Bioengineering

Department of Medical Engineering and Physics

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2004 was a very busy year in Bioengineering, hence the edition in March rather than December. We hope that the articles presented may be of interest and feedback is always welcome.

Supply of Primary Orthopaedic Hip and Knee Implants

Over 50 000 hip and knee replacements were performed in Australia in 2003. With an abundance of hip and knee designs currently in use in Australia; 141 hip stems, 124 acetabular components and 47 knee prostheses, there is a myriad of choice for the surgeon.

In an attempt to rationalise the number of suppliers and devices available to the public hospitals, a tender was called in late 2004 for the selection of hip and knee prostheses for use over the next five years. Categories included, fully cemented, uncemented, hemi and hybrid hip and knee arthroplasty for primary arthroplasty with a patient cohort of 80% of the 60 plus age group. As well as cost, the selection was based on 50% qualitative criteria, including demonstrated supply performance, local reps, training, warehousing etc, and 50% quantitative criteria, being clinical evidence (40%) and laboratory quality assurance testing (10%). The rationale was to improve on the original contract, allowing senior surgeons to select prostheses that reflect best practice in arthroplasty surgery. The selection of devices was based upon a minimum of 5 years clinical follow-up, with the clinical data rated on a scale of 1 to 5, 1 being registry information and 5, company monographs.

Bioengineering was contracted by Health Supply WA to help in the process of collating the clinical evidence for each device tendered and to perform a quality check on devices selected by the surgical panel. This was to ensure that devices conformed to relevant standards covering things such as packaging and labelling, microstructure, hardness, composition, dimensions and mechanical properties etc.

The collating of the clinical evidence proved to be a difficult task as many of the companies tendered shopping lists of items for each of the categories and some were unable or unwilling to provide a preferred device for each of the categories. More than 30 system combinations (stem, head and acetabular components) were tendered for one hip category by one of the companies! In addition it was perhaps surprising to see minimal clinical evidence/support for many devices. Additional literature was sourced via resources such as Pub Med, FDA Website, Registrys' etc as agreed by the surgical panel to aid in decision making. In terms of quality evaluation, it is of concern that some random samples sent to Bioengineering for evaluation contained a hair in the packaging, machining marks, liquid staining, chipped coatings, poor laser etching, and metal fragments in polyethylene components, to name a few. Interestingly, most of these problems would not likely be observed in a busy theatre environment. Some microstructures were also considered unacceptable with respect to implant standards. It is hoped that identification of these defects will lead to improved quality.

At present, the surgical committee is in the process of performing the final evaluation and recommendation process with a hope that the details may be finalised soon.

Custom Devices

2004 was another busy year for custom devices. There appears to be an unprecedented need for cranioplasty plates (13 plates, 2 bifrontal plates). Other devices including hip spacers, shoulder arthrodesis plates and compression nails were provided in addition to surgical models and a custom acetabular cage.

Implant Tracking: Up and Running!!

After many years of design and programming, implant tracking is a reality!! The current tracking module, available to all the major public hospitals in WA. and monitored in Bioengineering, is designed to access all Theatre Management System (TMS) information relating to insertion and removal of implants, particularly orthopaedic devices. Although TMS data on inserted devices has been available for a number of years, retrieved devices have never been tracked. The tracking of devices from insertion to removal, will address the TGA need for post market surveillance and provides important information on implant longevity, usage and failure rates. It will also provide an improved ability to track patients in the event of a device recall.

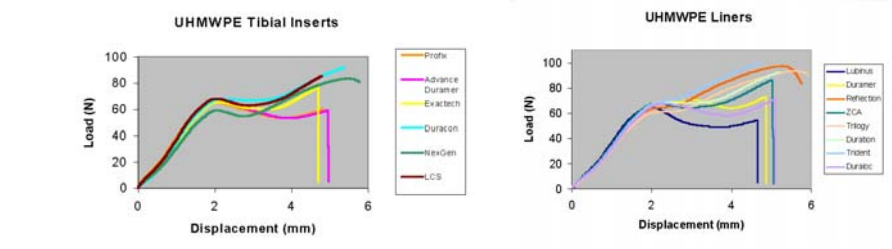
Bioengineering's interest in the tracking facility originates from its implant retrieval service that has been operating for almost 30 years with more than 4000 devices referred to our labs. Despite excellent clinical support, we have never had a mechanism to ensure that all failed devices were referred for investigation. The tracking module will facilitate orthopaedic devices retrieved in WA public hospitals to be recorded and then referred to Bioengineering for analysis and archiving. This is important when recognising failure trends and in providing a prompt response to surgeons, manufacturers and the TGA.

Implant device tracking, retrieval and analysis is the subject of a submission currently before the Health Department. The proposal was put forward to gain funding for a State facility, covering all implanted devices with the potential for inclusion of procedures conducted in the private hospitals, if requested. When implemented this will provide WA with a service emulating the highly regarded Scandinavian models.

The success of the implant tracking program is dependant on participating hospitals ensuring that all implant retrievals are recorded, and surgeons completing the electronic retrieval forms. We very much appreciate your continued support!!

Small Punch Testing: A novel way to characterise the mechanical behaviour of UHMWPE components !

Previously, one of the major problems in the mechanical testing of UHMWPE components including acetabular liners and tibial inserts, was in obtaining representative samples in sufficient numbers. Using the 'small punch test', sample disks (6.25mm Dia and 0.5mm thick) are removed from areas of interest and indented by a hemispherical punch according to ASTM F2183. Parameters such as stiffness, peak load and work to failure are obtained from the load-displacement data and can be used to compare UHMWPE devices. Subtle differences in UHMWPE grades, in degraded/non-degraded UHMWPE, in processing and in sterilisation/irradiation treatments, can be determined. In a recent study, pristine UHMWPE from seven different manufacturers, were compared. Of interest were the distinctly different behaviour of the crosslinked samples. The crosslinked liners including Reflection (XLPE, Smith&Nephew), Trilogy (Longevity, Zimmer) and Trident (Crossfire, Stryker) showed marked geometric strain hardening and higher work to failure (WTF) values compared to noncrosslinked liners. WTF is an important measure and has been correlated to wear rate. The thermally stabilised Duration (Stryker) samples, although not highly crosslinked, also demonstrated superior mechanical properties to the conventional UHMWPE samples.



The small punch test provides a means of determining the mechanical properties and status of UHMWPE samples, both new and retrieved, and suitably complements the current thin section oxidation studies.

Iontophoresis

The iontophoresis project continues within the Bioengineering Division. Project Manager, Kasia Michalak finished work on iontophoresis of cancellous bone graft and is currently contracting through UWA to Australian Orthopaedic Innovations (AOI), a company that has licensed the rights to commercialise iontophoresis of bone. Her main tasks as Project Manager will involve assisting the company in gaining approval from the TGA for Australian bone banks to produce and supply iontophoresed bone grafts for transplant. Work in the laboratory continues as part of this program. It is proposed that a multi-site international clinical trial using iontophoresed bone graft will be undertaken.

Tender Moments: Catheter Evaluation

As with the Hip and Knee tender, Bioengineering were commissioned to perform the scientific component of an evaluation of urinary catheters. Quality was assessed using the catheter standard (AS 2696), and two in-house tests comparing rigidity and friction. The affect of soaking in artificial urine was determined for both Nelation (24 hrs) and Foley (14 days) catheter types. Packaging, flow rates and balloon performance under load was considered acceptable in all cases, however a number of defects were apparent.

Numerous catheters did not comply with all the marking and dimension requirements. Surface irregularities, material debris, cracks near the eyelets (Fig.1), hole punch markings and the presence of an eyelet blank inside one of the catheters (Fig.2), were disturbing features. In addition, 40% of the Foley catheters did not meet the balloon minimum volume recovery requirements following soaking.

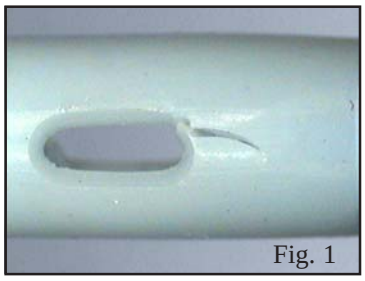


Fig. 1

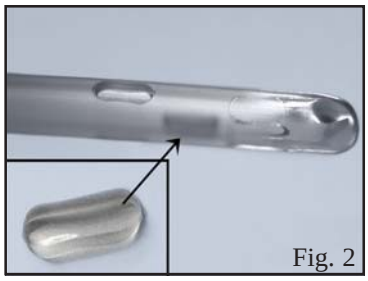


Fig. 2

The evaluation that may have appeared unnecessary at the outset highlighted a number of quality issues that have been referred to the manufacturers and the TGA.

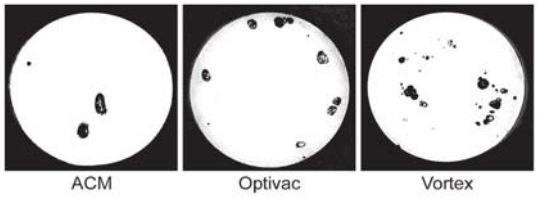
Non-implantable Surgical Items

Over the past year we have had three instances of fractured surgical instruments or drills that have either been retrieved or are currently *in situ*. Most surgical instruments including drills are manufactured from 400 series stainless steel. These alloys are hardenable, have good toughness and high hardness for edge retention. The 400 series alloys are not biocompatible and within a short period *in vivo* will corrode.

Retrieval of two such items, one drill and a fractured end of a bone lever, which were in situ for ~ 9-12 months demonstrated significant corrosion and deterioration. Chromium corrosion products may stimulate macrophages and induce an inflammatory response, which may further aggravate corrosion, thereby setting up a corrosion-inflammation-corrosion-inflammation feed back loop. 400 series stainless steels can produced Cr^{6+} corrosion products which may penetrate cell membranes, show toxicity and result in bone resorption. Our recommendation is that pieces of surgical instruments or fractured drills should be removed ASAP, however at a clinically acceptable time.

Vacuum Mixing Revisited !!

It is well recognised that vacuum mixing reduces the porosity in bone cement, thereby improving mechanical properties such as fatigue and shear strength.
Theatres (SPC) have been using the RPH VacuMix for nearly 7 years, but with increasing requests for mixing three batches of bone cement (120g powder), it was decided to evaluate three contemporary systems. The Stryker ACM (formally Hi Vac), the Smith & Nephew Vortex (identical to the Howmedica Artisan) and the Biomet Optivac were evaluated.
They were compared for design, ease of operation, cost and the quality and strength of the cement. Three mixes (120g) of Simplex P were tested in all systems. The percentage porosity and shear strength of bone cement are indicators of cement quality and were measured for both an experienced and an inexperienced user. Mixer type had a significant effect on shear strength, whilst across operators there was no variation. Despite all mixers effectively reducing porosity compared to hand-mixed cement, they all fell well short of the manufacturers' claims (0.1% porosity). Overall, little separated the Stryker ACM and the Smith and Nephew Vortex mixers, with costs possibly dictating the final choice.



Mixer porosities

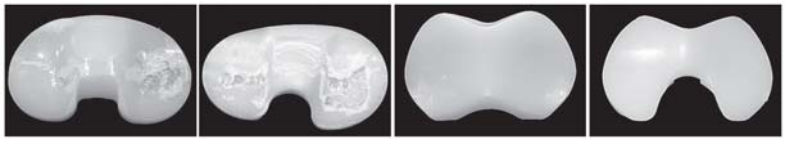
Mixer Evaluation Summary

Parameter	Stryker	S& N	Biomet
Quality & strength	1	2	3
Mixer Operation	2	1	3
Cost	2	1	1

Rating: 1 good - 3 not as good.

De Puy LCS Knees

A common finding in our implant retrieval studies is the remarkably low wear rates of retrieved LCS (De Puy) components for both the Rotating Platform (RP) and Anterior/Posterior Glide (APG) designs. This led to a tribological study of retrieved knee components in 2004. Thirteen LCS retrieved components including 10 APG and 3 RP designs with an implantation period ranging from 9-60 months were evaluated. Utilising a coordinate measuring machine (CMM) with an accuracy of 0.010 mm, we were able to determine the wear. Overall results indicated an average wear rate for the superior surface of the tibial insert of the APG bearings of 0.07mm/year and 0.09mm/year for the RP design. Given the complexity of making measurements, there are few results cited in literature. Wear rates between 0.025 and 0.35mm/year have been reported, with measurements tending towards the latter.

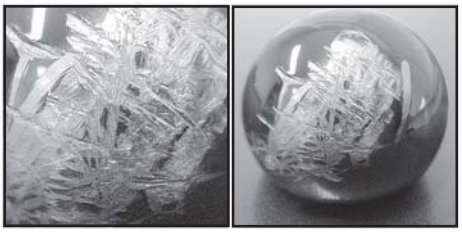


Fixed Bearings (4 -5yrs) *LCS (RP 5yrs)* *LCS (APG 4yrs)*

The most significant finding was the low wear and absence of delamination and surface deformation compared to typical fixed bearing inserts. Wear mechanisms including burnishing, pitting, scratching and abrasion were observed on both the superior and inferior tibial insert surfaces, however in contrast to 4 retreived fixed tibial insert designs , there were no signs of delamination or surface deformation. The APG design showed notable multi-directional scratching on the inferior tibial insert surface compared with the RP design. Short term retrieval analysis of the APG design demonstrates comparable low wear rates to the RP designs and significantly less surface degradation in comparison to fixed bearing designs. Longer-term quantitative wear measurements are required to confirm the superior performance of the APG design.

Oxinium Heads

At the 2004 Scientific Orthopaedic Meeting, an interesting case of a dislocated oxinium head was presented. The manufacturer claims that the oxinium material has all the benefits of ceramic and cobalt chromium materials with none of the risks. Clearly, the retrieved head demonstrated that no device is risk free. The concerns were reported to the TGA, who will continue to monitor the occurrence of dislocation in oxinium coated total hip replacements.



From a materials viewpoint, interest centres on the head structure, being a surface oxide layer (0.005mm) with a microhardness of 1235 Hv and substrate of 285Hv, which is relatively soft compared to common acetabular alloys. Laboratory testing of oxinium and cobalt chromium heads contacting a simulated titanium cup rim at a load of 700N resulted in more damage to the oxinium heads. Once the extremely hard surface is penetrated, the substrate is readily deformed. This also has been observed in a recent study by Smith and Nephew, acknowledging that in certain rare clinical situations, such as scraping against the acetabular shell during dislocation, the oxide could be penetrated. However in using relatively low indentation loads (445N laboratory simulation), the resultant damage was much less severe than in our retrieved head. Subsequent wear in a hip simulator showed similar results to undamaged cobalt chromium heads.The oxinium material offers some unique properties that may be beneficial in hip arthroplasty, however no material is 'risk free'. If a patient dislocates and is closed reduced, scrutiny of subsequent x-rays for accelerated wear is warranted to ensure that significant head damage has not occurred. A simple alloying modification to increase the substrate hardness may reduce the risk of dislocation damage.

SNIPPETS

Robin Higgs

We were pleased to welcome Prof Robin Higgs to our Department in 2004, who enlightened us especially with respect to the law and medical devices. His participation at the local AOA conference was also well received.

World Biomaterials Congress

Approximately 1700 delegates, including RPH Bioengineering personnel, attended the World Biomaterials Congress in Sydney in May 2004. Due to an overwhelming response (2000 abstracts for 700 oral presentations) scrutiny of abstracts was tough. Fortunately three of our papers were accepted. Particular areas of interest were polyethylene, implant retrieval, orthopaedic materials and arthroplasty tribology. Other peripheral interest areas included the huge increase in biomaterials usage for cosmetic surgery, bioglass and tissue engineered products.

Bioengineering Scholarship

Congratulations to Noel Jones on being awarded the inaugural Bioengineering Scholarship. Noel, a 4th year Materials Engineering student from UWA has been working on several projects including improving the production methods for titanium alloy used in the shoulder arthrodesis plate.

Contact us:

Department: 9224 2500
Eric Swarts: 9224 2997
Alan Kop: 9224 3228