CASE STUDY

1st Tarsometatarsal Arthrodesis for Correction of Hallux Abducto Valgus with Hypermobile 1st Ray Utilizing Bone Allograft and Novel Intramedullary Nail System

Paragon 28® Exclusively foot & ankle

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FEATURED PRODUCTS: Phantom® Small Bone Intramedullary Nail System, Lapidus Cut Guide System, PRESERVE™ Lapidus Angular Length Restoring Graft

Product Introduction

The Paragon 28® Phantom® Small Bone Intramedullary Nail System is comprised of intramedullary nails, locking screws and threaded pegs. The Phantom® Nails are offered in a variety of lengths to accommodate variations in patient anatomy. The Phantom® threaded pegs and locking screw insert through the intramedullary nail to secure the construct.

The system instruments include sphere wires, K-wires, combination tissue protector/drill-pin guide, obturator, drill bits, polyaxial targeting guide, outriggers, outrigger sliders, depth gauges, screw drivers and driver handles. The instruments are used to place the Phantom® Nail, threaded pegs and locking screw.

The Phantom® Nail is the first dedicated intramedullary device designed specifically for use in a 1st tarsometatarsal (TMT) joint arthrodesis. Being intramedullary, the Phantom® Nail has no prominence above the bony surface. This design is intended to potentially lessen pain associated with hardware prominence of traditional plating systems. The intramedullary design was also intended to preserve the blood flow of the periosteum which traditional plating systems may suffocate. The Phantom® Nail exerts a proportionate amount of force in all anatomic planes resisting recurrent hallux valgus (associated with medial plating with a straight plate) and plantar gapping (associated with dorsal plating)[13]. Finally, the system includes instrumentation to facilitate drilling and nail placement ensuring accurate positioning of the implants in a highly vascularized environment.

Presentation

A healthy 42 y/o female presented for an evaluation of painful bilateral bunion deformities that have progressed over the years. She complained of "bump pain" in all shoe gear, even gym shoes. She is a runner and experienced joint pain in both feet as well as increased irritation over the medial bumps. She had tried different conservative options including shoe gear changes and local treatment without resolution.

Examination

CLINICAL EXAM/PHYSICAL ASSESSMENT

The patient exhibited a clinically significant bunion on the left foot and moderate bunion on the right foot. There was mild hallux abduction with a slight tendency for under lapping of the second toe on the left foot. There was erythema noted over the 1st metatarsophalnageal joints (MPJs) bilaterally from wearing shoes the day of the exam. Motion of the left 1st MPJ was mildly limited in dorsiflexion with pain at the end range of motion (ROM) while plantarflexion was within normal limits and non-painful. Dorsiflexion and plantarflexion on the right were within normal limits and non-painful. She had a hypermobile 1st ray with elevation in stance resulting in calcaneal eversion and a dorsally prominent 1st metatarsal head. She had a slightly prominent tuberosity of the navicular bilaterally. Ankle, subtalar and midtarsal joint ROMs were within normal limits bilaterally.

PRESERVE™ BONE GRAFT SYSTEM

PHANTOM® INTRAMEDULLARY NAIL

Radiographic Assessement

The pre-op anteroposterior (AP) radiograph (**Figure 1A**) revealed an increased 1st intermetatarsal angle (IMA) of 13.7°, a hallux abductus angle (HAA) of 18.4° and deviated 1st MPJ. The medial cuneiform was noted to have an atavistic distal articulation. Minimal cartilage adaptation was noted of the 1st metatarsal head. Mild enlargement of the medial eminence was also identified.

The pre-op radiograph (**Figure 1B**) exhibited an elevated 1st metatarsal.

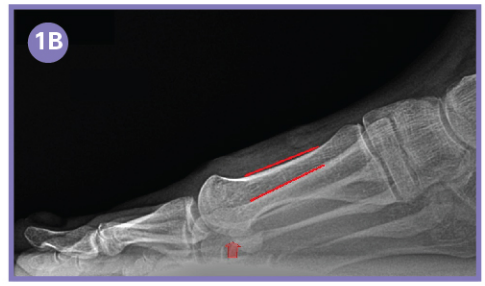

Figure 1: Weightbearing pre-operative radiographs (**A**) AP and (**B**) lateral.

Initial Management and Decision-Making

Introduction – Overview of Indication and Modalities of Treatment

The indications for hallux valgus correction are dependent on a multitude of factors. Conservative approaches are notably considered first including, but not limited to, shoe gear changes, padding, activity modifications, oral non-steroidal anti-inflammatory drugs (NSAIDS) for inflammation and pain, and orthotics to control function. Other important considerations revolve around the patient's past medical history and co-morbid conditions such as smoking, diabetes, and obesity. Patient expectations of the surgical results and post-operative course need to be understood and carefully reiterated back to the patient. As post-operative recovery can vary depending upon the procedures performed, it is not uncommon for a patient's pre-operative expectation of recovery and return to normal activity to become muddled and confused as post-operative recovery time progresses.

I have been performing hallux valgus correction for over 35 years. During my career, technology for the fixation and correction of hallux abducto valgus (HAV) involving fixation of osteotomies/fusions has evolved from simple K-wires, osteoclasps, staples, monofilament wire, single screw, multiple screws, buttress plates, compression plates, locking plates and a multitude of various combinations of one or more of these techniques. Additionally, approaches to HAV correction have traditionally relied upon 2-dimensional radiographic measurements of the 1st IMA, HAA, proximal articular set angle (PASA), distal articular set angle (DASA), hallux interphalangeus angle, tibial sesamoid positioning, joint congruency as well as overall foot alignment. Clinical exam has included ROM of the 1st MPJ, quality of motion, hypermobility of the 1st TMT joint, 1st MPJ cartilage adaptation and foot biomechanics.

About two years ago, I was introduced to the concept of the Center of Rotation Angulation (CORA)[1] approach and tri-planar correction [2,3] to address HAV deformity. Surgeons performing HAV surgery should spend the time to research these two concepts diligently, go back and review past HAV corrections and, where possible, follow up on a long-term basis both clinically and radiographically to, as objectively as possible, evaluate their results. I am in the process of completing this project in my own practice; however, studies have reported recurrence rates from 25-75%. [4,5]

Surgical Steps and Tips*

The patient is placed on the table in a supine position with the appropriately-sized bump under the ipsilateral hip to place the foot in a rectus position.

The approach involves a dorsolinear incision extending from the interphalangeal joint of the hallux proximally to the proximal medial cuneiform. A critical component of any surgical procedure is layered dissection and soft-tissue handling. My approach involves careful dissection of the periosteum off the 1st MPJ and 1st metatarsal shaft to the medial cuneiform (Figure 2). Keeping this layer intact ensures the vascularity provided by the periosteal tissues is maintained for proper healing after closure. It also encourages layered healing to decrease scarring post-op.

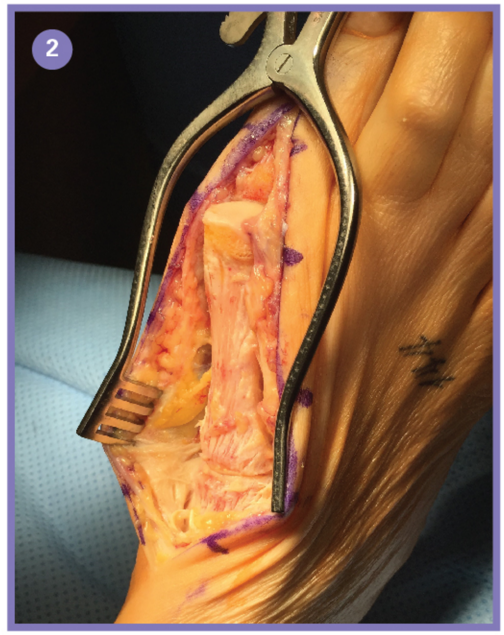

Figure 2: Dorsolinear incision for 1st TMT arthrodesis in HAV correction.

The 1st MPJ is then addressed with resection of any medial eminence and lateral releases. I have found very few occasions in which I have had to perform any form of lateral release.

It has been proposed by Dr. Paul Dayton, et al [6,7] that medial eminence resection may not be necessary based upon research by Coughlin and Freund [8], Martin [9], Thordarson and Krewer [10] where it was proposed that first metatarsal eversion/valgus rotation during HAV formation creates the illusion of a medial eminence. Once the 1st metatarsal is corrected in the frontal plane, the presence of a medial eminence disappears. I have applied this concept in one particular HAV formation with a younger patient where medial eminence both clinically and radiographically was absent. Correction of the HAV with a Lapidus approach allowed correction of the HAV without invading the 1st MPJ, thereby avoiding 1st MPJ scar tissue formation and limited ROM of the 1st MPJ post-operatively. However, in most cases, in my opinion, eminence formation is evidenced in long-standing HAV formation and requires resection as part of the procedure.

Attention is now paid to the 1st TMT joint which is freed of capsular tissues to visualize the joint. The Paragon 28 Lapidus Cut Guide System offers a unique and user-friendly means to allow for accurate bone resection of joint surfaces to permit correction in both the transverse and sagittal planes (Figure 3A, 3B). The set includes transverse correction from 8° through 20°.

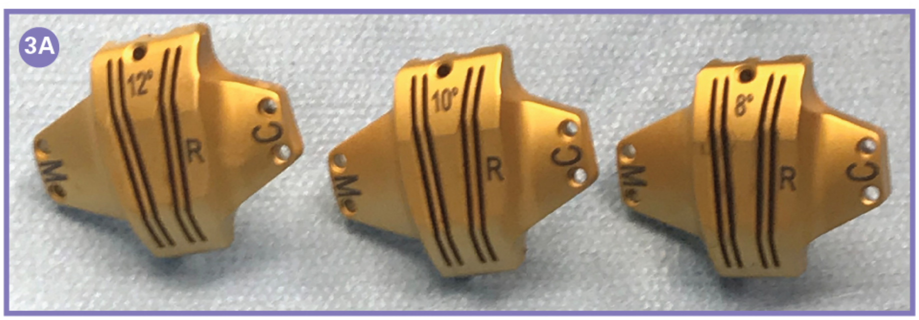

Figure 3A: Paragon 28 Lapidus Cut Guides showing sizes common with HAV deformity correction – 12° guide, 10° guide and 8° guide

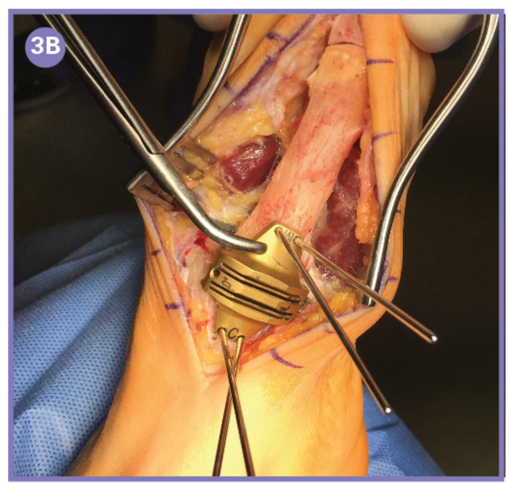

Figure 3B: Guide inserted in the 1st TMT joint.

The cut guides are designed to allow resection of the least amount of bone while ensuring cartilage removal (Figure 4A, 4B). Additionally, the cut guides ensure the plantarflexion component is obtained in the 1st metatarsal base. This is important in the final construct of the device.

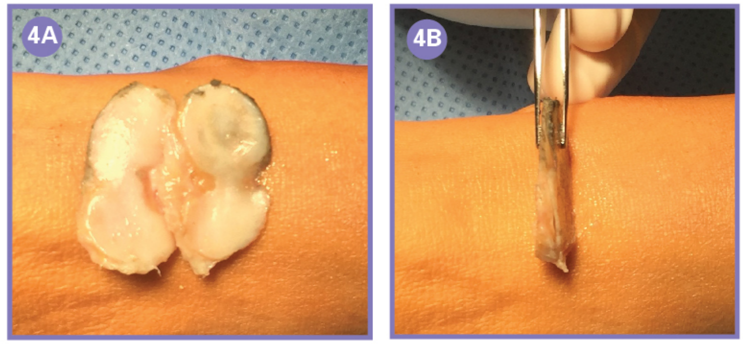

Figure 4: (**A**, **B**) Bone/Cartilage taken out after utilizing the Paragon 28 Lapidus Cut Guide System.

Once the joint surfaces are resected, the bone edges are fenestrated to promote vascular penetration. In some instances, depending upon the condition of the medullary bone, additional fish-scaling between fenestration holes can be performed with a bone chisel. Removal of the attachment of peroneus longus from the plantar aspect of the 1st metatarsal is routinely performed (Figure 5). This allows the base of the 1st metatarsal to be manipulated for fenestration and frontal plane rotation. Using a lobster claw bone clamp allows secure handling of the 1st metatarsal (Figure 6).

Attention is now focused on alignment of the 1st metatarsal and 1st MPJ. Utilizing a bone clamp, the 1st metatarsal is rotated in the frontal plane to correct for the everted position of the metatarsal head and alignment of the sesamoids. Temporary fixation is then accomplished with a .062″ K-wire and intraoperative radiographic imaging performed with the foot placed in a weightbearing position to assess frontal plane alignment of the sesamoids within the grooves on either side of the crista, transverse plane correction of the IMA, realignment of the 1st MPJ and sagittal plane positioning of the 1st metatarsal. Positioning of the K-wire is critical, running from plantar-distal-medial to dorsal-proximal-lateral across the fusion site to avoid interfering with the intramedullary placement of the Phantom Nail.

Figure 5: Removal of the peroneus longus tendon from the base of the 1st metatarsal.

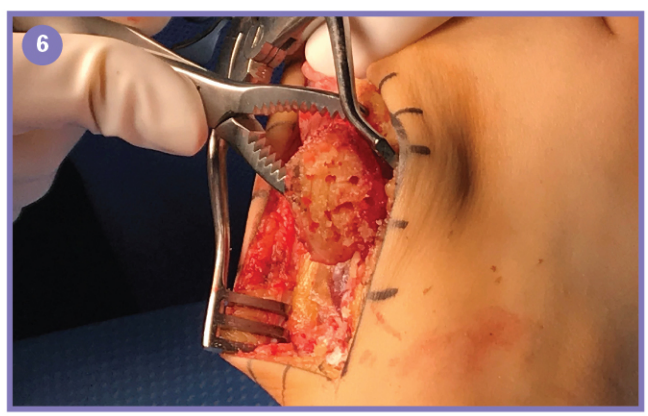

Figure 6: Use of a lobster claw bone clamp to manipulate/handle the 1st metatarsal.

Attention is now paid to establishing proper alignment of the Phantom Nail. Using intra-operative fluoroscopy, a sphere wire is placed at the most proximal and inferior aspect of the medial cuneiform (**Figure 7**). This sphere wire allows the surgeon to determine proper Phantom Nail length, alignment and termination. I have found placing a stab incision over the area allows for drilling of the sphere wire directly into bone preventing the wire from floating on the skin thereby changing its direction. Next, a positioning guide is placed at the fusion site and utilized to mark on the dorsal aspect of the 1st metatarsal for the entrance of the guide pin (**Figure 8**).

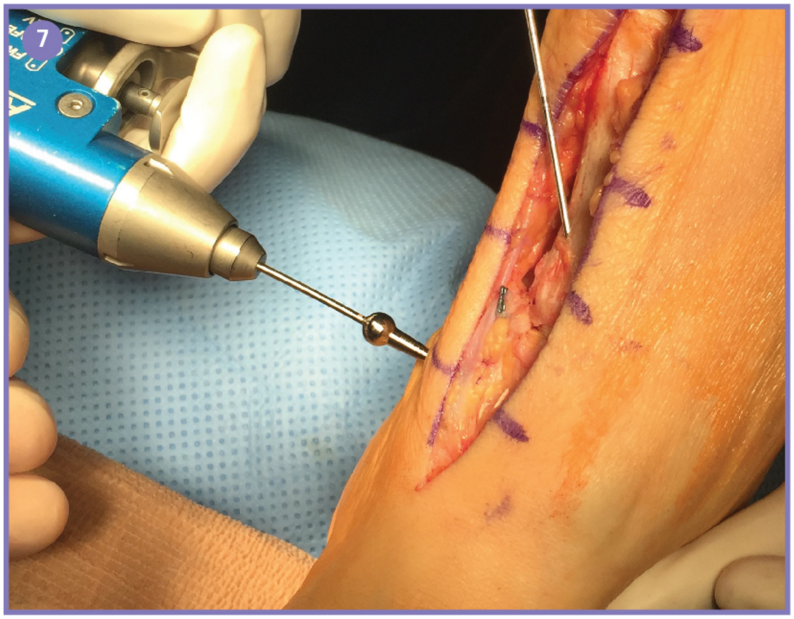

Figure 7: Placement of the sphere wire into the proximal inferior aspect of the medial cuneiform.

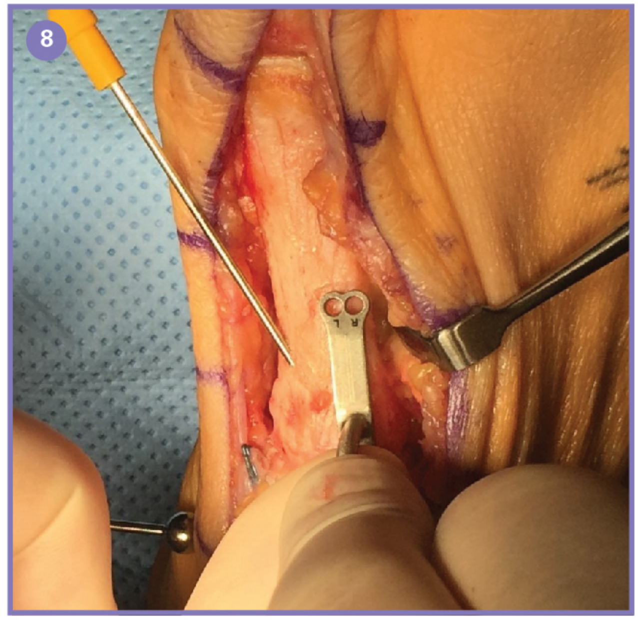

Figure 8: Phantom Nail positioning guide in place to set guide wire placement.

The polyaxial targeting guide is then attached to the sphere wire allowing placement of the guide wire through the dorsal aspect of the 1st metatarsal at the angle necessary to meet with the sphere wire in the medial cuneiform (**Figures 9A, 9B and 9C**).

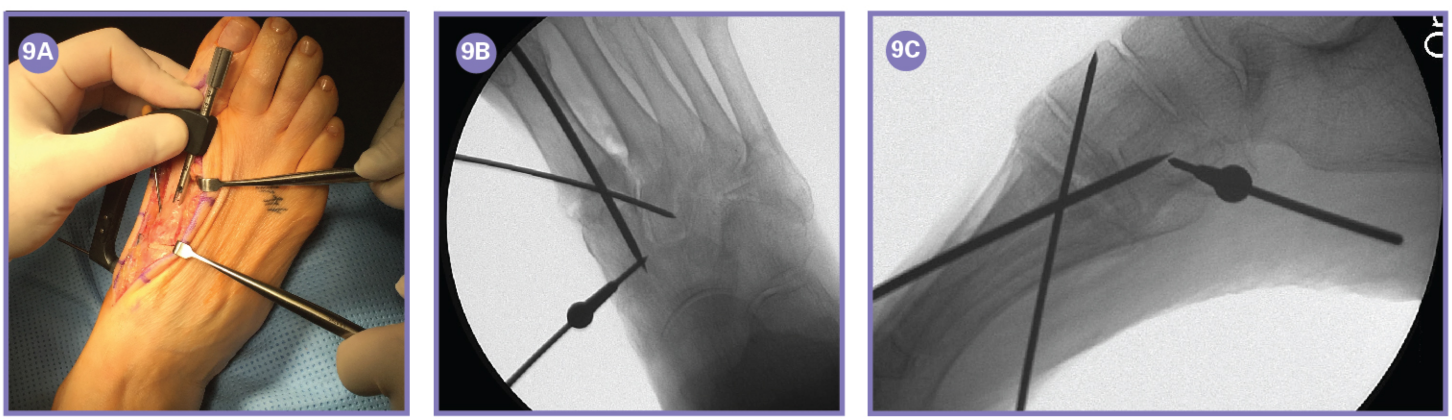

Figure 9: Guide wire placement. (**A**) Clinical picture of the polyaxial guide attached to sphere wire, aligning with mark set by the Phantom Nail positioning guide in Figure 8. (**B**) AP radiograph of guide wire placement, and (**C**) lateral radiograph of guide wire placement.

A depth gauge is then placed over the guide wire to measure the length of the Phantom Nail needed. While the surgeon is preparing the fusion site, temporarily fixating and performing length measurements for the Phantom Nail, the surgical tech assembles the jig for the appropriate length Phantom Nail. Next, a cannulated 5.5 mm drill is placed over the guidewire to ream out bone across the fusion site for placement of the Phantom Nail. The Phantom Nail is inserted into the reamed-out area with the attached outrigger. Alignment pins placed in the outrigger allow for identification of the anterior crest of the tibia as a reference point. With the outrigger in the appropriate position and alignment, drill sleeves and obturators are then placed into the outrigger assembly to line up with the appropriate slots in the Phantom Nail. The two proximal slots are then filled with the appropriate sized threaded pegs which are placed under direct visualization with C-arm (**Figure 10**).

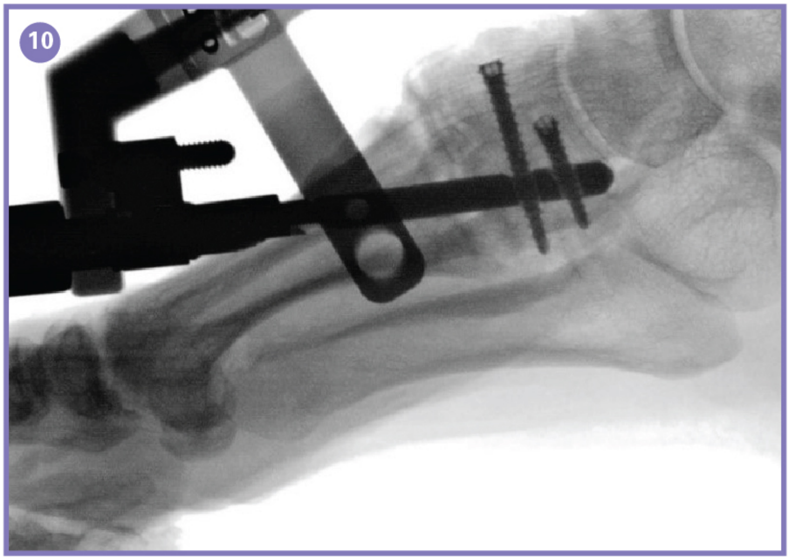

Figure 10: Lateral radiograph of the Phantom Nail attached to the outrigger with two threaded pegs placed in the medial cuneiform.

Next, compression is accomplished with the jig in place (**Figure 11**). Research has shown that there is a certain range of compression that can help drive fusion.[11, 12] Paragon 28 has also performed internal testing to show between 80 - 100N of force may promote osseous union.[13] The Phantom Nail system contains a unique, torque-indicating driver which allows the surgeon to apply the proper compression between 80 - 100 N. (**Figure 12**). With the appropriate compression obtained, a third threaded peg is placed into the 1st metatarsal base to ensure compression is maintained. Finally, a locking screw is inserted into the distal end of the Phantom Nail.

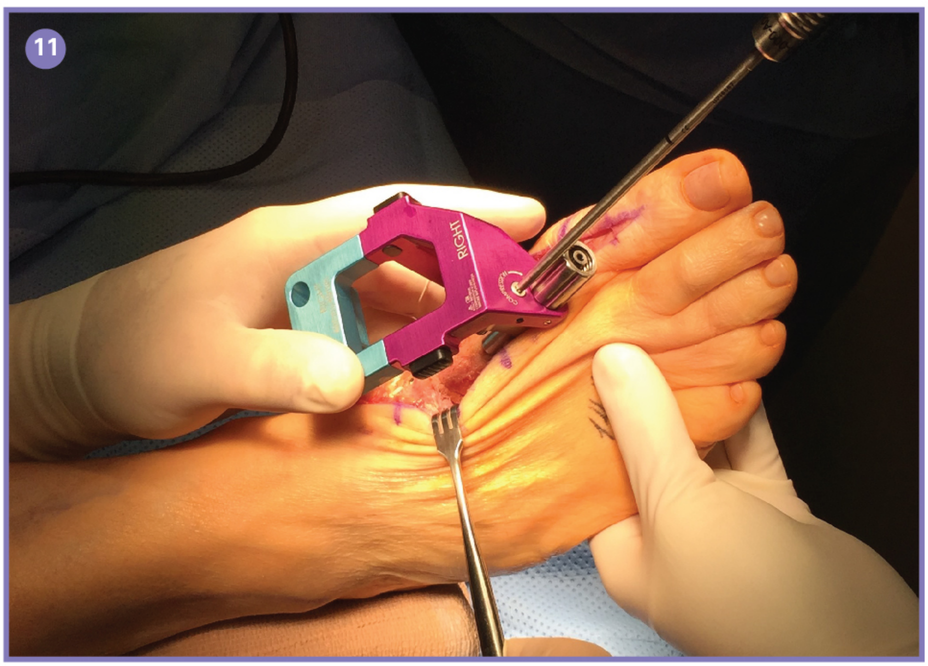

Figure 11: Compression of the 1st TMT joint using the Phantom Nail outrigger.

Figure 12: Close-up view of the torque-indicating driver, which has dash marks representing the zone between 80-100 N of force.

It should be noted that during the procedure, frequent use of the mini C-arm or regular C-arm is critical to ensure accurate positioning of the Nail and to validate anatomic correction. Following compression and osseous correction, the fusion site is observed in both lateral and AP views. The 1st MPJ alignment and sesamoid positioning is also confirmed. Soft tissue closure is then performed with complete layered closure of the periosteum to ensure return of vascularity to osseous structures. Skin closure is accomplished as per surgeon preference.

Postoperative Protocol

The patient is placed into a posterior splint and a first postoperative visit is scheduled two days after surgery, drain pulled if placed, and dressings changed. The splint is then reapplied. The patient remains non-weightbearing until their second postoperative visit at two weeks. The patient is maintained in the splint but permitted to remove the splint and start active ROM of the ankle while staying non-weightbearing. At three weeks postoperative, the stitching is removed and depending upon healing status of the incision, the patient is sent for physical therapy to begin 1st MPJ ROM and soft tissue work. Physical therapy is given strict instructions to stabilize the fusion site while working on the 1st MPJ. The rigid stability of the Phantom Nail construct allows for early ROM of the ankle and 1st MPJ. Between the fourth and fifth week postop, partial weightbearing is considered on the heel only in a Controlled Ankle Motion (CAM) walker. The decision for weightbearing is dependent upon patient weight and presence of co-morbidities such as smoking or diabetes and patient expectations.

Radiographs were taken 9 weeks post-operative (**Figures 13A, 13B**). X-rays confirmed accurate positioning of the allograft and complete contact of graft-host interface.

The patient is gradually moved to full weightbearing in the CAM boot over the next 4-6 weeks based upon clinical evaluations and radiographic progression of fusion. CT scan is routinely obtained around 10-12 weeks to confirm three-dimensional fusion. After 3 months, the patient is returned to all physical activities without restriction.

Postoperative Status

The patient followed the typical post-operative course and returned to all activities after 3 months, including running.

Figure 13: Weightbearing radiographs taken at 9 weeks postoperative (**A**) AP and (**B**) lateral.

1. Paley D. Principles of deformity correction. Berlin:Springer; 2002.
2. Eustace S, Obyrne J, Stack J, Stephens MM. Radiographic features that enable the assessment of first metatarsal rotation: the role of pronation in hallux valgus. Skel. Radiology 1993; 22:153–6.
3. Mizuno S, Sima Y, Yamaxaki K. Detorsion osteotomy of the first metatarsal bone in hallux valgus. J Japan Orthop Assoc. 1956; 30:813–9.
4. Iyer S, Demetracopoulos CA, Sofka CM, Ellis SJ. High rate of recurrence following proximal medial opening wedge osteotomy for correction of moderate hallux valgus. *Foot Ankle Int.* 2015;36:756–63.
5. Pentikainen I, Ojala R, Ohtonen P, et al. Preoperative radiological factors correlated to long-term recurrence of hallux valgus following distal chevron osteotomy. *Foot Ankle Int.* 2014; 35:1262–7.
6. Dayton P, Evidenced-Based Bunion Surgery - A Critical Examination of Current and Emerging Concepts and Techniques, Springer International Publishing, 2018
7. Dayton, P., Feilmeier, M., Kauwe, M, Hirschi, J., Relationship of Frontal Plane Rotation of First Metatarsal to Proximal Articular Set Angle and Hallux Alignment in Patients Undergoing Tarsometatarsal Arthrodesis for Hallux Abducto-Valgus: A Case Series and Critical Review of the Literature, The Journal of Foot and Ankle Surgery, Volume 52, Issue 3, 348 - 354.
8. Coughlin MJ, Freund E, Roger A. Mann award: the reliability of angular measurements in hallux valgus deformities. *Foot Ankle Int*. 22:369–379, 2001.
9. Martin DE. Preoperative radiographic evaluation in HAV surgery: a critical analysis of PASA and other soft tissue adaptation. In: Reconstructive Surgery of the Foot and Leg, edited by CA Camasta, NS Vickers, JA Ruch, Podiatry Institute, Tucker, GA, 1993.
10. Thordarson DB, Krewer P. Medial eminence thickness with and without hallux valgus. Foot Ankle Int 23:48–50, 2002.
11. Friedenberg, Z.B., French, G., The Effects of known Compression Forces on Fracture Healing, Surg. Gynec. And Obstect, 94:743-748, 1952.
12. Laros, G.S., Fracture Healing Compression vs. Fixation, Arch. Surg., 108:698-702, 1974
13. Paragon Test Report TR-17060501

* *Photos and X-rays shown in this section depict typical use of the Paragon 28® Lapidus Cut Guide System as well as placement of a Phantom Nail® and are not specific to this case study.*

Exclusively foot & ankle

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