Corrosion and Adverse Local Tissue Reaction in One Type of Modular Neck Stem

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ABSTRACT

Modular neck stems allow for optimization of joint biomechanics by restoring anteversion, offset, and limb length. A potential disadvantage is the generation of metal ions from fretting and crevice corrosion. We identified 118 total hip arthroplasty implanted with one type of dual-modular femoral component. Thirty-six required revision due to adverse local tissue reaction. Multivariate analysis isolated females and low offset necks as risk factors for failure. Kaplan–Meir analysis revealed small stem sizes failed at a higher rate during early follow-up period. Although the cobalt/chrome levels were higher in the failed group, these tests had low diagnostic accuracy for ALTR, while MRI scan was more sensitive. We conclude that the complications related to the use of dual modular stems of this design outweigh the potential benefits.

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Modular femoral necks that mate both with a proximal femoral stem and a modular femoral head afford the surgeon the luxury of adjusting femoral anteversion, leg length, and offset independent of the native femoral anatomy [1]. Despite the potential advantages of modularity, these component designs also offer a greater number of junctions through which complications may occur. Titanium alloy modular neck adapters can fracture [2,3], and there is a potential for dissociation at the Morse taper [4] due to surface cracks caused by fretting corrosion. It has been shown that modular necks made of cobalt/chrome alloy have lower micromotion at the stem–neck taper connection and a lower chance of fracture [5,6]. Modular necks made of cobalt/chrome alloy were therefore introduced to alleviate the problem of fracture. However, fretting and crevice corrosion at the modular stem–neck junction have the potential for metal ion generation when the protective oxidized metal surface is disrupted, which may lead to adverse local tissue reaction (ALTR) [7].

Gill et al [7] described their experience with the ESKA dual-modular short stem in which patients presented with worsening postoperative pain due to pseudotumor formation that required further surgery. Aseptic lymphocytic vaculitis associated lesions were demonstrated on histological analysis of tissue samples. A recent multicenter retrospective case series of twelve total hip arthroplasties (THAs) performed using the Rejuvenate dual modular stem (Stryker, Mahwah, NJ) revealed similar findings with all hips showing large soft-tissue masses and evidence of ALTR with dense lymphocytic infiltrate secondary to corrosion at the modular neck–body junction [8].

The goals of our study were to investigate the early symptomatic failures of THA using the Rejuvenate stem at our institution, analyze any associated risk factors for failure, and determine the accuracy and efficacy of the diagnostic studies commonly employed to detect ALTR including for this device. We attempted to create from these data points a diagnostic algorithm that may be used to identify patients who would be at high risk for developing symptomatic ALTR with this device.

Methods and Materials

Study Population

After obtaining institutional review board approval, we performed a retrospective review of our joint arthroplasty database to identify patients who had undergone THA with a Rejuvenate stem (Stryker, Mahwah, NJ) at our institute. The stem is made from a titanium–molybdenum–zirconium–iron alloy (TMZF) with a cobalt–chromium–alloy modular neck. The Rejuvenate stem was not used as the standard component for primary THA but was inserted in complex hips and in cases with proximal femoral deformity to adjust version and offset which constituted approximately 13% of all THAs performed during the study period.

We obtained clinical data regarding patient demographics that included age, gender, weight, BMI, and ASA grade as well as implant specifications from the patients’ clinical notes and hospital charts. Patients also filled out routinely a Harris Hip Score (HHS) questionnaire prior
to index surgery and postoperatively at latest follow-up. The routine follow-up schedule consisted of postoperative clinic visits at 6 weeks, 3 months, 1 year, 2 years, and every other year after that.

We identified 107 patients, who underwent 118 THAs (11 bilateral cases) performed by two surgeons during the following period: 12/1/2008–11/15/2011. A posterior approach was utilized in performing the primary THA in all cases. The mean age of our cohort was 60 years (range: 30–85) with an average BMI of 33 (range: 20–46). A total of 8 patients (9 THAs) were lost to follow-up, and hence our final cohort consisted of 99 patients (109 THAs) with 44 females and 55 males. Although these 8 patients lost to follow-up did not return to clinic for any type of evaluation after surgery, we did include their characteristics and demographical data in our description of the cohort. The primary outcome measure for failure was a symptomatic THA that was causing the patient to experience problems with activities of daily living.

**Laboratory Analysis**

Venous blood samples were collected from patients during their clinic follow-up and were sent for serological analysis. All patients in our cohort irrespective of whether they did or did not develop symptoms were contacted after the manufacturer recall and encouraged to undergo serological evaluation. We obtained ESR, CRP, and both serum cobalt (Co) and chromium (Cr) ion levels measured in μg/L. A Co to Cr ratio was then calculated. Serological studies were available for 101 patients and were obtained at an average of 24 months (range: 10–47 months) postoperatively from index surgery. Blood samples were obtained using a 21-gauge stainless steel needle and vacutainer into metal free royal blue Monoject blood tubes. The samples were stored at room temperature. The concentrations of Co and Cr in serum were measured using high-resolution, inductively coupled, plasma mass spectrometry. Serological analysis of the blood samples was performed at our institution and in some cases at other specialized centers that follow the same protocol described above.

Joint aspiration was attempted in 23 hips, but due to large amount of amorphous material present, our laboratory could not perform a cell count and differential on 8 of the aspirate samples. The remaining 15 hip fluid samples were cultured but did not yield an organism. Cell count and differential were performed on 9 of the 15 samples that were determined by an automated machine count and checked manually by our pathologist. Implementing previously established thresholds for PJI in THA [9], 8 of the 9 hip fluid samples had cell counts <3000 cells/μL.

**Magnetic Resonance Imaging**

We were able to perform a pelvic MRI on 84 of the 109 THAs present in our final cohort, of which 27 THAs were considered to be symptomatic. MRI was performed at an average of 26 months (range: 12–47) from index surgery. A 1.5-T magnet MRI (Signa HDX, GE Medical Systems, Wisconsin) with metal artifact reduction sequencing (MARS) protocol was employed which consisted of T1-weighted spin-echo and short tau inversion recovery (STIR) coronal and axial sequences. A radiological classification system previously conceived in metal on metal hip resurfacing arthroplasty was used to sub-classify these masses according to the degree of solidity dividing them into three classifications: Types I, II and III [10]. Predominantly cystic lesions were divided into two types: Type I with cyst wall thickness of less than 3 mm (Fig. 1A) and Type II with cyst wall thickness greater than 3 mm (Fig. 1B). Type III lesions were predominantly solid lesions, where the

**Fig. 1.** (A) Axial T1-weighted spin-echo image of a Type I mass shows a thin walled cystic lesion (red arrow). (B) Axial STIR image of a Type II mass shows a thick walled cystic lesion (red arrow indicates the thickened wall). (C) Coronal STIR image of a Type III mass with a predominantly solid consistency (red arrow) with a minor cystic component.

largest dimension of the solid components was greater than the diameter of the cystic components (Fig. 1C).

**Statistical Analysis**

All statistical analyses were carried out with SAS 9.3 (SAS Institute Inc., Cary, NC, USA). Patient specific and implant related variables were examined as risk factors for failure due to adverse local tissue reaction. The chi-square test and Fisher’s exact test were used to test for independence between categorical variables. Continuous variables were examined using a Student’s t-test. A p-value of <0.05 was considered significant.
were analyzed with simple logistic regression that was used to calculate
the odds ratios and to explore the relationship to failure with the Wald
chi-square statistic. A P-value of <0.05 was considered to be statistically
significant. A model of multiple logistic regression analysis was created
simultaneously to test and model risk factors for failure. The signiﬁcant
variables in the univariate analysis (P-value < 0.25) were used in the
backward selection process to construct the multivariate logistic regres-
sion model. Kaplan–Meier survival curves were created for variables
that approached signiﬁcance according to the simple logistic regression
analysis and could possibly explain failure. Survival rates were calcu-
lated at the 15 and 30 month intervals. The Cox regression model was used
to examine the possible time-dependency of the covariates stem size,
head length, and neck offset. The time-dependent relationship between
the variables studied and survival of the implant was not signiﬁcant,
hence we chose to use standard Cox regression curves for the covariates.
Proportionality was tested and all variables analyzed with the survival
analysis were not signiﬁcantly unproportional. Variables were selected
from the logistic regression models using backwards selection from a
full model as well as investigation priority/preference.

The serological tests including ESR, CRP, Co and Cr levels were com-
pared between the failed and non-failed groups using the Wilcoxon
rank sum test since the variables studied were non-normally distribut-
ed. Receiver operating characteristic (ROC) curves were employed to
assess the area under the curve (AUC) and to determine the optimum
cutoff value for Co, Cr, and Co/Cr ratio in differentiating between a failed
and an asymptomatic THA. With the determined optimal cutoffs, sensi-
tivity, speciﬁcity, negative predictive value (NPV), and positive predic-
tive value (PPV) were calculated along with their 95% conﬁdence
intervals. The diagnostic accuracy of MRI for the presence of a
pseudobursa and maximal size (>5 cm) as predictors for failure was cal-
culated. In addition, the relationship between the MRI classiﬁcation
(Types I, II, III) and failure was determined using ANOVA. We also com-
pared the Co and Cr ion levels among the three MRI classiﬁcations listed
above using the Kruskal–Wallis test.

The diagnostic methods including Co and Cr levels, Co/Cr ratio,
presence of pseudotumor on MRI, maximal size >5 cm of
pseudotumor, and the MRI sub-classiﬁcation of masses were utilized
to create a decision tree. The decision tree was created through binary
recursive partitioning with consideration given to the above men-
tioned variables. This tree was then pruned to remove relatively un-
important branches. The percentages at the endpoints depict the
accuracy of the decision tree in stratifying patients according to
whether they developed symptoms.

Results

THA was performed for the following etiologies: osteoarthritis (88),
post-traumatic osteoarthritis (7), AVN (6), hip dysplasia (2), failed
hip resurfacing (2), failed DHS (2), rheumatoid arthritis (1), non-
union of a femoral neck fracture (1). We encountered two calcar frac-
tures during insertion of two Rejuvenate stems that required cerclage
wiring ﬁxation.

Component Characteristics and Outcome

The implanted acetabular components included: 4 Anatomic Dual
Mobility cups (Stryker, Mahwah, NJ), 51 Trident shells (36 PSL, 15
Hemispherical) (Stryker, Mahwah, NJ), and 63 Tritanium shells
(Stryker, Mahwah, NJ). A ceramic head (Biolox delta, CeramTec,
Plochingen, Germany) was used in 37 hips while the remaining re-
ceived a cobalt–chrome bearing surface. The head diameters varied as
follows: 28 mm (3 THAs), 32 mm (4 THAs), 36 mm (49 THAs), 40 mm
(42 THAs), and 44 mm (11 THAs). A positive head length was used in
only 19 hips. The neck lengths included: 30 mm (24 THAs), 34 mm
(40 THAs), 38 mm (40 THAs), and 42 mm (5 THAs). A low offset neck
(132°) was used in 54 hips, and the remaining THAs received either
127° or 130° necks. The Rejuvenate stem sizes varied from sizes 7
(14 THAs), 8 (30 THAs), 9 (40 THAs), 10 (18 THAs), and 11 (7 THAs).

There were three postoperative complications after index THA: two
patients developed foot drop while one patient had a hematoma that
required surgical evacuation during their hospital stay. The incidence
of deep periprosthetic joint infection (PJI) in this cohort was 2.75%
(3 THAs) that developed during the ﬁrst year after index arthroplasty.
The organisms isolated were Propionibacterium acnes, methicillin sensi-
tive Staphylococcus aureus, and Beta Hemolytic Streptococcus Group B.
One patient passed away due to extensive medical comorbidities and
the remaining two THAs were revised for corrosion after receiving treat-
ment for PJI which included irrigation and debridement and intrave-
nous antibiotics.

We identiﬁed during our clinical follow-up 36 THAs (failure rate:
31%) that we considered as failed. To date a total of 33 THAs were re-
vised for adverse local tissue reaction to corrosion products, while the
remaining 3 hips are awaiting revision. Symptoms began on average
at 14.8 months postoperatively (range: 2.80–38.4) from index surgery.
The patients experienced pain most commonly in the buttock, lateral
thigh, and groin regions. The mean time to revision was 24.1 months
(8.77–50.2 months). Revision surgery included extensive debridement
of the large thickened pseudobursa that communicated with the joint
space in all cases and the majority of cases extended posteriorly, laterally
and distally along the vastus fascia and gluteus maximus tendon in-
sertion. All Rejuvenate stems were well ﬁxed at time of revision. There
was signiﬁcant accumulation of black corrosive debris at the femoral
stem–neck taper interface in all 33 THAs, while corrosion was appreci-
ated in only 8 head/neck junctions. Corrosion at the two modular inter-
faces was examined by eye only. The Rejuvenate stem was revised to a
modular tapered titanium revision prosthesis (Restoration Modular:
Stryker, Mahwah, NJ) using the posterior approach. During revision sur-
gery, we encountered two greater trochanter fractures that required
claw plating, a proximal femur fracture that was ﬁxed with cerclage ca-
bles, and a vascular injury to a branch of the profunda femoris that ne-
cessitated ligation. Intraoperative cultures were obtained for all THA
revisions; all cultures had negative growth. Histological analysis of tis-
sue samples sent revealed absence of acute inﬂammation indicating in-
fection or osteomyelitis. However, there was chronic inﬂammation with
dense lymphocytic inﬁltrate and an abundance of ﬁbrous tissue and an
infrquent giant cell reaction to focally birefringent material.

There was no signiﬁcant difference in the preoperative HHS between
the failed (mean: 59.1, SD: 12.3) and non-failed groups (mean: 58.9, SD:
12.0) (P = 0.983). Both groups improved after index arthroplasty with a
signiﬁcant increase in their scores (P = 0.005). However, the patients
with failed Rejuvenate stems (mean: 78.3, SD: 13.5) had lower HHS at
latest follow-up compared to the patients with asymptomatic stems
(mean: 88.5, SD: 13.5) (P = 0.023).

Risk Factors

The multivariate logistic regression analysis revealed that females
(chi-square 4.94, P = 0.026) and low neck offset (132°) (chi-square
4.43, P = 0.035) were at higher risk for failure from corrosion
(Table 1). Traditional and worst case scenario Kaplan–Meier survival
curves were constructed for the entire cohort and the variables studied:
neck offset, head length, and stem sizes taking the cutoff as 9 and 10
(Fig. 2A–E). The survival rates at 15 and 30 month intervals showed a
clinically steeper deterioration in survivorship at the 15 month follow-

Table 1

Results of the Multivariate Regression Analysis are Presented.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Chi-Square</th>
<th>Standard Error</th>
<th>Odds Ratio (CI)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Females</td>
<td>4.94</td>
<td>0.218</td>
<td>2.64 (1.12, 6.21)</td>
<td>0.026</td>
</tr>
<tr>
<td>Neck offset (132°)</td>
<td>4.43</td>
<td>0.218</td>
<td>2.51 (1.06, 5.92)</td>
<td>0.035</td>
</tr>
</tbody>
</table>

Cl: conﬁdence intervals.
up for the smaller stem sizes and lower neck offset (Table 2). On the other hand, positive head length displayed a divergent pattern on the survival curve with acceleration in failure after the 15 month period. Although none of these variables (stem size, neck offset, and head length) showed significant interaction with time (Table 3), it was noted that upon further inspection that stem size dichotomized at 9
and its interaction with time significantly described survival when looking only at failures within the 30 month window ($P = 0.031$) (Table 2).

### Laboratory Analysis

The serum Co and Cr levels and Co/Cr ratio of the 101 THAs tested were on average significantly higher in the failure group (Table 4). Although both ESR and CRP were significantly elevated in symptomatic patients, it should be noted that their average levels were <30 mm/h and 15 mg/dl respectively, which limits their clinical applicability. ROC curves were constructed for Co, Cr, and Co/Cr ratio to determine their sensitivity, specificity, and predictive values with AUC less than 0.8 (Table 5).

### MRI Findings

The presence of pseudotumor communicating with the joint space on MRI revealed poor sensitivity (74.1%; 63.9%–84.3%), specificity (54.5%; 43.0%–66.1%), PPV (50.0%; 38.4%–61.6%), and NPV (77.4%; 67.7%–87.1%) in differentiating patients with symptomatic and asymptomatic Rejuvenate stems. Only 74% of the symptomatic patients had a pseudobursa or pseudotumor on their MRI, while 45% of the asymptomatic patients had positive MRI findings. The failure rates according to the three pseudotumor subcategories I (46%), II (62%), and III (50%) were similar ($P = 0.101$). The specificity (86.4%; 78.3%–94.5%) and PPV (71.4%; 60.8%–82.1%) of MRI improved when using a pseudotumor size in maximal dimension $>5$ cm in predicting symptomatic THA, but at the expense of the sensitivity (60.0%; 48.4%–71.6%) and NPV (79.2%; 69.6%–88.7%). There was no significant difference in serum Co levels (chi-square: 2.70, $P = 0.260$) or Cr levels (chi-square: 1.24, $P = 0.538$) among the three MRI subcategories of pseudotumor described above.

### Diagnostic Algorithm

The decision tree was created using binary recursive partitioning, and after undergoing pruning revolved around the following variables: serum cobalt level, Co/Cr ratio, and the presence of a pseudotumor on MRI (Fig. 3). Patients with a serum Co level <6.25 μg/L had an 82% chance of not developing symptoms, while those with levels $\geq 18.5 \mu g/L$ were at very high risk of failure. The Co/Cr ratio was helpful in filtering patients with Co levels in between 6.25 and 18.5 μg/L, in which a ratio of $<5.74$ indicated a 67% likelihood of a symptomatic hip. The presence of a Co/Cr ratio $\geq 5.74$ with an MRI negative for presence of a pseudotumor emanating from the hip joint space is reassuring of a low likelihood of symptoms evolving.

### Discussion

Modular hip stems are designed to give the surgeon more versatility in adjusting offset, leg length, and femoral anteversion in order to restore optimum biomechanics and reduce the prevalence of postoperative dislocation [1,7]. However, modularity adds large crevice environments, which are subject to micromotion between contacting interfaces that result in high stresses at the modular stem–neck junction and inevitably lead to fretting induced crevice corrosion [7,11]. Recently, a multicenter retrieval analysis performed on Rejuvenate stems removed due to symptomatic soft tissue masses revealed severe corrosion at the modular neck–body junction [8]. Histology demonstrated large areas of tissue necrosis and a dense lymphocytic infiltrate in the capsular tissue, while the corrosion products that precipitated were identified as chromium phosphate. Chromium orthophosphate hydrate-rich particles were originally distinguished by electron micro-probe analysis and Fourier transform infrared microprobe spectroscopy within histiocytes or were surrounded by foreign-body giant cells in the pseudocapsule and membranes of the femoral bone–implant interface [12]. The histology obtained during revision of the 33 Rejuvenate stems in our cohort revealed similar findings of dense fibrous tissue, chronic lymphocytic inflammation with giant cell reaction to focally bi-refrangent material confirming failure due to crevice corrosion.

The corrosion debris generated during this process may be linked to a higher incidence of PJI. A review of the Medicare database revealed that MOM THA was associated with a higher risk of PJI after adjusting for patient and hospital related factors [13,14]. The rate of PJI in our cohort confirmed with positive cultures approached the 3% rate. One study has suggested that particulate debris of any composition promotes bacterial growth by providing a scaffold for bacterial adhesion and growth of biofilm and planktonic bacteria [15]. In addition, patients with MOM implants were shown to have a reduced number of circulating cytotoxic CD8+ T-cells necessary for defense against PJI [16].

Certain risk factors for failure due to symptomatic pseudotumor formation in hip resurfacing and MOM THA have been isolated [17,18]. Females are at a disadvantage and a higher risk for developing pseudotumors possibly due to differences in metal ion metabolism, consequent to disparities in lean body mass, cellular or extracellular storage, or renal excretion [10,19]. Another plausible explanation is that the gender association with component size could be a confounding factor where females have a greater propensity to receive smaller femoral components [18]. In a retrieval analysis of different femoral stems with a modular head, small stems with a consequently lower flexural rigidity were predictors of head and neck corrosion and head fretting [20]. These results corroborate our own conclusions where we found that females and small Rejuvenate stem sizes were significant predictors for
early failure within 3 year follow-up. Furthermore, the Rejuvenate stem is composed of TMZF alloy which is reported to have higher strength but lower elastic modulus than earlier titanium alloys which compromises the implants overall stiffness [21]. Although we are keen in cleaning the modular taper junctions intraperioperatively, the environment plays a critical role in the initial stability of modular hip taper connections where assembly of modular junctions in air (dry conditions) show the highest resistance to fretting compared to contaminated (wet conditions) that exhibit significantly larger micromotions [6,22]. Similarly, the use of femoral heads with positive head length was shown in laboratory analysis to have higher visual evidence of fretting damage during which micromotion measurements indicated that neutral heads tended to piston on the trunion, while those with positive length tended to rock [23]. We were unable to show statistical significance in correlating failure with use of head length in the multivariate analysis or the Kaplan–Meir curves, but this may be due a lack of power since femoral heads with positive head length were used infrequently (17% of the cases). In addition, the multivariate logistic regression analysis revealed that low offset necks were a significant risk factor for failure (P = 0.035). This may be due to the decrease in the hip moment lever arm, which inevitably would generate greater forces at the modular junctions and create an environment conducive to fretting and corrosion. These risk factors explain the high early failure rate of the Rejuvenate stem in our cohort with a slow decline in survivorship as time elapsed. This is due to the fact that corrosion worsens with implantation time [20,24]. Hence, we are very concerned that Rejuvenate failures will increase with mid to long term follow-up.

We were disappointed with the mediocre diagnostic accuracy of both serum Co and Cr levels in differentiating symptomatic and asymptomatic Rejuvenate failures as reflected in the low AUC of their ROC curves. However, we this was anticipated given that MOM THA patients revised for pseudotumors were found to have similar whole blood ions to those who were not revised [25]. Malek et al [26] obtained plasma levels of cobalt and chromium ions and MARS MRI scans on 209 consecutive, unilateral, symptomatic MOM THA. Using the MARS MRI as the standard for the diagnosis of ALTR, the sensitivity and specificity of Co levels with a cut-off of >7 μg/L were 57% and 65% respectively. Lowering the threshold to 3.5 μg/L for both Co and Cr ion levels improved the sensitivity to 86% but at the expense of specificity (27%). A similar study performed on the ASR MOM THA (Depuy, Warsaw, IN) revealed sensitivity and specificity of 56% and 76% for Co levels and 56% and 83% for Cr levels respectively in predicting the presence of ALTR on MRI [27]. Currently, there is no generally agreed upon threshold for metal ion concentrations in body fluids to diagnose ALTR. Therefore, it is imperative to perform future multicenter clinical studies with larger numbers of patients to improve the diagnostic accuracy of serum metal ion levels or possibly abandon these tests and embark on developing new unconventional methods.

The fluid cell count and differential of 9 hip aspirates performed in our cohort implementing previously established thresholds for PJI [9] was reliable in differentiating between an infected and non-infected THA with dual modular necks. However, there is one caveat that should be taken in consideration. We were unable to perform a cell count and differential or culture on 8 of the 23 hip aspirates due to prolific amounts of amorphous material (corrosion products) present in the joint. Wyles et al [28] recently reviewed 39 hip aspirates done prior to revision of MOM THA and found that fluid WBC count had poor predictive value in diagnosing PJI compared to synovial neutrophil percentage using 3000 cells/μL and 80% as thresholds respectively. One hypothesis is that abnormally high cell counts may occur when the automated machine counts the abundant metallic debris as cells. In our study, cell counts were checked manually by our institution’s pathologist that may explain the improved diagnostic accuracy of fluid cell count.

There is no clear association between pseudotumor formation in THA and the presence of symptoms. The prevalence of pseudotumor formation on MRI in painful and asymptomatic MOM THA is approximately 60% in each group with no differences in pseudotumor characteristics [29]. We found that the presence of pseudotumor

![Decision tree pruned and incorporating the variables: Co level, Co/Cr ratio, and presence of a pseudotumor on MRI. The percentages at the outcome nodes describe the accuracy of each decision of whether symptoms are present (yes) or not (no).](http://dx.doi.org/10.1016/j.arth.2015.04.039)
communicating with the joint space on MRI revealed poor prognostic value in distinguishing between symptomatic and asymptomatic Rejuvenate THA. Even when we classified the pseudotumour into three subtypes with increasing severity in solidity, the failure rates based on symptoms were similar between the three groups. Although segregating the pseudotumours according to size in maximal dimension with threshold >5 cm improved the specificity in detecting painful Rejuvenate THA, it was at the expense of the sensitivity. Chang et al [30] found similar results when they performed MRI imaging on 192 MOM THAs in which the presence of symptoms did not correlate with presence, size, or wall thickness of pseudotumours. Only bone marrow edema and tendon tearing were predictors of pain. Surprisingly, Co and Cr ion levels are unreliable predictors of periarticular soft tissue damage in patients undergoing revision surgery for symptomatic MOM THA [31]. We reached a similar conclusion given that metal ion levels did not significantly differ among the different MRI grades for pseudotumour.

There are certain limitations and caveats with our study that must be kept in mind when making conclusions for treatment and diagnosis of symptomatic Rejuvenate THA. First, the generalizability of our data analysis and the diagnostic algorithm we constructed are limited by the small size of our cohort consequent to the company recall of the implant. Furthermore, the algorithm requires validation by other centers in which case the variables and threshold values of the tree branches may vary. We still are unable to explain why some patients with minimal corrosion as per their metal ion levels and absent pseudotumours develop symptoms, while on the opposite pole of the spectrum some patients are asymptomatic. This could be related to a genetic predisposition for some patients to develop lymphocyte reactivity to in vivo metal debris exposure [32] while others may develop an exacerbated adaptive immune response to small amounts of metallic debris [33].

There are some provisions that can be undertaken to decrease the propensity of implants to corrode. Improving the tolerances of the mating surfaces would reduce micromotion and fluid accumulation at the interfaces [34]. Increasing the stiffness of the material and the size of the implant in general as well as its modular sections will improve the flexural rigidity and may reduce fretting and subsequent corrosion [20]. Ceramic components can produce less fretting and corrosion when coupled with Co or titanium alloys mitigating but not eliminating the problem of corrosion [32,35]. Finally, thorough cleaning of the fluid and tissue debris that may contaminate the tapers and modular portions during surgery is essential in decreasing micromotion at the taper connection [6].

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References