Are orthopaedic implants failing due to metal allergy?

Information overview

- There are multiple reports citing metal allergy as a cause of orthopaedic implant failure[1-7]
- In addition to Nickel, most patients are allergic to multiple metals.[8-9] Cobalt and Chromium have also both been cited as allergens leading to revision.[5-6, 17-18]

Published in The Journal of Bone & Joint Surgery, Hallab, et al. detailed the issue of metal allergies in orthopedic patients.[10] In their meta-analysis, they noted a relationship demonstrating a higher incidence of allergy to Nickel, Cobalt and Chromium among patients with poorly functioning implants than in patients with well performing implants. (Figure 1) A subsequent meta-analysis by Granchi et al supported this relationship noting "the probability of having a metal allergy was more than doubled in patients who had a failed replacement than in those with a stable replacement."[11]

Similar to patients with allergies to other substances such as pollen, pets, etc., several studies have shown the majority of patients with metal allergies demonstrate reactions to more than one metal, rather than reacting to a single allergen. (Figures 2a, 2b) While Nickel is the most often cited allergen, Cobalt and Chromium sensitivities have also both been often cited as the causes of hip and knee implant revisions.[1-7, 17-18] The severity of the symptoms can cause significant impact to the patient beyond just the failure of their prosthesis, which may only be relieved by revision.[2-4, 16]

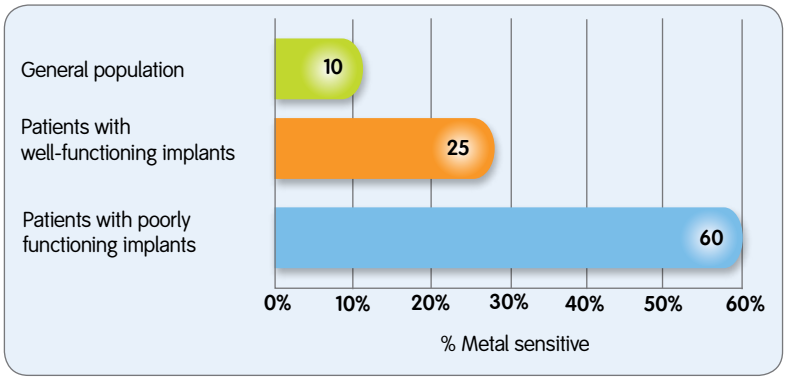

Figure 1: Prevalence of patients demonstrating metal sensitivity[11]

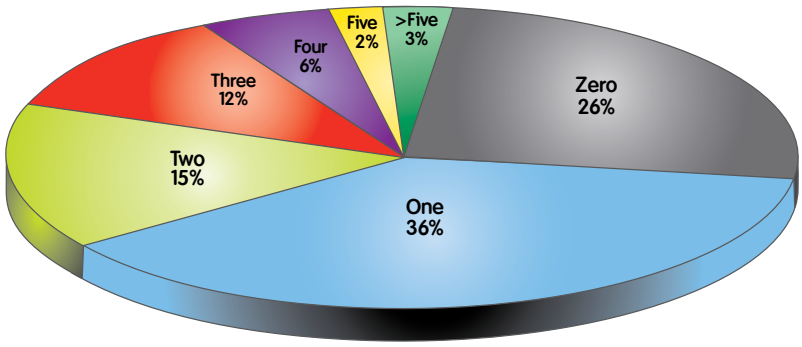

Figure 2a: Number of metals for which patients demonstrated metal reactivity (n=250)[8]

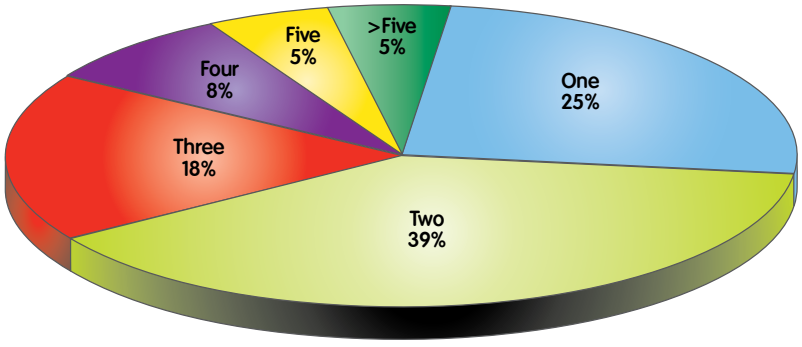

Figure 2b: Number of metals for which patients diagnosed with metal allergy were allergic (n=700)[9]

Smith & Nephew primarily uses one of three metals when producing its various metal hip and knee implants: Titanium Alloy, Cobalt-Chromium Alloy and Zirconium Alloy. Chemistry limits (in weight percent) for the alloys per the respective industry standards are shown here:

Cobalt Chrome Alloy (Co-Cr-Mo) ‡	
Cobalt Balance	(58.7-68.0)
Aluminum	0.10 max
Boron	0.01 max
Carbon	0.35 max
Chromium	27.00 – 30.00
Iron	0.75 max
Manganese	1.00 max
Molybdenum	5.00 – 7.00
Nickel	0.50 max
Nitrogen	0.25 max
Phosphorous	0.020 max
Silicon	1.00 max
Sulfur	0.010 max
Titanium	0.10 max
Tungsten	0.20 max

Zirconium Alloy (Zr) ‡‡	
Zirconium Balance	(96.8 - 97.5)
Carbon	0.027 max
Chromium	0.020 max
Hafnium	0.010 max
Hydrogen	0.0025 max
Iron	0.15 max
Niobium	2.40 – 2.80
Nitrogen	0.0080 max
Oxygen	0.09 – 0.13 max
Tin	0.0050 max

Titanium Alloy (Ti) ‡‡‡	
Titanium Balance	(88.1 – 91.0)
Aluminum	5.5 – 6.75
Carbon	0.08 max
Hydrogen	0.015 max
Iron	0.30 max
Nitrogen	0.05 max
Oxygen	0.20 max
Vanadium	3.5 – 4.5
Yttrium	0.005 max

‡ ASTM F-75
‡‡ ASTM F-2384
‡‡‡ ASTM F-1472

Like Titanium, Zirconium is one of the most biocompatible elements available. Moreover, the biocompatibility of OXINIUM® alloy has been confirmed and published via testing in accordance with ASTM and ISO standards.[12, 13] However, unlike OXINIUM, "perhaps the greatest drawback to Ti alloys is their relative softness compared to Co-Cr-Mo alloys and their relatively poor wear and frictional properties. Ti-6Al-4V is >15% softer than Co-Cr-Mo alloys and also results in significantly more wear than Co-Cr-Mo when used in applications requiring articulation, e.g., TKA or THA femoral heads."[14] In contrast, the surface of OXINIUM alloy is over twice as hard as the surface of CoCr alloys which provides excellent durability and resistance to abrasion.[15]

References

1. Kwon YM, Thomas P, Summer B, Pandit H, Taylor A, Beard D, Murray DW, Gill HS. Lymphocyte proliferation responses in patients with pseudotumors following metal-on-metal hip resurfacing arthroplasty. J Orthop Res. 2010 Apr;28(4):444–50.
2. Post, Z et al, Metal Sensitivity After TKA Presenting With Systemic Dermatitis and Hair Loss, Orthopedics, April 2013, Vol. 36, No. 4, p.525-528.
3. Parvizi, et al, Metal Hypersensitivity Following Total Knee Arthroplasty: Is it a Real Phenomenon? Poster Number 134. Proc AAOS 2009.
4. Thakur, R et al, Severe Persistent Synovitis After Cobalt-Chromium Total Knee Arthroplasty Requiring Revision, Orthopedics, April 2013, Vol. 36, No. 4, p.520-524.
5. Gao X et al, Dermatitis Associated With Chromium Following Total Knee Arthroplasty. The Journal of Arthroplasty Vol. 26 No. 4 2011.
6. Niki, Y et al, Screening for symptomatic metal sensitivity: a prospective study of 92 patients undergoing total knee Arthroplasty. Biomaterials 26 (2005) 1019–1026.
7. Pacheco, K. et al, Allergy Assessment Provides Clinically Relevant Results in Joint Replacement Patients. Poster Number 120. Proc AAOS 2014.
8. Valentine-Thon, et al. Neuroendocrinology Letters. 2003:24;57-64.
9. Khare A, Kellermann M, Kellermann G. MELISA® In-Vitro Methodology for the Detection of Metal Hypersensitivity in an American Population. Poster Presentation at the American Association of Clinical Chemists (AACC); July 28, 2010: Anaheim, CA.
10. Hallab N, Merritt K, Jacobs JJ. J Bone Joint Surg Am. 2001;83:428-436.
11. D. Granchi, E. Cenni, A. Giunti, N. Baldini, "Metal hypersensitivity testing in patients undergoing joint replacement," J Bone Joint Surg Br 2012; 94-B:1126–34.
12. J.A. Davidson, C.M Asgian, A.K. Mishra, and P. Kovacs, "Zirconia (ZrO2)-coated zirconium-2.5 Nb alloy for prosthetic knee bearing applications," Bioceramics, Yamamuro, T. Kokubo, and T. Nakamura (eds.), Kobunshi Kankokai, Kyoto, Japan, 1992, pp. 389-401.
13. S.B. Goodman, J.A. Davidson, V.L. Fornasier, and A.K. Mishra, "Histological response to cylinders of a low modulus titanium alloy (Ti-13Nb-13Zr) and a wear resistant zirconium alloy (Zr-2.5Nb) implanted in the rabbit tibia," J. Appl. Biomater., 4 (4), 1993, pp. 331-339.
14. Ratner, Buddy D et al, Biomaterials Science, Third Edition: An Introduction to Materials in Medicine, Academic Press, 2012.
15. Hunter, G., Dickinson, J., Herb, B., et al. Creation of Oxidized Zirconium Orthopaedic Implants. J. ATSM Int. 2(7), 2005.
16. Nasser S, Mott MP, Wooley PH. A comparison of ceramic and Oxinium total knee femoral components in patients with cobalt chrome hypersensitivity. Presented at the 74th Annual AAOS Meeting; February 14-16, 2007; San Diego, Calif.
17. Thomas P, Braathen LR, Dörig M, et al. Increased metal allergy in patients with failed metal-on-metal hip arthroplasty and peri-implant T-lymphocytic inflammation. Allergy 2009; 64:1157 -1165.
18. Cooper, H. John, et al. Corrosion at the Head-Neck Taper as a Cause for Adverse Local Tissue Reactions After Total Hip Arthroplasty. J Bone Joint Surg Am. Sept. 19, 2012; 94(18): 1655-1661

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