

FROM CIRCUIT DESIGN TO SERVICE DELIVERY – ESTABLISHING A CLINICAL FES SERVICE

Swain I.D.,^{1,2} Burridge, J.H.,³ Crook, S.E.,^{1,2} Finn, S.M.,¹ Johnson C.A.,¹ Mann G.E.,¹ Taylor P.N.,^{1,2} Wright P.A.,¹

¹ Dept. of Medical Physics and Biomedical Engineering, Salisbury District Hospital, U.K.

² Academic Biomedical Engineering Research Group, University of Bournemouth, U.K.

³ School of Health Professionals and Rehab Sciences, Southampton University, U.K.

Abstract

There are a number of components that are essential to the operation of a clinical FES service. Firstly we believe that FES is part of a treatment package and cannot be delivered by the simple provision of a stand alone device enabling the patient to treat their own stroke, MS etc. Therefore trained staff are required to deliver that service and in our experience this works best if this is a team of therapists and clinical engineers working closely together. Secondly the equipment has to be designed and manufactured to withstand the rigours of everyday life and reliability is essential. Constant patient support and education are also required and the problems that inevitably arise must be solved promptly. Patient selection is crucial. Finally data must be recorded and stored in a structured way (in Salisbury we have 1104 patients on the database and see 30 patients per week) to quantify the efficacy of treatment and to determine the design criteria for the next generation of devices.

Background

It is 40 years since Liberson (1) first used electrical stimulation to successfully correct foot drop 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 any other country as far as the authors are aware, even though in the UK alone there are up to 100,000 people who would benefit from such devices. Indeed it was not until 1997, that the first paper, Burridge et al (2), was published that employed a randomised controlled trial (RCT) to show the clinical benefit of an FES based orthosis, the Odstock Dropped Foot Stimulator (ODFS). Prior to that the few RCT's that did exist, Glanz (3), concentrated on the physiological changes rather than an increase in function. It is therefore not surprising that FES systems are not used routinely, as the clinical evidence needed to establish a case of need has until recently been very thin. This is at a time when evidence based medicine is becoming more widely practiced and FES has to compete for funding with other new treatment modalities such as advances in genetic engineering.

In Salisbury we provide a number of different FES treatment for patients with a range of neurological and musculoskeletal impairments. This includes implanted devices such as the FreeHand system combined with surgical techniques such as tendon transfer and medical treatments such as Botulinum Toxin injections, with medical, therapy and engineering staff working closely together in a clinical environment to provide the most appropriate treatment. This paper considers the various components that need to be drawn together in order to be able to provide a clinical FES service. The majority of the areas covered will be common to all countries although the method of funding will obviously differ.

Methods

Stimulator Development

The present generation of stimulators were all developed to meet a clinical need that was determined as a result of treating patients with a wide range of disabilities resulting from a number of different pathologies. The Mk I ODFS was designed as part of a Department of Health trial and as clinical experience increased a number of modifications were made culminating in the Mk III ODFS which is in use today (Patent Pending). This stimulator includes twelve minor and three major improvements, such as full control of the stimulation envelope and an adaptive footswitch design, which has proved considerably more reliable than the earlier version. The suggestions for improvements arise through the Departments ISO 9000 system which will be described in the next section.

The design of the other stimulators used in the Department is also achieved through the same iterative design process. All the stimulators used have been designed in the Department and initially all were manufactured in house. However, the demand has been such that now the manufacture of most common types is subcontracted to a local electronics company and only the more specialist devices, including bespoke stimulators, are manufactured internally.

Quality Control

The Department has ISO 9000 both for its stimulator manufacture and for its clinical service, this enables the stimulators to be CE marked which is essential to enable them to be used in other hospitals. Monthly management review meetings identify any problems that arise and feedback from patients, both informally and via structured questionnaires are used to improve both the clinical service and the stimulator design. The entire service is independently audited by the British Standards Institute every six months.

Clinical Service

Referrals are taken from both General Practitioners (Family Doctors) as well as from hospital specialists. Patients are then seen for an initial assessment and if appropriate they start upon a treatment programme. Careful referral criteria have meant that 82.5% of people referred are suitable for treatment. The patient is then seen on consecutive days and the technique explained and equipment provided. On the second day the patient attends already wearing the equipment so that if any problems are experienced they can be readily corrected. The patient is seen 6 weeks later, then 3 months after and then every 6 months all the time the patient uses the device. If there are few problems this period might be extended to one year. Every time the patient is seen, walking speed and effort, Physiological Cost Index (PCI), are measured both with and without the stimulator, to chart progress. The patient selection criteria ensure that 92.5 % of people starting treatment are still using the ODFS at 4¹/₂ months.

In addition to the clinic appointments a telephone helpline is available to ensure that any problems are solved rapidly. This is manned during office hours and an answerphone service provided at other times. Patients are also given spares of certain items such as footswitches to prevent any inconvenience. A user satisfaction survey was undertaken (4) which showed that a high level of patient satisfaction was achieved.

Funding

This will obviously vary from country to country but in the UK the majority of funding is provided by the National Health Service and distributed by local Health Authorities. Priorities for each Health Authority vary and as such we obtain more referrals from some than others. However, the main principle that we have learnt over the years is to have a good package of information to hand so that the case for treatment for each condition can be presented on demand. Our basic information pack consists of:-

Introduction to FES information leaflet
Cost of treatment, short and long term

Principle papers in peer reviewed journals (2,4,5)
Report to the Development and Evaluation
Committee of the Department of Health
Royal College of Physicians of England
guidelines for treatment of Stroke (6)

This information is also available on our Web site
www.Salisburyfes.com

Staff Training

We consider training of staff to be vitally important and as stated above we see FES as a mode of treatment and not simply an electronic device. Therefore we never sell equipment directly to patients, only to clinicians who have completed one of our training courses. To date we have run over 25 such courses the majority in the UK but some recently in other European counties. Over 350 clinicians have been trained.

Results

To date 1104 patients have been seen in the Salisbury FES clinic with a range of disabilities arising from many different pathologies, although difficulty walking due to a CVA form the largest group. The breakdown of patients by their primary pathology is as follows

CVA	559
Multiple Sclerosis	190
Spinal Cord Injury	88
Cerebral Palsy	36
Other *	231

*(inc. Parkinson Disease, Head Injury, Facial Palsy, etc)

The breakdown of patients by the function being enhanced is approximately as follows

Walking	800
Hand Function	300
Paraplegic Standing/exercise	100
Cough	1
Facial Expression	11

N.B. Some patients have treatment to enhance more than one function.

The results obtained with those with facial palsy (7) and with Multiple Sclerosis (8) were presented at last years IFESS meeting and are therefore not included here. In order to look at the long term effect of the clinical service this paper concentrates on the largest single group of patients we have seen, i.e. those using an ODFS following a stroke. Despite having seen 559 patients with a stroke, complete data over 3.5 years is only available on 23 patients. There are a variety of reasons such as missed appointments etc. Also as the

number of patients seen has increased dramatically over the past few years, the majority will not have been using the system for sufficient time. The longest anyone has used a stimulator has been 8 years

Pre use			
Mean PCI	Mean PCI	Mean Speed	Mean Speed
No stim.	Stim	No Stim	Stim
0.86	0.71	0.58ms ⁻¹	0.68ms ⁻¹

After 4.5 months use			
Mean PCI	Mean PCI	Mean Speed	Mean Speed
No stim.	Stim	No Stim	Stim
0.73	0.59	0.67ms ⁻¹	0.74ms ⁻¹

After 3.5 years use			
Mean PCI	Mean PCI	Mean Speed	Mean Speed
No stim.	Stim	No Stim	Stim
0.67	0.61	0.66ms ⁻¹	0.72ms ⁻¹

Analysis by the Wilcoxon Signed ranks test shows that use of the ODFS significant increased speed and reduced PCI, initially, after 4¹/₂ months, and after 3¹/₂ years. Speed and PCI were also significantly improved at 4¹/₂ months compared to the initial readings both with and without stimulation. There was however no significant difference between any of the results at 4¹/₂ months and at 3¹/₂ years. Results are similar for the 40 patients for whom we have complete data over 2.5 years

Discussion

The results obtained with this longer follow up period are similar to those reported previously (2,5), although it is encouraging that the effect seen at 4.5 months does not diminish with time despite the patients ageing.

Despite the vast amount of extra work that the development of a clinical FES service has generated and the considerable frustration with the bureaucracy involved, all agreed that it has definitely been worthwhile. We see approximately 30 people per week which has been beneficial for research as well as the treatment of patients. There are two ways in which such a clinical load benefits research. Firstly we have a very large database to use for analysing efficacy of treatment and selecting subjects for inclusion in clinical trials. Secondly as our clinical reputation increases we receive a greater number of referrals for an ever increasing range of neurological and musculoskeletal conditions. This in turn ensures that we are constantly presented with new avenues of research for which we know that there is a clinical need, rather than just developing new devices which may or may not be clinically relevant.

Establishment of the clinical service and the inevitable battle to secure funding has highlighted that despite

many papers having been published, over 5000 referenced on Medline, very few are suitable to use as evidence that FES has a significant role to play in rehabilitation. It is hoped that this situation will improve over the next few years so that FES becomes an accepted treatment modality and at long last loses its present label, that it is an interesting technique but still in the research stage.

Acknowledgements

We would like to thank the Department of Health and Action Research for funding the development and clinical trial of the ODFS and two channel systems respectively. Finally we would like to thank all the managerial staff of the Hospital, in particular Carol Donaldson, our Departmental Administrator.

References

- 1) Liberson, W.T., et al Functional Electrotherapy: stimulation of the peroneal nerve synchronised with the swing phase of gait in hemiplegic patients Arch. Phys. Med and Rehabil. 42,101, 1961
- 2) BurrIDGE JH, Taylor PN, Hagan,SA, Wood DE, SwainID. The Effect of Common Peroneal Nerve Stimulation on the Effort and Speed of Walking. A Randomised Controlled Trial with Chronic Hemiplegic Patients. Clinical Rehabilitation ;11: 201 - 210, 1997
- 3) Glanz M, Klawannsky S, Stason W et al Functional Electrostimulation in post-stroke rehabilitation – a meta analysis of randomised controlled trials. Arch Phys Med Rehabil, 77: 549-53, 1996.
- 4) Taylor PN, BurrIDGE JH, Wood DE, Norton J, Dunkerly A, Singleton, C., Swain ID Patient Perceptions of the Odstock Drop Foot Stimulator Clin Rehab 1999;13 439-446
- 5) Taylor PN, BurrIDGE JH, Wood DE, Norton J, Dunkerly A, Singleton, C., Swain ID Clinical Use of the Odstock Drop Foot Stimulator - its Effect on the Speed and Effort of Walking. Arch Phys Med Rehabil, 80: 1577-1583, 1999.
- 6) Royal College of Physicians of London. National Clinical Guidelines for Stroke 2000. ISBN 1-86016-120-0
- 7) Mann GE, Swain ID, Cole R. Initial experience in the use of functional electrical stimulation in a variety of neurological conditions resulting in facial palsy. 5th Ann Conf. IFESS, (ISBN 87-90562-01-1), pp. 110-112, Aalborg, Denmark, June 2000.
- 8) Swain ID, BurrIDGE JH, Johnson CA, Mann GE, Taylor PN, Wright PA. The efficacy of functional electrical stimulation in improving walking ability for people with multiple sclerosis. 5th Ann Conf. IFESS, (ISBN 87-90562-01-1), pp. 55-58, Aalborg, Denmark, June 2000.