

A Facile Technique to Make Articulating Spacers for Infected Total Knee Arthroplasty

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Background: To treat total knee arthroplasty, 2-stage revision, including removal and reimplantation, remains the standard treatment for the infected arthroplasty. Articulating cement spacer has been shown to provide better functional results after reimplantation. However, its cost as a manufactured product is not always easily affordable and the choice of antibiotics is not flexible either. The authors have developed a method for surgeons to make cement-on-cement articulating spacers themselves by using an impression-taking technique with polydimethyl siloxane. The current study was conducted to test their clinical efficacy.

Methods: Fifteen patients with infected total knee arthroplasties were prospectively treated with 2-stage revision using articulating spacers made by this technique. The clinical assessment included intraoperative finding, surgical records, radiographic and laboratory examination and final functional scores. All the patients were regularly followed-up.

Results: Fourteen of the 15 patients (93.3%) had infection eradicated, of which 13 patients received revision arthroplasty successfully. The average interval between the resection arthroplasty and the final procedure was 3.5 months. During this period, most of the patients could sit comfortably with bent knees and walk with partial weight-bearing. No patients had secondary bone loss. The range of motion after revision surgery achieved an average of 110 degrees. The average Hospital for Special Surgery score was 90.5 points, and none had recurrent infection after an average of 47.5 months of follow-up.

Conclusion: Treating infected total knee arthroplasty with these self-made articulating spacers eradicates infection effectively, improves the life quality before reimplantation and provides good final results without significant complications. [*J Chin Med Assoc* 2009;72(3):138–145]

Key Words: anti-infective agents, arthroplasty, knee, prosthesis-related infections

Introduction

In treating infected total joint arthroplasty, 2-stage revision surgery has a significantly higher success rate than 1-stage revision surgery.¹ Between resection arthroplasty and reimplantation, the use of antibiotic-impregnated cement spacers remains the standard choice to maintain high local concentrations with less systemic toxicity in an area that frequently develops scar tissue.^{2,3} Besides playing the role of drug vehicle, spacers can also act as a joint expander to maintain the space for reimplantation. However, the static knee spacer keeping the knee in extension leaves the extensor mechanism and joint capsule contracted, which

makes the subsequent exposure for reimplantation very difficult, sometimes requiring quadricepsplasty or tibial tubercle osteotomy to facilitate exposure, especially when a long interval between the 2 operations is needed to eradicate infection. Unexpected bone loss has also been reported to be associated with the migration and invagination of the cement block.^{4,5} The range of motion and functional outcome after 2-stage revision is poorer than aseptic revision total knee arthroplasty.^{6,7}

With a smooth and congruent interface, an articulating spacer allows range of motion between removal and reimplantation to prevent soft tissue contracture and improves the daily activity of patients.^{5,8–10} There



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are several manufactured products, but high cost and restriction in choices of antibiotics limit their use.

We made articulating spacers by developing an impression-taking technique, which aimed to be both cost-effective and versatile. A prospective study to evaluate these spacers was conducted, and the preliminary clinical results are presented here.

Methods

The articulating spacers were cast using self-prepared molds. They were fabricated from silicone rubber (Coltoflax; Coltène AG, Altstätten, Switzerland). Putty matrix, which is composed of polydimethyl siloxane and silica, is thoroughly mixed with the catalyst (alkyl silicate) to form dough in a proportion of approximately 10 mL of matrix to 1 mL of catalyst (Figure 1). The more catalyst that is added, the faster the mold sets. The dough is then applied on the prosthesis with

the desired size and shape. After 5 minutes of setting, the mold can be taken off. To make each set of knee spacers, separate molds for femoral and insert parts are required. The molds are then sent for hydrogen peroxide plasma sterilization. A series of molds, 3 sizes for both sides, were made for repetitive use.

From June 2003 to July 2005, the articulating spacers prepared by this technique were prospectively used on 15 cases of infected total knee replacement. The protocol was approved by the Institutional Review Board. Written informed consent was obtained from all the participants. All the cases met the following criteria: infective loosening, drainage sinus and recurrent infection after debridement with a positive bacterial culture.

During resection, all the components, cement, and infected tissues were removed. The size and shape of the spacer were determined according to preoperative templating and previous surgical records as well as intraoperative assessment. Simplex-P cement

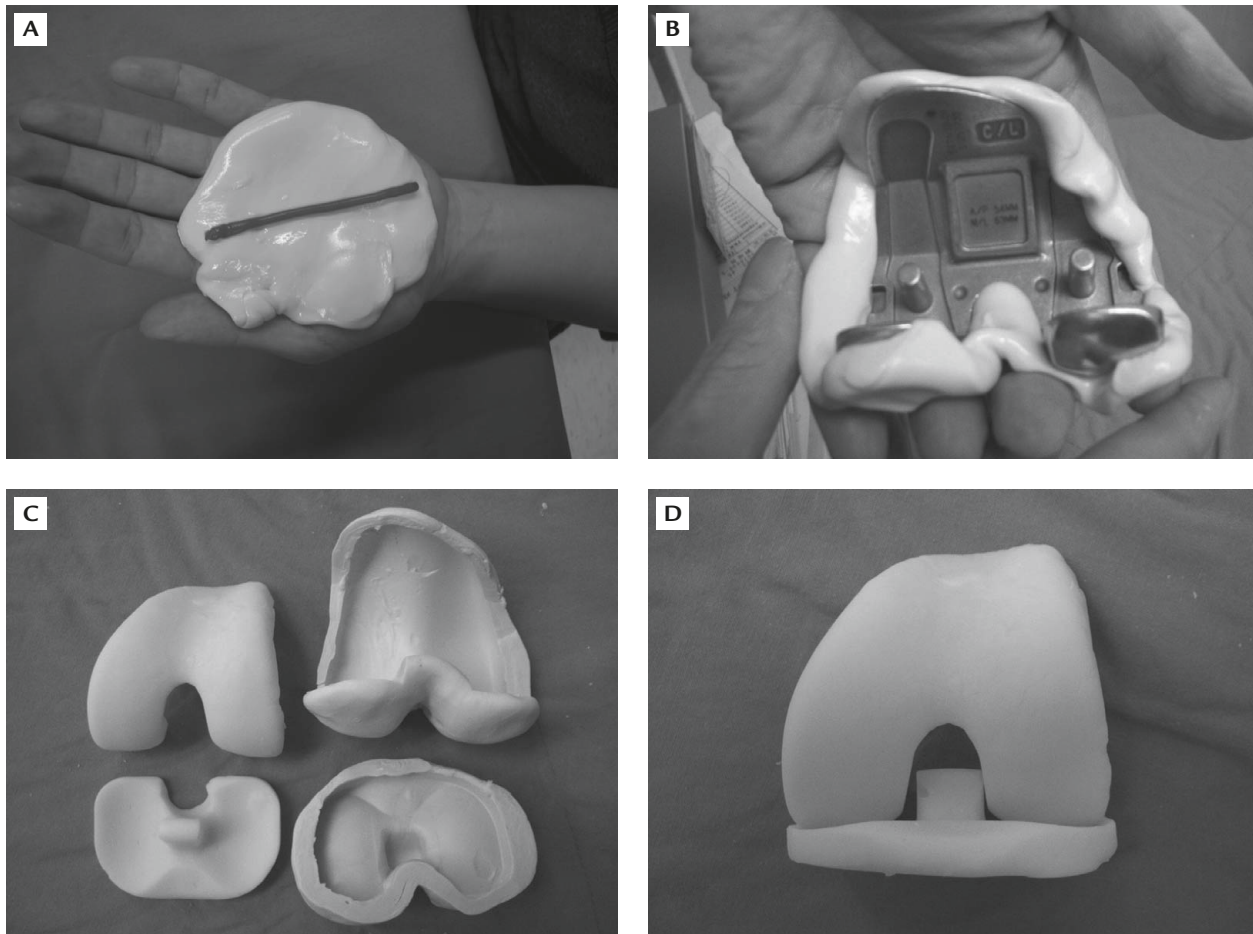


Figure 1. (A) The putty matrix is thoroughly mixed with catalyst. (B) The dough is mounted onto the prosthesis to take the impression. After several minutes of setting, the mold is sterilized for later use. (C) The antibiotic-loaded cement spacers are cast during surgery. (D) There is good conformity between components.

(Howmedica, Rutherford, NJ, USA) was used to fabricate the spacer. Each 40-g package of cement contained 2 grams of vancomycin. Ceftazidime was only used on 1 patient (Case 12) because her previous intraoperative cultures were positive for *Escherichia coli*, which was not sensitive to either vancomycin or aminoglycosides.

A total of 3–4 packs of cement were used for each patient. To make spacers, the first pack of cement was poured into the molds when it was in the manipulative stage. The cement did not adhere to the molds, and the use of sterile mineral oil was not necessary. After several minutes, it set to form spacers with smooth surfaces. Another 2–3 packs of cement were used sequentially to fix the spacers. The femoral component was loosely fixed to the bone first. Care was taken to restore the joint line. Then, the corresponding insert component was inserted with gap tension adjusted by the thickness of the cement (Figure 2). After surgery,

the patients were encouraged to perform range of motion exercise as tolerated and to walk with protective weight bearing. Use of crutches or walkers was advised for every patient. The knees that were operated on were simply wrapped with elastic bandages. Two patients were not allowed to flex the knee in the first postoperative week to ensure adequate soft tissue healing. Intravenous antibiotics were given for at least 4 weeks until infection control was confirmed with clinical observation and progressive decline of erythrocyte sedimentation rate and C-reactive protein, and then followed by oral antibiotics for continuous suppression. The criteria for reimplantation were C-reactive protein level <1.0 mg/dL 2 weeks after discontinuation of oral antibiotics and without clinical signs of infection.

Reimplantations were carried out via medial parapatellar approach. The revisional prostheses used in this series were all of the non-hinged type (LCCK, Zimmer, Warsaw, IN, USA). During surgery, the spacers were

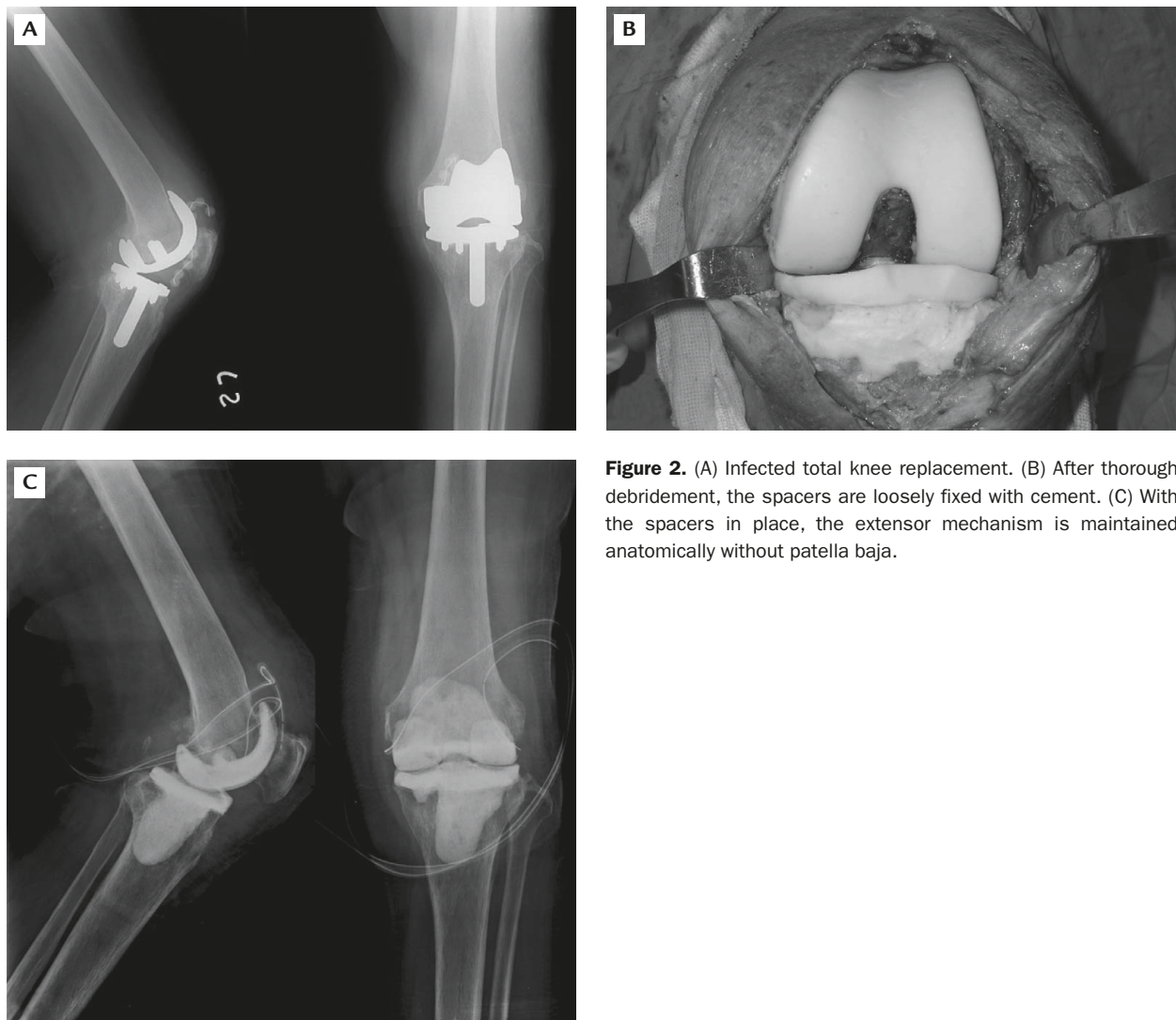


Figure 2. (A) Infected total knee replacement. (B) After thorough debridement, the spacers are loosely fixed with cement. (C) With the spacers in place, the extensor mechanism is maintained anatomically without patella baja.

removed easily without further damage to the remaining bone stock. Bone defects were recorded in the classification of the Anderson Orthopaedic Research Institute (AORI).¹¹ Bone loss was evaluated by comparing the radiographs and records between stages. Intraoperative bacteria cultures were taken, and soft tissue between the cement and bone junction was sent for frozen section. The intraoperative frozen sections were considered to be positive for active infection if there were at least 10 polymorphonuclear leukocytes per high-power field. In addition, soft tissue surrounding the joint line was sent for paraffin-embedding pathology examination to see if there was marked cement particle infiltration or any other adverse reactions. The antibiotics mixed with the fixation cement were the same as those used previously in the spacers. The clinical data and radiographs were traced regularly during follow-up. The functional scores of the knees were evaluated using the Hospital of Special Surgery (HSS) knee score¹² by an independent investigator in a blinded fashion.

Results

Of the 15 patients, 10 were women and 5 were men. The mean age was 72 years (range, 65–79 years) (Table 1). During the spacer stage, the average knee flexion was 87 degrees (maximum, 105 degrees). The average interval between the resection arthroplasty and the final procedure was 3.5 months (range, 2.5–5 months). During this period, most of the patients could sit comfortably with bent knees and walk with partial weight-bearing. Stability of the knees was maintained well without grossly false motion. Soft elastic bracing was used according to the patients' choice. The overall antibiotic protocols are listed in Table 2.

All but Case 4 had their infection eradicated. The infection-control rate was 93.3% (14/15). Two patients (Cases 3 and 4), who had cerebral infarct and diabetes, respectively, chose to receive fusion as the final procedure due to poor general condition and refractory infection, respectively. The other 13 patients underwent revision total knee arthroplasty. Slight flexion of the femoral spacers was noted in 2 patients (Cases 4 and 7), which was acceptable and did not result in apparent bone loss.

Histopathologic examinations of the soft tissue sampled around the cement-on-cement interface revealed chronic inflammatory processes in which histiocytes and lymphocytes were predominant. In the high-power fields, very few cement-particle-laden giant cells with mild inflammatory reactions were found

(Figure 3). The findings suggested favorable control of infection and no severe wear debris-induced immune response.

During revision surgery, all the approaches were performed through medial parapatellar arthrotomy. The average surgical time was 135 minutes (range, 105–160 minutes). There was no need to interrupt the extensor mechanism. No extensor lag was found at the final follow-up. By comparing the AORI classification of bone defect and the intraoperative findings before and after the spacers, no marked bone loss was noted. There was no extra need of bone grafting procedure for the use of the spacers. The average amount of knee flexion after revision surgery was 110 degrees (range, 95–120 degrees). The average HSS knee score was 90.5 points (range, 82–92 points). None of the patients had recurrent infection after a mean follow-up period of 47.5 months (range, 37–61 months).

Discussion

Effective antibiotics are one of the most important factors in determining the success of the treatment of infective total knee arthroplasty. However, most patients have received antibiotic treatment before they are referred to the specialist, and that usually hinders the accuracy of bacteriology. Therefore, empirical antibiotics are practical choices, but when the offending organism is evident, the specific antibiotics are still preferred. In our series, almost all the pathognomonic microorganisms were methicillin-resistant *Staphylococcus aureus*, so vancomycin was chosen.

In the past, the vast majority of physicians and surgeons advocated rest or immobilization for the infected knees. However, various clinical observations indicated that motion did not cause adverse effects in infection control.^{5,8,10,13} Fehring et al⁵ reported a series of 30 patients who were treated with articulating spacers impregnated with tobramycin. The reinfection rate was 7% compared to 12% in the control group, in which 25 patients were treated with static spacers. Hofmann et al⁹ reported the clinical results for articulating spacers mixed with a higher dose of tobramycin. The reinfection rate was 0% in their short-term follow-up. In their longer follow-up, the reinfection rate increased to 12% after a mean of 73 months of follow-up, but the rate was not higher than that with static spacers.¹⁰ According to their reports, the infections recurred at a mean of 35 months; the minimal follow-up time in this study was 37 months.

In our series, the infection-control rate was 93.3%. Only 1 failure in infection control was observed, and

Table 1. Clinical data of patients with articulating knee spacers

Case	Age (yr)/sex	Preop state	Bacteriology	Antibiotic in cement	Preop ROM (°)	Spacer ROM (°)	Rev TKA ROM (°)	Final procedure	Reinfection	Interval (mo)	Complications with spacer	Bone loss	HSS	F/U (mo)
1	68/F	Inf TKA	MRSA	Vancomycin	5-90	5-90	0-115	Rev TKA	-	3		-	88	61
2	79/M	Inf TKA	CNS	Vancomycin	5-100	10-90	0-120	Rev TKA	-	3		-	90	59
3	74/M	Inf TKA	MRSA	Vancomycin	10-80	10-80	10	Fusion	-	4		-	56	56
4	65/F	Inf Rev TKA	MRSA	Vancomycin	0-50	10-60	10	Fusion	-	5	Spacer flexed	-	66	54
5	76/F	Inf Rev TKA	MRSA	Vancomycin	10-80	0-100	0-110	Re-Rev TKA	-	4		-	94	55
6	69/F	Inf TKA	CNS	Vancomycin	0-100	0-100	0-115	Rev TKA	-	3		-	90	50
7	71/F	Inf TKA	MRSA	Vancomycin	5-90	40-95	0-95	Rev TKA	-	5	Spacer flexed	-	86	46
8	74/F	Inf TKA	MRSA	Vancomycin	0-100	0-105	5-115	Rev TKA	-	2.5		-	90	47
9	72/F	Inf TKA	MRSA	Vancomycin	10-100	15-90	0-110	Rev TKA	-	3		-	90	44
10	75/F	Inf Rev TKA	MRSA	Vancomycin	5-90	5-90	0-110	Re-Rev TKA	-	4		-	92	42
11	68/M	Inf TKA	MRSA	Vancomycin	0-100	10-70	0-110	Rev TKA	-	5		-	92	42
12	69/F	Inf TKA	<i>E. coli</i>	Ceftazidime	5-90	10-90	0-110	Rev TKA	-	3		-	92	43
13	74/M	Inf TKA	MRSA	Vancomycin	0-90	10-80	0-105	Rev TKA	-	3		-	90	40
14	67/M	Inf TKA	MRSA	Vancomycin	0-110	10-90	0-105	Rev TKA	-	4		-	92	37
15	79/F	Inf TKA	MRSA	Vancomycin	0-100	10-90	0-115	Rev TKA	-	2.5		-	90	37

Preop = preoperative; ROM = range of motion; Rev = revision; TKA = total knee arthroplasty; HSS = Hospital of Special Surgery knee score; F/U = follow-up; Inf = infected; MRSA = methicillin-resistant *Staphylococcus aureus*; CNS = coagulase-negative *Staphylococcus*.

Table 2. Antibiotic treatments

Case	Preop state	Bacteriology	Antibiotic in spacer	IV antibiotics	Oral antibiotics	Infection eradication
1	Inf TKA	MRSA	Vancomycin 6 g	Vancomycin 4 wk	Fucidin 6 wk	Yes
2	Inf TKA	CNS	Vancomycin 6 g	Teicoplanin 4 wk	Fucidin 6 wk	Yes
3	Inf TKA	MRSA	Vancomycin 6 g	Vancomycin 4 wk	Fucidin 10 wk	Yes
4	Inf Rev TKA	MRSA	Vancomycin 8 g	Vancomycin 6 wk	Fucidin 12 wk	Failed
5	Inf Rev TKA	MRSA	Vancomycin 8 g	Vancomycin + Teicoplanin 6 wk	Fucidin 8 wk	Yes
6	Inf TKA	CNS	Vancomycin 6 g	Vancomycin 4 wk	Fucidin 6 wk	Yes
7	Inf TKA	MRSA	Vancomycin 6 g	Vancomycin 5 wk	Fucidin 12 wk	Yes
8	Inf TKA	MRSA	Vancomycin 6 g	Vancomycin 4 wk	Fucidin 4 wk	Yes
9	Inf TKA	MRSA	Vancomycin 6 g	Vancomycin 4 wk	Fucidin 6 wk	Yes
10	Inf Rev TKA	MRSA	Vancomycin 8 g	Vancomycin 4 wk	Fucidin 10 wk	Yes
11	Inf TKA	MRSA	Vancomycin 6 g	Vancomycin 5 wk	Fucidin 12 wk	Yes
12	Inf TKA	<i>E. coli</i>	Ceftazidime 6 g	Vancomycin 4 wk	Cefuroxime 6 wk	Yes
13	Inf TKA	MRSA	Vancomycin 6 g	Vancomycin 4 wk	Fucidin 6 wk	Yes
14	Inf TKA	MRSA	Vancomycin 6 g	Vancomycin 4 wk	Fucidin 10 wk	Yes
15	Inf TKA	MRSA	Vancomycin 6 g	Teicoplanin 4 wk	Fucidin 4 wk	Yes

Preop = preoperative; IV = intravenous; Inf = infected; TKA = total knee arthroplasty; Rev = revision; MRSA = methicillin-resistant *Staphylococcus aureus*; CNS = coagulase-negative *Staphylococcus*.

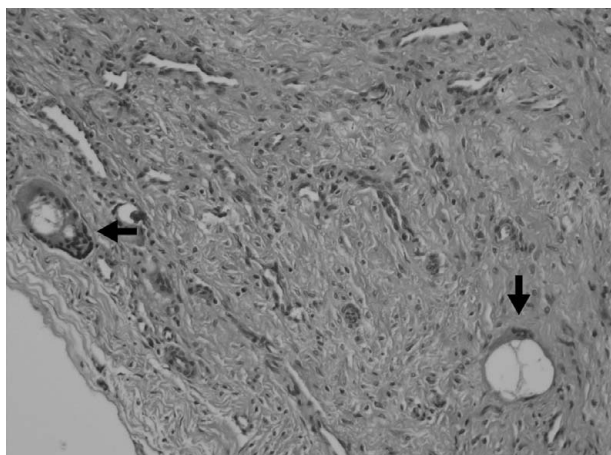


Figure 3. A few cement-particle-laden macrophages (arrows) and mild chronic inflammatory cell infiltration in the synovial tissue (hematoxylin & eosin, 100×).

this could have been due to immune compromise from diabetes rather than mobilization of the knee because even after arthrodesis, the infection recurred. Of the 13 patients who received reimplantation, the reinfection rate was 0% after a mean of 47.5 months of follow-up, and was comparable to those of other series.

Although revision of infected total knee arthroplasties with a 2-stage technique using static cement blocks has a higher success rate than the 1-stage technique, it is frequently associated with complications due to poor bone quality, patellar tendon avulsion, extensor lag, flexion limitation and extension instability.^{1,5,13-15}

In this series, revision in the presence of articulating spacers did not cause any complications for the extensor mechanism. All the approaches were done through medial parapatellar arthrotomy. The spacer components did not tightly interdigitate with the underlying bone surface, so the removal was simple. Gap tensioning was performed during spacer surgery, so there was no need for extensive scar release. The reimplantation surgery proceeded even more comfortably than aseptic revision surgery, which often takes a long time to remove the well-fixed components. The functional results at the latest follow-up, which averaged 90.5 points on the HSS, were comparable to those of other series.^{6,7,13}

There are different types of articulating spacers for knee joints.^{6,7,13,16-22} Failure to provide an anatomic articulating surface seems to cause more complications of instability. Several previously described methods, such as handmade or ball-and-socket type, have been reported to be unstable.¹⁹⁻²¹

Attempts have been made by surgeons to make smooth joint surfaces for articulating spacers,^{5,8,9,17} but they were not without drawbacks.

Emerson et al⁸ and Hofmann et al⁹ sterilized retrieved femoral components and added a new tibial insert as the interface of articulation. This method provides the advantage of smooth gliding with a polyethylene-on-metal interface, but it requires a new polyethylene insert and delivers fewer antibiotics than the whole block of cement. Fehring et al⁵ used a metal mold to cast the femoral component of the spacer and

applied mineral oil to prevent cement adhesion. The surface on the tibial side was made either flat or curved by impression with the femoral component. This type of spacer can carry a sufficient amount of antibiotics. However, sterile mineral oil is required, thus from its residuum arises the concern of allergic reaction. Furthermore, it is more costly to prepare steel molds once a different size or type of spacer is needed.

Ha¹⁷ used bone cement to fabricate the mold intraoperatively from the removed component. In his technique, the mold was flipped over and applied firmly to a bolus of doughy cement placed on the ends of the bone. The mold had to be removed before the spacer cement set completely. In that technique, the articular surface of the spacer tends to be deformed and needs to be reshaped. Furthermore, doughy cement may adhere to the cement mold even with lubricant. In addition, the articular surface is not as smooth as the spacer made by the technique outlined in this study.

The PROSTALAC system (Depuy, Warsaw, IN, USA) has been reported to provide satisfactory functional results after revision arthroplasty without compromising eradication of infection.^{13,18} However, its cost limits its extensive use. Therefore, the impression-taking technique described in this study was developed by the authors to provide a temporary but functional mobile spacer. With this method, an economic way is offered to help more patients who have suffered from this substantial complication of arthroplasty.

Coltoflax (Coltène AG), the raw material used in this method, is a condensation silicone impression material and is widely used in dental procedures. It is pliable and easy to handle. A mold made from this material has a smooth surface and precisely demonstrates the shape of the original prosthesis. It does not adhere to the cement, so there is no need to use any lubricant. The cost is less than US\$10 per mold, which is much more economical than manufacturing a steel mold. Also, it only takes a few minutes to make a mold. Most importantly, the surgeon can quickly fashion the articulating spacers precisely from the desired prostheses on their own. Durbhakula et al¹⁶ used a specially designed silicone mold to make spacers intraoperatively. The advantages of this method are similar to ours. However, their molds were locally manufactured at an approximate cost of US\$300 each. At this price, it might not be feasible for every institute to set up a varying series of molds.

Potential wear debris from the cement-on-cement surface of spacers has been a concern, but there is no report of the particle-related complication from their temporary implantation. Castelli et al²³ and Castelli and

Ferrari²⁴ reported the results of a preformed all-cement knee spacer. The spacer they used was industrially made and impregnated with gentamycin. In mechanical testing, the surface rugosity decreased an order of magnitude after 8 weeks of implantation.²³ The wear from the interface was not much higher than those produced by a polyethylene-on-metal interface. In their clinical results, 85% of the patients achieved satisfactory function and no device-related complications were reported.²⁴ With our technique, the roughness of the spacers varied slightly with different conditions of cement mixing. However, the articulating surfaces were generally smooth. In the current series, spacer implantations were temporary, for a mean length of 3.5 months. During that period, all the patients experienced some crepitation at the beginning, but the noise dissipated after 1 month. Otherwise, these spacers acted just like normal prostheses. The retrieved spacers were found to have a more polished surface in comparison with the new unused ones. Histopathologic examination of the soft tissue surrounding the interface revealed only a few cement particles with mild inflammatory activity. No osteolysis or substantial bone loss was found at the time of the revision surgery. Although most of the patients felt satisfied with the articulating spacers, long-term implantation of the spacers is not recommended as there is the possibility of bacteria relocalization after the antibiotics are exhausted.

In conclusion, we have reported the preliminary results of using self-made articulating spacers. It provided good infection control, and there was no recurrence of infection after revision surgery. All the patients achieved satisfactory functional results with few complications. This technique of making spacers is an effective option when commercial products are not available or their cost is prohibitive. The limitations of this study are the small number of patients and the lack of a control group. Further randomized controlled trials with larger case numbers are needed.

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