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METAL ALLERGY IN TKA: MYTH OR FACT?

Complications in Orthopaedics and Traumatology
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BACKGROUND

- 2 SYSTEMATIC PATCH TESTS + ON FRIDAY
- TKR PLANNED FOR NEXT THUESDAY
- LOGISTICALLY IMPOSSIBLE TO ORDER 2 HI
- USUAL TKR

WHAT'S THE RISK OF FAILURE?

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OUTLINE

- DEFINITION
- EPIDEMIOLOGY
- DIAGNOSIS
- BEFORE TKR
- AFTER TKR
- CONCLUSION

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DEFINITION

- ABNORMAL IMMUNOLOGIC REACTION TO METAL SUBSTANCE
- TYPE 4 ADAPTIVE IMMUNITY REACTION, DELAYED TYPE HYPERSENSITIVITY (DTH)
- NOT INNATE IMMUNITY REACTION

Type I	Type II	Type III	Type IV
IgE	IgG	IgG	CD4 Th1 CD4 Th2 CD8 cytotox.
Antigènes solubles	Ag cellulaires ou métalliques	Récepteur cellulaire	Ag soluble Ag soluble Ag soluble
Mastocyte	Complément Phagocytes, NK	Ac. albumine	Macrophage Eosinophiles Cytotoxicité
Anticorps	Complément	Immune-complexes	CD4+ Th1 CD4+ Th2 CD8+ CTL
Immune au contact	Paraphagocytes	Immune complexe	Paraphagocytes

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METAL ALLERGY IN ORTHOPAEDICS

Elemental Composition and Comparative Biological Reactivity of Common Orthopaedic Metals

Orthopaedic Metal	Relative Immunogenicity	Elemental Composition								
		Ni	Co	Cr	Mo	Ti	Al	Va	Fe	Other
Stainless steel 316L	High	8%-30%	—	20%	2%-3%	—	—	—	>50%	2% manganese, up to 1% silicone
Co-Cr-Mo	Moderate	0%-0.5%	60%-70%	27%-30%	5%-7%	—	—	—	—	Up to 1% manganese and silicone
Vitallium	Low	—	61%	32%	5.6%	—	—	—	—	~0.5% manganese and silicone
Titanium alloy	Low	—	—	—	0%-15%	85%-99%	0%-6%	0%-4%	—	—
Oxinium	Very low	—	—	—	—	—	—	—	97.5% zirconium and 2.5% niobium	
Nitinol	High	45%	—	—	—	55%	—	—	—	

Al = aluminum, Co = cobalt, Cr = chromium, Fe = iron, Mo = molybdenum, Ni = nickel, Ti = titanium, Va = vanadium
+ Indicates remaining balance. — indicates nil but may contain a trace (<0.01% composition by weight)

ROBERTS & AL. J Am Acad Orthop Surg 2017;25: 693-702

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EPIDEMIOLOGY & RISK FACTORS

- 10-15 % OF THE POPULATION EXHIBITS CUTANEOUS SENSITIVITY TO METAL
- FEMALE X4
- PIERCINGS, TATTOOS X3
- SMOKING X3

FACT

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EPIDEMIOLOGY

• SO... 10-15% OF MY PATIENTS WILL DEVELOPP TKR ALLERGY?

MYTH !!!

• WHY???

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EPIDEMIOLOGY

• THE REAL INCIDENCE IS UNKNOWN,
 • < 1%
 • THE ANTIGEN PRESENTING CELLS
 • THE DIAGNOSIS IS NOT EASY...
 • 35+18+11+6 = 70%

National Joint Registry of England and Wales, 2010

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DIAGNOSIS

• ANAMNESIS
 • IN VIVO TEST
 • IN VITRO TEST

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QUESTIONNAIRE

Société Française de Chirurgie
 SFHC
 Hanche et Genou

QUESTIONNAIRE ALLERGIE

Détection et évaluation du risque d'hypersensibilité aux métaux dans le cadre de la pose en première intention ou la révision d'un implant prothétique articulaire de genou ou de hanche.

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THE HYPERALLERGIC PATIENT

• IODE, PENICILLIN, LATEX, DOCTORS...
 • PROUD TO BE ALLERGIC
 • FEELING SPECIAL, DIFFERENT...
 • EVEN ALLERGIC TO HAPPINESS

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PATCH TESTING

• EASY TO USE, CHEAP
 • GOLD STANDARD...
 • FOR DERMATOLOGISTS...

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PATCH TESTING

- **HIGH SENSITIVITY (100%) POOR SPECIFICITY (64%)**
- **SKIN IS NOT THE JOINT** (HALLAB N, MERITZ K, JACOBS JJ. ASYMPTOMATIC PROSPECTIVE AND RETROSPECTIVE COHORTS WITH METAL-ON-METAL HIP ARTHROPLASTY INDICATE ACQUIRED LYMPHOCYTE REACTIVITY VARIES WITH METAL ION-LEVELS ON A GROUP-BASED / ORTHOPAEDIC RES 2013; 173-182)
- **INDIVIDUAL VARIATIONS, DIFFERENT RESULTS IN THE SAME PATIENT**
 - HIRSHMAN AL, BRIDGE AL, CHRISTENSEN OS. INDIVIDUAL VARIATION IN NICKEL PATCH TEST REACTIVITY. AM J CONTACT DERMAT. 1999; 10:42-47
 - SCHMIDCK PC, MEHREZ T, JOHANSEN JD, TAYLOR JL, WABASCH M, LIDEN C, BRUZE M, THYSSSEN JP. (2012) HYPERSENSITIVITY REACTIONS TO METALLIC IMPLANTS: DIAGNOSTIC ALGORITHM AND SUGGESTED PATCH TEST SERIES FOR CLINICAL USE. CONTACT DERMAT 66:6-19
- **PATCH TESTING ACCURACY & PREDICTIVE VALUE ARE QUESTIONABLE...**
 - THE PREVALENCE OF CONTACT ALLERGY TO NICKEL, CHROMIUM, AND COBALT WAS COMPARABLE IN PATIENTS WITH AND WITHOUT REVISION SURGERY. J
 - MUNCHIK RJ, JACOBSEN SS, OLSEN JT, MEHREZ T, SREBALIK K, JOHANSEN JD, THYSSSEN JP. THE ASSOCIATION BETWEEN METAL ALLERGY, TOTAL KNEE ARTHROPLASTY, AND REVISION ACTA ORTHOPAEDICA 2015; 85 (2): 5.

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HOWEVER...

Percentage with Metal Sensitivity

Group	Percentage with Metal Sensitivity
General Population	12%
Patients with well functioning implants	25%
Patients with poorly functioning implants	60%

Hallab N, Merritt K, Jacobs JJ. Metal sensitivity in patients with orthopaedic implants. J Bone Joint Surg Am. 2001;83:428-434.

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LITERATURE

- « TKA FAILURE WAS FOURFOLD MORE LIKELY IN PATIENTS WHO HAD SYMPTOMS OF METAL HYPERSENSITIVITY BEFORE TKA » GRANCHI D, CEHNI E, TIGANI G, TRISOLINO G, BALDINI N, GIUNTI A. SENSITIVITY TO IMPLANT MATERIALS IN PATIENTS WITH TOTAL KNEE ARTHROPLASTIES. BIOMATERIALS 2008;29(10): 1494-500.
- « 0.6% OF PATIENTS WITH TKA MAY HAVE A PROBLEM DUE TO HYPERSENSITIVITY TO NICKEL OR COBALT AFTER IMPLANTATION » THOMSEN M, ROZAK M, THOMAS P. USE OF ALLERGY IMPLANTS IN GERMANY: RESULTS OF A SURVEY ORTHOPAED. 2013;45(42):597-601
- « ALTHOUGH 20-25 % OF TOTAL JOINT ARTHROPLASTY PATIENTS DEVELOP METAL SENSITIVITY, ONLY A FEW HIGHLY SUSCEPTIBLE PERSONS (<1 %) EXHIBIT SYMPTOMS » THENFONTE E, BERGER Y. NO ALLERGIC REACTION AFTER TKA IN A CHROME-COBALT-NICKEL-SENSITIVE PATIENT: CASE REPORT AND REVIEW OF THE LITERATURE. KNEE SURG SPORTS TRAUMATOL ARTHROSC. 2013;21:636-40

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IN VITRO TESTING

- LEUCOCYTE MIGRATION INHIBITION TEST (LMI) (HALLAB)
- LEUCOCYTE ACTIVATION TEST (LAT) (GRANCHI)
- LEUCOCYTE TRANSFORMATION TEST (LTT) (CHRISTIANSEN)
- MEMORY LYMPHOCYTE IMMUNO STIMULATION ASSAY (MELISA) (VALENTINE-THON)

➢ EXPENSIVE, NOT REALISTIC IN DAILY CLINICAL PRACTICE...

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OPTIONS

J Bone Joint Surg. 2009 Apr;24(3):374-82. doi: 10.1016/j.jarth.2007.10.021. Epub 2008 Jun 4. Ceramic versus cobalt-chrome femoral components: wear of polyethylene insert in total knee prosthesis. Sander JL, Sander JL, et al. www.ncbi.nlm.nih.gov/pubmed/18500000

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CHOOSE YOUR WAY

- JUST IGNORE IT... PROBABLY LUCKY...
- ONLY USE HYPOALLERGENIC IMPLANT (HI)... CAREFULL...
- REVISE ALL THE PAINFULL TKR WITH HI...
- OR JUST GO FURTHER WITH SCREENING

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ACTUAL CONTEXT

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SYMPTOMS OF TKR ALLERGY

- NON SPECIFICS
- SWELLING 42,1%
- SYNOVITIS
- STIFFNESS
- PAIN 68,2%
- CUTANEOUS REACTIONS 35%
- LOCAL INFLAMMATORY REACTIONS: MYOSITIS, PSEUDO-TUMOR, DERMO-HYPODERMITIS,...

• EBEN R, WALK R, SUMMER B, MAIER S, THOMSEN M, THOMAS P. IMPLANT ALLERGY REGISTER—A FIRST REPORT DER ORTHOPAED [2009, 38(6):557-562]

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FAILED TKR = METAL ALLERGY?

- 1 EXCLUDE SEPTIC OR MECHANICAL CAUSE
 - BLOOD SAMPLE TEST (CRP, WBC)
 - BACTERIOLOGICAL CULTURE OF ARTICULAR FLUID, ALPHA DEFENSIN TEST
 - XRAYS, CT SCAN...
- 2 WITHOUT EVIDENT DIAGNOSIS, THINK ABOUT IT
 - ANAMESIS (90% WITHIN THE FIRST 3 MONTHS), CLINICAL EXAMINATION
 - PATCH TEST
 - IN VITRO TESTING
 - HISTOLOGICAL ASPECT
 - NO CORRELATION WITH IONIC METAL BLOOD CONCENTRATION

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HISTOLOGICAL ASPECT

- ALVAL SYNDROM (ASPETIC LYMPHOCYTIC VASCULITIS-ASSOCIATED LESIONS)
- WILBERT HG, BUCHHORN CH. METAL-ON-METAL BEARINGS AND HYPERSENSITIVITY IN PATIENTS WITH ARTIFICIAL HIP JOINTS. A CLINICAL AND HISTOMORPHOLOGICAL STUDY. J BONE JOINT SURG. 2005;87(4):28-36
- NECROSIS, GRANULOMA
- KRENN CLASSIFICATION : MODIFIED SLIM (SYNOVIAL LIKE INTERFACE MEMBRANE)

Fig. no. 1. Classification of the SLIM (Krenn et al. 2004b). The SLIM can be categorized as four histologic...

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ALGORITHM

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CONCLUSION : TAKE HOME MESSAGE

- IT'S NOT A MYTH
- BUT THIS FACT IS DIFFICULT TO PROVE
- PRIMARY TKR : MAKE YOUR CHOICE
- FAILED TKR :
 - EXCLUSION DIAGNOSIS
 - REVISION WITHOUT DIAGNOSIS GIVE BAD RESULTS

➤ MEANWHILE, MY 2 + PATCH TEST PATIENTS ARE HAPPY WITH THEIR CONVENTIONAL IMPLANTS...

