Early surveillance of ceramic-on-metal total hip arthroplasty

Ceramic-on-metal (CoM) is a relatively new bearing combination for total hip arthroplasty (THA) with few reported outcomes. A total of 287 CoM THAs were carried out in 271 patients (mean age 55.6 years (20 to 77), 150 THAs in female patients, 137 in male) under the care of a single surgeon between October 2007 and October 2009. With the issues surrounding metal-on-metal bearings the decision was taken to review these patients between March and November 2011, at a mean follow-up of 34 months (23 to 45) and to record pain, outcome scores, radiological analysis and blood ion levels. The mean Oxford Hip Score was 19.2 (12 to 53), 254 patients with 268 hips (95%) had mild/very mild/no pain, the mean angle of inclination of the acetabular component was 44.8° (28° to 63°), 82 stems (29%) had evidence of radiolucent lines of > 1 mm in at least one Gruen zone and the median levels of cobalt and chromium ions in the blood were 0.83 μg/L (0.24 μg/L to 27.56 μg/L) and 0.78 μg/L (0.21 μg/L to 8.84 μg/L), respectively. The five-year survival rate is 96.9% (95% confidence interval 94.7% to 99%).

Due to the presence of radiolucent lines and the higher than expected levels of metal ions in the blood, we would not recommend the use of CoM THA without further long-term follow-up. We plan to monitor all these patients regularly.

Traditionally, most total hip arthroplasties (THAs) have used metal-on-polyethylene (MoP) articulations.1 However, particulate debris resulting from wear of the polyethylene bearing surface can lead to failure due to osteolysis and subsequent loosening.2 As a result, alternative articulations such as ceramic-on-ceramic (CoC) and metal-on-metal (MoM) have been introduced in an endeavour to reduce wear and osteolysis, and to extend the life of the implant.3,4 Both of these bearing surfaces have been shown to produce less wear than MoP.5 However, with the recent problems observed with MoM THA, CoC is now considered to be the safer choice with low rates of wear and excellent survival, which in some studies is greater than that of MoP, at ten years and beyond, even in young, high demand patients.6-9

In spite of the low rates of wear of both CoC and MoM bearings, there are theoretical advantages to the use of ceramic-on-metal (CoM) bearings. The use of bearing surfaces with different levels of hardness may result in lower rates of wear.10 In CoM, the harder ceramic head may be more resistant to damage and stripe wear under edge loading than a metal head, and the use of a metal acetabular liner avoids the problems associated with ceramic liners, which may chip or crack during seating.7,11 In theory, blood metal ion levels should be lower than with MoM bearings and there are also unsubstantiated claims of reduced squeaking compared with CoC.12 Finally, metal liners can be made less thick than ceramic liners, allowing larger head sizes to be used; for instance, with the Pinnacle system (DePuy Synthes, Leeds, United Kingdom) it is possible to use a 36 mm head with a 50 mm acetabular component, whereas with a ceramic liner it is only available with a 52 mm implant. It was these theoretical advantages that prompted us to start using a CoM bearing in 2007.

Ceramic-on-metal (CoM) articulations are not widely used in THA. In the 2013 report from the National Joint Registry for England, Wales and Northern Ireland (NJR) only 2017 CoM THAs are recorded, with up to four years of follow-up data;13 in the Australian Orthopaedic Association Joint Replacement Registry (AOANJRR), there are only 316 such THAs.14 In the NJR, the four-year rate of revision for CoM is 4.15% (95% confidence interval (CI) 3.06 to 5.62),13 compared with 2.20% (95% CI 2.06 to 2.34) and 5.24% (95% CI 4.97 to 5.52) for cementless THA using CoC and...
MoM bearings, respectively. The AOANJRR reports a three-year rate of revision of 3.6%.\textsuperscript{14}

Due to the recent concern with the early failure of MoM THAs\textsuperscript{15} and the lack of clinical data available on the use of CoM THA, a surgeon-initiated surveillance programme was carried out at our hospital. This study reports a single-surgeon series of CoM THAs, with outcomes including implant survival, radiological outcomes, blood ion levels, and clinical outcomes including pain and patient-reported outcome measures (PROMs).

Patients and Methods

A total of 287 CoM THAs (271 patients) were performed under the care of the senior author (DEB) between October 2007 and October 2009. CoM was our bearing of choice for younger patients, and the mean age of patients in this cohort was 55.6 years (20 to 77). Of the 271 patients, 141 were women (150 hips, 52%) and 152 (53%) were right-sided. In all cases, a Corail femoral stem was used with a Biolox Delta ceramic head, and a Pinnacle metal liner (all DePuy Synthes, Leeds, United Kingdom). The Corail stem is available with three configurations of neck: standard (available with and without a collar), coxa vara (which has a collar) and high offset (which is collarless); 28 mm, 32 mm and 36 mm diameter modular heads were used; all were available with three lengths of neck (1.5 mm, 5 mm, 8.5 mm). The operations were undertaken with the patient in a lateral decubitus position using the posterior approach.

In our institution, patients are routinely reviewed at six weeks, one year and ten years by an arthroplasty nurse specialist. An additional review was carried out for this cohort between March and November 2011. Unfortunately, the paper was not submitted until now due to the volume of work and low staffing levels within the unit. At each visit, outcomes were assessed using the Oxford hip Score (OHS)\textsuperscript{16} in its original format (scoring from 12 (best) to 60 (worst)), Harris hip score (HHS)\textsuperscript{17} and a visual analogue score (VAS) for pain, with 1 being no pain and 5 severe pain. Anteroposterior (AP) pelvic and lateral hip radiographs were taken at one year and at the time of the review. At the review, blood was taken to measure cobalt and chromium whole blood ion levels. Samples were analysed in an approved laboratory using inductively coupled plasma mass spectrometry (Element2, Thermo Finnigan, Bremen, Germany). In order to give up to date data, survival is reported at the time of the submission of the paper, rather than at the time of the surveillance review. Patients were contacted via telephone, and the two that were lost to follow-up at the time of review were later verified as still having their THA by a relative.

Radiographs were analysed by an independent expert (JB). The angle of inclination of the acetabular component was measured using the teardrop method on the immediate post-operative AP radiograph.\textsuperscript{18} The presence and size of radiolucent lines (RLLs) were assessed and classified in Gruen\textsuperscript{19} zones (1 to 14, for the femoral component) and DeLee and Charnley\textsuperscript{20} zones (1 to 3, for the acetabular component). THAs were classified into one of five groups based on the width of radiolucency around the femoral component (0 mm, 1 mm, 2 mm, 3 mm to 4 mm or > 5 mm).

Statistical analysis. This was performed using SPSS v. 17 for Windows (SPSS Inc., Chicago, Illinois). Chi-squared testing for trend was performed to determine which factors affected the presence of radiolucency around the femoral stem. Outcomes included the rate of revision, pain score, OHS and HHS (one year and at most recent review) and metal ion levels (cobalt and chromium). Independent variables used in the analysis were age, gender, component sizes (head, acetabular component and stem), length of the neck and radiological inclination of the acetabular component. Paired samples $t$-tests were used to determine any significance between OHS, HHS and pain scores at different time points. Independent samples $t$-tests were used to establish whether the levels of cobalt and chromium in patients’ blood was different for males and females. Product moment correlations were used to determine correlations between blood metal ions and acetabular component inclination angle. A life table analysis was undertaken for 95% CI at five years. The median censor point was five years and ten months.

Results

The mean follow-up time for the surveillance review was 34 months (standard deviation (SD) 3.1; 23 to 45). At this time, three patients (four hips) had died, and two (two hips) had been lost to follow-up. Three patients (three hips) were unable to attend and were reviewed by telephone; these did not have radiographs or metal ion measurements. As a result, 281 hips (266 patients) were reviewed, of which 278 hips (263 patients) had radiographs and metal ion measurements. Since the surveillance review, a further three patients have died (Fig. 1).

The mean OHS was 19.2 (SD 8.8) and the mean HHS was 92.8 (SD 10.5). 254 patients (268 hips; 95%) reported mild, very mild or no pain (Fig. 2). The mean OHS and HHS pain scores improved significantly between pre-operative score and latest follow-up ($p < 0.001$ in all cases) (Table I). Six
patients (2%) complained of noise (clicking, grinding or juddering) from the hip, although patients were not asked about this routinely.

As of August 2014, eight patients (eight THAs) have undergone a revision due to pain (Table II) and six patients (seven THAs) have died. The rate of survival for all patients at five years is 96.9% (95% CI 94.7 to 99) (Fig. 3). Two further patients were offered revision as the first had a pseudotumour surrounding the greater trochanter and the second showed radiographic changes in zones 1, 7, 8 and 14, as well as experiencing pain. Neither, however, underwent the procedure. One was considered too high risk for anaesthesia and the other refused surgery as his symptoms were tolerable despite the identification of a pseudotumour.

### Table I. Oxford hip score (OHS) and Harris hip score (HHS) of patients

<table>
<thead>
<tr>
<th></th>
<th>OHS</th>
<th>HHS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (range)</td>
<td>Absolute p-value*</td>
</tr>
<tr>
<td>Pre-operative</td>
<td>47.1 (28 to 58)</td>
<td>-</td>
</tr>
<tr>
<td>1 year</td>
<td>21.8 (12 to 53)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Surveillance review</td>
<td>19.2 (12 to 53)</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

* compared with pre-operative score

### Table II. Reasons for revision surgery in eight patients (eight hips)

<table>
<thead>
<tr>
<th>Revision number</th>
<th>Time to revision (mths)</th>
<th>Symptoms</th>
<th>Metal ion levels (µg/L) at surveillance review</th>
<th>Metal ion levels (µg/L) prior to revision</th>
<th>MRI findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>36</td>
<td>Anterior thigh pain, radiological changes in zones 1, 7 and 8</td>
<td>Not done – revised before review took place</td>
<td>Not done</td>
<td>No evidence of soft-tissue mass or fluid collection</td>
</tr>
<tr>
<td>2</td>
<td>34</td>
<td>Thigh pain, restricted movement, periosteal reaction, radiological changes in zones 1 and 7, suggestive of infection</td>
<td>Co: 0.2; Cr: 0.5</td>
<td>Not repeated</td>
<td>Not done</td>
</tr>
<tr>
<td>3</td>
<td>49</td>
<td>On-going pain and progressive radiolucency on radiographs</td>
<td>Co: 1.1; Cr: 1.1</td>
<td>Co: 1.1; Cr: 1.3</td>
<td>No evidence of soft-tissue mass or fluid collection</td>
</tr>
<tr>
<td>4</td>
<td>61</td>
<td>Ongoing pain increasing in severity</td>
<td>Co: 2.4; Cr: 2.2</td>
<td>Co: 5.8; Cr: 1.6</td>
<td>Pseudotumour formation</td>
</tr>
<tr>
<td>5</td>
<td>55</td>
<td>Pain and noise reported as 'juddering' by the patient</td>
<td>Co: 5.1; Cr: 2.3</td>
<td>Co: 5.4; Cr: 2.6</td>
<td>Fluid collection around hip</td>
</tr>
<tr>
<td>6</td>
<td>55</td>
<td>Lateral thigh pain, sticking and grinding sensation</td>
<td>Co: 14.8; Cr: 4.0</td>
<td>Co: 57.3; Cr: 6.0</td>
<td>No evidence of pseudotumour</td>
</tr>
<tr>
<td>7</td>
<td>54</td>
<td>Sudden pain for six weeks prior to revision, unable to bear weight on hip</td>
<td>Co: 0.83; Cr: 0.5</td>
<td>Co: 2.3; Cr: 0.3</td>
<td>No evidence of pseudotumour</td>
</tr>
<tr>
<td>8</td>
<td>72</td>
<td>Developed start-up pain and difficulty walking</td>
<td>Co: 10.2; Cr: 5.6</td>
<td>Co: 12.6; Cr: 11.5</td>
<td>No evidence of pseudotumour</td>
</tr>
</tbody>
</table>

Co, cobalt; Cr, chromium
on MRI. If these patients had been revised, the overall five year survival would have been 96.2% (95% CI 93.8 to 98.5).

The median blood levels of cobalt and chromium in all 263 patients (278 THAs) were 0.83\(\mu\)g/L (0.24 to 27.56) and 0.78\(\mu\)g/L (0.21 to 8.84), respectively. A total of 31 patients (12.5%, 35 THAs) had blood cobalt levels of > 2 \(\mu\)g/L, and six patients had levels of > 7 \(\mu\)g/L (2.5%, seven THAs). For chromium, 26 patients (11.1%, 31 THAs) had levels of > 2 \(\mu\)g/L, and one patient (0.4%, one THA) had levels of > 7 \(\mu\)g/L (2.5%, seven THAs). For chromium, 26 patients (11.1%, 31 THAs) had levels of > 2 \(\mu\)g/L, and one patient (0.4%, one THA) had levels of > 7 \(\mu\)g/L (2.5%, seven THAs). The angle of inclination was > 45° in 135 THAs (132 patients; 47.7%) and it was > 50° in 46 hips (45 patients; 16.3%).

At the surveillance appointment, 84 stems in 82 patients (30%) had RRLs of > 1 mm in at least one Gruen zone. Overall, 22 stems in 22 patients (8%) had radiolucent lines of > 5mm. There was no correlation between any of the predictors studied and the extent of radiolucent lines. Patients receiving a stem without a collar (high offset or standard) were more likely to have radiolucency compared with those with a collar (standard or coxa vara; chi squared test for trend \(p < 0.001\)). Of the collared stems, 101 stems in 98 patients (73%) had no radiolucency compared with 63 stems in 63 patients (47%) of those with no collar; 15% of collarless stems had radiolucent lines of > 5 mm (Fig. 6).

**Discussion**

This study has shown acceptable PROMS in predominantly young patients receiving CoM THA. However, there was a higher that expected rate of revision and a high proportion of surviving patients with high metal ion levels in the blood and RRLs on radiographs. CoM is a relatively new articulation in THA and there are little data to support its use. Such studies that do exist report small numbers of patients with short follow-up.\(^{11,21-24}\) There is one prospective randomised controlled trial comparing CoM (\(n = 42\), with one lost to follow-up) to MoM (\(n = 39\), three lost to follow-up) which concluded that the rise in serum cobalt and chromium levels was similar in both articulations with similar clinical outcomes and no revisions in either group one year post-operatively.\(^{21}\)

Joyce et al\(^{22}\) presented a cohort of 56 patients with a mean age of 64 years, at a mean of 1.5 years following surgery. They reported a revision rate of 10.7% with revisions being largely for pain and femoral loosening,
however, the mean serum cobalt and chromium levels were < 2 μg/L. Kazi et al. reported a prospective study of 94 CoM THAs at two years, again finding low mean levels of metal ions (cobalt 1.37 μg/L; 0.12 to 10.68; chromium 1.09 μg/L; 0.00 to 5.51). Only one hip in that series was revised, and the authors concluded that CoM THA is safe and efficacious. However, they expressed concerns about the potential for chromosomal aberrations secondary to high levels of metal ions. Isaac et al. reported on 30 CoM THAs at a follow-up of 12 months, reporting a revision rate of 3.3% and median blood metal ion measurements of 0.72 μg/L and 0.43 μg/L for cobalt and chromium, respectively. There is one case report of a CoM THA failure associated with massive metallosis and pseudotumour in a 51-year-old female.24

The five-year revision rate for CoM THAs in this series is 3.1%, but if all patients suitable for revision had been revised, it would be 3.8% (95% CI 1.5% to 6.2%). Of the eight revised THAs, six were revised after > four years. The current revision rate is slightly lower than CoM THAs in the tenth NJR report (4.15% at four years).13

In well-functioning MoM THAs, the serum chromium level should be approximately 2 μg/L; this figure doubles in those who do not function well.25,26 One of the theoretical advantages of CoM is the potential reduction in blood metal ion levels when compared with MoM and our results would appear to concur as mean and median cobalt and chromium levels were much less than the suggested threshold of 2 μg/L for a well-functioning hip.26 The United Kingdom Medicines and Healthcare products Regulatory Agency (MHRA) considers levels of cobalt or chromium > 7 μg/L to be a concern, however, others have suggested that a level of 4 μg/L may be more appropriate.28 In our study, 11.4% had ion levels > 2 μg/L, 4.0% were > 4 μg/L and 2.2% were > 7 μg/L for either cobalt or chromium. Although these are relatively small numbers of patients, we consider this to be worrying. Despite the theoretical advantages, given the present concerns and our lack of understanding about the local and systemic effects of raised whole blood or serum metal ion levels, coupled with the availability of other satisfactory options for THA, we feel that CoM articulations should be avoided, at least until we have the data from follow-up studies at a minimum of ten years.

In this study, RLLs were more frequent in hips without a collar. We suggest that the collar may provide a barrier. Vidalain reviewed a series of 347 THAs (320 patients) who had undergone THA with a Corail stem and a polyethylene acetabular component using the standard neck type, with and without a collar. In 127 THAs they found, at a mean follow-up of 20.9±1.9 years, that while 89% of those with a collared stem had no radiolucency, this figure was only 81% for hips without a collar. RLLs were observed more frequently in our series (71% of collared stems had no radiolucency and 47% of uncollared stems had no radiolucency) after a much shorter follow-up. Previous authors have suggested that high offset stems may create high stresses at the stem/femur interface but none have shown a definite link.30

We have reported poor survival with a worrying level of blood metal ions and radiological changes in CoM THAs. We have not demonstrated CoM to be superior to the alternatives in terms of noise or ion levels and we would not recommend the use of this bearing couple in THA. We plan to monitor all our CoM patients regularly.

**Author contributions**

J. C. Hill: Writing and editing paper.
O. J. Diamond: Writing and editing paper.
S. O’Brien: Data acquisition, Editing paper.
J. G. Boldt: Analysis and interpretation of data.
M. Stevenson: Statistical analysis.
D. E. Beverland: Designing and editing paper.

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**References**


