Institution: University of Portsmouth

Unit of Assessment: 12 Aeronautical, Mechanical, Chemical and Manufacturing Engineering

Title of case study: Improved Surgical Practice through Engineering Research

1. Summary of the impact

Long-term fixation integrity is a critical issue in joint replacement surgery that affects both quality of life of patients and the economy. The unique comprehensive study of long-term acetabular cement fixation carried out at the University of Portsmouth has significantly informed orthopaedic surgeons and impacted on their *surgical practice*. In addition, research on a commercial hydrogel implant TRUFIT has informed *clinical and commercial decisions* on the use of the implant for load bearing applications, which has led to the withdrawal of the implant from the global market.

2. Underpinning research

The poor long-term survival rate of cemented acetabular cups in total hip replacements (THR) is a long-standing problem, which is often responsible for revision operations which are at least three times more costly than primary THRs. The Portsmouth team is the *first* in the UK to carry out a systematic study of long-term performance of acetabular fixation by developing a unique physiological testing system, utilising, *for the first time*, CT monitoring of damage evolution and advanced computational modelling [1; also *Tozzi*[1], *Lupton*[1], *Tong*[4]]. We have also carried out comparative studies to evaluate the mechanical performance of some typical cementless acetabular fixations using both experimental and numerical methods [2-4].

Since 2001, the Portsmouth team, led by *Tong*, has been working with orthopaedic surgeons *Hussell* (Consultant Surgeon, Queen Alexandra (QA) Hospital) and *Heaton-Adegbile* (Specialist Registrar, QA Hospital, 2002-2010; Consultant Surgeon, 2011-present, Pilgrim Hospital) on a number of critical issues associated with acetabular loosening in cemented THRs. Specifically, load transfer and stress distribution in cement mantle and near bone-cement interface have been studied, where the effects of clinical parameters such as cement thickness, cup size and cup orientation on stress distribution have been examined [2-4]. Finite element analyses have been carried out to model the reconstructed hip joints, where computer models [1, 5] have been developed from CT images. Fatigue behaviour in cemented acetabular replacements has been carried out on bovine bone samples utilising standard [4] and hip simulator testing [1]. The latter is unique in that it is the *first* of its kind for endurance testing of cement fixation. It has a greater operating envelope than most of the existing simulators for wear testing, incorporating stair climbing and combined loading blocks representative of patient routine activities as well as testing in simulated body fluid to provide the most complete physiological testing regime validated [5] to date. Both numerical and experimental results have revealed, *for the first time*, the dominant failure mode is at the bone-cement interface, and descending stairs is the worst-case scenario in terms of the long-term integrity of the cement fixation. The effect of cement penetration depth, however, is much less influential than previously thought. The research has attracted support from the NHS, MRC, ARC, the Royal Society and the University of Portsmouth, in collaboration with DePuy CMW and Stryker UK and the University of Siegen, Germany, and Beijing Huatuo Biomechanical Laboratory, China [5].

In the last few years, we have carried out collaborative research on the mechanical

performance of a scaffold implant TRUFIT from Smith and Nephew with *Cossey* (Consultant Surgeon, QA Hospital) and *Au* (Senior Scientist, Smith & Nephew), utilising *in situ* micro-CT testing and scanning, digital volume correlation and finite element analysis. The results [6] have shown, for the first time, that whilst the implant has a similar morphology to that of native tissues, it lacks the necessary mechanical strength under physiological loading conditions, hence is unsuitable for load bearing applications, such as in knee repair.

Key researchers:

Tong (Senior Lecturer: 2000-2003; Reader: 2003-2005; Professor: from 2006)
Tozzi (PhD: 2008-2011; Research Associate: 2011-2013; Lecturer: 2013-present)
Lupton (Research Officer/Fellow: 2001-present)
Zhang, QH (Research Associate/Fellow: 2008-present)
Heaton-Adegbile (Specialist Registrar: 2002-2010; Visiting Lecturer of UoP: 2005-present; Consultant Surgeon: 2011-present)
Hussell (Consultant Surgeon; Honorary Lecturer: 2001-present)
Cossey (Consultant Surgeon; Visiting Senior Lecturer: 2008-present)

3. References to the research

1.*N P Zant, P Heaton-Adegbile and J Tong (2008). In-vitro fatigue failure of cemented acetabular replacements: a hip simulator study, *J Biomech Eng*, Trans ASME, 130 (2), 021019. DOI: 10.1115/1.2904466
2. P Heaton-Adegbile (2005). In-vitro assessment of load transfers and strain distribution across the cement-bone and bone-implant interfaces in artificially replaced acetabulum, PhD thesis. *Available on request.*
3. P Heaton-Adegbile, B Russery, L Taylor and J Tong (2006). Failure of an uncemented acetabular prosthesis - a case study, Engineering Failure Analysis, 13, 163-169. DOI: 10.1016/j.engfailanal.2004.10.010
4.* P Heaton-Adegbile, N P Zant and J Tong (2006). In-vitro fatigue behaviour of a cemented acetabular reconstruction. J Biomech. 39, 2882-2886.
DOI: 10.1016/j.jbiomech.2005.10.010
5.* Q-H Zhang, J-Y Wang, C Lupton, P Heaton-Adegbile, J Tong, Z-X Guo, Q Liu (2010). A subject-specific pelvic bone model and its application to cemented acetabular replacements. *J Biomech*. 43(14), 2722-2727. DOI: 10.1016/j.jbiomech.2010.06.023 (*ZhangQH*[1])
6. K Madi, G Tozzi, Q-H Zhang, J Tong, D Hollis, F Hild (2013). Computation of full-field displacements in a scaffold implant using digital volume correlation and finite element analysis, *Medical Engineering and Physics*, 35(9) 1298– 1312.
DOI: 10.1016/j.medengphy.2013.02.001

* Papers that best indicate the quality of the underpinning research

Related external grants:

• Tong & Hussell: Towards Improved Long-term Fixation in Cemented Acetabular Cups. Arthritis Research UK (17192), £84,353. (2006-2008)
• Tong: Modelling of Implanted Acetabula.

Royal Society Research Grant (23872), £9,717. (2003-2004)
• Tong: Interface Behaviour in Artificially Replaced Acetabula.
Medical Research Council (63824), £52,069. (2003-2004)
• Tong: Load Transfer and Stress Distribution in Artificially Replaced Acetabula.
NHS Research Fund, £18,000. (2002-2005)
• Tong: Investigation of Bone-Cement Interfacial Properties. Collaboration with University of Siegen. British Council/DAAD; also in-kind support from University of Siegen. (2009-2011)

4. Details of the impact

THR is one of the most successful surgical procedures, although the long-term survival rate of cemented acetabular cup implants is a main life-limiting factor leading to costly revisions. More than 80,000 hip replacement operations were performed in England and Wales in 2011, where 54% were either total or partially cemented. The current revision rate for such operations is about 11%, with aseptic loosening identified as the number one reason cited for revision (National Joint Registry, 2012). A revision operation costs more than 3 times as much as a primary THR. In 2011 a total of 3502 cases were revised due to aseptic loosening at a total cost of £63 million. The increase in life expectancy and ageing population are expected to make osteoarthritis the fourth leading cause of disability by the year 2020 (Bulletin of the World Health Organization), this will inevitably lead to more THRs hence *research towards improving long-term survival rates of primary THRs thereby reducing revisions* will have a considerable impact on both *health* and *economy*.

As the first comprehensive study of long-term fixation integrity of acetabular implants in the UK, our research has provided timely and critical information for the orthopaedic research community, especially for surgeons we have collaborated with, as testified by their letters. The research has also been disseminated to regional/national, European and international orthopaedic research community through clinical meetings and scientific conferences, including Wessex Deanery R&D conferences, British Orthopaedic Research Society, International Medical Symposia and the International Society for Technology in Arthroplasty, as well as in publications in high impact international journals. These have had a significant impact on *surgical practice*, particularly in highlighting the factors that affect the long-term stability of acetabular implants in THRs (*Heaton-Adegbile; Hussell*). The research has prompted interdisciplinary explorations and contributed significantly to the decisions made by surgeons in selecting particular implants to use with a varied cohort of patients in surgical practice.

One particular subject we looked at was a Birmingham hip resurfacing component, which is essentially a metal-on-metal articulation. At the time of considerable excitement over this type of implants, we were amongst those who cast some doubts and reported the weaknesses in this type of implants, citing high bone-implant interfacial stresses and high contact stresses on the articular surfaces, which may ultimately result in wear and wear particles being released into the peri-articular tissue [2, 3]. As a result of our study, the Portsmouth NHS orthopaedic surgeons stayed away from this type of implants, which has since been officially withdrawn from the global market on the advice of the Medical Health Regulatory Advisory Committee.

Our research on cup alignments and angulation [2, 5] has also directly impacted on

surgical practice, as patients with an abnormal cup position would result in abnormally high stresses leading to impingement, earlier implant failure and higher revision surgery rates, hence ensuring the correct cup position is crucial in primary THRs. Finite element studies on optimum cement thickness confirmed, for the first time, that beyond a certain cement mantle thickness there was no benefit to cement fixation, which is often a misunderstood concept by practicing surgeons. The information has provided *an excellent foundation for educating junior trainee registrars and fellow consultant surgeons* on the effective use of cement in THRs. More recently, following a seminar talk given by *Tong* to a clinical research meeting at the QA hospital, a possible joint MSc Course on Orthopaedic Methods has been suggested by the surgeons (*Stapley, Hand*), with an aim to utilise the latest research outcomes like this immediately and systematically in surgical training and practice.

Tissue engineering repair of articular cartilage in synovial joints represents a potential osteoarthritis treatment strategy superior to current surgical solutions such as total/partial knee replacements. Research aims at using artificial scaffolds to repair localised osteochondral damage, although these scaffolds must have sufficient mechanical properties until the native tissues grow back; hence pre-clinical assessments are vital to obtain such information. Our research on TRUFIT implant, a product of Smith & Nephew, has produced the first series of comprehensive results on its mechanical properties under physiological loading conditions. Our results show that the implant in its current state is unsuitable for use in weight bearing applications, such as in knees, due to its insufficient mechanical strength. Smith & Nephew has since *withdrawn* this product from the market. The information has also been disseminated through meetings/conferences, which has further informed the clinical community in changing knee treatment strategies; and the prosthesis manufacturers in future scaffold designs for such applications.

5. Sources to corroborate the impact

1. National Joint Registry, 9th annual report, 2012 (http://www.njrcentre.org.uk/njrcentre/Portals/0/Documents/England/Reports/9th_annual_report/NJR%209th%20Annual%20Report%202012.pdf) (Current THR statistics, including cemented THRs and revision rates)
2. ARC press release (*Available on request*)
3. Contact from Consultant Orthopaedic Surgeon, Queen Alexandra Hospital, on impact of orthopaedic research at Portsmouth on surgical practice.
4. Contact from industry: Senior Scientist, Smith & Nephew Inc., on impact of orthopaedic research UoP on TRUFIT implant and its withdrawal from commercial market.
5. Letter from Consultant Orthopaedic Surgeon, Pilgrim Hospital, on impact of orthopaedic research at Portsmouth on surgical training and practice.
6. Letter from Consultant Orthopaedic Surgeon, Queen Alexandra Hospital, on impact of orthopaedic research at Portsmouth on TRUFIT implant and its withdrawal from load-bearing application.