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Is Routine Hardware Removal Following Open Reduction Internal Fixation of Tarsometatarsal Joint Fracture/Dislocation Necessary?

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A R T I C L E I N F O

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A B S T R A C T

Open reduction internal fixation (ORIF) is an accepted treatment for displaced tarsometatarsal joint (TMTJ) fracture dislocations. In general, hardware is routinely removed after 4 months to allow restoration of joint motion and avoid complications of hardware failure. Because few studies report outcomes of TMTJ fractures with retained hardware, there is little consensus regarding the optimal time for hardware removal or if hardware retention leads to adverse outcomes. We retrospectively reviewed the radiographic outcomes of retained hardware after ORIF of TMTJ fractures/dislocations in 61 patients. The mean age at the time of operation was 37.3 ± 14.9 years. ORIF was performed with 3.5 fully threaded cortical screws. Assessment of clinical and radiographic results was performed at 2 weeks, 6 weeks, 3 months, 6 months, and 12 months after surgical treatment. Out of the 61 patients that were included in this study, only 2 demographic variables demonstrated a trend for an adverse outcome. Older age correlated with lost reduction and elevated body mass index correlated with hardware failure. The presence of diabetes was correlated with an increased risk of postoperative infection but not hardware failure. During our follow-up period there were 49 patients (80.3 %) without failure of fixation. In conclusion, our study suggests that routine removal of hardware following open reduction and internal fixation of Lisfranc injuries in patients may not be necessary.

Although fracture/dislocations at the tarsometatarsal joint (TMTJ) complex are rare injuries, with an incidence of 0.2% for all fractures (1), they are associated with significant long-term morbidity. TMTJ injuries predispose patients to an increased risk of future midfoot pain, limitation of function, posttraumatic arthritis, and deformity (1,4–11). Early recognition and appropriate treatment interventions can lessen the early onset of poor functional outcomes (2,3).

Two accepted treatments for TMTJ fracture/dislocations are open reduction internal fixation (ORIF) and primary arthrodesis (2,3,6,12–15). The benefits of primary arthrodesis over ORIF are improved functional outcomes and little need for routine hardware removal. Hardware removal has been a routine practice following ORIF of TMTJ fracture dislocations to allow restoration of joint mobility and avoid hardware failure. Because there is a lack of consensus, the decision to remove hardware is often guided by surgeon preference; however, some report routinely removed hardware without patient complaint of symptoms (7,15).

The primary aim of this study was to evaluate radiographic outcomes and report adverse events in patients who have undergone ORIF of TMTJ fracture/dislocation without routine hardware removal.

Patients and Methods

Approval of the study was granted by our Institutional Review Board. Patient charts were reviewed from Parkland Memorial Hospital, level 1 trauma center, and the University of Texas Southwestern Medical Center, tertiary academic health care center.

We performed a retrospective chart review of patients treated for TMTJ fracture/dislocations by two foot and ankle surgeons (MDV and GTL) between November 2007 and August 2013. Inclusion criteria were ORIF of a TMTJ fracture/dislocation and presentation to our facility less than 2 weeks from initial trauma and that all ORIF was performed with in two weeks of the initial injury as shown in Figure 1A-C. We identified of 61 patients that met the inclusion criteria for this study. Exclusion criteria were primary arthrodesis for a TMTJ injury, history or presence of Charcot neuroarthropathy, active infection, or

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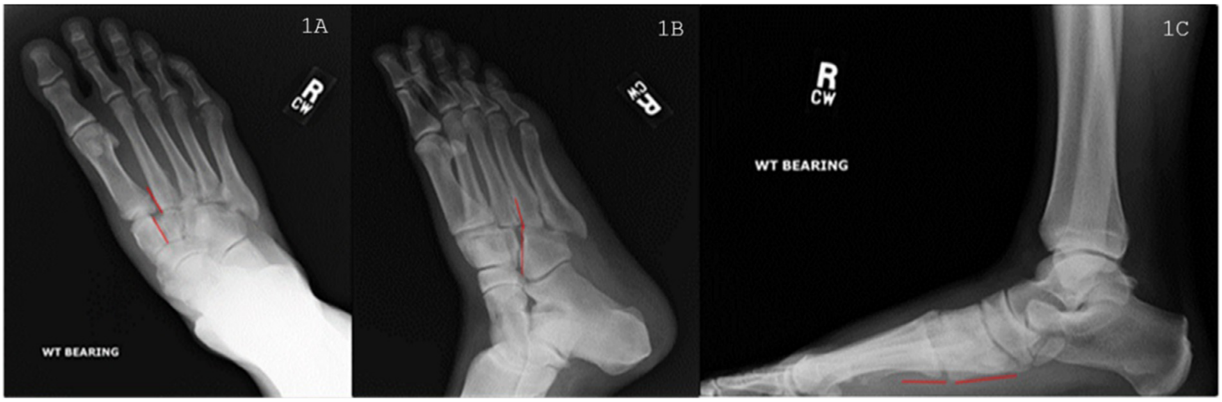

Fig. 1A. AP view right foot demonstrating lateral translation of the second metatarsal base on the second cuneiform with diastasis at the first cuneiform and second metatarsal base articulation. Fig 1B. Oblique view of the foot demonstrating fourth metatarsal cuboid incongruity. Fig 1C. demonstrates first metatarsal and cuneiform incongruity.

pathologic fracture. We recorded patient demographics, mechanism of injury, classification of injury, body mass index (BMI), history of diabetes, postoperative management including weightbearing status and immobilization devices, and use of smoking tobacco.

We recorded adverse events associated with ORIF of Lisfranc injuries. Adverse events were defined as presence of deep vein thrombosis (DVT), hardware failure, loss of reduction, wound dehiscence, unplanned return to the operating room, and surgical site infection. Patients requiring an additional surgery involving the repaired Lisfranc complex were also recorded as a complication. Indications for ORIF for TMTJ fracture dislocations were unstable fracture dislocations with greater than 1 mm of displacement of the medial column line and/or loss of alignment between the second metatarsal and middle cuneiform and/or loss of alignment between the fourth metatarsal and cuboid on standard radiographs (Fig. 1). For subtle ligamentous TMTJ injuries, fluoroscopic abduction stress tests or computed tomography scans were performed to identify widening of the medial cuneiform and second metatarsal base compared with the contralateral foot. The TMTJ injuries were classified using the Myerson classification system as shown in Fig. 2 (6).

A standard open approach was used and the reduction of the fracture was based on plain radiographs or intraoperative fluoroscopy of the contralateral foot. All patients had screw fixation for injuries involving the first through third TMTJs and percutaneous Kirschner wire fixation for injuries involving the fourth and fifth TMTJs. Postoperatively, limbs were protected in a posterior splint with a lateral stirrup, kept non-weightbearing for 2 weeks, followed by immobilization in a short leg cast for an additional 4 weeks. At 6 weeks, patients were allowed to weightbear in a protective boot. Plain radiographs were routinely performed at 2 weeks, 6 weeks, 3 months, 6 months, and 1 year postoperatively. Hardware failure was defined as screws that no longer maintained reduction of the TMTJ, screw breakage, or movement of screws indicated by radiographic peri-implant radiolucencies.

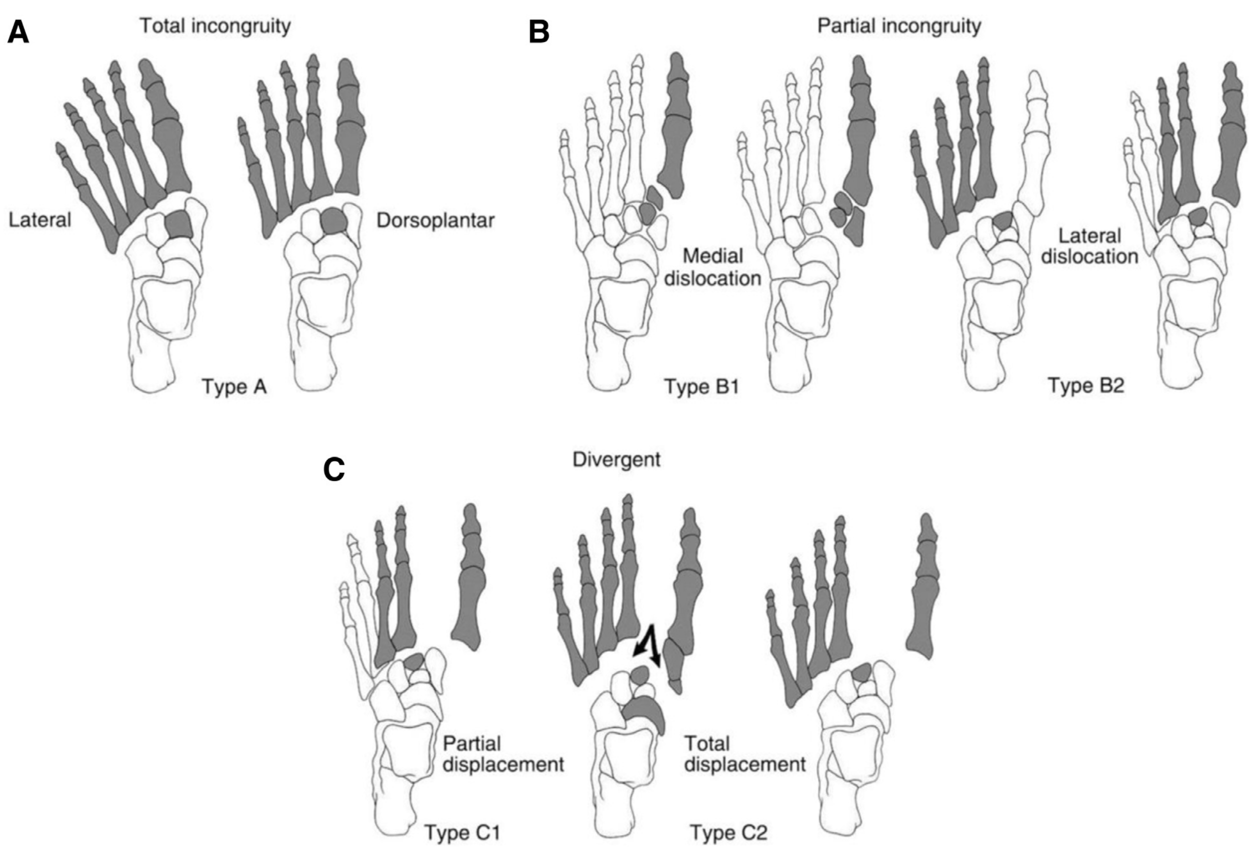

Fig. 2. Total incongruity (A) can be either medially or laterally displaced. Partial incongruity (B), either medial (left) or lateral (right). Divergent displacement (C), either partial (left) or total (right) (6). Used with permission.

Table 1
Correlation coefficients of adverse events based on subject demographic presentation (N = 61)

Variable	Second Surgery	Infection	Deep Vein Thrombosis	Wound	Reduction/ Healing Issue	Hardware Issue	Any Postoperative Adverse Issue
Age (r_{pb})	0.16; p = .21	0.01; p = .95	0.14; p = .27	0.03; p = .84	0.37; p = .001	0.14; p = .31	0.36; p = .008
Sex (φ)	0.06; p = .74	0.07; p = .55	0.16; p = .25	0.07; p = 1.00	0.10; p = .70	0.23; p = .14	0.13; p = .40
BMI (r_{pb})	0.02; p = .87	0.13; p = .34	0.07; p = .59	-0.18; p = .18	0.0; p = .98	0.24; p = .06	0.07; p = .59
Diabetes (φ)	0.12; p = .44	0.37; p = .04	0.11; p = 1.00	0.11; p = 1.00	0.22, p = .13	0.22; p = .13	0.77; p <.0001
Smoking (φ)	0.01; p = 1.00	0.12; p = 1.00	0.15; p = .56	0.36; p = .06	0.03; p = 1.00	0.14; p = .43	0.04; p = 1.00

Abbreviation: BMI, body mass index.

Table 2
Significant complications based on demographics (N = 61)

	Age, p	Sex, p	Body Mass Index, p	Presence of Diabetes, p	History of Smoking, p
Returned to surgery	<.001	<.001	<.001	.82	<.001
Postoperative infection	<.001	<.001	<.001	.05	<.001
Deep vein thrombosis	<.001	<.001	<.001	.014	<.001
Wound complication	<.001	<.001	<.001	.014	<.001
Loss of reduction	<.001	.016	<.001	.06	.17
Hardware failure	<.001	.53	<.001	.038	.53

Data Analysis

Six adverse events were evaluated: unplanned return to the operating room, surgical site infection, deep vein thrombosis, wound complications, loss of reduction/bone healing complications, and hardware complications (hardware breakage, loosening, pain). These adverse events were compared to independent patient variables that included age, sex, body mass index, smoking history, and the presence of diabetes.

Phi (φ) coefficients of association were calculated to determine the correlation when both variables were dichotomous. These included the correlation between adverse outcomes and the binary circumstances of sex, smoking, and the presence, or lack of, diabetes. For analysis in which the demographic variables were continuous (age and BMI), a point biserial coefficient (r_{pb}) was computed to evaluate the degree of correlation. Correlation coefficients lie on a continuum of −1.0 to +1.0, with a -1.0 value representing a perfect inverse relationship, 0 indicating no correlation, and +1.0 suggesting a perfect positive relationship. The strength of correlation values is classified as little if 0.00 to 0.25, low correlation if in the range of 0.26 to 0.49, moderate if in the range of 0.50 to 0.69, high if in the range of 0.70 to 0.89, and very high if greater than 0.90. Variables (age, elevated BMI, and the presence of diabetes) that demonstrated a significant relationship with at least 1 of the adverse outcomes were included in multivariate logistic regression analysis (Table 1).

Correlation coefficients were determined with the assistance of an online statistical package (www.vassarstats.net). Correlation coefficients were confirmed and logistical regression values were computed by a Microsoft Excel 2010 Data Analysis package (Microsoft, Redmond, WA). An α level of 0.05 was used for all correlation analyses.

A nonparametric Mann-Whitney *U* test was used to evaluate if there was a significant difference between both continuous and noncontinuous demographic outcome-independent variables (age, sex, BMI, diabetes, and smoking) and adverse outcome-dependent variables because the subject data failed the Shapiro-Wilk distribution normality test (Table 2). SigmaPlot 12 software (Systat Software, Inc., San Jose, CA) was used for all statistical analysis.

Results

The study population consisted of 41 males and 20 females, with a mean age of 37.3 ± 14.9 years and a mean BMI of 29.6 ± 5.5. The mean time to surgery was 12 ± 11.5 days. The mean duration of follow-up was 7.6 months. Twenty-one percent of the subjects had diabetes, and 29% had a history of tobacco use (Table 3). Of the 61 patients, there were 7 type A injuries, 7 type B1 injuries, 41 type B2 injuries, 3 type C1 injuries, and 4 type C2 injuries. Of the 7 total TMTJ ORIF patients that lost reduction, 4 were type B2 injuries, 2 type C2 injuries, and 1 type A injury as shown in Fig. 2.

Though strength of correlation was low, only 2 demographic variables demonstrated a trend for correlation with an adverse event as shown in Table 3. We found that patients greater than 37 years of age (older age group) as a continuous variable (r_{pb} = 0.37, p = .001) correlated with lost reduction or delay in wound healing or dehiscence. The presence of diabetes correlated with an increased risk for postoperative infection (φ = 0.37, p = .04). The rate of infection was 3.3% among all patients and 15% among patients with diabetes. The infections occurred in the postoperative period and were not related to hardware. The combination of older age, elevated BMI, and diabetes accounted for 45% of the postoperative surgical complications (r^2 = 0.45). As shown in Table 4, the odds ratio for any postoperative surgical complication (Infection, DVT, hardware failure, wound, loss of reduction and return to OR) was 2.3 (95% CI, 0.6 to 8.5, p = .33) for diabetics, 1.6 (95% CI = 0.41 to 6.3, p = .74) for smokers, and 1.2 (95 CI, 0.41 − 3.6, p = .79) for female subjects. Adverse events were significantly more likely if the patient was older, female gender, BMI greater than 30, history of diabetes, or tobacco use.

Discussion

ORIF of TMTJ injuries is commonly performed to stabilize the midfoot and thereby reduce deformity and early onset of posttraumatic arthritis.

Table 3
Demographic variables (N = 61 patients)

Variable	Value
Age, y, mean ± SD	37.3 ± 14.9
Sex, male/female, n (%)	41 (67.2)/20 (32.8)
Race/ethnicity, n/N (%)	
Hispanic	27 (44.3)
White	26 (42.6)
Black	7 (11.5)
Unknown	1 (1.6)
Body mass index, mean ± SD	29.6 ± 5.5
Diabetes, n/N (%)	13/61 (21)
Smoking, n/N (%)	17/59 (29); 41, no; 1, patch, history, or current; 2, unknown
Time to surgery, d, mean ± SD	12 ± 11.7, excluding 3 subjects with >6 mo
Return to surgery, n/N (%)	11/61 (18)
Infection, n/N (%)	2/61 (3.3)
Deep vein thrombosis, n/N (%)	3/61 (5)
Wound, n/N (%)	3/61 (5)
Loss of reduction/healing, n	7, reduction lost; 3, autofusion, arthritis, or nonunion; 9, lost to follow-up
Hardware issue, n	4, hardware failure; 3, hardware pain but no failure; 3, implant lucency; 9, lost to follow-up

Table 4
Demographic bivariate analysis

Complication	Diabetes (n = 13), n (%)	No Diabetes (n = 48), n (%)	Male Sex (n = 41), n (%)	Female Sex (n = 20), n (%)	Age <37 y (n = 35), n (%)	Age >37 y (n = 26), n (%)	BMI <30 (n = 34), n (%)	BMI >30 (n = 27), n (%)	OR (95% CI); *p* value
Any complication	7 (53.8)	22 (45.8)	16 (39)	13 (65)	10 (28.6)	19 (73.1)	12 (35.3)	17 (63)	2.261 (0.6335 to 7.368); .3354
Return to surgery	1 (7.7)	10 (20.8)	8 (19.5)	3 (15)	4 (11.4)	7 (26.9)	6 (17.6)	5 (18.5)	0.3545 (0.03013 to 2.237); 0.4384
Infection	2 (15.4)	0 (0)	1 (2.4)	1 (5)	1 (2.8)	1 (3.8)	0 (0)	2 (7.4)	Unable to calculate OR; .0361
Deep vein thrombosis	0 (0)	3 (6.3)	1 (2.4)	2 (10)	0 (0)	3 (11.5)	1 (2.9)	2 (7.4)	Unable to calculate OR; .99
Wounds	0 (0)	3 (6.3)	2 (4.9)	1 (5)	2 (5.7)	1 (3.8)	3 (8.8)	0 (0)	Unable to calculate OR; .99
Hardware complications	4 (30.8)	6 (12.5)	4 (9.8)	6 (30)	3 (8.7)	7 (26.9)	2 (5.9)	8 (29.6)	

Abbreviations: BMI, body mass index; CI, confidence interval; OR, odds ratio.

Routine removal of hardware is commonly performed with the intention of restoring TMTJ range of motion and return the patient to preinjury function. However, favorable clinical results following primary arthrodesis of TMTJ dislocations may suggest that loss of TMTJ motion may not negatively effect patient functional outcomes (13). In a cadaver study, Ouzounian and Shereff (16) demonstrate that the range of motion was 5° for medial cuneiform-first metatarsal, 1.8° for middle cuneiform-second metatarsal, 4.2° for lateral cuneiform-third metatarsal, 20.7° for cuboid-fourth metatarsal, and 19.2° for cuboid-fifth metatarsal. Outcomes of TMTJ dislocations support primary arthrodesis as a favorable treatment compared with ORIF, averting the need for late-stage arthrodesis for posttraumatic arthritis and routine hardware removal (2,13).

Ly et al (13) reported 16 of 20 patients having screw removal after ORIF of the Lisfranc joint at approximately 6.75 months after surgery. In their study, complications of lost reduction, degenerative joint disease and increasing deformity were noted radiographically after hardware removal. In our study, we identified 7 of 61 patients (11.5%) who had loss of reduction with hardware retained compared to Ly et al (13) with 15 of 20 (75%) after hardware was removed. This high rate of loss of reduction may be due poor stability following ORIF of primarily ligamentous TMTJ injuries included in their series.

In a previous study reported by Hennings et al (2), patients who were in the primary ORIF group had hardware removed at 3 to 4 months postoperatively according to their study protocol. They also had 1 patient with broken hardware at 3 months, compared with our patient group that had 4 hardware failures. However, our patient group began weightbearing at 6 weeks protected in a boot and their patients began gradual weightbearing in a boot after 3 months. Despite earlier weightbearing, our hardware failure rate was seen only in 4 of 51 patients who were seen at follow-up.

This is the first study reporting complications (adverse events) relating to hardware retention following ORIF of TMTJ fracture/dislocations. Of 61 patients, 7 (11.5%) had loss of reduction, 4 (6.6%) patients had hardware failure, and 3 (4.9%) patients reported pain from prominent hardware. Only 2 demographic variables demonstrated a moderate correlation with an adverse event: older age correlated with lost reduction and elevated BMI was correlated with hardware failure.

We had four hardware failures in 61 patients all in the Type B2 category. During our follow-up period, there were 49 (80.3%) patients without hardware complications. At a mean follow-up period of nearly 8 months, this study demonstrates that retention of transarticular screw fixation of TMTJ fracture/dislocations is generally well tolerated in patients. Arntz et al (7) reported a cohort of 40 patients treated with ORIF and routine screw removal. Two of their patients did not have their screws removed due to temporary loss to follow-up. The authors did not report adverse outcomes for these patients and included these 2 patients in their analysis. There were no reports of increased complications in their screw removal group. Conversely, our study saw a higher rate of hardware complications in the non-diabetic patient group with a higher BMI.

We recognize several limitations of our study. The study was based on a retrospective chart review without a control group for comparison. Second, 14 of the 61 patients (23%) had less than 90 days of follow-up. This could affect the correlative results of this study. Although diabetes mellitus was a significant risk factor for adverse events, we did not report on the presence of comorbidities, such as peripheral neuropathy, peripheral arterial disease, duration of diabetes, glycemic control, or insulin use, as potential causes of adverse outcomes. Finally, because this study was underpowered to detect statistically significant differences between groups, the possibility of type 2 error exists.

We found that patients with a BMI greater than 30, without diabetes, greater than 37 years of age, and tobacco use had complications associated with retained hardware at a higher rate, although strength of correlation was low. Overall, the rate of hardware complications was 16.4% in the patients who were available for follow-up. The radiographic outcome and the complication rates in our case series are comparable with ORIF series reported in literature. Our study suggests that routine hardware removal following ORIF of TMTJ fractures may not be necessary as retained hardware appears to be well tolerated in our patient series. Future studies may examine the economic impact of a return to the operating room for TMTJ hardware removal and associated direct and indirect costs.

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