■ HIP

Metal ion levels from well-functioning Birmingham Hip Resurfacings decline significantly at ten years

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A retrospective study was conducted to investigate the changes in metal ion levels in a consecutive series of Birmingham Hip Resurfacings (BHRs) at a minimum ten-year follow-up. We reviewed 250 BHRs implanted in 232 patients between 1998 and 2001. Implant survival, clinical outcome (Harris hip score), radiographs and serum chromium (Cr) and cobalt (Co) ion levels were assessed.

Of 232 patients, 18 were dead (five bilateral BHRs), 15 lost to follow-up and ten had been revised. The remaining 202 BHRs in 190 patients (136 men and 54 women; mean age at surgery 50.5 years (17 to 76)) were evaluated at a minimum follow-up of ten years (mean 10.8 years (10 to 13.6)). The overall implant survival at 13.2 years was 92.4% (95% confidence interval 90.8 to 94.0). The mean Harris hip score was 97.7 (median 100; 65 to 100). Median and mean ion levels were low for unilateral resurfacings (Cr: median 1.3 µg/l, mean 1.95 µg/l (< 0.5 to 16.2); Co: median 1.0 µg/l, mean 1.62 µg/l (< 0.5 to 17.3)) and bilateral resurfacings (Cr: median 3.2 µg/l, mean 3.46 µg/l (< 0.5 to 10.0); Co: median 2.3 µg/l, mean 2.66 µg/l (< 0.5 to 9.5)). In 80 unilateral BHRs with sequential ion measurements, Cr and Co levels were found to decrease significantly ($p < 0.001$) from the initial assessment at a median of six years (4 to 8) to the last assessment at a median of 11 years (9 to 13), with a mean reduction of 1.24 µg/l for Cr and 0.88 µg/l for Co. Three female patients had a > 2.5 µg/l increase of Co ions, associated with head sizes ≤ 50 mm, clinical symptoms and osteolysis. Overall, there was no significant difference in change of ion levels between genders (Cr, $p = 0.845$; Co, $p = 0.310$) or component sizes (Cr, $p = 0.505$; Co, $p = 0.370$). Higher acetabular component inclination angles correlated with greater change in ion levels (Cr, $p = 0.013$; Co, $p = 0.002$). Patients with increased ion levels had lower Harris hip scores ($p = 0.038$).

In conclusion, in well-functioning BHRs the metal ion levels decreased significantly at ten years. An increase > 2.5 µg/l was associated with poor function.

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The surgical treatment of young adults with end-stage hip disease has been a challenge.[1] Inferior survival of total hip replacement (THR) in the young adult,[1,2] perceived advantages of hip resurfacing *versus* THR[3] and advancements in tribology have led to the introduction of third generation metal-on-metal hip resurfacing arthroplasty (MoMHRA).[4] Although thousands of these prostheses have been implanted worldwide, an increasing number of revisions for unexplained pain and soft-tissue reactions to products of metal wear have caused controversy.[5] Metal particles and elevated levels of circulating metal ions are generated by wear and corrosion of the articulating surfaces.[5] Tribological and clinical studies have described a characteristic wear pattern of MoMHRA with an initial run-in period, followed by a lower-wear steady-state.[6] However, to date little information has been available on how the wear evolves during the steady-state. Some studies have shown the steady-state is followed by a 'bedding-in' phase minimising wear,[7] while others have described an increasing wear patch, eventually leading to edge loading.[8] In these implants where insufficient coverage of the femoral head by the acetabular component has been present, edge loading[9] has been associated with increased wear and adverse reactions to metal debris. Measurement of systemic metal ions has been recognised as a valuable tool to detect increased wear[10,11] and is advocated by regulatory agencies as a screening method for the *in vivo* performance of MoM hip implants.[12,13] Upper acceptable serum levels of chromium (Cr) and cobalt (Co) have been proposed for well-functioning unilateral (Cr 4.6 µg/l; Co 4.0 µg/l) and bilateral MoMHRA (Cr 7.4 µg/l; Co 5.0 µg/l) with a high specificity but low sensitivity.[14]

The aim of this research was to investigate: 1) how metal ions as surrogate markers of wear of MoMHRA evolve at minimum ten years post-operatively; 2) whether the progressive changes in metal ion levels is related to outcome; and 3) if there is an influence of gender, diagnosis, size or component position on change in metal ion levels.

Patients and Methods

Since 1998, 3900 MoMHRAs have been implanted by a single surgeon (KDS). The first 250 MoMHRAs, all Birmingham Hip Resurfacing (BHR; Midland Medical Tech. (MMT), West Midlands, United Kingdom) together with Finsbury Orthopaedics (Leatherhead, United Kingdom) and Centaur Precision Castings Ltd (Sheffield, United Kingdom)), implanted between 1998 and 2001 in 232 patients (18 bilateral BHRs) were included in this retrospective study. All patients were recalled specifically for this study at minimum of ten years post-operatively. For deceased, revised or lost patients, last follow-up data from medical records were used for survivorship and clinical outcome analysis. There were 163 men (70%) with 174 BHRs and 69 women (30%) with 76 BHRs. The mean age at surgery was 50.6 years (17 to 76). The primary diagnosis was osteoarthritis (OA) in 202 hips (80.8%), avascular necrosis (AVN) in 23 (9.2%), congenital dysplasia (CDH) in 11 (4.4%), rheumatoid arthritis (RA) in ten (4.0%), and traumatic OA and neurometabolic disease each in two hips (0.8%). The mean follow-up, including dead, revised and lost patients, was 9.7 years (median 10.5 (0.1 to 13.6)).

Clinical outcome was evaluated by computing the Harris hip score (HHS),[15] which assesses patients' pain and function, absence of deformity and range of movement of the hips. Patients were grouped according to the Charnley classification (A, single-hip arthropathy; B, contralateral hip arthropathy untreated (B1) or treated (B2); C, multiple arthropathies or medical comorbidities).[16]

Standing anteroposterior (AP) and lateral radiographs of the pelvis and resurfaced hips were obtained. Acetabular component inclination and anteversion were measured by an independent observer (AC) using Einzel Bild Röntgen Analyse (EBRA).[17] Optimum acetabular component orientation was defined as ± 10° about an inclination/anteversion of 45°/20°.[17] Radiographs were evaluated for radiolucent lines (thin radiolucent area alongside implant that may indicate fibrous fixation or progressive bone loss), reactive lines (stable bone condensation), bone remodelling (benign reaction to change in stress pattern or impingement), osteolysis (cavitary lesion of bone loss), component loosening (lucent lines around implant) or migration.

Serum metal ion measurements were performed routinely at every post-operative follow-up interval since 2006. Before 2006, ion measurements were only performed for research purposes in selected patients. Therefore, not all patients have metal ion values for follow-up exceeding ten years. Metal ion measurements were undertaken in serum samples collected according to a strict protocol using an intravenous catheter (Becton Dickinson Insyte-W, Sandy, Utah). The first 5 ml of blood was discarded to avoid metal contamination from the needle. A second 5 ml of blood was collected using metal-free vacuum tubes for metal ion measurements (Terumo Venosafe VF-106SAHL; Terumo Europe NV, Leuven, Belgium). Serum Cr and Co measurements were performed at the Laboratory of Toxicology, Ghent University Hospital, Belgium, using an inductive-coupled plasma mass spectrometry technique (ELAN DRC II; Perkin Elmer Life and Analytical Sciences, Shelton, Connecticut).

Since 1998, all patients' clinical, radiological, and metal ion data have been entered prospectively in a database (Orthowave; Aria Software Ltd, Arras, France). Patients are routinely asked to complete a questionnaire regarding renal problems and other potential sources of metal ions such as medication or food supplements containing Cr or Co, occupational exposure, or other metal implants such as total hip or knee replacements or spinal hardware.

The research questions were examined as follows: 1) The evolution of metal ion levels was evaluated in all unilateral BHRs for which at least two sequential ion measurements were available. Ion level change was defined as Cr or Co level at last assessment minus Cr or Co level at initial assessment. Only metal ion measurements at more than 12 months post-operatively, i.e. beyond the run-in phase, were taken into account. 2) Differences in outcome with increased and decreased ion levels were described and analysed using non-parametric statistical tests. 3) Correlations between change in ion levels and gender, diagnosis, and component size (small: < 50 mm; large: ≥ 50 mm) and position were evaluated.

Statistical analysis. Statistical analyses were performed using the IBM-SPSS Statistics 20 software (SPSS IBM, Chicago, Illinois). Kaplan–Meier implant survivorship with 95% confidence intervals (CI) with the endpoint revision for any reason was determined for the whole cohort and sub-analysis was performed by gender, diagnosis, age at surgery and femoral component size. For comparison of survival between subgroups, the log rank test (Mantel–Cox) was used. Since metal ion levels are not normally distributed, non-parametric statistical tests including the Mann–Whitney U and Kruskal–Wallis tests were used to assess differences in ion levels or outcome with increased and decreased ion levels. Pearson and Spearman's correlation coefficients were calculated for the relationship between ion levels, age, gender, component size and orientation. The level of statistical significance used was a p-value < 0.05.

Results

Out of 232 patients, 18 died of unrelated causes (five bilateral BHRs), ten were revised and 15 were lost to follow-up with their BHRs still *in situ* as confirmed by telephone contact (Fig. 1). One woman with a bilateral BHR was revised on one side while the other side was well-functioning at 12.7 years. In total 202 BHRs in 190 patients (136 men and 54 women) were evaluated at a minimum of ten years. The

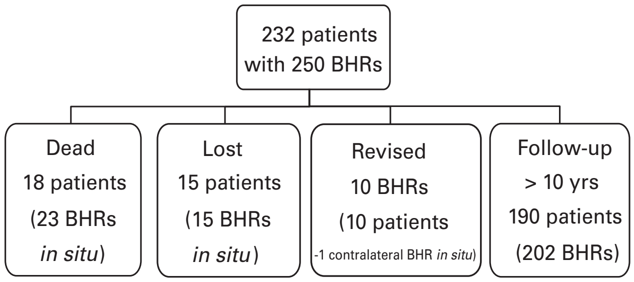

Fig. 1

Overview of total population, dead, lost and revised cases and Birmingham Hip Resurfacing (BHR) patients available for minimum ten-year clinical, radiological and metal ions review.

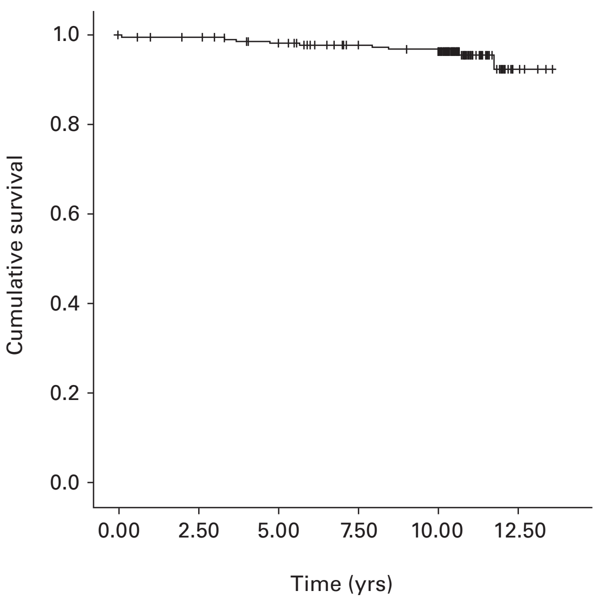

Fig. 2

Kaplan–Meier cumulative survival curve with the endpoint as revision for any reason, showing implant survival of 92.4% (95% confidence interval 90.8 to 94.0) at 13.2 years. 217 Birmingham Hip Resurfacings (BHRs) *in situ* at ten to 13 years, ten revised, 18 patients deceased with 23 BHRs *in situ*.

overall survivorship with endpoint revision for any reason was 92.4% at 13.2 years (95% confidence interval (CI) 90.8 to 94.0) (Fig. 2). Failure modes leading to revision included one fracture, one component malpositioning causing edge loading, two femoral head loosenings, one metal sensitivity, two impingements, one unexplained pain and two high metal ions and osteolysis (Table I). Revisions were performed at a mean of 6.8 years (median 6.8; 0.1 to 13.4) post-operatively. Survivorship in men was 98.7% (95% CI 97.5 to 99.8) at 13.5 years. In women survivorship was significantly inferior at 79.8% (95% CI 76.4 to 83.2) at 12.0 years (log rank, p = 0.001) and associated with age ≥ 55 years (log rank, p = 0.001). A significant difference in survivorship was found between < 50 mm diameter femoral heads (82.7% (95% CI: 78.9 to 86.5) at 11.9 years) and ≥ 50 mm femoral heads (97.6% (95% CI 96.4 to 98.8) at 13.4 years) (log rank, p = 0.003). After adjusting for head size, the difference in survival between males and females was no longer significant (log rank, overall p = 0.101).

In the non-revised cases, the mean HHS was 97.7 (median 100 points; 65 to 100) at a mean of 10.8 years (10.0 to 13.6). When adjusted for Charnley class, the mean HHS was 98.5 for class A (n = 162), 96.0 for class B (n = 20) and 88.5 for class C (n = 20) (Mann–Whitney U and Kruskal–Wallis tests: p < 0.001). Deceased and lost patients had a mean HHS of 98 (median 100; 70 to 100) and no adverse radiological findings (no signs of component loosening or migration, no radiolucent lines or osteolysis) at last follow-up.

Mean acetabular component inclination was 46.1° (23.8° to 62.9°) and mean anteversion 17.3° (-1.8° to 34.0°). In all, 221 BHRs (88.4%) were positioned in the safe zone.[17] In the 202 BHRs with a follow-up > ten years, reactive lines around the femoral stem were noted in 17 hips (8.4%), as a stable pedestal sign in 16, bone condensation in nine (4.5%). In five hips (2.5%) radiolucent lines (1 or 2 mm) around the stem were associated with acetabular and/or femoral osteolytic lesions in four (2.0%) and acetabular component migration in one hip (0.5%).

At more than ten years, the median ion levels were low for unilateral (Cr 1.3 µg/l; Co 1.0 µg/l) and bilateral MoMHRAs (Cr 2.9 µg/l; Co 2.0 µg/l) (Fig. 3; Table II). Besides the bilateral BHRs with more than ten years' follow-up on both sides, 23 additional patients had a bilateral MoMHRA, 18 with a contralateral BHR and five with a contralateral Conserve Plus hip resurfacing (Wright Medical Technology Inc., Arlington, Tennessee) implanted between 2002 and 2010. There was a statistically significant difference between the ion levels in the unilateral and bilateral groups (Mann–Whitney U and Kruskal–Wallis tests: p < 0.001) with patients with a contralateral Conserve Plus excluded from these analyses for data conformity. In 39 patients (23.2%) with a unilateral BHR, ion levels were below the detection limit of the laboratory (< 0.5 µg/l). In six patients in the unilateral group and four patients the bilateral group, Cr and Co levels were above the upper acceptable limits of 4.6 µg/l and 4.0 µg/l for unilateral MoMHRAs, respectively, and 7.4 µg/l and 5.0 µg/l for bilateral MoMHRA, respectively.[14]

The evolution of metal ions levels at a minimum of ten years post-operatively was investigated in 80 unilateral BHRs (56 men and 24 women; 20 with head size < 50 mm) for whom at least two sequential ion measurements were available. Overall Cr and Co levels decreased significantly (Mann–Whitney U and Kruskal–Wallis tests: p < 0.001) (Table III) from the initial assessment at four to eight years post-operatively (median 6 years) to the last assessment at ten to 13 years (median 11 years) with a mean reduction of 1.24 µg/l for Cr (-11.8 to 2.0; median -0.80 (SD 1.948)) (Mann–Whitney U and Kruskal–Wallis tests: p < 0.001)

Table I. Failure modes of revision cases

Failure (n)	Gender	Age at surgery (yrs)	Diagnosis*	Head size (mm)	Follow-up (yrs)	Pre-revision serum (Cr:Co)† (µg/l)	Reason for revision‡
1	M	42	OA	58	0.1	-	Fracture
2	F	54	OA	46	3.4	-	Metal sensitivity; neck narrowing; soft-tissue reaction; ALVAL
3	F	57	OA	42	3.7	-	Femoral head loosening
4	F	46	CDH	38	4.7	18.4 : 6.3	Femoral head loosening
5	F	58	OA	46	5.6	82.8 : 62.7	Malpositioning of both components; metallosis; soft-tissue reaction
6	F	59	OA	46	7.9	27.0 : 22.7	Impingement; neck narrowing; metallosis; soft-tissue reaction
7	F	55	OA	42	8.5	47.2 : 56.8	Osteolysis; increasing ions; metallosis; soft-tissue reaction
8	M	53	OA	54	10.0	-	Impingement, revised elsewhere
9	F	68	OA	50	10.7	-	Unexplained pain, revised elsewhere
10	F	59	CDH	42	13.4	7.2 : 5.8	Osteolysis; increasing ion levels

* OA, osteoarthritis; CDH, congenital dysplasia of the hip
† Cr, chromium; Co, cobalt. Pre-revision ion levels available in five cases were all above the acceptable levels for well-functioning metal-on-metal hip resurfacing arthroplasties[14]
‡ ALVAL, aseptic lymphocyte-dominated vasculitis-associated lesion
§ bilateral Birmingham Hip Resurfacing, other side *in situ* at 12.7 years

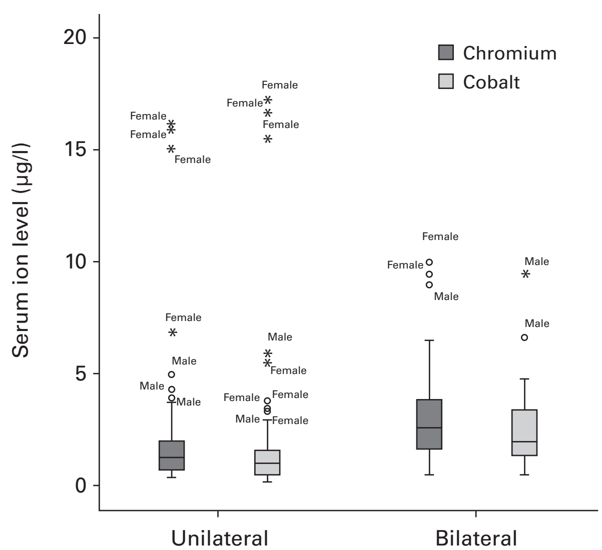

Fig. 3

Boxplot showing serum chromium and cobalt levels in 168 unilateral Birmingham Hip Resurfacings (BHRs) at a minimum follow-up of ten years (10 to 13 years) post-operatively (n = 168) and 29 bilateral BHRs (second BHR implanted between 1999 and 2010). Five patients with a contralateral Conserve Plus were excluded from the bilateral group for data conformity. The box and whiskers represent the median, interquartile range (IQR) and range of data. Outliers (°: ion values between 1.5× and 3×IQR from the edges of the box) and extremes (*: ion values > 3×IQR from the edges of the box) are labelled for gender.

(Fig. 4a) and 0.88 µg/l for Co (-7.5 to +5.3; median -0.75 (SD 1.645)) ($p < 0.001$) (Fig.4b).

An increase of ion levels was associated with worse outcome. Three female patients (4%) had an increase of Co ions > 2.5 µg/l, associated with head sizes ≤ 50 mm and with clinical symptoms including pain and radiological adverse signs including radiolucent lines or osteolysis.

Patients with increased ion levels at follow-up had lower HHSs (Mann–Whitney U and Kruskal–Wallis tests: $p = 0.038$). Lower HHSs correlated significantly with higher Co levels ($r = -0.178$; $p = 0.025$) but not with Cr levels ($r = -0.056$; $p = 0.486$).

There was no significant difference in the change of ion levels between genders (Mann–Whitney U and Kruskal–Wallis tests: Cr, $p = 0.845$; Co, $p = 0.310$) although Cr levels at initial and last assessments were higher in females ($p = 0.008$). There was no significant difference in ion levels with different diagnosis (Mann–Whitney U and Kruskal–Wallis tests: Cr, $p = 0.079$; Co, $p = 0.233$) but Cr levels were higher with head sizes < 50 mm compared with sizes ≥ 50 mm ($p = 0.001$). Co levels were not significantly different between size groups ($p = 0.057$) (Mann–Whitney U and Kruskal–Wallis tests). Component size did not correlate with change in ion levels (Cr: $r = -0.087$, $p = 0.505$; Co: $r = -0.071$, $p = 0.370$). There was a significant correlation between increasing acetabular inclination angles and increase in ion levels (change in Cr: $r = 0.390$, $p = 0.002$; change in Co: $r = 0.325$, $p = 0.013$) but not with anteversion angles (Cr: $r = -0.023$, $p = 0.872$; Co: $r = -0.006$, $p = 0.967$).

Discussion

Latterly MoMHRAs and MoMTHRs have been a cause for great concern for arthroplasty registries reporting inferior survivorship of certain designs with high rates of failure[18,19]

Table II. Metal ion levels in patients with Birmingham Hip Resurfacings (BHRs) at last follow-up. Unilateral BHRs tested at ten to 13 years post-operatively. Bilateral BHRs involved contralateral BHRs implanted between 1999 and 2010 (MoMHRA, metal-on-metal hip resurfacing arthroplasty)

	Unilateral BHR (n = 168)		**Bilateral MoMHRA (n = 29)***	
	Serum chromium (μg/l)	**Serum cobalt (μg/l)**	**Serum chromium (μg/l)**	**Serum cobalt (μg/l)**
Mean (range)	1.95 (< 0.5 to 16.2)	1.62 (< 0.5 to 17.3)	3.46 (< 0.5 to 10.0)	2.66 (< 0.5 to 9.5)
Median (SD)	1.3 (2.513)	1.0 (2.603)	2.9 (2.454)	2.0 (1.850)

* five patients with a contralateral Conserve Plus were excluded for data conformity

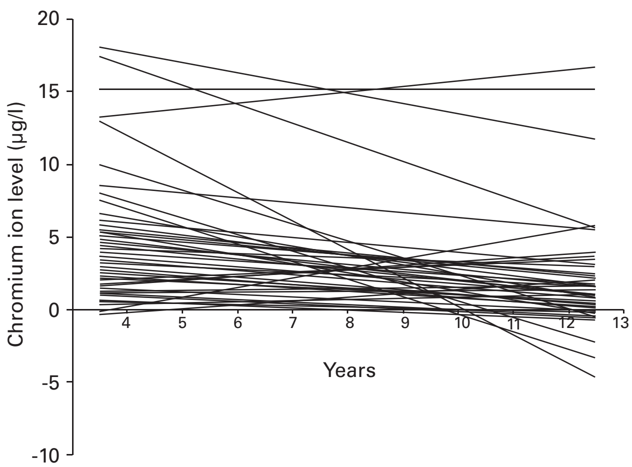

Fig. 4a

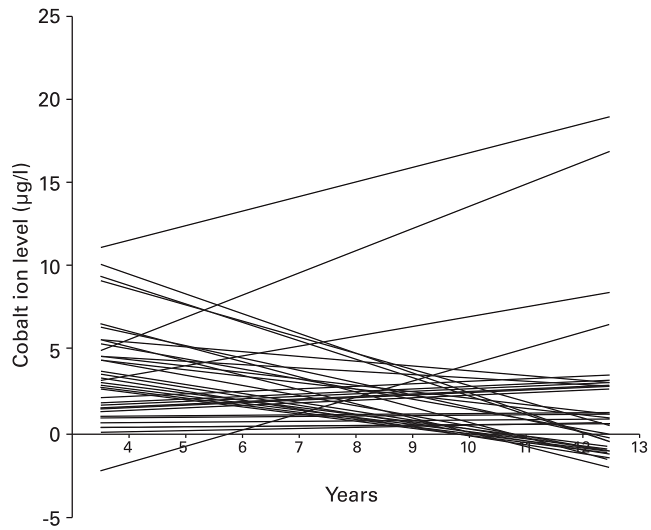

Fig. 4b

Graphs showing progressive changes in a) chromium (Cr) and b) cobalt (Co) ion levels in 80 unilateral Birmingham Hip Resurfacings (BHRs) from initial to last assessment. There was a significant decrease of Cr ion levels with mean decrease of 1.24 μg/l (-11.8 to 2.0; median -0.80 (SD 1.948)) ($p < 0.001$). There was also a significant decrease of Co ion levels with mean 0.88 μg/l (-7.5 to 5.3; median -0.75 (SD 1.645)) ($p < 0.001$).

Table III. Sequential metal ion levels in 80 unilateral Birmingham Hip Resurfacings (BHRs). Acceptable serum limits are considered to be 4.6 μg/l for chromium and 4.0 μg/l for cobalt[14]

	Serum chromium			**Serum cobalt**		
	Median 6 years (4 to 8)	**Median 11 years (10 to 13)**	**Change**	**Median 6 years (4 to 8)**	**Median 11 years (10 to 13)**	**Change**
Mean (range)	3.18 (< 0.5 to 15.1)	2.07 (< 0.5 to 16.2)	-1.24 (-11.8 to 2.0)	2.41 (< 0.5 to 14.7)	1.73 (< 0.5 to 17.3)	-0.88 (-7.5 to 5.3)
Median (SD)	2.50 (2.931)	1.45 (2.705)	-0.80 (1.948)	1.75 (2.449)	1.0 (2.961)	-0.75 (1.645)
p-value			< 0.001			< 0.001

associated with adverse soft-tissue reactions.[5] Cr and Co ions are released during the wear process of the articulating surfaces or by corrosion of the metal surfaces and wear particles.[5,6,10,11] Adverse local biological reactions to metal ions have been well documentedand may be associated with extensive soft-tissue necrosis and/or osteolysis,[5,11] potentially jeopardising the outcome of revision surgery.[11,20]

This study from an independent centre reports the survival at over ten years and metal ion levels of the BHR, and reflects an experienced hip surgeon's practice, including his learning period for the procedure. The overall implant survival of 92.4% at 13.2 years in young adults corresponded well with previous reports from designer centres[4,19] and recent registry reports of the BHR survival.[2,18,19] Survivorship in men was superior to registry reported figures of THR amongst young patients.[2,18,19] As in other series, survivorship in women was significantly inferior and related to smaller component sizes and age ≥ 55 years.[2,4,18-20]

Clinical outcome in the non-revised cases was good with no overall significant differences for gender, age or bearing diameter. However, patients with high or increasing Co levels had significantly lower or decreasing HHSs. Since 2006, serum metal ion measurements have been used routinely as an adjunct diagnostic tool in the management of patients with a MoMHRA at our institution. Patients are encouraged to have their metal ions measured at regular follow-up intervals (one, two, three, five, seven, ten and 13 years). Patients with metal ion levels above 4 µg/l are followed closely, even when asymptomatic, and further investigations including cross-sectional imaging are performed with ion levels > 10 µg/l.[14] In case of doubt (e.g. when further investigations show no abnormalities), ion measurements are repeated and other possible sources of metal ions (e.g. total knee replacement) are investigated.

Despite our rigorous follow-up protocol and the continuous data input and management in an arthroplasty database, we acknowledge limitations to our study. Because of the retrospective nature of the review, 15 patients with a BHR *in situ* were not available for a ten year clinical, radiological and metal ion follow-up. Evaluations were not always performed at strict time intervals and consecutive ion measurements were only available for 80 BHRs. Several patients had undergone additional arthroplasty procedures that may have confounded the interpretation of clinical scores such as the HHS and the metal ion levels, although patients with additional MoM hips were excluded from the latter analyses.

In general, the results of the present study confirm the low serum Cr and Co ion levels found in patients with well-functioning unilateral and bilateral MoMHRA[14] and the significantly higher ion levels with bilateral MoMHRA compared to unilateral implants.[14] In addition, our results demonstrate that ion levels in a well-functioning MoMHRA continue to be low even after more than ten years *in situ*. In this series, there were no symptomatic patients with low metal ion levels. The analysis of consecutive ion levels available for 80 unilateral BHRs, demonstrated a statistically significant overall decrease of Cr and Co levels with time. In 25% of patients ion levels were undetectable at more than ten years post-operatively. Increasing metal ion levels correlated with greater acetabular component inclination angles and levels > 10 µg/l were associated with poorly functioning MoMHRA. This is consistent with increased wear associated with malpositioned or loose components, leading to metal particulate debris and elevated metal ion levels.[5,10,11,20]

The *in vivo* decrease of metal ion levels with time is in accordance with tribocorrosion studies indicating a lower-wear bedding-in phase after the initial running-in phase of higher wear.[6,7] These studies also describe the formation of a passive protective film on the articulating metal surfaces after the initial wear-in, preventing further corrosion.[21,22] Ions are then mainly formed by corrosion of the metal particles provided there is no additional surface wear. The significant decrease in ion levels beyond ten years was confirmed in another study[23] on a small number of Conserve Plus MoMHRAs but seems in discordance with a report of 52 Cormet MoMHRAs (Corin, Cirencester, United Kingdom) describing initially declining levels until five years and subsequently rising ion levels.[24] However, registries report inferior survivorship with the Cormet MoMHRA compared with the BHR,[18,19] several patients with increasing ions in the Cormet study had a poorly functioning hip with clinical symptoms and high acetabular component inclination angles.[24]

Similarly, in our study, increase of ion levels > 2.5 µg/l after the run-in phase was an indication of increased wear and was associated with poor function. In well-functioning BHRs, metal ions decreased significantly at ten years. This study supports the proposition that all MoMHRAs should have sequential metal ion level testing as part of the routine follow-up.

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