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ORIGINAL ARTICLE

Mechanical complications and infection control comparison of custom-made and prefabricated articular hip spacers in the treatment of periprosthetic infection

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Total hip arthroplasty (THA) is considered to be one of the most successful orthopedic procedures and the only definitive solution to severe degenerative hip arthritis. Despite its general success, postoperative complications still occur. Revision rates of THA worldwide are low and occur only in 6% of cases five years after the procedure.[1] The second most frequent cause of revision is periprosthetic joint infection (PJI) following aseptic loosening. The incidence of PJI is reported to be between 0.5 and 2%.[2] Unfortunately, PJI remains one of the most devastating and hard-to-treat modes of failure after THA. Studies have evaluated the high cost of the treatment of PJI and the need for a long-term hospital stay.[3,4] Considering those facts and the rising prevalence of THA, there is a substantial necessity to provide effective therapy.

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ABSTRACT

Objectives: The purpose of our study was to compare the complication rate and the outcomes of custom-made spacers (C-spacers) and prefabricated articular spacers (P-spacers) in the treatment of periprosthetic infection.

Patients and methods: In this retrospective study, 78 patients (44 females, 34 males; mean age: 68.5±9.48 years; range, 47 to 82 years) with articular spacers implanted in our institution were analyzed between January 2009 and December 2019. We recorded implant results as per mechanical complications, infection control, the interval from surgery to definitive hip replacement, and the rate of achieving recovery of joint function after stage two arthroplasty.

Results: There were 29 revised spacers; 18 of them were C-spacers and 11 were P-spacers (p=0.0383). A total of 16 dislocations were recorded, of which six were dislocations of C-spacers, and 10 were dislocations of P-spacers (p=0.0082). Additionally, we registered four spacer breakages, all of which occurred in C-spacers (p=0.295). C-spacers failed early, at an mean interval of 2.2 weeks after implantation, and P-spacers failed later, with an mean of 9.3 weeks after implantation (p=0.0187). A total of nine reinfection complications of spacers were registered; only one infection of P-spacers, and eight infections related to C-spacers (p=0.2583). Definitive revision total hip arthroplasty (rTHA) after spacer explantation and successful treatment of the infection occurred in 63 cases out of 78 patients. Definitive rTHA occurred after the use of C-spacers in 41 (78%) patients and after the use of C-spacers in 22 (84%) patients (p=0.7816). C-spacers had a mean interval from spacer implantation to definitive rTHA of 6.56±6.03 months, and P-spacers had a mean interval of 4±1.93 months (p=0.0164).

Conclusion: Custom-made spacers were shown to have lower mechanical complication rates than prefabricated ones but more infection complications. Prefabricated spacers had more dislocations and fewer breakages. Custom-made spacer mechanical failures occurred earlier compared to prefabricated ones.

Keywords: Custom-made articular hip spacer, periprosthetic joint infection, prefabricated hip spacer.

According to the literature, single and two-stage revision, irrigation, and DAIR (debridement, antibiotics, and implant retention) are described as possible surgical options.[5] Before the publication of the 2011 Musculoskeletal Infection Society (MSIS) criteria for PJI and the new definition in 2018, there was a high degree of variability in the treatment of periprosthetic infections.[6,7] Nowadays, regarding strategies for PJI treatment, most orthopedic surgeons are inclined to a two-stage procedure with implantation of a temporary articulation spacer until the infection is remedied and revision THA (rTHA) is indicated.[8]

After the extraction of the implant, articular spacers are used to restore hip biomechanics, maintain joint function, and deliver local antibiotics.[9] Despite prefabricated spacers being available, a significant proportion of orthopedic surgeons prefer customized spacers. The possibility of anatomical reconstruction of the joint is sustaining custom-made hip spacers as an attractive, cost-effective option. Hence, the purpose of our study was to compare the complication rate and the outcomes of custom-made and prefabricated articular spacers in the treatment of periprosthetic infections. This article provides information on the use of antibiotic-loaded articular hip joint spacers, comparing those two types of spacers from a single orthopedic department using similar surgical techniques and material.

PATIENTS AND METHODS

In this retrospective study, data of 78 patients (44 females, 34 males; mean age: 68.5±9.48 years; range, 47 to 82 years) collected from a database of implanted spacers at the St. Anne's University Hospital and Faculty of Medicine, Department of Orthopaedic Surgery between January 2009 and December 2019 were analyzed. We recorded implant results as per mechanical complications, infection control, the interval from surgery to definitive hip replacement, and the rate of achieving recovery of joint function after stage two arthroplasty.

In the past, only custom-made spacers were used at the authors' orthopedic department. The same surgical technique was used in all of the cases. These were spacers modeled from a humeral nail with a diameter of 8 mm, a length of 190-250 mm, and 80 g of revision bone cement. The nail was bent by the surgeon, and the articulation surface and augmentation of the proximal part of the spacer were modeled from bone cement to restore the center of rotation, offset, and length of the limb as much as possible (Figure 1). Currently, surgeons prefer to use prefabricated spacers. For the purposes of this study, we refer to custom-made spacers as C-spacers and prefabricated spacers as P-spacers.

To achieve analysis of hip spacers in PJI, the only indication for an articular spacer was an infection of primary hip arthroplasty for the purposes of our study. Treatment of primary coxitis, status after a Girdlestone procedure, or other hip infections is out of the scope of this study. Patients with necrosis of the femoral head after coxitis and patients with tumorous hip replacement PJI due to the special surgical technique, extensive bone loss, and a higher complication rate were excluded. Furthermore, spacers made after revision of a failed spacer were excluded. The hip anterolateral approach was used in all cases (Watson-Jones). We defined PJI in accordance with Musculoskeletal Infection Society (MSIS) criteria.

For effective infection control, a bactericidal concentration of antibiotics in the joint cavity needs to be sustained for as long as possible. The Synicem (Synergie Ingenierie Medicale, Chamberet, France) prefabricated spacer made of polymethylmethacrylate

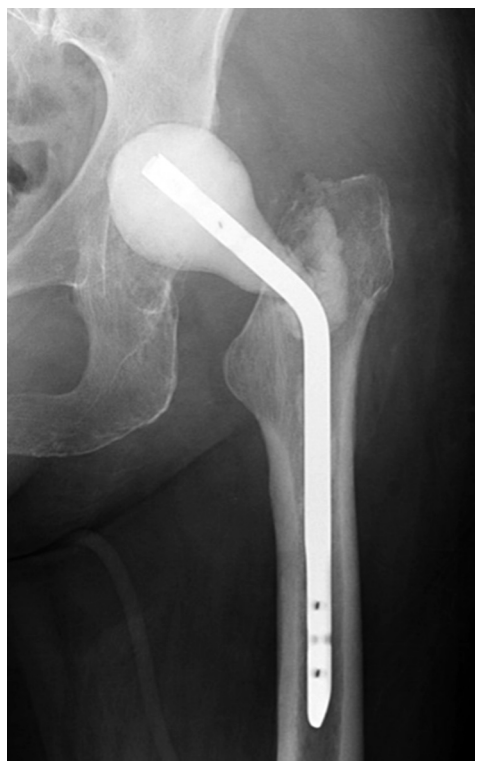

FIGURE 1. Custom-made antibiotic-loaded articular spacer modeled from bone cement and humeral nail in our department.

(PMMA) bone cement loaded with high concentrations of gentamicin was used in this study. To model a custom-made antibiotic-loaded spacer, 80 g of Refobacin R revision bone cement (Zimmer Biomet, Warsaw, Indiana, United States), which contains 0.5 g of active gentamicin per 40 g (the total content of gentamicin in the spacer is 1 g), was used.[10] Synicem prefabricated spacers contain a similar amount of an antibiotic (Figure 2). According to a pharmacokinetic study of gentamicin-loaded cement in total hip replacements and the manufacturer, the bactericidal concentration in the joint cavity is ensured for at least five days.[11]

Statistical analysis

The statistical analysis was carried out using R version 4.0.5. The Fischer exact test was done to compare categorical variables between the two groups. The nonparametric Mann-Whitney test was used to compare the clinical outcomes between the implants. A significance level of $p<0.05$ was used for all tests.

RESULTS

In total, 78 articular spacers were implanted in 78 patients. Of the total of 78 spacers, 52 were C-spacers, and 26 were P-spacers. The overall mean follow-up was 5.36±2.97 months, with 5.27±3.01 months for C-spacers and 5.56±2.89 months for P-spacers (Table I). Overall, there were 29 revised spacers; 18 of them were C-spacers, and 11 were P-spacers ($p=0.62$). The cause of revision (Table II) was mechanical in 20 cases and infection control in nine cases.

Mechanical complications

For the purposes of this work, we considered dislocation, breakage, and other spacer failures that required surgical intervention to be mechanical complications. Overall, a mechanical complication occurred 20 times, 10 times per type of spacer. A total of 16 dislocations were recorded, of which six were dislocations of C-spacers, and 10 were dislocations of P-spacers; the difference was statistically significant ($p=0.0082$). Moreover, we registered four spacer

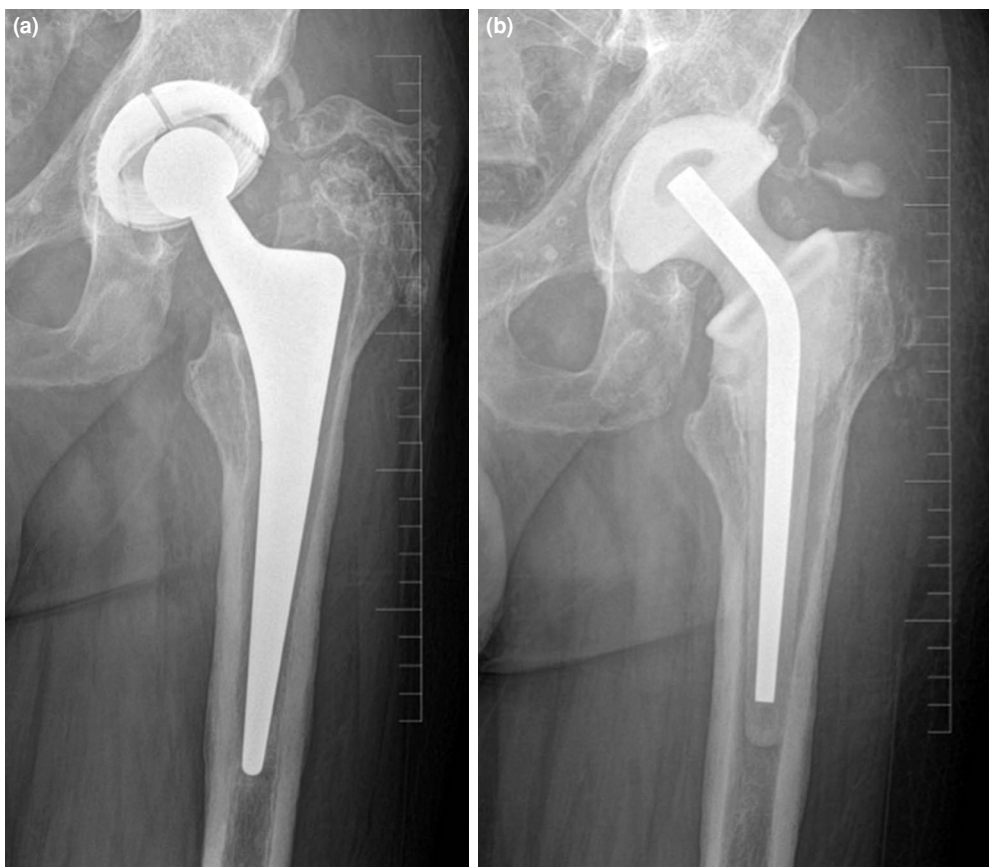

FIGURE 2. (a) A 52-year-old patient suffering PJI with loosening of the femoral stem; **(b)** prefabricated antibiotic-loaded hip spacer.
PJI: Periprosthetic hip joint infection.

TABLE I
Sample characteristics (n=78)

	Overall			C-Spacer (n=52)			P-Spacer (n=26)			
	n	%	Mean±SD	n	%	Mean±SD	n	%	Mean±SD	*p*
Age at inclusion (year)			68.5±9.48			69.2±8.73			68.2±10.9	0.953
Sex										
Female	44	56		28	64		16	36		
Male	34	44		24	70.5		10	29.5		
Follow-up (month)			5.36±2.97			5.27±3.01			5.56±2.89	0.6856
Diagnosis										
PJI after primary THA	78	100		52	100		26	100		
Approach										
Hip anterolateral	78	10		52	100		26	100		

SD: Standard deviation; THA: Total hip arthroplasty; PJI: Periprosthetic hip joint infection.

TABLE II
Causes of hip articular spacer revision

Cause of revision	Overall	C-Spacer	P-Spacer	
Revisions	29	18	11	0.62
Mechanical complication	20	10	10	0.098
Dislocation	16	6	10	0.0082
Spacer breakage	4	4	0	0.295
Infection control	9	8	1	0.2583

breakages, all of which occurred in C-spacers (p=0.295, Figure 3).

Furthermore, we evaluated the time interval to revise the spacers in the case of failure. C-spacers failed early, at an mean interval of 2.2 weeks after implantation. On the contrary, P-spacers failed later, on mean 9.3 weeks after implantation (Figure 4). The difference between results was statistically significant (p=0.0187).

Infection control

For this study, we consider an infectious complication to be a relapse or recurrence of an infection that was confirmed in the laboratory and required a revision procedure. A total of nine reinfection complications of spacers were registered; only one infection of P-spacers and eight infections related to C-spacers (p=0.2583). Definitive rTHA after spacer explantation and successful treatment of the infection occurred in 63 cases out of a total of 78 patients. Definitive rTHA occurred after the use of C-spacers in 41 (78%) patients and after the use of P-spacers in 22 (84%) patients. The difference between the results was not statistically significant (p=0.7816).

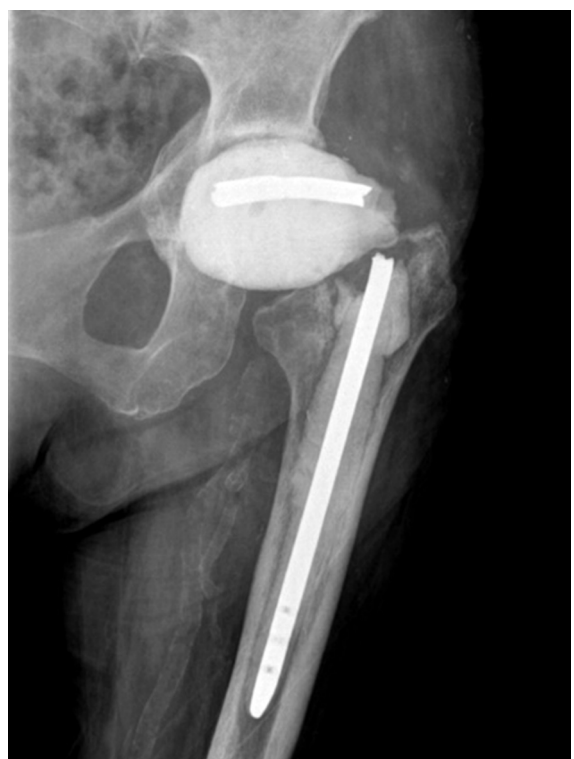

FIGURE 3. Mechanical failure - breakage of a C-spacer.

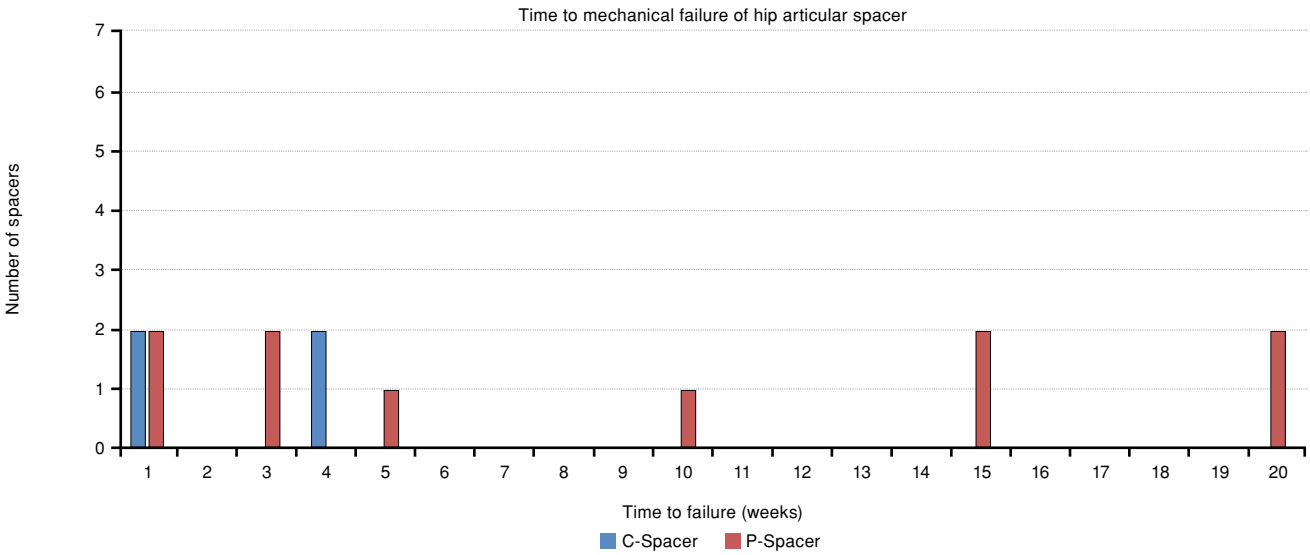

FIGURE 4. The time from procedure to mechanical failure of hip articular spacers.

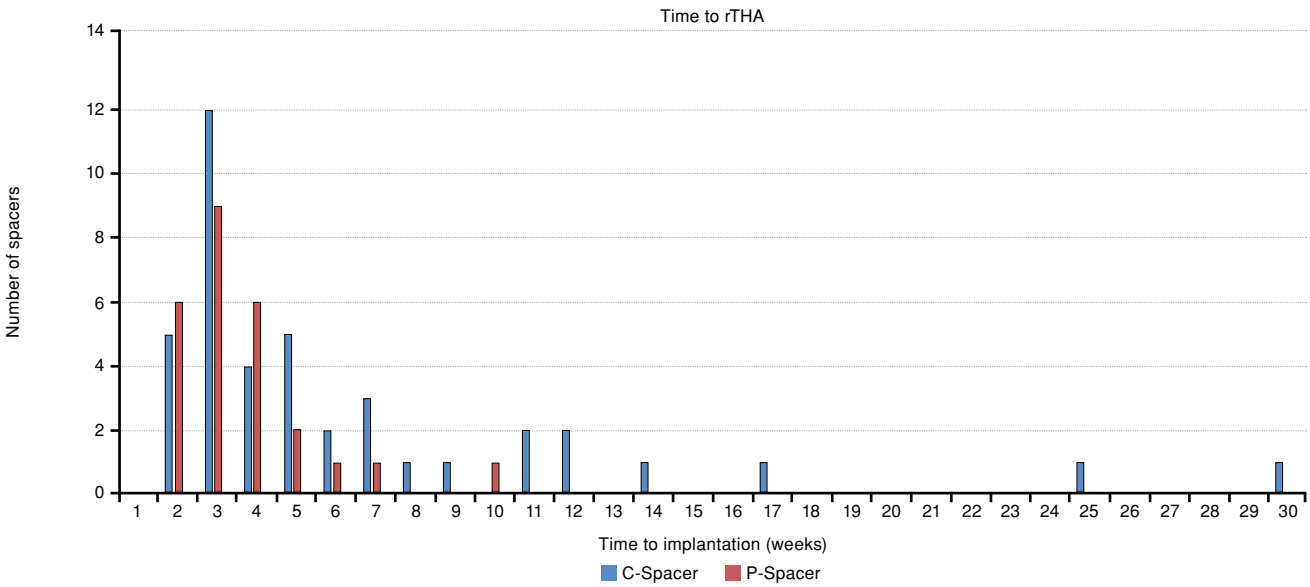

FIGURE 5. The time from spacer implantation to definitive rTHA.
rTHA: Revision total hip arthroplasty.

The mean interval from spacer implantation to definitive rTHA was 5.95±5.14 months; C-spacers had a mean interval of 6.56±6.03 months, and for P-spacers, it was 4±1.92 months (Figure 5). The difference between the results was statistically significant (p=0.0164).

DISCUSSION

Periprosthetic hip joint infection is a challenging disease that is difficult to cure and has devastating effects on the quality of bone and soft tissues.[12] Recent studies investigated two-stage revision using an antibiotic spacer as the gold standard in

the treatment of PJI, but no clear consensus was presented.[13] Despite prefabricated hip spacers gaining popularity among orthopedic surgeons, custom-made spacers are still the method of choice in some cases. This can be explained by the possibility to adjust self-made spacers to the situation in an individual patient, considering acetabular size, offset length, or bone loss. The prefabricated spacers are only available in a limited number of sizes, resulting in overstuffing or instability in some patients, which might lead to spacer dislocation.[14]

Our first hypothesis was that the two types of spacers would provide comparable results in terms of revision rate and definitive rTHA procedure. We found similar revision rates, with overall failure being 34% for custom-made spacers and 42% for P-spacers; our rates are slightly higher than those described in the literature. Hipfl et al.[15] described rates of spacer-related complications in two-stage procedure THA of around 24%.

Mechanical complications, particularly dislocation, occurred mainly with prefabricated spacers. A surprising fact was that C-spacers failed mostly in early postoperative care. The interval from procedure to mechanical failure was four times longer when the mechanical failure occurred in prefabricated spacers. From our results, it could be interpreted that the use of a C-spacer is a negative prognostic factor for early revisions. The prefabricated antibiotic-loaded spacer proved to be more robust, resisting breakage; only four breakage failures were registered. We suggest that a greater number of prefabricated spacer sizes and designs would allow greater intraoperative flexibility, making the biomechanic reconstruction stable. A recent study presented a high rate of mechanical failure of articulating PMMA spacers in two-stage revision hip arthroplasty (45%).[16] A retrospective review described a dislocation rate of 9% in antibiotic-loaded cement spacers, which was associated with a reduced femoral offset of >5 mm.[17] Another study recorded dislocation (16.4%) as the main complication of the preformed spacers.[18] In our study, the self-made spacers have a lower rate of mechanical failure (19%) comparing to P-spacers.

The international consensus meeting concerning PJI organized in 2013 stated that the type of spacer does not influence the rate of infection eradication in two-stage revision replacement of the hip.[19] A recent study described an 88.7% infection eradication rate using custom-made articular hip spacers.[20] Another study presented excellent results of prefabricated spacers with infection eradication in all of the cases.[21] In our study, we found infection control rates similar to those of studies in the literature, although prefabricated spacers were more effective in the treatment of infection. There was only a single revision in terms of infection recurrence, and there was a slightly higher success rate with these constructs (84%). This could be explained by the exothermic reaction of PMMA during formation, the limitation of thermostable antibiotics, and the release of antibiotics, which is difficult to set.[22] However, there is a lack of consensus on the type and concentration of antibiotic that should be incorporated into these spacers.[23] Moreover, there is controversy about the application of antibiotic-loaded PMMA, biofilm formation, antibiotic resistance, and toxicity.[24]

The interval from spacer implantation to rTHA was significantly shorter, and the approximate difference was about two months when a P-spacer was used. This could be explained by some cases of rTHA in patients with C-spacers being repeatedly postponed due to diseases or operating reasons. Furthermore, P-spacers had slightly higher rate of successful infection treatment and definitive rTHA. Definitive rTHA and successful treatment of the infection occurred in 63 cases out of a total of 78 patients. The rest of the patients were low-demand in activity patients with a complicated health condition, and due to the high risk of anaesthesia, these patients were unable to undergo rTHA.

Although the success rates of these constructs were similar, the cost of the two types of articular spacer is substantially different.[3] The utilisation rates of primary THA are rising, as well as the cost of this already expensive procedure. The rise in the number and cost of THA revisions has had a substantial economic impact on healthcare.[25] Commercially available prefabricated articular spacers are significantly more expensive regardless of the manufacturer. Our self-made spacers are modeled using antibiotic-loaded bone cement and a humeral nail. Moerenhout et al.[3] calculated that self-made hip spacers are at least 40 to 50% cheaper than prefabricated spacers.

There are some limitations to our study. The first is its retrospective design. Secondly, the sample size was limited to 78 spacers. Despite a similar surgical technique being used, procedures were led by seven different orthopedic surgeons. Finally, we used only one type of prefabricated spacer, the Synicem, and only one type of revision bone cement; nevertheless, this allowed homogeneous results. Considering the limitations, we suggest that relevant results were obtained.

In conclusion, custom-made spacers were shown to have lower mechanical complication rates than prefabricated ones but more infection complications. Prefabricated spacers had more dislocations and fewer breakages. Custom-made spacer mechanical failures occurred earlier compared to prefabricated ones. Despite its shortcomings, custom-made articular spacer provides surgeons with a cost-effective alternative for patients where no suitable prefabricated spacer is available.

Ethics Committee Approval: The study protocol was approved by the St. Anne's University Hospital Ethics Committee (date: 21.04.2023, no: EK-FNUSA-16/2023). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient Consent for Publication: A written informed consent was obtained from each patient.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: Investigation, writing, editing: J.E., V.A.; Investigation, methodology, data curation, writing, editing: J.E., VA.; Data curation: P.B., L.N., J.R; Methodology, review, editing: V.A.; Investigation, methodology, data curation: J.E., P.B., L.N.; Investigation, methodology, supervision: T.T.; Supervision, funding acquisition, resources, review: T.T. All authors approved the final version of this manuscript.

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