The Journal of Arthroplasty 29 Suppl. 2 (2014) 173–178

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

Adverse Clinical Outcomes in a Primary Modular Neck/Stem System

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ARTICLE INFO

Article history:
Received 11 November 2013
Accepted 19 January 2014

Keywords:
metal corrosion
cobalt
chromium
total hip arthroplasty
complications

ABSTRACT

We report our experience with 215 recalled neck modular stems due to corrosion. Among the 195 hips with 2 years follow-up, 56% had no clinical symptoms, 26% had groin pain (typical of corrosion), and 17% had other symptoms. Cobalt levels were comparable between asymptomatic (3.4 μg/L, range 0.7–7.3 μg/L) and symptomatic patients (4.0 μg/L range 0–13.2 μg/L). Abnormal imaging findings were seen in 46% of symptomatic and 11% of asymptomatic hips ($P = 0.001$). Twenty-six hips (13%) have either undergone revision surgery or have been scheduled. Evidence of corrosion was seen at revision surgery in all patients. Despite modest elevations in serum cobalt levels, abnormal imaging studies were seen in 36%, clinical symptoms were seen in 44%, and revision for corrosion was undertaken or scheduled in 13% of the hips.

Neck modular stems have been developed for use in primary and revision total hip arthroplasty (THA). Compared to femoral stems in which the body and neck are unified, neck-modular stems contain an additional modular junction between these two segments. The additional modular junction provides the surgeon with greater flexibility in implant position and ability to match the patient's native femoral offset, length, and version. However the addition of a modular junction creates a potential source of implant failure.

We report our minimum two-year results using a neck modular stem that has recently been recalled by the manufacturer due to elevated rates of early failure in post-market analysis. Our analysis includes clinical, radiological, and laboratory evaluation, implant survivorship, intra-operative findings at revision surgery, and clinical results of patients that have been revised. We propose an algorithm for managing both asymptomatic and symptomatic patients, including our indications for offering patients revision surgery.

Materials and Methods

Institutional review board approval for the study was granted. We identified 202 consecutive patients who underwent 215 primary THAs (13 bilateral) using a proximally coated, uncemented, neck-modular femoral component [Anatomic Benoist Girard (ABG II)-Modular, Stryker Orthopaedics, Mahwah, NJ] between January 1, 2010 and December 31, 2010. Our institutional total joint registry prospectively collects data on all patients undergoing arthroplasty. Patients were followed clinically for a minimum of two years, until failure of the arthroplasty, or until death. Efforts to complete two-year follow-up were attempted for all patients in our cohort. For patients who had not returned for clinical evaluation beyond two years, phone calls were made to conduct patient interviews.

The ABG II-Modular stem system consists of a proximally hydroxyapatite coated titanium-molybdenum-zirconia-ferrite (TMZF) alloy stem designed to obtain metaphyseal ongrowth and a cobalt–chromium (Co-Cr) modular neck segment with various options for neck length, version, and neck-shaft angle (Fig. 1). The geometry of the stem is based on the philosophy of fitting and filling the metaphyseal segment of the proximal femur in both the medial-lateral and anterior-posterior dimensions. The modular neck portion is made of Gas atomized dispersion strengthened (GADS) Vitallium, a proprietary Co-Cr alloy intended to optimize fatigue strength and corrosion resistance. Ten different necks can be mated to the stem via a Morse taper to the TMZF stem. The neck shaft angles are 125°, 130°, or 135°. Three different neck versions are available differing by 7°. A total of 18 different head positions are possible using this array of necks, with several different neck lengths being available for each head position. The necks have a V40 (Stryker Orthopaedics, Mahwah, NJ) trunion to accept heads composed of Co-Cr or delta ceramic.

The senior surgeon performed 89% of the arthroplasties through a direct anterior approach on a standard operating table, while the remaining 11% of arthroplasties were performed using a supine direct lateral approach. A Co-Cr head was used in 95% of the procedures, with a delta ceramic head being used in the remaining 5% of the procedures. The postoperative protocol for all patients was the same regardless of approach: early mobilization on the day of surgery, walking assistance with a walker for one week, then assistance with a cane for three more weeks.

The Conflict of Interest statement associated with this article can be found at http://dx.doi.org/10.1016/j.arth.2014.01.040.

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http://dx.doi.org/10.1016/j.arth.2014.01.040
0883-5403/

Fig. 1. The ABG II Modular stem system consists of a proximally hydroxyapatite (HA) coated titanium-molybdenum-zirconia-ferrite (TMZF) alloy stem with a cobalt–chromium (Co-Cr) modular neck segment with various options for neck length, version, and neck-shaft angle.

Upon announcement of the voluntary recall of the ABG II-Modular prosthesis, patients were sent a letter notifying them that the stem had been recalled and they were invited to return for evaluation at no cost. Patients returned for evaluation as indicated for evaluation of symptoms, or in response to the written invitation to be evaluated and educated about the significance of the prosthesis recall. Serum cobalt (Co), chromium (Cr), erythrocyte sedimentation rate (ESR), and C-reactive protein (CRP) were measured in symptomatic as well as in some asymptomatic patients and soft tissue imagining was performed with either metallic artifact reduction sequence magnetic resonance imaging (MARS MRI) or ultrasound. From the follow-up visits, clinic notes, registry data, and patient phone calls we recorded the rate of clinical symptoms. We also determined the number of patients who had undergone revision surgery or who were scheduled to undergo revision. In the course of collecting and analyzing patient data we found that patients generally fell into 3 groups: those who were asymptomatic, those who experienced typical corrosion related pain (insidious onset of progressive groin pain) [1], and those who experienced pain considered to be atypical of corrosion (buttock, lateral, or thigh pain). We compared the serum Co and Cr levels, ESR, and CRP between these patient symptom groups. Ion levels in patients with bilateral THA were analyzed separately. Soft tissue imaging results were characterized as normal, or as abnormal if any of the following were identified: fluid collections, soft tissue masses, or muscle damage. For patients undergoing revision surgery the operative reports were reviewed for the presence of visible taper corrosion (black staining of the neck stem taper) fluid collections, soft tissue masses, and muscle damage.

Descriptive statistics were utilized to report the cohort demographics and incidence of symptoms. Bivariate analysis was utilized to describe the relationship between the possible predictive variables and corrosion related symptoms. To determine the independent predictors of corrosion related symptoms, outcomes were modeled using logistic regression. A full model was created using all possible independent variables and then backwards stepwise regression to systematically prune the model, including imputation for missing values. All analyses were done using R software (version 3.0.1, May 16, 2013, Lucent Technologies, Murray Hill, NJ.).

Results

A total of 215 ABG II-Modular stems were implanted in 202 patients. The underlying diagnosis was osteoarthritis in 196 patients (97%). There were 83 females (86 hips) and 119 males (129 hips) with an average age of 61 years (range, 31–95 years), an average height of 172.6 cm (range, 147–198.1 cm), and an average weight of 83.8 kg (range, 47.6–126.1 kg), resulting in an average BMI of 28 kg/m^2 (range, 18.5–41.6 kg/m^2) (Table 1). Five hips (2.6%) underwent revision surgery for causes other than a corrosion reaction – two for early periprosthetic fracture, one for early aseptic femoral loosening, one for cup loosening and one for late periprosthetic joint infection. One asymptomatic patient died prior to completing two-year follow-up. Thirteen patients (fourteen hips) are currently lost to follow up. A minimum clinical follow-up of two years was obtained in the remaining 195 hips in 183 patients (91%), with a mean duration of follow-up of 30.6 months (range, 24–41 months).

For patients with at least 2-year follow-up, 110 hips (56.4%) were asymptomatic and 85 hips (43.6%) had symptoms of some type; 51 hips (26.2%) had symptoms of groin pain attributed to a corrosion reaction and 34 hips (17.4%) had isolated trochanteric, thigh or buttock pain atypical of corrosion (Table 1). The average time from surgery until the onset of corrosion-related groin pain was 16.6 months (range 0–31 months). In those hips in which groin pain attributed to corrosion was present, 10 hips (19.6%) also experienced lateral pain, 3 hips (5.9%) also experienced posterior or buttock pain, and 25 hips (49.0%) also experienced thigh pain. Groin pain resolved spontaneously in 1 patient after hip aspiration. This patient had been scheduled to undergo revision surgery that was subsequently cancelled. The groin pain was severe enough in 26 hips (13.3%) that they had either undergone femoral revision surgery ($n = 21$) or were scheduled to undergo a revision ($n = 5$) at the time this manuscript was written. No patient with atypical pain had sufficient symptoms to undergo revision surgery.

None of the clinical, demographic and surgical variables analyzed on the regression model, was found to be associated with the presence of any type of symptoms. These variables include patient's age, weight and height, the neck length or offset and stem size.

At the time of writing of this text, laboratory tests (Co, Cr, ESR and CRP) were available in 115/183 patients (62.8%). They were available in 40/110 patients (36.4%) without symptoms and in 75/85 patients (88.2%) with symptoms – 49/51 (96.1%) with groin pain and 26/34 (76.5%) with atypical pain. There were no significant differences in the laboratory results between any patient groups.

The mean Co level was 3.4 μg/L [standard deviation (SD) 1.7, range 0–7.3 μg/L] in asymptomatic patients, while in patients experiencing pain symptoms of any type, the mean Co level was 4.0 μg/L (SD 3.0, range 0–13.2 μg/L). In patients experiencing groin pain considered to be typical of corrosion, the mean cobalt level was 3.8 μg/L (SD 2.5, range 0.1–10.2 μg/L) while in patients with symptoms considered atypical of corrosion, the mean Co level was 4.4 μg/L (SD 3.7, range 0–13.2 μg/L). The mean Co level among all groups combined was 3.84 μg/L (SD 2.6, range 0–13.2 μg/L). The highest Co level in any patient was 13.2 μg/L and occurred in a patient with symptoms atypical for a corrosion reaction in whom the MRI was normal. This patient had no other source for elevated metal ion levels.

The mean Cr level was 1.2 μg/L (SD 1.2, range 0–7.2 μg/L) in asymptomatic patients, while in patients experiencing pain symptoms of any type, the mean Cr level was 1.2 μg/L (SD 1.0, range 0.1–7.8 μg/L). In patients experiencing groin pain considered to be typical of corrosion, the mean Cr level was 1.2 μg/L (SD 1.2, range 0.1–7.8 μg/L) while in patients with symptoms considered atypical of corrosion, the mean Cr level was 1.2 μg/L (SD 0.6, range 0.5–2.6 μg/L). The mean Cr level among all groups combined was 1.2 μg/L (SD 1.1, range 0–7.8 μg/L) (Table 2).