Is a Nickel Allergy Related to Poor Outcomes in Total Knee Arthroplasty

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INTRODUCTION:

Reasons for failure requiring revision following total knee arthroplasty (TKA) are commonly related to infection, instability, or malalignment. Revisions due to metal allergy (MA) have become more common in the last decade. 10-48% of patients have been reported to be sensitive to metal, with Nickel being the most common offender. A controversy surrounds the validity of whether MA leads to sub-optimal outcomes requiring revision arthroplasty. Two studies showed that symptoms were resolved following revision surgery with non-nickel containing components, however, evidence has been lacking to support the supposition of whether these outcomes are directly related to the MA. The only consensus between studies is that MA is considered a diagnosis of exclusion. The purpose of this study is to determine if there is a relationship between clinical outcomes and MA by evaluating asymptomatic post-operative TKA patients with well-functioning implants through quantitative MA testing.

METHODS:

With approval from the institutional review board (IRB), we performed a prospective cohort study that included a total of 41 patients (26 females, 15 males, mean age 70.9 ± 6.67, average BMI 34.3 ± 7.65) who underwent primary TKAs (L: 17 R: 24) between 2010 and 2020. Inclusion criteria included a primary TKA and a well-functioning implant with minimum 12-month post-operative follow up. Patients with an Oxford Knee Score (OKS) less than 40 and those with a TKA implant that did not contain cobalt chromium and nickel were excluded from the study. An informed consent was signed by all patients. A commercially available Lymphocyte Transformation Test (LTT) measures the amount of a Delayed Type Hypersensitivity lymphocyte immune response after exposure to a particular antigen. The level of immune reactivity to each metal is measured as a Stimulation Index (SI) with a score over 2 indicating a positive reaction to an allergen. MA results were divided into non-reactive, mildly reactive(2-4), reactive(4-8), and highly reactive(>8). T-test and Wilcoxon-Mann-Whitney test were performed to compare individual metal reactivity. Proportional odds ordinal logistic regression and exact chi-square test was used for testing homogeneity of metal reactivity.

RESULTS:

41 knees were included for analysis with mean follow up 73.7 months. Nickel had the highest incidence when compared to cobalt and chromium and is the only metal to show reactive (n=7) and highly reactive (n=10) scores based on the SI (Table 1; p-value <0.01). There was no correlation between metal reactivity and OKS score by metal (Table 2; Nickel rho = -0.082; Cobalt rho = 0.014; Chromium rho = -0.166). Figure 1 shows a linear regression correlation plot of MA SI and corresponding OKS.

DISCUSSION AND CONCLUSION:

To our knowledge, this is the first study looking at metal allergy in well-functioning TKAs. There is no correlation between clinical outcomes and the presence or absence of Nickel allergy. Based on the results of this study, surgeons should not base their decision to revise a painful or poorly functioning total knee solely based on a “positive” Nickel allergy test. Further studies are ongoing to see if sensitivity to other metals may be associated with poorer outcomes following TKA.

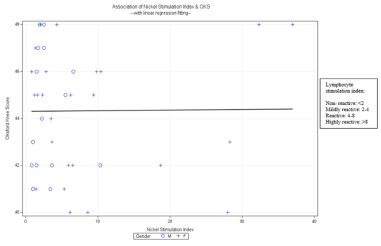

Table 1: Compare the incidence between metal individuals. Exact chi-square test for homogeneity of reactivity of metals.

Reactivity	Non-reactive	Mildly reactive	Reactive	Highly reactive	Total	p-value
Nickel	14 (34.2)	10 (24.4)	7 (17.1)	10 (24.4)	41	<.001
Cobalt	37 (90.2)	4 (9.8)	0	0	41	
Chromium	37 (90.2)	4 (90.8)	0	0	41	

Table 2: Correlation coefficient between mean OKS score in patients with metal allergy and their Stimulation index

	Mean (Std Dev)	Median (Q1, Q3)	(Min, Max)	Spearman Correlation	
OKS	44.3 (2.61)	45 (42, 46)	(40, 48)	rho	p-value
Metal Stimulation Index					
Nickel	6.9 (9.98)	3.5 (1.6, 6.6)	(0.8, 37)	-0.082	0.609
Cobalt	1.2 (0.63)	1.0 (0.8, 1.5)	(0.3, 3.1)	0.014	0.929
Chromium	1.2 (0.59)	1.2 (0.9, 1.4)	(0.2, 3.4)	-0.166	0.299