New Age Materials for Custom Acetabular Cages

As part of the patient-specific custom implant service, Bioengineering provided three custom tri-flanged acetabular cages in 2006. These custom cages were made for patients whose degree of acetabular damage precluded the use of commercially available cages. They were designed using the familiar techniques of CT imaging, 3D reconstruction and modelling, but the manufacturing method was new.

Recent advances in rapid manufacturing techniques allow the production of complex geometry in metal directly from computer data. Selective Laser Melting (SLM) is one such process, which has only very recently been applied to medical grade titanium alloys (Ti6Al7Nb). SLM uses a high intensity laser beam to selectively melt areas of a layer of metal powder into the desired shape. A new layer of powder is then laid down and the process repeated. Minor finishing steps, including heat treatment, machining of critical geometry such as screw holes, and cleaning up are all that is needed to produce the final implantable article. SLM was developed by a German company (MCP-HEK) who have made all the cages so far. The University of Western Australia is acquiring a unit that one-day may be able to produce items locally. As SLM is a new technique, only recently used for medical grade alloys, there has been a considerable amount of metallurgical assessment done on the material. Optimised heat treatment was developed at RPH and the RPH solution treatment and aging procedure applied prior to implantation of the cages. Future cooperative work planned with MCP-HEK includes reducing the porosity/ash content and improving microstructural control.

The three cages were implanted by Professor David Wood to treat massive pelvic defects. They are the first use of SLM in a total joint prosthesis, with only one previous implant (a bone plate) worldwide. There is great potential for the further application of SLM to patient specific orthopaedic implants and there are clear, identified avenues of research to improve the design and quality of the material. Work continues.

5000th Implant for Bioengineering

A major milestone was recently reached with the 5000th implant referred to our retrieval laboratory. The Bioengineering retrieval service has been in operation at Royal Perth Hospital now for more than 30 years and is unique in Australia in terms of size of the implant collection, level of reporting and history. In world terms, very few retrieval laboratories exist that are aligned to a major public hospital and therefore independent of commercial influences.

In a climate of increased accountability of device selection, the value of implant retrieval analysis to alert the orthopaedic community to poorly performing implants as well as providing feedback on successful designs, is essential.

Thanks to all the surgeons who support the retrieval service, and every endeavour will be made to continue to provide useful feedback on all referred devices.
Refobacin Plus - A New Antibiotic Bone Cement

Antibiotic bone cements have increased in popularity as a complementary treatment to systemically administered antibiotics for peri-prosthetic infection. One successful application of antibiotic bone cement is in the 2-stage revision of infected arthroplasties using antibiotic-loaded spacers, with the advantage of direct antibiotic delivery to the site of infection.

The mechanisms by which the antibiotic is released from the bone cement (PMMA) is still largely undefined. It is believed that the antibiotic is first released directly from the surface and subsequently flows from interconnecting voids and cracks through the cement rather than by a diffusion process.

Refobacin Plus (Biomet) contains gentamicin and is essentially a high viscosity bone cement, but has an initial low viscosity to allow for vacuum mixing and adequate delivery.

1. Elution Studies

Static and dynamic tests were performed on hand and vacuum mixed cement samples to determine gentamicin release over time. Refobacin Plus was compared with CMW3 Gentamicin (De Puy), which is currently used with the RPH hip spacer.

The findings are summarised as follows:

- For CMW3, there is an initial burst release of gentamicin (first day) with minimal release thereafter.
- Refobacin also has a burst release of gentamicin in the first 24 hours but, in contrast to CMW3, the gentamicin steadily releases over a long period. The concentration of gentamicin after 8 weeks is ~9 times higher than the concentration after 1 day and ~16 times higher than CMW3.
- Vacuum-mixed Refobacin showed better gentamicin release than the hand-mixed samples.
- The dynamic elution tests showed similar trends with greater release of gentamicin from Refobacin compared to CMW3.

2. Mechanical Tests (ISO 5833)

The mechanical properties of Refobacin Plus were determined using shear, compression and bending tests. Results were compared with previous laboratory studies and published values of other cements.

In summary, Refobacin bone cement has excellent elution characteristics and is superior to CMW3 for both the total amount of gentamicin release and the time over which the release occurs. The mechanical properties of Refobacin Plus compare favourably to other bone cements. We are currently evaluating this cement for use in the RPH Hip Spacer.

Charnley Wear Project

As part of our ongoing program to investigate series of implants in our retrieval collection, the wear characteristics of all Charnley low friction arthroplasties were analysed. 120 acetabular components were analysed using a coordinate measuring machine. (we acknowledge Rio Tinto for its use)

Determining the historical wear rate of the Charnley implant and analysis of contributory effects on wear, including, patient activity level, weight, age and sex, were of particular interest. Each of these factors, requested on the Bioengineering retrieval form, were required for inclusion in the study.

Of interest is that our collection includes 3 devices in situ for more than 30 years and 30 for more than 20 years!!

This is a work in progress, however it is interesting to note that the amount of wear cannot be easily predicted for an individual patient given the factors studied, as it is a probability phenomenon resulting in a considerable range in wear rates. We also found that recording the activity level as high, low or mobility with aids, at the time of retrieval did not describe the variation in the wear data either. In conclusion, time in situ, has the strongest correlation with wear, as expected, followed by sex and to a much lesser extent weight, age and activity level. Considering the age of device and the polyethylene being non-crosslinked and irradiated in air, we recorded a relatively low average wear rate of 0.16mm/yr.

In summary, the data is most useful as a reference, whereby measurements on alternative arthroplasties can be compared to determine wear performance.
A major study is under way to assess newly available nails from Synthes, Smith & Nephew and Stryker. This study originated from a retrieval analysis of 8 fractured PFN nails that failed via a fatigue mechanism. They account for a 2% failure rate and were reported to RPH surgeons in 2006. At that time neither the newer PFNA (Synthes, Europe), nor the similar TFN (USA), which claimed superior fatigue properties, were available in Australia (The PFNA is now in use). The work to assess these nails has been subdivided into:

- Fatigue strength - pure uni-axial cyclic loading to failure;
- Cut-out strength - the resistance of the lag screw to prevent femoral head varus and retroversion and subsequent cut-out – important given new single lag screw designs;
- Rotational stability - the ability of the lag screws to resist rotational forces;
- Clinical trial of nails - proposed to be carried out at RPH.

The laboratory studies should be completed in April.

**Footnote:** We were recently asked to assist in the removal of a failed PFNA (new design). As such, we now have a removal tool to reliably retrieve fractured PFNA's.

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**Device Alert!!**

**Fractured Tibial Stem and Fin Punch**

A tibial stem and fin punch (Smith & Nephew) used for knee replacement surgery, fractured in situ resulting in a significant section of the device lodged in the patient’s tibial canal. The incident was discovered after post-op x-rays. A replacement punch set supplied by S&N, also appeared destined for failure, with a pronounced hairline circumferential fracture at the identical location.

**Observations**

- **Fractured Punch**
  
  A 2cm section of the punch cleanly fractured along a weld zone approximately 2mm from the runout of the fins. It appears the punch had been modified to accommodate a longer punch end. The weld zone was poor with minimal penetration (~ 20% of cross sectional area) and not likely to sustain the predicted loading regimes. There were no indications of possible user error.

- **Replacement Punch**
  
  A replacement punch exhibited a fine circumferential crack in the same location. A dye penetrant crack test was performed to highlight the crack (see above). X-ray imaging of the intact punch suggests a likely after market modification. It is apparent that the construction is inadequate for the intended usage. Poor welding of the punch end extension to the punch housing provides a preferred crack path.

  The potential for failure of this device in its current form is high with possible adverse clinical outcomes, related to the retained metal and elevated metal ion release.

**Recommendation**

A report was sent to the TGA device incident reporting section with a recommendation “that all Smith and Nephew tibial stem and fin punches of similar design be immediately withdrawn from clinical use”. We have subsequently been advised that Smith & Nephew in conjunction with the TGA have initiated a world wide recall.
To Resurface or not to Resurface?

We worked collaboratively with Dr. Pat Campbell, (Director Implant Retrieval Lab, Orthopaedic Hospital, Los Angeles CA) in 2006 and were fortunate to have her give a seminar in January on Metal-on-Metal surface arthroplasties (MMSA). The Orthopaedic Hospital has a particular interest in these components with Prof. Amstutz and Prof. Schmalzried pioneers in the area. The seminar addressed the risks and concerns of resurfacing arthroplasty. It is difficult to summarise the seminar, however Pat’s presentation of over 100 retrieved resurfacings concluded with:

- Success of resurfacings are dependent on surgeon experience as the arthroplasty is not forgiving in surgical technique.
- There is a steep learning curve and malpositioned resurfacings are certain to fail.
- Careful patient selection is critical to the devices success, less successful in women and patients >65yrs;
- Cementing technique to avoid leaving the implant proud, and reducing the amount of cement in the heads is essential;
- Metal ion release is an issue, especially in young females where the resurfacing is not recommended.

We were privileged to have such an eminent person visiting us who gave a comprehensive coverage of the MMSA topic.

Screws ain’t Screws

A common referral to our laboratory is bone screws that have fractured during insertion, often with a question - is this part of a faulty batch?

A protocol based on the implant standards (AS 2255-03, ISO 6475-89) is used to measure the breaking torque and angle of rotation of the screws. Non-compliance for breaking torque and angle of rotation, as listed in the standard, can indicate poor batch quality and requires follow up with the TGA and the manufacturer.

Beside material or design factors, screw failure can also be due to sub-optimal screw insertion techniques involving drilling and tapping and patient related factors such as hard bone which can increase insertion torque.

Recent evaluations of both Synthes and S&N cortical and cancellous screws, revealed implant standard compliance for all screws. Of interest was that the 3.5mm cortical screws achieved higher breaking torques than the 4mm cancellous screws, principally due to their larger core diameter.

Please send any problem bone screws with a referral form for our attention.

Papers in Publication

Kop, A.M, Whitewood, C, Johnston, J.L, Damage of Oxinium TM femoral heads subsequent to hip arthroplasty dislocation – Three Retrieval Case Studies. Accepted for publication in J Arthroplasty

Kop, A.M, Swarts, E, Selection of primary hip and knee arthroplasty for public hospitals in Western Australia: A clinical evidence approach. ANZ J. Surg. 2006; 76: 1068–1074


Kop, A.M, Swarts, E, Quantifying polyethylene degradation in mobile bearing knees: A retrieval analysis of the Anterior-Posterior-Glide (APG) and Rotating Platform (RP) Low Contact Stress (LCS) knee. Accepted for publication in Acta Orthop Scan.

Plastic ‘not so fantastic’ - Polyethylene (UHMWPE) Alert!

It should be noted that UHMWPE components inserted pre-1998 are most likely sterilised in air and are therefore susceptible to oxidative degradation. This may vary from mild yellowing with minimal component degradation to extensive delamination, cracking and severe wear. In a recent Bulletin article we discussed the potential for ‘wear through’ of thin tibial inserts that were sterilised in air. To avoid potential adverse outcomes such as severe metallosis, osteolysis and component fracture, it may be necessary to monitor all arthroplasty patients with UHMWPE components implanted prior to 1998. Signs of severe wear or osteolysis may indicate intervention. Thin UHMWPE knee inserts are particularly at risk.

SNIPPETS

New Staff

David Morrison commenced work in Bioengineering in July. 2006. His principle responsibility is the set-up of the RPH Single-Use-Device re-manufacturing facility but he will also work on other projects. His previous biomaterials experience was at the Lions Eye Institute, where he worked on artificial corneas and other polymeric-based devices for ophthalmology. David has a BSc (Hons) in Industrial Chemistry and a PhD in biocompatible polymers from UNSW. So far, David has contributed to research on the kinetics of antibiotic release from bone cements and helped devise a new method for testing composite wheelchair cushions.

We also welcome Audrey Loo to the Bioengineering team, as a clerical assistant. Audrey has already greatly assisted in clearing the backlog of implant related, filing and database entry. She has a wide range of experience gained from working in a number of departments in the hospital over a period of 10 years.

Current Projects

- Evaluation of Proximal Femoral Nails.
- Metal sensitivity and its effect on the corrosion of biomaterials.
- Fracture Toughness determination of biomaterials using the Small Punch Test.
- Evaluation of implantable SLM titanium alloys.

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