Original Research
Retrospective Data Collection of Distal Interphalangeal Joint Fusion With X Fuse Superelastic Implant

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Purpose: Arthrodesis of the distal interphalangeal joint of the fingers and interphalangeal joint of the thumb is a common procedure for multiple diagnoses. The purpose of this study was to evaluate fusion rates and complications in patients who have been previously implanted with an X Fuse superelastic implant (Stryker).

Methods: All patients who underwent distal interphalangeal and/or thumb interphalangeal joint fusion between June 2013 and May 2019 were included by the senior author. A chart review was used to note demographics; hand dominance; and medical and surgical history, including complications, comorbidities, clinical recovery, absence of pain, and functional use. Pre- and postoperative radiographs were evaluated for angular deformity, postoperative correction of that deformity, boney consolidation, and tine cutout.

Results: Fifty-three patients (60 fingers; 43 women and 10 men) with a mean age of 62.6 years were included. The surgical diagnoses included hereditary osteoarthritis in 45 patients, rheumatoid arthritis in 4, psoriatic arthritis in 1, swan or mallet fingers in 5, ulnar motor loss instability in 2, and trauma or a fracture in 3. For X Fuse, an implant angle of 0° was used in 51 cases, whereas 15° was used in 9 cases. Bone consolidation was observed in all but 1 patient at an average time of 9.7 weeks (range 4.1–17.6 weeks). The X Fuse superelastic implant in small bones demonstrated minimal complications and a 98% (59/60) fusion rate.

Conclusions: The X Fuse superelastic implant produced a reliable fusion, with no implant prominence and a 1.7% (1/60) rate of hardware removal.

Type of study/level of evidence: Therapeutic IV.

Arthrodesis of the distal interphalangeal (DIP) joint of the fingers and interphalangeal (IP) joint of the thumb is a common procedure for multiple diagnoses—hereditary osteoarthritis (OA), inflammatory arthritis, and traumatic arthritis—as well as a mallet deformity and a distal or middle phalangeal fracture malunion or nonunion.1 Previous reports on various techniques for arthrodesis of the DIP and IP joints have been published.2–5 X Fuse superelastic implants (Stryker) have been widely studied.5–9 Memometal intramedullary memory bone fasteners are single-use bone-fixation appliances intended to be permanently implanted and are made of a superelastic nickel-titanium alloy. There are 3 angulations available: 0°, 15°, and 25°. The purpose of this study was to evaluate fusion rates and complications in patients who have been previously implanted with the X Fuse superelastic implant. The hypothesis was that the use of the X Fuse superelastic implant can result in a high fusion rate and prevent the complications of the prominent, long-term use of hardware in the distal tuft, necessitating a second surgery for its removal.

Materials and Methods

This study was a retrospective chart review of patients who had been previously implanted with the X Fuse superelastic implant for
a DIP and/or thumb IP joint arthrodesis between 2013 and 2019 by the senior author (C.K.M.). This study was approved by the institutional review board. Each patient documented their consent to research on their initial clinical admitting form. Each patient’s medical and surgical history was reviewed, and data from before surgery, during surgery, and standard-of-care follow-up visits after surgery were collected. The data reviewed and collected were sex, age, hand dominance, comorbidities (including smoking, diabetes, and type of arthritis), surgical diagnosis, bone graft used, and radiographic findings (including pre- and postoperative angulation). Angulation on the anteroposterior view was measured using the center axis of the distal phalanx and the center axis of the middle phalanx. If subluxation existed, a line was drawn parallel to the center axis to measure the angle. Fusion was determined to be healed when there was greater than 50% bone consolidation, as determined using x-ray, and no pain was reported with pinch activity. Preoperative angulation is demonstrated in Figure 1. Operative notes were reviewed to rule out the complications of intraoperative fracture, hardware cutout, or other iatrogenic problems. Standard-of-care postoperative clinic notes were reviewed to note any complications. The minor complications included stiffness, cold sensitivity, and prominent hardware. The major complications were nonunion, hardware removal, and any additional operative procedures.

Patients who met the following inclusion criteria were eligible for participation: 18 years of age or older at the time of the index procedure and those who had previously been implanted with the X Fuse superelastic implant.

Surgical procedure

For the procedure, an “H”-type incision was made over the dorsal DIP crease. The extensor tendon was cut transversely and carefully dissected off the dorsal osteophytes and preserved. The radial and ulnar collateral ligaments were cut. Hard, sclerotic, subchondral bone and arthritic articular cartilage were removed on each surface. Because most patients had a preoperative angular deformity, a 0.035-inch Kirschner wire (K-wire) was passed down the midaxis of each phalanx to confirm correct placement for the broaching tool. A centralizing drill bit was used in the same plane. Both bones were broached up to the appropriate implant size, and most often, a 0° implant angle was chosen for the finger DIP joint and 15° for the thumb IP joint. A 0.035-inch K-wire was fixed retrograde adjacent to the radial or ulnar side of the broach site for temporary postoperative fixation.

An autogenous bone graft was used in 55 cases, most often from the distal radius; however, other sources excised during a concomitant procedure, such as the trapezium or metacarpal head, were also used. At the radius, a 1-cm incision was made proximal and radial to the Lister tubercle. The extensor tendons were retracted and the radial cortex exposed. A 0.045-inch wire was used to perforate the dorsal cortex in a small square, and an osteotome elevated the cortical window. Metaphyseal bone was harvested using a curette. Gel foam was placed in the radius, bupivacaine (Marcaine; Pfizer Inc.) along with epinephrine was injected, and the skin was closed using a 4.0 monocryl suture (Ethicon Inc.).

The X Fuse superelastic implant was then tapped into the middle phalanx, the bone graft was placed dorsally and volarly, and the distal phalanx was impacted onto the X Fuse tines. The K-wire was advanced across the middle phalanx adjacent to the implant and cut 2–3 mm beyond the fingertip. The extensor tendon was repaired using a 3-0 undyed Vicryl suture. The skin was closed using a nylon suture. All patients were immobilized in a “Stax-type” orthosis for 6 weeks and instructed to move the proximal interphalangeal and metacarpophalangeal joints. At the 2-week postoperative visit, the stitches were removed. The patients returned at 6 weeks and the K-wire was pulled out, and orthosis fabrication was discontinued. X-rays were taken at the 6-week and 3-month postoperative visits for all patients. No pain at rest and no pain with applied tip pressure or pinching in the clinic were considered clinical healing. Patients with functional use without pain were not followed-up beyond the 90-day period.

Results

Fifty-three patients (60 fingers; 43 women and 10 men) with a mean age of 62.6 years (range 26–82 years) who had previously been implanted with the X Fuse superelastic implant for the fusion
of the DIP finger joint and/or IP thumb joint were identified. The average follow-up duration was 18.7 weeks (±18.9 SD). There were 27 (50.9%) nonsmokers, 23 (43.4%) former smokers, and 3 (5.7%) current smokers. Per the patients’ medical history, 5 (9.4%) had active diabetes, 5 (9.4%) had rheumatoid arthritis, 39 (75%) had OA, and 10 (18.9%) had osteoporosis. Right hand dominance accounted for 48 patients of this cohort, and the right hand was involved operatively in 29 surgical cases. The respective surgical digits involved are displayed in Table 1.

The primary radiographic endpoint was bone consolidation, observed on postoperative radiographs (Fig. 2A, B). Further evaluation included the absence of pain and swelling and the ability to pinch free of pain. Bone consolidation was observed in all but 1 patient at an average time of 9.7 weeks (±3.2 SD) (range 4.1–17.6 weeks). No significant difference was observed in bone consolidation between the nonsmokers and the current or former smokers (average time of 9.4 weeks [range 4.9–14.4 weeks] and 9.9 weeks [range 4.1–17.6 weeks], respectively [P = .55]). All patients achieved the appropriate postoperative angulation, except 1, who developed a nonunion. The correction of preoperative angular deformity was within 5° of the stated implant angle of 0°. In patients with a preoperative ulnar deviation or radial deviation (Fig. 3), the angle was corrected after surgery to 0° (22 patients) and 5° (4 patients). In all 12 patients with preoperative flexion deformities (range 10°–54°), the angle was corrected to 0°.

In a review of complications, 13 minor complications and 1 major complication were noted. The minor complications included proximal interphalangeal stiffness in 6 patients, metacarpophalangeal stiffness in 1, paresthesia in 3, cold sensitivity in 1, and drainage around the K-wires in 2. All the minor complications, except cold sensitivity, were resolved with occupational therapy within the 90-day period. Cold sensitivity persisted because the patient was a hemophiliac. Patients with functional use without pain were not followed-up beyond the 90-day period. For the 2 patients who had drainage around their K-wires, the wires were removed at 3 and 5 weeks, and the patients were treated with cephalixin (Keflex; Teva Pharmaceuticals USA, Inc.), with no further sequelae.

The major complication was nonunion. One patient developed a painful nonunion with lucency around the X Fuse implant and angulation of the ring finger DIP joint at 5.8 months. At 9.7 months, the patient underwent a revision fusion surgery for the removal of the implant and placement of an additional bone graft, K-wires, and interosseous wiring. At the time of the revision surgery, the implant was intact and cultures were negative for infection. There were no reports of intraoperative complications, hardware damage or cutout, or phalangeal fractures. After the surgery, there were no signs of nail deformity, painful hardware, skin necrosis, and deep infection.

### Discussion

Deformity of the DIP joint can be disabling, disfiguring, and painful. For the ring and small fingers, pain at the DIP joints interferes with power grip, and for the thumb and index finger, it interferes with pinching. The most common cause of deformity and pain is hereditary OA. In this study, 45 patients had OA, with an additional 5 with rheumatoid arthritis.

The primary indication for surgery was a painful joint. As seen in Figure 3, significant angular deformity and joint incongruity existed before the surgery as well. Fifty-three patients underwent fusion of their DIP joints and/or thumb IP joint with a regional bone graft (n = 55), temporary K-wire placement (n = 50), and an X Fuse superelastic implant. This device was chosen to act as an intra-medullary stabilizer of joint fusion. It has been reported to have lower complication rates than the Herbert headless compression screw and techniques reviewed by Stern and Fulton and Ijssellstein et al with interosseous wiring and cross K-wires.

In this series, only 1 patient (1 finger) developed a painful nonunion (which was revised at 9.7 months), demonstrating a 98% (59/60) fusion rate. All other patients demonstrated a healed fusion and correction of their angular or flexion deformity by an average time of 9.7 weeks. There were no reports of intraoperative complications, hardware damage or cutout, or phalangeal fractures.

Unique to this study is the use of a bone graft. Significant angular deformities before surgery and a very small surface area at the DIP joint can contribute to delayed healing and a nonunion, which is why bone grafting was performed. A bone graft was used in all cases in this study, and this difference might have helped reduce the time to fusion without causing additional morbidity. A radial bone graft was used in 55% of the cases. Following the initial 2-week postoperative visit, none of the patients needed additional wrist immobilization for pain or experienced a complication at the donor site. In 55 of the 60 cases, the bone that was resected as part of the simultaneous procedure was used as the graft. No patient had an adverse reaction to the demineralized bone graft.

To date, this is the largest series evaluating the X Fuse implant. Jakubek et al evaluated 24 patients in a prospective study, with only a 5% nonunion rate and no complications, including infection, intraoperative fracture, or delayed healing. Seitz and Marbella evaluated 16 patients, and their data correlate with the current study, demonstrating a 97% fusion rate within 10 weeks after surgery. Ameline et al compared the final fusion angles achieved with the initial postoperative angles and found a 10° variability, without clinical consequence. Ameline et al observed a 95% fusion rate in 38 fingers. The current study demonstrated the correction of

### Table 1

| Thumb/Fingers | % of Cohort Involved (No.) |
|---------------|---------------------------|
| Thumb         | 23.3 (14)                 |
| Index finger  | 28.3 (17)                 |
| Middle finger | 23.3 (14)                 |
| Ring finger   | 6.7 (4)                   |
| Small finger  | 18.3 (11)                 |

### Table 2

| Implant Angulation Sizes | 0° X Fuse | 15° X Fuse |
|--------------------------|----------|-----------|
| Total number of cases    | 51       | 9         |
| Extra small              | 7        | 0         |
| Small                    | 10       | 0         |
| Standard                 | 26       | 4         |
| Large                    | 6        | 2         |
| Extra large              | 2        | 3         |

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the preoperative angular deformity within 5° of the stated fixed angle of the X Fuse implant.

The current study was conducted retrospectively to review the fusion rates and complications of the X Fuse superelastic implant. In small osteoporotic fingers, the device achieved a solid union by an average of 9.7 weeks and did not cut out of the bone. In the 60 fingers reviewed, 59 achieved fusion in a 0° or 15° angulation, as the device permitted. Stern and Fulton reviewed 181 arthrodeses with 3 different techniques: crossed Kirschner pins (K-wires), interfragmentary wire and longitudinal K-pin, and Herbert screw. They evaluated each technique for minor complications, such as dorsal skin necrosis, cold intolerance, superficial wound infection, and prominent hardware. The Herbert screw technique contributed to 44% of minor complications, interfragmentary wire to 16%, and K-pins to 10%. The major complications were nonunion, malunion, and osteomyelitis. The nonunion rate was 12%, and the malunion rate was 3%. The technique studied in this article did not demonstrate the minor complication rates noted by Stern and Fulton. In this study, there was a 98% fusion rate, with only 1 (1.7%) nonunion, and minor complications were found in 21.7%, all of which resolved within the 90-day period, except cold sensitivity noted in 1 patient. There were no device-related adverse events or morbidity related to bone graft harvesting or the use of the demineralized bone graft.
A major limitation of this study is the relatively short follow-up duration. The patients typically had their first postoperative visit 10–14 days after surgery, and then, they returned at 6 and 12 weeks. Patients with functional use without pain were not followed-up beyond the 90-day period. Those with problems returned as needed. It is possible that a longer duration of follow-up would have resulted in additional long-term complication rates. However, these are rare once patients are doing well.

An additional limitation of this series is the use of the temporary supplemental K-wire used in 50 of the 60 cases. The technique manual states that the use of any other implant with the X Fuse superelastic implant is contraindicated. However, given the senior author’s (C.K.M.) experience, when the surface area for fusion was small and there was an intramedullary device centrally, soft metaphyseal bone distally, and a preoperative angular deformity, a bone graft and K-wire were added to ensure a high fusion rate.

In conclusion, the X Fuse superelastic implant produced reliable fusions, with no implant prominence and a 1.7% (1/60) rate of hardware removal in our series. The device offers different sizes and angles to meet the patient’s needs and avoids the risks of soft tissue complications noted with other techniques.

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