Material and Biofilm Load of K Wires in Toe Surgery: Titanium versus Stainless Steel

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Abstract

Background Recurrence rates for toe deformity correction are high and primarily are attributable to scar contractures. These contractures may result from subclinical infection.

Questions/purposes We hypothesized that (1) recurrence of toe deformities and residual pain are related to low-grade infections from biofilm formation on percutaneous K wires, (2) biofilm formation is lower on titanium (Ti) K wires compared with stainless steel (SS) K wires, and (3) clinical outcome is superior with the use of Ti K wires compared with SS K wires.

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Methods In this prospective nonrandomized, comparative study, we investigated 135 lesser toe deformities (61 patients; 49 women; mean $\pm$ SD age, 60 ± 15 years) temporarily fixed with K wires between August 2010 and March 2011 (81 SS, 54 Ti). K wires were removed after 6 weeks. The presence of biofilm-related infections was analyzed by sonication.

Results High bacterial loads (> 500 colony-forming units [CFU]/mL) were detected on all six toes requiring revision before 6 months. Increased bacterial load was associated with pain and swelling but not recurrence of the deformity. More SS K wires had greater than 100 CFU/mL bacteria than Ti K wires. For K wires with a bacterial count greater than 100 CFU/mL, toes with Ti K wires had a lower recurrence rate, less pain, and less swelling than toes with SS K wires.

Conclusions Ti K wires showed superior clinical outcomes to SS K wires. This appears to be attributable to reduced infection rates. Although additional study is needed, we currently recommend the use of Ti K wires for the transfixation of toe deformities.

Level of Evidence Level II, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

Introduction

Toe deformities are a common problem in orthopaedic foot surgery [6]. Various operative procedures include temporary fixation by percutaneous K wires. Recurrence rates of as much as 47% have been reported for toe deformities, with recurrences being mostly related to scar contractures [5, 6, 9]. Patients also frequently experience residual pain and swelling in the surgically treated toe [5, 6].

Infection is a serious complication in operative therapy and can be related to the implant materials. Infections may

be acute and easy to detect, but also can present as low-grade infections that are difficult to diagnose and likely to be missed. In percutaneous K wire fixation, the pins protrude from the skin. Therefore, the risk of subsequent infection is much greater than with implants under closed skin. Low-grade infections produce a bacterial biofilm on the implant, which is difficult to diagnose but can cause extensive scar formation [14]. In some cases, this scarring may be the cause of poor clinical results.

The amount of biofilm formation depends in part on the properties of the material used [4]. Titanium (Ti) plates and nails have less bacterial adhesion and biofilm formation than implants made of stainless steel (SS), as shown by *in vitro* [7, 15] and animal experiments [1, 7, 8, 10, 11, 16].

We hypothesized that (1) recurrence of toe deformities and residual pain are related to subclinical or low-grade infection from biofilm formation on the surface of percutaneous K wires, (2) biofilm formation can be reduced by using Ti K wires instead of SS K wires, and (3) clinical outcome is superior with the use of Ti K wires instead of SS K wires.

Patients and Methods

In this prospective, nonrandomized, comparative cohort study, we investigated all 135 toe deformities (61 patients) temporarily fixed with K wires between August 2010 and March 2011 at our institution. All patients had deformities with noncorrectable or only partially correctable contraction of the proximal and/or distal interphalangeal joint. Preoperative assessment included lateral and dorsoplantar weightbearing radiographs of the foot to assess the

deformity. There were 49 women and 12 men with a mean age of 60 ± 15 years (range, 19–89 years). The study was approved by the local ethical review committee. All patients provided informed consent. Patients with damaged skin owing to ulceration over the affected toes were excluded. SS K wires were used for the first 81 toes (38 patients); the next 54 toes (23 patients) received Ti K wires. All K wires were from Synthes AG (Oberdorf, Switzerland). No other changes to the surgical technique, antibiotic protocol, or aftercare were made during the period in question. No differences in diagnoses ($p = 0.370$) or comorbidities ($p = 0.663$) were found between the SS and Ti groups (Table 1). Mean time to K wire removal was 42 ± 10 days (range, 20–63 days), with no differences between the two groups (SS, 41 ± 10 SD [range, 20–60 days], Ti, 44 ± 10 SD [range, 21–63 days], [$p = 0.730$]). No patient was lost to followup. Owing to obvious contamination during removal or violation of the laboratory protocol, 23 K wires were removed from the biofilm analysis, which left 112 K wires (69 SS, 43 Ti).

As there were no comparable clinical data to perform an *a priori* power analysis, we performed sample size calculation followed by an intermediate data analysis after $\frac{3}{4}$ of the K wires had been included (81 SS, 54Ti). At this point, we found significant differences for the rates of deformity recurrence between SS and Ti K wires, and the study was halted.

Surgery was performed as follows. Patients were placed in a supine position, the whole lower leg was disinfected three times during a 5-minute period using an iodine disinfection solution (Betadine[®], Mundipharma Medical Company, Basel, Switzerland), and a tourniquet was inflated at the thigh. Single-shot antibiotic prophylaxis (cefuroxime, 1.5 g; Sandoz, Basel, Switzerland) was administered to all patients

Table 1. Diagnoses and comorbidities

Variable	Number of toes			p value
	All toes (n = 135)	SS K wire group (n = 81)	Ti K wire group (n = 54)	
Diagnosis				
Hammer/claw toe	100 (74%)	55 (68%)	45 (83%)	0.048
Rheumatoid arthritis	9 (7%)	7 (9%)	2 (4%)	0.315
Hammer/claw toe (reoperation)*	14 (10%)	11 (14%)	3 (6%)	0.160
Hallux valgus	3 (2%)	2 (3%)	1 (2%)	1.000
Other	9 (7%)	6 (7%)	3 (6%)	0.741
Comorbidities				
No comorbidities	108 (80%)	66 (82%)	42 (78%)	0.663
Diabetes	2 (2%)	2 (3%)	0 (0%)	0.516
Rheumatoid arthritis	9 (7%)	7 (9%)	2 (4%)	0.315
Additional complex surgery	12 (9%)	6 (7%)	6 (11%)	0.542
Charcot’s disease	4 (3%)	0 (0%)	4 (7%)	0.024

* Hammer/claw toe deformity after prior operative correction; SS = stainless steel; Ti = titanium.

before releasing the tourniquet. Dorsal longitudinal or transverse incisions over the proximal interphalangeal joints were used to approach the joints. After a soft tissue release, a condylectomy of the proximal phalanx and débridement of the distal joint surface were performed while protecting the neurovascular structures. After realignment of the toe, fixation of the correction was achieved with a 1.6-mm K wire. The K wire was first inserted to the joint distally, and the toe then was reduced and the K wire driven into the proximal phalanx. The positions of the K wires were checked using an image intensifier. Finally, K wires were fixed (K-Fix®; Integra, Plainsboro, NJ, USA) and cut to length.

Postoperative treatment varied according to the additional procedures that were performed. All patients were allowed full weightbearing wearing a postoperative shoe with a rigid sole for 6 weeks. Patients who underwent simultaneous midfoot or hindfoot surgery wore a full-weightbearing lower-leg cast for 6 weeks for immobilization. The cast allowed clinical assessment of the toes. The K wires were removed after 6 weeks.

Comorbidities considered to be potential confounders were defined as diabetes, arterial obstructive disease, rheumatoid arthritis, Charcot's disease, and whether toe correction was the main procedure or an adjunct procedure in combination with complex hindfoot surgery.

The outcome was recorded at the time of K wire removal and 6 months postoperatively. The clinical data collected included residual pain, swelling, reddening, warmth, and malalignment. Signs of recurrence were defined as medial or lateral deviation of the toe, rotational malalignment, inability of the surgically treated toe to touch the ground, and claw formation of the fused joint. In case of revision before the 6-month followup, clinical data before revision surgery were taken as the end point.

Biofilm analysis was performed using sonication. This is an established method [17] and has been shown to be superior to scraping of the surface [3]. To reduce the number of false-positive results, only the innermost 2 cm of the K wire was analyzed, and K wires with suspected contamination were excluded.

K wires were removed in the outpatient clinic. The wires were shortened with a sterile punch to approximately 2 cm (measured from the tip of the wire) and stored in sterile 10 mL Falcon™ tubes (BD Biosciences, Bedford, MA, USA). In the microbiology laboratory, 8 mL sterile Ringer's solution (1:4 concentration; Oxoid, Basel, Switzerland) was added. Samples were processed by sonication (BactoSonic®; Bandelin, Berlin, Germany; 40 kHz, 5 minutes) according to an established algorithm [4, 17]. Subsequently, quantitative and qualitative biofilm analyses were performed. Aliquots of 0.1 mL sonication fluid were plated onto each of the following three plates: sheep blood agar (bioMérieux, Geneva, Switzerland), chocolate agar (bioMérieux), and Schaedler agar

(bioMérieux), incubated at 35° C aerobically with 5% CO₂ (blood agar and chocolate agar) or anaerobically (Schaedler agar). These were read after 2, 5, and 10 days. The number of colony-forming units (CFU) on plates was recorded. Each unique colony was identified by Gram stain, catalase (ID Color Catalase; bioMérieux), and an agglutination test (SLIDEX® Staph-Kit; bioMérieux). The threshold for significant biofilm formation was set at 100 CFU/mL in line with the only comparable study in the literature [14].

Metric values are presented as mean ± SD with ranges. Fisher's exact test was performed to compare parameters with binomial and ordinal values between the SS and Ti groups. To determine a correlation between two parameters with binominal and ordinal results, we used Spearman's rho. A probability less than 0.05 was considered statistically significant. Statistical analyses were performed using IBM SPSS® Statistics 20 (IBM Corp, Somers, NY, USA).

Results

Thirty-eight of 135 toes (28%) had recurrence of the deformity, 51 (38%) had residual pain, and 41 (30%) had persistent swelling at the 6-month followup. There were correlations between recurrence and pain ($r = 0.370$; $p < 0.001$), recurrence and swelling ($r = 0.241$; $p = 0.005$), and pain and swelling ($r = 0.449$; $p < 0.001$). An increased bacterial load on the surface of the K wires correlated with increased pain ($p = 0.029$), but not swelling ($p = 0.076$) or recurrence rate ($p = 0.570$), which was independent of the used material ($p = 0.592$). Of the six toes (all SS) revised for recurrence of deformity before 6 months, one also had clinical signs of infection, and high bacterial loads (> 500 CFU/mL) were detected on the surfaces of the other five K wires. Of the four toes that had a clinically apparent infection (pus drainage along the K wire, three SS, one Ti), three were sonicated and showed bacterial growth greater than 500 CFU/mL (K wire one, SS: *Staphylococcus aureus*, coagulase-negative *Staphylococci* (CNS), and gram-positive rods, revised for recurrence before 6 months (see above); K wire two, SS, CNS; K wire three, Ti, gram-positive rods). The fourth toe (SS) was débrided operatively and the K wire was not examined; intraoperative biopsies showed *S. aureus*. That patient had a CRP of 151 mg/L, and a leukocyte count of 6.3×10^9 /L. The other three patients with clinically apparent infections presented only with slight increases in CRP (13, 15, and 17 mg/L, respectively) and normal leukocyte counts. All four toes with clinically evident infections had poor clinical results with pain and swelling, three had a recurrence of deformity, and one underwent repeat surgery. K wires with apparent infection were removed prematurely after a mean of 32 days (range, 21–42 days).

Bacterial colonization of the SS K wires was greater than that of the Ti K wires. Of the 112 K wires (69 SS,

43 Ti) available for the biofilm analysis, 61 K wires (32 SS, 29 Ti) had 100 CFU/mL or fewer bacteria on their surface, and 51 K wires had greater than 100 CFU/mL (37 SS, 14 Ti, $p = 0.034$) (Table 2). High numbers of bacteria (> 500 CFU/mL) were found on the surface of 35 SS and 10 Ti K wires ($p = 0.010$).

Clinical results in the Ti group generally were better than in the SS group. Of the nine toes with infection and/or reoperation for recurrence, eight were in the SS group (relative risk, 5.3; 95% CI, 0.7–41.4; $p = 0.085$). Patients in the Ti group had a lower recurrence rate ($p = 0.002$), less pain ($p = 0.004$), and less swelling ($p = 0.004$) compared with the SS group (Table 3). For K wires with a bacterial count greater than 100 CFU/mL, Ti K wires had a lower recurrence rate ($p = 0.184$), less pain ($p < 0.001$), but not significantly less swelling ($p = 0.099$) than SS K wires (Table 4).

Discussion

Percutaneous K wire transfixation is the most common method of temporary toe immobilization after surgical correction of lesser toe deformities [9]. However, recurrent deformity may occur in up to 47% of the patients [9]. The risk for recurrence has been linked to primary malalignment owing to insufficient correction, insufficient stability of the resected joint, and too aggressive postoperative mobilization [5, 9]. Another suspected factor is postoperative infection which may occur along the K wire. It has been suggested that infections may lead to excessive scarring around implants [14] and thereby increase the risk of recurrence after toe corrections. Our first hypothesis therefore was that

postoperative infections after K wire fixation of lesser toe deformity correction are associated with a higher recurrence rate. Extensive scarring may be associated with biofilm formation and subclinical or low-grade infection [2, 12, 14]. For orthopaedic implants, biofilm formation can be reduced by the material used. Ti implants have less biofilm formation than SS implants [1, 7, 8, 10, 11, 15, 16]. We therefore assessed the relationship between clinical outcomes and low-grade infections. Further, we investigated whether Ti K wires showed less biofilm formation and superior clinical results compared with SS K wires.

The main limitation to this study was that K wires were implanted in two consecutive series and not in a randomized manner. However, the operative setting and operating surgeons (BH, MK) were the same during the study period. The distribution of diagnoses and potential confounding factors between the two groups was comparable. As we found biofilm-containing and biofilm-free K wires in the same patients, individual patient characteristics did not seem to be the major factor for biofilm formation. Another limitation of the study was that we did not directly observe

Table 3. Clinical outcome according to implant material

Outcome	Number of toes		p value
	SS K wire group (n = 81)	Ti K wire group (n = 54)	
Recurrence	31 (39%)	7 (13%)	0.002
Pain	39 (48%)	12 (22%)	0.004
Swelling	29 (36%)	12 (22%)	0.126

SS = stainless steel; Ti = titanium.

Table 2. Results of biofilm analyses

Variable	Number of toes			p value (SS versus Ti)
	All toes	SS K wire group	Ti K wire group	
Biofilm analysis (total, n = 112; SS, n = 69; Ti, n = 43)				
Bacterial load ≤ 100 CFU/mL*	61 (55%)	32 (46%)	29 (67%)	0.034
Bacterial load > 100 CFU/mL	51 (45%)	37 (54%)	14 (33%)	
1 microorganism	37 (72%)	26 (70%)	11 (79%)	0.730
≥ 2 microorganisms	14 (28%)	11 (30%)	3 (21%)	
Bacterial load > 100 CFU/mL (total, n = 51; SS, n = 37; Ti, n = 14)				
CNS	40 (78%)	30 (81%)	10 (71%)	0.467
Gram-positive rods	14 (28%)	9 (24%)	5 (36%)	0.490
<i>Staphylococcus aureus</i>	10 (20%)	9 (24%)	1 (7%)	0.250
<i>Streptococci</i>	3 (6%)	3 (8%)	0 (0%)	0.552
Gram-negative rods	1 (2%)	0 (0%)	1 (7%)	0.275

* Of these, 47 K wires (26 SS, 21 Ti) were sterile; SS = stainless steel; Ti = titanium; CFU = colony-forming units.

Table 4. Outcome according to biofilm formation

Outcome	Number of toes					
	≤ 100 CFU/mL (n = 61)			> 100 CFU/mL (n = 51)		
	SS K wire group (n = 32)	Ti K wire group (n = 29)	p value	SS K wire group (n = 37)	Ti K wire group (n = 14)	p value
Recurrence	10 (31%)	5 (17%)	0.245	13 (35%)	2 (14%)	0.184
Pain	9 (28%)	7 (24%)	0.777	23 (62%)	1 (7%)	< 0.001
Swelling	8 (25%)	8 (28%)	1.000	16 (43%)	2 (14%)	0.099

CFU = colony-forming units; SS = stainless steel; Ti = titanium.

(by scanning electron microscopy) the biofilm consisting of a bacterial multilayer on the surface of the K wires. Although sonication of implants has been shown to be an ideal tool to remove biofilm from implant surfaces [14], we cannot completely exclude that planktonic bacteria also have been present on the surface of the K wires owing to contamination. We therefore analyzed only the innermost 2 cm of the K wire to reduce the number of false-positive results and excluded K wires with suspected contamination.

All revisions for recurrent toe deformities before 6 months showed a low-grade infection with a bacterial load greater than 500 CFU/mL on the surface of the removed K wires. This supports our primary hypothesis that the recurrence of toe deformities is related to low-grade infections. To our knowledge, this particular question has not been evaluated before in the context of recurrence after toe deformities.

In closed systems for fracture fixation (nails and plates), only in vitro [7, 15] and animal studies [1, 7, 8, 10, 11, 16] have shown the use of Ti implants might be superior to SS implants in terms of biofilm formation and infection rates. We found more SS K wires had significant bacterial load than Ti implants. Thus, our results confirm in humans the findings of these initial animal studies.

There is a lack of evidence in the literature indicating the incidence of infection is reduced by the use of Ti implants for internal fracture fixation in clinical practice. The only randomized controlled trial of which we are aware [13] showed an increased rate of severe infections and premature removal of wrist-spanning external fixators when using SS compared with Ti pins. In the current study, we were able to confirm our hypothesis that infections and biofilm formation can be reduced by using Ti K wires instead of SS K wires. We found superior clinical results for Ti K wires compared with SS K wires in the clinical end points recurrence of deformity and remaining pain. In the biofilm analysis, this between-group difference was found only in the presence of significant bacterial load. This suggests the differences in clinical outcome between the two materials are likely to be a result of their biofilm-related properties. In closed systems (plates, artificial

joints), the majority of biofilm-centered infections are monomicrobial, and approximately 80% are attributable to *S aureus* and CNS [18–20]. In our study, the detected strains varied from this common pattern seen in implant-related infections; CNS, a low-virulence skin microorganism, was detected in 78% of our biofilm-positive cases, but surprisingly, the highly virulent microorganism *S aureus* was detected much less frequently (20%). CNS and *S aureus* were found more often on SS K wires compared with Ti K wires, which confirms the available laboratory data for these materials [1, 7, 8, 10, 11, 15, 16]. CNS and gram-positive rods were most commonly detected. CNS and gram-positive rods are part of the normal skin flora and generally of low virulence. With implants, however, they contribute significantly to implant-associated infections. Furthermore, in more than ¼ of the cases, we found a polymicrobial biofilm with up to three microorganisms on the surface of a single K wire. Polymicrobial infections are uncommon with elective joint arthroplasties [19, 20] but can be found in association with fracture fixation devices [18]. For the K wires this may have been caused either during insertion or by later contamination through the skin perforation.

In the correction of toe deformities, Ti K wires showed less recurrence of deformity, pain, and biofilm formation than SS K wires. These findings are in line with the relatively small amount of literature on this topic, and further study is needed. Based on these findings, we recommend the use of Ti K wires instead of SS K wires for transfixation of lesser toe deformities. Future studies may investigate whether these findings can be generalized to other percutaneous K wire applications.

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