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Early Corrosion-Related Failure of the Rejuvenate Modular Total Hip Replacement

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Abstract

Background:
The Rejuvenate modular-neck stem implant (Stryker Orthopaedics, Mahwah, New Jersey) was recently recalled due to corrosion at the femoral neck-stem junction. The purpose of this study was to investigate the rate of corrosion-related failure and survivorship of this implant and analyze the correlation of implant and patient factors with serum metal ion levels and revisions.

Methods:
From June 2009 to July 2012, 123 Rejuvenate total hip arthroplasty stems (ninety-seven modular and twenty-six non-modular) were implanted in 104 patients by a single surgeon. Serum cobalt (Co) and chromium (Cr) levels (micrograms per liter [μg/L]) were measured postoperatively for all patients. Patients with persistent hip pain or elevated metal ion levels underwent magnetic resonance imaging for assessment of osteolysis or adverse local tissue reactions. Correlation of implant factors (stem size, head size, head length, and femoral head-neck offset) and patient factors (age, sex, and body mass index) with serum metal ion levels and revisions were analyzed with use of logistic regression models.

Results:
The mean duration of follow-up (and standard deviation) was 2.7 ± 0.6 years. The mean Co and Cr levels were 5.4 ± 5.7 μg/L (range, 0.2 to 31 μg/L) and 2.1 ± 1.5 μg/L (range, 0.1 to 4.3 μg/L), respectively. The differences in Co and Cr levels between the two groups (modular and non-modular) were significant: 48% of the total hip arthroplasties in the modular group resulted in elevated metal ion levels (Co >4.0 μg/L and Cr >2.0 μg/L; $p < 0.05$). The metal ion levels in the non-modular group were normal. In the modular group, higher metal ion levels were significantly correlated with younger age and a higher femoral

head-neck offset (p = 0.04). Pain and high Co serum levels were significant predictors of revision surgery (p = 0.006). The rate of revision at the time of this study was 28% in the modular group, with the majority of the revisions performed in the second year after surgery; the Kaplan-Meier survivorship was 40% at four years.

Conclusions:
The short-term high rate of corrosion-related revision with Rejuvenate modular-neck stems is striking.

Level of Evidence:
Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

Introduction

The interchangeable modular femoral neck was designed to provide increased intraoperative flexibility for adjusting femoral anteversion and neck length and femoral head-neck offset in total hip arthroplasty[1]. While the modular-neck design has gained popularity, authors of recent studies have expressed concerns regarding corrosion at the interface between the neck and stem[2,3]. As is the case with all modular junctions, eccentric loading, fretting, corrosion, excessive metallic debris[1,4-6], fracture[7,8], and dissociation[9] are potential complications. If the damaged metal layer is exposed and penetrated by body fluids, excessive oxidation and corrosion can occur[10].

The Rejuvenate hip stem (Stryker Orthopaedics, Mahwah, New Jersey) includes a modular-neck femoral component that has been recently recalled because of early failures[2]. Although there are no official reasons from Stryker (or on their web site) on this matter, the presence of metal corrosion may initiate a lymphocyte response and subsequent adverse local tissue reaction, leading to pain and failure of this stem as early as six months after implantation[2]. Adverse local tissue reactions can occur at metal-on-metal total hip arthroplasty articulations and can lead to severe soft-tissue destruction, pain, and implant failure[11-13]. There is only a limited number of clinical studies and case reports on the results of modern modular-neck stems[2,3,5,6]. The rate and modes of failure, and the implications of increased serum metal ion levels, have not yet been established.

The present study was performed to determine (1) the rate of corrosion-related failures and survivorship of this implant in our patients, and (2) whether any implant or patient factors correlated with serum metal ion levels, magnetic resonance imaging (MRI) findings, or failure rate.

Material and Methods

From June 2009 to July 2012, 123 total hip arthroplasties with the Rejuvenate stem were performed in 104 patients. Ninety-seven modular-neck implants (eighty-one patients) and twenty-six non-modular implants (twenty-three patients) were used. The body of the Rejuvenate stem is made of titanium (Ti) alloy and the modular neck is cobalt-chromium (Co-Cr). All arthroplasties were performed by the senior surgeon (S.J.I.) via a modified anterolateral approach. The mean age (and standard deviation) of the patients was 64 ± 12 years (range, twenty-eight to eighty-nine years). The majority of the patients had osteoarthritis.

After the recall of the Rejuvenate modular-neck implant by Stryker Orthopaedics in July 2012, notification letters were sent to all of the patients by the surgeon, encouraging them to return for follow-up. Nine patients (eleven total hip arthroplasties) had died and thirteen patients (eighteen total hip arthroplasties) were lost to follow-up despite multiple contact attempts, leaving eighty-one modular total hip arthroplasties (seventy patients) and thirteen non-modular total hip arthroplasties (twelve patients) for final analysis after institutional review board approval was obtained. A 28-mm femoral head with a mobile

bearing polyethylene liner (Anatomic Dual Mobility; Stryker) was utilized in approximately 30% of the cases, whereas head sizes of 32 to 44 mm were used in the remaining cases (Table I). The mean age of the final cohort with a modular implant was 63.7 ± 13 years (range, twenty-eight to eighty-nine years) and included thirty-eight women and thirty-two men. The mean body mass index (BMI) was 29 ± 5.5 kg/m^2.

TABLE I Implant Details of the Final Cohort

	Modular Total Hip Arthroplasties	Non-Modular Total Hip Arthroplasties
Head length		
+4	20	0
0	30	9
−2.5	8	1
−4	23	3
Stem size		
10	3	0
9	17	0
8	21	2
7	40	10
6	0	1
Head size		
44 mm	13	0
40 mm	10	1
36 mm	22	5
32 mm	11	3
28 mm (Anatomic Dual Mobility)	25	4

Our initial evaluation protocol included a laboratory work-up for serum Cr and Co levels (micrograms per liter [μg/L]) for all patients. Blood samples were obtained with use of the anti-contamination protocols previously described for serum metal ion measurements[14,15], with the first 5 mL discarded to avoid any metal contamination. The upper limit of normal values based on the laboratory report was 4 μg/L for Co and 5 μg/L for Cr. Patients who had elevated serum metal ion levels or symptoms related to the hip underwent MRI with use of a standard hip protocol designed to reduce metal susceptibility artifact[16]. MRIs were assessed for the presence of osteolysis and adverse local tissue reactions[17]. Our indication for revision initially consisted of symptoms related to the hip with either an abnormal MRI finding or elevated serum metal ion levels. If the MRI showed no evidence of adverse local tissue reaction or the ion levels were marginally elevated, the patients were followed with repeat measurements of metal ion levels every three months. Patients without elevated metal ion levels were encouraged to have a repeat laboratory work-up every six months for one year and annually thereafter.

Anteroposterior pelvic and lateral hip radiographs were evaluated for any change in the component position, radiolucency, malalignment, loosening, wear, and osteolysis by the senior surgeon (S.J.I.) and an arthroplasty fellow (M.M.). When patients had been lost to follow-up or did not return to the clinic, their last radiographs were analyzed. Subsidence of the femoral component was evaluated by measuring the distance between the most proximal-medial part of the femoral stem and the upper border of the lesser trochanter. Loosening of the femoral stem was defined as progressive radiolucency of >2 mm or

evidence of subsidence or any change in the component position.

Correlation of implant factors (stem size, head size, head length, and femoral head-neck offset) and patient factors (age, sex, and BMI) with serum metal ion levels and revisions were analyzed with use of logistic regression models. The patients with a non-modular Rejuvenate stem were considered a control group. All descriptive statistics (mean, standard deviation, 95% confidence interval [CI], and Pearson correlation coefficient [r]) were calculated and Kaplan-Meier survival analyses were performed with SPSS version-21.0 software (IBM, Armonk, New York). Cox proportional hazard regression analysis was used to determine the hazard ratio (HR). Two-tailed p values of <0.05 were considered significant.

Source of Funding

Results

The mean duration of follow-up (and standard deviation) was 2.7 ± 0.6 years (range, twelve to forty months). The mean Co and Cr levels in the modular group were 5.4 ± 5.7 µg/L (range, 0.2 to 31 µg/L; normal, 0 to 4 µg/L) and 2.1 ± 1.5 µg/L (range, 0.1 to 4.3 µg/L; normal, 0 to 5 µg/L), respectively. The mean Co and Cr levels in the non-modular group were 1.6 ± 1.5 µg/L (range, 0 to 4 µg/L) and 0.9 ± 0.5 µg/L (range, 0 to 2 µg/L). The differences in the Co and Cr levels between the two groups were significant (p = 0.04 and p = 0.01, respectively). One asymptomatic patient in the non-modular group with bilateral total hip arthroplasty had a Co level of 4 µg/L, the upper limit of normal values.

There was a correlation between metal ion levels and pain (r = 0.6), especially when the upper limits of the levels in the non-modular group were considered as the cutoff points. Therefore, we lowered the threshold for normal metal ion levels to ≤4 µg/L of Co and ≤2 µg/L of Cr. On the basis these thresholds, thirty-four of seventy patients (thirty-nine [48%] of eighty-one hips) in the modular group had elevated Co levels and fifteen patients (eighteen hips; 22%) had elevated Cr levels. Twenty-six percent of the patients with high metal ion levels had had bilateral total hip arthroplasty. There were twenty-four painful hips (30%) in twenty-one patients, and elevated serum metal ion levels were found in 62% of these cases. The mean Co and Cr levels in symptomatic patients were 8.1 ± 7.4 µg/L (range, 0.4 to 31 µg/L) and 2.5 ± 1.1 µg/L (range, 0.2 to 4.3 µg/L), respectively.

There was a significant correlation between elevated metal ion levels and younger age (p = 0.04, odds ratio [OR]: 0.9, 95% CI: 0.90 to 0.99). There was a 5% increase in the odds of a high Co level per each one-year decrease in age. There was a significant correlation between increase in femoral head-neck offset and high Co levels (p = 0.04, OR: 1.2, 95% CI: 1 to 1.6). Thirty-eight percent of the total hip prostheses associated with high metal ion levels also had high offset. There was a 30% increase in the odds of a high Co level per each 1-mm increase in offset. There was no correlation between higher metal ion levels and BMI, head length, head size, or stem size.

In a stepwise regression analysis, Co concentration was a significant predictor of pain (p = 0.03, 95% CI: 0.008 to 0.19). Also, pain and high Co levels were significant predictors of revision surgery (p = 0.006, OR: 8.5, 95% CI: 1.8 to 40), but high Cr serum levels were not (p = 0.14). In a Cox proportional hazard regression analysis, the rate of revision was 10.3-fold greater among symptomatic patients (p = 0.01, HR: 10, 95% CI: 1.6 to 63) and 9.9-fold greater in patients with high metal ion levels (p = 0.05, HR: 9.8, 95% CI: 0.9 to 98).

Twenty-three (28%) of the modular total hip arthroplasties (in nineteen patients) were revised because of pain thought to be referable to the prosthesis, and twenty-one of these cases had elevated metal ion levels. The revision rate was significantly greater (p = 0.0001) among patients with higher Co levels, with less time from the index total hip arthroplasty to the revision surgery as compared with patients with lower Co levels. Black corrosion was visible at the neck-stem junction intraoperatively

in all revision cases (Fig. 1). We did not find any major corrosion at the head-taper junction. Two revision cases (9%) were seen to have a pseudotumor on MRIs, and eight revision cases (35%) had some adverse local tissue reaction such as fluid collection, capsular thickening, osteolysis, or synovitis. Ten hips (43%) were revised because of pain, elevated metal ion levels, and MRI findings; eleven hips (48%), because of pain and elevated metal ion levels; and two (9%), because of persistent pain only. All revisions involved removal of the entire stem and implantation of a new, monolithic long, non-cemented Ti stem. There was no isolated modular-neck exchange. The median time to revision was twenty-seven months. Two revisions (9%) were performed within the first year after surgery; seventeen (74%), within the second year; and four (17%), within the third year.
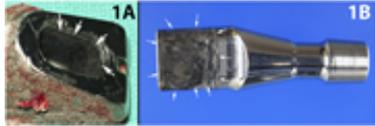

Photograph of a revised Rejuvenate stem, showing the modular neck (**Fig. 1-A**) and stem (**Fig. 1-B**) junction with visible corrosion (arrows).

In the modular group, the serum Co levels in the patients who did not have a revision showed a steady increase over time (Fig. 2); however, the Cr levels stayed mainly below the threshold. In revision cases, the Co levels sharply decreased as early as two months post-revision (Fig. 3). This decrease was not as dramatic for the Cr levels, which needed five months to demonstrate a slow decrease. The Kaplan-Meier survivorship, with revision related to metal corrosion as the end point, was 40% (95% CI: 27% to 53%) in the modular group at four years postoperatively at the time of this study (Fig. 4). The revision-free probability (Fig. 5) was much higher for patients with Co levels of <4.0 µg/L (93% compared with 45% for patients with Co levels of ≥4.0 µg/L, p = 0.004). There were no revisions in the non-modular group.
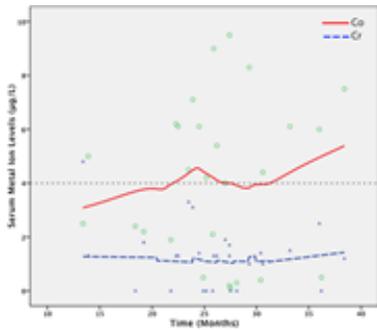
The serum metal ion levels in patients who did not undergo revision total hip arthroplasty. The mean Co levels show a steady increase (solid red line), but the mean Cr levels are below the threshold (dashed blue line).
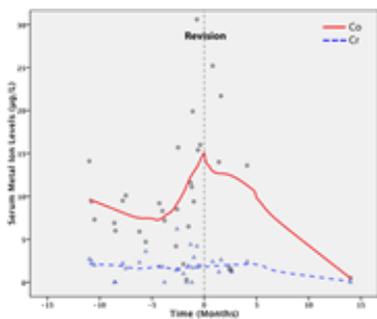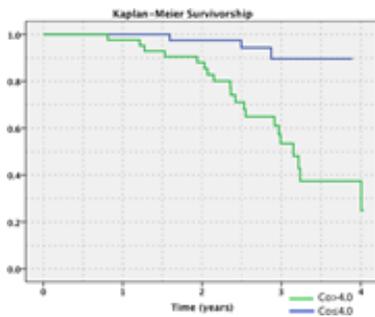

The serum metal ion levels in patients who underwent revision total hip arthroplasty. The mean Co levels (solid red line) show a sharp drop immediately after revision surgery (vertical dashed line); however, the mean Cr levels show a slow decrease (dashed blue line).
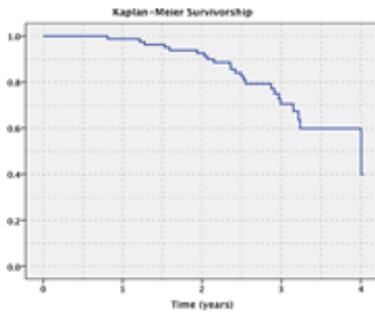
Kaplan-Meier survivorship curve with revision related to metal corrosion as the end point.

There was a significant difference in the revision-free probability for patients with Co levels of >4.0 µg/L (green line) as compared with patients with Co levels of ≤4.0 µg/L (blue line).

Discussion

To facilitate anatomic reproduction of lower-limb length and femoral head-neck offset, modular neck implants were introduced in the 1970s[16,18]. However, the more recent addition of modular necks introduces a new junction for fretting and corrosion[1-6,8,19]. This crevice corrosion at the neck-stem junction causes release of metal ions, adverse local tissue reactions, and elevated serum metal ion levels, leading to failure of the implant and systemic toxicity, similar to those associated with other modular junctions such as metal-on-metal bearing surfaces[11-13], resurfacing[20,21], and the head-neck junction with metal-on-polyethylene bearings[12,22,23]. The survivorship, with corrosion-related failure of the modular neck as the end point, was 40% at four years in our study of Rejuvenate implants. This high failure rate had a significant correlation with elevated serum Co levels (especially with an increasing trend) and pain. High serum Co levels were strongly correlated with younger age and increased femoral head-neck offset.

The etiology of corrosion and metal ion release remains unclear. The causes can be categorized as patient-related factors (body weight, activity level, and metal sensitivity) or implant-related factors (incomplete junction fitting, higher offset, or metallurgy mismatch). One important etiology for the increase in Co and Cr levels in patients with a Rejuvenate stem could be the metallurgy mismatch between the modular neck and stem. The Ti alloy used to make this stem, titanium-molybdenum-zirconium-iron (TMZF; Stryker), is marketed as a low-modulus Ti alloy, which in conjunction with a Co-Cr modular neck can be a factor contributing to corrosion[5,24,25]. This coupling in combination with an inadequate taper fit may lead to metallosis[26,27], corrosion and fretting at the interface[5,6,8], and a subsequent increase in serum metal ion levels[25]. In a retrieval study of modular-neck stems, Kop and Swarts[4] found that Co-Cr components had more fretting and crevice corrosion than Ti components. Similarly, several case reports have demonstrated good clinical results with surgical exchange of a Co-Cr to a Ti-based neck implant[28,29]. This phenomenon has also been reported for modular heads with head-neck corrosion[12,30,31]. The Ti alloy, unlike the Co-Cr alloy, is not susceptible to fretting damage[32,33].

The correlation of stem size and patient activity with metal ion levels and adverse tissue reactions in patients with a modular-neck implant has not been fully established. Several mechanical factors affect the extent of fretting damage, such as contact pressure and frequency of micromotion[33,34]. This micromotion at the stem-neck interface is influenced by material coupling, assembly, and load conditions[35,36]. We found increased metal ion levels to have a significant correlation with longer neck length (offset) and younger patient age. We attribute this finding to an increase in patient activity and in lever arm forces on the neck-stem taper junction.

The adverse local tissue reaction and lymphocyte response to metals debris can develop prior to clinical symptoms[37]. Therefore, metal ion levels have been used as a surrogate marker of corrosion wear at the articulating surface or modular junction[38], which may continue to increase for years after surgery[39]. However, interpretation of serum metal ion levels is controversial, and a universal safe zone has not been established. Van Der Straeten et al.[40] compared metal ion levels between patients with symptomatic and those with asymptomatic metal-on-metal total hip prostheses and proposed a Co level of 4 µg/L as the threshold. Similarly, we found that the rates of pain and subsequent revision surgery were significantly higher with Co levels of ≥4 µg/L. The upper limit of Co level in our asymptomatic control group was 4 µg/L as well. We found that 48% of the patients had elevated metal ion levels, 47% were symptomatic, and 47% had MRI findings of adverse local tissue reaction. However, not all patients with elevated Co-Cr levels were symptomatic or had evidence of adverse local tissue reaction, nor did all symptomatic patients have elevated metal ion levels. In thirteen (57%) of twenty-three revision cases, there were no detectable MRI findings; however, revision arthroplasty was performed because of increasing severity of hip symptoms and abnormal metal ion levels (with an increasing trend). Intraoperatively, all twenty-three revision cases had substantial corrosion at the modular neck-stem junction.

At present, after excluding infection and other causes of pain, we now make a diagnosis of corrosion-related failure of a modular Rejuvenate total hip arthroplasty when a patient has (1) persistent hip symptoms related to the total hip arthroplasty, (2) elevated Co-Cr levels (Co >4.0 µg/L and Cr >2 µg/L) with an increase in trend, and (3) abnormal MRI findings. When all of those criteria coexist, revision total hip arthroplasty must be seriously considered. We also recommend revision surgery for patients with persistent hip pain and increasing abnormal metal ion levels even if there is a lack of MRI findings. We highly recommend close monitoring of all patients with persistent hip symptoms, even if they have normal metal ion levels or a lack of MRI findings.

We propose that all patients with the modular Rejuvenate stem have baseline measurement of serum metal ion levels as well as a baseline MRI with metal suppression at the initial evaluation. All asymptomatic patients who have undergone total hip arthroplasty with a modular Rejuvenate stem require close follow-up. On the basis of our experience, asymptomatic patients with normal metal ion levels can be followed annually with repeat measurements of metal ion levels. Revision surgery for these patients is challenging. The stems in our patients were well osteointegrated and the metaphyseal filling design of this stem made the use of flexible osteotomes difficult. In one case a proximal femoral osteotomy was performed for removal of the implant.

There are several limitations to this study. First, it is retrospective; however, all of the clinical and radiographic outcomes were collected prospectively from a consecutive cohort. Second, although we had a comparison group of patients treated with a non-modular Rejuvenate stem, this group was small in number and the treatment was not randomized. Third, not all of the patients returned for follow-up at the time of this study (thirteen of 104 patients were lost to follow-up). Fourth, we did not obtain an MRI for every patient.

In conclusion, we found an alarmingly high rate of corrosion-related revisions of the Rejuvenate modular-neck design. Higher Co-Cr levels were seen in association with bilateral total hip arthroplasty, higher offset, and younger patient age. We believe that there will be future failures of the modular stems that had not yet been revised at the time of this study and that more

patients will become symptomatic. We believe that not only patients with pain and an increasing trend of elevated Co-Cr levels but also any symptomatic patient with a Rejuvenate modular-neck stem should be thoroughly evaluated as a potential candidate for revision surgery. Longer follow-up is required to ascertain the true rate of failures and systemic and local side effects of abnormal serum metal ion levels in patients with this hip prosthesis.

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