symmetrical biphasic waveform but only because calf spasticity had been reduced sufficiently for us not to need the effect of polarity to increase the eversion component.

Geraldine Mann
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An investigation into the effect of electrical stimulation of the calf in children who walk with a toe gait.

Durham S, Daniel C, Turner Simmonds C, Ewins DJ

Background:

Cerebral Palsy occurs in approximately 0.25% of live births. The most common form in children born at term is hemiplegia. Persistent toe walking frequently features in this population leading to impaired balance, asymmetry, likely development of fixed deformity and reduced function. Current treatment modalities, e.g. orthotics and surgery, show mixed results. An alternative approach could be electrical stimulation, which is effective in assisting gait in adult hemiplegia. We propose to investigate the effects of stimulating Triceps Surae (calf muscle group) in a group of ambulant children who walk with a toe gait. Triceps Surae has been selected as it is suggested that by using stimulation it can be 'taught' to contract more appropriately during walking. This study follows on from a study concluded recently, which investigated the effect of stimulating the Tibialis Anterior muscle to lift the foot up during the swing phase of walking.

Aims:

- To determine what effect electrical stimulation to Triceps Surae has on gait, in children with cerebral palsy who walk with a toe gait.
- To determine parameters predictive of outcome.
- The results from this study and earlier work on muscle stimulation will be used to inform the basis for a larger multi-centre trial.

If the results seen with adults are translated to children with CP, then electrical stimulation could be an important additional/alternative intervention to correct toe walking, preventing the development of secondary problems and subsequent further impairment of function. It is

also non-invasive, uses the subject's own musculature and could offer cost benefits over existing treatments and interventions.

Study Design:

In this study an A^1BA^2 approach will be used with 12 children. Each phase will last 3 months, with Phase B involving the use of the electrical stimulator. It is not possible to use a placebo or to use double blind studies due to the nature of the intervention. Following an initial screening/selection session, gait (walking) data will be collected from each child three times in phase A^1. In addition, we will ask the child to have a walk of about 30 minutes at any time during the day wearing whatever shoes or splints are normally worn to assist walking. The electrical stimulator will be set up at the start of phase B and used as part of the daily 30 minute walking schedule throughout this phase. The stimulator is a portable, battery powered, device, designed and manufactured (with CE registration) by Salisbury District Hospital. Stimulation will be applied to Triceps Surae and timed to come on during the stance phase of the walking cycle. Timing will be achieved through the use of a foot-switch placed in the shoe. Gait measurements will be repeated at the start and end of this phase, and the use of the stimulation will also be reviewed on two occasions. The final, A^2, phase is a repeat of the first A^1 phase. Gait measurements will be repeated at the start and end of this phase.

The gait measurements will be no different than those collected as part of routine clinical assessments in the Gait Analysis Laboratory at the Hospital. The equipment used is non-invasive and will enable us to quantify changes in each child's walking pattern. Key parameters will be changes in the heel-toe interval and muscle activation patterns.

In addition to the quantitative gait measurements, feedback from parents/children will be sought by the use of a questionnaire.
The project is funded by Cerebra, Wandsworth Primary Care Trust and the University of Surrey

For further information please contact Sally Durham or David Ewins at:
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London, SW15 5PN, Tel: 020 8355 2175, email: gaitlab@swlondon.nhs.uk

Topical Tips

Bilateral dropped foot correction with MS using the O2CHS II

Sometimes it can be difficult to achieve sufficient effect from stimulation of the common peroneal nerves. This can be due to greater tone in the extensors and poor proximal control of hip and trunk. Placing one electrode over the lateral boarder of the popliteal fossa can often be a way of producing a greater withdrawal reflex and there by achieving more knee and hip flexion as well as dorsiflexion and eversion. Another option the O2CHS gives you which is not available in the ODFS is the ability to increase the stimulation frequency. This will have 2 main effects. Firstly, by putting a pulse into the motor nerve more times every second, the muscles are made to work harder, as they will produce more contractions a second. Secondly, increasing the frequency helps to illicit the withdrawal reflex more effectively because a greater number of pulses travel up the sensory nerves and act on the reflex ark. The down side is that the muscles will fatigue more quickly. For this reason the frequency should not be increased more than is necessary.

Electrode conductivity and Pals

Some times it is difficult to achieve a good muscle contraction because the skin electrical impedance is too high. The easiest approach is to dampen the skin and electrode with ordinary water. Occasionally this is insufficient and we have found that using a bit of electrode gel (ultrasound gel works well) can increase the effect from the electrode. However, electrode gel will also reduce the adhesives of the electrode resulting in the electrode easily falling off. We have recently had some success at using TAC Gel (Henley's Medical Supplies Ltd, Bromfield, Welyn-Garden-City, Herts, AL7 1AN, UK. Tel.++44 (0)1707 333164). The gel improves the conduction of the electrode as before but also self adheres both to the skin and the electrode. The gel can be easily removed with warm water.

Electrodes not staying attached in the Popliteal Fossa?

The common peroneal nerve may be stimulated at the popliteal fossa site, in preference to the standard position, to improve eversion or dorsiflexion of the foot, knee flexion or hip flexion. One major disadvantage, however, of placing an electrode behind the knee is that it does not readily stay in place. Tubigrip does not help and transpore tape has limited success. A patient at the Salisbury FES clinic, who happened to use a catheter, commented that his lightweight catheter bag holder (80% Polyester, 20% Elastane) did an excellent job of keeping his electrodes in place. As a result of this helpful feedback we now routinely offer these inexpensive holders in small, medium and large to patients using the popliteal fossa site.

Another possible use for the Urisleeve is as a means of wearing the ODFS box on the leg. The Urisleeve has a pocket that can easily accommodate the stimulator. We now have footswitches that come with a 45cm lead and have a 2.5mm jack allowing direct connection to the box. Shorter electrode leads are also available.

The 'Urisleeve' Leg Bag Holder is available from:
Bard Limited
Forest House
Brighton Road
Crawley
West Sussex
RH11 9BP

tel. 01293 527 888

Toe scuff in very early swing phase?

Some ODFS users, despite having an excellent dorsiflexion and eversion movement when stimulated, continue to have toe scuff in very early swing phase. This is particularly noticeable in people who walk quickly. If reducing 'ramp up' time, or even increasing intensity, does not improve gait, then it may be worth considering triggering stimulation earlier in the gait cycle. If the footswitch is positioned under the heel of the non-stimulated leg, and the ODFS switched to 'heel strike', this sometimes triggers stimulation just early enough to avoid or improve that initial scuff.

Philip Write, Carol McFadden, Paul Taylor

Implanted Dropped Foot Update

It is now over year since we completed the pilot study of the Finetech Implanted Dropped Foot Stimulator. Five volunteers who had a dropped foot due to stroke received the implant. All five showed improvements in walking speed and walking range and all accepted the device very well. There was a report on this study in our last newsletter (see our web site www.salisburyfes.com). One year on all five continue to use the device without significant problems except for the failure of some early equipment, now redesigned. A more extended trial is now underway in Enschede, Holland. This project should produce sufficient data to allow statistical analysis to demonstrate the effectiveness of the device. A second trial is planned in the UK of its use with people who have a dropped foot due to incomplete spinal cord injury. The trial will take place at three spinal units, The Southern General in Glasgow, Stoke Mandeville and in Salisbury. 21 volunteers will be recruited and will include both current ODFS users and those who have not used FES before. The latter group will first use an ODFS to check their suitability before proceeding to use the implant.

The Implant is currently completing the final stages of obtaining the CE mark, which means it will comply with all necessary EU regulations and can be commercially available. For more information about the implant visit the Finetech Medical's web site www.finetech-medical.co.uk or telephone John Spensley at Finetech 01707 330942.

Paul Taylor

The ESTAMINET project: A brief description

Stand face to face with a handicap such as a spastic drop foot has a lot of dismal consequences. The most complex are situated on the social level. Not be able to walk fast, decreases the willingness to go outside the house, which leads to isolation and depression.
An important number of studies has proved that FES in stroke improves the quality of gait. However from our point of view this is not enough. Walking must aim at specific activities such as visiting a friend, buying a newspaper at the corner of the street or taking out the dog for a walk. This ability is the reflection of the remained social capacity of a stroke patient.
We as a research group at the Artvelde Institute for Physiotherapy are convinced that FES can mark social life after a stroke, but research is needed.

The ESTAMINET project will use the Odstock Dropped Foot Stimulator (ODFS).
40 Stroke patients have given written consent to participate in a controlled study. The criteria for acceptance are, having the ability to walk indoors without help of a third person but having major difficulties to walk outside. In case a patient is aphasic a third person (partner) will help to collect the required information on the patients' social life.

Two groups will be compared: one receiving FES in combination with motivating calls during the week, another receiving only motivation.

During the week, preceding the FES trial, patients are interviewed by phone about their 'socio-mobility'. A new standardized interview form is used. The same week they are scored on the Beck scale, which gives a rating of their mood and questioned about their perception of health using the SF 36 inquiry form. After that the participant has one week the time to become experienced in putting on the FES. During that period our team inspects on a regular base the tune up. The same week a gait analysis is planned. The influence of FES on following parameter will be investigated.

Timing and Force	Timing	Force
Active propulsion	Swing	Peak pressure of contact
Passive propulsion	Foot flat	Peak pressure of midstance
Single leg support	Midstance	Peak pressure of active propulsion
Double leg support		

The aim of the gait analysis is to discover critical parameters responsible for a possible improvement of 'socio-mobility'. This can help to improve FES techniques in the future.
From then on the real trial starts. The experimental group will use FES during 4 weeks. 3 times a week they will be called each time by a different assistant. A same scheme will be used in the control group. The evaluation of the latter is done by a different interviewer. At the end of the trial the Beck and SF 36 are repeated and the 'social mobility is compared with the baseline measurements.

The first results of this study will be available in November 2003 and will be presented at the FES user day in Birmingham.

We are looking forward to a possible collaboration with other FES teams willing to use a similar protocol.

This project is funded by the Comphas Research Foundation

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FES Courses For 2003/4

Before clinicians can prescribe the ODFS or 02CHS for their patients, they must attend a course. This is mandatory. Three courses are offered. The introductory course gives an introduction to FES and its application in neuro-rehabilitation. The course, which has a large practical content, is intended to enable clinicians to select candidates for the ODFS and use the device. The second course, intended for clinicians who have some experience of the ODFS, introduces the O2CHS, used for more complicated gait applications. The upper limb course expands on the introduction to exercises used in upper limb hemiplegia, given in the introductory course.

Introductory Single Channel FES Course

Some of these courses have not been finalised yet. For more details - see our web site or contact us again in the next month or so.

6th & 7th November 2003 - contact Joanne Walker, Physio, Morriston Hospital, Hoel Maes, Yr Eglwys, Morriston. Swansea. SA6 6NL Tel 01792 702222 bleep 929

23rd/24th (Fri/Sat) JAN 2004 - Lancaster - Val Cook, Physio Dept, Lancaster Royal Infirmary, Ashton Road, Lancaster. LA1 4RP 01524 583350 fax 01524 583358

FEB 2004 - Chichester - Contact Mr Lawrence Owers, Physio Dept, St Richards Hospital. Spitalfield Lane, Chichester. PO19 4SE Tel 01243 788122

March 2004 - Bristol Contact - Louise Austin Physio Department Bristol General Hospital Guinea Street Bristol tel 0117 9286373

2nd/ 3rd (Fri/ Sat) April 2004 - Farnham , Surrey - Contact Amanda Edwards, Physio Dept, Farnham Hospital, Hale Road, Farnham. Surrey. GU9 9QL 01483 782175

May 2004 - Salisbury - Contact Alison Leighfield, Medical Physics Department, Salisbury District Hospital, Salisbury. Wilts. SP2 8BJ Tel 01722 429065 fax 01722 425263 - ` `

For these next few please contact Alison Lieghfield in Salisbury (Tel 01722 429065 fax 01722 425263) for conformation, as they are not firm bookings yet.

June 2004 - Cumbria
Oct 2004 - Belfast
Jan 2005 – Stockton-on Tees
Feb 2005 – Leeds
March 2005 – Croydon Surrey
April 2005 – Swansea – (Paediatric based course)
May 2005 – Salisbury
June 2005 – Basingstoke

Upper Limb One Day FES Course

Open to participants who have not completed the single channel course or wish to cover more in depth the upper limb stimulation. Some participants may find some of the physiology hard going and it is preferred that they have attended the single channel course first

28th November 2003 – SALISBURY - Contact Alison Leighfield, Medical Physics Department, Salisbury District Hospital, Salisbury. Wilts. SP2 8BJ Tel 01722 429065 fax 01722 425263 -

Two Channel Courses

Participants must have completed the single channel course.

10th + 11th October 2003 - London contact Clare Dunsterville, Wellington Hospital, Neuro Rehab, North Building, Circus Road, London Tel 0207 5865959 ext 3760

November 2004 – Salisbury
December 2004 - Cumbria - to be arranged

Please contact the relevant person to arrange a place on your preferred course. There tends to be approximately 10 courses a year so please contact us regularly if your chosen course is full.

If you would like a course at your own hospital, please contact Alison Lieghfield Tel 01722 429065 fax 01722 425263

VAT exemption forms

If patients are paying for FES equipment privately, they can avoid paying VAT by filling out a VAT exemption form. This is a simple form that only takes a minute to fill out. The form is titled “Goods and services for disabled persons: eligibility declaration by an individual”. This can be obtained from your DSS office or we can supply you with one. Copies of the form are included at the back of this Newsletter. You can also now download this form from our web-site. We need this form to be completed and sent back before we can send out the equipment.

FES Equipment Order Form

Please use this form to order FES equipment from the department of Medical Physics & Biomedical Engineering - Salisbury District Hospital. All orders must have the name of the FES trained clinician. Please read the conditions of sale overleaf.

Name of supervising clinician or therapist
that has attended the Salisbury FES course:_____

Name & address to send the equipment to (stimulators
will only be sent to the trained therapist or clinician): _____

_____

_____

Name & address to send the invoice to: _____

_____

_____

Contact phone number for queries with this order: _____

Code	**Items**	**Number required**
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Stimulators can be supplied with electrodes, electrode and foot switch lead lengths and shoe inner sole size of your choice. Please specify your requirements.

Cheques should be made payable to *Salisbury Health Care NHS Trust*.

Please send order to:
Mr Stacey Finn, Department of Medical Physics and Biomedical Engineering, Salisbury District Hospital, Salisbury, Wiltshire, SP2 8BJ. UK
Fax: 0044 (0)1722 425 263, Tel: 0044 (0)1722 429 118, E-mail: s.finn@salisburyfes.com

Condition of sale

The Odstock® range of neuromuscular stimulators are supplied under the following conditions of sale:

> The supplied device will only be fitted by; a person who has been trained to the standards set by the Department of Medical Physics and Biomedical Engineering (MPBE) in the use of a given FES device, or a person approved as being competent in the use of FES techniques by MPBE. The said person must be registered in the list of accredited users held by MPBE.
>
> The registered person and their employer are considered responsible for the continuing support of the use of the device by the end user.

Warranty

The Odstock® range of stimulators and accessories are warranted for a period of twelve months from date of initial fitting by a FES trained and registered clinician. This is with the exception of the footswitch, which is warranted for a period of one month only. Also excluded are electrodes, and batteries, which are considered to be consumable items. Should the unlikely event of any failure of the device occur during the warranty period, the device should be returned to the address shown below for inspection. Should the failure be due to a manufacturing or material defect the device will be repaired or a replacement supplied free of charge. This warranty is valid providing that:

1. the failure cannot be attributed to misuse or improper fitting
2. the warranty registration form has been completed and returned to the address shown below within 14 days of initial fitting
3. it can be certified by demonstrable evidence that the fitting of the Odstock® was done by a registered accredited user.

This warranty is in addition to any statutory rights available to the purchaser

Repairs outside the warranty period

Repairs occurring outside the warranty period will be charged at a flat rate of £35* +VAT. Alternatively an extended 5 year (from first use of the device) warranty can be purchased at a cost of £100* + VAT. The extended warranty must be purchased at the same time as the device. The device accessories (leads, sounders etc.) are excluded from the extended warranty and are subject to a one year warranty only.

The Department of Medical Physics and Biomedical Engineering, Salisbury District Hospital, Salisbury, Wiltshire, SP2 8BJ, UK.

*Price correct at time of printing August 2003

GOODS AND SERVICES FOR DISABLED PERSONS:
ELGIBILITY DECLARATION BY AN INDIVIDUAL

I (full name):

of (address):

declare that I am chronically sick or disabled by reason of:
(give a full and specific description of your condition)

and that I am receiving from: (name and address of supplier)

- the following goods which are to be made available to me for domestic or my personal use: (description of the goods)

- the following services to adapt goods to suit my condition: (description of services and goods)

- the following services of installation, repair or maintenance of goods: (description of services and goods)

- the following building alterations to my private residence: (description of alterations)

- the services of monitoring a personal alarm call system

- the services of leasing a motor vehicle

and that I claim relief from value added tax under Group 12, Schedule 8 of the Value Added Tax Act 1994.

(Signature) (Date)

- Delete words not applicable

NOTE TO SUPPLIER

You must keep this declaration for production to your local VAT officer. The production of this certificate does not automatically authorise the zero rating of the supply. You must also ensure that the goods and services you are supplying qualify for relief.

NOTE TO CUSTOMER

If you are in any doubt as to whether you are eligible to receive goods or services zero rated for VAT you should consult VAT Notice 701/7 or seek advice from your local VAT office before signing the declaration.

Annex I
MEDICINAL PRODUCTS AND SUBSTANCES USED IN MEDICAL OR VETERINARY RESEARCH, PURCHASED BY A CHARITY ENGAGED IN MEDICAL RESEARCH, TREATMENT OR CARE

I (full name)

(status in organisation)

of (name and address of organisation)

declare that the above-named organisation is
*buying from/importing:
(name and address of supplier)

the following goods: (description of goods)

I also declare that the goods are to be directly used by the above-named organisation solely for the purpose of medical or veterinary care, treatment, or research.

I claim that the supply is eligible for relief from VAT under item 9/10 of Zero Rate Group 15 to the Value Added Tax Act 1994.

(Signature)

(Date)

*delete as appropriate

There are severe penalties for making a false declaration. If you are in any doubt about the eligibility of the goods or services you are buying, you should seek advice from any local VAT office before signing this declaration.

NOTE TO SUPPLIERS
You should retain customer declarations for production to your VAT officer. The production of such certificates does not authorise the zero-rating of the goods. It is your responsibility to ensure that the goods supplied are eligible before zero-rating them.

Service provision

The Clinic in Salisbury receives enquiries every day from people who want to receive FES treatment in their home area. While we try and help them by providing what information we can are hands are tied by the Data Protection Act, preventing us from releasing the names of people who have received FES training. Additionally, many trained clinicians are not in a position to receive referrals. We therefore need to produce a directory of clinicians who are willing to receive referrals and for their details to be passes on. The information will be used for the sole purpose of connecting potential clients with FES trained clinicians. However, if desired, we can add information to our web page so clinicians can be contacted directly. We have also been asked to provide this information to FESnet so they can send you information about their meetings and other activities. Please fill out and return the form below.

Name: _____

Work Address:

_____

_____

_____

Tel: _____

Fax: _____

E-mail: _____

Web page: _____

I provide a clinical FES service	Y / N
I am able to receive referrals for the Odstock Dropped Foot Stimulator	Y / N
The service is NHS funded	Y / N
The service is privately funded	Y / N
Please add my details to the directory	Y / N
Please add my details to the web page	Y / N
Please pass on may details to FESnet to be added to their data base of FES service providers	Y / N

Signed _____

Date _____

Please send to: Paul Taylor, Department of Medical Physics and Biomedical Engineering, Salisbury District Hospital, Salisbury, Wiltshire, SP2 8BJ, UK or e-mail p.taylor@salisburyfes.com

FES User Day
City Hospital, Birmingham
Friday 5th December
10am - 5pm

We also invite 15 minute presentations on any aspect of the clinical application of electrical stimulation. Presentations may be of original research, clinical experience or of case studies. The aim of the meeting is to promote discussion and the exchange of ideas in an informal setting. Please fill in the form below to reserve your place.

It is hoped to have sessions on the following areas:

Use of FES to improve mobility in stroke, MS, PD and spinal cord injury
FES in Cerebral palsy
FES in stroke upper limb
Electrical stimulation in conjunction with Botulinum toxin.
Facial palsy
Stimulator technology update

Please provide a 300-500 approx. abstract, which we will be made available on the day and will also be included in the winter addition of the FES Newsletter.

Power point, slides, OHP and video will be available for your use. If using power point, please bring your talk on disk, CDROM or Zip disk so a single computer can be used. This saves time between presentations.

The cost of the meeting is £30. Please make cheques payable to the Medical Physics Trust Fund.

++

Name _____

Address _____

_____

_____

Phone number _____

I will attend the FES User Day Meeting Y / N

I wish to present a presentation Y / N

Tittle _____

_____

Please return this form to Alison Leighfield, Department of Medical Physics and Biomedical Engineering, Salisbury District Hospital, Salisbury, Wiltshire, SP2 8BJ

Abstracts may be e-mailed (p.taylor@salisburyfes.com) or sent on a disk to Paul Taylor at the above address.