Commentary & Perspective

That's Why We Call It *BIO*mechanics!

Commentary on an article by H. John Cooper, MD, et al.: "Adverse Local Tissue Reaction Arising from Corrosion at the Femoral Neck-Body Junction in a Dual-Taper Stem with a Cobalt-Chromium Modular Neck"

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The introduction of total hip arthroplasty, in its modern form, by Sir John Charnley has been one of the most impactful medical advances of the last century, providing patients with pain relief, improved function, and better quality of life. Since then, surgeons and engineers have sought to improve surgical techniques and prosthetic designs and materials in an attempt to make a great intervention even better. The use of modularity, particularly at the femoral stem-neck junction, was an attempt to reproduce femoral offset and version and to restore limb length apart from stem fixation and appeared attractive in concept. Initial bench testing by Viceconti et al.[1] demonstrated minimal fretting and no evidence of corrosion at the taper junctions. These findings, coupled with the long-term success of a predicate modular stem, the S-ROM (DePuy, Warsaw, Indiana)[2], seemed to assuage the fears of failure related to these junctions. Despite little data to support any improvement in clinical outcomes, modular hip stems were introduced into the marketplace and their use was embraced by many.

This recent disturbing report by Cooper and associates represents a collaborative multicenter effort[3] detailing a series of eleven patients (a total of twelve hips) who underwent primary cementless total hip arthroplasty employing a modular femoral stem design (Rejuvenate; Stryker, Mahwah, New Jersey) consisting of a titanium-molybdenum-zirconium-iron alloy body (TMZF; Stryker) mated with a modular cobalt-chromium alloy neck (Rejuvenate; Stryker). The articular surfaces included both ceramic (eight hips) and cobalt-chromium (four hips) bearings against highly cross-linked polyethylene. All eleven patients presented with new onset pain at a mean of 7.9 months postoperatively. The authors describe a careful workup, including serologic studies (complete blood count, C-reactive protein, and erythrocyte sedimentation rate), the results of which varied from slightly elevated to normal. Ten of the twelve hips underwent aspiration as part of a protocol to rule out infection, and all ten had negative results. Serum metal ion analysis demonstrated a disproportionate elevation of cobalt and, to a lesser extent, chromium, with normal levels of titanium. Cross-sectional imaging on ten of the twelve hips with use of the metal artifact reduction sequence (MARS) magnetic resonance imaging (MRI) technique demonstrated either large fluid collections and/or pseudotumor formation in all but one.

On the average, 8.6 months transpired from the onset of pain until a diagnosis was established and revision surgery was performed. Due to presumptive adverse local tissue reaction related to the implant system, all patients underwent revision at a mean time of 15.2 months after the index procedure. Revision surgery was difficult in every case. Seven of the twelve hips required an extended trochanteric osteotomy to remove the implant; of the remaining five hips revised without osteotomy, three sustained a fracture during or after surgery. Histology of submitted tissue samples demonstrated marked necrosis and dense lymphocytic infiltrates in the majority of cases. Polymorphonuclear leukocytes, which one might observe in acute inflammatory conditions such as infection, were rare. Pale-green chromium phosphate particles, byproducts of corrosion, were observed in many of the samples. This finding was consistent with perhaps the most compelling piece of evidence for the cause of failure, the presence of severe corrosion at the femoral neck-body junction and, to a lesser degree, at the articular femoral head-neck junction in all of the retrieved femoral components.

This excellent report raises some unsettling questions. How will these patients fare following revision? In performing revision surgery on patients who suffer the same fate in the future, what is the best choice of implant and bearing combination? While the cohort denominator is unknown, do host factors exist in these patients that make them more susceptible to this local corrosion event?

The authors have outlined an excellent template for evaluating the painful total hip arthroplasty. Any patient with new-onset pain should have an infection workup, including a serologic screen and consideration of joint aspiration. While the role of serum metal ion levels continues to evolve, enhanced cross-sectional MRI has clearly given clarity to the phenomena of prosthesis-related adverse local tissue reaction[4]. Most important is early diagnosis followed by timely surgical intervention to mitigate the potential catastrophic effects of this corrosion-driven adverse tissue reaction.

Even more unsettling is the regulatory mechanism by which these modular implants have been introduced into the marketplace. The pathway, called the 510(k) process, by which predicate implant systems are used to reference substantial equivalence

to new designs, has facilitated the introduction of technologies without the need for more rigorous premarket clinical data. However, the definition of substantially equivalent predicate devices is, at best, vague. Recent attention to this problem within the orthopaedic community has been focused on metal-on-metal hip bearings[5].

But the report by Cooper and colleagues of modular femoral neck corrosion combined with recent reports[6] of other taper-related problems in hip replacement systems provides another disturbing example of the ineffectiveness of the 510(k) pathway. In the specific case of modular hip replacement implants, taper junctions between dissimilar metals with geometries unlike the referenced predicate systems may in fact NOT be substantially equivalent.

As initial reports of modular femoral neck taper junctions composed of titanium alloy demonstrated a small but real incidence of fracture, fatigue strength requirements became more stringent. The improved mechanical strength gained by the use of cobalt-chromium has been validated by the elimination of fracture. However, the combination of dissimilar cobalt-chromium and titanium alloy now appears to be associated with fretting corrosion and the development of extensive local adverse tissue reaction. While these implants passed mechanical benchmarks, their biologic effect was not appreciated. This raises an entirely new paradigm in orthopaedic implant use. Are we doing enough to identify these problems and to keep them from occurring in the future? Can we or should we require preclinical data investigating the potential for metal ion release and tribocorrosion problems with new implants prior to their introduction into the marketplace? And can preclinical tests appropriately anticipate all in vivo conditions, or are clinical trials the only true measure of safety and efficacy? We guess that's why we call it *BIO*mechanics!

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