Ideal implant choice for proximal interphalangeal joint arthrodesis in hammer toe/claw toe deformity correction: A systematic review

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Abstract

Intramedullary devices have been developed to reduce the problems associated with Kirschner (K)-wire fixation in proximal interphalangeal joint (PIPJ) arthrodesis. The purpose of this systematic review is to compare the surgical outcomes of K-wires versus novel internal fixation devices in PIPJ arthrodesis in claw/hammer toe surgery. The databases searched were PubMed, Scopus, Cochrane, and Embase with keywords “claw toe OR hammer toe” AND “proximal interphalangeal OR PIP” AND “fusion OR arthrodesis.” Clinical trials published in English with evidence levels I, II, and III were included. Five studies, including one randomized controlled trial and four case-controlled studies, were identified to meet the inclusion criteria. Overall, the studies showed promising results in union rates using the novel internal devices compared to K-wires. However, the novel internal devices seem not to present advantages in clinical parameters such as pain levels, patient satisfaction, foot-related function, or surgical complication rates.

Keywords

arthrodesis, claw toe, forefoot, fusion, hammer toe, proximal interphalangeal joint

Introduction

Lesser toe deformities are a common forefoot problem that greatly hinders the quality of life.¹ Hammer toe and claw toe are the most common deformities with ambiguous definitions as they are frequently used interchangeably.² Both of the deformities are characterized by a plantar flexion deformity in the proximal interphalangeal joint (PIPJ). The discrimination between these two terms is based on whether deformity concurrently occurs in a metatarsal phalangeal joint,² as flexion deformity in PIPJ is the only criterion for hammer toe. Therefore, the correction in PIPJ is crucial in the management of patients with hammer toe.

The etiology of hammer toe has been discussed by various studies, including inefficiency of the plantar structures (i.e. intrinsic flexors, plantar aponeurosis, and joint capsule),³ neuromuscular disorders, unsuitable shoes, inflammatory arthropathies, and so on. Nonsurgical management is usually the first choice for most patients, with the aim of pressure relief in the affected area and protecting the prominence.⁴ Shoe modifications (e.g. with wide and high toe box and without high heels), orthoses and splints with well-positioned buildup, and metatarsal padding are the most commonly used nonoperative management.⁵,⁶ In spite of the temporary symptom relief, these methods are not able to correct the existing deformities,⁶ especially for rigid joints.
Surgical intervention is a well-accepted method to improve morphology and relieve pain in such deformity. Based on the pathological changes in the surrounding tissues and subsequent osseous deformity, various soft tissue and bony surgical procedures have been used to correct PIPJ deformity. PIPJ fusion is one of the most common procedures and has demonstrated comparatively good results with predictable toe alignment and lower recurrence rates. After preparing the articular surfaces, the construct needs to be stabilized by an implant to achieve bony fusion.

Axial Kirschner (K)-wires are often used due to its widespread availability and low cost. Complications of using axial K-wires in joint fixation may develop, including inconvenience, pin-track infection, wire migration, and hardware failure especially since there is no compression or rotational stabilization in axial K-wires. Several alternative options have appeared in recent years, such as the Smart Toe (Stryker Corporation), TenFuse (Wright Medical Group), StayFuse (Tornier), Hat-trick (Smith and Nephew), and HammerFix (Extremity Medical). These internal fixation methods aim to reduce K-wire complications and aim to achieve a higher level of patient satisfaction, pain control, and union rates.

Abundant evidence has indicated that internal fixation devices may provide good results in different postoperative outcomes. However, the high cost of these novel internal devices is one of the major reasons hindering more universal utilization. The purpose of this study is to compare the surgical outcomes of K-wire fixation versus novel internal fixation devices in PIPJ arthrodesis in hammer toe surgery.

Methodology

Search strategy

A systematic research was conducted in September 2019 using the following databases: PubMed, Scopus, Cochrane, and Embase. The search terms and Boolean operators used to search the databases are presented as follows: (hammer toe OR claw toe) AND (PIP joint OR proximal interphalangeal joint OR PIPJ) AND (fusion OR arthrodesis). All relevant literatures were included from the inception of databases to September 2019. The reference lists in the articles underwent manual screening of both titles and abstracts to identify articles that were not retrieved in the first-round search.

Inclusion and exclusion criteria

The following inclusion criteria were obeyed: (1) randomized controlled trials (RCTs), non-RCT, and retrospective or prospective cohort studies; (2) patients aged >18 years; (3) comparing the effect of K-wire and novel internal fixation devices during PIPJ fusion procedure in hammer toe correction; and (4) reporting at least one of the following outcomes: regional pain, patient satisfaction level, foot-related function, complication rates, and union rate. The articles would be excluded if (1) not published in English, (2) including juveniles or children, (3) cadaver studies, (4) using a concurrent secondary procedure, (5) the aim of the study is to compare the clinical effect of PIPJ arthrodesis with other surgical procedure (e.g. comparing the effect of PIPJ resection and PIPJ fusion), and (6) including patients with non-hammer toe (e.g. hallux valgus) without reporting the outcomes separately.

Data extraction

Data extraction was performed by the author RXYW. Queries and uncertainty were discussed with supervisor SKKL. Publishing time, demographic information (i.e. patients and involved toe number, gender, and age), study design (i.e. level of evidence, inclusion and exclusion criteria, and definition of hammer toe/claw toe), intervention conducted in each group, and follow-up time were extracted and listed in a Microsoft Word table (Table 1). In each individual study, outcomes concerning pain, patient satisfaction, foot-related function, complication rates, and union rate in PIPJ were subsequently extracted and outlined in Table 2.

Quality appraisal and evidence grading

The level of evidence for each study was graded according to Oxford Centre of Evidence-Based Medicine guideline. The quality was assessed using Critical Appraisal Skills Program (CASP) by two independent reviewers RXYW and SKKL. The CASP appraisal system allowed researchers to systematically assess the trustworthiness, relevance, and results of published articles, comprising of different checklists for various types of researches. The checklist for RCTs included 11 questions and for cohort studies 12 questions. Both of them are based on three broad issues: (1) are the results valid, (2) what are the results, and (3) will the results help locally. The assessment results of the quality of article were presented in Appendix 1.

Results

Study selection and characteristics

The procedure of study selection is presented in Figure 1. A total of 92 studies were included in the first-round searching after duplication was removed from each electronic database. Titles and abstracts of all these literature studies were screened by the reviewers RXYW and 12 of them were selected for full-text assessment. Reference lists of the 12 studies were also manually checked and no additional articles were eligible. After excluding seven articles (two of them were review or technique description, two of them conducted different procedures, and three of them...
| Author and year | Level of evidence | Definition of claw toe/hammer toe | Inclusion criteria | Number of patients and toes | Average age (years) | Gender (proportion of female) | Intervention | Follow-up | Outcome measurements |
|----------------|-------------------|-----------------------------------|--------------------|-----------------------------|---------------------|-----------------------------|--------------|----------|----------------------|
| Obrador et al. 2018 | III | Not mentioned | Patients with isolated or multiple lesser hammer toes with rigid deformity | 96 patients 186 toes | 62.6 | 81.3% | Group A: K-wires  Group B: Smart Toe implants  Group C: TenFuse implants | 12 months postoperatively | VAS  SF-36  FFI  Patient satisfaction  Complication rates  Union rates |
| Richman et al. 2017 | III | Extension deformity of DIPJ, flexion deformity of PIPJ, and either a neutral or an extended MTPJ | Patients with hammer toes | 99 patients 149 toes | 61.5 | 82.8% | Group A: K-wires  Group B: CannuLink implants | 3 months postoperatively | VAS  Time to union  Complication rates  Union rates |
| Jay et al. 2016 | I | Concomitant flexion of PIPJ and hyperextension of MTPJ | Isolated, or multiple, hammer toes localized to second, third, or fourth rays | 91 patients 95 toes | 60.0 | 78.0% | Group A: K-wires  Group B: DCIMSS implant | >6 months postoperatively | BFS  FFI  Toe length and circumference  Union rates  Complication rates  Union rates |
| Scholl et al. 2013 | III | Not mentioned | Patients with hammer digits | 86 toes | 61.5 | 94% | Group A: K-wires  Group B: Smart Toe Implant | 388.6 days postoperatively | Complication rates  Union rates |
| Angirasa et al. 2012 | III | The deformity exists in the sagittal plane with a flexion contracture causing the proximal phalanx to become dorsiflexed, and the middle phalanx to become plantarflexed | 1. Have a hammer digit deformity with the apex of the deformity at the PIPJ. 2. Determined to be a candidate for end-to-end arthrodesis of the PIPJ for correction | 28 patients NA NA | | | Group A: K-wires  Group B: Smart Toe Implant | 4 weeks 8 weeks 6 months postoperatively | VAS  Patient satisfaction  Time for returning to full activity  Complication rates  Union rates |

K-wires: Kirschner wires; DCIMSS: dual-component, intramedullary, stainless steel; VAS: Visual Analog Scale; FFI: Foot Function Index; BFS: Bristol Foot Score; SF-36: Short Form 36 healthy survey; PIPJ: proximal interphalangeal joint; DIPJ: distal interphalangeal joint; MTPJ: metatarsophalangeal joint; NA: not available.
| Author and year | Last follow-up | Postoperative pain | Patient satisfaction | Foot function | Union rates | Complication rates |
|-----------------|----------------|--------------------|----------------------|--------------|-------------|-------------------|
| Obrador et al. 2018 | 12 months postoperatively | VAS | VAS | Smart Toe: | Fusion achieved radiologically: | Osseous union: | Complication rates: |
|                 |                |                  |                      | Very satisfied: 16 (59.3%) | 16 (24.6%) | 7.4% | 11 (16.9%) |
|                 |                |                  |                      | Satisfied: 25 (46.3%) | Fusion achieved radiologically: | Osseous union: | Wound complication: 3 (7.4%) |
|                 |                |                  |                      | Unsatisfied: 12 | Osseous union: 23 (35.4%) | Wound complication: | Recurrence: 6 (6.4%) |
|                 |                |                  |                      | (22.2%) | Nonunion: 3 (3.1%) | Implant fracture: | Complication rates of TenFuse: 5 (18.5%) |
|                 |                |                  |                      | Unsatissfied: 13 | TenFuse: | Implant fracture: 0 (0.0%) |
|                 |                |                  |                      | (24.1%) | Stable pseudoarthrosis: 16 | Adhesions: 2 (7.4%) |
|                 |                |                  |                      | Very unsatisfied: 4 | Fusion achieved radiologically: | Adhesions: 2 (7.4%) |
|                 |                |                  |                      | (4.7%) | Osseous union: | continued pain: 1 |
|                 |                |                  |                      |                  | Nonunion: 1 (3.7%) | Wound complication: |
|                 |                |                  |                      |                  |                    | Recurrence: 3 (11.1%) |
|                 |                |                  |                      |                  |                    | Implant fracture: |
|                 |                |                  |                      |                  |                    | Adhesions: 0 (0.0%) |
| Richman et al. 2017 | 3 months postoperatively | VAS: 1 (0.3)b | VAS: 1 (0.5, 3)b | 73% | 92.3% | Osseous union: 7.4% |
| Jay et al. 2016 | 6 months postoperatively | Pain domain of FFI: 21.3 | Pain domain of FFI: 19.4 | NA | NA | Osseous union: 22.2% |
| Scholl et al. 2013 | 3 months postoperatively | NA | NA | NA | NA | None |
| Angirasa et al. 2012 | 6 months postoperatively | VAS: 1.6 (1.8)d | VAS: 0.3 (0.8)d | 7.6 (1.9)d | 9.8 (0.4)d | None |

K-wires: Kirschner wires; IF: internal fixation; VAS: Visual Analog Scale; FFI: Foot Function Index; BFS: Bristol Foot Score; SF-36: Short Form 36 healthy survey; DVT: deep vein thrombosis; CRPS: chronic regional pain syndrome.

aData presented as mean (95% confidence interval).
bData presented as median (25th and 75th percentiles).
cData presented as n (%).
dData presented as mean (standard deviation).
compared the effect of different intramedullary implants without using K-wire, five articles were identified and selected for this systematic review. Considering the fact that hammer toe and other forefoot deformities (e.g., hallux valgus) are frequently observed, simultaneously, in clinic, such related studies without specific result for each deformity were still filtered according to the exclusion criteria, as the conclusive results without specific investigation make it difficult to justify the source of the clinic improvement or deterioration. Finally, all five studies were published in English. The earliest one was published in 2012 and the others were published from this year onward.

**Patient characteristics**

Demographic information in each study is presented in Table 1. A total of 544 toes were involved and the number of patients in one study was unknown.\textsuperscript{20} The average age of all patients recruited was 61.1 years (range 43–84 years) and most of the patients involved were female (the proportion of female was from 78.0\% to 94.0\%). All patients included were diagnosed with isolated or multiple lesser hammer toes with rigid or nonrigid flexion deformity in PIPJ.

**Intervention and novel internal fixation devices**

All studies recruited two groups of patients and conducted arthrodesis at the PIPJ, with the control arm used K-wire as a fixation support and the study arm implanted with the novel internal devices.\textsuperscript{20–23} except that Obrador et al. compared the effect of K-wire and other two devices.\textsuperscript{16} Four of five studies implanted K-wire by the inside-out technique where the K-wire was drilled out from the middle phalanx and retrieved at the tip of distal phalanx, the PIPJ fusion site was then reduced, and then the K-wire was drilled into the proximal phalanx. Scholl et al. used the K-wire as a buried intramedullary implant, by cutting the K-wire and just leaving enough exposed wire to be placed in the middle phalanx, being called “buried K-wire technique.”\textsuperscript{20}

The information of novel internal fixation devices used in included studies is outlined in Table 3. A total of four different types of devices were applied, among which Smart Toe was the one used most extensively.
Table 3. Information on the novel internal fixation devices.

| Company     | Material composition                              | Rotational stability | Compression across the joint line | Angulations available |
|-------------|--------------------------------------------------|----------------------|------------------------------------|-----------------------|
| Smart Toe®  | Memometal NiTinol (an alloy of 50% nickel and 50% titanium) | Yes                  | Yes                                | 0° or 10°             |
| TenFuse     | Wright Allograft                                  | Yes                  | Yes                                | 0° or 10°             |
| Nextra®     | Zimmer Biomet Stainless steel                    | No                   | Yes                                | 10°                   |
| CannuLink   | Wright Titanium alloy                            | No                   | Yes                                | 0°                    |

Pain

Four of five studies included in this review investigated the postoperative pain with or without recording preoperative pain level. Three evaluated pain by the visual analog scale scored 1–1016,21,23 and another used Foot Function Index (FFI)22 as the measuring instrument. Regardless of the tools, all studies report no significant difference between the groups.

Patient satisfaction

Three of the five studies used patient satisfaction as one of the surgical outcomes but were measured via different modalities. Patients included in Obrador et al.’s study16 were asked to complete a questionnaire about their satisfaction at 1-year follow-up which was divided into four levels from very satisfied to very unsatisfied. Statistical significance was found in the “satisfied” level (level 2) indicating that K-wire patients may be less satisfied with the surgical results. Richman et al.23 found a higher proportion of being not completely satisfied with the outcomes in K-wire group (27% in K-wire group and 7.7% in CannuLink group, respectively) but the p value was not reported. Angirasa et al.21 measured patient satisfaction on a 0–10 scale and found no statistical significance between the two groups at early (day 7) to and interim (6-month) post-surgery.

Foot function

Only two of five studies16,22 measured the foot-related functional outcomes before and after surgery. Obrador et al.16 found no statistically significant differences in FFI and Short Form 36 (SF-36) between the groups at 12-month follow-up. Jay et al.22 also reported similar results in FFI and Bristol Foot Score (BFS) at 6-month follow-up.

Complication rates

All studies reported complication rates in two comparative groups but the details were not clearly displayed in two studies21,22. In Richman et al.’s study,23 complication rate in K-wire group was remarkably higher than that in a novel internal fixation group with p < 0.05. Angirasa et al.21 also indicated that the novel internal fixation device outperformed axial K-wire in complication incidence as no notable complications were observed by using the former device. Scholl et al.20 and Jay et al.22 however, drew the conclusion that no difference was found between the two groups. Obrador et al.16 found no statistical significance in the total incidence of complication among three implants but actually reported a significantly higher incidence of implant breakage in the Smart Toe group.

Union rate

The postoperative union rate was reported in all studies by using X-rays. Only one study demonstrated similar results between two groups with p > 0.05,20 while the other four studies indicated that the union rates were significantly lower in the K-wire groups. Obrador et al.16 showed that K-wire fixation resulted in significantly higher nonunion rates compared with the two internal fixation devices; no difference in union rates was found between the two intramedullary implants. The results of Jay et al.’s study22 implied that patients in intramedullary implant group experienced both statistically and clinically (>10%) significant better phalangeal segment apposition. Richman et al.23 and Angirasa et al.21 observed lower fusion rates in the K-wire group but whether there was statistical significance remained unknown.

Discussion

PIP fusion is one of the most frequently used surgical procedures for the treatment of rigid hammer toe.1 Recently, an increasing number of articles investigated the different novel internal fixation devices with promising results in most of the publications.12 This systematic review, to our best knowledge, is the first one aiming to present the current evidence on the effectiveness of using traditional fixation with axial K-wires versus novel internal fixation devices to perform PIPJ arthrodesis for correction of hammer toe deformities. Overall, the studies showed promising results in union rates with 4/5 studies indicating that the union rate was higher using the novel internal devices when compared to using K-wires. However, the novel internal devices seem not to present advantages in clinical parameters such as pain levels, patient satisfaction, foot-related function, or surgical complication rates.
Four of the five publications included in this review are retrospective comparative studies, implying that they are vulnerable to bias, for example, covariates and potential confounders. Only one study was a high-level multi-center, randomized controlled trial.

Local pain in the PIPJ is an important outcome measure. In all four comparative level III studies, the novel internal fixation devices have similar postoperative pain levels with K-wire fixation subjects. Many case series investigating the effect of intramedullary devices reported a significant reduction in pain levels. Our review suggests that the pain relief may be attributed to the forefoot deformity correction regardless of the fixation device used.

The results upon patient satisfaction are inconclusive. Patient satisfaction levels could be influenced by a diverse group of factors, for example, pain, recurrent deformity, swelling, and sensation issues. Only one study, which showed less satisfaction in K-wire patients, discussed the possible reasons for the discrepancy. They postulated that in the initial weeks, the exposed K-wire sticking out from the distal phalanx may be quite inconvenient and may directly decrease patients’ satisfaction. However, the long-term result measured 1 year postoperatively in their study could more precisely reflect the effect of fixation devices. The author attributed the promising results to the angled implant in intramedullary fixation they used.

For foot function, two studies reported the results using BFS, FFI, and SF-36, which are all reliable, valid, and extensively used measurements in foot and ankle clinic. They speculated that the absence of a pin protruding from the distal phalanx and better bone-to-bone union resulted in higher BFS and FFI scores in intramedullary fixation.

It is hard to draw a conclusion on the complication rates due to the lack of a clear consistent definition of the adverse events. The reported complications in the five studies included infection, broken implants, severe pain, non-union or malunion, recurrent deformity, and symptomatic event (e.g. foot drop and contracture). The most commonly cited complication of K-wire is pin-tract infection. No significant higher rate of infection in the K-wire group compared with the intramedullary group was observed in the studies included in this review. This is supported by a retrospective review that analyzed 1115 hammer toe corrections using K-wire fixation and found a 0.3% infection incidence. This is lower than the results in Richman et al. and Obrador et al. studies which reported 3.2% and 4.6% in the K-wire group, respectively. The relatively small sample size may partly explain the discrepancy. Another study investigating the infection rate of K-wire, published in 1980s, reported an incidence of up to 18%. From this review, it seems that the infection rate in using axial K-wire devices is comparable to using internal fixation devices.

Some surgeons attempted to reduce pin-tract infection by proposing the buried K-wire technique. However, the desired outcome was suboptimal as almost one-third of the buried K-wires extruded from the skin and required revision surgery. Scholl et al. cut the K-wire shorter, leaving only just enough wire to be placed in the middle phalanx. However, the postoperative infection rate and whether the K-wire position shifted inside the medullary canal was not reported in their study.

In addition to avoiding pin-tract infection, providing rotational stability in the frontal plane is another theoretical advantage of the intramedullary implant over a single axial K-wire. However, no studies directly reported the rotational position of the toe during the postoperative follow-up.

The outcome measurement timing varied a lot between the studies and ranged from 2 months to 1 year. All studies supported that the intramedullary implants outperformed axial K-wires in union rate. The resistance of rotation, compression effect, and bone graft composition of intramedullary implants were identified as the main influencers on the improved fusion rate.

Implant breakage is also an important complication and the included studies observed a 0–7.1% breakage of K-wires. Surprisingly, two studies reported that the novel internal fixation device (Smart Toe) presented higher implant breakage rates. The postoperative weight-bearing regime and proper implantation procedure may be able to reduce the breakage rate of this type of internal implant. The thinner distal portion of the Smart Toe implant was the most common breakage site. Some of the breakage is attributed to the less ideal surgical positioning of the implant when it was unintentionally pushed too proximal in the proximal phalanx.

The high price of internal PIPJ fusion implants is the most important reason for its limited utility. However, the implant price is only a portion of the overall medical fee common to both K-wire and internal fixation devices, for example, theater cost, pharmacological uses (antibiotics), and nursing charges (dressing charges for K-wires). A cost-effectiveness analysis investigated health-care costs and outcomes associated with either K-wire or commercial intramedullary implant fixation, finding that additional benefits will be considered as worthwhile only if the implants cost ≤ USD $300. The current cost of these novel internal PIPJ fusion implants far exceeds this value.

**Limitations**

The current systematic review has certain limitations. First, the included studies lack high-level RCTs to help make conclusive statements. In the future, studies investigating the clinical effect of internal fixation devices should adopt a more rigorous trial design to provide convincing evidence. Second, we only included articles that specifically stated hammer toes and claw toes as the diagnoses. This
may mean that some articles that did not specify claw toe or hammer toes deformities were inadvertently excluded. Finally, there are many different novel devices for PIPJ arthrodesis, but only four types of internal fixation devices were investigated in the articles for this review. The implantation technique of the K-wire controls was not standardized and various size and surgical techniques were used. In addition, none of the included studies specified whether the K-wires were threaded or not. Although these were the most commonly used implant systems, a future review may categorize and compare the devices by their common peculiarities for a more conclusive recommendation.

**Conclusion**

This systematic review showed that the novel internal devices may outperform K-wires in union rate for PIPJ arthrodesis in hammer toe deformity correction. However, these internal devices seem not to present advantages in clinical parameters such as pain levels, patient satisfaction, foot-related function, or surgical complication rates. It should be taken into consideration whether the theoretical advantages of the novel interval devices are able to compensate for their high price compared to K-wires.

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### Appendix I

**Results of the methodological quality evaluation using CASP checklist**

**Table 1A.** CASP checklist for included cohort studies: response questions 1–6 and 9–12.*

| Author and year       | 1 | 2 | 3 | 4 | 5(a) | 5(b) | 6(a) | 6(b) | 9   | 10  | 11  | 12  | Total |
|-----------------------|---|---|---|---|------|------|------|------|-----|-----|-----|-----|-------|
| Obrador et al. 2018   | 2 | 1 | 2 | 0 | 1    | 0    | 2    | 2    | 2   | 2   | 2   | 2   | 18   |
| Richman et al. 2017   | 2 | 1 | 2 | 0 | 1    | 0    | 2    | 2    | 2   | 2   | 2   | 2   | 18   |
| Scholl et al. 2013    | 2 | 1 | 2 | 0 | 1    | 0    | 2    | 0    | 2   | 1   | 2   | 1   | 15   |
| Angirasa et al. 2012  | 2 | 1 | 2 | 0 | 1    | 0    | 2    | 2    | 2   | 1   | 2   | 1   | 17   |

CASP: Critical Appraisal Skills Program.

*The CASP Cohort Study Checklist had a maximum score of 24. Each question was graded on 2 = yes, 1 = can’t tell, and 0 = no.

**Table 1B.** CASP checklist for included RCT studies: response questions 1–6 and 9–11.*

| Author and year | 1 | 2 | 3 | 4 | 5   | 6   | 9   | 10  | 11  | Total |
|-----------------|---|---|---|---|-----|-----|-----|-----|-----|-------|
| Jay et al. 2016 | 2 | 2 | 2 | 0 | 2   | 2   | 2   | 2   | 2   | 16    |

CASP: Critical Appraisal Skills Program; RCT: randomized controlled trial.

*The CASP RCT Checklist had a maximum score of 18. Each question was graded on 2 = yes, 1 = can’t tell, and 0 = no.