INTRODUCTION

Welcome to the first Bioengineering Bulletin! Our intention is to report on items of interest arising from our retrieval service and research activities. We plan to release the bulletin biannually and look forward to any comments or queries.

Implant tracking and retrieval

The ability to track critical devices, including joint replacement, from supply to disposal is required under recent Therapeutic Goods Administration (TGA) determinations. This requirement is being integrated into the next upgrade of the Theatre Management System (TMS) at RPH, with the intent that all explanted devices will be routinely referred to the Biomaterials lab for analysis. Ultimately, referrals from all hospitals through similar TMS’s will greatly improve the accuracy of retrieval information and properly reflect state-wide practice. In the meantime, we continue to encourage all surgeons to send all devices for analysis and reporting, particularly those that have been damaged or failed. Over the 25 yrs that the retrieval service has been in operation, we have reported on over 3500 implants. We greatly appreciate the continuing support of the local orthopaedic community.

Intramedullary Hip Screw IMHS

In late 2001, a failed Smith and Nephew IMHS was referred for investigation. Whilst this is the first failure that has come to our attention, the mode of fracture is of interest. The device was retrieved from a male patient (age 79 yrs) 3 months after fracture fixation. The failure was associated with a traumatic fall. Metallurgically, the device complies with relevant standards for 316L stainless steel; however it is the proximal end design that warrants comment. One of the reported advantages of the IMHS device is the centring sleeve (12.7mm in diameter) which allows the lag screw to slide freely whilst preventing its rotation. Even though the proximal end diameter of the nail is 18mm, the transverse hole for the sleeve results in a wall thickness of less than 3mm.

DHS issues

In an orthopaedic trauma meeting at RPH, it was reported that there had been difficulty in the insertion of Mathys DHS’s; specifically the sliding of the DHS plate over the lag screw. The problem was found to be due to the deformation of the slot in the screw head which effectively increased the diametral dimension of the screw; hence the plate would not fit over the screw. This was found to be caused by the use of worn insertion wrenches. A spot check revealed several damaged insertion wrenches at RPH. A comparison with the Richards system previously used at RPH, found it to have a more robust design and as such would prevent this type of failure. Subsequently, a failed wrench was referred for evaluation. The failure was likely due to the drive lugs not being engaged into the DHS upon insertion; a contributing factor being a ‘questionable’ repair to the insertion wrench.
Outcomes:
- Avoid the use of a worn or deformed AO DHS insertion wrench.
- The AO system is not amenable to a minimal surgical approach which increases the forces on the wrench and the likelihood of deforming the drive lugs.
- Follow up is required to determine the extent of poor repair practices.

HG Liner Dissociation

Modularity of acetabular components has many advantages and is widely accepted. Despite the advantages of the modular type designs, dissociation of some liners remains a point of interest.

Bioengineering News

Snippets

- **Projects** There are many studies being conducted within the division as the workload explodes due to ‘registrar season’. Eight registrar projects are currently ongoing with four longer term projects involving four senior consultants.

- **LCS Knees** An investigation is currently under way to assess the wear performance of the DePuy low contact stress (LCS) knee arthroplasty. Explants sent to the laboratory show remarkably little wear even after 5 years invivo. The study aims to compare the LCS knee to other commonly available knee prostheses, with results due later this year.

- **3D Models** The service of providing 3D models for surgical planning and reconstruction continues. Recent models include a hemi-pelvis, lumbar spine, skull for cranioplasty, amongst others. Current research interest is in quick turn around 3D printed models for complex ankle trauma.
· **Hylamer** Over recent years, several Hylamer polyethylene components have been received which show signs of extensive polymer degradation caused principally by gamma sterilisation in air.

A recent MDA advice (DA 2001 06) confirmed our observations. The advice stated that patients should be closely monitored on a “minimum annual basis for evidence of accelerated wear, progressive osteolysis or fracture of the components”. It is our understanding that the manufacturers have recalled Hylamer products and notified all surgeons who have used this product.

**Recent reports**


![Fig 4. Failed Whiteside knee components.](image)

Metallurgical analysis of 6 failed implants concluded that fatigue failure of Whiteside knees was initiated at regions of high stress concentration including sharp corners, the interface of sintered beads and changes in section. Furthermore, metallurgical examination revealed a large variation in grain size, interdendritic carbides which promote easy crack paths and variable section hardness. A further 5 fractured Whiteside components have since been referred to the laboratory. The cautionary note is that these devices and other porous coated weight bearing implants made from cast Co-Cr-Mo alloys are susceptible to fracture, particularly when design, metallurgy and clinical factors are less than optimal.

**Custom Built Devices**
1. Custom humerus to integrate with existing shoulder and elbow arthroplasty.
2. Shoulder arthrodesis plate manufactured from Tivanium – previously stainless steel plates were used.
3. RPH compression nails for knee arthrodesis and femoral fracture non-union.
4. Cranioplasty plate from commercially pure titanium – now fully manufactured at RPH.—
5. Various removal tools for fractured devices.
7. Extended volar plate – 11 hole.

![Fig 5. Cranioplasty plate and 3D model](image)

**Ongoing Clinical services**
1. Hip spacers (44mm – 64mm head diam.)
2. RPH compression nails
3. Polyacetyl (Delrin) intramedullary nails
4. RPH vacuum cement mixers

**Bioengineering Team**

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