The Latest Breakthrough in
TTC Fusion Technology

Post-Operative Clinical Evaluation
A CASE REPORT
Dr. Samuel B. Adams, Jr., M.D.
Background

The DynaNail® TTC Fusion System is intended for use in tibiotalocalcaneal (TTC) fusion to treat various conditions including:

- Rheumatoid Arthritis
- Osteoarthritis
- Severe Deformities
- Degenerative Conditions
- Post-Traumatic Injury
- Failed Total Ankle Arthroplasty
- Non-Union from Ankle or Subtalar Arthrodesis

DynaNail contains an internal Nickel Titanium (NiTiNOL) Compressive Element that adapts to changes in loading across the joint. The Compressive Element is stretched intra-operatively (up to 6 mm) and fixed with screws in the calcaneus and tibia. After surgery, the Compressive Element can recover its stretched length in response to bone resorption or settling. This unloading allows DynaNail to sustain compression across the joint.

The figure to the left shows the axial compressive force applied by DynaNail in comparison to static intramedullary (IM) nails and an external fixation frame. Whereas static IM nails lose compression after 1 mm of resorption, DynaNail maintains compression for up to 6 mm of resorption, similar to an external frame.\(^1\)\(^2\)
Watch the Internal Element “In Action”

The unloading of the Compressive Element can be tracked by X-ray or CT scan using several methods:

1. In its fully stretched position, the Sliding Element extends plantarly from the outer body of the Nail. As resorption/settling occurs, the Sliding Element will retract back into the Nail Body.

2. The position of the calcaneal screws in their associated slots can be visualized under fluoroscopy and used to determine the extent the Compressive Element has unloaded. When the Compressive Element is in its fully stretched position, the calcaneal screws are located at the distal end of the slots (1) and a lucent region appears above the L-M screw (see X-ray above). As the Compressive Element unloads, the screws progressively shift upwards. The Compressive Element has completely unloaded when the screws are at the proximal end of the slot and the lucent region disappears (2).
Introduction

In many TTC fusion cases, achieving fusion can be challenging in high risk patient populations such as smokers, substance abusers, diabetics, and immuno-compromised patients.\textsuperscript{3} If a patient experiences severe bone loss due to a failed total ankle replacement, avascular necrosis, arthritis, neuroarthropathy or infection, structural bone allografts are often used to fill any bony defects or replace a missing talus. However, according to recent studies, only around 50% of patients who receive a bulk structural allograft achieve fusion.\textsuperscript{4,5}

This report presents two cases involving high risk patients who underwent TTC fusion surgery using a DynaNail (with one patient also receiving a structural allograft) to revise previously unsuccessful surgical treatments. The patients' successful outcomes using the DynaNail TTC Fusion System are reported here.

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Case Report #1

Background Information
The patient, a 26 year old female smoker and multiple substance abuser, was involved in a motor vehicle collision and sustained an open bimalleolar ankle fracture dislocation with medial malleolar loss and calcaneus fracture, including a large anterior and medial wound. Post-accident X-rays are shown to the right.

She underwent open reduction and internal fixation (ORIF) of the ankle and calcaneus along with multiple plastic surgery procedures for her large medial and anterior wound coverage. The patient continued to smoke. The ORIF failed by nonunion of the medial malleolus and fibula, ankle varus, and onset of early subtalar arthritis. X-ray images are shown to the left.
The patient subsequently developed end-stage ankle arthritis and underwent attempted isolated ankle arthrodesis, as the subtalar joint was mostly preserved. X-ray images are shown to the right.

She developed a painful nonunion at the ankle as well as subtalar arthritis, but continued smoking. CT images (left) demonstrate nonunion at the tibiotalar joint and end-stage subtalar arthritis.

**Procedure**

A revision ankle arthrodesis and primary subtalar arthrodesis (tibiotalocalcaneal arthrodesis) was performed with the DynaNail. The previous hardware was removed through a lateral approach. The ankle and subtalar joints were denuded of fibrous nonunion and arthritic cartilage and the subchondral bone was drilled and shingled. The arthrodesis sites were packed with concentrated iliac crest bone marrow aspirate mixed with fresh-frozen cancellous chips. A 10 x 220 mm DynaNail was placed according to the recommended surgical technique. The Compressive Element was stretched 6 mm prior to screw fixation, as shown to the right in an intra-operative fluoroscopic image.
Four millimeters of external manual compression was applied using the DynaNail Targeting Frame. The proximal tibial screws were then inserted. A 70 mm headless P-A screw and 40 mm headed cortical L-M screw were used in the calcaneus. The proximal and distal tibial cortical screws used were both 20 mm. The patient was placed in a non-weight-bearing cast.

Post-Operative Results

6 Weeks Post-Surgery:
The patient was pain free with minimal swelling and continued to smoke. She was placed in a controlled ankle motion (CAM) boot and allowed progressive weight-bearing. X-ray images were obtained and are shown to the right. The Compressive Element had unloaded a total of 5.5 mm in response to bone resorption and settling while still maintaining compression.

3 Months Post-Surgery:
The patient continued to be pain free while being full weight-bearing in the CAM boot. She continued to smoke. X-rays demonstrated excellent alignment of the leg and position of the nail, as shown to the left. The Compressive Element had fully unloaded.
A CT scan demonstrated solid fusion across the tibiotalar and subtalar joints, as shown to the right. She was progressed to full weight-bearing without restrictions.

6 Months Post-Surgery:
The patient continued to be pain free while being full weight-bearing in the CAM boot. She continued to smoke. X-ray images were obtained and are shown to the left.

Case Report #2

Background Information
The patient, a 55 year old male who fell and sustained a talar neck fracture, underwent open reduction and internal fixation. However, he developed avascular necrosis of the talus with subsequent collapse of the talus and both tibiotalar and subtalar arthritis, as shown in the X-ray image to the right.
Procedure

A primary tibiotalocalcaneal arthrodesis was performed, using the DynaNail, through a posterior approach. The talar body was removed and the tibial and calcaneal joint surfaces were denuded of arthritic cartilage. The subchondral bone was then drilled and shingled. Next, a frozen femoral head allograft was fashioned as an interpositional bone block to restore the appropriate leg length. The arthrodesis sites were packed with an allogeneic stem cell allograft. A 10 x 220 mm DynaNail was placed according to the recommended surgical technique. The Compressive Element was stretched 6 mm prior to screw fixation, as shown in the intra-operative fluoroscopic image to the left. No additional external manual compression was applied. The proximal tibial screws were then inserted.

Results

6 Weeks Post-Surgery:
The patient was pain free with minimal swelling. He was placed in a controlled ankle motion (CAM) boot and allowed progressive weight-bearing.

3 Months Post-Surgery:
The patient continued to be pain free and was weight-bearing without assistive devices. X-rays shown to the left demonstrated excellent alignment of the leg and position of the DynaNail. There was consolidation across the tibiotalar and subtalar arthrodesis sites. The Compressive Element had fully unloaded.

6 Months Post-Surgery:
The patient continued to be pain free and returned to activities as tolerated. Radiographs demonstrated excellent alignment of the leg and position of the DynaNail, as shown to the right.
A CT scan demonstrated solid union of the tibia and calcaneus to the femoral head allograft, as shown to the left. Interestingly, the interface of the talar neck and the femoral head did not heal. This area was prepared and grafted in the same manner as the tibia and calcaneus but was not fixed by the DynaNail. This area was asymptomatic.

12 Months Post-Surgery:
The patient continued to be asymptomatic. He was pleased with his outcome. X-rays to the right demonstrated excellent alignment of the leg and the position of the DynaNail. There was consolidation across the tibiotalar and subtalar arthrodesis sites.

Dr. Samuel Adams, M.D., is a board-certified orthopaedic surgeon at Duke University Medical Center in Durham, NC, specializing in conditions of the foot and ankle. Dr. Adams received his Doctor of Medicine degree from Jefferson Medical College in Philadelphia, Pennsylvania. He then completed an orthopaedic surgical residency at Duke University Medical Center. He then completed a fellowship in foot and ankle surgery at Union Memorial Hospital in Baltimore, Maryland. His clinical interests include foot and ankle trauma, ankle replacement, and foot and ankle sports medicine. He is involved in multiple clinical trials, including acting as Principal Investigator for the study "The Use of a Dynamic Compression Intramedullary Nail for Tibiotalocalcaneal Arthrodesis" utilizing the DynaNail (NCT02324907). He has been publishing and presenting on the foot and ankle field for over a decade.

This report is presented to demonstrate the clinical outcomes shown by Dr. Samuel Adams. MedShape, as the manufacturer of this device, does not practice medicine and is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient. Always refer to the package insert, product label, and/or product instructions prior to using a MedShape product.

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