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Original Research

# Long-Term Outcomes of Permanent Cement Spacers in the Infected Foot

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ABSTRACT

When osteomyelitis occurs in the infected foot, cement spacers have been used as a limb salvage tool. The aim of the present study was to assess the longevity and outcomes in high-risk, low-demand patients who have undergone resection of bone and subsequent placement of permanent antibiotic-eluting cement spacers in the foot. A retrospective review case series of 30 patients who had undergone placement of a permanent antibiotic-eluting cement spacer in the foot were evaluated for retention, spacer exchange, removal, amputation, and functional status. The minimum follow-up time for inclusion was 12 months. Two thirds of all patients had successful spacers (n = 20) that were either retained (n = 14) or successfully exchanged (n = 6). One third of all patients experienced spacer failure (n = 10) and required removal. Of the 10 patients requiring spacer removal, 4 underwent removal with subsequent arthrodesis and 6 underwent removal with subsequent pseudoarthrosis. Also, 8 of these patients (26.7%) required partial foot amputation of the ipsilateral foot. These amputations were not directly related to the use or removal of the spacer. The average time to spacer removal or partial amputation was 20.9 (range 0.2 to 60.9) months. The longest retained spacer in the foot was 76 months at the last follow-up visit. The longest exchanged spacer at the last follow-up visit was 111 months. All surviving patients were ambulatory at the last follow-up visit.



Surgical soft tissue and osseous reconstruction of the foot is a complex endeavor. The most common cause of foot infections are trauma and diabetes mellitus (DM). Patients with DM, over time, develop complications that are progressive, synergistic, and pervasive. The most common lower extremity complications include peripheral polyneuropathy and peripheral vascular disease, which are risk factors for ulceration, infection, and amputation (1,2). In the foot, the lack of robust soft tissue coverage over the osseous structures makes ulcerations an important predisposing factor for osteomyelitis (3). The loss of skeletal integrity in the foot ultimately results in biomechanical compromise, which has an effect on lower extremity function. Structural impairment and biomechanical instability lead to an unbalanced distribution of weight, resulting in increased pressures on an already "at risk" foot (4,5). Thus, these patients are prone to repeat ulceration, infections, readmissions, exposure to long-term intravenous antibiotics, anesthesia, and, unfortunately, repeated surgeries and amputations (6).

Wounds in the foot require a definitive assessment for osteomyelitis, because this is critical to aid in surgical planning and predicting postoperative residual function (7–9). Invariably, once infected and/or pressure-causing bone has been resected, the overall biomechanical and functional losses challenge subsequent limb salvage efforts and outcomes. The use of polymethylmethacrylate (PMMA) cement spacers can provide a viable reconstructive option. The use of PMMA antibiotic-eluting cement (PMMA-AEC) spacers can also mitigate the bacterial burden to local tissue, which could enhance long-term outcomes. Wound coverage after soft tissue and bone loss requires careful planning for complete and sustained closure. Currently, a paucity of evidence is available regarding the long-term outcomes for the use of permanent PMMA spacers after resection of infected bone in the foot.

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## Patients and Methods

A total of 41 patients were identified who had had cement spacers placed into an infected foot from January 2007 to December 2011 at a single institution. The electronic medical records and radiographs were used to confirm the location of an antibiotic-impregnated cement spacer. Patients with <12 months of follow-up data available

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were excluded (n = 7). An additional 2 patients were excluded because the spacer had been placed in the ankle, and 2 patients were excluded because the spacer was removed on the date of study closure. A total of 30 consecutive patients were included for the evaluation.

We performed a single-institution retrospective, institutional review board-approved clinical therapeutic study of a case series. The study was designed to investigate the longevity and overall long-term outcomes of patients who had had AEC spacers placed into a previously infected foot with the intention that the spacer remain as a permanent implant. The level of evidence was 4. All patients received culture sensitivity-driven antibiotics and medical management, including glucose and nutritional optimization. Surgical excisional debridement included removal of all nonviable and infected bone and soft tissue and irrigation with normal saline. Resected bone was sent for both culture and histopathologic examination to confirm the diagnosis of osteomyelitis.

Prepackaged PMMA cement was mixed as directed by the manufacturer. Antibiotic powder was then added during mixing. Once the cement had reached a "clay-like" consistency, the cement was roughly formed to be slightly smaller than the surgical dead space. The spacer was then placed into the surgical wound and trimmed using sterile scissors. Care was taken to ensure a proper fit before full curing of the PMMA cement. Vancomycin, gentamicin, or tobramycin was added singularly or in combination.

Age, body mass index, DM, renal disease, peripheral vascular disease (PVD), previous ipsilateral amputations, Charcot disease, number of debridement procedures before permanent cement spacer placement, spacer removal, spacer exchange, spacer retention, number of amputations, ambulatory status, follow-up duration, and the interval to spacer failure were documented. We defined spacer failure as removal of the spacer or subsequent amputation in which the spacer was included. We defined success as those who had undergone a spacer exchange without complications or had spacers retained without removal or amputation.

Statistical analysis using the chi-square test was performed to calculate the $p$ values; $p < .05$ was the cutoff for statistical significance. Logistic regression analysis was used to measure the relationship between the independent variables and the outcomes, with $p < .05$ considered statistically significant. The present study did not require any funding source.

## Results

A total of 30 feet were identified as having had an infection with debridement and osseous resection and the placement of a PMMA-AEC on the date of study closure. The mean patient age at the index procedure was 56.4 (range 38 to 87) years. The mean body mass index was 30.7 (range 19.3 to 45.4) kg/m$^2$. Of the 30 patients, 27 had DM (90%), 13 had PVD (43.3%), 9 had Charcot neuroarthropathy (30%), 5 had a history of ipsilateral digital amputation (16.7%), and 4 had renal disease (13.3%; Table 1).

The most common anatomic location of PMMA-AEC spacer placement was in the first metatarsophalangeal joint (23 feet; 76.7%); 4 were placed in the hallux, 1 in the medial cuneiform, 1 in the talonavicular joint, and 1 in the fourth or fifth tarsometatarsal joints (Table 1). The average number of surgical debridement before PMMA-AEC was 2.23 (range 1 to 7). Six patients required PMMA-AEC spacer exchange, and 14 spacers were left intact at the last follow-up visit for a total of 20 successful spacers (66.7%). Of the remaining 10 patients (33.3%), 4 required removal and subsequent arthrodesis and 6 required removal and closure with ultimate pseudoarthrosis. Of these 10 patients, 7 underwent eventual ipsilateral partial foot amputation, which occurred approximately 20.9 months postoperatively, and 1 underwent partial first ray amputation at 0.2 month postoperatively, for a total of 8 amputations (26.7%). The average time to spacer failure (removal or amputation) was 20.9 (range 0.2 to 60.9) months (Table 2). The minimum follow-up period was 12 months, with an average follow-up duration was 52 (range 12 to 111) months. The longest follow-up period for retained spacers was 76 months. The longest follow-up period for successful spacer exchange was 111 months.

No major amputations had been required of the ipsilateral side of the initial surgery during long-term follow-up. However, 3 patients underwent contralateral below-the-knee amputations within the follow-up period. On the date of the last patient follow-up visit, all the patients in the present study, who had received a permanent PMMA-AEC spacer, including those with spacers that had been removed remained ambulatory with inserts, bracing, or assistant devices such as canes or walkers. Four patients, who had stable spacers at death had died before July 2016.

**Table 1**
Demographic data* (n = 30)

| Variable | n (%) |
|---|---|
| Age (yr) | |
| Mean | 56.4 |
| Range | 38 to 87 |
| Sex | |
| Male | 22 (73.30) |
| Female | 8 (26.7) |
| Follow-up (mo) | |
| Mean | 52 |
| Range | 12 to 111 |
| BMI (kg/m$^2$) | |
| Mean | 30.7 |
| Range | 19 to 45.4 |
| Comorbidity | |
| Diabetes mellitus | 27 (90) |
| Renal | 4 (13.3) |
| Peripheral vascular disease | 13 (43.3) |
| Ipsilateral history of amputation | 5 (16.7) |
| Charcot foot | 9 (32.3) |
| Location | |
| Hallux | 4 (13.3) |
| First metatarsophalangeal joint | 23 (76.7) |
| Medial cuneiform | 1 (3.3) |
| Talonavicular joint | 1 (3.3) |
| Fourth or fifth tarsometatarsal joint | 1 (3.3) |

Abbreviation: BMI, body mass index.
* Patients were included more than once if multiple comorbidities were present.

No association was found between body mass index, DM, renal disease, PVD, a history of previous ipsilateral amputation, Charcot disease, or spacer location and spacer removal or amputation. No statistically significant difference was identified for any of these variables in relation to PMMA-AEC spacer failure (Table 3).

## Discussion

The present study explored the longevity and complications related to the implantation of a permanent PMMA-AEC spacer in a high-risk group of low-demand, predominately diabetic (90%) patients with frequent concomitant pathologic features. After control of infection and partial or complete bone excision, PMMA-AEC spacers provided the benefits of mitigating the local tissue bacterial burden, filling postoperative soft tissue voids, and preventing amputation.

In our cohort, the overwhelming number of patients had DM (90%). We defined spacer failures as those who required removal or

**Table 2**
Spacer failure,* exchange, and time to failure (n = 30)

| Variable | n (%) |
|---|---|
| Partial first ray amputation | 5 (17) |
| Transmetatarsal amputation | 2 (7) |
| Lisfranc amputation | 1 (3) |
| Removal with arthrodesis | 4 (13) |
| Removal with pseudoarthrosis | 6 (20) |
| Ipsilateral major (transtibial or proximal) amputation | 0 |
| Contralateral major (transtibial or proximal) amputation† | 3 (10) |
| Spacer exchange† | 6 (20) |
| Retained spacer† | 14 (47) |
| Time to failure (mo) | |
| Mean | 20.9 |
| Range | 0.2 to 60.9 |

* Some patients underwent spacer removal and also required amputations and, thus, were counted multiple times.
† Not defined as spacer failure.