

1 **Total Knee Arthroplasty in Patients with Retention of Prior Hardware Material:**

2 **What is the Outcome?**

3

4 **Abstract**

5 **Background:** There is an information gap in literature regarding postoperative outcome of total
6 knee arthroplasty (TKA) in patients with hardware in-situ from the previous knee surgery. The
7 present study aims to evaluate impact of retained hardware on short-term outcome of TKA
8 patients.

9 **Methods:** Perioperative radiographs of patients who had undergone TKA between 2007 and
10 2012 were reviewed and patients in whom partial or complete retention of hardware was evident
11 after TKA were included. These patients were matched in 1 to 2 ratio based on age (+/- 2years),
12 gender, surgeon and year of surgery to a group of patients that underwent primary TKA without
13 hardware in the affected knee. The average follow up of these patients was 43.45 (range 12-
14 155.2) months. Complication rates were compared between the two groups using statistical tests
15 that took into account the matched data structure.

16 **Results:** We included a total of 55 cases and 110 controls. The incidence of complications was
17 higher, although not all statistically significant, in the case group. Only mechanical
18 complications were significantly different in the cases group (5.5% versus 0%, p=0.01). Time to
19 event analysis using the mixed-effects Cox model didn't show a statistically significant
20 difference between two groups for various outcomes.

21 **Conclusions:** Presence of retained hardware around the knee may predispose the patient to a
22 higher rate of complications particularly mechanical complications of the implant after TKA.
23 Further studies are required to investigate impact of retained hardware around the knee in
24 patients undergoing TKA.

25

26 **Keywords:** Arthroplasty, Replacement, Knee, perioperative complication, implant-related

27 infection, , Internal fixation of fracture

28

29 **Introduction**

30 Knee trauma associates with fractures, deformities and ligament injuries requires fixation
31 and reconstruction using hardware. Secondary or post-traumatic osteoarthritis (OA) among these
32 patients are common and 12% of patients undergoing TKA suffering from secondary OA (1).
33 When patients with hardware in their knees undergoing TKA, presence of hardware may cause
34 technical difficulty and ultimately increase the risk of postoperative complications (2,3).

35 If correct placement of prosthetic components is no possible, based on the surgeon’s
36 decision, all or part of the hardware will be removed during knee replacement. However, there is
37 a paucity of data about the impact of a retained hardware on risk of postoperative complications
38 following TKA. Therefore, we conducted this study to evaluate if hardware in-situ affects risk of
39 short-term complications in patients undergoing TKA.

40

41 **Methods**

42 We conducted a retrospective, case-control study in a single institution. Following
43 institutional review board approval, we queried our institutional joint replacement database to
44 identify patients underwent primary TKA between 2007 and 2012. A total of 5,397 procedures
45 were identified that had available preoperative and postoperative knee radiographs. We
46 retrospectively reviewed perioperative radiographs of these patients and identified those patients
47 in whom partial or total retention of hardware material was evident after TKA. Preoperative
48 radiographs were reviewed to verify that hardware placement was performed prior and not
49 during the TKA. We identified a total of 59 patients that had hardware in place before and after
50 the TKA. Four patients were excluded, one had prior infection after internal fixation and three

51 were lost to follow-up. A total of 55 patients were included that completed a minimum 12-month
52 follow up. Mean age of patients was 56.7 (range: 31.8 – 76.2) years and 62% (34/55) them were
53 male. The average follow up of these patients was 43.45 (range 12-155.2) months based on
54 office appointments records and phone interview with the patients at the time of study.

55 These 55 patients were matched in a 1 to 2 ratio to 110 patients without history of knee
56 surgery and hardware placement in the affected knee based on age (+/- 2 years), gender, surgeon,
57 and year of TKA. The control group consisted of 110 patients with a mean age of 57.6 (range:
58 35.0 – 77.3) years and 62% (68/110) of them were male. The average follow up of these patients
59 was 40.52 (range 12-86.2) months.

60 Of the patients who had prior surgery on the knee with hardware in-situ, a total of 24
61 (43.6%) had a history of fracture that required open reduction and internal fixation, 24 (43.6%)
62 had an osteotomy, and 7 (12.8%) had a knee soft tissue repair. The hardware was retained in the
63 tibia, femur and both tibia and femur in 36, 15 and 7 cases respectively.

64 All study patients were managed preoperatively based on our institutional protocol
65 regarding prophylactic antibiotic, venous thromboembolism prophylaxis and physical therapy.
66 All TKAs were performed through a medial parapatellar approach and hardware removal
67 through the same incision. No drain placed and all components of TKA were cemented.

68 Specific complications were recorded. These complications are among those evaluated
69 and included by the Complications Workgroup of the Knee Society (4). The recorded
70 complications and the definition for the different complications were as follows: 1) artrofibrosis
71 which was defined as compromised range of motion less than 90 degrees of flexion or flexion
72 contracture of greater than 15 degrees; 2) the need for manipulation under anesthesia; 3)

73 presence of knee pain which was defined as persistent pain after 1 month postoperatively; 4)
74 mechanical failure, which was defined by component malposition, instability and loosening; 7)
75 wound problems such as blisters, dehiscence or necrosis which did not require surgical procedure
76 and deep surgical site infection (SSI) which was the one specified by the Center for Disease
77 Control and Prevention (CDC) criteria (5).

78 Statistical analyses were performed using R3.3.1 (R Foundation for Statistical
79 Computing, Vienna, Austria). Because of the matched nature of the data, paired tests were
80 performed using the 'coxme' package for Cox proportional hazards models with mixed effects,
81 and the 'lmerTest' package which allows for logistic regression with mixed effects. In both cases,
82 the mixed effect model was used to control for the matched patient. P-values less than 0.5 were
83 considered to be statistically significant.

84

85 **Results**

86 Patients with partial or total retained hardware have a significantly higher incidence of
87 mechanical failure (n=3 (5.5%) versus 0, p=0.01) compared to patients without any hardware.
88 Although rate of arthrofibrosis, manipulation under anesthesia, SSI, revision for non-septic
89 complications of the implant, residual knee pain and wound complications were higher in the
90 patients with history of hardware placement in the affected knee, it was not statistically
91 significant (Table 1).

92 Time to event analysis using the mixed-effects Cox model didn't show a statistically
93 significant difference between two groups for various outcomes. The hazard ratio with their
94 associated confidence intervals and p-values demonstrated in Table 2.

95 **Discussion**

96 This study demonstrated that presence of hardware in-situ might increase risk of
97 mechanical complication of the knee implant after TKA. Overall, patients with hardware in-situ
98 had tendency to have a higher rate complication however, the difference was not statistically
99 significant. Previous studies mainly focused on impact of prior surgical intervention for
100 fractures, alignment procedures and trauma around the knee without reviewing impact of a
101 retained hardware (2, 6-11) while in the present study we focused on the impact of a retained
102 hardware on outcome of patients after TKA.

103 Overall success rate following TKA in post-traumatic arthritis has been reported to be
104 only 71% (6) and TKA after fixation of fracture around the knee might be associated with a high
105 rate of complication (7). Presence of hardware material around the knee and the underlying
106 diagnosis of post-traumatic osteoarthritis may predispose patients to a higher rate of
107 complications after TKA. The higher rate of complications in patients with hardware in-situ can
108 be due to various factors. Technical difficulty in patients who have had previous fractures around
109 the knee has been reported in literature (2). This in turn can lead to increased surgical times,
110 increased exposure and increased bleeding/transfusions which have been shown to increase risk
111 of infection (8,10,11). In our study, although rate of SSI was higher in the patients with retained
112 hardware, it was not statistically different from those without hardware in place. Impact of
113 previous placement of hardware around the knee on the rate of infection following TKA is
114 controversial. Klatte et al (12) evaluated 124 patients who underwent TKA after removal of
115 fixation devices and concluded that previously implanted osteosynthetic fixation devices does
116 not increase risk of knee infection. However, in another study by Suzuki et al (13), patients with

117 remnant hardware after open reduction and internal fixation had higher rate of infection
118 following TKA.

119 In our study we found a trend to a higher rate of arthrofibrosis in patients with hardware in-
120 situ although it was not statistically significant. Retained hardware can cause persistence of
121 inflammation and may interfere with normal tissue gliding in knee during range of motion. Local
122 trauma has been proposed to be associated with signals that lead to increased activity of
123 inflammatory factors like prostaglandin E2 and bone morphogenetic proteins as well as
124 differentiation of mesenchymal stem cells into osteoprogenitor cells which leading to tissue
125 ossification (14). Additionally, local inflammatory reaction could potentially cause fibroblast
126 proliferation and extracellular matrix. Both of these factors can promote metaplastic changes and
127 scar tissue formation (15). This could potentially contribute to a higher incidence of artrofibrosis
128 after TKA in patients with hardware in-situ.

129 This study has several limitations. It is s retrospective study that limits the collected data to
130 what is available in patients' charts. Our sample size is small and the study might be
131 underpowered to detect the difference between two groups regarding other complications.
132 Information regarding the time of hardware implantation is unavailable and therefore no analysis
133 can be performed regarding the effect of the time interval from implantation to TKA on the
134 complication rate. Additionally, patients were not matched by comorbidities and follow up time
135 was relatively short.

136 Despite these limitations, this study was able to show that retained hardware may
137 increase risk of mechanical complications of the knee prosthesis. Further studies are
138 recommended to evaluate whether or not hardware should be partially or completely removed.

139 Additionally, there should be research conducted towards evaluating if removal should be
140 performed in one or two stages and if additional cultures should be performed to evaluate
141 colonized implants prior to TKA. Given the possibility of a higher rate of complication in
142 patients with previously placed hardware in the affected knee, it is important to inform the
143 patient about the potential risks of the surgery and observe them more closely for the signs and
144 symptoms that may indicate a prompt action to reduce later complications.

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146 **References**

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