#### **ORTHOPAEDIC SURGERY**



# Do cobalt and chromium blood metal ion levels normalize after revision of failed metal-on-metal total hip replacements?

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#### **Abstract**

**Introduction** Increased cobalt (Co) and chromium (Cr) serum levels are one reason for revision surgery in metal on metal (MoM) total hip arthroplasty (THA) patients. Dual mobility liners are a simple revision option; however, they preserve the metal shell and stem and it is therefore not clear if metal ion levels will fully normalize after revision surgery.

Material and methods Between April 2013 and December 2017 25 hips (24 patients) underwent revision from a MoM THA to an off-label dual mobility liner. Five patients were lost to follow-up and one patient refused leaving 18 patients (11 men, 7 female, average age 63.9 years) for pre- and postoperative metal ion level blood tests at a minimum follow-up of 2 years. Results Fourteen patients were revised for osteolysis, two for elevated metal ion levels and two for fluid or cysts around the femoral or acetabular component. The average preoperative Co and Cr levels were 8.3 μg/l and 5.0 μg/l, respectively. At a minimum follow-up of 2 years (30–95 months), metal ions dropped to 0.8 μg/l. Harris Hip Score (HHS), Hip Osteoarthritis Outcome Score (HOOS), Visual Analog Scale (VAS) and the UCLA activity score improved non-significantly from pre- to postoperative. There was one postoperative complication in the study cohort. One patient with persisting pain required revision surgery to a standard acetabular component during the follow-up period.

**Conclusion** The off-label use of a dual-mobility liner in the current study resulted in normalization of the metal ion levels suggesting that preserving the cobalt-chromium acetabular component has little impact on ion levels. In addition, dual mobility liners have a low complication and revision rate.

**Keywords** Metal-on-metal · Total hip arthroplasty · Revision · Chromium · Cobalt

#### Introduction

The goal of MoM bearing in THA was to improve survivorship by reducing polyethylene wear [1]. These benefits led to an increase of MoM THA and MoM hip resurfacing starting in 2000. With increasing awareness of the high revision rate due to adverse reaction to metal debris (ARMD) and

formation of pseudotumors, also known as aseptic lymphocyte-dominant vasculitis-associated lesion (ALVAL), this bearing fell out of favor [2, 11, 27]. Early revision is in general advised to prevent progression of secondary osteolysis and pseudotumors [20].

An increase of Co and Cr metal ion levels in the blood was reported for MoM bearings [12]. Cases of Co/Cr related cardiomyopathy, intoxication, malignancies and teratologic effects have been described [4, 7, 10, 19, 25].

Predictive factors for increased metal ion levels are female gender, bilateral MoM THA and higher activity level [14, 23].

Co levels have been shown to be significantly higher in MoM THA compared to hip resurfacing and increase over time [23]. The Co-Cr ratio correlates with the size of osteolysis on CT scan and might be a sign for corrosion between the different metals of a MoM bearing [24].

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The goal of this minimum 2-year follow-up study was to investigate the change in Co and Cr levels in patients undergoing revision to a dual mobility liner (ADM/MDMX3 dual mobility liner (Stryker, Mahwah, NJ, USA)) for a failed MoM Birmingham Hip Replacement (BHR) (Smith & Nephew, Inc., Memphis, TN, USA).

#### **Material and methods**

This retrospective study was approved by the local institutional review board at the authors' institution.

Twenty four patients (25 hips) underwent revision surgery of a MoM THA preserving the acetabular component and implanting a dual-mobility liner between April 2013 and December 2017. In all patients, a preoperative hip fluid aspiration to determine cell count, gram stains and microorganisms was performed to rule out infection. At the time of revision surgery, the metal head and sleeve were exchanged for an off-label ADM/MDMX3 dual mobility liner (Stryker, Mahwah, NJ, USA).

The patients were operated in a lateral position utilizing the initial posterior approach. The hip was dislocated and the head was removed and the trunnion inspected and cleaned. The stable fixation of the acetabular shell and lack of mechanical damage to the acetabular bearing surface were confirmed and a synovectomy including any adverse local soft tissue reaction was performed. Finally, the interface of the metal acetabular component and femoral component were cleaned using a needle tip MIDAS (Medtronic, Dublin, Ireland) and any areas of osteolysis were grafted using fresh frozen cancellous allograft chips. After irrigation, a 22 or 28 mm Oxinium head (Smith & Nephew, Memphis, TN) and ADM liner (Stryker, Mahwah, NJ, USA) were assembled in the usual fashion, the head applied to the femoral component and the hip reduced.

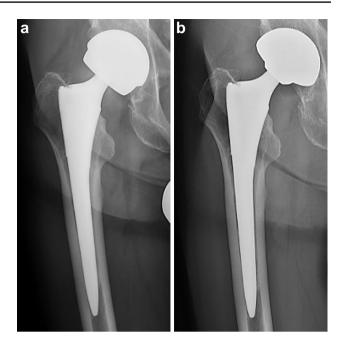
Patients were mobilized weight bearing as tolerated and hip precautions (no combined flexion and internal rotation) were enforced for 6 weeks. X-rays were performed at 4 weeks, 3 months and yearly intervals postoperatively.

All patients were contacted for a blood draw to determine blood levels of Co and Cr at a minimum follow-up of 24 months postoperatively.

#### Results

25 hips (24 patients, 14 male, 10 female, 1 bilateral) underwent revision surgery between April 2013 and December 2017 (Fig. 1a, b). One patient refused and five patients were lost to follow-up leaving 18 patients (11 men, 7 female).

Average age at revision surgery was 63.9 years (range 45–84 years), the affected side was the right side in 12 cases



**Fig. 1** a Preoperative AP X-ray of a MoM THA. **b** AP X-ray after off-label revision using a dual mobility liner in the pre-existing shell

and the left side in six cases. Time to revision ranged from 39 to 101 months (average 72.6 months) after the index procedure. Average BMI at time of surgery was 26.4 kg/m² (20.8–42.1 kg/m²). Reason for revision was osteolysis in 14 patients, elevated metal ion levels in the blood in two patients and formation of cysts or fluid around the hip in two patients. Osteolysis was present at the acetabulum and femur in one patient, at the acetabulum only in 12 patients and at the femur in one patient. Additional bone grafting was performed in 11 cases (61.1%).

All implants (stem and cup) were stable during revision surgery and were retained. For 17 hips, a 28 mm Oxinium (Smith and Nephew) head and for one hip a 22 mm Oxinium head were used. No intraoperative complications occurred in the cohort. Mean clinical follow-up was 53.2 months (30–95 months), and all patients were contacted to undergo a laboratory check-up at a minimum follow-up of 24 months postoperatively. One major postoperative complication, that required revision surgery was reported. A 67-year-old, active male patient had persisting pain for 5 years postoperatively. After an infection was ruled out, a revision of the acetabular component to a standard implant (Trident, Stryker) was performed. One patient died 7 years after revision surgery and was not available for postoperative Co and Cr blood levels.

Co and Cr values preoperatively ranged from 1.5 to 34.9  $\mu$ g/l (average 6.9  $\mu$ g/l) and 1.1–28.8  $\mu$ g/l (average 4.7  $\mu$ g/l), respectively and fell to 0.4–2.4  $\mu$ g/l (average 0.8  $\mu$ g/l) and 0.1–2.1  $\mu$ g/l (average 0.8  $\mu$ g/l) at a minimum follow-up of 24 months postoperatively (Table 1). Average



**Table 1** Pre- and postoperative cobalt/chrome values in  $\mu$ g/l.

		Mean	SD	t	df	Sig- nificance (2-sided)
Cobalt	Preoperative Postoperative	6.9 0.8	8.1 0.5	2.9	14	0.01
Chrome	Preoperative Postoperative	4.7 0.8	6.6 0.4	2.3	15	0.03

preoperative Co values of women were significantly higher (average 9.5  $\mu$ g/l) than those of male patients (average 4.7  $\mu$ g/l, p=0.05). Cr was significantly higher preoperatively in female (average 7.2  $\mu$ g/l) than in male patients (2.7  $\mu$ g/l, p=0.03).

The HHS improved non-significantly from preoperative 92.0 (range 65.9–100) points to 96.6 (83–100) points postoperatively. Pain on the visual analog scale persisted on the same level from average 1.8 (0–8) preoperatively to 1.9 (0–8) postoperatively (Table 2).

### **Discussion**

The current study reports that Co and Cr blood levels normalize in patients with retained Co-Cr metal acetabular components. In addition, the off-label use of a dual mobility liner in the preexisting shell had a low complication and revision rate.

A prior study by Kasparek et al. reported an excellent clinical and radiological short-term follow-up outcome in 11 revision THA, undergoing a revision to a dual mobility liner (ADM/MDM X3) in a Birmingham modular MoM-THA acetabular component. All patients had an MRI 2 years after revision which revealed no evidence of osteolysis or polyethylene wear. The HHS in this study, which included patients reported here, improved from 92.2 to 100. However, metal ion levels were not recorded in this initial study [13].

Metal ion levels have been shown to increase significantly after MoM THA and show an increase over time [19], a peak has been reported after 3–4 years postoperatively [15].

Although, there are no standard Co and Cr thresholds, the American Academy of Orthopaedic Surgeons (AAOS), the American Association of Hip and Knee Surgeons (AAHKS), and the Hip Society have identified serum cobalt or chromium levels of lower than 3 ng/mL as low risk for MoM failure [8, 17, 18].

According to a study by Kasparek et al., BMI had a negative correlation with Cr levels [14]. Contrarily, other studies did not find a correlation between metal ion levels and BMI [9].

No dislocation occurred in the current cohort. Dislocation rate after revision dual mobility range in frequency between 0 and 25% [3, 6, 26]. The current study suggests that dual mobility liner in combination with 6 weeks of postoperative hip precautions can protect from dislocation in this patient population.

Polyethylene wear could become a problem in the future due to possible macroscopically invisible irregularities of the cup surface in the revision patients. Thorough inspection of the retained metal shell is crucial before conversion to a dual mobility liner. The finding, that most motion in a dual mobility cup occurs between liner and head, might protect from aggressive plastic wear when implanting a new dual mobility liner in a retained acetabular component [5].

Previous studies have already described the off-label use of a dual mobility liner in a pre-existing cup. Plummer et al.

**Table 2** Scores pre- and postoperatively

		Mean	SD	t	df	Sig- nificance (2-sided)
HHS	Preoperative Postoperative	92.0 96.6	12.1 8.1	-1.4	13	0.2
HOOS	Preoperative Postoperative	78.0 94.6	36.0 10.0	-1.5	8	0.2
VAS	Preoperative Postoperative	1.8 1.9	2.9 2.6	-0.1	11	0.9
UCLA actual	Preoperative Postoperative	5.6 6.4	2.9 2.2	-0.7	10	0.5
UCLA desired	Preoperative Postoperative	7.2 7.5	2.6 1.4	-0.3	10	0.8



reviewed 14 MoM THA where a monoblock acetabular component was left in place and a liner exchange to a dual mobility liner was performed [21]. Also, Rahman et al. report a case of retention of an acetabular component in revision of a MoM THA [22]. Recalls of failed MoM THA had a high complication and reoperation rate 28.5% and 33.3% with dislocation being the most common complication [16].

The current study has following limitations: (1) it is retrospective in nature and ion levels were determined at different time periods during follow-up up. However, the study does show trends over longer periods of time towards normalization of metal ion levels but clear time intervals until when this happens cannot be established from the current data. (2) The study includes bilateral patients. While bilateral MoM THA might result in higher metal ion levels, the current study shows a similar return to normal levels compared to unilateral MoM THA.

#### **Conclusion**

Co and Cr levels return to normal after off-label revision surgery from a MoM THA to a dual mobility liner at a minimum follow-up of 2 years. Its rate of complication and revision surgery is low in the current study group.

**Author contributions** All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by AJ-W. The first draft of the manuscript was written by AJ-W and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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## **Declarations**

Conflict of interest FB receives royalties from Orthodevelopment Inc. and Smith and Nephew and compensation from Orthodevelopment Inc., Smith and Nephew, JNJ Depuy and Medtronic, unrelated to this research.

Ethical approval The study was approved by the institutional review board.

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