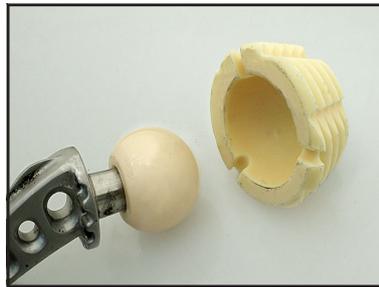


Welcome to the Third Bulletin!

Included in this edition is a snapshot of the work carried out in Bioengineering during 2003. As in past Bulletins, we hope to continue to provide items of orthopaedic interest. Your feedback is always welcome.

Autophor Cups - Removal Difficulty

Many of the retrieved Autophor (Mittlemeier) alumina cups received in our laboratory, have been fractured to facilitate removal. It is well known that the cups are difficult to remove, and it appears from discussions with company representatives and surgeons, that this is the preferred removal method. Our concern is that it is almost impossible to remove all the ceramic debris.



Embedded alumina



Worn femoral head

A recent Richards Reflection acetabular retrieval highlights this problem. The components had been insitu for just over 3 years and had previously replaced a loose Autophor cup. Stereomicroscopy revealed two distinct particles, suspected to be alumina, as well as fine metal debris embedded into the polyethylene bearing surface. Severe wear of the femoral head was noted near the apex and was consistent with the location of the particles. Scanning electron microscopy and energy dispersive X-ray analysis confirmed the particles to be Al_2O_3 (alumina).

The presence of alumina particles not removed during previous revision surgery contributed to 3rd body wear damage of both the liner and the femoral head. In consultation with a surgeon with long term experience in Autophor cup removal, the following is recommended:

- Expose the acetabular shell in the normal manner.
- Use the modified Stryker removal tool. If the shell is relatively loose it should turn out.
- If well fixed, then carefully 'drill out' the bone/fibrous tissue attached in the grooves of the shell, following the taper of the cone and re-try the removal tool. Several attempts may be necessary. Patience and persistence is the key !
- Preferably revise to a ceramic on ceramic arthroplasty.

Changing the Guard

It is with mixed feelings that I have passed the reins to a new Principal Bioengineer, Trevor Jones



(inset). Great pleasure, because I know TJ will do

a great job based on his invaluable experience with the Hospital and some pain because it is nearly 35 years since we started the 'experiment' called Bioengineering, under the tutorage of Sir George Bedbrook, Bill Gilmore and others. There are many exciting challenges (including survival) and I am fortunate that as Head of Department I am still in a position to mentor (some would say interfere with) Bioengineering to further improve its contribution to R&D, patient services and the advance of orthopaedics and rehabilitation in WA. An early initiative was to rename the Department to that of "Medical Engineering & Physics", a change that was well received by the Hospital and which reflects the prime role that engineering science has in the specialised mix of disciplines that make up the Department. Importantly, we are still well connected clinically and needless to say, my door is always open.



Merry Christmas
and a
Happy New Year
from
Bioengineering



Cemex System - Another integrated mixing system !

The long term success of cement fixation is largely attributed to choice of cement and cementing technique. Contemporary cementing techniques incorporating cement pressurisation, vacuum mixing and low viscosity cements have superior cement penetration, mechanical interlock and cement strength compared to the traditional hand-mixed techniques. Cementing systems, such as Boneloc and Cemex systems, feature clever innovations to reduce monomer

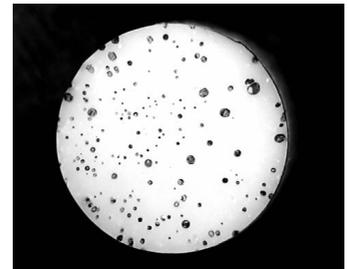


exposure and cement handling. Unfortunately, Boneloc did not live up to its attractive tag of “revolutionary, fully integrated, touch-free mixing system” because of poor mechanical properties.

A laboratory investigation of Cemex bone cement that was mixed in a “hands free” integrated system, showed

significantly lower tensile and shear strengths compared to vacuum mixed cements previously tested in this laboratory. Compared to hand mixed cements, Cemex had similar tensile strength but lower shear strength. Given the mechanical results, it was not surprising to observe high porosity values in the sectioned Cemex samples. The average porosity value of 5% is comparable with hand-mixed cements.

Despite some advantages of a fully integrated system, the Cemex system could only be considered as an alternative to hand-mixed cements. Its high porosity values and lower mechanical properties, makes it inferior to contemporary vacuum mixed/low viscosity cementing systems.

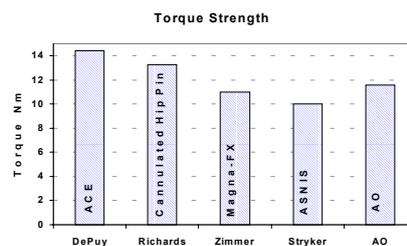
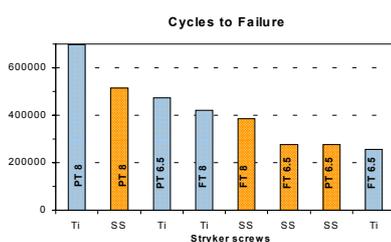


Cemex porosity (5%)

SCFE SCREW - What Choice ?

The main goals of treatment in slipped capital femoral epiphysis (SCFE) are to stabilise the epiphysis, prevent slippage and obtain epiphyseal fusion without avascular necrosis or chondrolysis. Despite the safety and efficacy of screw fixation, several problems are common including screw fracture and difficulty in screw removal. After some local misadventures, including screw fracture, it was decided to review SCFE screws.

A fatigue study focused on the Asnis screws (Stryker) in current clinical use and a screw removal study of 5 screw brands was conducted. The following graph shows that the 8mm-diameter titanium alloy screws have a greater fatigue life compared with the stainless steel screws and those partially threaded out performed the fully threaded screws.



Note: PT – Partially Threaded, FT – Fully Threaded, 8- ϕ 8mm screw, 6.5- ϕ 6.5mm screw, Titanium-ISO5832-3, Stainless ISO5832-1

The Ace screw (DePuy) showed the highest torque to failure, similar to the Cannulated Hip Pin (Richards) whilst in contrast, the driver stripped out the hex head for the Asnis (Stryker), AO and Magna-FX (Zimmer) screws. Fracture and difficulty in screw removal can be a complication of SCFE treatment. A partially threaded screw with an external hex drive and titanium alloy affords the greatest overall strength. In contrast, partially threaded screws manufactured from titanium can be difficult to remove. Whilst we haven't yet found the best screw, we have demonstrated the significant differences in those available. Work on the SCFE screw problem is continuing.

New Kids on the Block

Presently we are hosting *Rochelle Nicholls*, Post Doctoral Researcher with Prof. Markus Kuster at Fremantle. Rochelle has a newly minted PhD from UWA investigating ball-bat interaction in baseball using Finite Element Analysis (FEA). She will be using these skills with Prof. Kuster to investigate soft tissue balance in the knee after arthroplasty. Rochelle has been at RPH to gain some hands-on experience with bioengineering.

* * * * *

Kasia Michalak joined Bioengineering earlier this year to work in the area of bone chemical supplementation. The project, which will investigate the efficacy of iontophoresis for cancellous bone, is being funded from a WAIMR grant via the Perth Orthopaedic Institute (Prof Wood) over a 2 year period. Kasia completed her combined science/engineering degree at UWA and was most recently working at the Australian Research Centre for Medical Engineering - Murdoch University.

Clinical Ventures

Nail Removal

Occasionally a simple nail removal can be anything but! A recent case proved no exception. A previous removal attempt had failed to appreciate a fracture of the nail at the most distal of the proximal locking holes. During surgery, only the top end of the nail was removed, and unfortunately was not kept for future reference/sizing.

After exhaustive attempts with a long hook, a new purpose built mandrel and shear pin was successful in removing the nail. This design can be used for all cannulated nails. The procedure which took almost 4hrs was the most difficult nail Mr Croser had ever removed. Bioengineering now has an extensive tool kit for difficult metal removal. The take home messages are:

- report all fractured devices
- on several occasions this year, fractured devices evident on X-ray have not been reported which has led to surgical difficulties.
- if a device breaks, send any fractured components to Bioengineering for identification and planning subsequent removal procedures.
- when dealing with a difficult fractured device, consult Bioengineering as we may have had experience with the removal of a similar device.

A Charnley too long

Some 'on the bench' planning aided in cutting down a Charnley hip stem to fit a revision knee component. Many techniques were trialed, but it was a combination of drilling with a titanium nitride coated drill and a side cutting burr which Mr Wren used in the successful 'pruning' exercise. The burr in isolation would have taken considerably longer and generated more heat and debris.

Titanium – no worries

Titanium alloys are traditionally difficult to drill because they work harden. Drilling, tapping and insertion of a cross locking bolt was successfully done insitu on a custom built humerus by Prof. David Wood recently. Together with technical experience, the use of titanium nitride coated drills and taps made the job possible.

Surgical Models

Surgical planning models continue to be requested and have proved invaluable in spinal, acetabular reconstruction and hip revision cases. Even though we have sought prices and deliveries in the eastern states to perform the actual model making (stereolithography), a Perth company Solid Concepts continues to produce the models at relatively low cost and turnaround times of 2-3days.

Custom Devices

It has been the busiest year for custom devices in the history of the Bioengineering. This is partly due to the provision of a custom cranioplasty plate service, which has seen nine cases this year. The plates have ranged from palm to hand size. The same manufacturing technique (hydraulic pressing of 0.6mm titanium plate) can be used to create an exoskeleton for orthopaedic tumour cases.

The RPH compression nail continues to be used for knee fusion and non-union cases, with a retrograde femoral nail recently being used by Mr Beaver, which has added to the variants available.

The RPH Hip spacer ('Dick on the stick') has also been in demand and is now manufactured with a PEEK stem.

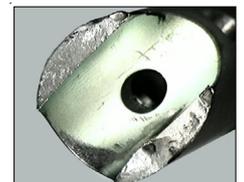


The use of a proven biocompatible polymer of superior properties is seen as a significant step forward.

See Bulletin No. 2. for full details.

Retrieval Incidents - Fractured PFN Nails

The AO/ASIF proximal femoral nail (PFN) is a relatively new addition to the range of intramedullary devices used to treat unstable proximal femoral fractures, and compares favourably to other intramedullary devices such as the Gamma nail and the IMHS. In the past year, 3 fractured PFN nails have been referred to our implant retrieval and analysis programme for failure analysis. Two nails fractured through the proximal neck screw shaft after 10 months *in situ*, the other fractured through the locking bolt hole, distally after two months *in situ*. Delayed union and high patient activity levels were associated with some of the failures.



Minimal Sectional Area

Fatigue was indicated in all failures, with distinct "beach" marks on the fracture surfaces. All fractures were initiated at regions of high stress concentration and of minimal cross-sectional area. Fracture through the femoral neck screw shaft, showed similarities with a recent IHMS nail failure (Bulletin No 1). Common to both designs is the large diameter of the femoral neck screw hole. This has resulted in minimal cross-sectional area in the region, 30% for the PFN and 42% for the IMHS, leading to susceptibility to fatigue and/or overload failure. Recent *in vitro* studies performed in our laboratory have not yet replicated the failure mechanism. In the meantime a cautionary approach is warranted, particularly if high activity levels or delayed union is likely, or the patient is a significant fall risk.

Smith & Nephew Trauma Devices -

How do they compare?

With the long term success of the Synthes/AO trauma devices, many manufacturers now have comparable designs, leading to many choices for the clinician. Often price may influence the choice of a particular device, however implant quality and performance should always be the deciding factor. As part of the quality assurance program of Bioengineering (RPH), it has become a regular practice to evaluate new devices prior to their clinical use. A selection from the Smith & Nephew TC-100 screw and plating system were subjected to a standard range of tests to assess quality and standard compliance.

All devices complied with implant standard requirements covering packaging, labelling, marking, dimensional tolerances and microstructure. A microstructural feature that required further investigation was the apparent non-uniform grain size and hardness differential between the head and shaft of the cortical screw. To determine any mechanical deficiency, the



torsional strength of ten screws was tested. All exceeded the requirements for torque strength and rotation angle. The corrosion profiles were typical of 316L stainless steel devices and are considered acceptable for temporary implants. All the devices complied with the relevant implant standards for metal composition.

In summary, the components comply with the relevant standards and are similar to implants currently used in this hospital in terms of material composition and design. Given the clinical success of AO/Synthes devices over a long period, it would be reasonable to assume the Smith and Nephew devices evaluated in this study would perform likewise.

Hip and Knee Tender

Representatives from Bioengineering have recently been invited to be part of a committee to formulate a tender for hip and knee arthroplasties used in the public hospitals over the next five years. We are looking forward to being involved in the process along with Senior Surgeons from the teaching hospitals and Health Department representatives.

Zirconia - Revisited

Even though there has been a worldwide recall of the zirconia ceramic heads manufactured by Saint Gobain in France there is still much interest in the material from a bioceramic viewpoint. Especially given the recent moves to introduce zirconia toughened alumina (ZTA) ceramics into the local market. There certainly is much promise with the new ZTA ceramics that combine the best properties from both alumina and zirconia. We are at present awaiting the supply of product for further analysis.

Trident – Continued....

Following the report in the last Bulletin and our submission to the TGA, we have a written response. To recap, there can be a problem when using the Trident ceramic system, in that the acetabular shells are relatively thin and can deform during insertion causing non-fitment of the liners. The TGA has recommended that the surgical instructions be amended; *'Use caution when inserting the Trident shell. Over reaming by 1 mm is recommended when dense, hard, sclerotic bone is encountered. This will still achieve a secure fit. In any case some care during impaction is required to avoid distortion of the relatively thin acetabular shell.'* The story continues with a recent FDA recall; *'The ball retaining sleeve on the Trident Insert Impactor can possibly disassemble'* (all impactors have been changed in WA). We are presently investigating the smaller Trident shells following reports of surgical difficulty. Watch this space...

World Biomaterials Congress

The 7th World Biomaterials Congress will be held 16-21 May 2004 in Sydney (Darling Harbour), the premier biomaterials conference. Several papers have been submitted and it is hoped that there will be representation from the Bioengineering Division. We encourage others to attend with several symposia of direct relevance to orthopaedics.



2003 Research Projects

- Fixation of proximal humeral fractures. (Mr Kitson, Mr Day)
- DePuy LCS tribology study. (Mr Harker, Mr Johnston Mr Swarts, Dr Kop)
- Bone chemical supplementation. (Prof Wood, Mr Day, Miss Michalak)
- Investigation of the Trident hip prosthesis design. (Mr Collopy, Dr Kop)
- SCFE Screws. (Mr Whitewood, Dr Kop)
- Analysis of PFN failures. (Mr Swarts, Dr Kop)
- Rigidity of intramedullary PEEK nails, a comparative study. (Dr Erak)
- Biomechanical comparison of the LCP for the distal radius. (Dr Lim)
- Establishment of an FTIR procedure for oxidation analysis of polyethylene. (Mrs Miller, Mr Swarts, Mr Day)

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