

# Dropped Foot Stimulator: From the first idea to a patient satisfactory device

Taylor P.N

Department of Clinical Sciences and Engineering, Salisbury District Hospital, Salisbury, UK

[p.taylor@salisburyfes.com](mailto:p.taylor@salisburyfes.com)

## Abstract

*The Odstock Dropped Foot Stimulator (ODFS) came about to address a clinical need: to improve the mobility of patients with stroke, MS and incomplete spinal cord injury. This paper describes the journey from initial prototype through clinical trial, clinical service and commercialisation. Significant factors in this journey are described.*

## Introduction

FES for correction for dropped foot in hemiplegia was first put forward by Liberson et al. in 1960. They demonstrated the provision of dorsiflexion by stimulation of the common peroneal nerve timed to the gait cycle using a switch under the heel. By provision of “function” from controlled electrical stimulation the term Functional Electrical Stimulation was coined and the rest as they say is history. Despite promising clinical results significant clinical use of the techniques was limited to a few specialist centres and barely used at all in the UK.

The Odstock Dropped Foot Stimulator (ODFS) was originally designed as a solution to improve walking for an individual patient who had dropped foot due to incomplete C6 SCI in 1987. We tried a commercial available device but found it did not have sufficient output for this individual. Hence a bespoke device was made. After about two weeks use of the device walking distance was increased from 2 or 3 steps to over 100m with a walking frame. At about the same time a 2 channel version of the device was constructed for another person with incomplete SCI Brown-Séquard syndrome who required knee extension in stance in addition to dorsiflexion in swing. This device enabled short distance ambulation with a walking frame where no walking was possible without FES. Both devices were constructed analogue and discreet logic circuitry and footswitches based on force sensitive resistors.

## Development

The devices were tried with other patients including those with MS and stroke. The clinical engineer worked directly with the patients with the assistance of the physiotherapist allowing direct contact with clinical problems. Hence solutions could be quickly devised, tested and further refined. Through this process the functionality of the device was iteratively improved. A test switch was added to allow easy adjustment of

stimulation level and electrode positions. The original fixed time of stimulation was replaced adaptive timing where the stimulation was ended as well as begun by the foot switch. An “extension” facility was added that prolonged the stimulation past heel strike, providing an eccentric contraction of the anterior tibialis, lowering the foot to the ground. Perhaps most significantly an adaptive threshold for detecting when weight was removed or returned to the foot switch was devised. This enabled stimulator to automatically search for a switching point, correcting for drift in FSR resistance over time and also automatically adjusting to the gait of a heavy adult or small child. This innovation significantly improved the clinical usability and reliability of the devices.

## RCT

In 1993 A randomized controlled trial (RCT) was conducted to evaluate the effect of the Odstock Dropped Foot Stimulator (ODFS) on effort and speed of walking in hemiplegic patients with dropped foot.<sup>1, 2</sup> Thirty- two chronic post-stroke (>6 months) subjects were randomized to either a treatment group receiving stimulation with the ODFS and concurrent physical therapy or a control group receiving physical therapy alone. During the first month of the trial, all subjects received 10 sessions of physical therapy. Each session was approximately one hour. Evaluations of walking speed over a distance of 10 meters were collected at baseline, 4 weeks, and 12 weeks following the initial device set-up. Comparisons were made between mean walking speed at baseline and mean walking speed at the conclusion of the study for each group. At 12-weeks follow-up, a mean increase in walking speed of 20.5% was observed for the treatment group (when the stimulator was in use) and 5.2% in the control group. The Physiological Cost Index (PCI), a measure of walking efficiency, was also evaluated in this study. Improvement was also demonstrated via a reduction in PCI at the conclusion of the study compared to baseline.

The treatment group had a 24.9% reduction of PCI (when the stimulator was in use) whereas the control group had a 1% reduction. During the course of this trial, no significant carryover effect of stimulation with the ODFS device was observed since there were no significant improvements in walking speed in the treatment group without the use of stimulation

### **Clinical Service**

Following the RCT the results were presented to the South and West Regional Health Authority Development and Evaluation Committee, the body that at the time was responsible for giving the go-ahead for new services in the Hospital. Their evaluation included cost benefit QALY (Quality Adjusted Life Years) analysis. The QALY gain was calculated using a combination of data including change in walking speed and physiological cost index, change in Hospital Anxiety and Depression Index (HAD) and change in a mobility score derived from a custom designed questionnaire closely aligned with the Health Related Quality of Life (IHQL). After 12 weeks of intervention it was calculated that the FES group received a QALY gain of 0.065 while the physiotherapy group had a gain of 0.023, a difference of 0.042. At 1996 prices this gave a cost per QALY of £10,037 over 5 years. In 2010 the report was re-examined and costs per QALY calculated for current prices<sup>15</sup>. This gave a cost per QALY of £39,047 at one year and between £13,524 and £19,237 at five years. However, this analysis assumes that a comparison is made with an individual who receives physiotherapy. In clinical practice the ODFS is used as a long term aid while physiotherapy is rarely received for more than a few weeks. It may therefore be fair to attribute the whole of the QALY gain seen by FES users rather than the difference between FES and Physiotherapy interventions. This gives a cost per QALY gain of £25,230 at 1 year and between £8,738 and £12,431 at 5 years.

Following permission, a clinical service was begun in 1996. However, the hospital's rehabilitation department was not in a position to take up the service so instead the service was run by the Medical Physics Department and was provided by the same staff who had worked on the RCT, part time while working on other research. Unusually, this resulted in physiotherapists being directly employed by a clinical engineering department and clinical engineers being involved in service provision. Mixing research and clinical service enabled researches to focus on real clinical issues and for intervention to be taken to the clinic more easily. It was also decided to continue with the same main outcome measures as the RCT, walking speed and PCI (Physiological Cost Index). This enabled audit of the FES service and it was subsequently demonstrated that results were at least as good as the RCT and for the first IFESS 2010

time a training benefit was demonstrated from using FES for the correction of dropped foot.

### **Technology transfer**

A condition for the funding of the RCT was that at the end of the project a two day training course would be given to teach clinicians from other centres the techniques we had learned. This implies that the clinicians who were trained would have access to the ODFS for their own patients hence the department extended its small scale production of devices. In fact a decision was made that devices would only be supplied to clinicians who had been trained in the use of FES. This was to ensure that clinical results obtained would remain at a high standard, protecting the reputation of the technique and the equipment. In 1998 CE marking for medical devices became compulsory in the UK. If we were to continue to supply these other clinics we either had to find a commercial partner to take over production and produce the devices under an approved quality system or become able to CE mark devices ourselves. As the market was small no commercial organisation was interested in what was seen as risky new technology, our best option was to establish our own quality system and become registered with the Medical Devices Agency as a manufacturer of medical devices. (In 2005 FDA approval for the USA was obtained through the 510k procedure.) As demand grew, production was subcontracted to local manufacturers but control of quality and distribution remained with the department.

Through word of mouth a demand for further courses was developed, resulting in a continuous series of courses, approximately 200 being run by 2010. To support the clinicians using the devices, detailed device documentation describing the clinical application was developed. This was further supported by a web page ([www.salisburyfes](http://www.salisburyfes)), FES Newsletter and clinical meetings. The intention was to create a community of FES clinicians who could support each other through sharing best practice.

In 2006 the Hospital created a spin out company Odstock Medical Limited (OML) to handle device production and sales and also clinical FES service provision. OML was England's first NHS (National Health Service) owned company. This enabled greater commercial freedom to operate and for the first time advertising. Up to that point promotion had been though educational activity only. However, the FES courses remain to this day the main promotional tool and training is still compulsory. Refinement of the ODFS and associated devices continued through this period and in 2009 the latest version, the ODFS Pace was released, bringing together the experience of the

previous years into a smaller digital unit. The ODFS Pace is designed as a holistic clinical tool both for orthotic dropped foot correction and gait training in physiotherapy where other muscles such as gluteal, quadriceps, calf or hamstring muscles can be stimulated in active gait training or in cyclic exercise.

In 2009 the National Institute for health and Clinical Excellence (NICE) produced guidance recommending the use of FES for dropped foot within the NHS. While this does not make it obligatory that the NHS funds FES, it does make it a recognized intervention for routine use. In 2010 further analysis of the cost effectiveness of FES was produced indicating an almost identical QALY gain as calculated 14 years previously. Evidence for reduction of falls following FES use, improvement in quality of life and efficacy in MS were also published in 2010.

### Conclusion

The main drivers in the development of the ODFS have been the need to respond to clinical need and clinical demand, providing solutions at costs sustainable within the NHS. In many ways, through necessity it has been a “cottage industry” approach to technology transfer and commercialisation. However this has enabled establishment of a new clinical technique within the UK’s NHS system and enable many thousands of patients to benefit from FES.

### Acknowledgments

The ODFS was developed under funding from the Department of Health who also funded the first RCT. The RCT in MS was funded by the MS Trust.

### References

1. Liberson, WT; Holmquest, HJ; Scot, D; et al (1961) Functional electrotherapy: Stimulation of the peroneal nerve synchronized with the swing phase of gait of hemiplegic patients. *Archives of Physical Medicine and Rehabilitation*, 42:101-105.
2. Taylor PN and Swain ID. Odstock Dropped Foot Stimulator system and peripheries. Patents applied for: UK, 0014968.2, 0021215.9 and 0021223.5; USA 09/652081; and Canada 2.317232, 2001.
3. Burridge JH, Taylor PN, Hagan SA, Wood DE, Swain ID. The effect of common peroneal nerve stimulation on quadriceps spasticity in hemiplegia. *Physiotherapy*, 83(2): 82-89, 1997
4. Burridge J, Taylor P, Hagan S, Wood D, Swain I. (1997) The effects of common peroneal nerve stimulation on the effort and speed of walking: A IFESS 2010

randomised controlled clinical trial with chronic hemiplegic patients. *Clin Rehabil* 11. 201-210.

5. Swain ID, Taylor PN, Burridge JH, Hagan SA, Wood DE. Report to the development evaluation committee Common peroneal stimulation for the correction of drop-foot (1996) <http://www.salisburyfes.com/dec.htm>

6. Taylor PN, Burridge JH, Wood DE, Norton J, Dunkerley A, Singleton C, Swain ID. Clinical use of the Odstock Drop Foot Stimulator - its effect on the speed and effort of walking. *Archives of Physical Medicine and Rehabilitation*, 80: 1577-1583, 1999.

7. Swain ID, Taylor PN. The clinical use of functional electrical stimulation in neurological rehabilitation. *In: Horizons in Medicine 16 – Updates on major clinical advances*. Ed. Franklyn J. Pub. Royal College of Physicians, ISBN 1-86016-233-9, London, pp. 3 15-322, 2004.

8. National Institute for Health Clinical Excellence (NICE). Functional Electrical Stimulation for drop foot of central neurological origin N1733 1P ISBN 84629-846-6 Jan 09 & Treating drop foot using electrical stimulation N1734 1P ISBN 1-84629-847-4 Jan 09 <http://www.nice.org.uk/Guidance/IPG278>

9. Economic Report. Functional Electrical Stimulation for dropped foot of central neurological origin. CEP10012. Published by the NHS Purchasing and Supply Agency Feb 2010 [www.dh.gov.uk/cep](http://www.dh.gov.uk/cep)

10. JE Esnouf, PN Taylor, GE Mann, CL Barrett. Impact on falls and activities of daily living of use of a Functional Electrical Stimulation (FES) device for correction dropped foot in people with multiple sclerosis. *Mult Scler* accepted for publication 10<sup>th</sup> feb 2010

11. Barrett CL, Taylor PN. The effects of the Odstock Drop Foot Stimulator on Perceived Quality of Life for People with Stroke and Multiple Sclerosis. *Neuromodulation* 2010 13, 1, pp: 58-64

12. CL Barrett, GE Mann, PN Taylor and P Strike. A randomized trial to investigate the effects of functional electrical stimulation and therapeutic exercise on walking performance for people with multiple sclerosis. *Mult Scler*. 2009 Apr;15(4):493-504