



Original research

Predictors of Adverse Local Tissue Reaction in a High-Risk Population

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ABSTRACT

Background: Adverse local tissue reaction (ALTR) is a recognized complication of total hip arthroplasty (THA) with metal-on-polyethylene (MoP) bearing surface implants. Specific models of THA implants have been identified as having a higher incidence of ALTR. The purpose of this study is to determine if serum metal levels, patient symptoms, implant factors, and imaging findings can be predictive of ALTR within this high-risk population.

Methods: We retrospectively reviewed an observational cohort of 474 patients who underwent MoP THA and were at increased risk of having ALTR. Patients were stratified based on the presence or absence of ALTR. Patient symptoms, serum metal ions, implant head offset, and imaging findings were compared.

Results: Patients with ALTR were more likely to be symptomatic (52.9% vs 9.9%, $P < .0001$). The presence of ALTR was associated with significantly higher serum cobalt and chromium levels (6.2 ppb vs 3.6 ppb, $P < .0001$; 2.3 ppb vs 1.2 ppb, $P < .0001$). Head offsets greater than 4 mm were associated with a higher prevalence of ALTR (53% vs 38%, $P = .05$). On metal artifact reduction sequence magnetic resonance imaging, patients with ALTR had larger effusions (4.7 cm vs 2.1 cm, $P < .001$) and a higher incidence of trochanteric bursitis (47% vs 16%, $P < .001$).

Conclusions: In high-risk MoP implants, serum cobalt and chromium levels are elevated, even in patients without ALTR. A larger femoral head offset is a risk factor for the development of ALTR. Our study suggests that patients presenting with painful THA and elevated metal ions require risk stratification based on patient symptoms, metal artifact reduction sequence magnetic resonance imaging findings, and implant factors.

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Introduction

Modularity in total hip arthroplasty (THA) was introduced in the 1980s and widely adopted for its intraoperative flexibility to adjust offset, leg length, and overall stability. It is now appreciated that modularity introduced a new potential problem with corrosion at the modular junction of the head-neck taper interface [1-3]. Mechanically assisted crevice corrosion has been identified as a cause of failure in metal-on-polyethylene (MoP) THA [4-7]. Mechanically assisted crevice corrosion can release corrosion and fretting debris into the local soft-tissue environment causing an

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immune-mediated inflammatory response termed adverse local tissue reaction (ALTR) that can result in osteolysis and destruction of the soft tissue around the joint [8–11].

Diagnosis of ALTR can be challenging. The use of a risk stratification system that uses serum metal ion levels, imaging findings, patient history and examination, and implant factors has been advocated to assist in its diagnosis [12]. ALTR is associated with an elevated serum cobalt or chromium level [5,13–15]. Imaging findings of a thickened pseudocapsule and extraarticular fluid extension have been found to strongly correlate with the degree of soft-tissue destruction in ALTR [16,17]. Furthermore, implant factors such as implant type and head offset, as well as patient factors, such as abductor weakness or unexplained symptoms, can assist in the diagnosis [15,18].

A specific model of recalled low-friction ion treatment (LFIT) cobalt-chromium (CoCr) head used in association with titanium-molybdenum-zirconium-iron (TMZF) stems has been identified as having an increased prevalence of ALTR [11]. While predictors of ALTR (ie, serum metal ion levels, imaging findings, patient factors, implant factors) have been well characterized in patients with standard-risk MoP bearing surface implants, their influence in these high-risk implants is unknown.

Accordingly, the purpose of this study was to (1) retrospectively analyze an observational cohort of patients with a recalled model of MoP femoral head to characterize metal ion levels and imaging findings in patients with hip prostheses that are at high risk for ALTR and (2) to investigate the influence of implant factors and patient characteristics on the prevalence of ALTR in this high-risk population.

Material and methods

Study design and patients

After receiving institutional review board approval, we retrospectively reviewed a cohort of 492 patients who were identified by searching databases from our multidisciplinary referral center as having received an MoP THA. The index procedure was performed by a single orthopedic surgeon between 2005 and 2008. Patients were included in the study if their index procedure used the recalled Stryker LFIT CoCr V40 femoral head in association with Accolade I TMZF stem (Stryker Orthopedics, Mahwah, NJ) and if they had serum metal analysis performed as a part of routine follow-up or before the revision surgery ($n = 270$) (Fig. 1). Some patients did not have serum metal ion levels before surgery

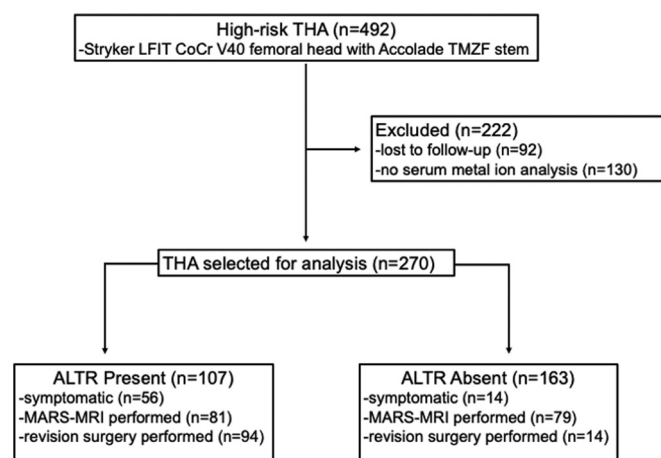


Figure 1. Flow of patients through the study.

Table 1
Patient characteristics.

Characteristics	ALTR absent (n = 163)	ALTR present (n = 107)	P value
Female sex, no. (%)	101 (62)	59 (55)	.26
Age at index surgery (y) ^a	64 (10)	63 (9)	.61
BMI (kg/m ²) ^a	28.4 (6.2)	28.9 (5.7)	.49
Symptomatic, no. (%)	14 (10)	56 (53)	<.0001
Follow-up (y) ^a	14.0 (0.81)	14.1 (0.90)	.25

^a The value is given as the mean and standard deviation.

secondary to gross trunnion failure and urgent revision. Acetabular components included the Trilogy acetabular system (Zimmer-Biomet, Warsaw, IN). Patient characteristics including age, sex, body mass index (BMI), and symptoms are summarized based on the presence or absence of ALTR in Table 1. Patient demographics were recorded at the time of index surgery during preoperative evaluation, while patient symptoms were recorded at routine follow-up before the revision surgery. Patients were deemed symptomatic if they reported pain, instability, or weakness on the side of the prosthesis.

Patients were stratified into two groups based on the presence or absence of ALTR for the analysis of serum metal ion levels and imaging findings. ALTR was diagnosed either by prerevision cross-sectional imaging or intraoperatively at the time of revision surgery. In a separate analysis on the effect of head offset, patients were stratified into either the large offset cohort (head offset greater than +4 mm) or the small offset cohort (head offset less than or equal to +4 mm). Patients within the cohort that we followed up all had a cup size greater than 50, and by virtue of the hip system that we use, a 36-mm head was available. Thus, all patients included had a 36-mm-size femoral head.

Metal ion levels

Serum analysis of cobalt and chromium ion levels was performed using an inductively coupled mass spectrometer with a detection limit of 0.3 ppb. Metal analysis was performed in all patients who presented for follow-up after notification of their implant recall and in patients who presented before the recall with a symptomatic implant. In patients who had multiple serum metal analyses performed, the highest value was used for the purpose of this study.

Metal artifact reduction sequence magnetic resonance imaging (MARS MRI)

In this cohort, MARS MRI was performed for symptomatic patients, patients with elevated serum metal ions, or patients who were both symptomatic and had elevated serum ion levels. If patients were asymptomatic and did not have elevated cobalt and chromium levels, they did not meet criteria for prophylactic screening MARS MRI. MRIs were acquired with a 1.5-T magnet on various scanners throughout our health-care system. On MARS MRI, ALTR was diagnosed by the presence of fluid collection of the

Table 2
Comparison of maximum ion levels between patients with and without ALTR.

Ions	ALTR absent (n = 163)	ALTR present (n = 107)	P value
Cobalt (ppb)	3.6 (0.4–23.6)	6.2 (0.5–33.3)	<.0001
Chromium (ppb)	1.2 (0.1–11.0)	2.3 (0.3–10.7)	<.0001
Cobalt/chromium ratio	3.2 (0.3–39.5)	3.1 (0.1–28.0)	.98

The values are given as the median with the range in parentheses.

Table 3
ALTR prevalence and ion levels by head offset.

Prevalence and ions	Head offset		P value
	≤4 mm	>4 mm	
	(n = 191)	(n = 45)	
ALTR, no. (%)	72 (38)	24 (53)	.05
Cobalt (ppb) ^a	4.6 (0.5–33.3)	5.4 (0.5–20.9)	.04
Chromium (ppb) ^a	1.4 (0.1–11)	2.3 (0.4–8.1)	.05
Cobalt/chromium ratio ^a	3.2 (0.3–39.5)	3.1 (0.6–8.3)	.01

^a The values are given as the median with the range in parentheses.

joint capsule that extended into the trochanteric bursa or other pericapsular regions. Trochanteric bursitis alone was not considered to be ALTR. For the purposes of our study, we evaluated the imaging findings of effusion size, pseudocapsule thickness, and presence of trochanteric bursitis.

In patients with contraindications for MARS MRI or those who presented with catastrophic trunnion failure as evidenced by a plain radiograph, ALTR was confirmed at the time of revision surgery by the presence of fluid collection, pseudotumor, or soft-tissue destruction adjacent to the prosthesis.

Statistical analysis

Continuous patient demographic factors of the ALTR and non-ALTR groups were described with means and standard deviations and tested with the two-sample t-test. Categorical variables were summarized with frequencies and percentages and compared between the groups with the chi-square test. Serum metal data were summarized with the median and range, and intergroup comparisons were made using the two-sample t-test. All statistical analyses were performed in SAS, and statistical significance was set at 0.05.

Results

Patient characteristics

A total of 270 patients were chosen for inclusion in this study. All patients underwent MoP THA using the recalled Stryker LFIT CoCr head in association with the Accolade I TMZF stem. For the patients included in this study, 160 (59.3%) were female, the average age was 64 years, and the mean BMI was 28.7 kg/m² (Table 1). Of the 270 patients included in this cohort, 107 (39.6%) were found to have an ALTR vs 163 (60.4%) who did not. There were no significant differences in age, sex, or BMI between the ALTR group and the non-ALTR group (Table 1). However, the ALTR group was more likely to be symptomatic (53% vs 10%, $P < .0001$).

Metal ion levels

Of the 270 patients in this cohort of high-risk MoP THA, 215 (79.6%) patients had serum cobalt levels greater than or equal to 1.0 ppb, while 55 (20.4%) patients had serum cobalt less than 1.0 ppb.

Table 4
MRI differences between patients with and without ALTR.

MRI characteristics	ALTR present (n = 81)	ALTR absent (n = 79)	P value
Effusion, no. (%)	58 (72)	40 (51)	.006
Effusion size (cm) ^a	4.7 (1.4–14.5)	2.1 (0.2–6.6)	<.001
Trochanteric bursitis, no. (%)	38 (47)	13 (16)	<.001

^a The values are given as the median with the range in parentheses.

Within the ALTR group, 98 (91.6%) patients had serum cobalt greater than or equal to 1.0 ppb, while 9 (8.4%) patients had serum cobalt levels less than 1.0 ppb. Within the ALTR absent group, 117 (71.8%) patients had serum cobalt levels greater than or equal to 1.0 ppb, while 46 (28.2%) patients had serum cobalt less than 1.0 ppb. Of the 270 patients in this cohort, 167 (61.9%) patients had serum chromium levels greater than or equal to 1.0 ppb, while 103 (38.1%) patients had serum chromium less than 1.0 ppb. Within the ALTR group, 79 (73.8%) patients had serum chromium levels greater than or equal to 1.0 ppb, while 28 (26.2%) patients had serum chromium levels less than 1.0 ppb. Within the ALTR absent group, 88 (54.0%) patients had serum chromium greater than or equal to 1.0 ppb, while 75 (46.0%) patients had serum chromium less than 1.0 ppb. When comparing the patients with a confirmed ALTR to those with a well-functioning implant within this cohort of high-risk MoP THA, the presence of ALTR was associated with statistically significant higher cobalt and chromium ion levels (6.2 ppb vs 3.6 ppb, $P < .0001$; 2.3 ppb vs 1.2 ppb, $P < .0001$) (Table 2). However, the cobalt-chromium ratio was not found to be significantly different between the two groups (3.1 vs 3.2, $P = .98$).

Implant factors

Forty-five (19.1%) patients had a large head offset greater than 4 mm, while 191 (81.0%) had a head offset of less than or equal to 4 mm (Table 3). Large-head offsets greater than 4 mm were associated with a higher prevalence of ALTR (53.3% vs 37.7%, $P = .05$). The large-head offset group was also associated with statistically significant higher cobalt and chromium serum ion levels (5.4 ppb vs 4.6 ppb, $P = .04$; 2.3 ppb vs 1.4 ppb, $P = .05$). Smaller head offsets (less than or equal to 4 mm) were associated with a statistically significant higher cobalt-chromium ratio (3.2 vs 3.1, $P = .01$).

Imaging results

One hundred sixty of the patients included in our study had a MARS MRI performed. Of those who had imaging, 81 were in the ALTR group while 79 were in the ALTR absent group (Table 4). The finding of effusion on MARS MRI was more likely within the ALTR group (72% vs 51%, $P = .006$), and the average maximum diameter of the effusions was significantly larger within the ALTR group (4.7 cm vs 2.1 cm, $P < .001$). In addition, patients who underwent ALTR were more likely to have imaging findings of trochanteric bursitis (47% vs 16%, $P < .001$).

Discussion

ALTR is an increasingly reported complication linked to MoP bearing use in THA. While its overall prevalence is estimated at 1.1%–3.2%, select implants are known to have an elevated risk of ALTR [6,11,19]. Risk factors and predictors of ALTR have been studied in patients with standard MoP THA, but data are lacking on patients with high-risk implants. This study examined a group of patients that had received a specific high-risk implant that went on to require revision THA. The goals of the study were to evaluate metal ion levels and implant characteristics in this population and investigate risk factors that could be predictive of ALTR.

Previous work has shown that elevated serum metal ion levels were associated with the diagnosis of ALTR in MoP THA. Kwon et al. reported a sensitivity and specificity for a cobalt level of 1 ppb to be 95% and 94%, respectively, in predicting head neck taper pseudotumor development [13]. In addition, the sensitivity and specificity of an elevated Co/Cr ratio of 2 was 83% and 72%, respectively [13]. Fillingham et al. reported similar findings with a cobalt level of 1 ppb having a sensitivity and specificity of 100% and 90%,

respectively, and a Co/Cr ratio of 1.4 with a sensitivity and specificity of 93% and 70%, respectively [20]. Other studies have also reported elevated cobalt levels as a recurring marker for ALTR [21,22]. In our study, there were significantly higher cobalt and chromium levels in patients with ALTR, which is consistent with the existing literature. However, unique to this study was the degree to which serum ion levels were elevated in patients without ALTR. Average cobalt levels were 3.6 ppb in patients without imaging or intraoperative evidence of ALTR, which is well above the generally accepted threshold of 1 ppb. At present, it is unclear whether this indicates impending ALTR in this at-risk population, or rather a benign elevation. Nevertheless, this has diagnostic implications such that an isolated finding of elevated serum metal ions cannot be used as a corollary for ALTR, and thus, risk stratification is of even greater importance.

Interestingly, we found no significant difference in the Co/Cr ratio. This may be reflective of the lower sensitivity and specificity of the Co/Cr ratio previously reported in comparison to absolute cobalt levels. Alternatively, this may indicate that this specific population with one high-risk implant could have a unique metal wear pattern that does not result in an elevated Co/Cr ratio. This possibility should be considered in monitoring patients with implants at high risk for ALTR.

Various implant factors have also been linked to ALTR in the existing literature. Geometry of the trunnion taper-head interface is known to be critical to the development of corrosion at the head-neck junction in THA [18,23,24]. However, other implant variables such as femoral head offset have also been associated with ALTR. Kwon et al. reported an association with both larger femoral stem offset and head offset and ALTR [25]. Furthermore, Martin et al. reported elevated metal ion levels with higher head offset [26]. In our study, femoral head offset greater than 4 mm was associated with higher rates of ALTR, which parallels the existing literature. This may be explained by the joint forces being transmitted through a smaller surface area of contact in a higher offset head.

MARS MRI is the gold standard imaging modality for identification of ALTR of THA, and for this reason, it was used to define the diagnosis of ALTR in this study [11]. Nawabi et al. reported that MARS MRI can be used to diagnose ALTR in MoM THA with a sensitivity and specificity of 94% and 87%, respectively [17]. Our study showed that the imaging findings of trochanteric bursitis, joint effusion, and the size of the effusion can be used to assist in the diagnosis of ALTR on MARS MRI. Of note, among the patients who did not have ALTR, 51% still had a joint effusion. This could be due to them being on their way to developing ALTR, but more follow-up visits are needed. While 51% of the non-ALTR group still had an effusion, the effusions were significantly smaller in size than those in the ALTR group. This suggests that while the presence of effusion alone may not be a specific marker of ALTR, the size of the effusion can be used in aiding diagnosis.

Nevertheless, our study is not without certain limitations. As a retrospective observational study, unintentional bias or misclassification could have impacted results. In addition, as the study design and data collection began after failure had occurred, a priori power analysis was not performed, and the ability to draw large conclusions regarding the effect of implant factors on outcomes is limited. MRI and intraoperative diagnosis are strong criteria for diagnosing ALTR, but these criteria are still prone to some level of subjectivity. Similarly, confounding variables such as patient activity were not accounted for among our patients. Our study used one single implant at known risk for ALTR, which strengthens the internal validity of our results but perhaps limits the generalizability of our findings. Finally, this study is limited by its sample size, which may have made it underpowered to detect a difference in Co/Cr ratios.

In conclusion, we observed elevated metal levels without a difference in Co/Cr ratio in association with ALTR in a population of patients with high-risk MoP THA implants. We also observed an association between high-offset femoral head components and ALTR. These relevant factors may be helpful to consider when evaluating patients with implants at high risk for the development of ALTR. This study presents the initial framework for future prospective studies investigating the causes and factors associated with ALTR.

Conflicts of interest

B.R.H. is a paid consultant for Smith Nephew. K.L.U. is a paid consultant for and receives research support from Smith Nephew and Peptilogics. K.L.U. is a board member/made committee appointments for AAOS and ASTM.

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