PHANTOM®

INTRAMEDULLARY NAIL

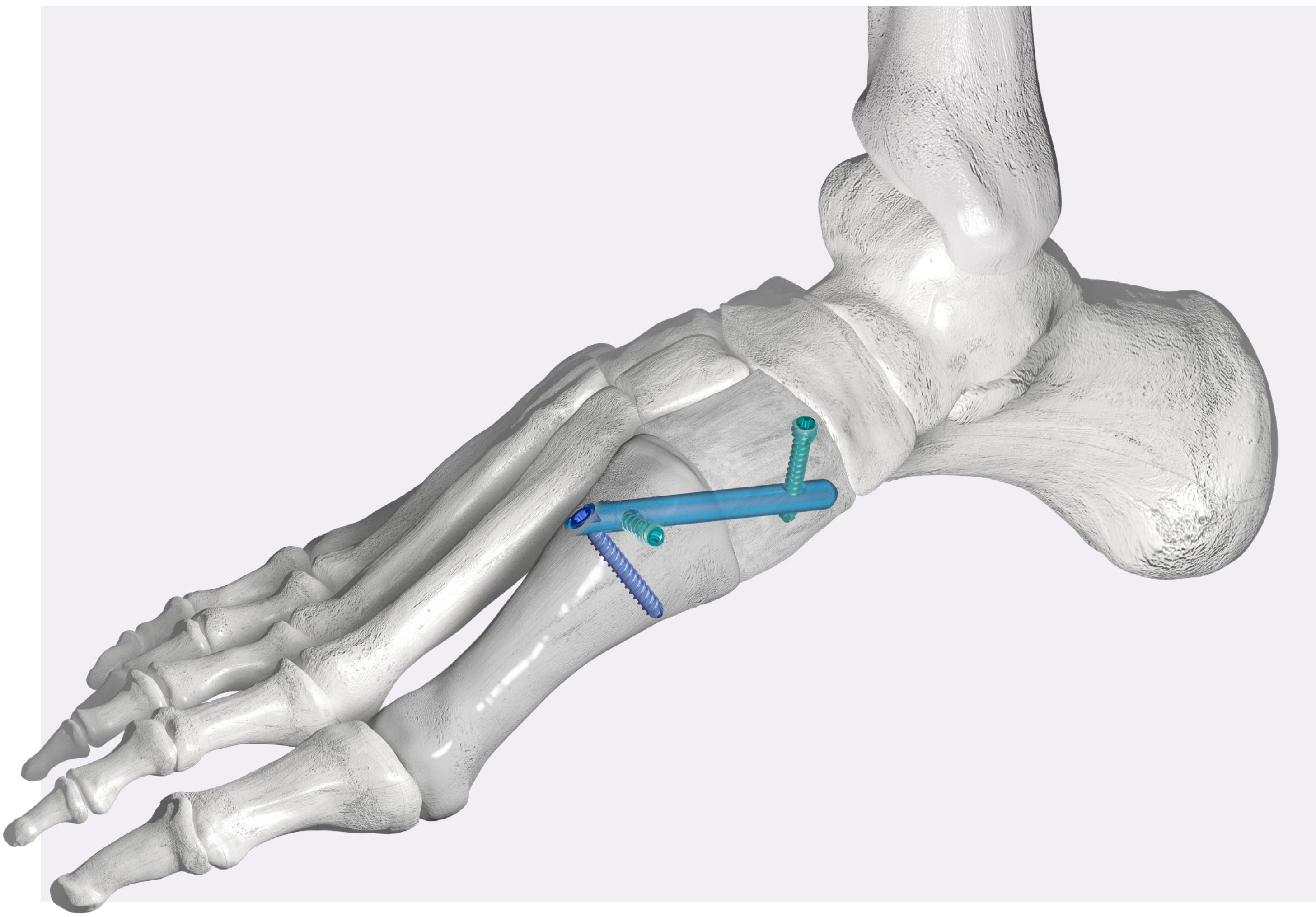
TECHNICAL MONOGRAPH

Exclusively foot & ankle

Paragon 28®

DESIGN

- The Phantom® Intramedullary Nail is a locking implant system used in the fusion of the first tarsometatarsal (TMT) joint to treat hallux valgus. The Phantom® Intramedullary Nail is designed to:
  - Provide a safe and effective intramedullary option for first TMT arthrodesis.
  - Minimize the disruption to bone and soft issue at and around the arthrodesis site.
  - Provide structurally sound fixation that prevents plantar gapping.
  - Dial in 80-100 N of compression across the fusion site to promote bone healing.



EVIDENCE

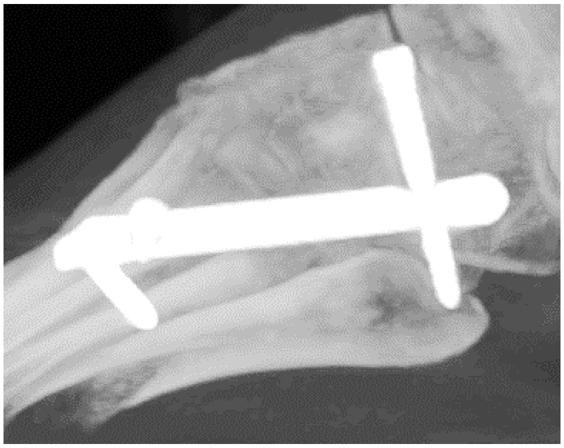


Figure 1. Radiographic imaging of a hallux valgus patient who was treated with a Phantom® Intramedullary Nail (12 weeks post-op).

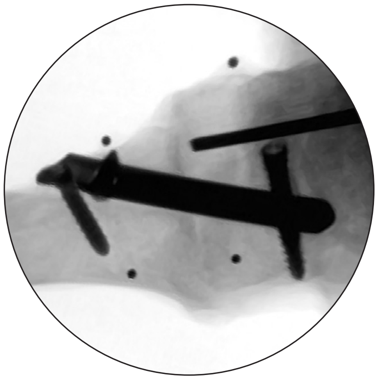


Figure 2. A Phantom® Intramedullary Nail undergoing in vitro cyclic testing.

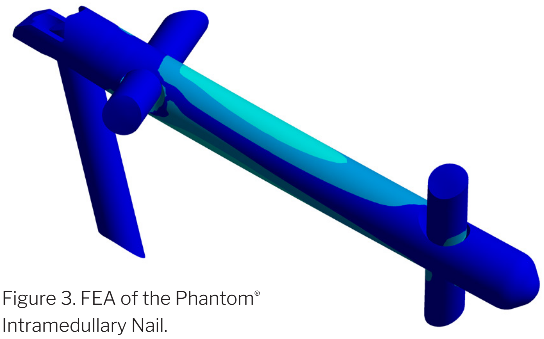


Figure 3. FEA of the Phantom® Intramedullary Nail.

Real-World Clinical Evidence

- Multiple studies involving the Phantom® Intramedullary Nail showed high union rates, low recurrence rates, and significant improvement in pain and function scores across a variety of patients (Figure 1).[1-6]

In Vitro Analysis

- The Phantom® Intramedullary Nail showed significantly less plantar gapping compared to screw fixation (Figure 2).[7]

Biomechanical Analysis

- Less disruption of the periosteum compared to biplanar plating.[8]
- Less disruption of the arthrodesis site compared to crossed screws.[8]
- Better multi-direction stability compared to dorsal plating and non-anatomic medial plating.[9]

Computational Analysis

- Finite Element Analysis (FEA) showed that the Phantom® Intramedullary Nail demonstrates less plantar gapping and implant stress when compared to two crossing screws and biplanar plating constructs (Figure 3).[10]

REAL-WORLD CLINICAL EVIDENCE

Multiple studies have been conducted to support the safety and effectiveness of the Phantom® Intramedullary Nail across varied patient populations.

Results from these studies reported high rates of union, low rates of recurrence, improved radiographic alignment, and improvement in function scores, quality of life scores, and pain scores.

High Union Rate

90%-96.7%[1-3,5,6]

Low Recurrence Rate

0%-3.3%[1,3,5]

Low Wound Complication Rate

0%-10%[1,3,5,6]

Minimal Shortening of the Medial Column

0.6%[3]

2.4mm[2]

Improved Function

FAAM ADL: 15.9 points[2]

AOFAS: 37.2-40.7 points[1,4]

FAOS ADL: 17.8 points[4]

Improved Quality of Life

Neuro QOL: 5.3 points[2]

FAOS QOL: 34.4 points[4]

Reduced Pain

VAS/Pain Scale: 2.3-4.7 points[1-4]

FAOS Pain: 20.6 points[4]

PROMIS Pain Interference: 3.0 points[2]

Improved Radiographic Alignment

Intermetatarsal Angle[1-6]

Hallux Valgus Angle[1-6]

Frontal Sesamoid Rotation Angle[4]

Distal Metatarsal Articular Angle[2-5]

Tibial Sesamoid Position[2,6]

Meary's Angle[2]

Note: Changes in pain, function, quality of life, and radiographic alignment based on averages at pre-op and post-op.

IN VITRO ANALYSIS

Background

- Excessive gapping between bones or too much interfragmentary motion can lead to delayed union or nonunion.[11,12]
- Compression across the fusion site can reduce the plantar gap and motion.[13]

Study Goal

- Determine the resistance to plantar gapping of the Phantom® Intramedullary Nail as compared to crossing screw fixation.[7]

Methods

- Cadaver specimens were implanted with either a Phantom® Intramedullary Nail or two crossing screws across the first TMT joint.
- 100 N of compression was applied through a torque indicating driver for all Phantom® Intramedullary Nails.
- The necessary anatomy was dissected and prepared for testing on the test frame.
- Radiopaque beads were used as motion markers and placed on each side of the first TMT joint.
- The metatarsal head was loaded from 10-40 N at 1 Hz for 20,000 cycles.

Results

- Compared to two crossing screw fixation, the Phantom® Intramedullary Nail had:

Less plantar gap widening (0.54mm vs 0.17mm, p = 0.014, Figures 4-6).

Smaller final plantar gap (1.37mm vs 0.48mm, p=0.022).

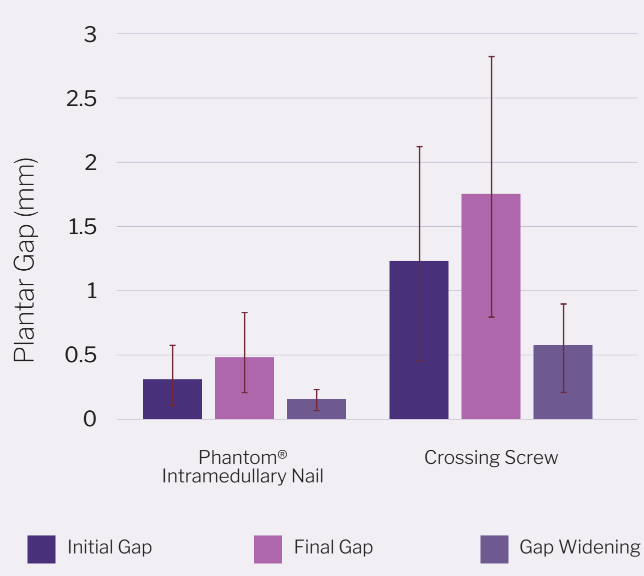


Figure 4. Average plantar gapping with 95% confidence intervals.

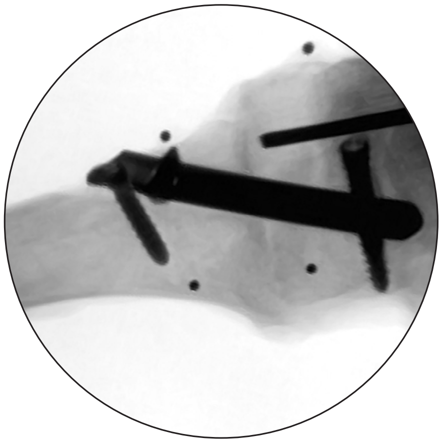


Figure 5. Phantom® Intramedullary Nail showing 0.3 mm of plantar gapping after 20,000 cycles.

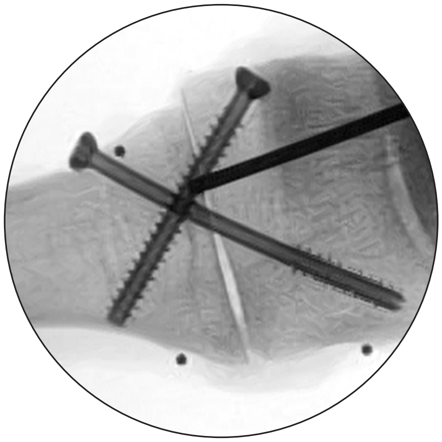


Figure 6. Two crossing screw fixation showing 1.7 mm of plantar gapping after 20,000 cycles.

Conclusion

The Phantom® Intramedullary Nail exhibited less gap widening and a smaller final gap which may result in a more conducive bone healing environment than two screw fixation.

BIOMECHANICAL ANALYSIS–BONE AND TISSUE DISRUPTION

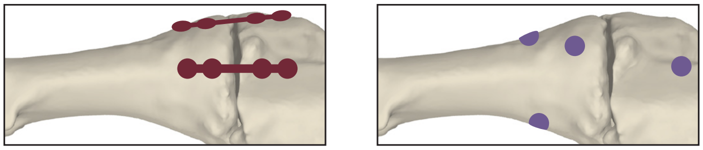


Figure 7. Periosteum disruption area for biplanar plating (left) and the Phantom® Intramedullary Nail (right).

The biplanar plating systems have over 3x the amount of surface area disruption when compared to the Phantom® Intramedullary Nail (Figures 7 & 8).[8]

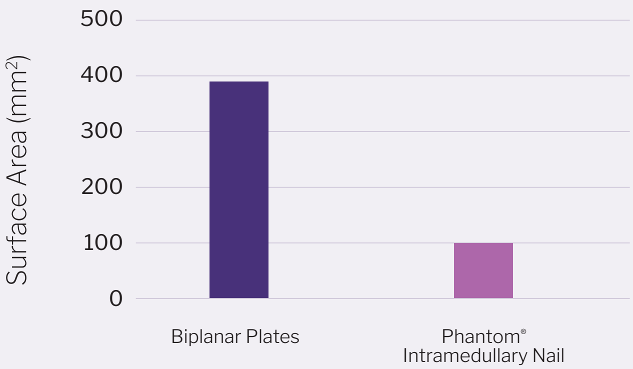
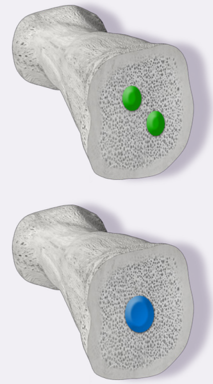


Figure 8. Comparison of periosteum disruption.



The Phantom® Intramedullary Nail has 10% less cross-sectional area than two 4.0 mm crossed screws at the arthrodesis site (Figure 9).[8]

Figure 9. Arthrodesis site disruption area for two crossing screws (top) and the Phantom® Intramedullary Nail (bottom).

BIOMECHANICAL ANALYSIS–STABILITY

The stability of the Phantom® Intramedullary Nail was compared with that of a dorsal plate and a straight medial plate (Figure 10).[9]

- Dorsal plating is strongest in the horizontal direction and weakest in the vertical direction.
- Straight medial plating is strongest in a vertical direction and weaker in the horizontal direction.
- The Phantom® Intramedullary Nail shows the same strength, regardless of directive forces.

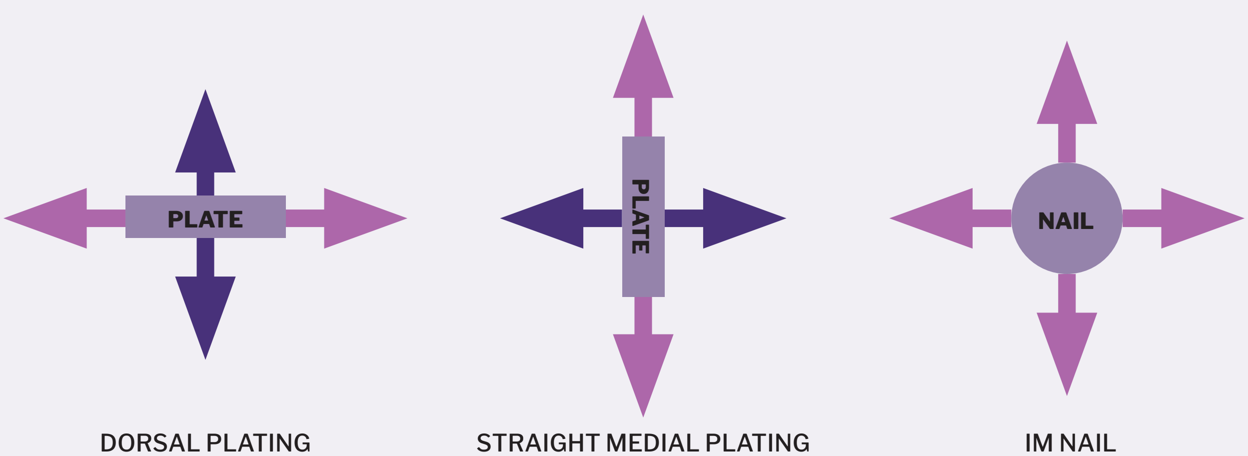


Figure 10. A generalized representation of first TMT arthrodesis hardware stability.

COMPUTATIONAL ANALYSIS *IN BRIEF*

Plantar gapping and implant stress was investigated for three different methods of fixation used in first TMT arthrodesis (Figure 11).[10]

- The Phantom® Intramedullary Nail
- Two crossing screws
- Biplanar plating

All devices were tested in the same fashion.

- Each device was virtually implanted.
- The first TMT joint was positioned to have either 0 mm or 2 mm of initial plantar gap.
- Compression was applied, where applicable.
- A load 243 N was applied to the metatarsal head to mimic forces seen during gait.[13]

Plantar gapping and implant stress were calculated and compared across devices.

Thresholds of 3mm of plantar gapping[14-16] and 940 MPa (the ultimate strength Ti-6Al-4V ELI) were used as references for failure.

The Phantom® Intramedullary Nail experienced the smallest plantar gapping and the least amount of implant stress when compared to 2 crossing screws and biplanar plating.

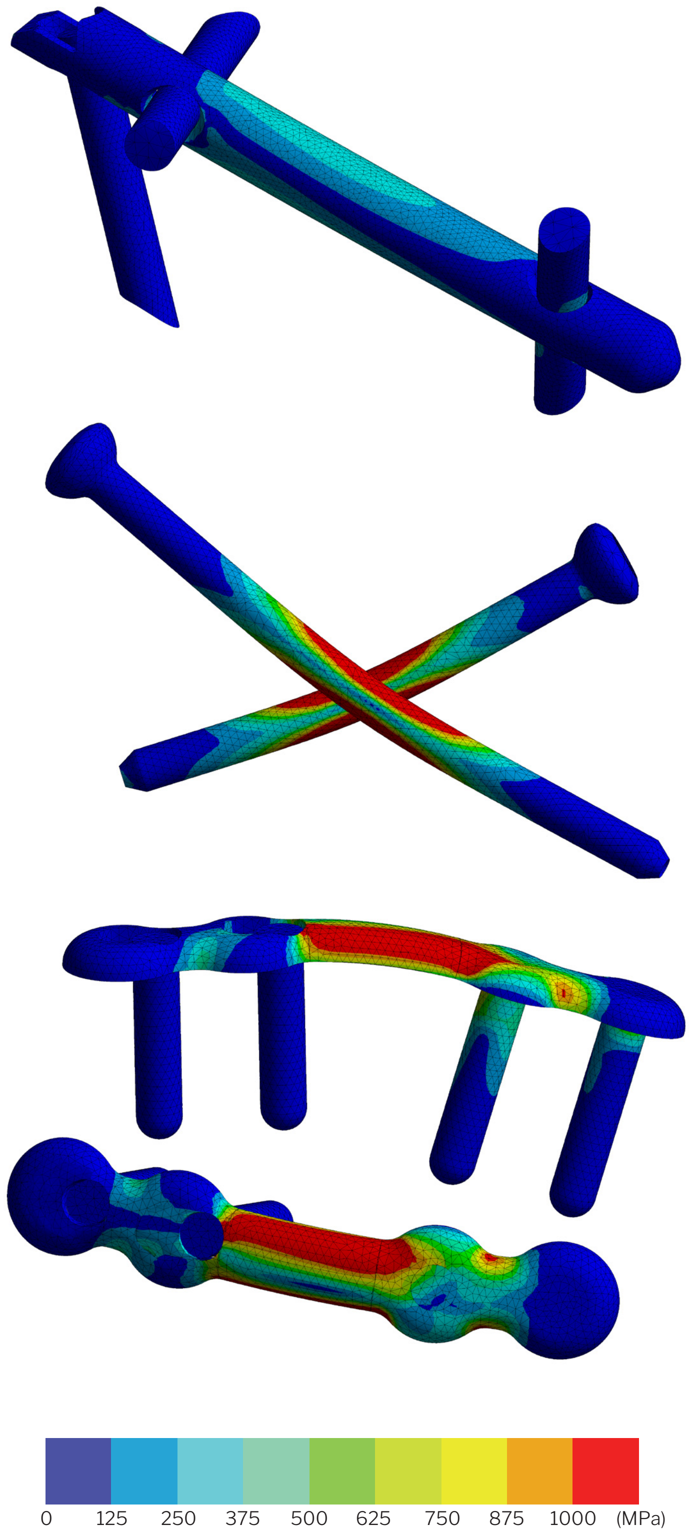


Figure 11. Implant stress for the Phantom® Intramedullary Nail (top), two crossing screws (middle), and biplanar plating (bottom) for the 2 mm initial gap scenario.

COMPUTATIONAL ANALYSIS–METHODS


Figure 12

Step 1
A weight bearing CT (WBCT) scan from a hallux valgus patient was identified (Figure 12).


Figure 13

Step 2
The first metatarsal and medial cuneiform were segmented to create 3D bone models (Figure 13).

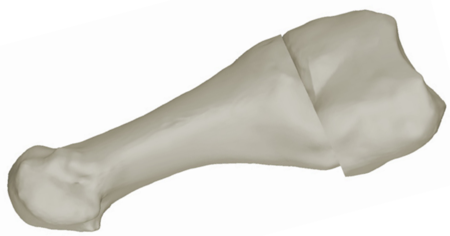


Figure 14

Step 3
Testing scenarios of 0 mm (left) and 2 mm (right) of plantar gapping were created (Figure 14). The 2 mm initial gap was created by removing an additional 2 mm of the metatarsal at the base.

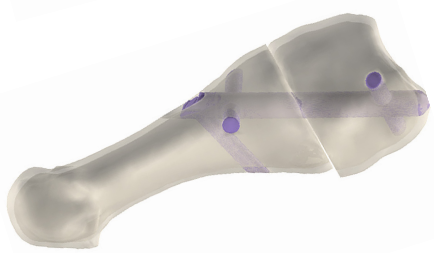
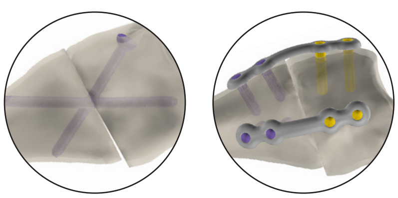


Figure 15



Step 4
A Phantom® Intramedullary Nail (left) two crossing screws (middle), and biplanar plates (right) were virtually implanted for each testing scenario (Figure 15).

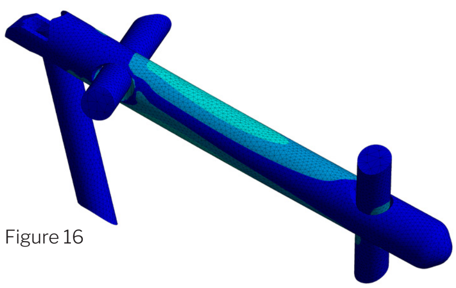


Figure 16

Step 5
FEA was performed (Figure 16).

COMPUTATIONAL ANALYSIS–METHODS

Applied Loads

In all models, a bending force of 243 N was applied to the head of the metatarsal. The force was oriented perpendicular to the ground to simulate weightbearing (Figure 17).

- For the Phantom® Intramedullary Nail construct, 100 N of compression was applied distally to proximally following the direction nail.
- No additional forces were applied for the two crossing screw construct.
- For the biplanar plate construct, 150 N of compression was applied distally to proximally.[14]

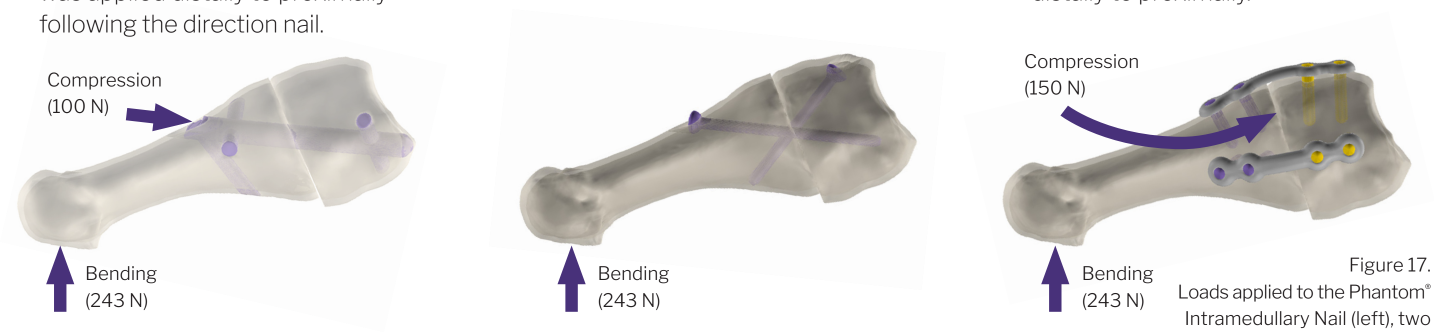


Figure 17.
Loads applied to the Phantom® Intramedullary Nail (left), two crossing screws (middle), and biplanar plates (right).

COMPUTATIONAL ANALYSIS–RESULTS

The resultant plantar gap for each testing scenario is shown below (Figure 18).

The 2 mm initial gap created a reduced moment arm after compression (where applied) and consequently reduced plantar gapping by a minimal amount (≤0.4 mm). Other ramifications of metatarsal shortening were outside of the scope of this study.

The Phantom® Intramedullary Nail demonstrated the least amount of plantar gapping in both the 0 mm and 2 mm initial gap scenarios compared to two crossing screws and biplanar plating.

Resultant Plantar Gap - 0 mm Initial Gap

Resultant Plantar Gap - 2 mm Initial Gap

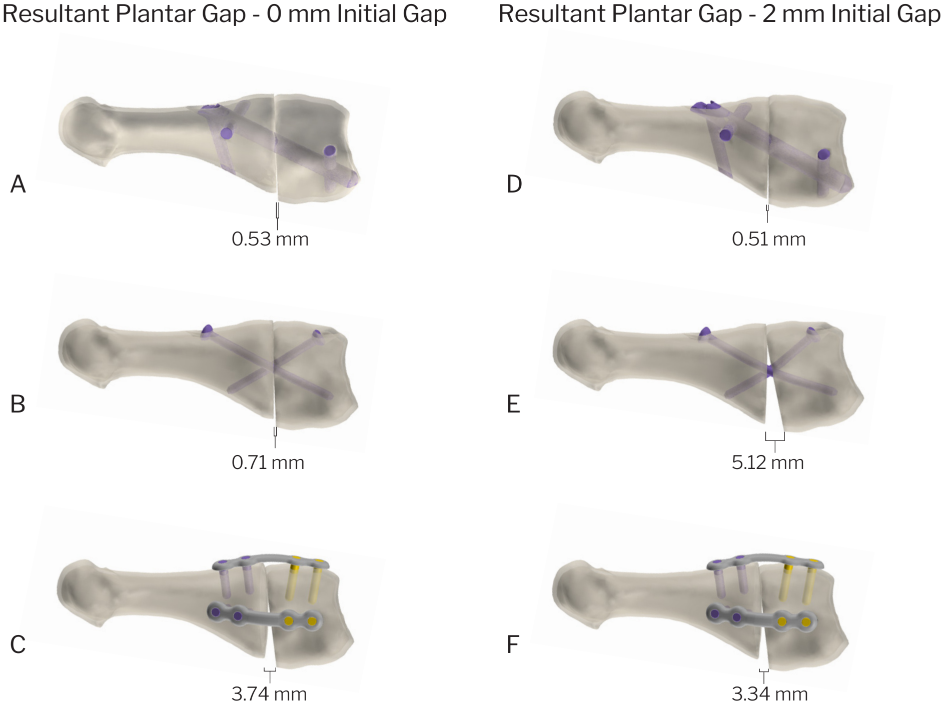
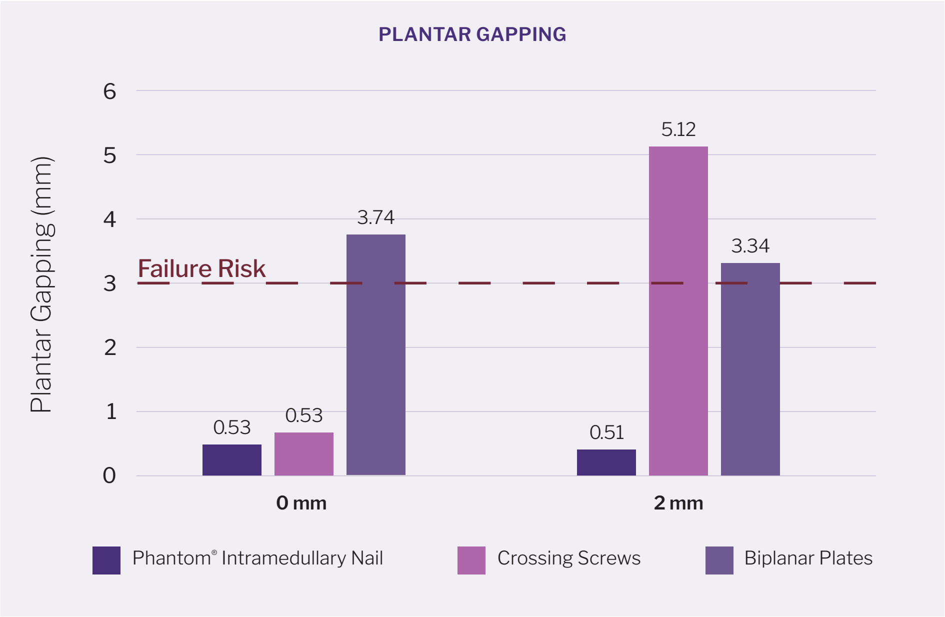


Figure 18. Resultant plantar gap after loading at 0 mm initial gap (A, B, C) and 2 mm initial gap (D, E, F) for the Phantom® Intramedullary Nail, two crossing screws, and biplanar plating.

COMPUTATIONAL ANALYSIS–RESULTS



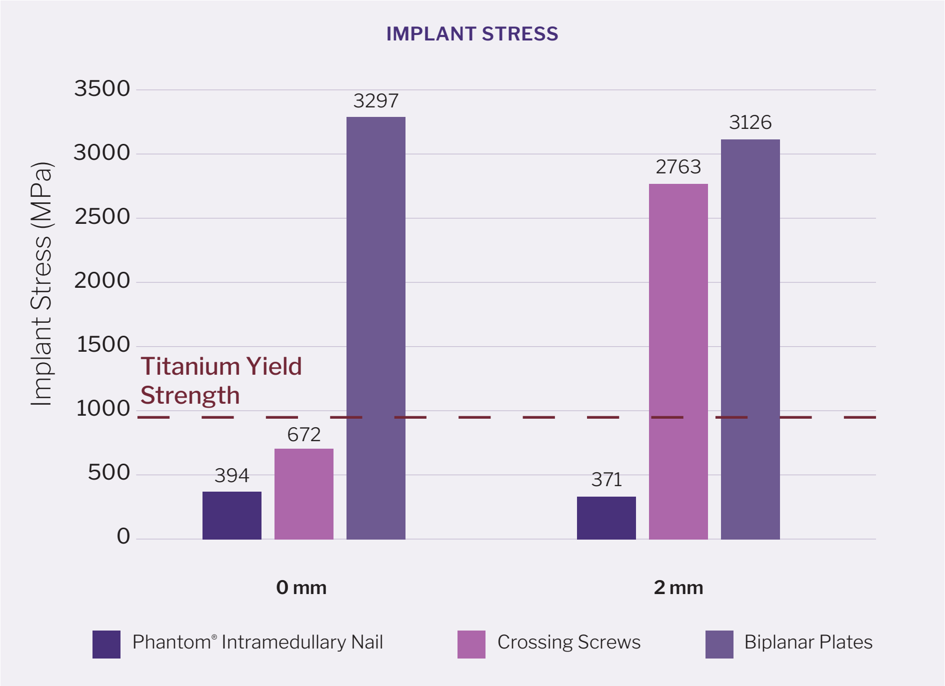


Figure 19. Plantar gapping (top) and implant stress (bottom) for each tested construct at initial gaps of 0 and 2 mm.

- Plantar gapping for the Phantom® Intramedullary Nail was below the failure risk threshold of 3 mm (Figure 19).
- Both two crossing screws and biplanar plating exceeded the failure threshold in at least one scenario.

- The Phantom® Intramedullary Nail experienced less stress than the other constructs tested.
- Both two crossing screws and biplanar plating experienced implant stress that exceeded the yield strength of titanium in one or more scenarios.

Conclusion

The Phantom® Intramedullary Nail experienced the smallest plantar gapping and the least amount of implant stress when compared to two crossing screws and biplanar plating. Based on this FEA simulation, Phantom® Intramedullary Nail may offer a biomechanical advantage over the alternative fixation methods tested.

REFERENCES

1. Data on File.

2. Data on File.

3. Bean B, Mangold DR, Abousayed M, Coleman MM, Thompson J, Guyton GP. Percutaneous Modified Lapidus Procedure with Early Weightbearing: Technique and Early Outcomes of the First 30 Cases. *Foot Ankle Orthop*. 2022;7(1). doi:10.1177/2473011421s00107

4. Williams S, Clancy C, Apt R, Clancy J, Hume D, Anderle M. Assessment of Correction of Hallux Valgus Deformity following Lapidus Bunionectomy Using Weight-Bearing CT Scans and Automatic Segmentation and Measurement Software. In: *Annual Scientific Conference, The American College of Foot and Ankle Surgeons*. ; 2023.

5. Chaparro F, Cárdenas PA, Butteri A, J Pellegrini M, Carcuro G, Ortiz C. Minimally invasive technique with intramedullary nail for treatment of severe hallux valgus. *Journal of the Foot & Ankle*. 2020;14(1). doi:10.30795/jfootankle.2020.v14.1158

6. Waters D, Lenertz E, Issac A. Minimally invasive lapidus with axial nail fixation: Surgical technique. *Foot & Ankle Surgery: Techniques, Reports & Cases*. Published online 2023:100339.

7. Prieto-Diaz C, Anderle MR, Brinker LZ, Allard R, Leasure J. Biomechanical Comparison of First Tarsometatarsal Arthrodesis Constructs Over Prolonged Cyclic Testing. *Foot Ankle Orthop.* 2019;4(4). doi:10.1177/2473011419892240

8. Data on File.

9. Data on File.

10. Data on File.

11. Marsell R, Einhorn TA. The biology of fracture healing. *Injury*. 2011;42(6). doi:10.1016/j.injury.2011.03.031

12. Claes L, Eckert-Hübner K, Augat P. The fracture gap size influences the local vascularization and tissue differentiation in callus healing. In: *Langenbeck's Archives of Surgery*. Vol 388. ; 2003. doi:10.1007/s00423-003-0396-0

13. Claes L, Recknagel S, Ignatius A. Fracture healing under healthy and inflammatory conditions. *Nat Rev Rheumatol*. 2012;8(3). doi:10.1038/nrrheum.2012.1

14. Aiyer A, Russell NA, Pelletier MH, Walsh WR. The Impact of Nitinol Staples on the Compressive Forces, Contact Area, and Mechanical Properties in Comparison to a Claw Plate and Crossed Screws for the First Tarsometatarsal Arthrodesis. *Foot Ankle Spec.* 2016;9(3). doi:10.1177/1938640015620655

15. Cohen DA, Parks BG, Schon LC. Screw fixation compared to H-locking plate fixation for first metatarsocuneiform arthrodesis: A biomechanical study. *Foot Ankle Int.* 2005;26(11). doi:10.1177/107110070502601114

16. Ehredt DJ, Kawalec J, Ligas C, et al. The Lapidus Arthrodesis: Examining the Effect of the Metatarsal Base Transfixion Screw. *Journal of Foot and Ankle Surgery.* 2021;60(2). doi:10.1053/j.jfas.2020.05.020

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