Adverse Local Tissue Reaction Arising from Corrosion at the Femoral Neck-Body Junction in a Dual-Taper Stem with a Cobalt-Chromium Modular Neck

H. John Cooper, MD, Robert M. Urban, PhD, Richard L. Wixson, MD, R. Michael Meneghini, MD, and Joshua J. Jacobs, MD

Investigation performed at Rush University Medical Center and Northwestern University Feinberg School of Medicine, Chicago, Illinois, and Indiana University School of Medicine, Indianapolis, Indiana

Background: Femoral stems with dual-taper modularity were introduced to allow additional options for hip-center restoration independent of femoral fixation in total hip arthroplasty. Despite the increasing availability and use of these femoral stems, concerns exist about potential complications arising from the modular neck-body junction.

Methods: This was a multicenter retrospective case series of twelve hips (eleven patients) with adverse local tissue reactions secondary to corrosion at the modular neck-body junction. The cohort included eight women and three men who together had an average age of 60.1 years (range, forty-three to seventy-seven years); all hips were implanted with a titanium-alloy stem and cobalt-chromium-alloy neck. Patients presented with new-onset and increasing pain at a mean of 7.9 months (range, five to thirteen months) following total hip arthroplasty. After serum metal-ion studies and metal artifact reduction sequence (MARS) magnetic resonance imaging (MRI) revealed abnormal results, the patients underwent hip revision at a mean of 15.2 months (range, ten to twenty-three months). Tissue specimens were examined by a single histopathologist, and the retrieved implants were studied with use of light and scanning electron microscopy.

Results: Serum metal levels demonstrated greater elevation of cobalt (mean, 6.0 ng/mL) than chromium (mean, 0.6 ng/mL) or titanium (mean, 3.4 ng/mL). MRI with use of MARS demonstrated adverse tissue reactions in eight of nine patients in which it was performed. All hips showed large soft-tissue masses and surrounding tissue damage with visible corrosion at the modular femoral neck-body junction. Available histology demonstrated large areas of tissue necrosis in seven of ten cases, while remaining viable capsular tissue showed a dense lymphocytic infiltrate. Microscopic analysis was consistent with fretting and crevice corrosion at the modular neck-body interface.

Conclusions: Corrosion at the modular neck-body junction in dual-tapered stems with a modular cobalt-chromium-alloy femoral neck can lead to release of metal ions and debris resulting in local soft-tissue destruction. Adverse local tissue reaction should be considered as a potential cause for new-onset pain in patients with these components, and early revision should be considered given the potentially destructive nature of these reactions. A workup including serologic studies (erythrocyte sedimentation rate and C-reactive protein), serum metal levels, and MARS MRI can be helpful in establishing this diagnosis.

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

A commentary by Douglas E. Padgett, MD, and Timothy M. Wright, PhD, is linked to the online version of this article at jbjs.org.

Modularity in total hip arthroplasty has become increasingly common in the last two decades. Following the successful introduction of modular heads, femoral stems with an additional modular junction between the neck and body of the stem soon became available. These so-called dual-taper stems allow for increased options for hip-center restoration by allowing for adjustments in offset, length, and version, which can be made independent of femoral stem fixation[1-3]. Most major device manufacturers offer stem designs with a modular neck option.

This additional modular junction creates new concerns, including the potential for corrosion between the neck and body of the stem. Although corrosion at this junction has been documented in retrieval analyses[4-6], in vitro studies[7,8], and case reports of modular neck fracture[9-11], the biological implications of taper corrosion at this junction are poorly understood. Recent studies have documented the potential for taper corrosion at the head-neck junction to lead to the release of metal debris and severe adverse local tissue reactions[12-16], such as that seen in patients with failed metal-on-metal bearings[17-20]. Similar reactions have been reported in a small series of patients with dual-taper stems[21], but these reactions have not yet been reported in a larger cohort of patients.

The purpose of the present study was to describe a series of patients who presented with painful adverse local tissue reactions secondary to corrosion at the modular neck-body junction and document the clinical presentation, diagnostic workup, and surgical findings.

Materials and Methods

Study Population

This study was designed as a retrospective descriptive case series of twelve hips in eleven patients who underwent revision of a total hip arthroplasty as a result of adverse local tissue reaction secondary to corrosion at the modular femoral neck-body taper junction. This was a multicenter, multisurgeon series involving six surgeons at five different institutions. Revision arthroplasties were performed over a nineteen-month period (December 2010 through June 2012). Images from one of the eleven patients have been recently published as a part of a review article[22]. The study group consisted of eight women and three men with an average age of 60.1 years (see Appendix). Approval was obtained from two institutional review boards where the authors worked; for the other three centers, specimens were sent to the "main" institution along with clinical data (prior to study initiation) to help those treating surgeons make the appropriate diagnosis. The study was initiated later, and the institutional review board at the "main institution" specified that specimens already in the implant retrieval laboratory could be used.

Patients initially presented with new-onset pain at a mean of 7.9 months (range, 5.1 to 13.3 months) after the index surgery, following an uneventful and asymptomatic initial recovery period (see Appendix). All patients presented with pain; the pain was localized to the groin in eleven of twelve hips, but commonly involved the buttock (five hips), trochanteric region (four hips), or thigh (three hips). A serious limp or weakness was evidenced in three patients (four hips), and one of these patients complained of marked leg swelling. A frequent finding on physical examination was pain localizing to the groin with straight leg-raise testing against gravity or resistance. Harris hip scores[23] averaged 43.2 points prior to revision surgery (range, 22 to 71 points) in the five patients for whom they were available.

Eleven primary procedures were performed via a posterior approach, while one was performed via an anterolateral approach; all were performed for a diagnosis of degenerative joint disease (see Appendix). The implanted acetabular components included ten Trident PSL shells (Stryker, Mahwah, New Jersey), one Tritanium shell (Stryker), and one Anatomic Dual Mobility cup (Stryker) that was used as part of a Mobile Bearing Hip System (Stryker). The bearing surface was ceramic (BIOLOX Delta; CeramTec, Plochingen, Germany) on highly crossed-linked polyethylene (X3; Stryker) in eight cases, and cobalt-chromium alloy on highly cross-linked polyethylene in the other four. All of the femoral components were a single design (Rejuvenate; Stryker) made from a titanium-molybdenum-zirconium-iron alloy (TMZF; Stryker) with a cobalt-chromium-alloy modular neck. This implant was voluntarily recalled by the manufacturer in June 2012. The implanted femoral components, femoral neck lengths, and femoral head sizes are provided in the Appendix.

Preoperative Workup

Inflammatory markers were assessed in every patient, including erythrocyte sedimentation rate and C-reactive protein. Aspiration of the hip was performed preoperatively in ten of twelve hips. Using analytical methodology previously described[24], serum metal ion levels were obtained at a specialized trace-metal-analysis laboratory for eight of the twelve hips; the metal levels for two additional hips were analyzed at a commercial laboratory. All patients underwent radiography of the hip at the time of initial symptoms. Magnetic resonance imaging (MRI) scans were performed with use of metal artifact reduction sequence (MARS) protocol in ten of the twelve hips (nine of the eleven patients) and were read by a musculoskeletal radiologist at the institution in which they were performed.

Revision Surgery

Revision surgery was performed at a mean of 15.2 months after the index procedure (range, 9.7 to 23.1 months). A posterior approach was utilized in all cases. Frozen sections and intraoperative cultures were taken upon entry into the joint in five hips. Capsular tissue was preserved in formalin, and was sent to a single specialized laboratory for histological analysis in ten of the twelve hips. Ten of the twelve explanted femoral components were sent for analysis to a specialized implant retrieval laboratory.

Laboratory Analysis

The excised capsule and surrounding tissue were graded (on a scale of 1 to 4 [see Appendix]) by the pathologist for presence of necrosis, inflammatory exudate, diffuse lymphocytes, perivascular lymphocytes, plasma cells, eosinophils, and polymorphonuclear leukocytes using light microscopy of routine paraffin sections stained with hematoxylin and eosin. The retrieved modular neck-body and head-neck junctions were examined for evidence of fretting and corrosion with use of a stereo light microscope at eight to fifty times magnification and with a scanning electron microscope (model 6490LV, JEOL U.S.A., Peabody, Massachusetts) at magnifications from 500 to 5000 (see Appendix). The degree of corrosion was graded by one of the authors (R.M.U.) as none (grade 1), mild (grade 2), moderate (grade 3), or severe (grade 4), according to the criteria of Goldberg[25].

Source of Funding

Results

The erythrocyte sedimentation rate was elevated in seven of eleven patients (mean, 31.2 mm/hr; range, 3 to 62 mm/hr; normal, <27 mm/hr), while CRP was elevated in five of eleven patients (mean, 14 mg/L; range, <5 to 36 mg/L; normal, <8 mg/L) (see Appendix). Both markers were elevated in four of eleven patients. Due to large amounts of amorphous material or cellular
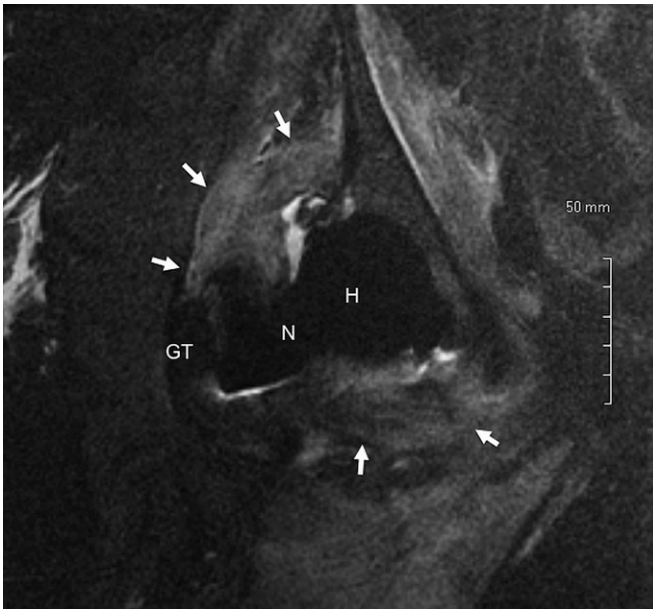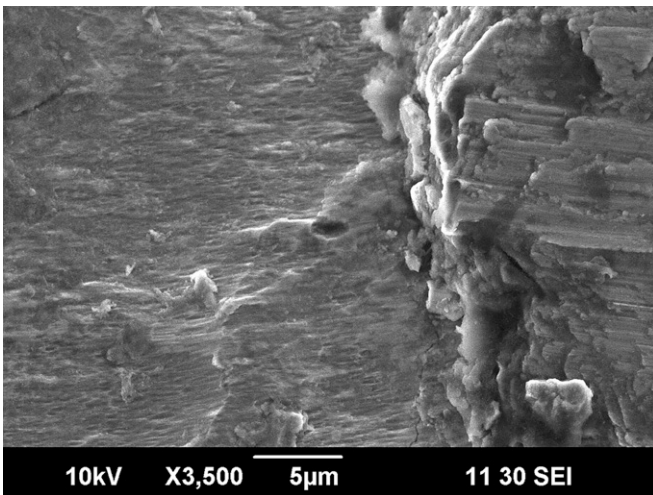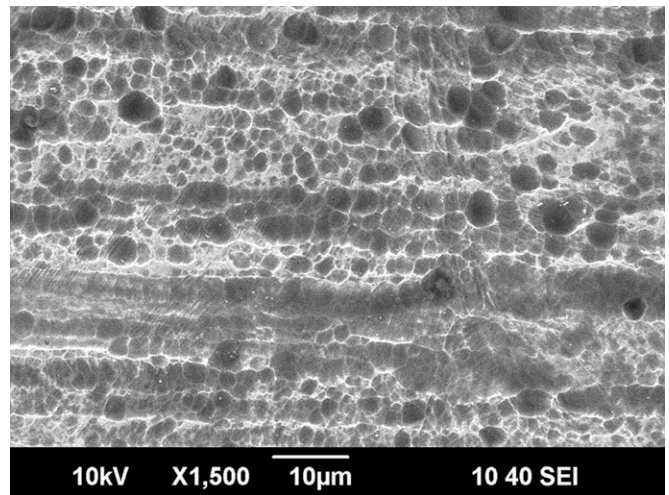
Fig. 1

Fig. 2

Fig. 3

Fig. 4

Fig. 1 Coronal short tau inversion recovery (STIR) magnetic resonance image acquired with use of metal artifact reduction sequence (MARS), demonstrating a large pseudotumor (arrows) surrounding the prosthetic hip joint, approximately twenty-one months following total hip arthroplasty (Case 3). As a reference, the greater trochanter (GT), modular prosthetic femoral neck (N), and modular femoral head (H) are labeled. **Fig. 2** Posterior (left) and medial (right) light microscopic images of modular femoral neck that was retrieved after approximately sixteen months in vivo (Case 2). Surface damage, consisting of fretting, corrosion, and black debris, was apparent on all retrieved cobalt-chromium modular femoral neck-body junctions. **Fig. 3** Scanning electron microscope image (×3500) demonstrating fretting and corrosion (left and center) as well as a thick deposit of fretting-corrosion debris (right) on the lateral aspect of a damaged neck-body junction that had been in vivo for approximately twenty months (Case 1). Similar findings were seen in all ten retrieved implants. **Fig. 4** Scanning electron microscope image (×1500) of a femoral head-neck junction that had been in vivo for sixteen months, demonstrating marked pitting corrosion of a cobalt-chromium femoral neck that was mated with a ceramic head (Case 6). Femoral head-neck corrosion was found in six of the ten implants analyzed (five with ceramic heads, and one with a metal head).

destruction in the aspirated samples of five of the ten hips that had undergone aspiration, the laboratory was unable to perform a cell count of the aspirated synovial fluid for those five hips; in the remaining five samples, the mean synovial fluid white blood-cell (WBC) count was 3427 WBC/μL (range, 2 to 11,500 WBC/μL) with a mean differential of 54% neutrophils (range, 32% to 90%), 22% lymphocytes (range, 1% to 39%), and 9% monocytes (range, 1% to 17%). On the basis of previously established thresholds[26], the synovial fluid WBC count was suggestive of infection in one case (11,500 WBC/μL), but this was not supported by the differential (34% neutrophils). This same patient had an elevated erythrocyte sedimentation rate (59 mm/hr) but
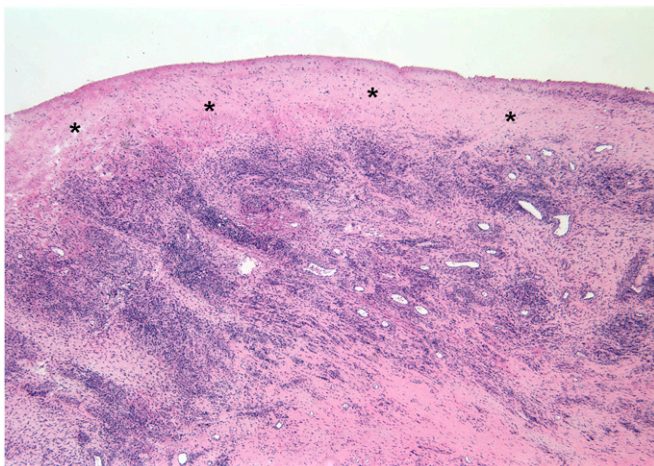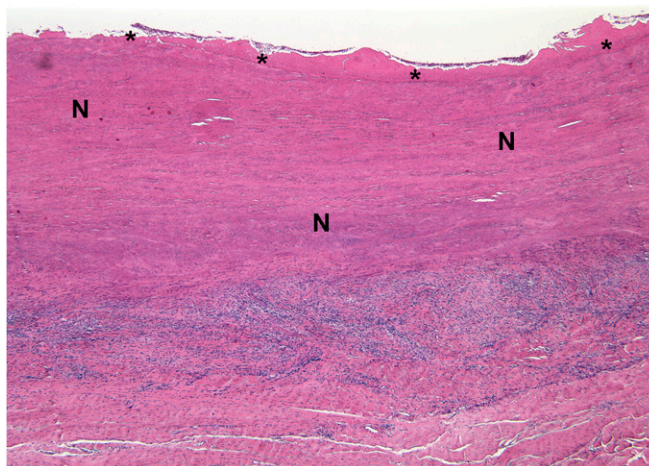
Fig. 5

Fig. 6

Fig. 5 Histological surgical specimen obtained 12.6 months following hip arthroplasty (Case 4), demonstrating abundant diffuse and perivascular lymphocytes in the joint pseudocapsule. The synovial lining is absent, and a layer of organizing fibrin exudate (*) covers the inner surface of the capsule (hematoxylin and eosin stain, ×25 magnification). **Fig. 6** Histological specimen obtained during revision surgery after 12.5 months in vivo (Case 5). A broad layer of the joint pseudocapsule is necrotic (N) and covered by a surface layer of fibrin (*). Diffuse lymphocytes and a lesser number of eosinophils form a distinct layer (hematoxylin and eosin stain, ×25 magnification).

a normal C-reactive protein level (7 mg/L). Aerobic and anaerobic cultures failed to demonstrate growth in any of the ten hips; and the patients were not taking antibiotics prior to aspiration.

Serum metal ion levels demonstrated a substantial elevation in serum cobalt, which was elevated to a greater extent than serum chromium; serum titanium levels were generally within the normal reference range of patients with a well-functioning total hip arthroplasty (see Appendix). Radiographs were interpreted as normal in most cases, but one demonstrated subtle scalloping of the bone along the medial femoral neck. MRIs were interpreted as normal in one patient, but the remaining studies demonstrated large fluid collections and/or hypertrophic soft-tissue reactions or pseudotumor formation (Fig. 1).

On the average, it took 8.6 months (range, 2.2 to 14.7 months) to establish a diagnosis and perform revision surgery after the patient's initial presentation of symptoms. Patients often sought second opinions when the etiology of the pain was unclear. One patient (Case 3) underwent a lumbar spinal fusion, which was not successful in alleviating any of her symptoms, before the underlying diagnosis of taper corrosion was made. Another patient (Case 1) underwent an exploratory irrigation and debridement, tissue biopsy, and modular head, neck, and liner exchange without relief of symptoms.

Surgical Findings

At the time of revision surgery, a large amount of fluid was typically encountered upon entry into the hip joint. In all tissue specimens obtained, frozen sections demonstrated no evidence of acute inflammation and intraoperative cultures eventually yielded no growth. Capsular hypertrophy and necrosis of the soft-tissue structures surrounding the hip joint were typical, resulting in large soft-tissue masses in several patients. A thorough debridement was performed, removing all abnormal

hypertrophic and necrotic soft tissue. In each hip, the modular junction between the neck and body of the femoral component demonstrated obvious corrosion, with fretting of the taper and deposition of black, flaky material at its base. The modular necks remained engaged on the tapers in all hips without any signs of loosening. The femoral components were revised in all hips. All components were well fixed with osseous ingrowth, with seven of twelve hips requiring an extended trochanteric osteotomy for component removal. Three hips that did not have an extended trochanteric osteotomy sustained a proximal femoral fracture during or after revision; one fracture was bypassed, the second
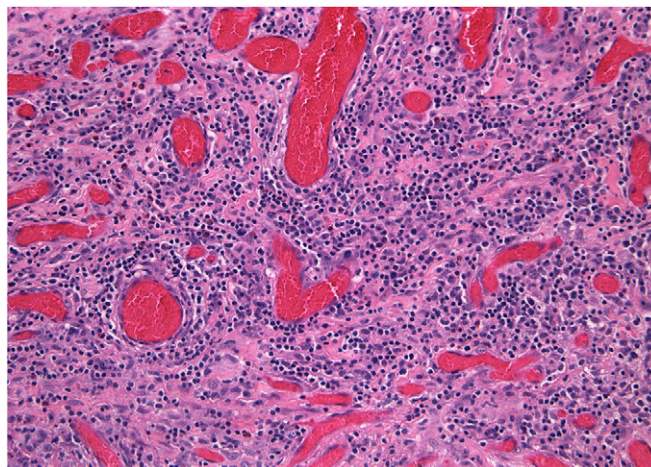

Fig. 7

Histological specimen removed during revision surgery (Case 1). The majority of the specimen was necrotic, but viable areas of pseudocapsule showed chronic inflammation dominated by diffuse lymphocytes and scattered eosinophils (hematoxylin and eosin stain, ×200 magnification).
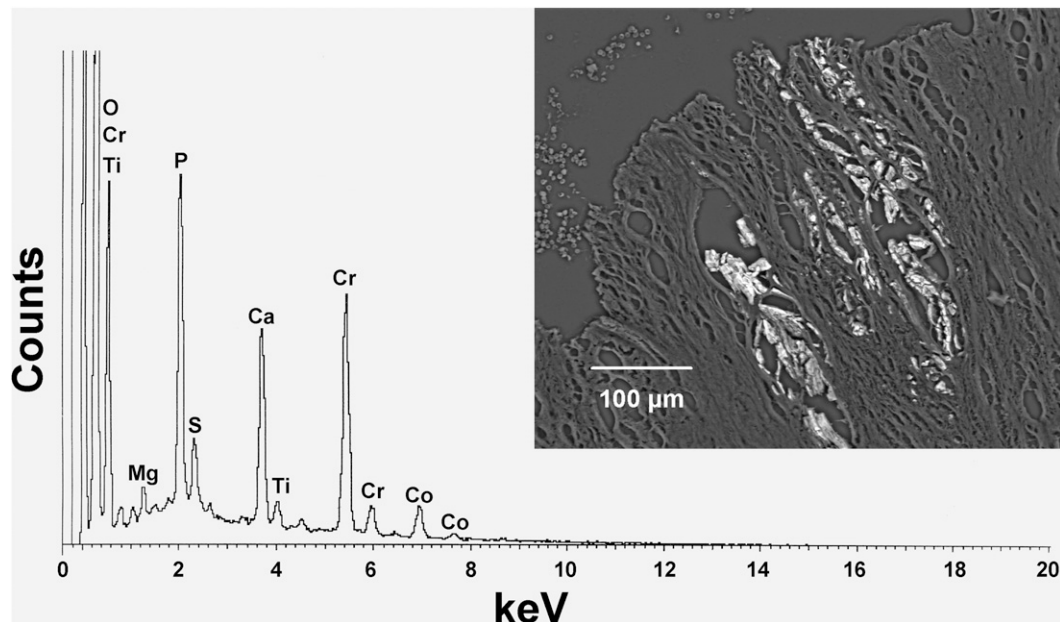
Fig. 8

An energy-dispersive x-ray spectrum (Case 5) reveals the elemental composition of particles rich in chromium (Cr) and consistent with chromium phosphate corrosion product. Traces of cobalt (Co) and titanium (Ti) are also present, the latter suggesting that these particles were generated by corrosion at the junction between the cobalt-chromium modular femoral neck and the titanium alloy stem. The particles (inset) lie in necrotic fibrous tissue of the joint pseudocapsule (backscattered electron micrograph, ×200). O = oxygen, Mg = magnesium, P = phosphorus, S = sulfur, and Ca = calcium.

was treated with a proximal cerclage cable intraoperatively with uneventful healing, and the third developed a postoperative trochanteric fracture requiring internal fixation with additional surgery. The acetabular component was well fixed in all hips but was concomitantly revised in the hip of one patient because the treating surgeon chose not to use the existing dual-mobility bearing; the modular liner was exchanged in the remaining eleven hips. In each hip, the existing bearing surface appeared normal without any evidence of wear.

Laboratory Analysis

There was severe corrosion at the modular femoral neck-body junction in all ten of the retrieved devices, with evidence of fretting, corrosion, and fretting-corrosion debris seen with use of light microscopy (Fig. 2) and scanning electron microscopy (Fig. 3). At the head-neck junction, pitting corrosion (Fig. 4) was severe in six cases (Cases 2, 3, 5, 6, 8, and 9) (see Appendix).

Stained histological sections were available from ten of the twelve revised hips. Seven of these had marked necrosis of the joint pseudocapsule, and seven showed mild to moderate surface fibrin (see Appendix). Viable areas of the pseudocapsule showed abundant perivascular and diffuse lymphocytes (Fig. 5). In six cases, diffuse lymphocytes dominated, and a more laminated appearance was evident (Fig. 6). The lymphocytes were often accompanied by plasmacytes and/or eosinophils (Fig. 7). Polymorphonuclear leukocytes were rare. The histology was normal in Case 12, for which only a small tissue sample was available. Numerous particles of translucent, pale-green chromium phosphate ($CrPO_4$) corrosion products were present in the tissues or within fibrin exudate covering the surface of the

joint pseudocapsule (Appendix; Fig. 8). Opaque metallic or bi-refringent polyethylene wear particles in macrophages were only rarely observed in the histological sections. Notably, there were no qualitative or quantitative differences in the appearance of the periprosthetic tissue between patients with elevated or normal inflammatory markers.

Discussion

The potential for corrosion at modular taper junctions in total hip implants was first described in the early 1980s[27] and, since that time, has been documented in numerous retrieval studies[25,28-36]. While there have long been concerns that corrosion at these modular junctions might produce soluble and particulate debris with the potential to migrate locally and systemically[37-39], there have been relatively few reports of adverse local tissue reactions and pseudotumor formation secondary to taper corrosion and the resultant metal debris; most have been described only recently[12-16,40]. These soft-tissue reactions appear clinically and histologically similar to the adverse local tissue reactions seen in failed metal-on-metal bearings[17-20]. To date, these reports have generally been limited to corrosion occurring at the modular head-neck junction rather than the modular neck-body junction.

Numerous concerns have arisen in recent years over potential complications specific to dual-tapered stem designs, including the potential for fracture of the modular neck component[9-11,41-45], dissociation of the modular neck from the body[46,47], and corrosion at the modular neck-body interface[4-8]. However, to date, there have been only two small case series describing a total of five cases of adverse local

tissue reaction in response to corrosion at the modular neck-body junction; these occurred in different dual-taper stem designs that also utilized modular cobalt-chromium-alloy necks[5,21]. The current study documents the potential for this process to cause pain and severe soft-tissue destruction around the hip in a larger cohort of patients, which can lead to early failure within the first several years of implantation.

Fretting and corrosion at the head-neck junction can also contribute to the generation of particulate and soluble products of corrosion and to an adverse local-tissue response when a cobalt-chromium-alloy head is mated with a cobalt-chromium-alloy or titanium-alloy stem[12]. In vivo fretting corrosion tests of one design indicated that zirconia heads mated with cobalt-chromium-alloy stems produced less fretting than that seen with cobalt-chromium-alloy heads mated with cobalt-chromium-alloy stems[48]. In the present study, fretting and extensive pitting corrosion were observed in six of ten head-neck junctions studied, five of which employed a ceramic head. Similar findings have been documented in a previous retrieval analysis of dual-tapered stems[4]. Surgeons should be aware that in vivo fretting and corrosion can occur with a ceramic head and a cobalt-chromium-alloy neck.

The etiology of the adverse local tissue reactions appears to be linked to release of metal ions and debris from the modular taper junction. This likely occurs through a process of mechanically assisted crevice corrosion, which was described as a combination of fretting and crevice corrosion[25,49]; scanning electron microscopy analysis of the retrieved components was consistent with this process. Factors that may contribute to corrosion at the modular interface include extended neck lengths[50] or contamination of the taper interface with debris[51]. There may also be factors related to the design of the taper junction itself. All of the stems in this series were from a single manufacturer. While this may relate to a susceptibility of this specific stem design to corrosion, adverse local tissue reactions have also been reported in association with other dual-taper stem designs that feature a modular cobalt-chromium-alloy neck[5,21].

The material composition of the modular components may also influence their susceptibility to corrosion; it is less likely that a modular neck made from a titanium alloy (thereby allowing for a titanium-titanium modular junction) would lead to adverse local tissue reaction[5] as there is no potential source for cobalt or chromium release from such a junction[52]. However, these titanium modular necks have been associated with fracture[9-11,41-45]. Furthermore, it is unknown if the unique composition of the titanium-alloy stem (TMZF; Stryker), which is a proprietary blend of titanium, iron, molybdenum, and zirconium, may influence the potential for corrosion or nature of the adverse local tissue reaction.

In the present series, several patients underwent extended evaluations before the diagnosis of taper corrosion was made; this may be because suspicion of an adverse metal reaction was quite low in patients with ceramic-on-polyethylene or metal-on-polyethylene bearing surfaces. However, once a diagnosis of taper corrosion is considered as a potential

etiology, the diagnostic workup is fairly straightforward. Physical examination is able to localize pain to the hip joint. MRI with use of MARS protocols typically demonstrates large fluid collections or adverse soft-tissue reactions. Serum metal-ion testing routinely demonstrates a greater elevation in serum cobalt than serum chromium, which has also been documented in reports of head-neck taper corrosion[12,53-55]. We have found this constellation of findings to be reliable in making a diagnosis of adverse local tissue reaction secondary to taper corrosion[12]. There are several reasons why serum levels of cobalt may be higher than those for chromium. The content of cobalt in cobalt-chromium alloy is higher than that in chromium. Furthermore, in some forms of corrosion, cobalt is selectively leached from the alloy[49]. Finally, some of the chromium released due to corrosion is precipitated as chromium phosphate corrosion product and sequestered locally rather than forming organometallic complexes in the serum.

It is important to note that erythrocyte sedimentation rate and C-reactive protein were frequently elevated in this series, as has been seen in previous studies of adverse local tissue reaction secondary to taper corrosion[12]. Although this may raise the suspicion for periprosthetic joint infection, an aspiration and synovial fluid analysis with cultures can be quite helpful to rule out this possibility. In our experience, the presence of metal debris and degenerated cells often hinders the ability of the laboratory to perform a cell count on this fluid.

We note several limitations to the present study design. First, the multicenter and retrospective nature of this study led to some degree of heterogeneity in the patients' workup and does not allow us to estimate the incidence of this problem. In addition, we only report on the preoperative and operative findings in the absence of follow-up. We believe that these limitations are outweighed by the need to report these findings, given the potential for adverse patient outcomes associated with these devices, particularly as this clinical entity remains poorly understood and has been rarely described to date.

In conclusion, corrosion at the modular neck-body taper of a dual-taper femoral component can produce severe soft-tissue damage about the hip and should be included in the differential diagnosis for occult hip pain following total hip arthroplasty in patients with these types of prostheses. After infection was excluded, the diagnosis was aided by obtaining serum metal ion levels and a specialized MRI. We recommend these tests for patients who have dual-taper femoral designs that utilize a modular neck component and who present with pain in the absence of a more obvious cause. Importantly, given the potentially destructive nature of these adverse soft-tissue reactions, consideration should be given to early revision surgery, with femoral component exchange, to remove the ongoing source of metal-ion and debris generation.

Appendix

(eA) Tables showing the demographic, clinical, laboratory, surgical, and implant data, the results of microscopic and histologic examination of implants and tissue removed at the time of surgery, and the preoperative metal levels for the twelve

hips (eleven patients) in the study group are available with the online version of this article as a data supplement at jbjs.org. ∎

H. John Cooper, MD
Robert M. Urban, PhD
Joshua J. Jacobs, MD
Department of Orthopaedic Surgery,
Rush University Medical Center,
1611 West Harrison Street,
Suite 300, Chicago, IL 60612.
E-mail address for J.J. Jacobs: joshua.jacobs@rushortho.com

Richard L. Wixson, MD
Department of Orthopaedic Surgery,
Northwestern University Feinberg School of Medicine,
680 N. Lake Shore Drive,
#924, Chicago, IL 60611

R. Michael Meneghini, MD
Department of Orthopaedic Surgery,
Indiana University School of Medicine,
541 Clinical Drive, Suite 600,
Indianapolis, IN 46202

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