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Efficacy of Antibiotic-Loaded Cement Augmentation for Correcting Low Grade Pedicle Screw Loosening

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Conflict of Interest
The authors have no financial conflicts of interest.

ABSTRACT

Objective: Altered biomechanics and bone fragility can contribute to pedicle screw loosening. This study aimed to evaluate the efficacy of antibiotic-loaded cement augmentation for correcting symptomatic screw loosening as a minimally invasive alternative to open revision surgery.
Methods: Ten consecutive patients who underwent percutaneous cement augmentation for pedicle screw loosening were included in this study. Low grade pedicle screw loosening was deemed clinically relevant in cases of continuous back pain with significant radiolucent halo zones at a vertebral level without screw backing out or stripping. We analyzed the screw loosening at the main location of halo formation. All patients were treated by fluoroscopy-guided antibiotic-loaded cement augmentation of the loosened pedicle screws. Patient demographics and pre- and postoperative data were also assembled and analyzed.
Results: Most (80%) halo formation locations were the inferior type. Augmentation was technically feasible in all but one patient, in whom the procedure was unsuccessful due to access difficulty. This patient ultimately underwent percutaneous screw re-implantation via a different trajectory. The other nine patients in whom cement filling was satisfactory reported significant pain relief at the final follow-up. Moreover, no severe complications such as wound infection or repeated screw loosening occurred during the follow-up period.
Conclusion: The most common halo formation location was the inferior type. In cases without access difficulty, antibiotic-loaded cement augmentation for the treatment of low grade pedicle screw loosening can relieve pain and avoid extensive open surgery.

Keywords: Bone cement; Prosthesis loosening; Screws

INTRODUCTION

Posterior instrumentation with pedicle screws is widely utilized in the treatment of various degenerative spinal diseases and spinal fractures. Despite immediate and strong fixation as well as a low rate of device-related complications, altered biomechanics and bone fragility may result in instrumentation failure, bone resorption, or spinal instability with progressive pain.[2,8,10]

Screw loosening, a representative complication of pedicle screw fixation, has an estimated incidence of 0.8–27% that can exceed 50% in patients with severe osteoporosis.[6,13] Despite

the relative frequency of symptomatic screw loosening, few treatment options exist. The typical treatment is extensive revision surgery to remove the pedicle screws using extended instrumentation and the insertion of more pedicle screws.

Recently, several small series of minimally invasive percutaneous cement augmentation to treat cases of clinically relevant low-grade screw loosening has been described.[1,5] Despite the widespread use of cement augmentation, there is a paucity of reports on its use to correct screw loosening. To the best of our knowledge, cement augmentation has not been proven as the definitive method for alleviating pain resulting from screw loosening. Moreover, screw loosening due to bone resorption around implants can be caused by infection, a relative contraindication for cement augmentation.[14] In fact, low-virulent microorganisms that are frequently detected on pedicle screws may be a main cause of screw loosening or failure.[11]

This study aimed to assess the results of percutaneous fluoroscopy-guided antibiotic-loaded cement augmentation for the correction of clinically relevant screw loosening, a common challenge in the wide usage of pedicle screw fixation.

MATERIALS AND METHODS

The study was approved by the Institutional Review Board (IRB) Chosun University Hospital Institutional Bioethics Committee (IRB No. 2020-05-002).

From the database of the spine surgery registry program, we obtained and analyzed the records of 10 consecutive patients who underwent percutaneous cement augmentation between June 2016 and July 2018 and subsequently experienced symptomatic low-grade pedicle screw loosening. These patients previously underwent lumbar interbody fusion and transpedicular screw fixation for degenerative lumbar spine diseases that was complicated by symptomatic pedicle screw loosening. The inclusion criteria were as follows: (1) development of continuous para-midline back pain resistant to conservative treatment such as medication or pain management after a pain-free interval, (2) typical finding of radiolucent halo zones around the screws at a vertebral level on both plain radiography and computed tomography (CT), (3) low-grade screw loosening without prominent screw backing out or stripping, and (4) screw fixation without bone cement augmentation.

Patients with significant coagulopathy or spondylitis with elevated markers of infection at the time of the previous lumbar interbody fusion or during the follow-up period were excluded. Patients with pronounced or multiple screw loosening requiring extensive open revision surgery were also excluded.

Demographic data of the 10 patients included age, sex, vertebral level, bone mineral density, main location of halo formation, and modified Macnab criteria at final follow-up (**TABLE 1**). The main location of halo formation was evaluated on simple radiographs and coronal CT scan (superior, inferior, medial, lateral, and whole type) (**FIGURE 1**). All patients underwent fluoroscopy-guided antibiotic-loaded cement augmentation in a biplanar angiosuite under local anesthesia. The antibiotic-loaded bone cement consists of 2 components-a powder and a-that were mixed before use (CMW-G; Depuy Synthes, Raynham, MA, USA). The powder contained 0.5 g of gentamicin per 20 g of bone cement and the fluid consisted of methylmethacrylate, dimethyl-p-toluidine, ethanol, ascorbic acid, and hydroquinone.

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TABLE 1. Demographic characteristics of the patients

Case	Age/sex	Level	Mean BMD	Time to revision surgery (mon)	F/U	Main halo location	Modified Macnab criteria	Remarks
1	70/M	L3	−2.2	14	6	Inf	E	-
2	67/M	L5	−2.4	11	8	Inf	P	Technical difficulty
3	72/F	L5	−3.2	8	6	Inf	E	-
4	60/F	L4	−3.0	10	7	Inf	E	-
5	74/F	L5	−2.8	9	8	Inf	G	-
6	63/F	L5	−3.0	10	12	Whole	G	-
7	78/M	L5	−2.0	8	9	Inf	E	-
8	60/F	L3	−2.5	14	10	Inf	F	-
9	56/F	S1	−2.4	12	11	Whole	E	-
10	69/M	L4	−3.1	17	11	Inf	G	-

BMD: bone mineral densitometry, E: excellent, F: fair, F/U: follow-up, G: good, Inf: inferior, P: poor.

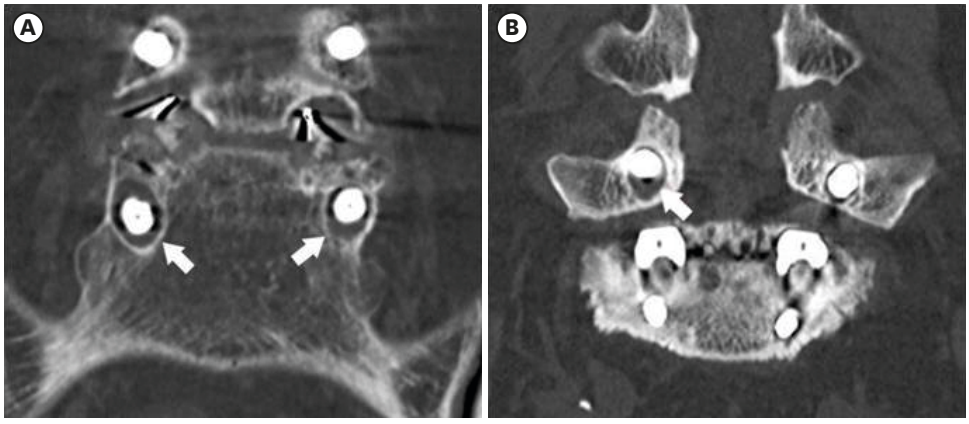

FIGURE 1. Main halo formation location on coronal computed tomography scan (arrows). (A) Whole type. (B) Inferior type.

Follow-up was performed clinically and radiologically at 1, 2, 3, and 6 months postoperative with a clinical visit using standing plain radiographic films. When deemed necessary, follow-up CT or magnetic resonance imaging (MRI) was performed; however, some patients did not consent to undergo CT or MRI. Therefore, the radiological assessment was based mainly on standing dynamic plain radiography films.

Vertebral body access

Analysis of the main halo location revealed that eight were the inferior type and 2 were the whole type. Accordingly, we targeted the halo site by positioning the vertebroplasty needle toward the bottom of the screw. Using a 115-mm 13-gauge beveled tip vertebroplasty needle, we contacted the midshaft of the screw, taking care to keep the beveled needle tip inside the bone resorption halo. Once screw contact was made, the beveled side was moved past the screw and advanced to the desired target within the vertebral body (**FIGURE 2**).

Safety and outcome measurement

Patients were evaluated during the follow-up period using visual analog scale (VAS) scores and modified Macnab criteria for characterizing clinical outcomes of spinal surgery at the final follow-up. The paired *t*-test was used to compare different time points, and differences were considered statistically significant at p-values <0.05.

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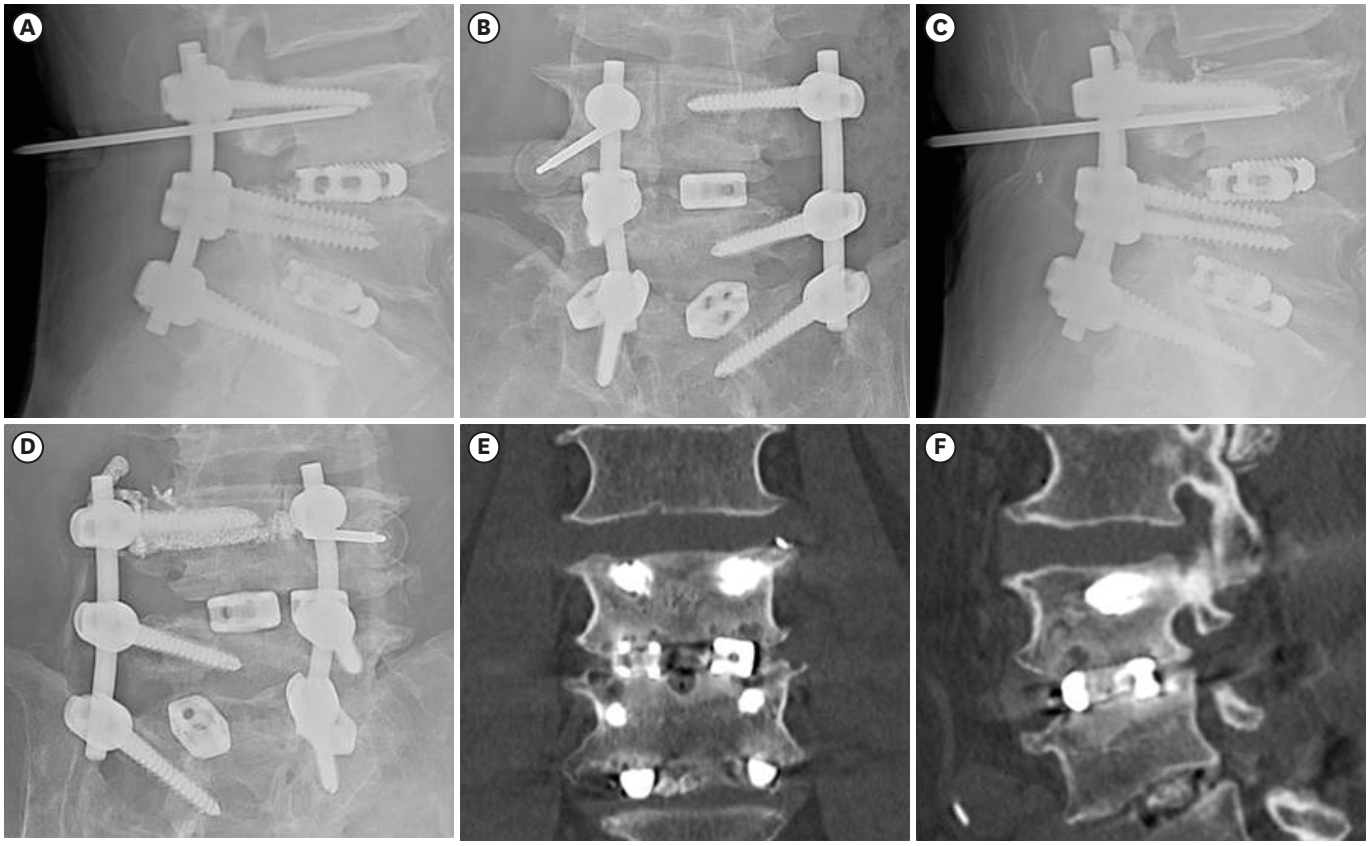

FIGURE 2. A 70-year-old man who underwent posterior lumbar interbody fusion at L3–4 and L4–5 developed halo formation in the lower part of the screw at L3. (A, B) Antibiotic-loaded cement augmentation was performed by inserting a needle under the screw on the right side. (C, D) The same procedure was performed by inserting the needle under the screw on the left side. (E, F) Coronal and sagittal computed tomography scans taken after the procedure show satisfactory filling of cement.

RESULTS

A total of 10 patients (4 men, 6 women) underwent percutaneous cement augmentation for the correction of symptomatic screw loosening. All patients had newly developed back pain after a period of pain relief. The mean time to revision was 11.3 months, mean patient age was 66.9 years (range, 56–78 years), and mean follow-up period was 8.8 months (range, 6–12 months). **TABLE 1** presents the patient demographics. All procedures but one were technically feasible and successfully performed. The failed procedure involved implant-related obscurity of the fluoroscopic landmarks, and cement filling was not successful into the halo. He was treated with percutaneous screw re-implantation via a different trajectory in the end. No periprocedural complications occurred, especially clinically significant cement leakage, in the other patients.

At the final follow-up after the revision surgery, 8 patients (80%) showed excellent or good outcomes based on the modified Macnab criteria. The mean pain VAS score was 6.9 before the revision surgery and 3.0 at 1 month postoperative. The mean pain score at the final follow-up was significantly improved compared to that preoperatively (VAS 3.5, $p<0.05$) but worse than that at 1 month postoperative.

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DISCUSSION

Although pedicle screws offer immediate and strong fixation with a relatively low rate of device-related complications, symptomatic screw loosening is a representative complication after screw fixation. Pedicle screw loosening is the main cause of morbidity among patients who undergo spinal instrumentation surgery. Potential reasons for screw loosening include poor initial bone quality, screw-induced stress shielding, and high static stress combined with cyclic loading.[10]

Several options have been proposed to avoid screw loosening or implant failure, including cement-augmented screw fixation and the use of expandable screws, bicortical screws, or cannulated and fenestrated screws.[4] However, few treatment options exist for screw loosening or implant failure. The typical treatment involves extensive surgery to remove the screws with the extension of instrumentation and reinsertion of more pedicle screws in another direction.[9] However, similar complications may still occur after these procedures with risks of further morbidity, high cost, and decreased patient satisfaction.

Extensive revision surgery is usually particularly contraindicated for elderly and fragile patients with medical comorbidities. Alternative minimally invasive treatment options using cement augmentation have recently been described.[3,5] Amoretti et al.[1] reported good results with a percutaneous consolidation technique for pedicle screw loosening. Cement augmentation aims to fill the halo of bone resorption around the screw to simulate screw oversizing and reduce or nullify screw micromobility. Whenever possible, the adjacent trabecular network is filled with cement in an effort to achieve a more stable anchoring cast between the screw and the vertebral body.

Cianfoni et al.[3] reported transpedicular access using a thin flexible beveled needle contacting the proximal screw shaft that was then bent and slid along the screw shaft. However, we used rigid beveled needle targeting the screw tip using a slightly more oblique course than the screw's path. The presence of dense metallic structures sometimes obscures visualization of the fluoroscopic landmarks. Approach routes are often occupied by implants, requiring the operator to seek other trajectories within narrow anatomic windows.

In most cases in our study, the radiolucent halo was observed at the bottom of the screw. Accordingly, the vertebroplasty needle generally targeted the area inferior to the previous screw insertion site. The vertebroplasty needle was guided from the bottom of the screw, high-viscosity cement was inserted into the halo space, and the vertebroplasty needle was targeted to pass over the anterior 3 quarters of the vertebral body to the midline from the lateral to medial direction. Transpedicular access was favored in the lumbar spine and a small-size 13-gauge beveled tip needle was used to allow the required steerability and flexibility to adequately fill the halo space. Proper needle positioning, proper bevel tip direction, and use of high-quality fluoroscopic guidance with high-viscosity cement may have contributed to the excellent safety and efficacy observed in this series.

Bone resorption around implants can be caused by infection. In cases of clinical and radiologic suspicion, cement augmentation is relatively contraindicated. The suboptimal sensitivity of spine biopsies and cultures for low-grade infections remains challenging in such cases.[12] Prinz et al.[11] reported that the low-virulent microorganisms frequently detected by sonification are a major cause of implant loosening. The most common isolated

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microorganisms were coagulase-negative staphylococci and *Cutibacterium acnes*. A study of changes in antibiotic-resistant *Staphylococcus aureus* from wound isolates in a South Korea university hospital over a 10-year period (2006–2016) showed that the antibiotic resistance rate changed with time. The resistance rates for penicillin, oxacillin, erythromycin, and gentamicin were 97.7%, 60.5%, 57.8%, and 48.8%, respectively. In 2013, the rates changed to 95.9%, 62.6%, 55.7%, and 28.6%, respectively. Gentamicin resistance decreased by 20.2% in 2016.[7] For this reason, it was deemed better to use gentamicin-loaded than erythromycin-loaded bone cement. We believe that low-virulent microorganisms around pedicle screws can cause screw loosening and that antibiotic-loaded bone cement for the treatment of screw loosening may decrease the need for subsequent surgeries, systemic antibiotic exposure, and a prolonged hospital stay.

There are potential limitations to the current study. The primary limitations include its retrospective study design, small sample size, short-term follow-up, intrinsically subjective definition of clinically relevant instrumentation failure, and subjective nature of pain self-assessment. Second, this study lacks other traditional therapeutic options for comparison. Moreover, we did not study the relationship between interbody fusion and halo formation around the screw. Thus, larger prospective cohort analyses with long-term follow-up periods focusing on bone fusion as well as biomechanical studies are required to provide more generalized outcome data and evaluate the long-term results of bone fusion. Third, antibiotic-loaded bone cement augmentation has exothermic properties and may lead to frequent complications such as cement leakage, although most cases are of minor leakage without consequential neurologic deficits. Moreover, for patients with pronounced multilevel screw loosening, extensive open revision surgery should be considered.

CONCLUSION

The findings of the current study suggest that minimally invasive antibiotic-loaded cement augmentation for selected cases of low-grade screw loosening can provide a well-tolerated alternative to extensive open surgery.

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