Institution: University of Glasgow
Unit of Assessment: B15: General Engineering
Title of case study: **Rehabilitation engineering innovations improve quality of life for patients with spinal cord injuries**

1. Summary of the impact

The University of Glasgow's Centre for Rehabilitation Engineering (CRE) has developed strategies and products that have influenced clinical practice in Spinal Cord Injury (SCI) worldwide. The CRE refined the concept of using Functional Electrical Stimulation (FES) for cycling and abdominal stimulation and defined its benefits to patients by establishing the nature of the medical benefits of the technology.

Working with clinical partners in the Southern General Hospital and Hasomed GmbH, the CRE co-developed FES products that are now used routinely in clinical rehabilitation. Hasomed sell ~500 units p.a. across the world, for use at home, in fitness centres and in SCI clinics to maintain health and wellbeing, thereby reducing patient morbidity and increasing their life expectancy.

Neuro-feedback, utilising a Brain Computer Interface for the treatment of pain associated with SCI, has also been developed into a clinical reality and a limited clinical trial has now shown its efficacy.

2. Underpinning research

The consequences of Spinal Cord Injury (SCI) include paralysis and loss of sensation in the legs, arms and torso with disruption of bladder, bowel and sexual function. It can also affect the autonomic nervous system, altering the regulation of blood pressure, heart rate, and breathing. Complications include a high incidence of pressure sores, loss of muscle mass and bone demineralisation. These effects can be mitigated by Functional Electrical Stimulation (FES) induced exercise in SCI patients.

Over the last 15 years research from the Centre for Rehabilitation Engineering (CRE) in the School of Engineering has resulted in innovations to target both primary and secondary complications of neurological impairment, with a focus on clinical applications in SCI. This research has been implemented in close collaboration with Mr David Allan, Director at the Queen Elizabeth National Spinal Injury Unit (QENSIU) at the Southern General Hospital, Glasgow, as the principal clinical partner. QENSIU is the only spinal injury unit in Scotland and one of only 11 in the UK. The CRE's embedded research facility at QENSIU is unique in the UK.

In the last fifty years morbidity and mortality following SCI has fallen dramatically except in instances where there are complications associated with cardio-respiratory problems and with depression. Both cardio-respiratory fitness and a feeling of wellbeing can be promoted by FES exercise – which, as a consequence of CRE's pioneering research, is most often achieved by FES cycling. In addition to the more immediate benefits from improved fitness, other benefits include improved pain relief, decreased spasticity and enhanced body image. Importantly, research in the CRE not only established these medical benefits of FES cycling but also improved the control strategies behind the technology, applying it to different areas such as abdominal stimulation to further assist pulmonary function.

The CRE has addressed a second research theme, to overcome the problems associated with the 40% of SCI patients who experience Central Neuropathic Pain (CNP). Here, the impact of the research has been focused on developing techniques in neuro-feedback using Brain Computer Interfaces to alleviate CNP.

Functional Electrical Stimulation for cycling and abdominal stimulation: From 1998 to 2009, the FES research theme was led by Professor Ken Hunt (Professor 1998-2009) with Dr. Henrik Gollee (Research Assistant 1998-2001, Marie-Curie Research Fellow 2001-03, Lecturer 2003-12, Senior Lecturer, 2012- present). A major focus of this work was the FES of paralysed muscles to stimulate exercise and promote cardiovascular fitness [1]. A recumbent tricycle with an auxiliary

electric motor was developed for paraplegic users. Through a series of EPSRC grants (GR/M94717, GR/T24951, GR/M47256, GR/R35759), Hunt and Gollee developed a novel electrical stimulation control system and the necessary mechanical modifications to adapt the tricycle for paraplegic patients. A full prototype was developed as a research system at the University of Glasgow.

From 2003-2006 (EPSRC GR/R92462), Hunt and Gollee collaborated in a unique multi-centre study with Professor Nick Donaldson, University College London (UCL), and Dr Tanya Kakebeeke and Dr Claudio Perrett at the Swiss Paraplegic Centre, Nottwil (SPC). This study focussed on prolonged and intense FES cycle training in subjects with SCI [2,3,4] and showed that regular FES cycle exercise leads to major improvements in cardio-pulmonary fitness, bone integrity, as well as muscle strength and endurance. While UCL focussed on the effect of FES cycling on tissue and muscle mass and SPC focused on cardiovascular effects, Hunt and Gollee made the critically important contribution to this research, demonstrating that FES exercise improved circulation and eased spasms. Importantly, working together with QENSIU, the Glasgow team transferred this technology into clinical practice.

Tetraplegics are individuals that have suffered an SCI to the neck region, resulting in complete or semi-paralysis of all their limbs and torso. As a consequence, they often require mechanical assistance with ventilation. Gollee's research first demonstrated how FES applied to the abdominal muscles could increase the tidal volume and cough peak flow in these patients, promoting weaning from mechanical ventilation in chronic and acute tetraplegic patients [5]. Gollee further adapted CRE's stimulation system developed for FES cycling therapy, including software developments, to make it suitable for abdominal stimulation.

Neuro-feedback for treatment of Central Neuropathic Pain (CNP): It is common for SCI patients with neuropathic pain to give up work. This is not a direct result of paralysis but because of their inability to concentrate as a result of the constant pain they experience. Dr Aleksandra Vuckovic (Lecturer, 2008-present), funded by the Medical Research Council (G0902257), identified features in brainwaves of SCI patients related to pain that can be detected by Electroencephalography [6]. She subsequently developed a training protocol and software linked to a custom-made brain computer interface device, for neuro-feedback training. Used in a clinical trial, this device and training method provides visual feedback of brain activity related to pain and trains patients to voluntarily target brain activity consistent with being pain-free.

3. References to the research

1. K.J. Hunt, B. Stone, N.-O. Negård, T. Schauer, M. Fraser, A.J. Cathcart, C. Ferrario, S.A. Ward, S. Grant, Control strategies for integration of electric motor assist and functional electrical stimulation in paraplegic cycling: utility for exercise testing and mobile cycling. *IEEE Trans Neural Sys Rehab Eng*, 12, 89-101, 2004. Link to pdf. *
2. K.J. Hunt, C. Ferrario, S. Grant, B. Stone, A.N. McLean, M.H. Fraser, D.B. Allan, Comparison of stimulation patterns for FES-cycling using measures of oxygen cost and stimulation cost, *Med Eng Phys*, 28 (7), 710–718, 2006. doi: 10.1016/j.medengphy.2005.10.006.
3. K.J. Hunt, B.A. Saunders, C. Perret, H. Berry, D.B. Allan, N. Donaldson, T.H. Kakebeeke, Energetics of paraplegic cycling: a new theoretical framework and efficiency characterisation for untrained subjects, *Eur J Appl Physiol*, 101(3), 277–285, 2007. Doi: 10.1007/s00421-007-0497-5. *
4. H.R. Berry, C. Perret, B.A. Saunders, T.H. Kakebeeke, N. Donaldson, D.B. Allan, K.J. Hunt, Cardiorespiratory and power adaptations to stimulated cycle training in paraplegia, *Medicine and Science in Sport and Exercise*, 40, 1573-80, 2008. Doi: 10.1249/MSS.0b013e318176b2f4.
5. H. Gollee, K.J. Hunt, D.B. Allan, M.H. Fraser, A.N. McLean, Automatic electrical stimulation of abdominal wall muscles increases tidal volume and cough peak flow in tetraplegia, *Technology and Health Care*, 16(4), 273-281, 2008. ISSN 1878-7401. Online version.

6. A. Vuckovic, F. Sepulveda, Delta band contribution in cue based single trial classification of real and imaginary wrist movements, Med. Biol. Eng. Comp., 46(6), 529–539, 2008. Doi: 10.1007/s11517-008-0345-8. *

* best indicators of research quality

4. Details of the impact

While SCI is infrequent (in the UK approximately 1200 people per year are paralysed from a spinal cord injury), the implications of SCI for patients, society and the health services are immense. It is estimated that around 30,000 people in the UK are currently living with SCI, with a significant cost associated with their care (depending upon their age at the time of trauma, the cost of each patient's care may be as much as £2M over their lifetime).

In addition, 21% of those discharged from SCI Centres go to nursing homes, hospitals or other care institutions rather than their own homes. 20% of people leave SCI centres with clinical depression. The spinal cord injury and associated disability will affect a patient for the rest of their life. This results in a duration-of-care commitment most often ranging from 30-40 years. For these reasons, research carried out by the University of Glasgow's CRE has focused on improving the health and quality of life of SCI patients, resulting in a reduced burden on carers, families and the health services.

Functional Electrical Stimulation (FES) for cycling and abdominal stimulation: The University of Glasgow team refined the concept of FES for cycling and abdominal stimulation, establishing the technology for routine medical practice by defining its benefits to patients. This enabled the transition of FES into widely-used care scenarios across the UK and internationally, throughout Europe, North America and Asia. The researchers in Glasgow also worked with industry to develop specialised cycles, making FES cycling a commercial reality.

Health benefits resulting from the research: SCI patients suffer from muscle atrophy, affecting their breathing and balance as well as reducing any remaining functionality in their limbs (making it more difficult to retain independence). By using FES, a series of electrical stimuli are sent to the muscle groups to create a pattern of contraction that is similar to that of an able-bodied person. This results in functional movement (e.g. enabling cycling or supporting breathing) thereby provoking a cardiovascular workout.

The University's FES cycling technology allows SCI sufferers to use adapted exercise bikes to maintain and build up their muscle mass throughout their lives. The use of FES cycling results in improved general fitness and health, delivering a range of benefits including decreased risk of cardiovascular disease, hypertension and stroke, decreased anxiety, pain and depression, as well as reductions in the prevalence of obesity, diabetes and bone demineralisation. Abdominal FES improves lung function and reduces the risk of respiratory infection. All of these outcomes reduce morbidity and mortality, evidenced by a reduction in rates of secondary hospitalisation and the associated medical costs. The increased physical activity results in greater strength, providing the patient with enhanced independence. Patients also experience improved levels of energy, improved social interaction, and a better quality sleep.

Two typical case studies from the CRE research involving QENSIU patients illustrate the health and quality of life benefits of FES:

- A paralysed patient started weekly FES cycling therapy with the aim of improving his health, an activity that lasted for over a decade until 2011. The patient reported increased muscle mass, improved body image and, after the FES exercise, felt physically fatigued and had reduced spasticity. Prior to the therapy he and his partner had been unable to conceive, however regular exercise improved his health sufficiently and through assisted conception, the patient's twins were born in 2011.
- A ventilator-dependent tetraplegic patient was given FES abdominal stimulation as part of a four-week weaning programme. The patient continued to wean but only managed to breathe 12 hours/day ventilator-free. With a further course of 4 weeks' abdominal stimulation therapy the

patient was ventilator-free, greatly improving his quality of life and reducing long-term care costs.

Commercial benefits resulting from the research: In 2007, in collaboration with Hasomed GmbH (Magdeburg, Germany) and Anatomical Concepts UK Ltd (Clydebank, UK), the CRE team incorporated the FES cycling technology into commercial products, making participation and access for end-users a realistic option. This has led to the production of a range of FES cycling products, including the RehaBike and a related FES cycling ergometer, the RehaMove (www.fescycling.com). The RehaMove is approved by the US Food and Drug Administration (FDA) and is available in the USA. In the UK, Anatomical Concepts sell on average 30-40 FES systems each year.

Hasomed's RehaBike and RehaMove are used by many hundreds of people at home, in clinics and in physiotherapy sessions in spinal cord injury centres across the world. Hasomed is the market leader in Europe, selling approximately 500 FES systems worldwide annually. Hasomed has over 50 distribution partners, including in Australia, Hong Kong, Malaysia, Mexico, Russia, UK, USA and Taiwan. Hasomed are currently integrating the abdominal stimulation technology with their existing stimulation system (Rehastim) for release to the market.

Neuro-feedback for treatment of Central Neuropathic Pain (CNP): SCI often leads to an intractable and difficult to treat neuropathic pain that is both severe and incapacitating. Until recently, treatment was limited to drugs, with significant side effects. However, Dr Vuckovic, in the CRE, has developed training protocols for neuro-feedback that provide patients with information about their brain activity so that they can voluntarily modify their brainwaves.

Five patients who were not responding to standard medication treatments have participated in Dr Vuckovic's initial clinical trial, receiving up to 40 neuro-feedback treatment sessions each. These resulted in a clinically meaningful pain reduction of >30% for four out of five patients. The benefits of neuro-feedback in the treatment of CNP are illustrated by the following case study:

- An incomplete SCI patient walking with crutches described his pain as "having two legs full of angry wasps". He felt benefits after three or four sessions of neuro-feedback treatment. His pain reduced from 7 to 3 on the visual analogue scale (1 = no pain, 10 = worst pain imaginable) and the effects lasted for two to three days. Prior to treatment, walking was impaired with spasms, and after each treatment he was spasm-free for several hours. After additional training sessions, he had developed sufficient understanding of the techniques required to manage his pain and could do this at home without the device. This degree of benefit has a significant clinical effect, can improve quality of life and leads to a reduction in medication.

5. Sources to corroborate the impact

Evidencing benefits to patients and carers

- Statement and contact details from Director of Queen Elizabeth National Spinal Injury Unit, Southern General Hospital;

Evidencing commercial benefits and benefits to patients

- Managing Director, Hasomed Gmbh (contact details provided);
- Managing Director, Anatomical Concepts (UK) (contact details provided);
- Hasomed website: University of Glasgow listed as development partner;
- Hasomed website: list of global distributors;
- Hasomed brochure: Rehabike developed in collaboration with University of Glasgow (pg 15);
- Rehabilitation Matters website**:** featuring a patient training on Rehamove and confirmation that research behind the bike was conducted at the Centre for Rehabilitation Engineering at the University of Glasgow and the QENSIUnit;
- Spinal Injuries Scotland Newsline, Summer 2012: Case study of Neuro-Feedback for treatment of CNP in SCI patient (pg 12).