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ORTHOPAEDIC SURGERY

The efficacy of an intramedullary nitinol implant in the correction of claw toe or hammertoe deformities

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Abstract

Introduction A multitude of procedures has been described in the literature for the treatment of lesser toe deformities and there is currently no general consensus on the optimal method of fixation. The aim of this study is to assess the clinical and radiological outcomes of an intramedullary nitinol implant for the correction of lesser toe deformities, and to determine if the distal interphalangeal (DIP) joint and metatarsophalangeal (MTP) joint are modified during patient follow-up after correction of the PIP joint.

Materials and methods A prospective analysis of 36 patients with claw toe or hammertoe who were treated with an intramedullary nitinol implant. Clinical manifestations and angulation of the metatarsophalangeal, proximal and distal interphalangeal (MTP, PIP, DIP) joints were evaluated in radiographic studies preoperatively, at first medical revision post-surgery, and after a minimum of 1 year of follow-up. Complications such as non-union rate, implant rupture, and implant infection were also evaluated during follow-up.

Results All patients were women with an average age of 65.5 (range 47–82) years. The average follow-up time was 2.4 (range 1–5.7) years. Fifty intramedullary nitinol implants were used. The MTP joint extension and PIP joint flexion decreased by 15.9° (95% CI – 19.11 to – 12.63) and 49.4° (95% CI – 55.29 to – 43.52), respectively, at the end of follow-up. Moreover, the DIP joint flexion increased progressively during follow-up (13.7° pre-surgery versus 35.6 in last medical check-up, 95% CI 13.24–30.57). There were four (8%) asymptomatic implant ruptures. The rate of fusion was 98%.

Conclusion The reduction of the PIP joint using an intramedullary nitinol implant is a good option in lesser toe deformities, with few complications and a high rate of arthrodesis. Moreover, the PIP joint reduction affects both the MTP and DIP joints.

Keywords Hammertoe · Claw toe · Arthrodesis · Smart-Toe® · Intramedullary implant · Forefoot disorders

Introduction

Lesser toe deformities are one of the most frequent pathologies of the forefoot. The incidence of claw toe or hammertoe varies between 20 and 30% [1–3]. Females are affected more often than males [4]. The second toe is the one most frequently affected, although the other toes may also be damaged [5]. The deformity occurs owing to an imbalance of the intrinsic and extrinsic musculature [6, 7].

The treatment can be conservative, in the form of advice about footwear, taping, non-steroidal anti-inflammatory drugs (NSAIDs) or silicone gel pads [8]. When conservative measures fail, surgical treatment is indicated. There are different surgical techniques available, such as soft-tissue procedures (soft-tissue release, Z-lengthening, tenotomies and tendon transfers) or bone procedures (Weil osteotomy, partial proximal hemiphalangectomy, forefoot arthroplasty

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or arthrodesis). When the objective is to achieve arthrodesis, although a multitude of procedures has been described in the literature [8–11], there is currently no general consensus on what the optimal method of fixation to use is [3].

The objective of any implant is to maintain alignment and stability at the point of the fusion [2]. The most widely recommended fixation method is Kirschner wire (K-wire) [12]. However, this method is not free from complications, such as pin-track infection [13–15], phalanx rotation, recurrence of deformity [16, 17], K-wire migration, delay of consolidation secondary to lack of compression, pain when K-wires are removed [15, 17] and K-wire rupture [16–18]. For these reasons, different intramedullary devices have been developed to reduce the complications reported with use of K-wires [7, 14, 19–24].

The objective of this study is threefold: (1) to evaluate the efficacy of using Smart-Toe® to correct the proximal interphalangeal (PIP) joint in hammertoe and claw toe deformity. (2) To assess the secondary complications arising when using the Smart-Toe® implant. (3) To determine if the distal interphalangeal (DIP) joint and metatarsophalangeal (MTP) joint are modified during patient follow-up after correcting the PIP joint.

Our hypothesis is that intramedullary fixation using the Smart-Toe® implant may offer a high rate of fusion with few complications.

Methods

Patients

A prospective study was performed. Ethical approval was obtained from the Regional Ethical Review Board at our institutions (reference code, 2018.079). All patients, before participating, gave written consent to take part in this study after receiving full oral and written information.

Our cohort consisted of 36 participants (41 feet, 22 right and 19 left) who had been treated for a symptomatic hammertoe or claw toe with PIP joint fusion with a Smart-Toe® implant over the period April 2013–October 2018. The senior author performed all the procedures. The demographic parameters are shown in Table 1.

Recruitment criteria were: patients over 18 years old, failure of conservative treatment, symptomatic claw toes or hammertoes treated with Smart-Toe® implant in PIP joint, a minimum of 1-year follow-up and other techniques (scarf osteotomy or akin osteotomy) were included when lesser toe deformities were associated with hallux valgus. Some patients were excluded if the patient had a previous history of surgery on lesser toes, if the patient had an active local infection, claw toes or hammertoes previously treated with K-wire and if the follow-up was less than 1 year.

Table 1 Demographic parameters

	Overall
Gender	
Female (%)	36 (100)
Age (range)	65.5 (47–82)
Side	
Right (%)	22 (53.7)
Left (%)	19 (46.3)
Time between surgery to first medical review, days (range)	46.5 (37–76)
Time between surgery to last medical review, years (range)	2.4 (1–5.7)
Hallux valgus	
No (%)	14 (34.2)
Yes (%)	27 (65.8)

Subjects were identified and recruited from the outpatients department. The diagnosis of lesser toe deformities was made by physical examination and X-rays (anteroposterior and lateral view with weightbearing). *Hammertoes* (Fig. 1a) were defined as a persistent flexion of PIP joint with or without DIP joint involvement. Claw toes (Fig. 1b) were defined as a rigid extension of the MTP joint with a persistent flexion of the PIP and DIP joints. Mallet toe (Fig. 1c) was described as neutral PIP joint with a continuous flexion of DIP joint. Follow-up was performed at 1–3 months post-surgery and a minimum of 1-year post-surgery. X-rays were taken at each visit.

Smart-Toe® device

The Smart-Toe®(Stryker Osteosynthesis, Selzach, Switzerland) device is an intramedullary monoblock implant made of an alloy of 50% nickel and 50% titanium. The implant has two distal legs, a central body and two proximal legs that are longer than the distal legs. The composition of the implant gives a memory effect that consists of an expansion of the proximal and distal legs when it passes from 0 to 30 ºC. This effect causes a decrease in length of the implant which results in compression at the arthrodesis site. The design of the implant prevents the rotation between the phalanges that we want to fuse. There are two types of implants, Smart-Toe®-straight (0° of plantarflexion) and Smart-Toe®-angled (10º of plantarflexion). Furthermore, it is available in different sizes (15–22 mm) which we chose according to the dimensions of the proximal phalanx and middle phalanx of the fingers of each patient. Regarding angulation, we selected implants-angled when the deformity was severe and implant-straight when the deformity was mild or moderate.

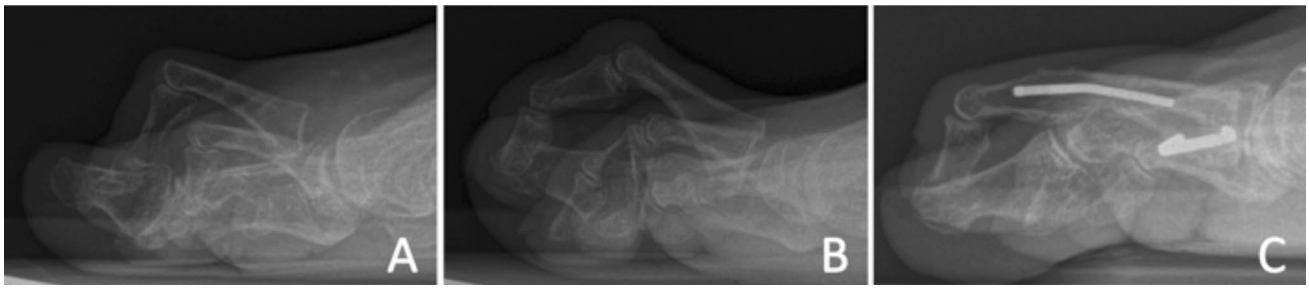

Fig. 1 Lateral X-rays that show different toe deformity. **a** Hammertoe deformity. **b** Claw toe deformity. **c** Mallet toe deformity

Surgical technique

The same surgical technique for correction of lesser toe deformity was performed in all cases. If the patient required other techniques such as scarf osteotomy, akin osteotomy or Weil osteotomy, we performed them during the same operation. We performed scarf osteotomy and akin osteotomy when the patient had hallux valgus deformity. Weil osteotomy with screw fixation (twist off screw, Biomet Trauma, Indiana, USA) was performed when the patient had metatarsal pain.

The patient was positioned in the supine position under general anesthesia. We used antibiotic prophylaxis according to the standard protocol established by the Infectious Disease Department of our center (2 g Cefazolin preoperatively and three doses after surgery every 8 h).

Before skin incision, an Esmarch bandage was used as a tourniquet around the ankle at 250 mmHg to exsanguinate the foot. We approached the site with a dorsal incision over the PIP joint. Then, the extensor digitorum longus tendon was incised longitudinally, later, a dorsal capsulotomy was performed that exposed the PIP joint. After that, we dislocated the PIP joint and we separated very carefully the collateral ligaments. A minimal osteotomy with excision of the articular surfaces was done with an oscillating saw. A 2 mm drill was used to make the entry points in each phalanx. We introduced the broach manually in each phalanx to create the site for the implant. To remove the Smart-Toe® from its support, we used a forceps. Initially, we had to insert the oblong-shaped side of the implant in the proximal phalanx until the forceps touched the phalanx. Next, we manually reduced the middle phalanx over the distal legs of the implant. The forceps must stay engaged until the middle phalanx is partially reduced over the implant. We removed the forceps and manually compressed the joint for approximately 1 min. Finally, we sutured the extensor digitorum longus tendon. The skin was closed with simple stitches. As the reduction was adequate, we did not perform additional surgical procedures such as capsular release or flexor tenotomy.

Postoperative care

All patients received thromboprophylaxis with low molecular weight heparin (3500 UI Bemiparin Hibor®) for 30 days after surgery. The patients spent the postoperative night in the hospital with the operated limb elevated, local cold and non-steroidal anti-inflammatory drugs. Patients were discharged on the first day after surgery, and allowed to mobilize and weightbearing as tolerated with the use of a postoperative rigid-sole shoe. Two weeks post-surgery, the sutures were removed. A postoperative shoe was used for 6 weeks after surgery.

Radiological outcomes

A weightbearing anteroposterior view was used to evaluate the arthrodesis of the PIP and signs of implant rupture or migration. The lateral view with weightbearing was used to measure three angles (flexion of DIP and PIP joint and extension of MTP joint). (1) DIP joint angle was designated as the angle between the distal phalanx and the middle phalanx (Fig. 2a). (2) PIP joint angle was determined as the angle between the middle phalanx and the proximal phalanx (Fig. 2b). (3) MTP joint angle was defined as the angle between the proximal phalanx and the metatarsal (Fig. 3). These angles were measured with the OsiriX v5.6 32-bit program during the pre-surgical period, at 1–3 months post-surgery and at the last medical checkup.

Complications

Complications were evaluated at 1–3 months post-surgery and at the last medical checkup (minimum follow-up of 1 year). We analyzed the clinical records for wound infection, implant mobilization, revision surgery, osteolysis around the implant, implant rupture, non-union, pain, wound healing and mallet toe after PIP arthrodesis. Wound infection was defined using the STONEES criterion [25]. Implant mobilization was measured by comparing the X-rays from the last medical revision versus 4–6 weeks post-surgery.

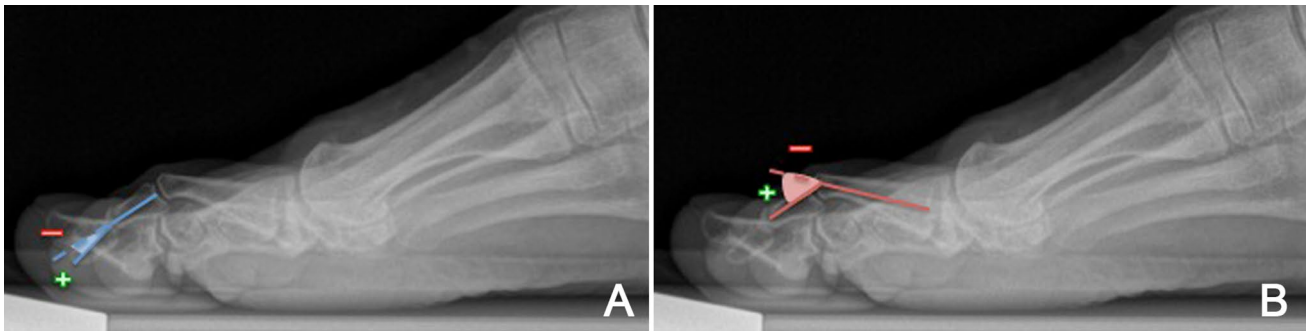

Fig. 2 Lateral X-rays showing two different angles. **a** DIP joint angle was defined as the angle between distal phalanx and middle phalanx. **b** PIP joint angle was defined as the angle between middle phalanx and proximal phalanx. Positive is defined when the joints are in flexion with respect to the diaphysis line of proximal bone. Negative is defined when the joints are in extension with respect to the diaphysis line of proximal bone

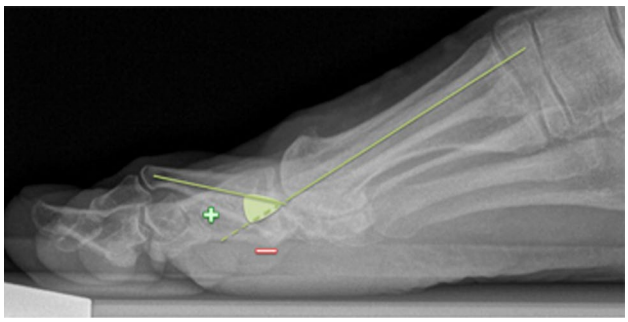

Fig. 3 Lateral X-ray showing the metatarsophalangeal joint angle, defined as the angle between proximal phalanx and metatarsal. Positive is defined when the joint is in extension with respect to the diaphysis line of proximal bone. Negative is defined when the joints are in flexion with respect to the diaphysis line of proximal bone

Osteolysis around the implant was described in the X-ray studies as a loss of bone around the implant. Non-union was described radiologically as a defect of union amounting to more than 50% in the anterior–posterior or lateral view.

Data statistical analysis

We could not estimate the appropriate sample size because previous studies, in which the Smart-Toe® implant was used [7, 19, 22], did not specifically study changes in the PIP joint. Therefore, we performed a statistical analysis of the power of our results analyzing change in the PIP joint according to the type of deformity, the type of implant used and the performance or not of the Weil osteotomy.

Descriptive statistics were obtained for the sample. The Shapiro–Wilk test confirmed the normal distribution of the variables. We used the paired sample *t* test to analyze differences between angulations of DIP, PIP, or MTP joints at the different times during follow-up. In addition, we analyzed the change in DIP, PIP, or MTP joint angulation using Student's *t* test according to reducibility of the deformity, Weil osteotomy, type of implant (straight or angled) or type of deformity (hammertoe or claw toe) at the different follow-up appointments. We used the Chi squared test to assess if there were associations between the lesser toe deformities treated with the mallet toe post-surgery.

A 0.05 level of probability was accepted as the criterion for statistical significance for all statistical tests. Confidence intervals were calculated, when possible, indicating a confidence level of 95%. All statistical tests were carried out using Stata software 12.0 version for Macintosh (Data Analysis and Statistical Software, Texas, USA).

Results

The mean age was 65.5 (range 47–82) years. All patients (36) were female (Table 1). Fifty Smart-Toe® implants were used, 36 (72%) in the second toe, 7 (14%) in the third toe, and 7 (14%) in the fourth toe (Table 2). Fifty-eight percent (29/50) were claw toes and 42% (21/50) were hammertoes. In 65.8% of the cases, the patients were also treated for hallux valgus (Table 1).

The average follow-up period between surgery and the first medical checkup was 46.5 (range 37–76) days and that from surgery to last medical checkup was 2.4 (range 1–5.7) years (Table 1). Table 2 shows detailed information for each toe treated. In second toe, there was a similar distribution in the type of implants used (50% Smart-Toe®-straight and 50% Smart-Toe®-angled). In third and fourth toe, we used more angled implants (5) than straight implants (2), respectively. The length of the implant used most in the second toe was 19 mm (49.5%) and 16 mm (39%), in the third toe it was 19 mm (57%) and the fourth toe it was 16 mm (57%).

At the end of follow-up, in the PIP joint, we observed a reduction of 49.4° (67.9° before surgery versus 18.5° in the last medical checkup post-surgery, 95% CI – 55.29 to

Table 2 Detailed information about each toe

	2nd toe	3th toe	4th toe	5th toe
Lesser toe deformity				
Claw toe (%)	21 (58.3)	4 (57.1)	4 (57.1)	
Hammertoe (%)	15 (41.7)	3 (42.9)	3 (42.9)	
Weil osteotomy				
No (%)	24 (66.6)	5 (71.4)	6 (85.7)	
Yes (%)	12 (33.4)	2 (28.6)	1 (14.3)	
Number of implants	36	7	7	0
Type of implant used				
Straight (%)	18 (50)	2 (28.6)	2 (28.6)	
Angled (%)	18 (50)	5 (71.4)	5 (71.4)	
Implant length used				
15 mm (%)	1 (3)	0 (0)	3 (43)	
16 mm (%)	14 (39)	3 (43)	4 (57)	
19 mm (%)	18 (49.5)	4 (57)	0 (0)	
20 mm (%)	2 (5.5)	0 (0)	0 (0)	
21 mm (%)	1 (3)	0 (0)	0 (0)	

– 43.52). Most of this reduction was obtained at 1–3 months post-surgery (Table 3). When we focused on the type of lesser toe deformities, we found that the PIP joint was corrected more in patients with hammertoe than patients with claw toe at 1–3 months post-surgery (51.5° versus 44°, respectively, 95% CI – 41.17 to 19.18, Table 4). However, during follow-up, we obtained a similar correction in the PIP joint when we used straight or angled implants (48.1° versus 46.4°, respectively, 95% – 13.47 to 10.13, Table 4). On the other hand, the PIP joint improved more when we did not perform the Weil osteotomy, although we found no statistical differences (Table 4).

After surgery, there was a progressive increase in DIP joint flexion (Table 3). This increase occurred more in patients with claw toes than in patients with hammertoes and in those patients when Weil osteotomy was not performed (Table 4). We found an association between patients with claw toe and the risk of developing mallet toe post-surgery ($p = 0.021$, Chi squared test). The type of implant used did not seem to affect the increase in DIP joint flexion (Table 4).

The correction of claw toes or hammertoes produced a decrease in MTP joint extension 1–3 months after surgery, the difference with respect to the pre-surgical moment being 15.1° (31.2° versus 46.3°, respectively, 95% CI – 18.21 to – 12.01, Table 3). This correction was maintained throughout follow-up (Table 3). In contrast, the correction of the MTP joint extension did not differ with

Table 3 Overall changes between each time

Comparison between first medical revision[a] post-surgery versus pre-surgery				
	Pre-surgery	First medical revision[a]	DIF[b]	95% CI[c]
DIP[d]	13.7	20.5	6.8	0.25 to 13.48*
PIP[e]	67.9	20.8	– 47.1	– 52.96 to -41.35*
MTP[f]	46.3	31.2	– 15.1	– 18.21 to – 12.01*
Comparison between last medical revision[g] versus first medical revision[1]				
	First medical revision[1]	Last medical revision[g]	DIF[b]	95% CI[c]
DIP[d]	20.5	35.6	15.1	10.75 to 19.32*
PIP[e]	20.8	18.5	– 2.24	– 4.68 to 0.18
MTP[f]	31.2	30.4	0.8	– 3.68 to 2.15
Comparison between last medical revision[g] versus pre-surgery				
	Pre-surgery	Last medical revision[g]	DIF[2]	95% CI[c]
DIP[d]	13.7	35.6	21.9	13.24 to 30.57*
PIP[e]	67.9	18.5	– 49.4	– 55.29 to – 43.52*
MTP[f]	46.3	30.4	– 15.9	– 19.11 to – 12.63*

*Statistical significance ($p < 0.05$)

[a]This period alludes at 46.5 (range 37–76) days of follow-up

[b]Difference between periods

[c]Confidence interval of 95%

[d]Distal interphalangeal

[e]Proximal interphalangeal

[f]Metatarsophalangeal

[g]This period time alludes at 2.4 (range 1–5.7) years of follow-up

Table 4 Overall changes between each time regarding deformity, type of implant, and Weil osteotomy

Deformity	Difference between first medical revision[a] versus pre-surgery				Difference between last medical revision[b] versus first medical revision[a]				Difference between last medical revision[b] versus pre-surgery			
	Claw toe (*N* = 29)	Hammertoe (*N* = 21)	DIF3	95% CI [d]	Claw toe (*N* = 29)	Hammertoe (*N* = 21)	DIF[c]	95% CI[d]	Claw toe (*N* = 29)	Hammertoe (*N* = 21)	DIF[c]	95% CI[d]
DIP[e]	13.5	– 2.3	15.8	3.12–28.6*	20.3	7.77	12.5	4.55–20.5*	33.8	5.4	28.3	12.67–44.11*
PIP[f]	– 44	– 51.5	7.5	– 4.17 to 19.18	– 3.3	– 0.6	– 2.7	– 7.61 to 2.22	– 47.3	– 52.1	4.8	– 7.17 to 16.78
MTP[g]	– 15.7	– 14.1	– 1.6	– 7.92 to 4.72	– 2.5	1.7	2.91	– 10.09 to 1.60	– 18.3	– 12.4	– 5.8	– 12.27 to 0.57
Type of implant	Straight (*N* = 22)	Angled (*N* = 28)	DIF[3]	95% CI[d]	Straight (*N* = 22)	Angled (*N* = 28)	DIF[c]	95% CI[d]	Straight (N = 22)	Angled (*N* = 28)	DIF[c]	95% CI[d]
DIP[e]	5.5	8	– 2.5	– 15.89 to 11	18.1	12.6	5.5	– 3.01 to 14.12	23.6	20.5	3.1	– 14.51 to 20.73
PIP[f]	– 48.1	– 46.4	– 1.7	– 13.47 to 10.13	– 3	– 1.7	– 1.3	– 6.19 to 3.69	– 51	– 48.1	– 3	– 14.88 to 9.04
MTP[g]	– 16.6	– 14	– 2.6	– 8.97 to 3.54	0.0	– 1.34	1.34	– 4.61 to 7.25	– 16.6	– 15.3	– 1.3	– 7.98 to 5.19
Weil osteotomy	No (*N* = 35)	Yes (*N* = 15)	DIF[c]	95% CI[d]	No (*N* = 35)	Yes (*N* = 15)	DIF[3]	95% CI[d]	No (*N* = 35)	Yes (*N* = 15)	DIF[c]	95%IC[d]
DIP[e]	10.4	– 1.4	11.8	– 2.35 to 26.01	14.8	15.6	– 0.8	– 10.24 to 8.64	25.2	14.2	11	– 7.82 to 29.86
PIP[f]	– 49	– 42.7	– 6.3	– 18.98 to 6.35	– 2.4	– 2	– 0.4	– 5.81 to 4.92	– 51.4	– 44.7	– 6.7	– 19.6 to 6.07
MTP[g]	– 16	– 13.2	– 2.7	– 9.49 to 4.08	0.0	– 2.5	2.5	– 3.92 to 8.87	– 16	– 15.7	– 0.3	– 7.38 to 6.92

*Statistical significance ($p < 0.05$)

[a]This period alludes at 46.5 (range 37–76) days of follow-up

[b]This period time alludes at 2.4 (range 1–5.7) years of follow-up

[c]Difference between periods

[d]Confidence interval of 95%

[e]Distal interphalangeal

[f]Proximal interphalangeal

[g]Metatarsophalangeal

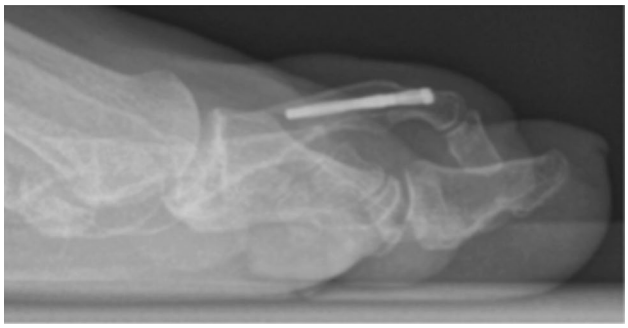

Fig. 4 Dorsal cortical erosion in middle phalanx after PIP joint arthrodesis

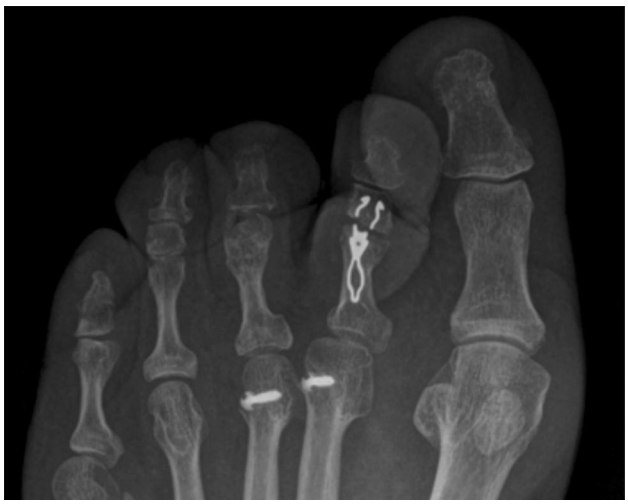

Fig. 5 Distal leg rupture of Smart-Toe® implant that caused non-union in PIP joint

the type of deformity in lesser toes (claw toe or hammer toe), the type of implant used (straight or angled) or Weil osteotomy (Table 4).

At the end of the follow-up, there was no wound infection, no implant infection, no implant mobilization, no revision surgery, no problems with wound healing (two patients developed keloid at 1–3 months post-surgery) and no chronic pain. In only one case, we found erosion in the dorsal cortical of the middle phalanx after arthrodesis, but it was asymptomatic (Fig. 4). There was a rate of 8% (4/50) asymptomatic implant ruptures. Of those, one occurred during surgery in the distal implant leg and three occurred during the follow-up. Only in one toe (2%) was the PIP arthrodesis not achieved, but the patient did not develop symptoms (Fig. 5). In the rest, fusion was achieved (98%). In 70% of the lesser toe deformities operated on, a mallet toe deformity developed (Fig. 1c), but this was asymptomatic.

The results of the power analysis for the change in the PIP joint according to the type of deformity was 96%, for the type of implant used was 66% and for the performance or not of the Weil osteotomy was 99%.

Discussion

The clinical relevance of the present study is that the Smart-Toe® implant corrected the lesser toe deformities and that there was a progressive increase in the DIP joint flexion and a decrease in the MTP joint extension during follow-up. The correction in PIP joint remained, with 2.4 (range 1–5.7) years as the average follow-up. The satisfaction rate after surgery was high, and arthrodesis occurred in all patients except in one case and none of the patients reported problems related to function.

Currently, there are no official guidelines available to assist clinicians in determining the optimal implant for the treatment of claw toes or hammertoes [3]. Since 1940 [12], the use of K-wires has been recommended to correct the PIP joint deformity. Although K-wires do not provide compression in the joint or control the phalanx rotation, a satisfactory result is obtained. Coughlin et al. [9] studied a total of 118 cases of PIP joint fusion with K-wires, in which 81% bone fusion, 92% pain relief and 84% patient satisfaction were achieved.

However, to reduce complications, reduce patient anxiety when the K-wire has to be removed, and achieve a higher rate of arthrodesis, different intramedullary implants have been developed [7, 11, 20, 21, 26, 27], including the Smart-Toe® device [7, 19, 22–24, 28]. These intramedullary implants seem to result in greater patient satisfaction and greater alignment of the arthrodesis than when using K-wire [21] because there is no exterior implant communication or disruption of DIP joint, no compression at the site of fusion, no phalanx rotational control, and no discomfort at the moment of K-wire removal.

In the literature reviewed, the Smart-Toe® implant is reported to produce good results in terms of PIP joint arthrodesis and patient satisfaction [7, 19, 22–24, 28]. Khan et al. [22] studied 82 patients during 6 months of follow-up. They observed 96.3% of arthrodesis with few complications and with good patient satisfaction. Roukis et al. [28] analyzed 30 Smart-Toe® implants in patients with diabetes and peripheral neuropathy with a follow-up of 10.2 months, and they observed that the arthrodesis occurred in 93% of the toes. Sandhu et al. [24] analyzed 65 Smart-Toe® implants with a mean follow-up of 27 months and observed fusion in 93.8% of cases. Our results were better than those described previously. After an average follow-up of 2.4 (range 1–5.7) years, we obtained an arthrodesis rate of 98%. Unlike these authors [22, 24, 28], we determined by how many degrees the deformity was corrected and how this correction changed according to the type of deformity that the patient presented

(claw toe or hammertoe). At 1–3 months post-surgery, we obtained a correction of 47.1° in the PIP joint, an increase of 6.8° in DIP joint flexion and a reduction of 15.1° in MTP joint extension (Table 3). These changes in PIP and MTP joints were maintained during follow-up. However, we have to advise patients that it is possible to develop a mallet toe because the DIP joint increased progressively during follow-up, and that in patients treated for claw toes, the DIP joint increases more than those treated for hammertoes (33.8° versus 5.4°, respectively, at the end of follow-up, Table 4).

Angirasa et al. [19] and Obrador et al. [23] compared the temporary fixation using K-wire with the Smart-Toe® implant. Angirasa et al. [19] studied 28 patients (15 patients treated with K-wire and 13 patients treated with Smart-Toe®) during a 6-month follow-up period. They observed that patients in whom K-wires were used had more pain, lower patient satisfaction, experienced a longer delay before returning to their daily activities, and had a lower rate of arthrodesis and a greater number of complications than in those cases in which the Smart-Toe® was used. Obrador et al. [23] obtained similar results to Angirasa et al. [19] and concluded that although intramedullary implants are more expensive than K-wires, they provide good alignment, pain reduction, and improved function at final follow-up.

As far as we know, this is the first study in the literature that has evaluated the change in the DIP, PIP and MTP joint according to the type of deformity (claw toe or hammertoe) and the type of implant used (straight or angled implant). Normally, the studies focus on whether arthrodesis is achieved, and on complications and patient satisfaction [7, 19, 22–24, 28]. Our result showed that the PIP joint was corrected in the hammertoes more than in the claw toes at 1–3 months post-surgery (52.5° versus 44°, 95% CI – 4.17 to 19.18), and that the Weil osteotomy did not imply statistically significant changes in the DIP, PIP and MTP joints (Table 4).

The use of the Smart-Toe® implant is not without complications, although these are usually less severe than when using K-wires [16, 19]. Angirasa et al. [19] did not report any complications when the Smart-Toe® implant was used. In contrast, they had 8 complications in 15 patients treated with K-wires. Khan et al. [22] describe this treatment in 82 patients, with persistent swelling in 8.5%, non-union in 3.7%, superficial infection and implant failure in 1.2%, respectively, and implant rupture in 2.4%. After 65 Smart-Toe® operations, Sandhu et al. [24] report rates of 6.2% non-union, 3% implant rupture and 1.5% implant migration. Roukis et al. [28] obtained, in 30 cases using Smart-Toe®, 7% of non-union and 7% malunion. Obrador et al. [23] observed rates of 10.6% implant rupture, 7.4% wound complications and 6.4% surgical revision. In our results, we found no wound infection, implant mobilization, chronic pain or revision surgery. Eight percent of patients (two patients) developed keloid in the surgical wound. However, this complication does not depend on the implant or the surgical technique. A dorsal erosion of bone cortex was found in 2% (1/50) of Smart-Toe® implants used (Fig. 4). Non-union (Fig. 5) happened in 2% (1/50), but the patient did not develop symptoms. Implant ruptures occurred in four cases (8%). Of these, two (50%) were in proximal legs (19-mm straight, Fig. 6, and 20-mm straight Smart-Toe® implant) and two (50%) were in distal legs (16-mm angled Smart-Toe® implant, Fig. 5). By contrast, Obrador et al. [23] and Khan et al. [22] found that the most frequent implant rupture (33.4%) was in the proximal thinner legs of the implant. Scholl et al. [7] suggested that a possible reason for the breakage of Smart Toe® might be incorrect implantation, malposition of the implant or mistaken implant selection.

Lehman et al. [29] observed a mallet toe in up to 40% of cases following PIP fusion performed for a hammertoe. We found a higher rate of mallet toe deformity (70%) but these cases were asymptomatic. Mallet toe might occur because the initial deformity causes a retraction of the flexor tendons of the lesser toes which, after correction of the deformity in the PIP joint, causes a stretching of the flexor tendons that produces a persistent flexion deformity of the DIP joint. Maybe, additional surgical procedures such as flexor tenotomy or capsule release might be indicated in the surgical moment or during the follow-up.

The fact that Smart-Toe® device is made of an alloy of 50% nickel and 50% titanium, is important for an allergic cohort. However, there is no generally established guide. Granchi et al. [30] performed a meta-analysis that evaluated the benefit of metal hypersensitivity tests in patients before an intervention where a surgical implant was used. They

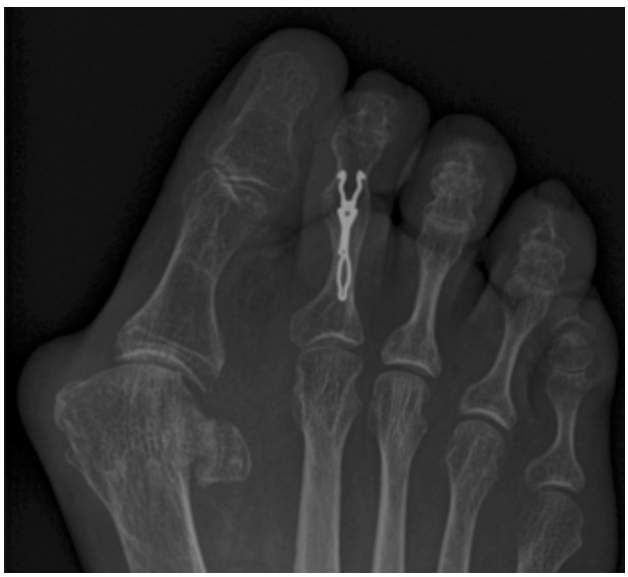

Fig. 6 Proximal leg rupture of Smart-Toe® implant

concluded that the hypersensitivity tests did not show any predictive value for the positive or negative results of the screening tests.

Sensitivity to metals (nickel, cobalt or chromium) is higher in patients with rejection of the implant than in a patient where the implant does not produce an alteration (60% versus 25%, respectively) [31], but is not known whether this phenomenon is a cause or an effect. Lohmann et al. [32] do not recommend the use of predictive tests as a standardized screening tool for all patients where a surgical implant is to be used. This would imply unnecessary expenses and positive results in asymptomatic patients. The diagnosis of metal allergy before implantation did not result in an increased risk of implant failure or revision surgery [33]. On the other hand, titanium is known for its excellent biocompatibility and reports on clinical allergy and adverse events have rarely been published [34].

In general, symptoms mainly exhibit within the first postoperative year after primary implantation. However, we did not have, after 2.4 (range 1–5.7) years of follow-up, symptoms or radiological findings that could make us think about a rejection of the implant.

According to the literature published and the results reported about the Smart-Toe® implant. This implant is well tolerated and it would not be advisable to perform nickel and titanium hypersensitivity tests before its implantation in any patient. Only in those cases in which the patient states that he has allergy to nickel or titanium, we should perform hypersensitivity tests, use another implant or warn of a possible rejection of the implant.

The outcomes in our cohort should be interpreted with some caution due to the potential limitations of this study. (1) We did not measure in the immediate postoperative the deformity correction. Despite the most of the correction is obtained intraoperatively, the complete function of the implant is achieved when joint fusion occurs (fibrous or bony bridge). For this reason, we measured the total effect of the implant in the PIP joint between the first and third postoperative month. (2) Functional results were not measured with a self-report score because they were usually associated with other procedures and, therefore, these scores could be biased. (3) We analyzed a relatively small sample size of Smart-Toe® implants. It would be advisable to study a greater number of implants to detect differences between them (straight or angled). In our results, there were no differences in the correction between the different types of implants due to the fact that we used the implant-angled when the deformity was severe and the implant-straight when the deformity was mild or moderate. This means that we do not completely reduce severe deformities and, therefore, we obtain a similar result when we compared it. (4) We did not perform a comparison with other implants. For this reason, a comparative study with others implant types and that evaluate the change in the DIP, PIP and MTP joints, it would be advisable to choose the optimal implant. (5) We did not performed a cost-effectiveness study that included the Smart-Toe® and K-wire implants, re-interventions and medical consultations. Therefore, more studies are required to assess the efficiency of each implant.

In summary, we recommend the use of implant-angled and that additional surgical procedures such as capsule release or flexor tenotomy should be performed intraoperative to avoid mallet toe. Regarding the size implant, it depends on the size of the phalanges. In general, we suggest using 19-mm implant in the second toe and 16–19 mm in the third toe and 15–16-mm implants in the fourth toe.

Conclusion

According to our results and the literature review, the K-wire and Smart-Toe® implants are a good option to reduce deformity in the proximal interphalangeal joint in claw toe or hammertoe deformities. The Smart-Toe® achieved good alignment of the toe, high rate of joint fusion with few complications and it produced an asymptomatic increase in the flexion of the distal interphalangeal joint and correction of extension in the metatarsophalangeal joints.

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Compliance with ethical standards

Conflict of interest Each author certifies that he or she has no commercial associations that might pose a conflict of interest in connection with the submitted article.

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References

1. Dunn JE, Link CL, Felson DT, Crincoli MG, Keysor JJ, McKinlay JB (2004) Prevalence of foot and ankle conditions in a multiethnic community sample of older adults. Am J Epidemiol 159:491–498
2. Golightly YM, Hannan MT, Dufour AB, Jordan JM (2012) Racial differences in foot disorders and foot type. Arthritis Care Res (Hoboken) 64:1756–1759. https://doi.org/10.1002/acr.21752
3. Schrier JC, Louwerens JW, Verheyen CC (2007) Opinions on lesser toe deformities among Dutch orthopaedic departments. Foot Ankle Int 28:1265–1270. https://doi.org/10.3113/FAI.2007.1265
4. Femino JE, Mueller K (2001) Complications of lesser toe surgery. Clin Orthop Relat Res 391:72–88
5. Canale ST (2003) Campbell's operative orthopaedics. Mosby, Philadelphia, p 4051
6. Marks R (1998) Anatomy and pathophysiology of lesser toe deformities. Foot Ankle Clin 3:199–213

7. Scholl A, McCarty J, Scholl D, Mar A (2013) Smart toe® implant versus buried Kirschner wire for proximal interphalangeal joint arthrodesis: a comparative study. J Foot Ankle Surg 52:580–583. https://doi.org/10.1053/j.jfas.2013.02.007
8. Chadwick C, Saxby TS (2011) Hammertoes/Claw toes: metatarsophalangeal joint correction. Foot Ankle Clin 16:559–571. https://doi.org/10.1016/j.fcl.2011.08.006
9. Coughlin MJ, Dorris J, Polk E (2000) Operative repair of the fixed hammertoe deformity. Foot Ankle Int 21:94–104
10. Edwards WH, Beischer AD (2002) Interphalangeal joint arthrodesis of the lesser toes. Foot Ankle Clin 7:43–48
11. Moon JL, Kihm CA, Perez DA, Dowling LB, Alder DC (2011) Digital arthrodesis: current fixation techniques. Clin Podiatr Med Surg 28:769–783. https://doi.org/10.1016/j.cpm.2011.07.003
12. Taylor RG (1940) An operative procedure for the treatment of hammertoe and claw-toe. J Bone Jt Surg 22:608–609
13. Herstik I, Pelletier JP, Kanat IO (1990) Pin tract infections. Incidence and management in foot surgery. J Am Podiatr Med Assoc 80:135–144
14. Jay RM, Malay DS, Landsman AS, Jennato N, Huish J, Younger M (2016) Dual-component intramedullary implant versus Kirschner wire for proximal interphalangeal joint fusion: a randomized controlled clinical trial. J Foot Ankle Surg 55:697–708. https://doi.org/10.1053/j.jfas.2016.03.017
15. Reece AT, Stone MH, Young AB (1987) Toe fusion using Kirschner wire. A study of the postoperative infection rate and related problems. J R Coll Surg Edinb 32:158–159
16. Klammer G, Baumann G, Moor BK, Farshad M, Espinosa N (2012) Early complications and recurrence rates after Kirschner wire transfixion in lesser toe surgery: a prospective randomized study. Foot Ankle Int 33:105–112. https://doi.org/10.3113/FAI.2012.0105
17. Kramer WC, Parman M, Marks RM (2015) Hammertoe correction with K-wire fixation. Foot Ankle Int 36:494–502. https://doi.org/10.1177/1071100714568013
18. Zingas C, Katcherian DA, Wu KK (1995) Kirschner wire breakage after surgery of the lesser toes. Foot Ankle Int 16:504–509
19. Angirasa AK, Barrett MJ, Silvester D (2012) SmartToe® implant compared with Kirschner wire fixation for hammer digit corrective surgery: a review of 28 patients. J Foot Ankle Surg 51:711–713. https://doi.org/10.1053/j.jfas.2012.06.013
20. Coillard J-Y, Petri GJ, van Damme G, Deprez P, Laffenêtre O (2014) Stabilization of proximal interphalangeal joint in lesser toe deformities with an angulated intramedullary implant. Foot Ankle Int 35:401–407. https://doi.org/10.1177/1071100713519601
21. Guelfi M, Pantalone A, Cambiaso Daniel J, Vanni D, Guelfi MG, Salini V (2015) Arthrodesis of proximal inter-phalangeal joint for hammertoe: intramedullary device options. J Orthop Traumatol 16:269–273. https://doi.org/10.1007/s10195-015-0360-0
22. Khan F, Kimura S, Ahmad T, D'Souza D, D'Souza L (2015) Use of Smart Toe(©) implant for small toe arthrodesis: a smart concept? Foot Ankle Surg 21:108–112. https://doi.org/10.1016/j.fas.2014.10.003
23. Obrador C, Losa-Iglesias M, Becerro-de-Bengoa-Vallejo R, Kabbash CA (2018) Comparative study of intramedullary hammertoe fixation. Foot Ankle Int 39:415–425. https://doi.org/10.1177/1071100717745854
24. Sandhu JS, De Carbo WT, Hofbauer MH (2013) Digital arthrodesis with a one-piece memory nitinol intramedullary fixation device: a retrospective review. Foot Ankle Spec 6:364–366. https://doi.org/10.1177/1938640013496458
25. Sibbald RG, Woo K, Ayello EA (2006) Increased bacterial burden and infection: the story of NERDS and STONES. Adv Skin Wound Care 19:447–461
26. Catena F, Doty JF, Jastifer J, Coughlin MJ, Stevens F (2014) Prospective study of hammertoe correction with an intramedullary implant. Foot Ankle Int 35:319–325. https://doi.org/10.1177/1071100713519780
27. Kominsky SJ, Bermudez R, Bannerjee A (2013) Using a bone allograft to fixate proximal interphalangeal joint arthrodesis. Foot Ankle Spec 6:132–136. https://doi.org/10.1177/1938640013480237
28. Roukis TS (2009) A 1-piece shape-metal nitinol intramedullary internal fixation device for arthrodesis of the proximal interphalangeal joint in neuropathic patients with diabetes. Foot Ankle Spec 2:130–134. https://doi.org/10.1177/1938640009336199
29. Lehman D, Smith R (1995) Treatment of symptomatic hammertoe with a proximal interphalangeal joint arthrodesis. Foot Ankle Int 16:535–541
30. Granchi D, Cenni E, Giunti A, Baldini N (2012) Metal hypersensitivity testing in patients undergoing joint replacement: a systematic review. J Bone Jt Surg Br 94:1126–1134. https://doi.org/10.1302/0301-620X.94B8.28135
31. Hallab N, Merritt K, Jacobs JJ (2001) Metal sensitivity in patients with orthopaedic implants. J Bone Jt Surg Am 83:428–436
32. Lohmann CH, Hameister R, Singh G (2017) Allergies in orthopaedic and trauma surgery. Orthop Traumatol Surg Res 103(1S):S75–S81. https://doi.org/10.1016/j.otsr.2016.06.021
33. Münch HJ, Jacobsen SS, Olesen JT, Menné T, Søballe K, Johansen JD et al (2015) The association between metal allergy, total knee arthroplasty and revision: study based on the Danish Knee Arthroplasty Register. Acta Orthop 86:378–383. https://doi.org/10.3109/17453674.2014.999614
34. Fage SW, Muris J, Jakobsen SS, Tyssen JP (2016) Titanium: a review on exposure, release, penetration, allergy, epidemiology and clinical reactivity. Contact Dermat 74(6):323–345. https://doi.org/10.1111/cod.12565