Evaluation of painful total hip replacements
modular metal taper junctions

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Intro & Background

Benefits of modularity in total hip arthroplasty are numerous. Modular femoral heads have been the standard of care for many years as they allow for per-operative adjustments in leg length and offset. More recently, modern primary total hip arthroplasty femoral components have emerged to include those with modular necks, these provide the surgeon the unique advantage to more exactly reproduce or correct the patient's anatomy and hip biomechanics. The modular necks come in a variety of offsets, lengths and versions that allow the surgeon to create the appropriate hip anatomical geometry, which may optimize abductor tension and strength, equalize leg length and enhance hip stability. In addition, the modular neck can facilitate femoral component insertion in more technically challenging surgical approaches, such as the direct anterior approach, where femoral exposure and mobilization can be difficult. These 'modular neck prostheses' therefore offer key benefits compared to standard components, especially in cases where deformity is present (e.g., dysplasia of the hip, post-traumatic arthritis, etc). These 'modular neck prostheses' do also allow for the use of modular heads and so have two modular junctions as opposed to the single modular junction with conventional 'modular head prostheses.'

With the additional taper junction, the modular neck femoral components provide an additional interface that may, in rare situations, be a potential source for metal fretting and crevice corrosion.1-3 Whenever two metal surfaces are in contact and there is the potential for relative motion, metal debris may be generated or corrosion can take place. There have been reports of fretting and/or corrosion between the stem and head of conventional modular head prostheses for many years. This has been reported with both titanium-titanium, CoCr-CoCr and CoCr-titanium taper junctions.

In vivo production of metal debris from implants has been the subject of much scrutiny recently. Metal on metal bearings, for example, produce small (20-80nm diameter) metallic wear debris whenever motion is present and, in cases of edge loading, the load of metal debris can be highly elevated compared to well positioned metal on metal bearings. Furthermore, elevated blood serum metal ion levels (it is believed these metal ions are produced by corrosion of the wear debris in the case of metal on metal joints) and metal hypersensitivity resulting in an adverse local tissue reaction (ALTR) may occur with metal-metal articularen surface bearings causing premature failure due to osteolysis, aseptic loosening and in some instances a devastating pseudotumor formation. It has been shown that a similar reaction and potentially premature failure of the total hip arthroplasty may occur in rare cases of patients with both modular head and modular-neck femoral components. Therefore, the intent of this manuscript is to discuss the clinical presentation, evaluation and workup of patients who present with persistent pain and symptoms after successful total hip arthroplasty with a metal taper junction suspected of fretting and/or corrosion. It should be noted that the clinical presentation and symptoms for reactions to metal debris can be similar to other complications such as infection. The intent is to provide the clinician a basic guideline, only at our current level of understanding based on very few reported cases, for the potential clinical presentation, evaluation, pathology and treatment of such patients, including when to consider revision surgery.
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Clinical Presentation
Patients with persistent pain in a total hip arthroplasty with a modular neck or modular head primary femoral component who, after thorough evaluation, lacks a clinically evident etiology should be considered for a potential adverse local tissue reaction to fretting corrosion at the modular taper junction. The patients will typically present with pain which may be located in the anterior, lateral or posterior aspect of the hip. Patients may or may not have pain at rest, but more reliably have pain with weight-bearing. Patients will typically have pain with motion of their hip and with loading of the hip joint on physical examination. In the rare cases of pseudotumor formation, the patients may feel a large mass or fluid collection in the region of the hip and in those cases an investigation for significant local soft tissue destruction should be considered.

Evaluation for Infection
All patients with a painful total hip arthroplasty, regardless of the femoral component type used, should be evaluated for infection as soon as possible. There are both anecdotal cases and reported cases in the peer-reviewed literature documenting superimposed bacterial infection in the face of clinical ALTR from metal-metal articulations.24 It is not clear if the infection led to the ALTR however there is also evidence that alteration of the local pH may create an environment, which facilitates metal corrosion which suggests that the pH alteration in occult periprosthetic infection may be a precursor to corrosion in metal taper junctions.25 Further confounding the issue is the reported rare incidence of patients with an ALTR from metal hypersensitivity presenting with a clinical picture mimicking infection, including elevated serum inflammatory markers.26 Regardless, the initial workup for a patient with a painful total hip arthroplasty should be a screening ESR and CRP and if either or both of those tests are elevated, a hip aspiration should be performed. It is essential that infection be ruled out as a potential cause of pain in patients with a total hip arthroplasty.

Serum Infection Markers and Hip Aspiration
Hip aspiration is highly recommended in patients with an elevated ESR and/or CRP. It should be performed with a large bore 18 gauge needle under radiographic guidance. Fluid shouild be sent for culture and sensitivity, but also for cell count and differential. If a radiologist performs the aspiration, the fluid should be obtained without any radiopaque dye or contrast to confirm intra-articular needle placement, as this may result in a dilution of the cell count concentration, which is critical for accurate diagnosis of infection. Recently, evidence has emerged that demonstrate cutoff values for patients with elevated serum inflammatory markers that indicate infection is likely if synovial cell count and differential is elevated. Della Valle et al. reported that patients with a serum ESR > 30mm/hr and a C-Reactive protein > 10mg/dL who have a synovial fluid aspirate with a white cell count of greater than 3000 white blood cells per mL have a greater specificity, sensitivity and positive predictive value for the diagnosis of infection.26 If patients have normal ESR and CRP, the data further supports infection is not present with 100% specificity.27 The appearance of the aspirated fluid has not been definitely proven to be indicative of a tissue reaction or lack thereof. With patients with ALTR with metal on metal bearings the aspirated fluid has been described as brownish or grey in colour with a turbid appearance. Given the differences in mechanism of metallic debris production with modular junctions this fluid appearance may or may not be similar. In patients with a painful hip replacement with a modular taper junction, who do not have evidence for a diagnosis of infection, it is recommended the patient undergo a workup for the possibility of ALTR from metal junction fretting corrosion as well as other etiologies such as soft tissue impingement.

Serum Metal Ion Levels
When metallic debris is produced in vivo it can be corroded and the corrosion products can be detected in the blood as metal ions. Therefore, it is imperative that with those patients presenting with a painful THA and who have a modular metal taper junction the surgeon obtain whole blood or blood serum metal ion levels. This rationale is due to increased serum ion levels being associated with painful or poorly functioning metal-on-metal bearing total hip arthroplasties and have been shown to be valuable as a diagnostic tool in the workup of painful metal-on-metal hip replacements.27 The relationship between blood/blood serum metal ion levels and fretting and/or corrosion of modular junctions has yet to be definitively established. However, De Smet et al demonstrated that chromium ion levels above 17μg/L and cobalt ion levels above 19μg/L were associated with high joint fluid ion levels and metallosis with metal on metal bearings.27 These values may represent levels at which clinical significance might be considered for serum metal ion concentrations. In a recent study, Kwon et al. reported on a total of 201 metal-on-metal resurfacing arthroplasties evaluated at a mean follow-up of 61 months using ultrasound/magnetic resonance imaging and serum/hip aspirate cobalt and chromium measurements.28 Pseudotumors found in 7 patients (4%)
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were associated with significantly higher cobalt and chromium levels and inferior functional scores. The median serum cobalt and chromium levels in female patients with bilateral arthroplasty in the pseudotumor group were 9.0 μg/L and 12.0 μg/L, respectively. These metal ion levels were significantly greater than the median serum cobalt and chromium levels in female patients with bilateral arthroplasty without pseudotumor, which were 2.9 μg/L and 3.2 μg/L, respectively. The authors concluded that elevated levels of cobalt and chromium ions suggest that pseudotumors are associated with increased wear generated from metal-on-metal articulations.29 The Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom has suggested a cut-off level of 7 parts per billion (ppb). However, the 7 ppb cut-off level for the maximum of cobalt or chromium has been shown to have a specificity of 89% and sensitivity 52% for detecting a pre-operative unexplained increase in serum cobalt and chromium.30 However, the 7 ppb cut-off level for the maximum of cobalt or chromium was 4.97 ppb and had sensitivity 63% and specificity 86% and was concluded that blood metal ions have the ability to separate failed from well-functioning hip replacements.29 Furthermore, it was reported the optimal cut-off level for the maximum of cobalt or chromium was 4.97 ppb and had sensitivity 63% and specificity 86% and was concluded that blood metal ions have the ability to separate failed from well-functioning hip replacements.29 These findings may or may not be relevant to hips with modular taper junctions as the process of metal debris formation is different in a taper junction compared to an articulation. However, it is may be that higher blood or blood serum ion levels are indicative of higher levels of metal debris production in the joint. In summary, while we are continuing to develop an understanding of serum metal ion levels and their correlation to adverse local tissue reactions in hip arthroplasty, the above values provide some context at our current understanding for evaluation of painful total hip arthroplasties suspected of an ALTR with modular taper junctions.

**Metal Hypersensitivity**

Nickel is the most common metal sensitizer in humans, followed by cobalt and chromium. Cell-mediated types of response with which orthopaedic implant-associated hypersensitivity reactions (metal sensitivity or metal allergy) are generally associated or are classified as type IV delayed-type hypersensitivity.30 The incidence of metal sensitivity, as determined by patch testing among patients with both well and poorly functioning implants, is approximately 25%, roughly twice as high as that of the general population. The average incidence of metal sensitivity among patients with a “failed” implant is approximately 50% to 60%.29 This increased prevalence of metal sensitivity among patients with a failed implant has prompted speculation that a metal allergy may contribute to implant loosening. However, there is a lack of a clear connection between incidence of metal sensitivity and implant duration, infection, reason for removal, or pain. At this time, it remains unclear what role, if any, metal sensitivity plays in implant loosening. Specific types of implants with greater propensity to release metal in vivo may, theoretically, be more prone to induce metal sensitivity (such as metal on-metal bearing surfaces or, to a lesser extent metal fretting corrosion of modular tapers). Although general patch testing and commercial kits exist for a variety of commonly antigenic substances there is mounting concern about the value of dermal testing to the study of immune responses to orthopaedic implants. The in vitro lymphocyte transformation test (LTT) involves measuring the proliferative response of lymphocytes (obtained from peripheral blood) following exposure with antigen. Reports indicate the LTT may be equally or better suited for the testing of implant-related sensitivity compared to dermal patch testing.31, 32 Thomas et al. investigated 16 patients with a failed metal-metal bearing hip arthroplasty due to lymphocyte dominated periprosthetic inflammation.32 In 13/16 patients (81%), systemic metal sensitivity was found based on PT and/or LTT.32 In summary, as an additional piece of information in evaluating these challenging patients, diagnostic testing in the form of either patch testing or an in vitro lymphocyte transformation test should be considered in addition to serum ion levels to address the patient’s level of metal ion exposure and their potential hypersensitivity.30 Whilst these tests are not definitive, the additional information provided may help the diagnosing surgeon determine the appropriate treatment pathway.

**Radiographic Analysis**

Radiographic analysis of painful total hips should always include plain radiographs to evaluate for loosening, osteolysis and for assessment of implant position. Of particular concern in patients with demonstrated adverse local tissue reactions from metal debris or ions is early loosening or osteolysis. Particular attention should be paid to the medial calcar, trochanteric and peri-acetabular regions for cortical lucency or erosion. In many cases of ALTR from metal wear debris from any source, the plain radiographs are normal without any
evidence of bony erosion (Figure 1). In patients with persistent pain, who have elevated metal ion levels or positive metal hypersensitivity testing and normal plain radiographs, it is recommended that advanced imaging studies be considered. Ultrasound has been employed to evaluate solid or fluid soft-tissue collections and masses associated with pseudotumors or seen adjacent to the implants, however, more recently, CT and/or Magnetic Resonance Imaging (MRI) with metal artifact reduction techniques have been useful to delineate more subtle soft-tissue findings associated with ALTR around metal-metal bearings. MRI detects osteolysis and complications in the periprosthetic soft tissues such as wear-induced synovitis, periprosthetic collections, neurovascular compression, and quality of the muscle and tendons of the rotator cuff of the hip. While there are local soft tissue abnormalities adjacent to all total hip replacements, those findings detailed above occurring next to metal-metal bearings in greater frequency supports the notion that MRI is an appropriate modality to further investigate ALTR associated with a total hip arthroplasty affected by modular taper fretting corrosion. If one is considering an MRI evaluation of a painful THA suspected of metal wear debris associated ALTR, detailed dialogue with radiologists knowledgeable in the metal artifact reduction techniques are necessary to optimize the information available from these advanced imaging techniques. MRI may also be a valuable tool in determining if the source of pain is in fact soft tissue impingement such as from the iliopsoas.

**Recommended Surgical Treatment**

There is currently no specific clinical data to guide the surgeon in the treatment of patients who are found to have a painful total hip arthroplasty with modular taper junction fretting corrosion at either the head-neck or modular neck-stem junction. Based upon the current, limited information, certain tenets and patient care strategies should be considered. First, while difficult and stressful for the surgeon and patient, it is not recommended that observation without surgical intervention be used for any significant time period once the diagnosis of an adverse local tissue reaction has been confirmed. As has been reported with metal-metal bearings, pseudotumor formation with soft tissue destruction has been reported in patients with fretting corrosion of metal taper junctions albeit in only single case reports. In severe cases these pseudotumors can render abductors completely absent or via mass effect cause neurovascular compromise of surrounding nerves or vessels. It is generally believed that the longer the source of metal debris is present, the worse the soft tissue damage may be. Therefore, surgical...
intervention is warranted once all other sources of pain have been eliminated and an adverse local tissue reaction from metal fretting corrosion (or other source of metal debris) is strongly suspected. As always, a detailed discussion of the risks of observation versus operative intervention with the patient must take place prior to surgery.

Once the decision to surgically intervene has been made, the method of revision reconstruction most likely should employ the principle of minimizing any modular metal taper junctions in this particular patient, as the presumption is that either their immune system plays a role in development of an ALTR via hypersensitivity or that their local biology may create an environment supportive of fretting corrosion for reasons that are as yet unclear. Acetabular components can typically be retained if well-fixed and in acceptable position. The acetabular liner should likely be composed of highly cross-linked polyethylene, although ceramic liners may be utilized as well. Furthermore, if a femoral component with a modular neck was used, this should be removed and replaced with a femoral component that does not utilize a modular neck. In addition, it is suggested that if a metal femoral head was utilized, a ceramic femoral head be used in the revision surgery with a new stem. It has been shown that ceramic-metal modular junctions have less fretting corrosion than metal-metal modular junctions, although only in an in vitro test using zirconia heads. The majority of studies that report surgical treatment of ALTR due to metal-metal bearings by conversion to an alternative bearing such as ceramic-ceramic or metal-polyethylene have reported resolution of pain and symptoms in the majority of patients. (Figure 3). Femoral stem tapers should not be re-used with new femoral heads or necks unless the new combination is specifically indicated in the manufacturer’s product labelling.

**Intra-operative Findings**

Evidence of fretting corrosion of the modular taper junction (either at the neck-head or neck stem junction) is visualized by irregular black material on the surface of the metal contained within the junction (Figure 4). Further, the black material is typically associated with and in approximate location to surface irregularities on the metal taper surface in contact with the opposite metal surface, consistent with crevice corrosion. Adverse local tissue reactions may also create a substantial amount of intra-articular joint fluid, as is typically seen preoperatively on MRI, and is reported to be a brownish or grey color with a turbid consistency. While this fluid collection has been described, the intra-articular fluid characteristics have not been consistently characterized macroscopically or with respect to laboratory analysis and cell count at the time of this publication to our knowledge. Local soft-tissue necrosis has been seen in some cases of ALTR from metal debris and can extend as far as the peri-articular capsule, the abductor musculature and tendinous insertion onto the greater trochanter (Figure 5) with necrotic bone seen in
the most severe cases. In addition, there have been observations of medial femoral neck or calcar resorption, aseptic loosening and osteolysis associated with ALTR from metal debris and ion production and these may be encountered intra-operatively as well.

**Summary**

For patients with a persistently painful total hip arthroplasty that has a metal modular taper junction, it is suggested that a comprehensive workup for occult infection be undertaken. If no other mechanical, soft tissue impingement or infectious etiology for the persistent pain is identified, then a thorough evaluation should be performed for possible ALTR from metal debris via fretting and/or corrosion mechanisms at the modular taper junction. The evaluation should likely include serum metal ion levels, metal hypersensitivity testing and radiographic analysis including plain radiographs and preferably a metal-artifact reducing MRI. While no single test is sensitive or specific enough to confirm the diagnosis of an adverse local tissue reaction from metal debris or ion production, the clinician should use the tests outlined above in conjunction with their clinical judgment and a thorough discussion with the patient to determine the appropriate treatment. If surgical intervention is deemed appropriate, attention to the techniques and principles of minimizing metal modular taper junctions should be employed as is feasible. In addition, patients who are suspected of having an ALTR from metal debris production should be followed closely to prevent the rare, but devastating progressive soft-tissue destruction that has been reported in this clinical setting.

Modularity within total hip replacement allows for more precise restoration of the patient’s anatomy during the operation. Increasing the modularity, such as by using modular necks as well as modular heads, increases the options available to the surgeon. Additional modular junctions are an additional interface, the incidence of fretting and/or corrosion of these junctions appears to be rare. There may be patient specific factors such as local chemistry influenced possibly by underlying infections however, there is little if any strong evidence in the literature. The most important thing to the surgeon and indeed the patient is the swift and unambiguous diagnosis of the cause of pain in a painful total hip arthroplasty so that in the rare cases where fretting and/or corrosion has occurred, there are no delays in providing the appropriate treatment.
References:


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