Institution: Queen's University, Belfast

Unit of Assessment: 12

Title of case study: Precision Techniques for Hip Joint Replacement Surgery Improves Quality of Life for over 10,000 Patients

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

Over 100,000 hip joint replacements are performed each year in the UK. **The correct restoration of joint centre is critical to the successful outcome of total hip replacements.** Failure to do so results in dislocation, increased wear and leg length discrepancy.

In collaboration with QUB, **over 4,000 patient-specific *custom hip prostheses* were manufactured and implanted at Musgrave Park Hospital, Belfast, leading to accurate restoration of anatomical joint centre**.

As a consequence a **new surgical instrument has been developed and utilised in more than 4,000 surgeries**. Surgical costs are reduced compared to the alternative of computer-aided surgery. The **DePuy Synthes Companies are funding the development of a** later version of this **surgical instrument**

2. Underpinning research (indicative maximum 500 words)

The founding work of Professor John Orr (JFO) in the mid-1990's established Queen's University Belfast at the forefront of innovation in fixation of total hip replacements and related surgical procedures. Central to this was the pioneering work on photo-elastic measurement of strain in hip joints, which addressed the contemporary problems of hip stem fracture and led to standardised test methodology (BS ISO 7206-4:2010). JFO was **awarded the prestigious Samuel Haughton Silver Medal in 2002 by the Royal Academy of Medicine in Ireland** as acknowledgment of his outstanding contribution to this field [1].

JFO's ongoing research collaboration with Professor David Beverland (DEB), Consultant Orthopaedic Surgeon at Musgrave Park Hospital (MPH) Belfast led to him being appointed as Honorary Professor within the School of Mechanical and Aerospace Engineering in 2011. **Professor Beverland is a member of a development group of 10 world leading orthopaedic surgeons who advise DePuy Synthes on clinical aspects of their hip joint development strategy.** For example, DEB was one of the first surgeons to recognise issues relating to the DePuy ASR hip prior to its highly publicised product recall in 2010.

The JFO-DEB collaboration attracted **DePuy Synthes to locate the world's first custom hip joint factory in Belfast in the mid 1990s.** Over 4,000 custom hips were precision manufactured on-site to exactly fit the unique anatomical geometries of every patient. Custom hip replacements were implanted over a 15 year period, with 5 and 10 and 15 year follow-ups providing clear evidence of success and low revision rates [2]. As a consequence of surgeons' requirement to make informed decision regarding hip joint fixation a PhD project (research student Nicholas Dunne, supervised by JFO, 1993-1996) was undertaken in association with the hip joint factory at MPH. This work led to reproducible cement mantle thickness for customised hips at MPH, a crucial step in implant survivorship.

In a strategic move to further strengthen joint replacement research at QUB, Professor Fraser Buchanan (FJB) was recruited in 1998 and then Dr Nicholas Dunne (NJD) in 2003. FJB had studied degradation of polymers used in hip joint replacements; which complimented the research activities of JFO. They have published joint work that finally **shed light on understanding the biggest worldwide issue for the orthopaedic device industry- hip joint wear.** Between them they discovered that the wear process was a multi-factorial problem relating to patient gait [3] and the polymer degradation processes [4]. NJD is an **internationally leading authority on cement fixation technologies for total hip replacements** [5].

In association with JFO (a trustee) the Belfast Arthroplasty Research Trust (BART) has been established (2001) to support clinically relevant research with DEB's surgical team at MPH. The Trust has appointed its own two research staff (both previously completed PhDs under supervision of JFO, FJB and NJD) and fully funded two PhDs at QUB (supervisors JFO, FJB; NJD, A Lennon). **This successful clinical/academic collaboration has contributed to the development of a new surgical device for restoration of hip centre** focussing on the femoral component of the total hip joint [6]. Furthermore research focussing on the acetabular (pelvic bone) component has identified a novel device to allow the surgeon to choose and record operative inclination accurately during total hip arthroplasty surgery [7]. This has significant potential to reduce hip joint dislocations.

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

Key Journal Outputs

1. Orr JF, Images from Waves- Photoelastic Modelling of Bones, Irish Journal of Medical Science, 2003, 127 (4) 209-213.
2. O'Brien S, Wilson RK, Hanratty BM, Thompson NW, Wallace ME, Nixon JR, Engela DW, Orr JF, Isaac GH, Beverland DE. The cemented custom femoral stem-a 10 year review, Hip International, 2007; 17(4):194-204.
3. *****Bennett D, Orr JF, Beverland DE, Baker R, The Influence of Shape and sliding Distance of Femoral Head Movment Loci on the Wear of Acetabular Cups in Total Hip Arthroplasty, Proceedings of IMech E Part H, 2002, 216, 393-402. **Awarded IMechE Professional Engineering Publishing Prize.** DOI: 10.1243/095441102321032184
4. The Effect of Patient Gait on the Material Properties of UHMWPE in Hip Replacements; Davey, S.M., Orr, J.F., Buchanan, F.J., Nixon, J.R., Bennett, D., Biomaterials, 26 (24), 4993-5001 (2005). DOI: 10.1016/j.biomaterials.2005.01.007
5. *****Dunne NJ, Orr JF, Development of a Computer Model to Predict Pressure Generation Around Hip Replacement Stems, Proceedings of IMechE Part H, 2000, 214, 645-658. **Awarded IMechE Medical Engineering Duncan Dowson Prize**. DOI: 10.1243/0954411001535679
6. *****Hill JC, Salazar-Torres JJ, Orr JF, Pooler Archbold HA and Beverland DE, A Low-Cost Solution for the Restoration of Femoral Head Centre during Total Hip Arthroplasty, 2013, doi: 10.1177/0954411913482438
7. Sykes AM, Hill JC, Beverland DE, Orr JF, A novel device to measure acetabular inclination with patients in lateral decubitus, Hip Int. 2012; 22(6):683-9. doi: 10.5301/HIP.2012.10292.

*Best 3 outputs

Key Funding

- Buchanan FJ, Orr JF and Nixon J. 1998-2001, Ageing and Characterisation of UHMWPE for Hip Replacements, Department of Trade and Industry, CAM12, £141,000
- Orr JF, Buchanan FJ. PhD Studentship and associated costs, BART, £50,000, 2009-2012
- Orr JF, Inter-Trade Ireland Fusion 2010-2012, Hip Fracture Fixation Device, SOTA Orthopaedics Ltd, £64,000. Irish Times Inter-Trade Ireland Award-**Best North/South Fusion Programme (2012)**
- Buchanan, FJ, Orr JF. Inter-Trade Ireland Fusion 2010-2012, Non-Destructive Test Method for UHMWPE used in Total Hip Replacements, QUB-Outsource, £64,000 (DePuy Synthes, Cork)
- Dunne NJ, Lennon, A, Orr JF. PhD Studentship and associated costs, BART, £110,000, 2013-2016

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

Since 2008 impact has been on an international scale with close collaborations having been developed with major multinational medical device company DePuy Synthes (Johnson & Johnson), the largest, most comprehensive orthopaedic and neurological business in the world. New surgical techniques being disseminated to the international orthopaedic community. Furthermore the research can be related to current and future improved quality of life for patients undergoing orthopaedic surgery.

Custom Hip Technology

The aim of the custom hip factory was to enhance survival outcomes of total hip replacements through restoration of natural geometries, biomechanics and fixation. **Over 4,000 custom hip joints were implanted during a 15 year period, commencing in 1991.** The hip joint factory (consisting of precision CAD/CAM manufacturing tools and two full time staff, employed by DePuy Synthes) in association with DEB's surgical team **consistently achieved hip joint placement within 6mm of natural joint centre.** Joint placement tolerance of 10mm and above is perceptible to the patient and was the standard achieved for conventional hip joint replacement surgery over the same period.

The aims have been realised and outcomes continue 20 years on from the first joints being implanted. **The major impacts being on patients' qualities of life and confidence in their activities to maintain employment and leisure pursuits.** A 10 year outcomes review indicated 77% of patients were still living in 2008 and, of the 464 cases reviewed, **only 2.2% had required full revision surgeries within the review period** compared to rates of 10% revision reported elsewhere [3]. Of the 23% of review cases that had deceased prior to 2008, all died with a functioning total hip replacement in situ [reference 2, section 3].

Surgical Device Development

Instrumentation originally designed to facilitate accurate placement of custom hip implants continues to be used and developed by the QUB team to **reduce the incidences of leg length inequalities.** In the majority of cases, it is the misplacement of the femoral component that results in a clinically significant leg length discrepancy. This can transform an excellent clinical result with respect to range of motion, pain relief and function into a surgical failure due to patient dissatisfaction. **Leg length inequality, particularly a long operated leg, is also the most common source of litigation following joint replacement in the United States** [4] and fourth most common in the UK.

Through use of a calliper measurement instrument, **improvements in leg length discrepancy have been achieved and demonstrated.** The first generation calliper has been used in **over 4,000 conventional hip replacement surgeries since 2005** (over 2,000 since 2008). This device achieves placements within 6mm of target measurements and below the level of patient perception. This has been through collaboration with DePuy Synthes, Leeds, UK, who have provided long-term funding and technical support.

The third generation calliper has now been designed and is based on the same fundamental principles as the first generation device. Prototypes have been both manufactured and laboratory validated using QUB facilities. This project is now in partnership with DePuy Synthes, who have provided funding in the region of £115,000 for its development. **The benefit of the third generation device is that it is independent of hip joint design, therefore can be used for placement of any design produced by any manufacturer. Once the design is finalised,** it will undergo clinical trials with the eventual aim of launching the device to their entire hip joint replacement market.

The only alternative to using the calliper is computer-aided surgery (CAS) for assisting the surgeon in achieving correct component placement. However, the added cost and increase in theatre time have inhibited widespread take-up of CAS. Therefore **the calliper technology is the only economical and clinical proven method to achieve accurate component placement on a repeatable basis.**

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

1. Two Musgrave Park Hospital Orthopaedic Surgeons, directly involved in QUB collaborative developments

2. DePuy Synthes (Johnson & Johnson), Head of Hip Replacement Development, involved in industrial funding and commercial developments

3. Typical revision rate for joint replacements: http://orthoinfo.aaos.org/topic.cfm?topic=A00510

4. Report of litigation relating to leg length discrepancy http://www2.aaos.org/bulletin/apr06/orm2.asp