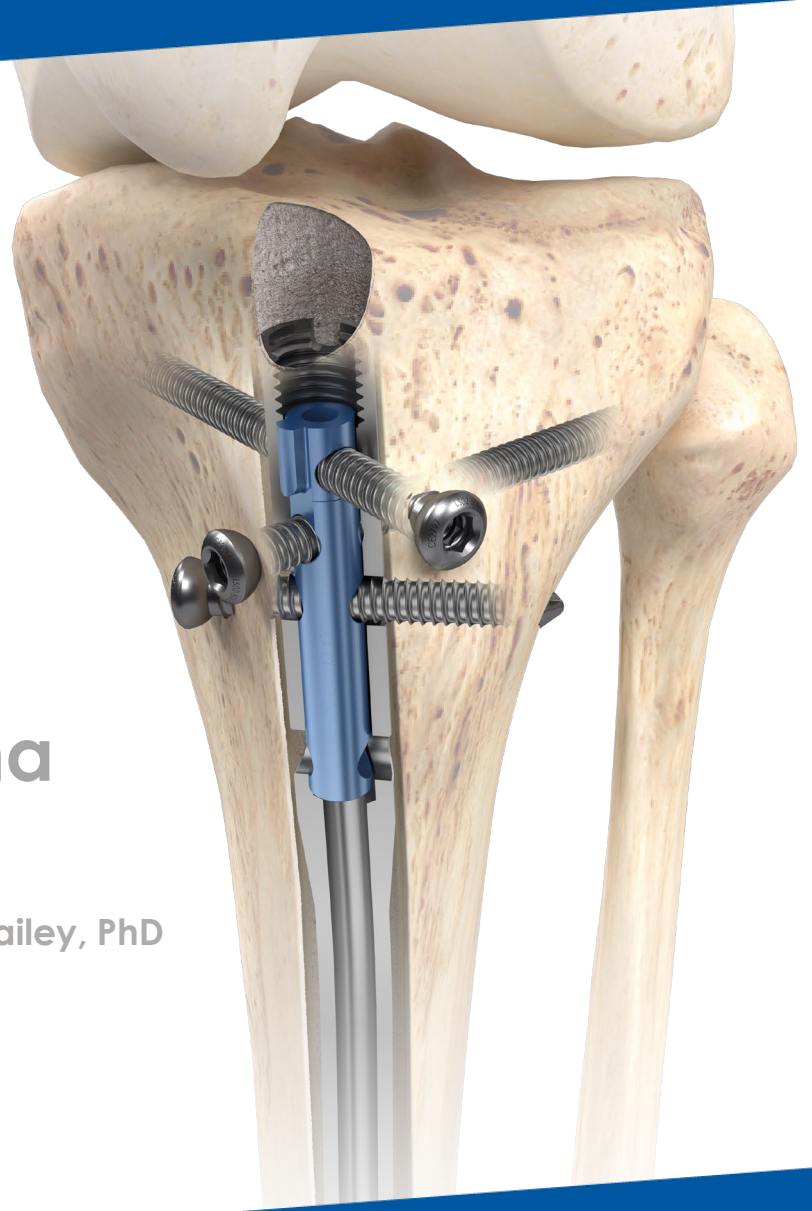
APEX
AXIAL MICROMOTION NAILS



OTA Podcast

Healing in Motion:

Innovations in Orthopedic Trauma with Apex Nailing Systems

Featuring Sean Campbell M.D., Augustine Saiz M.D., and Hannah Dailey, PhD

ORTHOXEL

Introductions

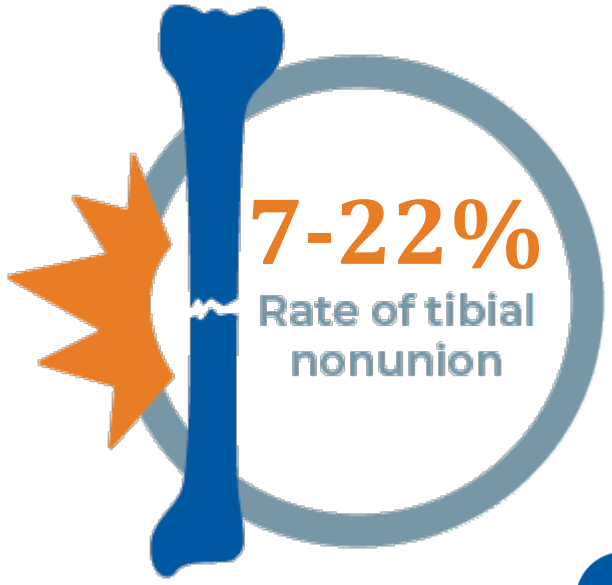
Hannah Dailey, PhD
CSO and Co-Founder of OrthoXel
Associate Professor of Mechanical Engineering & Mechanics at Lehigh University

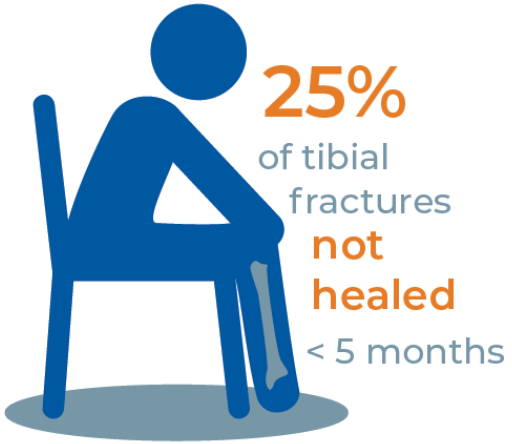
Sean Campbell, M.D.
Orthopedic Trauma Surgeon at University of California, Davis

Augustine Saiz, M.D.
Orthopedic Trauma Surgeon at University of California, Davis

Clinical Problem

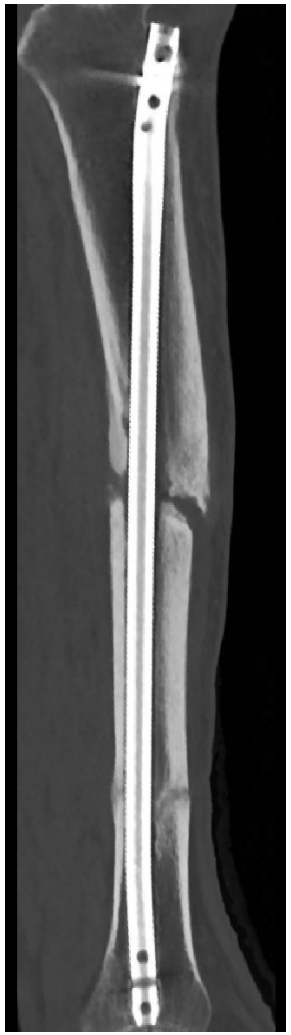
- Tibial shaft fractures represent ~37% of all long bone fractures in adults[1]
- Tibial nonunion rates have been reported ranging from 7-22%; consensus nonunion rate from largest studies is ~12% (references in next slide)
- Delayed healing is also a significant issue, with 25% of tibial fractures not healed within 5 months[2]
- Burden of failed fracture healing
- Risk factors for compromised healing



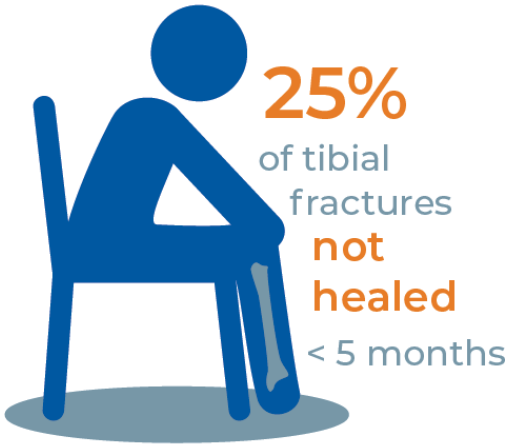


[1] Court-Brown+, *Injury*, 2006
[2] Dailey+, *J Orthop Trauma*, 2018

Statistics on Nonunion and Delayed Healing



Tibial Fractures Treated in…	Consensus Nonunion Rate	Nonunion References
North American Level I Trauma Centers **U.S. Managed Care Claims Data** **UK + Europe**	12%	[3] O'Halloran+, *Clin Orthop Relat Res*, 2016 (15%) [4] Lack+, *JBJS*, 2014 (7%) [5] Fong+, *J Orthop Trauma*, 2013 (13.5%) [6] Bhandari+, JBJS, 2008 (14% reop) [7] Bhandari+, J Orthop Trauma, 2003 (22% reop) [8] Zura+, *JAMA Surg*, 2016 (14%) [9] Antonova+, *BMC Musculoskel Disord*, 2013 (12%) [10] Dailey+, *J Orthop Trauma*, 2018 (12%) [11] Metsemakers, *Injury*, 2015 (12%) [12] Massari, *Biomed Res Intl*, 2018 (12%)



Time to Union Literature Data (1003 Reamed IM Nails, Open/Closed)	
Median (IQR)	17 (14-20) weeks
[2] Dailey+, *J Orthop Trauma*, 2018	

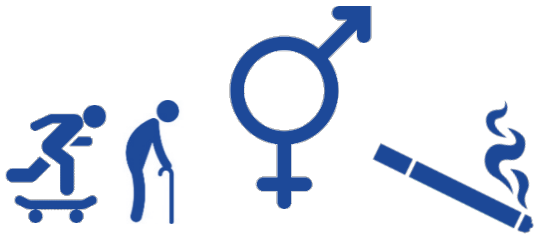
Risk Factors for Nonunion

Nonunion is a **complex multi-factorial problem** with many risk factors:

Injury-Related

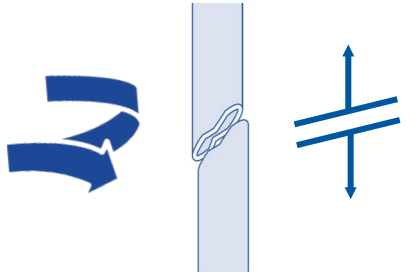
Fracture Pattern (OTA/AO)
Soft Tissue Injury Severity
Bone Loss, Infection
Compartment Syndrome

Patient-Dependent



Age, Sex
Cigarette Smoking, Diabetes
Chronic Disease (HIV, Hep)

Surgery-Related



Malreduction
Fixation Instability
Vascular Disruption

Significant nonunion risk factors in multivariate statistical models	
Factor	**Refs.**
Age (nonlinear factor)	2
Compartment Syndrome	3
Chronic Disease	3
Excessive Fracture Gap / Poor Cortical Continuity	3,5,12
Fracture Classification (OTA/AO Type)	2
Infection	2,13
Open Injury / Gustilo-Anderson Classification	2,3,13,14
Polytrauma	10
Smoking	13
Unstable Fracture	12

Burden of Failed Fracture Healing

$74,000

Estimated total cost of care for treating a non-united tibial shaft fracture[15]

Estimated annual cost of tibial nonunions requiring **revision surgeries**[9]

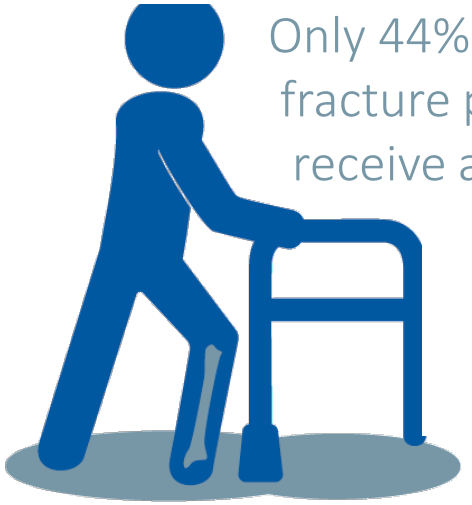
$340M

Indirect costs, mainly due to lost productive work time, estimated up to

x 7-9 times

direct healthcare costs[9,16]

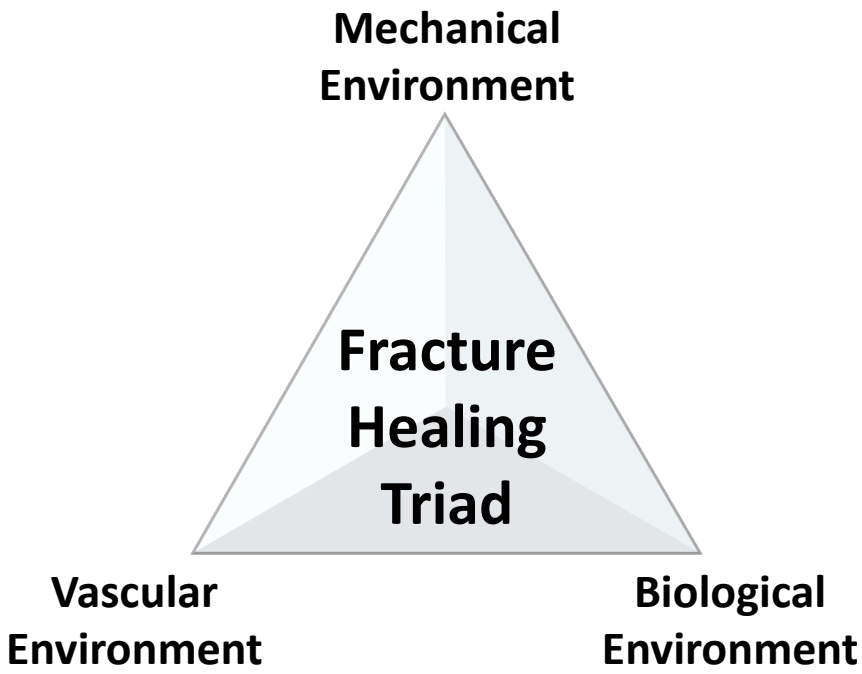
Tibial nonunions can lead to prolonged **disability** in addition to higher rates of **depression, opioid use** and **narcotic dependency**[8,9,17]



Only 44% of lower-extremity fracture patients who receive a **nonunion** diagnosis are able return to work within six months and **only 59% return to work by one year**[18]

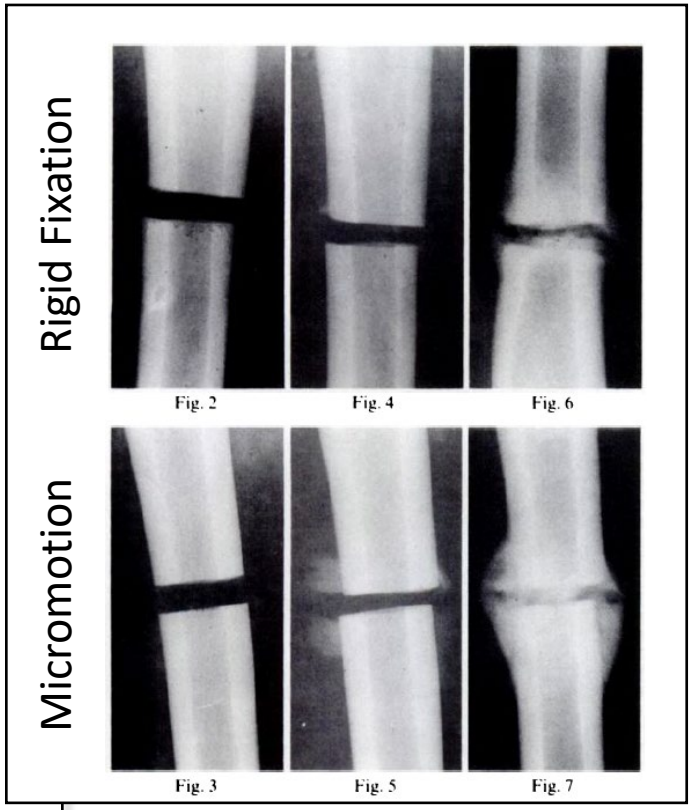
Mechanobiology of Fracture Healing

- Successful fracture healing requires a supportive **biological environment**, **vascular environment**, and **mechanical environment**.
- Vascularity and biology are mostly non-modifiable factors.
- The mechanical environment can be influenced through the choice of implant and the intra-operative design of the construct.



Inspirational acknowledgement:
[19] Giannoudis+ *Injury*, 2007.

Scientific Rationale for Micromotion



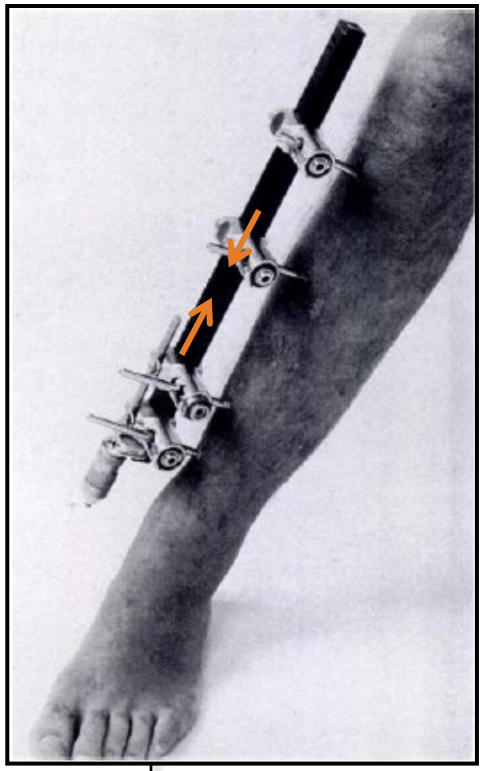
Axial micromotion at the fracture site:

- Stimulates callus development in sheep
- Increases stiffness

1985

[20] Goodship AE and Kenwright J. "The influence of induced micromovement upon the healing of experimental tibial fractures." *J Bone Joint Surg Br*. 67(4):650-655, 1985.

Scientific Rationale for Micromotion



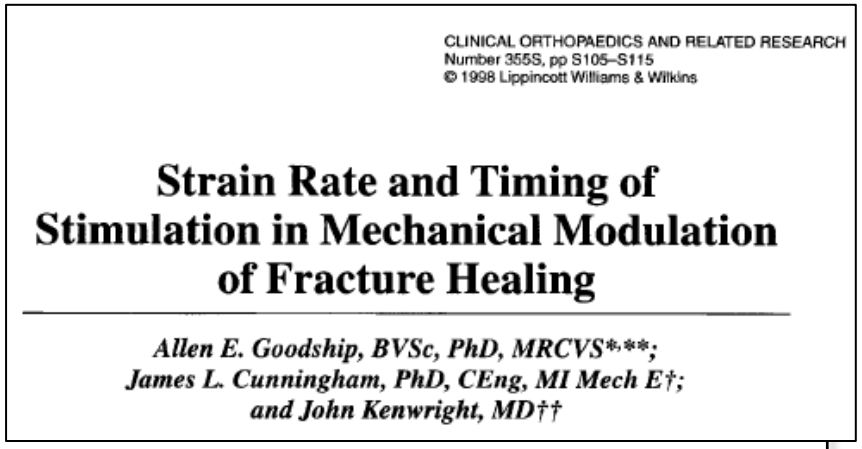
Clinical trials showed that micromotion:

- Stimulates callus development
- Reduces healing time by 20%

1989 & 1991

[21] J Kenwright and AE Goodship, "Controlled Mechanical Stimulation in the Treatment of Tibial Fractures," *Clin Orthop Relat Res.*, 241:36-47, 1989.
[22] J Kenwright *et al.*, "Axial Movement and Tibial Fractures," *J Bone Joint Surg Br*, 73-B:654-659, 1991.

Scientific Rationale for Micromotion



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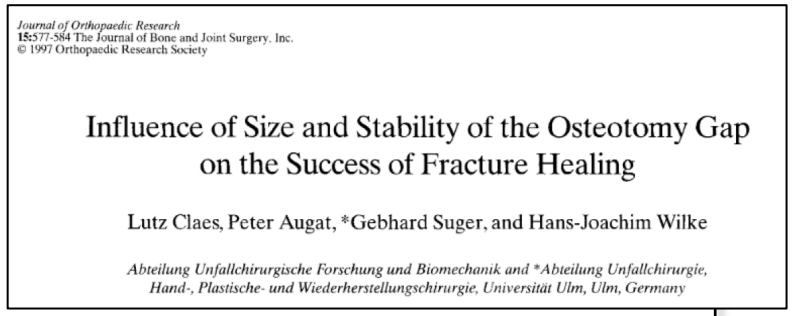
Strain Rate and Timing of Stimulation in Mechanical Modulation of Fracture Healing

Allen E. Goodship, BVSc, PhD, MRCVS,**;*
James L. Cunningham, PhD, CEng, MI Mech E†;
and John Kenwright, MD††



Journal of Orthopaedic Research
15:577-584 The Journal of Bone and Joint Surgery, Inc.
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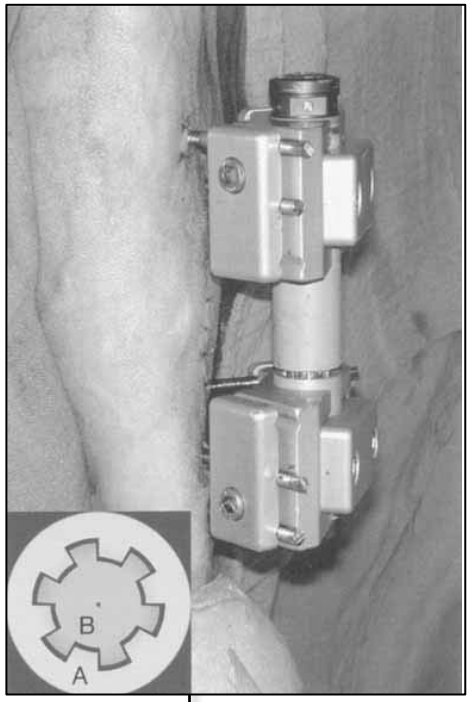
Influence of Size and Stability of the Osteotomy Gap on the Success of Fracture Healing

Lutz Claes, Peter Augat, *Gebhard Suger, and Hans-Joachim Wilke

*Abteilung Unfallchirurgische Forschung und Biomechanik and *Abteilung Unfallchirurgie, Hand-, Plastische- und Wiederherstellungschirurgie, Universität Ulm, Ulm, Germany*



Micromotion must:

- Start early (within the first 6 weeks)
- Not be excessive (1 mm is ideal)
- Be axial in direction

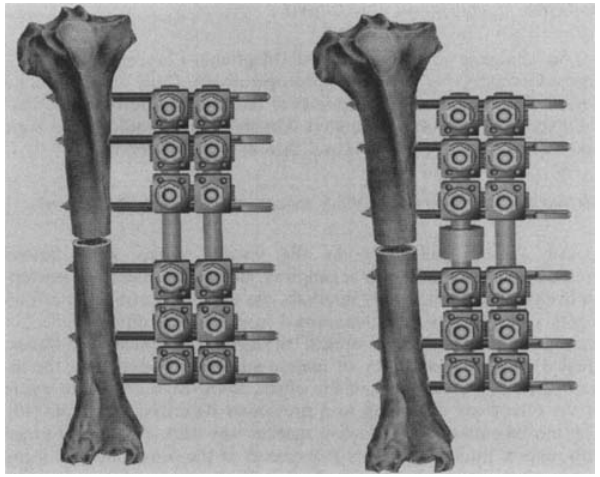
1997 1998 2003

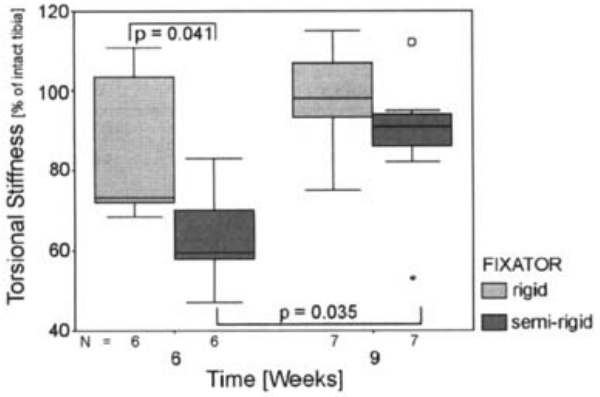
[23] Goodship AE, Cunningham JL, and Kenwright J. "Strain rate and timing of stimulation in mechanical modulation of fracture healing." *Clin Orthop Rel Res*. (355): p. S105-S115, 1998.
[24] Claes L, Augat P, Sugar G, and Wilke H-J. "Influence of size and stability of the osteotomy gap on the success of fracture healing." J Orthop Res. 10(5): p. 227-234, 1997.
[25] Augat P, Burger J, Schorlemmer S, Henke T, Peraus M, and Claes L. "Shear movement at the fracture site delays healing in a diaphyseal fracture model." *J Orthop Res*. 21(6): p. 1011-1017, 2003.

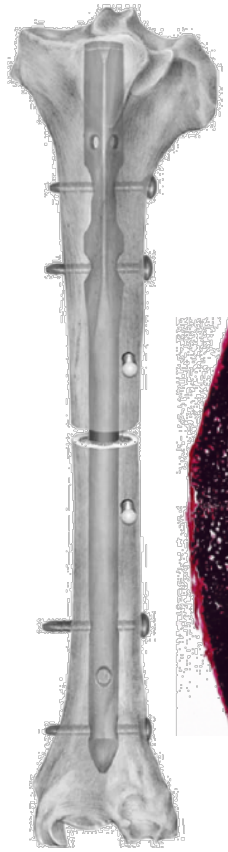
Scientific Rationale for Torsional Stability

Shear instability produces:

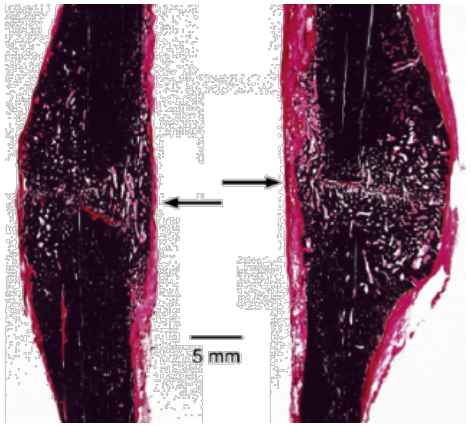
- Mechanically inferior callus







Angle-Stable Locking



2005

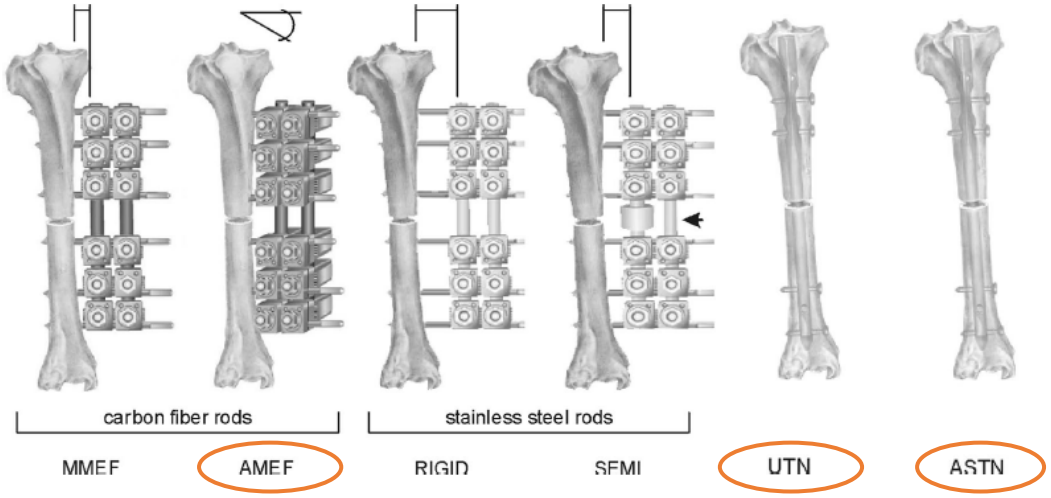
[26] Schell H, Epari DR, Kassi JP, Bragulla H, Bail HJ, and Duda GN. "The course of bone healing is influenced by the initial shear fixation stability." *J Orthop Res*. 23(5):1022-1028, 2005.

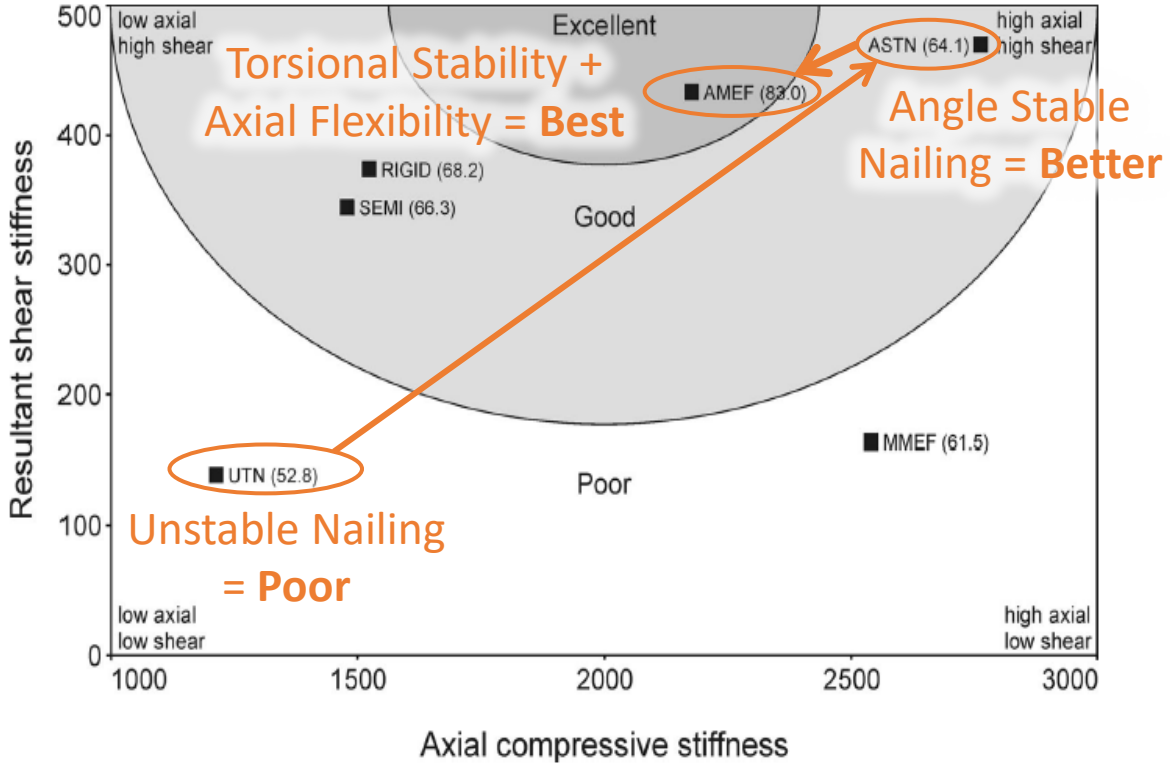
[27] Kaspar K, Schell H, Seebeck P, Thompson MS, Schutz M, Haas NP, and Duda GN. "Angle stable locking reduces interfragmentary movements and promotes healing after unreamed nailing - study of a displaced osteotomy model in sheep tibiae." *J Bone Joint Surg - Am*. 87A(9):2028-2037, 2005.

Torsional Stability + Micromotion

For fastest healing:

- Minimize torsional/shear instability
- Allow some axial flexibility

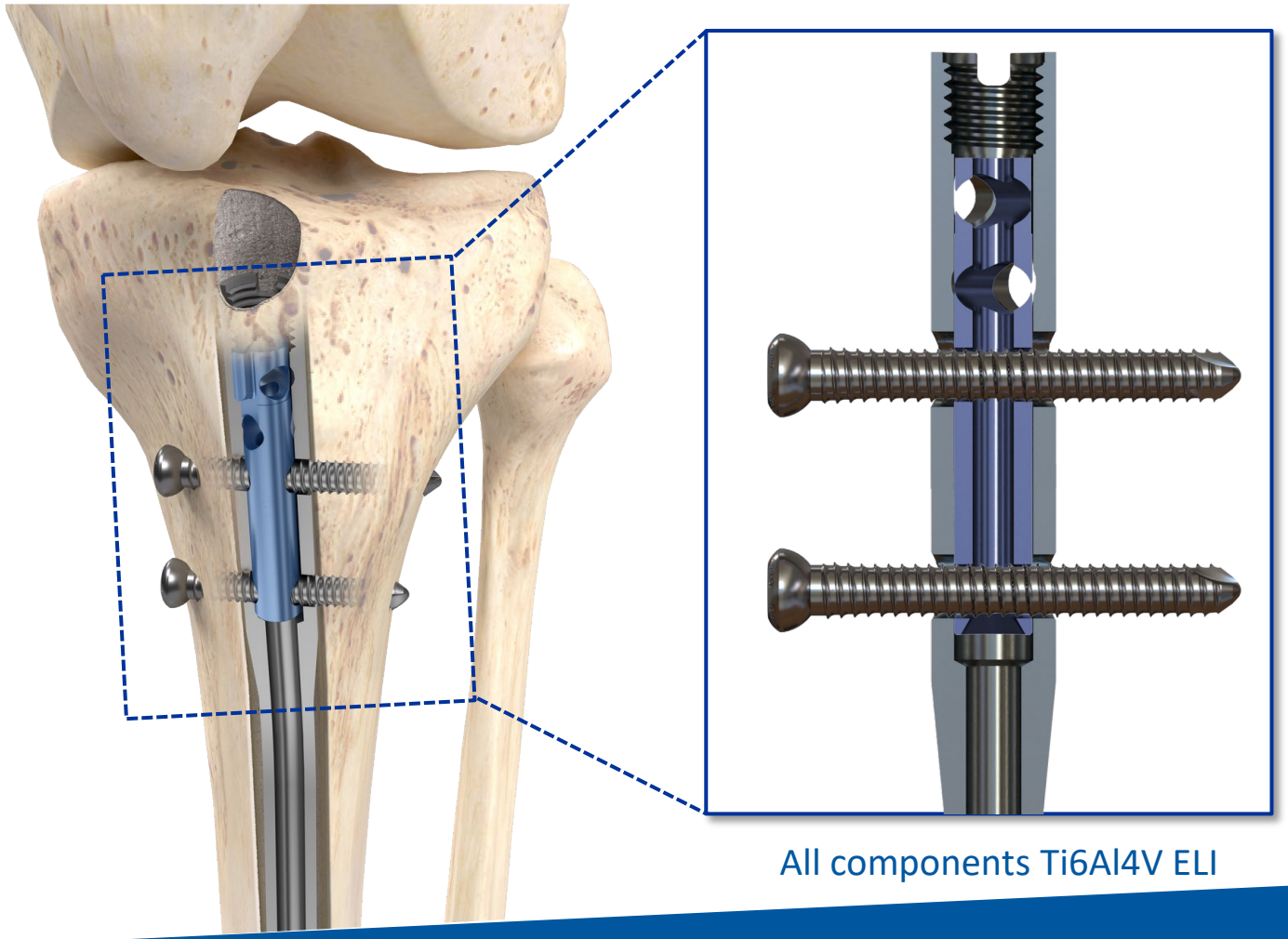




2007

[28] Epari DR, Kassi JP, Schell H, and Duda GN. "Timely fracture-healing requires optimization of axial fixation stability." *J Bone Joint Surg Am*. 89A(7):1575-1585, 2007.

Apex Micromotion Nailing: Designed to Optimize Mechanobiology



All components Ti6Al4V ELI

High Torsional Stability

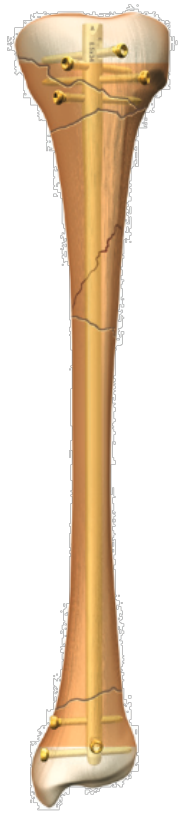
insert prevents rotation of the bone fragments

+

Controlled Axial Micromotion

1 mm gliding axial motion mechanically stimulates callus

Apex Clinical Performance



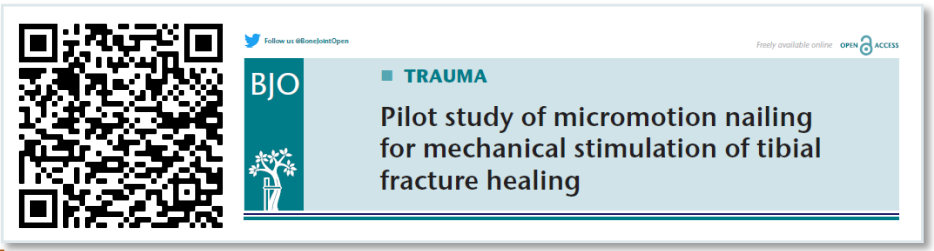
N = 46

Control Group	Clinical Outcomes	Micromotion Group
11%	**Nonunion** Secondary Surgery	0%
28%	**Delayed Union** Healed Slowly > 20 weeks	14%
61%	**Union** Healed < 20 weeks	86%

Smith & Nephew TRIGEN

OrthoXel Apex

N = 37



Fewer complications:
significant reduction† in delayed union and nonunion compared to standard of care[29]

† Chi-squared test of proportions, asymptotic significance (2-sided): $p = 0.014$

Apex Clinical Performance

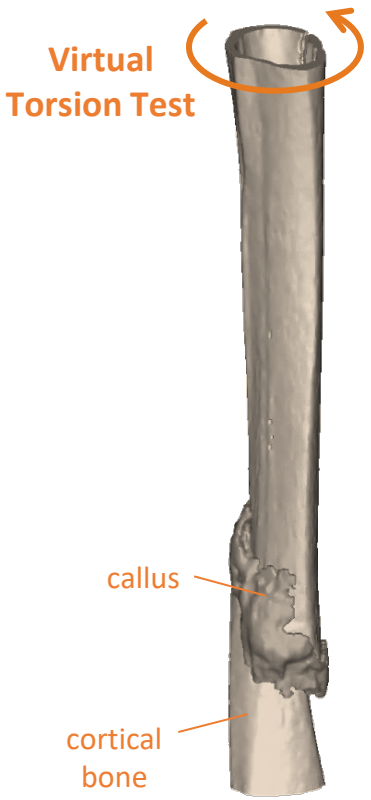
Proportion of United Fractures at Each Scheduled Follow Up			
Time	**Control**	**Apex**	**Sig.**
12 Weeks	30%	54%	$p = 0.030$*
18 Weeks	59%	81%	$p = 0.029$*
24 Weeks	74%	97%	$p = 0.004$*
52 Weeks	89%	100%	$p = 0.030$*

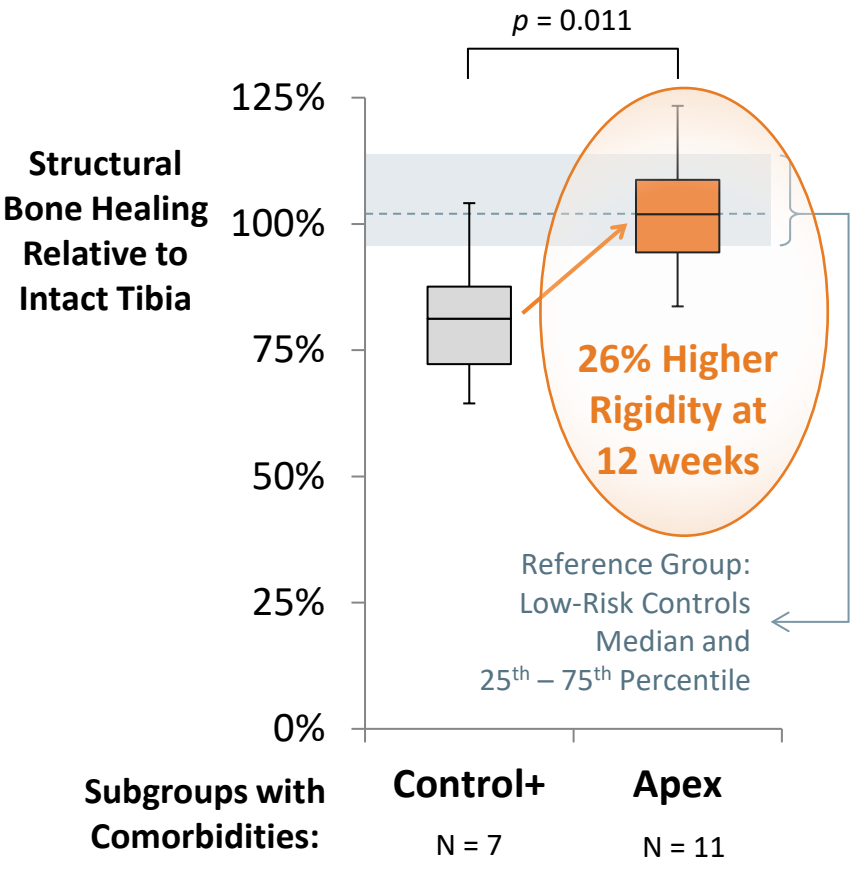
* Chi-squared test of proportions, asymptotic significance

Faster Healing:
All patients benefit from micromotion to accelerate healing[29]

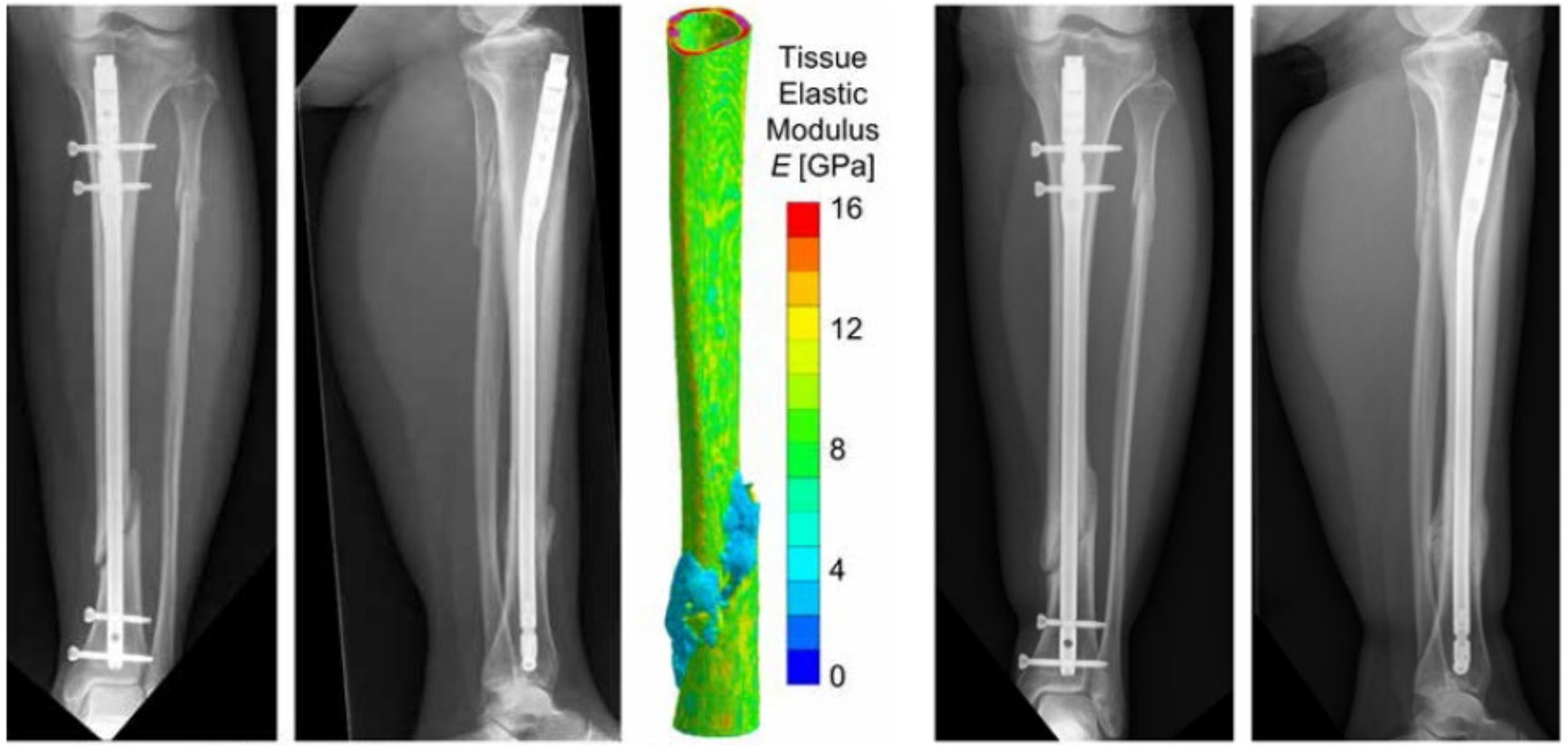
Apex patients with comorbidities healed like low-risk controls[29]

Apex: Enhanced Early Callus Formation in Patients with Comorbidities





Successful Healing in High-Risk Cases



12-Week X-rays and CT Model
CT-Based Normalized VTR = 1.03 (fractured/intact)

24-Week X-rays

Case A Female, age 46, insulin-dependent brittle diabetic, closed 42-A1.

Achieved robust structural healing on 12-week X-rays and CT and uncomplicated clinical union.

Whitepaper:
Apex Tibial Nailing System: Early Healing in High-Risk Fractures Following Apex Micromotion Fixation
https://www.orthoxel.com/micromotion-clinical-evidence/

Surgeon Experience

- Overview of surgical technique and similarities to a conventional tibial nail
- Instrumentation experience

Dr. Campbell:

“It's straightforward, similar to any other tibial nailing system that you're going to use!”

Dr. Saiz:

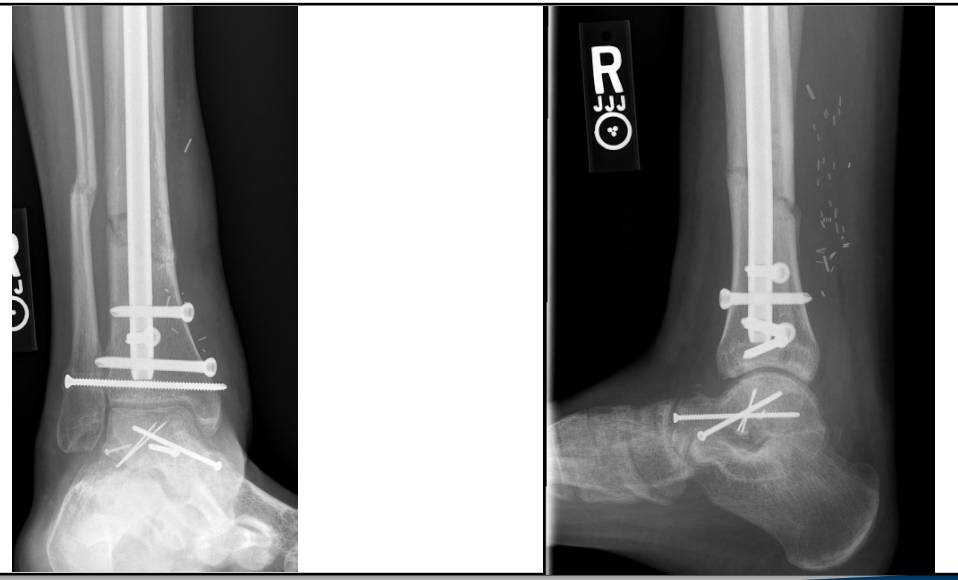
“It changes literally nothing about your algorithm. It's like any tibial nail - part of the beauty of it.”

UC Davis Case Discussion

- Young patient, high-energy injury, large open medial wound
- Polytrauma
- Type 3b open tibia and fibula fractures
- Type 3b talar body fracture dislocation
- Debridement, nailing with Apex micromotion tibial nail, ORIF talus, temporary wiring of the talonavicular and subtalar joints, ORIF syndesmosis, free flap
- Initial immobilisation (12 weeks) – talus healed but tibia showed no signs of union
- Mobilization from 3 months
- Tibia healed at 6 months

Pre-Op

6 Months Post-Op



Broader Applications and Clinical Value

- Apex Tibial Nailing System — Published clinical outcomes data
- Apex Antegrade Femoral Nailing System
- Apex Retrograde Femoral Nailing System

APEX
AXIAL MICROMOTION NAILS

ORTHOXEL

Closing Remarks & More Information

Invitation:

Join Dr. Campbell and Dr. Saiz at OTA in Phoenix, AZ

📍 Thursday, October 16th at 5 PM

OrthoXel's Booth #822

Visit OrthoXel.com for more details.

References

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