The Two-Component Implant for Interphalangeal Fusion in Toe Deformities

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Background: Although Kirschner wire implantation is popular for treating toe deformities, complications frequently occur. To prevent pin-tract infection and difficult Kirschner wire extraction, several implants have been developed to improve treatment outcomes.

Methods: Patients who had undergone an interphalangeal fusion by two-component implant for the treatment of toe deformities were included. Thirty-one toes of 21 patients were evaluated retrospectively. American Orthopaedic Foot and Ankle Society (AOFAS) forefoot scores were used in clinical evaluation.

Results: The mean operation duration per toe was 16.4 min (range, 13–26 min). The average AOFAS forefoot score was 42.76 (range, 23–57) preoperatively and 88.76 (range, 70–95) at 34.4 months (range, 26–46 months) after surgery. Mean follow-up was 14.8 months (range, 12–19 months). Compared with before surgery, the AOFAS score was increased significantly after surgery ($P = .03$ by t test). Three minor complications were encountered. In one patient an infection was observed. After the implants were removed (first month) she was treated successfully by debridement and antibiotic agents and, finally, Kirschner wire placement. The second patient had a fissure fracture at the proximal phalanx, but routine follow-up did not change. In the third patient, the locking mechanism had become loose (detected on day 1 radiography); it was remounted under fluoroscopy without opening the wound. No patients had a cutout, loss of alignment, recurrence, or persistent swelling.

Conclusions: Outcomes of arthrodesis using the two-component implant were found to be safe and reliable, especially for hammer toe and fifth toe deformities. (J Am Podiatr Med Assoc 110(4): 1-5, 2020)

Toe deformities are common foot problems, affecting one-third of the general population.[1-4] The most common lesser toe deformity is hammer toe deformity. The etiologies of hammer toe deformity include hallux valgus, inflammatory arthritis, diabetes, neuromuscular diseases, advanced age, and trauma.[2,5]

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Proximal interphalangeal joint flexion is the main characteristic of hammer toe deformity. The complaints of patients include pain, numbness, problems wearing shoes, and aesthetic concerns. Hammer toe deformities can be treated conservatively with shoe modification, metatarsal pads, or orthoses. However, surgical options should be considered if conservative treatment is unsuccessful. Depending on the flexibility of the deformities, soft-tissue and bone surgeries—such as metatarsophalangeal joint capsular release, extensor tendon lengthening and release, transfer of the flexor tendon to the extensor tendon, plantar plate repair, and metatarsal shortening osteotomies—have been described.[6] Arthroplasty and arthrodesis are recommended for rigid deformities. Bone and soft-tissue surgeries are frequently performed simultaneously.

To address hammer toe deformities, arthrodesis of the interphalangeal toe joint using a Kirschner

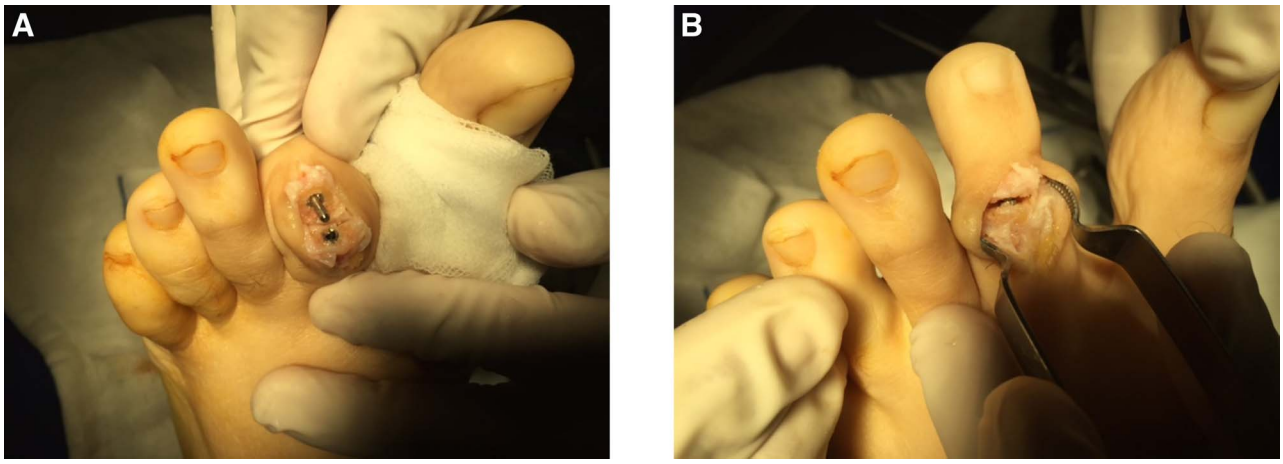


Figure 1. Devices implanted in the proximal and distal phalanges (A) are mounted together (B) before closure.

wire of 0.9 to 1.6 mm in diameter is the gold standard.[7] Caterini et al[4] reported that cannulated screws can be used.

Complications such as pin-tract infection, Kirschner wire breakage and migration, and recurrence of the deformity 4 to 8 weeks after Kirschner wire removal can occur after hammer toe surgery.[3,5,8,9] Unnecessary violation of the distal interphalangeal joint is another complication of the Kirschner wire technique.[10] To prevent these complications, several implants for proximal interphalangeal joint arthrodesis have been developed recently.

The Nextra implant (Nextremity Solutions, Warsaw, Indiana) is a two-component implant for fusion of the proximal interphalangeal joint of the toe. It has two size options for the proximal phalangeal component and three size options for the middle phalangeal component. After preparing both sides of the phalanges by removing the cartilage, the proximal and distal components of the implants are mounted (Fig. 1). When locking the components, 10° of flexion is naturally given to the interphalangeal joint.

The aim of this study was to evaluate the outcomes of arthrodesis to address toe deformities by using the Nextra implant as an alternative to the Kirschner wire. We hypothesized that a two-component implant (Nextra) would provide satisfactory results for clinical and radiologic aspects.

Patients and Methods

Patients

After approval from the Istanbul Medeniyet University institutional review board was obtained, patients who had undergone surgery for toe deformity between January 1, 2012, and May 31, 2015, were included in the study. According to the hospital records, patients who underwent surgery by a single surgeon (A.S.) because of complaints of persistent pain due to pressure (painful calluses) and pain in shoe wearing were included in the study. The minimum follow-up duration was determined to be at least 1 year. Patients with preoperative foot circulation problems and crush injury were excluded from the study.

Patients' American Orthopaedic Foot and Ankle Society (AOFAS) forefoot scores, clinical information, and radiologic images were obtained from hospital records. Patients were invited to the hospital, and the last control follow-up was performed. In addition to AOFAS scores, toe pain, edema, implant failure, or radiologic union were also noted at the last follow-up.

Surgical Procedure

After administration of a single-dose prophylactic antibiotic drug (Cefozin, 1 g; Zentiva, Kırklareli, Turkey) before the operation, a digital tourniquet was applied. Under general or local anesthesia, a dorsal longitudinal incision was performed. After skin incision, the extensor digitorum longus tendon was reached. The extensor tendon was passed split through, and the interphalangeal joint arthrotomy was performed. Condyles of the proximal phalanges were removed by an oscillating saw. Then the cartilage at the distal phalanx was removed. By using a canal finder, the medullar diameter was revealed and the sizes of the components were determined. Then the components of both sides were introduced to the medulla. Finally, the components were mounted to each other and the wound was closed in a routine manner.

Table 1. Patient Data Set and Complications

Variable	Toes (No. [%]) (N = 31)
Surgical indications	
Hammer toe deformity	26 (83.9)
Chronic fifth-toe dislocation	5 (16.1)
Concomitant deformities	
Hallux valgus	13 (41.9)
Rheumatoid arthritis	3 (9.7)
Chronic dislocation	5 (16.1)
Complications	3 (9.7)
Infection	1 (3.2)
Locking failure	1 (3.2)
Fissure fracture at the phalanx	1 (3.2)

Results

In total, 31 toes of 21 patients were included in the study. Patients' clinical and radiologic information was obtained from the hospital records. Of the 31 toes, 26 (83.9%) had hammer toe deformity and five (16.1%) had chronic fifth-toe (interphalangeal) dislocation. Twenty were second toes, three were third toes, three were fourth toes, and five were fifth toes. Twelve, eight, and one patient underwent surgeries on one, two, and three lesser toes simultaneously, respectively (Table 1).

The mean patient age was 46.5 years (range, 20–67 years). Eight of the patients were male and 13 were female. Etiologically, three of the patients had rheumatoid arthritis and 13 had hallux valgus deformities. All of the hammer toe deformities were rigid. In five patients, chronic toe deformity was secondary to trauma (Fig. 2 and Table 1).

The mean follow-up duration was 14.8 mo (range, 12–19 mo). The mean operation duration per toe was 16.4 min (range, 13–26 min). The average AOFAS forefoot score was 42.76 (range, 23–57) before surgery compared with 88.76 (range, 70–95) at 34.4 months (range, 26–46 months) after surgery.

According to a Kolmogorov-Smirnov test, preoperative AOFAS scores had a normal distribution. Compared with before surgery, the AOFAS score was increased significantly after surgery, as determined by the t test ($P = .03$).

None of the patients had a cutout, impaired toe alignment, recurrence of the deformity, or persistent swelling. In one patient, whose fifth toe was operated on, an infection developed at 1 month. In another patient, the locking mechanism had become loose; the mechanism was remounted under fluoroscopy without opening the wound. In another patient, a fissure fracture at the proximal phalanx occurred during the operation. Because the implant was stable, the patient underwent routine follow-up and has made good progress.

Discussion

Physical and systemic diseases (diabetes, Charcot-Marie tooth, and intracranial aneurysm), biomechanical disorders (intrinsic and extensor tendon



Figure 2. Successful alignment of the fifth toe. Clinical (A) and radiologic (B) views of the deformity before surgery and the radiologic view after surgery (C).

instability, and intrinsic disorder), foot deformities (pes cavus, hallux valgus, hallux limitus, pes planus, equinus, and metatarsal parabola anomaly), inflammatory arthropathies, systemic neurologic disorders, and inappropriate use of footwear have been reported to be associated with toe deformities.[5,11] In this study, 42% of the patients had hallux valgus deformity.

Several methods can be used to correct hammer toe deformity, eg, silicone implants, bone allografts, stainless steel sutures, titanium screws, and absorbable screws.[4,5,8,9,12,13] Sixty-eight medical products are in use for proximal interphalangeal joint arthrodesis.[1]

Kirschner wire is an economical method for proximal interphalangeal joint arthrodesis[1,5,6,10,13-16]; however, complications can occur, eg, infection and Kirschner wire breakage.[10,14] Zingas et al[17] reported a 3.2% rate of Kirschner wire breakage in their series of 1,002 patients. In contrast, the average union rate of proximal interphalangeal joint arthrodesis with Kirschner wire is 80%,[4] possibly due to failure to maintain compression at the fusion site. In addition, Kirschner wire breakage after exposure of the Kirschner wire from the toe (eg, due to erroneous removal of the dressing) causes patient dissatisfaction and occasionally pain and anxiety during removal.[3,4,18,19] Therefore, Canales et al[1] suggested that Kirschner wires should not be exposed from the skin. Nonexposure of the implant from the skin, the longevity of the implant, rapid return to daily life, stability on application of rotational forces, and a 10° interphalangeal flexion angle represent the advantages of intraosseous devices over the Kirschner wire, resulting in greater anatomical correction than is possible using the Kirschner wire, which provides a flat fixation.[3] Thus, the popularity of intraosseous devices has increased. In a recent study, Jay et al[9] compared the intramedullary devices with Kirschner wire fixation techniques and found that intramedullary devices provide more satisfactory clinical outcomes in the early (1 week) and late (6 months) periods. The critical reason for this is that the intramedullary device does not exceed from the skin. This provides rigid fixation, so rapid recovery and early return to work is possible with these devices.

Surgery to correct malalignment of the fifth toe is difficult. Because the fifth phalanx has short bones, the Kirschner wire does not provide sufficient stability. Thus, intraosseous devices can prevent erroneous hardware extraction and recurrence of the deformity. In this study, 16% of the toes were fifth toes, all of which were successfully treated (Fig. 2).

In this study, three complications (9.7%) were observed with the two-component intramedullary implant compared with 6.1% to 13% in previous reports.[5,8,10,14] It is seen that the complications we faced with the Nextra device in the present study are in accordance with the literature. The known complications of implants similar to Nextra include malunion (2.4%–7%), which is mostly asymptomatic[9,14,19]; nonunion (1.5%)[8,14]; implant failure (3%–5%)[8,14,20]; and implant cutout (2.4%).[18] The most important complications are implant fracture and recurrence. In this study, which had a sufficient follow-up duration, no effusions occurred; this complication is common with silicone implants. In addition, unlike absorbable implants, there was no fracture or malalignment of the toe. We observed two complications during the surgery, one of which was a fissure fracture at the proximal phalanx that occurred early in the learning period. Care should be taken, and one should not be rough while loading the components. Another complication was related to the mounting procedure. Sometimes because of the oily circumstances the mounted components may loosen. Therefore, the surgeon should check the stability of the device before closing the wound. The AOFAS scores suggested that the patients were satisfied with the surgical treatment and implants. In this study, a 46-point improvement in AOFAS scores was seen compared with 19 points with the use of intramedullary devices in a previous study.[10] Therefore, in terms of AOFAS forefoot scores, the two-component implant is reliable and leads to satisfactory outcomes, similar to other smart intramedullary devices.[21,22]

In a cost-effective analysis, a recent study found that surgery with commercial implants is more expensive than surgery with Kirschner wires.[16] They concluded that because the outcomes of these treatment options are relatively the same at long-term follow-up, commercial implants need to be cheaper to be more cost-effective.[16] However, we think that the fifth toe should be considered different. In this point of view, because stabilization is more difficult in the fifth toe, commercial implants would have the advantage.

This study was limited by its retrospective design and relatively small number of samples. Another limitation was the heterogeneous patient population, due to the fact that toe deformities are generally accompanied by different levels of hallux valgus. Therefore, more prospective, comparative studies are needed to demonstrate the outcomes of this relatively new treatment method.

In conclusion, the results of this study indicate

that the two-component implant (Nextra) is safe and reliable for the surgical treatment of, especially, hammer toe and fifth toe deformities.

Financial Disclosure: None reported.
Conflict of Interest: None reported.

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