Het komt er niet op aan hoe oud men is, maar hoe oud men al is.

San Cristóbal, Galápagos
No superiority of cemented metal-on-metal over metal-on-polyethylene total hip arthroplasty in a randomized trial at 10-year follow-up

Wierd P. Zijlstra
Jos J.A.M. van Raay
Sjoerd K. Bulstra
Robert Deutman

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ABSTRACT

In a randomized controlled trial, 102 cemented Stanmore 28-mm metal-on-metal total hip arthroplasties (THAs) were compared to 98 metal-on-polyethylene THAs in 195 patients. At a mean follow-up of 10 years, 11 patients (11 hips) were lost to follow-up, 53 patients (55 hips) died, and 6 patients (6 hips) underwent revision. Average age of the surviving patients was 79 years. Harris Hip Scores and Oxford Hip Scores had increased significantly in both groups (p<.001). Ten years postoperatively, mean Harris Hip Score was 86 in the metal-on-metal patients and 87 in the metal-on-polyethylene patients (p=.441); Oxford Hip Scores were 27 and 24, respectively (p=.494). Wear was present in 30 of 52 polyethylene cups. Periprosthetic radiolucencies were seen in 57% of the metal-on-metal patients and in 52% of the metal-on-polyethylene patients (p=.680); they were mainly seen in DeLee & Charnley’s zones 1 and 2. Serum cobalt and chromium concentration were higher in the metal-on-metal group (cobalt 1.1, chromium 1.0 vs 0.5 and 0.5 μg/L, respectively; p<.001). Patients with high ion levels (maximum 9.5 and 11 μg/L, respectively) all showed high Harris Hip Scores and few or no periprosthetic radiolucencies, and none were revised. Ten-year survival was 95.5% in the metal-on-metal group (4 revisions) and 96.8% in the metal-on-polyethylene group (2 revisions; p=.402). All revisions were indicated for aseptic loosening. One case of aseptic lymphocytic vasculitis-associated lesions (ALVAL) and no pseudotumors were observed. The absence of clinical superiority of the cemented metal-on-metal bearing and the concerns over their biological effects have led us to favor the cemented metal-on-polyethylene THA.
INTRODUCTION

The long-term results of total hip arthroplasty (THA) are hampered by polyethylene wear which can lead to osteolysis and eventually failure of the implant. Metal-on-metal (MM) articulation is an alternative bearing with a reduced wear rate. It was widely used between 1960 and 1975. MM articulation was discouraged by the early success of the Charnley prosthesis and the high loosening rate of the McKee-Farrar and other first-generation MM hips. The emerging adverse reactions of polyethylene wear lead to a resurgence of metal-on-metal articulations in the early 1990s. Improved wear-performance was achieved by modifications in metallurgy, sphericity and radial clearance in second-generation MM articulations. It is hypothesized that the reduction in prosthetic wear would lead to less osteolysis and superior prosthetic survival. Indeed, studies have reported negligible osteolysis in well-fixed components.

However, metal-on-metal arthroplasty has not demonstrated clinical superiority over metal-on-polyethylene articulation yet, regardless of favourable hip simulator study results. Moreover, reports regarding the outcome of cemented second-generation MM prostheses are scarce and randomized controlled trials (RCT) and long-term follow-up studies are lacking.

Our objective was to evaluate and compare cemented total hip prostheses with a metal-on-polyethylene articulation (MP) with prostheses with a metal-on-metal articulation (MM). The metal inlay in the cup of the MM articulation was the only difference between both prostheses. Clinical performance was the primary outcome. Radiological performance, serum metal ion analysis and prosthetic survival were secondary outcome measures. We hypothesized equal clinical performance of the two bearings. The aim of the present report is to describe the 10-year follow-up results. The 5-year results were published earlier.

MATERIALS AND METHODS

Patients

Consecutive patients with non-inflammatory degenerative hip joint disease including osteoarthritis, avascular necrosis and traumatic arthritis were included. Exclusion criteria were active infection, revision arthroplasty, marked bone loss precluding adequate fixation, unwillingness or inability to follow instruction, severe vascular insufficiency of the affected limb and severe instability or deformity of the soft tissues precluding stability of the prosthesis.
The randomization procedure was based on sequentially numbered opaque sealed envelopes, produced by an external institution not involved in the selection, care and evaluation of the patients. The local Medical Ethical Committee approved the study design and procedures (registration number 97-19). Informed consent was obtained in all patients. The trial was conducted in compliance with the Helsinki Declaration.

**Operative technique and implants**

The surgeries were performed in 1998 and 1999 by five orthopaedic surgeons and two orthopaedic residents. Both the posterolateral and direct lateral approach were used. Antibiotic prophylaxis with a first-generation cephalosporin was given for twenty-four hours intravenously. We used third-generation cementing techniques. Postoperative analgesia and mobilization adhered to a standardized protocol in all patients. An oral coumarin-derivate was given for 6 weeks postoperatively.

The MM Stanmore cup (M2A®, Biomet, Warsaw, United States of America) was manufactured by moulding a block of ultra-high molecular weight polyethylene (UHMWPE) around a highly polished cobalt-chromium-molybdenum alloy bearing insert, meeting ASTM F1537 requirements. The MP acetabular components were standard Stanmore cups made from UHMWPE, packaged in an Argon environment and sterilized with gamma irradiation. This polyethylene was not highly cross-linked. Both types of acetabular components were available in sizes from 40 to 57 mm. The 28-mm head used in all cases had a radial clearance of 30 to 60 μm and was made of cobalt-chromium-molybdenum alloy. This head had various neck lengths if necessary. The Stanmore femoral stem had a straight (straight stem) or slightly curved contour (standard stem) and a satin surface finish with a roughness of 0.8 μm Ra. The stem was made from forged cobalt-chromium-molybdenum alloy; five sizes were available.

**Clinical scores, radiographic evaluation, metal ion analysis**

Patients were assessed pre-operatively with the Harris Hip Score (HHS)\textsuperscript{13,14} and the Oxford Hip Score.\textsuperscript{15} All patients returned for follow-up at regular intervals, at least annually. HHS and Oxford Hip Scores were scored at 1, 5 and 10 years postoperatively. The examiners were not blinded.

At each follow-up visit supine anteroposterior (AP) pelvic hip radiographs (115% magnification) were taken. See Figure 1 for an example. At the 10 year follow-up, radiographs of the stems were reviewed for presence of radiolucent lines and scored according to Gruen et al.\textsuperscript{16} and periacetabular radiolucencies were assessed according to De Lee and Charnley.\textsuperscript{17} Radiological loosening and migration were noted if present. Scoring was
undertaken by a senior orthopaedic registrar (WPZ) and a senior orthopaedic surgeon (JJAMVR) and consensus was sought.

In a subgroup of patients, venous blood samples were taken. Cobalt ion concentrations were determined preoperatively and 5 and 10 years postoperatively; chromium ion concentrations were only measured 10 years postoperatively. We used inductively coupled plasma mass spectrometry (ICP-MS; Agilent 7500 Series, Agilent Technologies, United States of America) and graphite furnace atomic absorption spectrophotometry with Zeeman correction (GFAAS; Varian 220Z, Varian Inc., United States of America). The reference values of our laboratory were <6.8 nmol/l (0.40 μg/l) for cobalt and <48 nmol/l (2.50 μg/l) for chromium.

**Statistical analysis**

In order to detect a least clinical relevant difference in Harris Hip Score of 5 points in a non-inferiority design with a standard deviation of 12, 144 hip arthroplasties were needed (alpha 0.05, power 0.80). To compensate for death and loss to follow-up, 100 hip arthroplasties in each group were aimed for.

We used the Statistical Package for the Social Sciences (SPSS Inc, Chicago, USA). Non-parametric tests were used for comparisons of means within groups (Wilcoxon’s Signed Ranks test) and between groups (Mann-Whitney test). Chi-square (Fisher’s Exact) tests were employed for analysis of categorical variables. Prosthetic survival was calculated by Kaplan-Meier time series (Mantel-Cox log rank test). A two-sided p-value of <0.05 was adopted as significance criterion.
RESULTS

Patient groups

Ninety-eight metal-on-polyethylene articulations and 102 metal-on-metal articulations were allocated to 195 patients. Five patients underwent staged bilateral hip replacements (1 MM/MM, 1 MP/MP, 3 MM/MP). No differences were present between the patients groups in terms of gender, operated side, preoperative HHS and Oxford Hip Score (Tables 1 and 3). Mean age at operation was higher in the MM group.

In 2008 and 2009, on average 10 years after surgery, all patients were contacted to come in for review. Fifty-three patients (55 hips) had died of non-related causes. The number of deaths did not differ between the 2 prosthetic groups (Chi-Square Fisher’s Exact test, p=0.528). Eleven patients (11 hips) had moved or were lost to follow-up. Eight patients (8 hips) did not want to cooperate anymore. Eighteen patients (18 hips) were not able to come to the hospital due to severe medical problems. In none of these patients was revision performed or pending. Six patients (6 hips) needed revision surgery. Consequently, a total of 102 hips (55 MP, 47 MM; 99 patients) remained for follow-up at an average of 121 + 4 months (range 109-128); see Table 2.

Clinical outcome

Both groups improved significantly (Table 3). Harris hip and Oxford hip scores at 10-year follow-up did not differ between the two groups. Eleven out of the eighteen patients with severe medical morbidity were reviewed by Oxford scores alone since they were unable to attend the clinic.

Table 1. Preoperative demographics in the metal-on-polyethylene (MP) and metal-on-metal (MM) groups.

<table>
<thead>
<tr>
<th></th>
<th>MP</th>
<th>MM</th>
<th>Total</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of hips</td>
<td>98</td>
<td>102</td>
<td>200</td>
<td></td>
</tr>
<tr>
<td>Male/female †</td>
<td>20/78</td>
<td>21/81</td>
<td>41/159</td>
<td>1.000</td>
</tr>
<tr>
<td>Side (right/left) †</td>
<td>57/41</td>
<td>56/46</td>
<td>113/87</td>
<td>0.671</td>
</tr>
<tr>
<td>Mean age (standard deviation) in years ‡</td>
<td>69 (8)</td>
<td>72 (7)</td>
<td>71 (8)</td>
<td>0.018</td>
</tr>
</tbody>
</table>

†P-values were calculated by Chi-Square (Fisher’s Exact) tests.
‡P-values were calculated by Mann-Whitney tests.
Table 2. Number of hips included and followed-up in the metal-on-polyethylene (MP) and metal-on-metal (MM) groups.

<table>
<thead>
<tr>
<th></th>
<th>MP</th>
<th>MM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomized and operated</td>
<td>98</td>
<td>102</td>
</tr>
<tr>
<td>Died (not related to surgical procedure)</td>
<td>25</td>
<td>30</td>
</tr>
<tr>
<td>Lost to follow-up</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Refused cooperation</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Unable due to comorbidity</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>Revised</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Remaining for follow-up</td>
<td>55</td>
<td>47</td>
</tr>
</tbody>
</table>

Table 3. Mean and standard deviation of the Harris Hip (HHS) and Oxford Hip Scores in the metal-on-polyethylene (MP) and metal-on-metal (MM) groups, pre-operatively and at follow-up.

<table>
<thead>
<tr>
<th></th>
<th>MP</th>
<th>MM</th>
<th>P-value †</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HHS</td>
<td>Oxford</td>
<td>HHS</td>
</tr>
<tr>
<td>Preoperatively</td>
<td>46 (13)</td>
<td>40 (8)</td>
<td>0.746</td>
</tr>
<tr>
<td>1 yr</td>
<td>85 (13)</td>
<td>18 (7)</td>
<td>0.446</td>
</tr>
<tr>
<td>5 yr</td>
<td>87 (13)</td>
<td>18 (8)</td>
<td>0.791</td>
</tr>
<tr>
<td>10 yr</td>
<td>87 (10)</td>
<td>24 (9)</td>
<td>0.441</td>
</tr>
<tr>
<td>P-value‡</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

†P-values between groups were calculated by Mann-Whitney tests.
‡ P-values within groups were calculated by Wilcoxon’s Signed Rank tests (preoperatively versus 10 yr).

Complications

One femoral shaft perforation occurred intra-operatively without long-term clinical sequelae (MP group). There were 6 hematomas, 5 superficial wound infections (none of these patients needed revision), and 1 posterior dislocation without further sequelae. Cardiovascular and urogenital events occurred in 12 patients. Two patients (1 MP, 1 MM) suffered a periprosthetic femoral fracture 5 years postoperatively. These were treated with osteosynthesis; revision was not needed. Long-term clinical improvement was seen in both patients.

Radiological outcome

After 10 years no focal osteolysis was seen, but radiolucent lines were noted especially in De Lee & Charnley’s zone 1 and 2 and to a lesser extent in Gruen zones 1 and 7 (Table...
4). Statistical analysis revealed no differences between the groups. Two cups (1 MM, 1 MP) were radiologically loose according to the Zicat criteria, but these patients had no complaints (HHS 81 and 83). All other cups were stable. Polyethylene wear was noted in 30 of the 52 polyethylene cups.

**Serum cobalt and chromium analysis**

Postoperative cobalt and chromium concentrations were significantly higher in the MM group. Median cobalt concentration increased 2.1 times in the metal-on-polyethylene group and 6.1 times in the metal-on-metal group (Table 5). One patient showed cobalt levels of 7.0 µg/l at the 5-year follow-up. Her HHS was 88, her Oxford-score 12 and she showed no periprosthetic radiolucencies at 5 years. At the 10 year review she was not able to come to the hospital due to comorbidity (mamma carcinoma) but her Oxford-score was 14. One patient presented with a cobalt level of 11 µg/l and a chromium level of 9.5 µg/l at the 10 year follow-up. She had no complaints, her HHS was 95, her Oxford-score 14 and no radiolucencies were seen. All other 10 year cobalt and chromium levels were below 2.5 µg/l. None of these patients needed revision surgery.

<table>
<thead>
<tr>
<th>Zone</th>
<th>MP</th>
<th>MM</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stem (Gruen)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>5</td>
<td>6</td>
<td>0.532</td>
</tr>
<tr>
<td>2</td>
<td>0</td>
<td>1</td>
<td>0.447</td>
</tr>
<tr>
<td>3</td>
<td>0</td>
<td>1</td>
<td>0.447</td>
</tr>
<tr>
<td>4</td>
<td>1</td>
<td>0</td>
<td>1.000</td>
</tr>
<tr>
<td>5</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>4</td>
<td>0</td>
<td>0.125</td>
</tr>
<tr>
<td>Cup (De Lee &amp; Charnley)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>17</td>
<td>13</td>
<td>1.000</td>
</tr>
<tr>
<td>2</td>
<td>16</td>
<td>9</td>
<td>0.495</td>
</tr>
<tr>
<td>3</td>
<td>9</td>
<td>8</td>
<td>1.000</td>
</tr>
</tbody>
</table>

Number of hips with a radiolucency 27 (52%) 24 (57%) 0.680

*Chi-Square (Fisher’s Exact) tests were used to test for statistical differences between the metal-on-metal (MM) and metal-on-polyethylene (MP) groups.
Table 5. Median and range of the serum cobalt and chromium concentrations (μg/L) in the metal-on-polyethylene (MP) and metal-on-metal (MM) groups, preoperatively and at follow-up.

<table>
<thead>
<tr>
<th></th>
<th>MP</th>
<th>MM</th>
<th>P-value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preoperatively</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>cobalt</td>
<td>0.24</td>
<td>0.18</td>
<td>0.185</td>
</tr>
<tr>
<td>Range</td>
<td>0.18-0.65</td>
<td>0.18-1.77</td>
<td></td>
</tr>
<tr>
<td>5 yr</td>
<td>0.30</td>
<td>0.88</td>
<td>0.001</td>
</tr>
<tr>
<td>cobalt</td>
<td>0.29-1.65</td>
<td>0.29-7.02</td>
<td></td>
</tr>
<tr>
<td>10 yr</td>
<td>0.50</td>
<td>1.10</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>cobalt</td>
<td>0.40-1.30</td>
<td>0.50-11.0</td>
<td></td>
</tr>
<tr>
<td>10 yr (chromium)</td>
<td>0.50</td>
<td>1.00</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Range</td>
<td>0.50-0.90</td>
<td>0.50-9.5</td>
<td></td>
</tr>
<tr>
<td>P-value‡</td>
<td>0.037</td>
<td>0.042</td>
<td></td>
</tr>
</tbody>
</table>

*N is the number of hips at 10 year follow-up; preoperatively N was 24 MM versus 19 MP
†P-values between groups were calculated by Mann-Whitney tests.
‡ P-values within groups were calculated by Wilcoxon’s Signed Rank tests (cobalt preoperatively versus 10 yr).

Analysis of revisions

All 6 revisions (4 MM, 2 MP) were undertaken because of aseptic loosening. In the MP group one patient was revised after 21 months because of pain associated with radiolucent reactions surrounding the stem. All prosthetic material was removed. A cemented THA using bone impaction grafting was implanted. In a second MP patient radiographic loosening was noted of both the stem and cup after nine years. A total revision was performed ten years postoperatively.

The first MM acetabular revision surgery was performed at 26 months postoperatively for pain and emerging radiolucent lines around the cup. The second patient had a 2 x 3 cm cyst in the cranial acetabulum that was initially treated by excavation and cement filling. Three months postoperatively a radiolucent zone in this area emerged, suggesting insufficient initial fixation of the MM cup. At revision operation 33 months postoperatively, the cup was loose. The third patient suffered from protrusio acetabuli and arthrosis. Two and three years postoperatively recurrent posterior dislocations occurred. Fifty-six months postoperatively, X-rays showed a cyst cranial to the MM acetabular component in the prior protrusion region and subtle migration. The loose cup was revised. The femoral component was well-fixed in all the above patients. The fourth patient had a history of tuberculosis in both her lung and hip but had been asymptomatic for at least 15 years. Intra-operative cultures and histology ruled out infection and tuberculosis at the time of implantation of the MM hip. Seven years postoperatively progressive radiolucencies were noted and a Girdlestone hip was created due to insufficient bone-stock for reimplantation. Histology showed no signs of tuberculosis.
In all of the revision cases infection was ruled out by culture and/or histology. Lymphocytic infiltration was seen in only one case (the second MM revision described above). In this patient’s periprosthetic tissues, eosinophiles and macrophages were also seen. Macrophage presence was noted in two other patients as well (1 MP, 1 MM). Giant cell proliferation was described in one case (the first MM patient above).

**Survivorship**

Survival at 10 years (revision for any reason as well as aseptic loosening was 95.5% in the metal-on-metal group (95%-confidence interval (CI) 91.2-99.8%; 37 patients at risk) and 96.8% for the metal-on-polyethylene articulation (95%-CI 92.3-100%; 46 patients at risk). There were no significant differences between the two survival curves (Mantel-Cox log rank test, p=0.402). The survival rates for the acetabular component were similar. Stem survival was 98.6% (95%-CI 96.1-100%) in the metal-on-metal group, and 96.8% (95%-CI 92.3-100%) in the metal-on-polyethylene group (any reason as well as aseptic loosening; Mantel-Cox log rank test, p=0.606). Assuming that all patients lost to follow-up (including those that had moved, were unable to attend the clinic or did not want to cooperate anymore) were also failures, the worst-case 10-year survival was also calculated: 19 MM survival was 80.5% (95%-CI 70.9-90.1%) and MP survival was 86.2% (95%-CI 77.6-94.8%). This difference was not statistically significant.

**DISCUSSION**

The objective of the present randomized controlled trial was to evaluate and compare cemented metal-on-metal total hip articulations with metal-on-polyethylene articulations. Both articulations lead to significant clinical improvements. At 10-year follow-up, Harris and Oxford hip scores did not differ between the two groups. Focal osteolysis was not observed. Periprosthetic radiolucent lines were mainly seen in De Lee & Charnley’s zone 1 and 2 and the frequency of radiolucencies did not differ statistically between the two articulations. Ten-year prosthetic survival was 95.5% (4 revisions) for the metal-on-metal articulation and 96.8% for the metal-on-polyethylene articulation (2 revisions), with no statistically significant difference.

We aimed to compare metal-on-metal and metal-on-polyethylene articulations as comparative studies on cemented second-generation metal-on-metal total hip arthroplasty were scarce at the time of conception of our study. 20 In our clinic, we have been using the Stanmore metal-on-polyethylene prosthesis since 1975. 21, 22 We have shown survival to be 85% at 22 years. 23 By only changing the metal inlay in the cemented cup we could ensure that the only varying parameter was the articulation and we could eliminate learning curves or prosthetic design failures.
Our study suffers from limitations. Our patients were relatively old at the time of entry into the trial. Many patients therefore died before the 10-year review. The surviving patients were 79 years old on average, and quite a few patients were unable to visit the clinic due to co-morbidity. Some could be reviewed via the Oxford questionnaires. One can argue that our total of 102 hips remaining for follow-up is less than the calculated sample size of 144 that was needed to detect a 5 point difference in Harris Hip Score. HHS standard deviation at 10 years was 10 however instead of the assumed 12. This means that 51 hips in each group were sufficient to detect a 5 point difference.

With respect to clinical improvement and survival our results are comparable to other reports. Dorr et al. analyzed 70 Metasul metal-on-metal articulations with a cemented Weber cup. Survival was 98% at 5.2 years in 56 patients; average HHS was 90 points. Acetabular osteolysis was not seen, but calcar resorption was noted in two hips. A 94% survival at 3.7 years follow-up was shown by Levai et al., describing 122 cemented Metasul metal-on-metal hips. They noted radiographically probable loosening in 11 hips and when the patients with progressing radiolucencies were taken into account the calculated 5-year survival decreased to 80%. This group therefore discontinued cementing the Metasul cup. Eswaramoorthy et al. describe 6 revisions in 85 Metasul metal-on-metal hips at 10.8 years follow-up. A cemented cup was implanted in half of the subjects. Survivorship was 94% at ten years. Lazennec recently described their 9-year results for the cemented Metasul cup. Survival rates were between 89% (revision for any reason) and 91% (revision for aseptic cup loosening). This group stopped using the cemented metal-on-metal cup.

Cementless metal-on-metal total hip arthroplasties have been tested in RCTs and have shown satisfying short and medium-term results. Lombardi et al. reported the 5-year results of 53 metal-on-metal versus 46 metal-on-polyethylene THAs. Survival rate was 100% at 5.7 years in both groups; radiological and clinical differences were absent. MacDonald et al. showed equal clinical and radiological performance of 18 cementless metal-on-metal THAs compared to 23 metal-on-polyethylene THAs. After a mean follow-up of 3.2 years, survival was 100% in both groups. Jacobs et al. reported good clinical results and equal radiological outcome in 95 Ultima metal-on-metal cups compared to 76 polyethylene cups. In all, none of the studies proved superiority of the metal-on-metal bearing over polyethylene.

From a tribological point of view, the main advantages of metal-on-metal over conventional metal-on-polyethylene are the low wear-rate and the use of larger, more stable heads. Several factors appear crucial for this low wear performance. Hip simulator and retrieval studies have shown that metal-on-metal wear rates decrease with increasing head size (>40mm), low radial clearance (120-200 μm) and high carbon content. The radial clearance in our study was satisfactorily low (30-60 μm), carbon content was
high (0.2-0.3%), but the 28mm articulation may not have developed the optimal fluid film lubrication necessary for low wear-rates. We were unable to measure wear in our metal-on-metal articulations as this is impossible through conventional radiographs. We did see wear in a large proportion (30/52) of the metal-on-polyethylene articulations. The polyethylene used was not highly-crosslinked. Had this been the case, the observed polyethylene wear might have been less. The frequent presence of polyethylene wear indicates its fragility in long-term usage.

The value of periprosthetic radiolucencies in metal-on-metal articulations remains open to debate. A high number of these lucencies were present in both the metal-on-polyethylene (52%) and the metal-on-metal articulations (57%). Focal osteolysis was not seen. Lazennec found radiolucent lines and osteolysis in 26% of the cemented Metasul cups after 9 years. The higher age and thus inferior bone quality of our patients may partly explain these lucencies, as may cementing technique and initial fixation. Higher friction torques generated by the metal-on-metal articulation may stress the bone cement interface more than in metal-on-polyethylene articulation. Whether these lucencies are suggestive of future cup failures remains to be seen in the next 5 years.

High serum metal ion concentrations may indicate failure of a metal-on-metal implant. Hence we monitored systemic cobalt and chromium levels. Median serum cobalt concentration at 10-year follow-up was 1.10 μg/l in the metal-on-metal bearings and 0.50 μg/l in the metal-on-polyethylene bearings; medium chromium concentration was 1.00 and 0.50 μg/l, respectively. Brodner et al. found a 0.7 μg/l cobalt concentration after 5 years and 0.75 μg/l after 10 years. Lazennec reported cobalt levels of 1.55 μg/l and chromium levels of 1.49 μg/l after 9 years. We could not relate cobalt or chromium concentration to periprosthetic radiolucency or prosthetic failure. Although the observed systemic cobalt and chromium levels may inhibit osteoblast proliferation in vitro by as much as 18% (personal data), our patients seemed to tolerate this well. Patients with high ion levels all showed high Harris Hip scores, few or no periprosthetic radiolucencies, and none were revised.

Biologic effects of the submicron metal-on-metal wear particles are under growing investigation and concern. Metal allergy, metal sensitivity, and chromosomal damage are described. Metal sensitivity refers to a type IV delayed-type hypersensitivity reaction and we have reported this phenomenon earlier. The histologic features are described as aseptic lymphocytic vasculitis-associated lesions (ALVAL). In one of our four revised MM patients lymphocyte, eosinophile and macrophage infiltration was described, suggesting possible ALVAL. In the other cases these characteristics were not mentioned, but ALVAL was not that well recognized at the time.

We compared cemented second-generation metal-on-metal total hip arthroplasty to metal-on-polyethylene hip arthroplasty in a randomized controlled trial. At 10 years fol-
low-up both prostheses lead to significant but equal clinical improvement. Cobalt and chromium serum levels were higher in the metal-on-metal patients. We did not observe fewer periprosthetic radiolucencies with the metal-on-metal bearing, nor did we see enhanced prosthetic survivorship. The absence of clinical superiority of the cemented metal-on-metal bearing and the concerns over their biological effects have lead us to favor the cemented metal-on-polyethylene total hip arthroplasty in our clinic.

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Conflict of interest

No competing interests declared.
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Onder in steend seil is it maklik kloetsjen.
Onder een staand zeil is het gemakkelijk bomen.