Welcome to the 2008 Bulletin. A snapshot of the work carried out in the Biomaterials Laboratory over the past year is presented. We welcome any feedback or requests for further information.

Implant Tracking and Contract Compliance

In late 2007, a request was made to Bioengineering by Health Corporate Network to look at public hospital compliance with the 2004 primary hip and knee contract. The Implant Tracking module, available in all major public hospitals in Western Australia, allows tracking of implants by linking the unique patient medical record number to the implant components, procedure, operation date and hospital, for both insertion and removal events. A useful application is the monitoring of implant trends as illustrated by the plot for hip stem insertions at RPH/SPC.

By focusing on the period 2004 to present, performance in accord with the contract could be assessed. All hip and knee insertion events for RPH/SPC, SCGH and Fremantle Hospitals were accessed via an implant activity report generated for the contract period. Data for the three hospitals is illustrated.

- Compliance with the hip and knee contract approximates 70%. This appears a good result especially considering:
  - this is the first time such a comprehensive tender has been conducted;
  - there is a need to accommodate a patient’s specific implant requirements outside the contract scope, and
  - the competitive nature of implant marketing and the large number of new designs/innovations being offered.

- The three hip stems that significantly affected contract compliance were Accolade (RPH), Secur-Fit (RPH) and CPCS (SCGH). These items were not selected in the 2004 tender because they either failed to meet the 5 year clinical history requirement or had insufficient clinical data. Similarly, the PFC knee (RPH, FH) was not included in the contract.

- Surgeon preference and historical alignment between implant type and hospitals appear to influence contract compliance.

Implant tracking is not only beneficial in evaluating implant trends and contract compliance but can also assist in determining aspects of implant performance including longevity, failure rates and monitoring technology driven changes in arthroplasty usage.

“We can’t make any judgement on a joint until its been in use for a good 5 years” – Mr Roger Smith, secretary of the British Orthopaedic Association.
Proximal Nail Study
Following on from a report in our last bulletin, the laboratory evaluation of four proximal femoral nails has now been completed. The study initiated from a retrieval analysis of 8 fractured proximal femoral nails (Synthes PFN), that demonstrated poor fatigue properties. With the interest of the Department of Orthopaedics (RPH), Synthes (PFNA), Stryker (Gamma 3) and Smith and Nephew (Trigen, Intertan) nails were compared to the superseded PFN (Synthes) intramedullary device.

Testing was conducted in three areas:
• cut out resistance, the most important clinical failure mode,
• rotational stability, which is claimed to often initiate cut out,
• fatigue, being the mechanism of failure in 8 PFN retrievals.

No single nail was superior across all tests compared to the PFN; however this does not necessarily equate to an inferior clinical performance, as the new generation nails are based upon a different clinical philosophy. All the new generation nails have single element femoral head/neck fixation, which has reported advantages including, simplification/ease of clinical use, less bone removal/destruction, an integrated anti-rotation/sliding capability with or without locking, and the potential for minimally invasive surgery.

Cutout resistance results show a large variation due to manufacturers using test conditions favourable to their implant, as such, all nails were tested supported (complete neck fracture apposition) and unsupported (neck fracture gap - the worst case scenario). Both the Gamma 3 and Trigen Intertan performed well when compared to the PFN, whilst the PFNA was inferior when tested unsupported but similar to the Trigen Intertan and Gamma 3 in the supported test case. Of interest are several clinically noted instances of axial cut out of the PFNA blade, which were predicted by the unsupported test.

Fatigue studies confirmed that none of the nails were as strong when compared to the PFN even when manufactured from stainless steel. This was expected, as the cross-sectional area in the region of the proximal lag screw, where all PFN failures had occurred, was smaller for all new generation nails. There does not appear any scientific evidence to support this reduction in dimensions, other than claims of facilitating minimally invasive surgery, minimisation of incision length, and less bone removal. Albeit, when used strictly in accordance to the companies indications, and for patients who readily heal, (thus early load sharing), all new nails will most likely have adequate fatigue strength. For the more difficult cases, eg. large statue patients, prophylactic tumour treatment, or impaired/compromised healing, a design trial is currently under way in Bioengineering to produce a higher strength custom device.

Rotational stability testing was conducted as it has been reported that varus collapse may initiate via neck/head rotation. None of the new nails out performed the PFN with its 2-element fixation. The Trigen Intertan with its interlocking screw design was superior to the PFNA with the standard Gamma 3 design significantly poorer, however the Gamma 3 with U-blade, which adds an anti-rotation element to the lag screw, performed similarly to the PFNA.

In summary, the laboratory testing elucidated the mechanical performance of the nails in vitro, highlighting advantages and weaknesses in design. None of the nails were superior in all tests when compared to the PFN, however a planned clinical evaluation at RPH should ensure the most appropriate nail/s are selected for clinical use.
The Margron Story

The Margron implant was introduced in 1997 with great interest due to its unique femoral stem with differential threads and modular neck component. Clinical advantages of the proximal neck design are intraoperative adjustment of leg length via the neck-head taper and femoral anteversion via the neck-stem taper with the aim of optimising the patients’ biomechanics. However, the take up of the arthroplasty has been limited and Australian registry results show 10.6% cumulative revision at 5 years, with revision 3 times more likely than other cementless stems. Implants sent to RPH have predominantly been revised due to pain and loosening; however recent observations of Margron components have revealed another problem, namely extensive fretting and crevice corrosion at the stem-neck tapered joint. This is of concern as fretting and crevice corrosion can lead to the generation of soluble and particulate debris that migrate locally or systemically and may contribute to periprosthetic osteolysis. The laboratory study demonstrated that despite an optimal taper design, (being a large taper to maximise construct stiffness and minimise fretting) and use of proven corrosion resistance alloys, that increased modularity can lead to fretting and crevice corrosion. Furthermore this may result in significant metal ion generation and particulate debris.

Bone School

The Bioengineering Division was back in the classroom in 2007 with a series of 8 lectures commissioned by Prof. Allan Skirving for the Bone School. The topics ranged from the most basic (what is a force?) to cutting edge biomechanics and biomaterials.

The course aimed to prepare Registrars for their exams while still providing broad background knowledge. This difficult task was made harder by the variation of experience among the Registrars. This should be less of an issue when the new training scheme is introduced, as everyone will take the course at the same point in their training.

We hope to improve the course and make it more relevant to the needs of the whole orthopaedic community. One suggestion was a series of refresher lectures for practising surgeons, to keep them abreast of recent developments. If anyone is interested in this idea, please contact the Division.

Preservation Unicompartmental Knees

Recently an increasing number of Preservation Uni-compartmental knee arthroplasties (UKA) have been received for retrieval analysis. As a consequence, we decided to collate all the retrieval data (n=19) in order to determine if there were common failure modes. All the devices were cemented, with an average patient age of 78 years and implantation time of 2.2 yrs. We found a high incidence of component loosening, particularly femoral loosening, with approximately equal numbers of mobile and fixed bearing Preservation UKA’s. In contrast, the AOA registry showed double the revision rate of the mobile bearing UKA’s compared to the fixed UKA’s, with implantation of the mobile knee significantly reducing since 2002. Unfortunately, the Australian registry does not publish reasons for removal, however in a recent publication by Mariani et al. (J Arthroplasty, vol 22, 6, 2007), there was a 40% failure rate reported for fixed Preservation UKA’s due to femoral loosening (n=39), which correlates with our retrieval findings. Literature suggests that the extended femoral component may allow increased flexion, which in turn promotes edge loading and pushes the femoral component off the end of the femur. A lateral X-ray in maximum flexion was found to be useful in ascertaining femoral loosening. Given the usage of Preservation UKA’s (n=108) in the public system, we are likely to see more retrievals.

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<tr>
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New Instron Biaxial Testing Machine

A new Instron 8874 servo-hydraulic materials testing machine has been commissioned, replacing the much larger Instron 1341, which after 20 years of faithful testing has finally surrendered to the digital age. This servo-hydraulic testing machine will be ideal for axial-torsional cyclic and static testing of biomedical, advanced materials and manufactured components. The new controller also facilitates the use of ‘gait’ loading patterns. An obvious application will be cut out testing of intramedullary nails where both torsional and axial forces can be applied, which will better simulate the biomechanics in vivo. The design of a high-strength custom proximal femoral nail is currently in progress.

From the sublime to the ridiculous

Bioengineering tested its smallest bones ever in 2007. Researchers at the Molecular Bone Biology Laboratory (Concord Repatriation Hospital) and the Centre for Cancer Research & Cell Biology (Queen’s University, Belfast) have developed a transgenic mouse to study bone formation, particularly targeting osteoporosis. The genetic manipulations changed the bone structure, but did it change the strength?

Neither group had expertise in bone mechanics so RPH Bioengineering was asked to measure the strength of their mouse tibiae. These averaged 15 mm long, 5mm shorter than the previous record rat tibiae, and as such we had to develop a new 3 point bending rig for testing such tiny bones.

Even our small Instron, familiar to generations of Registrars, produces 10kN; much greater than the 10–15 N breaking strength of the tibiae. Just loading such small bones without breaking them was a challenge. The effort proved worthwhile, with highly significant differences in both strength and stiffness between the groups.

In contrast, the strongest bones we have ever tested were equine pasterns, which broke at over 80kN.

Conferences 2007/08

- EPSM (Engineering and Physical Sciences in Medicine - Fremantle)
  - Day, R. Complex Acetabular Reconstruction using SLM
  - Day, R. Iontophoresis
  - Swarts, E. Implant Surveillance
  - Kop, A. Biomechanical Evaluation of Intramedullary Devices
- SLM Users Group (Germany)
  - Day, R. Complex Acetabular Reconstruction using SLM
- AOA Continuing Education (Sydney)
  - Day, R. Iontophoresis
- 8th World Biomaterials Congress (The Netherlands)
  - Swarts, E. Evaluating Implant Performance using Implant Tracking and Retrieval Analysis

SNIPPETS

New Staff:
Ting Phila recently joined us as a Laboratory Technician to cover for Susan Miller who is currently on maternity leave. Ting has extensive research experience having worked at the UWA School of Medicine & Pharmacology, Pathwest and Clinical Physics (RPH).

Jessica Down is another addition to the Bioengineering team. She is a graduate Mechanical Engineer from UWA. Apart from assisting in laboratory work, Jessica will be investigating the mechanical properties of titanium alloys produced by the Selective Laser Melting technique. These alloys and production method are currently used in custom implant devices, principally custom acetabular cages.

Grant Success:
Rob Day, David Wood & Roger Price (Medical Technology & Physics at SCGH) have received NH&MRC funding to extend the iontophoresis technique developed by Megson, Day and Wood. Iontophoresis appears to protect cortical allografts from peri-operative infection (JBJS Br 88(11) & 88(9)). This project, as part of Rob’s PhD studies, proposes a new way to load antibiotics into bone that could be cheaper and easier than iontophoresis.

Custom Devices & TGA Compliance:
Bioengineering is working towards full compliance with the TGA Regulations for custom devices. The changes in paperwork are mainly internal, with a focus on Design and Failure Modes and Effects Analysis and meeting the 14 essential principles for manufacture. However it is now also critical to have a signed consultation form for all custom devices prior to delivery.

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