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# Surgical Site Infection After Polymethyl Methacrylate Pedicle Screw Augmentation in Osteoporotic Spinal Vertebrae: A Series of 537 Cases

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## ABSTRACT

**Background:** Retrospective observational study of prospectively collected outcomes.

**Objective:** The use of transpedicular screws augmented with polymethyl methacrylate (PMMA) is an alternative for patients with osteoporotic vertebrae. To investigate whether using PMMA-augmented screws in patients undergoing elective instrumented spinal fusion (ISF) is correlated with an increased risk of infection and the long-term survival of these spinal implants after surgical site infection (SSI).

**Methods:** We studied 537 consecutive patients who underwent ISF at some point within a 9-year period, involving a total of 2930 PMMA-augmented screws. Patients were classified into groups: (1) those whose infection was cured with irrigation, surgical debridement, and antibiotic treatment; (2) those whose infection was cured by hardware removal or replacement; and (3) those in whom treatment failed.

**Results:** Twenty eight of the 537 patients (5.2%) developed SSI after ISF. An SSI developed after primary surgery in 19 patients (4.6%) and after revision surgery in 9 (7.25%). Eleven patients (39.3%) were infected with gram-positive bacteria, 7 (25%) with gram-negative bacteria, and 10 (35.7%) with multiple pathogens. By 2 years after surgery, infection had been cured in 23 patients (82.15%). Although there were no statistically significant differences in infection incidence between preoperative diagnoses ($P = 0.178$), the need to remove hardware for infection control was almost 80% lower in patients with degenerative disease. All screws were safely explanted while vertebral integrity was maintained. PMMA was not removed, and no recementing was done for new screws.

**Conclusions:** The success rate for treatment of deep infection after cemented spinal arthrodesis is high. Infection rate findings and the most commonly found pathogens do not differ between cemented and noncemented fusion. It does not appear that the use of PMMA in cementing vertebrae plays a pivotal role in the development of SSIs.

**Level of Evidence:** 4.

Complications

Keywords: osteoporotic vertebra, risk factors, augmentation technique, polymethyl methacrylate, instrumented spinal fusion, surgical site infection, *Staphylococcus aureus*, cement, elderly population, fenestrated augmented pedicle screws, spine surgery complication

## INTRODUCTION

Instrumented spinal fusion (ISF) is an increasingly common procedure in patients of advanced age.[1] Population aging is a worldwide trend, and the life expectancy of women is projected to reach 90 years by 2030.[2] One unavoidable drawback, however, is the occurrence of complications related to the procedure itself and the hardware used in this age group.

The introduction of transpedicular screws augmented with polymethyl methacrylate (PMMA) has resulted in good clinical outcomes, and this technique appears to be the safest and most efficient method of strengthening pedicular screws, thus achieving stable fixation of osteoporotic bone in older patients.[3–5] However, instrumentation and cement augmentation increase the risk of neurological complications and surgical site infection (SSI) because of the prolonged duration of surgery, increased blood loss, and use of foreign materials in the spinal bone.[6,7]

Concerns have been raised about whether PMMA-augmented screws or longer duration of surgery due

to cementation increase the risk of SSI and how to manage this type of infection in older patients.[8] Most patients who are aged 75 years or older have multiple comorbidities and a substantially weakened immune system, which may facilitate the presence and spread of low-virulence bacteria around the cemented vertebrae. This type of infection may migrate from the posterior column to the vertebral body and PMMA, thus complicating infection management.[9,10]

Percutaneous vertebroplasty and kyphoplasty (VP/KP) are minimally invasive procedures for PMMA augmentation of spinal cement in the treatment of vertebral tumors and osteoporotic vertebral fractures that do not respond to conservative treatments. Though VP/KP is mostly performed in older patients and is only rarely the occurrence of subsequent infection,[11,12] scarce data are available on the possible influence of PMMA-augmented ISF on the appearance and treatment of SSI, particularly concerning medium- and long-term outcomes for patients with infection of the cemented ISF and the risk factors for an unfavorable outcome.

The aims of this study were (1) to determine whether the use of PMMA-augmented screws in a cohort of elderly patients undergoing elective ISF of the thoracolumbar spine is associated with an increased risk of developing SSI; (2) to identify whether cementation could complicate infection management; (3) to identify preoperative risk factors of severe infection; and (4) to identify the long-term survival of PMMA-augmented transpedicular screws after SSI.

## MATERIALS AND METHODS

### Study Design

We performed a retrospective analysis of SSIs in a prospective cohort of 537 consecutive patients who underwent cemented ISF in our institution for degenerative spine disease, spinal deformity, trauma, or cancer at some point during the study period, between 2008 and 2017. We included in our study those patients with SSIs who met the criteria of the Centers for Disease Control and Prevention with confirmed data on deep wound and organ/space infection[13] and who had positive culture findings and had been monitored for a minimum of 2 years. The criteria state that (1) a superficial SSI involves only the skin and subcutaneous tissue of the incision; (2) deep SSIs involve the deep soft tissues (fascial and muscle layers) of the incision; and (3) SSIs of the organ/space involve any part of the anatomy other than the incision that is opened or manipulated during the procedure.

We conducted the study in adherence to norms in force with regard to research ethics and personal data protection, and our protocol was approved by our institution's review board.

We collected data on patients' demographics, comorbidities, diagnosis, date of surgery, type of surgery, measurable perioperative risk factors, perioperative laboratory findings, date of infection diagnosis (based on the date of symptom onset as reflected in clinical records), infection parameters in blood and cultures, empirical antibiotic treatment, targeted antibiotic treatment after assessment of culture and antibiogram findings, and treatment duration.

Early-onset infection was defined as infection that occurred within the 3 months after the primary procedure and placement of an implant for fusion, whereas late-onset infection was defined as occurring more than 3 months after the primary procedure.

Patients were classified into 1 of 3 groups according to treatment response:

1. Patients whose infection was cured with standard treatment, consisting of irrigation and surgical debridement (single or multiple times) and antibiotic treatment, meaning that the patients were asymptomatic after wound closure and that their infection parameters were within the normal range, as evidenced by laboratory test findings at the end of the follow-up period.
2. Patients whose infection was cured after standard treatment failed, with treatment failure indicated by a need for removal or replacement of the hardware in order to control the infection.
3. Patients with treatment failure caused by persistent clinical signs and symptoms of infection, prolonged elevation of acute-phase reactants, persistent wound discharge, or chronic fistulae; patients requiring long-term or permanent suppressive treatment with antibiotics for infection control; and patients who died of infection-related causes.

### Surgical Protocol and Postoperative Period

For all patients included in our study, primary surgery was performed in accordance with a previously published protocol.[10,14] As part of the authors' routine practice, dual x-ray absorptiometry (DEXA) scans were requested for female patients aged >65 years, male patients aged >70 years, and those aged between 60 and 75 years with osteoporosis risk factors. We routinely used fenestrated screws in all patients aged >70 years and in those patients aged

between 60 and 70 years with positive DEXA scan for osteoporosis or in the presence of risk factors for osteoporosis despite negative DEXA scans due to the possibility of a false negative. The decision to augment was always based on the combination of patient's age (>75 years), preoperative DEXA scans for patients aged between 60 and 75 years, confirmed by the intraoperative tactile feel resistance of the vertebral body to the pedicle probe, or suboptimal grip feel upon insertion of the fenestrated transpedicular screw.

The prophylactic antibiotic regimen consisted of cefazolin (2 g) and gentamicin (240 mg); vancomycin (1 g) was given to patients allergic to cefazolin. For interventions lasting for more than 3 hours, intraoperative redosing with cefazolin was done.

In the event of a suspected wound infection (fistula with persistent wound discharge, fever, and worsening of lumbar pain, or elevated levels of acute-phase reactants), patients were transferred to an operating room for irrigation and surgical debridement. For patients who did not have sepsis, empirical antibiotic treatment was delayed until a culture had been taken of the wound in sterile conditions.

Empirical parenteral antibiotics were administered intravenously until an antibiogram was obtained.[15] For patients with continued problematic wound healing, serial surgical debridement and irrigation with abundant saline solution were performed, followed by repeated collection of deep tissue samples. Once the wound was closed and C-reactive protein (CRP) levels had returned to normal, antibiotic therapy was then changed to oral administration until the 3-month treatment period concluded. Removal and/or primary or staged revision of the implants was performed in case of persistent infection, even after several surgical irrigations with debridement and after completion of antibiotic treatment.

### Statistical Analysis

Qualitative variables were frequency and percentage values, and quantitative data were mean and SD or median and interquartile range, depending on the degree of asymmetrical distribution. Associations between qualitative variables were analyzed using contingency tables and the $\chi^2$ test or Fisher exact test. For all statistical analyses, a $P$ value of 0.05 was considered statistically significant. Data analysis was performed using SPSS Statistics (version 22.0; IBM, Armonk, NY, USA).

## RESULTS

The study group included 537 patients who together received a total of 2930 cemented screws in a total of 1465 instrumented vertebrae. The population comprised 413 women and 124 men; the average age was 79 years (range, 46–91 years). Of the 1465 vertebrae fused using instrumentation, 1284 (87.6%) involved the lumbar spine and 181 (12.4%) involved the thoracic spine. The surgical diagnosis was degenerative spinal disease (spinal stenosis or spondylolisthesis) in 376 patients (70%), adult spinal deformity (coronal, sagittal imbalance or angular deformity that compromises the inclusion of at least 5 segments in the construct) in 157 patients (29.2%), and spinal tumor in 4 patients (0.74%). We found no statistically significant differences in the incidence of infection between the 3 diagnostic categories ($P$ = 0.178); this finding may be related to the low number of patients with spinal tumors in our sample. Had this group been closer in size to the other 2 groups, the difference might have been statistically significant. Of the procedures, 413 (76.9%) were primary surgeries and 124 (23.1%) were revision surgeries. The mean number of segments fused per patient was 2.87 (range, 1–10 segments). All patients received fresh frozen allograft chips for posterolateral fusion. Mean follow-up duration was 4.52 years (range, 2–8 years).

Twenty eight (5.2%) of the 537 patients who underwent cemented spinal fusion developed an SSI; 8 (8/28; 28.6%) were men and 20 were women (20/28; 71.4%), and their average age was 75.1 years (range, 60–85 years). Thirteen patients were between 60 and 75 years old, and 15 were older than 75 years. Tables 1 and 2 present demographic data. With regard to the surgical diagnosis, 10 of the 28 patients who developed an SSI underwent surgery for the treatment of adult spinal deformity (10/157; 6.37%), 17 for degenerative spinal disease (17/376; 4.5%), and 1 (1/4; 25%) for a tumor with spinal involvement (Table 3). According to the type of surgery, 19 developed an SSI after primary surgery (19/413; 4.6%), and 9 did so after revision surgery (9/124; 7.25%). The mean number of segments fused in patients who developed an SSI was 2.96 (range, 2–5 segments). Table 4 presents data for qualitative variables; Table 5 presents data for quantitative variables.

A univariate analysis was conducted to measure the potential impact of the clinical characteristics and their association with SSI development. With regard to body

**Table 1.** Qualitative data for patients who developed an infection ($n$ = 28).

| Variable | *n* (%) |
|---|---|
| Gender | |
| Men | 8 (28.6) |
| Women | 20 (71.4) |
| Revision surgery | |
| Yes | 9 (32.1) |
| No | 19 (67.9) |
| Area | |
| Thoracic spine | 2 (7.1) |
| Lumbar spine | 20 (71.4) |
| Thoracolumbar spine | 6 (21.4) |
| No. of segments fused | |
| 2 | 10 (35.7) |
| 3 | 11 (39.3) |
| 4 | 5 (17.9) |
| 5 | 2 (7.1) |
| Antibiotic prophylaxis | |
| Cefazolin | 17 (60.7) |
| Vancomycin | 1 (3.6) |
| Cefazolin + aminoglycoside | 7 (25.0) |
| Cefazolin + gentamicin + rifampicin | 2 (7.1) |
| Unspecified | 1 (3.6) |
| Obesity (by body mass index [kg/m$^2$]) | |
| <30 | 12 (46.2) |
| 30–35 | 12 (46.2) |
| >35 | 2 (7.7) |
| Smoking | |
| Yes | 1 (3.6) |
| No | 27 (96.4) |
| Malnutrition | |
| No | 28 (100) |
| American Society of Anesthesiologists class | |
| I | 10 (35.7) |
| III–IV | 18 (64.3) |
| History of infection | |
| Yes | 1 (3.6) |
| No | 27 (96.4) |
| Time at which infection occurred | |
| Early | 28 (100) |
| Infection level | |
| Deep | 28 (100) |
| Bacteria | |
| Gram-positive | 11 (39.3) |
| Gram-negative | 7 (25.0) |
| Mixed | 10 (35.7) |
| Sonication | |
| Performed | 2 (7.4) |
| Not performed | 25 (92.6) |
| Pathogen concordance | |
| Yes | 13 (46.4) |
| No | 15 (53.6) |
| Surgical procedure performed | |
| Debridement with instrument retention/ replacement | 27 (96.4) |
| Complete removal | 1 (3.6) |
| No. of irrigations | |
| 1 | 3 (46.4) |
| 2 | 2 (42.9) |
| 3 | 1 (3.6) |
| 4 | 1 (3.6) |
| 6 | 1 (3.6) |
| Status at 2 year follow-up evaluation | |
| Infection cured with debridement | 23 (82.1) |
| Infection cured with hardware replacement | 4 (14.8) |
| Treatment failure | 1 (3.6) |
| Plastic surgery | |
| Yes | 4 (14.3) |
| No | 24 (85.7) |
| Vacuum-assisted closure therapy | |
| Yes | 6 (21.4) |
| No | 22 (78.6) |

mass index, 39.29% of the 537 patients operated had a body mass index >30 kg/m$^2$, compared with 50% of the patients with an SSI ($P$ = 0.352). Of the 28 patients in whom an SSI occurred, only 1 was an active smoker. No patients were diagnosed with malnutrition, as determined by a serum albumin of <3.0 g/dL. Patients with a physical status of American Society of Anesthesiologists class III or IV comprised 43.39% of our study population, compared with 64.29% of patients who developed an SSI ($P$ = 0.048). The average Charlson Comorbidity Index[16] among patients who developed an infection was 4.46 (range, 2–7). Fifteen of the 28 patients with an SSI presented with multiple risk factors: 11 with diabetes mellitus, 24 with arterial hypertension, 2 who had undergone previous immunosuppressive treatment, and 8 who had a history of malignancy.

All diagnosed infections were early onset (occurring within the first 90 days after surgery). The mean number of days between surgery and the appearance of symptoms was 17.35 (SD, 13.9). Different preoperative and intraoperative samples were obtained from each patient for culturing. Eleven patients (11/28; 39.3%) had positive findings for gram-positive pathogens, the most frequent being *Staphylococcus aureus* in 7 patients (7/28; 25%) and *Enterococcus faecalis* in 4 patients (4/28; 14.3%). Seven patients (7/28; 25%) had positive findings for gram-negative bacteria, the most common of which was *Escherichia coli*, found in 5 patients (5/28; 17.8%). Ten patients (10/28; 35.7%) had a polymicrobial infection. Only 13 patients (13/28; 46.42%) had concordant results between the preoperative and intraoperative cultures obtained, and *Enterococcus* spp. (100%) and *Proteus mirabilis* (75%) were the microorganisms most commonly found in both cultures. In laboratory test results, the average level of CRP (<0.5 mg/dL) at the time of infection diagnosis was 19 mg/dL (SD, 13.3; range, 0.8–48 mg/dL).

The average length of intravenous empirical antibiotic treatment was 5.0 days (SD, 2.5; range, 2–15 days). Culture and antibiogram results were used to establish a specific antibiotic approach in accordance with the antimicrobial susceptibility pattern of the causative pathogen. The average length of specific antibiotic treatment was 70.0 days (SD, 35.5 days; range, 27–270 days).

The success rate, defined as a fully healed site of primary surgery (stable, definitive wound closure, and normal inflammatory markers evidenced by laboratory test results and a preserved primary implant) at the 2-year follow-up evaluation, was 82.15% (23/28). Twelve patients (12/28; 42.8%) required more than 1 irrigation and surgical debridement. Five patients (5/28; 17.85%)

**Table 2.** Quantitative data for patients who developed an infection ($n$ = 28).

| Variable | Mean ± SD or Median (Interquartile Range) | Minimum, Maximum |
|---|---|---|
| Age, y | 75.1 ± 6.58 | 60.0, 85.0 |
| Length of procedure, min | 236 (82.0) | 143, 760 |
| Blood loss, g/dL | 3.12 ± 1.11 | 1.40, 5.60 |
| Charlson Comorbidity Index | 4.46 ± 1.20 | 2.00, 7.00 |
| Body mass index, kg/m$^2$ | 29.9 ± 3.95 | 23.4, 37.7 |
| Serum albumin levels, g/dL | 4.21 ± 0.38 | 3.20, 4.80 |
| Time elapsed between the initial operation and infection occurrence, d | 14.0 (8.00) | 7.00, 74.0 |
| C-reactive protein level at admission, mg/dL | 19.0 ± 13.3 | 0.80, 48.0 |
| Duration of empirical antibiotic therapy, d | 5.00 (2.50) | 2.00, 15.0 |
| Duration of targeted antibiotic therapy, d | 70.0 (35.5) | 27.0, 270 |
| Total duration of antibiotic therapy, d | 75.0 (38.5) | 34.0, 284 |

with proven infection required removal or replacement in 1 or 2 stages of the hardware used in fusion to control the infection (organ/space or spondylitis). Of those 5 patients, 1 patient (5.9%) had been treated for a degenerative spinal condition, and 4 patients (40%) had undergone complex reconstructive surgery to treat deformity. This difference between the surgical diagnosis and the outcome at 2 years after surgery was statistically significant ($P$ = 0.030); specifically, the need to remove hardware for infection control was almost 80% lower in the degenerative disease group (Table 6). Two patients who had undergone repeat surgical procedures and antibiotic treatment had such a decrease in symptoms and an improvement in laboratory test results that it was possible for implant revision to be carried out in the same operation (1-stage revision). One patient with positive results on repeat cultures for methicillin-sensitive *S aureus* required 2-stage revision to achieve normal CRP levels and imaging findings. A fourth patient, who had been receiving oral antibiotic suppression for 3 years, had acute hematogenous spread of multidrug-resistant enterobacteria that could not be treated with oral antibiotics and thus underwent 2-stage revision surgery, which had a favorable outcome as of the time this report was written. Another patient, who required implant removal without the possibility of replacement, died (1/28; 3.57%). In all revisions, screws were safely explanted while maintaining vertebral integrity, and the PMMA was not eliminated. No recementing was performed on the new screws. The screws used in revision surgery had the same length as those of the primary surgery, but they were 1 mm larger in diameter.

**Table 3.** Surgical diagnoses in the study population ($N$ = 537).

| Condition for Which Surgery Was Performed | *n* | No. (%) of Infections in Group |
|---|---|---|
| Deformity | 157 | 9 (6) |
| Degenerative disease | 376 | 18 (5) |
| Cancer | 4 | 1 (25) |

Vacuum-assisted closure of the wound was necessary in 6 patients. Four patients required plastic surgery to achieve delayed primary closure: a reverse latissimus dorsal flap was used in 3 patients, and a superior gluteal artery perforator advancement flap was used in 1 patient.

## DISCUSSION

SSI is one of the most serious complications of ISF, and it may cause devastating consequences. The increasing prevalence of antibiotic-resistant organisms has made SSI treatment more complex.[17,18]

ISF of the thoracolumbar region is associated with a 2% to 10% risk of infection in adults and up to 15% in specific patient populations.[19,20] PMMA augmentation has been shown[21] to increase pedicle screw pull-out forces in the osteoporotic spine by up to 348%. However, there is concern as to whether augmented transpedicular screws have an added risk of SSI, and doubts remain about how best to manage this type of infection in older patients. The widespread use of VP/KP has given surgeons experience and consistent data, indicating a low risk of infection associated with cement augmentation. To our knowledge, however, the present study is the first report of the influence of cement-augmented ISF on the appearance and treatment of deep SSI.

Haddad et al[22] investigated the impact of deep SSI on surgical outcome in 444 patients who underwent surgery for adult spinal deformity. In total, 20 patients developed an SSI, indicating an incidence of 5.18%. Presence of infection was associated with a greater number of complications and revision procedures. In their study of 481 consecutive patients undergoing noncemented ISF because of various conditions (eg, degenerative disease, trauma, and tumor), Núñez-Pereira et al[23] reported an 8.9% rate of deep SSI ($n$ = 43). The average age of their patients was 52.1 years, and the mean rate of implant survival at the end of

**Table 4.** Qualitative variables by group.

| Variable | Deformity, *n* (%) | Degenerative Disease, *n* (%) | *P* Value |
|---|---|---|---|
| Gender | | | |
| Men | 4 (44.4) | 4 (22.2) | |
| Women | 5 (55.6) | 14 (77.8) | 0.375 |
| Revision surgery | | | |
| Yes | 2 (22.2) | 7 (38.9) | |
| No | 7 (77.8) | 11 (61.1) | 0.667 |
| Area | | | |
| Thoracic spine | 1 (11.1) | 1 (5.6) | |
| Lumbar spine | 3 (33.3) | 16 (88.9) | |
| Thoracolumbar spine | 5 (55.6) | 1 (5.6) | 0.003 |
| No. of segments fused | | | |
| 2 | 1 (11.1) | 8 (44.4) | |
| 3 | 3 (33.3) | 8 (44.4) | |
| 4 | 3 (33.3) | 2 (11.1) | |
| 5 | 2 (22.2) | 0 (0.0) | 0.057 |
| Antibiotic prophylaxis | | | |
| Cefazolin | 4 (44.4) | 13 (72.2) | |
| Vancomycin | 1 (11.1) | 0 (0.0) | |
| Cefazolin + aminoglycoside | 3 (33.3) | 4 (22.2) | |
| Cefazolin + gentamicin + rifampicin | 0 (0.0) | 1 (5.6) | |
| Unspecified | 1 (11.1) | 0 (0.0) | 0.207 |
| Obesity (by body mass index [kg/m$^2$]) | | | |
| <30 | 5 (55.6) | 7 (43.8) | |
| 30–35 | 3 (33.3) | 8 (50.0) | |
| >35 | 1 (11.1) | 1 (6.2) | 0.840 |
| Smoking | | | |
| Yes | 1 (11.1) | 0 (0.0) | |
| No | 8 (88.9) | 18 (100) | 0.333 |
| No malnutrition | 8 (100) | 18 (100) | 0.050 |
| American Society of Anesthesiologists class | | | |
| II | 1 (11.1) | 9 (50.0) | |
| III | 8 (88.9) | 9 (50.0) | 0.091 |
| History of infection | | | |
| Yes | 1 (11.1) | 0 (0.0) | |
| No | 8 (88.9) | 18 (100) | 0.333 |
| Early infection | 8 (100) | 18 (100) | 0.050 |
| Deep infection level | 9 (100) | 18 (100) | 0.083 |
| Bacteria | | | |
| Gram-positive | 3 (33.3) | 7 (38.9) | |
| Gram-negative | 4 (44.4) | 3 (16.7) | |
| Polymicrobial | 2 (22.2) | 8 (44.4) | 0.268 |
| Measurement of C-reactive protein level | | | |
| Performed | 0 (0.0) | 1 (5.9) | |
| Not performed | 7 (100) | 16 (94.1) | 1.000 |
| Sonication | | | |
| Performed | 1 (12.5) | 1 (5.6) | |
| Not performed | 7 (87.5) | 17 (94.4) | 0.529 |
| Pathogen concordance | | | |
| Yes | 4 (44.4) | 9 (50.0) | |
| No | 5 (55.6) | 9 (50.0) | 1.000 |
| No. of irrigations | | | |
| 1 | 3 (33.3) | 10 (55.6) | |
| 2 | 4 (44.4) | 7 (38.9) | |
| 3 | 1 (11.1) | 0 (0.0) | |
| 4 | 0 (0.0) | 1 (5.6) | |
| 6 | 1 (11.1) | 0 (0.0) | 0.303 |
| Plastic surgery | | | |
| Yes | 3 (33.3) | 2 (11.1) | |
| No | 6 (66.7) | 16 (88.9) | 0.295 |
| Vacuum-assisted closure therapy | | | |
| Yes | 4 (44.4) | 2 (11.1) | |
| No | 5 (55.6) | 16 (88.9) | 0.136 |

follow-up was 77%. There is no evidence suggesting that retention of spinal hardware limits the capability of treating deep SSIs in the acute phase.[24] In fact, the conservation of the implant is essential to ensure a stable setting in which to carry out spinal fusion.[25,26] In our series of interventions performed with the use of cement-augmented hardware in patients with an average age of 75.1 years, only 5 patients required removal or replacement of the hardware. The survival

**Table 5.** Quantitative variables.

| Variable | Deformity[a] | Degenerative Disease[a] | *P* Value |
|---|---|---|---|
| Age (y) | 73.9 ± 7.69 | 76.2 ± 5.83 | 0.642 |
| Duration of procedure (min) | 309 (210) | 218 (60.2) | 0.010 |
| Blood loss (g/dL) | 3.36 ± 1.18 | 3.01 ± 1.12 | 0.368 |
| Charlson Comorbidity Index | 4.89 ± 1.76 | 4.28 ± 0.83 | 0.298 |
| Body mass index (kg/m$^2$) | 29.5 ± 4.54 | 29.9 ± 3.72 | 0.934 |
| Serum albumin levels (g/dL) | 4.06 ± 0.42 | 4.30 ± 0.35 | 0.119 |
| Time (d) elapsed between the initial operation and infection occurrence | 14.0 (8.00) | 13.0 (5.00) | 0.244 |
| C-reactive protein level (mg/dL) at admission | 18.0 ± 15.9 | 19.6 ± 12.2 | 0.560 |
| Duration (d) of empirical antibiotic therapy | 4.50 (1.50) | 5.00 (2.75) | 0.465 |
| Duration (d) of targeted antibiotic therapy | 90.0 (19.8) | 63.5 (27.5) | 0.039 |
| Total duration (d) of antibiotic therapy | 94.5 (21.5) | 67.5 (27.0) | 0.048 |
| Duration (d) of intravenous treatment | 30.0 (23.0) | 21.5 (17.8) | 0.537 |

[a]Data are expressed as mean ± SD. The exceptions are for data on duration expressed in minutes or days, which are expressed as medians (interquartile ranges).

rate of the original implants was 82.15% at the end of follow-up in our study.

Furthermore, our cumulative experience shows that despite the failure of conservative treatment, it is feasible to carry out 1- or 2-stage hardware revision with cement augmentation once the infection has been controlled. Regarding this issue, we have observed an association between the type of initial surgery (ie, for degenerative disease vs deformity) and the 2-year outcome. In particular, we found that patients receiving surgery for a degenerative condition have an 80% lower need for hardware removal to control infection than do patients with deformity, which is a statistically significant difference. Núñez-Pereira et al[23] described an association between the number of spine segments fused and the need for removal of the material or death in patients who developed an SSI after ISF. Thus, our finding that deformity is a factor associated with hardware removal to control the infection is consistent with the findings of Núñez-Pereira et al. We did not observe degradation at the bone-cement interface. All screws were safely explanted, and vertebral integrity was maintained. The PMMA was not eliminated.

In 2008, Chang et al[27] published one of the first reports about patients who underwent decompression and ISF with PMMA-augmented cement. Their series included 41 patients with a range of conditions (eg, osteoporotic fracture, spinal stenosis, and malignancy). Two patients (4.87%) had deep SSI throughout follow-up. In all patients, the infection responded well to conservative treatment and cycles of intravenous antibiotics. Singh et al[28] conducted a systematic review of all studies reported between 2000 and 2017 to shed light on pressing issues related to the use of cement-augmented pedicle screws. They found 17 such studies of a total of 1085 patients (sample sizes ranging from 7 to 313 patients). A superficial infection was found in 16 patients (1.5%), and infections in all of them responded well to antibiotic therapy. Twenty-one patients (2.1%) developed a deep SSI and were treated with surgical debridement and antibiotics. In the present study, 28 of the 532 patients who underwent cemented spinal fusion (5.2%) developed an SSI. This result is inline with findings reported in the current literature (29%–38%) (Table 7); the infection rates occurring in cemented and uncemented hardware are similar. Gram-positive pathogens (39.3%) and *S aureus* were the most frequent species in our cohort, these being part of the normal skin flora and also responsible for most noncemented spinal SSIs. The rate of polymicrobial infections was also relatively high (35.7%) in our cohort. It is unclear whether these infections are related to the advanced age of our study population or other factors, including cementation. Abdul-Jabbar et al[29] reported 41.4% polymicrobial cases among 239 noncemented SSIs.

ISF with PMMA-augmented transpedicular screws has been shown to be a safe technique. The use of PMMA increases initial screw fixation, mean anchorage, and resistance to fatigue, and it allows expanded use of pedicle screw instrumentation in older patients with degenerative diseases of the lumbar spine.[10,40]

**Table 6.** Frequency and percentage of successful and unsuccessful curing of infections in the 2 largest treatment groups.

| Outcome at 2 y After Surgery | Deformity, *n* (%) | Degenerative Disease, *n* (%) | Relative Risk (95% CI) | *P* Value |
|---|---|---|---|---|
| Infection cured with debridement | 5 (55.6) | 17 (94.4) | 1.70 (0.94, 3.08) | 0.030 |
| Infection cured with hardware removal/replacement | 3 (33.3) | 1 (5.6) | 0.15 (0.02, 0.98) | 0.030 |
| Treatment failure (antimicrobial suppression failed or death occurred) | 1 (11.1) | 0 (0) | | |

**Table 7.** Prevalence and characteristics of SSI among various studies. Noncemented spinal instrumentation.

| Author/Year | Patients, *n* | SSI, *n* (%) | Mean Age, y | Infection Characteristics | Implants Removed, *n*(%) | Implants Retained and ATB Suppression, *n* (%) | Implants Retained and Cured, *n* (%)<br>Days of Oral Antibiotics |
|---|---|---|---|---|---|---|---|
| Zhang et al, 2022[30] | 27,881 | 521 (1.8%), 191 needing revision surgery | 55.3 | Most common microbe: *Staphylococcus aureus* (43.4%) | 7 Of the 191 revisions (3.6%) | 15.2% | 175 Of the 191 revisions (91.6%)<br>Complications secondary to antibiotic treatment was 7.8% |
| Kuroiwa et al, 2022[31] | 1832 | 44 (2.4%) | 50.7 | Most common microbe: *S aureus* (47%) | 20 (45.5%) SSI needed >2 debridement or instrumentation removed or SSI led to death | - | 24 (54.5%) |
| Cáceres et al, 2019[32] | 799 | 32 (4%)<br>3 Lost in follow-up | 54.9 | Most common microbe: *S aureus* | 1 (4%) | - | 24 (96%)<br>8 wk |
| Khanna et al, 2018[33] | - | 67 | 61.9 | Most common microbe: *S epidermidis* | 19 (9%) | 25 (37%) | 17 (25%)<br>255 d (Range 7–689) |
| Manet et al, 2018[34] | 1694 | 46 (2.7%)<br>9 Lost in follow-up | 55 | Most common microbe: *S aureus* | 2 (4%) | - | 31 (84%)<br>6 mo (Range 3–9) |
| Tsubouchi et al, 2018[35] | 3967 | 55 (1.4%) | 72 (60–77) | Estimated blood loss significantly associated with implant removal | 21 (38%) | - | 33 60%) |
| Cho et al, 2018[36] | - | 102 | 63 (50–70) | Most common microbe: methicillin-resistant *S aureus* | 19 (18.6%) | 35 (34.3%) | 48 (47%)<br>52 d (Range 34–88) |
| Yin et al, 2018[37] | 4057 | 42 (1%) | 68.9 | Most common microbe: *S epidermidis* | 1 (2.4%) | | 41 (97.6%) |
| Takizawa et al, 2017[38] | 665 | 21 (3.2%), 9 Methicillin-resistant *S epidermidis* | 64.3 | - | 2 Of the 9 methicillin-resistant *S epidermidis* SSI (22.2%) | | 7 Of the 9 methicillin-resistant *S epidermidis* SSI (77.8%) |
| Wille et al, 2017[39] | 4290 | 129 (3%)<br>1 Lost in follow-up | 57 | Most common microbe: *S aureus*<br>Polymicrobial infection associated with relapse | 5 (3.8%) | 17 (13.2%) | 106 (82.2%) |

Abbreviations: ATB, antibiotic; SSI, surgical site infection.

The risk of infection when using cement augmentation is low and compares well against noncemented techniques. Some authors recommend using antibiotic-loaded cement in routine procedures. However, because the effects of antibiotics on the structural properties of PMMA used for vertebral augmentation, with its varying degrees of viscosity, they have not been adequately studied to date. Furthermore, the rate of SSIs reported in studies using antibiotic-loaded PMMA is not greater than the rate for procedures using noncemented hardware.

Our study has certain limitations:

- Our research was based on the work of 5 different surgeons, each with differing levels of experience with this type of treatment.
- This case series included no group for comparison.
- Our analysis of the sample did not take into account factors that might have influenced surgical outcome, such as the advanced age of the patients.
- Contamination of fresh frozen allograft chips has not been investigated.
- Cementation requires a longer duration of surgery than does surgery without cement.

Multicenter and randomized studies of homogeneous populations and with a control group would perhaps be necessary to establish a direct comparison of the risk of infection, its treatment, and of the possible risk factors associated with the use of cemented and noncemented instrumentation.

## CONCLUSION

SSI is one of the most serious complications of ISF and can have devastating consequences. The risk of infection when using cement augmentation is low and compares well with noncemented techniques. The infection rate, most commonly found pathogens, and implant survival do not differ between cemented and noncemented fusion. None of the patients in our study required removal of cement from the vertebral body because of any deep infection in the cement. The success rate for treatment of deep infection after cemented spinal fusion is high.

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