Institution: Wales Institute for Research in Art & Design (Cardiff Met, USW and UWTSD)

Unit of Assessment: 34

Title of case study: Using Product Design Techniques to Improve the Lives of Reconstructive Surgery Patients while Reducing the Cost to the NHS and Tax Payer

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

Over the last 15 years the Medical Applications Group (MAG) has engaged in applied research into the use of product design techniques and technologies in medical procedures. Their work has directly led to better, safer, faster, more accurate and less intrusive surgical procedures. The group has worked with surgeons at NHS hospitals all over the UK to deliver well over 2,000 medical models for surgical use during the period. A number of hospitals have adopted MAG's techniques, meaning that the Group's research has improved the dignity, comfort and quality of life of around two and a half thousand people since 2008 whilst saving the UK tax payer many thousands of pounds.

[Throughout this template, references to underpinning research are numbered **1**-**6**; sources to corroborate are numbered **7**-**15**]

2. Underpinning research (indicative maximum 500 words)

The research base from which MAG grew formed in 1994 with the launch of the Design Engineering Research Centre (DERC), a research institute at Cardiff Metropolitan, now called PDR. At the time, DERC's research focussed on the effective utilisation of rapid prototyping (RP) within the design process. Brown (Director 1994-2012) saw an opportunity to exploit RP in the medical field **[1]**. He formed MAG in 1998 and appointed Bibb to lead it. When Bibb left for Loughborough University in 2008, he handed leadership to Eggbeer.

MAG does not conduct curiosity-driven research. It collaborates closely with medical practitioners and applies the resulting techniques. For this reason much of its research results in impacts on NHS practices. MAG also disseminates its research outside of academic circles; presenting case studies and running training events specifically aimed at medical practitioners and manufacturers **[13, 14, 15]**. Much of their funding comes from device sales to the medical profession, museums and charities, although they also receive funding from, e.g., the TSB/EPSRC and Welsh Government (A4B Knowledge Transfer Centre, see REF5).

MAG's research focuses primarily on maxillofacial reconstruction procedures and new RP-based methods for surgical planning. In a formative phase of the research they developed new facilitative processes to promote more effective communication between clinical and design technologists **[2]**. This culminated in methods to translate medically generated 3D imagery such as Magnetic Resonance Imaging (MRI) or Computerised Tomography scans into a format readable by Computer Aided Design (CAD) Systems.

A second critical breakthrough was in the manipulation of these data. It is virtually impossible to manipulate complex organic forms using traditional CAD input methods. MAG's research into the working practices of prosthetists led them to experiment with new manipulation techniques. Their breakthrough was to 'borrow' technology from the computer gaming industry which uses haptic tools in character creation. Haptic technology allows users to 'feel' and mechanically manipulate items in a virtual environment using a special force-feedback stylus. It has been likened to 'virtual sculpting' and transforms how organic CAD data can be used. For example in the case of a person requiring a plate to rebuild a section of their skull, CAD data from the undamaged side can be 'mirrored' to the damaged side to create a naturally shaped plate. Humans are never symmetrical so further alterations occur via 'sculpting' of the plate for an exact fit, after which fixing points and other design detail can be added. The CAD data are used to digitally manufacture a precise and anatomically correct implant **[4]**.

Together, MAG's methods for translating medical imaging files into CAD data and the means to effectively manipulate them have facilitated the design of products based on organic geometry **[3]** both by MAG and by NHS groups using their techniques. These are the methods that have led to many of the impacts described in 4.

Under Eggbeer's leadership, the original research remit and close clinical collaborations of the group remained while new areas of exploration opened up. For example the group researched exploiting MRI bone density data to create unique anatomical jigs. Using these, surgeons are guaranteed stable, high density anchorage points for prostheses such as artificial ears. MAG has also investigated the use of product design technologies in orthopaedics **[6]** and, most recently, they have begun an investigation into the processes of developing artificial limbs, expanding the reach of both the research and its impact. They are researching the use of non-contact 3D scanning systems to capture anatomical information and ways to merge it with medical imaging data. They expect to use the insights to improve prosthetic limb production leading to similar impacts as have been achieved through their work in the maxillofacial field **[5]**.

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

The underpinning research for this impact case study has been published in double-blind peer reviewed international journals (1, 2, 3, 4, 6) and in an edited book (5). Between 2008 and 2013 the research has attracted competitive research funding in excess of £1.3m and led to the production of medical models and devices for hospitals that has brought in over £750K. The research is also valued by practicing clinicians, and as a result members of the group are often invited to speak about their research at clinically-led conferences and training events.

1. Bibb R, Brown R, "The Application of Computer Aided Product Development Techniques in Medical Modelling" Biomedical Sciences Instrumentation 2000; 36: 319-24, ISSN: 0067-8856, http://www.ncbi.nlm.nih.gov/pubmed/10834252
2. Sugar A, Bibb R, Morris C, Parkhouse J, "The development of a collaborative medical modelling service: organisational and technical considerations" British Journal of Oral & Maxillofacial Surgery 2004; 42: 323-30, ISSN: 0266-4356, http://dx.doi.org/10.1016/j.bjoms.2004.02.025
3. Hughes CW, Page K, Bibb R, Taylor J, Revington P, "The custom-made titanium orbital floor prosthesis in reconstruction for orbital floor fractures" British Journal of Oral and Maxillofacial Surgery 2003; 41(1): 50-3, ISSN: 0266-4356, http://dx.doi.org/10.1016/S0266435602002498
4. Winder RJ, Bibb R, "Medical Rapid Prototyping Technologies: State of the Art and Current Limitations for Application in Oral and Maxillofacial Surgery" Journal of Oral and Maxillofacial Surgery 2005; 63(7): 1006-15, ISSN: 0278-2391, http://dx.doi.org/10.1016/j.joms.2005.03.016
5. Bibb R, "Medical modelling: the application of advanced design and development technologies in medicine", Woodhead Publishing Ltd., Abington Hall, Abington, Cambridge, CB1 6AH, October 2006, ISBN: 1-84569-138-5
6. Eggbeer D, Bibb R, Evans P, "Digital Technologies in Extra-Oral, Soft Tissue, Facial Prosthetics: Current State of the Art", Journal of Maxillofacial Prosthetics & Technology 2007, 10: 9-16, https://repository.cardiffmet.ac.uk/dspace/handle/10369/5079

Selected funding examples

a) £1m TSB/EPSRC grant to work with a large industrial partner to advance the Group's research and application, 2013
b) Funding from the Welsh Government to use the research knowledge to develop new services for industry (Knowledge Transfer Centre "Patient Specific Medical Devices", £340K, 2009-2012)

c) The sale of these devices to hospitals also generated income of £754K which helped to further the research interests of the group

Invited speaking

a) Advanced Digital Technologies in Head and Neck Reconstruction Conference (This conference is the main international forum for collaboration between professionals and industry partners to identify advanced technologies in head and neck reconstruction: http://www.adt-conference.com) 2011
b) The AO Foundation (a medically guided non-profit organisation led by an international group of surgeons specialising in the treatment of trauma and disorders of the musculoskeletal system: http://www.aofoundation.org/Pages/home.aspx)
c) Institute of Maxillofacial Prosthetists and Technologists (IMPT) congress (a professional body that oversees the training, qualifications and practice of Maxillofacial Prosthetists: www.impt.co.uk) 2005; 2010; 2011

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

MAG's research has led to better, safer, faster, more accurate and less intrusive reconstructive surgical procedures. The direct impacts of the research have been:

1. improved dignity, comfort and quality of life for thousands of people and;
2. significant savings for the UK taxpayer.

MAG has worked with 84 hospitals since 2008. At least 2,214 individuals have directly benefitted from their work in the period **[7]** and a further 282 have benefitted from NHS services exploiting processes and techniques pioneered by the group **[8]**. In 2012 alone, MAG provided 550 custom medical models and devices for the NHS, research organisations, charities and museums. They have disseminated their techniques and processes to over 330 individual company and public sector representatives and scoped the potential for bespoke medical device design and production with 198 companies in the period **[9]**.

MAG's impacts are achieved in four ways:

1. by reducing invasive patient interactions;
2. by increasing the speed of delivery of prostheses;
3. by improving quality and consistency of prostheses, and;
4. by reducing cost.

Such impacts are confirmed by surgeons and other clinicians with whom MAG has collaborated in the period **[10**, **11]** and are discussed in more detail below.

MAG's techniques allow digital data to be used both to plan surgery and develop prostheses without the need for patients to repeatedly attend the hospital. This has typically reduced the number of invasive patient interactions from four to one **[10]**. Before MAG's processes became available it was necessary to produce a series of prostheses at ever increasing levels of fidelity until a 'correct' fit was achieved; a process which typically took up to a year to complete. The use of MAG's techniques has reduced this process typically down to six weeks **[11]** because the prosthetic device consistently fits the patient first time. In addition, the production of more accurate prostheses has resulted in a reduction in theatre time for patients. This significantly reduces the risk of infection, another key benefit to patients of methods enabled by MAG.

The accurate positioning of a prosthesis requires a full understanding of the anatomical 'environment' into which it is fitted. Computer Aided Design (CAD) allows this in a way that cannot be achieved by traditional means. MAG's techniques have allowed the production of accurate digital models of a patient's anatomical structure thereby improving the quality and, importantly, the consistency of prostheses. The use of CAD tools has also reduced the 'craft' aspect of prosthetic development thereby facilitating a previously impossible level of consistency of output **[13]**.

In addition to the impact the use of these procedures has had on patients, their introduction has also reduced the amount of time required of surgeons and other medical professionals. This has the effect of reducing the cost of such procedures to the NHS and consequently the UK tax payer. For example, use of MAG's methods has led to a 19% reduction in the cost of delivering an average sized semi-digital cranioplasty when compared with conventional methods **[12]**.

In summary, the impact of the implementation of methods researched and developed by MAG have benefited a combined total of at least 2,496 patients since 2008. The introduction of MAG processes have ensured that prostheses fit accurately and properly first time and reduced each patient's experience of invasive procedures associated with device fitting by, on average, 75%. Each patient has been saved an average of 46 weeks without an implant which equates to more than 2,200 patient years of improved dignity, comfort and quality of life.

Adoption of the methods developed by MAG have enabled the NHS to provide a better service to these patients, more efficiently and at a reduced cost.

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

7. PDR/Cardiff Metropolitan University Invoice Data demonstrating numbers of devices sold
8. Statement from Consultant Maxillofacial Prosthetist / Laboratory Manager, University Hospitals, Coventry and Warwickshire NHS Trust
9. Dorrington P. 2013, Patient-Specific Medical Design Knowledge Transfer Centre, Welsh Government
10. Statement from Consultant Oral & Maxillofacial sugeon, Department of Oral and Maxillofacial Surgery, Craniomaxillofacial Surgery, University Dental Hospital, Cardiff
11. Statement from Chief Maxillofacial Prosthetist, Maxillofacial Unit, Morriston Hospital, Swansea
12. Peel S., 2013, Clay Vs. CAD: Design Processes For Bespoke Implants, 26th Scientific Congress of The Institute Of Maxillofacial Prosthetists and Technologists, 4th-6th September 2013, Inverness, UK
13. Eggbeer D, Evans P, Bibb R, "A Pilot Study in the Application of Texture Relief for Digitally Designed Facial Prostheses", Journal of Engineering in Medicine 2006; 220(6): 705-714, ISSN: 0954-4119, http://dx.doi.org/10.1243/09544119JEIM38