**Institution:** University of Southampton

**Unit of Assessment:** 03 Allied health professions, dentistry, nursing and midwifery, and pharmacy

**Title of case study:** 03-07 Innovative Technologies for Stroke Rehabilitation

## 1. Summary of the impact

Treating stroke consumes 5% of the NHS budget. Government objectives for improving stroke rehabilitation have driven our important advances in aiding recovery of movement and independence. We have developed and evaluated innovative technologies and directly ensured translation into clinical practice and home use. Over 2,500 therapists have received training in functional electrical stimulation (FES) in the UK and abroad. Our research into FES and upper-limb robot therapy has attracted great media attention, as well as international clinical and commercial success. FES is now incorporated into National Institute of Health and Care Excellence (NICE) and Royal College of Physicians (RCP) Stroke Guidelines. We have demonstrated successful adoption of technologies in practice (the main UK commercial provider reports 16,000 sales of FES devices), and we have published evidence for their continued use.

## 2. Underpinning research

From 1993 researchers in the Faculty of Health Sciences at the University of Southampton, led by Professor of Restorative Neuroscience Jane Burridge, have investigated how innovative technologies could provide more effective rehabilitation and reduce the NHS burden of stroke on patients, families and society.

The use of Functional Electrical Stimulation (FES) has been central to the team's research. Between 1993 and 1997 Burridge et al conducted the first randomized controlled trial of an FES common peroneal stimulator (ODFS) [3.1], [Grant A], demonstrating statistical and clinical improvement in walking. This, together with further evidence published by us and other international teams, demonstrated patient-reported benefit and excellent compliance [3.2].

Burridge's work on surface FES demonstrated that critical factors in patients discontinuing to use the ODFS were: positioning electrodes, skin irritation, discomfort, inconvenience and poor cosmetic appearance. All these problems had the potential to be overcome by an implanted device. This led in 2007 to Burridge's collaboration with Aalborg University in Denmark to develop and clinically evaluate the 'ActiGait', an implanted, single-cuff, four-channel stimulator which enabled selective activation of muscles controlling ankle dorsiflexion to produce a more natural gait pattern. Research was funded by Danish venture capital company Neurodan A/S and has been published in two key papers [3.3, 3.4] presenting clinical effectiveness and positive users' views.

In 2003 the Southampton team secured £350k funding from the US-based Alfred Mann Foundation (AMF) for a four-year project in which micro-stimulators were implanted into the arms of post-stroke patients [Grant B]. This was the first clinical trial of the devices in stroke patients and the results showed significant improvement in upper limb function and reduction of impairment [3.5]. Also with AMF funding, beginning in 2003, the team developed and validated an instrumented rig allowing precise measurement and modeling of wrist movement. Data from the rig enabled us to understand more about the mechanisms of recovery, critical to advancing both research and clinical applications. Our findings (published between 2008 and 2013) showed improved motor control, reduction of spasticity, increased strength and range of movement and how these related to function. Four wrist rigs have since been built and are being used in clinical settings.

In 2006 the team led by Burridge, comprising Hughes (originally appointed as Research Fellow and now leading the clinical work) and Freeman and Rogers in the University's Faculty of Physical and Applied Sciences, began a series of studies, funded by the EPSRC into combining FES with upper limb robot therapy, using Iterative Learning Control (ILC) [Grant C]. ILC had previously only been used in industrial robotic applications. It was the first time FES output had been controlled in response to performance and this work has demonstrated both feasibility of the concept and effective recovery of motor control and function in small samples of stroke patients [3.6]. Building on Southampton's work, research groups worldwide are now applying ILC algorithms to controlling FES output as evidenced by >220 citations of our publications since 2009. Current EPSRC funding [Grant D] has enabled the work to progress to control of wrist and hand movement, reduced the

need for an expensive robot and moved the development towards a low-cost home-based system.

In 2009 the team were partners in a £1.9 million grant from the National Institute for Health Research (NIHR) to research how rehabilitation technologies could translate into clinical practice [Grant E]. Southampton's contribution applied qualitative and quantitative methodologies to examine the barriers and opportunities for the use of technology in upper limb stroke rehabilitation.

Our research has also practically addressed the need to provide home-based rehabilitation for stroke patients through a NIHR Research for Patient Benefit project [Grant F]. A website, currently undergoing clinical trial, is designed to support and motivate patients undergoing upper limb rehabilitation using constraint-induced movement therapy at home.

## 3. References to the research

### Publications


*3.1* Burridge JH, Taylor PN, Hagan SA, Wood DE, Swain ID. (1997) The effect of common peroneal stimulation on the effort and speed of walking. A randomised controlled trial of chronic hemiplegic patients. *Clinical Rehabilitation*,11.3: 201-210. http://cre.sagepub.com/content/11/3/201.long

3.2 Taylor PN, Burridge JH, Dunkerley AL, Wood DE, Norton JA, Singleton C, Swain ID. (1999) Patients' perceptions of the Odstock Dropped Foot Stimulator (ODFS). *Clinical Rehabilitation*, 13: 439-446. http://cre.sagepub.com/content/13/5/439.long

3.3 Burridge JH, Haugland M, Larsen B, Pickering RM, Svaneborg N, Iversen H, Brøgger Christensen P, Haase J, Brennum J and Sinkjaer T (2007). A phase II trial to evaluate the ActiGait implanted drop-foot stimulator in established hemiplegia. *Journal of Rehabilitation Medicine,* 39(3): 212-8.

http://www.medicaljournals.se/jrm/content/?doi=10.2340/16501977-0039&html=1

3.4 Burridge JH, Haugland M, Larsen B, Svaneborg N, Iversen HK, Brøgger Christensen P, Pickering RM, Sinkjaer T. (2008) Patients' perceptions of the benefits and problems of using the ActiGait implanted drop-foot stimulator. *J Rehabil Med*, 40: 873–875. http://www.medicaljournals.se/jrm/content/?doi=10.2340/16501977-0268&html=1

3.5 Turk R, Burridge JH, Davis R, Cosendai G, Sparrow OCE, Hughes AM, Roberts HC. (2008) Therapeutic effectiveness of electrical stimulation of the upper limb post-stroke using implanted microstimulators. *Arch Phys Med Rehabil* 89 (10): 1913-1922. http://www.sciencedirect.com/science/article/pii/S0003999308004334

3.6 Hughes AM, Freeman C, Burridge J, Chappell P, Lewin P, Rogers E. (2009) Feasibility of Iterative Learning Control mediated by Functional Electrical Stimulation for reaching after stroke. *Journal of Neurorehabilitation and Neural Repair*, 23 (6): 559-568. http://www.ncbi.nlm.nih.gov/pubmed/19190087


### Grants


A. Swain. (Burridge employed as RF). Evaluation of Functional Electrical Stimulation systems for spinal cord injured and CVA patients. Department of Health: 1992-95. (£160,000)

B. Burridge (Turk employed as RF). A preliminary clinical study of facilitating upper limb function in hemiplegia using BION implanted electrodes: The Alfred Mann Foundation (US): 2003-07 (£347,436)

C. Burridge. Iterative Learning Control for re-education of upper limb function mediated by electrical stimulation EPSRC: EP/C51873X/1: 2006-09 (£350k)

D. Freeman, Burridge and Hughes. Restoration of Reach and Grasp in Stroke Patients using Electrical Stimulation and Haptic Feedback: EPSRC EP/I01909X/1: 2011-14 (£464,231)

E. Swain, Burridge et al (Demain and Hughes employed as RFs) Development of an integrated service model incorporating innovative technology for the rehabilitation of the upper limb following stroke NIHR Programme Grant: RP-PG-0707-10012: 2009-14: (£1.9M)

F. Burridge, Yardley, Hughes et al. Development and pilot evaluation of a web-supported programme of Constraint Induced Therapy following stroke (LifeCIT) PB-PG-0909-20145: 2011–2014: NIHR RfPB. (£249,634).

## 4. Details of the impact

Every year about 150,000 people in the UK have a stroke and approximately one-third require rehabilitation to help them to recover movement and independence. Treatment of stroke consumes 5% of the NHS budget. More people are now surviving and living longer following stroke, putting increasing strain on NHS resources. Traditional, one-to-one rehabilitation is expensive; there is therefore great practitioner and government interest in finding more effective and less labour-intensive therapies. Our research has developed significant new approaches to stroke rehabilitation that increase its effectiveness and reduce the need for practitioner-led therapy. These approaches are now used internationally and have been adopted as part of the training for rehabilitation practitioners. The technologies have been commercialised generating sales world-wide.

### Impact on health

Our research has been highly influential in making Functional Electrical Stimulation (FES) developed by Burridge et al available and routinely practised in over 70 countries. The National Institute of Health and Care Excellence (NICE) approved the use of FES for drop-foot of neurological origin in 2010 [5.1], citing evidence from our clinical trial and subsequent research. The Royal College of Physicians' (RCP) guidelines (September 2012) for stroke [5.2] recommends its clinical use, as does the International Review of Evidenced-Based Research in Stroke Rehabilitation (EBRSR), a trusted resource for clinicians internationally [5.3], which concludes: 'There is strong (Level 1a) evidence that FES treatment improves upper extremity function in acute stroke'. In 2006 Burridge was named Alfred Mann Foundation Scientist of the Year for her research into FES for upper-limb function [5.4].

Our research into robot therapy combined with FES [5.5, 5.6], a new therapy that enables supported repetitive motor practice without one-to-one therapist input, has benefited from collaboration with world-leading rehabilitation robotics company, Hocoma [5.7], where Burridge is a member of the Scientific Advisory Board. Both Hughes and Burridge are partners in the EU-funded COST Action on Robotics for Neurorehabilitation, and Southampton hosted the first annual two-day COST conference, attracting over 150 delegates and seven commercial sponsors. These research and dissemination activities have been highly influential in advancing the field and translating useful technologies into clinical practice for improved provision of neurological rehabilitation.

Other outputs of the team's research into ways to facilitate the adoption of new technologies, driven by the findings of our NIHR Research Programme research [5.8], include the LifeCIT Online web resource [5.9]. The site, which went live in 2012, supports and motivates patients undergoing upper-limb rehabilitation at home and provides a telemedicine link to family, friends and clinicians.

### Impact on commerce and the economy

FES devices have been successfully commercialized. The largest UK manufacturer, Odstock Medical Limited (OML) [5.10] reports over 16,000 sales. In the US the stimulator is sold by Bioness [5.11] - a spin-off from the Alfred Mann Foundation (AMF) - where Burridge has acted as scientific advisor. They report 85,000 patients on their database using their devices. Our published work on patient usability problems with stimulators that used surface electrodes and wired sensors led to Burridge's collaboration with Aalborg University in Denmark and the development of an implanted stimulator [5.12], the ActiGait, which is now marketed by the world's largest manufacturer and distributor of orthotic and prosthetic devices, Otto Bock Healthcare [5.13]. The device is now CE marked and beginning to be used clinically across Europe.

Our research team has been instrumental in setting up the International Industry Society in Advanced Rehabilitation Technology (IISART) group of manufacturers, influencing the design, commercialization and clinical adoption of rehabilitation robotics. Hughes is a steering committee member and Burridge is the IFESS representative on the Board of Directors.

### Impact on practitioner education

*FES Education:* Publication of the clinical trial results led to demand for training courses in FES. Burridge led the design and provision of training courses and set-up over 12 satellite clinics in NHS hospitals. Over 2,522 therapists in 14 countries have now been trained in using FES (e.g. Burridge

has run courses in Saudi Arabia and The Netherlands) and it is included in UK and international undergraduate and postgraduate physiotherapy and Medical Physics and Biomedical engineering programmes. The International Functional Electrical Stimulation Society (IFESS), of which Burridge is currently President [5.14], and the IFESS UK and Republic of Ireland Chapter, which Burridge launched in 2008, host workshops to train therapists and other clinical and non-clinical rehabilitation specialists in FES during their annual Conferences.

*International post graduate multidisciplinary education:* In 2012 Southampton's reputation for rehabilitation technology research, commercialization and translation into clinical practice enabled the team to secure funding of €518k through the EU Erasmus Lifelong Learning Programme to develop a European MSc Programme in Advanced Rehabilitation Technologies (ART) [5.16]. The collaborative programme, led by the Southampton team, involves 11 universities in eight EU countries and is pivotal to advancement of the field. The MSc ART is multi-disciplinary, providing appropriate courses for clinicians, engineers, commercial developers and scientists and will utilise innovative on-line learning technologies. Critically, it will provide a shared learning environment for students from academic, clinical and industrial backgrounds to significantly advance the clinical use, research and commercialisation of rehabilitation technologies.

**5. Sources to corroborate the impact**


5.1 NICE approval in 2010 http://www.nice.org.uk/guidance/IPG278.

5.2 Recommendations for clinical use: the RCP Guidelines for stroke http://bookshop.rcplondon.ac.uk/)

5.3 Evidenced-Based Research in Stroke Rehabilitation (EBRSR) v14 (www.ebrsr.com/)

5.4 Media coverage of Burridge's work with the AMF and Bion micro-stimulators http://www.guardian.co.uk/science/2003/oct/14/sciencenews.health

5.5 http://www.fastuk.org/research/projview.php?id=1472

5.6 EU COST ACTION on Rehabilitation Robotics http://www.cost.eu/domains_actions/bmbs/Actions/TD1006

5.7 Scientific BoD of Hocoma http://www.hocoma.com/about-us/company/people/scientific-advisory-board/

5.8 https://portal.nihr.ac.uk/sites/nihr-ccf/ATRAS/Pages/Description.aspx

5.9 Link to a web-based intervention that enables stroke patients to undergo stroke rehabilitation at home and provides a telemedicine link to family/friends and clinicians. To enter the website, users need to register with a username comprising two letters and two numbers and a password of their choice: www.lifeguideonline.org/player/play/LifeCIT_demo

5.10 Commercialization for example: www.odstockmedical.com (OML) in the UK

5.11 www.bioness.com

5.12 http://www.patentmaps.com/inventor/Jane_Burridge_1.html

5.13 Otto Bock A/S of the ActiGait implanted stimulator http://www.ottobock.nl/cps/rde/xbcr/ob_nl_nl/im_646a225_gb_actigait_productinformatie_Engels.pdf

5.14 The International Functional Electrical Stimulation Society: www.ifess.org

5.15 Link to University of Southampton MSc ART website http://www.rehabtech.soton.ac.uk/