COMPARING KIRSCHNER WIRE FIXATION TO A NEW DEVICE USED FOR PROXIMAL INTERPHALANGEAL FUSION

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CHAPTER **30**

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INTRODUCTION

The most common fixation for proximal interphalangeal fusion is provided by a smooth 1.1 mm (0.045") or 1.6 mm (0.062") Kirschner wire (K-wire) placed in an antegrade manner through the middle and distal phalanges while proximal interphalangeal joint extension and distraction are maintained. It is then placed in retrograde fashion into the proximal phalanx. Pin fixation is necessary for 4-6 weeks after surgery (1). The pins are capped to prevent the sharp ends of the pins from catching on objects such as the patient's bed sheets. (Figure 1) Although percutaneous K-wires are effective, nonunions can be quite common. Other treatment challenges associated with K-wire fixation include migration and loss of fixation (2). Issues such as pin tract infections as well as difficult postoperative management by patients make alternative fixation methods desirable (3).

Having used percutaneous K-wires to provide fixation to the resected proximal interphalangeal joint, surgeons seek a means of providing fixation that is more stable than a K-wire as well as to mitigate the difficult postoperative management required by patients receiving this type of fixation. This article compares test results of the K-wire and an intramedullary device with a new design.

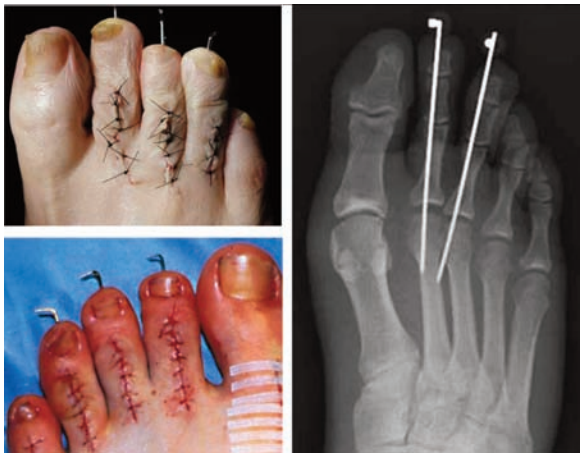

Figure 1. Postoperative stabilization with K-wires.

IMPLANT DESIGN CRITERIA

In planning and research prior to design of the implant, the surgeon design team identified performance objectives for the new implant that would offer clinical advantages over current implant alternatives. These design imperatives included:

Stable fixation

- Keep completely intramedullary with no parts of the implant exposed outside the skin.
- Maintain the initial compression applied at insertion.
- Resist the rotational and pull-out forces affecting the lesser toes.

Simple implant design

- Avoid introducing potential stress-risers and the need to assemble intraoperatively by developing a one-piece design.
- Provide anatomic sizing to fit a broad range of patient anatomy.
- Fit the patient's natural toe anatomy by providing a neutral and 10° plantar angle.
- Minimize bone removal with a low-profile design.
- Uniform strength characteristics throughout the implant.
- Ensure the product material has a proven long term biocompatibility so it can be safely implanted permanently. Will not require removal like the K-wire.

Efficient technique

- Create an operative technique similar to that for K-wire fixation with little additional complexity, such as drilling and tapping necessary to accommodate a threaded device.
- Remove little or no bone when preparing the bone for implant insertion.

Proven material

- Must be biocompatible, clinically proven, extensively studied and commonly used for permanently implanted medical devices.

- Bending and fatigue characteristics able to endure the forces exerted on the lesser toes without having to add unnecessary material volume.
- Capable of being efficiently manufactured to ensure reproducible results.
- Does not require special handling or storage.

Simple instrumentation

- Instrumentation resembles those with which surgeons are familiar.
- Emphasize simplicity to ensure reproducible results.

IMPLANT DESIGN

The Arrow-LOK™ Digital Fusion System (Arrowhead Medical Device Technologies, Collierville, TN) includes an implant (Figure 2) designed to improve upon the performance of the K-wire, the accepted standard for fixation of osteotomies, arthrodesis, and reconstruction in the lesser toes following corrective procedures. The surgeon-designers maintained the same basic surgical technique as the one to which they were well accustomed. The device provides more stable fixation than the K-wire and reduces the incidence of complications that can be caused by pin tract infections. Since the Arrow-LOK is intended to be permanently implanted, the surgeon avoids having to remove the device.

Machined from a single piece of 316L stainless steel, the Arrow-LOK is a solid, 1.5 mm (0.059") diameter shaft with a three-dimensional arrow shape at each end. The implants are available in 3 lengths (16 mm, 19 mm, 22 mm) to fit the lesser toes of a wide range of patients. It also comes in 2 different angles: one with a neutral orientation, the other with a 10° plantargrade angle (Figure 3).

PERFORMANCE TESTING

The Arrow-LOK implant was compared to the K-wire in a series of performance tests. The results of the tests confirmed that the design characteristics of the Arrow-LOK improve upon the fixation performance of the K-wire (Table 1).

Dynamic Four-Point Bend Testing

Four-point bend testing was conducted by the Georgia Institute of Technology's Mechanical Properties Research Laboratory in accordance with the methods prescribed in ASTM F 564-02, Standard Specification and Test Methods

Figure 2. Arrow-LOK Digital Fusion System Implant (19 mm).

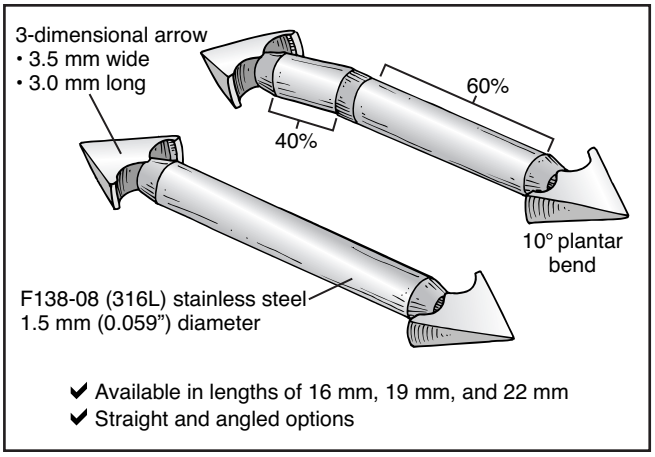

Figure 3. Arrow-LOK implant design.

Table 1

TESTING SUMMARY TABLE

Test	Results
Dynamic Four Point Bend Testing	Equivalent to the K-wire in fatigue testing
Resistance to Pullout	Over 20 times more resistant to double-sided pull-out than a K-wire.
Rotational Stability	Over 10 times more resistant to rotational forces causing initial deviation than the K-wire

for Metallic Bone Staples. In this test, the Arrow-LOK device with a 3.5 mm diameter arrow, 1.5 mm shaft diameter and 50 mm in length was compared to the K-wire (1.6 mm diameter X 50 mm long). An Arrow-LOK implant 50 mm in length was tested since this represented the worst case as the bending moment increases with length.

Results: The Arrow-LOK implant produced comparable test results to a K-wire in tests determining the force displacement response and the stress displacement response. The peak maximum and minimum stresses for the Arrow-LOK implant were also comparable to those of the K-wire. The small variance in the results was expected and is attributed to the difference in the diameter between the 2 devices (0.10 mm). The Arrow-LOK implant exhibited equivalent appearance to the K-wire after being subject to 250,000 cycles in fatigue testing, showing no signs of cracking or any other indications of fatigue.

Conclusion: The Arrow-LOK is equivalent to the K-wire in fatigue testing. There are no stress-risers introduced into the Arrow-LOK as a result of any of its design features.

Resistance to Pull-out

Testing was conducted to evaluate the force needed to pull the 3.5mm diameter Arrow-LOK and a 0.062" (1.6 mm) K-wire out of polyurethane block and bone models.

Results: The mean force required for initial deviation of the Arrow-LOK was 21.9 Newtons (N) compared to 1.9N for the K- wire. Complete pull-out of the devices tested required a mean of 62.1N and 2.9N respectively (Table 2).

Conclusion: The Arrow-LOK device is significantly superior to the K-wire with respect to the resistance to pull-out forces.

Rotational Stability

Testing was conducted to compare the rotational forces necessary to produce movement in a polyurethane bone implanted with either the 3.5 mm diameter Arrow-LOK or a 0.062" (1.6 mm) K-wire.

Results: The mean force required for initial deviation of the Arrow-LOK was 19.3 Newtons (N) compared to 1.6N for the K-wire. Rotation to a point greater than 20 degrees required a mean of 29.6N and 3.2N respectively. The data indicates the Arrow-LOK exhibited significantly greater resistance to rotational forces than the K-wire (Table 3).

Conclusion: The Arrow-LOK is significantly superior in its resistance to rotation than the K-wire.

Table 2

PULL-OUT TESTING SUMMARY RESULTS

	0.062" (1.6mm) Kwire	Arrow-LOK
Single-Sided Pullout: Mean Force Causing **Initial** Deviation	1.5N	13.9N
Single-Sided Pullout: Mean Force Causing **Complete** Pull-out	2.1N	29.9N
Double-Sided Pullout: Mean Force Causing **Initial** Deviation	1.9N	21.9N
Double-Sided Pullout: Mean Force Causing **Complete** Pull-out	2.9N	62.1N

SURGICAL TECHNIQUE: INSERTION

The surgical technique recommends preoperative templating to ensure the intramedullary canal can accommodate the 3.5 mm width of the implant. Proper use of instrumentation does not remove cancellous bone but rather compacts it against the cortical bone to create a stable foundation of compacted cancellous bone against the implant.

After gaining exposure to the joint, resect the head of the proximal phalanx and the base of the intermediate phalanx bones.

Table 3

ROTATIONAL TESTING SUMMARY RESULTS

	0.062" (1.6mm) Kwire	Arrow-LOK
Mean Force Causing Initial Deviation	1.6N	19.3N
Mean Force Causing Deviation >20	3.2N	29.6N

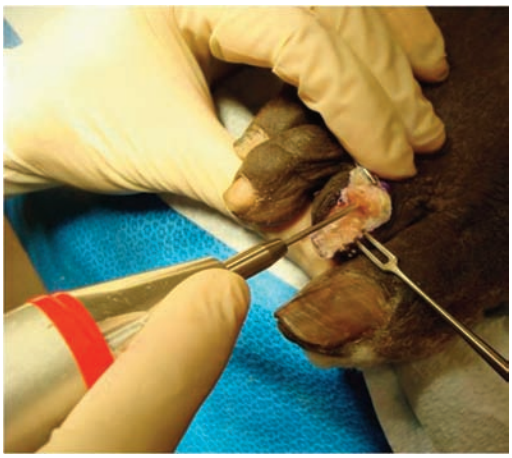

Figure 4.

Figure 5.

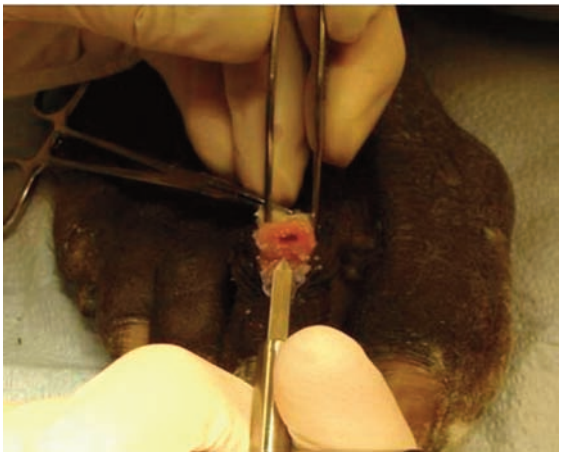

Figure 6.

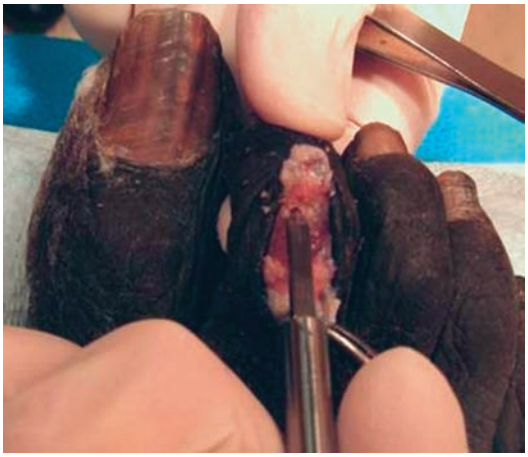

Figure 7.

Ream

Create a pilot hole in the intramedullary canals of both the proximal (Figure 4) and intermediate (Figure 5) phalanx with the Arrow-LOK Reamer. The reamer is a 152 mm long 316L stainless steel wire with a diameter of 1.6 mm. It has a smooth trocar tip that creates a pilot hole without removing bone. The 5 mm graduations from the tip serve as a depth gauge for implant insertion.

Broach

Prepare the pilot hole on both the proximal (Figure 6) and intermediate (Figure 7) phalanges with the Arrow-LOK Broach. Broach each phalanx to the depth estimated during preoperative planning. Make note of the depth marking to which the broach was inserted in each phalanx. The Arrow-LOK Broach prepares the pilot hole that was just created by the reamer to create a shape in the intramedullary canal that will accept the three-dimensional arrowhead tip of the Arrow-LOK implant. The Broach conserves bone by compacting the cancellous bone of the phalanx to enhance the engagement of the Arrow-LOK implant's arrowhead tip.

Insert and Compress

Grasp the Arrow-LOK implant with the Arrow-LOK Insertion Tool at the depth corresponding to the broaching depth of the proximal phalanx. The Arrow-LOK Insertion Tool firmly grasps the Arrow-LOK implant preventing both rotation and translation to ensure the implant is placed securely in the broached pilot hole. Insert the Arrow-LOK into the proximal phalanx (Figure 8), locking it into the intramedullary canal. Grasp the digit and insert the distal aspect of the implant into the entry portal prepared in the intermediate phalanx (Figure 9) locking the implant into the intramedullary canal (Figure 10). Release and remove the Insertion Tool. Grasping the digit firmly, compress the two bones together to advance the implant both proximally and distally to its final locked position. Close the wound in accordance with generally accepted surgical technique.

Figure 8.

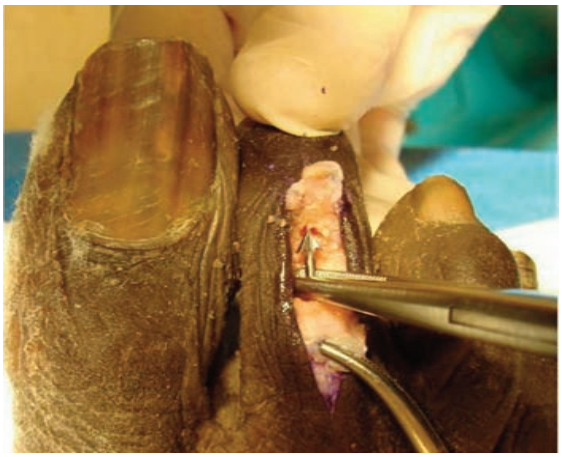

Figure 9.

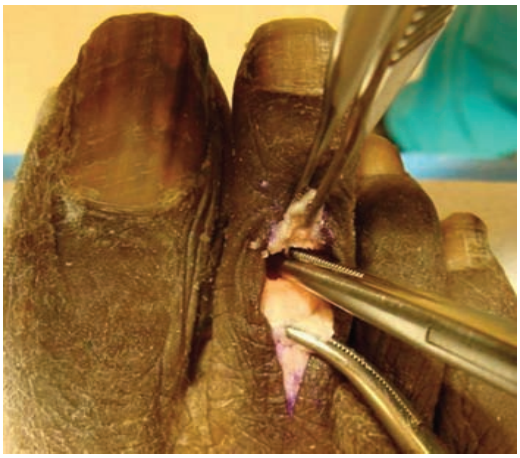

Figure 10.

OPTIONAL: SURGICAL TECHNIQUE FOR REMOVAL

In the event that the Arrow-LOK™ requires removal, standard instrumentation common to most surgical centers and hospitals facilitates the procedure. The following is an overview of the recommended technique for removal of the Arrow-LOK.

1) Access the surgical site through generally accepted surgical technique. Expose the Arrow-LOK implant with resection of the bone or fibrous tissue using either hand or power instrumentation. 2) Cut the Arrow-LOK implant using a wire cutter (Figure 12) exposing the shaft of the implant into the surgical site on both the proximal and intermediate phalanges (Figure 13). 3) Resect the bone around the implant shaft utilizing a side cutting burr on power instrumentation or a 3.5 mm cannulated drill bit. Note that the 3.5 mm cannulated drill bit is the same width as the head of the 3.5 mm Arrow-LOK implant. 4)

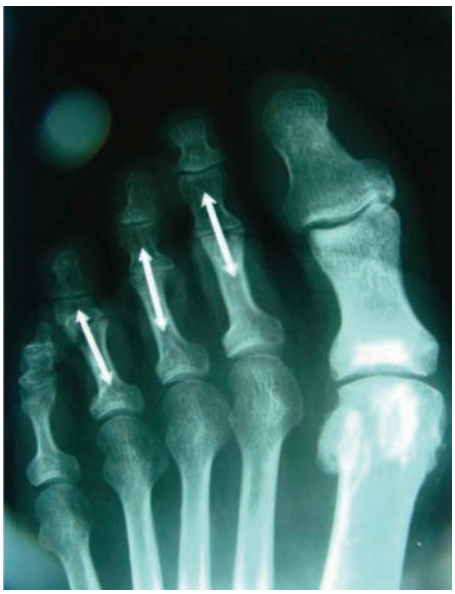

Figure 11. Postoperative radiograph of the Arrow-LOK.

The implant shaft is now exposed (Figure 14). 5) Grasp the exposed implant shaft with surgical needle nose pliers or a straight hemostat (Figure 15). Pull the implant from surgical site.

CONCLUSION

The most common fixation for proximal interphalangeal fusion is provided by a smooth K-wire. Although percutaneous K-wires have been used extensively for years, complications are well-documented. Surgeons have attempted to overcome the shortcomings of K-wires with a variety of surgical techniques, designs and materials, each presenting its own compromises and trade-offs. After

Figure 12.

Figure 13.

Figure 14.

Figure 15.

considering the key objectives of proximal interphalangeal fixation, surgeons developed an implant combining the benefits of K-wires with a design offering more stable fixation. The Arrow-LOK Digital Fusion System exhibits the potential to offer surgeons an alternative solution to proximal interphalangeal fixation that will provide patients a more effective clinical outcome than current treatment alternatives.

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