Do Dynamic Cement-on-Cement Knee Spacers Provide Better Function and Activity During Two-stage Exchange?

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Abstract

Background Implantation of an antibiotic bone cement spacer is used to treat infection of a TKA. Dynamic spacers fashioned with cement-on-cement articulating surfaces potentially facilitate patient mobility and reduce bone loss

as compared with their static counterparts, while consisting of a biomaterial not traditionally used for load-bearing articulations. However, their direct impact on patient mobility and wear damage while implanted remains poorly understood.

Questions/purposes We characterized patient activity, surface damage, and porous structure of dynamic cement-on-cement spacers.

Methods We collected 22 dynamic and 14 static knee antibiotic cement spacers at revision surgeries at times ranging from 0.5 to 13 months from implantation. For these patients, we obtained demographic data and UCLA activity levels. We characterized surface damage using the Hood damage scoring method and used micro-CT analysis to observe the internal structure, cracking, and porosity of the cement.

Results The average UCLA score was higher for patients with dynamic spacers than for patients with static spacers, with no differences in BMI or age. Burnishing was the only prevalent damage mode on all the bearing surfaces. Micro-CT analysis revealed the internal structure of the spacers was porous and highly inhomogeneous, including heterogeneous dispersion of radiopaque material and cavity defects. The average porosity was 8% (range, 1%–29%) and more than 1/2 of the spacers had pores greater than 1 mm in diameter.

Conclusions Our observations suggest dynamic, cement-on-cement spacers allow for increased patient activity without catastrophic failure. Despite the antibiotic loading and internal structural inhomogeneity, burnishing was the only prevalent damage mode that could be consistently classified with no evidence of fracture or delamination. The porous structure of the spacers varied highly across the surfaces without influencing the material failure.

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Introduction

Infection continues to be a rare but devastating complication of TKA, occurring in 1% to 2% of cases [3, 7, 8, 12, 13]. Despite the low incidence, infection is associated with patient morbidity, increased healthcare costs, and reinfection, while also being challenging to control [8, 12, 14]. Previous infection treatments of antibiotic irrigation with tissue débridement and retention of components resulted in inconsistent infection control rates ranging from 16% to 80% [16]. Other attempts involved a one-stage revision procedure, where new sterile components were implanted and secured with antibiotic-loaded bone cement [3, 16]. This treatment option resulted in higher rates of infection control, although it was still coupled with a large variability in successful infection control ranging from 73% to 100% [16]. A two-stage revision also was introduced in which a monoblock spacer, comprised completely of antibiotic-loaded bone cement, maintained the joint space while eluting antibiotics into the surrounding area for 6 to 12 weeks before reimplantation. Although implantation of a static spacer increased infection control rates to ranges of 91% to 100% [6, 20], it also has been associated with bone loss, soft tissue contracture, increased scar tissue, and lower knee ROM after surgery [3, 5, 9, 18, 20].

In attempts to solve the problems associated with static spacers, dynamic cement-on-cement spacers are fashioned with articulating surfaces that replicate the geometry of a total joint arthroplasty to facilitate patient mobility during recovery [4, 5, 9]. Dynamic cement-on-cement spacers, which either can be manufactured premolded or molded by surgeons at the time of surgery, potentially increase patient activity, reduce muscle atrophy, and reportedly increase knee ROM before and after reimplantation [7, 15]. The infection control rates of dynamic spacers in the treatment of infections have been shown to be within the same ranges as static spacers [4, 20]. However, bone cement is not typically used for articulation and has a porous internal structure that can act as a stress riser in the material and reduce strength [2, 19]. During the past few years, cement spacer use has been increasing, with 11,836 spacers implanted in 2006 and 15,817 in 2009 (claims data from the Healthcare Cost & Utilization Project Nationwide Inpatient Sample [1]). The motion between two cement surfaces is likely to lead to wear and generation of cement particles. Abrasion wear from cement spacers has been observed experimentally through fatigue testing in vitro and within only 6 weeks of implantation in vivo [6, 21]. Although cement spacers are perceived as short-term implants with 6-week implantation cycles, in some patients the cement spacer may be retained for much longer periods [17, 20, 22]. However, it is unclear whether dynamic spacers allow greater patient function than static spacers

during the period of implantation and whether and to what degree there is wear of the spacer articulating surfaces over such longer periods.

We therefore asked (1) whether the dynamic spacers increased patient activity and function while implanted, compared with their static counterparts, (2) what internal and surface damage modes (if any) were prevalent after implantation in dynamic spacers, and (3) whether there were correlations between porosity and structural damage in dynamic spacers.

Materials and Methods

We collected 36 knee antibiotic bone cement spacers (22 dynamic, cement-on-cement, and 14 static) at revision surgeries in an institutional review board-approved multicenter retrieval program between 2007 and 2011. Retrieved dynamic and static spacers were implanted for, on average, 3.8 months (range, 0.5–13 months) and 2.9 months (range, 0.6–5.1 months), respectively (Table 1). All spacers were revised as part of two-stage revisions for infected knee arthroplasties. The average age of the patients at implantation was 69 years (range, 56–84 years) and 68 years (range, 44–82 years) for dynamic and static retrievals, respectively (Table 1). Twelve of 36 patients were male, 21 were female, and three were unknown. The average weight was 91 kg (range, 46–112 kg) for the patients with dynamic spacers and 85 kg (range, 55–123 kg) for patients with static spacers. After explantation, the implants were cleaned in 10% bleach solution, exposed to ultrasonication to remove loosely adhered tissue, and then stored at room temperature with components separate for further analysis. Before spacer explantation, Knee Society scores (KSS) and ROM data were collected for 18 of 22 patients with dynamic cement-on-cement spacers and eight of 13 patients with static spacers. UCLA activity scores also were collected for 20 of 22 patients with dynamic spacers and 10 of 13 patients with static spacers. Patient data on sex, height, weight, and implantation time were collected from the medical records.

In 20 of 22 cases, dynamic cement-on-cement spacers were created by surgeons in the operating room using

Table 1. Clinical data for patients with dynamic and static spacers

Spacer type	Age (years)	BMI	Implantation time (months)
Dynamic	69 ± 7	32 ± 6	3.8 ± 0.2
Static	68 ± 12	33 ± 6	2.9 ± 1.0

Values are expressed as mean ± SD.

StageOne™ Knee Cement Spacer Molds (Biomet, Inc, Warsaw, IN, USA) with either Palacos® (Zimmer, Inc, Warsaw, IN, USA) or Cobalt™ (Biomet, Inc) bone cement and a variety of antibiotic loadings from 2.5 to 12.2 wt/wt% (Table 2). In two of 22 cases, spacers were manufactured premolded (InterSpace®; Tecres SpA, Verona, Italy) and cemented in place with Cemex™ (Tecres SpA). The 14 retrieved static spacers were molded to shape by surgeons with a range of antibiotic loadings from 3.7 to 11.2 wt/wt% and used for comparison with dynamic spacers.

We evaluated the articulating surfaces of the tibial and femoral components for each spacer on a scale of 0 to 3 under up to $\times 40$ magnification for seven distinct modes of surface damage (pitting, embedded debris, scratching, delamination, surface deformation, burnishing, and abrasion) using the method of Hood et al. [10]. We evaluated eight regions on the articulating surfaces of each component for surface damage. Nineteen of the dynamic spacers then were scanned using micro-CT (Scanco USA, Inc, Wayne, PA, USA) with a resolution of 0.074 mm and evaluated using the commercial software Analyze (Mayo Biomedical Imaging Resource, Rochester, MN, USA) to observe the internal structure of the cement, cracking, and cavity defects. Porosity was assessed from three 5-mm³ sections selected directly below the bearing surface. Three spacers were excluded from micro-CT analysis because of fracturing during retrieval. The majority of the static spacers were not imaged with micro-CT owing to the size

restrictions of the equipment. We assessed the normality of the distributions of the UCLA activity scores, KSS, ROM, BMI, age, weight, porosity, and implantation time using the Shapiro-Wilk test of normality. We evaluated differences in weight, BMI, age, implantation time (normally distributed data) using the independent-sample t-test and the differences in UCLA activity score, KSS, ROM, and porosity (nonnormally distributed data) using the Mann-Whitney U test between patients with dynamic and static spacers. Correlations with porosity or UCLA scores and damage scores were assessed using a Spearman's rho correlation test. All statistical tests were performed using SPSS® statistics package (Version 19.0.0; IBM Corp, Chicago, IL, USA).

Results

The UCLA activity score was greater ($p = 0.013$) for patients with dynamic spacers (mean, 5; range, 2–8) than for patients with static spacers (mean, 3; range, 1–10) (Fig. 1). Similarly, the KSSs were greater ($p = 0.005$) for patients with dynamic spacers (mean, 26; range, 0–85) than for patients with static spacers (mean, 2; range, 0–19), as was ROM ($p = 0.001$) (dynamic: mean, 62°; range, 0°–100°; static: mean, 9°; range, 0°–70°). Additionally, there was no difference ($p \geq 0.16$) in weight, BMI, or age between the spacer groups (Table 1). Implantation time was similar ($p = 0.26$) in the two spacer groups.

Damage scoring of the articulating surfaces revealed burnishing on the bearing surface of the retrieved tibial and femoral components (Fig. 2). Burnishing was associated with wear polishing of the surface and was the dominant mode of damage. Scratching or abrasion of the surfaces also was observed, and embedded debris to a lesser extent on some of the implant surfaces. In the few cases of embedded debris, the debris appeared to be mostly tissue

Table 2. Antibiotics used and loadings in dynamic cement-on-cement spacers

Dynamic spacer	Antibiotic	Amount added (g/bag of cement)	Loading (w/w)
Premolded 1	Gentamicin	NA	2.5%
DS 1	Gentamicin	NA	NA
DS 2	Tobramycin/vancomycin	3.6/3.0	11.2%
DS 3	Tobramycin/vancomycin	3.6/1.5	8.7
DS 4	Tobramycin/vancomycin	3.6/3.6	12.2%
DS 5	Tobramycin/vancomycin	3.6/3.0	11.2%
DS 6	Tobramycin/vancomycin	3.0/1.5	7.7%
DS 7	Tobramycin/vancomycin	3.6/3.0	11.2%
DS 8	Tobramycin/vancomycin	3.6/3.0	11.2%
DS 9	Tobramycin/vancomycin	1.5/3	7.7%
DS 10	Tobramycin/vancomycin	2/2	6.8%
DS 11	Tobramycin/vancomycin	3.6/1.5	8.7%
DS 12	Tobramycin/daptomycin	3.6/1	7.8%
DS 13	Tobramycin/vancomycin	3.6/3.0	11.2%
DS 14	Tobramycin/vancomycin	3.6/3	11.2%
DS 15	Tobramycin/vancomycin	3.6/3	11.2%

Complete antibiotic information was available for 15 of 22 dynamic spacers; DS = dynamic spacer; NA = not available.

Fig. 1 The UCLA activity scores were higher ($p = 0.013$) for patients with dynamic spacers than for those with static spacers. Box (top) = 75th percentile; box (bottom) = 25th percentile; whiskers = the minimum and maximum of the data set; horizontal line through box = median; open circle = outlier.

Fig. 2 A bar graph shows the average damage scores for the seven modes of damage on bearing surfaces. Burnishing and pitting were the prevalent modes of damage. Error bars = SD.

Fig. 3 Pitting was visible on spacer surfaces.

fragments or extra bone cement in the articulating surface. There was no evidence of delamination or surface deformation in any of the cases. Pitting was the second most prevalent mode of damage; however, it was difficult to distinguish between actual pitting and regions that exposed porous internal structure of the bone cement (Fig. 3). Pitting or porous areas of the surface were observed predominantly in the regions of the spacer with high levels of burnishing. We observed a correlation between UCLA score and burnishing ($p = 0.544$, $p = 0.024$) but none between UCLA score and scratching, pitting, or embedded debris ($p = 0.476$, $p = 0.052$).

We found no fracture or subsurface cracking in the internal porous structure of the retrieved spacers. Micro-CT analysis revealed the internal structure of the spacers was porous and highly inhomogeneous. Regions of radiopaque material, and a zone of irregularly mixed cement and open-cavity defects, were detected within 3 mm of the articulating surface (Fig. 4). In addition, porosity analysis using the micro-CT datasets revealed at least 10 of the 19 scanned spacers had pores greater than 1 mm in diameter ranging from 1% to 15% of the total pore volume. These

Fig. 4 Zones of irregular mixing and radiopaque deposits along the articulating surface of the dynamic spacer are shown.

were present in operating room-molded and premolded spacers. The average porosity was 8% (range, 1%–29%) with a mean pore diameter of 0.305 mm (range, 0.074–0.7027 mm). There were no correlations between porosity and the different damage scores or implantation time ($p = -0.21$, $p = 0.76$).

Discussion

Evolving from débridement and antibiotic washes for improved treatment for knee arthroplasty infections, dynamic cement-on-cement spacers have the potential to surpass their static counterparts by offering patients enhanced mobility while resolving the infection with time. Although dynamic spacers possess the potential for higher patient mobility, the in vivo performance and potential for damage in spacers are not fully understood. We therefore evaluated the in vivo performance and damage modes of dynamic antibiotic bone cement-on-cement spacers by asking (1) whether patients with dynamic spacers had higher activity levels while implanted when compared with patients with static spacers, (2) what internal and surface damage modes (if any) were prevalent after implantation, and (3) whether there were correlations between porosity and structural damage in the spacers.

There are several limitations to this study. First, the resolution of our micro-CT scans was 74 μm , so pore sizes lower than this were not incorporated in porosity calculations and pore distribution analysis. However, larger pores and cavities are more often sites of stress concentration and failure and were more applicable for investigating potential modes for failure [2, 19]. Second, the surface damage modes analyzed in this study were developed for articulating polyethylene tibial surfaces and do not quantify volumetric wear for these implants. Although wear would

help assess damage accrued by these spacers, the primary focus was to characterize damage on the bearing surface and internally that has not been previously reported. In addition, the number of spacers retrieved from our three partner institutions limited the sample size of this study. Finally, the study was restricted to cement-on-cement spacers, which are the primary dynamic spacer type used at the collection centers involved in this study. The wear and damage properties discussed here are specific to cement-on-cement bearing surfaces and do not reflect potential wear in other articulating spacer surfaces such as metal-on-polyethylene or metal-on-ceramic. Nevertheless, the focus of this study was to evaluate the functional performance of nontraditional bearing surfaces (cement-on-cement) since the wear and damage modes of these surfaces are unknown.

We observed increased activity levels for patients with dynamic spacers compared with those with static cement spacers based on UCLA activity scores; increased ROM values and KSSs for the patients with dynamic spacers supported these findings. Previous studies have shown increased ROM in joint arthroplasties after the explantation of dynamic spacers as compared with static spacers [4, 5, 9, 11, 20]; however, we aimed to show the effective mobility gained during dynamic spacer implantation and joint ROM achieved. Patients with dynamic spacers achieved an average UCLA score of 5 (maximum, 10) and were able to maintain moderate levels of activity in their daily lives. Increased mobility during the treatment of an infected TKA is a perceived benefit of a dynamic spacer but has not been quantified in the literature. Most often, the research in the literature is focused on the postoperative advantage of increased ROM in dynamic spacers compared with static spacers, which is perceived to be gained from reduced bone loss and muscle atrophy [3, 20, 21]. In addition to facilitating better recovery postoperatively, our evidence suggests higher mobility of these patients during implantation.

We identified only a minor amount of damage on the spacers even though they were constructed of a nonoptimized biomaterial for articulation. Other than the apparent burnishing on the surface of most spacers, the dynamic spacers were retrieved relatively unscathed. Activity scores and KSSs confirmed the patients were actively using their joint; thus, the low degree of damage was not attributable to nonuse of the joint. The high prevalence of burnishing over other damage modes could be explained through the innately rougher surface of the spacer [21]. The initial wear is the smoothing of the surface as the contact area between the tibial and femoral components becomes larger, as was seen in a previous *in vitro* fatigue study with premolded cement-on-cement spacers [21]. Although we observed the damage modes on these spacers, we could not quantify the actual volume of wear

incurred from burnishing and scratching of the surface. In addition, we found no correlation between UCLA score and scratching, pitting, or embedded debris; however, there was a correlation between UCLA score and burnishing. In addition, some spacers appeared to be molded with less-thorough mixing than others (bone cement creases, rougher surfaces) but still performed well for the patients, with activity scores ranging from 2 to 6. These findings imply dynamic cement-on-cement spacers are resistant to major and critical surface damage during short-term implantation (average, 3.8 months). The effects of long-term implantation or higher-activity patient populations on dynamic spacers, however, are still unknown.

Micro-CT images and porosity measurements revealed internal structural inhomogeneity, with cavities and zones of poorly mixed cement within 2 mm of the articulating surface. The irregular mixing (Fig. 4) most likely can be attributed to poorly distributed barium sulfate and antibiotics in the bone cement, which could indicate poor mixing of the monomer and powder components of the bone cement and could impact antibiotic elution kinetics. Despite the aforementioned irregularities in the internal structure, there was no evidence of fracture or delamination on the surface. The porous structure of the spacers varied highly across the surfaces from 1% to 29% porosity without influencing the failure of the material. There was no correlation between porosity and any damage mode scored or implantation time. Large pores also were observed in the premolded spacers, which are molded with highly regulated temperature, humidity, and powder mass parameters [17, 21]. Additionally, premolded spacers often have a lower loading of antibiotics (2.5 wt/wt%) than their surgeon-molded counterparts (6.8–11.2 wt/wt%) [17, 21]. However, the porosity variability and size range for premolded spacers were not noticeably different from those of the surgeon-molded spacers and still exhibited comparable levels of surface damage. This retrieval collection needs to be expanded to include more premolded spacers, although, in this study, premolded spacers performed similarly to their surgeon-molded counterparts and porosity did not influence the failure of the materials. Although lower levels of porosity may offer improved strength and wear characteristics of the spacer, this may adversely affect the elution of antibiotics from the spacer. Therefore, further study also will be needed to identify the influence of porosity on antibiotic elution kinetics to create an optimum spacer for mechanical properties and antibiotic release.

Patients who had dynamic cement-on-cement spacers implanted for treatment of an infected TKA experienced higher levels of activity and ROM than patients who had static spacers implanted. Additionally, the predominant mode of damage was burnishing with no evidence of abrasion or delamination and appeared as a polishing of the

surface. Subsurface cavities, zones of irregular mixing, and variable porosity were observed after short-term implantation without catastrophic failure of the material or subsurface cracking. No differences were detected between surgeon-molded and premolded dynamic spacers; however, more retrievals must be collected to confirm these findings. In addition, the study should be expanded to include other spacer-bearing surfaces.

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