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Corrosion and Fretting of a Modular Hip System: A Retrieval Analysis of 60 Rejuvenate Stems

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A R T I C L E I N F O

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A B S T R A C T

Femoral stems with dual-taper modularity were introduced to allow independent control of length, offset, and version. Corrosion and fretting related to micromotion at the neck-stem junction are thought to stimulate an adverse local tissue reaction (ALTR). Analysis of 60 consecutively retrieved modular-neck stem implants (Rejuvenate, Stryker) revised primarily for ALTR was done to determine the variables influencing corrosion and fretting patterns at the neck-stem interface. Taper damage evaluation was performed with stereomicrocopic analysis with two observers. Evidence of fretting and corrosion was seen at the neck-stem taper in all implants, including three implants revised for periprosthetic fractures within four weeks of the index surgery indicating that this process starts early. Femoral stems paired with the long overall neck lengths had significantly higher corrosion scores. Correlation of the corrosion severity at particular locations with the length of implantation suggests that the neck-stem junction experiences cyclic cantilever bending in vivo. The positive correlation between the length of implantation and fretting/corrosion scores bodes poorly for patients who still have this implant. Scanning electron microscopy on a subset of specimens was also performed to evaluate the black corrosion material. We strongly urge frequent follow-up exams for every patient with this particular modular hip stem.

With the introduction of modular head/neck junctions into total hip arthroplasty in the 1980's, modularity has allowed surgeons a multitude of combinations intraoperatively to restore hip biomechanics and stability [1]. Additional modularity at the stem/neck junction was introduced to allow independent control of not only length and offset, but also version. Initial designs were constructed of titanium alloy necks with a taper connection that mated to a titanium alloy stem. Unfortunately, these designs provided insufficient fatigue strength, and clinical failures caused by implant fracture were reported [1,2]. To increase implant stiffness and prevent fractures, necks were manufactured from cobalt chromium alloy. While this change resulted in a decrease in fractures of dual-taper modular components, retrieval analyses demonstrated corrosion and fretting related to micromotion at the mixed-alloy neck/stem junction [3–5].

The resulting corrosion debris generated from the neck-stem junction appears responsible for adverse local tissue reactions (ALTR) in many patients who received dual-taper femoral components [6–9]. This process is different from wear or corrosion debris generated from the bearing surfaces. Reports of ALTR in metal on metal (MoM) hip prostheses as manifested by severe tissue destruction, hip instability, and pain are well described [10–14]. Corrosion and fretting at modular junctions are thought to be an impetus for ALTR, but presently no method exists to evaluate or quantify corrosion and fretting in vivo. Micromotion promotes corrosion and fretting [1,2], and micromotion between dissimilar metals may increase the rate of clinical failure [1].

The Rejuvenate modular-neck femoral stem (Stryker Orthopaedics, Mahwah, New Jersey) has been recently recalled because of early failures as a result of ALTR due to corrosion of the modular neck-stem taper junction [15].

The senior author implanted 199 Rejuvenate modular stems between April 2010 and March 2012, which were revised at a rate of 30%, similar to that reported by Meftah et al [16] in their clinical series with the Rejuvenate stem. We examined a large cohort of patients who had received the recalled Rejuvenate modular stem at our institution. In the current study, we identified the 60 implants that were revised from this clinical cohort. Retrieved components were examined with the goal of evaluating the damage patterns at the neck/stem junction so as to answer three research questions: (1) Does a specific pattern of corrosion and fretting exist at the junction? (2) Does a correlation

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Table 1
Patient Demographics Collected From Medical Records for the 60 Retrieved Components.

Variable	Number
Female	39
Right	36
Age at revision (years)	64.6 ± 8.4
LOI (months)	21.4 ± 8.2
Reason for revision	
ALTR detected with MRI	53
ALTR detected with US biopsy	3
ALTR detected with US biopsy (MRI negative)	1
Periprosthetic fracture	3
Clinical presentation	
Patients asymptomatic	12
Patients symptomatic (pain)	45
Patients symptomatic (fracture)	3

exist between the severity of corrosion and fretting and construct variables such as neck shaft angle, stem size and overall neck length? (3) Does a correlation exist between the severity of corrosion and fretting and the length time that the devices had been implanted?

Materials and Methods

Study Design, Cohort Selection, and Clinical Information

This is a retrospective case series of 60 consecutively retrieved implants from 55 patients who had received a Rejuvenate modular hip stem as part of primary total hip arthroplasty and who also underwent revision at our institution. All procedures were performed by the senior author using a posterolateral approach. The patient cohort included 35 women and 20 men with an average age of 64.6 years (range: 45–79 years) at the index procedure. All implants were collected as part of our institutional review board-approved implant retrieval system. The Rejuvenate stem is made of a titanium-alloy (Ti-12Mo-6Zr-2Fe or TMZF), and the modular neck is made of cobalt-chromium alloy (Co-Cr-Mo). The bearing surfaces consisted of Co-Cr-Mo (V40 LFIT CoCr, Stryker) and ceramic (V40 BIOLOX delta, Stryker) femoral heads articulating against a highly cross-linked polyethylene acetabular liner (X3, Stryker).

Patient demographic data were collected from medical records (Table 1) including age, BMI, length of implantation (LOI), and reason for revision. The series had a mean LOI of 21 ± 8 months. The average patient age at revision was 65 (±8) years. Indications for revision included ALTR (n = 57) and periprosthetic femur fracture (n = 3). The diagnosis of ALTR based on clinical features and cross-sectional imaging (MRI and ultrasound) was histologically confirmed in all cases. The three patients who sustained periprosthetic fractures all required open reduction with internal fixation and revision of the femoral stem within four weeks of the index surgery.

We examined three implant characteristics that were thought to have the greatest potential to affect fretting and corrosion: the neck shaft angle, stem size, and overall neck length (the sum of the neck and head lengths). The neck angle was 127° in 42 hips and 132° in 18 hips (Table 2). The neck length included 30 mm (23 hips), 34 mm (30 hips), and 38 mm (7 hips). Component version and femoral head material and size were not addressed. In our cohort, only 4 of the 60 modular necks had been placed anteverted or retroverted. Femoral heads were CoCr (58 hips) and ceramic (2 hips). Femoral head sizes were 28 mm (59 hips) and 36 mm (1 hip). The femoral stems ranged from size 7 to size 11, with a majority being size 7 or size 8 (Table 2). For our analysis, we grouped the larger stems (sizes 8–11; n = 35) to compare to the smallest stem (size 7; n = 25).

Table 2
Implant Characteristics of the Retrieved Rejuvenate Cohort.

Variable					
Stem size	Size 7	Size 8	Size 9	Size 10	Size 11
	25	20	11	2	2
Neck angle	127°	132°			
	42	18			
Neck length	30 mm	34 mm	38 mm		
	23	30	7		

Taper Damage Evaluation

Retrieved implants were disinfected in a 10% bleach solution for 20 minutes, and subsequently washed with a mild detergent and tap water. This was followed by rinsing in methanol after which the implants were left to air dry.

Implants were examined visually by two independent orthopedic surgeons experienced with wear analysis (IDM and JA) under a stereomicroscope (magnification 6× to 10×, Wild Type 376788 Microscope, Heerbruug, Switzerland) to assess the presence and severity of fretting and corrosion. An inter-rater reliability analysis using the Cohen's weighted Kappa statistic (κ) was performed to determine consistency among raters.

Each modular neck and stem was assessed by zones and graded for fretting and corrosion according to Goldberg's criteria [17] on a scale from 1 to 4 (1 = none, 4 = severe). Each face of the neck taper (anterior, posterior, medial, and lateral) was divided into proximal and distal zones. Thus, a total of eight zones were examined and scored independently (Fig. 1). The taper interface of the femoral stem was assessed within four zones (anterior, posterior, medial, and lateral). Each zone of the stem was scored independently.

Scanning Electron Microscopy

Five necks were examined using scanning electron microscopy (Supra™ 55VP, Carl Zeiss SMT, Inc., Thornwood, NY), and energy dispersive analysis of x-rays (EDAX) was employed to identify the elements present in the corrosion debris. We selected the least severely effected modular neck to serve as a 'control' surface. The remaining four were the most severe modular necks on the basis of fretting and corrosion scores and were examined in the regions of the most severe damage.

Statistical Analyses

Fretting and corrosion scores of the modular neck and femoral stem were described using mean (± standard deviation). Multiple linear regression with the use of a generalized estimating equation (GEE) was performed to determine differences in fretting and corrosion scores between two regions (proximal and distal) and among the four zones (anterior, posterior, medial and lateral). The GEE method does not require a

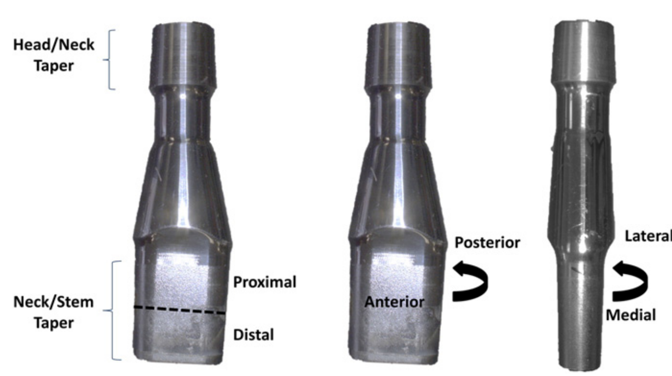

Fig. 1. Regions of interest on the modular neck used to evaluate the severity of fretting and corrosion using the Goldberg scoring. A total of eight regions on the modular neck were assessed. The proximal taper (at the head/neck junction) was not assessed in this series. All results presented are related to the neck/stem taper.