

Metal Ion Levels in Well-Functioning and Failed Metal-on-Metal Bearings in Hip Arthroplasty

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Abstract

Background

Whole blood cobalt testing is widely used in surveillance of metal-on-metal (MoM) hip arthroplasty, but clinically validated reference values for well-functioning implants are not well defined, and modest elevations are often misinterpreted as pathologic. This study aimed to establish outcome-validated cobalt ranges and evaluate their use in distinguishing adverse wear-related failure (AWRF) from trunnion corrosion failure (TCF).

Methods

We analyzed early (1 to 5 year) cobalt levels in MoM hip resurfacing arthroplasty (HRA) and total hip arthroplasty (THA) patients with confirmed implant survivorship at 10 and 15 years, and compared these to cases that failed due to AWRF, TCF, and other causes. AWRF and TCF classification was based on intraoperative and imaging findings independent of ion results. The influence of implant design and postoperative activity level was also assessed.

Results

Mean cobalt in well-functioning unilateral HRA was 1.2 ± 1.2 $\mu\text{g/L}$; all successful implants had levels below 14 $\mu\text{g/L}$. All 18 AWRF cases had cobalt levels of 15 $\mu\text{g/L}$ or higher (mean 74.0 ± 47.0 $\mu\text{g/L}$), a clean separation from successful implants. TCF cases ($n = 7$) showed only modest cobalt elevation (mean 5.3 ± 2.0 $\mu\text{g/L}$) that overlapped substantially with successful implants, and a definitive diagnostic threshold for TCF could not be established given the small cohort. Activity level did not significantly influence early ion levels.

Conclusion

Cobalt levels below 14 $\mu\text{g/L}$ are consistent with normal MoM bearing function, while levels of 15 $\mu\text{g/L}$ or higher strongly suggest AWRF. Ion testing reliably identifies bearing-related wear failure but is not diagnostic for TCF, which requires additional clinical and imaging correlation. These outcome-validated thresholds may help reduce unnecessary revision surgery and improve MoM surveillance.

Introduction

The decline of metal-on-metal (MoM) hip arthroplasty has been driven largely by concerns over adverse wear-related failure (AWRF). Early registry reports and surgeon series demonstrated high revision rates in certain implant designs and patient subgroups, raising broad concern about the safety of MoM bearings. Evidence suggests that AWRF is strongly associated with edge loading and loss of fluid film

lubrication related to component positioning, particularly excessive inclination or anteversion and reduced covered arc, rather than the bearing material itself [1–6]. These biomechanical conditions, not the MoM bearing itself, drive elevated wear, inflammatory soft tissue reaction, and eventual failure.

Metal ion data have clarified this relationship. By correlating whole blood ion levels with acetabular component position in a large HRA cohort, we previously developed and validated the Relative Acetabular Inclination Limit (RAIL), a safe zone guideline for acetabular inclination based on implant size [4, 5]. In our database of over 7700 HRAs, no case implanted within the RAIL has developed AWRF.

Unlike HRA, MoM total hip arthroplasty (THA) carries two distinct sources of inflammatory debris: AWRF and trunnion corrosion failure (TCF), arising from the modular head-neck junction. MoM THA implants vary substantially in bearing geometry, coverage arc, radial clearance, head size, and head-trunnion ratio, all of which influence susceptibility to these two failure modes; detailed design categories are provided in Supplemental Table 1. In the early 2000s, before the mechanical behavior of mixed-metal trunnions was well understood, elevated cobalt and inflammatory reactions in MoM THA were largely attributed to bearing wear, and registries did not distinguish AWRF from TCF. AWRF is uncommon in HRA when component position is appropriate, and HRA has no modular trunnion [7–20]; much of the failure historically attributed to MoM wear in THA may therefore reflect trunnion corrosion. Not all MoM THA systems failed at high rates: designs with favorable coverage geometry and low trunnion torque, or resurfacing style designs with optimized junction mechanics, have achieved survivorship comparable to registry benchmarks [23, 24].

Guidance on acceptable ion levels has historically relied on expert consensus rather than outcome correlated data, and existing thresholds do not distinguish AWRF from TCF or account for implant design or long-term outcomes. Because HRA generates metal debris exclusively from the bearing surface, it provides a model for isolating the relationship between component position, wear, and ion levels with minimal confounding. Using our clinical database of implant positioning, ion measurements, and long-term outcomes, we aimed to define outcome-validated cobalt reference ranges for well-functioning MoM HRA and THA, characterize ion levels associated with AWRF and TCF, and, as a secondary objective, evaluate whether postoperative activity level influences early ion levels.

Materials and Methods

Our institutional database includes over 7700 MoM HRAs performed by a single surgeon since 2002, along with 211 THAs with a resurfacing Magnum bearing and 335 THAs with a 38 mm MoM bearing (M2a-38) since 2000 (Fig. 1). Beginning in 2007, we began routinely obtaining ion levels for all patients at 2 years postoperatively; previously treated patients were also retrospectively contacted for ion testing at their current postoperative interval (range 2 to 15 years). Of cases with minimum 2-year follow-up, 3508 uncemented Magnum-ReCap HRA cases (71.7%), 148 Magnum THA cases (70.1%), and 113 M2a-38 THA cases (33.7%) complied with testing. We included patients with ion measurements obtained 1 to 5 years postoperatively and documented follow-up of at least 10 or 15 years; when multiple early

measurements were available, only the earliest within the 1- to 5- year window was analyzed. Our objective was to characterize early postoperative ion levels in implants that remained well-functioning at 10 and 15 years, proposed as clinically appropriate reference ranges for successful MoM hip arthroplasty.

We divided these cases into unilateral sub-cohorts with well-functioning implants at 10 and 15 years, and sub-cohorts with confirmed AWRF, TCF, or other failure (Table 1). AWRF and TCF classification was determined from intraoperative findings, including tissue staining, fluid character, and trunnion appearance, and from imaging, independent of the ion result, to avoid circularity between the classifier and the outcome being validated. We additionally identified a small cohort of ceramic-on-polyethylene (CoP) THA, expected to have no cobalt release, and a cohort of cobalt-chrome metal-on-polyethylene (MoP) total knee replacements (TKR), known to release cobalt [25, 26], to provide additional context for expected blood metal ion ranges across device types.

Table 1
Cobalt levels and time to failure across unilateral study groups.

Unilateral Group	n	Cobalt ($\mu\text{g/L}$) mean $\pm$ SD (range)	Time to failure (years)	p-value vs. Group 1
Group 1: Successful MoM HRA, > 10 yrs	1120	1.2 $\pm$ 1.2 (0.0-13.2)	N/A	N/A
Group 2: Successful MoM HRA, > 15 yrs	659	1.1 $\pm$ 1.1 (0.0-10.9)	N/A	0.08
Group 3: Successful Magnum MoM THA, > 10 yrs	56	1.5 $\pm$ 1.8 (0.0-11.2)	N/A	0.076
Group 4: Successful Magnum MoM THA, > 15 yrs	46	1.3 $\pm$ 1.9 (0.0-11.2)	N/A	0.59
Group 5: Successful M2a-38 MoM THA, > 10 yrs	61	2.6 $\pm$ 2.5 (0.3–10.0)	N/A	< 0.0001*
Group 6: Successful M2a-38 MoM THA, > 15 yrs	61	2.6 $\pm$ 2.5 (0.3–10.0)	N/A	< 0.0001*
Group 7: Successful CoP THA (any follow-up)	19#	1.2 $\pm$ 1.0 (0.2–3.6)	N/A	1.000
Group 8: Successful MoP TKR (any follow-up)	20#	0.7 $\pm$ 0.3 (0.0-1.2)	N/A	0.063
Group 9: AWRF, all MoM bearings	18#	74.0 $\pm$ 47.0 (15.0-173)	8.7 $\pm$ 5.5 (1.7–21.4)	< 0.0001*
9a: AWRF, MoM HRA	17#	71.7 $\pm$ 47.9 (15.0-173)	9.1 $\pm$ 5.4 (1.7–21.4)	< 0.0001*
9b: AWRF, MoM THA	1#	109.0	1.8	N/A
Group 10: TCF, all MoM THA	7#	5.3 $\pm$ 2.0 (1.5–16.8)	11.4 $\pm$ 3.1 (7.1–15.6)	< 0.0001*
10a: TCF, Magnum MoM THA	3#	4.1 $\pm$ 2.7 (1.5–6.8)	11.9 $\pm$ 3.0 (9.5–15.3)	< 0.0001*
10b: TCF, M2a-38 MoM THA	4#	6.1 $\pm$ 1.0 (4.6–16.8)	11.0 $\pm$ 3.5 (7.1–15.6)	< 0.0001*
Group 11: Other MoM HRA failures	70	3.0 $\pm$ 2.4 (0.3–9.3)	4.0 $\pm$ 2.7 (0.3–12.6)	< 0.0001*
Group 12: Other MoM THA failures	7#	4.1 $\pm$ 2.5 (1.5–8.2)	3.5 $\pm$ 3.9 (0.1–8.5)	< 0.0001*

indicates groups with fewer than 30 cases; statistical power to detect significant differences is limited. * indicates a statistically significant p-value.

Although both cobalt and chromium are released from MoM articulations, chromium and the cobalt/chromium ratio have not been shown to add diagnostic value beyond cobalt alone in identifying adverse local tissue reaction [6, 21, 27]; we therefore limited threshold analyses to cobalt.

Data Analyses

A two-tailed t-test was used to compare group means, with significance set at $\alpha = 0.05$. Given the exploratory nature of these subgroup comparisons, no correction for multiple comparisons was applied, and p-values should be interpreted descriptively rather than as confirmatory hypothesis tests.

Results

Table 1 presents cobalt levels and, where applicable, time to failure for all unilateral study groups. Mean cobalt for well-functioning unilateral Magnum-ReCap HRA was $1.2 \pm 1.2 \mu\text{g/L}$ ($n = 1120$); a threshold set two standard deviations above this mean ($4.8 \mu\text{g/L}$) would encompass approximately 98% of cases if cobalt were normally distributed. Because cobalt levels are right-skewed, we instead report the full observed range: among implants confirmed successful at 10 to 15 years, all early values fell below $14 \mu\text{g/L}$. Bilateral cases showed levels approximately 25% higher (Supplemental Table 2). Mean cobalt for Magnum THA successful at 15 years ($1.3 \pm 1.9 \mu\text{g/L}$) did not differ significantly from HRA ($p = 0.6$); M2a-38 THA levels were higher ($2.6 \pm 2.5 \mu\text{g/L}$; $p < 0.0001$), reflecting its less robust mixed-metal trunnion, but all successful cases across implant types remained below $14 \mu\text{g/L}$. Cobalt in successful CoP THA ($1.2 \pm 1.0 \mu\text{g/L}$) and MoP TKR ($0.7 \pm 0.3 \mu\text{g/L}$) was similar to MoM HRA, though both comparison groups were small.

Eighteen confirmed AWRF cases (17 HRA, 1 Magnum THA) all had grey cobalt debris at revision, acetabular inclination outside the RAIL, and, in all but one case, a large complex fluid collection on MRI (Fig. 2). Mean cobalt among AWRF cases was $74.0 \pm 47.0 \mu\text{g/L}$ (range 15.0 to 173), and no AWRF case had a level within the successful implant range.

Seven TCF cases were identified, all with severe inflammatory reaction and no visible metal debris at revision; three were Magnum THA and four were M2a-38 THA, the latter group also showing black debris at the cobalt-titanium junction. Mean cobalt for TCF ($5.3 \pm 2.0 \mu\text{g/L}$) was higher than successful implants but substantially lower than AWRF, and the cohort was too small for definitive statistical separation. The highest TCF cobalt level ($16.8 \mu\text{g/L}$) overlapped narrowly with the AWRF range, while most TCF levels fell within the successful implant range, since cobalt in TCF arises from the trunnion alone rather than a wear-generating bearing surface.

All other HRA failures ($n = 70$) and other MoM THA failures ($n = 7$) had mean cobalt of 3.0 and 4.1 $\mu\text{g/L}$, respectively, which is higher than successful implants ($p < 0.0001$) and similar to TCF.

Patient activity level at the time of ion testing did not significantly correlate with early cobalt levels (Table 3; $p = 1.000$).

Table 3
Ion comparison between low- and high-activity ReCap HRA patients.

ReCap HRA	Low Activity (n = 108)	High Activity (n = 1725)	p-value
Cobalt (µg/L)	1.4 ± 1.1 (0.0-7.3)	1.4 ± 1.1 (0.0-13.2)	1.000
Chromium (µg/L)	1.1 ± 0.9 (0.0-6.3)	1.1 ± 0.9 (0.0-8.8)	1.000
UCLA Activity Score	3.4 ± 0.9	9.6 ± 0.5	< 0.0001*
<i>High activity is defined as UCLA score ≥ 9 at 1–2 year follow-up. Low activity is defined as UCLA score ≤ 4 at 1–2 year follow-up.</i>			

Table 4 summarizes intraoperative and imaging features distinguishing AWRF from TCF. AWRF was consistently marked by extensive grey cobalt-chrome staining, thick pressurized fluid collections, and metal-stained osteolysis; TCF showed brown, non-metal-stained fluid and black corrosion debris limited to the modular junction, with acetabular position within the RAIL in all cases.

Table 4
Summary of features distinguishing AWRF from TCF

Symptoms	AWRF	TCF	Benign / Other
	Generalized pain	Generalized pain	Pain with weight-bearing with a loose implant
Cobalt, mean	74.0 µg/L	5.3 µg/L	3.7 µg/L
Cobalt, range	15–173 µg/L	1.5–16.8 µg/L	0.3–9.3 µg/L
X-ray	Well-fixed implant; minimal lysis; diffuse neck narrowing in chronic HRA cases	Well-fixed implant; minimal lysis; calcar erosion	Change of implant position; occasional radiolucencies with a loose implant
MRI	Large complex collection with solid components	Large complex collection with solid components	Thin-walled collection without debris
Fluid appearance	Thick, white, under pressure	Brown	Serous or blood-tinged
Metal visibility	Grey cobalt-chrome	None	Black tissue if titanium debris from a loose implant
Trunnion	N/A	Black debris; visible trunnion damage	Normal trunnion
Muscle damage	None	Frequent	None

Discussion

Guidance on acceptable MoM ion levels has historically been limited. Van Der Straeten and De Smet [28] produced one of the few analyses to correlate ion levels with implant function, although their thresholds were serum-derived and drawn at a mean of 4.3 years. Widely cited regulatory and consensus guidance, including the UK MHRA 7 µg/L threshold [29], which has been retained through successive guidance revisions, and a Hip Society consensus adopting the same cutoff [30], was derived from population reference ranges and expert opinion rather than longitudinal outcome data. None of these distinguished bearing-related AWRF from TCF or accounted for implant design. Since implementing routine ion surveillance in 2007, we have found ion data essential for early AWRF detection and for differentiating it from TCF, forming the basis for the reference ranges proposed here.

The nonspecific historical use of the term "pseudotumor" has further complicated interpretation of adverse local tissue reactions [22, 31]; fluid collections and soft tissue masses have variably been attributed to wear debris, corrosion, allergy, or other inflammatory processes without clear distinction between failure mechanisms. Retrieval analyses show that AWRF is characterized by edge-loading wear and visible cobalt-chrome deposition, while TCF reflects trunnion corrosion without macroscopic bearing debris, and benign serous collections are common around well-functioning MoM and non-MoM implants alike [32–35]. By correlating ion levels with confirmed surgical findings, this study establishes mechanism-specific reference ranges intended to reduce this diagnostic ambiguity.

Van der Straeten and De Smet [28] proposed upper limits of cobalt below 4.0 µg/L (unilateral) and below 5.0 µg/L (bilateral) using a percentile-based method in 453 unilateral and 139 bilateral hips followed a mean of 4.3 years. In our cohort, 87% of unilateral and 75% of bilateral HRA cases fell within standard non-implant laboratory reference ranges, typically 1 to 5 µg/L [36], and 99% fell within the De Smet and Van der Straeten optimal range (Table 2), consistent with their findings. Applying the same three standard deviation approach to our larger cohort yields a similar range (0 to 4.8 µg/L). However, because our cohort includes patients with documented survivorship at 10 to 15 years, we also examined the full observed range of early cobalt levels among these durable cases, all of which fell below 14 µg/L. This wider outcome-validated upper bound exceeds the prior literature-based optimal and acceptable categories shown in Table 2, reflecting the additional years of confirmed survivorship behind it, and is further supported by the fact that the lowest cobalt level among confirmed AWRF cases (15.0 µg/L) sits just above it.

Table 2
Metal ion reference categories applied in this study.

Unilateral, Cobalt	Normal¹	Optimal²	Acceptable³	Problematic³	Potentially Toxic²
	< 1.5 µg/L	< 4.0 µg/L	4.0–10 µg/L	10–20 µg/L	> 20 µg/L
Unilateral, Chromium	< 1.5 µg/L	< 4.6 µg/L	4.6–10 µg/L	10–20 µg/L	> 20 µg/L
Bilateral, Cobalt	< 1.5 µg/L	< 5.0 µg/L	5.0–10 µg/L	10–20 µg/L	> 20 µg/L
Bilateral, Chromium	< 1.5 µg/L	< 7.4 µg/L	7.4–10 µg/L	10–20 µg/L	> 20 µg/L
1. Common laboratory normal range for patients without metal bearings. 2. According to De Smet and Van Der Straeten [27]. 3. According to our previous analysis [37].					

In contrast, cobalt in TCF cases overlapped substantially with well-functioning implants (5.3 ± 2.0 versus 1.2 ± 1.2 µg/L), indicating that cobalt elevation alone cannot reliably distinguish TCF from normal bearing function. AWRF should be suspected when cobalt exceeds 15 µg/L with a large complex fluid collection on imaging; TCF should be considered with modest cobalt elevation in a symptomatic patient with acetabular position within the RAIL, though intraoperative findings remain necessary for definitive diagnosis. We have not observed a case with combined AWRF and TCF and cannot comment on how such a presentation would appear.

This study has several limitations. It represents a retrospective, single-surgeon series, which may limit generalizability to lower-volume centers or other implant systems. The number of confirmed AWRF and, especially, TCF cases is small, limiting the precision of threshold estimates and preventing a definitive diagnostic cobalt value for TCF. Only patients who complied with postoperative ion testing and long-term follow-up were included; because compliance ranged from 33.7% to 71.7% across implant groups, the direction of any resulting bias is uncertain. Asymptomatic patients with excellent outcomes may be less motivated to return for testing, while symptomatic patients may have sought care elsewhere, and either pattern could shift the reference ranges reported here. Only early postoperative ion levels were analyzed; later measurements may provide additional diagnostic insight. External validation in cohorts outside our own group, which established the RAIL and has followed these implant cohorts since implantation, would strengthen confidence in the proposed thresholds.

By correlating blood metal ion levels with confirmed failure mechanisms and long-term clinical outcomes, this study proposes outcome-validated cobalt reference ranges for MoM hip arthroplasty. For well-functioning unilateral MoM HRA, mean cobalt was 1.2 ± 1.2 µg/L, with all successful cases below 14 µg/L regardless of implant type; bilateral cases and M2a-38 THA showed modestly higher levels but remained within this range. Cobalt levels in successful cobalt-free CoP THA and MoP TKR were comparable to successful MoM HRA, reinforcing that modest cobalt elevation is not inherently pathologic. All confirmed AWRF cases had cobalt at or above 15 µg/L, with a markedly elevated mean

(74 ± 47 $\mu\text{g/L}$), while TCF cobalt levels overlapped with successful implants and did not yield a definitive diagnostic threshold. Postoperative activity level did not significantly affect early ion levels. These findings indicate that cobalt testing is a valuable tool for detecting bearing-related wear failure but must be interpreted alongside clinical and imaging findings when TCF is suspected, and they may help reduce unnecessary revision surgery by clarifying which ion elevations warrant further workup.

Declarations

Ethics approval and consent to participate

This study was reviewed by WCG IRB, an independent central institutional review board registered with the U.S. Office for Human Research Protections and the U.S. Food and Drug Administration as IRB00000533 (Cary, North Carolina, USA). WCG IRB determined that the research is exempt from further review under 45 CFR 46.104(d)(4) as secondary research use of existing clinical records (IRB Tracking Number 20260832; study submission #45745786.0; board action date 6 March 2026), under the umbrella protocol "Retrospective Analysis of Existing MONPA Joint Replacement Perioperative Database" submitted by Midlands Orthopaedics & Neurosurgery, P.A., Columbia, South Carolina, USA. The requirement for informed consent was waived, as the study involved secondary analysis of existing clinical records with no patient contact or intervention.

Consent for publication

All radiographic and intraoperative images presented in this manuscript are fully de-identified and contain no patient-identifying information.

Availability of data and materials

The datasets analyzed during the current study are not publicly available because they derive from an institutional clinical registry containing protected health information, but de-identified data are available from the corresponding author on reasonable request.

Competing interests

TG is a paid consultant to JointMedica Ltd. JointMedica had no role in the design of this study, in the collection, analysis, or interpretation of data, or in the preparation of this manuscript, and the devices evaluated in this study are not manufactured by JointMedica. DGC declares no competing interests.

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Authors' contributions

TG performed all surgical procedures and conceived the study. DGC designed the analysis, curated and verified the dataset, performed the statistical analysis, and drafted the manuscript. TG contributed to interpretation of the intraoperative and imaging findings used for failure-mode classification. Both authors critically revised the manuscript and read and approved the final version.

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Figures



Figure 1

Hip Arthroplasty Devices

Hip arthroplasty devices. From left to right: Magnum-ReCap uncemented HRA, Magnum THA, M2a-38 THA. The Magnum THA has a cobalt head and titanium taper adapter with a very large trunnion and bore at the mixed-metal junction, and a smaller titanium-titanium connection at the smaller high-torque trunnion and bore.

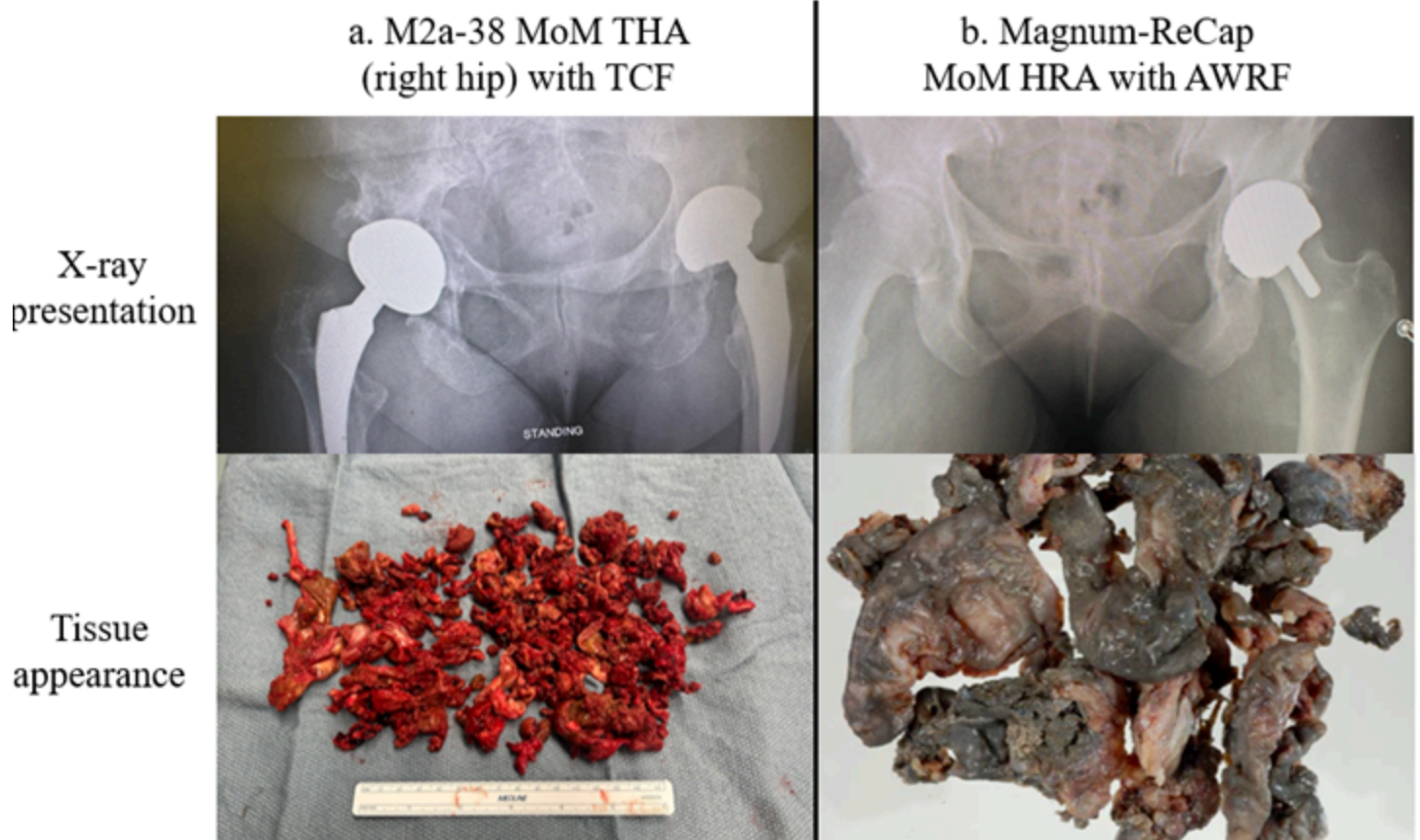


Figure 2

Distinguishing between TCF and AWRF

A-B. Imaging and intraoperative findings distinguishing TCF from AWRF. (A, top) Radiograph of a right hip with TCF at 19 years postoperatively in a patient symptomatic for 3 months; blood cobalt and chromium were both 1.6 µg/L. Osteolysis and calcar erosion are visible. A massive complex fluid collection was present on MRI and confirmed intraoperatively. (A, bottom) Intraoperative photograph from the same case showing an inflammatory mass without visible metal debris; the hip was revised to a dual-mobility head. (B, top) Radiograph of an asymptomatic patient with AWRF at 2 years postoperatively; Harris Hip Score was 100 at most recent follow-up. Routine ion testing showed cobalt of 173 µg/L and chromium of 111 µg/L. Acetabular inclination of the 46-mm femoral bearing was 56 degrees, outside the RAIL of 40 degrees for this implant size. No fluid collection was seen on CT, and this represents the single AWRF case in this series without a fluid collection on imaging. (B, bottom) Intraoperative photograph from the same case showing grey-stained cobalt tissue; the implant was well-fixed with minimal fluid.