



Bioengineering Bulletin

Metal-on-Metal THA

Department of Medical Engineering and Physics Royal Perth Hospital November 2011

Welcome to the Bioengineering Bulletin. This issue is focussed on metal-on-metal hip arthroplasty.

Background

Metal on Metal (MoM) arthroplasty, first marketed as the McKee-Farrar, dates back to 1953. They were largely abandoned in the early 70's due to loosening, wear and the need for early revision. Investigations carried out at RPH attributed an adverse tissue reaction to wear debris as a likely etiology of loosening and pain.

MoM devices in cobalt based alloy were revisited in the 1990's when developments in the metallurgy of high carbon alloys and improved machining tolerance were introduced to promote fluid film lubrication and reduce wear. Claims of reduced dislocation risk, more natural hip motion and reduced wear, (1000X less wear than metal-on-plastic) has lead to wide spread clinical use.



Fig 1. McKee-Farrar, 40 yrs in situ

Demographics

The RPH retrieval collection has over 7000 devices with ~2% being MoM, (Table 1). The principle reason for revision of the 155 MoM retrievals is given in Fig 2.

Table 1. MoM arthroplasties in RPH retrieval collection.

| Type | Qty | Male | Female | Average Age at removal | Average time in situ |
|-------------------|------------|-----------|-----------|------------------------|----------------------|
| ASR | 49 | 26 | 23 | 61.9 | 2.72 |
| BIRMINGHAM | 9 | 3 | 6 | 56.4 | 4.40 |
| MITCH | 9 | 5 | 4 | 71.4 | 0.88 |
| DUROM RESURFACING | 6 | 5 | 1 | 41.7 | 2.67 |
| METASUL LDH | 4 | 2 | 2 | 55.7 | 2.05 |
| PINNACLE ULTAMET | 4 | 1 | 3 | 65.7 | 6.22 |
| ADEPT | 3 | 2 | 1 | 44.8 | 3.64 |
| BIOSURF | 2 | 1 | 1 | 47.7 | 1.42 |
| T.A.R.A | 9 | 2 | 7 | 60.3 | 13.72 |
| MCKEE-FARRAR | 60 | 26 | 34 | 69.1 | 12.05 |
| TOTAL | 155 | 73 | 82 | 57.5 | 4.98 |

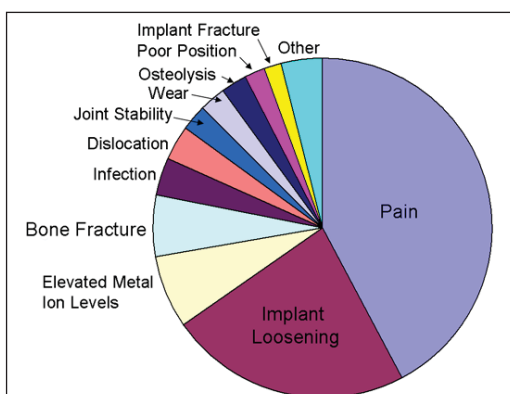


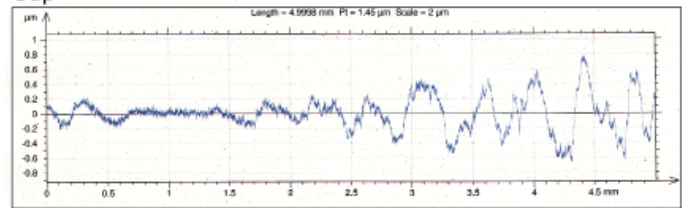
Fig 2. Causes of failure as reported by surgeon.

Metrology

In addition to macro-observations, accurate measurement of the articulations is key to assessing volumetric wear. We are currently using a combination of coordinate measuring ($\pm 0.5\mu\text{m}$), surface roughness (Ra), Fig 3. and out of roundness measurements to assess wear.

Out of roundness - A trace of thousands of points are taken from the head or shell bearing and an average diameter is calculated, this is then superimposed with the actual readings, giving an idea of deviation from a perfect circle. (Fig 4)

Cup



Head

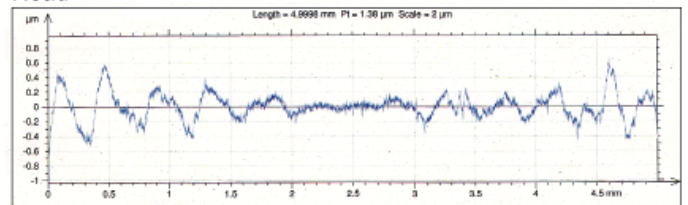


Fig 3. Roughness

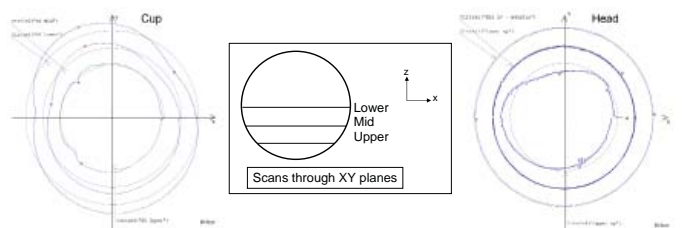


Fig 4. Out of roundness graphs

Metrology findings to date include

- Uneven wear/edge loading of the acetabular cups.
- Extensive scratching of the femoral head and cups
Max Ra = $0.25\mu\text{m}$, (Mirror Finish Ra $\sim 0.1\mu\text{m}$)
- Out of roundness deviations up to $20\mu\text{m}$ in worn condition.
- Small areas at the pole of the cup with no wear suggesting a possible mismatch of heads and cups.
- Little evidence for claimed fluid film lubrication in retrieved devices that show deep scratches.

CORROSION and FRETTING



Fig 5. Examples of crevice corrosion and fretting

for modular neck THA's, even without a MOM articulation. Specifically, chromium orthophosphates, pale greeny deposits (Fig 5) have been associated with ALVAL and pain [1]. Fretting, due to large applied torque and bending loads, is also known to exacerbate metal debris production and corrosion. In summary, corrosion and fretting for large head MOM devices is of considerable concern.

In the past, minor corrosion observed on retrieved head/stem tapers after many years insitu (>10yrs) was seen as inconsequential for small femoral head devices (<30mm) . In contrast, significant corrosion and fretting of the head/neck taper in large head MoM devices, is observed in early retrievals (<4yrs, Fig 5). We now know that corrosion products can induce a significant tissue response (ALVAL) as seen

METAL ION LEVELS IN SERUM / WHOLE BLOOD AND IN PERIPROSTHETIC TISSUE

Metal ion levels in serum or whole blood is currently used as a surrogate measure of bearing wear and can be a helpful tool when considering revision of the arthroplasty[2]. In blood, metal ions are transported both in plasma and within blood cells. The concentration in the serum only corresponds to the extracellular component, giving incomplete total elemental concentration of cobalt and chromium [2]. Whole blood concentrations are a better measure of systemic exposure to metals [2,3]. These tests can be performed by PathWest.

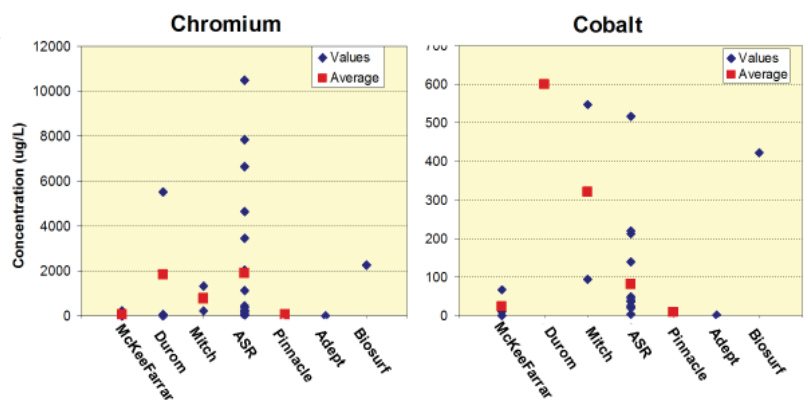


Fig 6. Metal ion levels in periprosthetic tissue

We perform routine analysis of Co and Cr levels on periprosthetic tissue, as shown in Fig 6. (Refer to back page for details)

HISTOPATHOLOGICAL FINDINGS

- The most common tissue reaction to metallic debris is called histiocytic response. This is characterised by reactive fibrosis with infiltration of plump histiocytes filled with granular black metal particles, consistent with a foreign body reaction [2,4].
- ALVAL or aseptic lymphocyte dominated vasculitis associated lesion is not a metal allergy, but rather a specific tissue response found in patients that develop metal hypersensitivity. The histological presentation includes perivascular lymphocytes infiltration in a diffuse or follicle pattern accompanied with extensive necrosis and fibrin deposition [2,4-9].
- Pseudotumour is a periprosthetic inflammatory solid or semi-solid mass found around joints and described as the product of a metal hypersensitivity reaction to metal particles or debris. The histological features are similar to ALVAL but also involve effusion and formation of fluid filled or semi-solid mass around the joint [5,6].
- Common symptoms of metal hypersensitivity are on-going groin pain or discomfort often accompanied with effusion that may progress to a mass or pseudotumour [8].

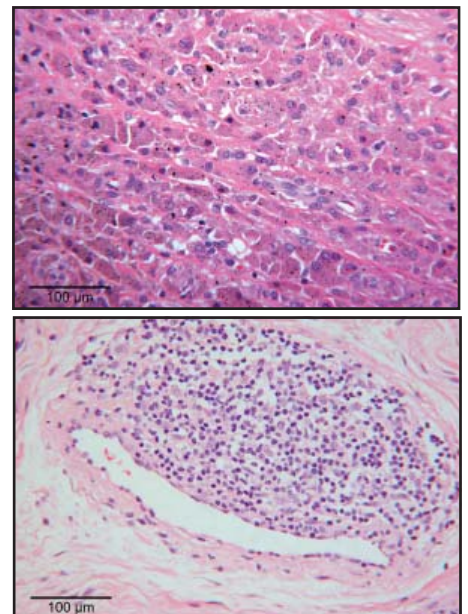


Fig 7. Tissue response around MoM devices. (A) Histiocytic response, numerous plump histiocytes containing fine metallic debris. (B) Lymphocytic response, lymphocytes arranged in a follicle around a large blood vessel. In this particular case, both responses were seen in the same patient.

Examples of histiocytic and lymphocytic responses in periprosthetic tissue are shown in Figure. 7.

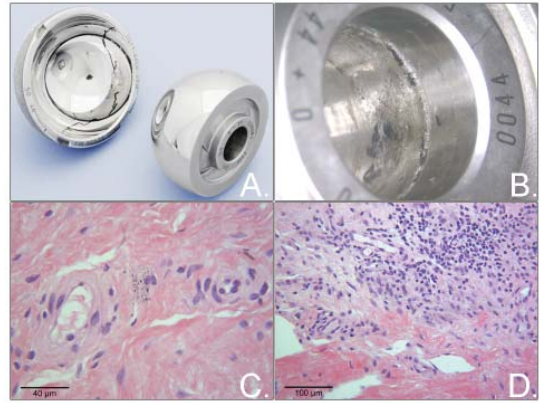
CASE 1 (Corrosion) Mitch Stryker

- 78 yr old female, BMI= 24.5, mod activity. Time in situ: 2 yrs 4 months
- Reasons for removal: pain, elevated serum metal ions (Co, Cr).
- Operative Obs: tissue staining, loose component, cloudy fluid collection.

Acetabular Cup: Flattened granules on ingrowth surface indicative of micromotion. 10% bone ingrowth localised on one side. Unworn patches toward the rim of bearing surface, remainder presents a dull appearance, excessive wear and numerous fine scratches (Fig. A).

Modular Head: Fine scratches in the polar region, unworn toward the rim. Moderate to severe corrosion fretting. Green corrosion products, likely chromium orthophosphate [10] at the taper junction (Fig B).

Histopathology: Fragments of loose fibrovascular tissue, numerous macrophages containing fine metallic particles (Fig C). Blood vessels surrounded by lymphocytes (Fig D). Tissue response could represent ALVAL but changes are not well developed at this stage.



CONCLUSIONS

Excessive and uneven wear of the bearing and corrosion at the taper surface has generated wear particles that have accumulated in periprosthetic tissue, leading to increased serum metal ion levels, an adverse tissue response [6,9] and revision.

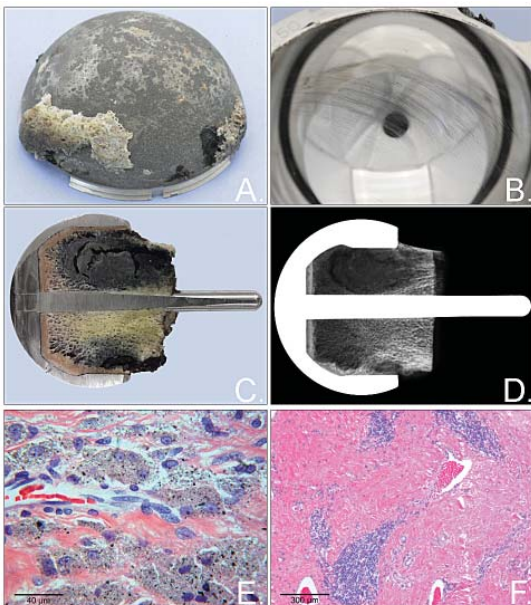
CASE 2 (Metallosis & ALVAL) Durom Resurfacing Zimmer

- 54 yr old male, BMI= 32.7, high activity. Time in situ: 6 yrs and 9 months.
- Reasons for removal: extremely elevated metal ion (Co, Cr) levels.
- Operative Obs: tissue staining, metallosis.

Acetabular cup: Fibrous tissue covers ingrowth surface (Fig A). 15% bone ingrowth in two areas towards the edge, with deeply stained fibrous tissue. Gross wear of bearing, deep, large scratches (Fig B).

Head: Excessive wear, deep scratches, some unworn areas. Inner surface: necrotic, stained tissue, bone cement at the rim. Deep penetration of metallic into bony trabeculae, large region of necrotic bone (Fig C, D).

Histopathology: Papillary structure, moderate no. of multinucleated giant cells and numerous macrophages (Fig E) filled with metallic fragments. Deeper in tissue: Moderate number of blood vessels, surrounded by numerous lymphocytes (Fig F). Changes correspond to ALVAL [5,7].



CONCLUSIONS

Metallosis has led to necrosis, lymphocytic and histiocytic reactions in periprosthetic tissue. Gross and uneven wear of the bearing has generated particles that accumulated in periprosthetic tissue around the components, leading to increased metal ion levels, metallosis, and adverse tissue response.

CASE 3 (Edge Wear) ASR DePuy

- 67 yr old female, 80 kg. Time in situ: 4 yrs
- Reason for removal: Poor position
- Operative Obs: tissue staining, elevated blood metal ion levels (Co=160 and Cr= 50 $\mu\text{g/L}$).

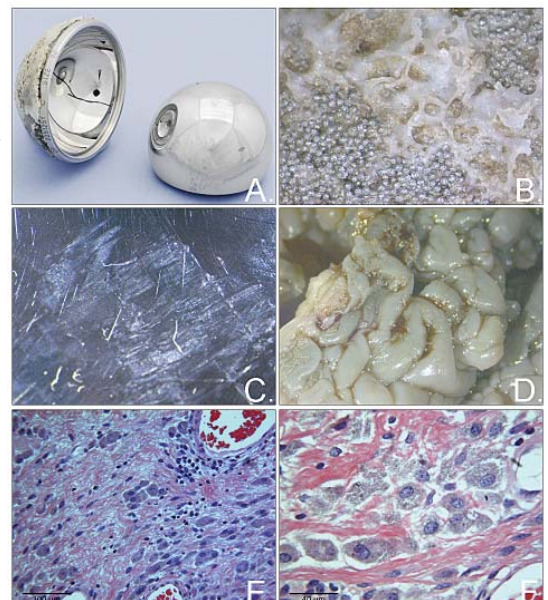
Acetabular cup: Excessive wear on one side - edge loading. On the other side, deep scratches, surface etching, localised corrosion and pitting. 50% bony ingrowth, indicating a well-fixed component. Stained fibrous tissue at the rim. Interposition of fibrous tissue between the beads and bone (Fig B).

Modular Head: Deep scratches concentrated in polar region (Fig C). Fine scratches and pits throughout.

Periprosthetic tissue: A papillary appearance, 'cauliflower', metal stained (Fig D). Histopathology showed a papillary structure with numerous macrophages containing fine metallic debris, (Fig E, F) and few multinucleated giant cells. Deeper in tissue: collagen fibres with numerous blood vessels and few lymphocytes. Features could represent ALVAL but the changes are not well developed.

CONCLUSIONS

Likely edge loading of the cup has caused excessive wear of the bearing, resulting in accumulation of metallic debris leading to a histiocytic response.



WHAT CAN THE BIOMATERIALS LABORATORY DO FOR YOU??

- We are working in collaboration with Dr Jeremy Parry, a RPH Histopathology Consultant, who has an interest in the tissue response to particulate debris around prostheses.
- We are very interested in the tissue response for ALL device-implant interfaces. We generally take tissue from the ingrowth surface. If you would like us to perform this analysis, please send components fixed in formalin with a signed pathology form and we will take care of the rest.
- We perform routine analysis of Co and Cr levels in periprosthetic tissue. If you would like us to perform this test, please send us a minimum of 0.5g (size of a 5 cent coin) in formalin and indicate on the retrieval form in the space provided. (See new form).

SUMMARY

THE PROBLEM

- Many retrieved MoM components are observed to have excessive wear, corrosion and adverse tissue response.
- Pain and increased metal ion levels in blood can be indicative of the development of metal hypersensitivity in some patients.
- Wear of MoM components is significant but not the only problem. Corrosion of the trunion can be a contributory factor and may lead to patient metal hypersensitivity and pain.
- Literature shows that the placement of the acetabular cups is critical. Incorrect positioning can lead to accelerated wear.

MONITORING

- Whole blood monitoring is currently the best way to determine increased metal ion levels, this can be provided by *Pathwest*. Patients must not be taking mineral supplements for a week prior to testing and special collection tubes must be used. Normal levels should be <7 µg/L for Co and Cr, increased levels can be indicative of tissue compromise, however, recent literature recommends <5 µg/L [11].

TAKE HOME MESSAGE

- Subsequent to degradation, cobalt chromium debris appear to initiate adverse tissue reaction.
- We are building up knowledge of the histological response at the tissue/device interface.
- Some modular cobalt chromium devices have shown fretting and corrosion and adverse tissue response even when there is no MOM articulation [12].

REFERENCES

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- [12] Kop, et al, *In press, Clin Orthop Rel Res* (2012).

STAFF SNIPPETS

Dr. Moreica Pabbruwe recently joined us from Bristol, England to cover a period of long service leave. Moreica brings us a particular interest and expertise in the response of periprosthetic tissue to retrieved devices. This expertise has led to a renewed focus on the tissue attached to retrieved devices.

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