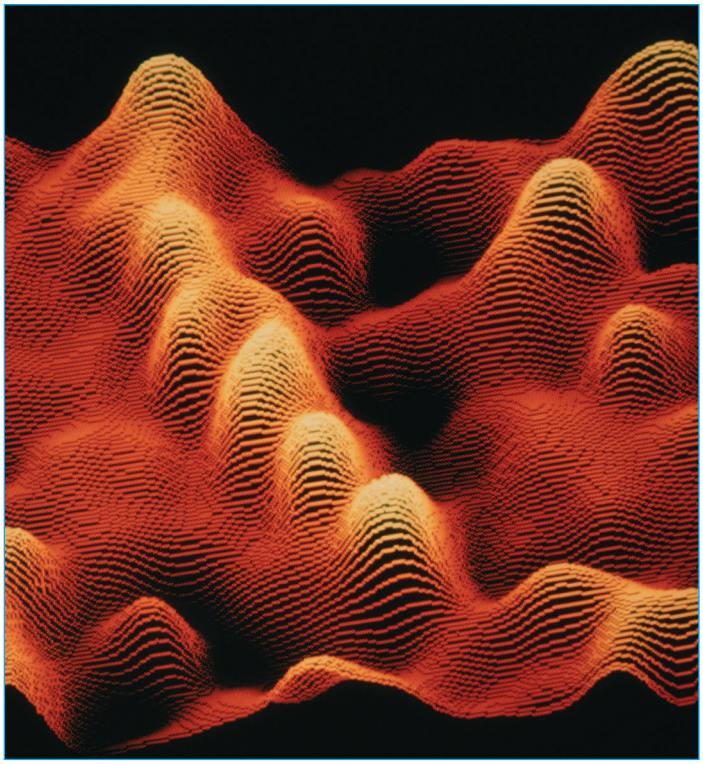
Horizons in Medicine 16



Updates on major clinical advances

Edited by Jayne Franklyn

Royal College of Physicians of London

Horizons in Medicine

number **16**

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Editor's introduction

This volume in the Horizons in Medicine series represents an update of a wide-ranging group of subjects reaching across all areas of medicine. As organiser of the 2004 Advanced Medicine Conference, I was allowed the luxury of seeking out UK leaders of national and international repute working at the cutting edge in their field and inviting them to contribute. This publication reflects their input to one of the most important, topical and popular conferences organised by the Royal College of Physicians.

The trend of increasing specialisation, and even subspecialisation, within medicine determines that it is increasingly difficult to keep abreast of new developments in fields other than our own. The vast array of information available, especially electronically, sometimes hinders rather than helps, emphasising the need for those at the forefront of their field to put such information into context and to give pragmatic advice based on their practical experience.

The chapters reflect many aspects of medicine. Topics covered include the importance of preventive medicine and the potential impact of better management of highly prevalent risk factors such as obesity and hypertension; information about novel therapies and interventions in common medical diagnoses such as gastrointestinal bleeding, lung cancer and chronic liver disease; best practice in areas of medicine such as coronary artery disease and osteoporosis where a sometimes bewildering array of options is available; and also the role of 'super-specialist' input in complex areas such as the medicine of pregnancy, hepatology and nephrology. In addition, this volume reflects the conference highlights: the Lumleian lecture, which illustrates to perfection the translation of molecular biology to disease management and risk prediction, and the Croonian lecture, which so elegantly displays the genetic and biological unravelling of multiple sclerosis, an all too common disease.

In these times of change for the physician, both in training and in consultant practice, it is easy to lose sight of the clinical excellence which exists within the UK. Academic medicine is perceived as being under threat. It remains critical to protect professional flexibility and time, within both the NHS and university sectors, to allow the fostering and development of talents and innovations, which could all too readily be swamped by increasing constraints.

This volume illustrates some of those talents and, in so doing, provides a practical guide to best practice in medicine in 2004.

JAYNE FRANKLYN
August 2004

The clinical use of functional electrical stimulation in neurological rehabilitation

Ian Swain and Paul Taylor

☐ INTRODUCTION

Electrical stimulation is not a new technique; it dates back to the Ancient Greeks who used rubbed amber and torpedo fish to produce a number of physiological responses, primarily to cause muscular contractions. Its development followed that of advances in physics by Volta and Faraday during the 18th and 19th centuries which led to more reliable, controllable sources of electricity, and in neurophysiology as a result of the work of Galvani and Duchenne. Various researchers then showed that denervated muscles respond to stimulation only by connecting and disconnecting a direct current source and do not respond to alternating or Faradic current. However, there was a contraction when a muscle was stimulated by a Faradic current via an intact motor neurone. All the work described in this chapter refers to the use of functional electrical stimulation (FES) in upper motor neurone conditions in which the muscle is contracted via nerve stimulation. If there is damage to the peripheral nervous system, for example by a prolapsed lumbar disc, the resulting denervated muscles can still be directly stimulated, although the length of the pulses required means that work to date is limited to the research laboratory.

Over the last twenty years electrical stimulation has been used to treat a wide range of clinical conditions. It is not possible to cover all these in detail in this chapter; for more information, readers should consult the web sites of the International Functional Electrical Stimulation Society[1] and the International Neuromodulation Society.[2]

The uses of FES are shown in Table 1. Some of these (eg pain relief, cochlear implants, pacemakers) are widely used in the clinical environment, whereas others (eg visual prostheses) are still in the research stage. This review will concentrate on the middle ground, discussing techniques that have been developed to a level where they are now clinically applicable without the need for bioengineering support but where they are not widely used in the NHS. These are primarily devices to improve gait or restore limited hand function following neurological conditions such as stroke, multiple sclerosis, spinal cord injury, head injury and cerebral palsy.

☐ HISTORY OF FUNCTIONAL ELECTRICAL STIMULATION

The first functional use of electrical stimulation to improve gait was performed by Liberson in 1961[3] who used electrical stimulation successfully to correct foot drop

Table 1 Conditions in which functional electrical stimulation is used.

- Pacemakers and cardiac assistance
- Limb movement
- Bladder and bowel control
- Cochlear implants
- Visual prostheses
- Deep brain stimulation for tremor
- Scoliosis correction
- Pain relief
- Tissue regeneration
- Phrenic pacing for high level tetraplegics
- Treatment of facial palsy

as a result of a stroke. Despite the passage of 40 years, routine treatment using FES is still not available in the UK – or indeed in any other country as far as the authors are aware – even though in this country alone there may be up to 100,000 people who would benefit from such devices.

It was not until 1997 that Burridge *et al* published the first randomised controlled trial (RCT) to show clinical benefit of an FES based orthosis, the Odstock Dropped Foot Stimulator (ODFS).[4] Prior to that, the few RCTs that did exist concentrated on the physiological changes rather than on increase in function.[5]

Today, developments in microelectronics and computing can provide increased function for a large number of people with neurological disabilities. Some of these are implanted devices in which electrodes are directly attached to the nerves or sutured to the surface of the muscle. An example of such an implanted system is the FreeHand system, developed at Case Western Reserve University in Cleveland, Ohio,[6] designed to enable gripping function in people with tetraplegia. An alternative approach is to use electrodes on the skin to stimulate the muscles transcutaneously, as in devices like the ODFS[4] and the Handmaster.[7]

In Salisbury, a number of different FES treatments are provided for patients with neurological and musculoskeletal impairments, the most common being one- and two-channel transcutaneous systems to improve walking, and exercise regimens to strengthen muscles and reduce spasticity in both the upper and lower limbs. There are also implanted devices like the FreeHand system combined with surgical techniques such as tendon transfer, and FES combined with medical treatments such as botulinum toxin injections. These treatments necessitate medical, therapy and engineering staff working closely together in the clinical environment to provide the most appropriate treatment.

□ RESEARCH BACKGROUND

Work in Salisbury has concentrated on the development of simple practical devices which are affordable for the NHS and of sufficient flexibility to be applicable in a

variety of clinical conditions. There are considerable advantages in having the engineering and clinical services working closely together; this has ensured that the present generation of stimulators has been developed to meet a clinical need that was determined as a result of treating patients.

The MkIII Odstock dropped foot stimulator

The MkI ODFS was designed as part of a Department of Health (DH) trial. A number of modifications were made as clinical experience increased, culminating in the MkIII ODFS which is in use today (Fig 1).

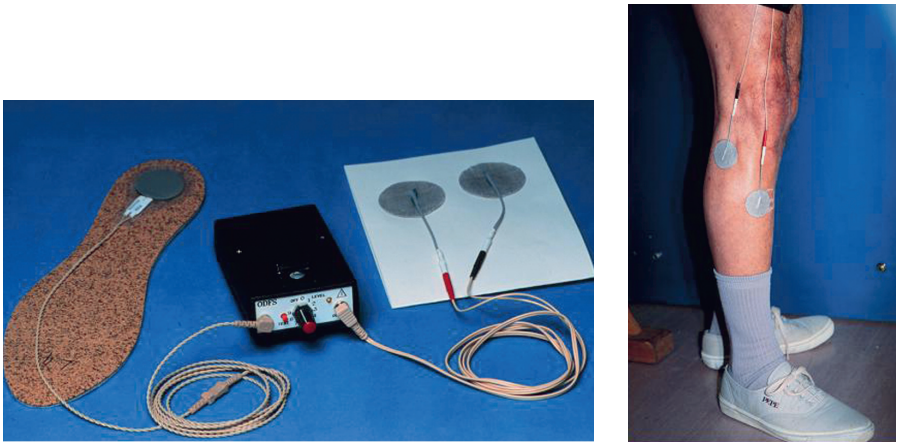

Fig 1 The Odstock Foot Dropped Stimulator showing standard electrode positions.

The MkIII ODFS is a single-channel, foot-switch triggered stimulator designed to elicit dorsiflexion of the foot by stimulation of the common peroneal nerve (maximum amplitude 100 mÅ, 350 μs pulse, 40 pps). Skin-surface electrodes are typically placed over the common peroneal nerve as it passes over the head of the fibula and the motor point of tibialis anterior. The rise and fall of the stimulation envelope and the extension after heel strike can be adjusted to prevent both a stretch reflex in the calf muscles and 'foot flap' due to the premature ending of dorsiflexion. The provision of dorsiflexion and eversion enables the foot to clear the ground more easily during swing phase. This reduces the compensatory mechanisms such as circumduction and hip hitching, hence reducing effort, which in turn can lead to a reduction in associated reactions. Repeated use of the stimulator can lead to a more 'normal' gait pattern being learnt. Heel strike with evasion is achieved at initial contact, so weight bearing is made along the centre line of the foot; stability at the ankle is therefore increased, making gait safer and increasing confidence.

The ODFS was the subject of an RCT in which 32 stroke patients who had had a stroke more than six months previously were randomly allocated to a treatment group who used the device and received 12 sessions of physiotherapy or to a control group who received only physiotherapy.[4] Compared with the controls, the treatment group showed a significant increase in:

- walking speed
- reduction in effort, as measured by the Physiological Cost Index (PCI) (defined as the change in heart rate divided by walking speed)
- Hospital Anxiety and Depression score, and
- reduction in quadriceps spasticity.

The ODFS has been widely used since then for a variety of neurological conditions.[8] It has been recognised by the Development and Evaluation Committee of the South-West Regional Health Authority and the Royal College of Physicians of England in their guidelines on stroke.[9]

Other stimulators

The design of the other stimulators used in the department at Salisbury is also achieved through the same iterative design process. In addition to exercise stimulators, there is a two-channel version which can be used for stimulation either of the bilateral common peroneal nerve or of one common peroneal nerve and a separate muscle group.[10] In the two-channel stimulator, only one foot switch is required to control both channels, the relative timing being adjusted when the system is first fitted. Therefore, the system can be used in swing phase to stimulate hamstrings to achieve greater knee flexion, in stance phase to stimulate gluteae to improve hip extension or with quadriceps to improve knee stability.

CLINICAL SERVICE

Referrals are taken from general practitioners and hospital consultants. Patients have an initial assessment and, if appropriate, they start on a treatment programme. Careful referral criteria have meant that over 82.5% of people referred are suitable for treatment. When the equipment is provided, the patient is seen on consecutive days:

- *1st day*: the technique is explained and the patient taught how to find the optimum electrode positions.
- *2nd day*: the patient attends wearing the equipment so that any possible problems can be readily corrected.

The patient is seen again after six weeks and three months, then every six months throughout the time the device is used. If there are few problems, the monitoring interval might be extended to one year. For people using the walking systems, walking speed and the effort involved, measured by the PCI, are recorded both with and without the stimulator at each appointment in order to monitor progress. The patient selection criteria ensure that 86% of people starting treatment are still using the ODFS one year after first issue.

A telephone helpline is available so that any problems can be solved rapidly. Patients are also given spares of certain items such as foot switches to prevent any inconvenience. A user survey showed a high level of patient satisfaction; patients also said that they were more confident and that walking was less effort.[11]

□ RESULTS

To date, 1,683 patients have been seen in the Salisbury FES clinic with a range of disabilities arising from many different pathologies, although difficulty in walking due to a cerebrovascular accident (CVA) forms the largest group. The breakdown of patients by their primary pathology and function is shown in Table 2.

To consider the long-term effect of the clinical service, this review will concentrate on the two largest patient groups seen at Salisbury: those using an ODFS following a stroke and those with MS.

Table 2 Patients seen in the Salisbury functional electrical stimulation clinic, by pathology and function (n = 44).

	Breakdown		
By pathology		**By function**	
Cerebrovascular accident	786	Walking	1,233
Multiple sclerosis	391	Hand function	350
Spinal cord injury	108	Paraplegic standing/ lower limb exercise	282
Cerebral palsy	53		
Other (TBI, PD, FSP etc)	345	Facial	25
		Assisted cough	1

N.B: some patients have treatment to enhance more than one function.
FSP = familial spastic paraplegia; PD = Parkinson's disease; TBI = traumatic brain injury.

Stroke

Despite having seen 786 patients with a stroke, complete data over 3½ years are available only on 44 patients (Table 3), for a variety of reasons including missed appointments. It is also because over the past few years the number of patients has increased dramatically, most of whom have not used the system for sufficient time for analysis. The longest any stroke patient has used a stimulator is over 10 years. All data were analysed by the Wilcoxon signed ranks test. There is no significant difference between any of the results at 4½ months and 3½ years.

Multiple sclerosis

The results presented in Table 4 were calculated from subjects for whom there are complete data, including those who have a two-channel system for bilateral foot drop. Thus, people were not included if they could walk the set 10 m course only when using the stimulator. Comparisons were made using the Wilcoxon signed ranks test.

Unlike the results for people after CVA, there is no carry over in the MS patients. There is, however, a continued orthotic gain at each of the assessments. After 72 weeks they are still walking slightly faster and with less effort when using the stimulator than without stimulation at the initial appointment, although the difference is not statistically significant.

Table 3 Effects of functional electrical stimulation following cerebrovascular accident at initial assessment, 18 weeks and 3½ years (n = 44).

	Median PCI (heartbeat m^{-1})		Mean speed (ms^{-1})	
	No stimulation	**Stimulation**	**No stimulation**	**Stimulation**
Initial assessment:	0.73	0.61	0.49	0.56
OG		p <0.01		p <0.01
After 18 weeks:	0.64	0.51	0.63	0.71
OG		p <0.01		p <0.01
CO	NS		p <0.01	
TOE		p <0.01		p<0.01
After 3½ years:	0.68	0.57	0.58	0.66
OG		p <0.01		p <0.01
CO	NS		p <0.01	
TOE		p <0.01		p <0.01

Orthotic gain (OG): the difference between Physiological Cost Index (PCI) or walking speed, with and without stimulation at any given appointment.
Carry over (CO): the difference between walking speed or PCI at a set time period compared with the initial assessment.
Total orthotic effect (TOE): the difference between PCI or walking speed with stimulation at a set time period compared with values without stimulation at the initial assessment.

Table 4 Effects of functional electrical stimulation in people with multiple sclerosis at initial assessment, 18 weeks and 72 weeks (n = 61).

	Median PCI (heartbeat m^{-1})		Mean speed (ms^{-1})	
	No stimulation	**Stimulation**	**No stimulation**	**Stimulation**
Initial assessment:	0.57	0.49	0.64	0.75
OG		p<0.01		p<0.01
After 18 weeks:	0.55	0.46	0.67	0.78
OG		p <0.01		p <0.01
CO	NS		NS	
TOE		p <0.01		p <0.01
After 72 weeks:	0.65	0.52	0.60	0.69
OG		p <0.01		p <0.01
CO	p <0.01*		p <0.01*	
TOE		NS		NS

* Without stimulation the walking ability of subjects had significantly deteriorated over the 72 weeks.
See Table 3 for key.

The difference between the response of people following CVA and with MS is illustrated in Fig 2 which compares the single-channel ODFS users. The CVA group showed a significant improvement in walking speed and PCI both with and without the ODFS over 72 weeks. In contrast, the walking ability of the people with MS improved when they used the stimulator, but deteriorated over time without the stimulator.

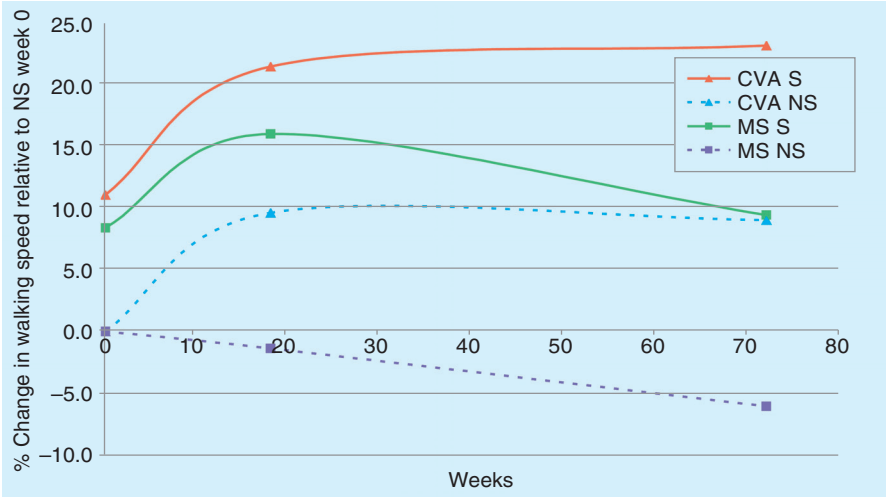

Fig 2 Median percentage change in walking speed for cerebrovascular accident (CVA) (n = 116) and multiple sclerosis (MS) (n = 42) using the single-channel Odstock Foot Dropped Stimulator. Initial walking speeds: CVA 0.57 ms^{-1}, MS 0.68 ms^{-1} (NS = no stimulation; S = stimulation).

☐ STAFF TRAINING

Part of the initial funding from the DH was to establish a training course to facilitate dissemination of FES throughout the NHS. We consider training of staff to be vitally important and see FES as a mode of treatment, not simply an electronic device. Therefore, equipment is never sold directly to patients, only to clinicians who have completed one of our training courses. To date, over 60 such courses have been held, most in the UK but recently some also in other countries (South Africa, Qatar, Turkey). Over 600 clinicians have been trained. A list of future training courses is available on our web site.[12]

☐ DISCUSSION

The results obtained with the 3½-year follow-up period are similar to those reported previously,[4,8] although it is encouraging that the effect seen at 4½ months does not diminish with time despite ageing of the patients. Although not unexpected, it is interesting to note the difference between users following CVA and those with MS. It appears that in the latter group the ODFS works primarily as an orthosis, whereas CVA use of the ODFS has a significant therapeutic effect. Nevertheless, those with MS still obtain significant benefit: 93% of 125 MS patients who started using the ODFS between 1999 and 2001 were still using it after one year.

☐ FUTURE WORK

At present, an RCT on the use of FES in MS and a pilot study into its effects in Parkinson's disease are being undertaken. The Salisbury FES clinic is also part of two multicentre projects:

- to develop a new generation of implanted systems for both the lower and upper limbs, and
- to investigate the long-term health benefits of paraplegic cycling.

Acknowledgements

We would like to thank the DH and Action Research for funding the development and clinical trial of the ODFS and two-channel systems, respectively. We would also like to thank all the staff of the Department of Medical Physics and Biomedical Engineering at Salisbury for their hard work and enthusiasm over the past ten years.

Note: the ODFS, the two-channel walking stimulator and the two- and four-channel exercise stimulators are CE marked; they are available for purchase from the Department of Medical Physics and Biomedical Engineering in Salisbury.

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