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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.

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 less 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

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Level of Evidence: Level III.

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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 year, 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 transported and 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 pseudotumor was defined as any mass, solid orcystic, in continuity with the hip joint. Isolated distension or thickening of a non-communicating trochanteric bursa was not included. Pseudotumor size assessment was based on the greatest dimension of the lesion in either the axial or coronal plane, measured in centimeters.

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

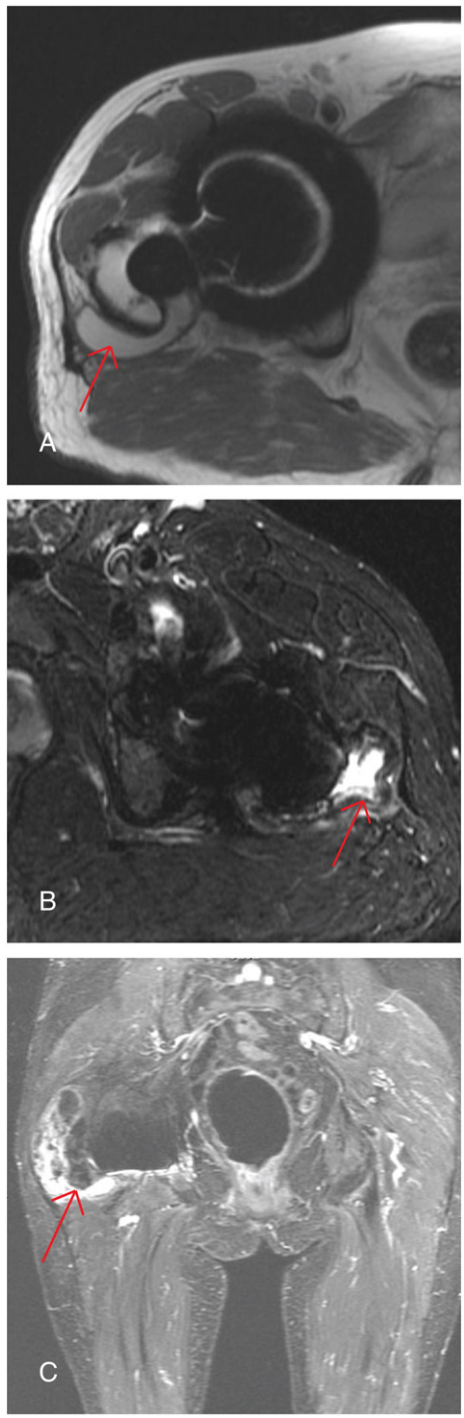

Fig. 1. (A) Axial T1-weighted spin-echo image of a Type I mass shows a thin walled cystic lesion (red arrow). (B) Axial STIR image of a Type II mass shows a thick walled cystic lesion (red arrow indicates the thickened wall). (C) Coronal STIR image of a Type III mass with a predominantly solid consistency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

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