COPYRIGHT 2024 © BY THE ARCHIVES OF BONE AND JOINT SURGERY

CASE REPORT

An Innovative Approach to Produce Silicone Mold-Based Antibiotic-Loaded Knee Spacer for Infected Knee Arthroplasty

Reza Ganji, MD; Negin Armide, MD; Mohamad Amin Younessi Heravi, PhD

Research performed at Imam Ali Hospital, North Khorasan University of Medical Sciences, Bojnurd, Iran

Received: 17 March 2024 *Accepted: 24 July 2024*

Abstract

This study aimed to evaluate the efficacy of antibiotic-loaded cement articulating spacers produced through a silicone mold in the two-stage revision of infected total knee arthroplasty. Five individuals were prospectively treated with 2-stage revision using spacers made by this mold. Clinical assessment was conducted during and after implantation using the WOMAC Score, Oxford knee score, and range of motion (ROM). The results showed that the ROM increased by an average of 35 degrees during the spacer stage, with an average ROM of 100 degrees. Furthermore, there was an average gain of 85.2 points in the Knee Society Score and an average rise of 22.8 points in the total WOMAC scores. This approach had a similar effect on improving infection, motion performance, and patients' satisfaction with metal articular molds but without high-technology equipment and low-cost price. Therefore, this method could be applied to any operating room that performs arthroplasty surgery.

Level of evidence: IV

Keywords: Knee spacer, Silicon mold, Total knee arthroplasty

Introduction

Nowadays, osteoarthritis (OA) is a leading cause of adult impairment, with a rising trend.[1] One of the main therapeutic options for knee osteoarthritis is total knee arthroplasty (TKA).[2] Deep vein thrombosis, femoral shaft fractures, prosthetic fractures, loss of limb motion, knee instability, and postoperative infection are just a few of the postoperative problems that can develop following TKA.[3] Even though postoperative prosthesis-related infections are uncommon, they are one of the most serious postoperative consequences.[4] As the number of TKAs grows, so does the occurrence of TKA-related infections. Despite advancements in infection prevention, up to 3% of people still contract infection.[5] There is currently no test that can definitively identify prosthetic joint infection (PJI).[6] As a result, the diagnosis of PJI is often challenging. The 2018 ICM Philly criteria definition of PJI is the sole verified diagnostic criterion at the moment. The existence of a fistula and two positive growths of the same organism using conventional culture techniques are two of the major criteria used in the ICM Philly Guidelines 2018 for PJI diagnosis.[7] Minor criteria include serum C-reactive protein (CRP), D-dimer, elevated synovial white blood cell count, elevated serum erythrocyte sedimentation rate (ESR), elevated synovial polymorphonuclear neutrophil, single-positive culture, positive histology, and positive intraoperative purulence.[8]

Implant infection can be treated surgically using one of two methods: a one-stage revision that involves implant retraction, debridement, and the implantation of a new prosthesis, or a two-stage revision that involves implant retraction, debridement, wound closure, and the implantation of a new cemented prosthesis after a few weeks.[9] Two-stage revision arthroplasty is currently the recommended treatment for late-chronic infections.[10]

Spacers can be created in a variety of ways, including articulating or non-articulating, prefabricated or custom, and made on a table with or without molds.[5] Initially, cement spacers were static and did not offer enough range of motion (ROM).[11] As a potential solution for the issues with static spacers, the attempt to produce a degree of ROM

Corresponding Author: Mohamad Amin Younessi Heravi, Department of Medical Physics and Radiology, School of Medicine, North Khorasan University of Medical Sciences, Bojnurd, Iran

Email: A.younessi7@gmail.com

THE ONLINE VERSION OF THIS ARTICLE ABJS.MUMS.AC.IR

Copyright © 2024 Mashhad University of Medical Sciences. This work is licensed under a Creative Commons Attribution-Noncommercial 4.0 International License https://creativecommons.org/licenses/by-nc/4.0/deed.en

utilizing dynamic cement on cement spacers with a joint shape attracted interest.[12] Dynamic spacers have different types, such as handmade spacers and molding spacers. Handcrafted spacers produce undesirable outcomes, have a rough surface, and are not congruent. Instability, a restricted range of motion, and excessive wear have been noted as a result.[13]

For the purpose of producing antibiotic-loaded cement articulating spacers during the intervention, we have developed a silicon mold based on high temperature and pressure. We believe that using this spacer is a viable strategy for treating problematic deep TKA infections as it is quick, inexpensive, and simple to implement in all operating rooms. The aim of this study was to assess the effectiveness and function of a new spacer made of silicon mold in the two-stage revision of an infected knee arthroplasty.

Case Presentation

The present trial was approved by the Ethics Committee of North Khorasan University of Medical Sciences, Bojnurd, Iran (IR.NKUMS.REC.1402.056) and was registered at the Iranian Registry of Clinical Trial database (IRCT20191111045400N2). A signed informed consent was obtained from all patients prior to participation in the study. A total of five individuals with chronic infections in their TKA underwent a two-stage revision procedure. The mean age of these patients was 66.8 years, with a range of 61-73 years. This study exclusively incorporated type II (late-chronic) infections. Here, we diagnosed a PJI by observing a fistula, which is one of the major diagnostic criteria of ICM Philly.

To create the tibial component of the spacer, molds were created using a hydraulic press machine (Tondar Machine Co., Iran) for making silicone molds in three different sizes. The material for the hydraulic press machine is silicon rubber for centrifugal casting (Temcorubber Co., Iran), which is more cost-effective than metals and can be easily fabricated. The device consists of two arms, each connected to a metal plate with a thermostat. The pressing force is applied by pressure to the upper and lower arms. Due to continuous pressure on the rubber, it prevents sponginess and excessive hardness. The top and bottom plates are separately equipped with thermostats with a temperature between 100°C and 180°C. To produce a mold, the tibial prosthesis piece in different sizes is fixed inside a metal cylinder, and silicone is placed on it, causing the mold to be made under pressure and at a temperature of 150°C. Since this mold is produced at high temperatures, it can be easily autoclaved like other surgical instruments and used several times. These molds shape the spacer according to the desired specifications during the surgery. This approach has been patented in the Iranian Patent Organization under Declaration No 108616.

Typically, the treatment of infected TKA involves a two-stage exchange arthroplasty using an antibiotic-impregnated cement spacer. We adopted this method in our study. In two-stage revision TKA, antibiotic-loaded cement spacers are employed. Surgeons must avoid soft tissue contraction between both stages of the process in order to minimize complications during the second-stage implantation. Thus, it is crucial that the surgeon maintain adequate joint stability while administering antibiotics intra-articularly and preventing all foreign objects from infecting the knee joint. The gentamicin and vancomycin antibiotics are incorporated into the cement, with a ratio of 0.5g gentamicin per 40g package and 4g vancomycin per 40g package. Typically, two to three packages of cement are sufficient to create the spacer, depending on the desired size. Once the appropriate mold is selected, the cement containing antibiotics is poured into the mold during the final stages of solidification. After achieving polymerization, the mold is cautiously removed, leaving the spacers ready for implantation.

Surgeons initially place and attach the tibial component to the upper part of the tibia using antibiotic-infused cement to maintain the joint line. Following this, the femoral component of the prothesis is situated and secured to the lower part of the femur using more antibiotic-infused cement. While the cement is still malleable, the spacer must firmly adhere to the bone surface and remain in place until it fully solidifies. However, it is crucial to prevent excessive cement penetration into the surrounding bone, as this could cause further harm to any remaining bone when the spacer is taken out during the second stage. The wound was closed after checking ROM, patellar tracking, and knee stability. Based on the agent and intraoperative observations, the surgeon prescribed the appropriate intravenous and oral antibiotics. Patients started continuous passive motion with assistive devices 12 hours after the operation, and ambulation commenced on the third day following surgery. All patients were regularly followed up for clinical assessments, including the WOMAC score, Oxford knee score, ROM, and anterior-posterior, lateral radiographic, and laboratory examinations. The same surgeon, who was not a member of the surgical team, performed separate examinations of each knee. The clinical assessments were recorded pre- and post-operatively, and the responses were evaluated. Figure 1 illustrates the tibial mold and spacer with X-rays before and after the implantation of the spacer [Figure 1].

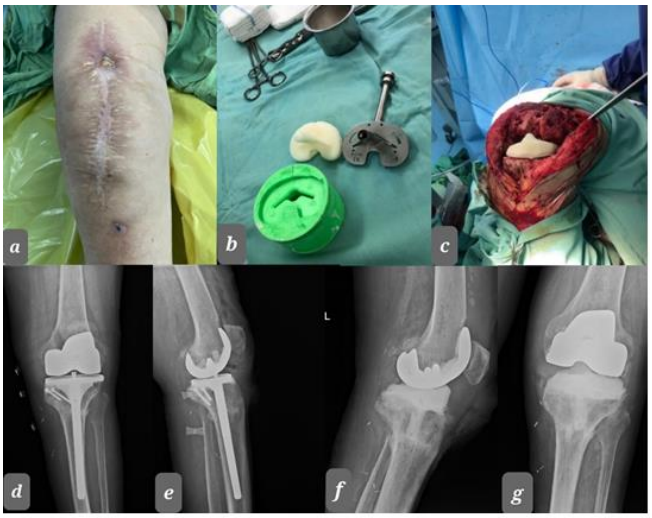

Figure 1. (a) fistula (one of the major criteria in ICM Philly 2018). (b) Tibial mold and spacer. (c) Implantation of the intraoperative molded knee spacer. (d) X-ray of knee joint before implantation of the spacer (anteroposterior view). (e) X-ray of knee joint before implantation of the spacer (lateral view). (f) X-ray of the knee joint after implantation of the spacer (anteroposterior view). (g) X-ray of the knee joint after implantation of the spacer (lateral view)

Results

Five patients with a mean age of 66.8 years (range 61-73) participated in this study. Males accounted for three and females for the two subjects. Four patients were diagnosed with OA, and one of them had rheumatoid arthritis along with OA. All patients had femoral component prosthesis and silicon-based cement spacer in the tibia. Table 1 presents the demographic information of patients [Table 1]. One patient was infected with Pseudomonas, and another was infected with Streptococcus viridians. Staphylococcus aureus infected three other patients, accounting for 60% of the cases. Before the spacer implantation, the mean ESR value and CRP were 78.4 mg/L (range: 49 mg/L to 115 mg/L) and 24.42 mg/L (range: 16.8 mg/L to 33.2 mg/L), respectively. All patients had their infection eradicated. Serial CRP and ESR readings were used to confirm the subsidence of the infection; in every case, these results corresponded with clinical recovery. In all patients, the passive motion was started 12 hours after the surgery, and assisted walking was permitted. After one week following the surgery, the patients were able to walk while bearing weight and had reached a knee flexion of 78-90 degrees. Table 2 tabulates the clinical assessment of the patients [Table 2]. The ROM increased by an average of 35 degrees during the spacer stage, with an average ROM of 100 degrees. Furthermore, there was an average gain of 85.2 points in the Knee Society Score and an average rise of 22.8 points in the total WOMAC scores. None of the patients mentioned any stickiness, a scratchy or grating sound from the joint, or any locking incidents when we specifically asked them about these symptoms. These results were in a good arrangement by anterior-posterior and lateral X-rays. One patient with a knee spacer was satisfied and decided not to have second-stage knee revision; however, others underwent revision arthroplasty. At the 12-month final follow-up, the four patients who had revision arthroplasty reported no pain, while the patient with a knee spacer experienced slight pain. They were moving comfortably with assistance devices, and all of them had effectively eradicated their infection.

Table 1. Demographic information of patients

Patient	Age	Gender	Diagnosis	Organism	CRP	ESR 1h
1#	64	Female	OA	Pseudomonas	21.9	49
2#	61	Male	RA + OA	Streptococcus viridans	33.2	115
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

Table 2. Clinical assessment of the patients

Patient	Range of motion preop	Range of motion postop	Knee Society Score preop (clinical + functional)	Knee Society Score postop (clinical + functional)	WOMAC score preop	WOMAC score postop
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

Discussion

Despite the fact that there are several therapies available for periprosthetic joint infections, the main objective of all is to provide a painless and functional uninfected joint. This study aimed to propose a silicon-based mold for intraoperative production of articulating spacers for infected total knee arthroplasty.

The results of this study showed that the ability to walk while bearing the weight and early ROM without fractures or dislocation were obtained based on our designed mold. All patients' ROM, stability, and weight-bearing exhibited better conditions than before the surgery. The infection control results also showed that the infection disappeared after 12 months of follow-up. Given that the spacer used in this study was loaded with antibiotics, it can act as a factor to remove the infection.

A number of methods for building mobile spacers and their efficacy have been documented, such as custom-molded, prefabricated, handmade, or 3D printing-assisted spacers.[14-17] Although prefabricated or 3D printing-assisted spacers aid in creating a well-shaped spacer, which allows mobility, their high cost keeps them out of reach for nations with limited medical resources. Additionally, the dose of integrated antibiotics is frequently insufficient for treating chronic infections, and they cannot be customized for each patient. Su et al. have suggested a handmade, adaptable, and inexpensive articulating spacer that uses the impression-taking method.[18] the most important disadvantage of this method is that it prevents the cement from expanding inside a closed mold during polymerization, which would have resulted in a flat surface on the finished cement spacer. An aluminum mold has been proposed by Kohl et al. to create intraoperative cement spacers.[19] Although producing aluminum molds is only accessible in well-industrialized

areas and too expensive to produce in small amounts in the present study, a silicone-based mold was developed under pressure and high temperature, and it created an intraoperative cement spacer with a smooth and polished surface similar to aluminum molds but with a simple construction and a much lower cost. In addition, our designed mold does not require high technological equipment and its material is inexpensive (costing up to 30 dollars to make a mold). Moreover, the sterilization techniques on our designed mold were the same in metal mold and orthoses. The present mold allows flexibility in using antibiotics. The passive motion was started 12 hours post-operatively. The patients achieved 80-90 degrees knee flexion at week one after the surgery. These results are in good agreement with metal mold-based studies.[18,19]

The silicone-based mold in the present study permitted the simple extraction of the cement spacer from the mold, even without any lubricant. This feature is comparable to that of industrial and metal spacer molds. Since available molding articular is expensive in some countries, handmade spacers are still widely used. Considering all the advantages and disadvantages of different types of spacers, we have developed a low-cost mobile cement spacer using a silicone mold to produce antibiotic-loaded cement articulating spacers during the intervention. The outcomes of utilizing this spacer are extremely encouraging; to the point, patients have expressed satisfaction with the spacer and no longer desire to undergo second-stage revision arthroplasty, which validates our knee score and WOMAC score. For the purpose of this study, we aim to explore its potential benefits. It is recommended that this approach be performed with a larger number of patients, longer follow-up periods, and a control group with other spacers. In this study, tibial knee spacers with femoral prostheses were evaluated. In a case series study conducted by Pietsch et al., all patients had femoral component prosthesis and silicon-based cement spacer in the tibia.[20] The spacer was created using a silicone mold (with unique characteristics mentioned in the method section with high pressure and temperature) to produce a smooth antibiotic cement with an accuracy of 1 mm. Suitable ROM was established in the patient after the operation. The use of cemented mold for both parts could be a subject for further studies in the future. We also suggest the production of silicon molds for other joints, such as the hip, considering their advantages.

Conclusion

The results of our investigations showed that the use of spacers made from silicone molds had a similar effect on improving infection, patient performance in daily activities, and satisfaction when compared to similar available molds made of aluminum and other materials. This mold, like other available molds, has advantages over static spacers and other types of mold spacers, which are commercially available. Our mold-making process does not require highly technological equipment that can be used on various joints. Silicone molds may be cleaned and reused to create spacers with smooth surfaces, high stability, and a low cost. This method could be applied to any operating room that performs arthroplasty surgery.

Acknowledgement

The authors would like to thank all the people who participated in this study. This study was supported by the Research and Technology Deputy, North Khorasan University of Medical Sciences. (Grant Number No.4020007).

Authors Contribution:

Study concept or design: Reza Ganji and Mohamad Amin Younessi Heravi.

Data collection: Negin Armide and Mohamad Amin Younessi Heravi.

Data analysis or interpretation: Mohamad Amin Younessi Heravi.

Writing the paper: Negin Armide, Mohamad Amin Younessi Heravi and Reza Ganji.

Declaration of Conflict of Interest: The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

Declaration of Funding: This study is funded by Deputy of Research and technology, North Khorasan University of Medical Sciences (grant number: 4000377).

Declaration of Ethical Approval for Study: The present trial was approved by Ethics Committee of North Khorasan University of Medical Sciences, Bojnurd, Iran (IR.NKUMS.REC.1402.056) and was registered at Iranian Registry of Clinical Trial (IRCT) database (IRCT code: IRCT20191111045400N2).

Declaration of Informed Consent: A signed informed consent was obtained from all patients prior to participation in the study.

Reza Ganji MD [1]
Negin Armide MD [2]
Mohamad Amin Younessi Heravi PhD [3]

1 Department of Orthopedic Surgery, School of Medicine, Imam Ali Hospital, North Khorasan University of Medical Sciences, Bojnurd, Iran

2 Student research committee, School of Medicine, Imam Ali Hospital, North Khorasan University of Medical Sciences, Bojnurd, Iran

3 Department of Medical Physics and Radiology, School of Medicine, North Khorasan University of Medical Sciences, Bojnurd, Iran

References

1. Jaiswal A, Goswami K, Haldar P, Salve H R, Singh U. Prevalence of knee osteoarthritis, its determinants, and impact on the quality of life in elderly persons in rural Ballabgarh, Haryana. J Family Med Prim Care. 2021; 10(1):354-360. doi: 10.4103/jfmpc.jfmpc_1477_20.
2. Zhang W, Moskowitz RW, Nuki G et al. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. Osteoarthritis Cartilage. 2008; 16(2):137-62. doi: 10.1016/j.joca.2007.12.013.
3. The function of sonication in the diagnosis of periprosthetic joint infection after total knee arthroplasty. Arch Bone Jt Surg. 2022; 10(9): 735-740. doi: 10.22038/abjs.2020.44329.2212.
4. Kalore N V, Gioe TJ, Singh JA. Diagnosis and management of infected total knee arthroplasty. Open Orthop J. 2011; 5: 86–91. doi: 10.2174/1874325001105010086.
5. Garg P, Ranjan R, Bandyopadhyay U, Chouksey S, Mitra S, Gupta SK. Antibiotic-impregnated articulating cement spacer for infected total knee arthroplasty. Indian J Orthop. 2011; 45(6):535-40. doi: 10.4103/0019-5413.87126.
6. Rodriguez-Merchan EC. Re-revision Total Knee Arthroplasty: Causes, Risk Factors and Results. Arch Bone Jt Surg. 2024; 12(5):328-332. doi: 10.22038/ABJS.2024.75456.3490.
7. Yilmaz MK, Abbaszadeh A, Tarabichi S, Azboy I, Parvizi J. Diagnosis of Periprosthetic Joint Infection: The Utility of Biomarkers in 2023. Antibiotics. 2023; 12(6):1054. doi: 10.3390/antibiotics12061054 .
8. Shohat N, Bauer T, Buttaro M, et al. Hip and knee section, what is the definition of a periprosthetic joint infection (PJI) of the knee and the hip? Can the same criteria be used for both joints? Proceedings of international consensus on orthopedic infections. J Arthroplasty. 2019; 34(2):S325–7. doi: 10.1016/j.arth.2018.09.045.
9. Odekerken JC, Welting TJ, Walenkamp GH, Arts JJ. Experimental models in orthopedic infection research. In Management of Periprosthetic Joint Infections (PJIs) (pp. 81-116). Elsevier 2017. doi:10.1016/B978-0-08-100205-6.00005-7.
10. Meek RMD, Masri BA, Dunlop D, et al. Patient satisfaction and functional status after treatment of infection at the site of a total knee arthroplasty with use of the PROSTALAC articulating spacer. J Bone Joint Surg Am. 2003; 85(10):1888-92. doi: 10.2106/00004623-200310000-00004.
11. Classen T, Von Knoch M, Wernsmann M, Landgraeber S, Löer F, Jäger M. Functional interest of an articulating spacer in two-stage infected total knee arthroplasty revision. Orthop Traumatol Surg Res. 2014; 100(4):409-12. doi:10.1016/j.otsr.2014.01.010.12.
12. Vasarhelyi E, Sidhu SP, Somerville L, Lanting B, Naudie D, Howard J. Static vs articulating spacers for two-stage revision total knee arthroplasty: minimum five-year review. Arthroplast Today. 2022:13:171-175. doi: 10.1016/j.artd.2021.
13. Jämsen E, Stogiannidis I, Malmivaara A, Pajamäki J, Puolakka T, Konttinen YT. Outcome of prosthesis exchange for infected knee arthroplasty: the effect of treatment approach.Acta Orthopaedica. Acta Orthop. 2009; 80(1):67-77. doi: 10.1080/17453670902805064.
14. Martínez-Pastor JC, Maculé-Beneyto F, Suso-Vergara S. Suppl 2: acute infection in total knee arthroplasty: diagnosis and treatment. Open Orthop J. 2013:7:197-204. doi: 10.2174/1874325001307010197.
15. Craig A, King SW, van Duren BH, Veysi VT, Jain S, Palan J. Articular spacers in two-stage revision arthroplasty for prosthetic joint infection of the hip and the knee. EFORT open Rev. 2022; 7(2):137–52. doi: 10.1530/EOR-21-0037.
16. Li Z, Xu C, Chen J. Articulating spacers: what are available and how to utilize them? Arthroplasty. 2023; 5(1):22. doi: 10.1186/s42836-023-00167-6.
17. Zhang W, Fang X, Shi T, Cai Y, Huang Z, Zhang C, Cemented prosthesis as spacer for two-stage revision of infected hip prostheses: a similar infection remission rate and a lower complication rate. Bone Joint Res. 2020; 9(8):484–92. doi: 10.1302/2046-3758.98.BJR-2020-0173.
18. Su YP, Lee OK, Chen WM, Chen TH. A facile technique to make articulating spacers for infected total knee arthroplasty. J Chin Med Assoc. 2009; 72(3), 138–45. doi: 10.1016/S1726-4901(09)70039-5.
19. Kohl S, Krueger A, Roeder C, et al. An aluminium mold for intraoperative production of antibiotic-loaded PMMA knee prostheses. Acta Orthop. 2009; 80(3):389-91. doi: 10.3109/17453670902876771.
20. Pietsch M, Hofmann S, Wenisch C. Treatment of deep infection of total knee arthroplasty using a two-stage procedure. Oper Orthop Traumatol. 2006; 18(1):66-87. doi: 10.1007/s00064-006-1163-5.