Salisbury FES Newsletter
Spring 2004

IFESS conference 2004 in the UK!

This is a great chance to attend the Conference '**Getting FES into Clinical Practice**' held by the International Functional Stimulation Society. Delegates will be able to fill in any gaps in their FES training such as 2 channel or upper limb stimulation courses as these will be offered at a subsidised rate.

Places limited apply now!!!

Note: Closing date for abstracts of conference presentations or posters is 1st May 2004. See website www.ifessnet2004.tk for details.

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".

This newsletter is a FES business case special. We are frequently asked by clinicians that are trying to set up a clinical service for information to help them make their case to the hospital management. We have two sample business cases, one based on a stand alone service and the other based around an orthotics service. There is also glossary of terms and a list of people you may need to contact when writing your plan.

This September (6^{th} – 9^{th}) the Salisbury FES team will be hosting the annual meeting of the International FES Society (IFESS) entitled **'Getting FES into Clinical Practice'**. 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 pier. In addition to reports on the latest technology and implanted techniques the conference will have a strong clinical emphasis. On the Saturday and Sunday preceding the conference (4^{th} and 5^{th}) there will be a series of one day course on the clinical application of FES. These include the FES for dropped foot, FES in upper limb stroke, the two channel course, FES in Paediatrics and FES for paraplegic cycling. Course places are restricted to conference attendees only and places will be limited. Book early to avoid disappointment. There is still time to submit abstracts for poster or oral presentation and reports of clinical experience are always welcome. For more information about the conference visit the conference web site www.ifessnet2004.tk

Increasingly we are contacted by people seeking FES treatment, 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. Please complete and return the form on the back of the newsletter, if you are in a position to provide a FES service (either NHS or private) and would like to be included on this database.

Also included in this edition are 3 abstracts from the Decembers FES User Day. The next FES User Day will take place on Friday 26th November 2004 and will be hosted by the Astley Ainslie Hospital in Edinburgh.

Thanks to all who have contributed to this newsletter, in particular to Ingrid Wilkinson for putting it all together. 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 the autumn, so please send copy by then. This and all back issues of the Salisbury FES Newsletter are on our web page www.salisburyfes.com

We look forward to seeing you at IFESS in September,

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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 else we could put up there? Please let us know. Our web page is www.salisburyfes.com.

Setting up a clinical service special

Getting started is problematic!

In a previous job as an outpatient neurorehabilitation physiotherapist working in a general hospital I tried (and failed!) to get a local FES service 'off the ground'. I was asked by one Finance Administrator how much time and money was spent treating drop foot currently and how this would change with the introduction of FES…a question I found impossible to answer and this from someone who was trying to be helpful!!! Support for any proposed FES service needs to be widespread and extend into local management, finance and consultant levels. Also any clinician contemplating this should investigate in depth their local financial position, who pays for what generally and especially any current FES funding/activity levels.

You will quickly become aware of the correct 'lingo' but below I have asked Sue Borrett, our Bussiness Manager to outline some of the main terms and

responsibilities of various bodies and individuals. She takes a large number of phone calls asking for help from clinicians and we hope this information will cover the commonest queries.

Below Sue's item is a business plan template produced by Christine Singleton, Birmingham, and one produced in Manchester. The Birmingham plan is based around a 'stand alone' FES service and the Manchester plan is an orthotics/FES model, they have kindly allowed them to be shared via the Newsletter. I hope you will find these helpful in getting started but please bear in mind any plan needs to reflect local services. In addition, please consider including a training budget to keep you up to date, allow you to attend Conferences/User Day etc. or should you need it access our experience by getting us to visit you and help with problem patients, or you come here to Salisbury. These activities allow you to improve your confidence and effectiveness using FES and all unfortunately cost money!

Regards
Ingrid Wilkinson
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Sue Borrett – some sources of help and definitions

When considering starting up a service, one of the important things you will need to know is, historically, how many patients have been referred for this treatment. Your local Primary Care Trust (PCT) should have this information going back 2 years. Your PCT will hold details as all patients will have been referred to Salisbury or Birmingham. This was referred to as Out of Area Treatment Service (OATS) until 2002 and information about OATS was kept by the Health Authority until then.

You will need this information on numbers to build your business plan and plans based on actual history provide greater confidence. It is the same PCT that will agree your plan and provide you with finances, unless your own hospital is prepared to fund your service from their funds.

When writing your plan you will need help from others and they could be:

-Directorate Manager-	(own hospital)
-Contracts Team-	(own hospital)
-Finance Department-	(own hospital)
-Business Manager-	(own hospital)
-Head of Department-	(own hospital)
-Therapy Manager-	(own hospital)
-Local PCT-	

Please especially note the paragraph below

Assessments: There is a potential ethical issue regarding assessing patients with FES, particularly the walking stimulator, if funds for treatment and ongoing follow up are not assured. Unlike many other forms of treatment, at assessment the patient is instantly aware of the benefits received from electrical stimulation. Trying the equipment is an essential part of assessment. Assessments should only be performed when it is known that the patient could be fitted with equipment within 8 weeks and arrangements for ongoing follow up are in place.

Report on FES service delivery following an Audit of all FES activity in Birmingham
from April 1996 to August 2003

Background information: -
Functional Electrical Stimulation (FES) can help people who have had damage to their brain or spinal cord to move more easily. The FES clinic was established at City Hospital (CH), Birmingham in 1996 and a second clinic was established at the West Midlands Rehabilitation Centre (WMRC) Birmingham in 2000. The former is a hospital within the Sandwell and West Birmingham Hospital NHS Trust. The latter is a tertiary regional specialist centre within the South Birmingham Primary Care NHS Trust. This audit represents activity by these 2 clinics from April 1996 to August 2003 i.e. 864 patients over 7 ½ years. The results have set standards of care for future audit cycles and provided an evaluation of outcome measures currently used by clinicians.

Neurological patients are referred to the outpatient FES Clinics via Consultant, GP, Therapists and Specialist nurses nationally. FES is also used for orthopaedic patients, particularly for acute problems. Current referral rate to combined FES Clinic is 23 per month and shows a 21% growth rate year on year.

Patient profile: - 30% CVA, 30% MS, 40% other neurological conditions.

On assessment 64% of patients are suitable for treatment and they are provided with electrical stimulators as per protocol. The patient may use the stimulator on a daily basis. Stimulators are used as either functional or exercise tools. After the 1st year of treatment patients are reviewed on an annual basis until discharge. There is carryover in some neurological conditions leading to weaning off from equipment. 24.6% of equipment issued was returned upon discharge and reused in the clinics. Treatment protocol is varied on clinical judgement as necessary. Treatment costs include resource costs, loan and maintenance of equipment, and necessary consumables. Borderline patients do not progress to treatment following assessment.

Patients have commented on the high standard of service delivery and ongoing support (recent questionnaire). Patients are compliant with attending treatment sessions (95%). The few DNA's are pursued. Hardware equipment is reusable as it is returned if no longer in use. Ongoing development in equipment hardware may render returned equipment as obsolete.

An acute service is provided on CH stroke unit. Experience shows that speed of functional recovery from stroke i.e. walking & upper limb control is improved. Further audit and research is required to support anecdotal evidence.

The protocol for treatment is based on guidelines provided by Salisbury (Research base). See attached product realisation process for FES pathway. Particular emphasis is placed on thorough education and instruction to patients to ensure successful application of the equipment. Goals and outcome measures are agreed with patients at assessment and fitting appointments. Outcome measures are re-recorded at subsequent appointments. All hardware equipment is purchased from Salisbury by trained clinicians to maintain standards. Consumables are purchased elsewhere. All equipment has a British Standards Institution certificate of registration and conform to EC regulations for quality assurance. The Birmingham FES Clinics work in collaboration with Salisbury on research, development and data collection. The CH Birmingham Clinic represents the first autonomous clinic outside Salisbury. Other clinics have been established namely, Liverpool, Glasgow, Edinburgh and London. Salisbury FES service and ongoing research and development are recognised internationally.

FES SERVICE DEVELOPMENT

Recommendation
An initial start up cost for a FES clinic would involve an investment of £10,000 for equipment stock as follows:

12 x ODFS	
12 x MS2	Purchased from
2 x Channel 4	Stacey Finn
1 x Channel 2	Physics & Biomedical Engineering Dept.
40 x Foot switches	Salisbury District Hospital
10 x Foot switch leads	Salisbury,
10 x electrode leads	Wiltshire, SP2 8BJ

Insoles of various sizes – suggested supplier Algeo Ltd, Sheridan House, Bridge Industrial Estate, Speke Hall Road, Liverpool L24 9HB

Electrodes: - Ref 879200 - 5 cm round x 200
Ref 879300 - 7 cm round x 10
Ref 891200 - 30mm x 54mm x 10
Ref 901220 - 5 x 5cm x 20 (hypoallergenic electrodes)

Suggested supplier – Nidd Valley Medical Ltd, Conyngham Hall, Knaresborough, North Yorkshire, HG5 9AY

Sundries: - Heart rate monitors, Stop watches, ultrasound gel, Tubigrip size F & G, double sided tape, screwdrivers, batteries 9 volt, calculator, duplicate book for equipment orders, permanent markers etc.

Suggested Treatment Protocol Costings
All figures quoted include equipment and resource cost per treatment session

Treatment	Cost
1st year	
• Assessment	£100
• Fitting of equipment over 2 days	£400
• 6 week review	£200
• 3 month review	£200
• 6 month review	£200
• = 1 x assessment & 5 x treatments	£1100
subsequent years	
• annual reviews thereafter	£200

Alternatively the service can be divided into resource and equipment costs with funding from appropriate budgets e.g.: therapy and orthotic budgets. The audit showed an average resource need of £54,061 p.a. and an equipment need of £15,000 p.a. to provide FES services to 864 patients throughout the audit period. This equated to an average of £599.50 per patient on the database regardless of length of FES use by patients.

Typical Equipment start-up costs per patient

Equipment (usually only one of 4 types)		Price
ODFS	(functional tool)	£273
ODFS 2 channel	"	£379
Microstim	(exercise tool)	£268
4 channel	"	£296

Consumables

Electrodes @ £5 per packet (6 x p.a.)	£30
Foot-switches @ £22.40 (3 x p.a.)	£67.20
Leads @ £10 (2 x p.a.)	£20
Rechargeable battery pack	£27.50
Insoles, Tubigrip and gel	£10

Assessments:
There is a potential ethical issue regarding assessing patients with FES, particularly the walking stimulator, if funds for treatment and ongoing follow up are not assured. Unlike many other forms of treatment, at assessment the patient is instantly aware of the benefits received from electrical stimulation. Trying the equipment is an essential part of assessment.

Assessments should only be performed when it is known that the patient could be fitted with equipment within 8 weeks and arrangements for ongoing follow up are in place.
The Salisbury team is in agreement with the above protocol.

Clinical prioritisation (in descending order)

- at risk of tripping/falling whilst walking and patient has rejected AFO for whatever reason
- at risk of tripping/falling whilst walking and patient using an AFO
- patient undergoing Botulinum toxin injection programme
- use of the stimulator to reduce pain and improve mobility e.g.: subluxed shoulder
- use of the stimulator would reduce spasticity
- use of the stimulator would increase mobility
- use of the stimulator would maintain mobility
- use of the stimulator would increase muscle power
- use of the stimulator to facilitate lost activity e.g.: flacidity following a stroke

Outcome Measures regularly used
10m walking test
Physiological Cost Index (PCI) to measure effort of walking
Visual Analogues for subjective assessments
Gait Lab analysis or video recordings of function
Questionnaires
Goal Attainment Scores (GAS)

Appointments
A maximum of 4 patients per clinician should be seen on each clinic day. This allows flexibility for troubleshoots, administration, stock maintenance and dealing with phone calls. Current activity in Birmingham (approx. 278 active patients) has been managed on three clinic days per week. Realistically, 150 patients per clinician is manageable with 3 clinic days per week, A & C support is required. Tech III assistant is recommended for managing equipment and appointment needs.

Budgeting for a FES service should be calculated with ongoing review provision. Discharge rate will depend on pathology being treated.

An example: - (figures inclusive of resource and equipment costs)

First year

30 patients assessed @ £100 per patient	£ 3000
64% of patients (n = 20) progress to treatment with a minimum of 5 treatments each @ £200 each	£20000

Second year

20 patients receiving 1 treatment @ £200 per treatment	£ 4000
30 patients assessed @ £100 per patient	£ 3000
64% of patients (n = 20) progress to treatment with a minimum of 5 treatments each @ £200 each	£20000

Third and subsequent years

20 patients receiving 1 treatment @ £200 per treatment	£ 4000
20 patients receiving 1 treatment @ £200 per treatment	£ 4000
30 patients assessed @ £100 per patient	£ 3000
64% of patients (n = 20) progress to treatment with a minimum of 5 treatments each @ £200 each	£20000

Experience has shown that one therapist can be responsible for a large number of patients under treatment. Regular reviews allow for monitoring of patient's condition and providing treatment as appropriate in combination with FES thus reducing the potential for complications and unnecessary deterioration for chronic neurological patients. The treatment protocol sits very comfortably with the National Service Framework (NSF) for long term conditions, which is expected to be published in 2004.

Acute neurological conditions, e.g. stroke, can respond well to early intervention with FES and is appropriate for in-patient treatment. Collaborative FES service provision across trusts is an efficient and effective way of providing a specialist treatment modality. FES may be considered as a dynamic orthosis and could be attached to an orthotic department with regard to budgets for equipment provision.

References:

A list of references for FES treatment can be accessed from the website at www.salisburyfes.com
Another useful website is http://fesnet.eng.gla.ac.uk

Proposal for a pan-Manchester Functional Electrical Stimulation service for neurological patients.

Executive summary.

Many people who suffer from central neurological problems, including stroke and Multiple Sclerosis (MS) exhibit foot drop. This term describes the inability to lift the foot when swinging the leg forwards during walking (swing phase) and results in slow, unsteady gait and a high risk of falls. Current provision for Greater Manchester patients with foot drop is poor. Typically they might

receive physiotherapy and an orthotic device to stiffen the ankle joint. The evidence base for these treatment options is weak and, despite often recurrent treatment from physiotherapists, the patient is frequently left with poor gait, an increased risk of falling and long-term reduced independence.

This document proposes the introduction of a functional electrical stimulation (FES) service as an alternative to current treatment options for drop foot. There is a growing clinical evidence base to support FES for drop foot in both stroke and, more recently, MS and it is recommended by the Royal College of Physicians National Clinical Guidelines for Stroke and the NSF for Older People (Standard Five: Stroke). The proposed service structure would be in line with recommendations in the two recent Audit Commission reports on the provision of aids to older and disabled people. Introduction of such a service would improve the quality of service to patients with foot drop and reduce their long-term dependence on other rehabilitation services. It is anticipated that a Manchester FES service would attract significant out-of-area interest and hence generate income.

Proposal for a pan-Manchester Functional Electrical Stimulation service for patients with damage to the central nervous system.

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[3] Salford PCT

Introduction

Functional Electrical Stimulation (FES) is a technique in which electrical impulses are used to produce muscular contraction and hence restore lost or impaired function in people with damage to the central nervous system. As such it is applicable to people with neurological conditions such as stroke, spinal cord injury, head injury, Multiple Sclerosis and Cerebral Palsy. The two principal patient groups are stroke and MS, who together typically represent 65-75% of the case-load of UK clinics. It is not suitable for patients with peripheral nerve damage, including Polio and Motor Neuron Disease.

This proposal is concerned with the establishment of a pan-Manchester service to meet the clinical demand for FES supported independence. More specifically, it proposes the establishment of a clinic to provide FES to patients with drop foot. The effectiveness of the treatment for this condition is well documented in the literature for both stroke and spinal cord injury [1,2,3] and more recently MS [3,4] and it is recommended in the Royal College of Physicians Clinical Guidelines on Stroke[5]. The service would address key recommendations in the Older People NSF[6]and is likely to be in line with

recommendations in the forthcoming NSF for chronic disease. Based on predicted demand, the service would generate significant revenue from external referrals from Greater Manchester and across the North of England.

Service overview and evaluation

As will be described later in the proposal, the Orthotics Unit would host the service at Hope Hospital, based on a "hub and spoke" model, recommended by the two recent Audit Commission reports [7,8](see Appendix 1). Hope Hospital's Medical Physics Department would provide the ongoing technical support, including equipment repair and patient technical support. There is no equivalent service in the region and the service model proposed is based on successful services developed at Birmingham and the Salisbury District Hospital group (http://www.salisburyfes.com/).

The Greater Manchester Neurosciences Centre is based in Salford Royal Hospitals Trust and Stroke is clinically part of the Neurosciences Directorate in Salford. This evidence-based, innovative treatment would complement the existing high standard of clinical care in both neuroscience and stroke and improve patient outcome in patients with stroke, MS and other neurological disorders. Evaluation of the service would comprise of an annual clinical audit and a users' steering group. Underpinning these activities would be ongoing, externally funded research in these areas currently undertaken at the Universities of Manchester and Salford (see Appendix 2).

Drop foot and the risk of falls

The predominant application of FES is in the treatment of drop foot. Drop foot is the term describing the inability to lift the foot when swinging their foot forward during walking, caused by weakness and/or spasticity in the lower limb. People with a drop foot have a slow, effortful gait pattern, loss of independence and are at a high risk of falls [9].

Potential number of referrals

There are approximately 5000 new strokes annually in the Greater Manchester area. A recent pan-Manchester survey identified that 60% of stroke patients have a drop foot at 1 month post-stroke, which is a long-term problem in at least 20% of patients. The numbers of patients with drop foot resulting from other neurological conditions are estimated to be of a similar order. Based on experience of a similar service in Birmingham, referral rates would grow rapidly from an initial estimate of 10/month to 20-30/month. A pan-Manchester service would provide economies of scale and comply with Audit Commission recommendations on specialised rehabilitation services [7,8]. It is our experience that, as a specialised service, it is uneconomic and impractical to sustain local small-scale provision.

Alternative treatments

Despite the scale of the clinical need, there are relatively few treatment options for this patient group. Typically, patients with foot drop receive a course of physiotherapy and, in certain cases, also an ankle foot orthosis (AFO) to mechanically stiffen the ankle joint. There are no agreed guidelines on the duration of such treatment and hence current treatment costs are not

easy to establish. A typical course of treatment for a stroke patient might be 6 weeks at 3 times per week, at an estimated £50/session [10]. It is not uncommon for patients to return for physiotherapy over periods extending to several years. Prescription of an AFO costs an average of £285 (hardware and fitting costs) [11]. Therefore, a patient who receives an AFO and a typical course of physiotherapy would receive treatment costing in excess of £1000 in the first year. The evidence base supporting the use of physiotherapy in conjunction with an AFO for drop foot is limited and, in certain respects, contradictory.

Patient and clinician interest

Patient demand for the service, from both stroke and MS patients, is growing. Evidence for this statement includes the proactive funding of a trial of FES by the MS Trust, in response to pressure from patients http://www.mstrust.org.uk/?section=aboutms&content=proj372.

There is also considerable interest from local clinicians, as evidenced by the training courses on FES for physiotherapists organised at Trafford General/Hope and MRI over the past two years.

Service model

The proposed service model is based on the service delivered by the Birmingham FES clinic, as it serves an urban area of comparable size to Greater Manchester. The Birmingham service, which began in 1996 and moved to a regional tertiary centre in 2000, receives referrals to the outpatient FES clinic from Consultant, GP, Therapists and Specialist nurses, both from within the area and nationally. There is no substantial service north of Birmingham and hence they receive a growing number of out of area referrals from the North of England and Scotland. The majority of referrals are for drop foot and the treatment protocol for this is now well established. The current referral rate is 25 per month, with the patient profile reflecting a range of neurological conditions (30% CVA, 33% MS, 37% other neurological conditions). The demand for the service has increased rapidly since its inception in 1996 and the service currently supports 230 active users. The staffing level is 1 full time physiotherapist per 250 active patients (50 patients per 0.2 fte). Cost estimates provided by the Birmingham service are given in Appendix 3.

Patient assessment and fitting

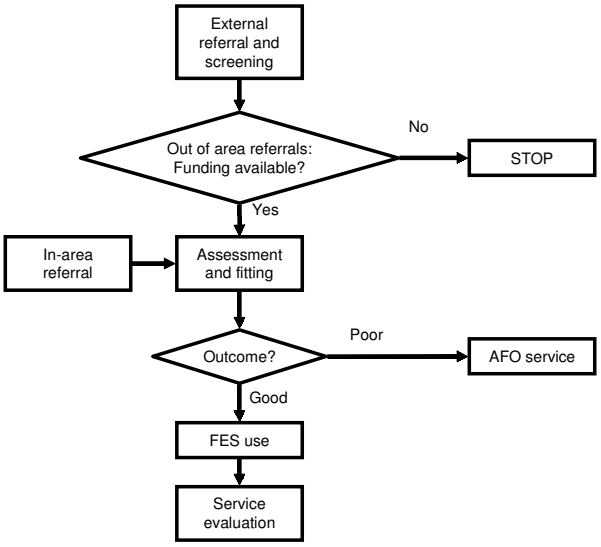
Patients undergo an initial assessment (lasting approximately 1 hour) and then, if suitable (70% of assessed patients) two clinic appointments are made on consecutive days for fitting of the drop foot stimulator. On the first day the stimulator is set up and its use explained to the user. On the second day the user is asked to attend wearing the device so the clinician can assess the user's ability to set up the device independently. Further adjustments are made and training given as necessary. Users are followed up after 6 weeks, after a further 3 months, 6 months and then yearly for as long as they continued to use the stimulator. Further visits to the clinic can be also made if difficulties are experienced between scheduled appointments. When setting up the stimulator for the first time, great emphasis is put on training the user, and their carer if appropriate, to use the equipment appropriately. Patient

compliance with the treatment is high, with 93% compliance at 18 weeks and 86% at 1 year. Patients comment on the high standard of service delivery at Birmingham and are compliant with attending treatment sessions (95%). Patients are supplied with an appropriate set of consumables (electrodes and footswitches) at their initial visit and are re-supplied as necessary. The Birmingham service has found that, out of a case load of 230 active users, typically 3-4 stimulators/month are returned for repair.

For some patients, using the stimulator leads to a permanent improvement that carries over to walking without the stimulator, allowing 25% of stimulators to be used by more than one patient.

The proposed Manchester model.

The Manchester service would be located within an established regional tertiary rehabilitation unit. In our case, this would be the orthotic unit, with the service delivered by a trained physiotherapist. There are already approximately 15 physiotherapists in Greater Manchester who have attended the necessary training course who could deliver the service and further staff training costs are unlikely at start up. Technical support would be provided by the Hope Hospital Medical Physics group. A small amount of administration support for the evaluation and clinical audit would also be required. A flow diagram giving an overview of the proposed service is given below.



Conclusions

Within Greater Manchester clinical provision for patients with foot drop is inadequate. Patients too often still suffer from poor gait, long term reliance on rehabilitation services and hence reduced independence. Current treatment options for this condition are not well-supported by the literature and guidelines on the appropriate frequency of provision of the current service and associated costs remain difficult to identify. There is a clear and growing demand for an FES service in the region that would serve to address some of these shortcomings.

The proposed service would be supported by a clear and growing evidence base, be in line with the NSF for older people, National Stroke Guidelines and fit in with current drives towards larger scale integrated specialist provision in the area of orthotics and walking aids. There would be a substantial number of out-of-area referrals and consequent income generation. Service costs, would be both more easily quantifiable and potentially lower than current ad-hoc approaches to rehabilitation of this patient group. Evaluation of the service would be undertaken by a user-led steering group and complemented by existing externally funded research in this area.

Appendix 1: Hub and Spoke Model (from Audit Commission Report)

The British Society of Rehabilitation Medicine has recommended the development of hub-and-spoke models for the provision of orthotic, prosthetic and wheelchair services. The model provides the opportunity to deliver high quality specialist services for people with complex or specialist needs at the hub, while providing accessible, responsive and quality assured local services at satellite clinics via the spokes.

Significant economies of scale can be delivered by this approach.

There would be sufficient scale to:

• allow for the employment of a NHS orthotist at the hub to assure the quality of the work of privately employed orthotists working in satellite clinics;

• improve professional development and career opportunities for staff, enabling them to rotate and specialise;

• commission gait-and-motion analysis from specialist regional centres;

• work in partnership with suppliers to deliver cost and quality improvements; and

• undertake a full programme of clinical audit.

Note- The set up at Hope already conforms to most of what is meant by a hub and spoke model. The introduction of a centralised FES service supporting satellite clinics around Gtr Manchester would serve to improve the throughput of the orthotics clinic and help to integrate the services.

Appendix 2: Current research into FES at the Universities of Salford and Manchester.

Ongoing externally funded research into FES and alternative approaches to foot drop at the Universities of Salford and Manchester would complement this service. For instance, Salford University is funded through two EU projects (FPV TUBA (£70k) and FPVI Healthy Aims (£300k)) to develop and evaluate new control approaches for FES in foot drop. These projects are both in collaboration with the leading UK group in this field, Salisbury District Hospital. There is also substantial clinical research into stroke gait and balance rehabilitation, centered around the work of Dr Sarah Tyson and colleagues. Research subjects in FES studies would be supported in the long term by a local FES service and the results from current FES studies and future clinical evaluation studies would help to guide the direction of clinical services in the region for drop foot patients.

Appendix 3: Costings estimates

(All figures quoted include equipment and resource cost per treatment session and are provided by Christine Singleton, Birmingham FES service, see previous article)

Reference List

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2. Burridge JH, Taylor PN, Hagan SA, Wood DE, Swain ID. The effects of common peroneal stimulation on the effort and speed of walking: a randomized controlled trial with chronic hemiplegic patients. Clin.Rehabil. 1997;11:201-10.
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9. Jorgensen L, Engstad T, Jacobsen BK. Higher incidence of falls in long-term stroke survivors than in population controls: depressive symptoms predict falls after stroke. Stroke 2002;33:542-7.
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11. Lindsay S. Costs of AFO prescription. Personal communication. 2004

‘Flow Chart of ODFS Set-up’ Please tell us what you think about it!

We recognise most clinicians reading this do not use FES everyday of their working lives and many use it infrequently. Feedback has indicated that sometimes this leads to a lack of confidence tackling problems. We felt that one way to help may be to produce a relatively straightforward flowchart. We hope this may act as a ‘crib sheet’ of the commonest problems associated with ODFS set up/use and some ideas for solving them. It is produced as a simple reminder and so cannot be completely comprehensive. The instruction manual and course documents remain the main information source. We have put it on the web site www.salisburyfes.com in PDF format so that it can be easily printed off and I would appreciate any feedback regarding omissions, additions or if it has indeed been helpful.

ODFS set up flow chart

Subjective assessment as initial assessment form

Pacemaker - liase with a cardiac technician
Epilepsy - monitor fit frequency to ensure stable
Pregnancy - not tested for safety

Assess gait identifying main problems e.g.
-general alignment
-hip/knee instability
-ankle - tonal changes/clonus
-compensations e.g. hip hitching, circumduction or vaulting on supporting leg

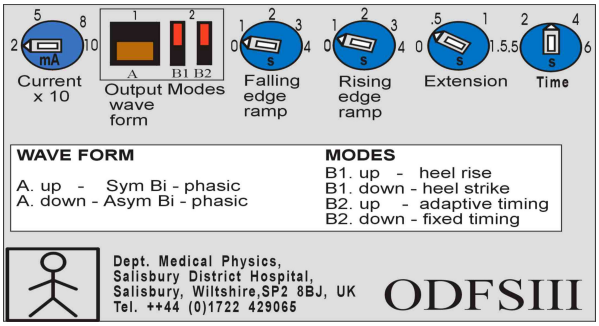


Fig. 1

Set up In sitting leg extended, try ODFS with standard internal set-up Fig. 1 and standard electrode position as shown Fig. 2. Gradually turn up output via pulse width dial.

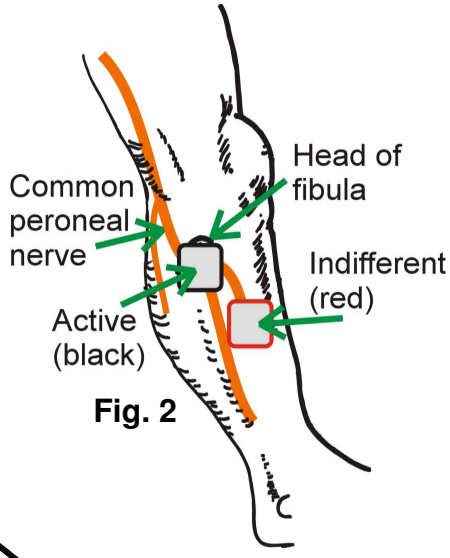


Fig. 2

Is there contraction of ant tib/evertors producing dorsiflexion with some eversion?

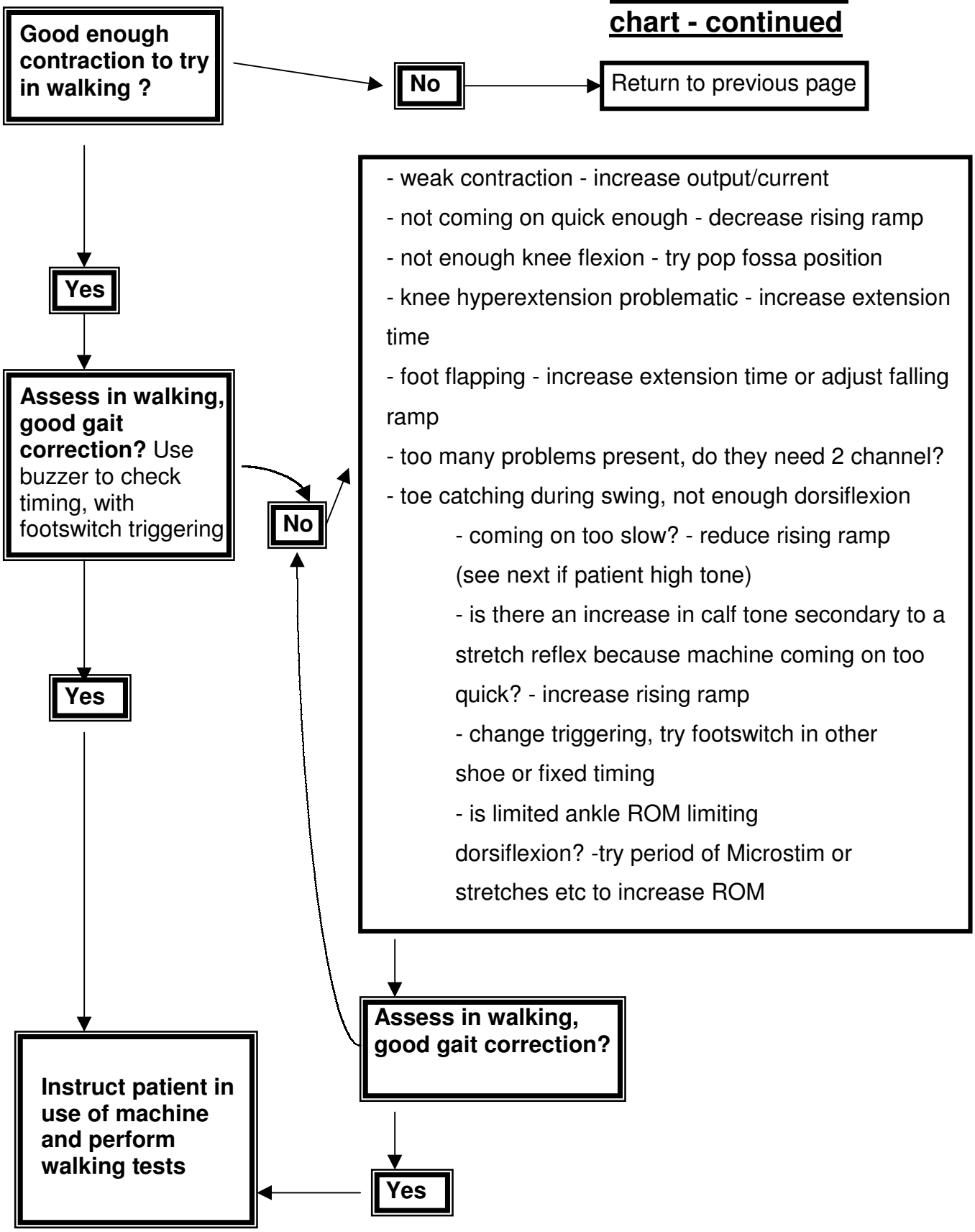
no

- alter current and output dial
- check electrode positions, electrode contact and battery
- too much eversion - alter fib head electrode >anteriorly
  - reverse polarity
  - change to biphasic
- not enough eversion - alter fib head electrode > posteriorly or > superiorly
- not enough dorsiflexion - adjust inactive red electrode
  - adjust active >anteriorly
  - reverse polarity
- increased calf tone, clonus, sensitivity - increase rising ramp, try blue electrodes, adjust electrode position, adjust intensity, change to biphasic or try period of stimulation with Microstim to get used to sensation.
- poor contraction - consider muscle fatigue as a cause - rest or try Microstim to increase muscle strength over time.

yes

Continue on next page

ODFS set up flow chart - continued



Trouble shooting

Problems with positioning
- further education
- take a photo
- mark sites in pen
- are they using it often enough/daily? Or are they out of practice?
- are they appropriate for ODFS

Problems with foot switch disconnecting
- foot switch cover
- longer lead
- Tubigrip/Urisleeve
- tuck a little slack lead into top of sock or Tubigrip

Problems with triggering
- test/replace footswitch and lead
- unreliable heel strike try triggering from opposite heel
- ensure good connections
- try fixed timing

Problems with variable output
- worn connections or electrodes
- replace worn leads
- replace flat battery?

Look forward to your feedback
Ingrid Wilkinson
E-mail: i.wilkinson@salisburyfes.com

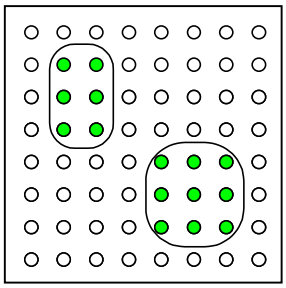
Improved Control of Ankle Movement using an Array of Mini-Electrodes.

Ben Heller, Tony Barker, Ning Sha, Jemma Newman, Elizabeth Harron.
Medical Physics, Sheffield Teaching Hospitals and University of Sheffield.

Introduction
The usual approach to correct foot-drop is to use one electrode to stimulate both the deep and superficial branches of the common peroneal nerve. Electrode position is critical for correct foot response: a 5mm electrode

movement may produce a 20• change in foot position[1]. Difficulty in locating the correct electrode site is the principal reason (after improvement in mobility), for discontinuing FES treatment[2].

The use of arrays of electrodes with a random search strategy has been suggested as a means of automatically finding the correct stimulation location[3]. A shortcoming of this approach is that it does not use any *a-priori* knowledge: we do know approximately where the site of stimulation should be and in general terms how the response of the foot changes with electrode movement. Patients are usually able to locate the correct site to within a couple of centimetres. Our approach is to use an array of ' mini-electrodes' with an overall size just large enough to cover the stimulation site, allowing for error in placement. Groups of these electrodes may be activated simultaneously to produce one or more ' virtual electrodes' - see figure below.

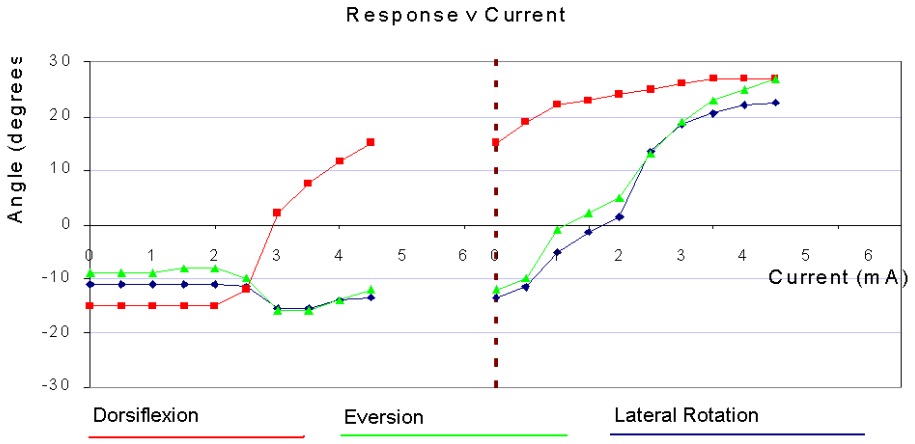


Our simple search strategy is to find one ' virtual electrode' that maximises dorsiflexion (presumed to correspond to the deep peroneal branch) and another that maximises eversion (presumed to correspond to the superficial peroneal branch). The stimulation amplitudes of these virtual electrodes are then independently adjusted to achieve the desired foot movement.

Methods and Results

A prototype electrode array was constructed from 8x8 flat-topped 4.5mm diameter bolts inserted through a thin rubber sheet at 7mm spacing. The entire array measured 54mm x 54mm. Each electrode had a wire connection to an 8x8 arrangement of 4mm sockets. Sixteen plugs on flying leads were used to manually activate up to 16 of the electrodes at one time, connecting each one to a separate constant current source. These were organised in two groups of eight, with one amplitude knob controlling each group.

The array was strapped to the leg just below the head of fibula. A large (150x140mm) indifferent electrode was placed on the anterior shank. A



typical result is shown. The array was scanned by activating electrodes in groups of 4 to produce maps of dorsiflexion, inversion and pain. Using this data one group was used to produce 15• dorsiflexion (response shown on the left of the graph) and then a second was added to steer the foot from inversion to eversion (additional response shown on the right). It can be seen that sufficient dorsiflexion was achieved and that full control of inversion/eversion was possible. Fifteen degrees of dorsiflexion together with zero inversion/eversion was achieved in 6 out of 12 normal subjects. Better array positioning may have facilitated the desired contraction for 4 additional subjects. Of the remaining two, one could not voluntarily dorsiflex beyond neutral and one could not tolerate the sensation of stimulation.

In conclusion, it has been shown that selection of groups if electrodes from an array allows improved control of foot position, work is on going to create a clinically usable system.

References

1. Carrioni-Burnett D., Webber K. Mapping foot spatial measurements with small movements of FES electrode positions 2002. FESNet 2002 conference, Glasgow September 2002
2. Taylor PN, Burridge JH, Wood DE, Norton J, Dunkerley A, Singleton, C, Swain ID. Patient perceptions of the Odstock Drop Foot Stimulator. *Clinical Rehabilitation,* 13: 333-340, 1999.
3. Whitlock TL., Peasgood W. Fry ME, Bateman A, Jones R. Self-optimising electrode arrays*. Proc. of 5th IPEM Clinical Functional Electrical Stimulation Meeting.* Salisbury March 1997:76-7)

FES-assisted exercise as a rehabilitation option in tetraplegia.

S. Coupaud[1], H. Gollee[1], K.J. Hunt[1,2], A.N. McLean[2], M.H. Fraser[2]

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At least half of all Spinal Cord Injuries (SCI) in the U.K. result in a lesion at the cervical level, leading to tetraplegia. To date, the focus of FES research for tetraplegia has mostly been on functional systems for the upper limb, but we propose that both functional and health benefits can be gained from FES-assisted arm-cranking exercise (FES-ACE). Improvements in muscle strength and cardiopulmonary fitness resulting from FES-assisted leg-cycling have already been reported (see [1]). The cardiopulmonary benefits of FES-arm cranking are likely to be of lesser magnitude than in leg-cycling due to the smaller muscle bulk recruited for upper limb work. Nevertheless, we aim to show that an intensive and progressive FES-ACE training regime can be a useful rehabilitation and recreational tool in tetraplegia.

Arm-cranking can be achieved by individuals with a C4-C6 SCI through surface stimulation of the biceps and triceps (provided there is no significant denervation of these muscles). Each of the four channels (biceps right and left, triceps right and left) is switched on and off according to the position of the cranks. The crank position is measured in real-time, through a serial communications link from the instrumented ergometer to the PC, while the stimulator is controlled by the PC via an isolated RS232 link (see [2] for further details). The ergometer also provides torque data, which are continuously recorded and used here as an indicator of muscle strength. Currently, five people with cervical SCI are involved in the four month programme. This starts with one month of muscle strengthening and familiarisation with equipment, followed by a three-month progressive FES-ACE training regime. For a cardiopulmonary fitness assessment of this form of exercise, constant load and incremental exercise tests are carried out at set points throughout each person's participation. This allows us to monitor changes in cardiopulmonary variables over time.

One individual (38 years old, C5/6 incomplete) has now completed the full programme. Steady increases in both maximum power output and peak oxygen up-take were recorded over the 3-month FES-ACE exercise intervention period. From the data obtained so far, it seems that FES-ACE exercise could be a very useful rehabilitation and recreational tool for tetraplegics with a C5-C6 SCI. However, with our C4 subjects, problems related with weak voluntary shoulder muscle control suggest that the benefits of FES-ACE for individuals with a higher cervical SCI (C4 and above) may be limited. We are, however, investigating the addition of electrical stimulation of key shoulder muscles to see if some of these problems can be alleviated. The greater muscle bulk recruited through this could also provide additional power for smooth and effective FES-ACE exercise in C4 (and above) SCI.

References:

[1] T.W.J. Janssen, R.M. Glaser, and D.B. Shuster. "Clinical efficacy of electrical stimulation exercise training: effects on health, fitness and function" *Topics in Spinal Cord Injury Rehab.*, 3(3): 33-49, 1998.

[2] H. Gollee, K.J. Hunt, S. Coupaud, A.N. McLean, and M.H. Fraser. "An apparatus for FES-assisted arm-cranking exercise in tetraplegia" *Proc. 7th Ann. Conf. Int. FES Soc., (Ljubljana, Slovenia)*, 2002.

Signal characteristics of the centre of force during FES walking in stroke and its relation to social mobility and patient satisfaction

J Van Vaerenbergh [1,2], L. Briers[2] , A. De Kegel [1], S. De Ruyter [1], Y. D'Hont [1], S. Vandenberghe [1], B. Honoré [3], M. D'Haese [3]

Gait analysis in FES users is necessary to detect, describe, assess and predict any benefit of its use. In a first part of the ESTAMINET project, the centre of force (COF) travelling along the sole of the foot opposite to the stimulation was investigated in new FES users having stroke for at least six months and presenting with an obvious drop foot. The one channel Odstock stimulator was used to correct abnormal gait. The preliminary results obtained from the first 11 patients are described.

To record the COF trajectories the Fscan system (Tekscan Inc.) was used. Ultra-thin flexible insole sensors were placed in the shoes of the subjects. Measurements were made without and with FES. All recordings were done during walking at a self-generated, comfortable speed.

In this study the optimised COF trajectory was considered as a 6^{th} order polynominal. The acceleration profile in X and Y direction had the appearance of an invariant sequence of 3 pulses around 2.34Hz, dropping nearly to zero between adjacent peaks suggesting a sequence of 3 blended submovements originating from heel strike, midstance and push off.

In stroke patients unrolling of the unaffected foot was clearly disturbed and apparent visible. This coincided with a high rate of isolated COF movement segments in X and Y direction and a poor blending of the 3 main submovement sequences. This was expressed by a power density spectrum showing high power in different frequency fields (2-11Hz).

The hypothesis is that improvement of motor control is established by a progressively blending and overlapping of movement sequences. This is partially based on the minimum jerk theory. Indeed FES normalised the power in most frequencies fields ($p \bullet 0.005$), and gait was clinically described as more stable and fluent. At the same time this approach seemed to be a reliable quantitative cost/efficiency estimate in motor control, hence some evidence points in the direction of a relation between peak power reduction in some frequency fields and patient satisfaction. However further research is required.

Acknowledgments:
This study is financially supported by the Compahs research foundation and the CMAT

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[3] Maria Middelares Hospital, Kortrijksesteenweg 1026, B-9000 Gent

Correspondence: jo.vanvaerenbergh@cmat.be

Topical Tips

One of our patients has recommended the use of Cohesive Support Bandage to help maintain the position of the electrodes of her ODFS. In particular the bandage is useful for an electrode placed in the popliteal fossa. The flexible, breathable and water resistant bandage is impregnated with a form of latex. The bandage does not stick to hair or skin but is adhesive to itself. Consequently, no form of fastening is required to maintain its position. It can be reused several times and will also stand up to gentle washing, extending its use further. Our patient sometimes used it with a covering of Tubigrip, which helped prevent rucking of the bandage while pulling trousers on. A 5cm x 4m role of the Cohesive Support Bandage is available from Boots Chemist price £3.99

Equipment News

Coming soon – New improved ODFSIII (V6.2)

The current ODFSII has been upgraded.

- The new version has an improved output power management system that will be more stable with battery voltage changes. This means that ODFS users will not need to adjust the level control as the battery runs down and may, in some cases, extend the battery life.
- The device has also been fitted with a low battery indicator. The output indicator LED will flash yellow as before to indicate an output but will flash red when the battery is nearing the end of its life. The stimulator will remain operable for a short time, giving the user opportunity to find a replacement battery.
- We have also changed the ramp times of the stimulator. Previously, both rising and falling edge ramps had a maximum duration of 4 seconds. This was far longer than was ever needed in practice. The new ODFS has rising and falling ramps of maximum 2 seconds. This will make the ramps easier to set. Remember that it is usual to have a rising edge ramp of 0.5 s or less. Longer ramps are only used occasionally for very slow walkers where calf tone is a significant problem.
- We have found new replacements for the front panel level control and belt clip. The components are more robust and will improve the reliability of the device.

The new ODFS will be supplied as standard and will be available some time this summer.

New Research

Proposal Acronym: Healthy AIMS (Ambient Intelligent Micro-Systems for Health)

European Union 6th Framework Programme Integrated Project

The Healthy AIMS project is an integrated project involving 27 partners from industry, academia and health care in 9 countries, with the intention of developing microsystems technology in the field of medical implants. The technology is aimed at a wide range of applications but with similar requirements, enabling the exploitation of common core components and techniques. In this way costs can be reduced for any one application and the speed of development increased. The project was originated from the NEXUS Association Medical Application Group. This is a trade association that aims to promote the development of microsystem technology by encouraging interaction between its members. The project application process was lead by Diana Hodgins of European Technology for Business (ETB) who has now taken on the role of project co-ordinator. The project began in December 2003 and will run for 4 years.

The project will develop applications in the following areas:
- Cochlea implants for restoring hearing
- Functional Electrical Stimulation (FES) for restoring movement
- Artificial intraurethral sphincter for restoring continence
- Retina implant and glaucoma sensor for restoring site
- Inter-cranial pressure sensor for monitoring pressure

These devices all have common requirements in the following areas
- Communication - a body area telemetry network will be developed
- Micro-electrodes and needles
- Micro-packaging and interconnects
- Power sources
- Sensors and actuators
- Bio-materials and functional Bio-interfaces

Salisbury has been asked to take the lead in developing and testing FES applications.

FES Applications

Loss of upper or lower limb mobility due to paralysis is a problem effecting many hundreds of thousands of individuals in Europe each year. About 600,000 are paralysed due to stroke, about 20,000 due to cerebral palsy, a similar number due to multiple sclerosis and around 6000 due to spinal cord injury. As medical care improves, life expectancy has increased leading to many more people with paralysis living in the community. Despite great

advances in medical science, little has been possible to restore useful function to affected limbs.

FES (Functional Electrical Stimulation) is a technique that produces useful controllable movement in paralysed muscles by the application of electrical impulses to the nerves that supply the effected muscle. Traditionally, stimulation has been applied by the use of skin surface electrodes. While this has been relatively successfully used for exercise applications and the correction of dropped foot, further applications have been limited by the practicality of applying the necessary hardware each time the system is used. These problems would be removed by the use of an implanted FES device, significantly extending the usefulness of the systems. Several attempts have been made to develop such technology and benefits have been demonstrated, in particular the provision of a useful grasp in tetraplegia and the correction of dropped foot in stroke. However, to date, systems have been application specific and relatively expensive. Additionally, devices have been "open loop", lacking feedback of the user' s situation, including feedback could be used to improve the performance of the systems.

The nature of the disability varies between the patient groups. The paralysis in the case of stroke and cerebral palsy is incomplete and spasticity is a common problem, usually in the flexor muscle groups in the upper limb and extensors of the lower limbs. In the upper limb, as the severity of a case increases, often proximal areas of the limb are affected. In less severe cases only the hand may be significantly affected. In spinal cord injury, the pattern of paralysis can vary from incomplete injuries, with a few to most muscles being effected below the spinal cord lesion to a complete lesion where all the muscles will be affected. It is therefore plain that a range of solutions is required to restore function in all these different cases. However, each solution requires common components:

- Actuators - a means of stimulating muscles to produce movements
- Sensors - to provide feedback of system status
- Power sources - to energise the system
- Control techniques - to allow the user to interface with the system

By developing a modular design of implant, technology can be efficiently shared between applications, lowering overall costs and providing a common philosophy to solutions for different clinical problems. The commonality will allow greater and more rapid dissemination of the technology to clinical users throughout the EU.

The implanted device and external control hardware will be developed by partners in the Healthy AIMS project, lead by Finetech Medical Ltd. Salisbury' s role is to identify clinical applications for the device, investigate the feasibly of these interventions and plan the clinical procedures for the implementation. The control techniques required for the recipient to use the device will be developed and finally a number of procedures will be carried out with volunteers to demonstrate the use of the technology. Information from the clinical investigation will be used to plan larger clinical trials to be carried out at a later stage (not under present funding).

Possible applications

In this project we wish to develop areas of use of the implant system, building directly on clinical and R&D experience in Salisbury District Hospital. We plan to look at three principal areas, upper limb function, gait assistance and standing / transfer function. The first two areas are applicable to stroke, incomplete spinal cord injury and cerebral palsy, the last area is specific to paraplegia.

The first part of the project will be an option appraisal of the possible implant applications. A limited subgroup will be chosen for further analysis and will, where possible, be tested using external FES techniques to verify possible control strategies. Finally, once the implant device is available, it will be tested in one or possibly two applications.

Paul Taylor

Courses

FES Courses For 2004/5/6

Before clinicians can prescribe the ODFS or 02CHS for their patients, they must attend a course. This is mandatory. Three courses are offered.

Single Channel Course
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. Upper limb stimulation is also introduced.

Two Channel Courses
Participants must have completed the single channel course. The second course, intended for clinicians who have some experience of the ODFS, introduces the O2CHS, used for more complicated gait applications.

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. The upper limb course expands on the introduction to exercises used in upper limb hemiplegia, given in the introductory course. Some participants may find some of the physiology hard going and it is preferred that they have attended the single channel course first.

2004

Upper Limb	21 May	Salisbury	Sue Borrett 01722 429065

Single Channel	21/22 June	Cumbria	Tracey Mifflin 01946 523636
Single Channel 2 Channel Upper limb Peadiatrics Paraplegic cycling	4/5 September	Bournemouth IFESS Conference	Paul Taylor 01722 42119
Single Channel	October	Belfast	Siobhan Macauley (028) 9026 3851
2 Channel	November	Salisbury	Sue Borrett 01722 429065
2 Channel	December	Cumbria	Tracey Mifflin 01946 523636

2005

Single Channel	January	Stockton-on-Tees	Claire Hoggarth 01642 624654
Single and Upper	February	Leeds	Moira Keith 0113 392 4523 moira.keith@leedsth.nhs.uk
Single Channel	February	Falmouth	Sonya Veale 01326 434728
2-Channel	March	Croydon – Surrey	Debbie Foster 0208 401 3093
Single Paediatrics	April	Swansea	Wendy Gadd 01792 285371
Single Channel	May	Salisbury	Sue Borrett 01722 429065
Single Channel	June	Basingstoke	Juliette Bell 01256 314764
Single Channel	July	Cheltenham	Nicola Smith 08454 222107
Single Channel	September	Ireland	Patricia Lucey Patricia@mscork.iol.ie
2-Channel	October	Salisbury	Sue Borrett 01722 429065

Single Channel	November	Newcastle	Alex Haugh 0190 219 5668

2006

Single Channel	January	Norwich	Ailsa Jukes 01603 711685
Single Channel	February	Eastbourne	Ann Canby Physio Dept Eastbourne District General Hospital, Kings Drive Eastbourne BN21 2UD
Single Channel	March	Inverness	Michaela Smith Raigmore Hospital Royal Northern Infirmary 01463 242860

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

FES Equipment Price list

ODFS	Odstock Dropped Foot Stimulator kit	£272.25 (excluding VAT)
O2CHS II	Odstock Two Channel Stimulator kit	£379.00 (excluding VAT)
O2CHS II	without double foot switch and lead	£330.00 (excluding VAT)
O4CHS	Odstock 4 Channel exercise Stimulator kit	£295.40 (excluding VAT)
MS2 V2	Microstim 2 (version2) exercise stimulator kit	£267.75 (excluding VAT)

All stimulators are supplied with all accessories necessary for their use. Stimulators can be supplied with electrodes, electrode and foot switch lead lengths and shoe inner sole size of your choice. Please specify your requirements. Stimulators are guaranteed for one year. There is a 10% discount on orders of 5 or more stimulators. Our equipment is CE marked indicating that it complies with required standards.

Electrodes

Order Code	Electrode Size/Type	Price 1-9 Exc. VAT	Price 1-9 Ixc. VAT	Price 10-29 Exc. VAT	Price 10-29 Inc. VAT	Price 30+ Exc. VAT	Price 30+ Inc. VAT
J10R00	25mm (1") Round. PALS Plus	£5.63	6.61	5.34	6.27	5.06	5.95
879100	32mm (1 ¼") Round. PALS Plus	£5.63	6.61	5.34	6.27	5.06	5.95

881150	38mm (1.5") Round. PALS Plus	£5.70	6.70	5.42	6.37	5.13	6.03
879200	50mm (2") Round. PALS Plus	£5.96	7.00	5.66	6.65	5.36	6.30
879300	70mm (3") Round. PALS Plus	£7.49	8.80	7.11	8.35	6.74	7.91
891200	30X50mm (1¼"X2") Rectangular. Pals Plus	£5.75	6.76	5.47	6.43	5.18	6.09
895220	50X50mm (2X2") Square. Pals Plus	£5.63	6.61	5.34	6.27	5.06	5.95
901220	50X50mm (2X2") Square-Blue. PALS Plus Hypoallergenic	£5.94	6.98	5.64	6.63	5.35	6.29

Accessories

Code	**Item**	**Price (exc. VAT)**
EL-JACK(100 or 150mm)	Electrode leads, 3.5mm Jack	£8.90
EL-SHROUD(50, 75, 100 or 150mm)	Electrode leads, Shroud	£8.90
FSL(45, 60, 75, 100, 120 & 150)	Foot switch leads (60, 75, 100, 120 or150 cm)	£11.20
DFSL(60, 75, 100, 120 or 150)	Double Foot Switch Leads	£22.40
	Other lead lengths are available on request	
FSR	Foot switch	£22.40
FSRJK	Foot switch with jack connector (45cm) (for use with ODFS strapped to leg)	£26.00
DFSR	Double foot switch	£34.70
FSC	Foot switch lead couplers	50p
HNDSW	Hand switch	£22.40
SOUNDER-JACK	Sounder with 3.5mm jack connectors	£10
SOUNDER-SHROUD	Sounder with shrouded connectors	£10
FP	Wow pedal (for O4CHS)	£75
PP3	Duracell Batteries (pack of 10)	£15
CHARGER-KIT	2 NiMH Rechargeable Batteries with charger	£25
PROBE-JACK	Stimulation probe	£15
PROBE-SHROUD	Stimulation probe	£15

Y-CON	Y connector	£3.50
IS (L for ladies or G for gents, shoe size,)	Cork inner sole pair available in ladies or gents sizes L4, L5, L6, L7, G7, G8, G9, G10, G11, G12	£1.50

VAT and Delivery Costs

VAT is payable on all orders except for the following cases:

- English NHS trusts (excludes Wales, Scotland, Northern Ireland),
- countries in the EU that can provide a VAT registration number,
- countries outside the EU,
- disabled individual (certificate of eligibility required),
- charity organisation (certificate of eligibility required).

Items sent overseas will also incur a postage delivery cost.

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

Astley Ainslie Hospital, Edinburgh
Friday 26th November
9.30am - 5pm

Please fill in the form below to reserve your place. 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.

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 £40. 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 Sue Borrett, 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.