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Complications - Infection

Midterm Results After Tantalum Cones in 1-Stage Knee Exchange for Periprosthetic Joint Infection: A Single-Center Study

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ABSTRACT

Background: The use of tantalum cones to reconstruct extensive bone defects in revision total knee arthroplasty has been established. We aimed to evaluate the midterm results after 1-stage knee exchange for periprosthetic joint infection using tantalum cones.

Methods: Seventy-two patients (mean age, 70 ± 8.2 years) treated with a 1-stage exchange for infected total knee arthroplasty using porous tantalum cones, between 2011 and 2016, were retrospectively included. Either rotating or pure hinge system in combination with femoral and/or tibial cones was used. Survivorship analysis (septic and aseptic) was performed. Prospectively, functional outcome was assessed at a mean follow-up of 49.9 ± 18.8 months (range, 24-88).

Results: A total of 15 patients (21%) were rerevised, 8 (11.1%) for infection and 7 (10%) for aseptic loosening, requiring cone exchange in 12 patients (17%). Cone-related survival free from any revision was 83% ± 3.8 standard deviation (95% confidence interval, 74-90), and infection-free survival was 89% ± 4.2 standard deviation (95% confidence interval, 76-93). No significant correlation was reported between the types of prosthesis used ($P = .8$) or implanted cones and failure ($P = .6$). History of a previous septic revision increased the risk of cone revision after the index surgery ($P < .001$). Preoperative Hospital for Special Surgery knee score improved from 47 ± 16 (range, 14-87) to 60 ± 17 (range, 24-84) points at the latest follow-up.

Conclusion: First study reports on outcomes of the 1-stage exchange using tantalum cones for knee periprosthetic joint infection with additional severe bone loss. Midterm cone-related and infection-free survival offered good results and provided reasonable functional outcomes.

Periprosthetic joint infection (PJI) is one of the most feared complications that can occur after total knee arthroplasty (TKA). The 1-stage exchange for PJI of the knee has shown a success rate of about 90% and offers the advantage of performing only 1 surgery, reducing the duration of antibiotic treatment, decreasing the length of hospital stay and associated costs [1,2].

Major bone defects that compromise the metaphyseal region as a result of implant removal or after the radical debridement can complicate the 1-stage knee exchange. For substantial metaphysical defects, bone grafting, metal augment blocks, and tumor implants have been used. However, because bone grafts carry the risk of disease transmission and are susceptible to infection, they are contraindicated in septic revisions. Hence, tantalum cones and sleeves are recommended for bone defects type IIB and type III, showing good midterm results [3–6].

Tantalum cones are associated with high-volume porosity, an interconnected pore space, and a low modulus of elasticity similar to that of cancellous bone, leading to a high bone ingrowth

Hussein Abdelaziz and Philipp Biewald contributed equally to this manuscript.

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potential [7,8]. Besides, experimental studies have shown a lower adherence to *Staphylococcus aureus* compared with other types of metal implants [9]. Because of the properties of these implants, they could be very useful tools in the management of the infected TKA with extensive bone defects.

Excellent midterm results have been recently reported using metaphyseal tantalum cones in the management of staged septic knee revision [10]. However, the literature is lacking regarding the outcome of using such implants to reconstruct major bone defects during the 1-stage approach.

The purpose of this study was to evaluate the midterm results after 1-stage exchange for PJI of the knee using porous tantalum cones in patients with severe femoral and/or tibial bone loss.

Materials and Methods

This study was performed after obtaining approval by our institutional review board. All subjects gave informed consent to participate in the present study.

Study Design

A total of 91 patients treated with 1-stage exchange procedures and porous tantalum cones for infected TKA between 2012 and 2016 at our institution were identified using our institutional database. The inclusion criteria were the use of femoral and/or tibial porous tantalum cones during the 1-stage exchange for PJI of the knee. Patients who underwent staged exchange procedures were excluded.

The retrospective collection of data included demographic characteristics, implant information, reoperations, and complications. The clinical results were prospectively assessed at the latest follow-up using the Hospital for Special Surgery knee scoring system and range of motion. Patients who were unable to return to the regular follow-up were contacted to exclude possible reoperations at external hospitals and evaluate the functional outcome. Progressive radiolucency or osteolysis around the components and at the cone-bone interface was assessed at the latest follow-up. Of the 91 patients identified, 72 patients could be finally included (19 patients were lost to follow-up; 21%). The average follow-up was 49.9 ± 18.8 months (range, 24-88).

Demographics

There were 31 females (43%) and 41 males (57%) with a mean age of 70 ± 8.2 years (range, 47-86) at the time of index surgery. The mean body mass index was 29.7 ± 4.7 kg/m^2 (Table 1).

Explanted Implants and Surgical History

The revised implants at the time of index surgery were rotational hinge prostheses in 47 patients (65%), hinge prostheses in 10 patients (14%), posterior stabilized knee systems in 9 patients (12%), constrained bicondylar revision system in 3 patients (4%), and distal femoral knee replacement system in the remaining 3 patients (4%). Sixty-three patients had additional knee surgery after the primary TKA (88%), with an average number of 3.1 procedures before the index revision surgery (range, 1-9). Thirty-seven patients (51%) had prior septic knee surgeries, with an average of 2.4 procedures. These procedures included 14 two-stage exchanges, 6 one-stage exchanges, 6 debridement, antibiotics and implant retention) with insert exchanges, 6 open irrigations, and 5 arthroscopic lavages (Table 2).

Table 1
General Demographics of the Study Group.

Characteristic	Value
Age (mean)	70 y (SD = 8.2)
Gender; female-male (*n*/%)	31/43% - 41/57%
BMI (mean)	29.7 (SD = 4.7)
ASA (mean/median)	2.5/2

SD, standard deviation; BMI, body mass index (kg/m2); ASA, American Society of Anesthesiologists.

Table 2
Surgical History Before Index 1-Stage Exchange and Implants Data.

Previous Knee Arthroplasty Surgery (Mean)	3.1 (Range, 1-9)
Prior septic procedures (n = 37/51%)	
Two-stage exchange	14
One-stage exchange	6
DAIR	6
Open irrigation	6
Arthroscopic lavage	5
Explanted prostheses, n (%)	
Rotational hinge	47 (65)
Hinge knee	10 (14)
Constrained bicondylar	3 (4)
Posterior stabilized	9 (12)
Distal femoral arthroplasty	3 (4)
Implanted prostheses, n (%)	
Rotational hinge	53 (74)
Hinge knee	19 (26)

DAIR, debridement, antibiotics and implant retention.

The 1-Stage Exchange

The indication for the 1-stage exchange was the diagnosis of PJI with a known causative organism. Except for 4 patients with culture-negative PJI, all patients had positive preoperative cultures, and an intraoperative sampling confirmed the results (Table 3). Generally, failure of preoperative identification of the causative microorganism and the presence of sepsis are contraindications for the 1-stage exchange at our institution. Further relative contraindications are considered individually, such as previous multiple failed 1-stage procedures or intraoperative findings such as the extension degree of bone and soft tissue infection, including the involvement of neurovascular structures. Two fully cemented revision knee systems were used in all patients, the rotating knee prosthesis and the hinge knee system (Waldemar Link, Hamburg, Germany). About 53 patients (74%) underwent 1-stage exchange using the rotating knee prosthesis, whereas the hinge knee system was implanted in 19 patients (26%). In case of patella maltracking, pure hinge systems were preferred. No bone grafts were used in any patient.

Surgical Technique

Surgeries were performed in the supine position. After an extra-articular debridement, the knee joint was radically debrided, including the collateral ligaments. All infected tissues, including bony structures, had to be debrided. Complete removal of all foreign materials was performed. Multiple periprosthetic tissue samples were sent to the microbiological and histological examination. Systemic antibiotic therapy was then started according to the recommendation by our infectious disease consultant. After irrigation with pulsatile lavage using a polyhexanid solution, a redraping was performed. After adequate testing with the probe cone, the appropriate cone was selected by attaining the largest contact area to the host bone to achieve primary rotational stability

Table 3
Pathogens Responsible for Index Periprosthetic Infections (PJI) and Reinfections.

Bacteria	*N* (%)
Staphylococcus epidermidis	28 (39)
Streptococcus sp	11 (15)
S aureus	9 (13)
Staphylococcus sp	8 (11)
Enterococcus sp	3
Propionibacterium sp	2
Escherichia coli	2
Pseudomonas aeruginosa	1
Klebsiella sp	1
Proteus sp	1
MRSA	1
Others	1
Culture negative	4
Septic failures ($n = 8$)	
Pathogen for index PJI	Reinfection
Staphylococcus sp	Staphylococcus sp
Staphylococcus sp	MRSA
S aureus	*S epidermidis*
Streptococcus sp	Staphylococcus sp
S epidermidis	Streptococcus sp
S epidermidis	*S aureus*
Propionibacterium sp	*S epidermidis*

PJI, periprosthetic joint infection; MRSA, methicillin-resistant *Staphylococcus aureus*.

and subsequently impacted. Antibiotic-loaded bone cement was used for both the fixation of the new prosthesis.

All patients received systemic antibiotic therapy based on the recommendation of the infectious disease consultant, who also recommended the topical antibiotic in the bone cement and supervised the whole course of antibiotic treatment during hospitalization.

The Tantalum Cones

Tantalum cones were available in different sizes, widths, and heights for tibial and femoral defects (Zimmer Biomet, Inc, Warsaw, IN). The indication for the use of tantalum cones was large bony defects of the distal femur or proximal tibia. The intraoperative assessment of the bone loss, according to the Andersen Orthopedic Research Institute classification system, confirmed the final decision. About 47 patients had uncontained bone defects, whereas 25 patients had cavitary defects. An apparent lack of host bone contact with the tibial keel or femoral box of the prosthesis components could be signs of cone requirement. Because the vast majority of our patients had type IIB and III Andersen Orthopedic Research Institute bone defects, initial rotational stability with only antibiotic-loaded bone cement was not assured. Although only femoral cones were implanted in 29 patients (40%) and tibial cones in only 14 patients (20%), the reconstruction using tantalum cones on both femoral and tibial sides was required in 29 patients (40%) (Table 4). Although metaphyseal cones have been implanted in 51 patients, the reconstruction using diaphyseal cones has been performed in 21 patients.

Outcome Measurement

We defined septic failure as any patients with local or systemic symptoms of infection, needing further surgery as a result of persistent PJI or because of reinfection with new pathogens and patients who died after generalized sepsis. Criteria for successful infection control were no clinical signs of infection, no further surgery with the diagnosis of PJI, and no further positive cultures after the 1-stage exchange. A septic failure of the prosthetic device was any procedure in which a component exchange was performed for reasons unrelated to PJI or sepsis. The aseptic failure of the cone was defined as any procedure that required cone removal.

Table 4
AORI Classification of the Bone Defects Requiring Tantalum Cones in the Study Cohort.[a]

AORI	Femoral Side ($n = 58$)	Tibial Side ($n = 43$)
IIA	0	5
IIB	10	9
III	48	29

AORI, Andersen Orthopedic Research Institute.
[a] A total of 101 cones in 72 patients.

Statistical Analysis

Descriptive analysis using number, mean, median, and standard deviation (SD) for metric values has been performed. Shapiro-Wilk test was used for verification of the normal distribution of the data. The comparison between groups was carried out with the *t* test. Otherwise, the Mann-Whitney *U* test was used. Fisher exact test was applied to compare the distribution frequency of a categorical variable. All tests were bilaterally calculated. The cone survivorship was estimated using Kaplan-Meier survival analysis considering any revision of the tantalum cone as an endpoint. In addition, a bivariate analysis to determine *P* values, including possible factors concerning the need for cone revision, was performed. A relationship was considered significant at $P < .05$. The data processing and statistical analyses were carried out using SAS 9.3 (SAS Institute, Inc, Cary, NC).

Results

At the latest follow-up, a total of 15 patients (21%) had undergone further rerevisions of the index knee joint at a mean of 4 years of follow-up (49.9 ± 18.8 months; range, 24-88). Among them, the implanted cone during the 1-stage exchange had to be rerevised in 12 patients (17%) after a mean of 2.4 years (SD, 0.07). The cone-related revision-free survivorship was 83% ± 3.8 SD (95% confidence interval, [95% CI], 74-90) (Fig. 1). There was statistically no significant difference between the femoral and tibial cones ($P = .6$). Regarding failure because of any reason, 13 rotating knee systems and 4 pure hinge knees had failed, showing no significant difference between the types of prosthesis implanted ($P = .8$). Among several possible patient-related, joint-related, and surgery-related factors, a history of a previous septic revision was associated with significantly increased risk of further surgery requiring cone revision ($P < .01$) (Table 5).

Septic Failure

At the latest follow-up, 8 of 72 patients (11%) had been rerevised for infection (1 pure hinge knee [1 of 19]; and 7 rotating hinge knees [7 of 53]). The mean time to septic revision was 11 ± 8 months (range, 6-32). The survival estimation demonstrated 48-month infection-free survivorship of 89% ± 4.2 SD (95% CI, 76-93). The vast majority of the reinfections occurred because of new pathogens (Table 3). In 6 of the patients with reinfection, a second 1-stage exchange was performed. The other 2 patients underwent subsequent revisions, implant removal, and finally, knee amputation because of persistent infection. None of the patients with reinfection was managed with chronic suppression therapy. All these patients had a septic surgical history before the index 1-stage

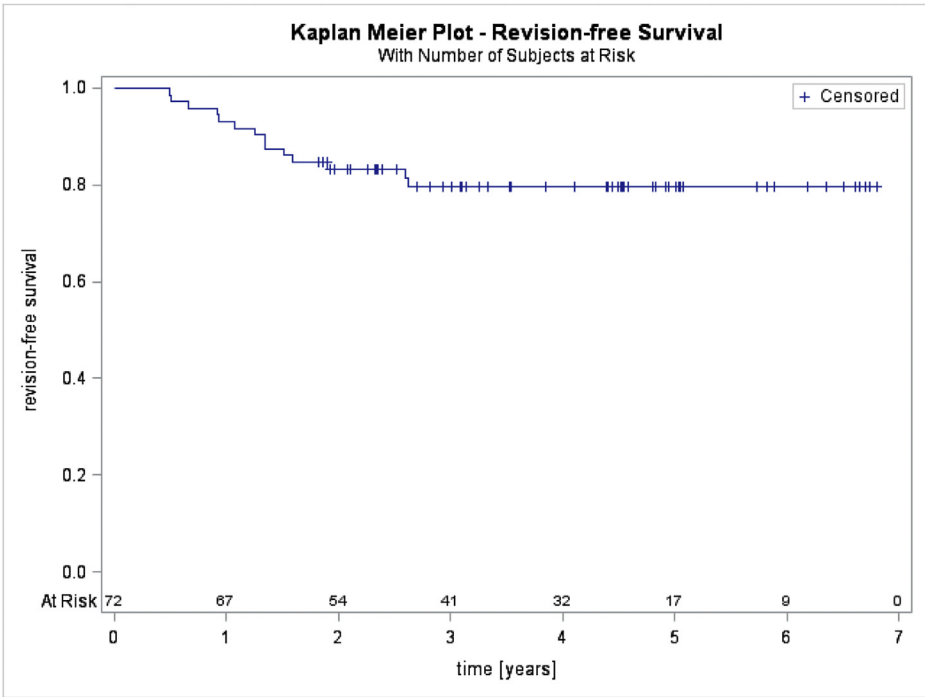

Fig. 1. Kaplan-Meier survival analysis of cone-related revision for any reason.

exchange having an average number of 3.3 procedures that was significantly higher compared to patients with successful infection control ($P < .01$).

Aseptic Failure

Seven patients (10%) had been rerevised for aseptic reasons. Only 4 index femoral cones were rerevised (6%) demonstrating cone-related survival free from rerevision because of aseptic failure of 94% ± 2.4 SD (95% CI, 88-98). However, there was aseptic osteolysis around the cones in further 2 patients at the latest follow-up resulting in a total of a cone-related aseptic failure rate of 8%. The remaining 3 patients have undergone other aseptic revision procedures such as exchange of the opposite component rather than the index cone. Considering the design of the knee prosthesis, aseptic failure for pure hinge knees included cone exchange in 1 patient and the nonrevised 2 patients with osteolysis, resulting in a total of 3 patients (3 of 19; 16% vs 6 of 53; 11% among the rotating hinge knee patients). The mean time to cone revision for aseptic loosening was 25 ± 8 months (range, 13-32). One patient had a final amputation among the whole aseptic group.

Table 5
P Values of Potential Factors Regarding Cone Revision for Any Reason.

Variable	*P*
Age	.472
BMI	.738
Gender	.765
ASA	.815
History of septic surgery	<.001
History of aseptic revision	.252
Implanted prosthesis	
Rotating hinge	.592
Hinge knee	
Tantalum cones	
Femoral	.289
Tibial	
Sinus tract	.438
ALBC	
G + C + V	.743
G + V	
G + C	
G + C + M	
Bacteria	
Staphylococcus epidermidis	.632
Staphylococcus aureus	
Streptococci	
Others	

BMI, body mass index; ASA, American Society of Anesthesiologists; ALBC, antibiotic-loaded bone cement; G, Gentamicin; C, Clindamycin; V, Vancomycin; M, Meropenem.

Clinical Outcome

The preoperative Hospital for Special Surgery knee score improved from 47 ± 16 (range, 14-87) to 60 ± 17 (range, 24-84) points at the latest postoperative follow-up. The average knee flexion was 94° ± 21 (range, 30°-140°); however, with a mean extension lag of 5° ± 6 (range, 0°-30°) at the final follow-up.

Radiographic Evaluation

The radiographic assessment showed that the cones were well positioned in the immediate postoperative radiographs in all patients. The average preoperative mechanical axis was 1.2° ± 4° of varus (range, −9.8° to 9.9°) and that of the rerevised cases was 0.7° ± 2.5 of valgus (range, −4.7 to −2.8). A neutral alignment has been achieved in most of the patients who underwent rerevision surgery. A total of 52 patients (72%) had a radiographic evaluation at the latest follow-up (Fig. 2). Eleven patients presented progressive radiolucency in the stem-bone interface, and all of them were rerevised. Among them, 6 patients underwent aseptic exchanges, whereas septic revisions were necessary for 5 patients. At the latest follow-up, further 2 cones presented aseptic osteolysis. If exclusively patients with available radiological follow-up were considered, including the 2 nonrevised patients with osteolysis, the radiological survival free from signs of aseptic loosening was 75% at the latest follow-up (39 of 52 patients).

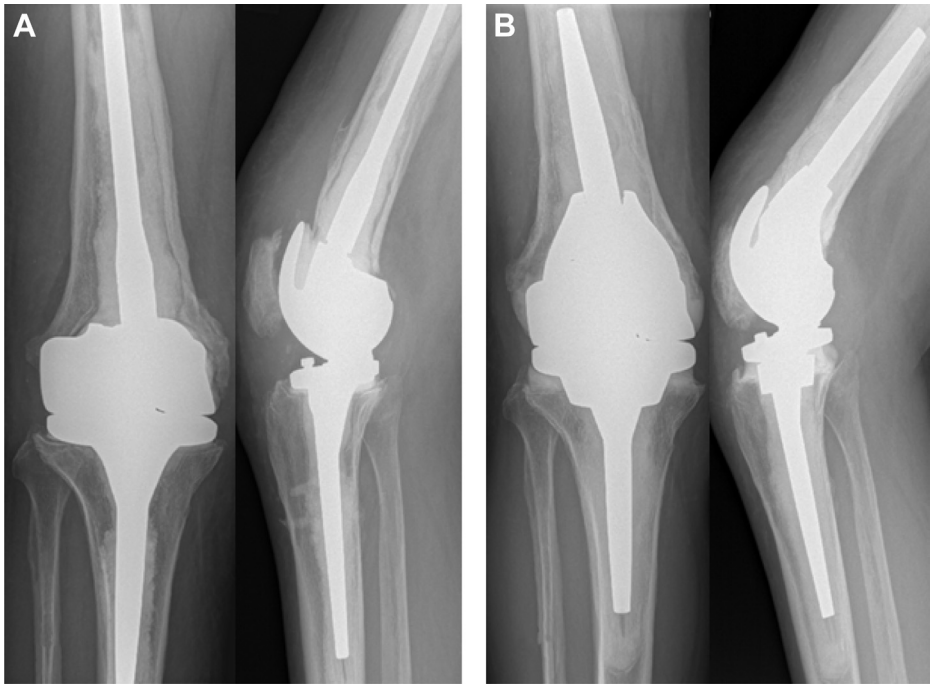

Fig. 2. Radiographs of the right knee joint of an 80-year-old male patient (at time of index surgery). A periprosthetic joint infection had been diagnosed. (A) Preoperative X-rays showing an implanted rotating hinge knee system with obvious loosening of the femoral component. (B) X-rays at 3-year follow-up after 1-stage exchange using both femoral and tibial cones.

Discussion

The tantalum cones have demonstrated to be a valid option in severe metaphyseal defects during revision TKA, showing an excellent capability to enhance tissue ingrowth and implant stability [11]. Nevertheless, their indication in septic revision surgery has not been well reported. Furthermore, the 2018 International Consensus Meeting on musculoskeletal infection had failed to give a recommendation regarding the value of tantalum augments against reinfection after the 1-stage exchange [12].

Our results demonstrate that metaphyseal tantalum cones are a reliable option during the relatively complex 1-stage exchange procedures. After a mean of 4 years, 79% of the knees did not require any revision surgery. Considering the cone exchange, the survival rate free from revision was 83%. Although the infection-free survival rate of 89% was relatively lower than that reported in other series of the 1-stage exchange, we were facing complex cases with major bony defects [1,13,14]. Although the reinfection rate was 7% in our previous report without the use of tantalum cones at a minimum follow-up of 9 years [1], we demonstrated a rate of 11% in the present study. However, we report here on midterm results with a mean follow-up of 4 years. Considering the rerevision because of aseptic loosening, the rate was nearly 9% in the present study compared with 10% in the previous report. However, the extent of bone loss has not been described [1]. Furthermore, the rate of cone exchange was only 6% in our study. On the other hand, our patients with septic failure had a significantly higher number of prior septic procedures.

In a large cohort study, 75 cases of reimplantation for the management of knee PJI using the 2-stage approach and implanting femoral cones had been included demonstrating a 5-year survivorship free from cone revision of 81% and that for any revision of 68%. Another important finding highlighted in that study is that there were no significant differences in survival rates between the whole cohort and the cases of PJI [15]. The overall revision rate for aseptic or septic complications was 27% at a mean follow-up time of 70 months, with an 11% rate of infection and 5% of aseptic tibial cone exchange in another study reporting on 26 of 66 patients who underwent 2-stage exchange [16].

More recently, Burastero et al [10] have shown more favorable results of 60 patients who underwent a 2-stage exchange for infected TKA using tantalum cones at the time of reimplantation at a mean of 3.5 years of follow-up. The infection-free survival was 96.7%, and the cone-associated survival rate was 97.8% in their study.

In a systematic review analyzing the outcomes of tantalum cones in revision TKA, the authors concluded that there was no significant difference in terms of survival rate, clinical and radiological outcome between femoral and tibial cones, with an overall reported survival rate of 95% and an infection rate of 7.1% [17].

The tantalum cones have proven to be a feasible option for restoration of metaphyseal fixation during revision TKA and are effective secondarily as structural supports for the prosthesis. Their biomechanical properties that favor an osteointegration with the host bone combined with the cone geometry facilitate initial mechanical stability [7,8,11]. As described previously, the metaphyseal zone 2 is crucial to ensure rotational and axial stability, hence the achievement of a stable fixation for the longevity of the implant. Once metaphyseal ingrowth occurs, the loads to the implant-host bone interface are dispersed away from the joint line [18]. However, the decision about which stem fixation method is still a preference-based surgeon's choice. There was no difference in the frequency of radiolucent lines around uncemented or cemented stem extensions in a retrospective small cohort study [19]. In our study, the 1-stage exchange entailed antibiotic-loaded cemented diaphyseal stems in all patients.

The design of the implanted prosthesis could have an impact on the outcomes, including the rate of aseptic loosening that might influence the ultimate durability. The degree of constraint could be a main prognostic factor for the functional outcome as better results for hinged knees have been reported than for varus-valgus

constrained designs [20]. However, Potter et al [15] observed a notable trend in their study between aseptic loosening and the use of a hinged TKA prosthesis for type III bone defect. We have recently reported on our long-term results of the reconstruction of metaphyseal bone loss, using the same cones in this study in aseptic revision TKA, presenting a higher rate of rerevision because of aseptic loosening among the pure hinged knees compared with the rotating hinge designs [21]. In the present study, we did not find a significant difference between both designs.

For the management of knee PJI, hinged prostheses are not always necessary because high success rates have also been reported after including patients who underwent 1-stage exchange using semi-constrained knee designs [22,23]. However, as a part of our strict management protocol, radical debridement, including the collateral ligaments, is crucial during the 1-stage procedure. Hence, the implantation of hinged prosthesis had to be performed.

The first limitation of our study is the bias associated with the retrospective reviews. Second, the loss to follow-up and the absence of radiographs at the final follow-up represents the main limitations to the present study. Also, a longer follow-up would be necessary for further evaluation of the reconstruction of major defects with tantalum cones at a long-term period.

In summary, this is the first study that reports on the outcomes of 1-stage exchange using metaphyseal cones for knee PJI with additional severe bone loss. The midterm overall cone-related survival and infection-free survival, offered good results and provided reasonable functional outcomes. Continued follow-up is required to assess the long-term durability of such implants in the management of extensive bone loss during the 1-stage exchange for infected TKA.

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