Institution: Bournemouth University

Unit of Assessment: 12

Title of case study: How our electrical stimulation devices have improved long-term medical conditions

Period when the underpinning research was undertaken: 2013-2020

Details of staff conducting the underpinning research from the submitting unit:

Name(s):	Role(s) (e.g. job title):	Period(s) employed by submitting HEI:
Professor Ian Swain	Professor in Clinical Engineering	1992-current
Dr Jon Cobb	Principal Academic	2008-current
Tom Wainwright	Associate Professor of Orthopaedics	2015-current
Professor Robert Middleton	Professor, Director of Orthopaedic Research Institute	2015-current
Professor Paul Taylor	Visiting Professor	2017-current
Choukri Mecheraoui	Visiting Fellow	2017-current

Period when the claimed impact occurred: August 2013-31 December 2020

Is this case study continued from a case study submitted in 2014? N

1. Summary of the impact (indicative maximum 100 words)

Bournemouth University (BU) has worked with the Salisbury NHS Foundation Trust and Odstock Medical Limited in electrical stimulation for many years, developing new devices and pioneering treatment methods. Since 2013, the devices have been used to help more than 10,000 people nationwide to improve their walking. Over 25,000 devices have been sold and sales of a new wireless system (Pace XL), developed by BU, have generated more than GBP1,000,000 in sales. A new orthopaedic stimulator is now commercially available.

The new devices and treatments have been used to help people with a range of conditions, including Bell's Palsy, Parkinson's Disease, orthopaedic problems, people with multiple sclerosis and those recovering from strokes.

2. Underpinning research (indicative maximum 500 words)

Electrical stimulation (ES) is a method of externally controlling muscles following either neurological problems, where signals from the brain are interrupted due to neurological disease or accident (stroke etc), or in musculoskeletal problems due to muscle weakness or imbalance. When ES is used to provide a specific function, such as walking or hand grasp, it is known as functional electrical stimulation (FES).

The clinical service in Salisbury started after Professor Swain undertook the world's first randomised controlled clinical trial of an FES orthosis in people who had a dropped foot as a result of a stroke. Results showed that it had significant advantages over traditional physiotherapy, as people receive therapy while they are walking, in addition to its orthotic effect, hence improving walking ability and quality of life [R1].

BU took the lead in patenting the original Odstock Dropped Foot Stimulator (ODFS) in 2001, later known as the ODFS Pace, and in the early work of establishing the first NHS company in

England, Odstock Medical Limited (OML), in 2006. Since then, Swain has led a collaboration between BU, Salisbury NHS Foundation Trust (SFT) and OML, with the clinical service expanding to include the treatment of people with multiple sclerosis (MS), spinal cord injury and Parkinson's disease as well as stroke. This is an ideal working relationship, with BU providing the academic infrastructure, SFT providing clinical supervision, and OML providing commercial expertise and promoting FES techniques and equipment, running training courses and developing marketing materials.

The group (BU, SFT, OML) achieved a number of world and European firsts, working with other universities such as Surrey, Southampton, Salford and UCL; these included the first implanted dropped foot stimulator clinical service in the world in 2006 and, through the development of the National Clinical FES Centre in Salisbury, also in 2006, the largest clinical service in the world based on the results of clinical trials.

Clinical trials undertaken at SFT, supervised by Swain and Taylor, have shown that, in people who have had a stroke, FES is well accepted and 43% of participants improved their speed [R2]. In people with MS, there was also a highly significant improvement in walking speed and a training affect in those people who were less impaired [R3].

Swain recently held a GBP117,576 National Institute for Health Research Programme Grant, which looked at the use of technology (including FES) in improving upper limb function post-stroke. This enabled the development of an upper limb service [R4] as this research showed that FES was the assistive technology treatment with most evidence of clinical efficacy. Two further grants from spinal cord injury charity The Inspire Foundation, worth a total of GBP183,440, demonstrated that it is possible to use surface electrodes to restore useful hand function to people with tetraplegia [R5].

Research on a wireless system by BU led directly to the development of OML's wireless ODFS Pace XL system shown in Figure 1 [R6].

Figure 1: OML Pace XL stimulator with wireless footswitch (courtesy of OML).

Swain's move to the Orthopaedic Research Institute (ORI) at BU to work with Wainwright and Middleton has enabled techniques developed for people with neurological problems to be applied to those with orthopaedic problems [R7]. Combining this expertise has led to the development of new stimulators and training courses.

3. References to the research (indicative maximum of six references)
R1-R7 were all subject to rigorous peer review.

R1: Taylor, P. N., Humphreys, L. and Swain, I. (2013), "The long-term effectiveness of the use of Functional Electrical Stimulation for the correction of dropped foot due to upper motor neuron lesion," *J Rehabil Med*; 45: pp. 154–160. DOI: 10.2340/16501977-1090

R2: Street, T., Swain, I. and Taylor, P. (2017), "Training and orthotic effects related to functional electrical stimulation of the peroneal nerve in stroke," *J Rehabil Med*; 49(2): pp. 113-119. DOI: 10.2340/16501977-2181

R3: Street, T., Taylor, P. and Swain, I. (2015), "Effectiveness of Functional Electrical Stimulation on Walking Speed, Functional Walking Category, and Clinically Meaningful Changes for People

with Multiple Sclerosis," *Arch Phys Med Rehabil*; 96(4): pp. 667-672. DOI: 10.1016/j.apmr.2014.11.017

R4: Farmer, S. E, Durairaj, V., Swain, I. and Pandyan, A.D. (2014), "Assistive technologies: can they contribute to rehabilitation of the upper limb after stroke?", *Arch Phys Med Rehabil*.; 95(5): pp. 968-85. DOI: 10.1016/j.apmr.2013.12.020

R5: Venugopalan, L., Taylor, P. N., Cobb, J. E., and Swain, I. (2020), "TetraGrip - a four channel upper limb FES device for people with C5/C6 tetraplegia: device design and clinical outcome," *J Med Eng Technol;* 44(1) pp. 38-44. DOI: 10.1080/03091902.2020.1713239

R6: Mecheraoui, C., Swain, I. and Cobb, J. (2013) "A distributed three-channel wireless Functional Electrical Stimulation system for automated triggering of stimulation to enable coordinated task execution by patients with neurological disease," *Biomedical Signal Processing and Control*, vol. 8 (2), pp. 176-183. DOI: 10.1016/j.bspc.2012.08.006

R7: Burgess, L. C., Swain, I., Taylor, P. and Wainwright, T. W. (2019), "Strengthening Quadriceps Muscles with Neuromuscular Electrical Stimulation Following Total Hip Replacement: a Review," *Current Physical Medicine and Rehabilitation Reports,*7, pp. 275-283. DOI: 10.1007/s40141-019-00225-8

4. Details of the impact (indicative maximum 750 words)

Health benefits

The findings from the BU, OML, SFT partnership have helped to develop the National Clinical FES Centre in Salisbury, the largest clinical service in the world. As of February 2020, 7,790 people have been treated in Salisbury (excluding those on clinical trials) and a wide range of clinical services has been provided.

In addition to those with walking problems, the following numbers of patients have been treated since 2014; 148 upper limb, 16 facial problems such as Bell's Palsy and 8 for constipation. It has been established that our ES systems have radically changed people's lives, increasing people's functional ability and improving their quality of life, and hence participation in society [E1, E2, E3]:

> 'The ODFS Pace has given me my life back and I can't imagine life without it. I am now able to do things around the house like cooking and cleaning. It also stops me relying on people all the time.'
>
> 'One day I was in a wheelchair, the next day I was walking. FES has changed my life.'
>
> 'I have been using a single channel stimulator for foot drop, due to MS, for five years. I wear it every day and it has allowed me to carry on working full-time. It is the single most helpful thing in this journey as a patient, and has allowed me to remain as active as possible. I can't praise the Odstock Medical staff enough!'
>
> 'Benefits are that it is strengthening his legs, his movement, more so when he is running, you can see that he's lifting his leg more. He's definitely participating more in school, getting involved with football.' [E4a, E4b]

Over the past six years, other FES centres have been established in the UK, using our equipment, with the West Midlands Rehabilitation Centre having seen more than 1,400 patients, the National Hospital for Neurology and Neurosurgery in London, more than 700, and Sheffield's Northern General Hospital more than 500 [E5].

BU research has shown that, in people with stroke, there is both a clinically significant orthotic effect in the walking speed, with 43% of participants improving their speed, and a training effect (improvement when stimulation removed) in the least disabled [R2]. In people with MS, due to

the nature of the disease, there was no significant training effect, but people did have a 27% increase in walking speed, with 95% maintaining or improving their functional walking category (FWC) [R3]. Effort and fear of falling were reduced and people more able to achieve their goals. Actual falls were shown to be reduced by 72% and 73% in two trials [E6].

Policy impacts

FES obtained NICE approval in 2009 and, in 2016, a further NICE device specific publication, Medical Innovation Bulletin, MIB56, focused on the PACE system [E7]. Swain was also a professional expert on the development of new NICE guidelines (IPG 677) published in August 2020 on the use of electrical stimulation in non-neurological long-term conditions [E8].

The Royal College of Physicians has positively commented on FES in its 2016 Stroke Guidelines: 'People with stroke who have reduced ability to dorsiflex the foot ("foot-drop") should be offered functional electrical stimulation to improve their gait.'

The Department of Health requested the establishment of training courses for professionals to spread the use of the techniques and FES technology worldwide. Since 2014, OML has trained more than 600 staff in the UK and abroad in how to implement the devices and treatments developed with BU for people with lower limb restrictions and more than 400 staff in upper limb courses [E5].

Economic benefits

In order to compare the efficacy of FES to other medical treatments, QALY (quality adjusted life years) analysis was undertaken, initially by the NHS Purchasing and Supplies Agency. This showed that the cost of FES per QALY was calculated at GBP9,658, compared to a hip replacement, GBP5,623 and hip resurfacing GBP12,370. A figure of GBP20,000 per QALY (keeping a person in a good state of health for one year) is the usual criteria for NHS funding.

Using data obtained since 2014, this has been recalculated at GBP4,086 per QALY when the reduction in falls in MS patients is taken into account. In a recent independent paper from the National Hospital for Neurology and Neurosurgery, which exclusively used equipment developed by our group, a cost per QALY of GBP6,137 was calculated [E10]. The mean length of usage of the system is 6.2 years, although many people use it far longer, with more than 25% of people using it for more than 11 years.

OML's remit is to develop and sell FES/ES products, train staff and provide patient treatment, both to the NHS and privately, utilising technology developed at BU. In total, more than 25,000 stimulators have been sold in 13 overseas countries [E5], including developing countries such as India, with the US, Denmark and Germany being the biggest markets. The number of full-time staff employed by OML has increased since 2013 (see table below) [E5]:

Period	Up to 2013	Up to 2020
Staff employed	**16.4**	**25**
Patients treated	**4,996**	**7,790**
People trained	**2,565**	**3,620**
Countries where FES is distributed	**20**	**20**

FES sales have increased in value from GBP1,507,975 in 2012/13 to GBP2,122,360 in 2016/7 [E5]. Since 2016, OML has sold more than GBP3,000,000 of FES equipment, including 3,300 wireless systems worth more than GBP1,000,000 [E5]. A new orthopaedic stimulator, Orthopaedic Microstim, designed by ORI and marketed by OML, is also commercially available [E5]. It is suitable for the entire patient journey through joint replacement surgery: from pre-conditioning, to reduction of oedema and pain immediately after surgery, to building up muscle strength once the patient has been discharged.

5. Sources to corroborate the impact (indicative maximum of 10 references)

E1: MS Trust. (2020). *Functional electrical stimulation (FES)*. [online] Available at: https://www.mstrust.org.uk/a-z/functional-electrical-stimulation-fes [Accessed 19 February 2021].

E2: Different Strokes. (2020). *Drop Foot & FES* [PDF]. Available at: https://differentstrokes.co.uk/wp-content/uploads/2020/02/Drop-foot-and-FES.pdf [Accessed 19 February 2021].

E3: INSPIRE Foundation. (2018). *2. TETRAGRIP II - INSPIRE Foundation*. [online] Available at: https://www.inspire-foundation.org.uk/1-development-of-a-functional-electrical-stimulation-fes-device-for-promotion-of-hand-function-in-incomplete-tetraplegia-tetra-grip/ [Accessed 22 February 2021].

E4:
E4a: Sample of testimonials from patients of OML.
E4b: Odstockmedical.com. (n.d.). *Home | Odstock Medical Ltd (OML)*. [online] Available at: https://www.odstockmedical.com/testimonials [Accessed 19 February 2021].

E5: Odstock Medical Limited. (2021). Testimonial letter to Ian Swain, 17 February.

E6: Odstockmedical.com. (n.d.). *Clinical Evidence | Odstock Medical Ltd (OML)*. [online] Available at: https://odstockmedical.com/clinical-evidence [Accessed 19 February 2021].

E7: NICE. (2016). ODFS Pace and Pace XL functional electrical stimulation devices for treating drop foot (Medtech innovation briefing [MIB56]). Newcastle and York External Assessment Centre: NICE.

E8: NICE. (2020). Electrical stimulation to improve muscle strength in chronic respiratory conditions, chronic heart failure and chronic kidney disease (Interventional procedures guidance [IPG677]). NICE.

E9: Intercollegiate Stroke Working Party, (2016). *National clinical guideline for stroke*. Royal College of Physicians, pp. 75-76.

E10: Juckes, F. M., Marceniuk, G., Seary, C. and Stevenson, V. L. (2019). "A cohort study of functional electrical stimulation in people with multiple sclerosis demonstrating improvements in quality of life and cost-effectiveness," *Clinical Rehabilitation,* Vol 33(7) pp. 1163-1170. DOI: 10.1177%2F0269215519837326