



Metal Hypersensitivity in Orthopaedic Implants

A Position Statement from the Canadian Orthopaedic Association

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Approved by the COA Board of Directors on June 11, 2025

Key Messages

- Contact metal hypersensitivity is observed clinically in up to 11% for nickel and less than 2% for cobalt and chrome in the general population.
- Patch testing can return positive results for up to 20% of individuals for nickel with lower percentages for other metals. However, reactions to implanted metals remain rare.
- This statement focuses exclusively on metal hypersensitivity in static implanted fixation devices (e.g., plate and screw fixation) and excludes joint replacements or articulating

Non-Technical Summary

Metal hypersensitivity refers to a rare immune reaction in response to implanted metal devices. While contact metal hypersensitivity is relatively common, reactions to orthopaedic implants are rare and unpredictable. Symptoms may include skin rashes, swelling, pain and implant loosening, though a clear cause-and-effect relationship has not been definitively established. Testing methods such as patch testing and lymphocyte transformation tests (LTT), lack specificity and predictive accuracy. Current research suggests that removing implants may resolve symptoms, but the evidence supporting this is limited. Additionally, hypoallergenic implants have not demonstrated superior outcomes and may carry higher risks due to unfamiliar surgical techniques. Given the uncertainties surrounding metal hypersensitivity, clinical decisions should involve shared decision-making with patients, considering the low incidence of metal reactions and the limitations of existing diagnostic tools.

Background

Metal implants are widely used in orthopaedic surgery for fracture fixation, trauma repair, and reconstructive procedures. Despite the high prevalence of contact metal hypersensitivity, documented cases of true hypersensitivity reactions to implanted static devices are rare. The mechanisms behind these reactions involve metal ion release and immune responses, but a direct cause-and-effect link remains unproven.

Clinical Questions

Can patients experience clinical reactions to in-vivo metal implants?

- Yes. Symptoms may include cutaneous eruptions, impaired wound healing, pain, swelling, chronic inflammation and implant loosening. (5,7)
- Localized reactions are more common in static implants and often resolve after implant removal. (5, 8)

What is the incidence of metal hypersensitivity reactions to implanted static devices?

- Rare (exact percentage uncertain).

Does implant removal result in symptom resolution?

- Yes, as suggested by case reports. Patients may develop sensitivity due to pre-existing conditions or de novo reactions resulting from implant wear and corrosion. (7, 18-22)

Is there a proven cause-and-effect relationship between implanted metal devices and clinical reactions?

- No. Metal corrosion can release ions that trigger localized or systemic immune responses, but the mechanisms remain unclear. (5, 6)
- Cutaneous reactions are typically delayed-type hypersensitivity mediated by T-lymphocytes, while non-cutaneous responses involve complex immune processes. (6)

Is patch testing a reliable predictor of in-vivo metal reaction?

- No. Patch testing is commonly used for diagnosing metal hypersensitivity, but it is limited by interpretation bias and lacks predictive accuracy for deeper tissue immune responses. (7, 11-15)

Is there a clinical test to diagnose metal allergy in suspected in-vivo metal reactions?

- No, diagnosis is primarily by exclusion.
- Lymphocyte transformation tests (LTT) offer a more specific method but suffer from high costs, inter-laboratory variability, limited availability, and undefined sensitivity/specificity thresholds. (11, FDA 2019)

What we Found:

- The relationship between metal hypersensitivity and implant failure remains uncertain.
- Registry results show no difference to implant failure rates between patients with positive and negative patch tests.
- Even in patients with known metal hypersensitivity, standard implants rarely lead to complications requiring revision.
- Hypoallergenic implants have uncertain long-term outcomes and may introduce technical risks due to surgeon unfamiliarity.
- Further research is needed to clarify the cause-and-effect relationship between metal sensitivity and implant failures.

We Conclude That:

- No clear causal link has been established between metal allergy and orthopaedic implant failure.
- Patch testing and immunological tests lack predictive reliability for in-vivo metal reactions.
- Hypoallergenic implants have not been shown to provide superior outcomes and come with additional risks.
- Clinical decision-making should involve discussions with patients regarding implant selection and associated risks.
- Further research is necessary to establish clearer guidelines for metal sensitivity in orthopaedic implants.

Current data do not support routine screening or special precautions for metal hypersensitivity in orthopaedic fixation. Despite widespread use of metal implants and high rates of contact dermatitis, true implant reactions remain extremely rare.

Testing methods (patch tests, LTT) are unreliable for predicting in-vivo responses.

Consent processes should focus on common risks, as hypersensitivity reactions fall below the legally required threshold for inclusion (<0.001%)

Unless patients explicitly report a documented metal allergy, discussing hypersensitivity risks is not typically necessary in routine informed consent.

Further research is required to better understand immune responses to implanted metals, ensuring more definitive recommendations for surgeons and patients.

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