Ceramic-on-metal bearings in total hip replacement

WHOLE BLOOD METAL ION LEVELS AND ANALYSIS OF RETRIEVED COMPONENTS

This study reports on ceramic-on-metal (CoM) bearings in total hip replacement. Whole blood metal ion levels were measured. The median increase in chromium and cobalt at 12 months was 0.08 μg/1 and 0.22 μg/1, respectively, in CoM bearings. Comparable values for metal-on-metal (MoM) were 0.48 μg/1 and 0.32 μg/1. The chromium levels were significantly lower in CoM than in MoM bearings ($p = 0.02$). The cobalt levels were lower, but the difference was not significant. Examination of two explanted ceramic heads revealed areas of thin metal transfer. CoM bearings (one explanted head and acetabular component, one explanted head and new acetabular component, and three new heads and acetabular components) were tested in a hip joint simulator. The explanted head and acetabular component had higher bedding-in. However, after one million cycles all the wear rates were the same and an order of magnitude less than that reported for MoM bearings. There were four outliers in each clinical group, primarily related to component malposition.

The use of metal-on-metal (MoM) bearings made from high-carbon cobalt-chromomolybdenum alloys has increased significantly for both conventional total hip replacement (THR) and surface replacement in recent years because of increased stability and reduced volumetric wear. However, the potential long-term effects of elevated levels of metal ions have remained a concern.1–4 Short-term complications such as joint instability and dislocation have been attributed in part to malpositioning of the acetabular component.5,6 Using a radiological measurement of orientation Lewinnek et al7 proposed a ‘safe zone’ which was defined as an inclination of 40° ($±10°$) and an anteversion of 15° ($±10°$). Significantly elevated metal ion levels have been attributed to malpositioning of the acetabular component.8–13

The bearing couple consisting of a ceramic head articulating against a metal acetabular liner (CoM) has been shown to reduce wear and friction compared to MoM bearings in vitro.12,14 Lower wear has been attributed to a reduction in corrosive wear, smoother surfaces, improved lubrication and differential hardness reducing adhesive wear.13,15 A randomised prospective clinical trial was undertaken using CoM, MoM, ceramic-on-polyethylene and ceramic-on-ceramic bearings in an otherwise identical THR procedure. The initial clinical results comparing CoM and MoM were encouraging13 but were limited in number (seven patients in each cohort) and duration of follow-up (more than six months).

This report consists of two parts. First, a further clinical review of whole blood metal ion data from the CoM and MoM bearings reported previously,13 but with an increase in the number of patients and a longer duration of follow-up. Second, a laboratory examination of two explanted CoM bearings to assess any in vivo changes, and to assess their effect on the wear performance of the CoM bearings by comparing the wear of the explanted bearings with three new CoM implants in a hip joint wear simulator. The further research questions being asked are, first, does the increased follow-up with an increase in the number of patients support both the laboratory studies and the early clinical data? Second, do retrieved components show any evidence of changes that would undermine the conclusions from the laboratory data?

Patients and Methods

Clinical. This study is a subset of a larger study where the only variable was the bearing surface. In addition to CoM and MoM, ceramic articulating against a cross-linked polyethylene and ceramic articulating against ceramic were compared. All the patients received identical components, a Corail HA-coated femoral component and a Pinnacle acetabular component, both
made from Ti-6Al-4V alloy. One patient was revised to a femoral component made from a cobalt-chrome alloy but was kept in the study. In the data reported here the bearing surfaces comprised a 28 mm diameter femoral head made from either zirconia toughened alumina (Biolox Delta) or wrought high-carbon, cobalt-chrome-molybdenum alloy (Ultamet) articulating against a wrought high-carbon, cobalt-chrome-molybdenum alloy (Ultamet) acetabular liner. All components were supplied by DePuy International Ltd, Leeds, United Kingdom. In this study metal ion data on the first 30 CoM patients (18 women, 12 men, mean age at arthroplasty 53 years (18 to 72)) and the first 30 MoM patients (21 women, nine men, mean age at arthroplasty 55 years (32 to 71)) were measured. Of these, one CoM patient had been revised; however, the components were retrieved, analysed, and the findings reported in this study. The patients were assessed pre-operatively, and at three, 12 and > 24 months (median 32 months (19 to 44)). Whole blood was collected at regular follow-ups using Venflon needles (Becton Dickinson, Helsinborg, Sweden) with disposal of the first 5 ml of blood to avoid metal contamination, a technique described by Seldinger.16 Samples were then frozen and analysed in batches using high-resolution inductively coupled plasma -mass spectrometry (ICP-MS, Element2, Thermo Electron, Bremen, Germany). Two aliquots were taken from each sample and both were diluted and analysed in triplicate. The resulting six measurements were then averaged to give a single data point. All values are reported in μg/l, which is equivalent to parts per billion (ppb). The limit of detection of this technique varies depending on the metal being analysed. These limits are 0.015 μg/l and 0.1 μg/l for cobalt (Co) and chromium (Cr), respectively. Any value falling below the level of detection is assumed to be half the level of detection. A combined metal ion level (Co+Cr) was also calculated. All recruited patients are included irrespective of clinical outcome. However, some patients failed to attend specific follow-up, some blood samples were not taken, and some contaminated samples had to be discarded. Patients receiving a contralateral THR containing a metal bearing were not included from that point onwards. Statistical significance was analysed using a two-tailed non-parametric comparison (Mann-Whitney test) or two tailed Student’s t-testing as appropriate. A p-value < 0.05 was considered significant.

Laboratory. Two retrieved components were available for analysis. Both were revised for reasons unrelated to the bearing surface (sample A: infection, sample B: periprosthetic fracture) and are described in Table I. One retrieval (sample A) had 12 months of metal ion data and is included in the clinical dataset. The second (sample B) was revised at five weeks, had no follow-up metal ion data, and is not included in the clinical dataset. Both retrieved components were visually examined and imaged using a digital camera. Surface profilometry was performed using a 2D contacting profilometer (Form Taly-surf, Taylor Hobson, Leicester, United Kingdom). Traces were taken in the unworn regions and across notable surface features, with a trace length of 15 mm. Analysis was performed using a Gaussian filter with 0.8 mm cut-off (bandwidth 100:1) and the data fitted to a least-squares arc to eliminate form.

Scanning electron microscopy (SEM) (gaseous secondary electron (GSE)) was used to image the regions of transfer on the ceramic heads, and EDX (energy dispersion of x-rays) to assess the transfer composition (Philips XL30 ESEM, FEI group, Hillsboro, Oregon). SEM images were taken with a spot size of 6, at 0.6 Torr/20 keV. Because of the high penetration of the beam it was not possible to identify the composition of the surface film with a beam energy at 20 keV. Therefore, the EDX analysis was performed with a reduced beam energy of 10 keV.

Hip simulator testing was conducted for 2 million cycles comparing the explanted bearings with three new 28 mm CoM bearings. Tests were performed in a Prosim hip simulator (SimSol, Stockport, United Kingdom), which applied a twin peak loading cycle with a peak load of 3 kN. Flexion-extension of -15° to 30° was applied to the head and internal-external rotation of ± 10° was applied to the acetabular component; components were mounted in the anatomical position with the acetabular component angle corresponding to an approximate abduction angle of 45°. The lubricant was 25% (w/v) calf serum supplemented with 0.03% (w/v) sodium azide and was changed approximately every 0.33 million cycles, and wear was measured gravimetrically at 0.5, 1 and 2 million cycles and converted to volumetric wear (mm³), assuming the density of the metal alloy and ceramic material to be 8330 kg/m³ and 4365 kg/m³, respectively. Wear rates are expressed as volumetric wear per million cycles (mm³/million cycles).

Table I. Details of retrieved components

<table>
<thead>
<tr>
<th>Sample</th>
<th>Components</th>
<th>History</th>
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<tbody>
<tr>
<td>A</td>
<td>Head + acetabular components</td>
<td>14 months in vivo</td>
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<tr>
<td></td>
<td></td>
<td>Retrieved for infection</td>
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<tr>
<td></td>
<td></td>
<td>Patient had fallen</td>
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<tr>
<td>B</td>
<td>Head only</td>
<td>5 weeks in vivo</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Retrieved for periprosthetic fracture</td>
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<tr>
<td></td>
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<td>Patient had fallen</td>
</tr>
</tbody>
</table>
Results

Clinical. Of the 30 patients recruited, at the three- and 12-month time points there were between 21 and 24 patients available for analysis in both the CoM and the MoM cohorts. A smaller number of patients had reached the > 24-month point (ten and nine, respectively). This reduction in numbers was caused primarily by patients missing follow-up appointments, blood samples not being taken, a contaminated sample, and implantation of a joint with a metal bearing on the contralateral side. The core dataset analysed in this study comprised all patients (22 CoM and 19 MoM) who had both pre-operative and 12-month blood samples.

The CoM and MoM cohorts had the same median metal ion levels pre-operatively, at which time the Co levels were higher than the Cr levels (Student’s paired two-tailed t-test, p = 0.017). The median Cr and Co levels were lower with the CoM bearing than with MoM at all measurement points following implantation except one (three-month Cr), where there was equivalence. At 12 months the median CoM Cr and Co levels were 0.43 μg/1 and 0.72 μg/1, respectively. The comparable values for MoM were 0.66 μg/1 and 0.83 μg/1 (Fig. 1).

The median increase from pre- to post-operative levels at three and 12 months provides a common baseline and simplifies the trends over time. The Co levels were lower with CoM than with MoM, but the gap narrowed at 12 months (Fig. 2). Conversely, the changes in Cr were the same at three months but thereafter the CoM values were lower than with MoM. At 12 months the median increase in CoM, Cr and Co levels was 0.08 μg/1 and 0.22 μg/1, respectively. The comparable values for MoM were 0.48 μg/1 and 0.32 μg/1. There were insufficient data points at 32 months to make a meaningful comparison of increases in metal ions, and the MoM cohort was skewed by a small number of outliers. Median Cr and Co levels for CoM were 0.34 μg/1 and 0.32 μg/1, respectively. Comparable values for the MoM group were 2.94 μg/1 and 5.72 μg/1. Cr and Co metal ion values were added together for each patient to give a total metal ion load. The median increases in metal ion load at three and 12 months, respectively were -0.01 μg/1, 0.35 μg/1 for CoM; and 0.36 μg/1, 0.91 μg/1 for MoM.

The level of significance of differences between CoM and MoM of actual (absolute) values and changes from pre-operative levels (difference) are shown in Table II. There was no significant difference between the Co levels at three months (p = 0.159, p = 0.134 for absolute and difference levels respectively). At three months there was a trend for the combined difference value to be lower (p = 0.057). At 12 months there was a trend of reduced Cr absolute levels with CoM compared to MoM (p = 0.059). Also at 12 months the Cr difference values were significantly lower for CoM (p = 0.020). Comparison of the combined levels at 12 months showed that CoM was significantly lower for absolute (p = 0.05) and difference values (p = 0.04).

Laboratory. A summary of the history of the retrieved components is given in Table I. The implantation times were 14 months (sample A) and five weeks (sample B). The surfaces of the components are characterised in Figures 3 and 4, respectively. Visual inspection of the explanted bearings showed some evidence of transfer material on the ceramic

| Table II. The p-values of the Mann Whitney U tests comparing the median chromium (Cr) and Cobalt (Co) ion release, and their combined median values, at two intervals and using the absolute and difference from the pre-operative values, for the ceramic on metal and metal on metal articulations  |
|-----------------|--------|-------|----------|
| Absolute (mths) | Cr     | Co    | Combined |
| 3               | 0.451  | 0.159 | 0.117    |
| 12              | 0.059  | 0.191 | 0.050    |
| Difference (mths) | 0.665 | 0.134 | 0.057 |
| 12              | 0.020  | 0.250 | 0.040    |
heads (Figs 3 and 4). These comprise areas of ‘heavy’ and ‘light’ metal transfer, and areas that had not changed following implantation. Examination of the metal acetabular component (only sample A was available) showed no evidence of rim damage and only slight evidence of scratching within the bearing surface.

Talysurf traces were taken of the retrieved heads and are summarised in Table III. Traces traversing regions of ‘heavy’ material transfer on sample A (Fig. 3) clearly show a rougher surface (Ra) with larger peaks (Rv) and more positive skew (Rsk) compared to sections on the same trace where transfer material was not apparent. Traces taken through regions of ‘light’ surface transfer on sample A did not show significantly different surface parameter values from a section of the trace that had no transfer film, suggesting that the ‘light’ surface material transfer did not disrupt the surface integrity. A trace through an area visually identified as comprising ‘heavy’ transfer on sample B (Fig. 4) shows only marginal disruption to the surface. Table III also shows that this area of transfer did not exhibit any measurable surface roughening and had a surface profile that was no different from that of areas without transfer.
material. SEM was performed on both ceramic heads in the regions of visually observed ‘heavy’ material transfer (Figs 3 and 4). Further analysis of the transfer film using EDX showed a composition including cobalt and chromium elements, suggesting that the transfer material is from the cobalt-chromium acetabular component.

The total overall mean wear rate for the new CoM bearings at 2 million cycles of wear testing was 0.047 mm³/million cycles (± 0.06). The mean wear rate for the explanted head articulated with a new acetabular component was slightly lower at 0.034 mm³/million cycles. The mean wear rate for the explanted head and acetabular component was highest at 0.15 mm³/million cycles (Fig. 5). It was noted that the explanted head/acetabular component combination had higher bedding in wear than the other bearings, but the steady-state wear was comparable with that of the other bearings. Negative wear was observed and attributed to the limits of the measuring system. The effect of bedding-in is further illustrated by Figure 6, which clearly shows that upon completion the steady-state wear rate is virtually identical for all three wear test configurations. This reinforces the conclusion that the transfer (both heavy and light) observed on the retrieved components has little or no effect on the ongoing wear rates.

In the majority of cases more wear occurred on the acetabular component than the head. The wear on the new heads ranged from 0.022 to 0.061 mm³ after 2 million cycles, which represents a mean value of 38% of overall wear. In terms of absolute values, these results span the
range for retrieved components, which were 0.035 mm³ for the explanted head and new acetabular component, and 0.053 mm³ for the explanted head and acetabular component. The percentage of acetabular component to head wear was 32% and 17%, respectively. In general, the similarity in hip simulator performance between retrieved and wear was 52% and 17%, respectively. In general, the similarity in hip simulator performance between retrieved and wear was 52% and 17%, respectively.

Discussion
The background levels of Co were significantly higher than those of Cr. The median Co/Cr ratio of the background levels was 1.95. It is always difficult to compare results from different studies, but it seems reasonable to compare Co/Cr ratios as this will to a certain extent mitigate differences in sampling and measurement techniques. Other reports of pre-operative levels show a wide variation in this value, from 0.18 to 18,12,17-19 indicating that local conditions such as water content and industrial contamination will have a significant effect on pre-operative levels. The relatively small increases in metal ion levels following implantation of MoM bearings means that pre-operative levels will affect the levels measured post-implantation, and any metal ion data that do not take account of pre-operative levels may give an incorrect assessment of the performance of the bearing surface. It is therefore important that increases in metal ion levels from pre-operative levels are used as the primary ion level outcome, because in this study the background level will be of the order of 30% to 50% of the overall value. The use of ‘differences’ rather than ‘absolute’ values changes the level of significance for Cr at 12 months from p = 0.059 to p = 0.02 (Table II). The reason for the relatively high Co levels in the current study group is unknown.

Hart et al20 used the concept of total metal ion load (Co+Cr) to try and accentuate metal ion level differences between patients undergoing biochemical changes and those who were unaffected. This measure was used in this study to try and differentiate between metal ion levels in CoM and MoM bearings. Levels of significance were low for all Co measures, and levels of significance for combined values were lower than those observed for Cr alone. This indicates that the use of a combined value was not helpful in trying to discriminate between CoM and MoM performance.

The general conclusion that CoM wears less is in line with hip simulator data,13 but the difference is less than that predicted in the laboratory and is much more pronounced with Cr than with Co, and is only significant in the former. In hip joint simulator studies the debris produced has a Co-Cr ratio in line with the stoichiometric value of 2.5.21 At all measurement points in this study the Co-Cr ratio was less than the stoichiometric value. The ratio for CoM was relatively constant and did not change appreciably from pre-operative levels, varying from 1.57 to 1.68. In contrast, the MoM values initially rise from the pre-operative values of 1.65 to 2.10 at three months, dropping back to 1.24 at 12 months. The difference between the three- and 12-month values is not significant, but shows a strong trend (p = 0.07). The reason for these observations are unknown. However, one may hypothesise that it is related to the corrosion effects previously noted in the laboratory.15

There were eight ‘outliers’ (either Cr or Co > 10 μg/l), four in each of the CoM and MoM groups. These were generally related to component position. With the exception of two marginal outliers (< 15 μg/l), one in each group, the other six outliers had either a high acetabular component abduction angle (> 50°) or a high anteversion angle (> 25°), or in some cases both. These six outliers were therefore outside the Lewinnek safe zone of 30° to 50° of inclination and 5° to 25° of anteversion.7 Other studies with the same design of component and bearing diameter have reported no significant outliers.17,22 An observation that increases the likelihood that the outliers were related to component position and not to design. In both CoM and MoM outlier groups the Co and Cr levels were much higher than in the non-outlier or ‘normal’ group. At the latest follow-up for each of the outliers, the mean CoM, Cr and Co levels were 11.29 μg/l and 28.06 μg/l, respectively and the comparable levels for MoM were 32.61 μg/l and 48.83 μg/l. However, with such small numbers any differences between CoM and MoM outlier groups are not meaningful. Furthermore the latest follow-up for the MoM group (3.24 years) was longer than that of the CoM group (2.2 years), making comparison difficult. Despite the small numbers involved it does serve to illustrate the fact that, in common with other metal ion studies,6,8-12 including an early report of CoM,13 component malposition (both CoM and MoM) may result in significantly elevated metal ion levels. The ‘normal’ group may also be considered separately. At 12 months this group comprised 21 CoM and 18 MoM cases.
Interestingly, there are seven CoM and six MoM cases in each group, which although outside the Lewinnek ‘safe zone’ do not exhibit abnormally high metal ion levels. This is also consistent with other studies. The reason for this is unknown, but it may be postulated that it is related to the biomechanics and anatomy of individual patients. It could be argued that the significant difference between CoM and MoM Cr levels at 12 months was influenced by the outliers. However, if the same test is applied to the increase in Cr ions in ‘normals’ at 12 months then p = 0.013. This is a higher level of significance than for the whole group (p = 0.02, Table II), indicating that the outliers are a confounding factor in this dataset. One patient was revised to a femoral component made from a Co-Cr alloy. It was decided to keep this patient in the study as clinical evidence suggests that such components do not add to the metal ion burden.

Regions of material transfer were identified on both explanted ceramic heads, which were identified as CoCr material by EDX analysis, suggesting metallic transfer from the acetabular component. This transfer film could only be detected when using a relatively low beam energy of 10 keV. When a beam energy of 20 keV was used no metallic transfer could be detected, indicating that the film was very thin. Profilometry traces across the retrieved heads showed that they were generally the same roughness as areas of the retrieved component where no transfer film was observed, and also the same roughness as new, ‘unused’ heads. This demonstrates that the presence of transfer can be deceptive in this bearing couple. A feature that would visually appear to be disruptive to the bearing surface has an immeasurable effect on the surface topography. However, one area of sample A was noted to have a measurably higher surface roughness than unused heads (Fig. 3). This may have been caused by normal articulation, but could have been related to this patient falling.

The wear test showed higher bedding-in wear rates for the explanted head/acetabular component bearing (sample A) than for the new CoM bearings tested. However, the orientation of these implants in vivo was unknown, hence it was not possible to align the components for wear testing. Thus one explanation is that the elevated wear during bedding-in of the explanted head/acetabular component bearing may be due to a difference in the alignment of the components. This explanation is consistent with wear tests following removal and cleaning, measurement and replacement of components, whereby small jumps in wear rates are occasionally observed. Another explanation for this higher bedding-in is the previously noted area of measurable ‘heavy’ transfer on this head in the contact area, and it is possible that this may have temporarily increased the wear rate. This explanation would also be positive, as this would suggest that areas of transfer can be polished away, leaving a pristine surface. Regardless of explanation (either a second bedding-in process or removal of heavy transfer film), following bedding-in the simulator wear rates were identical to both retrieved heads tested against a new acetabular component and totally new components. The bedding-in process in the worst case is still relatively quick, and appears to take between 0.5 and 1.0 million cycles. The wear rates of the explanted ceramic head against a new acetabular component were comparable with the new bearings both in the bedding-in and steady-state phases, further suggesting that the presence of metallic transfer or indeed any other changes to the ceramic head does not adversely affect the wear behaviour of CoM bearings. The above issues notwithstanding, it should also be noted that comparable wear rates for a MoM bearing would typically be 2.03, 0.22 and 0.58 mm³/million cycles for bedding-in, steady state, and overall wear rates, respectively. These levels are much higher than the worst-performing combination (retrieved head/retrieved acetabular component) in this study, where comparable values would be 0.3, 0.002 and 0.15 mm³/million cycles.

Of the two retrieved components, sample B was only implanted five weeks prior to revision, had only the head available for analysis, and no meaningful metal ion data. However, sample A had 12 months of metal ion data and both components were retrieved, warranting further discussion. The patient was a female, aged 65 years at the time of the replacement. The acetabular component inclination was 39°. The pre-operative metal ion levels were 0.31 μg/l for Cr and 0.69 μg/l for Co. The values at 12 months were lower, at 0.25 μg/l and 0.39 μg/l, respectively. This reduction is likely to have been caused by sample variability. Nevertheless, it demonstrates that in this particular case there was no measurable increase in metal ions and, by inference, that the metal transfer noted on the head had not resulted in significant wear. Sample A was revised for infection, but the patient had suffered a fall. It is likely that this bearings were articulating normally prior to retrieval, suggesting that significant metal transfer on to the ceramic head is a normal and non-detrimental feature of CoM wear in vivo. However, it is also possible that the metal transfer was caused by the fall.

This study has significantly clarified the performance of CoM bearings in THR. The CoM bearing produced lower levels of metal ions than comparable MoM bearings at all time points. The increase in Cr ion levels was significantly less at 12 months, but Co levels, albeit lower, were not significantly different. The earlier report of a subset of the current cohort showed a similar trend.

Retrieved components exhibited only cosmetic damage, and when placed in a simulator had a steady state of wear rates that were indistinguishable from those of new CoM components, and much less than reported hip simulator data for MoM bearings. Although these results are positive from a clinical performance standpoint, there are a number of questions that need to be answered before this new bearing system is fully understood. The difference between CoM and MoM in whole blood metal ion studies is less than that predicted from hip simulator tests. The observation that this
difference is confined to chromium, whereas the cobalt values are very similar, was not predicted from simulator studies. Finally, the non-stoichiometric Co-Cr ratio of whole blood metal ion values and their true relationship to wear of the joint needs to be understood, both for this study and for MoM bearings in general.

Supplementary Material
A further opinion by Mr R. F. Spencer is available with the electronic version of this article on our website at www.jbjs.org.uk

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References