Institution: University of Bradford

Unit of Assessment: B12

Title of case study: *SmartPoint*: dramatically reducing the failure rate of root canal treatments in orthodontistry

1. Summary of the impact

A manufacturing process developed by Bradford researchers has revolutionised the way endodontists perform root canal treatments. When coated with a hydrophilic polymer, the highly-filled hygroscopic material has enabled UK company DRFP to develop *SmartPoint* – a new endodontic technique that dramatically reduces failure rates of root canal treatments from 11-30% over five years to approximately 1%, and gives lower levels of post-operative pain when compared with conventional techniques. The technology has won three awards for innovation and DRFP has expanded significantly, with a dedicated production facility and sales team offering visits to dentists to demonstrate the benefits of the technology.

2. Underpinning research

The Bradford Centre for Polymer Micro and Nano Technology (MNT) is internationally recognised for its expertise in micro scale moulding processes (1,2,3) which has grown from pioneering initial studies which commenced in 2001 when dedicated micromoulding technologies began to transfer from lab scale developments to full industrial hardware solutions. Under the Directorship of Phil Coates (Professor 1993-present) researchers involved included Dr Ben Whiteside (PDRA 2001-2006, Lecturer 2006-present), Keith Norris (Experimental Officer 2008-present), Dr Majiid Actar (PDRA 2008-2009), Andrew Czencusz (Process Technician 2008-2010) and John Wyborn (Process Technician 2009-present).

In 2006, researchers the Centre were approached by UK company DRFP Ltd. to help it develop a new market for its hydrophilic polymer technology. The company realised its hydrophilic polymer could be used to seal irregular shaped spaces, such as root canals in endodontistry, but was struggling to find a partner who could make the necessary core material to enable this application. The Centre was able to offer the company significant expertise in material selection and compounding, ultra high precision moulding, in-line process monitoring (4) and high-resolution product characterisation (5), which was required to satisfy the needs of the project.

In order to fit the requirements for endodontistry, the core material needed to be flexible enough to fit random shapes of root canals but stiff enough to insert. It also needed to be compatible with DRFP's hydrophilic polymer, enabling it adhere to the core and to swell only in the radial direction. Two further challenging requirements were that the core had to be radio-opaque (visible on x-rays) and compatible with a mass-manufacturing technique such as micro-injection moulding. These two requirements were particularly challenging, as a highly filled, radio-opaque, material is very difficult to mould in the high aspect ratios required for this application.

A multi-component polymer matrix and micro-powder filler material needed to be accurately blended to provide good consistency and the correct degree of radiopacity. Key parameters included polymer ratios and filler particle size. Materials were assessed based on their flow behaviour, mechanical properties and radiopacity (assessed using x-ray). The use of such heavily filled (60% ZrO_2 by weight) hygroscopic materials then required careful material preparation and handling prior to, and during, the micromoulding process as a moisture content outside a very small range would result in brittle, or incomplete components.

Rheological assessment of the candidate materials was the key to moulding success and previous pioneering research work (6) investigating flow behaviour at very high shear rates (characteristic of this type of geometry) allowed the materials to be tested in environments which were outside the scope of standard testing methods. In addition, these tests showed significant differences between the anticipated and actual flow behaviour, which were used to modify the production process in order to achieve a high quality product.

To achieve the required feature sizes and tolerances, specialized manufacturing techniques were needed to produce the cavity forms for the micromoulding process. Microsystems UK (www.microsystems.uk.com) were selected from the extensive network of companies known to Polymer MNT as the provider of the mould cavities. Off-line surface characterisation techniques were used to verify cavity forms prior to the moulding process.

The product form required the accurate high-pressure and high-speed injection rates offered by one of the Microsystem 50 micromoulding machines available at the Centre which was specifically designed for moulding abrasive materials such as the ZrO_2 composite used in this research. State-of-the-art data acquisition techniques combined with the expertise of the staff within the Centre developed during previous research activities ensured that the optimised process window could be identified and the high aspect ratio cavity was completely filled in a repeatable manner, a feat which previously had been impossible during trials at leading commercial injection moulders.

Once the products had been verified in use over a range of clinical trials, the University worked to develop a production process capable of meeting the required demand for products which involved the design and manufacture of a completely new tooling solution capable of making parts in a fully automated system within an ISO Class 7 clean room environment. With the new system, production rates are typically 3000 components per 6-hour shift.

3. References to the research

1. Whiteside BR, Martyn MT, Coates PD, Greenway G, Allen P, Hornsby P. (2003) Micromoulding: process characteristics and product properties. *Plastics, Rubber and Composites* 32(6): 231-239.

2. Whiteside BR, Martyn MT, Coates PD, Greenway G, Allan PS, Hornsby PR. (2004) Micromoulding: process measurements, product morphology and properties. *Plastics, Rubber and Composites: Macromolecular Engineering* 33(1): 11-17.

3. Whiteside BR, Martyn MT, Coates PD. (2006) Introduction to Micromoulding, in Greener J and Wimberger-Friedl R (eds) *Precision Injection Moulding*. Munich:Carl Hanser Verlag: 239-264.

4. Whiteside BR, Martyn MT, Coates PD. (2005) In-process monitoring of micromoulding-assessment of process variation. *International Polymer Processing* 20(2): 162-169.

5. Whiteside BR, Spares R, Coates PD. (2006) In-process 3D assessment of micromoulding features, in Gorecki C, Asundi AK, Osten W. (eds.) *Proceedings of SPIE 6188*, *Optical Micro- and Nanometrology in Microsystems Technology*. Strasburg, France:SPIE.

6. Kelly AL, Gough T, Whiteside BR, Coates PD. (2009) High shear strain rate rheometry of polymer melts. *Journal of Applied Polymer Science* 114(2): 864-873.

(2), (5), and (6) are the three references best indicating the quality of the work.

The quality of the research is evidenced by the following peer-reviewed and competitive awards:
EPSRC, 2001-2003, *Micromoulding* £229,000, PI Coates.
Yorkshire Forward/ERDF, 2005-2008, *Nanofactory,* £872,000, Contract No. 901117; PI Coates.
DTI, 2006-2009, £753,000, Project No.CHBS/007/00050C, PI Coates.
FP7, 2008-2012, COTECH, £330,000, PI Coates.
ERDF, 2009-2013, *Nanofactory,* £1,124,000 Contact No. 903771. PI Whiteside.

4. Details of the impact

The filled polymeric material manufacturing process developed at Bradford has enabled the introduction of a product that has revolutionised the way root canal treatments are performed (a). The manufacturing techniques pioneered at Bradford are today used to manufacture more than 150,000 points annually using the moulding facilities at the University and the production facility in Sheffield. These are used by orthodontists in the UK and the Netherlands and have received excellent feedback (see testimonials on DRFP's website) (b). The technology has also gained FDA approval in the US. This collaborative research work enabled DRFP to launch its product in 2007 and the company has since grown from three people in 2006 to 12 employees in 2013 based at a dedicated manufacturing facility in Sheffield where the points are coated, packaged and shipped to distributers in the UK, Holland and the USA (c).

There are several reasons why this product has proved so popular: it is much simpler to use than conventional techniques; gives quick, long-lasting results; and gives a better outcome for the patients. In 2007 a three-year clinical trial with annual check-ups for patients was started using *SmartPoint*. Informal feedback based on cases that have been monitored for in excess of three years has indicated the clinical results are good with good healing and no complications (c). A user panel of approximately 20 dentists has been set up to provide feedback on DRFP products. To date, there have been over 1,200 cases documented with 14 failures (retreatment required). This failure rate of approximately 1% compares favourably with typical retreatment/failure rates taken from the literature of 11-30% for endodontic procedures over a 5 year period. The wide variation in the figures can be attributed to the broad range of studies which consider a variety of problems to be treated and conditions of the tooth. Informal feedback from various sources (customers, user panel members, and the clinical trial) (d,e) indicates that patients report low levels of post-operative pain, which was attributed to a less "aggressive" procedure and the good healing attributes of the product. No force is required to compact the obturation point into the prepared canal, which can cause stress inside the tooth. Research studies completed by dentists have also validated the functionality (f) and biocompatibility (g) of the *SmartPoint* solution. The product now has a history of use over five years with proven benefits as demonstrated in leading dentistry journals, and this product is now in increasing demand in a highly risk-averse marketplace.

There has been an increasing demand for the product from the dental community in mainland Europe and UK and the product range has expanded since *SmartPoint* first hit the market in 2008. The products have been refined in this period and now include a radio-opaque coating in addition to the core as a response to the requests of practitioners. The technology has also won numerous awards (h,i,j).

The collaborative work is now concentrating on process scale-up due to recent FDA approval opening up the North American marketplace. Critical to this goal will be a significant increase in core output utilizing multi-cavity tooling with improved process repeatability and better product quality with tighter tolerances. The company continues to work with the University to develop new solutions to the scale up requirement including automated inspection and handling systems to increase quality and throughput.

In addition, company employees are working in the University to manage their own manufacturing process, which is the final stage in the knowledge transfer process. They can configure, run and troubleshoot the manufacturing process with minimal support required and implement their own quality control procedures on site, which has seen significant improvement in product yield throughout the process chain. This allows Bradford University staff more time to spend developing new innovations to improve quality and reduce costs.

In addition, the methods and processes developed during this work have enabled the Centre for Polymer Micro and Nano Technology at the University to explore further applications of these technologies and build bespoke solutions for a range of other companies wishing to develop new micro-injection moulded products. This work has provided significant value as a key case study to showcase our ability to deliver research projects that are near-market and, since this project, we have delivered over 20 new research and development projects with UK-based industrial Partners as a direct result of the knowledge gained during this process. This work has enabled the securing of Industrial R&D-focussed, grant-funded opportunities. Key examples include the ERDF-funded *Nanofactory* programme which included Bradford in a consortium of six Yorkshire-based Universities that has assisted over 100 small and medium enterprises in the region, and the EU FP7 COTECH programme, which was a highly successful 25-partner programme (of which Bradford was a major RTD contributor) that saw the creation of three key technology platforms and eight industrial prototypes (k).

The underpinning research on polymers and the knowledge base available at Bradford has been key to developing and manufacturing the *SmartPoint* device. This device has brought benefits in terms of improved endodontic treatments worldwide. This project has also enabled the Centre to build an effective R&D platform for completion of a range of other programmes with Industrial partners.

5. Sources to corroborate the impact

a. Article in Medical Device Technology "Whiteside BR, Manser P (2009) Micromoulding – the route to a successful product, *Medical Device Technology*, 20(2): 18, 20-1. Online version here: http://www.emdt.co.uk/article/micro-moulding-route-successful-product

b. Product website – www.smart-seal.co.uk

c. Operations manager, DRFP Ltd.

d. *The Dentist*, 26(10): 74, November 2010. Available online at http://www.smart-seal.co.uk/wp-content/uploads/downloads/2013/07/updated-tina-ferguson-case-study.pdf

e. *The Dentist*, 27(1): 62, January 2011. Available online at http://www.smart-seal.co.uk/wp-content/uploads/downloads/2013/07/the-dentist-JAN-2011006.pdf

f. Eid AA, Nikonov SY, Looney SW, Didato A, Niu L, Levin MD, Reuggebberg /fa, Pashley DH, Watanabe I, Tay FR. (2013) *In vitro* biocompatibility evaluation of a root canal filling material that expands on water sorption. *Journal of Endodontics* 39(7): 883-888.

g. Didato A, Ashraf AE, Levin MD, Khan S, Tay FR, Rueggeberg FA. (2013) Time-based lateral hygroscopic expansion of a water-expandable endodontic obturation point. *Journal of Dentistry* 41(9): 796-801.

h. Plastics Industry Awards 2008 Winner - http://www.plasticsawards.com/GJZ97083/2632

i. Medical Design Excellence Award 2011 award for the 'Best Technology Application': http://www.canontradeshows.com/expo/awards/awards/index.php?catId=-1&year=2011&view=View

j. Winner of a European Medical Device Technology Award 2012 in the Dental Instruments or Equipment category. http://www.emdt.co.uk/article/taking-lead-medtech-innovation

k. FP7 Cotech final brochure http://www.fp7-cotech.eu/uploads/media/Cotech_final_brochure_02.pdf