Prospective Randomized Multicenter Comparative Effectiveness Study Comparing; Two Component Modular Digital Implant Versus K-Wire Fixation For Surgical Correction of Hammertoes

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Abstract

Digital deformities are very common and painful conditions that often progress despite conservative treatment and require surgical intervention. Numerous surgical techniques and options of orthopaedic hardware exist that offer the foot and ankle surgeon a myriad of choices to achieve surgical correction and arthrodesis. While the post-operative objectives may be similar, different surgical approaches and the surgeon's choice of implant can effect healing time, patient satisfaction, fusion times, and overall foot function. This study evaluates two different methods of fixation.

A prospective randomized multicenter, central IRB approved, comparative effectiveness trial was conducted to analyze the outcomes of two surgical treatments for correcting digital deformities through arthrodesis of the proximal interphalangeal (PIP) joint. A total of 91 patient were consented (95 toes) and 58 patients (58 toes) met the inclusion – exclusion criteria and were randomized into the trial. In the first group a total of 50% (n=29) of the digits were managed with a standard arthrodesis procedure which included PIP joint resection, followed by traditional percutaneous stabilization with a Kirschner wire (K-wire). In the second group 50% (n=29) of the digits were treated with a unique modular two-component implant with distal anatomic angulation (Nextra® Hammertoe Correction System, Nextremity Solutions; Warsaw, IN). Patient were evaluated pre-operatively and at 5 intervals over a six month time period.The primary study objective was the comparative rate of digital arthrodesis and, the secondary objective was to evaluate the post-operative patient experience and satisfaction, as measured by the Bristol Foot Score (BFS) and the Foot Function Index (FFI).

After final radiographic examination, complete osseous union was recorded in 24 or 83% of the patients who had the two-component implant arthrodesis, compared to 4 or 14% who underwent K-wire fixation ($p<.001$). The investigators also found the change from baseline in the Bristol Foot Score Survey was significantly higher in the two-component implant group ($p<.05$). Additionally, comparison of the FFI subcategories (pain, disability, activity limitations) by treatment group revealed in all categories statistically significant differences in improvement in score with the two-component group ($p<.05$) versus standard K-wire fixation.

The results suggest that the two-component implant was clinically and radiographically more effective in achieving fusion of the interphalangeal joints, reducing pain, improving quality of life, and increasing ambulatory activity versus standard K-wire fixation. Therefore this study demonstrates that this new unique two-component implant is a highly effective alternative for achieving digital fusion and improving patient outcomes.

Level of Clinical Evidence: 1

Key Words:

Arthrodesis, Digital Deformity, Hammertoe, Bristol Foot Score (BFS), Foot Function Index (FFI), Nextra® Joint Implant, Toe Implant, Toe Fusion, Nextradesis, Proximal Interphalangeal joint, K-Wire.

Introduction

Digital deformities such as hammertoes, mallet toes and claw toes are a very common orthopaedic complaint that up to 60 million or more patients suffer from, with the number growing higher annually (1). Recent research by iDATA, reports that there were an estimated 550,000 hammertoe surgeries in the U.S. in 2012 and market research projects this number will increase to almost 648,000 by 2017(1). Population based studies in Australia and Sweden have shown that surgical correction of digital deformities comprises about 28-46% of all forefoot surgery performed (2, 3, 4).

Etiology of digital dysfunction has been linked to foot structure (pes cavus, hallux valgus, hallux limitus, pes planus, equinus, and metatarsal parabola anomalies), biomechanical dysfunction (intrinsic vs. extrinsic tendon imbalances and intrinsic minus foot), trauma, physiology and systemic disorders (diabetes, charcot-marie tooth, seronegative/seropositive arthropathies, as well as systemic neurologic conditions), and the improper fitting and wear of shoe gear. (4,5).

From a biomechanical prospective there are three causes of digital dysfunction and they are flexor stabilization, flexor substitution, and extensor substitution. Flexor stabilization is known to be the most common of the three and occurs frequently in patients that actively pronate and have flat feet. Digital deformity is often classified by the anatomic order of the biomechanical dysfunction: Hammertoes (plantarflexion at the PIP joint only), mallet toes (plantarflexion at the DIP joint only), claw toes (plantarflexion at both the PIP joint and the DIP joints), crossover 2nd toe transverse plane deformity, overlapping fifth toe, clinodactyly/curly toe, and pre-dislocation syndrome (progressive imbalance from the metatarsal phalangeal joint ligaments)(4,5,6,7).

Surgical intervention for digital deformities range from: soft tissue (tenotomy/capsulotomy, tendon balancing/transfers, and skin-plasties) to osseous (arthrodesis, arthroplasty, and amputation) or a combination of both. Soft tissue correction has been noted to be effective but is not always definitive (4,5). Girdlestone was the first to transfer the flexor digitorum longus tendon to the extensors in 1947 (8). Kuwada and Dockery modified this transfer using a drill-hole in the anatomical neck of the phalanx (9). Newer approaches have been described including a "dorsal suspension stitch" (10) and a release of the FDL-FHL inter-tendinous connection at the knot of henry (11).

Regardless of the surgical technique utilized, there are objectives that need to be achieved through surgery. These objectives include delaying the progression and severity of the deformity, providing greater stability at the PIP joint, restoring and maintaining the patient's ambulatory ability, and diminishing the discomfort or pain experienced by the patient. (4,5,6,12,13). Given these objectives a boney procedure is usually needed to achieve a stable correction.

Arthrodesis is the most common surgical procedure utilized for digital correction (6). Soule (14) was the first to describe the end-to-end fusion in 1910, and in 1931 Higgs suggested the "spike and hole" or peg-in-hole (15). Taylor was the first to use the K-wire in 1940 and it has been a standard ever since (16). Other methods of fusion have been described including: chevron osteotomy (17) and conical reaming (18). In a 2001 study, Lamm et al. compared the peg-in-hole arthrodesis to the end-to-end and the "V" arthrodesis in 30 cadaveric specimens. The peg-in-hole was found to be the most biomechanically stable construct when fixated with a 0.045 K-wire (19). Klammer et al. in a 2012 comparative prospective randomized trial, showed that K-wires left in place for 6 weeks lead to less interphalangeal joint motion

and less recurrence of deformity as compared to K-wires only used for 3 weeks; suggesting that time may be a factor influencing fusion with K-wires (20). K-wires however are still well known for their myriad of complications, which include: superficial pin tract infection, deep infection, mal-union, non-unions, vascular impairment, loosening, pin breakage or phalanx fracture, and floating toe syndrome (12,20,21,22). There is also great patient dissatisfaction with the exposed wire and the inability to bath normally or return to regular shoe gear for prolonged periods of time (23).

Considering all the downfalls associated with K-wires over the last 15 years many foot and ankle surgeons have considered more advanced options for internal fixation to improve stability and appearance of the digital fusion. These options include: Cerclage wire, AO screws/cannulated screws, staples, absorbable pins, cadaveric bone dowels, one-component implants, and two-component implants with the ideal toe implants having a slight anatomic angulation for toe purchase (6).

Stainless steel and titanium are most common alloys used for these products, but other metals such as nitinol, a shape memory nickel-titanium alloy is also an option and has demonstrated a 68.9% - 93.8% fusion rate in recent studies (24,25,26). A recent trial with a one-component titanium implant has shown an 83.8% fusion rate (27); and a report of a small case series, using the same one-component implant had 100% fusion rate (28). A two-component inter-locking device was noted in two studies; one which had a 73% fusion rate in 150 toes (29) while Ellington et al. in 2010 looked at 38 toes in 27 patients, and showed a bone union rate of 60.5% (30).

To date there has been no research (performed or published) demonstrating peer-reviewed level-one evidence using a two-component digital implant that also has anatomic angulation, and comparing this to a more standard form of fixation such as a kirshner wire. The two-component implant may provide the surgeon with the most versatility in achieving hammertoe arthrodesis with the appropriate anatomic angulation also providing the best function, patient satisfaction and cosmesis compared to a K-wire.

The purpose of our comparative study is to evaluate a unique two-component digital implant (Nextra® Hammertoe Correction System, Warsaw, IN) that is anatomically shaped with a two-piece design for the proximal phalanx and the base of the middle phalanx that has ten degrees of distal anatomical angulation, as well as an adjustable feature to allow reversible assembly and fit (RevLock™), as well as an internal ratchet design for progressive tightening during intramedullary targeting (31) versus standard K-wire fixation.

Figure 1: Nextra® Hammertoe Correction System

Figure 2: Standard Kirschner–wire (K-wire)

The primary objective of this randomized prospective study was to directly compare the rate of digital arthrodesis. The secondary objectives included evaluation of the post-operative patient experience and satisfaction, comparing the two-component implant versus standard K-wire fixation using two standardized scoring systems.

Materials and Methods

A prospective, randomized, multicenter, WIRB approved (Protocol #: 20112151), registered (clinical trials.gov NCT01604070) comparative effectiveness trial was conducted to analyze the outcomes of two surgical treatments for correcting digital deformities through arthrodesis of the proximal interphalangeal (PIP) joint. Nine pre-selected research sites chosen across the United States underwent WIRB approval. Consent was obtained prior to any study-related procedures and all patients signed an Investigational Review Board (IRB) approved informed consent form, in compliance with applicable regulatory requirements and adhering to Good Clinical Practice (GCP). This study was conducted in accordance with the provisions of the Declaration of Helsinki. In addition, all products used in this study were manufactured, handled and stored in accordance with applicable Good Manufacturing Practices (GMP). Patient consents, screening and evaluation was conducted by all principal investigators at the IRB approved research centers. Senior authors RMJ, AL, and DSM validated case report forms and X-ray findings.

Table 1: Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Adults between the ages of 18 and 75	**Previous digital fusion or arthroplasty surgery**
	Hallux valgus creating a crossover with 2nd toe
Pain in the toe reported for greater than 3 months	**Inability to walk without an assistive device**
	Infection
	Rheumatic joint disease
Failure of Conservative Care	**Peripheral vascular disease**
	Sensory loss to the toe
Subjects are males or females, diagnosed with a hammertoe, contracture of the PIP joint, or other condition requiring digital PIP joint fusion	**Pregnant**
	Osteoporosis
	Obvious loss of digital bone density
	Severe respiratory disease
	Open wounds
Deformity of a lesser digits (2^{nd}, 3^{rd}, or 4^{th})	**Patients presently taking drugs for neuropathic pain, which include: Gabapentin, and Pregablin**
Subjects willing to sign an informed consent	**Diabetics**
	Narcotic dependence
Subjects willing to return for follow-up visits and fill out Quality of Life questionnaires	**Inability to consent to the research**
	Concurrent involvement in another clinical trial
	Known allergy to the device components
	Known metabolic bone disease
	Renal disease (CRI, CRF)
	Skeletal muscle spasticity or paralysis
	Obesity
	Tobacco use

91 consecutive patients (95 toes) undergoing hammertoe surgery at the nine sites were consented and then screened for the study. After conducting the initial screening based upon the inclusion/exclusion guidelines (Table 1) site principal investigators performed baseline data collection leading each subject through clinical evaluations utilizing the Bristol Foot Score (BFS), Foot Function Index (FFI) questionnaires (32,33).

In addition, a Semmes Weinstein 10g monofilament sensation test was performed. Photographs and standard anterior-posterior (AP), medial-oblique (MO), and lateral (L) radiographic views were taken of each foot that was being enrolled.

Randomization of subjects occurred on the day of surgery by administering each patient a sequentially numbered envelope that contained a code indicating either the two-component implant approach or the K-wire fixation approach. Based upon protocol, each surgeon was blinded to the contents of the envelope until the day of surgery.

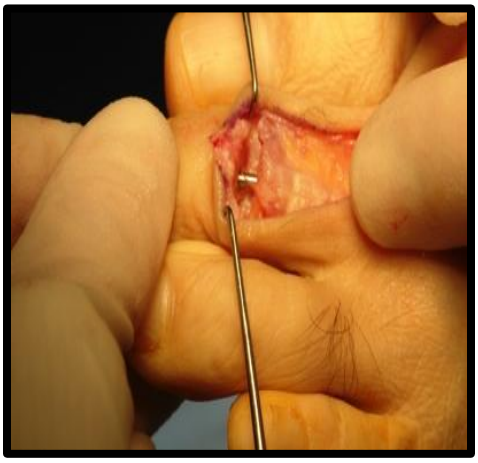
58 patients (58 toes) were randomized into one of two groups: those having digital arthrodesis with the two-component implant, and those receiving the standard of care digital fusion with K-wire. The subjects were followed for a period of 6 months. In total, 29 patients (29 toes) were treated with the two-component implant, and 29 patients (29 toes) were treated with the standard of care K-wire fixation.

Procedure:

Skin incisions were made over the PIP joints of either the second, third or fourth digits. These were deepened to expose the PIP joint. A transverse incision was made through the extensor tendons and all soft tissue attachments including the collateral ligaments were freed from both the head of the proximal phalanx and base of the middle phalanx. Preparation for arthrodesis consisted of removal of the entire cartilaginous base and subchondral plate of the middle phalanx. However, to accommodate the unique anatomic design of the two component implant, the head of the proximal phalanx was cut at a 10˚ angle from dorsal to plantar; the proximal phalanx cut was made straight at 0˚for all K-wire subjects.

Two Component Implant Procedure Technique

Two pilot holes were drilled with reamers provided, one through the proximal phalanx head, and the other through the base of the middle phalanx. The implant components were screwed into each phalanx using the progressive tightening mechanism of the threads. The two components were connected and clicked together with the adjustable locking feature (RevLock™; Fig 3a, b) and the bone margins were noted to be in contact at the arthrodesis site when the internal ratchet mechanism was finalized. (31)



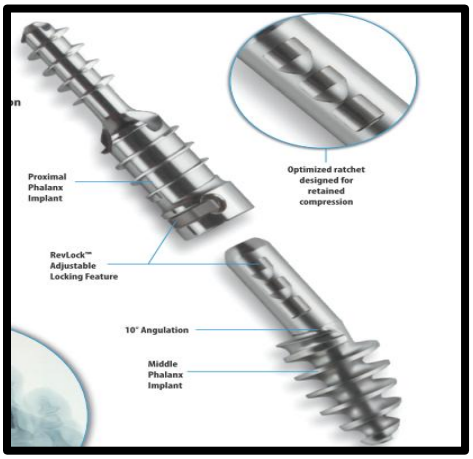


Figure 3a: Second toe arthrodesis with the two implants locked at the arthrodesis site.

Figure 3b: RevLock™ system with internal ratchet. (Nextremity Solutions, Warsaw, IN)

K-wire procedure technique

A standard 0.045 K-wire was drilled distally into the middle phalanx and through the distal phalanx, exiting at the tip of the toe. The protruding K-wire was then retrograded proximally, across the

fusion site. While the arthrodesis site was stabilized to ensure boney contact, the pin was driven further into the proximal phalanx. Position was checked on fluoroscopy to make sure the pin did not enter the metatarsal-phalangeal joint. The K-wires were left in place for up to 6 weeks or until osseous fusion occurred.

Follow-up protocol

Patients were allowed immediate partial weight bearing in the post-operative period in a hard soled post-operative shoe and well-padded dressing from day 1. They were progressed to full weight bearing as tolerated. Patients were subsequently evaluated during the following post-operative intervals: Week 1, 3 and 6, and at 3 months and 6 months. At each visit, radiographic measurements were taken in order to evaluate the status of osseous healing seen at the PIP joint arthrodesis site, as well as to document any implant positioning and alignment issues. The use of all medications and all adverse events were documented.

Third party validators evaluated the radiographs in order to assess positioning and osseous union throughout the six-month follow-up. During this evaluation, blinding was not possible since each radiograph would divulge the type of implant used. A rating system was designed specifically for this study, and is noted in Figure 4a-4g.

Radiographic Classification System

PIP JOINT demonstrating a gap (grade 1) after K-wire removal
PIP JOINT with Nextra™ implant demonstrating a gap (grade 1)
PIP JOINT with Nextra™ implant demonstrating bone contact (grade 2)
PIP JOINT with K-wire demonstrating bone contact (grade 2)
PIP JOINT with Nextra™ implant demonstrating bone union (grade 3)
PIP JOINT demonstrating bone union after K-wire removal (grade 3)

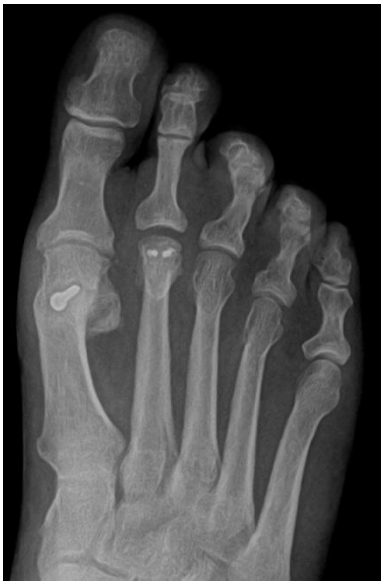


Figure 4a : Grade 1 Gap

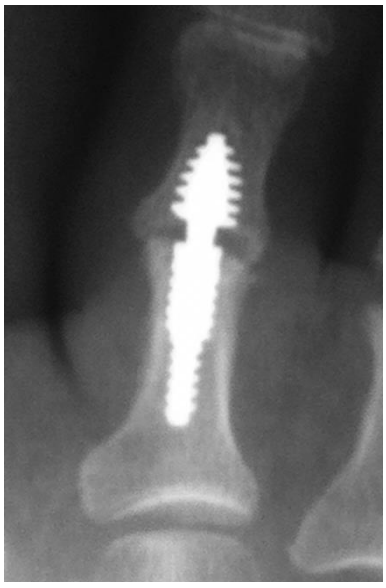
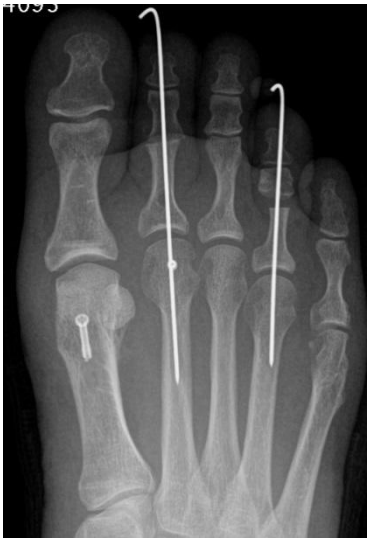


Figure 4b: Grade 1 Gap



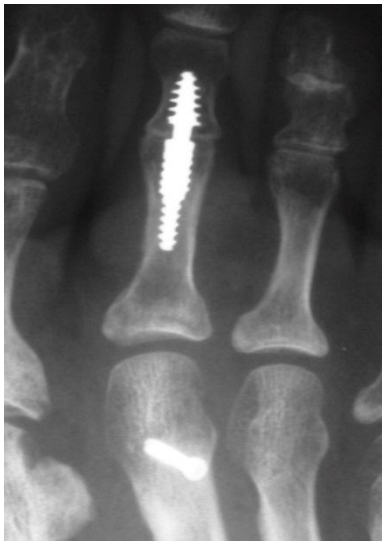
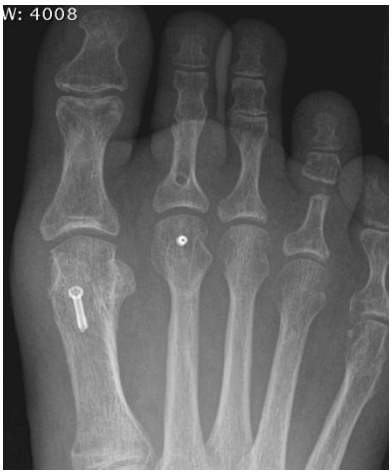


Figure 4c – Grade 2 Contact **Figure 4d – Grade 2 Contact**



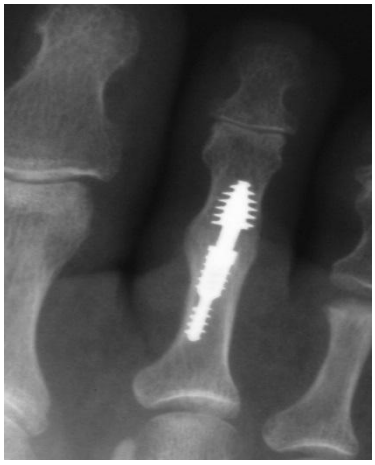


Figure 4e – Grade 3 Fusion **Figure 4g - Grade 3 fusion**

Figure 4, a-g: Grading system used to evaluate PIP JOINT post-op status, Grade 1= Gap, Grade 2=Contact or Grade 3=Union

Study Endpoints

Every patient's reported foot pain and physical symptoms were collected and compared using the BFS and FFI at baseline, and again during each of the follow-up periods (32,33). Bone contact at fusion site, resorption around pin or implant, and bone callus were reviewed by standard foot radiographs. Measurements of bone length, angulation, width, and density were also included. Pre-op and post-op measurements were recorded clinically and on all radiographs. The study's final endpoint was the patient's final six-month follow-up.

Outcome Measures

All primary outcome measures were based upon individual radiographic assessments. Secondary outcome measures were assessed using the FFI and BFS scoring systems (32,33).

Statistical Methods

The population that was analyzed consisted of both all randomized subjects and those who completed the study through six months of follow-up. The data was interpreted by an analysis of covariance (ANOVA) that included the effects of treatment group and the baseline measure as the covariate subtracted from baseline levels and compared using both a parametric (ANOVA) and a nonparametric (Wilcoxon rank-sum) statistical test. Incidence of adverse events, serious adverse events and surgical complications were tabulated for each study group, with data presented by the total number of events and by the total number of subjects with at least one event. The Wilcoxon rank-sum test was used for analysis of severity and relationship to treatment**.**

Questionnaires

Foot-related quality of life (QOL) was subjectively measured using patient-reported outcomes, namely the BFS and FFI. The BFS consisted of 15 self-reported items that focused on patient-centered foot-related QOL. These instruments have been validated and are reliable and known to produce meaningful information (32,33,34,35).

To obtain a measurement using the BFS, each patient read the questionnaire and scored each question numerically. The questions focused on how each patient's foot influenced his or her daily activities over the preceding two-week period. The scores ranged from a minimum of 15 to a maximum of 73 points, with lower scores indicating better foot-related quality of life outcomes (32,34).

The FFI consisted of 23 self-reported items divided into three subcategories, namely: pain, disability, and activity limitation. The patient read the questionnaire, and scored each question on a scale from 0 (no pain or difficulty) to 10 (worst pain imaginable or so difficult it requires help), that best described their foot over the past week. The pain subcategory consisted of 9 items and measured foot pain in different situations, such as "walking barefoot" versus "walking with shoes." The disability subcategory consisted of nine items that measured how greatly foot problems contributed to difficulties in functional activities, such as climbing stairs. The activity limitation subcategory consisted of five items and measured activity limitations caused by foot problems, such as staying in bed all day (33,34,35).

Results

This prospective cohort study was comprised of 58 toes in 58 patients. Our first participant enrolled in the study on 06/18/2012, and the last participant enrolled on 10/14/2013. The mean participant age was 60.0 ± 11.8 (range 18 to 79) years. In regard to gender distribution, 67.24% of the participants were female and 32.76% were male. Random treatment allocation resulted in 50% (n=29) of the toes being fused with the use of a standard K-wire, and 50% (n=29) fused using the two-component implant.

Data was analyzed using the mean change from baseline which was adjusted by the model to a common baseline for each treatment group. The mean difference between treatment groups in their change from baseline is also calculated along with a 95% confidence interval on the difference. The p-value represents the results of the test of the hypothesis that the mean changes from baseline for the two treatment groups are identical.

There were no statistically significant differences in age, sex, body mass index, and comorbidities at baseline.

At baseline, BFS and FFI were neither statistically nor clinically significantly different between the treatment groups (as would be expected with random treatment allocation, which equally distributes clinical variables at baseline and eliminates selection bias).

Overall, both approaches to hammertoe correction – by either K-wire or two component implant procedures – clinically and statistically significantly improved the BFS and FFI scores from baseline to the six-month primary efficacy endpoint (Tables 2 and 9). Table 2 reveals that at every measurement period, except the three-month period, BFS scores following the arthrodesis procedure were statistically

significantly improved compared to the K-wire procedure. Tables 3-5 shows that while FFI scores following the arthrodesis procedure initially worsened in the first post-operative week, they also steadily improved afterward, to a statistically significant degree compared to the K-wire procedure.

In a statistical comparison of the two groups, the arthrodesis procedure with the two component implant and K-wire procedure outcomes have similar trends, but also interesting and significant differences. Both procedures have an initial recorded increase in BFS score post-procedure, with a progressive improvement in the following months. The improvement curve of the two component implant procedure group recorded in terms of the BFS is significantly better than that of the K-wire improvement curve and the long-term improvement is significantly better in terms of the BFS as well. The pain subscore shows an immediate decline in the score compared to baseline for the two component group with continued decreasing pain over the six month follow up. The K-wire procedure shows an immediate increase in pain, followed by a decrease in pain over the follow-up period. In both the two component and K-wire procedures, the disability subscale shows an increase and then gradual decrease in the subscale score. This trend is typical for a post-procedure scale. Interestingly, the two component implant group shows statistically significant better improvement in disability scores during the follow-up period (Table 4). The activity subscale shows a trend similar to the disability subscale, with, again, superior improvement in the activity subscale for the two component implant cohort compared to the K-wire cohort (Table 5).

Table 2: Mean Baseline and Change From Baseline in the Bristol Foot Score Survey

	Kwire	**Nextra® Implant**	**Difference (95% CI)**	**P-value**
Baseline mean ± Std	**43.8 ± 9.6**	**43.1 ± 9.4**		
Change at 1 wk	**11.0**	**3.8**	**7.2 (1.9, 12.6)**	**0.009**
Change at 3 wks	**6.1**	**-0.2**	**6.3 (1.1, 11.4)**	**0.019**
Change at 6 wks	**-0.3**	**-8.2**	**7.9 (2.1, 13.7)**	**0.009**
Change at 3 mos	**-12.3**	**-14.6**	**2.3 (-3.5, 8.1)**	**0.42**
Change at 6 mos	**-11.9**	**-19.0**	**7.1 (1.7, 12.6)**	**0.012**

For both the K-wire group and the two-component implant group, comparisons showed that the BFS and composite (total) FFI initially worsened in the first post-operative week, then improved at every subsequent time period from the third week to the six-month follow-up. The investigators noted that the two-component implant procedures resulted in a statistically and clinically significantly better BFS at the one-week postoperative measurement and a clinically significantly better BFS at the three-month postoperative follow up. This comparison shows a statistically significant improvement with the two-component implant over K-wire fixation in the early post-operative phase. Moreover, the patients receiving the two-component implant resulted in a clinically significantly better FFI at the one-week, three-week, three-month, and six-month postoperative follow-up measurements.

Comparison of the FFI subcategories (pain, disability, activity limitations) by treatment group (Tables 3-5) revealed a substantial number of statistically significant differences. The two component implant cohort significantly outperformed the standard K-wire fixation cohort in terms of both pain relief and disability at every interval except at three months ($p<.05$). The implant group also significantly outperformed the standard K-wire fixation group in terms of activity at every measurement interval except for six weeks and three months. While the two component implant group was not significantly better than K-wire fixation group in any category at the three-month interval, it was significantly better in all three categories at the six-month interval ($p<.05$).

Table 3: Mean baseline and Change From Baseline in the Pain Subscale

	Kwire	Nextra® Implant	Difference (95% CI)	P-value
Baseline mean ± Std	**40.8 ± 13.9**	**40.5 ± 16.6**		
Change at 1 wk	**10.4**	**-2.9**	**13.3 (3.4, 23.1)**	**0.009 †**
Change at 3 wks	**1.8**	**-9.1**	**10.9 (0.7, 21.1)**	**0.038 ***
Change at 6 wks	**-8.2**	**-18.3**	**10.1 (1.2, 19.0)**	**0.027 ***
Change at 3 mos	**-18.5**	**-24.2**	**5.6 (-1.9, 13.2)**	**0.14**
Change at 6 mos	**-16.4**	**-26.0**	**9.6 (1.6, 17.7)**	**0.020 ***

* Significant at a (p<.05) level
† Significant at a (p<.01) level

Table 4: Mean baseline and Change From Baseline in the Disability Subscale

	Kwire	Nextra® Implant	Difference (95% CI)	P-value
Baseline mean ± Std	**38.5 ± 21.1**	**38.3 ± 23.5**		
Change at 1 wk	**26.7**	**10.8**	**15.9 (4.1, 27.7)**	**0.009 †**
Change at 3 wks	**13.1**	**0.03**	**13.1 (1.9, 24.2)**	**0.023 ***
Change at 6 wks	**1.8**	**-10.9**	**12.6 (2.4, 22.9)**	**0.017 ***
Change at 3 mos	**-10.6**	**-19.3**	**8.8 (-1.5, 19.0)**	**0.094**
Change at 6 mos	**-7.2**	**-24.1**	**16.8 (6.6, 27.1)**	**0.002 †**

* Significant at a (p<.05) level
† Significant at a (p<.01) level

Table 5: Mean Baseline and Change from Baseline in Activity Limitation Subscale

	Kwire	Nextra® Implant	Difference (95% CI)	P-value
Baseline mean ± Std	**10.8 ± 7.5**	**10.6 ± 9.0**		
Change at 1 wk	**21.8**	**14.0**	**7.8 (0.2, 15.4)**	**0.045 ***
Change at 3 wks	**13.3**	**5.8**	**7.4 (0.7, 14.2)**	**0.032 ***
Change at 6 wks	**5.0**	**0.7**	**4.3 (-1.6, 10.1)**	**0.15**
Change at 3 mos	**-0.3**	**-2.8**	**2.5 (-2.2, 4.3)**	**0.29**
Change at 6 mos	**0.6**	**-4.6**	**5.2 (0.4, 10.0)**	**0.036 ***

* Significant at a (p<.05) level
† Significant at a (p<.01) level

At all postoperative time periods, the radiographic measurements showed significantly better apposition and union of the PIPJ fusion interface when the two component implant was used instead of the K-wire (Tables 6-9). This radiographic difference was associated with a statistically significant difference in patient satisfaction, as measured using the BFS or the FFI, at nearly every measurement interval (Table 9).

Table 6: Radiographic findings by treatment group (N = 58)

Postoperative time period	Treatment						*p*-value*
	K-wire (n = 29)			Nextra® Implant (n = 29)			
	Gap	Contact	Union	Gap	Contact	Union	
1 week	10	19	0	1	28	0	.003
3 weeks	11.5	17.5	0	3	24	2	.005
6 weeks	15	14	0	3	8	18	< .001
3 months	14	14	0	3	2	24	< .001
6 months	14	10	4	3	2	24	< .001

*Cuzick's test for trend across ordered groups

^ One patient from the K-wire group was lost to follow up after 6 weeks postoperative

One patient had a value of (Gap/Contact) and was assigned a score of 1.5

Table 7: Radiographic findings by treatment group K-wire (N = 29)

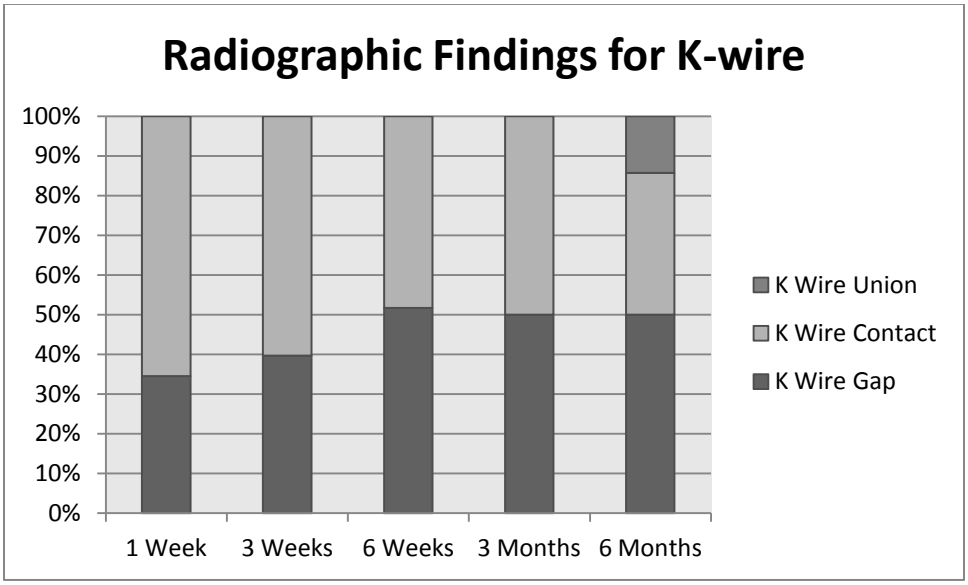


Table 8: Radiographic findings by treatment group Nextra® Implant (N = 29)

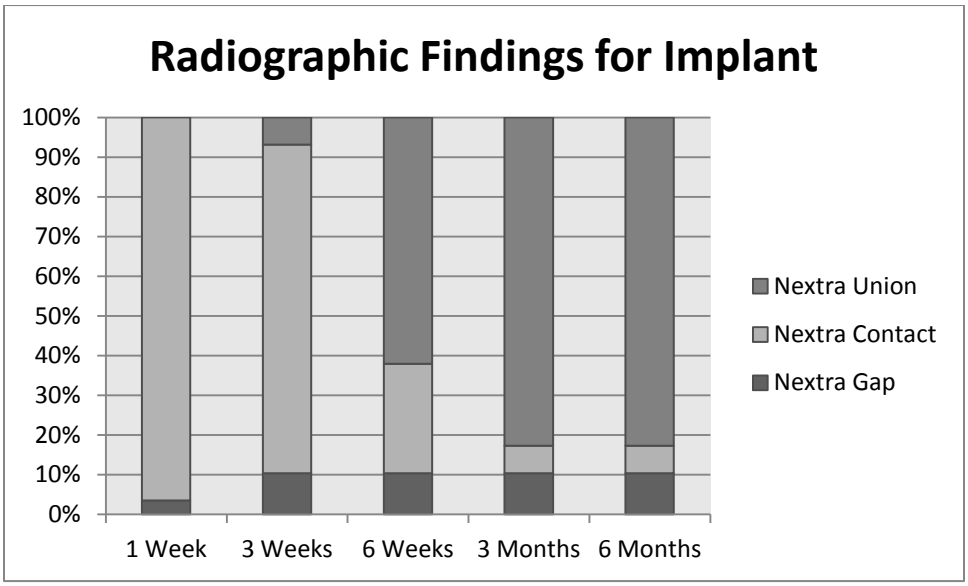


Table 9: Patient Satisfaction (BSF and FFI) and Radiographic Union

Patient Satisfaction (BSF and FFI) and Radiographic Union							
	BSF				Pain		
	K-WIRE	NEXTRA® IMPLANT	p value		KWIRE	NEXTRA® IMPLANT	p value
Baseline	43.8	43.1		Baseline	40.8	40.5	
1-W	54.8	46.9	0.009†	1-W	51.2	37.6	0.009 †
3-W	49.9	42.9	0.019*	3-W	42.6	31.4	0.038*
6-W	43.5	34.9	0.009†	6-W	32.6	22.2	0.027 *
3-M	31.5	28.5	0.42	3-M	22.3	16.3	0.140
6-M	31.9	24.1	0.012*	6-M	24.4	14.5	0.020 *
	Disability				Activity		
	KWIRE	NEXTRA® IMPLANT	p value		KWIRE	NEXTRA® IMPLANT	p value
Baseline	38.5	38.3		Baseline	10.8	10.6	
1-W	65.2	49.1	0.009 †	1-W	32.6	24.6	0.045 *
3-W	51.6	38.33	0.023 *	3-W	24.1	16.4	0.032*
6-W	40.3	27.4	0.017 *	6-W	15.8	11.3	0.15
3-M	27.9	19.0	0.094	3-M	10.5	7.8	0.29
6-M	31.3	14.2	0.002 †	6-M	11.4	6.0	0.036 *

* Significant at a (p<.05) level

† Significant at a (p<.01) level

Adverse Events

The investigators listed no serious adverse events in either arm of the study. There were no pin tract or post-operative infections, symptomatic non-unions or complications that required a return to the operating room in either fixation group.

Adverse events listed by investigators for K-wire subjects included: one un-related blood clot, K-wire mal-function with wire backing out prematurely, and one incident of trauma to the operative digit due to falling after surgery. Among the two component implant subjects, adverse events included: blood clot, and a patient with an episode of confusion and a patient with symptoms consistent with a transient ischemic attack.

Discussion

There are many different techniques and orthopaedic implants that can be used to achieve fusion of the PIP joint for reconstruction of digital deformities. Historically, while K-wires have been the most commonly used fixation device, over the past 15 years many newer implants have become available and the trend to use these newer implants is on the rise. The importance of focusing on evidence based medicine when a surgeon makes his/her choice of implants is critical as good science; and a focus on reproducible clinical results in our patients should always be at the forefront of our clinical decision making (55,56,57).

Since Taylor first used the stainless steel K-wire in 1940, it has long been considered the gold standard for this procedure (16). Recently, Klammer et al. showed in a 2012 prospective study looking at hammertoe arthrodesis; comparing 23 toes with a K-wire used for 3 weeks and 23 toes with a K-wire used for 6 weeks, that the 6 week fixation time had only 8.7% recurrence rate vs. 47.8% recurrence for 3 weeks which was statistically significant. This clearly showed that if K-wires are chosen for fixation the surgeon should certainly maintain the wire in place for 6 weeks. While in this specific study no pin tract infections were reported, the controversy is still very prevalent that leaving implanted wires exposed for up to 6 weeks in a hammertoe arthrodesis increases the chance for increased post-operative complications including infection and leads to decreased patient satisfaction (20).

Reese et al. reported an 18% infection rate with wires fixated for 6 weeks (22). Coughlin et al. studied 118 toes and inferred that 3 weeks of fixation is more ideal, but ended up having 3 superficial infections that resolved with wire removal and oral antibiotics. In this study they had an 81% osseous fusion rate with 19% going on to fibrous union (12).

In addition to pin tract infections, leaving K-wires exposed for prolonged periods of time can lead to wire breakage and potential toe fracture. Zingas et al. in a 1995 study of 1,002 toes (565 patients), had 33 broken wires, of which all were in 0.045 size wires that crossed the metatarsal-phalangeal joint (21). Galli et al. showed in a cadaveric study that pinning across the metatarsal-phalangeal joint with a K-wire for hammertoe corrections will cause roughly 1.8% ± 0.4% articular cartilage damage to the MTPJ. They also found that the surgeon usually drives the wire away from the center of the joint which could prove detrimental to the intended correction (36).

Other complications including loosening and vascular impairment, tend to be other common reasons for deferring K-wire use as noted in the literature. (12,20,22).

Another approach or technique for K-wire fixation in hammertoe arthrodesis is a buried wire technique. Scholl et al. validates the use of buried 0.062 K-wires vs. intramedullary titanium-nickel (nitinol) hammertoe toe implants in a retrospective comparative study of 58 nitinol implants and 28 buried K-wires. The rate of mal-union, non-union, fracture, and need for revision was not statistically significant suggesting that buried K-wires can function similar to digital implants (24).

Smooth buried wires are very similar to another commonly used implant for digital arthrodesis, which is a smooth absorbable pin and cortical bone allograft pin, but again these devices do not provide arthrodesis

site compression either, are not as strong as a buried wire, and require degradation by the body which may still impair the rate of fusion and increase the rate of complication after surgery (37,38).

While Scholl et.al saw no difference in complications between smooth wires and nitinol implants, Angirasa et al. did a similar study evaluating 28 patients, and found the intramedullary titanium-nickel (nitinol) hammertoe implants were superior to K-wires because patients returned to work sooner, there was less pain and less complications (39). A faster return to activity, less pain and a lower rate of complications is a persuasive argument for the foot and ankle surgeon to consider an implantable hammertoe device.

There are numerous digital implants available that all have different biomechanical designs in order to ease the intramedullary targeting, attain fusion, increase patient satisfaction and provide a cosmetic outcome. One of the more basic designs is the cannulated screw. Cannulated screws are mechanically ideal due to their wider cancellous thread pattern which is perfect for increased purchase in medullary bone of the phalanx leading to compression of the PIP joint in a rigid fashion (40). Lane used these screws for 20 fusions and all healed uneventfully (41). Caterini et al. used the same type of screw in 51 digits and had 48 fusions, and 3 asymptomatic non-unions, with a final AOFAS score average of 86.54. They did have to remove 7 of the screws though due to extreme pain and swelling (42). Cannulated screws may be the ideal way to produce compression but they are not ideal for intramedullary targeting and due to their size often create more pain (42).

An angulated implant is the wave of the future because of ease of surgical insertion, as well as accounting for the pull of the extrinsic flexor digitorum longus tendon on the distal phalanx. Coillard et al. reviewed 156 PIP joint fusions fixated with an angulated intramedullary implant inserted at 15-20˚ angulation, with an 83.8% fusion rate at 1 year follow-up; the average AOFAS-LMIS score improved from 40.4 pre-op to 85.5 post-op (27). Mallet toe deformity was found in 2 cases and there were 7 complications (2 intra-op, 5 post-op). The problem with this specific implant is the surgeon must perform the 15-20˚angulation cut removing up to 5mm of bone from each of the phalanxes purely by eye where there can always be an increased room for error (27,43) Also, the internal barbs must lock to the bone to work which is not ideal for the osteoporotic patient. In a small case series of 7 toes (3 patients), Witt and Hyer utilized a one component hammertoe implant and had 100% fusion rate. They discussed the ease of the single stem implant with 10˚ distal anatomic angulation and broad-flat barb that provides compression as well as frontal plane stability(28).

Catena et al. published in 2014, a case series of 53 toes (29 patients) again using a one-piece memory nitinol intramedullary hammertoe implant. The implant expands and conforms to bone at body temperature 37˚C. They had an average 12 month follow-up which yielded 42 toes (24 patients). There were 81% that went on to bony union, and 100% in "good alignment", with average AOFAS scores improving from 52 to 71, and the VAS pain score decreasing from 5 to 1 (25). Another study by Sandhu et al. in 2013 using the same implant had a 93.8% fusion rate with 65 implants in 35 patients. Their complication rate was 6.1% (26).

Two-component titanium inter-locking devices are yet another option in hammertoe arthrodesis. The Stayfuse (Tornier, Bloomington,MN) is the first two-component titanium alloy device that inter-locks with "audible clicks" as it engages across the joint. It does provide stable end-to-end apposition as well as rotational and angular stability, but does not allow for plantar declination or angulation. There are two studies on this two-component implant. Ellington et al. in 2010 looked at 38 toes in 27 patients, and bone union rate was 60.5%. The overall complication rate was 55.3% which included: non-union, fracture, rotational deformity, and implant break-down (30). There was another more recent study by Fazal et al. in 2013 with an 18 month follow-up. The authors had a 73% fusion rate in 150 toes (140 patients). AOFAS scores improved from 22.9 to 81.6, 95% of patients were satisfied, and only 3.3% needed revision surgery. The main problems noted included: complete detachment of both phalanx components in six, and one implant broke directly at the coupling mechanism. The authors revealed that although the two-component device is great for intramedullary positioning, the coupling mechanism is "delicate" and requires "gentle handling" to make sure the mechanism engages before closure. The device is also not

angulated so rotational deformity can occur a lot easier if the implant is not placed directly in the center of the medullary canal and lack of toe purchase is common. (29).

The unique two-component stainless steel implant (Nextra® Hammertoe Correction System, Nextremity Solutions; Warsaw, IN) studied in this trial, provides powerful level one clinical evidence of success in comparison to a standard K-wire. To a statistically significant level of $P<0.05$ at 6 months follow-up, the data in this prospective, clinical, multi-center randomized study clearly demonstrated that in comparison to the K-wire and with regard to both BFS and FFI quality of life measures the outcomes of the two-component implant were superior. Additionally, the radiographic results for evidence of union were significant ($p<.001$) with this two component implant over the K-wire fixation. In the overall measure of successful arthrodesis between the groups, 24 out of 29 toes (83%) exhibited radiographic union with the two-component implant, versus 4 out of 29 toes (14%) with the K-wire. This reflects a wide margin for arthrodesis failure in K-wire fixation

There are many reasons why the two-component implant may have fared better in this multi-center trial. This unique two-component digital implant utilizes a large shear area to maintain its position relative to the intramedullary boney substrate. Cortical screws need shorter threads as they are used in denser cortical bone. The implant studied has wider threads which create interfragmentary compression by design (Figure 5), and are able to capture and compress the smaller surface area and often osteopenic bone of the phalanges, thus providing PIP joint stability when the two implants are locked in place (31,44,45). The device also has an exclusive RevLock™ mechanism. The advantage of this mechanism it that it allows the implant to be easily unlocked, removed, and re-implanted intra-operatively for exact intramedullary targeting, with minimal bone loss and superior compression. (31). The device also offers an obvious advantage over conventional K-wire fixation in that there is no external post-operative implant exposure, therefore improving patient satisfaction. Also, the 10 degree angulation offers superior toe purchase

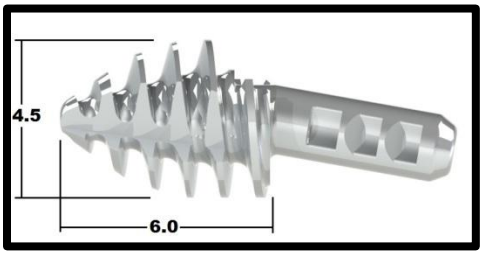


Figure 5: 4.5mm Nextra® implant with deep pitch threads

Additionally the implant is constructed of stainless steel which is less likely to deform compared to the titanium implants that have more limited ductility, and can deform before failure (46,47,48),

K-wires, while for many years serving as the mainstay for foot and ankle surgeons in fixating hammertoes, did not fare as well in this trial the authors believe for many reasons. The K-wires do not provide for compression or rotational stability across the joint. Truly, the primary goal of K-wire fixation is the standard AO principle of "splintage", thus allowing only secondary bone healing to occur across the PIP which is less likely (49). The wire will simply provide a stable lever arm so that the long and short flexors can function to provide stability for the metatarsal phalangeal joint during gait (50).

The main reason however why so many arthrodesis's fail with K-wire fixation, is perhaps due to thermal necrosis and K-wire design of the implants more commonly used. It has been extensively studied that smaller wires, as well as tips that are trocar or smooth shaped will elevate insertion temperature due to more resistance as compared to diamond or Medin shaped tips (51). The increased temperature will thus increase the chance of thermal necrosis and osteolysis at the fusion site which and certainly affect healing and fusion

Even looking at threaded wires, the results do not differ much. The pull-out strength of a threaded wire in cortical and cancellous bone is greater than that of a smooth wire, but by very little (52,53). In addition, it

is difficult to predict what weight bearing forces will do to a K-wire. In 2011 a study was conducted comparing a unique barbed arrow-headed single component implant to standard smooth 0.062 K-wires. During the "resistance to pull-out testing", the digital fusion system was over 20 times more resistant to pullout than a K-wire. In "rotational stability testing," the digital fusion system was over 10 times more resistant to rotational angulation than the K-wire (54). It is evident why K-wires will often "piston" during deforming forces of weight bearing since they provide no compression. (Figure 6)

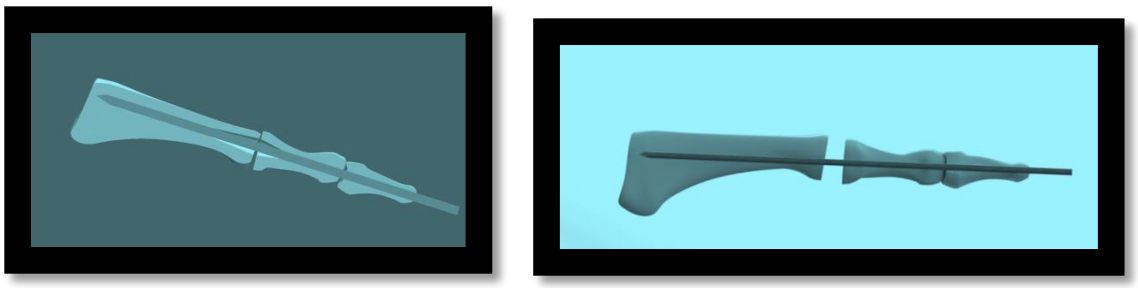


Figure 6. A K-wire will piston on it's axis.

The most significant measure of a surgical outcome is patient satisfaction. For this reason, we chose to use two time-honored, reliable methods of measuring patient outcomes, namely the Bristol Foot Scale and Functional Foot Index. These measurements took into consideration what is important to patients, namely pain and disability, as well as specifically considering the role of feet in influencing these outcomes. Both the BFS and the FFI have recently been validated in systematic reviews (34,35).

Overall, the findings, as measured by the Bristol Foot Scale, show that hammertoe correction via arthrodesis with the two-component implant resulted in a statistically significant improvement over K-wire fixation in patient-oriented and foot-related quality of life in the early postoperative period and long term follow up. Functional Foot Index scores for subjects undergoing arthrodesis with the two-component implant also showed clinically significant improvement over K-wire fixation in both the early and final post-operative follow-up periods. Better scores early in the postoperative phase are easily understood, since those that underwent surgery with the two component implant did not have to deal with a K-wire extruding from the digit. Later higher score reflect the overall statistically significant difference in fusion rate and patient satisfaction.

Sample size is very important and while our "N" could always have been larger, we powered our sample size estimate on an expected difference between the interventions, and this difference was observed in the outcomes measured.

Finally with regard to the radiographic examination, osseous union was recorded in 24 or 83% of the patients who had the two-component implant arthrodesis, compared to 4 or 14% who underwent K-wire fixation which was markedly statistically significant.

The results suggest that the two-component implant was clinically and radiographically more effective in achieving fusion of the interphalangeal joints, reducing pain, improving quality of life, and increasing ambulatory activity versus standard K-wire fixation.

Limitations of this study include the fact that multiple surgeons at multiple facilities were performing the evaluation, surgery and follow-up on each patient. The variation in surgeon technique, practice and patient population can lead to significant variability, which can limit the studies' validity. However, it should be noted that even with the variability of surgeons in this trial, the results remained statistically significant with all results carefully reviewed by surgeon validators prior to analysis. There was also only a single two-component implant that was tested and there were no other implants to compare to this, thus further studies comparing other digital implants to this novel and unique orthopaedic device versus the standard of care to determine the reproducibility or our findings would be in order for the future

Conclusion

In conclusion, the future holds that most surgeons will make their decisions in the operating room setting with the aid of evidence based medicine. Level one studies provide the most scientific and compelling data for the foot and ankle surgeon to rationalize their choice for the appropriate hammertoe implant for each patient's individual needs (55,57).

The unique two-component implant studied in this randomized, controlled, multi-center trial was clearly superior in all aspects when compared to standard K-wire fixation. This is the first level-one study to evaluate a two-component modular intramedullary implant with anatomical 10˚ angulation and an internal compression system versus standard K-wire fixation. The 83% bone union rate was statistically significant and the highest recorded for a two-component digital implant study published with level one evidence. There were no implant breakdowns, bone purchase was exceptional, and there was no complication with the two-part coupling mechanism. The two-component implant resulted in a statistically significant improvement in patient satisfaction as well as decrease in pain and increased ambulatory activity from baseline to six months post-operatively as compared to the standard of care K-wire.

Therefore, this study demonstrates that this new unique two-component implant is a highly effective alternative for achieving digital fusion and improving patient outcomes.

Acknowledgements:

The authors would like to thank Jeffrey Belancio, D.P.M. of the Inspira Health Network, the research fellows of the Presbyterian Medical Center of the University of Pennsylvania, Nathan Jennato, D.P.M. and Melissa Younger, D.P.M, for their assistance during and in the completion of this trial .

References:

1. Bones/Orthopaedics.http://www.medicalnewstoday.com/releases/249109.php. August 17, 2012.

2. Menz HB, Gilheany MF, Landorf KB. Foot and Ankle Surgery in Australia: A descriptive analysis of the Medicare Benefits Schedule database, 1997-2006. *J Foot Ankle Res.* 1(1):10, 2008.

3. Saro C, Bengtsson AS, Lindgren U, Adami J, Blomqvist P, Felländer-Tsai L. Surgical treatment of hallux valgus and forefoot deformities in Sweden: A population-based study. *Foot Ankle Int.* 29(3):298-304, 2008.

4. Shirzad K, Kiesau CD, DeOrio JK, Parekh SG. Lesser Toes: Review Article. *J Am Acad Orthop Surg.* 19:505-514, 2011.

5. Thomas JL, Blitch EL, Chaney DM, Dinucci KA, Eickmeier K, Rubin LG, Stapp MD, Vanore JV. Clinical Practice Guideline: Diagnosis and Treatment of Forefoot Disorders. Section 1: Digital Deformities. *J Foot Ankle Surg.* 48(3):418e1-9, 2009.

6. Zelen CM, Young NJ. Digital Arthrodesis. *Clin Podiatr Med Surg.* 30(3):271-282, 2013.

7. Myerson MS, Shereff MJ. The pathological anatomy of claw and hammer toes. *J Bone Joint Surg Am. 71(1):45-49, 1989.*

8. Girdlestone GR. Physiology for the foot and hand. *J Bone Joint Surg.* 29:167, 1947.

9. Kuwada GT, Dockery GL. Modification of the flexor tendon transfer procedure for the correction of flexible hammertoes. *J Foot Surg.* 19:38, 1980.

10. Dayton P, Smith D. Dorsal Suspension Stitch: An Alternative Stabilization After Flexor Tenotomy for Flexible Hammer Digit Syndrome. *J Foot Ankle Surg.* 48(5):602-605, 2009.

11. Vaseenon T, Phisitkul P. A Novel Tendinous Interconnection Release Technique for Claw-Toe Deformity. *Iowa Orthop J.* 30:157-160, 2010.

12. Coughlin MJ, Dorris J, Polk E. Operative repair of the fixed hammertoe deformity. *Foot Ankle Int.* 21(2):94-104, 2000.

13. Coughlin MJ. Lesser toe abnormalities. In: Coughlin MJ, Mann RA editor. Surgery of the foot and ankle. 8th edition. Philadelphia: Mosby Elsevier; 2007; p. 364

14. Soule RE. Operation for the correction of hammer toe. *N Y Med J.* 84:649-650, 1910.

15. Higgs SL. *Hammer-Toe.* Medical Press. 131:473, 1931.

16. Taylor RG. An operative procedure for the treatment of hammer-toe and claw-toe. *J Bone Joint Surg. 22:608, 1940.*

17. Miller JM, Blacklidge DK, Ferdowsian V, Collman DR. Chevron arthrodesis of the interphalangeal joint for hammertoe correction. *J Foot Ankle Surg.* 49(2):194-196, 2010.

18. Weil LS Jr. Hammertoe arthrodesis using conical reamers and internal pin fixation. *J Foot Ankle Surg.* 38(5):370-371, 1999.

19. Lamm BM, Ribeiro CE, Vlahovic TC, Bauer GR, Hillstrom HJ. Peg-in-hole, end-to-end, and V arthrodesis. A comparison of digital stabilization in fresh cadaveric specimens. *J Am Podiatr Med Assoc.* 91(2):63-67, 2001.

20. Klammer G, Baumann G, Moor BK, Farshad M, Espinosa N. Early complications and recurrence rates after Kirschner wire transfixion in lesser toe surgery: a prospective randomized study. *Foot Ankle Int.* 33(2):105-112, 2012.

21. Zingas C, Katcherian DA, Wu KK. Kirschner wire breakage after surgery of the lesser toes. *Foot Ankle Int.* 16:504-509, 1995.

22. Reece AT, Stone MH, Young AB. Toe fusion using Kirschner wire. A study of the postoperative infection rate and related problems. *J R Coll Surg Edinb.* 32:158-159, 1987.

23. Femino JE, Mueller K. Complications of lesser toe surgery. *Clin Orthop Relat Res.* 391:72-88, 2001.

24. Scholl A, McCarty J, Scholl D, Mar A. Smart toe implant versus buried Kirschner wire for proximal interphalangeal joint arthrodesis: a comparative study. *J Foot Ankle Surg.* 52(5):580-583, 2013.

25. Catena F, Doty JF, Jastifer J, Coughlin MJ, Stevens F. Prospective Study of Hammertoe Correction With an Intramedullary Implant. *Foot Ankle Int.* 35(4):319-325, 2014.

26. Sandhu JS, DeCarbo WT, Hofbauer MH. Digital arthrodesis with a one-piece memory nitinol intramedullary fixation device: a retrospective review. *Foot Ankle Spec.* 6(5):364-366, 2013.

27. Coillard JY, Petri GJ, van Damme G, Deprez P, Laffenêtre O. Stabilization of Proximal Interphalangeal Joint in Lesser Toe Deformities With an Angulated Intramedullary Implant. *Foot Ankle Int.* 35(4):401-407, 2014.

28. Witt BL, Hyer CF. Treatment of Hammertoe Deformity Using a One-piece Intramedullary Device: A Case Series. *J Foot Ankle Surg.* 51(4):450-456, 2012.

29. Fazal MA, James L, Williams RL. StayFuse for Proximal Interphalangeal Joint Fusion. *Foot Ankle Int.* 34(9):1274-1278, 2013.

30. Ellington JK, Anderson RB, Davis WH, Cohen BE, Jones CP. Radiographic analysis of proximal interphalangeal joint arthrodesis with an intramedullary fusion device for lesser toe deformities. *Foot Ankle Int.* 31(5):372-376, 2010.

31. Nextra Hammertoe Correction System Surgical Technique and Product Guide. Page 1. Nextremity Solutions. Colts, Neck, NJ. 2013.

32. Barnett S, Campbell R, Harvey I. The Bristol Foot Score: Developing a patient-based foot-health measure. *J Am Podiatr Med Assoc.* 95(3):264-272, 2005.

33. Budiman-Mak E, Coonrad KJ, Roach KE. The Foot Function Index: a measure of foot pain and disability. *J Clin Epidemiol.* 44(6):561-570, 1991.

34. Riskowski JL, Hagedorn TJ, Hannan MT. Measures of Foot Function, Foot Health, and Foot Pain. *Arthritis Care Res.* 63(S11):S229-S239, 2011.

35. Budiman-Mak E, Conrad KJ, Mazza J, Stuck RM. A review of the foot function index and the foot function index – revised. *J Foot Ankle Res.* 6(1):5, 2013.

36. Galli MM, Brigido SA, Protzman NM. Pinning across the Metatarsophalangeal Joint for Hammertoe Correction: Where Are We Aiming and What Is the Damage to the Metatarsal Articular Surface? *J Foot Ankle Surg.* 53(4):405-410, 2014.

37. Konkel KF, Sover ER, Menger AG, Halberg JM. Hammer toe correction using an absorbable pin. *Foot Ankle Int. 32(10):973-978, 2011.*

38. Ford TC, Maurer LM, Myrick KW. Cortical bone pin fixation: a preliminary report on fixation of digital arthrodesis and distal chevron first metatarsal osteotomies. *J Foot Ankle Surg.* 41(1):23-29, 2002.

39. Angirasa AK, Barrett MJ, Silvester D. SmartToe implant compared with Kirschner wire fixation for hammer digit corrective surgery: a review of 28 patients. *J Foot Ankle Surg.* 51(6):711-713, 2012.

40. Brutus JP, Palmer AK, Mosher JF, Harley BJ, Loftus JB. Use of headless compressive screw for distal interphalangeal joint arthrodesis in digits: clinical outcome and review of complications. *J Hand Surg.* 31:85-89, 2006.

41. Lane GD. Lesser digital fusion with a cannulated screw. *J Foot Ankle Surg.* 44(2):172-173, 2005.

42. Caterini R, Farsetti P, Tarantino U, Potenza V, Ippolito E. Arthrodesis of the toe joints with an intramedullary cannulated screw for correction of hammertoe deformity. *Foot Ankle Int.* 25(4):256-261, 2004.

43. IPP-ON Interphalangeal Implant. Surgical Technique Product Guide. Integra Life Sciences Corporation, Lyon, France. 2006.

44. Parker MJ, Handoll HH. Osteotomy, compression and other modifications of surgical techniques for internal fixation of extracapsular hip fractures. *Cochrane Database Syst Rev.* Apr 15, 2009.

45. Pietrzak WS, Leesek TP, Perns SV. A bioabsorbable fixation implant for use in proximal interphalangeal joint (hammer toe) arthrodesis: Biomechanical testing in a synthetic bone substrate. *J Foot Ankle Surg.* 45(5):288-294, 2006.

46. Holton A, Walsh E, Anayiotos A, Prohost G, Venugopalan R. Comparative MRI Compatability of 316L Stainless Steel Alloy and Nickel – Titanium Alloy Stents. Department of Biomedical Engineering, University of Alabama at Birmingham, 1075 13th Street South, Hoehn 370, Birmingham, AL.

47. McGeachie J, Smith E, Roberts P, Grounds M. Reaction of skeletal muscle to small implants of titanium or stainless steel: a quantitative histological and autoradiographic study. *Biomaterials.* 13(8):562-568, 1992.

48. Geetha M, Singh AK, Asokamani R, Gogia AK. Ti based biomaterials, the ultimate choice for orthopaedic implants – A review. *Progress in Materials Science*. 54:397-425, 2009.

49. Muller M, Allgower M, Schneider R, Willenegger H: *Manual of Internal Fixation.* New York, Springer-Verlag, 1991, pp. 1-426.

50. McGlamry E, Jimenez LA, Green DR. Lesser Ray Deformities, *McGlamry's Comprehensive Textbook of Foot and Ankle Surgery*, Third Edition, Chap. 9, Part 1: pp. 284-285, Lippincott Wiliams & Wilkins, 2001.

51. Piska M, Yang L, Reed M, Saleh M. Drilling efficiency and temperature elevation of three types of Kirschner-wire point. *J Bone Joint Surg Br*. 84-B(1):137-140, 2002.

52. Fincham BM, Jaeblon T. The Effect of Drill Bit, Pin, and Wire Tip Design on Drilling. *J Am Acad Orthop Surg*. 19(9):574-579, 2011.

53. Ray RG. Methods of Osseous Fixation: Principles of Internal Fixation, *McGlamry's Comprehensive Textbook of Foot and Ankle Surgery*, Third Edition, Chap. 4 Part 1: pp. 72-73, Lippincott Wiliams & Wilkins, 2001.

54. Roman SR. Comparing Kirschner Wire Fixation To A New Device Used for Proximal Interphalangeal Fusion. *Podiatry Institute Update 2011. Chapter 30, pp. 148-153.*

55. Pinney S, Glazebrook M, Baumhauer J, Thordarson DB, Richter M. SYMPOSIUM. Evidence-Based Medicine: What Is It And How Should It Be Used? *Foot Ankle Int.* 31(11):1033-1042, 2010.

56. Hunt KJ, Hurwit D. Use of patient-reported outcome measures in foot and ankle research. *J Bone Joint Surg Am.* 95(16):e118(1-9), 2013.

57. Zaidi R, Abbassian A, Cro S, Guha A, Cullen N, Singh D, Goldberg A. Levels of evidence in foot and ankle surgery literature: progress from 2000 to 2010? *J Bone Joint Surg Am.* 94(15):e1121-10, 2012.