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Clinical Evaluation of Two-Stage Revision Total Knee Arthroplasty Using Silicone Mold-Based and Metal Mold-Based Antibiotic-Loaded Knee Spacers: A Comparative Study

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Abstract

Background: The gold standard for managing infection following total knee arthroplasty (TKA) is two-stage revision surgery, which entails the placement of a spacer in the knee during the initial stage. This study aimed to compare metal mold-based and silicone mold-based spacers regarding clinical evaluation and infection control in patients with infected TKAs.

Methods: In this study, we assigned fourteen individuals with infected knees following arthroplasty to either the metal mold-based spacer group (control) or the silicon mold-based spacer group. The WOMAC Score, Knee Society Score (KSS), and range of motion (ROM) were utilized for clinical evaluation prior to spacer implantation and during the post-first stage of surgery follow-up. Gain score analysis (post–pre difference) was conducted to assess functional improvement over time. The Wilcoxon signed-rank test and the Mann–Whitney U test were applied for statistical analysis using SPSS software.

Results: Knee infection was eliminated in all participants across both groups. Post-surgery, ROM improved from 59.28 ± 20.29° to 99.00 ± 5.65° in the control group, while the intervention group demonstrated an increase in ROM from 66.42 ± 24.78° to 101.42 ± 8.01°. Additionally, the KSS improved from 38.28 ± 23.78 to 123.71 ± 20.53 in the control group and from 35.71 ± 30.99 to 124.85 ± 27.49 in the intervention group. The WOMAC score increased from 48.71 ± 9.23 to 70.57 ± 5.28 in the control group and from 47.71 ± 12.03 to 72.57 ± 6.32 in the intervention group. There were no statistically significant differences between the two groups in terms of ROM ($P = 0.751$), WOMAC ($P = 0.678$), or KSS ($P = 0.806$) in the gain scores analysis.

Conclusion: Metal mold-based spacers and silicone mold-based spacers demonstrate no significant differences in functional assessment (ROM, KSS, and WOMAC) or infection control. These findings indicate that silicone mold-based spacers may serve as a reliable alternative to conventional metal mold-based spacers, particularly in low-income countries.

Keywords: Total Knee Arthroplasty, Two-Stage Revision, Knee Spacer, Metal Mold, Silicon Mold

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Introduction

One extremely dangerous side effect of total knee arthroplasty (TKA) is infection (1). Periprosthetic joint infection (PJI), considered one of the most alarming complications for orthopedic surgeons, is currently among the most frequent reasons for revision following TKA (2, 3). Two-stage revision surgery is regarded as the gold standard for treating an infected TKA (4). This procedure involves the removal of the original implants, debridement, and the implantation of a temporary spacer impregnated with antibiotics (5).

Traditionally, spacers are categorized into two types: articulating (dynamic) and static (6). Static spacers maintain

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↑What is "already known" in this topic:
In Iran, commercially available metal molds for producing antibiotic-loaded spacers are costly and generally not accessible. To address this limitation, a locally manufactured silicone mold spacer was developed and patented. Previous studies have not assessed its clinical efficacy or infection control.

→What this article adds:
This study provides evidence that silicone mold-based spacers are as effective as metal molds in achieving functional outcomes and eradicating infections in two-stage revision knee arthroplasty. Therefore, this study supports their use in resource-limited settings as a practical and affordable alternative.

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the knee joint in its maximum extension or minimum flexion. Although they restrict knee motion, they also facilitate local antibiotic delivery and preserve joint space. The static spacer can be regarded as a temporary knee arthrodesis infused with antibiotics (3).

According to some studies, the use of static spacers can facilitate improved recovery of infected soft tissues, while other research has reported no significant difference between these spacers (7, 3). However, both patients and surgeons have encountered several issues following surgery and during the second revision. The primary drawback associated with static spacers is the development of joint stiffness, which often leads to a limited range of motion after the completion of the second stage of revision surgery. Additionally, although less frequently observed compared to dynamic spacers, the use of static spacers has occasionally been linked to joint instability and complications related to wound healing (3, 8). Furthermore, some experts assert that, particularly in individuals with higher body weight, static spacers do not adequately restore the original anatomic joint shapes, increasing the likelihood of spacer displacement and resulting in significant bone loss (9).

The primary benefit of an articulating spacer is its effectiveness in eradicating infection while preserving knee range of motion during the interim between surgical phases (10). Allowing mobility throughout these phases helps maintain the extensor mechanism at an appropriate length and elasticity, prevents the formation of scar tissue around the knee joint, shortens the quadriceps, and avoids capsular thickening and contracture, which may facilitate simpler reimplantation during revision surgery (11-13). Although static spacers are less expensive than their articulating counterparts, articulating spacers demonstrate improvements in long-term function scores, enhanced patient satisfaction, and greater final ranges of motion. Therefore, despite the higher costs, dynamic spacers are preferable for both patients and surgeons (14, 15).

Dynamic spacers, as previously mentioned, offer several advantages over static spacers. However, handcrafted mobile spacers also possess limitations, including an inability to maintain stability and a lack of a well-shaped and congruent articular surface. Furthermore, the molded type of dynamic spacers is expensive and often unavailable in low-income countries, resulting in the continued use of static spacers in some of these regions (16, 17).

In our previous study, we introduced a low-cost mobile cement spacer that utilizes a silicone mold and does not require expensive technology (17). In this study, we aim to compare the effectiveness of metal mold-based dynamic spacers with that of our silicone mold-based .spacers in patients undergoing TKA surgery

Methods

The current comparative study received approval from the Ethics Committee of North Khorasan University of Medical Sciences, Bojnurd, Iran (IR.NKUMS.REC.1403.061), and was registered with the Iranian Registry of Clinical Trials (IRCT) under the code IRCT20191111045400N4. Eligible participants were those with a confirmed diagnosis of periprosthetic joint infection (PJI) based on the 2018 ICM Philadelphia criteria and a clinical indication for two-stage revision arthroplasty as determined by the treating surgeon. According to the ICM Philadelphia criteria, PJI is established when at least one major criterion or a combination of minor criteria is met. Major criteria include the presence of a sinus tract communicating with the prosthesis or the identification of an identical pathogen from two distinct culture samples. Minor criteria—of which more than three are required for diagnosis—include elevated serum CRP (>10 mg/L) or ESR (>30 mm/h), increased synovial fluid leukocyte count (>3,000 cells/μL) or neutrophil proportion (>80%), a positive leukocyte esterase or alpha-defensin test, histopathological evidence showing more than five neutrophils per high-power field in periprosthetic tissue, and a single positive culture result. Exclusion criteria included polyarticular joint involvement, immunodeficiency or chronic corticosteroid therapy, significant systemic comorbidities, and withdrawal of consent during the follow-up period. A total of 14 older adult patients were randomly assigned to either the Silicone-Mold Group (Intervention) or the Metal-Mold Group (Control) in a 1:1 ratio using a computer-generated randomization sequence.. Demographic data—including age, sex, and the diagnosis at the time of the index operation—were documented. Microbiological information was obtained from both preoperative and intraoperative culture samples. Range of motion (ROM), the Oxford knee score, or Knee Society Score (KSS), and the WOMAC score were measured as pre- and postoperative clinical evaluations. The participants were divided into two groups: the control group received femoral and tibial spacers manufactured with a metal mold (Zimmer BioMet, Study Warsaw, IN, USA), while the other group received spacers made with a silicone mold. This silicone mold was created using a hydraulic press machine (Tondar Machin Co., Iran), as mentioned in our previous study (17).

Surgical technique

As is standard practice, infected total knee arthroplasty (TKA) is treated with a two-stage exchange arthroplasty using a cement spacer impregnated with antibiotics. All surgeries were performed by the same surgeon. In the two-stage revision of TKA, antibiotic-loaded cement is utilized instead of regular bone cement to deliver high doses of antibiotics (18). In this study, a commercially available gentamicin-loaded bone cement (SYNICEM 3G with gentamicin, France), containing 500 mg of gentamicin per 40 g of cement, was used in conjunction with 4 g of vancomycin powder (Exir, Iran). It is recommended to use this cement alongside intravenous antibiotics appropriate to the infection-causing organism following surgery.

Typically, two to three bone cement packs are sufficient to fabricate the spacer, depending on the required size. After selecting the appropriate mold, the antibiotic-loaded cement is injected into the mold during the late phase of cement hardening. Once polymerization is complete, the mold is carefully removed, and the spacers are prepared

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for implantation. To restore and maintain the joint line, the tibial component is first positioned and fixed to the proximal tibia using antibiotic-impregnated cement. The femoral component of the prosthesis is then positioned and secured to the distal femur with additional antibiotic-loaded cement. While the cement remains moldable, the spacer must achieve firm adherence to the bone surface and be held in position until complete hardening occurs. However, it is important to avoid excessive penetration of cement into the surrounding bone, as this may compromise the remaining bone stock and complicate spacer removal during the second-stage procedure. Flexing and extending the knee joint were used to evaluate its stability and mobility once both parts had been positioned, and ultimately, the incision was closed. Patients were allowed to walk with the use of two crutches, engage in continuous passive motion (CPM), and practice partial weight-bearing immediately. Figure 1 illustrates the medical instrument, an example of knee surgery, and its radiographic images following knee spacer implantation for the two groups.

Follow-up

Clinical evaluations of the knee joint were assessed by range of motion (ROM), the WOMAC and Oxford Knee Score, both prior to surgery and six weeks following the first stage of revision. Laboratory tests, including C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR), as well as radiographic assessments, were conducted to screen for postoperative infections and their implications. During the patient's visit, ROM, KSS, and WOMAC scores were recorded by the physician.

Statistical analysis

Statistical analyses were performed using SPSS version 18.0 (SPSS Inc., Chicago, IL, USA). Continuous variables were reported as mean ± standard deviation (SD), while categorical variables were summarized as frequencies and percentages. The Wilcoxon signed-rank test was utilized for within-group comparisons (preoperative vs. postoperative values), and between-group differences were assessed using the Mann–Whitney U test. Gain scores (post–pre

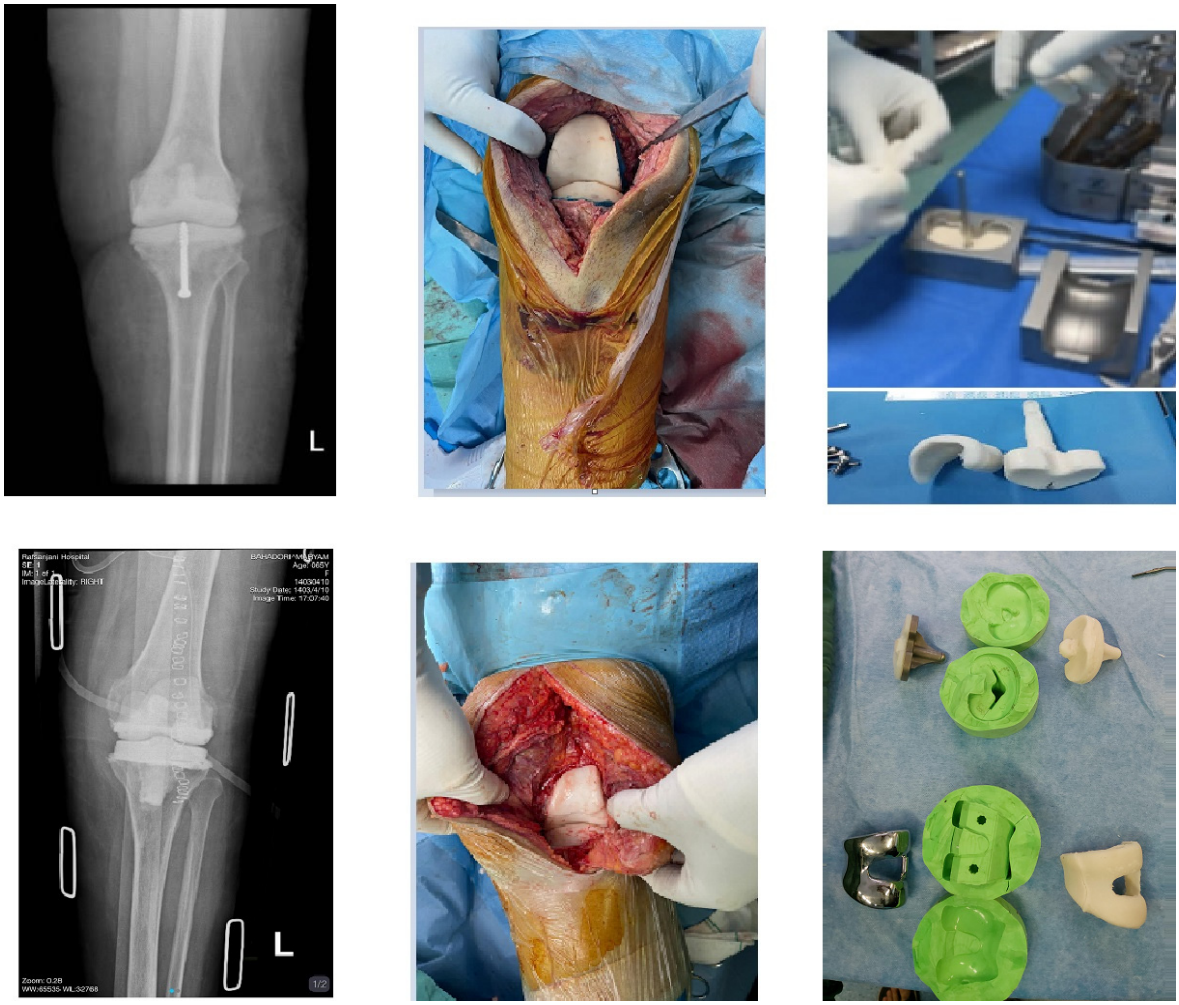

Figure 1. Medical instruments used for the manufacture of antibiotic-loaded knee spacers, along with an example of knee surgery and radiographic images following knee spacer implantation for the metal mold-based (upper images) and silicone mold-based (lower images) groups.

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values) were calculated for ROM, KSS, and WOMAC. P-values < 0.05 were considered statistically significant. To better reflect clinical significance, 95% confidence intervals (CIs) were calculated for mean differences.

Results

The study included fourteen patients (7 women, 7 men) who underwent a two-stage revision surgery. Table 1 presents the demographic data of these patients. In the control group, which utilized a metal mold-based spacer, seven patients with a mean age of 66.28 ± 5.52 years participated. This subgroup comprised three men and four women, all diagnosed with osteoarthritis (OA). The identified causative microorganisms included Streptococcus viridians in two patients and Staphylococcus aureus (staph) in the remaining five. Prior to spacer implantation, the mean erythrocyte sedimentation rate (ESR) was 70.71± 21.18 mm/h, and the mean C-reactive protein (CRP) level was 24.67 ± 4.12 mg/L.

The intervention group, which utilized a silicon mold-based spacer, consisted of seven patients with a mean age of 67.14 ± 3.97 years. This subgroup included four men and three women. Diagnoses within this group comprised OA in five patients, while two patients had both OA and RA. The identified infectious agents included Pseudomonas in one patient and Streptococcus viridians in another, with Staphylococcus aureus (staph) infecting the remaining five patients. Prior to spacer implantation, the mean ESR was 75.14 ± 25.16 mm/h, and the mean CRP level was 24.74 ± 4.98 mg/L. There was no significant difference in demographic variables between the two groups. All patients in the study achieved eradication of their infection. The resolution of infection was confirmed by serial CRP and ESR measurements, which correlated with clinical recovery in all cases. Postoperatively, all patients commenced passive ROM exercises 12 hours after surgery and were allowed to bear weight. Within one week of the procedure, patients were ambulating independently and had achieved knee flexion of 78–90 degrees. Table 2 provides a detailed clinical evaluation of the patients. Both groups experienced no complications during the first stage of the arthroplasty. The assessment of infection serological markers following the first stage confirmed that the infection had been eradicated in every instance. After an average of 9.2 weeks (range 6–11) from the first stage, the second stage was conducted. During the second stage, all spacers were stable and could be easily removed with light tapping using a hammer. Following the first stage, serial

Table 1. Demographic characteristics of patients receiving silicon mold-based antibiotic-loaded knee spacers (intervention group) compared with those receiving metal mold-based antibiotic-loaded knee spacers (control group).

Patient		Age	Gender	Diagnosis	Organism	CRP (mg/l)	ESR (mm/h)
Intervention group	1#	64	Female	OA	Pseudomonas	21.9	49
	2#	66	Male	RA + OA	Staphylococcus aureus	26.2	61
	3#	73	Male	OA	Staphylococcus aureus	16.8	56
	4#	65	Male	OA	Staphylococcus aureus	26.5	105
	5#	71	Female	OA	Staphylococcus aureus	23.7	67
	6#	62	Male	RA + OA	Streptococcus viridans	33.2	115
	7#	69	Female	OA	Staphylococcus aureus	24.9	73
Control group	1#	59	Female	OA	Staphylococcus aureus	20.1	55
	2#	74	Male	OA	Staphylococcus aureus	22.2	59
	3#	71	Male	OA	Staphylococcus aureus	30.7	101
	4#	66	Female	OA	Streptococcus viridans	21.9	53
	5#	60	Female	OA	Staphylococcus aureus	24.8	69
	6#	65	Male	OA	Staphylococcus aureus	30.1	100
	7#	69	Female	OA	Streptococcus viridans	22.9	58

Table 2. Clinical evaluation of patients with silicon mold-based antibiotic-loaded knee spacers (intervention group) and metal mold-based antibiotic-loaded knee spacers (control group).

Patient		ROM preop	ROM postop	KSS preop	KSS postop	WOMAC score preop	WOMAC score postoperatively
Intervention group	1#	65	100	0	110	50	77
	2#	95	95	69	104	61	75
	3#	75	95	70	179	55	81
	4#	75	115	63	143	50	63
	5#	15	95	8	110	32	66
	6#	75	100	10	105	30	75
	7#	65	110	30	123	56	71
	Mean (SD)	66.42(24.78)	101.42(8.01)	35.71(30.99)	124.85(27.49)	47.71(12.03)	72.57(6.32)
	95% confidence interval (CI)	44.28-88.58	93.77-109.09	7.42-63.99	101.02-148.70	36.57-58.85	66.74- 78.40
Control group	1#	45	93	15	100	48	70
	2#	80	95	53	121	50	80
	3#	30	100	6	110	40	65
	4#	60	100	60	125	55	75
	5#	85	95	69	110	63	68
	6#	45	100	25	140	50	70
	7#	70	110	40	160	35	66
	Mean (SD)	59.28(20.29)	99.00(5.65)	38.28(23.78)	123.71(20.53)	48.71(9.23)	70.57(5.28)
	95% confidence interval (CI)	40.32-78.26	93.77-104.23	16.3-60.3	104.7-142.7	40.21-57.29	65.72-75.51

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CRP and ESR measurements were obtained to verify that the infection was eradicated. The infection was completely eliminated in all patients. Twelve hours after surgery, all patients began passive movement and were permitted to walk with assistance. One week post-procedure, the patients were able to walk while bearing weight, and no adverse events were observed during the 6-week follow-up.

Table 2 presents the clinical evaluation of the patients. During the spacer stage, the intervention group's ROM increased by an average of 35 degrees, while the control group's ROM increased by 40 degrees. Furthermore, the overall WOMAC scores improved by an average of 25 points in the intervention group and 22 points in the control group, while the KSS rose by an average of 89 points in the intervention group and 85 points in the control group.

A statistical test indicated that there was no significant difference between the two groups regarding preoperative ROM, WOMAC, and knee score (*P*-values = 0.631, 0.859, and 0.889, respectively). Similar results were observed postoperatively, with *P*-values for ROM, WOMAC, and knee score being 0.36, 0.58, and 0.93, respectively.

After surgery, the ROM improved from 59.28 ± 20.29° to 99.00 ± 5.65° in the control group, compared to an increase from 66.42 ± 24.78° to 101.42 ± 8.01° in the intervention group. Additionally, the KSS improved from 38.28 ± 23.78 to 123.71 ± 20.53 in the control group and from 35.71 ± 30.99 to 124.85 ± 27.49 in the intervention group. The WOMAC score increased from 48.71 ± 9.23 to 70.57 ± 5.28 in the control group and from 47.71 ± 12.03 to 72.57 ± 6.32 in the intervention group. Both groups demonstrated significant improvements in ROM ($P = 0.678$), KSS, and WOMAC ($P = 0.778$). In the control group, significant differences were observed between pre- and post-operative measurements for ROM ($P = 0.002$), WOMAC ($P < 0.001$), and knee score ($P < 0.001$). Similarly, the intervention group exhibited significant differences between pre- and post-operative measurements for ROM ($P = 0.001$), WOMAC ($P = 0.001$), and knee score ($P < 0.001$).

The differences between pre- and post-variables were calculated, and these values were compared in two groups based on a gain analysis. The gain scores (post values - pre values) in the intervention group were 35.00 ± 24.83, 24.85 ± 11.90, and 89.14 ± 29.01 for ROM, WOMAC, and knee score, respectively. In the control group, the gain scores were 39.71 ± 21.26, 21.85 ± 8.66, and 85.42 ± 29.18 for ROM, WOMAC, and knee score, respectively. There were no significant differences between the two groups in ROM ($P = 0.751$), WOMAC ($P = 0.678$), and knee score ($P = 806$).

Discussion

In this study, we examined the effects of antibiotic-loaded knee spacers made from silicone and metal molds on infection eradication and motor function in patients with infected total knee replacements. The findings of our investigation revealed no significant difference between the two groups regarding range of motion (ROM), infection elimination, or functional evaluation. Although silicone molds are more cost-effective than Zimmer molds or other metal molds, we did not observe any discernible differences in the outcomes of these spacers.

There are several types of dynamic spacers available, including handcrafted or prefabricated all-cement spacers, as well as low-friction spacers made of metal and/or polyethylene. Specifically, articular spacers can be categorized into several groups: cement-on-cement, cement-on-polyethylene, and metal-on-polyethylene (5). These dynamic spacers can be either handmade (intraoperatively by a surgeon) or molded. Various types of molds are utilized for creating spacers, such as aluminum molds, the injection-molded StageOne® dynamic spacers for hips and knees (Zimmer BioMet, Study Warsaw, IN, USA), or COPAL® knee molds. Although these molded articulating spacers require less time to fabricate intraoperatively, they are associated with a higher cost (19, 20).

When selecting an articular spacer for each patient, factors such as patient age, infection severity, and cost must be considered (19). The antibiotic-containing cement spacer is typically removed six weeks after the first stage of revision (21). Consequently, since this phase is not a permanent or long-term solution, movement and range of motion are not critically important between the two stages. However, due to the postponement of elective procedures in several countries during the COVID-19 pandemic, some PJI patients experienced delays in their second-stage revision (22). Therefore, while awaiting the second stage of revision, it is crucial to utilize a high-quality cement spacer that allows for ambulation.

The debate continues regarding the efficacy of antibiotic-loaded articulating cement spacers compared to static spacers in eradicating infections and preventing soft tissue contractures (23). While earlier studies suggested that static spacers were more effective than articulating spacers in infection eradication, several recent investigations have indicated that articulating spacers are equally effective as static spacers in eliminating infections. Moreover, articulating spacers have been shown to improve postoperative range of motion (ROM) (3). Consequently, the primary advantage of articulating spacers lies in the enhanced knee mobility they provide following surgery, which significantly improves the patient's quality of life (24).

Although articular spacers offer several advantages over static ones, many low-income nations continue to utilize static spacers due to the high cost associated with articular spacers; the expense of these spacers and their molds significantly exceeds that of static or handmade spacers. Despite the availability of various types of articular spacer molds, as previously mentioned, they are difficult to obtain due to their prohibitive prices. Consequently, we developed a reusable silicone mold that can be sterilized, thereby reducing the manufacturing costs of the cement spacer, which we introduced in our previous study (17).

The results of fabricating spacers using this silicone mold are quite promising, as they yield well-shaped spacers that allow for mobility post-surgery. It can be asserted that spacers produced from this mold provide

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patients with an appropriate range of motion, enhance satisfaction, and improve their overall quality of life. Furthermore, due to their low cost, they serve as a suitable alternative to conventional molds in countries with limited medical resources. Therefore, an ideal cement spacer should be affordable, easy to manufacture, allow for the incorporation of antibiotics, facilitate pain-free movement of the affected joint, and possess sufficient strength to withstand stresses during weight-bearing(25).We can conclude that we have addressed the limitations associated with the metal-based mold approach while still achieving the desired outcomes. Consequently, this silicone mold-based method can be considered a viable alternative. For future studies, we recommend measuring serum antibiotic levels at various time points post-surgery to assess systemic exposure and ensure patient safety. A limitation of the present study is the small sample size; due to the limited number of cases, the generalizability of our findings may be constrained. Future studies with larger sample sizes are necessary to validate the effectiveness of .silicone mold-based spacers in two-stage revision

Conclusion

In this study, the gain score for the silicone mold-based group was determined to be 35.00±24.83 for the ROM, 24.85±11.90 for the WOMAC, and 89.14±29.01 for the knee. In the metal mold-based group, the ROM, WOMAC, and knee scores were 39.71±21.26, 21.85±8.66, and 85.42±29.18, respectively. The WOMAC, knee score, and ROM did not significantly differ between the two groups. Thus, metal mold-based spacers and silicone mold-based spacers demonstrated no differences in functional assessment and infection control. However, because silicone molds are easier to produce and more cost-effective, they represent an excellent alternative in low-income countries. Overall, given that silicone molds are more affordable and simpler to manufacture, they are a viable option in low-income nations.

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Conflict of Interests

The authors declare that they have no competing interests.

Authors' Contributions

Mohamad Amin Younessi Heravi and Reza Ganji contributed to the study design and methodology. Ismaeil Garivani and Negin Armide were responsible for data collection, analysis, and interpretation of the study. Additionally, Mohamad Amin Younessi Heravi and Negin Armide contributed to writing and editing the manuscript.

Ethical Considerations

The current comparative study received approval from the Ethics Committee of North Khorasan University of Medical Sciences, Bojnurd, Iran (IR.NKUMS.REC.1403.061), and was registered with the Iranian Registry of Clinical Trials (IRCT) under the code IRCT20191111045400N4.

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Data Availability

The data from this study is available from the corresponding author upon reasonable request.

AI Use Statement

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