Preformed Articulating Knee Spacers in 2-Stage Total Knee Revision Arthroplasty

Minimum 2-Year Follow-Up

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Abstract: Two-stage revision arthroplasty using articulating spacers for the treatment of infected total knee arthroplasty (TKA) is a successful management technique. Our purpose was to report our results using preformed, commercially available articulating spacers made of gentamicin-impregnated cement. Thirty-three patients with infected primary or revision TKAs were treated with these spacers using a 2-stage revision technique. In most cases, the spacers were modified intraoperatively by adding a stem of reinforced antibiotic-impregnated acrylic cement. Successful eradication was achieved in 30 of 33 cases at a minimum 2-year follow-up interval. Two patients required a second spacer before successful revision TKA. No spacer fractures or dislocations occurred in this series. No adverse soft tissue effects were noted from the use of this type of articulating spacer.
Keywords: articulating spacer, infected total knee, revision total knee, cement spacer.

Deep infection after total knee arthroplasty (TKA) is a serious complication with a reported incidence of 1% to 4.4% in series ranging in size from 431 to 12 118 primary arthroplasties [1-5] and from 3.2% to 15% in series ranging from 40 to 1214 revision arthroplasties [2-4]. Although different treatment modalities have been described in the literature, 2-stage revision arthroplasty remains the most successful eradication technique of deep infection after TKA with success rates averaging 92% from 37 published studies [6-15].

Initially, static spacers for 2-stage revision arthroplasty were developed to serve as a reservoir for local antibiotic delivery while maintaining tension of the surrounding ligaments and tissue [7]. Articulating spacers, in addition to providing similar function as static spacers, are a more recent development to improve the functional status of patients and decrease subsequent complications such as dislocations or cement fractures during the interstage period. Reports have demonstrated improved postoperative range of motion and decreased tibial and femoral bone loss using articulating spacers as compared with static spacers with similar eradication rates [8,9].

A more recently developed type of articulating spacer is a premanufactured cemented spacer that is ready for immediate implantation. There have been several short-term and longer term reports of preformed implants for 2-stage revision after total hip arthroplasty with satisfactory eradication results [10-13]. However, to our knowledge, there is only one study reporting on preformed articulating knee spacers [14]. Therefore, our purpose was to report our results using a commercially available articulating cement spacer for the treatment of deep infection in primary and revision TKA. Institutional review board approval from our institution was obtained before the commencement of this study.

Materials and Methods

A series of 41 consecutive patients with infected primary or revision TKA were treated in our institution from October 2005 to August 2009 by the senior authors in one center (Methodist Hospital, Houston, Tex). Although cement spacers were used in all cases, 5 patients were excluded from the study because of our intent to report on only preformed spacers and not other types of spacers. Three patients were excluded because a "fusion nail" spacer was used because of extreme bone loss [15]. A total of 33 patients completed the 2-stage

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reimplantation protocol using preformed articulating spacers and were included in the analysis. The articulating spacer (InterSpace Knee; Exactech, Gainesville, Fla) was commercially available in 3 sizes and contained 1.2 g of gentamycin in each of the femoral and tibial components. The minimum follow-up time was 24 months (range, 24-62 months; mean, 44 months) for inclusion. Patient demographics are summarized in Table 1.

In all cases, patient records and radiographs were reviewed. The diagnosis of infection in 85% of the cases was confirmed using positive cultures of elevated erythrocyte sedimentation rate (ESR > 20) and C-reactive protein level (CRP > 1.0). In the 15% of cases (5 cases) that had negative results in culture, intraoperative findings included obvious purulent material within the knee joint (along with an elevated ESR and CRP). All 5 patients had received antibiotics before referral to our institution. Comorbidities in our series included 5 patients with diabetes mellitus, 1 patient with hepatitis C, and 17 patients with obesity (body mass index > 30). According to the staging system for patients with prosthetic joint infection, of the 33 patients, 30% (10 cases) were classified as stage A, 58% (19) as stage B, and 12% (4) as stage C [16]. No cases of mortality occurred.

Two patients had culture positive for *Candida*. In these 2 cases, we added amphotericin in the cement spacers (50 mg per vial, 2 vials per cement batch). We do not routinely use an antifungal agent for all cement spacers, but we do use them when a fungal organism is present on culture. We currently prefer variconizole (200 mg per vial, 2 vials per cement batch) for any documented fungal infection when fabricating cement spacers because variconizole is considered more heat stable than amphotericin.

The surgical protocol was similar to what we have previously described using customized articulating spacers [15]. All patients underwent a staged reimplantation procedure through a medial parapatellar approach with careful removal of prosthetic components and all bone cement, debridement of inflammatory or devitalized tissue and bone, and irrigation with 9 L of pulsating saline solution.

Table 1. Patient Demographic Data

	Patients (n = 33)
Age, y	70 ± 11 (range, 49-86)
Gender	22 male, 11 female
Primary/revision	25/8
Right/left	18/15
Weight, kg	93 ± 23 (range, 62-145)
Height, cm	175 ± 12 (range, 152-195)
Body mass index, kg/m^2	31 ± 7 (range, 20-46)
Comorbidities	
Type II diabetes	5
Coronary artery disease	10
Hypertension	14
Obesity (body mass index > 30)	17
Hepatitis C	1

For cases in which stems were not fabricated intraoperatively, trial components were used to balance the flexion and extension spaces. The spacers were sequentially cemented into place (tibia first). In these cases, 1 or 2 batches (40 g) of bone cement (Simplex; Stryker, Mahwah, NJ) were mixed with 3 g of vancomycin and 3.6 g of tobramycin. A small amount of methylene blue dye was added to the cement to aid visualization, which helped cement removal at the time of revision surgery.

More commonly, a stem was added to each spacer component. A 6-mm metal rod of variable length was placed in a mold designed to uniformly coat the rod with antibiotic-impregnated cement (Nimbic Systems, Sugarland, Tex) to produce a 13-mm diameter "stem" that was then manually cemented to the preformed cement spacer. This typically involved 3 bags of cement: 1 for coating the 2 rods, 1/2 to 1 to cement the rods to the components, and 1 to 1 1/2 to cement the final spacers to the bone ends (so, for 3 bags of cement, 9 g of vancomycin and 10.8 g of tobramycin were used). With these components, final cementing was limited to the bone surfaces and just enough metaphyseal bone to gain stability as determined by the surgeon (Fig. 1).

Once the stemmed spacers have been assembled, they are cemented using cement only on the condylar bone surface and as little metaphyseal bone as necessary to achieve some stability. These are, in fact, intentionally cemented with "poor" cement technique to facilitate later removal. The implants are advanced, and the doughy cement is allowed to escape around the condylar portions. The spacers were not aggressively impacted into place. The final compression force placed on the spacer implants is achieved once both spacers are in place and the joint is reduced by extending the knee to approximately 10° of flexion and holding it there until the cement is hardened. At this point, excess cement is cleaned away. The amount of cement typically used can be seen in Fig. 1C.

All patients were given a postoperative, removable knee brace and kept immobilized for 3 to 4 weeks in full extension to allow soft tissue healing, followed by gentle knee flexion exercises—both passive and active. Ambulation was begun immediately with the knee brace initially locked in extension with incremental gains in flexion depending. Patients were encouraged to gently bear weight (70 lb) as tolerated. The range of knee motion obtained before reimplantation surgery ranged from 35° to 110° of flexion, with most patients achieving 65° to 80° of knee flexion.

All patients had 6 weeks of intravenous antibiotic therapy under the direction of an infectious disease specialist. The surgical wound was monitored closely for

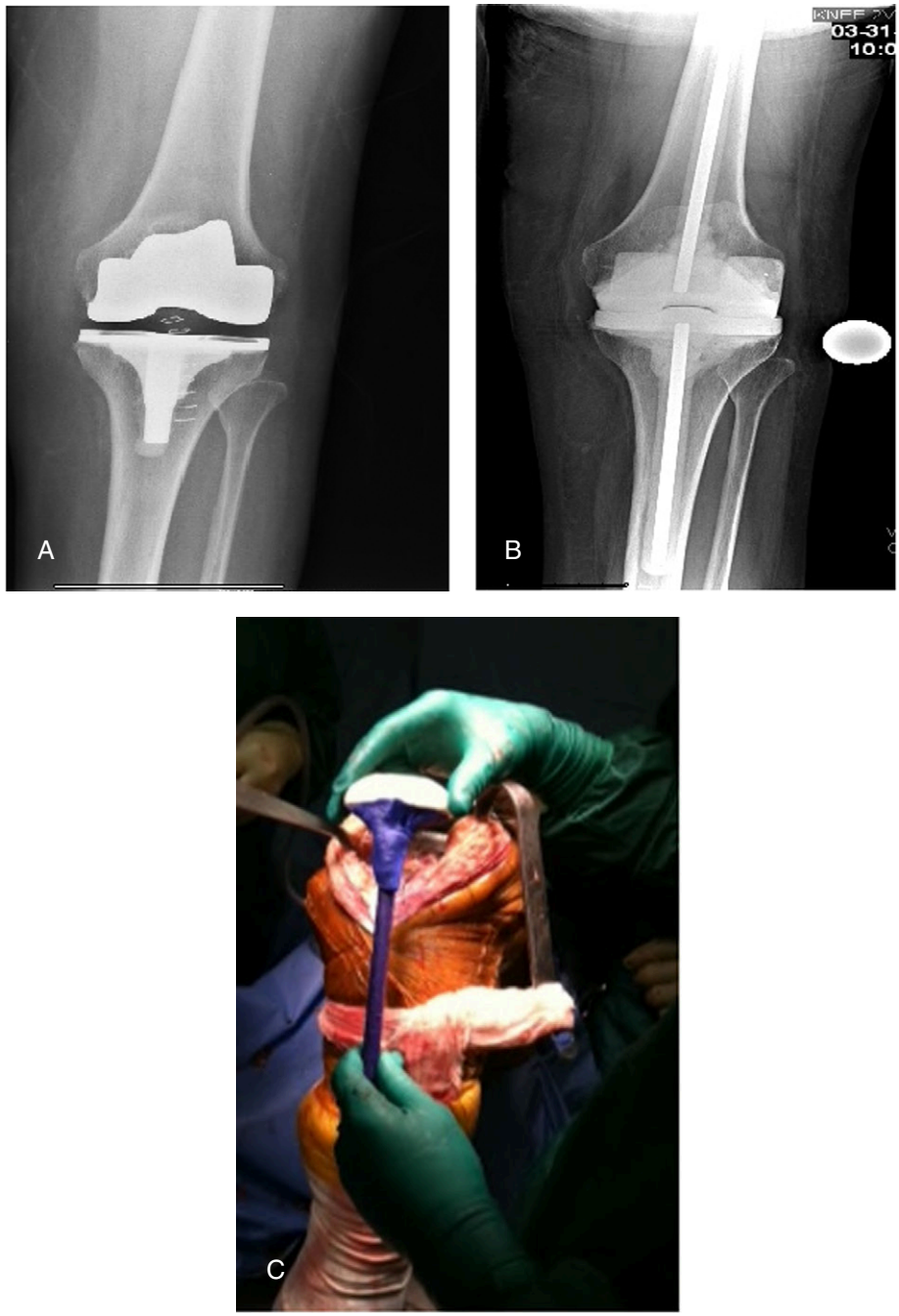

Fig. 1. (A) Radiograph of an infected total knee arthroplasty and (B) with stemmed articulating spacers in place. (C) Intraoperative view of the spacer with minimal metaphyseal cement before implantation.

any signs of infection along with periodic ESR and CRP measurements. A 2-week antibiotic holiday occurred before knee aspiration followed by the second-stage revision procedure. Revision TKA surgery was scheduled if the knee joint aspirate culture showed no growth. The reimplantation procedure was done through the original incision with no patient requiring a quadriceps snip, V-Y quadricepsplasty, or extensile exposure. All revision components were cemented using commercially available bone cement with premixed tobramycin (Simplex with Tobramycin; Stryker). In the 2 cases of a positive fungal culture, an antifungal agent was added to each batch of cement at the time of reimplantation. Frozen tissue section analysis or gram stain was not routinely performed as the authors have not found them to be helpful. Frozen section and gram stain were performed if there was any tissue necrosis or cloudy-appearing fluid at the time of spacer removal. Culture specimens were taken, and the reimplantation was performed if, in the surgeon's judgment, neither

necrotic tissue nor visible signs of infection were present. Successful eradication was considered when a patient had no infection-related procedures for the initial infection at the latest follow-up visit.

Results

Staphylococcal species predominated as the organism responsible for infection (Table 2). The average time from index operation to diagnosis of infected total knee was 41 months (range, 1-192 months). Of the 31 patients, 18 (58%) had more than one prior surgery on the infected knee before spacer placement and referral to our institution. Most cases presenting with infection were after primary TKA (25/31). Two patients, who we treated with component removal and spacer placement, required the removal and reimplantation of new spacers because of intraoperative findings of persistent infection and required a postponement of their revision procedure. Both of these patients are infection-free at last follow-up. Six patients had previous spacer implantation performed before arriving at our institution, and all were treated with our spacer technique by us before revision TKA.

After a minimum of a 24-month follow-up interval, the presenting infection was eradicated in 30 of 33 cases for a yielded success rate of 91%. One case after primary TKA continued to exhibit signs of infection after the 2-stage reimplantation procedure, whereas 2 of 6 infected revision TKA cases continued to have signs of infection. Of the 3 failures, one had a successful arthrodesis, one remains on long-term use of suppressive antibiotics while an above-the-knee amputation is considered, and the last one underwent a second 2-stage revision procedure and, at early follow-up, has a revision TKA in place and remains on long-term use of suppressive antibiotics.

No signs of breakage, dislocation, or loosening were noted in any of the cases. In no case was it felt necessary to perform a formal synovectomy due to abnormal synovitis presumably because of cement spacer abrasion. The spacers showed no visible signs of wear as well. The average time frame of spacer implantation was 14 weeks (range, 8-31 weeks).

Table 2. Organisms Cultured in the 33 Cases Undergoing 2-Stage Revision Arthroplasty Using Preformed Spacers

Organism	No. of Patients
Staphylococcus aureus	
Methicillin sensitive	8
Methicillin resistant	7
Coagulase-negative *Staphylococcus*	8
Streptococcus	
Group B	2
Candida albicans	2
Escherichia coli	3
Enterococcus faecalis	1
Oligella urealyticum	1
Anaerobes	1
Polymicrobial	1
Cultures with negative results	5

Discussion

Several different forms of articulating spacers have been described yielding eradication rates in greater than 90% of cases. One method involves the intraoperative removal and reimplantation of a sterilized existing femoral component and polyethylene liner. The components are then re-cemented using antibiotic-laden cement [17]. Another approach to the problem involves the fabrication of articulating spacers using a plastic mold or a metal femoral component with a cement construct that is molded intraoperatively to achieve proper fit [18]. Preformed molds, on the contrary, do not require the use of previous components and are manufactured to maximize strength and surface finish that should, theoretically, minimize wear debris from the articulating cement surfaces [6,19,20].

There have been relatively few reports in the literature on the use of preformed articulating spacers. Westrich et al [21] reported the use of the Exactech spacer in 3 cases of 75 knees with no significant difference in eradication rates between types of articulating spacers. Meanwhile, Pitto et al [14] reported a 100% eradication rate in a series of 21 patients using a different type of preformed spacer but with similar design and concept to the Exactech spacer used in our series. However, no distinction is made in treating the infection from primary or revision TKA in their report. Our lower eradication rate (91%) compares favorably with other reports even with the inclusion of more complex cases involving multiple previous surgeries, resulting in longer times of active infection as well as compromised bone and soft tissue. Interestingly, the 3 patients who failed treatment were all classified as McPherson stage B.

We did not experience any spacer dislocation, fracture, or fragmentation using preformed spacers. We believe these types of spacers are convenient to use and provide well-defined mechanical properties that theoretically should be less prone to failure. The expense of these spacers is a consideration; however, in general, infection cases can be extremely expensive.

We used stem extensions initially for bone loss; however, we now add intramedullary stems in almost all cases for several reasons. First, the stems facilitate antibiotic delivery into the medullary canals. Second, in our view, the stemmed implants are more amenable to balancing flexion and extension gaps, which is especially important in cases of bone loss and soft tissue compromise. Although perfect balance is not achievable in every case, most patients function quite well with a hinged, off-the-shelf knee brace. Previously, patients with severe bone loss received antibiotic-impregnated cement-

coated "fusion nails" to deal with joint instability. These devices, however, are prone to fatigue fracture, unlike an articulating spacer. We therefore now prefer stemmed articulating spacers even in these cases. Third, anecdotal reports of dislodgement with subsequent pain and soft tissue disruption have discouraged some surgeons from using these types of spacers. We believe that the addition of an intramedullary stem provides additional stability to avoid spacer dislodgement.

One criticism of this study is that our definition of infection does not technically comply with the newly published definition for periprosthetic joint infections [22]. Under these guidelines, 2 positive joint fluid cultures are required to satisfy the criteria. In the case of a culture with negative results, other criteria must be satisfied, such as an elevated CRP value and ESR, elevated synovial fluid white blood cell count, and elevated synovial fluid polymorphonuclear cell count. At the time the study was performed, we did not routinely obtain these studies. It should be recognized, however, that the authors of these new guidelines state in their publication "a prosthetic joint infection may be present even if these criteria are not met." We believe that these cases do represent true deep infections and would satisfy the new criteria if the appropriate studies were used.

A potential disadvantage of the premade spacer is the limited type of antibiotic and amounts. We have achieved satisfactory results using a higher dose of antibiotics in the additional batches of cement used for fixation of the spacers.

Our study was limited because of no randomization or control group comparison. We feel, however, that our sample size is comparable with what has been reported in the literature, and based upon our results, adding stems to the spacers represents a potential improvement in the treatment of patients with infected revision TKAs.

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