Exclusively foot & ankle

Paragon 28®

Phantom Lapidus Nail Technical Monograph

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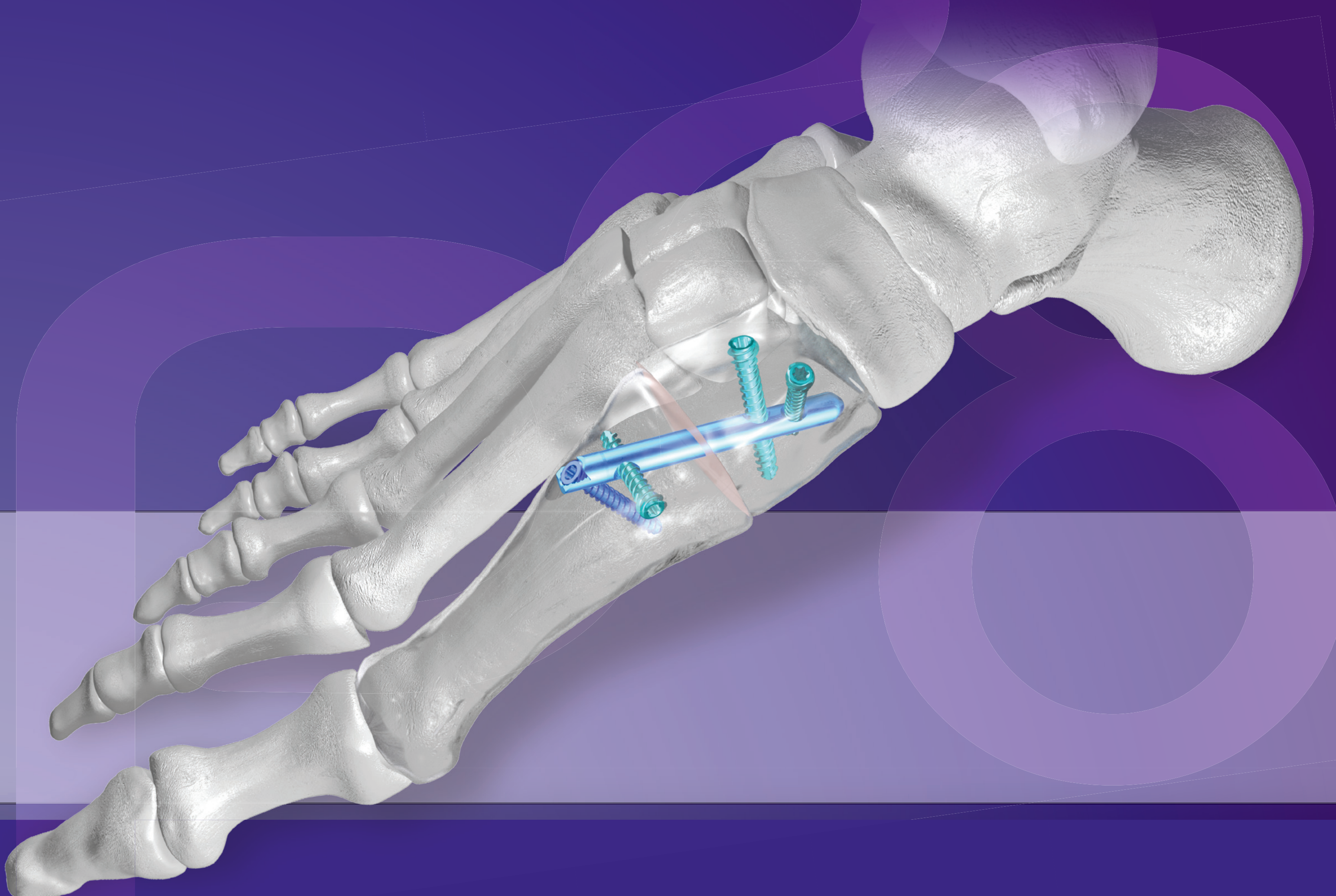


PHANTOM™

INTRAMEDULLARY NAIL

BONE REPAIR BACKGROUND

The speed and quality of bone repair depends on both biologic and mechanical factors. From a biologic perspective, more extensive damage takes more time to repair and compromised blood supply can delay healing. From a mechanical perspective, excessive interfragmentary motion can damage newly formed tissues in the repair zone and may ultimately result in nonunion or malunion. Large fracture gaps tend to heal slowly or not at all.[1] Smaller gaps tend to heal in stages with fibrous tissue being replaced by cartilage that subsequently ossifies and is remodeled. Sufficient stability at a bone repair site combined with compression to close a fracture gap creates a mechanical environment that is conducive to direct formation of bone.

Bone repair follows one of two pathways:

A. Primary healing as characterized by direct formation of bone via intramembranous ossification.

B. Secondary healing as characterized by sequential maturation of intermediate tissues followed by endochondral ossification and remodeling.

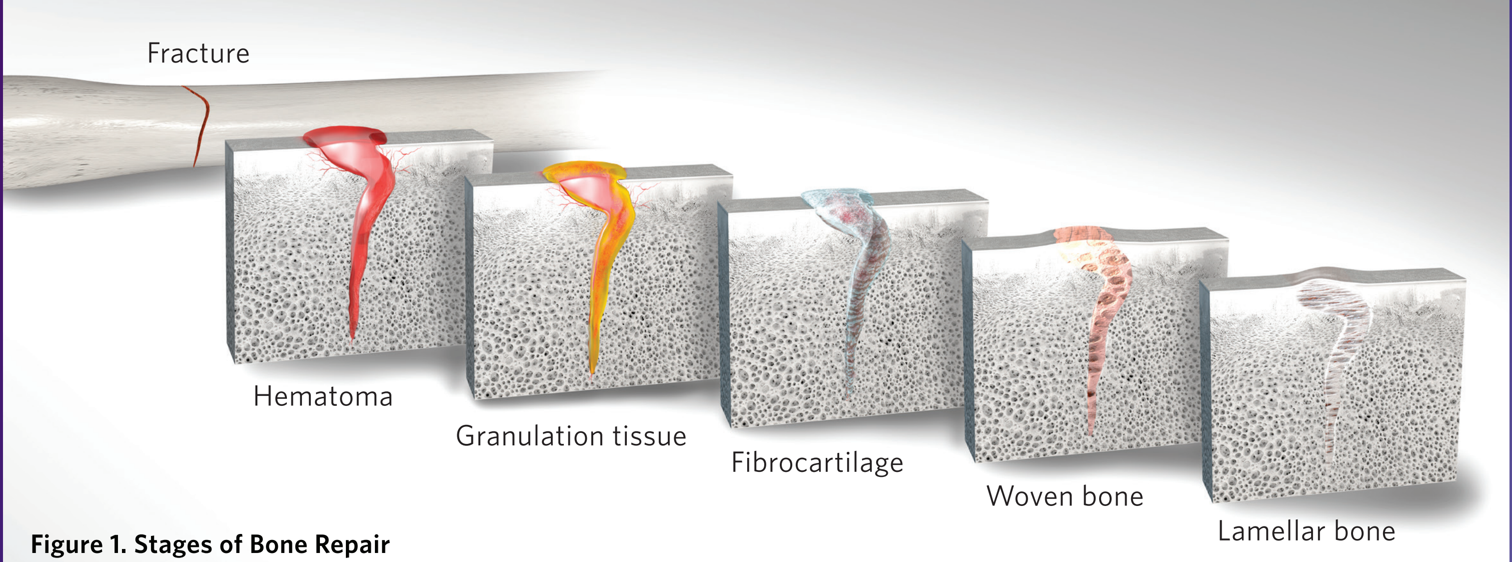


Figure 1. Stages of Bone Repair

Primary bone healing skips intermediate tissues (granulation tissue, fibrocartilage, woven bone) laid down during bone repair and directly deposits lamellar bone at the repair site (Figure 1). Intermediate tissues are otherwise necessary to gradually increase local stability until bone cells can survive at the repair site. The goal of internal fixation is to aid in the primary bone repair and go directly to depositing lamellar bone at the repair site.

Compression and rigid fixation can be achieved with many devices provided on the market such as screws, plates with screws and compression staples. If the implant creates stiffness and not adequate compression, the construct may block healing. If the devices provide initial compression but loses compression over time due to resorption or poor biological conditions, the construct may result in delayed or non-union.[2] Stiffness and adequate compression create an environment conducive to bone healing.

PROBLEM STATEMENT

To optimize the healing environment for fusion following arthrodesis of the first tarsometatarsal joint, the operative procedure should:

1. Be simple and straightforward.

Longer operative times are correlated with higher risk of infection.[3,4,5]

2. Minimize damage of tissues at the arthrodesis site.

Compromised blood supply reduces availability of nutrients essential for healing.[6]

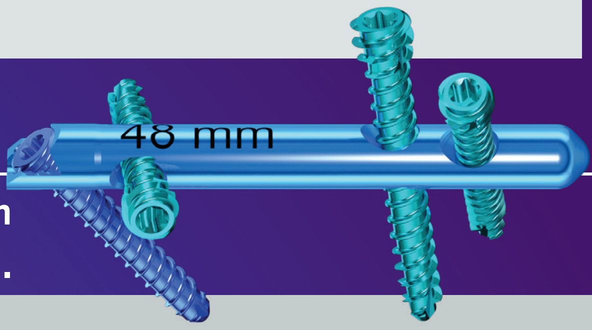
3. Simplify bone preparation for fusion and close any gaps at the arthrodesis site.

Primary healing by intramembranous bone formation is only possible with gap reduction at the arthrodesis site. Congruent surfaces with smooth, flat cuts provide the best clinical results since gaps present a major risk for delayed union or nonunion.[1,7]

4. Provide bony compression and stability to allow earlier return to daily activities without damaging newly formed tissue.

By compressing the gap with hardware that provides sufficient stiffness, interfragmentary strains are reduced to a level tolerated by mature bone.

SOLUTION



The Phantom™ Lapidus Nail System addresses each of these four design challenges.

1. SIMPLE AND STRAIGHTFORWARD

Instrumentation specific to the implantation of the Phantom Lapidus Nail facilitates the positioning of the nail and insertion of the threaded pegs in a highly vascularized environment.

- The sphere wire allows the surgeon to establish proper nail length, position and termination in the medial cuneiform (Figure 2).
- The targeting assembly repeatedly allows placement of a guide wire through the 1st metatarsal into the medial cuneiform to simplify intramedullary drilling and nail positioning (Figure 3).

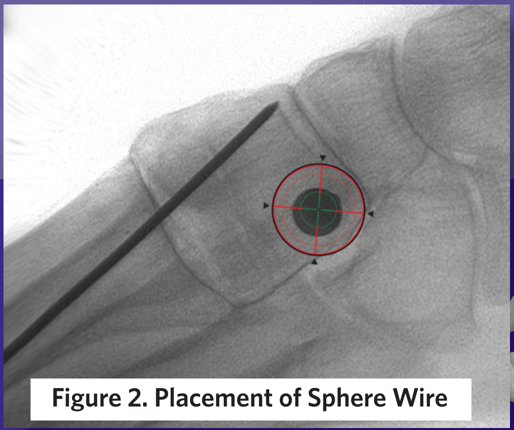


Figure 2. Placement of Sphere Wire

Figure 3. Targeting Assembly

- The outrigger construct targets the threaded pegs through the nail. The outrigger is then used to compress the metatarsal and medial cuneiform joint and holds compression until the third peg is placed through the metatarsal, thus locking in the compression (Figure 4).
- After outrigger removal, a locking peg is placed through the end of the nail to complete the construct and work as an end cap for the nail.

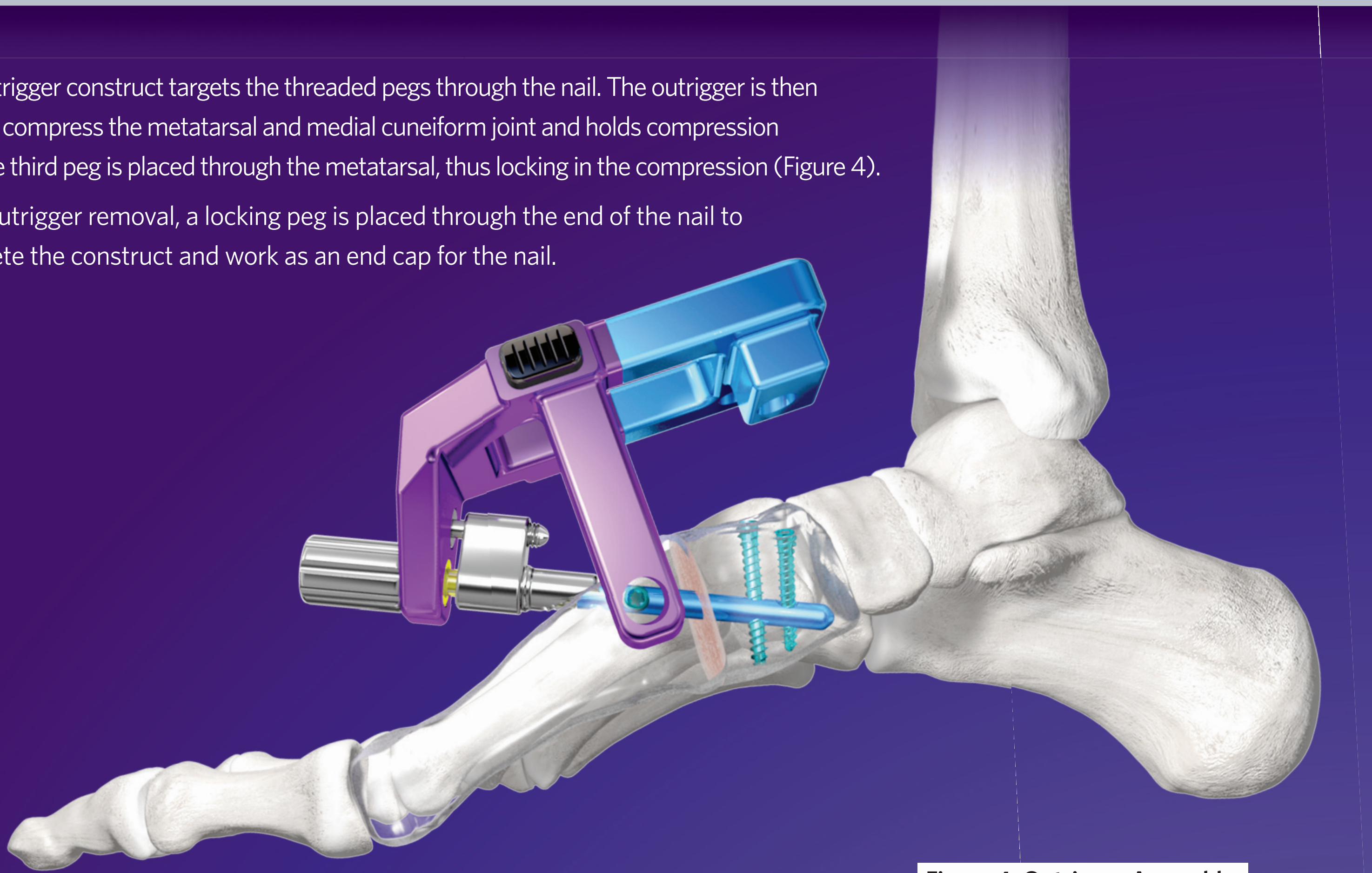
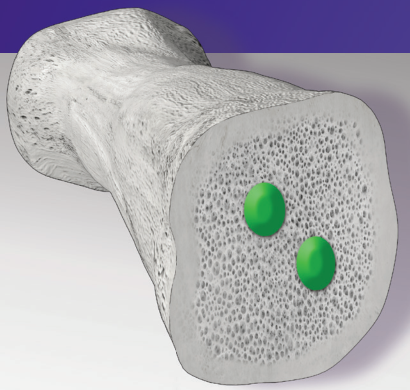


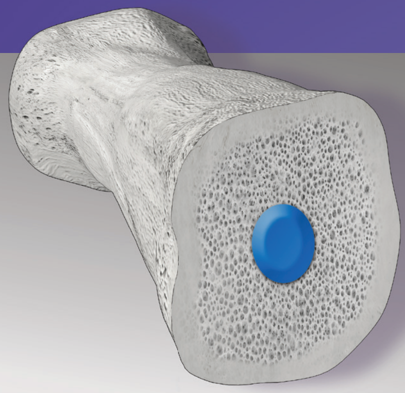
Figure 4. Outrigger Assembly

2. MINIMIZE DAMAGE OF TISSUES AT THE ARTHRODESIS SITE.

The minimally invasive technique minimalizes the disruption of the nutrient arteries, endosteal blood supply vessels and periosteum providing blood supply to the bone with the exception of the entry points for the screws and the nail itself. [8,9,10]



The cross-sectional area of two 4.0 mm diameter screws crossing the osteotomy line disrupts 33 mm^2 of intramedullary bone.



In contrast, the 5.5 mm diameter Phantom Lapidus Nail disrupts 27 mm^2, an improvement of 18%.

Figure 5. Cross Sectional Size Comparison

The surface area of the Phantom Lapidus Nail at the arthrodesis site is smaller compared to two 4.0 mm crossed screws - reducing the disruption of healing at the fusion site. When placed properly, the Phantom Lapidus Nail should cross the arthrodesis sight slightly plantar to the central axis of the prepared joint (Figure 5).

3. SIMPLIFY BONE PREPARATION FOR FUSION AND CLOSE ANY GAPS AT THE ARTHRODESIS SITE.

Primary healing by intramembranous bone formation is only possible with gap reduction at the fusion site. Congruent surfaces with smooth, flat cuts provide the best clinical results since gaps present a major risk for delayed union or nonunion.[1,7] Removal of all bony fragments specifically in the plantar aspect of the joint is part of obtaining congruent surfaces of the fusion site. The Phantom Nail system provides instrumentation which aids in joint preparation and removal of the cartilage and bone fragments. The instruments provided include a pin distractor, Lapidus nipper, subchondral perforating drill and joint preparation chisel (Figure 6).

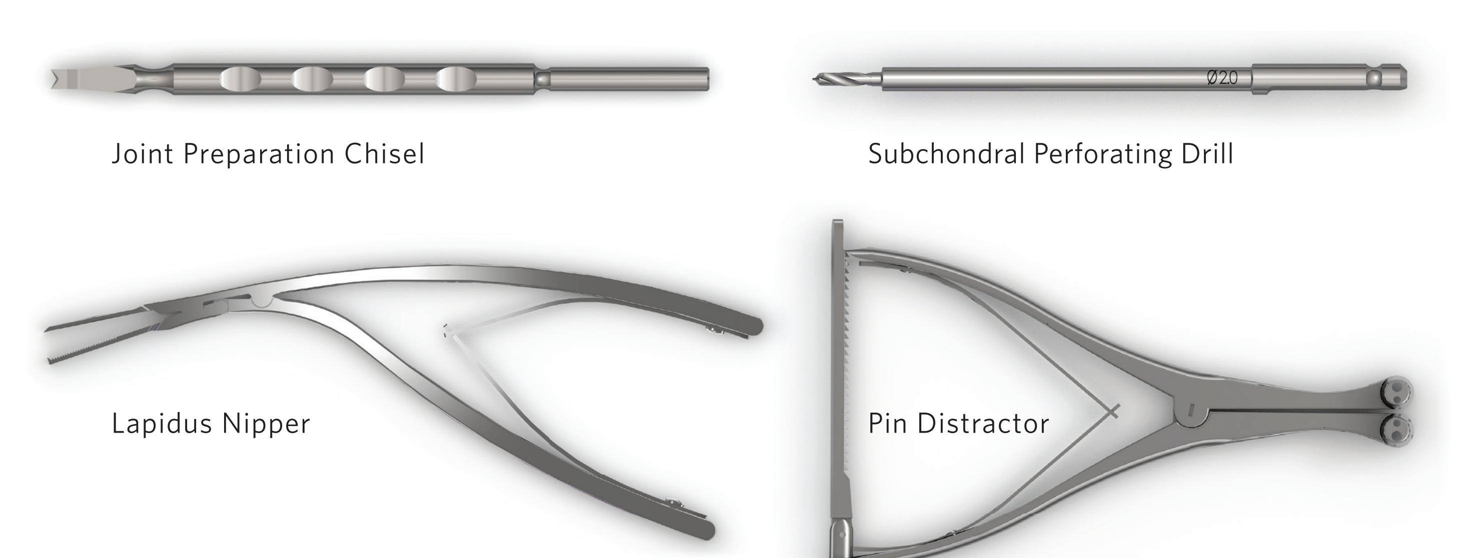


Figure 6. Joint Preparation Instrumentation

4. PROVIDE BONY COMPRESSION AND STABILITY

The outrigger features a screw drive to achieve closure and compression of the 1st metatarsal/medial cuneiform joint for stability under load(Figure 7a and 7b). This allows direct bone formation rather than relying on cartilage formation followed by ossification of the cartilage. This type of bony repair is the goal of ORIF (Open Reduction and Internal Fixation) and is known as primary healing as first described by Danis. [11]

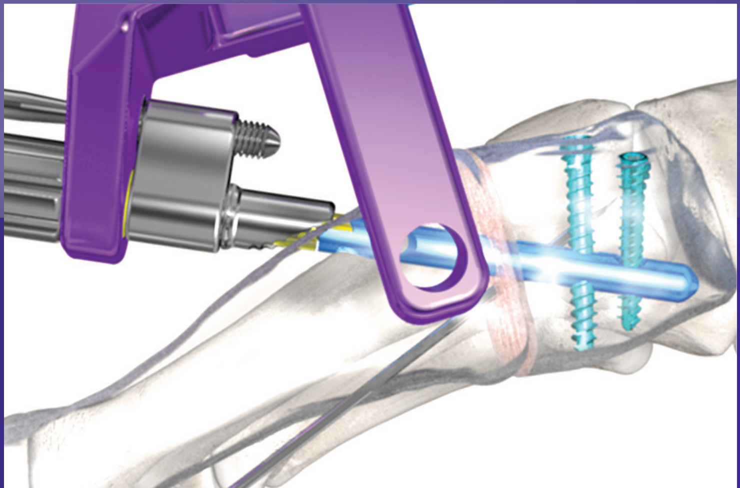


Figure 7a. Phantom Nail with NO Compression

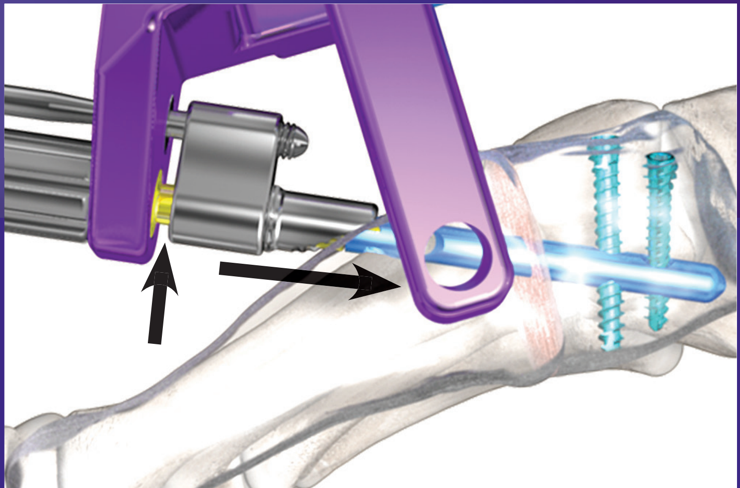


Figure 7b. Phantom Nail with Compression

Granulation tissue can be stretched to twice its original length without damage, so this tissue type is viable in early secondary healing. In contrast, mature cortical bone can only be stretched 2% before creating a fracture.[12] To achieve primary healing, the arthrodesis region where bone is forming needs to be maintained with both proper bony alignment and compression to avoid damaging the new bone . Due to the stable environment provided by the Phantom Lapidus Nail, osteons may directly bridge the repair zone without formation of fibrocartilage or hyaline cartilage as would most likely occur with endochondral ossification.

FEA testing of the Phantom Lapidus Nail (Figure 8a) shows the nail with zero compression with stress placed on the nail and fusion site resulting in plantar gapping and no stabilization. With 100N of compression (Figure 8b) the testing shows an absence of gapping in the fusion site when stress is applied to the fusion site with more uniform compression on the entire surface area of the joint.

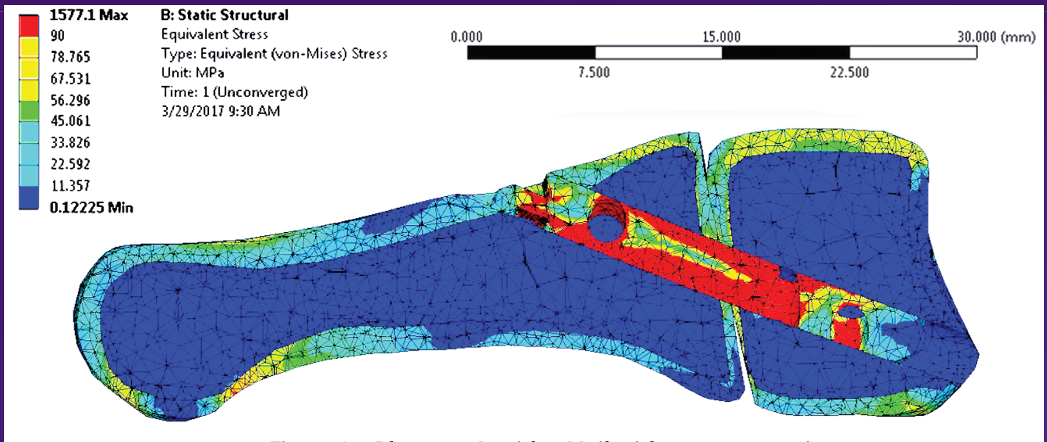


Figure 8a. Phantom Lapidus Nail with no compression

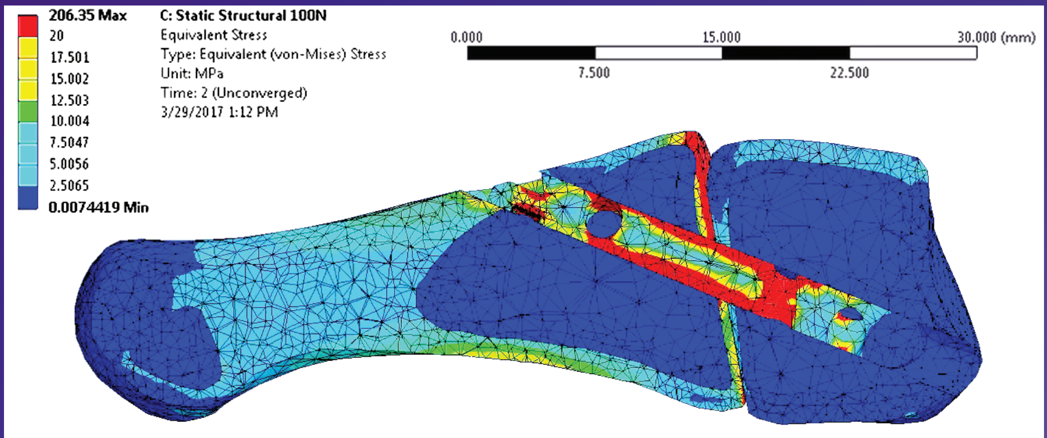


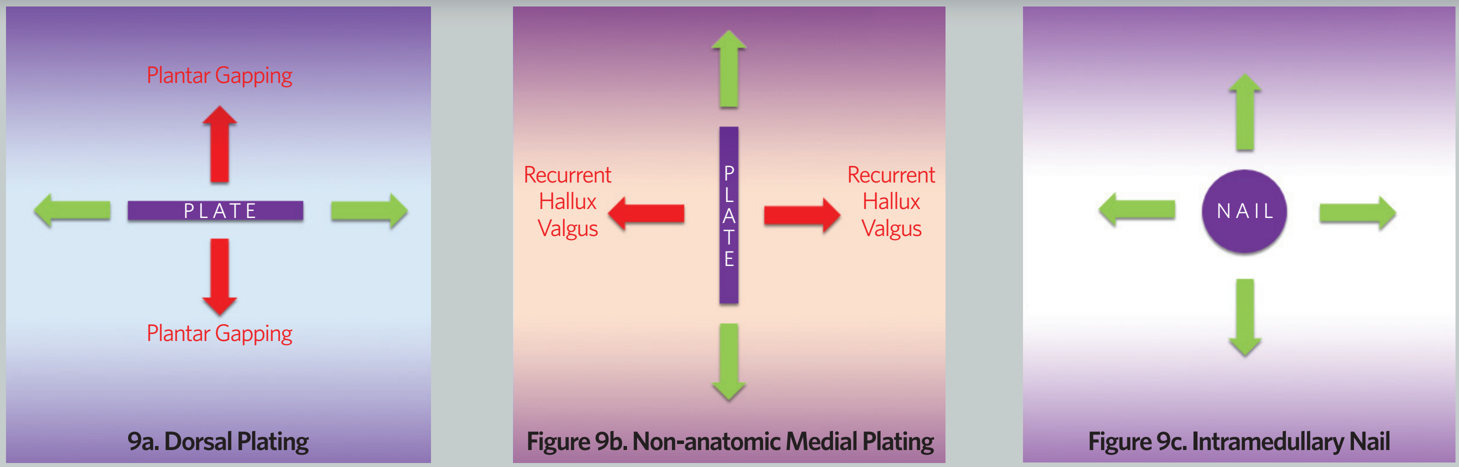
Figure 8b. Phantom Lapidus Nail with Compression

The Phantom Lapidus Nail directs compression to the center of the joint providing the entire surface area of the joint with more uniform compression compared to staples and plates which direct pressure at the surface of the bone. Cortical or cancellous screws may only gain the compression needed in patients with good bone quality where the screw threads purchase in the bone. With screw use, movement or gapping of the site may occur if there is bone resorption or inadvertent early weight bearing and can result in non-union or pseudoarthrosis.[13]

In order to heal a joint, compression is best achieved by keeping the strain at the interface between 2% and 10%. Too little compression results in a non-union and too much can lead to necrosis. The amount of strain is calculated by the displacement divided by the width of the fracture gap.[2]

Hart *et. al.*, show the highest rates of unions are found with moderate compression in the range of 80N. Less compression led to non-union and more compression led to bone resorption and non-union.[14,15,16,17] Taking this research in to consideration, testing was performed and the sizing of the area of the first TMT joint found 80N to 100N to be the suggested compression in a properly reduced tarsometatarsal arthrodesis site.

The Phantom Lapidus Nail construct was designed with these studies, research and testing in mind. Compression and stability are achieved by "dialing in" the compression with the outrigger. This is achieved by applying pressure to the metatarsal, which is met with resistance from the two crossing screws in the medial cuneiform. Contact surface area is a key variable in determining the ideal compression zone. This means that each joint has a unique zone based on the size of the joint.



9a. Dorsal Plating

Figure 9b. Non-anatomic Medial Plating

Figure 9c. Intramedullary Nail

Evidence of stability is provided from biomechanical tests. Comparing the in situ stiffness of a dorsal plate, a medial plate, and the Lapidus IM nail at the 1st TMT joint, the medial plate and the IM nail provided 6.0 - 6.5 times more stiffness than the dorsal plate. The Phantom Lapidus Nail has been demonstrated to resist both recurrent hallux valgus and plantar gapping based on these biomechanical tests.[18]

- Dorsal plating is not an ideal clinical solution since the plate is strongest in the medial-lateral direction and weakest in the dorsal-plantar direction (Figure 9a).
- Non-anatomic medial wall plating is strongest in a dorsal-plantar direction and weaker in a medial-lateral direction resulting in possible recurrent hallux valgus as the distal portion of the first metatarsal may redirect medially following placement of the plate (Figure 9b).
- Intramedullary nails show the same strength regardless of directive forces (Figure 9c).

Screws and staples also have a wide range of 25N to 100N of compression depending on the technique used, size ranges and patient-specific criteria. In Lapidus procedures, a crossed screw construct is popular but the compressive force provided is highly dependent on the initial tightening of the first screw and bone quality of the patient. Chang ***et. al.***, determined that placing a second screw will not enhance the compressive forces generated by the construct. Nitinol memory staples are designed to have a dynamic or residual compressive force across the fusion site and can adjust over time due to multiple factors related to the procedure and post-operative protocol.[13]

DESIGN RATIONALE

Challenge	Design Feature	Acceptance Criteria	Benefit
Compressive joint preload	Threaded barrel on outrigger allows for controlled fusion site compression	User-adjustable joint compression before placement of final two crossed screws into the metatarsal	Complete closure of joint space allows primary bone healing
Size range to fit most patients	Nails available in varying lengths	38 mm to 60 mm lengths in 2 mm increments	Achieve strong fixation in best quality bone Provides anatomic fit
Zero prominence	Nail and screws have minimal profile	All hardware designed to be at or slightly below level of the bone surface	Reduced or no soft tissue irritation
Sufficient rigidity	Structural titanium alloy nail with equal parts on each side of joint	Stiffness equal to or greater than medial plating options	Nail resists loading at least as well as a medial plate Encourages primary healing
Minimal periosteum interruption	Five small bone pathways for one nail and four screws	Less interruption of periosteal vasculature than with plating options	Better nutrient supply for faster bone fusion

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