Implant Retrieval and Analysis

Since the introduction of implant tracking in 2002, the number of implants referred to the Implant Retrieval Service has more than doubled from 200 to over 500 in 2005. The benefit of more retrievals is the improved capture rate of devices, leading to a better understanding of failure trends.

There is however a need to rationalise the retrieval program to effectively manage the increase in workload. To this end, the focus has shifted to evaluating series of implants with common modes of failure. Equally, positive performance indicators such as low wear rates or extensive bone ingrowth in implant series are of interest.

So whilst significant individual cases will always be reported back to the surgeon, we see that an overview of the retrieval collection and a focus on common success or failure modes of a series of implants will be of most value.

To manage this change we propose the following triage for retrieved devices:

1. **Surgeon report** – a report to be provided only on surgeon request as specified on the retrieval form.
2. **Laboratory report** – no specific request from the surgeon, but warrants preliminary or even full investigation. Reporting back to the surgeon will depend on any significant findings.
3. **Storage** – devices with no significant adverse features will be stockpiled and may be used in series evaluation.

A number of implant series requiring further study have been identified including: Exeter (HNSS), Omnifit, Butel and Margron stems. Also, evaluation of PFN nails, LISS plates, HG shell/liners, Birmingham Resurfacing and Duracon and Preservation knees are continuing.

Some interesting statistics from our retrieval collection over the past 5 years:

- **Most common hips**: Charnley, Omnifit, PCA
- **Most common knees**: Duracon, MG, Ortholoc
- **Fractured stems**: 4 Exeter, 4 Omnifit, 3 Butel, 2 Charnley, 1CPT, 1 C-stem.
- **Fractured knees**: 5 Ortholoc
- **Liner dissociation**: 15 MG -patella, 8 HG liners
- **Fractured nails/plates**: 5 PFN, 3 LISS, 1 IMHS

Implant Tracking Update

Although implant tracking has only been fully operational in the three major WA public hospitals over the past few years, in reality, implant tracking information via the theatre management system has been captured over a much longer period.

Royal Perth Hospital main theatres had its first implant insertion event recorded almost 8 years ago. In 1999, SPC, SCGH and Fremantle theatres came on line. Since that time, thousands of implant insertions have been recorded. Implant removals were first recorded in RPH in late 1999, in Fremantle in 2001 and SCGH in 2002, thereby finally enabling the tracking of all devices from insertion to removal.

Retrieval Forms

The recent introduction of electronic retrieval forms in public hospitals has only been mildly successful. Our experience is that the paper retrieval forms appear to be better utilised and are more comprehensive in terms of data provided.

As such, all theatres have been sent updated paper forms and surgeons are encouraged to complete them when referring their implants.
Worn Through knees

Over the last 5 years an increased number of knee arthroplasties have been received where the tibial polyethylene inserts have worn-through, resulting in metal-on-metal wear. In some cases both the tibial insert and tibial tray have been destroyed. In both these scenarios, significant implant debris is noted in the retrieval documentation with any or all of the following: gross tissue staining, metallic fragments, implant loosening, bone reaction, resorption, and osteolysis.

In these cases, arthroplasty revision is more demanding and there is the potential of decreasing the life of the revision components due to extraneous wear debris. In several cases it was evident that had the tibial insert been replaced prior to destruction, revision of the tibial and femoral components may not have been necessary. The most commonly worn through inserts we have received are summarised below:

<table>
<thead>
<tr>
<th>Knee</th>
<th>LabeL Thickness mm</th>
<th>Actual Thickness mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whiteside Ortholoc</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>Tricon</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Genesis</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>Howmedica PCA</td>
<td>7</td>
<td>4</td>
</tr>
</tbody>
</table>

After scrutinising the retrieval database, it was found that ~ 92% of worn-through knees have a polyethylene thickness of <8mm (actual thickness, not labelled thickness). Commonly, the failure mechanisms are delamination as a result of sterilisation in air and high contact stresses, as well as severe pitting, and fracture. Most bearings worn to a thickness <2mm are fractured. Wear life predictions are difficult, as wear rates are non-linear, however a ballpark figure for these bearings is 0.4 - 0.6mm/yr. Tibial inserts are therefore expected to wear through in approximately 8-10 years. At present it is recommended that patients with the identified knee arthroplasties and with tibial inserts <10mm in thickness be followed up between 7-10 yrs with a CT scan to determine wear progression. A protocol has been formulated for CT measurement of polyethylene thickness and is available on request.

Effect of UHMWPE Sterilisation Treatment: Stock control considerations

From 1960 till the mid-90’s, UHMWPE components for joint replacements were gamma sterilised in air. It has been established that oxidation of free radicals persist for years after irradiation in air, even during shelf storage.

The end result is that the UHMWPE components show varying degrees of oxidative degradation, which has a detrimental effect on mechanical properties, often resulting in gross wear damage, osteolysis and ultimately component failure. This is most obvious in bearing surface delamination and yellowing (see below). A major change in sterilisation practices occurred between 1995-1998, when companies began to sterilise their polyethylene components in an inert atmosphere (low oxygen). Gamma sterilised components were also barrier packaged. Other sterilisation processes including gas plasma and ethylene oxide sterilisation were also employed.

In the retrieval studies it has become apparent that components sterilised by any of these new techniques have significantly less oxidation damage than components produced prior to 1998. A recent retrieved Duracon insert has raised a few concerns that may be relevant to some theatres. This component was inserted in 2001, at least 3 years after the company had revised its sterilisation procedure.

On examination the tibial insert displayed regions of delamination typical of UHMWPE components that have been gamma sterilised in air. Further investigation revealed the insert was in fact a pre-1998 component, obviously sterilised in air and stored on the shelf for at least 3 years.

This raises the possibility that some components sterilised prior to 1998 may still be in stock, particularly if no expiry date is displayed. This may not be relevant to consignment stock as most companies regularly replace expired stock. It is recommended that theatres check their non-consignment stock and replace all UHMWPE components that are sterilised in air (pre-98).

An increasing number of oxidation effected UHMWPE retrievals are anticipated over the next 10 years, before the beneficial effects of the new sterilisation methods are fully realised.
Hip and Knee Tender

In the last bulletin it was reported that the evaluation committee was in the final stages of the selection of hip and knee arthroplasty for the public hospital system in WA. The tender is currently in a transition period of implementation into the major public hospitals. The table below outlines the devices selected for use in primary arthroplasty cases.

<table>
<thead>
<tr>
<th>Hip</th>
<th>Zimmer</th>
<th>Smith &amp; Nephew</th>
<th>De Puy</th>
<th>Stryker</th>
<th>Link/Orthotech</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monobloc hemi-arthroplasty</td>
<td>Austin Moore</td>
<td>Thompson</td>
<td>Elite Plus &amp;</td>
<td>Exeter V40 &amp;</td>
<td>Lubinus SP II &amp;</td>
</tr>
<tr>
<td>Fully-cemented THA</td>
<td>CPT &amp; ZCA</td>
<td>Spectron &amp;</td>
<td>Elite Ogee</td>
<td>Contemporary V40</td>
<td>Lubinus SP II</td>
</tr>
<tr>
<td>Cemented hemiarthroplasty</td>
<td>CPT</td>
<td>Spectron</td>
<td>Charnley,</td>
<td>Elite Plus</td>
<td></td>
</tr>
<tr>
<td>Hybrid THA</td>
<td>CPT &amp; Trilogy</td>
<td>Spectron &amp;</td>
<td>Charnley, Elite</td>
<td>Exeter V40 &amp;</td>
<td></td>
</tr>
<tr>
<td>Fully-uncemented THA</td>
<td>Allclassic, CLS &amp;</td>
<td>Spectron &amp;</td>
<td>Plus &amp; Duraloc</td>
<td>Omnifit &amp; ABG II</td>
<td></td>
</tr>
<tr>
<td>Uncemented hemiarthroplasty</td>
<td>Synergy</td>
<td>Reflection</td>
<td>Coral</td>
<td>ABG II</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Knee</th>
<th>Total knee arthroplasty</th>
<th>Nex Gen</th>
<th>Genesis II</th>
<th>LCS (Mobile)</th>
<th>Duracon</th>
<th>Exatech (Mobile)</th>
</tr>
</thead>
</table>
| Acetabular Components Stems

The evaluation panel was aware that any selection of arthroplasty would create robust discussion and reduction in choice may create some difficulties. Confidence in the tender outcome however is based upon a rigorous assessment process with clinical evidence being the primary consideration. Balancing the commercial aspects of the tender with laboratory assessment and qualitative criteria also contributed to the selection process. Ultimately the success of the tender will be determined by clinical outcomes, tender compliance, and cost savings.

Fractured HNSS Stems

A joint study has been undertaken with Piers Yates, currently in the Avon Orthopaedic Centre, Bristol, on the failure of 14 modern, high nitrogen stainless steel (HNSS) stems. A control cohort of 203 CPT stems was used for the study. Fractured stems included 5 Exeter's, 8 CPT's and one C-stem. Interestingly, both the CPT and Exeter stems showed variable microstructural grain-size.

In terms of fatigue resistance, the importance of a fine, homogeneous microstructure for high nitrogen stainless steel is quite a complex physical metallurgy argument. In summary, for fatigue crack propagation in materials that are sensitive to grain size, the grain boundaries act as microstructural barriers in stage I of the fatigue fracture process. I.e. the more boundaries (finer grain size), the greater resistance to fatigue crack propagation.

The clinical and radiological data suggested that the potential for a catastrophic complication is real but requires a combination of factors including excessive BMI, poor proximal support and inadequate microstructural control. A comparison of the canal morphology between the control cohort and the fracture group revealed that the fracture group had predominantly "Champagne glass" shaped canals. When the non-fractured group with similar shaped canals were considered, measurements revealed a more substantial cement mantle in the calcar region, zone 1 and at the lesser trochanter. Despite this, the stem sizes were larger in the non-fractured group, which strongly suggests that aggressive removal of cancellous bone is better in order to allow more complete cement mantles and the use of larger sized stems.

Investigation suggests that care must be taken in "Champagne-glass" femurs to make sure that the proximal mantles are of the highest standard. Lateral entry to the femur avoids varus positioning of the stem and allows larger broaches to be used, which improve cement mantles in the critical areas and allow the use of larger stems. In heavy patients, it is perhaps wise to consider using higher strength alloys and/or uncemented stems.

Omnifit Hips

Since May 2000 we have received 4 fractured Omnifit femoral stems for failure analysis. Of most interest is that all four stems have fractured in the neck region below the modular femoral head. The fracture surfaces are highly crystalline which raised concerns with respect to the implant microstructure and its predisposition to failure. Investigations are continuing, however preliminary findings reveal a very coarse grained material with a propensity for grain boundary carbide precipitation - certainly not a preferred structure. Your contribution in continuing to refer all fractured devices is appreciated.
BP Ankle
WA has the largest number of BP ankle implants in Australia, (n =150), and during 2005 we received four explants. Upon investigation, there appears to be little published literature on the BP ankle other than from its inventors Buechel and Pappas. The retrievals were characterised by good or excellent bony ingrowth in the talar component, little ingrowth in the tibial component and loose bead impaction in the minimally worn polyethylene bearing. It has been suggested that a review of patients who have received a BP ankle may make an interesting clinical study.

The metal components are striking in nature due to their titanium nitride ‘gold’ appearance, which has been reported to reduce wear. Titanium nitride has long been used in metalworking especially on twist drills to maintain their cutting edge due to the superior hardness of the diffusion layer.

New arthroplasties including the CCI knee and ACCIS hip (Munich) are coated with titanium nitride.

Custom Devices
Routine work in Bioengineering includes the provision of a custom device service for Orthopaedics and other specialties. 2005 saw the completion of in excess of 15 cranioplasty plates and hip spacers, several arthrodesis nails and shoulder plates, compression nails, knee spacers and surgical models.

In addition there were two extremely difficult metal removal cases. Of note was the removal of an Austofix hip nail. In this case, the most proximal fixation screw had penetrated the lateral cortex, and become firmly ‘stuck’ in the nail. Attempts to remove the screw had further deformed the head.

Upon referral, Dermott Collopy asked us to provide suitable removal tools. The removal device was based upon a diamond-tipped coring bit more commonly used to drill through reinforced concrete. The proximal end of the nail was used as a guide and the high nitrogen stainless screw was cut through with ease and safely removed. Thanks to Dermot for his referral and successful removal.

Bioengineering Scholarship
Congratulations to Joe Allen on being awarded the 2005/2006 Bioengineering Scholarship. Joe, a UWA 4th year Engineering student, is working on the development and importantly, the experimental validation of a finite element model for the pre-clinical testing of femoral stem prosthesis.

SNIPPETS
Single use Devices (SUD’s)
TGA has ruled that from March 2006 health care facilities cease the re-use of critical SUD’s and December 2006 for semi-critical devices. As a consequence of the new TGA rules, Bioengineering has been given the responsibility of establishing a SUD re-manufacturing facility at RPH for public hospitals in WA. Staff and space have been allocated, and a fully operational facility will be up and running soon.

AOA Annual Scientific Meeting: Perth 2005
A number of Bioengineering staff were fortunate to attend a well organised and particularly relevant national meeting. Four Bioengineering papers were presented including ‘Evidence based selection of primary hip and knee replacements’, ‘The use of iontophoresed allografts in revision arthroplasty’, ‘Implant device tracking, retrieval and analysis’ and ‘Quantifying wear in mobile bearing knees’.

New Laboratory Equipment
A long awaited replacement Leica stereo microscope with associated digital imaging has been a welcome addition to our microscope facilities.

We are also thankful to the Orthopaedic Dept (RPH) for assisting with the purchase of a “state of the art” operating system (BlueHill) for our Instron materials testing machine. Any orthopaedic registrar or consultant wishing to use the Instron for future projects will appreciate a more ‘user friendly’ machine.

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