Serum aluminium and cobalt levels after ceramic-on-ceramic and metal-on-metal total hip replacement


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Peri-prosthetic osteolysis is associated with aseptic loosening of a total hip replacement (THR). It is understood to be a biological response to wear particles, with polyethylene debris thought to be the major cause of the long-term failure. Alternative bearing surfaces such as ceramic-on-ceramic and metal-on-metal eliminate polyethylene wear. Explanted metal-on-metal articulations made of cobalt-chromium-molybdenum (Co-Cr-Mo) alloy have been shown to have extremely low rates of linear wear, and ceramic-on-ceramic bearings even less. A ceramic-on-ceramic articulation was first implanted in 1970 in France. Long-term reports have shown excellent clinical results.

Concern has been expressed, however, about the biological response to metal particles released from metal-on-metal couplings. The levels of cobalt and chromium ions have been measured in the blood and serum in patients with successful THR but information about the possible release of aluminium from ceramic-on-ceramic articulations is lacking.

In a randomised study, 28 patients with a mean age of 62.2 years (32 to 81) with osteoarthritis or avascular necrosis of the hip received either a ceramic-on-ceramic or a metal-on-metal total hip replacement. Apart from the liners the acetabular and femoral components were made of Ti-Al-Nb alloy. The serum aluminium and cobalt levels were measured before, and at one year after surgery.

The 15 patients in the ceramic-on-ceramic group had a median pre-operative aluminium level of 1.3 µg/l (0.25 to 8.4) and a cobalt level below the detection limit. At one year the aluminium level was 1.1 µg/l (0.25 to 2.3) and the cobalt level was 0.4 µg/l (0.15 to 0.7). The 13 patients in the metal-on-metal group had a median pre-operative aluminium level of 1.9 µg/l (0.25 to 4.4) and a cobalt level below the detection limit. At one year the median aluminium level was 0.9 µg/l (0.25 to 3.9) whereas the cobalt level was 1.4 µg/l (0.5 to 10.5).

This increase in the cobalt level at one year was significant (p < 0.001).

Our findings indicate that ceramic-on-ceramic bearings do not cause elevated levels of serum aluminium in the first post-operative year.

Patients and Methods

Patients with unilateral primary osteoarthritis or avascular necrosis of the hip were eligible for inclusion in our study. Those with rheumatoid arthritis or renal malfunction were excluded to avoid the introduction of confounding variables. Rheumatoid patients often have, or require, other joint replacements and chronic renal failure has been shown to be a contraindication to metal-on-metal articulations because of the accumulation of metal ions. Patients with other metal implants were also excluded.

Between November 2000 and February 2002, 28 patients were randomly assigned to receive either a ceramic-on-ceramic or a metal-on-metal bearing. Of these, 26 had osteoarthritis and two avascular necrosis. There were 18 women and ten men with a mean age of 62.2 years (32 to 81) at the time of operation. Their mean body mass index was 28.2 kg/m² (19.6 to 37.3). Ethical approval for the study had been obtained.

Every patient received the same type of prosthesis except for the bearing surface. Of the 28 patients, 15 (8 women, 7 men) had a ceramic-on-ceramic component and 13 (10 women, 3 men) a metal-on-metal component.

Table I. Pre-operative levels of aluminium and cobalt

<table>
<thead>
<tr>
<th>Articulations</th>
<th>Obs†</th>
<th>25% Quartile</th>
<th>Median</th>
<th>75% Quartile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Al Ceramic</td>
<td>15</td>
<td>0.8000000</td>
<td>1.3000000</td>
<td>2.6000000</td>
</tr>
<tr>
<td>Al Metal</td>
<td>13</td>
<td>1.0000000</td>
<td>1.9000000</td>
<td>2.4000000</td>
</tr>
<tr>
<td>Co Ceramic</td>
<td>15</td>
<td>0.1500000</td>
<td>0.1500000</td>
<td>0.1500000</td>
</tr>
<tr>
<td>Co Metal</td>
<td>13</td>
<td>0.1500000</td>
<td>0.1500000</td>
<td>0.1500000</td>
</tr>
</tbody>
</table>

* Al, aluminium; Co, cobalt
† Obs, number of observations

Blood was drawn using cobalt-free Vacutainer needles and glass tubes without additives (Becton-Dickinson and Company, Franklin Lakes, New Jersey) before surgery and at follow-up at 12 months. The serum aluminium and cobalt levels were determined using a 5100-ZL atomic absorption spectrometer (Perkin Elmer, Shelton, Connecticut) at wavelengths of 309.3 and 242.5 nm. The laboratory technician was blinded to the analyses. The detection limit for aluminium in serum was 0.5 µg/l and for cobalt 0.3 µg/l in our laboratory. Concentrations below the limit of detection were defined as 0.25 µg/l for aluminium and 0.15 µg/l for cobalt, to allow statistical calculation.

Additionally, a routine clinical follow-up was performed which included radiography and measurement of the Harris hip score and the University of California at Los Angeles (UCLA) activity score.

Statistical analysis. In order to investigate a potential increase in serum concentration, four separate sign tests for paired data were performed (cobalt and aluminium in both treatment groups). A p value of ≤ 0.05 was considered to be statistically significant. All computations were performed using SAS software version 8.2 (SAS Institute Inc., Cary, North Carolina).

Results

Pre-operative data on aluminium and cobalt levels, presented as the median and quartiles, are shown in Table I.

In the ceramic group the median pre-operative level of aluminium was 1.3 µg/l (0.25 to 8.4) and that of cobalt was below the limit of detection of 0.3 µg/l. At one year after operation the median aluminium level was 1.1 µg/l (0.25 to 2.3) and that of cobalt 0.40 µg/l (0.15 to 0.70).

In the metal group the median pre-operative level of aluminium was 1.9 µg/l (0.25 to 4.4) and that of cobalt was below the limit of detection. At 12 months the median level of aluminium was 0.9 µg/l (0.25 to 3.9) and of cobalt 1.4 µg/l (0.5 to 10.5). The changes are shown in Figure 1.

One year after operation no significant increase in the serum level of aluminium or of cobalt was found with the ceramic-on-ceramic articulations (p = 1.00, p = 0.508, respectively). In the metal-on-metal group the cobalt level increased significantly at one year (p < 0.001). The decrease in the levels of serum aluminium was also found to be significant using the Sign test (p = 0.012).

The mean Harris hip score in the ceramic-on-ceramic group improved from 58.4 (24.4 to 82.3) pre-operatively to 86.6 points (56 to 78) at one year and in the metal-on-metal group from 50.4 (15.1 to 71.4) to 85.1 points (61.1 to 100). For both groups the UCLA activity score was seven to 100. For both groups the UCLA activity score was seven to 100. For both groups the UCLA activity score was seven to 100. For both groups the UCLA activity score was seven to 100.
Cerasul ceramic-on-ceramic bearings has been published.

Aluminium.

bearings are not associated with elevated levels of serum


ceramic-on-ceramic bearings were not studied.

The number of hard-on-hard bearings used in THR has

Discussion

This is the first report of the measurement of the serum con-

centration of aluminium after ceramic-on-ceramic THR.

The number of hard-on-hard bearings used in THR has been increasing in all age groups. It has been shown that cobalt and chromium ions are released from THRs with metal-on-metal bearings, and some authors have postu-

lated that the serum concentrations of cobalt and chro-

mium may increase as a function of the life of the implant in patients.

Ceramic-on-ceramic bearings have the advantage of low wear and high biocompatibility. Alumina-ceramic particles are essentially insoluble in organic media and ionisation is therefore unimportant. In a previous report the level of serum aluminium was not found to be altered by THR, but ceramic-on-ceramic bearings were not studied. The serum aluminium in that report was comparable to our findings.

At one year after operation we found no evidence of system release of aluminium in the ceramic-on-ceramic or the metal-on-metal groups. However, changes in the level of serum cobalt at one year showed a significant difference between the two groups ($p < 0.001$) (Fig. 1).

An in vitro comparison of Metasul metal-on-metal and Cerasul ceramic-on-ceramic bearings has been published.

Using a Stanmore Mk-III hip simulator the authors tested 28 mm heads over 2 to $5 \times 10^6$ cycles. Measurements of the wear of the components showed similar abrasive wear behaviour for both types of articulation.

In another prospective, randomised study involving a total of 514 patients alumina ceramic bearings were compared with Co-Cr metal-on-polyethylene bearings. The mid-term results were published in 2002 and did not show any significant difference in clinical performance between the two types of bearing.

Aluminium has been linked to various neurological disorders including Alzheimer's disease. Although a causal relationship between aluminium and Alzheimer's disease has not been established there is evidence that it may exacerbate events associated with this disorder.

Our short-term data from an in vivo comparison of two hard-hard articulations show that ceramic-on-ceramic bearings are not associated with elevated levels of serum aluminium.

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