ICD-10 C&M Meeting – March 17, 2020

Code Request - Joint Fusion via Intramedullary Sustained Compression Internal Fixation

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Attendee: Kathryn Smith, PhD – Director of Marketing – MedShape, Inc.

Joint Fusion – Introduction

- Process: merge bones by eliminating problematic joint between them

- Goal: pain relief, stability, and enhanced patient function

- > 55,000 fusions annually in foot and ankle alone (Best 2015)

Fused ankle and subtalar joints

Joint Fusion – Role of Mechanical Factors

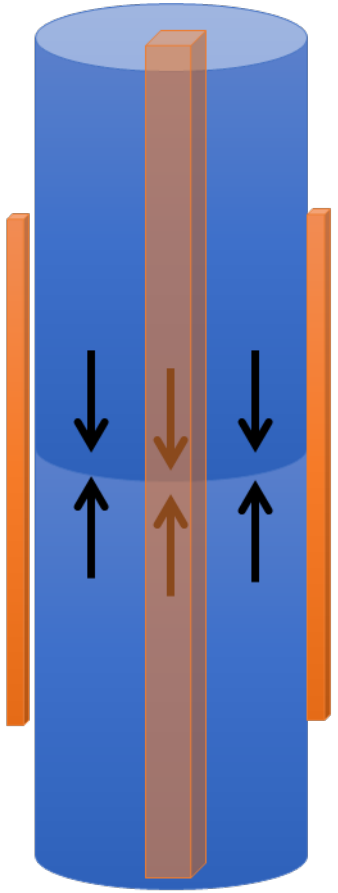
Mechanical factors important for joint fusion (Clifford 2015, Mueckley 2006/2007, Parker 2009, Bennett 2005, Evers 2017, Berend 1997)

High bony contact area

Stiffness and stability by rigid immobilization

Load sharing between device hardware and bones

Sufficient compression across fusion site (contributes to all above)



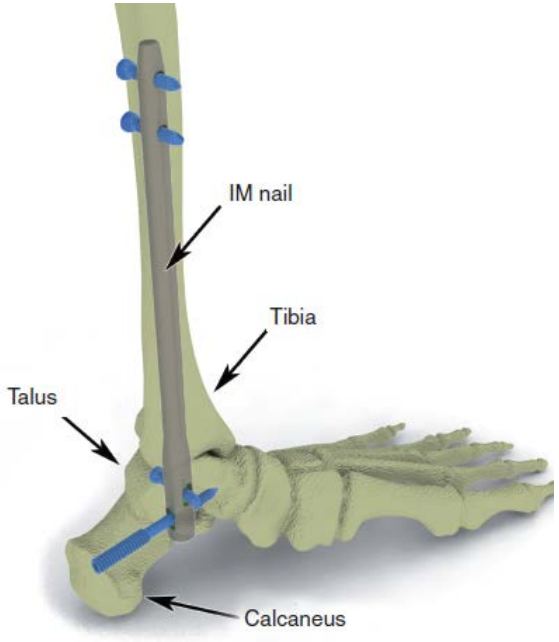
Fusion of bones (blue) at joint depends on compression and stabilization by devices (orange)

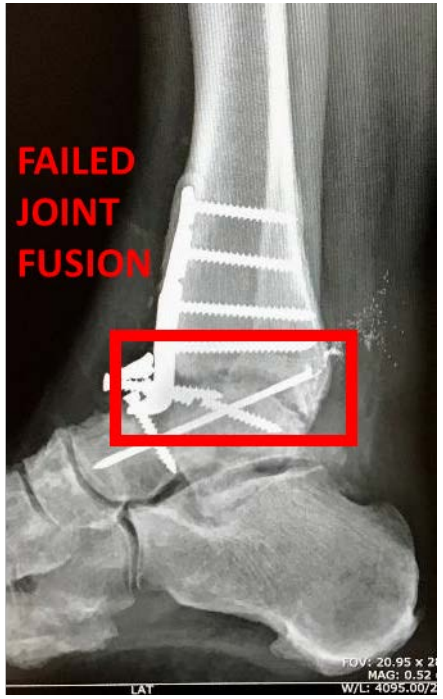
Joint Fusion - Devices for Providing Stability and Compression

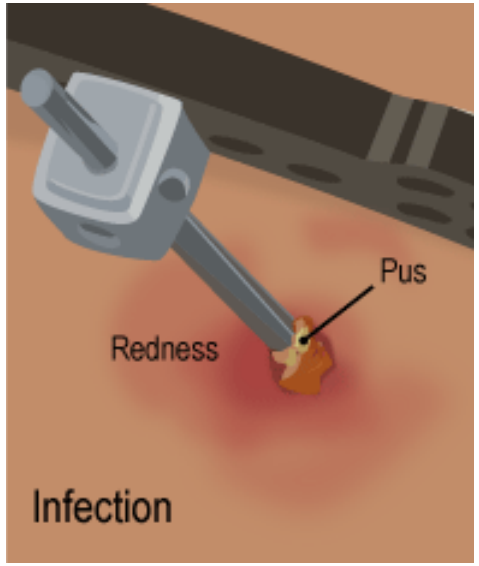
- **Internal Fixation – 0SG-Device value 4**
  - Intramedullary nails, plates, screws
  - High multiplanar stability
  - **Minimal post-operative compression**

- **External Fixation - 0SG-Device value 5**
  - **Sustained compression during fusion**

  Patient pain and infections/fractures from pins
  Limited multiplanar stability







Problems with Internal Fixation for Joint Fusion

- **Low fusion rates in challenging cases** (Wukich 2015, Jehan 2011, Jeng 2013, Bussewitz 2014, Parker 2009)

  Tobacco users, diabetics, bulk bone defects, revisions, etc.

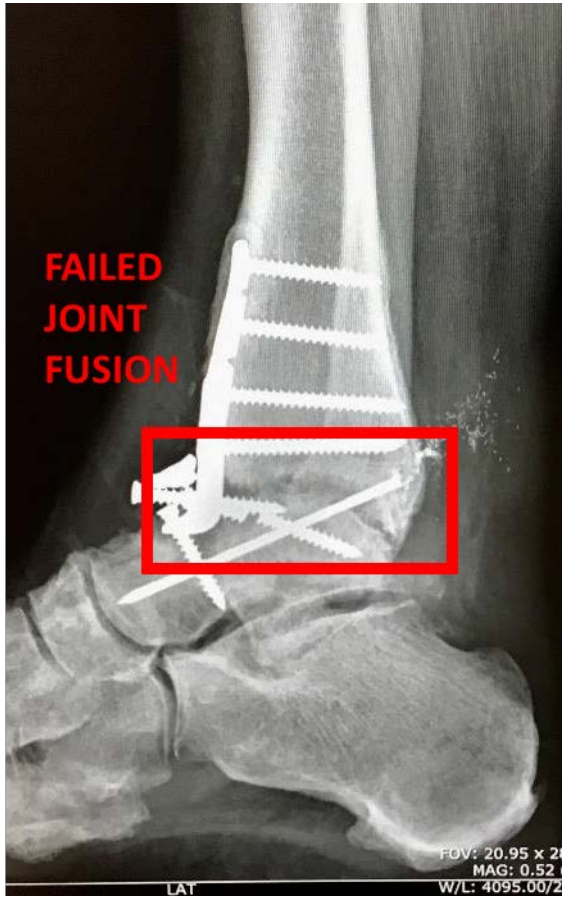
  Non-union → amputation (MacKenzie 2007)

- **High complication rates including device fracture** (Gross 2014, Jehan 2011, Wukich 2015)

- **Joint fusion takes time – most devices cannot compress over time**

  Compression loss from bone resorption, joint settling, implant loosening (Mueckley 2006/7, Kinmon 2013, Gabarre 2017)

  Bone gaps → non-union and device failure (Karakasli 2015, Rosa 2017)

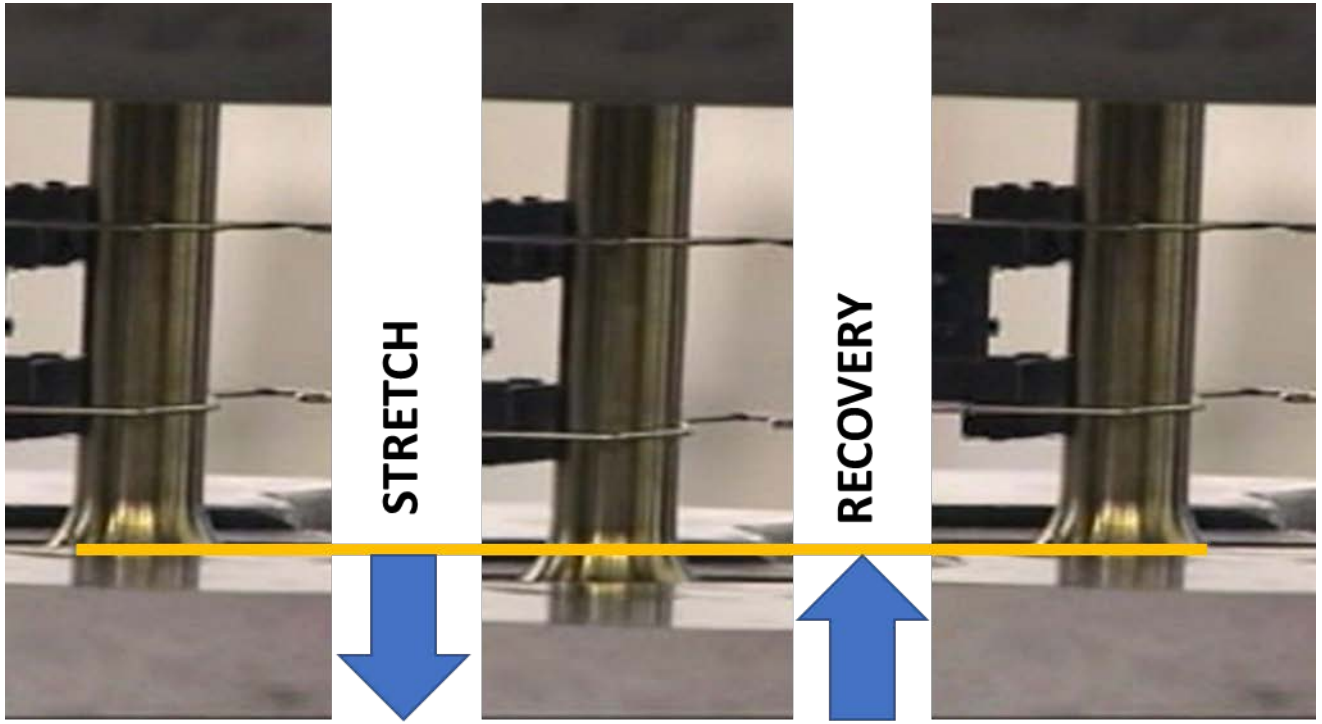


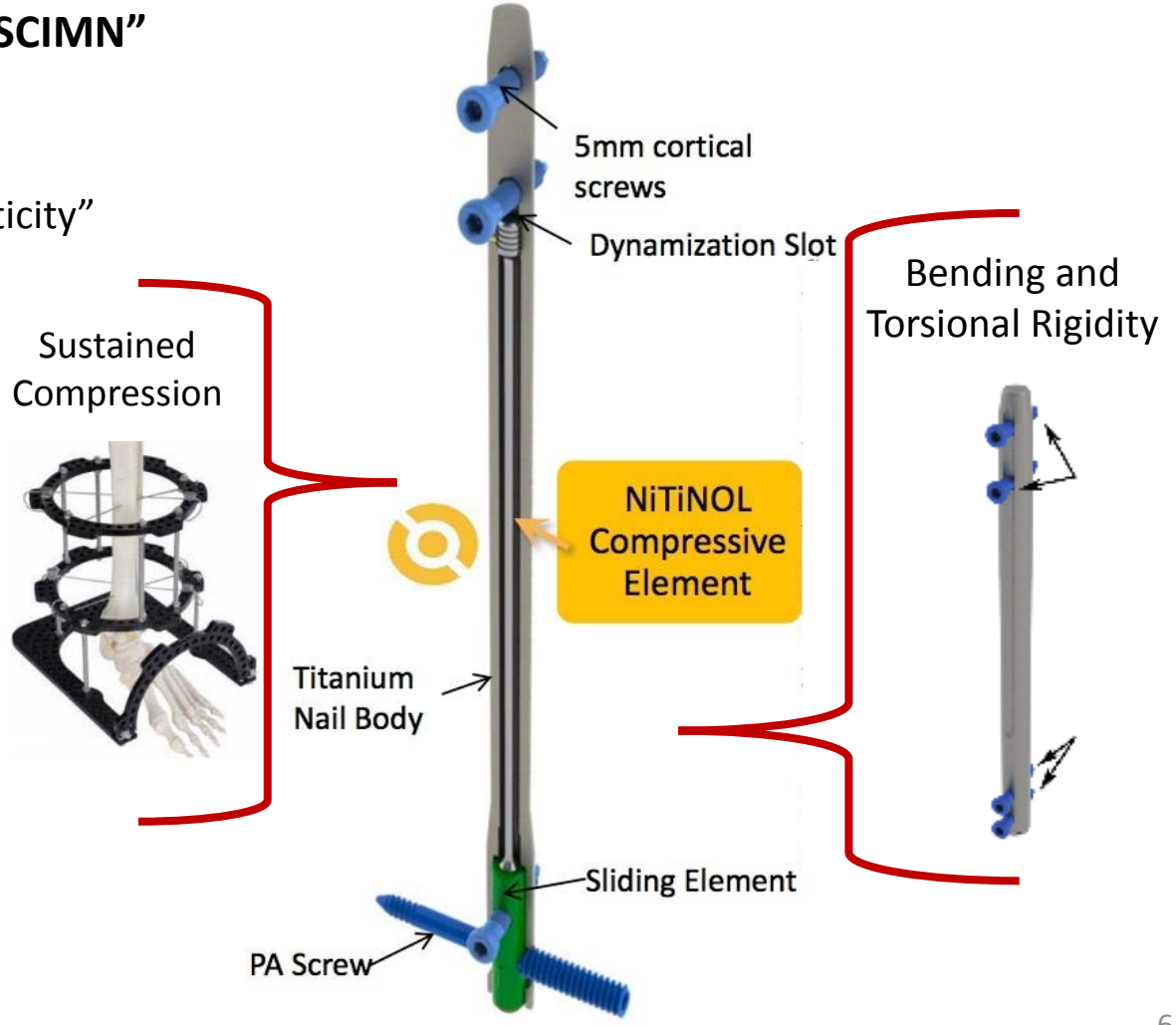
Problems with Internal Fixation for Joint Fusion – Solution

- **Incorporate sustained compression mechanism within IM nail – "SCIMN"**

  (DynaNail®, MedShape, Inc. – FDA 510(k) clearance 2012)

  Benefits of external fixation with IM nail
  NiTiNOL compressive element deforms ~10X > other metals – "pseudoelasticity"
  Stretched element retracts like rubber band + compresses during recovery





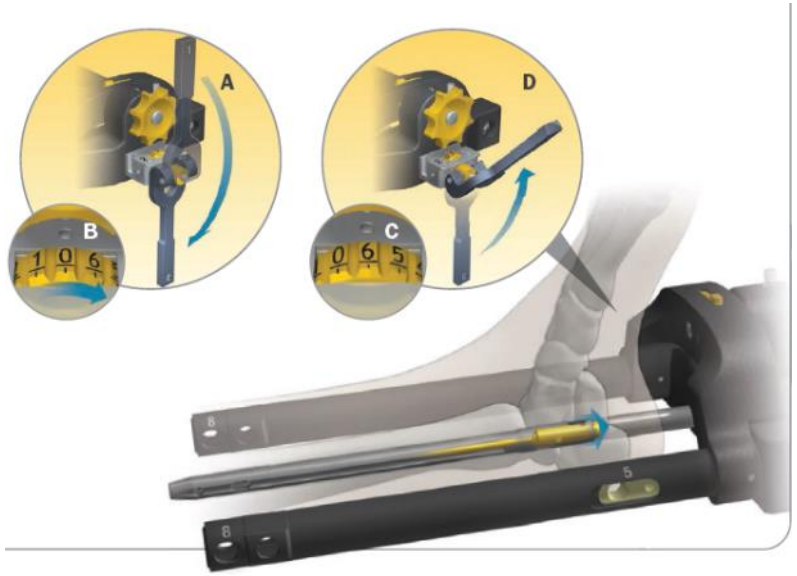
DYNANAIL
TTC FUSION SYSTEM

MEDSHAPE

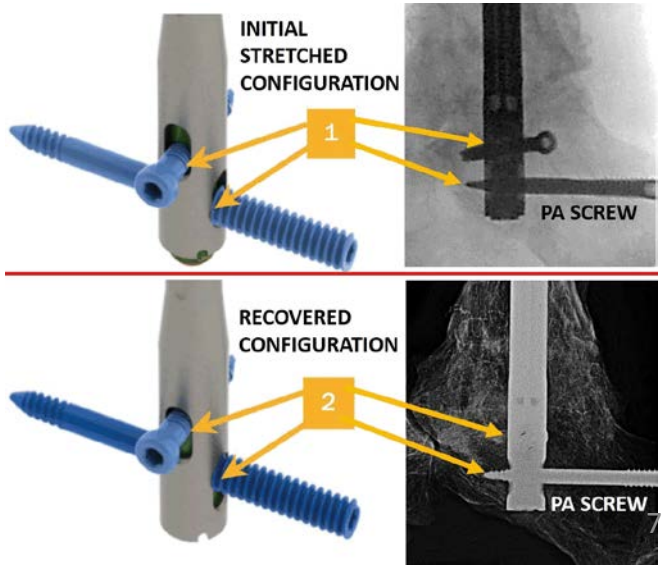
SCIMN – Surgical Procedure Overview

Following joint preparation, the general SCIMN surgical technique is as follows (tibiotalocalcaneal arthrodesis example):

1. Assemble Targeting Frame
2. Insert Guidewire into tibial canal
3. Drill entry tunnel with 7 mm and 9 mm Drills
4. Ream to appropriate size using Reamer Shaft and Reamer Heads
5. Load Nail Implant onto Targeting Frame
6. Insert Nail Implant into reamed tibial canal
7. Stretch the Compressive Element by pulling down on Lever [1]
8. Set the amount of compression by turning Stop Wheel [2]
9. Return lever by pulling up when finished [3]
10. Attach Outer Tube Brace and PA Attachment
11. Drill into the calcaneus and insert P-A Headless Screw [4]
12. Drill into the calcaneus and insert L-M Cortical Screw [5]
13. Drill medial-to-lateral into distal interlocking screw hole of the Nail Implant [6]
14. Apply External Compression by turning the Manual Compression Knob [7]
15. *(Optional) Insert most proximal tibial Cortical Screw in DynaNail XL Implants.* Drill and insert proximal tibial Cortical Screw into proximal interlocking screw hole [8]
16. Insert distal tibial Cortical Screw [9]
17. Release Nail Implant from the Targeting Frame
18. Replace End Cap and close incisions



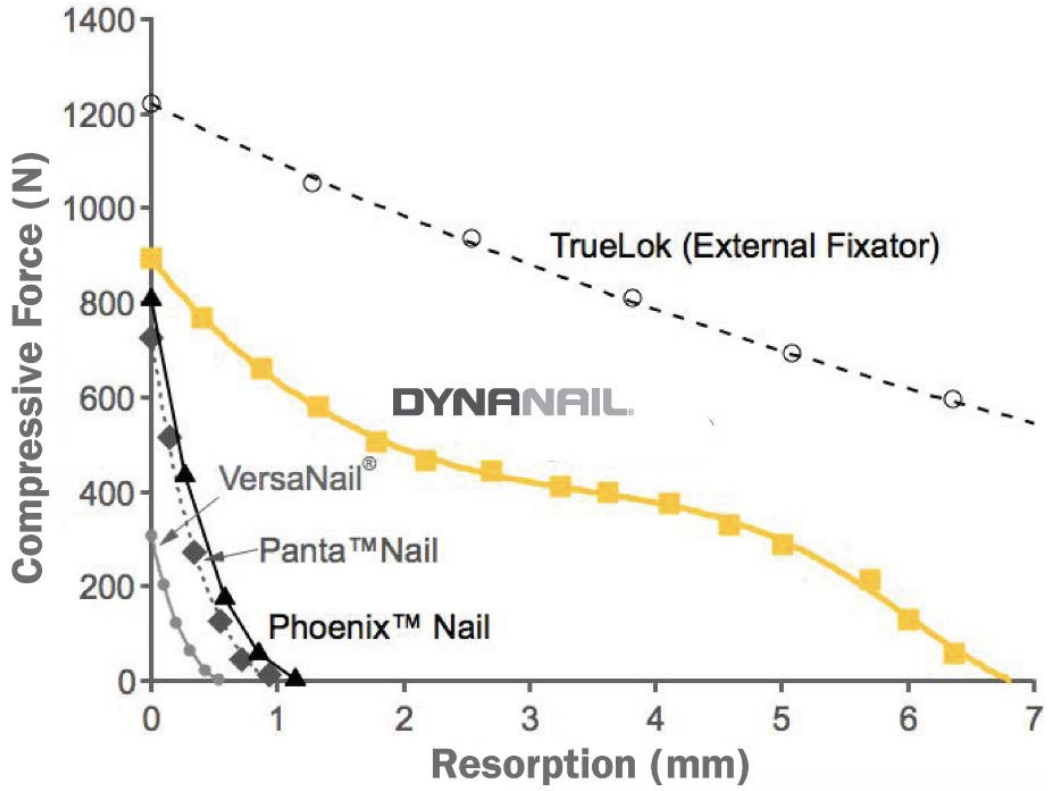
The stretched element is linked to bones by screws passing through nail



SCIMN – Features – Sustained Compression

- 6 mm of intraoperative external compression via delivery frame

- **Additional 6 mm sustained compression via stretched compressive element**

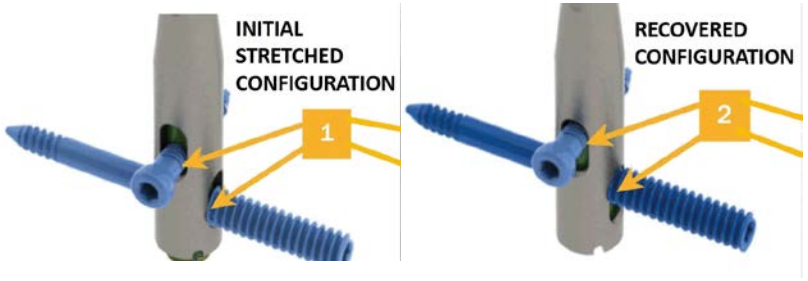


- Other nails lose joint compression after ~1 mm of bone resorption (Yakacki 2010, Yakacki 2011, Latt 2017)

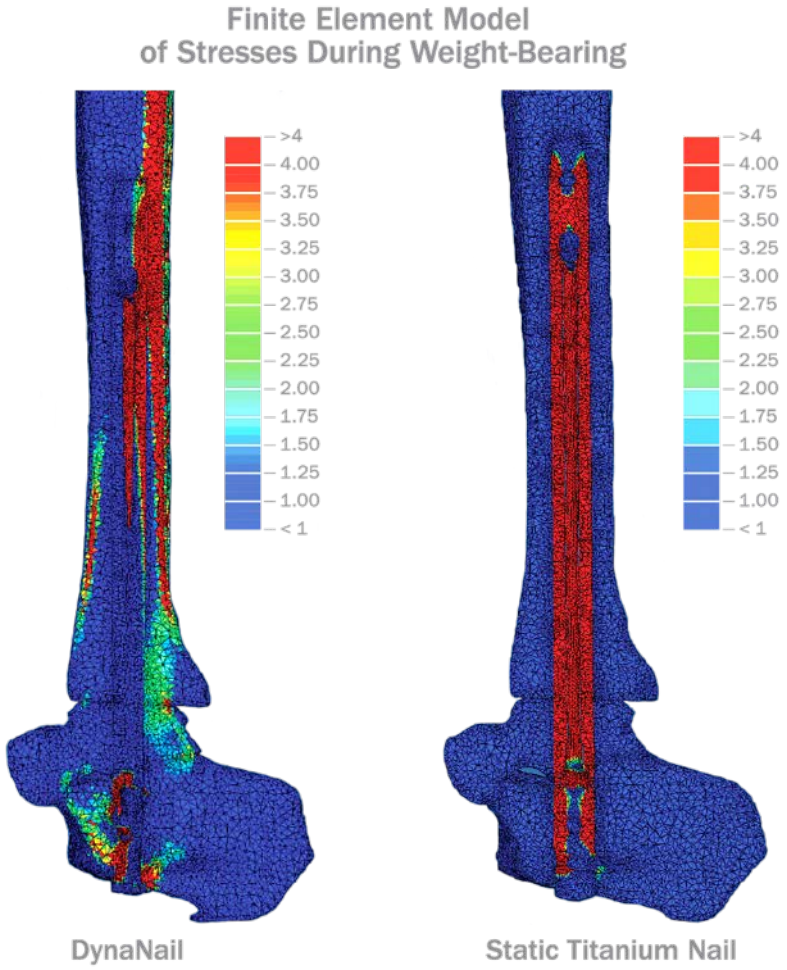
- DynaNail compresses for 6+ mm of resorption

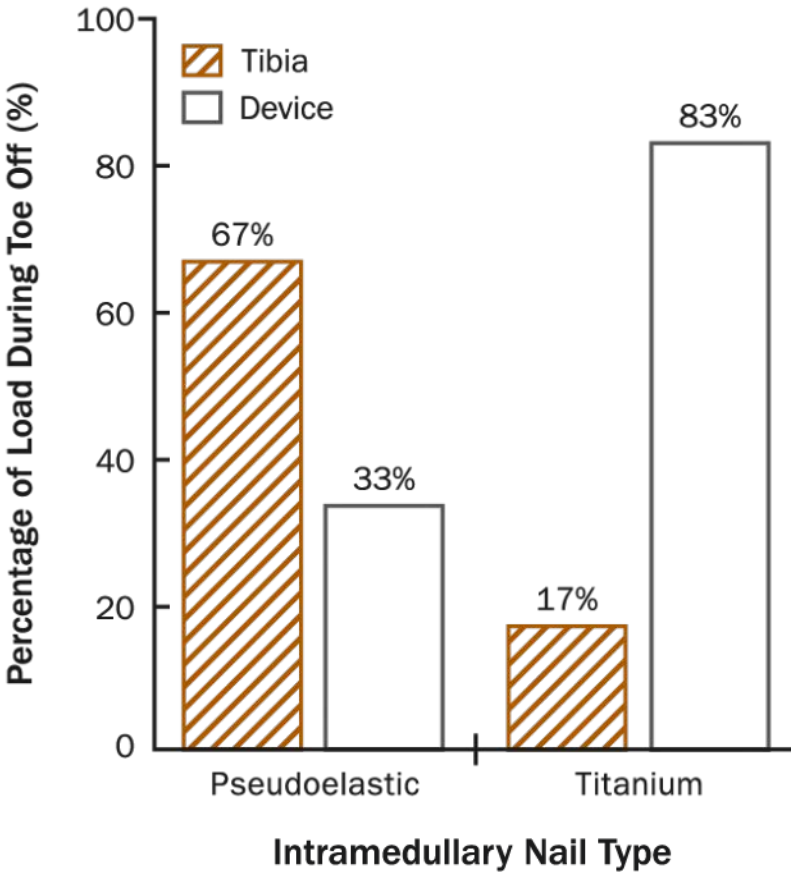
SCIMN – Features - Immediate Dynamization and Load Sharing

- Element allows **dynamization** (screws can slide in slots) at surgery with maintained stability



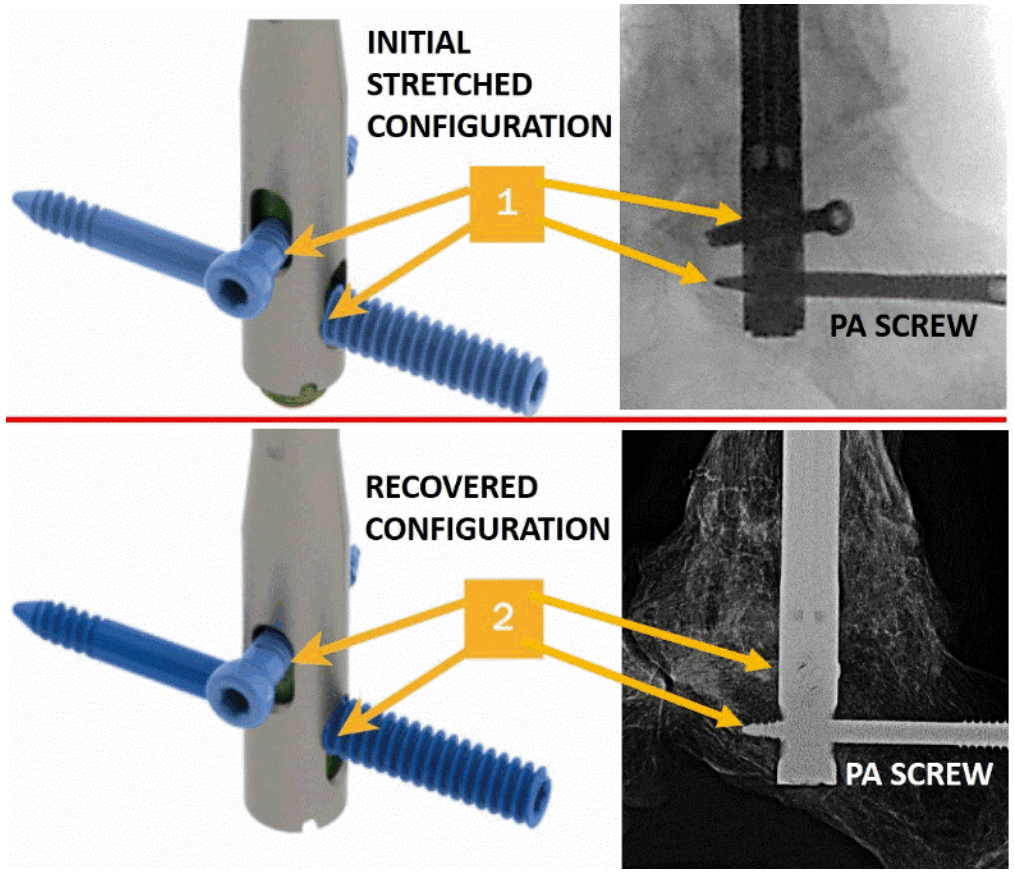
- Static or non-dynamized nails can stress shield bones → hardware fatigue failure (Anderson 2016)
- Dynamization plus compression allows load sharing with bones → increased bone formation (Anderson 2016)

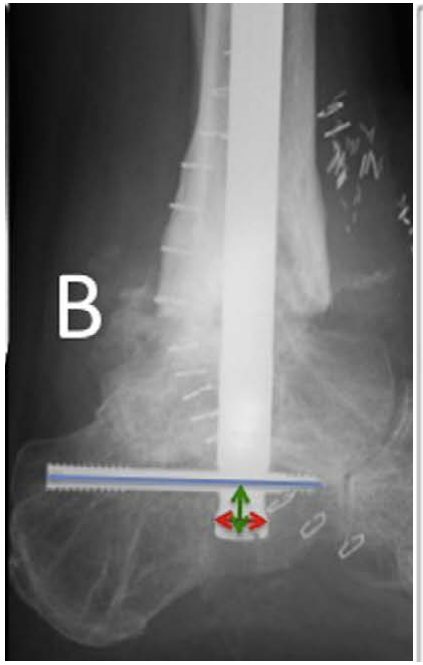


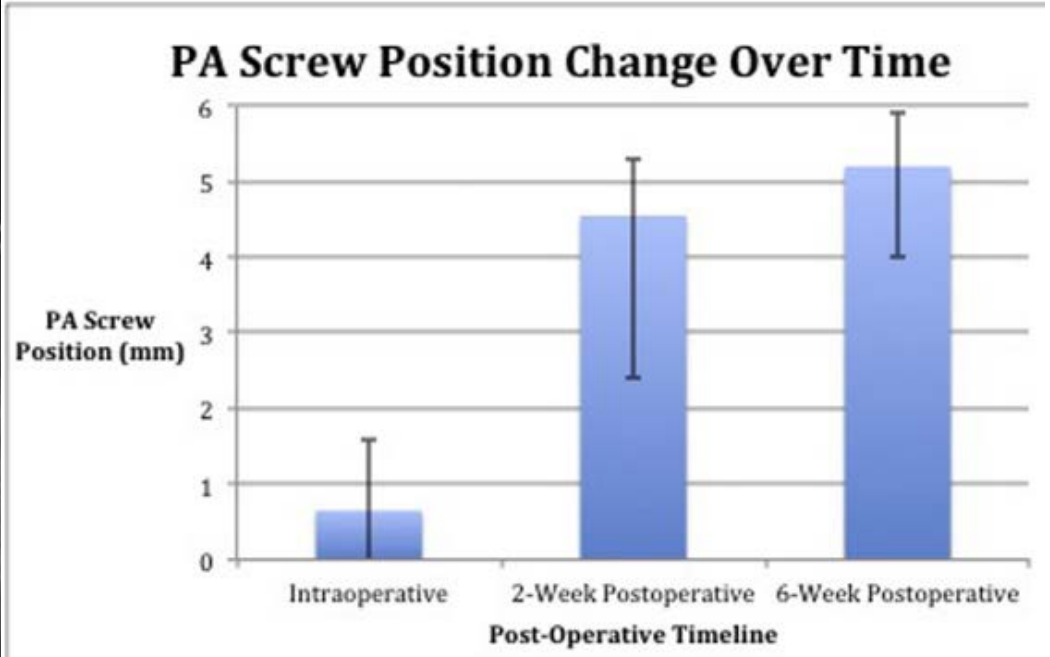


SCIMN – Clinical Post-Operative Compressive Element Tracking

Screw position can be measured over time on X-rays → corresponds to retraction of compressive element

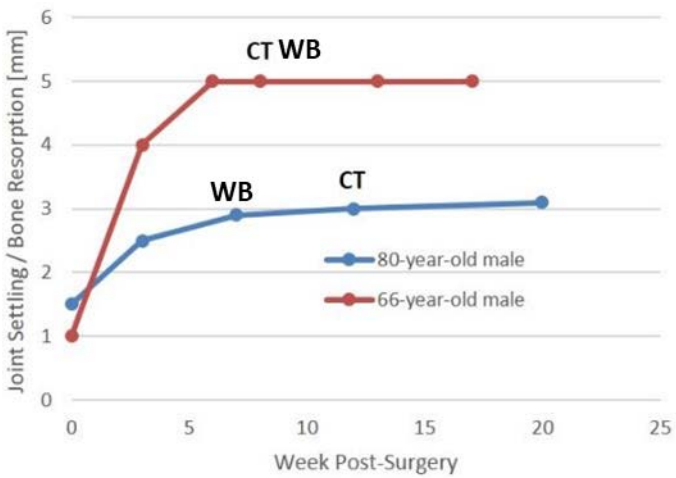


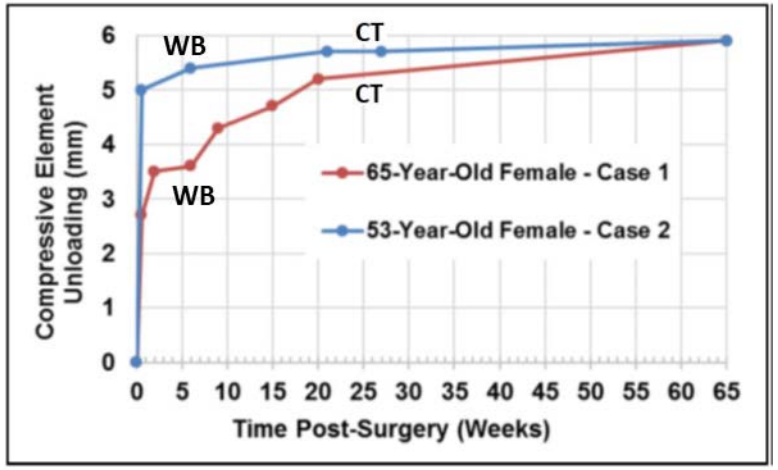




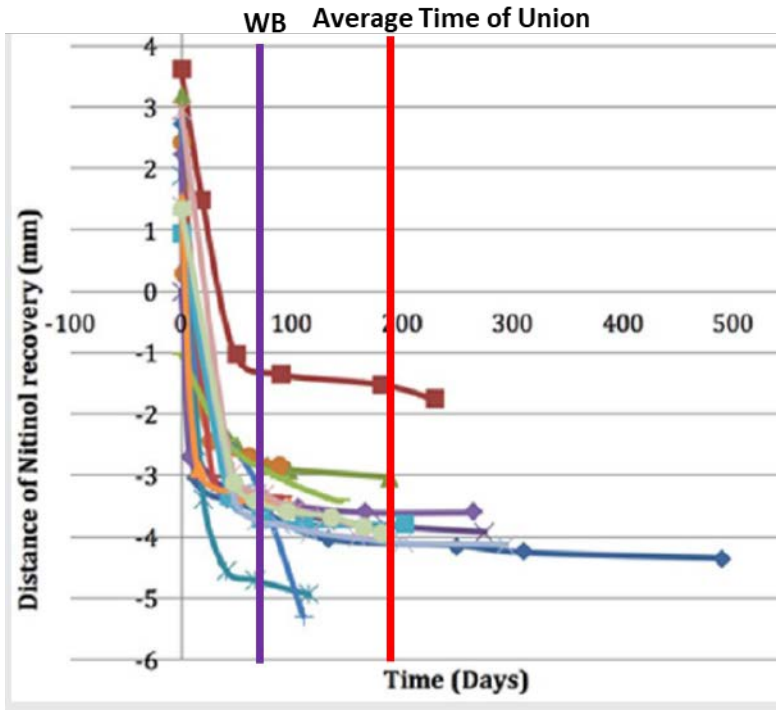
SCIMN – Element Recovery, Weight-Bearing, and Fusion Assessment

- CT scans > X-rays for assessing fusion, but are costly and not always available (Coughlin 2006)
- Element tracking data suggests recovery levels off before union - element "locked" in place within bone (Kildow 2016, Latt 2017, Conklin 2018)
- Tracking data + X-rays + clinical examination enhance confidence in fusion assessment and increased patient weight-bearing (WB) → CT less needed to confirm union





Element recovery levels off before confirmation of union via imaging



SCIMN – Improved Outcomes and Unique Capabilities

- **10 Peer-Reviewed Clinical Publications** (Hsu 2015, Kildow 2016, Latt 2017, Kreulen 2017, Dekker 2018, Conklin 2018, Ford 2019, Lachman 2019, Steele 2019, Dupont 2019)
  - Higher fusion rate versus other IM nails (Steele 2019)
  - Significantly faster time to fusion (3.9 months faster) (Steele 2019)
  - Improved outcomes despite patients with significantly more conditions linked to non-union (Steele 2019)
  - Compressive element recovery tracking (Kildown 2016, Latt 2017, Conklin 2018, Ford 2019)
  - Multi-mm element recovery in most patients measured suggests sustained compression need

- **Case for New ICD-10-PCS Code**
  - Currently no code for joint fusion (0SG / 0RG) using sustained compression internal fixation device
  - Data indicate novelty and superiority of SCIMN over other internal fixation devices for joint fusion
  - DynaNail used in foot & ankle fusions, but principles of sustained compression and dynamization apply to other joints
  - Precedent - ICD-10-PCS code for novel IM nail – 0PH/0QH (Bone Insertion), Device 7 – Internal Fixation Device, Intramedullary Limb Lengthening

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