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Case Report

The Use of a Novel On-bone Femoral Spacer Molding Device for Reducing Femoral Spacer Complications in Periprosthetic Total Knee Infection: Preliminary Results

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ABSTRACT

Background: The complications of mobile cement spacer are common. To address these issues, a novel on-bone femoral molding device (FMD) has been developed to enhance stability between the spacer-bone. This study investigated the clinical outcomes and complications associated with this novel FMD.
Methods: The FMD was developed using a reverse engineering program with the on-bone molding concept. Five knees of 4 patients were examined. The bone status, ambulatory ability, knee range of motion, and femoral spacer complications were followed up until 3 months after the second-stage surgery.
Results: The infection was successfully treated in all patients. The interim period was 21.6 ± 4.5 weeks. The range of motion measured before the first surgery, before the second surgery, and 3 months after the second surgery was 104.2 ± 43.1, 105.8 ± 20.0, and 124.0 ± 18.5 degrees, respectively. No femoral spacer complications were observed. One knee joint subluxation and 1 minor tibial spacer fracture occurred.
Conclusions: Newly developed FMD appears safe during initial proof-of-concept in patients with stage 1 to 2B bone loss. It prevents femoral spacer complications in a specific bone defect type without causing additional bone loss and facilitates range of motion during the interim period. Precise gap assessment and appropriate tibial cement spacer thickness could prevent knee dislocation.

Introduction

Chronic periprosthetic joint infection (PJI) following primary total knee arthroplasty is a severe complication. The gold standard treatment for PJI is 2-stage revision surgery. The first stage involves surgical debridement, removal of the implant, and placement of an antibiotic cement spacer. Once the infection has been eliminated, the spacer is removed and the revision prosthetic is implanted. The duration between the 2 surgeries can reach 3 months depending on the virulence of the pathogen and its response to antibiotic treatment. Consequently, the cement spacer should withstand weight-bearing to ensure patient comfort and mobility throughout the treatment period.

Two types of knee cement spacers are available: static and mobile. The popularity of mobile spacers has recently increased because they permit knee motion. Mobile spacers can be created using molded cement in the shape of the distal femur and proximal tibia. The articulation between the femoral and tibial cement spacers allows knee motion and promotes patient ambulation. However, numerous studies have revealed complications associated with use of mobile spacers [1–3], including cement spacer fracture, tilting-subluxation, and dislocation of the knee joint. These adverse events are often caused by spacer size mismatch, improper positioning, and preexisting bone deficiency, which can

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cause instability of the cement spacer [2]. Spacers are usually prefabricated or molded during surgery using a surgical mold [4]; however, this can prevent a perfect fit between the spacer and bone surface, allowing motion at the interface between the spacer and bone. This looseness can result in displacement, dislocation, and fracture of the spacer, causing an unstable knee joint.

A technique that establishes stability between the spacer and bone surface could prevent such complications associated with the spacer. We devised an innovative approach in which the femoral spacer is directly molded onto the bony surface. We hypothesized that this technique would significantly improve femoral spacer stability and reduce complications, especially in patients with bone loss. Through collaboration between clinicians and the faculty of engineering, we manufactured an on-bone femoral molding device (FMD). This preliminary study was performed to assess the clinical outcomes, the femoral spacer complications, and other potential complications associated with utilization of the FMD.

Design rationale and manufacturing process

The FMD was designed using reverse engineering [5] as follows.

Measurement and analysis of the femoral prosthesis

The femoral prosthesis dimensions were scanned by computed tomography and converted from 2 to 3 dimensions using Mimics software (Materialise NV, Leuven, Belgium, Fig. 1). The 3-dimension model was developed using a stereolithography file extension.

Design of the FMD

The 3-dimensional model was subsequently modified using a computer-aided design program. The femoral prosthesis geometry was meticulously measured, analyzed, and adjusted as per the following details (Fig. 2).

The device was structured with front, middle, and back sections connected by 2 screws. This design allows for easy separation and removal of the FMD once the bone cement has fully set.

The back part was 15 mm thick, resembling the typical flexion gap. This design facilitates easy insertion of the FMD when the knee is flexed.

Grade 304 stainless steel was selected as the material for the FMD. The polished surface of this material allows for easy removal of the molding block and can be sterilized in an autoclave because of its high heat tolerance.

Manufacture of the FMD

The FMD was manufactured using computer numerical control. The 3-axis computer numerical control machine utilized in this project was the Model V-30iR by Leadwell (Taichung City, Taiwan) with a total production time of 109 hours (equivalent to 4 days 13 hours). Figure 1b shows an FMD made of grade 304 stainless steel through computer numerical control machining, and Figure 1c–e illustrates the application of the FMD.

Material and methods

The study was approved by the Ethical Clearance Committee on Human Rights Related to Research Involving Human Subjects, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Thailand (protocol number ID 2672). The study is also registered in the Thai Clinical Trials Registry under protocol ID TCTR20230814001 (http://www.thaiclinicaltrials.org).

This study involved patients diagnosed with PJI according to the classification proposed by Parvizi et al. (2018) [6] from August 2021 to June 2022 and from October 2022 to December 2022. The inclusion criteria were PJI and intact collateral ligament function. Patients were excluded if they were bedridden before surgery or had less than grade 3 quadriceps muscular weakness as determined by the Medical Research Council grading system [7]. All patients underwent 2-stage revision surgery. During both the first and second stages, we collected data on the preoperative knee range of motion (ROM), operative time (defined as the duration from incision to skin closure), and intraoperative bone loss as classified by the Anderson Orthopaedic Research Institute [8]. The knee ROM and ambulatory status were recorded before first- and second-stage surgeries and 3 months after reimplantation. Additionally, we evaluated cement spacer complications, including spacer fracture, spacer tilting in the coronal and sagittal planes, spacer dislocation, and knee dislocation from preoperative radiographs taken before the second-stage surgery. Clinical measurement of knee ROM was

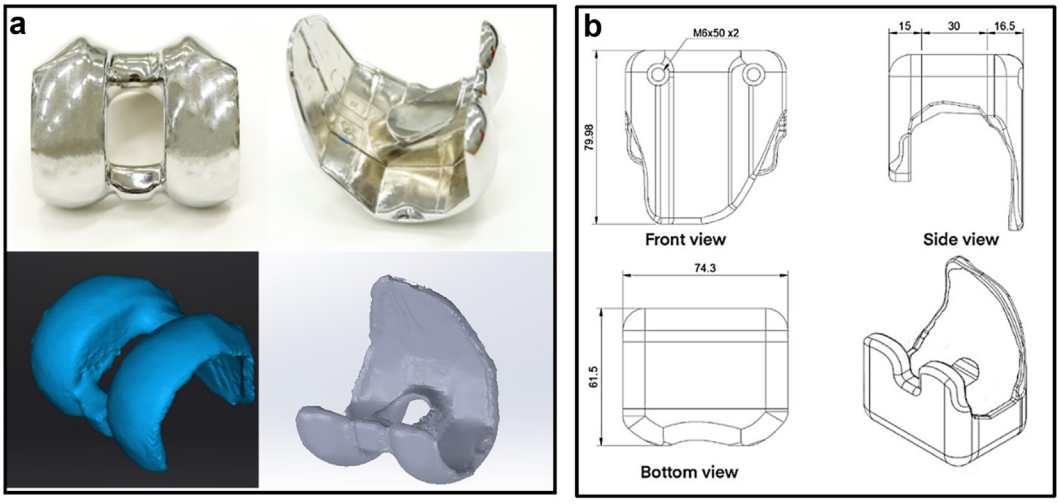

Figure 1. (a) The femoral prosthesis was scanned and converted to a 3-dimensional (3D) model using a computer-aided design program. The 3D model was subsequently analyzed and adjusted. (b) The FMD was developed using the reserve engineering techniques.

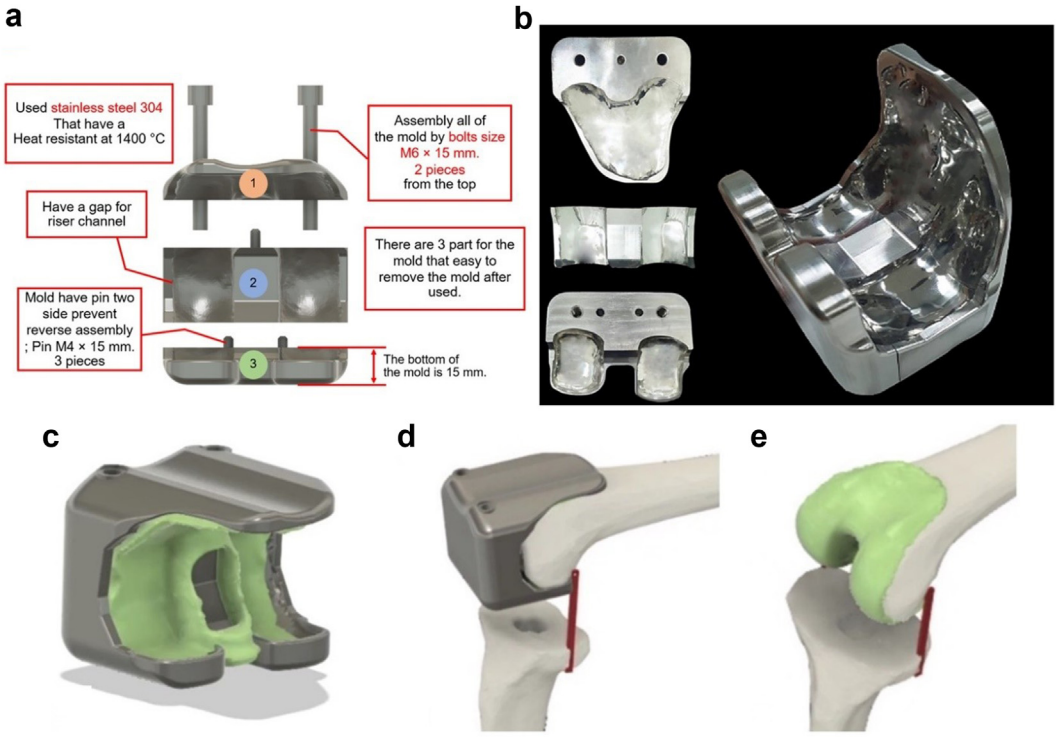

Figure 2. (a) Three-dimensional design of an on-bone femoral spacer molding device. (b) The device after complete manufacture. (c) Application of the on-bone femoral spacer molding block involves applying bone cement to the molding block. (d) The molding block is then gently compressed onto the prepared distal femur. (e) Once the bone cement has fully settled, the molding block is removed by separating the front, middle, and back parts.

performed using a goniometer with the patient in the supine position. All patients were followed up to evaluate the presence of recurrent infection for a period of 1 year.

An over 1000 experienced joint arthroplasty surgeon (K.C.) performed all operations. The medial parapatellar approach was used, and total synovectomy was performed. The infected implants were removed, and representative solid tissue specimens were sent for microbacterial culture in accordance with the treatment protocol [6,9]. The Anderson Orthopaedic Research Institute classification was used to evaluate bone loss in the distal femur and proximal tibia. After adequate debridement, 2 packs of high-viscosity antibiotic bone cement (SmartSet GHV; DePuy Synthes, Raynham, MA) were prepared (one for the femoral cement spacer and the other for the tibial cement spacer), with an additional 2 g of vancomycin added to each pack. An FMD was assembled, and the bone cement was applied into the device. After 3 minutes, the device was gently compressed onto the distal femur (Fig. 3a), excess bone cement was removed, and the cement was allowed to harden completely before the FMD was removed. The extension and flexion gaps were measured to estimate the thickness of the tibial cement spacer (Fig. 3b and c). The proximal tibia was then subluxated anteriorly, and the tibial cement spacer was molded by hand (Fig. 3d). After the tibial cement spacer had settled, the knee joint was reduced (Fig. 3e). An intra-articular drain was inserted. Following the surgery, an infectious disease specialist was consulted. The patients started ambulation training and ROM exercises as soon as possible.

The indication for second-stage surgery includes completing the antibiotic course of treatment, ensuring ESR is less than 30 and CRP is less than 10, or observing a downward trend in ESR-CRP levels, and reaching an agreement between the surgeon and infectious disease doctor that the infection has been completely eradicated. During the second-stage operation, an osteotome was used to remove the cement spacer (Fig. 4), and the bone quality and loss were inspected. The type of prosthesis constraint and the need for metal augmentation were determined based on the knee stability and extent of bone loss. All patients received routine postoperative care.

Results

This study involved 5 knees of 4 patients. Three patients underwent unilateral 2-stage revision surgery, and 1 patient underwent bilateral 2-stage revision surgery. Notably, 1 patient had a history of multiple failed surgical debridement, and another had a preexisting periprosthetic distal femoral fracture malunion. The patient's demographic and the perioperative data are summarized in Tables 1 and 2.

Case 1

A 61-year-old woman with chronic PJI who had fail 2-time debridement, antibiotics and implant retention was scheduled for 2-stage revision surgery. Her perioperative data are shown in Table 2. During the interim period, she was able to discontinue using gait assistance and a knee brace at 4 weeks. The spacer remained intact before reimplantation (Fig. 5b), and no spacer-related complications occurred. During the second-stage surgery, there was no increase in bone deficiency after removal of the cement spacer when compared with removal of the first-stage implant. The knee arch of motion was 77 degrees, 75 degrees (Fig. 5c and d), and 84 degrees during the first-stage preoperative assessment, after placement of the cement spacer, and 3 months following the second-stage surgery, respectively.

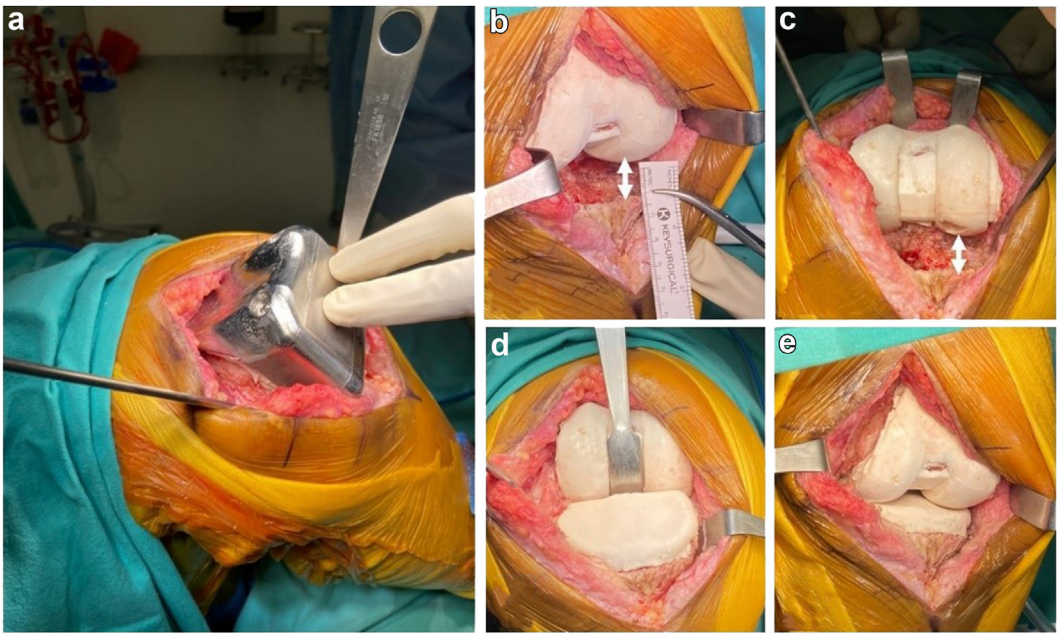

Figure 3. (a) Application of the on-bone femoral spacer molding device. (b and c) Measurement of the extension and flexion gaps. (d) The tibial spacer is manually molded with its thickness based on the measured gap. (e) The knee joint is reduced, and knee stability is checked.

Case 2

A 55-year-old man was diagnosed with bilateral PJI, and bilateral 2-stage revision surgery was scheduled. His perioperative data are shown in Table 2. The bone loss in both knees was classified as stage 2A for the femoral side and stage 1 for the tibial side (Fig. 6). Four weeks following the first-stage surgery, he was able to ambulate without using any gait assistance. During the 24-week interim period, the femoral spacer remained intact in both knees. At the 11-week follow-up, a minor tibial spacer fracture was present at the anterior rim of the spacer in the left knee, but it did not compromise knee stability (Fig. 7a–c). The condition of the left tibial spacer fracture remained unchanged until second-stage surgery. In the second-stage surgery, the cement spacer was successfully removed with no significant increase in bone loss compared with the first stage (Fig. 4). With the spacer, the right and left knee demonstrated a maximum flexion ROM of 106 and 116 degrees, respectively (Fig. 7d and e).

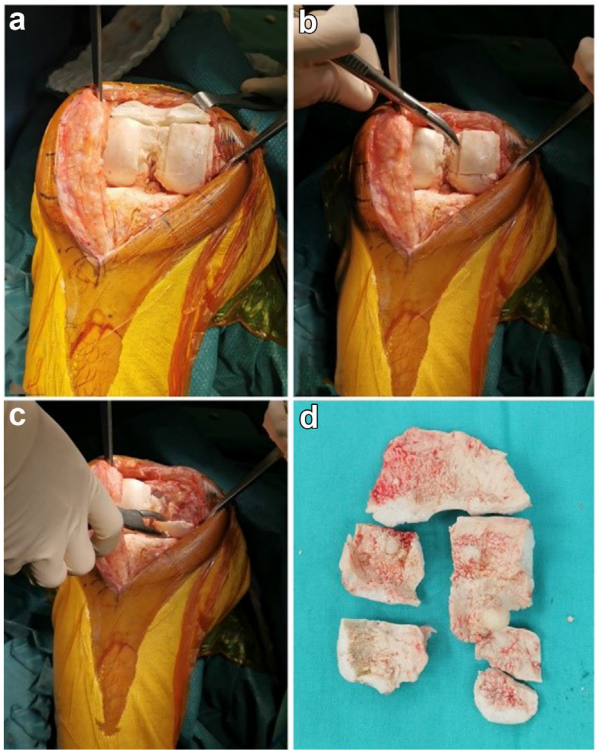

Figure 4. Method for removing the on-bone femoral spacer: The femoral spacer was broken using osteotome at its (a) anterior and (b) posterior part. (c) The cement fragment was removed with bone rongeur. (d) the cement spacer fragments were completely removed. No bone was attached to the cement, indicating that this on-bone technique does not result in further bone stock loss.

Table 1
Demographic data.

Patient no.	1	2	3	4	Mean ± SD
Demographic data					
Age	61	55	75	71	65.5 ± 9.2[a]
Sex	F	M	F	F	
Underlying (1 = present)					
Diabetes	1	0	0	0	
Hypertension	1	0	1	0	
Cardiovascular	0	0	1	0	
Rheumatoid arthritis	0	1	0	0	
Venous thromboembolism	0	0	0	1	
BMI (kg/m^2)	31.1	25.9	17.8	30.5	26.3 ± 6.1[a]
Preoperative laboratory					
WBC ($cell/mm^3$)	6830	8880	7630	7740	7770 ± 843.8[a]
Hb (g/dL)	12.8	13.7	9.5	9.3	11.3 ± 2.6[a]
GFR ($ml/min/1.73m^2$)	95.3	106.9	86.6	96.7	96.4 ± 8.3[a]
Albumin (mg/dL)	40.3	33.3	28.1	31.1	33.2 ± 5.2[a]
HbA1C (mg %)	8.08	5.57	5.62	5.56	6.2 ± 1.2[a]

BMI, body mass index; dL, deciliter; F, female; GFR, glomerular infiltration rate; Hb, hemoglobin; kg, kilogram; M, male; m, meter; mg, milligram; mm, millimeter; WBC, white blood cell.
[a] Mean ± standard deviation.

Table 2
Perioperative data and spacer complications.

Patient no.	1	2	3	4	Mean ± SD
PJI diagnosis score 2018 [6]	8	8	8	8	
Identified pathogen	Negative culture	Negative culture	*Enterococcus Faecalis*	*Klebsiella pneumoniae*	
First-stage operative time (min)	136	268 (Rt 148, Lt 120)	188	133	145 ± 11.6[a]
First-stage PRCs (units)	0	2	2	2	1 (0–2)[b]
Total Hb loss (g/dL)	0.1	6.1	2.9	2.4	2.3 ± 1.3[a]
Duration between stages (wk)	24	20	28	16	21.6 ± 4.5[a]
Second-stage operative time (min)	187	272 (Rt 127, Lt 145)	179	190	165.6 ± 12.5[a]
Second-stage PRCs (units)	0	0	2	0	0 (0–2)[b]
Total Hb loss (g/dL)	2.4	2.7	3.6	1.5	2.04 ± 1[a]
Femoral bone loss	2A	Both knees; 2A	2B metaphyseal bone loss	1	
Tibial bone loss	2A	Both knees; 1	2B metaphyseal bone loss	2A	
Ambulatory status between stages	Single cane	No gait aid	Walker	Walker	
Spacer complications	None	Left; Minor tibial spacer fracture at 11-wk	None	Knee joint subluxation at 12-wk	

dL, deciliter; g, gram; Hb, hemoglobin; min, minute; PJI, peri-prosthetic joint infection; PRCs, packed red cells.
[a] Mean ± standard deviation.
[b] Median (range).

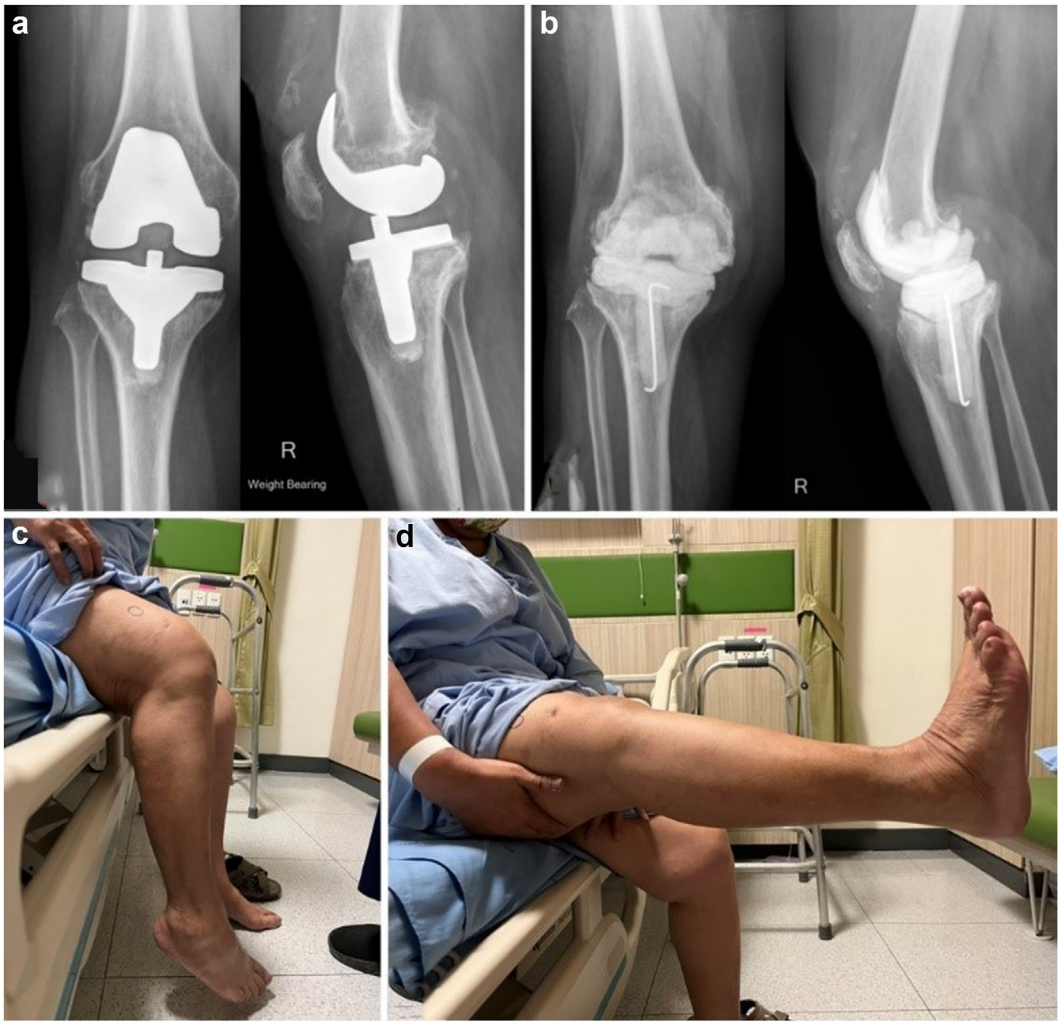

Figure 5. (a) Radiographs from the preoperative first-stage surgery and (b) the spacer condition before reimplantation. The knee's range of motion before the second-stage surgery is shown in (c) flexion and (d) extension.

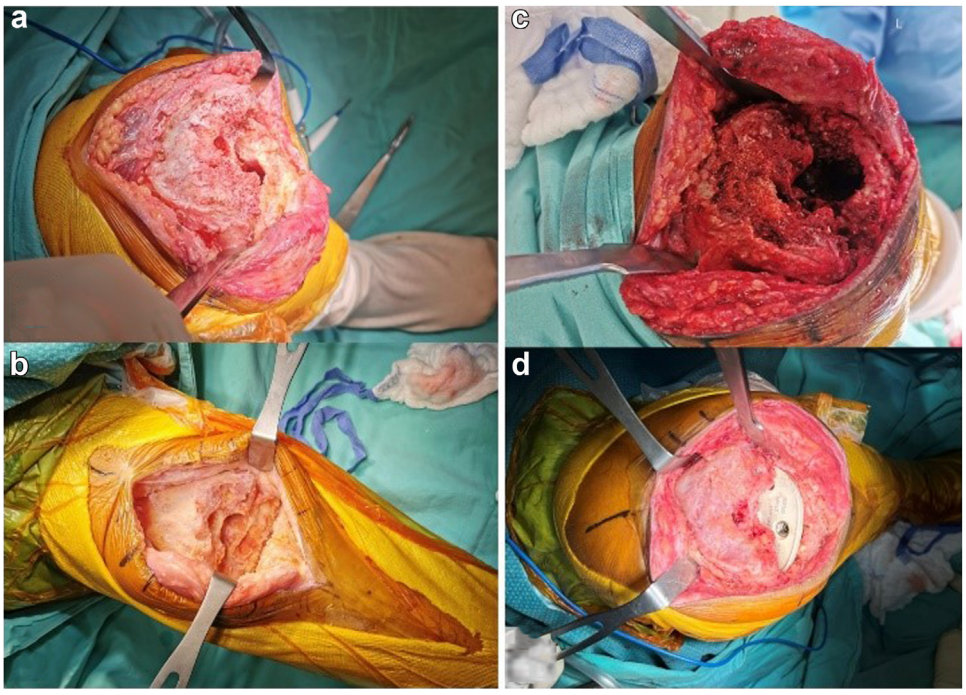

Figure 6. Intraoperative bone condition during the (a) first-stage and (b) second-stage surgery of the right knee and (c) first-stage and (d) second-stage surgery of the left knee. The femoral bone loss was stage 2A, while the tibial bone loss was stage 1 on both sides (unchanged from the first-stage surgery).

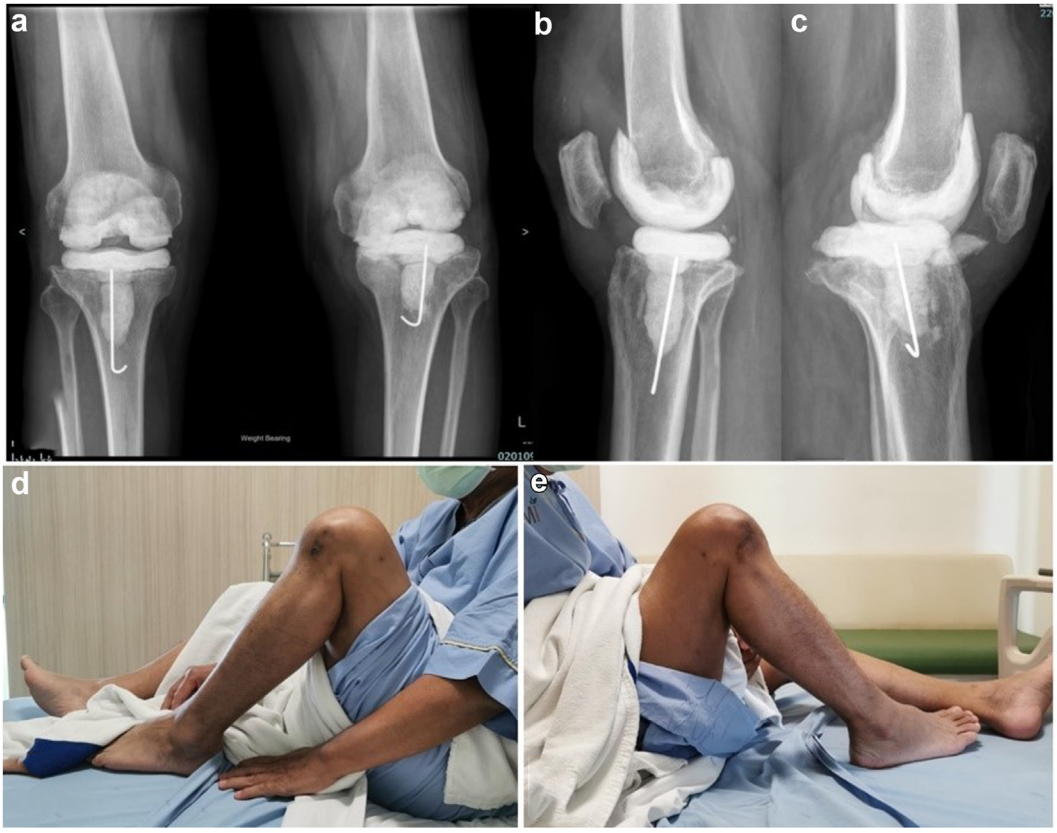

Figure 7. (a–c) Preoperative radiograph before reimplantation. No femoral spacer complications were observed in either knee. (c) Nevertheless, in the left knee, a minor rim fracture of the tibial spacer was present without causing significant knee instability. Flexion range of motion of the knee before reimplantation: (d) left knee, (e) right knee.

Case 3

A 75-year-old woman who had been using a wheelchair for 1 year because of PJI and malunion of a distal femoral fracture (Fig. 8a) underwent 2-stage revision. In the first-stage surgery, the femoral bone loss was classified as stage 2B, and a varus-external rotation deformity of the distal femur was present. Following debridement, the bone defect was filled with antibiotic cement and compressed using an FMD. During the 28-week interim period, she was able to independently ambulate with a walker. Notably, no complications related to the cement spacer were identified on a radiograph (Fig. 6b). During the second-stage surgery, no change in the bone loss was observed compared with the first-stage surgery (Fig. 9), and metaphyseal sleeve augmentation was performed (Fig. 8c). The ROM increased from 89 degrees preoperatively in the first-stage surgery to 97 degrees in the second-stage surgery (Fig. 8d and e) and further to 118 degrees 3 months after the second-stage surgery.

Case 4

A 71-year-old woman diagnosed with PJI and tibial tray loosening underwent 2-stage revision. The bone loss assessment was stage 1 for the femoral side during both the first- and second-stage surgeries. No cement spacer fracture or subluxation from the bone occurred. However, posterior subluxation of the knee joint was noted at the 11-week follow up (Fig. 10). Despite this, with the utilization of long hinge knee brace, she exhibited independent ambulation with a walker. The second-stage procedure was performed 16 weeks following the initial surgery. The ROM improved from 30 degrees preoperatively in the first-stage surgery to 97 degrees in the second-stage surgery, and further to 116 degrees 3 months after the second-stage surgery.

Overall, the on-bone femoral spacer technique showed a mean flexion arc of 92.2 ± 9.7 degrees during the between-stage period. The flexion ROM increased from 104.2 ± 43.1 to 124 ± 18.5 degrees from the preoperative first-stage measurement to the 3-month postoperative second-stage measurement. All patients had a flexion arc of >70 degrees during the between-stage period (Table 3).

The mean duration between the first and second stages was 21.6 ± 4.5 weeks (Table 2). The mean operative time was 145 ± 11.6 and 165.6 ± 12.5 minutes for the first and second stages, respectively. The mean total hemoglobin loss was 2.3 ± 1.3 g/dL after the first-stage surgery and 2.04 ± 1 g/dL after the second-stage surgery.

All patients were able to ambulate with full weight-bearing, with or without gait assistance, on the cement spacer. No femoral spacer fractures or dislocations from the distal femur occurred. However, 1 patient developed a minor tibial spacer fracture that did not compromise the weight-bearing area, and 1 patient developed partial knee subluxation. Regarding the cement spacer removal technique, the osteotome was utilized to break the spacer, followed by the meticulous extraction of spacer fragments (Fig. 4). The spacer was successfully removed without difficulty in all knees. The bone stock status after removing the spacer remained consistent with the assessment conducted during the initial stage for all knees.

During the perioperative period of the second-stage surgery, standard antibiotics for preventing surgical site infection were administered. The intraoperative cultures were negative in all patients and patients were discharged without requiring an extended course of antibiotics. At the 1-year follow-up, none of the patients exhibited recurrent infection.

Discussion

Numerous studies have revealed complications associated with mobile spacers, with rates ranging from 43% to 87% [2,4,10]. These

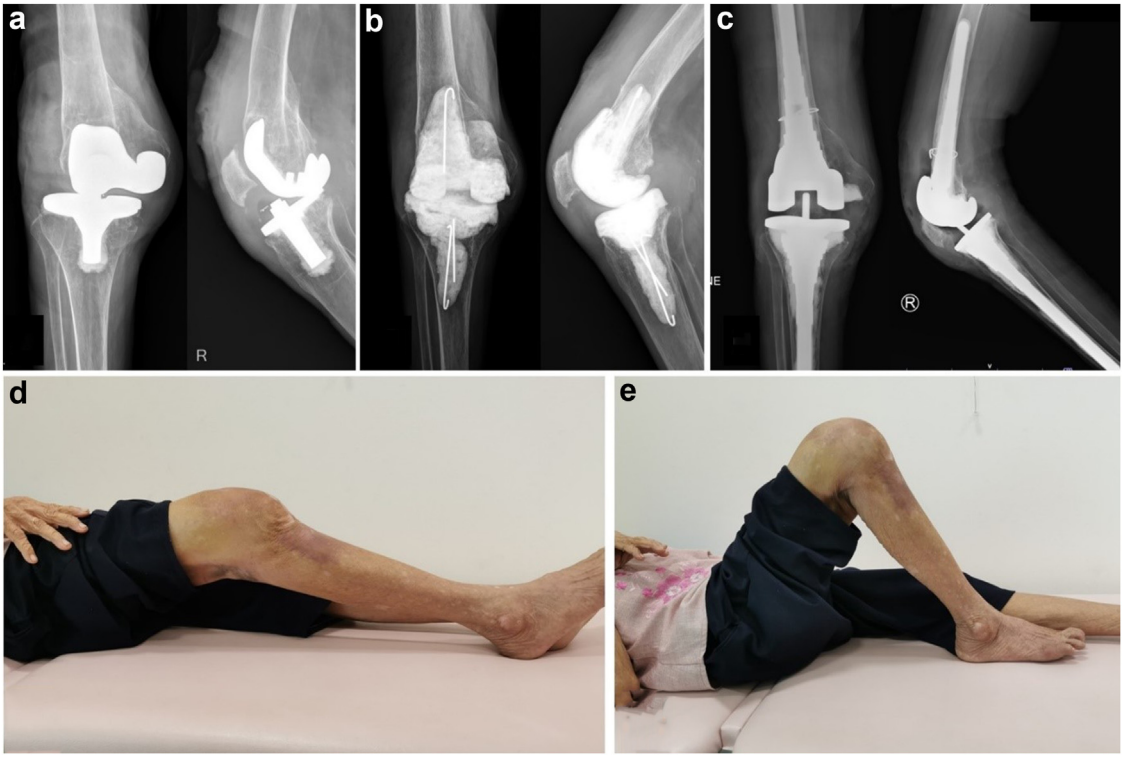

Figure 8. Radiographs (a) before the first-stage surgery, (b) showing the spacer condition before reimplantation, and (c) after reimplantation. Range of motion of the knee before the preoperative second-stage surgery: (d) flexion, (e) extension.

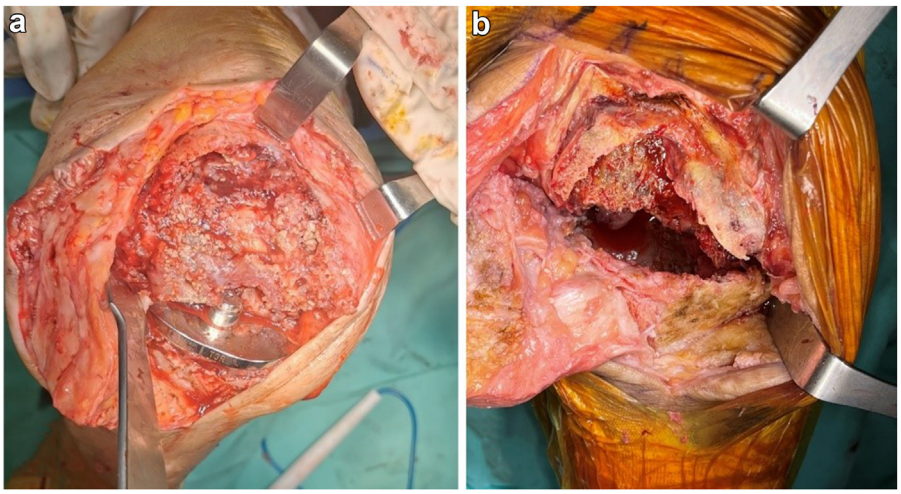

Figure 9. Intraoperative bone condition during (a) first-stage surgery and (b) second stage surgery. The femoral bone loss was stage 2B (unchanged from the first-stage surgery).

complications include spacer tilting, mediolateral translation, spacer dislocation, spacer fracture, and knee subluxation. Among these, femoral spacer complications are the most common [10]. The main causes of femoral spacer complications described in the literature are spacer size mismatch and inadequate spacer stability [1,4]. The most common methods for creating a mobile spacer are the use of a prefabricated cement spacer and intraoperative fabrication by the surgeon [4]. Despite the availability of various molding sizes, achieving spacer stability remains a significant challenge, particularly in patients with bone loss or bony deformities.

To address these issues, we devised a novel approach to femoral spacer creation by employing the on-bone molding concept, in which the molding block is applied directly onto the distal femur. This ensures femoral spacer stability, even in patients with bony deformities, and the bone loss that is commonly observed in revision situations. We have herein introduced this novel technique for creating femoral spacers with the aim to reduce femoral spacer complications and have presented our clinical results following the application of this new method.

In this study, the femoral spacer remained intact on the distal femur for 21.6 ± 4.5 weeks. The interim period in the study appears to be longer than usual due to coronavirus disease 2019 restriction policies during the study period [6,9]. No femoral spacer mispositioning or fractures were observed on the preoperative second-stage radiograph. However, posterior subluxation of the knee joint occurred in 1 patient. This complication may have been avoided through meticulous tibial spacer molding, adjustment of the thickness of the tibial spacer, or implementation of a spacer post-cam mechanism [11].

In the current study, the ROM with the spacer reached 105.8 ± 20 degrees, while the postoperative flexion range after reimplantation was 124 ± 18.5 degrees. This outcome was superior to that of numerous previous studies, which reported ROM ranging from 31 to 91 degrees with a cement spacer and 77.37 to 115 degrees after reimplantation [12–15]. Our result may have been attributed to use of the FMD technique, which provides greater spacer stability during knee flexion and fewer spacer complications. This technique also facilitated patient ambulation; all were able to ambulate with full weight-bearing capacity with or without gait assistance.

The mean operative time of the first-stage surgery was 145 ± 11.6 minutes. Despite our use of sequential femoral molding spacer placement followed by tibial spacer molding, which likely contributed to an increased duration of the first-stage surgery, the operative time was comparable to that of most previous studies (155.8-175.5 minutes) [13,16].

After removal of the cement spacer in the second-stage surgery, the bone deficiency remained unchanged compared with the assessment conducted during the first stage. This suggests that the direct on-bone femoral spacer molding technique does not impact the bone loss condition.

Based on our limited preliminary investigation in a small convenience sample, it does not appear as through the use of the custom FMD is associated with increased spacer complication rates and may prove to reduce some common femoral spacer adverse events such as femoral spacer tilting, fracture or femoral spacer

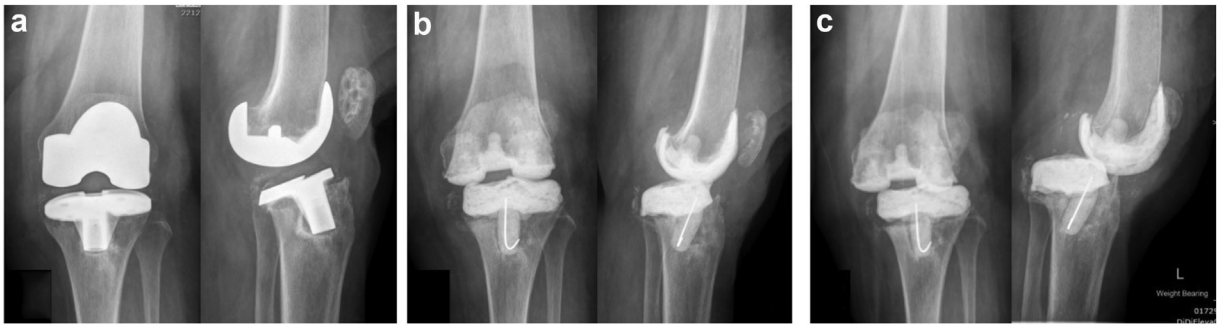

Figure 10. Radiographs (a) before the first-stage surgery, (b) showing the spacer condition at 6-week follow up and (c) showing the spacer condition at 11-week follow up, before reimplantation.

Table 3
Range of motion before first-stage surgery, before second-stage surgery, and 3 months after reimplantation.

Knee no.	1	2	3	4	5	Mean ± SD
Before first-stage surgery (degrees)						
Flexion	103	126	133	129	30	104.2 ± 43.1
Extension	26	0	5	40	0	14.2 ± 18.0
Arc	77	126	128	89	30	90 ± 40.3
Before second-stage surgery (degrees)						
Flexion	75	106	116	129	103	105.8 ± 20.0
Extension	0	12	18	32	6	13.6 ± 12.3
Arc	75	94	98	97	97	92.2 ± 9.7
3 months after second-stage surgery (degrees)						
Flexion	92	131	132	139	126	124.0 ± 18.5
Extension	8	9	5	21	10	10.6 ± 6.1
Arc	84	122	127	118	116	113.4 ± 17

SD, standard deviation.

dislocation. However, a notable drawback of this technique is the potential increase in spacer molding time because the tibial spacer must be molded after full settling of the femoral spacer. Despite this, the overall operative time was not significantly different from previous studies. It is important to note that the operative time for revision surgery may be influenced by various factors other than the spacer molding time. An additional downside of the cement spacer surface is the potential for friction sensation and patient discomfort during knee motion. The metal-plastic temporary spacer may be better suited for individuals with these concerns [17]. However, the cost of the metal-plastic temporary spacer tends to be higher than that of using cement alone. Further investigation into the cost-benefit analysis is warranted.

This study had 2 main limitations. First, it was a descriptive study without a comparison group. Nevertheless, to the best of our knowledge, this study is the first to describe the concept of the on-bone spacer molding technique and to present the FMD and its manufacturing process. Second, the small size of this case series may have impacted the predictive power regarding overall spacer complications. However, the results of the present study cover a diverse range of PJIs, including unilateral and bilateral total knee infections, infections with implant loosening, and cases with severe bone loss combined with malunion deformity. Future studies with larger sample sizes are necessary to validate our findings.

Conclusions

Molding of the femoral spacer directly onto the bone may reduce the occurrence of specific femoral spacer complications by enhancing stability on the distal femur without affecting the bone loss condition. This method likely improves knee flexion capability and enhances ambulation. Precise intraoperative gap assessment and appropriate tibial cement spacer thickness are important to prevent knee joint dislocation. Nevertheless, further independent validation studies using the custom on-bone femoral spacer mold are needed to confirm the suggested safety profile and to demonstrate value in wider setting.

Conflicts of interest

The authors declare there are no conflicts of interest.

For full disclosure statements refer to https://doi.org/10.1016/j.artd.2024.101400.

Informed patient consent

The author(s) confirm that written informed consent has been obtained from the involved patient(s) or if appropriate from the parent, guardian, power of attorney of the involved patient(s); and, they have given approval for this information to be published in this case report (series).

CRediT authorship contribution statement

Kulapat Chulsomlee: Writing – original draft, Project administration, Methodology, Investigation, Conceptualization. **Eakkachai Warinsiriruk:** Investigation, Conceptualization. **Nutchanat Thongchuea:** Investigation. **Nithid Sri-utenchai:** Resources. **Sorawut Thamyongkit:** Resources. **Chavarat Jarungvittayakon:** Resources. **Siwadol Wongsak:** Resources. **Paphon Sa-ngasoongsong:** Resources. **Satetha Vasaruchapong:** Writing – review & editing.

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