″Nickel Free″ Hypoallergenic versus Standard Cobalt-Chrome Containing Total Knee Replacement: Is there a Difference in Synovial Metal Ions at Minimum 2-Year Follow-up?

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INTRODUCTION:

Metal allergy is a topic of debate in total knee replacement (TKA) and adverse local tissue reaction (ALTR) to metal ion debris in TKA is starting to be recognized as a potential mode of failure. Despite the enormous importance of this data, no study has assessed intraarticular synovial fluid metal ion levels in well-fixed TKA beyond the first postoperative day. The aim of this study was to compare intraarticular synovial fluid levels of metal ions in patients who underwent cemented primary TKA for osteoarthritis with a hypoallergenic TKA implant versus a matched cohort with a standard cobalt-chromium (Co-Cr) containing at minimum 2-years post-surgery.

METHODS:

A retrospective, matched, case-control study was performed using prospectively collected data from a single institution. A total of 22 cases (metal allergy/sensitivity with hypoallergenic TKA implants) and 18 controls (no metal allergy/hypersensitivity with standard Co-Cr TKA implants) met inclusion criteria, with a median follow-up of 4.9 (IQR 4.0 to 5.2) years. Cases and controls where matched for patient age (*P*=0.405), sex (*P*=1.000), body mass index (*P*=0.781), comorbidity classification (*P*=0.340), indication for TKA (*P*=1.000), femoral component design (*P*=0.498), patellar resurfacing (*P*=0.435), and time from TKA surgery (*P*=0.119) (Table 1). Synovial fluid from sterile aspirations of the study knees were analyzed for metal ion levels of cobalt (Co), chromium (Cr), nickel (Ni), and titanium (Ti). All knees had radiographic confirmation of well-fixed implants. Functional outcomes were analyzed.

RESULTS:

The median Ni ion level in the synovial fluid of the hypoallergenic cases was 3.6 times higher than standard Co-Cr containing implant controls (1.0 vs. 0.28 ug/L, *P*<0.001) (Table 2). Co ion levels in the hypoallergenic cases were 17.7 times lower compared to the standard Co-Cr controls (0.07 vs. 1.24 ug/L, *P*<0.001). Similarly, the Cr ion levels in synovial fluid of the hypoallergenic case knees was 3.2 times lower compared to the standard Co-Cr control knees (0.39 vs. 1.26 ug/L, *P*<0.001). The Oxford Knee Score (*P*=0.577), Forgotten Joint Score (*P*=0.675), SF-12 PCS (*P*=0.530), and SF-12 MCS (*P*=0.073) scores were similar between cohorts.

DISCUSSION AND CONCLUSION:

Patients with metal allergy or hypersensitivity who underwent TKA with a “nickel-free” hypoallergenic implant had intraarticular synovial Ni ion levels that were 3.6 times higher than a control group with standard Co-Cr containing implants at a median of 4.9 years from surgery. To our knowledge, this is the first study to report synovial fluid levels on this patient population beyond post-surgery day 1 in well-fixed implants. Our results do not support the use of this hypoallergenic implant for patients with Ni allergy or hypersensitivity. Due to the lower synovial Co and Cr levels in cases, if ALTR to metal debris such as Co does become a bigger issue in TKA, our data support the use of the hypoallergenic implant. Further definitive study on the subject matter is necessary and warranted.

Table 1. Baseline and Demographic Data for Cases and Controls.

Variable	Oxinium (n=22)	Standard Co-Cr (n=18)	*P*-value
Patient age, yrs (mean, range)	67.8 (57 – 78)	68.2 (57-77)	0.405
Sex, n (100%)	22 (100)	18 (100)	1.000
BMI (mean, range)	29.3 (18.3 – 40.0)	27.8 (19.8 – 38.7)	0.781
ASA, n (%)			0.340
I	2 (9.1)	1 (5.6)	
II	16 (72.7)	10 (55.6)	
III	4 (18.2)	7 (38.9)	
Diagnosis primary OA, n (%)	22 (100)	18 (100)	1.000
Femoral component design, n (%)			0.498
PS	5 (22.7)	6 (33.3)	
CR	17 (77.3)	12 (66.7)	
Patella resurfacing, n (%)			0.435
Yes	6 (27.3)	7 (38.9)	
No	16 (72.7)	11 (61.1)	
Time from surgery, yrs (median, IQR)	4.5 (3.7 – 5.4)	5.2 (4.6 – 5.2)	0.119

Abbreviations: Co-Cr = cobalt-chromium; yrs = years; BMI = body mass index; ASA = American anesthesiologists association classification; OA = osteoarthritis; PS = posterior stabilized; CR = cruciate retaining; IQR = interquartile range.

Table 2. Synovial Metal Ions Levels for Cases and Controls.

	Oxinium Cases	Standard Co-Cr Controls	*P*-value
Cobalt, ug/L (median, IQR)	0.07 (0.05 – 0.25)	1.24 (0.62 – 2.83)	<0.001
Chromium, ug/L (median, IQR)	0.39 (0.29 – 0.62)	1.26 (0.68 – 2.69)	<0.001
Nickel, ug/L (median, IQR)	1.0 (0.48 – 2.0)	0.28 (0.18 – 0.53)	<0.001
Titanium, ug/L (median, IQR)	2.6 (2.1 – 6.0)	1.6 (1.48 – 2.13)	<0.001