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Tibiotalocalcaneal Arthrodesis Using Retrograde Intramedullary Nail Fixation: Comparison of Patients With and Without Diabetes Mellitus

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ABSTRACT

Retrograde intramedullary nailing for tibiotalocalcaneal arthrodesis is a salvage procedure reserved for severe cases of deformity. The aim of the present study was to compare the outcomes of this technique in patients with and without diabetes mellitus (DM). A total of 61 patients with and 56 without DM underwent retrograde intramedullary nailing and had a minimum follow-up period of 12 months. The overall incidence of complication was 45.2%; however, the overall incidence of complications between those with and without DM was not significantly different (odds ratio [OR] 0.79, 95% confidence interval [CI] 0.38 to 1.65, $p = .54$). Patients with DM had a significantly greater rate of superficial infections (OR 8.3, 95% CI 1.01 to 68.67, $p = .03$). However, no difference was seen in the rate of deep infection (OR 0.90, 95% CI 0.34 to 2.46, $p = .83$) or noninfectious complications (OR 0.50, 95% CI 0.23 to 1.13, $p = .09$). Successful limb salvage was achieved for 96.8% of the patients with DM and 94.7% of those without DM ($p = .66$). A femoral head allograft was used in 32 (27.4%) of 117 patients to substitute for an osseous void. Of the 32 patients who required a femoral head allograft, 21 (67.7%) experienced a complication compared with 32 (37.6%) of 85 patients who did not require a femoral head allograft (OR 3.16, 95% CI 1.35 to 7.41, $p = .008$). The incidence of patient satisfaction was 80% for patients with DM and 72% for those without DM ($p = .36$). Despite a high incidence of complications, limb salvage was accomplished in approximately 95% of patients with complicated deformities. Four patients (6.56%) with DM experienced a tibia fracture; therefore, we now routinely use a 300-mm-long nail for this reconstruction.

Severe hindfoot and ankle deformity can be physically and mentally debilitating for patients. Various etiologies, such as arthritis of the subtalar and ankle joints (whether degenerative, inflammatory, or posttraumatic), Charcot neuroarthropathy (CN), DM neuropathy of other etiology, failed ankle and/or hindfoot arthrodesis, failed total ankle arthroplasty, acquired or congenital rigid equinovarus deformities, and avascular necrosis of the talus, can result in deformity and impairment that could potentially require tibiotalocalcaneal arthrodesis (TTCA). Various methods have been used to stabilize an ankle/hindfoot arthrodesis, including plates, screws, external fixation, and intramedullary nails. The contraindications specific to using the intramedullary nail (IMN) technique include active infection, severe angular deformity of the distal tibia, severe osteoporosis, and an intact subtalar joint (1). TTCA has been used as a method for limb salvage to avoid major amputation, in particular, in diabetic patients with lower extremity complications (2–9). This technique has gained popularity over the years, in part owing to the increased rigidity of the construct compared with that of other fixation techniques. A construct of greater rigidity allows maintenance of proper alignment after correction. Multiple studies have shown biomechanically superior bending and torsional properties with the IMN compared with lag screws (10–12). Successful limb salvage has been reported using retrograde intramedullary nailing; however, the procedure can be fraught with many complications, such as nonunion rates ranging from 0% to 71% (2,3,5,7–9,13,14). A preliminary study of 40 patients from our institution demonstrated significant improvement in the American Orthopaedic Foot and Ankle

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Society scores in patients with and without diabetes mellitus (DM), despite high complication rates in both groups (14). The purpose of the present study was to expand the findings of the previous study and evaluate the success of this technique as a limb salvage procedure for severe hindfoot and ankle deformity, comparing patients with and without DM. Another goal of our study was to report on the lessons learned as a result of our ongoing experience with TTCA.

Patients and Methods

The investigational review board at our medical center designated our study as an exempt study. We reviewed the foot and ankle surgical database of the senior author (D.K.W.), searching for patients who had undergone arthrodesis of the ankle and hindfoot. A comprehensive foot and ankle registry was created in our division in January 2005, and every surgical patient was prospectively entered at surgery. Demographic data and the International Classification of Diseases, Ninth Revision (ICD-9) diagnosis codes (arthritis of the ankle and foot, codes 715.7 and 716.7; CN, code 713.5; and deformity of the ankle or foot, code 736.7) and Current Procedural Terminology codes (codes 27870 [ankle arthrodesis], 28705 [pantalar arthrodesis], 28715 [triple arthrodesis], and 28725 [subtalar arthrodesis]) were entered into the spreadsheet (15,16). Postoperative complications were recorded prospectively in the comprehensive foot and ankle registry by categorically denoting the absence (code 0) or presence (code 1) of specific complications. Patients who underwent major arthrodesis were identified from the comprehensive foot and ankle registry, and the electronic medical records and digital radiographs were reviewed. All the procedures and postoperative follow-up evaluations were performed by the senior surgeon (D.K.W.) from January 1, 2005 until June 30, 2013.

After identifying the patients from the registry, data were extracted from the review of the electronic medical records and digital radiographs by one of us (B.R.M.). The following 3 retrograde intramedullary nailing systems were used: T2 Ankle Arthrodesis Nail (Stryker, Mahwah, NJ), Trigen Hindfoot Fusion Nail (Smith and Nephew, Memphis, TN), Versa Nail (Depuy Synthes, Warsaw, IN). The T2 Ankle Arthrodesis Nail (Stryker) was used exclusively for the last 77 reconstructions because of our preference for a 5° valgus nail. The primary indications for surgery are listed in Table 1.

Postoperatively, the patients were generally seen at 1, 3, 6, and 12 weeks and subsequently at 3-month intervals. After 1 year, the patients were either seen every 6 months or annually depending on outcome. The postoperative protocol was standardized for patients according to the presence or absence of neuropathy. Patients with neuropathy were placed in a short-leg non-weightbearing cast for 12 weeks. Patients without neuropathy were placed in a short-leg non-weightbearing cast for 6 weeks, followed by a short-leg weightbearing cast or controlled ankle motion boot for an additional 6 weeks. All patients, regardless of the presence or absence of neuropathy, were eventually transitioned to removable walking boots until radiographic evidence of healing was verified. Those patients with DM were subsequently placed in a brace (molded ankle foot orthosis, double upright brace, or Charcot restraint orthotic walker) for ≥12 months postoperatively. The American Orthopaedic Foot and Ankle Society ankle hindfoot scores were also calculated at the final follow-up visit (17,18). During each postoperative visit, anteroposterior, lateral, and oblique radiographs were evaluated for osseous healing or manifestation of complications.

The present study included a consecutive series of 117 patients with a minimum follow-up duration of 52 (range 52 to 403) weeks. All the patients were >18 years old. During the study period, 119 patients underwent surgery, but 2 did not have the requisite minimum follow-up period. One patient died of a myocardial infarction 10 weeks postoperatively, and 1 patient relocated 13 weeks after surgery. At their last follow-up evaluation, no complications were observed; however, they were excluded from the present study. The demographic data, including gender, age, body mass index, tobacco use, presence of DM neuropathy, presence of DM, presence of CN, length of surgery, length of follow-up, ambulatory status, need for ongoing bracing, postoperative infection, presence of previous ulceration, need for additional surgery, nonunion, and presence of DM arterial disease, were extracted from the electronic medical records. We also recorded the preoperative laboratory values, including fasting glucose, creatinine, and hemoglobin. Patients with DM or DM neuropathy also had the hemoglobin A1c measured within 1 month of surgery. Peripheral neuropathy was defined as a Michigan Neuropathy Screening Index score of ≥2.5 (19). Patients with abnormal findings on a pedal pulse examination underwent measurement of the ankle brachial index. Peripheral arterial disease was considered present if the ankle brachial index was <0.9 (20).

Table 1
Indications for surgery (N = 117 patients)

Indications for Surgery	Patients With DM (n = 61; 52.14)	Patients Without DM (n = 56; 47.86)
Charcot neuroarthropathy	44 (72.13)	7 (12.5)
Osteoarthritis of ankle and subtalar joints	8 (13.12)	10 (17.86)
Traumatic arthritis	6 (9.84)	12 (21.43)
Acquired equinovarus deformity	0	9 (16.07)
Failed total ankle replacement	1 (1.64)	2 (3.57)
Revision arthrodesis	2 (3.28)	11 (19.64)
Avascular necrosis of the talus	0	5 (8.93)

Abbreviation: DM, diabetes mellitus.
Data presented as n (%).

Table 2
Demographic and preoperative variables (N = 117 patients)

Variable	DM (n = 61)	No DM (n = 56)	*p* Value
Age (y)	59.4 ± 12.3	56.9 ± 12.8	.2831
BMI (kg/m^2)	32.7 ± 8.0	32.2 ± 6.01	.7310
Charcot neuroarthropathy	44 (72.1)	7 (12.5)	<.0001
DM			
Type 1	12 (19.7)	NA	NA
Type 2	49 (80.3)		
Insulin use	39 (66.9)	NA	NA
Diabetes duration (y)	18.75 ± 13.2	NA	NA
Male gender	31 (50.8)	25 (45.5)	.5637
Peripheral neuropathy	58 (95.1)	27 (48.2)	<.0001
Peripheral arterial disease	12 (19.7)	1 (1.8)	.0023
History of foot ulcer	24 (39.3)	14 (25.0)	.0979
Renal disease (creatinine >1.4 mg/dL)	21 (34.4)	2 (3.6)	<.0001
Rheumatoid arthritis	3 (4.9)	4 (7.1)	.7083
Tobacco use			.1174
0 (never used)	35 (57.4)	38 (67.9)	
1 (current)	17 (27.9)	16 (28.6)	
2 (former)	9 (14.8)	2 (3.6)	
History of solid organ transplantation	9 (14.75)	0	.0030
Previous surgery			.4504
0	26 (42.62)	20 (35.71)	
1	34 (55.74)	36 (64.29)	
3	1 (1.64)	0	
Serum creatinine (mg/dL)	1.1 ± 0.5	0.9 ± 0.4	.0008*
Fasting glucose (mg/dL)	153.2 ± 71.5	95.8 ± 13.0	<.0001
HbA1c (%)	6.9 ± 1.7	5.8 ± 0.3	.0094*
Hemoglobin	12.4 ± 1.9	13.4 ± 1.6	.0067
ASA class			<.0001
1	0	1 (1.82)	
2	3 (5.00)	23 (41.82)	
3	55 (91.67)	31 (56.36)	
4	2 (3.33)	0	

Abbreviations: ASA, American Society of Anesthesiologists; BMI, body mass index; DM, diabetes mellitus; HbA1c, hemoglobin A1c; NA, not applicable.
Data presented as mean ± standard deviation or n (%).
* Wilcoxon Mann-Whitney test.

The analyzed outcomes included infectious and noninfectious complications. Superficial infections were defined as those treated with outpatient local wound care and oral antibiotics (20). Deep infections were defined as those that required hospital admission for treatment, intravenous antibiotics, and/or surgical debridement (20). Noninfectious complications included nonunion, the need for symptomatic hardware removal, and postoperative tibia fractures. Radiography was routinely used to assess for osseous union. If osseous union was not able to be assessed using radiography (owing to hardware considerations), computed tomography was performed to more accurately assess union. Patients who complained of pain at 6 months with intact hardware also underwent computed tomography. Union was defined as ≥50% osseous fusion of the ankle joint as seen on the radiographs or computed tomography scan. Additionally, nonunion was defined as failure to achieve osseous fusion by the 12-month follow-up evaluation or catastrophic hardware failure. An infected nonunion was considered an infectious complication rather than a noninfectious complication. An overall complication rate was determined by combining the infectious and noninfectious complications. Limb salvage was defined as preservation of the ankle joint, which equated to avoiding transtibial amputation.

Descriptive statistics are summarized as frequencies and percentages for categorical data or as the mean ± standard deviation or median and interquartile range for normally or non-normally distributed continuous data, as appropriate. Examination of normal distribution assumption for continuous data was determined using Q–Q plots and histograms. Pearson's chi-square or Fisher's exact test, as appropriate, was used to compare the frequency distribution of the categorical variables between the groups. A 2-sample *t* test or Wilcoxon Mann-Whitney test was performed to determine the differences between groups for the normally or non-normally distributed continuous data, respectively. Univariate logistic regression analysis was applied to assess the strength of the association between the predictor variable (DM) and the dichotomous outcome of interest (superficial infection, deep infection, infectious complication, noninfectious complication, and overall complication). The magnitude of associations between the potential predictor variables and outcome was quantified using the odds ratio (OR) and corresponding 95% confidence interval (CI). All tests were 2 sided, and the significance level was set to $p = .05$. All analyses were conducted using SAS, version