TTC fusions in high risk patient’s using a Pseudoelastic Nail.

Thomas S. Nordquist, DPM, DABPM
Board Certified in Podiatric Medicine
Advanced Foot & Ankle Surgeons, Inc.
Sycamore/ Yorkville IL
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- No financial disclosures regarding this talk
What is a Pseudoelastic Nail?

- Has a NiTi dynamic element encased in a Titanium Sheath with a sliding mechanism that locks the Calcaneus to the distal nail and provides sustained dynamic compression and complicity in weight bearing load.

  - DynaNail™, Medshape, Inc. Atlanta, GA

- There are no other Pseudoelastic IM Nails in the market, but lightly comparative devices would constitute a static compressed IM Nail with crossed locking screws.
  - Valor Nail™, Wright Medical. Memphis, TN
  - T2 Nail™, Stryker Corp. Mahwah, NJ
  - Versa Nail™, Depuy Synthes. Warsaw, IN
  - Panta Nail™, Integra. Plainsboro, NJ
Generation 4 IM Nail with Pseudoelastic Capabilities

The Dynalith™ Ankle Arthrodesis Nail maintains close apposition of target fusion bones by applying sustained compression and adapting to bone resorption.

**The "Rubber-band" Effect**

The Dynalith™ takes advantage of the pseudoelastic properties of its internal IM Nail (IMT) element. When the element is stressed, the IMT element expands, its length increases, and resists any high-strength rubber band.

**SUSTAINED COMPRESSION**

Compression of a fusion is essential in ensuring joint stability and restoring bony union. The Dynalith™ IM Nail with its pseudoelastic capabilities allows for sustained compression of the fusion site, ensuring long-term stability.

**PERFORMANCE**

The Dynalith™ provides the sustained initial compression of an external fixation, while sealing the bone graft and rigidly fixing it in place.

**Competitive Performance Summary**

- Adapts to resorption, thanks to the pseudoelastic behaviors of the internal dynamic elements.
- Improved Load-sharing Capacity
- Enhanced Neutral Stiffness

**Dynamic Element**

The IMT element is designed to undergo shape memory and pseudoelastic recovery, ensuring sustained compression throughout the fusion process.
1st, 2nd, 3rd Generation IM Nails

Focus of Biomechanical Studies are “Rigidity”/”Stiffness” of the construct.

- Essentially we are measuring the rigidity of the construct as it stress shields the fusion site!

- But each new Gen Nail improves compression!
Indications for use of a TTC Nail

- Combined STJ/Ankle Arthrosis
  - Inflammatory Arthrildites
    - Rheumatoid, Mixed Connective Tissue Disorder, Hemophilia
- Isolated Ankle Arthrosis?
  - Chondrodesis of STJ
- AVN Talus
- Post Traumatic DJD
  - Primary Fusion in Severe Trauma
- Failure of Ankle Arthroplasty
  - STAR, INBone, Salto-Talaris, Beuchel-Pappas, Agility, Ex-Fix Diastasis
- Charcot Neuroarthropathy
- Foot Drop
  - Common Peroneal Nerve Damage, CVA, Parkinson's, Multiple Sclerosis, Post-Chemo
- Severe Cavo-Varus Deformity
  - Polio, Charcot-Marie-Tooth, Neglected Club Foot
- Failed IM Nail
Contra-indications

- Ongoing Osteomyelitis
- Non-bypassable Peripheral Arterial Disease
- Deep Space Wounds/ Abscess
- Chronic Infected/ Contaminated Ulceration
- Relatively Small Diameter Tibia
TTC Fixation Techniques

• Crossed Lag Screws

• Blade Plate

• Locking Plate

• Uniplane Ex-Fix

• Ilizarov External Fixation

• Intramedullary Nail

• Combination,..
The Right Amount of Micromotion = Improved Vascularity

• Regarding Bone Graft (Specifically Allograft): Following implantation, cell survival is the key issue.
  • Incorporation of rapid revascularization strategies is essential, particularly for large volume defects.

Fig. 1 The triangular relationship at the heart of fracture healing.
Malunion Ankle Fracture/Non-union Fibula with STJ pain

**Static Nail**
(Valor, Phoenix, Versa, Panta, Synthes, Orthofix)

Immediate Post Op

Tight Tibio-Talar Bone-Bone apposition
Malunion Ankle Fracture/Non-union Fibula with STJ pain

Static Nail
(Valor, Phoenix, Versa, Panta, Synthes, Orthofix)

Gapping Bone-Bone apposition

16 weeks Post Op

*****NON-UNION*****
NON-UNION!

- 33 articles included after review of 165 titles
  - 641 joints for final review.
- What is the union rate of TTC c static IM Nail?
  - 86.7% of Joints fused at the end point!!!!!! (This includes revision)
  - 26% revision fusion
  - 13.25% non-union rate overall!!

- Nature and Rate of Complications of TTC c IM Nail
  - Overall 55.7%;
  - 30.0% Metalwork – Stress Shielding?
  - 23.8% Non-union.
- Nature and Rate of Reoperation?
  - 22%
- Proportion of cases with prior surgery before TTCA
  - 48.5% of cases had prior surgery
Primary vs. Secondary Bone Healing: Primary Bone Healing

- **Contact Healing**
  - < 1mm
  - <200 um gap
  - Intramembranous Ossification
    - Via: Cone and Cutting of Osteoclast/Osteoblast

- **Gap Healing**
  - > 1mm gap
  - Lamellar Bone Repair

- **Need Stability**
  - Need Sustained Compression
  - Need Load Sharing
  - Need to adapt to LFE resorption

- **Do Not want Rigidity!!**
  - Initial Compression decreases by 42% after 2 weeks with Compression Lag Screw Technique
    - Mueller AO/ASIF

Contact Healing

Gap Healing

Intramembranous

Fibroid and Collagen replaced by Lamellar bone
Secondary Bone Healing

- **Endochondral Ossification**
- Occurs with motion
  - Callus Formation on radiograph
  - Endosteal Blood Supply revascularizing unstable callus

**Need Periosteal/Endosteal sheath!!!**

Biology of Compression

- Compression relates to Stability
- Instability brings callus formation:
  - Secondary: Callus formation and endochondral ossification
- Strain, Shear, Torsion, Compression, Tension, Dynamization??????????
  - To what effect?
- Anatomically cannot achieve secondary bone fusion in joint union surgery
  - Callus comes from Periosteum and Endosteum.
  - Where do we get periosteal and endosteal coverage in a TTC fusion vs a long bone osteotomy or fracture?
Mechanical Loads do play a role in pluripotential cell differentiation!

Compression with Stability is a safe bet!

Area of high shear (motion) = “pseudomucin” (non-union)
Center of fracture gap: Area of High Strain and Increased Hydrostatic Pressure
Area of Low Strain and Intermediate Hydrostatic Pressure = Callus formation
High Hydrostatic Compression = Periosteal Bone Resorption (pressure necrosis)

What is Ideal Mechanical Fixation?

Is it the construct or the Compression?

1. Promote correct micromotion for angiogenesis
2. Achieve good bone to bone apposition
3. Provide Stability to the micro-environment
4. Compression as osteogenic/ avoid pressure necrosis
5. Promote load sharing and avoid stress shielding
6. Avoid Torsional Instability: (The non-union maker)
“We protect these patient’s from weight bearing to avoid bone resorption, implant loosening and subsequent non-union and implant failure.”


- 12/14 solid fusion at end point

- Avg time to partial WBing was 10-14 weeks

- Avg time to full WBing was 14-19 weeks


**Stress Shielding Leads to Resorption. Loss of compression leads to stress shielding.**
Increasing capacity to provide initial compression from 1\textsuperscript{st} to 2\textsuperscript{nd} to 3\textsuperscript{rd} generation nails.

- All the studies measure the construct in an inert model immediately after implantation and initial compression of the nail.

- We asked ourselves the question:
  - What happens when the cells at the fusion site demonstrate apoptosis to the iatrogenic fracture and begin to show bone resorption at the Local Fusion Environment?
Bench top studies do not account for “living” bone reaction to cyclical loading in rigid/Stress Shielded constructs in vivo.

- **Average of 2.3mm of movement (Resorption) occurred due to impaction and dynamization.**

- **Muckley acknowledges that would likely be loss of compression due to the “in vivo” response and while the exact response is uncertain it will affect all IM devices equally.**
Ex fix vs IM nail in the face of bone resorption.

  - 12mm x 180mm Integra Nail
  - 12mm x 200mm Depuy Nail
  - Ace-Fisher Ex Fix (2 tibial rings and 1 foot plate)
  - True/Lok Ex Fix ((2 tibial rings and 1 foot plate)
Ex fix vs IM nail in the face of bone resorption.

90% of the Compressive Load is lost after 1mm of resorption.

>2cm of resorption before 90% of compressive load is lost.
Applied similar loads and simulated bone resorption with a dynamic element pseudoelastic IM Nail.

NiTi element enclosed in a Titanium Sheath
Compared to 2010 FAI study data points.

We looked at the load sharing properties of 1st through 3rd Gen. Static IM Nails and Compared to the DynaNail™

- Normalized to simulate a 225lb person walking slowly.

Static Nail: 9% Load Sharing; 74μm axial micro-motion

compression and transferred 71% of the walking forces through the bone.

10% decrease in bone density = 3.4% increase in load to the nail and 0.5% increase in load to the bone.

Pseudoelastic Nail: 71% Load Sharing; 555μm axial micro-motion
Also: Compression increased from 631N-779N (hysteresis of NiTi)****
Influence of Compression on Torsional Stability in Ankle Arthrodesis.

Compression Load
DynaNail: 475N
Pantanail: 363N
Versanail: 316N

Pitz K. Gall K. Accepted as Masters Thesis at Georgia Tech University, Atlanta, GA
-Initial Stiffness not significantly affected by Compression (Construct: think PA vs ML screw)

-Yield Curve is affected by compressive load (Think about loss of compression with bone resorption)

Compression Validation at various levels of bone resorption.
70 y/o female: Obese, DM, HTN.

History of previous Triple Arthrodesis;

Approximately 8 months after union of the Triple the patient presented with collapse of the talar body and Charcot Ankle Changes.
Separate Procedure to Remove Hardware

• Reduce OR time.

• Reduce chance of “hanging up” on hardware (abandon reconstruction – patient acceptance)

• Get better look at the destruction and “real estate” available for reconstruction.
Pantalar with Fresh Frozen Femoral Head, Infuse rhBMP-2, DBM with ground autograft, DynaNail Fixation

Transmalleolar with Medialization of foot.

No Ex Fix, No Blade Plate - 850N sustained compression.
I prefer transmalleolar for these. In Cases where I try to preserve the fibula and medial malleolus, I notch out the lateral aspect of the medial malleolus to medialize the whole foot.

Is there a biomechanical study showing the difference between sustentacular fixation and calcaneal body fixation?
80 year old retired postal worker.

- Suffered ankle fracture 35 years ago.
- Recent onset of instability and falls related to ankle and STJ as well as pain.
- Pain for 30 years, told. “nothing could be done” – according to patient.
Immediate Post Op  5/1/13
8 weeks post op

CT Scan at 6/24/13 showed 100% fusion at AJ and 40% fusion at STJ – asymptomatic.
v67 y/o Diabetic male s/p ankle fracture at age 14 and subsequent ankle fusion. Subsequent Midfoot DJD secondary to fusion and varus.

Reconstruction: 12/7/12
Valgus Tibial Wedge Osteotomy
PanTalar Fusion
2 weeks post op
CT scan 4/5/13: 100% TTC fusion, continued bony bridging at the Midfoot.

2 weeks post op

8 weeks post op
Painful Fusion s/p Aneurysmal Bone Cyst removal. Total Ankle Joint extraction fusion with en bloc femoral head graft. Nickel and Molybdenum Allergy

Multiple attempts to eradicate aggressive Aneurysmal Bone Cyst from the talus
Total Ankle Joint extraction fusion with en bloc femoral head graft. Nickel and Molybdenenum Allergy

DOS: 4/30/14
CT from 7/25/14: “fusion of tibia, talus, calcaneus traversed”
Total Ankle Joint extraction fusion with en bloc femoral head graft. Nickel and Molybdenenum Allergy

CT Scan showed talus fractured inferior to the Femoral Head Block
Total Ankle Joint extraction fusion with en bloc femoral head graft. Nickel and Molybdenum Allergy
Total Ankle Joint extraction fusion with en bloc femoral head graft. Nickel and Molybdenum Allergy

DOS: Second IM rod 9/9/15

CT SCAN: 11/28/15
1. Interval TTC fusion with resection of the distal fibular diaphysis and bone grafting along the lateral aspect of the ankle. The previously seen talar fracture demonstrates interval healing. There are numerous additional fusions of the ankle and midfoot, as detailed above.

Throughout the entire process had 4 serious discussions about BKA.
Literature:

- **Duke University Study:**
  - Mulligan, Adams, Easley, DeOrio, Nunley. FAI 2017
  - 28 pts LTF w/ lateral locking plate vs. 38 pts PATS approach using static IM nails.
  - 64% union rate in LTF/Plate
  - 76% union rate in PATS/IM Nail
  - 71% Overall Union Rate
    - Symptomatic Non-union:
      - 16% revision in the IM Nail vs 7% in the LTF/Plate

- **Griffin and Coughlin - JFAS 2018**
  - Retrospective review of 19 patient’s over 4 years
  - Fusion rate of 65% on first attempt
  - With Subsequent Dynamization
    - 88% fusion at the AJ
    - 77% fusion at the STJ
    - TAR salvage with allograft or synthetic bone block resulted in 83% fusion (50% of those required dynamization)
25 patients from 2003 - 2011 needing Fresh Frozen Femoral Head Graft with TTC fusion.

- Average Follow Up 1.5 years
- 12 successful fusions (48%)
- 21 Braceable Limbs (84%)
- 4 BKA (16%)
TTC using Bulk Femoral Head Graft.

Indications: failed total ankle replacement, avascular necrosis of the talus, trauma, osteomyelitis, Charcot, or failed reconstructive surgery.

32 patient’s

71% salvage rate with braceable asymptomatic non-union

16 fusions (50%)

16 non-unions (50%)
  - 7 asymptomatic
  - All 9 diabetic patient’s went on to non-union.
    - 100% nonunion rate for DM.
Use of an Intramedullary Nail with Internal NiTiNOL Compression Element in Salvage Tibiotalocalcaneal Arthrodesis: Case Series of 19 Patients

Douglas Pacaccio DPM¹, Thomas Nordquist DPM¹,², Nicholas Vogelsang DPM¹, Jennifer Pacaccio DPM¹
¹Advanced Foot and Ankle Surgeons, Inc. – Sycamore/Yorkville, IL, ²Fellow, Reconstructive Foot and Ankle Surgery

Procedures

Of the 19 patients, two cases were excluded from analysis: one due to septic resection with no follow-up (Figure 2), and another due to intraoperative complications (Figure 3). Of the remaining cases, 17 patients had successful fusion, including 15 patients with a fusion rate of 94.7%. The remaining two patients with failed fusion were due to infection and non-union, respectively.

Results

This case series describes the use of an IM nail with an internal compression mechanism for treating high-risk patients in TTA fusion surgery. The goal of this procedure is to reduce the risk of non-union, infection, and failure due to technical errors. Among the 19 diabetic patients, there was no surgical complication, and the majority of patients achieved successful fusion. Furthermore, the procedure offered improved bone healing and reduced the risk of infection compared to traditional TTA procedures. This suggests that the IM nail with internal compression is a viable option for treating high-risk patients in TTA fusion surgery.

Discussion

This case series demonstrates the potential benefits of using an IM nail with internal compression in salvaging high-risk patients in TTA fusion surgery. The procedure is associated with reduced surgical complications and improved fusion rates, particularly in diabetic patients. The results highlight the importance of considering individual patient factors and surgical techniques in the selection of treatment options for high-risk patients. Further studies with larger sample sizes are needed to validate these findings and to explore the long-term outcomes of this procedure.
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Study Design

- 19 patients Case Series
- 2 excluded due to sepsis and death prior to 1 year follow-up
- 5 females, 12 males with average age of 59 years
- Comorbidities: Diabetes (4), Charcot (3), Tobacco Users (3), Non-diabetic neuroarthropathy(3), Revisions of failed fusions (6)
- Minimum 1 year follow-up

Results

- 32/34 joints fused (94% fusion rate) confirmed on CT
- Average fusion time: 8 weeks
- 1 non-union due to talar AVN, Eventually became a delayed union
- 4 Re-operations:
  - Median time to WB: 8.0 +/- 3.2 weeks
  - NiTiNOL Element recovered average 5.1 +/- 0.8 mm

47 year old female patient with nonunion from prior fusion surgery at A) 1 week post-surgery. and F) 1 year post-surgery

80 year old male patient with severe arthritis, end stage degenerative joint disease. Radiographs shown are Left) 2 weeks post-surgery. Right) 14 weeks post-surgery

PRESENTED at 2018 ACFAS in Nashville
33 patients undergoing TTC fusion w/ Pseudoelastic IM Nail.

- 90% overall fusion rate
- 94% overall fusion rate in patient without Charcot
- 71% fusion rate in Charcot
  - Charcot identified as a significant risk factor for STJ non-union
- Average of 3.9mm of bony resorption at the fusion site.
  - Tracked by measuring the travel of the PA screw in the Nail sleeve.
Thank You!

[Logos of A, Foot & Ankle Foundation, and Northwest Illinois Foundation]