Institution: London South Bank University

Unit of Assessment: Sport and Exercise Sciences, Leisure and Tourism

Title of case study: Development and commercialisation of a range of medical devices that stimulate improved blood circulation and improve general health.

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

Research carried out by the SESRC has resulted in the development of three novel devices that improve foot and lower limb circulation. These have been commercialised by Actegy Health Ltd.

Since 2008, impact arising from this research includes,

- successful product efficacy trials satisfying Advertising Standards Authority requirements;
- filing of three patent applications;
- generation of total revenues of £53M of which in 2012 two thirds were overseas (£16.3M);
- created 22 direct jobs with significantly more indirect jobs in manufacturing, logistics and marketing;
- a Red Dot Good Design international award in 2012;
- recognition of Actegy Ltd as a Sunday Times fast track 100 company in both 2010(4th) and 2011(17th).

2. Underpinning research (indicative maximum 500 words)

This impact case study is underpinned by research carried out in the Sports and Exercise Science Research Centre (SESRC) at London South Bank University since 2001 and which continues. The research was undertaken by Drs Paul Sumners (Research Fellow, 2003 to date), Katya Mileva (Senior Research Fellow, 2001 to date) and Joanna Bowtell (Senior Lecturer, 1999 - left LSBU in 2011).

The SESRC researchers have developed a considerable body of scientific knowledge and expertise in physiological effects of electro-mechanical interventions including electrical (1, 2), vibratory (3, 4) and magnetic (4) stimulation. This has enabled the addition of novel research and development programmes for improving human physical activity and health.

Research since 2001 using noxious and innocuous electrical nerve stimulation demonstrated close coupling between muscle activation and joint kinetics and kinematics via spinal reflex modulation (1). In 2008, experiments were undertaken to determine the potential of novel electrical stimulation parameters (1ms pulse width) to engage central neural circuits and increase stability and structural integrity of the foot. The research demonstrated potentiated intrinsic foot muscle activation and acute beneficial impact from electrical foot stimulation on the coordination of foot structures during subsequent movement (2).

These findings imply a potential for increased movement range and enhanced plantar-venous plexus function thus producing an increased venous ejection volume from the foot and calf structures. Enhanced muscle oxygen dynamics and oxidative energy metabolism were also found during voluntary exercises with superimposed vibration (3).Prolonged voluntary (5) and vibration-evoked (4) muscle activity was also found to produce significant modulation of the corticospinal excitability and the peripheral excitatory and contractile processes.

This knowledge has enabled the development of novel technological approaches for stimulation of the peripheral sensory receptors that could be used during activity to improve exercise performance by simultaneously enhancing muscle excitation, perfusion and oxygenation (3).

Building up from these results, the SESRC undertook a novel experimental programme to investigate the effects of innocuous foot plantar surface electrical stimulation on lower limb blood flow and swelling. In 2011 the potential of this novel intervention to alleviate peripheral circulatory deficits and associated pain and discomfort was compared to that of mild voluntary contractions in a series of randomized controlled trials utilising Doppler Ultrasound, Laser

Doppler Flowmetry, Near-Infrared Spectroscopy and Opto-electric Volumetry.

The findings demonstrated enhanced venous outflow and tissue perfusion, improved muscle oxygenation and reduced swelling in healthy participants with induced venous insufficiency via 40 minutes of immobility (6). These factors had not previously been systematically investigated utilising foot plantar surface stimulation.

Based upon these findings further experiments were designed to devise approaches for enhanced physiological efficiency via improvements to the existing plantar surface stimulation technology.

The research has demonstrated that:

- incorporation of a rocking mechanism to allow ankle movement during stimulation leads to an increased venous ejection volume and more natural movement patterns.
- stimulation with wider pulses allows lower stimulation intensities to be used to achieve efficient muscle activation similar to voluntary recruitment patterns.
- incorporating longer rest periods between evoked contractions allows an increased efficiency of the muscle pump, enhanced venous return and improved tissue oxygenation.

3. References to the research (indicative maximum of six references)

1. Mileva K., Green, D.A. and Turner, D.L. (2004). Neuromuscular and biomechanical coupling in human cycling: Modulation of cutaneous reflex responses to sural nerve stimulation. *Exp Brain Res*, 158(4): 450-464.
2. James, D., Chesters, T., Sumners, D., Cook, D., Green, D., & Mileva, K. (2013). Wide-Pulse Electrical Stimulation to an Intrinsic Foot Muscle Induces Acute Functional Changes in Forefoot-Rearfoot Coupling Behaviour during Walking. *IntJSportsMed*, 34(5), 438-43.
3. Mileva, K., Naleem, A.A., Biswas, S. K., Bowtell, J.L. (2006). Acute Effects of a Vibration-like Stimulus during Knee Extension Exercise. *MedSciSportsExerc* 38(7): 1317-1328.
4. Mileva, K.N., Bowtell, J.L., Kossev, A.R., (2009). Effects of low frequency whole body vibration on motor evoked potentials in healthy men. *ExpPhysiol*, 94(1):103-116.
5. Mileva, K.N., Sumners, D.P., Bowtell, J.L., Decline in voluntary activation contributes to reduced maximal performance of fatigued human lower limb muscles. *Eur J Appl Physiol.* 2012 Dec; 112(12):3959-70.
6. Mileva K.N., James, D., Hunter, S., Zaidell, L., (2011). Circulation Booster™: Investigation of the effects of transcutaneous electrical foot stimulation on the peripheral macro- and micro-circulation. Research report to Actegy Health Ltd (report available on request from LSBU).

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

Poor circulation is an increasing health problem in clinical (eg diabetics, peripheral vascular disease) and non-clinical groups (eg. obesity, pregnancy, high alcohol consumption and frequent long-haul flying (economy class syndrome)). Worldwide an estimated 30 million people across all age groups suffer with peripheral vascular disease, with over 100,000 people newly diagnosed each year in the UK alone. Many more people are estimated to suffer from chronic venous insufficiency due to lifestyle factors. Current treatment regimens rely on pharmaceutical and compression therapies or surgical interventions, with highly variable efficacy and demand on health-care resources.

SESRC's research has led to the development and subsequent retail of a range of improved circulation boosters (Revitive™ range) for and by Actegy Ltd, a health device company based in Ascot.

In 2006, Actegy approached the SESRC to explore the possibility of it marketing and selling a breathing device (YouBreathe) invented and developed by the SESRC. As a result of this interaction, Actegy became aware of the SESRC's expertise and knowledge in electro-mechanical stimulation. In 2008, Actegy awarded the SESRC funding to evaluate the physiological efficacy and

performance of its Circulation Booster product in order to provide scientific evidence to update and defend its physiological performance claims. Actegy was able to provide sufficient evidence to Advertising Standards Agency reviewers to justify the claimed performance benefits (1) and to continue trading.

The results identified the opportunity to materially improve product performance and to identify clinical indications such as diabetes. As a consequence, in 2008, Actegy commissioned the SESRC to undertake a product development programme aimed at expanding the range of advanced circulation products based upon its current Circulation Booster technology. By 2011, the SESRC's work had led to three differentiated products which Actegy subsequently had manufactured and launched under its Revitive™ range (2). The IsoRocker, WidePulse and On/Off ratio technologies developed by the SESRC deliver a more natural user experience than comparable competitor products. Patents applications on all three products were applied for by Actegy during 2013 with SESRC staff named as inventors (3, 4, 5).

The new innovations are user focussed and improve the user experience. The IsoRocker increases circulation and gives greater comfort during use. The Wide-Pulse stimulation reduces the required voltage making the device safer to use. The On/Off ratios product increase circulation with each "pump" of the muscles.

Since 2008, and as a direct result of the SESRC's work, Actegy has (6):

- Progressed from a single to a multi-product brand built around the Revitive range, with enhanced marketing collateral;
- Built a patent portfolio for its range of circulation boosters. Actegy had no Intellectual Property prior to its engagement with the SESRC;
- Evolved from an on-line retailer to a medical device manufacturing company;
- Become the market leader in the circulation booster product category with sales over the period 2008-2012 of £53.1M;
- Generated net profits of £1.32M on sales of £16.3M in its most recent audited accounts in 2012;
- Expanded its sales in overseas territories from zero in 2008 to £10.5M in 2012;
- Created 22 direct new jobs with significantly more indirect jobs in manufacturing, distribution and marketing;
- Won a Red Dot Good Design international award in 2012 for Revitive IX (7);
- Been recognised for two consecutive years (2010 (4th) and 2011 (17th)) as one of the fastest growing companies in the Sunday Times Fast Track 100 list, one of only 2 companies to remain in the top 20 for two consecutive years (2).

A Director of Actegy has stated that: "the collaboration with LSBU continues to enable us to differentiate our products and allow us to enter new markets" (6).

A leading consultant cardiovascular surgeon has commented "*We have used Revitive and have found that it is very effective at stimulating the muscles of the feet and lower legs, causing a very good increase in blood flow. I am so impressed that I will be using it myself*" (8).

There are many positive testimonials to the benefits of Revitive on social and commercial web sites. For example, Sir Steve Redgrave is quoted on the Boots web site extolling the value of Revitive (8) and a Type 2 diabetic posted on Amazon that "*the Revitive IX Circulation Booster feels as though it really does me a lot of good in terms of maintaining good circulation in my feet and ankles, and, my ankles no longer swell" (9).*

The relationship between Actegy and the SESRC continues to this day with total contract research and consultancy awards of £239,000 to the SESRC up to 31st July 2013. The Head of the SESRC is currently a consultant to Actegy to advise and guide on the clinical trials of its RevitiveIX circulation booster, which will allow the product to achieve 510K FDA Certification, allowing the device to be sold as a medical device in the US and other countries.

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

1. Contact: Director, Actegy Ltd
2. www.revitive.com
3. Patent Application No. for : Isorocker - WO2013024241
4. Patent Application No. for : Wide-Pulse and On/Off - WO2013150257
5. Patent Application No. for : Conditioning Pulse - WO2013144544
6. Independent Consultant's (The Innovation Partnership) Report, 2013 – Contact: Managing Director, The Innovation Partnership. Report covers an interview with a Director of Actegy Ltd on the SESRC's involvement and contribution to Actegy's development and performance post 2008.
7. http://www.red-dot-21.com/products/revitiveix-electricalstimulationdevice
8. http://www.boots.com/en/Revitive/Revitive-leg-and-foot-treatment/Choose-the-right-Revitive-for-you/
9. http://www.amazon.co.uk/product-reviews/B00BKVG0NO/ref=dp_top_cm_cr_acr_txt?ie=UTF8&showViewpoints=1