The Latest Breakthrough in TTC Fusion Technology

Post-Operative Clinical Evaluation
CASE REPORT
Dr. Eric Giza, MD

DYNANAIL
TTC FUSION SYSTEM
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 Arthrodesis

DynaNail contains an internal Nickel Titanium (NiTiNOL) **Compressive Element** that adapts to changes in loading across the joint. The Element is stretched intra-operatively (up to 6 mm) and fixed with screws in the calcaneus and tibia. After surgery, the 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 resorption, **DynaNail maintains compression for up to 6 mm of resorption**, similar to an external frame.¹²

Watch the Internal Element “In Action”

The unloading of the 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 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, the patient experiences severe bone loss due to a failed total ankle replacement, avascular necrosis, neuroarthropathy or infection. In these instances, a bone graft is used to fill any bony defects or replace a missing talus. However, achieving fusion using bone graft materials has proven challenging in high-risk patients with degenerative bone conditions or who are immuno-compromised. A study by Jeng et al. reported a 50% non-union rate in patients who underwent TTC fusions using a femoral head allograft and in particular, no fusions in diabetic patients.\(^3\)

This report presents two cases with diabetic patients who both underwent a TTC fusion procedure after previous treatment proved inadequate. Their successful outcomes using the DynaNail TTC Fusion System in combination with bone graft materials are reported here.

Performing Surgeon

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Case Report #1

Background Information

The patient, a 66 year old female, with a history of diabetes mellitus, spinal cord injury, ankle osteoarthritis, and flail ankle, previously underwent an attempt at posterior tibial tendon transfer and lateral ligament reconstruction.

Procedure

A lateral extensile approach was used to prepare the joints and perform a fibular ostectomy. An 11 mm tunnel was drilled through the calcaneus into the tibia, with a 13 mm tunnel in the calcaneus to accommodate the distal end of the implant. A 10 x 220 mm DynaNail was inserted according to the recommended surgical technique. The Compressive Element was stretched to a setting of 6 mm before fixating with screws. A 70 mm headless posterior-anterior (P-A) screw and 40 mm headed cortical L-M screw were used in the calcaneus. The proximal and distal tibial cortical screws used in the medial-lateral direction were both 25 mm. Fibular autograft and BMP-7 were used. An intra-operative X-ray image is to the right. 1 mm of Compressive Element unloading was noted, likely due to initial settling.

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Results

**Immediate Post-Op:**
No post-op complications were reported. The patient was placed in a posterior splint.

**2 Weeks Post-Surgery:**
Week 2 P-A and M-L X-ray images are at the right. As observed on the radiograph, the position of the P-A screw in the calcaneus indicates that the Compressive Element has unloaded a total of 4 mm in response to bone resorption and settling while still maintaining compression. The wound had healed, and the patient was experiencing minimal pain with mild to moderate swelling.

**6 Weeks Post-Surgery:**
The patient was no longer immobilized. A removable posterior splint was placed.

**8 Weeks Post-Surgery:**
Minimal swelling was present and the patient reported no pain.

**9 Weeks Post-Surgery:**
Ankle fusion was evident. The Compressive Element had unloaded a total of 5 mm while still maintaining compression.

**12 Weeks Post-Surgery:**
100% fusion was noted based on X-ray imaging. The patient was full weight-bearing in a boot with wean from boot over 1 month.
Case Report #2

Background Information
The patient, a 68 year old female, had a history of diabetes mellitus type II with pilon ankle fracture approximately two years seven months prior to the current procedure. After initial operation, she developed Charcot neuroarthropathy with non-union and severe arthritis with deep infection. This led to a secondary operation approximately two months prior to the subject procedure, in which she had ankle incision and drainage, hardware removal and placement of antibiotic beads with placement of an external fixator/spatial frame. She received six weeks of intravenous antibiotics, but continued to experience non-union.

Procedure
The patient had a large resection of the tibia and talus. Femoral retrograde intra-articular aspiration of bone graft was performed. The 10 x 220 mm DynaNail was placed through a Zimmer Trabecular Metal™ knee augment implant and then coated in autograft and BMP-7. The Compressive Element was stretched to a setting of 6 mm before the nail was fixed in the calcaneus with a 70 mm P-A screw and a 45 mm L-M screw, and proximally in the tibia with two 25 mm screws in the M-L direction. An intra-operative X-ray image is shown to the right.

Results

Immediate Post-Op:
No complications were reported, and a removable posterior splint was placed. Immediate post-op X-rays are to the right.
5 Weeks Post-Surgery:
The Compressive Element had unloaded a total of 5 mm in response to bone resorption and settling while still maintaining compression. The patient's wound had healed.

6 Weeks Post-Surgery:
Ankle fusion was evident. Minimal pain was reported by the patient and minimal swelling was observed.

10 Weeks Post-Surgery:
The patient was no longer immobilized and began weight-bearing in a boot. No pain was reported by the patient.

13 Weeks Post-Surgery:
The Compressive Element had continued to be unloaded a total of 5 mm in response to bone resorption and settling while still maintaining compression. Near-complete consolidation of autograft around implant had occurred as observed by X-ray. There was no report of patient pain or swelling.
For further product information or to arrange a product demonstration, please contact your local MedShape representative or call Customer Service at 877-343-7016. You can also visit www.medshape.com.

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