Institution: Glasgow Caledonian University

Unit of Assessment: Allied Health Professions, Dentistry, Nursing and Pharmacy

Title of case study: Personalised Foot Orthoses using 3D Printing

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

Glasgow Caledonian University researchers have dramatically changed the manufacture of custom ankle-foot and foot orthoses through additive manufacturing (3D printing) combined with improved design personalisation. The research has beneficially impacted on health and well-being as new 3D printed orthoses have been designed and trialled with patients with positive outcomes reported. Moreover, European SME companies in the orthotic design and manufacture sector have benefitted through the commercialisation of new orthotic products and computer-based design optimisation software. The research has also led to raised global awareness of the capabilities of additive manufacturing for the orthotic sector and beneficially influenced manufacturing research and development funding at the European policy level.

2. Underpinning research (indicative maximum 500 words)

Formed in 2006, Woodburn's research group has been conducting research to characterise and quantify changes in foot structure and function in important musculoskeletal conditions, to adopt manufacturing and enabling technologies to support this work[1-3], and to develop and test highly personalised foot orthoses as part of complex interventions[4-6] [grants (G) 1-6]. The group has focused on inflammatory joint disease as it provides a good model of joint and soft tissue damage, impairment and walking disability, which can be targeted by orthotic treatment[4,6] [G3-5]. Researchers have successfully developed and tested dynamic, multi-segmented biomechanical models of the foot and applied them through gait analyses to characterise changes in joint movement and forces, muscle action and plantar pressure distribution[2] [G1]. We have shown that in some forms of arthritis, altered foot function occurs early, is heterogeneous, and if non-optimally treated is associated with irreversible disability [G3-5]. The group has translated this knowledge into new paradigms of care using subject-specific biomechanical data to establish new therapeutic targets for orthotic therapies[5,6] [G1,2]. We have published over 50 peer-reviewed articles and have been awarded over £4million in external funding [G1-6].

The group has led the development of functional customisation of orthoses through the integration of personalised biomechanical data with new capabilities in orthotic design and manufacturing technologies[4-6] [G1,2,6]. We were the first to establish proof-of-concept for additive manufacturing using selective laser sintering for personalised foot orthoses in patients with rheumatoid arthritis[4]. During 2009-2013, Woodburn coordinated the *A-FOOTPRINT* project (€5.3M European Commission (EC), Framework 7 Programme) bringing together 12 interdisciplinary SME, large industry and academic partners from 7 countries [G1]. Within this collaboration, GCU developed a highly detailed biomechanical simulation model (The *Glasgow-Maastricht Foot Model*, AnyBody Technology) to enable personalisation of custom orthoses based on optimising foot and ankle biomechanics[2]. This permits new freeform design opportunities that can be developed and made through 3D printing which isn't achievable with current manufacturing techniques. In clinical studies, we have shown that digital technologies including 3D surface scanning and computer-aided design can be successfully integrated with 3D printing to produce orthoses that are safe and effective for patient use[3,4,6] [G1]. We produced primary evidence to establish dose-response for 3D printed orthoses in adult-acquired flat foot[5]. We have also shown in a phase II clinical trial that two forms of 3D printed orthoses (selective laser sintered and fused-deposition method) are safe and

well tolerated in patients with early rheumatoid arthritis[6] [G1]. GCU has also produced the first 'mode-of-action' data quantifying the biomechanical effects (control of joint motion and forces and distribution of pressure on the plantar foot surfaces) of 3D printed orthoses in comparison with standard devices[6]. Finally, we have shown the novel integration of embedded sensors for capturing free-living activity and important parameters such as temperature and pressure through the exploitation of design freedom offered by computer-aided design and additive manufacturing processes. In September 2013, the European Commission Research Directorate awarded the *A-FOOTPRINT* 'Flagship Project' and 'Success Story' status because of its immediate impact and benefits to European citizens. Further funding (2013-15) has been secured from the EC for the *D-FOOTPRINT* project to continue this research.

Key Researchers
Professor Jim Woodburn, Director, Institute for Applied Health Research
Dr Scott Telfer, EU Marie Curie International Research Fellow (commenced 01/12/09)
Professor Martijn Steultjens, Professor of Musculoskeletal Health (commenced 01/03/10)
Dr Deborah E Turner, Arthritis Research UK Senior Lecturer in Podiatry
Dr Ruth Barn (née Semple), Arthritis Research UK, Allied Health Professional Fellow

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

1: Telfer S, Pallari J, Munguia J, Dalgarno K, McGeough M, Woodburn J. Embracing additive manufacture: implications for foot and ankle orthosis design. BMC Musculoskeletal Disorders 2012 May 29;13:84. (doi: 10.1186/1471-2474-13-84).
2: Oosterwaal M, Telfer S, Tørholm S, Carbes S, van Rhijn LW, Macduff R, Meijer K, Woodburn J. Generation of subject-specific, dynamic, multisegment ankle and foot models to improve orthotic design: a feasibility study. BMC Musculoskeletal Disorders 2011 Nov 10;12:256. (doi: 10.1186/1471-2474-12-256).
3: Telfer S, Gibson KS, Hennessy K, Steultjens MP, Woodburn J. Computer-aided design of customized foot orthoses: reproducibility and effect of method used to obtain foot shape. Arch Phys Med Rehabil. 2012 May;93(5):863-70. (doi: 10.1016/j.apmr.2011.12.019).
4: Pallari JH, Dalgarno KW, Woodburn J. Mass customization of foot orthoses for rheumatoid arthritis using selective laser sintering. IEEE Trans Biomed Eng. 2010 Jul;57(7):1750-6. (doi: 10.1109/TBME.2010.2044178).
5: Telfer S, Abbott M, Steultjens MP, Woodburn J. Dose-response effects of customised foot orthoses on lower limb kinematics and kinetics in pronated foot type. J Biomech. 2013 May 31;46(9):1489-95. (doi: 10.1016/j.jbiomech.2013.03.036). Available in REF2.
6: Gibson KS, Woodburn J, Porter D, Telfer S. Functionally optimised orthoses for early rheumatoid arthritis foot disease: A study of mechanisms and patient experience. Arthritis Care Res (Hoboken). 2013 Jul 8. (doi: 10.1002/acr.22060). Available in REF2.

Key grants:
1: Woodburn: *A-FOOTPRINT* (Ankle and Foot Orthotic Personalisation via Rapid Prototyping); European Union FP7 Nanotechnologies, Materials and New Production Technologies Cooperation Work Programme; (01/10-09 – 30/09/13); €3,729,043.
2: Woodburn: Personalised insoles via additive manufacturing for the prevention of foot ulceration in diabetes; European Commission FP7 People, International Outgoing Fellowship; (14/10/13 - 13/10/15); €196,682.
3: Woodburn: Senior Lecturer in Podiatry; Arthritis Research UK; (31/03/07 – 30/03/12); £89,000.
4: Woodburn: A randomised controlled trial of intensive podiatry-led foot care in Juvenile Idiopathic Arthritis; Arthritis Research UK; (30/09/07 – 29/09/10); £89,000.
5: Woodburn: Tibialis posterior tenosynovitis in RA: electromyographic and ultrasound response following orthotic and local corticosteroid injection treatment; Arthritis Research UK; (01/10/08 – 30/09/11); £162,553.
6: Telfer: Biomechanical effects of low cost personalised orthotics during activities of daily living in patients with musculoskeletal disorders; Tenovus Scotland; (01/07/12 -30/06/13); £10,000.

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

Since 2009, GCU's research within the *A-FOOTPRINT* project has demonstrated innovative collaboration with SMEs and large industry. Its research and knowledge transfer outcomes have made their primary impact on commercial partners, specifically the adoption of 3D printing as a new manufacturing technology for custom foot orthoses by Peacocks Medical Group (PMG), a SME project partner based in the North of England (between 2012-present). GCU supplied PMG with evidence, through a number of clinical trials, that 3D printed orthoses are safe and effective and provide an enhanced patient experience. This process of product verification within the additive manufacturing value chain was critical to technology implementation and commercialisation [Source (S) 1]. Consequently, PMG is the first European-based orthotic SME to adopt additive manufacturing technology for custom orthotics production [S2] (between 2010-present). New foot orthotic products developed and verified in clinical trials are in phased production, and commercialisation began in September 2013 (www.podfo.com). GCU is supporting commercialisation activities through a dedicated training programme on additive manufacturing for prescribing clinicians (www.podfo.com/education) [S2].
PMG Research and Development Manager states:
"Through the A-FOOTPRINT project, the research collaboration with GCU has given us confidence that we can develop radically innovative orthotic products which are safe and effective. GCU's clinical trial research in particular has provided invaluable data on our new 3D printed orthotics mode of action as well as showing improved outcomes and enhanced patient experience. As a company we will be differentiate ourselves from the competition by adopting additive manufacturing with a strong scientific knowledge, engineering and evidence-base for its products and services." [S3]

GCU's research has also created commercial benefits for *A-FOOTPRINT* partner SME companies in the area of enabling technologies that support the design and functional optimisation of 3D printed orthoses. One specific example is the *Glasgow-Maastricht Foot Model* by SME AnyBody Technology (Aalborg, Denmark) [S4,5]. The software, for mainstream desktop application, has been commercialised (March 2013) as an advanced biomechanical model within the AnyBody Modelling Repository. The company has targeted global markets in large-industry orthopaedic devices, SME-based Orthotics, and industry-based assisted-living rehabilitation research and development. This product enables companies to improve product design optimisation through musculoskeletal simulations that complement experimental and clinical test protocols [S6].
AnyBody Technology CEO states:
"The cooperation with GCU has helped AnyBody Technology with both the data necessary and insight needed to build the most complex and comprehensive foot model currently available in any computer simulation software. This has given us specific consultancy opportunities with orthopedic companies across the world and opens up for new opportunities at specific potential customers segments in e.g. the sports industry which would not have been otherwise possible."

GCU-led dissemination and demonstration activities in the *A-FOOTPRINT* project have raised global awareness of the capabilities of additive manufacturing for the orthotic sector. Targeting multiple stakeholders in the scientific, technical and industry sectors through multimedia, conference, scientific paper publication and targeted demonstration events has enabled the project to reach approximately 25,000 key stakeholders across Europe, e.g., *'ORTHOPAEDIE + REHA-TECHNIK 2012'* exhibition in Leipzig Germany. Globally, a further 8,400 stakeholders from 104 countries have engaged with a dedicated project website (www.afootprint.eu), media and press releases (1,048 project newsletter downloads), and secondary dissemination across the additive manufacturing technology sector [S1,7]. Prototype orthotic products emerging from this research collaboration feature in an exhibition of 3D printing (*3D:Printing the Future*) at the London Science

Museum attended by approximately 78,000 visitors since the event opened 09/10/2013 (Science Museum audience research team).

(http://www.sciencemuseum.org.uk/visitmuseum/Plan_your_visit/exhibitions/3D_printing_the_future.aspx).

Dissemination activities led by GCU have significantly changed attitudes, knowledge, and acceptance towards 3D printing in the International orthotic sector. A targeted and sector-wide survey (clinical, industrial, and SME) revealed that the *A-FOOTPRINT* project had led to positive changes in attitudes towards 3D printing in **62.9%** of responders, improved knowledge in **66.7%** and that **32.3%** believed it would fundamentally change the sector within the next three years. **88.9%** of responders indicated that *A-FOOTPRINT* had given them the belief that they would be investing in or using 3D printing within the next three years [S8].

As *A-FOOTPRINT* Coordinator, Woodburn has successfully contributed to EC policy successes and future visions in Horizon2020. He has achieved this by:

- Contributing as a 'success demonstrator' at key EC events including '*Industrial Technologies 2012'* [S9],
- Successful participation in EC-level technology forums including the *Footwear European Technology Platform* and *prosumer.net* [S10],
- Successful collaboration in a global *Intelligent Manufacturing Systems* 'MiGOODs' project [S10].

These initiatives have enabled the project and its results to reach key stakeholders in the EC industrial technologies sector and important end-users, validating the benefits of the project at the European level and leading to the award of 'Flagship Project' status.

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

1. www.afootprint.eu (*A-FOOTPRINT* EU project website).
2. Peacocks Medical Group orthotic product information website (www.podfo.com).
3. Peacocks Medical Group, Newcastle, UK (Company R&D manager).
4. AnyBody Technology (Company CEO).
5. AnyBody Technology Glasgow-Maastricht Foot Model product information website (as webcast: http://www.anybodytech.com/199.0.html, as product information: (http://www.anybodytech.com/fileadmin/AnyBody/Docs/Tutorials/A_Getting_started_AMMR/lesson2.html).
6. BBC website news item (http://www.bbc.co.uk/news/uk-scotland-glasgow-west-19660736) and press material in Scotsman and Glasgow Herald newspapers: (http://www.scotsman.com/news/health/glasgow-experts-unveil-first-virtual-human-foot-1-2536058), (http://www.heraldscotland.com/news/health/first-footing-scots-scientists-reveal-computer-creation.18916787).
7. Mixed media/press material (http://www.bbc.co.uk/news/uk-scotland-20020600 [translated to 8 languages]).
8. European Commission A-FOOTPRINT project market survey report (confidential commission report).
9. EC industrial Technologies awareness (http://industrialtechnologies2012.eu/).
10. EC-level technology forum involvement (*(http://www.afootprint.eu/media/a-footprint/content/newsletters/Newsletter_Issue3.pdf), (http://prosumernet.eu/research-state-of-the-art/)*, (http://www.ims.org/2011/10/migoods-manufacturing-intelligence-for-consumer-goods/).