CASE STUDY

Hammertoe Correction Utilizing a Novel PEEK Titanium Plasma Spray Implant

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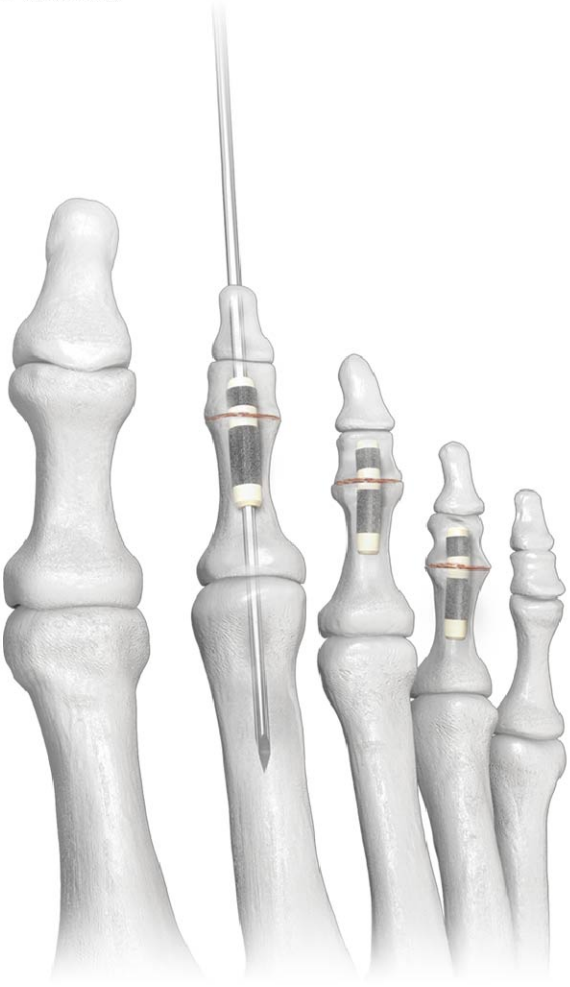
FEATURED PRODUCT: HammerTube™ Hammertoe System

Product Introduction

The HammerTube™ System is comprised of a sterile, PEEK (Polyetheretherketone) fixation device and stainless steel K-wires. The PEEK implants are offered in diameters of Ø2.75 mm and Ø3.50 mm, with 0 degree and 10 degree angled options. The K-wires range in diameters from Ø1.1 mm to Ø1.6 mm. The system instruments include inserters, drills, planers, a trephine removal tool, and a threaded extractor.

The patent-pending HammerTube™ is a single piece titanium sprayed PEEK (Polyetheretherketone) implant intended for use in proximal interphalangeal (PIP) joint fusions. The HammerTube™ implant is constructed from PEEK, a non-reactive biomaterial which closely matches the mechanical properties of the bone.[1] The HammerTube ™ implant is coated both proximally and distally with a porous titanium spray designed to increase fixation on either side of the joint when compared to uncoated PEEK implants.

The instrumentation provided supports versatility in surgical technique, allowing for surgeon preference to dictate technique. A standard technique can be performed that allows direct drilling and placement of the implant. Alternatively, a retrograde technique can be performed with initial K-wire placement determining toe position. The retrograde technique allows for a K-wire to be left in to temporarily stabilize the MTP joint when used with a straight implant, if desired.



Indications For Use

The HammerTube™ System is indicated for fixation of reconstruction and fusion of toes during correction procedures for hammertoe deformity, claw toe deformity, shortening osteotomies of the phalanges and mallet toe deformity as well as revision hammertoe procedures.

The cannulated and solid HammerTube™ implants may be used without any other additional device. The cannulated implants may be used with K-wires for delivery of implants or for the temporary stabilization of nearby joints, such as the metatarsophlanageal joint.

The implantable K-wires are indicated for use in the stabilization and fixation of small bones for use in bone reconstruction, osteotomy, arthrodesis, fracture repair and fixation, appropriate for the size of the joint. Additionally, the implantable K-wires are indicated as guide pins for insertion of instruments and implants in the HammerTube™ System.

Presentation

A 65 year old female presented with pain wearing closed shoes over her right 2nd and 3rd toes. She had tried wearing wider toe box shoes and still had pain. Also, she was unhappy with the appearance of the wide toe box shoes despite being more comfortable while wearing them. She had no pain over the medial eminence of 1st metatarsal. She was otherwise healthy and active.

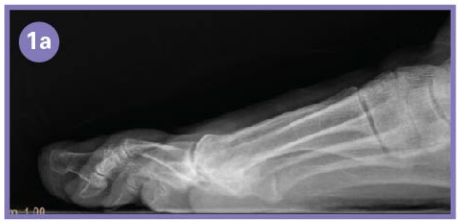
Examination

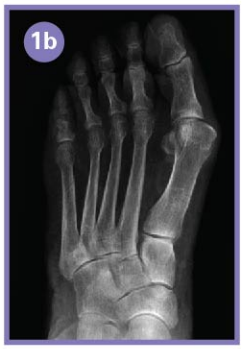
CLINICAL EXAM

Physical examination revealed fixed right 2nd and 3rd hammertoe deformities with approximately 40 degree fixed flexion deformity at the PIP joint and 20 degree flexible MP joint extension contracture. She had no tenderness over the medial eminence of hallux with mild hallux valgus. She had no other areas of tenderness over her foot and a full, pain-free range of motion of all MP joints and ankle/hindfoot joints.

Radiographic Imaging

Radiographs displayed minimal hallux valgus and hallux valgus interphalangeus. While she had flexion deformities of the 2nd/3rd PIP joints, there were no arthritic changes anywhere in the foot nor varus or valgus of MP joints. The hallux was not abutting the 2nd toe (**Figure 1a and 1b**).





Initial Management And Decision-Making

On her first clinic visit, she was advised to continue using her wide toe box shoes. In addition, she was given a double Budin toe splint to strap down her 2nd and 3rd toes. She was advised that this conservative treatment was the only means to avoid surgery due to the fixed structural deformity of the foot. The patient ultimately elected surgery to achieve correction of the deformity.

Introduction

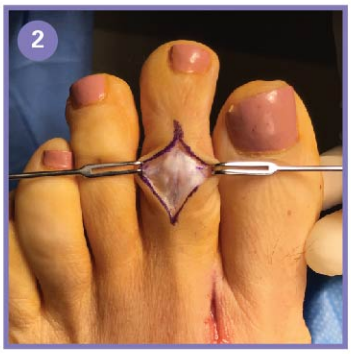
Hammertoe deformities are one of the most common foot problems encountered by foot and ankle surgeons. Technically a hammertoe is defined as a flexion deformity of the PIP joint with a corresponding extension deformity of the MP joint and usually a straight DIP joint. Hammertoe can occur in isolation such as the 2nd toe alone or with multiple toes. They are often associated with MP synovitis which typically manifests first with pain at the MP joint but they often eventually develop varus at that joint. Hammertoes are frequently associated with hallux valgus and, when present, the valgus deformity of the great toe must be repaired to make room for the 2nd toe to sit adjacent to the hallux. In more extreme cases, the patient will develop a crossover 2nd toe where the 2nd hammertoe completely crosses over the hallux with more severe 2nd MP varus. The 2nd MP will often become unstable as the plantar plate attenuates which creates an even more complex scenario.

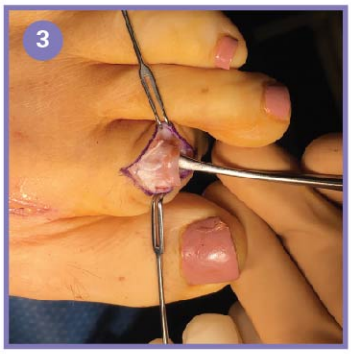
Historically, hammertoes were treated by resection arthroplasties of the PIP joint and subsequently temporary pinning of the PIP joint was added. Despite the temporary pinning modification, many patients eventually develop a new deformity at the PIP resection arthroplasty site, often a recurrent flexion or even valgus molding against the hallux. This risk of subsequent deformity has led to the development of implants such as the HammerTube™, to serve as permanent internal fixation so subsequent deformities do not develop. Multiple different implant systems have been developed, but there are a number of design features for the HammerTube™ which make it optimal. The straight implant has the option of leaving the temporary K-wire in place for a few weeks after surgery to maintain alignment and to protect an MP joint repair. Also, occasionally in osteoporotic patients, the pin can be left in until the first postoperative visit if there is any concern about the quality of the bone around the implant. The HammerTube™ system also offers surgeons a 10 degree flexed implant if the patient is more concerned about the toe touching the ground after the surgery which may be more important to patients who engage in yoga and other such activities. In the event of removal, the uncoated part of the implant at the PIP joint level can be cut through with minimal difficulty in contrast to needing to destroy the dorsal aspect of the proximal and middle phalanx in order to remove a solid implant.

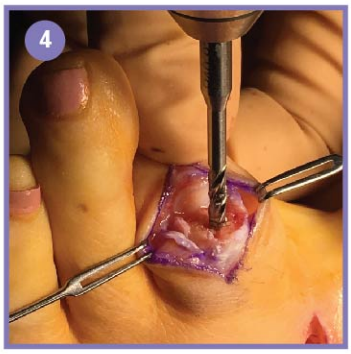
Specifically for the case below, straight implants for the 2nd and 3rd toes were chosen to minimize the risk of subsequent deformity in light of the patient having a risk of abutment of the hallux against the 2nd toe at times which could lead to a valgus deformity at the 2nd PIP joint. These deformities can cause painful rubbing between the hallux and the end of the 2nd proximal phalanx and a very cosmetically unappealing appearance.

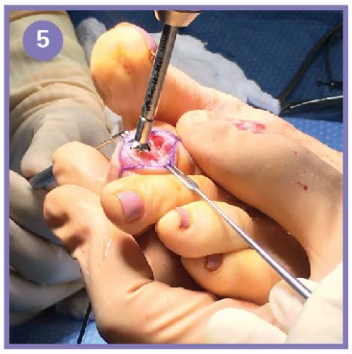
Surgical Technique

Surgery was performed on both the 2nd and 3rd toes in this case but not the mild bunion. A longitudinal incision was marked over the 2nd and 3rd PIP joints of 1.5-2 cm in length (Figure 2). A transverse, elliptical excision of the extensor mechanism is performed, widely exposing the PIP joint. A Freer Elevator is used to lever the proximal phalanx up (Figure 3) and is used subsequently under the middle phalanx to do the same. This technical pearl greatly facilitates the preparation of both sides of the joint by creating mobilization. A variable amount of the proximal phalanx is then resected creating a flat cancellous surface. The toe should be held straight before and after the resection to confirm the proper toe length was achieved by bone preparation. A guide pin is then placed down the proximal phalanx and it is drilled to the 2nd laser marking on the cannulated drill (Figure 4). The guide pin is then inserted retrograde out the tip of the toe and the planer can then be used to create a flat cancellous surface at the base of the middle phalanx (Figure 5).

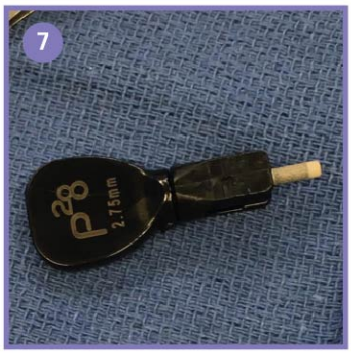


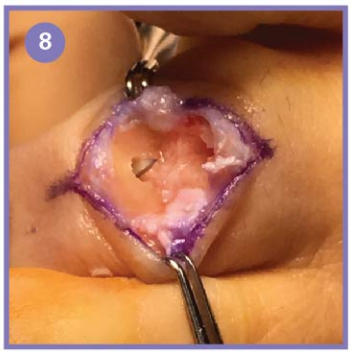


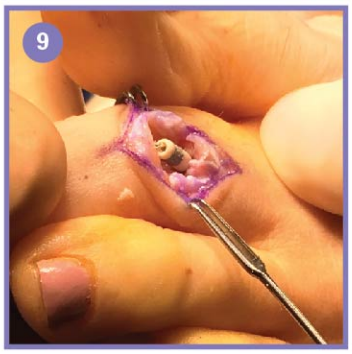




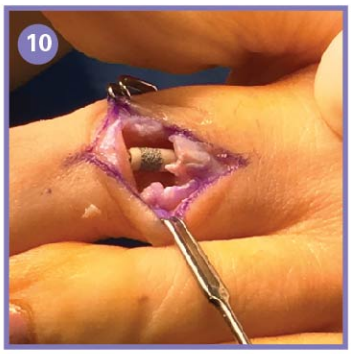
After the planer is removed, the cannulated drill is then inserted to the 1st laser line into the middle phalanx (Figure 6). At this time, the guide pin is backed out until the tip is just visible in the drill hole of the middle phalanx as it will serve as a guide for implant placement. The implant is then placed in the inserter (Figure 7). The smaller implant (2.75mm diameter) was selected due to the tightness of the proximal phalangeal intramedullary canal, dictating the size needed. Figure 8 shows the 2 holes at the arthrodesis site and, although difficult to see, the tip of the guide pin is in the middle of the hole in the middle phalanx. The implant is then pushed into the hole in the proximal phalanx until only half of the PEEK mid-portion is visible (Figure 9).

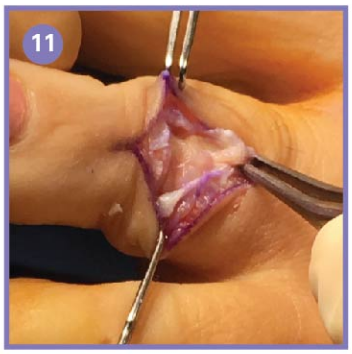






In cases where the fit of the implant to the canal is too tight for final positioning, a small impactor can be used to tamp the implant in the rest of the way (Figure 10). Then the middle phalanx needs to be fed over the implant with the guide pin going into the implant. Once the implant is fully seated, the guide pin can be removed or advanced to the base of the proximal phalanx for added temporary instability (Figure 11).





It can also be advanced across the MP joint, if needed, as part of an MP realignment. As a final step, a push-up test (i.e. assess MP alignment with tourniquet deflated and ankle in neutral flexion) is performed to see if an MP extension contracture is present. If so, a percutaneous MP release can be performed after wound closure. Multiple fluoroscopic views are obtained throughout and final views saved. A soft dressing and postoperative shoe is applied at the end of the case.

Postoperative Protocol

The patient was allowed to be full weightbearing in her surgical shoe immediately after surgery. At her 2 week postoperative visit, her sutures and pins were removed. At that time, she was allowed to transition to loose-fitting athletic shoes. As her pain permitted, she was able to advance shoe gear and activities to her tolerance. While toe swelling improves more rapidly in patients with implants as opposed to temporary K-wires, the toe swelling continued to improve for 4-6 months.

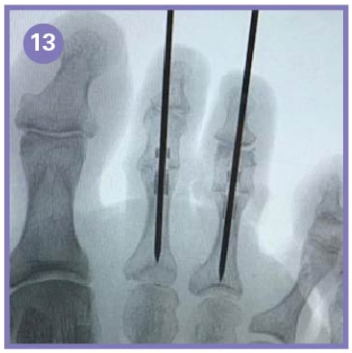
PRELIMINARY RESULTS

We have placed over 30 of these implants during the last year. While we have not critically evaluated the radiographs for solid bony fusion, there has been no loosening or recurrent deformity consistent with a clinical union in all patients. Another frequent scenario is use of the implant with concomitant hallux valgus. A standard hammertoe operation can be performed and the implant used in the same fashion as performed, with temporary pin placement across the MP joint to protect it from stress during the initial postoperative period.

Additional Fixation Options

HammerTube™ is cannulated, allowing for additional fixation and stability to be achieved by utilizing a K-wire across the DIP and MP joints.

Note: Figures 12 and 13 represent post-operative K-wire utilization across the distal interphalangeal joint.



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[1] Kurtz S, Devine J, PEEK Biomaterials in Trauma, Orthopedic, and Spinal Implants. Biomaterials. 2007. Nov 28 (32); 4845-4869.

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