Arthroplasty Today 5 (2019) 221–225

Contents lists available at ScienceDirect

Arthroplasty Today

journal homepage: http://www.arthroplastytoday.org/

Original research

Early to midterm results of "low-friction" articulating antibiotic spacers for septic total knee arthroplasty

Steven Lyons, MD [a, *], Katheryne Downes, PhD, MPH [a, b], Jason Habeck, MD [a], Zachary Whitham, BS [c], Matthew Werger, MD [a], Scott Stanat, MD [a]

[a] Florida Orthopedic Institute, Temple Terrace, FL, USA
[b] Foundation for Orthopedic Research and Education, Tampa, FL, USA
[c] Morsani College of Medicine, University of South Florida, Tampa, FL, USA

ARTICLE INFO

Article history:
Received 17 November 2018
Received in revised form
18 March 2019
Accepted 19 March 2019
Available online 22 April 2019

Keywords:
Infection
Total knee
Antibiotic spacer
Articulating

ABSTRACT

Background: Infection of total knee arthroplasty is a complex problem often resulting in multiple surgeries for the patient. We examined the early to midterm results of a retained cemented "low-friction" metal-on-polyethylene articulating antibiotic spacer in total knee arthroplasty.
Methods: We retrospectively reviewed patients with a total knee cemented articulating antibiotic spacer performed for joint sepsis. Patients were allowed full weight bearing and normal activities after eradication of the infection at 6 weeks postop. Two months later, patients were given the option of conversion to a revision implant vs retention of the spacer. We examined infection cure rate, mechanical failure, Knee Society Scores, range of motion, and patient factors associated with spacer retention.
Results: Fifty-five knees were studied with average follow-up of 1.8 years (0.2-8.4). Among patients choosing spacer retention (40%), the average follow-up time of the spacer was 3.3 years (0.6-8.4). Five patients (9.1%) required a repeat spacer for recurrent infection.
Conclusions: Usage of articulating cement antibiotic spacers with a metal-on-polyethylene bearing couple provides excellent infection eradication, while also resulting in good functional outcomes. Early evidence suggests that use of the implant can be extended beyond typical timeframes and, in certain patient populations, may be suitable for a single-stage procedure.

Introduction

Infection is one of the most dreaded complications in total knee arthroplasty, and it is among the most common reasons for reoperation [1]. Its incidence in primary procedures is currently 0.4%-2%, with a societal cost approaching $1 billion [2-6]. As the expected number of total knee arthroplasty procedures continue to rise, periprosthetic joint infections (PJIs) will become more prevalent [5].

The principles of chronic PJI management involve removal of the infected component, thorough debridement of necrotic tissue and foreign debris, placement of a cement spacer or new components, and culture-directed antibiotics. Surgical decision-making often depends upon several factors including chronicity of infection, microorganism, health of the patient, fixation of the prosthesis, remaining bone stock, and surgeon preferences. When temporary spacers are placed, they are typically planned for a second-stage surgery with delayed removal and revision arthroplasty after eradication of the infection, typically around 6 weeks to 3 months after the first stage.

Since originally proposed by Insall et al [7] in 1983, 2-stage exchange arthroplasty has emerged as the gold standard for treatment in chronic PJI. With this technique, successful eradication of PJI with the addition of antibiotic cement and culture-directed antibiotic therapy averages 91% but has a range of 59%-100% [8].

During 2-stage exchange arthroplasty, there are several options: (1) resection arthroplasty, (2) static cement spacer, or (3) articulating "low-friction" metallic/polyethylene or articulating "high-friction" cement spacer [9]. The low-friction option has a new or

One or more of the authors of this paper have disclosed potential or pertinent conflicts of interest, which may include receipt of payment, either direct or indirect, institutional support, or association with an entity in the biomedical field which may be perceived to have potential conflict of interest with this work. For full disclosure statements refer to https://doi.org/10.1016/j.artd.2019.03.004.

* Corresponding author. Florida Orthopedic Institute, 13020 Telecom Pkwy N, Temple Terrace, FL 33637, USA. Tel.: +1 813 391 5116.
E-mail address: slyons14@gmail.com

https://doi.org/10.1016/j.artd.2019.03.004

resterilized femoral implant articulating with a new polyethylene insert on the tibia which creates the lower coefficient of friction. The high friction articulation is composed of either premade cement implants or molded cement implants created at the time of surgery, which creates a slightly rougher surface and therefore a slightly higher coefficient of friction. Regardless of friction type, recent reports have noted improved knee range of motion (100.1° vs 82.9°), lower reinfection rates (7.5% vs 13.6%), and lower complexity at reimplantation with the use of articulating as opposed to static spacers [10]. These spacers are planned for removal and a secondary reconstruction after eradication of the infection.

Several studies have demonstrated that not all patients undergoing 2-stage exchange proceed with the second stage with removal of the spacer and reimplantation of definitive components [11-16]. The decision for retention of the spacer is often based on patient comorbidities and/or satisfaction with the clinical result. The results from these retained total knee spacers have been sparsely published in small series of patients [14-16]. The purpose of this study is to report early to midterm outcomes of retained "low-friction" articulating antibiotic spacers used in planned 2-stage knee revision for PJI.

Material and methods

From 2002 to 2011, 49 consecutive patients with 55 knees were treated with planned 2-stage exchange arthroplasty with a first-stage spacer placement using a standard metallic femoral component and polyethylene tibial insert fixed with antibiotic-loaded cement. The femoral implant was a standard Natural Knee II or Gender Flex Femoral component and its corresponding tibial poly insert without the tibial baseplate. (Zimmer Inc., Warsaw, IN). Eradication of the infection was documented by normalized erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) inflammatory markers, physical examination, and, if warranted, aspiration of the knee after all antibiotics had been stopped for a minimum of 6 weeks. Six weeks was selected as a cutoff in order to be absolutely sure that the effects of the antibiotics had dissipated and that any possible regrowth of the bacteria would be clinically observable in the appearance of the aspirate. If deemed infection free, patients with a functioning spacer were given the option to proceed with the second-stage procedure or retain their spacer.

After Institutional Review Board approval, follow-up results of these 49 patients (55 knees) were retrospectively reviewed. All the cases were performed by the first author (S.L.) with no change in protocol throughout the time frame.

Preoperative evaluation prior to the initial surgery included a thorough history and physical, plain radiographs, infection laboratory work-up (complete blood count with differential, ESR, and CRP), and medical consultation. A preoperative joint aspiration was attempted when prior evidence of infection was not culture proven. The aspirate was sent for cell count with differential and culture with gram stain (aerobic, anaerobic, acid-fast bacilli, and fungus).

The intraoperative infection protocol was to give intravenous (IV) antibiotics only after tissue cultures and pathology were obtained. Aerobic and anaerobic synovial fluid cultures as well as tissue cultures were sent for STAT gram stain and culture plating. Tissue samples were sent for frozen section examination. They were determined to be positive for acute inflammation with more than 5 polymorphonuclear cells per high power field [17].

For patients who went on to a second-stage revision, the last clinical visit before the revision was utilized for outcomes. For patients who opted to retain their spacer, the most recent clinical visit as of December 31, 2011 was utilized for outcomes. Outcomes measured were Knee Society Scores (KSSs) [18] and range of motion (ROM). The longevity of the implant, infection recurrence, mechanical failure, and percentage of articulating spacer implants as the definitive procedure were all recorded. We also compared characteristics of patients who opted to retain their spacer vs those who proceeded with second stage.

Surgical technique: knees

A medial parapatellar approach was used with meticulous soft tissue management. The intra-articular sequence of events is as follows: (1) complete synovectomy and polyethylene removal, (2) implant removal, (3) irrigation and debridement, and (4) implant trialing with gross ligament balancing utilizing a gap balancing technique with various polyethylene thicknesses. The prior femoral component was thoroughly cleaned of any soft tissue and cement and then resterilized in the autoclave intraoperatively, which has been shown to be safe and cost effective [19]. If the femoral component was of an appropriate geometry to mate with a new tibial ultracongruent poly component, it was used for reimplantation in the articulated antibiotic spacer. When the prior femoral component was not of an appropriate geometry or was damaged from prior wear, a new nonporous femoral component from the same manufacturer of the polyethylene (Zimmer Biomet Inc.) was used. This was mated with an ultracongruent (cruciate sacrificing) polyethylene tibial insert without the tibial base plate in 100% of cases. The posterior cruciate ligament was removed in 100% of cases. The bottom of the polyethylene was scored with a high-speed burr or roughened with a saw blade, again to facilitate interdigitation with the cement. The tibial component was then cemented first, with as close as possible to a perpendicular alignment with respect to the mechanical axis and allowed to cure to maintain appropriate rotation and alignment for patellar tracking and overall ligament balancing. The femur was then cemented separately after fine tuning the gaps by allowing the femur to seek a position of stability when it contacts the tibia in extension, occasionally having cement mantle thickness of 3-5 mm depending on bone loss. The patella was resurfaced if the prior bone quality was allowed and was done in all cases. This entailed removal of the prior button and cement and then using the prior lug holes if possible or making new ones for acceptance of a new all poly button (Zimmer Inc.). The rationale for doing this was to protect the surface of the bone from erosion and soft tissue adherence, which, in a future definitive surgery, enables a new poly button to be placed onto a bed of bone that was as robust as possible. The spacer also allows for smoother tracking of the patellofemoral articulation without potentially catching or creating pain during ROM. The wound was closed in the standard manner without a drain (Figs. 1 and 2).

Surgical technique: antibiotic cement protocol

The antibiotic cement mixture protocol was to mix 1 bag (40 g) of Simplex (Howmedica, Rutherford, NJ) cement powder with the powdered antibiotics. For each 40 g bag of cement, one of the following powdered antibiotic options was added: (1) 4 g of vancomycin (Gram-positive organisms), (2) 4.8 g of tobramycin (Gram-negative organisms), or (3) 2.0 g of vancomycin and 2.4 g of tobramycin (mixed flora). In most cases, 1 batch of cement was utilized for the tibia and 1.5 batches for the femur. The decision of which combination to use was based on whether there was prior identification of the organisms preoperatively and whether they were Gram positive or Gram negative. In cases where identification was not possible or mixed flora was noted, a combination of vancomycin and tobramycin was noted. The cement was then mixed by

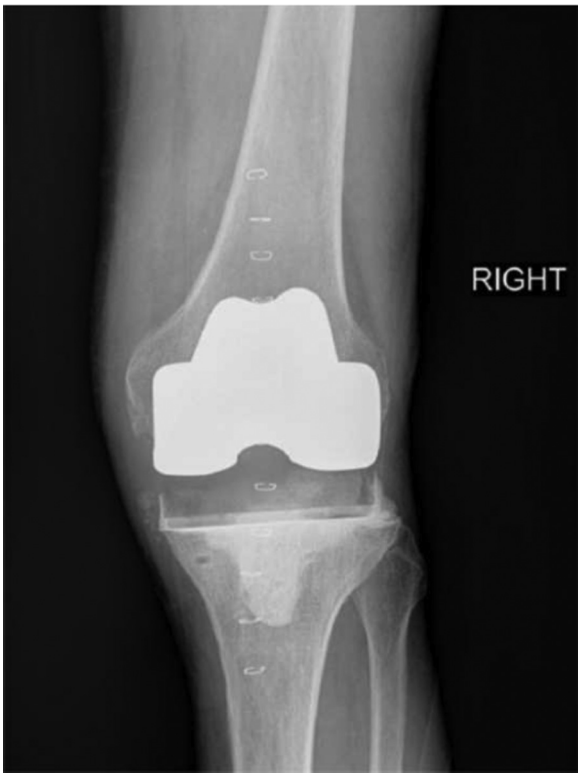

Figure 1. Anteroposterior radiographs of an infected total knee arthroplasty treated with an articulating antibiotic spacer. Note the slight varus positioning of the tibial polyethylene component, accounting for ligamentous tensioning for a clinically balanced knee.

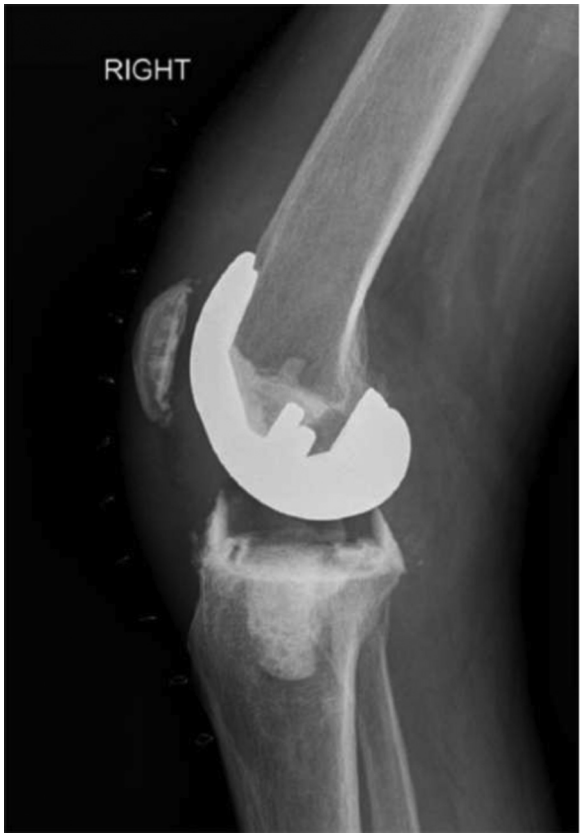

Figure 2. Lateral radiographs of an infected total knee arthroplasty treated with an articulating antibiotic spacer.

hand with the monomer without any vacuum assistance. Care was taken to insure a homogenous mixture. Methylene blue dye was then added for identification of cement vs bone and removal of the cement upon possible revision procedure.

Postoperative protocol

Postoperatively, the patient was allowed touch down/foot flat weight bearing to the extremity and ambulation with a walker for 6 weeks to allow the soft tissues and the joint to rest. After 6 weeks, full weight bearing was allowed. Free active and passive ROM was instituted, unless limited by the soft tissue status immediately postoperatively from either soft tissue tension or muscle flap coverage as dictated by a plastic surgeon. The antibiotic regimen was managed by an infectious disease specialist. This usually included IV antibiotics for a minimum of 6 weeks followed by an oral antibiotic regiment for a variable amount of time at their discretion. The patients' clinical follow-up schedule was 2 weeks, 6 weeks, 3 months, 6 months, 12 months, and yearly thereafter. Plain radiographs were taken at every visit to evaluate for any signs of progressive radiographic loosening, cement fracture, or implant subsidence. If there were signs of continuing infection, a repeat antibiotic articulating antibiotic spacer was planned, provided there was appropriate bone support and soft tissue viability. After 6 weeks of IV antibiotics, an additional 6 weeks of oral antibiotics were occasionally given if warranted by infectious disease for an aggressive organism. An antibiotic-free interval of 6 weeks was instituted to evaluate adequacy of treatment. A preliminary check for eradication of infection consisted of an ESR and CRP. If the inflammatory laboratories were elevated then an aspiration was done, and this occurred in 8 patients. Otherwise, if the inflammatory laboratories were normalized and the patient was doing well clinically with no pain or swelling, we determined that there was an absence of infection. With lack of implant failure and patient acceptance, the patient was given the option of retaining the spacer implant or converting to the "second stage" of the revision. If choosing to retain the implant they were followed every 6-12 months. If deciding to convert to the "second-stage" revision, they had the spacer removed and a revision prosthesis implanted at their convenience. The average time from initial placement of spacer to revision was 6 months. Standard preoperative medical workups were done and a preoperative joint aspiration was performed if we had any concern regarding possible recurrence. Intraoperative frozen sections were routinely done to ensure that there was no acute inflammation. Typically, 4 separate specimens are sent from different locations within the knee joint. If pathology was positive for acute inflammation, the patient underwent a repeat antibiotic articulated spacer.

Statistical analyses

Descriptive statistics are reported as frequencies and percentages for categorical variables and as means and standard deviations or medians and interquartile ranges, depending on the normality of the distribution. Bivariate comparisons were performed with Fisher's exact test for categorical variables and *t*-tests or Wilcoxon rank-sum tests for continuous variables, where appropriate. A *P*-value less than .05 was considered statistically significant. All analyses were performed with STATA 15.1 (StataCorp LLC, College Station, TX).

Results

Overall, there were 55 knee procedures in 49 patients. The average age was 63 years (standard deviation 10), 41.8% were male, and average body mass index (BMI) was 33.0 (standard deviation, 7.6). In total, 26% were diabetic and 18.2% were smokers (Table 1). The average preoperative KSS was 62 (standard deviation 17). Postoperatively, the average KSS was 82 (37-103) and the flexion achieved averaged 87° (10°-140°). The ROM data were recorded from the last visit in the office if the spacer was currently in or the last visit prior to getting the spacer revised.

The mortality rate at the time of last follow-up was 11.8% (n = 6) (average follow-up of 1.8 years, range 0.2-8.4) (Table 1). Three of the deaths occurred in the retained spacer group and 3 occurred in the revision group. Regarding the timing of the 6 deaths, patients died at 13, 32, 39, 44, 52, and 69 months out from their spacer surgery. All patients died of causes unrelated to their prior spacer surgery.

The most common organisms identified from the index procedure culturing were methicillin-resistant *Staphylococcus aureus* (14.5%) and methicillin-susceptible *S aureus* (12.7%) (Table 2).

A total of 33 knees had removal of the spacer within 12 months: 26 of 33 (78.8%) were removed and underwent the second stage once deemed free of infection, 5 knees had repeat spacer placement due to persistence of infection or acute inflammation at the time of planned "second-stage" reimplantation, 1 knee had resection arthroplasty, and 1 knee had an above-knee amputation. Isolating the failures associated with recurrent infection, it was seen that a failure of the soft tissue envelope or issues with the muscle flap coverage or integrity was contributory. Of the 3 knees with rotational flaps in the study, 2 were noted in the failure group. Both had developed areas of breakdown at the margins of the flap and skin graft compromising the soft tissue integrity. This could imply that a larger flap was needed for better coverage. Another patient got reinfected from a separate infection site that communicated to the knee joint from supracondylar hardware that had still been in place. The other 2 patients had tenuous closures due to thin soft tissues and may have needed rotational flaps for coverage. In these 5 patients, clinically they were stable to stressing in the anterior/posterior and varus/valgus planes and all radiographs were without loosening. Therefore, there were no instances of mechanical failure. A total of 22 of 55 (40%) declined the conversion and retained their spacer for over 12 months.

Table 1
Patient characteristics and overall outcomes.

Patient characteristics	n (%)
Age, mean (SD)	63 (10)
BMI, mean (SD)	33.0 (7.6)
Sex: male	23 (41.8)
Diabetes	14 (25.9)
Smoking	10 (18.2)
Spacer longevity	2 (2)
Retained spacer	22 (40)
Revision procedure	
ABX spacer	5 (9.1)
AKA	1 (1.8)
Resection arthroplasty	1 (1.8)
TKA	25 (45.4)
TKA→infection recurred	1 (1.8)
None: retained spacer	22 (40)
Preoperative KSS, mean (SD)	62 (17)
Postoperative KSS, mean (SD)	82 (15)
Postoperative ROM, mean (SD)	87 (30)
Mortality	6 (11.8)

ABX, antibiotics; AKA, above-knee amputation; SD, standard deviation; TKA, total knee arthroplasty.

Table 2
Species detected.[a]

Bacterial species	n (%)
Staphylococcus (not otherwise specified)	3 (5.4)
Methicillin-susceptible *Staphylococcus aureus*	7 (12.7)
Methicillin-resistant *Staphylococcus aureus*	8 (14.5)
Methicillin-susceptible *Staphylococcus epidermidis*	2 (3.6)
Candida albicans	1 (1.8)
Escherichia coli	1 (1.8)
Enterococcus faecalis	3 (5.4)
Group B strep	1 (1.8)
Pseudomonas aeruginosa	3 (5.4)
Coagulase-negative staphylococci	2 (3.6)
Propionibacterium acnes	3 (5.4)
Serratia marcescens	1 (1.8)
Gram-positive culture (not otherwise specified)	3 (5.4)
Culture negative	10 (18.2)

[a] An additional n = 10 patients had culture results not available due to destruction of medical records.

When we compared patients with retained spacers to those who were revised (Table 3), we found that the retained group tended to be slightly older (67 vs 61, $P = .04$), with lower BMIs (average of 30.1 vs 35.0, $P = .02$) and substantially lower incidence of obesity (BMI ≥30) (36.4% vs 67.7%, $P = .03$). When we compared KSSs and ROM, we found that the retained spacer group had significantly better ROM (100 vs 85, $P = .053$) and tended to have higher scores (both preoperatively and postoperatively) as well; however, the latter differences did not reach statistical significance (Table 3).

Discussion

Currently in the United States, the mainstay of treatment for established prosthetic joint infection is the 2-stage revision [7] with planned reimplantation after eradication of the infection. There is an abundance of clinical data to demonstrate the success of this method with either static or articulated spacers [20]. The benefits of a mobile spacer include improved maintenance of soft tissue tension and pliability with decreased bone loss at revision [7], increased performance scores and ROM after revision [14-16], as well as decreased surgical time and blood loss at revision [15]. In addition, these achieve equivalent or better eradication of infection in knees when compared to multiple prior studies [14-16,21].

With the advent of antibiotic-impregnated cemented spacers, there are options. One is cement-on-cement/high friction either premade or formed at the time of surgery. Another is low-friction utilizing portions of the total knee implants, namely the femoral component, cementing it onto the femur after it has been resterilized and using a new polyethylene insert on the tibia. The other option is to utilize a brand new femoral implant articulating onto

Table 3
Retained vs revised characteristics/outcomes.

Patient characteristics	Retained (n = 22)	Revised (n = 33)	*P* value
Age, mean (SD)	67 (12)	61 (8)	.04
BMI, mean (SD)	30.1 (6.0)	35.0 (8.0)	.02
Obese (BMI ≥30)	8 (36.4)	21 (67.7)	.03
Sex: male	10 (45.4)	13 (39.4)	.78
Diabetes	5 (22.7)	9 (28.1)	.76
Smoking	4 (18.2)	6 (18.7)	.99
Preoperative KSS, median (IQR)	65 (42-83)	63 (51-73)	.92
Postoperative KSS, median (IQR)	93 (74-96)	82 (73-92)	.19
Postoperative ROM, median (IQR)	100 (85-123)	85 (65-95)	.053
Spacer duration (y), median (IQR)	2.7 (1.4-4.7)	0.6 (0.4-1.0)	NA

IQR, interquartile range; SD, standard deviation.

the new polyethylene insert. Studies with long-term follow-up [14-16] demonstrate not only equivalent or superior functional outcomes and clearance of infection with low-friction spacers, but also increased ease of reimplantation at the second stage when compared to spacers constructed with cement-on-cement or high-friction bearing surfaces. Thus, as an extension of this, the possibility of prolonged use of this type of spacer with potential of full activity and weight bearing may allow adequate function without a second-stage revision.

The current study's protocol uses a high dose of antibiotics equal to or greater than 4 g per batch of cement. This agrees with prior recommendations [22] for a similar dosing for therapeutic treatment infections. The theoretical reduction in cement strength did not cause any failures that required revision of the components, yet we exercise caution as this represents short to midterm follow-up only.

Currently, single-stage revision to treat an infected total knee is not commonplace in the United States. The results of this study support the possibility in which the metal-on-polyethylene bearing antibiotic cement spacer's implanted longevity can be extended beyond the short-term use during the first stage of a 2-stage procedure. At the time of the last follow-up, the average implant longevity of the antibiotic spacer was 3.3 years in patients who retained their spacer. Many patients (40%) chose to retain their spacer indefinitely. Theoretically, this approach may be especially desirable for advanced age patients with multiple medical comorbidities. In this instance, a single surgery would be ideal, rather than exposing the patient to all the risks of surgical complications twice. Although we believe that this protocol would be particularly advantageous to older, less healthy patients, when we examined our own data, we found that, although they were slightly older, those who retained the spacer were generally also healthier (significantly lower BMI, lower incidence of obesity, slightly lower incidence of diabetes) and also tended to have higher postoperative KSS and significantly better flexion. The postoperative KSS difference did not reach statistical significance, but we believe that was likely attributable to the smaller sample size. Larger future studies are necessary to gain further insight into the outcomes associated with retained spacers, as well as patient factors that may be predictive of outcomes.

This study demonstrated similar infection cure rates and complications rates as compared to prior published data for mobile cement antibiotic spacers [9,10,14-16]. There were no late complications due to prolonged activity or weight bearing on the prosthesis. In addition, if there were late stage loosening, subsidence, or instability of the joint, it could be managed by the already anticipated second-stage revision procedure.

The weakness identified in this study is the retrospective nature of the review, as well as the smaller sample size. In addition, the decision of whether to proceed with the second-stage revision vs to opt out for the single-stage arm was not random as it was up to the patient's discretion. Designing a prospective randomized protocol with specific exclusion criteria and standardizing all other parameters in the future would allow us to examine the functional, economic, and social outcomes in a more in-depth analysis.

Conclusions

This study was able to demonstrate the early to midterm results of low-friction articulating spacers in the treatment of PJIs. By lengthening the time of service of a prior published and successful technique [23], the "low-friction" antibiotic metal-on-polyethylene spacer can be retained by the patient without prolonged activity restriction, possibly forgoing the second stage if they are doing well clinically, and still achieve good results.

Acknowledgments

Statistical and writing support for this project was funded in part by the Foundation for Orthopaedic Research and Education (foreonline.org).

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