New Surgical Approach For Hammertoe Patients

(PR NewsChannel) As a podiatrist, Scott Roman, DPM, has helped countless patients suffering from proximal interphalangeal joint flexion deformity, commonly known as hammertoes. This is a progressive and often painful condition in which the toes are held in a flexed or bent position. In response to this condition, Roman has invented the ARROW-LOK Digital Fusion System to aid in post-operative recovery.

The traditional surgical approach for correcting hammertoes utilizes a Kirschner wire to hold the bones of the toes in position after surgery so they can fuse into the correct alignment. The wire is usually left protruding from the toe for four to six weeks after surgery. “Not surprisingly,” Roman notes, “that causes anxiety for many patients, who worry about stubbing the toe with the wire sticking out, or even accidentally pulling it out.”

The protrucing wires can also increase the risk of post-operative infection and the wires have to be removed before the bone has completely healed. “I used to embed a short wire to provide a balance of effectiveness and comfort for my patients, but stability was not as solid as I wanted it to be,” says Roman. “The segments of the toes would sometimes distract off the wire or gap at the fusion site. K-wires have been in use for over 40 years. We needed to overcome the challenges of the current procedure and create a better approach," states Roman.

Roman envisioned an arrow-shaped device that could be used in place of the traditional external wire. The challenges of taking a medical device through the FDA clearance process and creating a national distribution channel, however, presented challenges that Roman, already involved in a busy medical practice, could not meet on his own. “I had ideas, I had prototyping,” Roman says, “but I didn’t have a team of experienced professionals supporting me.”

At the urging of a professional associate, Roman connected with Patrick Mullaney, whose 20-year career has been largely focused on selling and commercializing medical devices. Recognizing the originality and market potential of Roman’s hammertoe device, Mullaney and Tom Twardzik, a professional associate with 25 years in the industry, co-founded Arrowhead Medical Device Technologies, LLC, in 2010. The company is focused on introducing new devices for treatment of musculoskeletal disorders. Roman’s hammertoe solution became the company’s first product.

The initial design received 510(k) FDA clearance in the fall of 2010, which meant that doctors could start using the product in patients. Feedback from surgeons led to development of a “second generation” implant design that made the product easier to use and able to fit a wider range of patient anatomies. Cleared by the FDA in October 2011, the ARROW-LOK Digital Fusion System has since been launched in

over 20 of the nation's key markets.

Since the system's availability in December 2010, Roman has used the system on his own patients, "both young and old, with excellent results. The system is designed to maintain stability until the bone is fully healed, to reduce patient anxiety about the removal of external wires and to reduce the possibility of post-operative infections. I've had several patients that have been putting off surgery for years because they didn't want to go through the experience with the external wires, the most common manner of fixation. The ARROW-LOK system is a comparatively anxiety-free post-op experience for them.

"As we bring the device to doctors across the country, the patient population will become more aware of the product, and discover that they can have hammertoe surgery without wires protruding from the ends of their toes," states Roman. In determining whether surgery is appropriate for a given patient, Roman always starts with the most basic, and important, consideration: "The first question I ask patients is if they are experiencing pain that alters their activities of daily living. When the benefits outweigh the risks of surgery, that's the time to have the procedure to get the toes corrected."

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