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Tibiototalcaneal Arthrodesis Utilizing a Titanium Intramedullary Nail With an Internal Pseudoelastic Nitinol Compression Element: A Retrospective Case Series of 33 Patients

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ABSTRACT

Nitinol has been shown to generate durable compression under loading via pseudoelastic shape memory. The purpose of this study was to evaluate the effectiveness of a hindfoot arthrodesis nail with an internal pseudoelastic nitinol compression element. Patients who had undergone tibiototalcaneal arthrodesis from 2013 to 2016 were identified at 2 tertiary referral centers (12-week follow-up minimum). Patients managed with a tibiototalcaneal nail with an internal nitinol compression element were identified for review. Sagittal computed tomographic scan reformats were reviewed to calculate a percentage of joint surface bony union. Intraoperative and postoperative radiographs were compared to calculate postoperative screw position change generated by the nitinol element, a surrogate for postoperative unloading of compressive forces. Thirty-three patients were included in analysis and 81% of patients had successful union of both tibiotalar and subtalar joints. Overall, 90% of all arthrodesis surfaces united. The union rate of arthrodesis surfaces among patients without Charcot osteoarthropathy was 94%. A history of Charcot was identified as a risk factor for subtalar nonunion ($p = .04$) and was associated with less complete computed tomography-based tibiotalar union: 94% versus 71% ($p < .01$). The posterior-to-anterior screw translated an average of 3.9 mm proximally relative to the rigid portion of the nail from intraoperative to initial postoperative radiographs ($p < .0001$). High rates of computed tomography-confirmed union were demonstrated in the face of challenging clinical scenarios. Shortening of the pseudoelastic nitinol element occurs early in the postoperative period, indicating continued unloading of the nitinol compression element through the arthrodesis sites after initial implantation.

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Tibiototalcaneal (TTC) arthrodesis using a retrograde intramedullary nail is an increasingly common procedure used for end-stage hindfoot and ankle pathology. Current indications include adjacent tibiotalar and subtalar joint arthritis, severe hindfoot deformity, talar osteonecrosis, inflammatory arthritis (e.g., rheumatoid arthritis), failed total ankle arthroplasty, severe pilon fractures, and Charcot osteoarthropathy (1–4). Devries et al (5) estimate that salvage procedures using TTC arthrodesis are successful in avoiding amputation approximately 88% of the time with a small minority not experiencing pain relief or functional improvement. Because satisfactory outcomes rely on 2 joint

surfaces fusing in an often complex and medically comorbid patient population, nonunion is often a cause for poor outcomes. Known risk factors for nonunion include the use of bulk femoral head allograft for bone defect reconstruction and a history of diabetes mellitus (6,7). A wide range of TTC nonunion rates, ranging from 3% to 43% (mean, 13%), have been reported in the literature, highlighting the heterogeneity of patients treated and techniques used, particularly when allograft femoral head is required to reconstruct bony defects (2,4,8–11).

To facilitate bony union at an arthrodesis site, bony surface area available for fusion, construct stability, and compression across an arthrodesis site must be optimized. The heterogeneity of reported nonunion rates may stem from differences in the construct stiffness and compression generated with other TTC arthrodesis implants. With regard to construct stability, 2 cadaveric biomechanical studies have shown that intramedullary nails are comparable in stability to blade plate and screw constructs and Ilizarov frames (12,13). Two separate cadaveric studies evaluated the stability of lateral-to-medial versus posterior-to-anterior (PA) calcaneal screws, concluding that PA

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interlocking screws facilitate a more stable construct, resisting both dorsiflexion and rotational stresses with superior performance (14,15). Additionally, Mückley et al (16) demonstrated that intramedullary nails used in compression mode had greater primary stiffness than uncompressed nails. In a recently published retrospective review comparing uncompressed and compressed nails, a dramatically lower rate of TTC nonunion was observed in the cohort treated with compressed nails (43% vs 21%, respectively), although these nonunion rates are much higher than those reported by other authors (10). Compression generated with modern second-generation TTC nails may dissipate with time, however, theoretically caused by settling of the arthrodesis surfaces and bone resorption during the early phase of bone healing (17). In a cadaveric biomechanical study published in 2010, standard intramedullary devices were found to generate 90% less load after 1 mm of simulated bone resorption at the arthrodesis surface (17). A stable TTC nail that maintains compression may improve union rates for TTC arthrodesis.

To date, no clinical series has been published on an internal implant with the ability to maintain compression across a TTC arthrodesis after surgical implantation. The DynaNail® (Medshape Solutions, Inc., Atlanta, GA) has an internal shape memory nickel titanium alloy (nitinol) element designed to generate sustained compression in addition to the initial compression introduced during implant placement. Finite element analysis of this device has demonstrated a true pseudoelastic stress plateau between 0.5% and 4.5% strain that rebounds with maintenance of pseudoelastic potential despite reloading of the implant during a simulated gait cycle (18). Simulated gait load testing also demonstrates that the nitinol element-mediated compression remains essentially constant during loading, because the vast majority of the axial compressive force during gait is transferred to the bone through the rigid portion of the nail, allowing for load sharing during load bearing (18). This sustained compression, not seen with other modern hindfoot nails, has been shown to persist

despite simulated bone resorption with loading characteristics similar to thin wire frames (17,19).

In examining a cohort of patients who underwent TTC arthrodesis using a titanium intramedullary nail with an internal pseudoelastic nitinol compression element, we hypothesized that union rates will be higher than those reported in the literature with similar complication rates. Second, we aimed to define a more precise computed tomographic (CT) scan-based fusion rate for TTC arthrodesis. Finally, we sought to define the timing and quantity of unloading of the implant's internal nitinol compression element during the postoperative period.

Patients and Methods

Patients undergoing TTC arthrodesis at 2 tertiary care referral centers from January 2014 to December 2016 using an intramedullary nail with an internal nitinol compression element (DynaNail®, Medshape Solutions, Inc.) were retrospectively identified via a consecutive list of patients for the following indications: end-stage tibiotalar arthritis with or without subtalar arthritis, severe ankle and/or hindfoot deformity, Charcot osteoarthropathy, failed total ankle arthroplasty, severe pilon fractures, neuromuscular hindfoot imbalance (e.g., Charcot-Marie-Tooth disease), and select cases of talar avascular necrosis. Patients were excluded if their follow-up was <12 weeks postoperative without going on to ipsilateral below-the-knee amputation or death. CT scans were performed at a minimum of 2 months of follow-up. Medical records and imaging were reviewed to determine procedural results.

All TTC arthrodeses were performed by 1 of the 2 senior authors using a standard technique. All arthrodesis joint surfaces were opened for standard joint preparation, typically via a lateral approach that included fibular resection. Cases of deformity were addressed with corrective osteotomies before nailing when applicable. The internal nitinol compression element is pretensioned 0 to 6 mm before nail insertion, depending on the amount of dynamic compression desired. Once the nail is inserted, the targeting frame is used to place the lateral-to-medial and PA screws into the calcaneus. Once the nail is locked to the calcaneus distally, additional external compression is applied using the targeting frame and the proximal interlocking bolts are placed. A locking cap is then placed into the distal end of the nail, locking the construct into position and compression. Standard postoperative care included postoperative splinting for 2-3 weeks before transitioning to a controlled ankle motion boot or cast and a non-weightbearing period of ≥6 to 8 weeks after surgery.

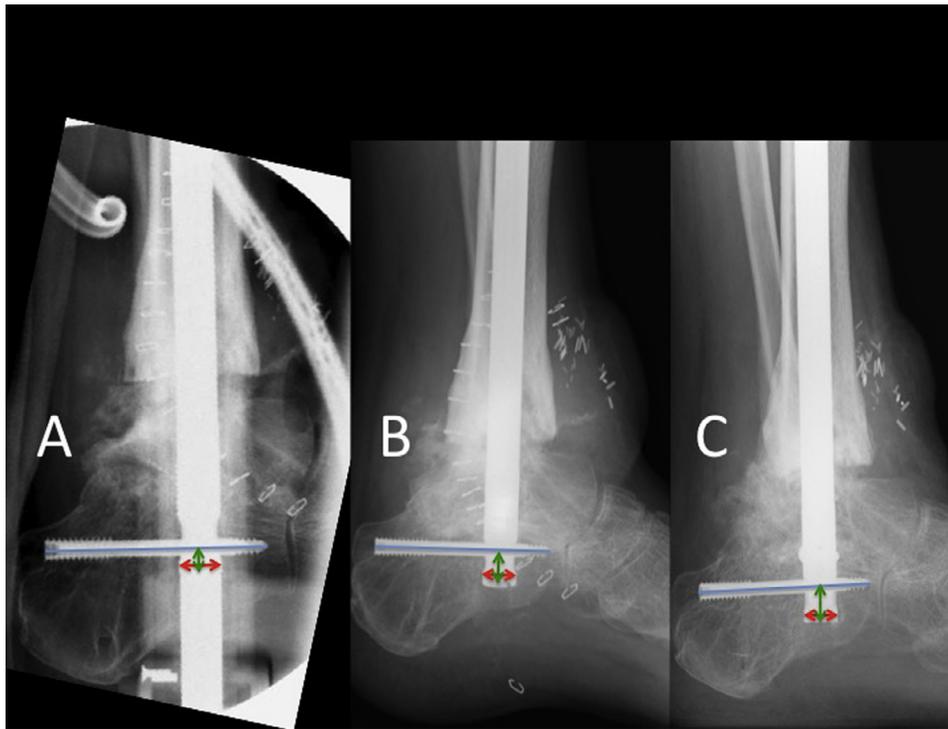


Fig. 1. Method of radiographic measurements (patient SS). Consecutive intraoperative (A), 2-week postoperative (B), and 6-week postoperative (C) lateral ankle radiographs demonstrating positional change of the posterior-to-anterior screw within the dynamic compression hole owing to unloading of the internal nitinol compression element. The width of the base of the nail (red arrows) was used to calibrate images for measurement. The position of the posterior-to-anterior screw within the dynamic slot was then measured (green arrows), using the base of the nail and the center of the posterior-to-anterior screw (blue lines) within the midline of the nail as references.

The primary outcome variable was defined as radiographic union as determined by CT imaging of the tibiotalar and subtalar joints. Union was defined as $\geq 50\%$ osseous bridging across the arthrodesis site on sagittal or coronal CT scan reformats, with particular focus turned to the posterior facet when examining the subtalar joint (20–25). Percentage union was also defined as a continuous variable based on CT measurements, generated from the total joint surface area fused divided by the total joint surface area available for fusion. CT scans were performed with a maximum cut-by-cut thickness of 2.0 (range 1.2 to 2.0) mm. CT scans were reviewed by 2 of the 3 authors, and neither inter-observer nor intraobserver reliability of measurements was assessed. Joint areas obscured by implant and metal implant-associated artifact were excluded from the joint surface area available for evaluation.

Secondary outcome variables included the need for revision surgery, postoperative infection, and postoperative compression unloading of the nitinol element as demonstrated by change in PA calcaneal screw position within the dynamic compression interlocking hole on plain radiographs. Postoperative compression unloading was measured by comparing 2-week and 6-week radiographs with intraoperative films. Plain radiographs were calibrated for measurement of PA screw position within the dynamic compression slot based on the known 12.5-mm base diameter (red arrows) for the implant (Fig. 1). The distance (green arrows) from the base of the nail to the center of the long axis of the PA screw (blue lines) was measured on lateral radiographs in parallel with the midline of the implant in a standardized fashion to reduce interobserver and intraobserver variability. The length from the base of the implant to the center of the distal portion of the distal interlocking hole (7.5 mm) was then subtracted from these measurements to generate a final value for screw position. PA screw position at intraoperative and postoperative time points was then compared to assess postoperative compression via unloading of the nitinol element.

Additionally, patient demographic and operative details were examined. Patient factors assessed included obesity, diabetes mellitus, end-stage renal disease, coronary artery disease, peripheral vascular disease, peripheral neuropathy, and a history of organ transplantation on current immunosuppression. The presence of Charcot osteoarthropathy or talar osteonecrosis within the hindfoot was also noted. Obesity was assessed using the body mass index as a continuous variable and patients were categorically grouped based on severity. For patients with a history of diabetes, hemoglobin A1c, if available, was documented. For patients with end-stage renal disease, disease staging and dialysis dependence was noted. Social data collected included tobacco use (type, packs per day, and pack-years), alcohol use (drinks per week), and recreational drug abuse. Operative data collected included bone graft, allogenic stem cells, and other osteogenic or osteoinductive products, if used. Patient-reported outcome measures were unavailable for review in this retrospective series.

Data were collected and stored in our electronic research database (REDCap). Standard descriptive statistics were calculated and reported, including measures of central tendency (mean and median), variance (standard deviation/interquartile range), as well as frequencies and proportions. For bivariate analyses, χ^2 or Fisher's exact tests were used for categorical data (e.g., complications between groups) to determine statistical differences. For continuous variables (e.g., age), a Wilcoxon rank-sum test was used to compare differences between groups. All data were analyzed using SAS Enterprise Guide 9.3 (Cary, NC).

Results

A total of 35 patients were identified. Two patients were excluded because of inadequate follow-up, leaving 33 patients for inclusion in analysis. Basic demographic and past medical history data are displayed in Table 1. Importantly, 30% (10/33) were diabetic, and 18% (6/33) and 45% (15/33) were current or former tobacco users, respectively. Twelve percent (4/33) had end-stage renal disease, one of whom was dialysis dependent, and 36% (12/33) were diagnosed with peripheral neuropathy. Twenty-four percent (8/33) of patients were diagnosed with Charcot osteoarthropathy and 24% (8/33) with talar osteonecrosis. One patient each had a past medical history significant for Charcot-Marie-Tooth disease, psoriatic arthritis managed with chronic prednisone and methotrexate, and prior diabetic foot infection with osteomyelitis treated successfully in a thin wire frame. Four (12%) patients had undergone prior TTC arthrodesis that had failed to unite.

Regarding bone graft use, 90% (30/33) of patients were treated with a nonstructural autograft and 16% (5/33) with an allograft (6% cancellous bone chips; 10% structural) (Table 2). Specific autograft harvest sites used were distal fibular (64% of cases) and proximal tibial (26% of cases). Bone morphogenic proteins (bone morphogenic protein-7 or recombinant human bone morphogenetic protein-2) were used off-label in 30% (10/33) of cases, and bone marrow aspirate from the iliac crest was used in 32% (11/33) of cases. Allograft stem cell tissue (Trinity

Table 1

Basic descriptive patient characteristics (N = 33 patients)

Patient Characteristics	Median or no. (%)
Patient age	59
Gender	
Male	19 (58)
Female	14 (42)
Past medical history	
Body mass index	31
Diabetes mellitus	10 (30)
End-stage renal disease	4 (12)
Peripheral neuropathy	12 (36)
Charcot osteoarthropathy	8 (24)
Talar osteonecrosis	8 (24)
Prior tibiotalocalcaneal arthrodesis nonunion	4 (12)
Tobacco history	
Current user	6 (18)
Former user	15 (45)

The standard patient was overweight or obese, and most were either current or former smokers.

Table 2

Details regarding intraoperative bone graft and biologic augmentation for the stimulation of union (N = 33 patients)

	% (no./No.)
Operative variables	
Bone autograft	
Distal fibula	64 (21/33)
Proximal tibia	26 (9/33)
Total	90 (30/33)
Bone allograft	
Nonstructural	6 (2/33)
Structural	10 (3/33)
Total	16 (5/33)
Biologics	
BMP-7/rhBMP-2	30 (10/33)
Bone marrow aspirate	32 (11/33)
Allograft stem cell	67 (22/33)

Most patients were treated with morselized distal fibular or proximal tibial cancellous autograft. A combination of potentially osteoinductive and osteogenic materials were used in a heterogeneous fashion, as well—bone morphogenic proteins (BMP), bone marrow aspirate, and allograft mesenchymal stem cells.

ELITE, Orthofix, Lewisville, TX) was placed in 67% (22/33) of arthrodesis sites, as well. Proximal tibial autograft use strongly correlated with bone morphogenic protein-7 osteoinductive supplementation (7/9 cases, 78% concomitant use), and a distal fibular autograft was frequently used in conjunction with allograft stem cell tissue (19/21 [90%] cases) based on attending surgeon preference.

Regarding the primary outcome measure, CT-based union of the tibiotalar and subtalar joints using a conservative 50% bony bridging cutoff for union, 81% (22/27) of patients went on to both tibiotalar and subtalar union (Table 3, Fig. 2–3). CT scans were performed at a mean of 9 (median 4.8; range 2 to 34) postoperative months and were unavailable for 6 patients. CT scans were, thus, available for review in

Table 3

Union rates and effective surface area of unions (N = 33 patients)

Joint	Union (%)	Median Surface Area Fused (%)
Tibiotalar	88	91
Subtalar	93	89
All joints	91	—
Patients in whom both joints fused	81	—

Ninety-one percent of all arthrodesis surfaces united, and 81% of patients had both their tibiotalar and subtalar arthrodesis sites unite. Union facilitated by the implant was generally near complete.

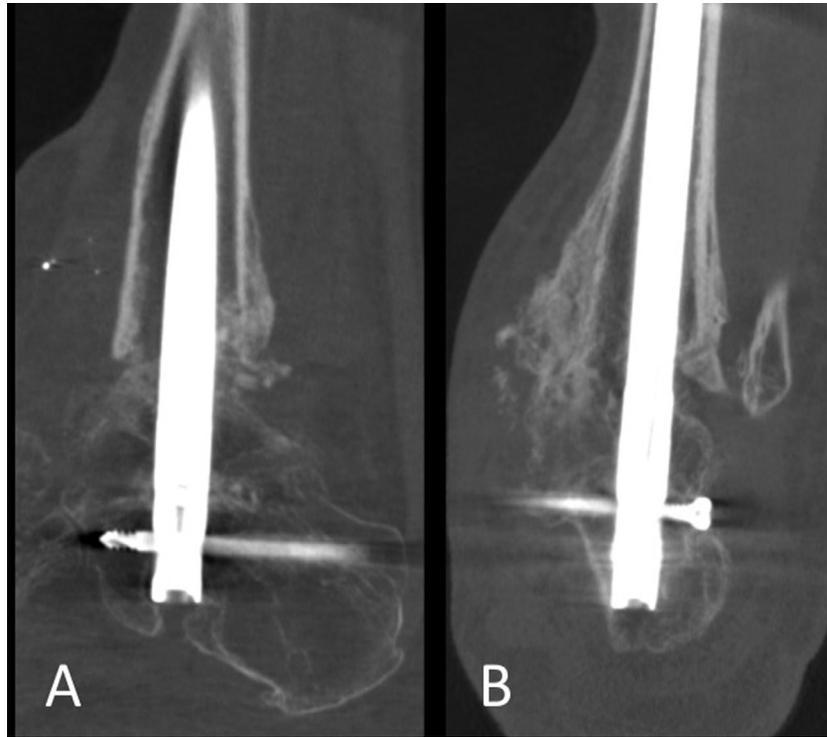


Fig. 2. Computed tomographic assessment of union (patient SS). Sagittal (A) and coronal (B) computed tomographic scan cuts 3 months after tibiotalocalcaneal arthrodesis demonstrating >50% bony bridging at the tibiotalar and subtalar arthrodesis sites.

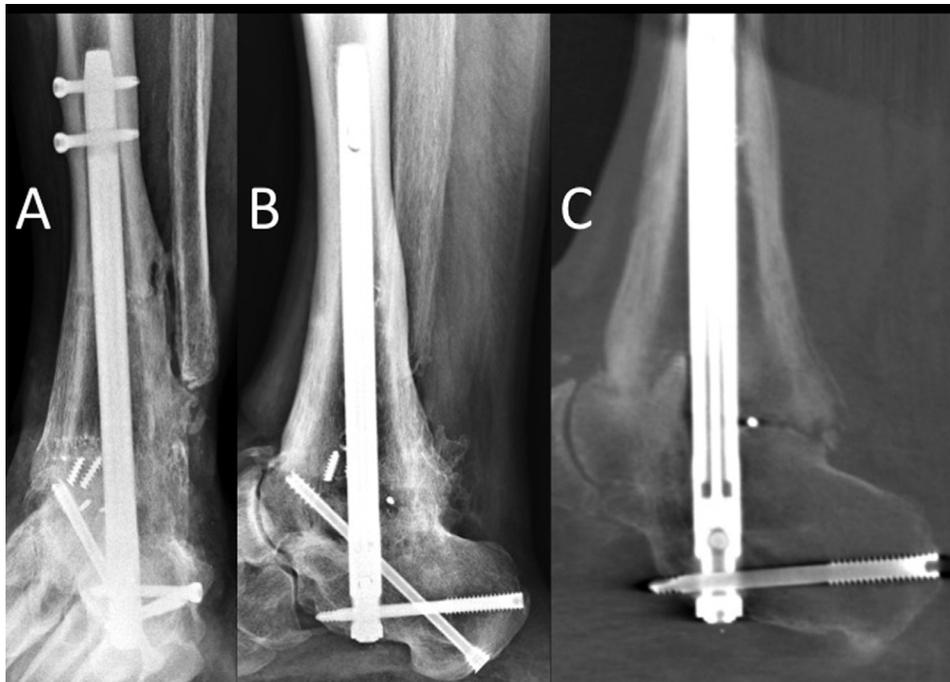


Fig. 3. Case example imaging (patient BW). Final anteroposterior (A) and lateral (B) radiographs after revision tibiotalocalcaneal arthrodesis for persistent tibiotalar nonunion using a titanium intramedullary nail with an internal pseudoelastic nitinol compression element. Sagittal computed tomographic reformats (C) reveal complete bridging over the arthrodesis site anterior to the nail in addition to complete subtalar bony bridging from prior arthrodesis procedures.

27 patients, and a single previously fused subtalar joint was omitted owing to prior fusion in a previous operation, leaving 53 total joints available for per-joint analysis. Ninety percent (48/53) of all arthrodesis surfaces (tibiotalar and subtalar combined) united. The individual

CT-based joint surface union rate among patients without Charcot osteoarthropathy (21 patients) was 94% (39/41). The presence of Charcot osteoarthropathy was identified as a risk factor for subtalar nonunion based on fisher exact test analysis ($p = .04$) (Table 4).

Table 4

Specific risk factors for nonunion and reduced joint surface fusion area were examined, including Charcot osteoarthropathy, talar osteonecrosis, and tobacco abuse history (N = 33 patients)

Covariates		Union	Nonunion	p Value
Union				
Charcot osteoarthropathy				
Tibiotalar	Yes	5	1	.99
	No	18	2	
Subtalar	Yes	4	2	.04*
	No	21	0	
Total	Yes	9	3	.07
	No	39	2	
Talar osteonecrosis				
Tibiotalar	Yes	8	0	.53
	No	15	3	
Subtalar	Yes	7	0	.99
	No	18	2	
Total	Yes	15	0	.30
	No	33	5	
Tobacco use				
Tibiotalar	Current	4	1	.73
	Former	9	1	
	No	10	1	
Subtalar	Current	6	0	.80
	Former	9	1	
	No	10	1	
Total	Current	10	1	.82
	Former	18	2	
	No	20	2	
Median percentage of joint surface area fused				
Charcot osteoarthropathy				
Tibiotalar	Yes	No		<.001*
	71	93.5		
Subtalar	Yes	No		.78
	82	89		
Talar osteonecrosis				
Tibiotalar	Yes	No		.93
	90.5	91		
Subtalar	Yes	No		.30
	92	86.5		
Tobacco use				
Tibiotalar	Current	Former	No	.19
	93	93.5	79.5	
	87	87	93	
Subtalar	Current	Former	No	.74
	87	87	93	
	87	87	93	

A history of Charcot osteoarthropathy was found to place patients at risk for subtalar joint nonunion ($p = .04$) and reduce the surface area of tibiotalar arthrodesis sites that united ($p < .001$). Tobacco abuse was not found to correlate with nonunion in this series.

* $p < .05$

Regarding surface area of union, a median of 91% and 89% of the tibiotalar and subtalar joint surfaces united, respectively (Table 3). A history of Charcot osteoarthropathy was associated with less complete CT-based tibiotalar union (94% vs 71%; $p < .01$), but an association between Charcot and tibiotalar nonunion was not evident. Talar osteonecrosis and histories of diabetes mellitus or tobacco use were not found to correlate with either tibiotalar or subtalar nonunion.

The reoperation rate was 21% (7/33). Seven revision surgeries were required at a median of 9 months postoperatively, including 3 amputations, all for deep infection (9%). No additional deep infections were noted. One patient underwent debridement and closure for a wound dehiscence and another required removal of a prominent PA screw. One patient required tibial open reduction internal fixation for a peri-prosthetic fracture, and 1 patient electively had periarticular ectopic bone excised at approximately 1 year after the index procedure.

The PA screw, which locks into the internal nitinol compression element and can travel proximally up to 6 mm as the nitinol element unloads, was found to migrate an average of 3.9 mm when comparing intraoperative to initial 2- to 3-week postoperative radiographs ($p < .0001$) (Figs. 1 and 4). The PA screw traveled an additional 0.7 mm on average between the 2- to 3-week postoperative follow-up

radiographs and radiographs taken at 6 weeks. Final postoperative compression was on average 4.6 mm after insertion of the nail in the operating room.

Discussion

Despite the high level of medical complexity encountered in this cohort of patients, 81% of patients went on to unite both arthrodesis sites. In the previously reported literature, hindfoot arthrodesis nails successfully catalyze union in approximately 87% of all joints fused, which is comparable with the 90% fusion reported in this series (11). This finding demonstrates that a titanium intramedullary nail with an internal pseudoelastic nitinol compression element is at least equivalently effective in facilitating union when compared with previously reported union rates for other hindfoot nails, all of which used less-stringent plain radiographs to define union (2,4,8–10).

Charcot osteoarthropathy, diagnosed in 8 patients included in this series, was found to correlate with subtalar nonunion and decreased surface area of tibiotalar joint fusion, which serves as evidence that Charcot patients are at high risk for nonunion after TTC arthrodesis. These findings are based on a limited cohort of 8 patients with Charcot osteoarthropathy who were included, limiting the power of this finding. It is important to note that it is unknown what impact sustained compression has when applied in catabolic Charcot tissue. Impressively, 94% of joints in non-Charcot patients united. A median of 91% and 89%, respectively, of the total tibiotalar and subtalar joint surface available for arthrodesis united.

Considering the high-risk nature of patients undergoing this limb salvage procedure, our 9% amputation rate for deep infection is consistent with the published literature, which is 5% to 10% in similar series (26,27). Two of the 3 patients who went on to amputation had a history of prior osteomyelitis in the setting of Charcot osteoarthropathy. These 2 patients likely had latent suppressed intracellular bacterial persistence that re-emerged in the wake of additional surgery (26). Overall, 21% of patients underwent revision procedures, which is also consistent with the prior literature. Importantly, no revisions were performed in this cohort for nonunion.

Finally, the radiographic evidence of postoperative compression serves as clear evidence of the implant's ability to sustain compression across an arthrodesis site as bone resorbs during the initial inflammatory phase of bone healing (Fig. 4). An impressive amount of nail shortening, 3.9 mm on average, was observed to occur between surgery and the initial follow-up with an additional 0.7 mm thereafter secondary to the sustained compression of the internal nitinol element.

Although this is the largest series in the literature reporting on clinical outcomes using a nitinol dynamic compression nail, there are several weaknesses of this work that should be recognized. First, this was a retrospective study and subject to accuracy of the medical record and previous documentation. Second, although clinical and radiographic outcomes were examined, patient-reported outcomes were not. Although a high rate of arthrodesis may predict improved postoperative function and satisfaction, this factor cannot be determined with certainty given lack of patient-reported data. Additionally, it is unclear what impact the various types of bone autograft, bone allograft, and other osteoinductive materials used may have had on union. Finally, this study reported on the use of a single implant without direct clinical comparison to other devices or a control group. As such, a discussion of implant cost effectiveness is beyond the scope of this study, especially without comparative patient-reported outcome data.

In conclusion, the titanium intramedullary nail with an internal pseudoelastic nitinol compression element is safe and effective in generating axial compression across both the tibiotalar and subtalar joints in TTC arthrodesis. Patients with Charcot osteoarthropathy less effectively generate bony unions and are prone to subtalar nonunion. The

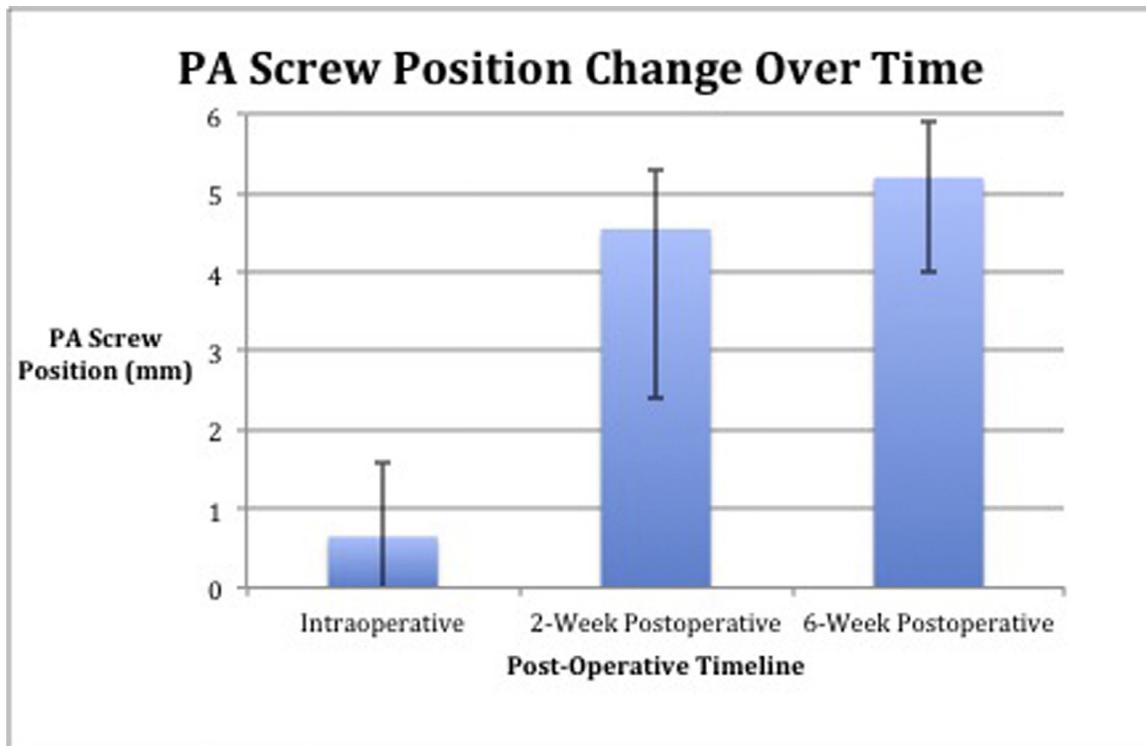


Fig. 4. Radiographic evidence of pseudoelastic nitinol compression element unloading (N = 33 patients). Posterior-to-anterior (PA) screw position relative to the distal-most portion of the distal interlocking hole within the oblique interlocking hole with upper and lower quartiles at 2-week ($p < .0001$) and 6-week ($p < .0001$) postoperative time points. These data demonstrate that the internal nitinol compression element maintains its dynamic compressive potential through the early phase of bone resorption in the arthrodesis healing process.

majority of unloading of the pseudoelastic nitinol element occurred over the first 2 to 3 postoperative weeks, demonstrating in vivo the endurance of potential energy stored within the nitinol element. Thus, the implant examined effectively provides continuous dynamic compression across arthrodesis sites after implantation.

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