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Long-term follow-up of ceramic-on-metal total hip arthroplasty

From Musgrave Park Hospital, Belfast, UK

G. Baker,[1] J. Hill,[1] F. O'Neill,[1] J. McChesney,[1] M. Stevenson,[1] D. Beverland[1]

Primary Joint Unit, Musgrave Park Hospital, Belfast, UK

Correspondence should be sent to G. Baker gavin.baker@belfasttrust.hscni.net

Cite this article: *Bone Jt Open* 2024;5(11): 971–976.

DOI: 10.1302/2633-1462.511.BJO-2024-0087.R1

Aims

In 2015, we published the results of our ceramic-on-metal (CoM) total hip arthroplasties (THAs) performed between October 2007 and July 2009 with a mean follow-up of 34 months (23 to 45) and a revision rate of 3.1%. The aim of this paper is to present the longer-term outcomes.

Methods

A total of 264 patients were reviewed at a mean of 5.8 years (4.6 to 7.2) and 10.1 years (9.2 to 10.6) to determine revision rate, pain, outcome scores, radiological analysis, and blood ion levels. Those who were unwilling or unable to travel were contacted by telephone.

Results

The all-cause revision rate at six years was 3.1% (eight THAs), increasing to 8.8% (18 THAs) at ten years. Of these, there were four and then seven bearing-related revisions at six and ten years, respectively. There was a statistically significant deterioration in the visual analogue scale pain score and Oxford Hip Score (OHS) between six and ten years. There were 18 CoM THAs in 17 patients who had a cobalt or chromium level over 4 ppb and ten CoM THAs in nine patients who had a cobalt or chromium level higher than 7 ppb with a statistically significant increase in chromium levels only between the two timepoints. Overall, 84 stems (39.1%) had significant radiolucent lines at ten years compared to 65 (25.5%) at six years.

Conclusion

When compared to the original review, there has been a significant deterioration in pain score, OHS, radiograph appearance, and, most critically, survival has fallen to 91.2%, which does not meet the Orthopaedic Data Evaluation Panel (ODEP) 10 A* 95% threshold. Although this bearing is no longer on the market, 2.5% were bearing-related revisions, which have relevance to the discussion around modular dual-mobility implants that have a similar metal interface.

Take home message

- This is the largest review of ten-year results for ceramic-on-metal total hip arthroplasty from one centre showing progression in all-cause revision rate, pain score, Oxford Hip Score, radiolucent lines, as well as ion levels.
- This implant does not meet the level to be certified Orthopaedic Data Evaluation Panel 10 A*, and any patient with ion levels exceeding 7 ppb will have ongoing follow up as per the Medicines and Healthcare products Regulatory Agency.
- The source of excess metal ion release and the bearing-related revisions may have potential relevance to modular dual-mobility constructs. This forms part of our future work.

Introduction

Ceramic-on-metal (CoM) was one of the bearing combinations proposed when hard-on-hard total hip arthroplasty (THA) was introduced. In contrast to ceramic-on-ceramic (CoC) and metal-on-metal (MoM), only a small number were implanted, with the UK National Joint Registry (NJR), which collects data from England, Wales, Northern Ireland, Isle of Man, and the States of Guernsey, reporting 2,152 CoM THAs up to December 2019 with a published ten-year revision rate of 7.95% (6.83 to 9.25).[1] Unlike MoM, there have not been the same specific protocols for long-term follow-up of this patient cohort. Schouten et al[2] reported metal ion levels in CoM THAs that matched those of the MoM THAs at six and 12 months (results at

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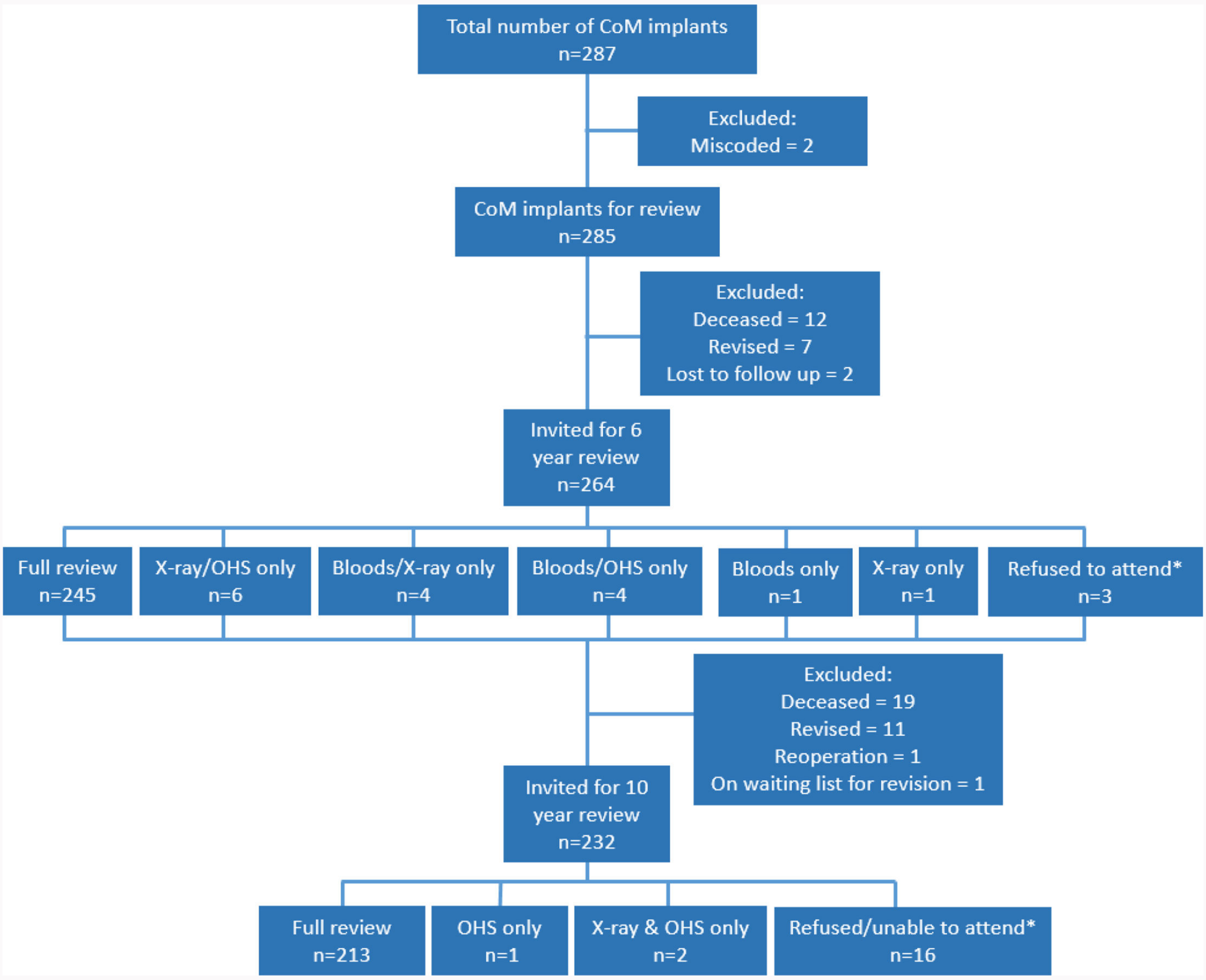

Fig. 1
CONSORT diagram. *Patients who failed to provide data due to being unable or unwilling to attend. CoM, ceramic-on-metal; OHS, Oxford Hip Score.

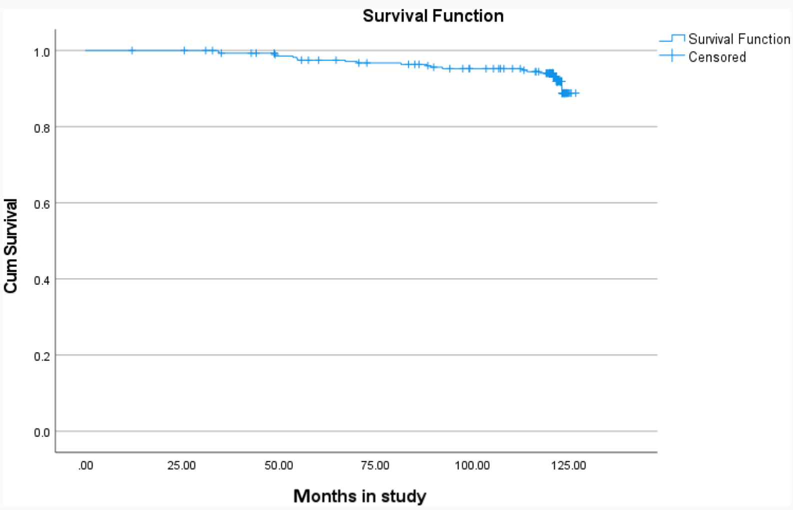

Fig. 2
Survival curve for ceramic-on-metal implants.

12 months: cobalt – CoM 1.77 ppb, MoM 1.57 ppb; chromium – CoM 1.84 ppb, MoM 1.73 ppb) with no statistical significant difference. They still recommended continued monitoring.[3]

Evidently, the CoM bearing has been associated with increased metal ion levels; the ion source is not established. One possible source is the metal-metal interface, a design feature that is shared with modular dual-mobility implants.

Table I. Reasons for patient revisions.

Reason for revision	Number
Bearing-related*	7
Stem loosening/undersized	8
Infection	2
Periprosthetic fracture	1
Total	18

*Incurred due to sequelae from ceramic-on-metal implant – wear process.

Table II. Pain score, Oxford Hip Score, and ion levels at six and ten years.

Variable	6 yrs	10 yrs	Difference	95% CI	p-value
VAS pain score	1.7	1.9	0.2	0.11 to 0.42	< 0.001
OHS	20.0	22.7	2.7	1.54 to 3.91	< 0.001
Cobalt, ppb	1.2	1.4	0.2	-0.36 to 0.79	0.46
Chromium, ppb	1.0	1.4	0.4	0.23 to 0.60	< 0.001

OHS, Oxford Hip Score; VAS, visual analogue scale.

This may become an issue in the future with increased use of dual-mobility implants and, as such, is an area where further research is needed.[4]

In 2015, we reported early surveillance results for a series of CoM THAs in an implant which has now been taken off the market.[5] The aim of this paper was to present the six- and ten-year outcomes for this same patient cohort in terms of survival, patient-reported outcomes, metal ion levels, and radiological changes.

Methods

Between October 2007 and July 2009, 285 CoM THAs were implanted in 269 patients. This cohort was originally 287 cases, but two patients were actually Pinnacle MoM and had been miscoded. Otherwise, the Methods are as described previously.[5] The review was carried out due to a clinical concern with the implant, and so no ethical approval was needed, but patients consented to review and data collection. At five and ten years, patients who were still alive were invited for review. Any patients who were unable or unwilling to attend were contacted by telephone to determine the status of their joint and Oxford Hip Score (OHS).[6,7] The OHS in its original format (scoring from 12 (best) to 60 (worst)) was used along with a visual analogue score (VAS) for pain, with one being no pain and five being severe pain. Those attending for review had anteroposterior pelvic and lateral hip radiographs, a blood specimen for cobalt and chromium levels, and, if clinically appropriate, an MRI scan. Survival is reported at a mean of 10.1 years (9.2 to 10.6).

Radiographs were analyzed by the senior author (DB) in groups based on four Corail stem types, namely Standard Offset with (KA) and without (KS) collar, the Coxa Vara (KLA) with collar, and the High Offset (KHO) without collar at six years and ten years. The two radiographs for each patient were not analyzed consecutively but at different timepoints so as to minimize the impact of intraobserver variation. A 10% sample of radiographs was also read by GB to assess interobserver variation. The presence and size of radiolucent lines (RLLs) were assessed on criteria stipulated in a previous paper from the same centre, and included the following four criteria: having lines in more than two zones (either complete or incomplete), any line in zone 7 (either complete or incomplete), two complete lines in any two zones, or an osteolytic lesion greater than 5 mm.[8]

Statistical analysis

The main analysis of six- and ten-year data involved the 213 patients (Figure 1) who provided data at both timepoints. Consequently, this involved paired *t*-tests with 95% CIs for differences. Survival was subjected to survival graphs and incidence of RLLs (which was analyzed using all patients who had radiological review) was described by odds ratios (ORs) and CIs relative to the KA stem type. Initially, SPSS v. 25 (IBM, USA) was used, but the latest and final analysis was provided within SPSS v. 28.

Results

Of the 285 CoM THAs performed, 16 were bilateral. There were 135 CoMs (47.4%) in 128 male patients and 150 (52.6%) in 141 female patients with a mean age of 55.6 years (20 to 77). Figure 1 shows a CONSORT diagram of the number of CoMs invited for review.

Revisions

Figure 2 shows the survival curve for the CoM implants in the study, and at the time of the ten-year review, there were 18 revisions from a total of 285 implants; using the same life table as the original paper, this meant a revision rate of 8.8% (Supplementary Material). All-cause revision is shown in Table I. Two patients were lost to follow-up and one patient's revision had been delayed due to medical reasons. The decision to base revision cause on either bearing-related or implant undersizing/RLLs was made based on the clinical findings of the patients with either pseudotumour at the time of revision or significantly raised ions, as well as stem sizing and progressive RLLs.

Pain score, OHS, and blood metal ion levels

There was a statistically significant deterioration in the pain score and OHS in the interim between six and ten years. The mean blood ion results at the six-year review was 1.2 ppb for cobalt and 1.0 ppb for chromium, which increased to 1.4 ppb for cobalt and 1.4 ppb for chromium at ten years (Table II). When reviewing results for individual patients, there were 18 CoM THAs in 17 patients who had a cobalt or chromium level over 4 ppb and ten CoM THAs in nine patients who had a cobalt or chromium level higher than 7 ppb (one of these patients had an ASR THA on the other side, which may account for the high metal ion level). There was no statistically

Table III. Six- and ten-year results for radiolucent lines on radiograph.

Timepoint	Stem type	Total patients, n	Patients with sig RLLs, n (%)	OR (95% CI)	p-value
6 yrs	KA	90	15 (16.7)	1.00	
	KLA	36	3 (8.3)	0.45 (0.12 to 1.68)	0.21
	KS	70	23 (32.9)	2.45 (1.16 to 5.16)	0.019
	KHO	59	24 (40.7)	3.43 (1.60 to 7.33)	0.001
10 yrs	KA	70	16 (22.9)	1.00	
	KLA	34	7 (20.6)	1.02 (0.35 to 3.00)	0.97
	KS	60	33 (55.0)	4.45 (2.01 to 9.88)	< 0.001
	KHO	51	28 (54.9)	5.99 (2.62 to 13.72)	< 0.001

KA, standard offset with collar; KHO, high offset without collar; KLA, Coxa Vara with collar; KS, standard offset without collar; OR, odds ratio; RLLs, radiolucent lines; sig, significant.

significant difference in the ion levels depending on the size of head used – 19% having a 28 mm head and 81% having a 36 mm head. Table II shows the values at six and ten years for the 213 patients with full data.

Radiolucent lines on radiograph

There were 65 patients (25.5%) out of the 255 x-rayed at six years, and 84 patients (39.1%) out of the 215 x-rayed at ten years that had significant RLLs. The results are shown in Table III, with the collarless KHO and KS stems having the most significant RLLs at 54.9% and 55.0%, respectively, at ten years. The collared KA and KLA stems had significantly fewer RLLs (22.9% and 20.6%, respectively) at ten years. The largest group (KA) was selected as the base group, and all other groups were analyzed in relation to this, providing ORs and 95% CI which revealed a significant difference between the KA stem and the KS and KHO stems, in keeping with results already published from this centre.[8]

Discussion

This case series of 285 is the largest reported study on the CoM bearing combination with the longest follow-up and a revision rate of 8.8% at ten years, as compared to 4.5% reported by Mehta et al[9] in 96 CoM implants at nine years. Of the 18 revisions, six (2.1%) had either a Corail size eight or nine stem. These smaller stems are now known to have a higher revision rate.[10] Clearly, such revisions are avoidable with appropriate templating. However, seven of the 18 revisions (2.5%) were bearing-related, which pushed survival below the ODEP 10 A* rating of a 5% revision rate at ten years. The ion levels in the bearing-related revision group were significantly elevated compared to the non-bearing revision group – cobalt 15.05/chromium 5.37 and 0.62/0.82, respectively.

With regard to metal ions at ten years post-surgery, for those not revised the mean cobalt and chromium ion levels were both 1.4 ppb, well above normal laboratory ranges, which are < 0.7 ppb and 0.1 to 0.4 ppb, respectively.[11] However, 18 of the CoM THAs (8.4% of those who had a ten-year review) had a cobalt or chromium level higher than 4 ppb and ten (4.7%) were above the Medicines and Healthcare products Regulatory Agency's 7 ppb level of concern.[12] These are still being followed up by revision arthroplasty surgeons in our unit.

There are three possible interfaces that could account for the excess ions with this bearing combination: the trunnion, the liner shell interface, or the head liner interface. Trunnionosis is a well-recognized clinical issue[13–18] that is caused by motion at the trunnion head interface and can lead to pseudotumour formation.[19,20] The first became a major issue with large-diameter MoM hips, both in resurfacing and in THA with higher failure rates.[21–23] Classically, trunnionosis results in a higher cobalt than chromium level.[24] Our results did not display any significant difference between the two (chromium 1.5 ppb and cobalt 1.8 ppb). We also saw no significant difference when comparing the mean metal ion levels for the two different head diameters as with the 28 mm diameter head, there were 41 patients with mean ion levels of 1.1 ppb for cobalt and 1.0 ppb for chromium, while with the 36 mm heads, there were 174 patients with mean ion levels of 1.2 ppb for cobalt and 1.1 ppb for chromium. In addition, none of the operative findings commented on any trunnion issue. It therefore seems unlikely that trunnionosis plays a role in the CoM bearing.

The liner shell interface is known to contribute to elevated blood metal ions;[25–29] Matsen Ko et al[26] reported on 100 consecutive patients with a modular dual-mobility construct where 21% of patients had a serum cobalt level above the normal range, with 9% significantly above normal (1.6 ppb), at a mean of 27.6 months postoperatively, which raises concerns about fretting corrosion at that interface. These values are very similar to our own (mean chromium and cobalt both 1.4 ppb). This could prove to be an issue in the future and has been highlighted in a paper in 2023 on the use of dual-mobility acetabular shell-liner tapers, with the MoM contacts being susceptible to fretting corrosion.[30]

Another potential liner issue relates to the press fit of the liners into the shell. Squire et al[27] demonstrated measurable compression deformity during press fit which, in turn, means that there can be difficulty in correctly seating CoM bearing liners. A ceramic liner malseating may result in a ceramic liner fracture. Reduced diametral clearance may increase wear at the articular surface, and the lack of full engagement may also result in a potential source of metal ions. Again, there are no specific comments about this interface during surgery, but in two cases it was not possible to remove the liner, so this remains a possible source of ion production in our series.

The final source of metal debris was the articulating interface. In addition to the possible impact of reduced diametral clearance above, Zhu et al[29] reported a spectroscopic study zirconia-toughened alumina (ZTA) femoral heads belonging to CoM hip prostheses demonstrating frictionally driven metal transfer to the ceramic lattice, which could also explain a rise in metal ions. In two cases at the time of revision, there was a comment about stripe wear, and both the ion levels were markedly elevated with cobalt over the normal value of 20 ppb (21.7 and 53.7) and chromium over 6 ppb (6.0 and 14.7).

Given the present data, we were unable to determine the source of excessive metal ion release in the seven cases revised for bearing issues. Of the 18 revisions, 13 were sent to the University of Leeds Implant Retrieval Centre. Future work involves a collaboration with Leeds to examine these specimens and determine which interfaces could have contributed to the excess metal ion load.

As stated in the introduction, the main issue to be raised through this paper is that of implants used with articulating surfaces which can produce wear debris. This may be an issue in the future with the ever-increasing use of dual-mobility implants, with the sequalae of this yet to be fully appreciated.

Overall, the rate of revision in this cohort was 8.8% at ten years falling outside the ODEP 10 A* rating. All eight of the stems revised for loosening demonstrated significant RLLs, particularly in the proximal zones. In the non-revised cases there were more significant RLLs in non-collared stems ($p < 0.001$). This was most marked in the KHO as opposed to the KS, but the difference was not significant.

Limitations to the study include the fact that the revised patients did not have ten-year pain scores, and this may have increased the overall change in pain levels. There were two patients who were lost to follow-up for different causes, covered in the CONSORT flowchart, with three further patients refusing to attend to provide data at six years due to health reasons and a further 16 at ten years.

In this study, we compared the six- and ten-year results of 285 CoM THAs performed over 22 months. Overall, there was an increase in both the cobalt and chromium levels from our initial paper in 2015. In ten cases, as compared to three in the original paper, ion levels exceeded the 7 ppb set by the MHRA as a threshold for concern. Our results to date suggest that bearing issues with excessive metal ion release contributed to revision in seven cases (2.5%). Our future work plans to determine the source or sources of ion release. This may have relevance to the design of modular dual-mobility constructs.

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Supplementary material

Survival table for implants.

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Author information

G. Baker, MB BAO, BCh, FRSI (Tr&Orth), Specialist Trainee, Trauma and Orthopaedics
J. Hill, MEng, MSc, PhD, Research Manager
F. O'Neill, MB BCh, NUI, Consultant Orthopaedic Surgeon, Research Manager
J. McChesney, DN, RN, BSc (Hons), Research Manager
M. Stevenson, BSc, FSS, Research Manager
D. Beverland, MD, FRCS, Consultant Orthopaedic Surgeon, Research Manager
Primary Joint Unit, Musgrave Park Hospital, Belfast, UK.

Author contributions

G. Baker: Formal analysis, Writing – review & editing.
J. Hill: Conceptualization, Data curation, Formal analysis, Methodology, Writing – review & editing.
F. O'Neill: Supervision, Writing – original draft.
J. McChesney: Data curation.
M. Stevenson: Data curation, Formal analysis, Methodology, Resources, Software, Validation.
D. Beverland: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Supervision, Writing – original draft, Writing – review & editing.

Funding statement

The authors disclose receipt of the following financial or material support for the research, authorship, and/or publication of this article: D. Beverland reports funding for this study from TORC - Trauma Orthopaedic Research Trust.

ICMJE COI statement

D. Beverland reports funding for this study from TORC - Trauma Orthopaedic Research Trust, as well as consulting fees, speaker payments, support for attending meetings and/or travel, and patents from DePuy Synthes, which are unrelated to this study.

Data sharing

The datasets generated and analyzed in the current study are not publicly available due to data protection regulations. Access to data is limited to the researchers who have obtained permission for data processing. Further inquiries can be made to the corresponding author.

Ethical review statement

This review was carried out due to a clinical concern with the implant, and so no ethical approval was needed.

Open access funding

The open access fee for this study was self-funded via TORCNI - Trauma and Orthopaedic Research Charity Northern Ireland.