Adjustable 2-Piece Metal Fusion Device for Correction of Hammertoe Deformities in Lesser Toes

Richard M. Jay D.P.M., FACFAS¹, Stuart D. Katchis, MD², Douglas R. Doxey, DPM³, Jeffrey M. Belancio, DPM³, Ghadeer Alami, DPM³

¹Temple University - Philadelphia, PA
Professor of Orthopedics
Regional Medical Center - South Jersey HealthCare - Vineland, NJ
Chief - Foot and Ankle Surgery - Education and Training

²Lenox Hill Hospital - New York, NY
Section Chief
Foot and Ankle Surgery
Department of Orthopedic Surgery

³Regional Medical Center - South Jersey HealthCare - Vineland, NJ
Resident – Foot and Ankle Surgery
INTRODUCTION

Hammertoe deformities, congenital or acquired, can result in significant pain and reduction of functionality for patients. The hammertoe is noted for its dorsiflexion at the metatarsal phalangeal joint (MTPJ) and plantarflexion at the proximal interphalangeal joint (PIPJ). Although conservative measures often aid in decreasing pain and assist in increased mobility, surgical intervention may be inevitable.

The hammertoe deformity has three commonly accepted biomechanical etiologies: flexor stabilization, flexor substitution, and extensor substitution. Each of these manifests themselves at different stages of the gait cycle and resultantly may be addressed throughout the course of the surgical procedure. Additionally, hammertoes may result from a long second ray, metatarsal phalangeal joint synovitis and instability, inflammatory arthropathies, neuromuscular conditions, and ill-fitting shoe wear.

Identifying the digit’s deforming force is imperative when planning surgical intervention. In doing so, the surgeon determines to employ either an arthroplasty or arthrodesis at the proximal interphalangeal joint in combination with adjunctive soft tissue work to reduce the digit to a more anatomical position.

DIGITAL ARTHRODESIS

Digital PIPJ arthrodesis is employed to stabilize muscular contracture when joint instability or contracture is noted. Further, the technique is indicated to address fixed and dynamic deformities that would likely reoccur if arthroplasty of the PIPJ alone were utilized.

When fixating an arthrodesis, the surgeon may commonly utilize a Kirschner-wire (K-wire) that crosses the distal interphalangeal joint in addition to the proximal interphalangeal joint to hold the correction and fusion site. This technique carries with it the inherent risks of leaving exposed hardware including pin breakage, accidental removal and infection including osteomyelitis. In addition, because the pin must be removed within 3-4 weeks of surgery there is a risk of recurrent deformity if solid fusion has not been achieved prior to fixation removal.

Currently there are several digital implants and techniques to achieve arthrodesis, yet there is a lack of research and follow-up on the devices.

The Nextra Hammertoe System (Nextremity Solutions, Colts Neck, NJ), uses an innovative 2-piece anatomical digital implant made of a 316L Stainless Steel Alloy to fuse the PIPJ. It has 10° flexion angulation and an intermediate locking fusion mechanism. The implant allows for variable osseous dissection and resection to adjust toe length. Its most unique feature is that intraoperatively, once locked, it may be unlocked for assessment or further modification of the seeded appliance and toe.
The Nextra Implant has been used to create fusions between the proximal and middle phalanges of the 2nd, 3rd, and 4th toe.

**Case Study #1**

**History and Physical Exam**

A 48-year-old male presented to the office for an evaluation of painful hammertoe deformities of the left foot. *Figure 1* The patient had a history of multiple revascularizations of the lower extremity as well as right knee replacement and left hip surgery. During physical examination the patient was noted to have a leg length discrepancy with weakness of the flexors, evertors, and invertors.

Upon digital examination the patient had a semi-reducible hammertoes of digits 2, 3, 4, and 5 of the left foot. The patient opted for surgical correction of the deformities.

**Surgical Procedure**

Four incisions were made in a double elliptical fashion over the proximal interphalangeal joints of 2nd, 3rd, 4th, and 5th digits. These were deepened to PIPJ capsule. A transverse incision was then made through the extensor tendons and the collateral ligaments were incised. All soft tissue attachments were freed from both the head of the proximal phalanx and base of the middle phalanx of all digits.

At this point, two pilot holes were drilled, one through the proximal phalanx and the other through the base of the middle phalanx. Reamers from the Nextra implant set were then used to denude the cartilage of the head of the proximal phalanx and the base of the middle phalanx; a concave reamer proximally and convex reamer distally. A ball and socket type of articulation was thus created at the PIPJ of digits 2, 3, and 4. The Nextra implant was then screwed into the proximal phalanx head and into the base of the middle phalanx. After fluoroscopic confirmation of implant position was obtained, the two implants were joined at the arthrodesis site. Final radiographs confirmed that the toes were in a rectus position. *Figure 2*
The patient returned to the office one week after the procedure where he was fully ambulating with a surgical shoe.

At three weeks status post Nextra arthrodesis, the toes were noted to be minimally edematous. The patient returned wearing sandals, although he was given specific instructions to remain in a surgical shoe. X-rays were reviewed and showed good alignment. *Figure 3*

Four months post operatively the patient returned with no complaints of pain or swelling. Upon evaluation of X-rays there was union at the proximal and middle phalanx interface - digits two through four.

**Case Study #2**

*History and Physical Exam*

A 57 year old male presented with a painful hammertoe of the 2nd toe of the right foot. The patients history included stage II adult acquired flatfoot deformity and painful bunion deformity. He was treated by another physician with an Evans lateral column lengthening, posterior tibial tendon reconstruction and 1st metatarsal osteotomy. At first presentation, he was noted to have a non union of the Evans osteotomy and a recurrence of the bunion deformity. These areas were revised and a medial calcaneal osteotomy was added. A rigid 2nd hammertoe was noted but initially asymptomatic and was not treated. Approximately one year later after the previous surgeries had healed; the patient had increased his activity and noticed worsening pain in the hammertoe deformity.
**Surgical Procedure**

The surgery was performed via a 2 cm dorsal longitudinal incision over the PIP joint. The PIP joint was exposed in standard fashion via a transverse capsulotomy with release of the collateral ligaments from the head of the proximal phalanx. The articular surface of the PIP joint was then resected with a micro sagittal saw. The cuts were made to allow a ten degree flexion angle at the fusion site. The distal and proximal Nextra implants were inserted in accordance with the surgical protocol of the manufacturer. Proper alignment and position were achieved. There were no intraoperative complications.

**Post-Op**

The patient was placed in a soft dressing and post operative shoe and allowed full weight bearing as tolerated. At one week follow-up, there were no signs of infection or edema, and the x-ray showed good position of the toe. The patient was switched to an athletic shoe. Upon follow-up at weeks two and six x-ray evaluation noted good bone alignment, position, and early stages of fusion. The patient was very satisfied and pain free.

**Case Study #3**

**History and Physical Exam**

A 44 year old male presented with a painful hammertoe deformities of the right foot; toes 2, 3, and 4. The patient is a construction worker and on his feet all day. The patient had a rigid deformity of the second toe and flexible deformity of toes 3 and 4. He had pain with active and passive range of motion of toes 2, 3 and 4 along with a cavus foot type. The patient’s neurovascular status is intact and he has a medical history of MRSA, osteoarthritis and hepatitis C. The patient exhausted conservative treatment options and was prepared for surgical intervention.

Radiographs revealed an osteoarthritic 2nd MTPJ as well as contractures of the 2nd, 3rd and 4th toes. The proximal phalanx was dorsiflexed at the MTPJ and the middle phalanx was plantarflexed at the PIPJ.
Surgical Procedure

The surgery was performed utilizing two semi-elliptical incisions dorsal to the 2nd PIPJ with a linear incision extending proximally to the 2nd MTPJ. Figure 6 This was deepened to the capsule of the PIPJ. A transverse incision was made through the extensor tendon and the collateral ligaments were incised. All soft tissue attachments were freed from both the head of the proximal phalanx and base of the middle phalanx.

The pilot hole was then driven into the proximal phalanx and middle phalanx. Reamers were then utilized to remove the cartilage from the head of the proximal phalanx and the base of middle phalanx. The Nextra implant was then inserted according to product guidelines. Figure 7, 8

Following the initial dissection dorsal contracture was still present at the 2nd MTPJ. An intraoperative decision was then made to perform a MTPJ capsulotomy.

To control MTPJ instability during a traditional arthrodesis, a K-wire is used to maintain the desired position. The surgeon runs the wire through the distal tip of the toe extending through the intramedullary canal across the MTPJ and into the metatarsal. 13 When inserting an implant this technique may not be utilized.

In this case we present an alternative approach to controlling the MTPJ alignment.
to hold the toe in a rectus position. After the joint was adequately reduced a 0.062 K-wire was placed from a dorsal-proximal to plantar-distal direction through the 2nd metatarsal head and into the base of the proximal phalanx. This adequately held the 2nd toe in proper alignment. Figure 9 Following correction of the 2nd toe, traditional arthroplasties were performed on toes three and four.

Post-Op

The patient was then placed in a soft dressing with Betadine™ splint. Patient received a rigid surgical shoe and was to partial weight bear to the heel. Figure 10, 11 Patient followed up one week after surgery. Upon evaluation on first post-operative visit the incisions were clean, dry, and intact. Patient had minimal pain and radiographs verified the implant was intact. The pin was removed at the third week, the patient remains pain free with a rectus alignment of toe and the MTPJ.
DISCUSSION

Digital arthroplasty may be an option for certain hammertoe deformities. These procedures may initially give correction, but without identifying the origin of the deformity, a high predilection for recurrence may be unavoidable. 10

Traditional temporary fixation of a hammertoe deformity with a percutaneous K-wire does not provide compression or solid fixation and is a potential source of complications. These complications include, but are not limited to, infection, delayed union or nonunion, recurrent deformity, pain and excessive edema.5

Digital fusions require meticulous surgical technique to appropriately dissect and align the digits. Proper resection of cartilage is necessary to maintain digit length. Further, rigid fixation and bone on bone contact at the fusion site are essential to restore function and obtain acceptable cosmesis.

The intramedullary implant used in these case reports demonstrated the ability to fix the bones in a stable and accurate position. Fusion of the digits was achieved and the patients’ pain and deformity resolved.

Over the years, a multitude of techniques have been described and employed for digital arthrodesis. The end-to-end arthrodesis essentially involves resection of the cartilaginous surfaces of the head of the proximal phalanx and the corresponding base of the middle phalanx. Fixation with a Kirschner wire is commonly employed for a period of five to eight weeks.

Unfortunately, using K-wire fixation for the stabilization of an arthrodesis does not maintain or provide any compression to the fusion site and poses certain problems. K-wires have the potential of twisting during the healing process and interrupting the union of the two desired bones.

As the K-wires also extend out of the distal aspect of the toe, creating discomfort for the patient and resulting in anxiety for future removal. In addition, the patient must keep the wound dry for up to six weeks as to prevent pin tract infections. Unprotected weight-bearing will allow a bending moment across the arthrodesis site, that is likely to result in fatigue failure of the pins as well as a loss of correction by separating the fragments to be fused.

Further migration of the pins can present a complicated problem. All of these factors can be frustrating to both the surgeon and the patient and need to be considered when performing a digital arthrodesis.

FUSION VERSUS ARTHROPLASTY

A patient may be dissatisfied with hammer toe surgery for several reasons. Persistent swelling, flail toe, pain, and recurrence of deformity are the most common complaints. While an arthroplasty may seem to be a rather benign straightforward procedure, the surgeon needs to consider the potential complications.

The most common source of dissatisfaction after an arthroplasty is pain; often, this is as a result of a persistent or recurrent deformity, with pressure or friction over a bony prominence. The goal of an arthroplasty is to regain motion in an otherwise contracted digit. The procedure may initially straighten
the digit, but effectively destabilize the digit and create an environment for possible deformity recurrence.\textsuperscript{10}

Additional complications also include bone regeneration. Most often, the bone does not regenerate to any significant extent, but rather an exostosis formation or spurring leads to a boney prominence. This exostosis further leads to a prominent lesion and callus which is aggravating to the patient.

For some patients, a shorter fatter toe or a painful stiff toe after surgery is simply unacceptable. The lesser toes are prone to infection by virtue of their position in contact with the ground as well as their propensity for swelling. Additionally, the use of K-wires provides a portal of entry for infection.

Flail toe usually results from excessive bone removal from the toe or failure of the scar tissue to form a filler in the previous joint space. If a toe has been excessively shortened, it is difficult to regain length and only rarely should an attempt be made to do so. When the flail toe is unacceptable to the patient, syndactylization has been described as a salvage procedure for this flail toe, but is cosmetically displeasing. It is best to prevent flail toe in the first place by avoiding excessive bone resection, particularly from the proximal phalanx.\textsuperscript{11}

Additionally, floating toe is also seen in which one or more toe fails to purchase the weight bearing surface during ambulation. Specific causes are attributed to contractures of the extensor tendons or dorsal capsular structures. On the other hand, proximal interphalangeal joint arthrodesis provides a stable, pain-free construct over time and a more predictable toe posture.\textsuperscript{12, 13, 14, 15}

\textbf{CONCLUSION}

New innovations and technology have greatly advanced digital arthrodesis surgical technique from when it was originally described in 1910 by Soule.\textsuperscript{10}

The Nextra implant is exclusive in its design such that the implant can be easily unlocked, removed and reimplanted intraoperatively with minimal trauma to the bone. The surgical technique is familiar to foot and ankle surgeons (i.e. drilling, reaming and screw insertion). The device offers an advantage over conventional K-wire fixation in that there is no external postoperative implant exposure, which minimizes pin tract infections and improves patient acceptance. In addition, the Nextra implant is constructed of biocompatible materials.\textsuperscript{16}

Although further study is warranted, these case reports support the use of the anatomical 2-piece metal fusion device tested for the correction of a hammertoe deformity. When this implant is positioned accurately results are satisfactory and rewarding to both the patient and the surgeon.

Based on these case studies, the Nextra digital implant is a viable digital arthrodesis implant option. This adds to the surgical armamentarium to create a properly aligned interphalangeal joint, with a greater predictability of fusion for the foot and ankle surgeon.

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