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Short-Term Metal Ion Trends Following Removal of Recalled Modular Neck Femoral Stems

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ABSTRACT

Elevated serum metal ions have been well documented with the Rejuvenate modular neck femoral stem (Stryker, Mahwah, NJ); however, the rate at which ion levels decline following revision is less clear. This study included fifty-nine consecutive revisions of Rejuvenate stems for symptomatic ALTR. Blood tests prior to revision and postoperatively at 6 weeks, 3 months, 6 months, and 1 year measured serum cobalt and chromium concentrations, ESR, and CRP. At six weeks following revision of a unilateral Rejuvenate, cobalt and chromium levels dropped from preoperative levels by 67% and 42%, respectively. At three months, cobalt levels declined to 19% of preoperative values, but chromium levels remained stable. With this information, surgeons can set realistic expectations for serum metal ion levels following Rejuvenate stem revision.

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The Rejuvenate Modular Hip Stem (Stryker Orthopedics, Mahwah, NJ) was voluntarily recalled after an elevated failure rate was noted during routine post-market analysis [1,2]. Symptomatic patients were found to have pain, elevated chromium (Cr) and cobalt (Co) ion levels, and adverse local tissue reactions (ALTRs). Certain series have shown that up to thirty percent of patients with Rejuvenate stems are symptomatic [3]. The Rejuvenate modular stem was designed to allow the surgeon intra-operative flexibility to optimize stability, range of motion and leg length by adjusting the neck length. The taper junction of the neck stem interface has fallen under scrutiny after several studies reported that mechanically assisted crevice corrosion (MACC) at the dual taper junction leads to elevated Co and Cr ion resulting in ALTR [2,4–7]. The diagnosis of a taper junction corrosion and metallosis usually relies on the patient narrative, physical exam, laboratory tests, and advanced imaging, specifically MRI [8].

The natural history of metal ion levels after removal of poorly performing total hip arthroplasty (THA) implants is not well characterized in the literature. The senior author (GW) has found that, although revision surgery improves pain symptoms, patients remain concerned about metal ion levels after revision. However, currently there are no data examining the trends of serum metal ions levels following revision of the Rejuvenate stem. Pivec et al recently published an expert's opinion of how to deal with a recalled implant, including surveillance of serum metal ions. The authors suggest that erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), and serum metal ions should be ordered at presentation and followed serially [8]. We prospectively examined 54 patients, including five patients with bilateral Rejuvenate stems, to determine the trends of metal ion levels and ESR/CRP both pre and post-revision. The goal of the study was to determine the change in metal ion levels and inflammatory markers after Rejuvenate stem revision. We hope that our data will assist surgeons as they counsel patients before and after revision of a femoral stem with a dual taper modular neck.

Materials and Methods

Study Design, Patient Cohort

The senior author implanted 199 Rejuvenate modular stems between April 2010 and March 2012 and the revision rate is approximately 30%, consistent with previous clinical series [3]. From this group of patients, we have collected a consecutive series of 59 Rejuvenate Modular hip implants from 54 patients. Patients included in the study underwent revision surgery of a modular Rejuvenate stem at our institution and all patients had greater than six months of follow up. Cohort 1 included three unilateral patients who had the index surgery elsewhere. We excluded patients who were revised for reasons other than pain and suspicion of ALTR. The Rejuvenate stem is made of a titanium-alloy (Ti12-Mo-6Zr-2Fe or TMZF), and the modular neck is made of cobalt–chromium alloy (Co-Cr-Mo). Cohort 1 included patients with unilateral Rejuvenate stems and consisted of 27 female and 22 male patients.

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Table 1
Cohort 1 Patient Demographics.

Characteristic (n = 49)	Number of Patients
Sex	
Male	22 (44.9%)
Female	27 (55.1%)
Age	
<50	2 (4.1%)
50–59	7 (14.3%)
60–69	22 (44.9%)
70–79	17 (34.7%)
>80	1 (2.0%)
Side	
Left	22 (44.9%)
Right	27 (55.1%)
Has another artificial joint	9 (17.7%)
Peri-prosthetic fracture intra-operatively or within 6 weeks	5 (10.2%)

Cohort 2 included 5 patients (4 females and 1 male) with bilateral Rejuvenate stems. The average patient age at revision was 65.2 (±8.1) years in cohort 1 and 60.0 (±5.8) years in cohort 2 [Table 1]. Prior to revision, patient demographics, revision indication, length of implantation, MRI/pathology results, metal ion levels (Co/Cr), and ESR/CRP were recorded into our prospective database. All MRI imaging was completed using our institution's metal suppression protocol.

We obtained a preoperative MRI using a standardized protocol (multi-acquisition with variable resonances image combination (MAVRIC)) optimized to reduce metallic susceptibility artifact on all patients in the unilateral cohort (49 patients, 49 hips) [9]. The unilateral cohort's MRI findings were graded as 12 mild, 18 moderate, and 14 severe cases [Table 2]. Using the histologic description of pseudotumor-like tissues for metal on metal hips, nearly 90% of the unilateral hips had an ALVAL score >5 and therefore were considered positive ALVAL cases [10]. The ALVAL scoring system described by Campbell et al, the mean synovial lining score was 2.54 (SD 0.65, range 1–3), the mean inflammatory infiltrate score was 3.18 (SD 0.89, range 0–4), and the mean tissue organization score was 2.25 (SD 0.86, range 1–3). The mean total histological ALVAL score was 8.02 (SD 2.07, range 3–10). Additionally, 71.4% of unilateral patients had histologic evidence of corrosion products [Table 3].

Using the preoperative MRI and the previously mentioned criteria for ALVAL for the bilateral Rejuvenate patients, 2 were mild, 5 were moderate, and 3 were severe grades. 100% of the bilateral patients had a histological diagnosis of ALVAL based on the score >5. The mean synovial lining score was 2.6 (SD 0.52, range 2–3), mean inflammatory infiltrate score of 3.2 (SD 0.42, range 3–4), and mean tissue organization score of 2.4 (SD 0.84, range 1–3). The mean total histological ALVAL score was 8.2 (SD 1.3, range 6–10). Additionally, 70% of the bilateral patients had histological evidence of corrosion products [Table 3].

Nine patients (18.36%) of our unilateral patient cohort had other metallic orthopedic implants within their bodies [Table 1]. Obviously, 100% of our bilateral patients had multiple orthopedic implants.

Blood collection was performed by trained phlebotomists in our clinic. All samples were sent to one of two laboratories (Quest Laboratories, Chantilly, VA or ARUP Laboratories, Salt Lake, UT) depending on each patient's insurance providers. Patients were encouraged to avoid diet and nutritional supplementation prior to blood draws. Whole

Table 2
Pre-Operative MRI ALTR Grades.

MRI Grade	Cohort 1	Cohort 2
Mild	12 (24.5%)	2
Moderate	18 (36.7%)	5
Severe	14 (28.6%)	3
MRI score not available	5 (10.2%)	0
Total	49	10

Table 3
Histologic Grades of Intraoperative ALTR Tissue Samples According to the ALVAL (Aseptic Lymphocytic Vasculitis-Associated Lesion) Scoring Criteria.[a]

	Cohort 1 (Unilateral)		Cohort 2 (Bilateral)	
ALVAL Grading Category	Average and SD	Range	Average and SD	Range
Synovial lining	2.54 ± 0.65	1–3	2.6 ± 0.52	2–3
Inflammatory infiltrate	3.18 ± 0.89	0–4	3.2 ± 0.42	3–4
Tissue organization	2.25 ± 0.86	1–3	2.4 ± 0.84	1–3
Total	8.02 ± 2.07	3–10	8.2 ± 1.3	6–10
Percentage of samples with ALVAL score ≥5	87.75% (43/49)		100% (10/10)	
Percentage of samples with evidence of corrosion products	71.43% (35/49)		70% (7/10)	

[a] Campbell P, Ebramzadeh E, Nelson S, Takamura K, De Smet K, Amstutz HC. Histological features of pseudotumor-like tissues from metal-on-metal hips. Clinical Orthopaedics and Related Research® 2010;468:2321-7.

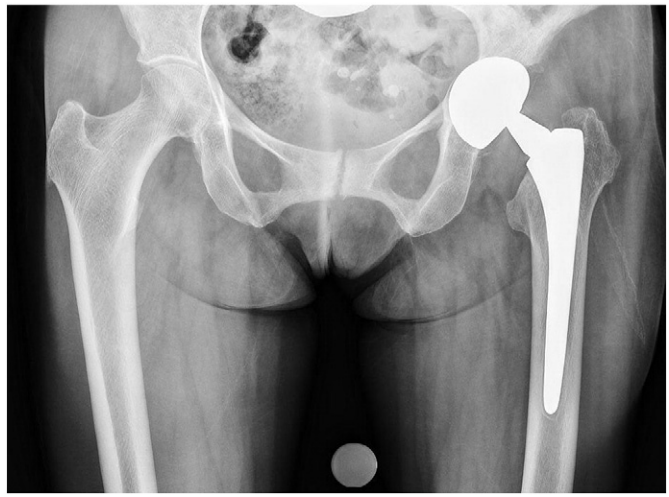

Fig. 1. Left primary THA using the Rejuvenate modular neck femoral stem (Stryker, Mahwah NJ).

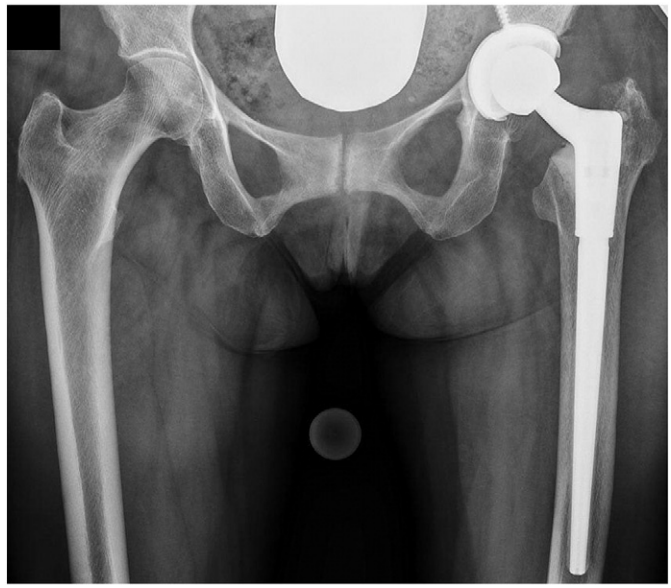

Fig. 2. Left revision THA using the Restoration Modular Stem (Stryker Orthopedics, Mahwah, NJ).