

Clinical Outcomes of Antibiotic-Impregnated Cement Spacers in the Treatment of Infected Total Hip Arthroplasty: A Pilot Randomized Clinical Trial

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Received 2025 November 13; Accepted 2026 January 15.

Abstract

Background: Two-stage revision arthroplasty remains the gold standard for managing periprosthetic joint infection (PJI) following total hip arthroplasty (THA) and involves temporary implantation of an antibiotic-loaded cement spacer.

Objective: This pilot randomized clinical trial aimed to compare silicone mold-based articulating spacers with commercially prefabricated spacers regarding infection eradication and functional outcomes in patients with infected THA.

Methods: Fourteen patients diagnosed with infected THA were randomly assigned to receive either a prefabricated spacer (control group) or a silicone mold-based spacer (intervention group). Clinical outcomes were assessed using the Hip Osteoarthritis Outcome Score (HOOS) before spacer implantation and six weeks after the first-stage revision. Functional improvement was evaluated using gain score analysis. Statistical analyses were performed using SPSS, with $p < 0.05$ considered statistically significant.

Results: Infection eradication was achieved in all patients in both groups. In both groups, after surgery, there were significant differences in HOOS ($p < 0.001$) compared with before surgery. Mean HOOS improved significantly after surgery in the control group (from 49.60 ± 9.79 to 71.60 ± 4.72) and in the intervention group (from 48.52 ± 8.64 to 69.67 ± 3.77). Gain score analysis showed no statistically significant difference between groups ($p = 0.77$).

Conclusion: Silicone mold-based spacers demonstrated clinical and infection-control outcomes comparable to those of prefabricated spacers. Given their lower cost and ease of fabrication, silicone mold-based spacers may serve as a practical and cost-effective alternative, particularly in resource-limited settings.

Keywords: Total hip arthroplasty, Two-stage revision, Hip spacer, Silicon mold.

1. Background

Total hip arthroplasty (THA) is one of the most effective surgical procedures for relieving pain and restoring function in patients with advanced hip disease.

Nevertheless, infection remains one of the most serious and potentially devastating complications of THA (1). Periprosthetic joint infection (PJI) remains a major challenge for orthopedic surgeons and is

among the most common causes of revision surgery after THA (2).

Currently, the gold standard treatment for infected THA is a two-stage revision procedure. This strategy includes removal of the prosthetic components, extensive debridement, and placement of a temporary antibiotic-loaded spacer to maintain joint space and deliver local antibiotics until the infection is eradicated (3).

Hip spacers are generally categorized as static or articulating (dynamic). Static spacers maintain the hip in maximal extension or minimal flexion, restrict motion, provide local antibiotic delivery, and help preserve limb length and joint space. Conceptually, they function as a temporary antibiotic-impregnated arthrodesis (4).

The relative advantages of static spacers remain debated. Some reports suggest that static spacers may promote favorable healing of infected soft tissues, while others have not found meaningful differences between spacer types in terms of infection control (5). However, both patients and surgeons often experience complications during the interim period between stages and at the time of re-implantation. One important limitation of static spacers is postoperative stiffness and reduced range of motion after the second-stage revision (6,7). Additional concerns, such as instability and wound-healing complications, have also been described, although less frequently than with dynamic spacers. Furthermore, static spacers may not adequately restore native anatomy in heavier patients, potentially increasing the risk of displacement and bone loss (8).

Articulating spacers were introduced to address these limitations by maintaining motion during the interim period while still providing effective antibiotic delivery. Maintaining joint mobility may preserve extensor mechanism length, reduce periarticular fibrosis, improve function during

the waiting period, and facilitate re-implantation at the second stage (9). Although static spacers are generally less expensive, articulating spacers have been associated with improved long-term functional scores, higher patient satisfaction, and better final range of motion, which often makes them the preferred option despite their higher cost (10).

Despite these advantages, articulating spacers may not always be feasible. Handcrafted mobile spacers may be unstable and have an imprecise articulating surface, whereas commercially manufactured dynamic spacer systems are expensive and may not be readily available in low-income settings (11). Consequently, static spacers remain in use in many resource-limited regions. In a previous study, we introduced a low-cost silicone mold-based articulating knee spacer that could be produced without expensive manufacturing technology (12). Building upon that concept, the present study aimed to develop a silicone mold for hip spacer production and to compare silicone mold-based hip spacers with commercially prefabricated spacers in terms of infection eradication and clinical outcomes.

2. Objective

This pilot randomized clinical trial aimed to compare silicone mold-based articulating spacers with commercially prefabricated spacers regarding infection eradication and functional outcomes in patients with infected THA.

3. Methods

3-1. Participants and Study Design

This pilot study included 14 older adults (7 per group) diagnosed with infected THA. Participants were randomly assigned to either the prefabricated spacer group (control) or the silicone mold-based spacer group (intervention). Randomization was performed using a computer-generated

sequence with block randomization (two blocks comprising seven sizes). Group assignments were labeled 1 and 2 for the control and intervention groups, respectively. Allocation concealment was maintained using sequentially numbered sealed envelopes prepared by an independent coordinator. Both participants and outcome assessors were blinded to group allocation.

Eligibility criteria required a definitive diagnosis of PJI according to the 2018 ICM Philadelphia criteria and a clinical indication for two-stage revision arthroplasty based on the surgeon's judgment (13). According to the ICM criteria, infection is confirmed if a major criterion is met or if a sufficient number of minor criteria are present. Major criteria include the presence of a sinus tract communicating with the prosthesis or isolation of the same pathogen from two separate samples. Minor criteria (more than three required for diagnosis) include elevated serum CRP (CRP >10 mg/L) or ESR (ESR >30 mm/h), elevated synovial WBC count (>3,000 cells/ μ L) or neutrophil percentage (>80%), a positive leukocyte esterase test or alpha-defensin test, positive histological analysis of periprosthetic tissue (>5 neutrophils per high-power field), and a single positive culture result. Exclusion criteria included polyarticular joint involvement, immunodeficiency or long-term corticosteroid therapy, severe systemic comorbidities, and withdrawal of consent during follow-up.

Recorded demographic variables included age, sex, and diagnosis at the index procedure. Microbiological data were obtained from preoperative and intraoperative cultures. Clinical outcomes

were evaluated using the Hip Osteoarthritis Outcome Score (HOOS) before spacer implantation and during the follow-up after the first stage. HOOS is a 40-item questionnaire assessing patient-relevant outcomes across five subscales: pain, symptoms, activities of daily living, sport and recreation function, and hip-related quality of life (14). Patients in the control group received commercially prefabricated hip spacers (Vancogen[®]-Space Hip). Patients in the intervention group received spacers fabricated using a silicone mold. To fabricate the hip spacer in this group, silicone molds were produced with a hydraulic press (Tondar Machine Co., Iran) in three different sizes.

The press uses silicone rubber material for centrifugal casting (Temcorubber Co., Iran), which is more cost-effective than other materials and easier to fabricate. The device features two arms connected to metal plates that include thermostats. Pressure is applied to the upper and lower arms to achieve molding. Continuous pressure prevents the rubber from becoming bubbly or overly hard. Each top and bottom plate has its own thermostat, maintaining temperatures between 100°C and 180°C. To create a mold, the hip prosthesis piece in the desired size is clamped inside a metal cylinder, silicone is applied, and the mold is formed under pressure at 150°C (12). Because the mold is produced at high temperature, it can be autoclaved like other surgical instruments and reused multiple times. These molds shape the spacer to match the required specifications for use during surgery. [Figure 1](#) shows an example of a silicone-based hip spacer.

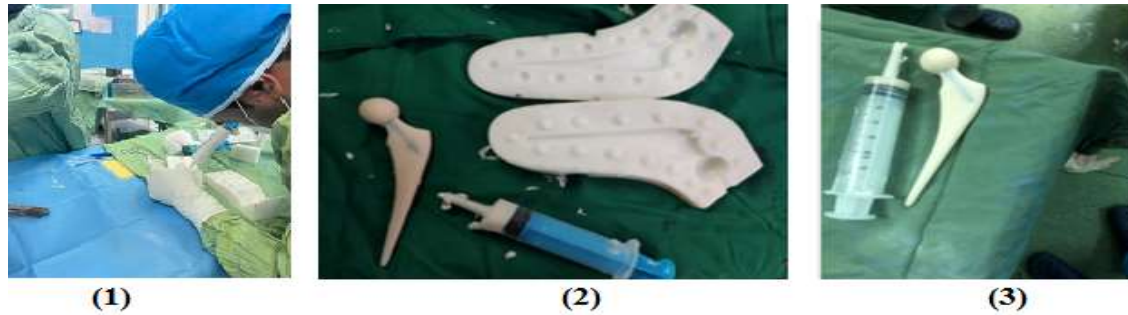


Figure 1. The silicone – based hip spacer. (1) Injection of Antibiotic-Impregnated Cement Spacers into silicone mold, (2) Silicone mold and hip spacer, (3) hip spacer.

3.2. Surgical procedure

The standard approach for treating infected THA is two-stage exchange arthroplasty with an antibiotic-loaded cement spacer. The same surgeon performed all procedures. Antibiotic-loaded cement was used instead of standard bone cement to deliver high local antibiotic concentrations. In this study, commercially available bone cement containing 500 mg gentamicin per 40 g cement (SYNICEM® 3G with gentamicin, France) was mixed with 4 g vancomycin (Exir, IRAN). Postoperative intravenous antibiotics were administered according to culture results and institutional protocol.

Two or three cement packages were used, depending on spacer size. The spacer was implanted and fixed with cement, and stability was assessed intraoperatively by flexion and extension of the hip. The incision was then closed. After recovery, patients were allowed to ambulate immediately using two crutches, and continuous passive motion (CPM) and partial weight-bearing were permitted.

3.3. Follow-up

Clinical evaluation was performed using HOOS before surgery and six weeks after the first stage. Laboratory tests (CRP and ESR) and radiographic evaluation were conducted to assess infection status and postoperative complications. HOOS was measured by the physician at follow-up visits.

3.4. Statistical analysis

Analyses were performed using SPSS 18.0 (SPSS Inc., Chicago, IL, USA). Continuous variables were expressed as mean \pm standard deviation (SD), and categorical variables were reported as frequencies and percentages. Within-group comparisons (pre- vs. post-surgery) were analyzed using the Wilcoxon signed-rank test, and between-group comparisons were evaluated using the Mann–Whitney U test. Gain scores (post–pre differences) were calculated for HOOS. A p-value <0.05 was considered statistically significant.

4. Results

Fourteen patients (7 women and seven men) were enrolled in the study and underwent the two-stage revision procedure. By the end of the follow-up period, 11 patients remained and were included in the final analysis. The flow of participants, including withdrawals and exclusions during follow-up, is presented in [Figure 2](#). Baseline demographic and clinical characteristics are summarized in [Table 1](#). In the control group (prefabricated spacer group), five patients were evaluated, with a mean age of 68.80 ± 5.14 years; three were male, and two were female. All patients in this group were diagnosed with osteoarthritis (OA).

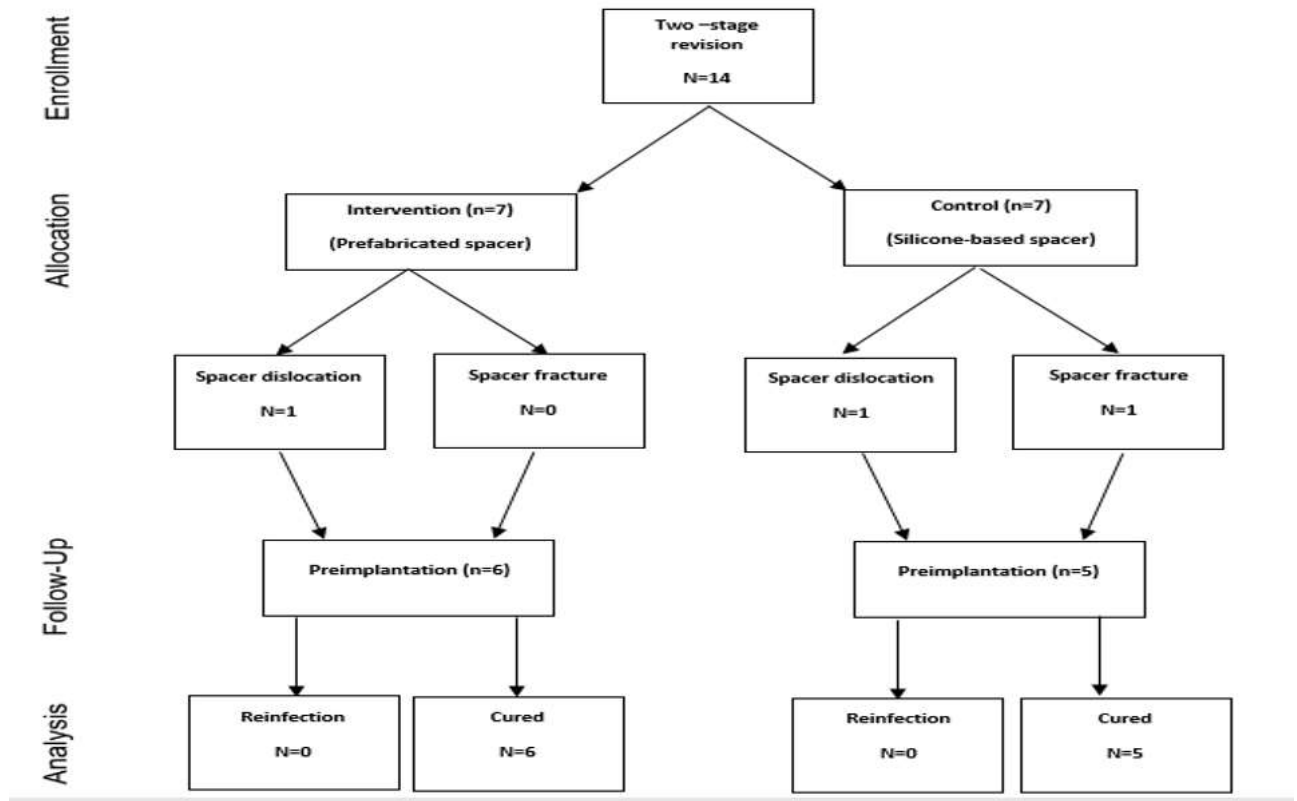


Figure 2. Flowchart of four phases (enrollment, allocation, intervention, follow-up, and data analysis) of a parallel randomized trial of two groups.

Table 1. The demographic information of patients with silicon mold-based antibiotic-loaded hip spacer (intervention group) and prefabricated antibiotic-loaded hip spacer (control group)

Patient	Age	Gender	Diagnosis	Organism	CRP	ESR 1h	
Control group	1#	61	Female	OA	Pseudomonas	21.9	55
	2#	98	Female	OA	Staphylococcus aureus	27.3	59
	3#	75	Male	OA	Staphylococcus aureus	24.9	73
	4#	71	Male	OA	Staphylococcus aureus	23.7	67
	5#	69	Male	OA	Streptococcus viridans	30.1	100
Intervention group	1#	62	Female	OA	Staphylococcus aureus	28.6	66
	2#	72	Female	OA+RA	Staphylococcus aureus	22.2	64
	3#	67	Male	OA	Streptococcus viridans	22.3	65
	4#	60	Male	OA+RA	Staphylococcus aureus	29.8	58
	5#	66	Male	OA	Streptococcus viridans	33.7	95
	6#	68	Male	OA	Staphylococcus aureus	26.8	55

Regarding microbiological findings, one patient was infected with Streptococcus viridans, while Staphylococcus aureus was identified in four patients. Before spacer implantation, the mean ESR and C-reactive protein (CRP) levels were 25.38 ± 4.31 mg/L and 71.00 ± 18.17 mg/L, respectively. In the intervention group (silicone mold-based spacer group), six patients were evaluated, with a mean age of 65.83 ± 4.31 years; four were male, and two were female. Four

patients were diagnosed with OA, and two had rheumatoid arthritis (RA) in addition to OA. Microbiological assessment showed that two patients were infected with Streptococcus viridans, while Staphylococcus aureus was isolated in five patients. Before spacer implantation, the mean ESR and CRP levels were 27.23 ± 4.46 mg/L and 67.16 ± 14.30 mg/L, respectively. Overall, there were no statistically significant differences between the two

groups in baseline demographic variables.

Infection eradication and postoperative course

Infection eradication was achieved in all patients. Serial CRP and ESR measurements were used to confirm subsidence of infection, and in all cases, laboratory improvement corresponded with clinical recovery. No complications were observed during the first-stage revision in either group. The postoperative assessment of serological markers of infection confirmed eradication of infection in all patients.

On average, the second-stage re-

implantation was performed 8.5 weeks after the first stage (range: 6–11 weeks). At the time of the second-stage procedure, all spacers remained stable and were removed without difficulty using light hammer taps. Twelve hours after surgery, patients began passive motion and were allowed to ambulate with assistance. By one week postoperatively, patients were able to bear weight while walking. No adverse events occurred during the six-week follow-up period. The surgical procedure and radiographic images for both groups are illustrated in [Figures 3 and 4](#).

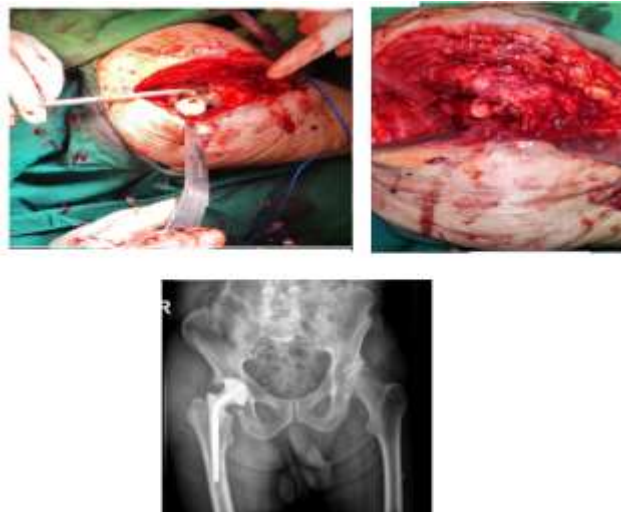


Figure 3. Prefabricated antibiotic-loaded hip spacers.



Figure 4. Silicone mold-based antibiotic-loaded hip spacers

Functional outcomes

Clinical outcome measures are presented in Table 2. There was no statistically significant difference between the two

groups in preoperative HOOS scores ($P = 0.85$). Similarly, no significant difference was observed between groups in postoperative HOOS scores ($P = 0.47$).

Table 2. The clinical outcomes of the patients with silicon mold-based antibiotic-loaded hip spacer (intervention group) and prefabricated antibiotic-loaded hip spacer (control group)

Patient		HOOS pre-op	HOOS post-op	Gain score
control group	1#	61	79	18
	2#	53	74	21
	3#	33	69	36
	4#	56	71	15
	5#	45	65	20
Intervention group	1#	34	65	31
	2#	52	66	14
	3#	46	72	26
	4#	50	71	21
	5#	63	76	13
	6#	46	68	22

In the control group, HOOS improved from 49.60 ± 9.79 preoperatively to 71.60 ± 4.72 postoperatively. In the intervention group, HOOS increased from 48.52 ± 8.64 to 69.67 ± 3.77 . Therefore, HOOS improved significantly in both groups ($p < 0.001$). Within-group analyses showed significant improvements in HOOS after surgery in both the control ($p < 0.001$) and intervention ($p < 0.001$) groups.

To compare the magnitude of improvement between groups, gain scores (postoperative minus preoperative values) were calculated. The mean gain score in the control group was 21.60 ± 8.27 , while the intervention group showed a gain score of 23.00 ± 8.43 . Gain score analysis indicated no statistically significant difference between the two groups ($p = 0.77$). Overall, the findings suggest that silicone mold-based spacers and prefabricated spacers yielded comparable functional outcomes (HOOS) and achieved similar infection control.

5. Discussion

In this study, we evaluated the effectiveness of antibiotic-loaded hip spacers fabricated using a reusable silicone

mold compared with commercially prefabricated spacers in patients undergoing two-stage revision for infected total hip arthroplasty. Our findings showed that both spacer types achieved complete infection eradication and resulted in significant functional improvement. Importantly, no statistically significant differences were observed between the two groups in terms of infection control or functional outcomes. Although silicone mold-based spacers are substantially more cost-effective than prefabricated spacers, our results suggest that this lower-cost approach does not compromise clinical effectiveness.

Several previous studies have compared articulating and static spacers in septic revision total hip arthroplasty. Despite considerable heterogeneity in study designs and outcome definitions, a systematic review by Craig et al. reported that most studies demonstrate similar infection eradication rates between articulating and static spacers (15). It is consistent with our findings, as infection was eradicated in all patients regardless of spacer type.

Different spacer molds and fabrication systems have been described in the

literature, including aluminum molds, StageOne® dynamic spacers for hips and knees (Zimmer Biomet, Warsaw, IN, USA), and COPAL® hip molds. Molded articulating spacers can be fabricated efficiently during surgery; however, their use is often associated with higher costs (16, 17). In comparative cohorts, Zhang et al. reported significantly fewer complications in patients treated with functional articulating spacers (n=13) compared with nonfunctional articulating spacers (P = .006) (18). Similarly, Veltman et al. found significantly better patient-reported outcomes across all evaluated measures in patients treated with functional articulating spacers (n=15) compared with nonfunctional spacers (n=55), while infection recurrence and dislocation rates were comparable between cohorts (19). These reports support the role of articulating spacers in improving functional status during the interval between revision stages, which aligns with the functional improvements observed in our study.

Selection of the optimal spacer should consider multiple factors, including patient age, infection severity, bone quality, and cost. Typically, antibiotic-loaded cement spacers are exchanged or removed approximately six weeks after the first-stage procedure, meaning the interim period is not intended to be a permanent solution. Therefore, achieving full long-term joint mobility may not be essential for all patients. However, real-world circumstances may extend the interval between stages. For example, during the COVID-19 pandemic, elective procedures were delayed in many settings, resulting in prolonged time to re-implantation for some PJI patients. Under such circumstances, a stable and functional spacer that allows ambulation becomes particularly important.

A key advantage of articulating spacers is preservation of joint motion during the interim period, which can improve patient

mobility and quality of life (20). However, access to commercially manufactured molds may be limited in many healthcare systems due to cost. To address this barrier, we developed a reusable silicone mold that can be sterilized and reused, thereby reducing manufacturing expenses, as described in our previous study (12). The present results suggest that spacers produced with this mold provide an appropriately shaped construct that supports postoperative mobility, patient comfort, and functional improvement. Given their low cost and accessibility, silicone mold-based spacers may be a practical alternative in countries with limited medical resources.

In general, the ideal cement spacer should be affordable and easy to manufacture, provide effective antibiotic delivery, allow painless joint motion, and possess adequate mechanical strength to tolerate weight-bearing forces (21). Based on our findings, the silicone mold-based approach appears to meet many of these criteria. Moreover, this method may overcome some limitations of metal-based molds while achieving comparable clinical outcomes, suggesting that silicone mold-based spacers are a feasible alternative.

Mechanical complications have been reported with articulating spacers, particularly in specific patient subgroups. Yang et al. reported that younger patients may have a higher risk of mechanical complications after receiving articulating spacers, likely because they are more physically active (22). In our study, mechanical complications were also more likely in younger patients and those with higher body mass index, which may increase mechanical stress and contribute to spacer displacement. This observation emphasizes the importance of careful patient selection, spacer positioning, and postoperative weight-bearing guidance, especially in individuals at higher mechanical risk.

This study has limitations. Most notably,

the sample size was small, which limits the generalizability of the findings. Also, the follow-up period was short. Larger studies with longer-term follow-up are therefore needed to confirm the effectiveness and safety of silicone mold-based spacers in two-stage revision arthroplasty. Nonetheless, our results suggest that silicone mold-based spacers may represent a reliable alternative to conventional prefabricated systems, particularly in low-income settings where cost and availability are significant constraints.

6. Conclusion

This study compared silicone mold-based spacers and prefabricated spacers with respect to functional outcomes and infection control in patients undergoing two-stage revision for infected total hip arthroplasty. The gain score (postoperative minus preoperative HOOS) was 23.00 ± 8.43 in the intervention group and 21.60 ± 8.27 in the control group, with no statistically significant difference between groups. Similarly, infection eradication was achieved in all patients, and no meaningful differences in infection control or functional improvement were observed between the two spacer types. Overall, silicone mold-based spacers demonstrated clinical performance comparable to prefabricated spacers while offering advantages in affordability and ease of fabrication. Therefore, silicone mold-based spacers may serve as a cost-effective and practical alternative for managing infected THA, particularly in low-income countries and resource-limited healthcare systems.

Acknowledgements: The authors sincerely thank all participants in this study and the Orthopedic Department of North Khorasan University of Medical Sciences for their valuable support and cooperation throughout this project.

Availability of data and materials: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Conflicts of interests: The authors declare no conflict of interest.

Consent for publication: Not applicable.

Ethics approval and consent to participate: This pilot double-blinded randomized clinical trial was approved by the Ethics Committee of North Khorasan University of Medical Sciences, Bojnurd, Iran (IR.NKUMS.REC.1403.097) and registered in the Iranian Registry of Clinical Trials (IRCT code: IRCT20191111045400N5). The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. Written informed consent to publication (including images, personal and clinical details of the participant) was obtained from the patient.

Financial disclosure: This study was supported by a grant from North Khorasan University of Medical Sciences (Grant number: NKUMS4030080).

Author contributions: All authors contributed to the Study design, Methodology, data collection, analysis, and interpretation. All authors approved the final manuscript and agree to be accountable for all aspects of the work.

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