Measurement of Nitinol Recovery Distance Using Pseudoelastic Intramedullary Nails for Tibiototalocalcaneal Arthrodesis

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Disclosure

• Dr. Adams and Dr. Parekh report personal fees from Medshape Inc., outside the submitted work

• Dr. Easley reports grants and personal fees from Medshape Inc., during the conduct of the study
Background

• Compression across the fusion sites in tibiotalocalcaneal arthrodesis is necessary to obtain fusion

• Up to 90% of the initial compression achieved intra-operatively is lost over time with just 1mm of bone resorption using standard intramedullary nails\(^4\).

• Current methods to dynamize across fusion sites include:
  - ring external fixators: cumbersome, pin site infections
  - dynamized nails: require invasive manipulation of proximal screw
Nitinol

- **Nickel Titanium**
- **Discovered by US Naval Ordinance Laboratory**

- **Pseudoelastic property**: Nitinol element stretched across fusion site
  - Nitinol material responds by conforming back to original length while applying constant force across fusion site in response to bone resorption

Yakacki et al.
Pseudoelastic IMN

Adapts to resorption

Slotted calcaneal screw holes

Cross-section

Pseudoelastic element

Sliding element

Yakacki et al.
Methods

- **Purpose:** to measure the in vivo movement of the Nitinol element over time.
- **Methods:** 15 patients
  - Inclusion: All patients indicated for TTC fusion
  - Exclusion: Active infection, non-ambulatory
  - Serial Radiographs at 0, 2, 6, 12, 24, 52 weeks to measure distance of Nitinol element migration proximally

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<td>Diabetes (% yes)</td>
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*Nitinol element stretched outside titanium rod

*Nitinol element migrating proximally in response to bone resorption

**Figure 5.** Intraoperative fluoroscopic image showing Nitinol element distal to intramedullary rod (left). X-ray showing migration of Nitinol element 3 months post operation.
Procedure

- The nail was inserted in retrograde fashion until the distal screw holes were centered in the calcaneus
  - Two distal calcaneal screws placed
- The Nitinol element was stretched 6mm
- 3 millimeters of external compression was applied
- Two proximal tibial screws were placed.
- [https://www.youtube.com/watch?v=Wevz5MbZ160](https://www.youtube.com/watch?v=Wevz5MbZ160) (Dr. Selene Parekh)
Results

- All 15 subjects who had TTC arthrodesis using MedShape Inc. Dynanail
  - at least 2.38mm of Nitinol element migration proximally with mean 5.58 (+/- 1.38), (range, 2.38-8.11) mm
  - Average follow up time to date of 195 (+/- 106.3), (range: 89 to 490) days.

- On average, 86% of the total recovered distance took place within the first 39.7 (+/– 10.03) days
Results: Proximal Nitinol Migration

The Nitinol element recovers distance when stretched intraoperatively and maintains moderate compression in response to bone resorption.
Discussion

• In a systematic review by Jehan et al., out of 641 TTC arthrodesis procedures using IMN, 556 obtained union (86.7%)\(^3\)
  – complication rate was 55.7% of which 23.8% were due to direct non-union.

• To date there is no data correlating loss of compression to bony non-union.

• Our study did not analyze fusion rates

• No fusion rates reported for Medshape Inc. Dynanail
References