Use of an Intramedullary Nail with Internal NiTiNOL Compression Element in Salvage Tibiotalocalcaneal Arthrodesis: Case Series of 19 Patients

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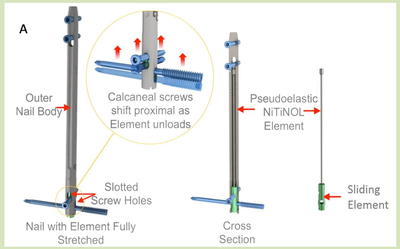
Statement of Purpose

Tibiotalocalcaneal (TTC) fusion procedures are performed to correct severe foot deformity and relieve patient pain, many times as a last attempt to save the patient's limb before amputation. This case series presents the clinical outcomes with TTC fusion surgery using a novel intramedullary (IM) nail with an internal pseudoelastic NiTiNOL component that is stretched during surgery and recovers its length post-operatively in response to bone resorption or settling. The NiTiNOL component allows the IM nail to hold compression for up to 6 mm of compression.[1]



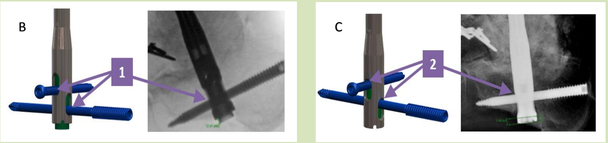


Figure 1. A) Intramedullary nail featuring internal NiTiNOL compressive element. B) Immediately post-surgery: Compressive element is fully stretched and PA Screw is located distal in the nail body slot indicating 6 mm of post-operative compression available. C) Weeks to months post surgery: Compressive element has fully recovered as indicated by the proximal position of the PA Screw in the nail body slot.

Methodology & Hypothesis

To date, there are no case series reporting the clinical outcomes of a pseudoelastic IM nail in TTC fusion with at least one year follow-up. The goal of this study is to evaluate the overall clinical and radiographic outcomes using the pseudoelastic IM nail in uninfected and aseptic TTC fusion procedures, specifically looking at its use in high-risk patient populations. Radiographs were taken to assess the extent of bony bridging across both joints at each follow up for a minimum of one-year post-surgery. CT was taken at a mean 9.5 weeks post-surgery. The recovery of the IM nail's internal element was assessed using image analysis software by measuring the position of the PA screw in the Nail Body slot on lateral radiographs and correlated to bone resorption (1 mm of recovery = 1 mm bone resorption) (Figure 2). The statistical mean and standard deviation were calculated for time to fusion, time to weight bearing, and bone resorption for the patients included in this case series.

This study hypothesizes that a pseudoelastic IM nail will maintain post-operative compression and increase fusion rates in in hindfoot salvage procedures.

Procedure

Nineteen patients underwent TTC fusion surgery using the pseudoelastic IM nail between December 2012 to September 2016. Of the 19 cases included in this data series, sixteen operations were performed by the lead author with a standard trans-malleolar approach. After reaming the entry tunnel, the IM nail was inserted using the targeting frame, and the internal NiTiNOL element was stretched to allow for 6 mm of recovery post-surgery. A posterior-anterior screw and lateral-to-medial screw were then placed in the calcaneus. Manual compression was then applied to tighten up the joints by turning the wheel on the targeting frame. Two medial-to-lateral screws were then placed in the tibia. A DBM biologic was used to pack the joints in all cases. Three patients received a femoral head allograft to replace a missing or necrotic talus.

Literature Review

While static (IM) nails are commonly used in salvage hindfoot fusion procedures, the literature reports low union rates with these devices, particularly in high-risk patient populations where fusion rates are as low as 50% overall.[2,3] Specifically, Jeng et al in 2013 and Bussewitz et al. in 2014 showed that the co-morbidity of diabetes in IM nails for complicated ankle salvage was 100% predictable for non-union.[2,4] These lower rates with IM nails have been partially attributed to their inability to maintain compression post-surgery, a property that ensures biologic stability and promotes the bone healing process. An IM nail with a pseudoelastic internal element has been shown to sustain post-operative compression while also allowing for post-operative quantitative assessment of bone resorption inherent in the healing process.[5,6] The pseudoelastic nail also allows for approximately 70% load sharing during weight bearing which is pivotal for eliminating stress shielding that can result in bone resorption and hardware failure.[7]

Results

Of the 19 patients, two cases were excluded from analysis: one due to septic nonunion and the second case due to patient death from unrelated causes prior to one year follow-up. There were 5 females (29%) and 12 males (64%) with an average age of 59 years (range 30-80 years). Co-morbidities included 4 patients with diabetes, 3 with Charcot Neuroarthropathy, 3 that used tobacco, 6 had post-traumatic degenerative joint disease, 3 patients with osteoarthritis, 3 patients with non-diabetic neuroarthropathy, 1 patient with an aggressive bone tumor of the talus and 1 patient with AVN of the talus. Six cases were revisions of prior attempted fusion surgeries.

Of the 17 patients included, 32/34 joints fused successfully at an average time of 8 weeks post-surgery (confirmed on CT), yielding an overall fusion rate of 94%. One nonunion was due to talar avascular necrosis. Four patients required reoperation: 1 hardware removal due to nickel allergy, 1 guillotine amputation due to gas gangrene infection, 1 revision due to talar AVN and non-union of the tibio-talar joint, and 1 revision subtalar joint non-union with exchange pseudoelastic nailing that resulted in successful fusion The internal NiTiNOL element inside the IM nail recovered an average of 5.1 +/- 0.8 mm at the last follow-up, indicating that an average of 5.1 mm of bone resorption had occurred and compression was still being maintained across the joints. The median time for patients to reach weight bearing was 8.0 +/- 3.2 weeks. The overall salvage rate related to the total TTC fusion surgeries using a pseudoelastic IM nail was 95%.

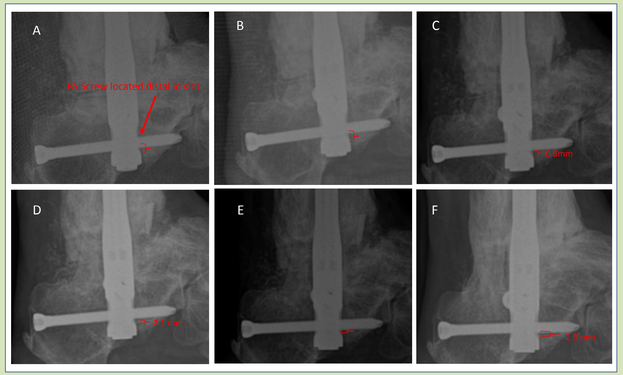


Figure 2. Lateral radiographs of 47 year old female patient with previous painful nonunion at various points during healing to monitor the recovery of the internal NiTiNOL compressive element. A) X-ray taken 1 week post-surgery. B) X-ray taken 4 weeks surgery. C) X-ray taken 6 weeks post-surgery, showing 0.6mm recovery. D) X-ray taken 10 weeks post-surgery, showing 2.1 mm of recovery. E) X-ray taken 12 weeks post-op F) X-ray taken 1 year post-op, showing 2 mm of recovery. The amount of recovery by the internal element is indicated in red on each image.

Figure 3. Radiographs taken of 80 year old male patient with severe arthritis, end stage degenerative joint disease and ankylosis, and equinus deformity at various points during healing to monitor the recovery of the internal NiTiNOL compressive element. A) X-ray taken 2 weeks post-op. B) X-ray taken 6 weeks post-op. C) X-ray taken 10 weeks post-op. D) X-ray taken 14 weeks post-op, showing 5.7 mm recovery.

Discussion

This case series describes the use of an IM nail with an internal compression mechanism for treating high-risk patients in TTC fusion surgery. The goal of this procedure is to fuse the ankle and subtalar joints, allow for limb salvage, decrease pain, and restore hindfoot alignment. Among the 4 diabetic patients with Charcot neuropathy included in this case series, 3 achieved successful fusion and the 4th was lost to acute gas gangrene infection unrelated to index surgery. In comparison, prior studies by Myerson and Bussewitz et al. report a 0% fusion rate for diabetic patients.[2,3] Furthermore, Devries reports an average time to full weightbearing of 100.6 +/- 36 days compared with the average time to full weightbearing in this present study of 61 +/- 22 days.[8] Additionally, the mean bone resorption measured in this study via the recovery of the internal element recovery was 5.1 mm. This data updates Pelton's 2006 study showing an average 2-3 mm of resorption in static locked nailing cases for TTC fusion and underscores the importance of having a device to maintain 6mm of compression throughout the healing process.[9] The results of this study suggest that the compression mechanism of a pseudoelastic IM nail increases successful fusion in hindfoot salvage procedures. This technique should be given strong consideration particularly in high risk patients such as diabetes, Charcot, and end stage renal disease and other biologically bankrupt conditions.

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