Bioengineering Bulletin

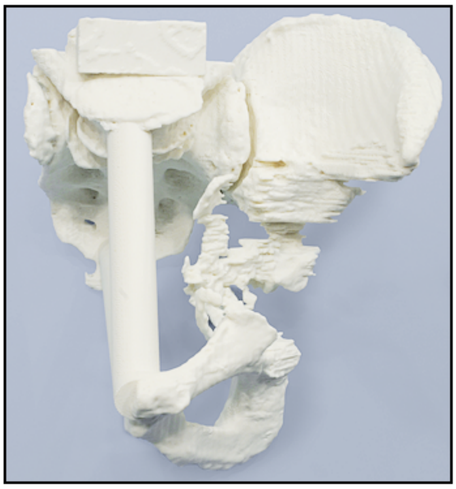
Department of Medical Engineering and Physics Royal Perth Hospital March 2010

Welcome to the 2010 Bulletin. A summary of the work carried out in the Biomaterials Laboratory over the past year is presented. We welcome any feedback or requests for further information.

Rapid Prototyping Service

The Department recently purchased a 3D printer which has the capacity not only to aid in design processes, but produce functional parts from ABS plastic. Our use has included the in-house production of surgical planning models, to facilitate the design of custom devices and produce functional moulds for cranioplasty manufacture.

To date, surgical planning models for pelvic reconstruction and scoliotic spines have been made. The models can be used for pre-planning but it is also possible to sterilise the models (Ethylene Oxide) and access them in theatre. Using data from a fine-slice CT, it is possible to construct anatomically accurate models showing the region of interest. Existing implants *(in situ)* can be included in the 3D model or excluded, leaving only the extant bone.



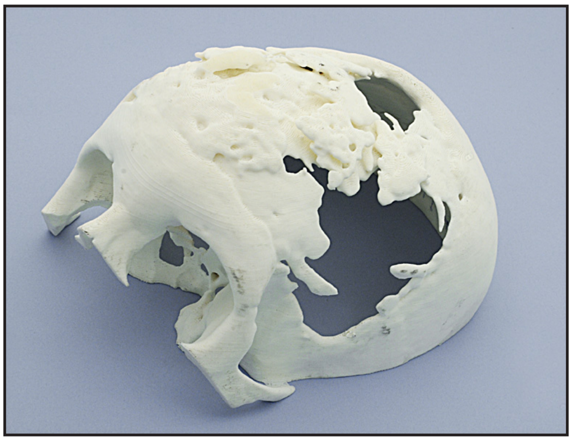
Hemi-pelvis model with strut

Spine model with support material

Spine model

The capacity of the printer is such that we can produce models as large as a full pelvis and as long as a femur with a resolution of 0.25mm. Printing times range from 8 to 36 hours, depending on the size of the model. The model is initially produced with support material which is subsequently dissolved away in a mildly basic solution.

The printer is also in routine use for our custom cranioplasty service. A 3D model of the cranial deficit is generated from fine slice CT data and then printed. A reconstruction plate, based on the existing anatomy, is computer-designed and then a printed mould for creating the plate is made. The titanium plate is hydrostatically pressed into the mould and after finishing, checked against the 3D deficit model for fit.

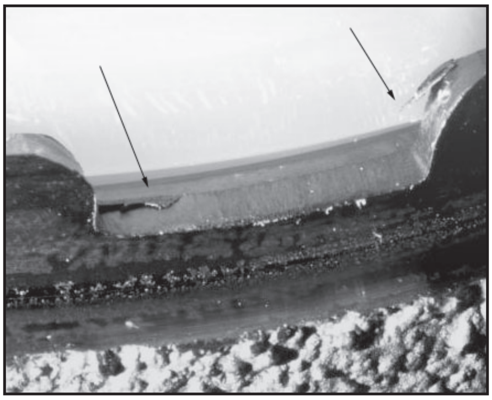


ABS Model for cranioplasty planning

The modelling service is now well established and it is possible to generate models and design custom implants in a reasonably short time frame – the turnaround time is often dependant on the quality of the CT data available to model the anatomy. Ideally, a fine-slice CT should be requested when a surgical planning model or custom implant is required. If you wish to access the service please contact Bioengineering.

Trident Shell Quality Issues

A recent Trident shell retrieval illustrates the process involved to prompt action from both the regularity authority (TGA) and the manufacturer. In this case, macro examination of the shell, retrieved because of loosening and infection, revealed metal shards and burrs around the removal slots. Their presence is indicative of poor manufacturing and a lack of quality control, rather than damage caused from removal.



Machining artifacts in removal slot

Of most concern was a metal fragment embedded in the liner. Re- examination of 14 retrieved Trident shells showed embedded metal fragments in four of the liners and machining artefacts on four of the shells. The suggestion that poor machining on the shell may be a source of embedded metal in the liner and debris in the surrounding tissue is a real possibility. Scanning electron microscopy studies are necessary to confirm this.

An incident report sent to the TGA prompted a "please explain" from the manufacturer. The response of the manufacturer was of interest. They replied: "*no material or manufacturing non-conformances have been identified after inspection of 200 components, however a number of initiatives have been set in place*, *namely:*

- *The deburring section of the machining procedures will be reviewed and improved.*
- *A visual standards team has been initiated plant wide.*
- *A study will be undertaken to assess the ability of personnel to determine defects.*
- *All manufacturing team members will be trained on the visual standards requirements."*

Only time will tell if these initiatives are successful. In the meantime, rigorous inspection (under 10x magnification) of consignment stock is recommended.

Corail Stem Retrievals

Recent retrieved Corail stems have shown good bony attachment to the hydroxyapatite (HA) coating. As this is our largest collection of fully coated HA stems, the extent and location of bone ongrowth as well as the amount of HA resorption was examined. 16 Corail stems were included in the study, 10 of which were combined with ASR acetabular components. The average time in situ: 1.2yrs.

Observations

- The major reasons for removal was loosening (44%) and infection (25%).
- High loosening rate attributed to ASR metal-on-metal heads also noted in the 2009 *Australian Joint Registry*.
- Greater bone attachment distally than proximally. No correlation between distal or proximal bone ongrowth with time.
- No significant difference in amount of HA resorption, distal or proximal – weak correlation with time.
- Bone ongrowth occurs on all surfaces although rarely in the proximal calcar region.
- Bone ongrowth commences very early.
- Bone preferentially deposits in the grooves of the stem.

Distal bone ongrowth

Summary

There appears excellent bone ongrowth to the Corail HA stems, with more bone attached distally. The main reason for revision is complication with the acetabular components particularly the metal-on-metal articulations, rather than the stem.

Metal-on-Metal Bearings:
How effective?

The increase in use of metal-on-metal (MoM) bearings over the past 5 years has been dramatic. The claimed advantages of low wear and reduced dislocation risk should be balanced against increased metal ion release and generation of fine metal wear particles. The *Australian Joint Registry* (2009) identified MoM bearings, in particular ASR (DePuy) and Durom (Zimmer) resurfacings, as having higher than average revision rates. In 2008, the FDA issued a recall on Durom cups because of unacceptable loosening rates.

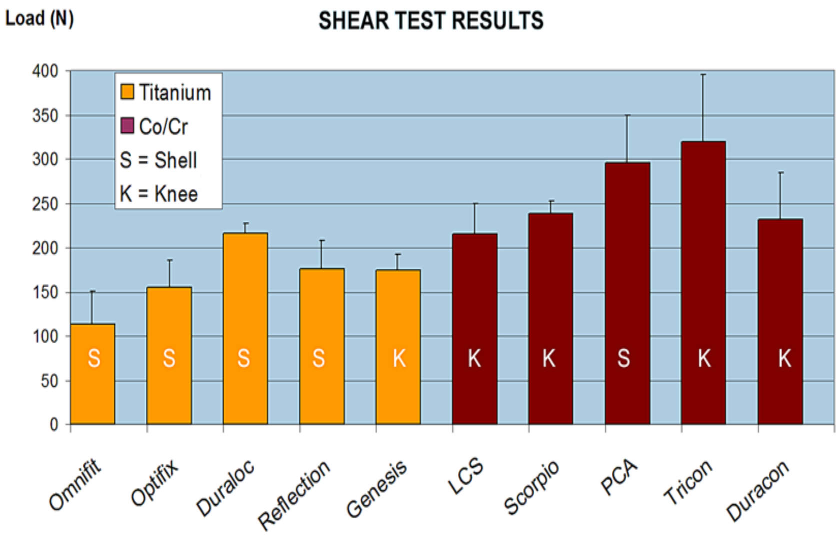
Durom and ASR MoM bearings sent for analysis, show high rates of loosening (41%), extensive wear markings on the articular surfaces, and fine corrosion pitting near the rim of the heads. All components are Co-Cr-Mo alloy but differ in composition and manufacturing (cast or forged). Some of the microstructures revealed carbide precipitation at the grain boundaries – features that can affect wear and mechanical performance. Some questions remain:

- What is the cause of fine corrosion pitting on the bearing surfaces despite excellent in vitro corrosion resistance?
- What is the relationship between metal hypersensitivity, osteolysis and implant failure (loosening, infection)?
- Is there a correlation with increased reporting of pseudotumours or ALVAL with usage of MoM bearings?

Bead Shedding

Bead shedding is not an uncommon complication with porous coated arthroplasties. Bead loss varies between designs and components. In our implant retrieval collection, 42% of Omnifit shells (Dual Geometry), 36% of Optifix shells and 27% of LCS knees demonstrated bead shedding.

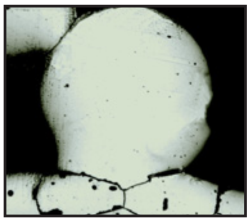
Shear Tests: The shear load to failure at the bead-substrate interface was determined for a range of retrievals using a high strength indentor and an Instron materials testing machine.



Acetabular liner with embedded beads

Shell with missing beads

Bead shear testing



Poorly sintered beads

Both Omnifit and Optifix shells which have high rates of bead loss, recorded the lowest shear load to failure. Bead-substrate contact area ranged between 5-30% for all components, however there was only a weak correlation with shear load. A correlation between bead size and bead contact area was noted, with the larger the bead size the greater the bead-substrate contact area. Overall there appears higher resistance to shear with cobalt–chromium beads compared to titanium beads.

Metallurgical Features:

- *Co-Cr beads:* poor sintering, carbides prominent at the grain boundaries, voids and cracks at the bead-substrate interface.
- *Titanium beads:* poor fusion of the beads, cracks and voids at the interface. Localised heating effects noted as microhardness at the interface was consistently less then at the substrate.

Component loosening also plays a significant role in bead shedding. 86% of the retrieved Omnifit shells with bead loss were noted to be loose or had minimal bone ingrowth.

Trabecular Titanium - a solution to bead shedding?

Trabecular surface

Lima have utilised electron beam melting technology (EBM) in the design of the new trabecular titanium Delta acetabular cup. The cup is built up by melting titanium alloy powder layer by layer. The ability to produce a porous surface fully integrated wtih the substrate is a novel way of avoiding problems associated with poor interface strength (ie. bead shedding). As with many new devices, candidate evaluation was undertaken to test the claims of the manufacturer and provide an unbiased assessment of quality.

Summary

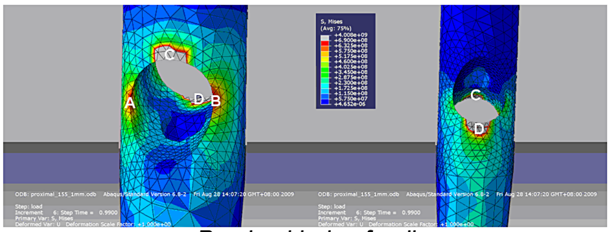
- The material composition and corrosion properties are similar to other Ti-6Al-4V medical devices.
- The microstructure is acceptable and though imperfections such as melt defects and porosities were observed, they are possibly less of a problem in low fatigue risk devices.
- Microhardness values are similar to implant grade Ti-6Al-4V. However, suitability for load bearing implant applications can only be determined with further tensile and fatigue testing.
- Shear strength at the trabecular interface was low; however the trabecular structure deformed rather than fractured off like beads.

Recent shear strength studies (highlighted above) indicate the need for improved quality control in terms of bead application. The use of EBM technology to produce continuous porous structures may be a viable alternative. EBM can also be used for custom device manufacture, particularly for implants with complex geometries.

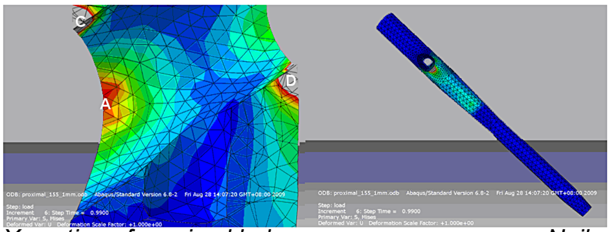
RPH Tough Nail

Fractured proximal femoral nails have been reported in previous bulletins. As a consequence, an evaluation of new nails was undertaken. As they did not show superior fatigue resistance, it was decided to design a nail with a significantly improved fatigue life. The design constraints included not wanting to significantly increase the proximal diameter of the nail or decrease the lag screw diameter. To achieve this, we engaged a specialist Finite Element Analysis Engineer who put many designs through their paces. An optimised geometry is currently being manufactured and tested. We are confident that using medical grade high nitrogen stainless steel will also improve the fatigue life.

We hope to produce a nail which can withstand higher than normal loads (high demand patients) and one that can survive for a longer period of time. We aim to have the nail routinely available by years end.



Proximal hole of nail



X-section of proximal hole *Nail*

White = Highest stress Blue = Lowest stress

Tissue Engineering

In recent times there has been great interest in tissue engineering as a means of regenerating diseased or traumatised tissue to restore function. The number of scientific articles and conferences is burgeoning, with a huge research effort both in the United States and throughout Europe. In fact, the Netherlands has a national program in Regenerative Medicine and Tissue Engineering. With this background, Bioengineering has embarked on a new program in tissue engineering.

There are many interesting developments in ceramic, polymeric and metallic materials, which can be used as biomimetic scaffolds. Our involvement centres on our experience with the production of biocompatible materials that can be manufactured in a form suitable for cell inoculation, proliferation and differentiation. This work is being carried out in conjunction with Cell and Tissue Therapy WA (RPH) who have TGA approved production processes for cells and cellular therapies.

Scientific Articles 2008/2009

Kop A, Swarts, E, Corrosion of a Hip Stem With a Modular Neck Taper Junction, A Retrieval Study of 16 Cases.
J Arthroplasty. 2009

Jones N.L., Day R.E., Kop A.M., Sercombe T.B. Heat Treatment of Ti-6Al-7Nb Components Produced by Selective Laser Melting.
Rapid Prototyping Journal, 2008.

Swarts, E, Kop, A, Jones, N, Keogh, C, Miller, S, Yates, P, Microstructural features in fractured high nitrogen stainless steel hip prostheses: A retrieval study of polished, tapered femoral stems.
Journal of Biomed Mater Res A. 2008.

L Lam, K Stoffel, A Kop, E Swarts, Neck fracture in 4-cobalt-alloy hip arthroplasty femoral components.
Acta Orthop. 2008.

SNIPPETS

Tenders:

Bioengineering has again been asked to participate in the new hip and knee tender for the public hospitals of WA. Our role is to provide unbiased technical advice and aid in compliance testing of tendered devices. Interestingly some of the devices not chosen for inclusion in 2004, have subsequently been reported to have problems, which gives weight to the selection of devices based upon at least 5yrs clinical follow up.

New Faces:

We recently welcomed Anastasia Nilsaroya for a short period covering long service leave. Anastasia comes to us from the Uni of NSW and has been working on polymers for tissue engineering. We also had the services of Mechanical Engineer Chris Jiajie who worked for 3 months on the finite element modelling of the RPH tough nail.

Retrievals:

Just an update when sending tissue for metal ion determination. In many cases following metal analysis, it is useful to send the remaining tissue attached to the retrieval for further histo work. Can you please send a signed Path West form to accompany the tissue.

Contact us: 9224 2500

trevor.jones@health.wa.gov.au

Bioengineering Staff:

Trevor Jones
Alan Kop
Eric Swarts
Rob Day
David Morrison
Susan Miller
Cathie Keogh