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No Increased Risk of Knee Arthroplasty Failure in Patients With Positive Skin Patch Testing for Metal Hypersensitivity: A Matched Cohort Study



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ABSTRACT

Background: It is unclear whether a positive skin patch test for metal allergy in patients with skin hypersensitivity to metals is associated with an increased risk of total knee arthroplasty (TKA) failure. Our aim was to determine whether patients with a history of metal allergy who had a positive skin patch test (SPT+) had worse outcomes after primary TKA compared with those with a negative skin patch test and compared with controls.

Methods: Over 12 years, 127 patients underwent 161 TKA after skin patch testing (SPT; 56 were positive). Cases were matched by age, gender, body mass index, American Society of Anesthesiologists score, implant type, and implant manufacturer to 161 control knee arthroplasties without any prior history of metal allergy and no SPT. Median follow-up was 5.3 years. Differences in outcome measures were assessed between groups.

Results: Patients with a SPT+ to metal did not have a higher complication, reoperation, or revision rates compared with patients with a SPT– and matched controls. Survivorship free of revision at 5 years was 98.1% for SPT+; 100% for SPT–; 97.6% for SPT+ controls, 99.0% for SPT– controls. There was no statistically significant difference in postoperative pain between SPT+ and SPT– patients and matched controls.

Conclusion: This study was designed to evaluate the effect of metal hypersensitivity on TKA outcomes and the role of SPT in patients before TKA. In this study, a SPT+ for metals was of little practical value in predicting the midterm outcome after TKA and cannot be strongly recommended as a method to guide the selection of implant type.

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Each author certifies that his or her institution approved the reporting of this study and all investigations were conducted in conformity with ethical principles of research. The Mayo Clinic Institutional Review Board has approved this study, and consent from all patients was granted. This work was performed at Mayo Clinic Rochester, MN.

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Metal allergies have long been debated in the field of orthopedic surgery. Metals in contact with biological systems corrode and release ions which then form complexes with native proteins [1]. These metal-protein complexes are candidate antigens, and an association with orthopedic implant loosening, periprosthetic osteolysis, and failure has been suggested [1]. Metal hypersensitivity has also been shown to imitate chronic infections in total knee arthroplasties which is important to differentiate [2]. Up to 10% of the population at large may experience skin hypersensitivity to metals with the most common source of contact being jewelry [3]. Skin hypersensitivity to metals has been reported in 25% of patients with well-functioning arthroplasties and up to 60% with poorly functioning arthroplasties [2,4,5]. Whether cutaneous skin hypersensitivity identified preoperatively predisposes a

patient to problems with metallic orthopedic devices remains unclear. Previous authors have not found a causal relationship between cutaneous hypersensitivity to metal and implant failure [4].

In clinical practice, there are a substantial number of patients who present with a history of skin hypersensitivity to metals. As such, many have had skin patch testing (SPT) to determine their metal hypersensitivity. It is unclear whether a preoperative positive skin patch test (SPT+) for metal hypersensitivity should be interpreted as a true allergy to metals in orthopedic implants and if SPT+ influences the performance or survivorship after total knee arthroplasty (TKA). We designed a retrospective matched control study to determine whether a SPT+ is associated with increased complications, worse clinical outcomes, and decreased survivorship after primary TKA.

Materials and Methods

We reviewed all TKAs performed at 1 institution between 1997 and 2009. Within this period, 127 patients underwent 161 knee arthroplasties after SPT for a described history of metal allergy. These patients were initially identified by cross-referencing the Mayo Clinic total joint registry and the Mayo Clinic dermatology skin patch test database. The most common metal alloys used in orthopedic surgery are cobalt-chromium, stainless steel, and titanium-aluminum-vanadium alloys [6]. A SPT was considered positive if patient proved to be sensitive to one of the previously mentioned metal alloys commonly identified in knee arthroplasties [7]. Cases were matched by age, gender, body mass index, American Society of Anesthesiologists (ASA) score, implant type, and implant manufacturer to 161 control knee arthroplasties without any prior history of metal allergy and no SPT. Within the 161 knee arthroplasties (158 Total Knee Arthroplasties + 3 Unicompartmental Knee Arthroplasties), 56 knees had a SPT+, whereas 105 had a SPT-. Within those with a SPT+, 17 knees had a so-called hypoallergenic TKA (group 1a), whereas 39 cases were implanted with a standard TKA (group 1b; Fig. 1). We, therefore, had several groups for comparison (Fig. 1). SPT+ were compared to SPT- and SPT+ controls, SPT- were compared to SPT- controls, and within the SPT+ group, we had a subgroup that was implanted with a hypoallergenic TKA.

The median follow-up for the entire cohort was 5.3 yrs. (0.2–15.6). Eighty-one percent of the cohort was female with a mean age of 66.6 years (36.0–92.0) and a mean body mass index of 32.1 kg/m² (20.2–55.9; Table 1). Main outcomes included revision, reoperation, complications (with special emphasis on arthrofibrosis <90 degrees of flexion and instability), and pain and function assessed by the original Knee Society Score (KSS) [8]. Time points included

Table 1
Demographics of All Cases and All Controls.

Demographics	0-Control(N = 161)	1-Case(N = 161)	Total(N = 322)
Gender			
Female	130 (80.7)	130 (80.7)	260 (80.7)
Male	31 (19.3%)	31 (19.3%)	62 (19.3%)
Age at surgery			
N	161	161	322
Mean (SD)	66.7 (10.1)	66.6 (10.4)	66.6 (10.2)
Median	67.0	67.0	67.0
Q1, Q3	61.0, 74.0	61.0, 74.0	61.0, 74.0
Range	(40.0–89.0)	(36.0–92.0)	(36.0–92.0)
BMI			
N	161	161	322
Mean (SD)	32.1 (6.8)	32.2 (6.8)	32.1 (6.8)
Median	31.6	31.6	31.6
Q1, Q3	26.6, 35.4	27.0, 35.3	26.9, 35.4
Range	(20.2–55.9)	(20.4–55.4)	(20.2–55.9)
ASA score			
1	4 (2.5%)	4 (2.5%)	8 (2.5%)
2	102 (63.4)	102 (63.4)	204 (63.4)
3	55 (34.2%)	55 (34.2%)	110 (34.2)
Side			
Left	79 (49.1%)	77 (47.8%)	156 (48.4)
Right	82 (50.9%)	84 (52.2%)	166 (51.6)

BMI, body mass index; ASA, American Society of Anesthesiologists.

preoperative, postoperative (within 12 months of surgery), and last follow-up. Implant survivorship, reoperation, and complication rates were assessed using the Kaplan-Meier method, and between-group differences in these outcomes were evaluated using Cox proportional hazards regression; the robust variance estimate was used in the Cox models to properly account for bilateral involvement. Functional outcomes were assessed between subgroups and over time using linear regression in a generalized linear models framework using generalized estimating equations to account for the within-patient correlation due to bilateral involvement. The alpha level was set at 0.05 for statistical significance.

Results

Patients with a preoperative SPT+ to metals did not have a higher complication rate as compared to SPT- patients or compared to matched controls as shown in Table 2 for arthrofibrosis and for instability. There was a statistically significant difference in survivorship free from arthrofibrosis between SPT- and SPT- controls, with a lower survivorship seen in patients who carried a diagnosis of metal allergy but tested negative for it based on a SPT- results.

Patients with a preoperative SPT+ did not have a higher risk of reoperation or revision as compared to SPT- patients or to their matched controls, as shown in Table 3. Survivorship free of reoperation at 5 years was 96.3% (95% confidence interval [CI]: 91.4–100) for SPT+; 89.1% (95% CI: 82.7–96.0) for SPT-; 94.1% (95% CI: 87.7–100) for SPT+ control group and 94.2% (95% CI: 89.8–98.8) for SPT- control group (Fig. 2). Reoperation hazard ratio = 0.5, $P = .24$ for SPT+ versus SPT-; hazard ratio = 1.00, $P > .99$ for SPT+ versus matched controls; and hazard ratio = 1.9, $P = 0.16$ for SPT- versus matched controls.

Survivorship free of revision at 5 years was 98.1% (95% CI: 94.4–100) for SPT+; 100% for SPT-; 97.6% (95% CI: 93.1–100) for SPT+ controls and 99.0% (95% CI: 97.0–100) for SPT- controls (Fig. 3). Revision hazard ratio = 2.7, $P = .29$ for SPT+ versus SPT-; hazard ratio = 1.5, $P = .65$ for SPT+ versus matched controls; and hazard ratio = 0.9, $P = .95$ for SPT- versus matched controls (Table 3).

There was no statistically significant difference in postoperative pain between SPT+ and SPT- patients and matched controls. Pain

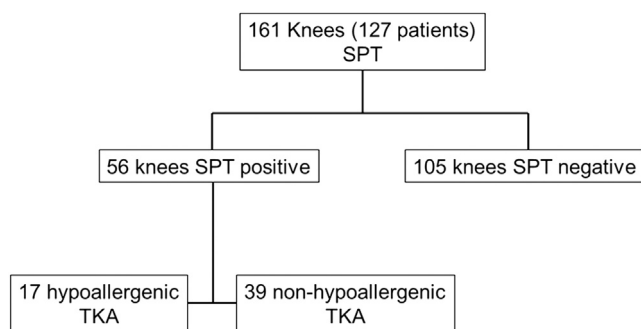


Fig. 1. Patient population, matched to 161 control knees with no history of SPT testing or skin hypersensitivity to metals. In addition, there are 2 hypoallergenic knees in the SPT negative group, not shown in the figure. SPT, skin patch test; TKA, total knee arthroplasty.

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