Institution: University of Salford

Unite of Assessment: A3 Allied Health Professions, Dentistry, Nursing and Pharmacy

Title of case study: Foot health devices

1. Summary of the impact

University of Salford researchers have transferred knowledge from research in the foot health devices sector into products and services in commercial and clinical settings, supporting a £100 billion global healthcare equipment and supplies industry, contributing to economies and to quality of life on a daily basis for those with foot and lower limb health problems, world-wide. The benefiting partners are part of global businesses and public and private sector clinical services and researchers have pioneered the connection of research to commercial foot health contexts on a unique scale:

- Supporting innovation in foot related clinical practice and thus improved quality of life for people with a range of health challenges;
- Bringing credible and science led innovation in foot health devices to commercial partners and the market, contributing significant economic benefit internationally.

2. Underpinning research

The key researchers and positions they held at the institution at the time of the research are as follows: Professor Chris Nester, 1996 to present, Dr Richard Jones, 2006 to present, Dr Steve Preece, 2008 to present, Dr Farina Hashmi, 2010 to present, Dr Anita Williams 2004 to present, Dr Anmin Liu, 2002 to present, School of Health Sciences. The impact of *foot health devices* is underpinned by the following research:

1) *Footwear and foot orthotic research* has provided new insight into foot and lower limb function using a range of novel techniques integrated with footwear and orthotic design innovation in partnership with clinicians, patients and industrial partners.

- **2005-2008:** Supported by a Knowledge Transfer Partnership (£82k), Nester researched and developed a prefabricated foot orthosis through, focus groups with clinicians and orthotic users; mechanical testing of orthotic materials properties; and evaluation of the effect of the new orthotic on foot movement. The research led to the establishment of a spin-off company (salfordinsole).
- **2006-ongoing:** Supported by Arthritis UK (£106k) and the University, Jones has led development and commercialisation of a modified salfordinsole orthotic, proven to reduce pain and improve function in knee osteoarthritis. Numerous laboratory and clinical studies have demonstrated its benefits comparable to other therapies but Salfordinsole operates at a fraction of the cost, and with greater patient compliance and patient satisfaction. There is now emerging research evidence of the potential for this orthosis to reduce the progression of knee arthritis in the contralateral knee.
- **2008-2013:** Supported by successive industry funds FitFlop, (£308k over 3 grants) Jones led research into shoe sole geometries and various material properties and their effect on movement, plantar foot pressure and muscle activity during gait, helping guide product development and marketing claims.
- **2008-ongoing:** In a partnership worth £1.7M between the University and SSL International PLC, owner of the *Scholl* footcare brand, Nester undertook clinical and laboratory trials to measure plantar soft tissue properties using ultrasound, study plantar pressure under varied loading conditions, and investigate insole and footwear effects. The research helped develop a more scientific basis to product development, market positioning of the brand and products, and reduced risk from product claims.
- **2009-ongoing:** Supported by multiple EU funds (£794k), Preece and Nester continue to systematically research how plantar pressure responds to changes in shoe sole and foot orthotic features, providing recommendations as to which design features should be standardised for patients with diabetes, and which features require bespoke settings. Their research outcomes are embedded in prescription systems by working with technology partners. The research involves close working with groups of NHS clinicians to investigate

the role of digital technology in advancing and standardising prescription and reducing prescription errors. In addition, these technologies are being researched to improve patient and practitioner education and thus compliance with orthotic devices.

- **2013–ongoing:** Through funding from the UK Government's Technology Strategy Board (£260k) intended to support economic growth, Nester is working with groups of NHS clinicians and industry partners to integrate the advances in additive manufacturing with orthotic prescription practices. The research is seeking to improve the match between foot features and material and orthotic performance characteristics, specifically for cases of diabetes.

2) Foot skin research: Common foot skin problems such as corns, callus, heel fissures and blisters are painful and can impair mobility (especially in older people). However, we know little of their anatomy, biomechanical, etiology and response to treatment. As such, public and private sector clinical treatments and commercial home treatments are poorly evidenced and innovation stifled.

- **2010-ongoing:** Supported by Reckitt Benkiser (owners of the Scholl brand) (£482k) Hashmi and Nester are characterising corn, callus, fissures and blisters (n=160), using a bespoke loading device to understand skin response to various external loads. The research is characterising foot skin mechanical properties in each lesion, measuring the effects of podiatry and home remedies on skin properties, and seeking to observe, for the first time, of the physiological events preceding and during formation of these common skin lesions.

3. References to the research

Key outputs

1. Majumdar R, Laxton P, Thuesen A, Nester CJ, Richards B, Liu A. Design, development and biomechanical evaluation of a prefabricated anti pronation foot orthosis. *Journal of Rehab Res & Development:* vol: 50, iss:9. DOI
2. Jones RK, Nester CJ, Richards JD, Kim WY, Johnson DS, Jari S, Laxton P, Tyson SF. A comparison of the biomechanical effects of valgus knee braces and lateral wedged insoles in patients with knee osteoarthritis. *Gait Posture*. 2013, 37(3); 368-7212 Aug 21. DOI
3. Jones RK, Chapman GJ, Findlow AH, Forsythe L, Parkes MJ, Felson DT. A new approach to prevention of knee osteoarthritis: Reducing medial load in the contralateral knee. J Rhematol. 2013, 40(3); 309-15. *Arthritis Res Care*. DOI
4. Chapman JD, Preece S, Braunstein B, Höhne A, Nester CJ, Brueggemann P, Hutchins S. Effect of rocker shoe design features on forefoot plantar pressures in people with and without diabetes. *Clin Biomech* (Bristol, Avon). 2013 Jun 1. DOI
5. Forghany S, Nester CJ, Richards B, Hatton AL, Liu A. Rollover footwear affects lower limb biomechanics during walking. *Gait Posture*. 2013 Aug 1. doi:pii: S0966-6362(13)00317-2. 10.1016/j.gaitpost.2013.07.009. DOI
6. Hashmi F, Richards BS, Forghany S, Hatton AL, Nester CJ. The formation of friction blisters on the foot: the development of a laboratory-based blister creation model. *Skin Res Technol*. 2012 Aug 14. DOI

Key grants

1. **2013:** EU (Framework 7): SOHEALTHY: Research and education strategy for EU footwear sector £192k
2. **2013:** Technology Strategy Board: Additive manufacture value chain to deliver bespoke orthotics within 48 hours with greatly improved health economics. £260k.
3. **2013:** EC (Framework 7) SMARTPIF: Smart tools for the prescription of orthopaedic insoles and footwear £192k.
4. **2012:** Fit Flop – Footwear research £89k.
5. **2012:** Arthritis Research Campaign: New Treatment for Knee Osteoarthritis £22k.
6. **2011:** SSL PLC/ Reckitt Benkiser – Foot skin properties and treatment efficacy £290k.
7. **2011:** Technology Strategy Board and SSL PLC/Reckitt Benkiser (KTP) — Foot blister testing technologies and efficacy testing £192k.
8. **2010:** Fit Flop – Footwear research £85k.

9. **2009:** EC (Framework 7) SSHOES: Special Shoe Movement £365k.
10. **2008**: SSL PLC Feet Matter Partnership, £976k.
11. **2008:** SSL PLC Making Foot Science Relevant £38k.
12. **2009:** Arthritis Research Campaign: New Treatment for Knee Osteoarthritis £84k.
13. **2008:** Technology Strategy Board and Fitflop KTP - Footwear research £131k.

4. Details of the impact

Research by Nester et al has accelerated innovation of footwear, foot orthotic and footcare products, and related services and processes to increase mobility, independence and quality of life for a wide range of users – from health care consumers to patients in NHS settings. Commercial and public sector partners are integrated into our research throughout its development and translation into practice or product, and range from SME's such as salfordinsole to global brand owners such as Scholl, FitFlop. Commercial partners commission research only where they can identify economic benefit in doing so. Nester et al have secured continuous funding contracts totalling an investment of £2M at Salford since 2008, plus further £0.5M in EU funds during a challenging economic climate and acquisition of partners by competitor companies. *Foot Health Devices* demonstrates the following impact:

Bringing credible and science led innovation in foot health devices to commercial partners and the market, contributing significant economic benefit internationally:

- The *salfordinsole* brand and company was launched in 2008 and more than 50,000 pairs of orthoses have been sold to the NHS and private sectors, with two overseas distributors appointed. The company has turned over circa £750k in this period, creating 3 jobs. In addition, the company supports 1 EU and 1 TSB funded research projects with the University (worth £460k to the University). The latter aided an additive manufacturing micro SME attract £860k of venture capital funding for its own growth. Salfordinsole has also made equipment/software donations to the University.
- Research using the salfordinsole led to a new orthotic design (EU registered design) for knee arthritis, adopted by the Arthritis UK ROAM programme between Salford and Manchester Universities. In April 2013 this design was launched under the Boots Pharmaceutical brand, projected to sell 12,000 per annum across over 400 Boots stores.
- Research from the EU SHOES project concerning optimal rocker shoe angles was adopted by the Langer Orthotics company (in collaboration with Salford) to improve the design of their recently launched diabetes shoe range (June 2013). Langer also adopted research by Williams to inform the position of this footwear in the marketplace.
- Foot skin research is benchmarking various branded home treatments for common foot skin problems against Podiatry management and assessing how severity of skin lesion affects treatment response. Results have directly influenced future global R&D strategy and expenditure for the Scholl foot skincare brand (and led to further funding).
- Research in the area of footwear and orthotics helped create a more creditable explanation for industry partners (Scholl, FitFlop) and consumers as to why products might offer health benefits (e.g. reduce pain, improved comfort). The stronger consumer message and intention to purchase, and increased product and brand equity have been valued by commercial partners.
- In addition, this research helped commercial partners reduce risk and financial exposure by aligning product claims to research data. Research data was central to their CE marking and product technical files for regulatory purposes (e.g. FDA regulations). Scholl commissioned biomechanics research led to moderation of product claims on how footwear affects muscle function (so called "toning" footwear). They avoided expensive litigation and fines applied to a number of other footwear companies (fines in excess of $20M in some cases).

Supporting innovation in clinical practice and improved quality of life for people with a range of health challenges:

- All orthotic projects involve direct involvement with a large number of clinicians from across the UK, typically through focus groups (Nester, Williams) ensuring projects and orthotic products/tools are informed by issues facing current and future NHS and private sector foot

health services. Expected to enhance adoption of technologies and the quality of patient care and orthotic devices available by educating clinicians are also engaged in the research process and improving their willingness to engage with research.

- The knee arthritis orthotic developed by Jones has demonstrated equal benefits at a fraction of the cost of knee braces and other therapies. This offers excellent opportunities for reduced use of analgesics, expensive manual therapy, improved mobility and quality of life, as well as some reduction in demand for knee surgeries (a small number of patients have come off knee surgery waiting lists). Evidence for the potential to prevent arthritis in the contralateral knee is now emerging.
- Footwear and orthotic designs for the health care sector remain largely craft and intuition based. Research in EU projects is creating a more systematic understanding of the interaction between foot biomechanics and orthotic/footwear device design. For example, in the SSHOES project Preece and Nester developed an algorithm to support decisions on the choice of shoe sole rocker angle for each specific patient, which has been incorporated into a software system that manages data flow between clinicians and footwear manufacturers (with INESCOP (Spain) and DUNA (Italy)). A similar process for foot orthoses is now in development.
- Salfordinsole orthotic materials have been shown to offer greatly improved durability and hygiene compared to market leading orthotic materials. This addresses clinician issues of durability and user issues of hygiene, the orthotic being pioneering in being entirely machine washable and guaranteed for 5 years.
- The EU SMARTPIF and UK funded Additive Manufacturing orthotic projects are building on prior research by Williams, focusing on the potential for digital technology to enhance patient education and improve compliance with foot orthoses and footwear, leading to improved health outcomes.

5. Sources to corroborate the impact

a) The Feet Matter collaboration – Final partnership report: *"This is a great opportunity for a global commercial business such as SSL to work with an innovative university such as Salford to develop further great consumer facing healthcare products. Within Scholl we want to work with the best experts that share our vision and Salford do this."* Head of Innovation for Scholl.
b) Letter from R&D Director of Foot Care and Dermatological Skincare, Reckitt Benckiser:
c) Letter from Special Projects Manager, FitFlop:
d) EU registered designs: 002160572
e) Patient testimonials from people with a range of healthcare challenges include: *"Can't believe that something so simple can make such a huge difference to relieving the pain I was suffering from." "The insoles have benefited me and my injury. Soon to attempt some hill walking!" "This has been the first time I have had an improvement in my injury for months."*