

Making Sense of Metal Allergy and Hypersensitivity to Metallic Implants in Relation to Hand Surgery

Thomas J. Christensen, MD,* Shefali A. Samant, MD,† Alexander Y. Shin, MD‡

All metals implanted into a biological system undergo some degree of corrosion depending upon its composition. The electrochemical process of corrosion produces free metal ions, which may activate the host's immune system through a variety of mechanisms. Whereas dermal metal hypersensitivity is common, affecting 10% to 15% of the population, the immune reaction from implanted metals is much less common (< 0.1%), but has been associated with metal allergy and hypersensitivity producing a multitude of patient symptoms. Superficial symptoms may be mild to severe forms of dermatitis, urticaria, pruritus, and vasculitis, whereas deep sequelae include metallosis-related pseudotumor, implant loosening, and joint stiffness. Currently, there are clinical tests to evaluate patients for metal hypersensitivity, but there is little agreement regarding the ideal timing and clinical situation prompting the work-up of a patient for a metal allergy or hypersensitivity. An understanding of the epidemiology, etiology, basic science, diagnostic testing, and treatment of patients with suspected metal allergy, as it pertains to the current literature, will aid orthopedic and plastic surgeons of all subspecialties in the management of patients requiring metallic implants. (*J Hand Surg Am.* 2017; ■(■):■—■. Copyright © 2017 by the American Society for Surgery of the Hand. All rights reserved.)

Key words Metal allergy, hypersensitivity, orthopedic implants.

DEFINITIONS AND EPIDEMIOLOGY

In the past several years, patients who required open reduction internal fixation of fractures treated electively after emergent reduction and splinting have, prior to surgery, stated that they were allergic to metal and were concerned regarding orthopedic implants. Several of these patients were adamant that metals containing nickel or other specific metals could not be used as they were “severely allergic” to these metals. After extensive metal allergy testing, which was often

inconclusive, we proceed with fixation using implants that the patients were supposedly allergic to and, after years following the fixation, have had little to no problems. The recent event in which 1 such patient claimed a severe nickel allergy was found to have a stainless steel plate open reduction internal fixation of the ankle, 20 years prior, with no problems. This prompted this detailed review of the literature to determine the role of metal allergy in the implants used in the upper extremity. Whereas we recognize that total joint replacements of the lower extremity may create a metal allergy burden secondary to the size of the implant and metallosis created by debris of wear, the upper extremity presents a unique situation when dealing with metal allergies. In this critical review, we hope to enlighten the reader about metal implant allergies and to guide the surgeon to make the best decisions for their patients.

Over the last several decades, increased access to and implantation of metallic devices have led to a valid concern regarding the implications and management

From the *Reno Orthopaedic Clinic, Reno, NV; the †Kaiser Permanente, Los Angeles, CA; and the ‡Department of Orthopedic Surgery, Division of Hand Surgery, Mayo Clinic, Rochester, MN.

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Corresponding author: Alexander Y. Shin, MD, Mayo Clinic, 200 First St. SW, Rochester MN 55905; e-mail: shin.alexander@mayo.edu.

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of metal hypersensitivity; evidence has accumulated to support this concern. The evidence, however, is primarily level IV and V, reflecting the relatively rare and incompletely understood nature of this entity. Allergy is most commonly defined as a hypersensitivity immune response (immunoglobulin G [IgG] or IgM) to an otherwise innocuous substance (ie, antigen). In the context of this review and the related literature, allergy and hypersensitivity are used synonymously to describe this immune response.¹

The prevalence of metallic contact dermatitis, based on skin patch testing, is high in comparison with the extremely low prevalence of hypersensitivity to implanted metallic orthopedic prostheses or fixation devices composed of the same metals. Of the 70 allergens tested by the North American Contact Dermatitis Group (NACDG) in their most recent patch testing study from 2009 to 2010, nickel was the most common allergy identified, affecting 15.5% of the general population.^{2,3} It is estimated that even more patients, 20% to 25%, develop metal hypersensitivity after total joint arthroplasty.^{4,5} Although this figure is surprisingly high, the prevalence of allergic symptoms related to metal implants has been reported to be less than 0.1%.^{6,7} It is not completely understood why many patients with known metal hypersensitivity do not react to their implants. Reed et al⁸ report a case of implantation of a stainless steel plate in a patient with a known nickel allergy and positive patch test with no adverse reactions. This difference is at least in part related to skin being a highly immunogenic organ as well as to the property of these metals being stable as part of an alloy to a much greater degree than as free ions.⁵ The occurrence of metal allergy to implants also depends upon the immune and atopic status of the individual as well as to the corrosion potential of the metal.

A recent meta-analysis focusing on metal sensitivity testing after total joint arthroplasty demonstrated increased incidence in failed arthroplasty compared with stable arthroplasties.⁹ The trend of using metal-on-metal (MOM) total hip arthroplasties (THA) seen in the last decade has increased both public and health care provider awareness of metal hypersensitivity. Increased serum metal ion levels seen with MOM THA is associated with not only cutaneous symptoms but also deep sequelae such as metallosis-related pseudotumor, implant loosening, and/or periprosthetic joint stiffness.^{10–12} The incidence of these complications is difficult to define because they are often limited to case reports and small series. A meta-analysis of approximately 14,000 cases estimated the incidence of pseudotumor to be

approximately 0.6%,¹⁰ which is higher than the incidence of metal allergy itself. The revision rate in this series was 3.9%. As a result, MOM arthroplasty has become a major recent discussion topic. Therefore, a full review of this entity is beyond the scope of this article and it has been recently described elsewhere.^{9,11–14} The correlation between metal ion concentrations and hypersensitivity has been studied. However no absolute ion concentration as a predictor of the likelihood of developing metal hypersensitivity has been established.^{4,10,12,13,15}

PATIENT CHARACTERISTICS AND SYMPTOMS

As part of any standard clinical consultation, patients should be queried regarding any medication or non-medication allergies, such as metals. Patients who report a metal allergy most commonly have symptoms related to wearing jewelry, belt buckles, or watches.¹⁶ It is most commonly related to jewelry containing nickel sulfate, but also cobalt chloride, palladium chloride, beryllium sulfate, and chromium chloride.^{7,8} Allergic contact dermatitis symptoms typically manifest as cutaneous eruptions, dermatitis, hives, eczematous rash, edema, and pruritus.^{1,5,17,18} There is an unexplained, yet apparent, slight predilection to metal allergies in women.^{6,8,19} In the study by Reed et al,⁸ 39 of 44 patients (89%) undergoing patch testing were females, which is speculated to be related to increased awareness and sensitivity from jewelry.

In contrast to contact dermatitis, symptoms from an allergy to an implanted metallic device are much more ill-defined and difficult to definitely ascribe to a specific cause. An unexplained skin rash overlying an implanted orthopedic device is the most common cause for referral to the dermatology department concerning a possible metal allergy⁸; other less common reasons include chronic pain localized to the implant site, periprosthetic joint stiffness, and aseptic loosening of unknown etiology.^{5,7,8,10} Patients may also experience severe hair loss or a localized rash that progresses to systemic dermatitis, which has been demonstrated to occur even years after developing implant-related pain and stiffness.^{4,10} If not referred for an allergy work-up by their orthopedic surgeon, patients have been shown to also be likely to self-refer to a dermatologist.⁸ In addition to orthopedic devices, patients may have similar symptoms associated with pace makers, surgical clips, and cardiac stents.^{1,20–22}

IMPLANT CHARACTERISTICS

In order to withstand the physiological stress placed upon the skeleton, the majority of orthopedic implants

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