Autoclaved metal-on-cement spacer versus static spacer in two-stage revision in periprosthetic knee infection

Yu-Pin Chen, Cheng-Chun Wu, Wei-Pin Ho

Abstract

Background: Periprosthetic knee infection is troublesome for Orthopedic surgeons and a catastrophy for patients. Reported rates of periprosthetic joint infection following primary total knee arthroplasty (TKA) are 0.39–2%. Two stage revision arthroplasty, which has success rates exceeding 90%, has been the gold standard for treating subacute and chronic periprosthetic infection following TKA. Antibiotic spacers, a well established means of delivering local antibiotic therapy, maintain soft tissue tension during two stage revision arthroplasty. However, controversy remains around whether static or mobile antibiotic impregnated spacers are superior for treating infection following TKA. Various mobile spacers are available, including cement-on-cement, cement-on-polyethylene and metal-on-polyethylene. In this study, the efficacy of the modified metal-on-cement spacer, consisting of reinsertion of the autoclaved femoral component and implantation of antibiotic-loaded cement in the proximal tibia, is assessed.

Materials and Methods: Records of 19 patients diagnosed as periprosthetic knee infection were reviewed in this retrospective study. Among these patients, 10 patients received first stage debridement with the autoclaved metal-on-cement spacer and 8 patients with the static spacer, who eventually underwent two-stage re-implantation, were listed in the final comparison. Patient demographics, infection eradication rates, average range of motion (ROM), surgical time and blood loss during the second-stage of the surgery, and Knee Society (KS) knee scores at last followup after revision total knee replacement were clinically evaluated.

Results: At a minimum of 2-year followup after re-implantation, infection eradication rates, surgical times, blood loss during the second-stage of the surgery, and KS knee score after re-implantation were similar for the two groups. Patients receiving autoclaved metal-on-cement spacers had superior ROM after re-implantation compared to that of patients with static spacers.

Conclusions: The autoclaved metal-on-cement spacer is an effective and simple method for two-stage re-implantation of a periprosthetic knee infection. Through this spacer, the good interim ROM can be achieved without the additional cost of prefabricated molds or new polyethylene tibial inserts. In addition, ROM after re-implantation is better than that with static spacers.

Key words: Mobile spacer, periprosthetic knee infection, two-stage re-implantation
MeSH terms: Arthroplasty, replacement, knee, knee joint, knee prosthesis, surgical infection

Introduction

Periprosthetic knee infection is troublesome for Orthopedic surgeons and a catastrophy for patients. Reported rates of periprosthetic joint infection following primary total knee arthroplasty (TKA) are 0.39–2%.[1,2] As the number of patients undergoing primary TKA is increasing, there is an increase in the number of periprosthetic joint infection also.

Two-stage revision arthroplasty, which has success rates exceeding 90%, has been the gold standard for treating subacute and chronic periprosthetic infection following TKA.[3,4] Antibiotic spacers, a well-established means of delivering local antibiotic therapy, maintain soft tissue tension during two-stage revision arthroplasty.[5] However, controversy remains around whether static or mobile

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antibiotic impregnated spacers are superior for treating infection following TKA.

Although static spacers deliver local antibiotic therapy, they markedly restrict knee motion. In contrast, mobile spacers, which allow mobility during the interim period between the first and second stage of revision arthroplasty, reportedly improve range of motion (ROM) after second-stage procedures.[6-8] Various mobile spacers are available, including cement-on-cement, cement-on-polyethylene, and metal-on-polyethylene.[5] Although each mobile spacer has its own advantages and advocates, commercial mobile spaces are not always affordable or applicable to each patient. Continued efforts are needed to develop temporary spacers for two-stage revision arthroplasty.

To the best of our knowledge, data regarding the effectiveness of metal-on-cement spacers are rare. In this study, the efficacy of the modified metal-on-cement spacer, consisting of reinsertion of the autoclaved femoral component and implantation of antibiotic-loaded cement in the proximal tibia, is assessed.

Materials and Methods

19 consecutive patients who were diagnosed with chronic periprosthetic knee infection and received two-stage debridement between February 1999 and February 2012 were assessed in this retrospective study. There were no exclusion criteria on the basis of the cause of infection. Review Board approval was acquired for this retrospective study of medical records and radiographs; that is data for treatment and followup were collected retrospectively from patient records.

There were 17 females and 2 males aged between 20 and 88 (mean 71.2 years) years. Indications for TKA were osteoarthritis (n = 16), rheumatoid arthritis (n = 2) and osteonecrosis of the femoral condyle (n = 1). 15 of 19 patients had at least one comorbidity. Diabetes mellitus was diagnosed in 11 patients. Latent osteoarticular tuberculosis infection, liver cirrhosis, and end-stage renal disease was diagnosed in three patients separately. Median time from the index operation and the first-stage operation was 55.7 months (range 9–145 months).

The diagnosis of infection was based on symptoms such as persistent pain, swelling, local warmth, restricted and painful ROM disproportionate to the expected recovery from the surgery.[1] All infections were confirmed with joint fluid analysis and serological tests including C-reactive protein (CRP) levels, erythrocyte sedimentation rate (ESR) and leukocyte count.[1] Bacterial cultures of synovial fluid samples or of perioperative specimens identified the pathogen in 11 patients [Figure 1].

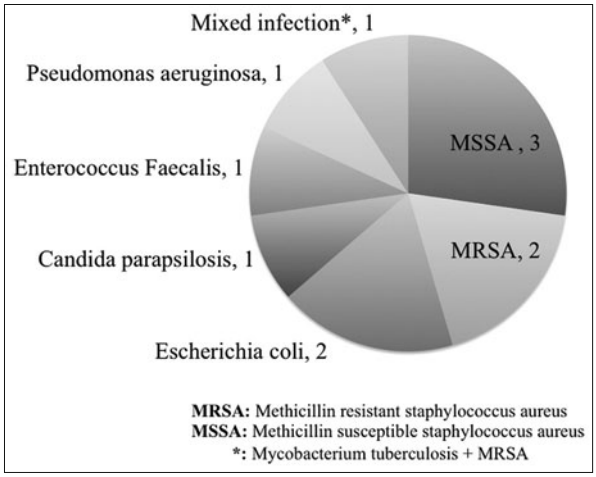

Figure 1: Infecting organisms by culture tests

Treatment strategy and evaluation methods

The two groups in this study were based on treatment protocols for two-stage revision [Figure 2]. Between February 1999 and June 2006, 10 patients were treated with static antibiotic-impregnated spacers [Figure 3]. Among these 10 patients, two patients did not undergo re-implantation (one died of pneumonia and the other refused re-implantation due to high mortality risk under anesthesia). Therefore, only eight patients who received second-stage revision could be included in the final comparison. Furthermore, among these eight patients, two patients had a recurrent infection during followup. These two patients then received two-stage revision again with mobile spacers.

After June 2006, 11 patients (including nine who had no previous debridement surgery and two who had previously failed two-stage revision surgery with static spacers) were treated with autoclaved metal-on-cement antibiotic-impregnated spacers [Figure 4]. However, among these 11 patients, one patient refused re-implantation because of satisfaction for the mobile spacer without motivation for revision. Therefore, only 10 patients who received re-implantation could be listed in the final comparison.

Successful two-stage re-implantation was defined as no evidence of infection for at least 2 years after revision TKA. Infection eradication rates, average ROM, surgical time, blood loss during second-stage procedure, as well as Knee Society (KS) knee score[9] at last followup after revision TKA were compared. Knee ROM was examined through a goniometer, and clinical results were recorded by one Orthopedic surgeon (W-P H).

Operative procedure

All patients underwent two-stage revision surgery by one Orthopedic surgeon (W-P H). During the first-stage of surgery, all patients underwent extensive

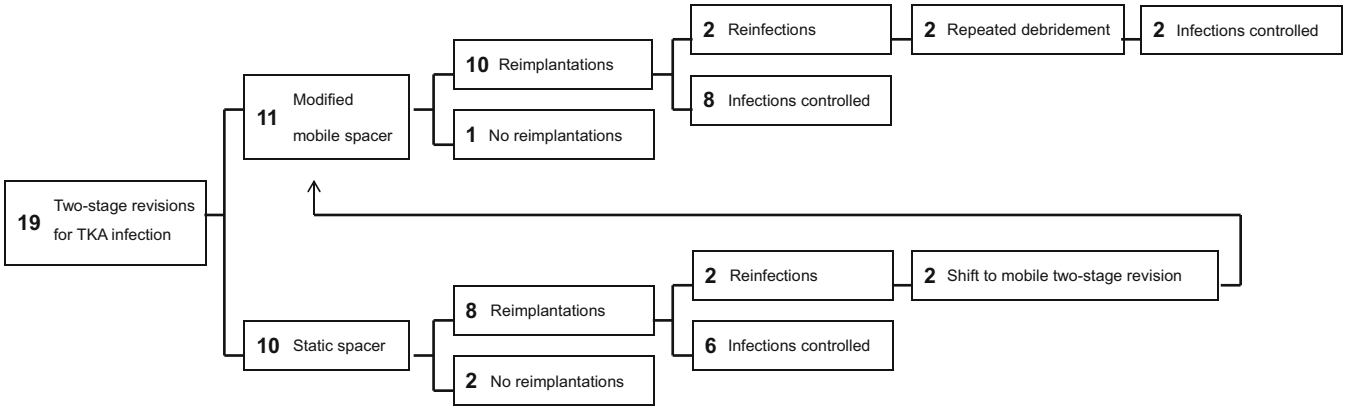

Figure 2: Treatments and outcomes of patients treated for periprosthetic knee infection

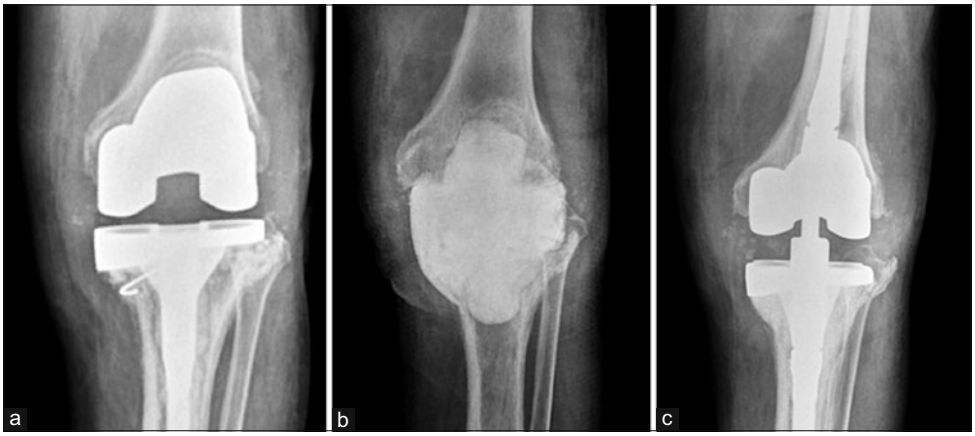

Figure 3: Anteroposterior radiograph of the knee of a 72 year old female with infection after total knee arthroplasty who was treated with the static spacer showing (a) loosening of implant (b) After static spacer insertion (c) After re-implantation of implant

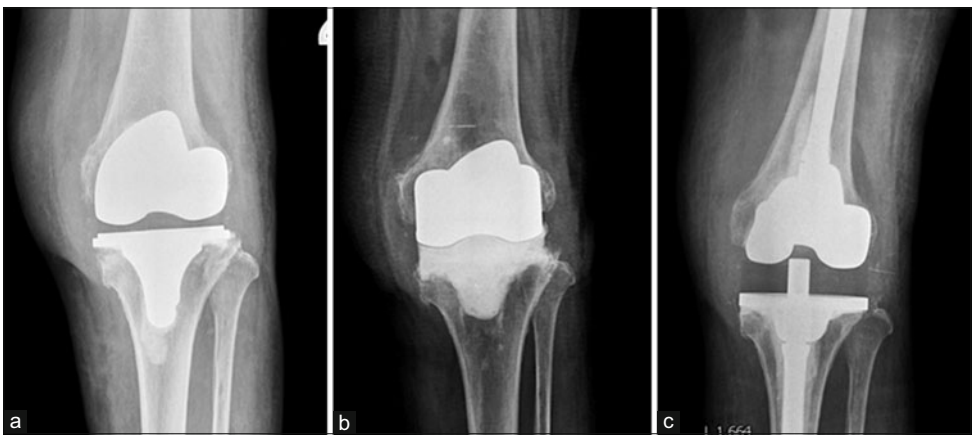

Figure 4: Anteroposterior radiographs of the knee of 88-year-old female with infection after total knee arthroplasty who was treated with the autoclaved metal-on-cement spacer. (a) Radiograph showing loosening of the prosthesis. (b) After autoclaved metal-on-cement spacer insertion. (c) After re-implantation

debridement at the time of implant removal. A complete synovectomy was performed, and medullary canals were thoroughly debrided. Antibiotics were encased in the cement according to the sensitivity profile of the infecting organism or 2 g vancomycin/40 g bone cement powder was used for patients with negative preoperative culture results. Temporary spacer alternatives were static antibiotic-impregnated spacers and autoclaved metal-on-cement spacers. With the static spacers, antibiotic-loaded cement filled the extension gap after removal of all implants [Figure 3b].

For autoclaved metal-on-cement spacers, we prepared them as follows:

- Step 1: Preparation of the autoclaved femoral component:
  The removed femoral component was cleaned to remove bone cement and debris, washed and sterilized in an autoclave for 7 min at 137°C in the operating room
- Step 2: Preparation of the temporary tibial cement component:
  A flexible template was utilized to enclose the space filled with antibiotic-loaded cement according to the size of the removed tibial plate [Figure 5a and b]. The autoclaved femoral component was then utilized to press onto the temporary tibial cement spacer before cement polymerization to ensure a smooth articulating surface between the metal and cement components [Figure 5c]. Excess cement was removed
- Step 3: Reinsertion of the femoral and tibial components:
  The femoral component was reinserted with antibiotic-impregnated cement first to restore its original joint height, according to reference from the epicondylar axis (average 23 mm from lateral epicondyle and 28 mm from medial epicondylar). Next, the tibial cement component was placed while the knee was in full extension position under gentle traction. The gap between the tibia cement component and tibia bone surface was filled with antibiotic- impregnated cement. All spacers were fixed loosely with antibiotic-impregnated cement during the near rubber phase of cement polymerization, in order to decrease infiltration of cement into the trabecular space of the bone surface and facilitate later removal. The effort was made to restore the original joint line and maintain proper alignment, as well as balanced soft tissue tension [Figure 5d].

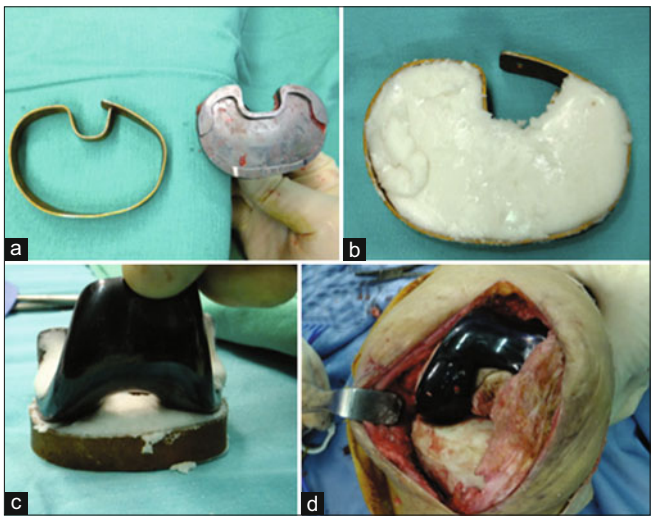

Figure 5: (a and b) Photograph showing antibiotic loaded cement preparation by removed tibial plate and flexible template (c) Photograph showing cement spacer being pressed by autoclave femoral component before cement polymerization (d) Peroperative photograph showing insertion of autoclaved femoral component and tibial cement component

After staged operations with static or mobile spacers, antibiotics were administered intravenously for 2 weeks according to the sensitivities of infecting organisms, followed by a 4-week course of oral antibiotics. After surgery, a temporary long leg splint was applied for 2 weeks in patients in the static group; while range of motion (ROM) of the knee was allowed after applying a knee brace in the mobile group. Weight bearing, when tolerated, was allowed in both groups.

The second-stage procedure was performed only when signs of infection were not present. Before the second-stage of revision, normal laboratory findings (ESR, CRP) were required for at least 2 weeks after withdrawal of antibiotics. The surgical approach for re-implantation followed the principles of revision TKAs. All prostheses were fixed with antibiotic-impregnated cement. Bone defects were filled with augments or bone grafts. After the operations, patients were clinically reviewed using ESR and CRP and for any signs of recurrent infection.

Statistical analysis

The primary outcome variables were infection eradication rate, perioperative ROM, and postoperative KS knee scores. The Mann–Whitney U-test was applied to compare variables. To compare categorical variables, the Chi-square test with Fisher's exact test was used. $P \leq 0.05$ was considered statistically significant. Analytical results given are mean (range).

Results

All patients were followed up for at least 2 years after revision TKA. Ten patients in the modified mobile spacer group and eight in the static spacer group who underwent revision TKA were compared [Table 1]. No significant differences existed between the two groups for age, gender, and sites of a knee infection. Prior to the first operation, patients in the modified mobile spacer group achieved 40° (range 30–75°) ROM, compared with an average 38.1° (range 5–90°) of ROM for the static spacer group. Preoperative ROM between these two groups did not differ significantly.

During the interim period between the first and second surgery, patients in the modified mobile spacer group achieved a 81° (range 45–100°) of ROM, compared with an average of 5° (range 0–30°) of ROM for the static spacer group. Average period between the first and second surgery was 135.9 days (range 61–296 days) and 155.8 days (range 49–420 days) in the mobile spacer group and static spacer group, respectively ($P = 0.897$). Notably, among the patients treated with the mobile spacer, five of 10 (50%) complained about knee instability while walking. All ten patients walked with the assistance of a knee brace.

Table 1: Patient demographics and clinical outcome of two-stage revision arthroplasty

Patient demographics	Mobile spacers (mean/range) (*n*=10)	Static spacers (mean/range) (*n*=8)	*P*
Age	68.9 (20-88)	73.9 (63-82)	0.857
Gender	9 female, 1 male	5 female, 3 male	0.275
Infected site	6 left, 4 right	6 left, 2 right	0.638
ROM before first-stage surgery	40° (30°-75°)	38.1° (5°-90°)	0.423
Duration between first- and second-stage surgery (days)	135.9 (61-296)	155.8 (49-420)	0.897
ROM after first-stage surgery	81° (45°-100°)	5° (0°-30°)	0.000
Surgical time during second-stage surgery (min)	173.7 (150-225)	183.1 (150-220)	0.562
Blood loss during second-stage surgery (ml)	145 (50-500)	143.8 (50-300)	0.503
Prosthesis options for revision	PSA (*n*=6); LCCK (*n*=4)	PSA (*n*=3); LCCK (*n*=5)	
ROM after second-stage surgery	94.5° (70°-125°)	74.3° (50°-90°)	0.023
Knee society knee score	74.7 (62-88)	71.4 (60-81)	0.327
Infection eradication rate (%)	8/10 (80)	6/8 (75)	1
Followup after second-stage surgery (months)	32 (24-46)	40.8 (25-56)	0.056
Complications	V-Y quadriceps plasties (*n*=2); Wound dehiscence (*n*=1)	V-Y quadriceps plasties (*n*=1); Nonfatal DVT (*n*=1)	

Patients who did not undergo a second-stage procedure are excluded. PSA=United Orthopedic's U2 PSA Revision Knee system, LCCK=The Zimmer NexGen Legacy Constrained Condylar Knee system, DVT=Deep vein thrombosis, ROM=Range of motion, PSA=Prosthetic specific antigen

During the second operation, no differences existed between the mobile and the static spacer groups in terms of operative time (mean 173.7 vs. 183.1 min, $P = 0.562$) or the operative blood loss (mean 145 vs. 143.8 min, $P = 0.503$). Two patients in the mobile spacer group, and one in the static group needed V-Y quadriceps plasties for better exposure and lengthening of quadriceps tendon due to contracture. Further, no fracture of cement spacers was identified during re-implantation for these two groups. However, variance existed in terms of prosthesis used in revision surgery [Table 1].

At final followup after re-implantation, patients in the modified mobile spacer group achieved a 94.5° (range 70–125°) of ROM, compared with an average 74.3° (range 50–90°) of ROM for the static spacer group; these differed significantly ($P = 0.023$). The average KS knee scores in the modified mobile and static spacer groups were 74.7 (range 62–88) and 71.4 (range 60–81), respectively. No significant differences existed in scores at final followup ($P = 0.327$). Two-stage re-implantation without reinfection was successful in eight of 10 (80%) patients in the modified mobile spacer group and in six of eight (75%) patients in the static spacer group. Infection eradication rate between these two groups did not differ significantly ($P = 1$). Although the followup duration for the static spacer group (mean 40.8 months) was longer than that for the modified mobile spacer group (mean 32 months), the difference was not significant ($P = 0.056$). Besides, one patient's postoperative course in the static spacer group was complicated by nonfatal deep vein thrombosis during the period between the two operations and needed anticoagulant therapy during the treatment course.

Two patients in the static spacer group were reinfected after followup for 12 and 23 months, respectively. The first patient had culture report of *Pseudomonas aeruginosa*, treated with quinolone group. The second patient failed to have positive culture report, empirically treated with vancomycin. These two patients with previously failed infection control subsequently received two-stage revision with autoclaved metal-on-cement mobile spacer. Fortunately, after followup for at least 2 years, there was no recurrence of infection. However, another two patients in the modified mobile spacer group were reinfected 11 and 15 months after re-implantation, respectively. Bacterial cultures yielded methicillin-resistant *Staphylococcus aureus* in the first patient but failed to yield organisms in the second patient. These two patients were all treated with vancomycin and underwent repeated debridement, eventually achieving infection control after followup for at least 1-year. No correlation between infection eradication rates, the yielding organism and giving antibiotics could be identified in these patients with recurrent infection.

Discussion

Periprosthetic knee infections are significant challenges for orthopedic surgeons. Even with successful eradication, these infections can be devastating and catastrophic, resulting in long term disability.[10] Currently, two-stage revision with antibiotic spacers is commonly performed to treat an infection after TKA. However, debates remain as to which antibiotic spacers are ideal. The static spacer provides only temporary joint stability and is considered a simple procedure and an ideal antibiotic-delivery system.[11] Nevertheless, concerns regarding static spacers have focused on spacer subluxation and dislocation, spacer fracture, bone erosion, as well as knee stiffness due to prolonged immobilization between stages.[12] Instead, the mobile spacer has many advantages, including potentially

effective maintenance of the joint space, allowing for limited weight bearing and facilitating joint motion.[5] Similar infection eradication rate was also demonstrated among these two types of spacers.[12,13] Although the mobile spacer is becoming popular due to these advantages; debate still remains regarding methods for preparing a mobile spacer.

Theoretically, an ideal mobile spacer effectively eradicates infection and preserves good interim ROM. Moreover, procedure simplicity and the cost-effective and availability of materials should also be considered when preparing a mobile spacer. Ha CW (2006) advocated intraoperative handmade mobile cement-on-cement spacers to treat infections after TKA and reported a 100% infection eradication rate with an average 104° ROM postoperatively.[14] However, the technical proficiency needed to produce friction-less, cement-on-cement articulation remains a concern. Commercially prefabricated molds simplify and standardize the production of cement-on-cement spacers. Although studies of prefabricated molds for preparing mobile cement spacers had optimistic outcomes for infection eradication rate and better ROM compared with those of static spacer groups,[6,15,16] the additional cost of commercial molds prevents some patients from choosing this treatment.

To manage infection after TKA, several studies have reviewed the use of mobile, metal-on-polyethylene spacers.[7,8,17] Haddad *et al*. treated 48 patients with periprosthetic knee infections with metal-on-polyethylene spacers made from commercial molds and implants (PROSTALAC, Depuy, Warsaw, IN, USA). At 4-year followup,[8] the infection eradication rate was 91% and average ROM was 95° after re-implantation, demonstrating the benefits for this treatment. Nevertheless, the high cost for commercial products precludes this choice for many patients, which are also not applicable to all patients. Although concerns exist about infection control and clinical safety, another metal-on-polyethylene spacer with a reinserted femoral component after resterilization plus new tibial polyethylene insert have proven reliable for treating infection after TKA.[7,17] Jämsen *et al*. compared autoclaved metal-on-polyethylene spacers with cement-on-cement spacers, demonstrating that eradication rates for these two spacers were similar.[17] Better articulation and less surface friction for potentially better interim ROM are other advantages of metal-on-polyethylene spacers; however, the additional cost of polyethylene inserts and the limited availability of commercial products in many countries still need to be addressed.

Each method for preparing a mobile spacer has its merits and drawbacks. At present, no consensus exists regarding the best spacer preparation method. Data are lacking on the effect of metal-on-cement spacers to manage two-stage revision of periprosthetic knee infection. In this study, infection eradication rates for the autoclaved metal-on-cement spacer and static spacer were similar, showing that reinserted components after resterilization and motion between operations did not increase the reinfection rate. Although no significant difference existed for surgical time and blood loss during the second surgery, the autoclaved metal-on-cement spacer group had better interim and post-re-implantation ROM than the static spacer group. Even though KS knee scores after re-implantation were not significantly different between these two groups, this study demonstrates that metal-on-cement spacers allow good knee motion compared with static spacers.

Interestingly, five of 10 patients treated with the resterilized metal-on-cement spacer complained about knee instability while walking. Concerns exist on the instability and allowing weight bearing with the mobile spacer, which may cause more bone loss. However, all of the reported instability was minor and did not pose significant limitations for ambulation under protective knee brace. During the second-stage revision in the mobile spacer group, there were no identified components loosening, as well as a significant bone loss. Therefore, with an effort to restore the original joint line during insertion of autoclaved metal-on-cement spacers, we believed that there were no significant problems for a second-stage revision even with minor instability in our mobile spacer group.

Some studies reported that mobile spacers allow satisfactory ROM during the life of the cement spacers, thereby decreasing the magnitude of soft tissue contracture, facilitating surgical exposure and soft tissue balancing during revision.[7,16] However, this study did not identify any difference in the need for extensive exposure with V-Y quadriceps plasties between mobile and static spacers. V-Y quadriceps plasties performed in these two groups depended on needs for better exposure and quadriceps tendon contracture necessary for better ROM after re-implantation. Furthermore, one patient in the static spacer group developed nonfatal deep vein thrombosis. Limited knee motion for long periods between stages was thought to be a risk factor for this complication with static spacers.

Table 2 compares studies on different spacers. Interestingly, average ROM and KS knee score of patients treated with the autoclaved metal-on-cement spacer in this study are not as good as those in other reports. This might be attributed to the small case number in this study and the history of failed revision surgery for infection after TKA in two of ten patients in the mobile spacer group.

The relative small sample size is the main limitation in our study. It is also limited by the biases inherent to a

Table 2: Comparison of studies on different type of spacers

Reference	Type of spacer and preparation	Number of knees	Infection control	Average ROM/KSS or HSS (at final followup)
Ha[14]	C/C; Handmade cement molds made by applying cement on removed implants for C/C spacer	12	100%	ROM 104°; KSS 87
Park *et al*.[6]	Static versus C/C; Prefabricated silicone mold for C/C spacer	Static 20; C/C 16	Static 85%; C/C 94%	ROM: Static 92°; C/C 108° (sig) HSS: Static 80, C/C 82 (sig)
Fehring *et al*.[15]	Static versus C/C; Prefabricated metal molds for femoral components plus handmade tibial component for C/C spacer	Static 25; C/C 30	Static 88%; C/C 97%	ROM: Static 98°; C/C 105° (NS) HSS: Static 83, C/C 84 (NS)
Hsu *et al*.[16]	Static versus C/C; Prefabricated silicone mold for C/C spacer	Static 7; C/C 21	Static 86%; C/C 91%	ROM: Static 78°; C/C 95° (sig) HSS: Static 81.4, C/C 88.9 (sig)
Haddad *et al*.[8]	M/PE; Commercially made mold and implants for M/PE spacer (PROSTALAC)	45	91%	ROM 95°; HSS 72
Emerson *et al*.[7]	Static versus M/PE; Autoclaved femoral components and new PE inserts as M/PE spacer	Static 26; C/C 22	Static 92%; M/PE 91%	Flexion: Static 93.7°; M/PE: 107.8° (sig)
Jämsen *et al*.[17]	C/C versus M/PE; Handmade C/C spacer versus autoclaved femoral components plus new or autoclaved PE inserts as M/PE spacer	C/C 10; M/PE 24	C/C 90%; M/PE 83%	ROM: C/C 92°; M/PE: 103° (NS) KSS: C/C 79, M/PE 81 (NS)
Current report	Static versus M/C; Autoclaved femoral components on handmade tibial cement component as M/C spacer	Static 8; M/C 10	Static 75%; M/C 80%	ROM: Static 74.3°; M/PE: 94.5° (sig) KSS: Static 71.4, M/PE 74.7 (NS)

C/C=Cement-on-cement, M/PE=Metal-on-polyethylene, M/C=Metal-on-cement, ROM=Range of motion, KSS=Knee Society knee score, HSS=Hospital for special surgery score, Sig=Significant difference, NS=Nonsignificant difference, PROSTALAC=Prosthesis with antibiotic-loaded acrylic cement

retrospective analysis. Other limitations include clinicians who were not blinded to spacer type and the various options for prostheses during re-implantation. Moreover, followup duration for the static group was longer than that for the mobile group. These limitations may also confound analytical results and lead to potential bias.

To conclude autoclaved metal-on-cement spacer is an effective and simple method for two-stage re-implantation for cases of infection after TKA.

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Conflicts of interest

There are no conflicts of interest.

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