Metals and Device Allergy

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I am a member of the American Contact Dermatitis Society.

I will be discussing non-FDA approved allergens.
Metal-associated Allergic Contact Dermatitis

- Jewelry
- Piercings
- Cosmetics
- Tattoos
- Snaps/zippers
Metals as Allergens: NACDG 2013-1014

- Nickel 20.1%
- Cobalt 7.4%
- Chromium 2.2%
- Gold not on standard tray
- Titanium not on standard tray
- Palladium not on standard tray
Nickel Allergy

- Contact Allergen of the year 2008
- Most common cause of allergic contact dermatitis
- 20.1% (NACDG 2013-2014)
- women > men (may change with piercing patterns)
- Incidence continues to increase
- Ubiquitous
  - Jewelry, zippers, snaps, coins, food
  - Cell phones, lap tops
New Controversy:

Metal Devices and Patch Testing
Why are we talking about this?

- Orthopedic implants
  - > 1 million procedures annually
    - > 600,000 knees
    - 421,000 hips
  - > $18 million
  - Metal on metal implants increasing
- Dental implants
- Cardiac devices
- Nuss procedure
Why are we talking about this?

- Metal sensitivity rates are higher in patients with failed implants
- Increasing malpractice cases
- No standard of care in dermatology or orthopedics
- Paucity of evidence based research
Metal Devices and Patch Testing

- No firm evidence based guidelines
- No randomized controlled trials
- 20% of PT population nickel sensitive
- Until recently no significant interest in testing by surgeons
  - Now some surgeons are requiring it
- Metal allergens
  - Stainless steel- Nickel, cobalt, chromium ( molybdenum)
  - Titanium
  - Vitallium
  - Nitinol ( Ti and Ni)
Scope of Issue

- Prevalence of metal hypersensitivity to implanted devices not known
  - 0-5%??
- Long term pain outcomes after joint replacement
  - Knee- 20%
  - Hip- 9%
- Nickel hypersensitivity in patch test population - 20.1%  (NACDG 2013-2014)

Metal Hypersensitivity Testing - Tools

- **Patch testing**
  - Limitations
  - ?validity in determining deep tissue allergy
  - Negative result ? Most valuable

- **LTT- lymphocyte transformation test**
  - in vitro measurement of lymphocyte proliferation from blood in presence/absence of allergens
  - Not widely available
  - Often not covered by insurance

- **MIF- migration inhibition factor test**
  - Detects in vitro release of lymphokine from lymphocytes in contact with an allergen
  - Not readily available
Patch testing

- Gold standard for diagnosing allergic contact dermatitis
- Cutaneous applications of allergens
- 48 hour occlusion with two readings
- Is it helpful in deep tissue allergy??
Environment of the joint

- No clear model to replicate the immunologic environment
- Can cutaneous patch testing be used to determine joint hypersensitivity?
- Currently not many other options....
Studies show conflicting data

- Large case-control study- 356 cases, 712 controls
  - Risk of surgical revision of THA not increased in patients with metal allergy
  - Risk of metal allergy was not increased after THA
- Retrospective series - 165 patients
  - Significantly higher rate of patch test positivity in those with problems
- Higher rate of metal allergy in patients with joint loosening and failure
- Prevalence of metal allergy
  - 25% in well-functioning hip implants
  - 60% in poorly functioning implant

Metal Devices and Patch testing: Should this be done

- Patch test referrals are increasing
- Some surgeons require it
- Some patients request it
- SET EXPECTATIONS AT THE BEGINNING
- 0-5% of implanted orthopedic devices with metal hypersensitivity reactions
- No randomized controlled trials
Metal Devices and Patch Testing

Setting Expectations

- Should it be done pre-implantation?
  - Not predictive of future allergy
  - Results only indicative of current allergy
  - Does not recreate environment of the metal device

Is it helpful post-implantation?

- A positive patch test result does not prove causation

- what about other allergens?
  - Acrylates/cements
  - Antibiotics

- Debate amongst experts….
Few studies looking at effect of patch testing on implant selection

- Patients with a history of metal allergy preimplantation - patch tested
- If positive patch test to metal
- Surgeon changed implant to avoid allergen
- No problems post operatively

- Limitation- small sample size and no control group

Metal Hypersensitivity and Implants

- Static device with overlying dermatitis more clear
  - Remove/resolve
- Joint pain, joint loosening more difficult
  - Did allergy cause loosening or did loosening cause sensitization?
Patch testing for evaluation of hypersensitivity to implanted metal devices: a perspective from the ACDS

- Pre-implant testing – no history of metal allergy
  - Not recommended

- Pre-implant testing – patient history of metal allergy
  - Recommend patch testing in some cases
  - Self-reported history of jewelry allergy at best 60% predictive of nickel positive patch test
  - Manufacturer discs - limited utility
  - If positive patch test aim to avoid allergens

Metal Hypersensitivity and Devices

- Post-implant testing
  - Metal exposure can cause sensitization
  - Positive reaction does not prove causation
  - Decision to remove joint complicated- surgeon/patient

Lack of Clinical Studies

- No clear connection between metal sensitivity and implant outcome
- Patients with known metal allergy often do not react to implants
- No evidence that patients with known metal allergy have higher failure or revision rate than those who do not have metal allergy
- Anecdotal reports showing support for revision with titanium alloy or zirconium

Orthopedic perspective

- Some requiring patch testing
- Others not asking the question
- No universally accepted protocol
- No universally accepted testing methods
- Nickel felt to be the biggest concern
- Metal hypersensitivity as the problem is a diagnosis of exclusion
- Causal association of metal allergy and joint failure unproven
Orthopedic implants

- Total knee arthroplasty components
  - Femoral component of cobalt-chrome alloy
  - Articulates with ultra-high-molecular-weight polyethylene tibial component
  - With or without metal backing and a polyethylene patella component
- 20% with good anatomical surgery are dissatisfied for many reasons
- Metal hypersensitivity for 18 years “insignificant cause of failure of modern TKA”
- Serum metal levels of unknown meaning – often elevated in well-functioning implants

Metal Hypersensitivity: Orthopedic perspective

- Difficult diagnosis- lack of robust clinical evidence
- Metal hypersensitivity after total knee is rare
  - Dermatitis
  - Persistent painful synovitis
- Diagnosis of exclusion
  - Low-grade infection
  - Instability
  - Component loosening/malrotation
  - Referred pain
  - Chronic regional pain syndrome

Metal Hypersensitivity: Orthopedic perspective

- Revision is a last resort
- No evidence-based medicine to guide management of this
- “Given the limitations of current testing methods, the widespread screening of patients for metal allergies before TKA is not warranted”

Metal Devices and Allergy

- Ongoing problem
- Not going away
- ACDS white paper
- Need robust evidenced base data……