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ORIGINAL STUDY

Radiologic and clinical outcome of the cement augmented pedicle screws after a minimum 2-year follow-up

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T55 patients with cement-augmented pedicle screw were retrospectively analyzed. All patients underwent computed tomography at a minimum of 2 years after index operation. Computed tomography scans were analyzed to determine pedicle screw loosening, cement leakage, and fusion rates at augmented levels. The purpose of this study was to analyze the efficacy and complications of cement augmentation in elderly patients. Screw loosening occurred at fused levels in all patients, except one patient with pseudoarthrosis. All cases of screw loosening occurred at levels without interbody fusion. Extravasation of cement was performed in 7 (12.7%) patients and three (5.4%) patients had asymptomatic pulmonary cement emboli. Three (5.4%) patients had deep wound infection, and they were treated successfully with debridement and antibiotic therapy without need for instrument removal. Cement augmentation of PSs in elderly osteoporotic patients prevents screw pull-out. However, a very low rate of screw loosening may be seen at the levels without interbody fusion.

Keywords : pedicle screws ; osteoporotic patients ; elderly ; cement augmentation ; mechanical failure ; osteoporosis ; screw loosening ; interbody fusion ; elderly osteoporotic patients ; screw pull-out.

INTRODUCTION

The geriatric population is increasing due to a longer life expectancy. By 2050, it is expected that 54% of the population in developed countries will be above age 65 *(6)*. As the elderly population rapidly increasing, the number of patients with orthopedic diseases, such as osteoporosis and degenerative spine, has become major worldwide problem *(12,15,17)*.

Pedicle screws (PSs) are commonly used by spine surgeons to achieve stability during the contemporary surgical management of various conditions including osteoporotic fractures, tumors, instabilities, and spinal stenosis *(10)*. However, there is an increased risk of screw loosening and migration when PSs are used in elderly osteoporotic patients.

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In recent years, stronger PS fixations have become the principal aim of spinal surgeons, and various studies have been performed in this area *(9,22, 26,27)*. Previous experimental studies report that cement-augmented PSs have a significantly greater resistance against axial pull-out and transverse bending *(8,10)*. However, there are few clinical reports in which cement-augmented PSs are used.

The aim of this study was to perform a retrospective analysis of the radiologic outcomes and complications in elderly osteoporotic patients who underwent the application of cement-augmented PSs.

METHODS

Between August 2006 and September 2010, patients who underwent the application of cement-augmented PSs at more than 5 segments with T scores under -2.5 were retrospectively analyzed. All patients signed an informed consent form before the operation, and surgical procedures were performed at a single center by the same surgeon. We received no funding for this study, and there are no conflicts of interest.

There were 55 patients (40 female, 15 male) with a mean age of 69 years (range, 52–85 years) included in the study. Preoperative diagnoses included spinal stenosis in 41 patients, trauma in 1, infection in 5, and spinal revision surgery in 8. Two patients died due to other causes during follow-up and were not included in the study. The anterior-posterior bone mineral densities were assessed using a dual energy x-ray absorptiometry (DXA) device. Patients with T scores -2.5 or lower were diagnosed with osteoporosis based on the World Health Organization's criteria. Patients were categorized into three groups based on their T scores. T scores between -2.5 and -3.2, -3.2 and -4.0, and under -4.0 were found in 13, 33, and 9 patients, respectively. All patients had various degrees of neurologic deficits on preoperative neurologic examination and electromyography.

The PSs were inserted using the standard technique, which included making an initial hole to the medial process of the pedicle and enlarging it to the required diameter. Bone cement (Kyphx, Sunnyvale, California, USA) was prepared in an appropriate consistency (neither very solid nor very liquid) before inserting the PSs, and injection was carried out with special cannulas, which injected approximately 2 cc to each lumbar vertebra pedicle and 1 cc to each thoracic vertebra pedicle. Immediately after injection, the titanium pedicle screws (Medtronic Sofamor Danek, Memphis, TN, USA) were inserted into both pedicles.

In order to prevent cement and pulmonary embolism, a mechanical aspiration was performed using the transpedicular cannula prior to injection.

After a minimum period of 24 months postoperatively, three-dimensional CT scans were performed on the levels that had cement-augmented PSs to assess PS loosening, cement leakage, and fusion at the instrumentation site. The CT scans were evaluated by a musculoskeletal radiologist and presence of a radiolucent area between the bone and screw that measured 1 mm or greater was defined as screw loosening. Bridging interbody bone and absence of continuous interbody radiolucent lines were defined as fusion. Postoperative chest radiographs were obtained for all patients and were evaluated by radiologists to investigate the presence of pulmonary cement embolism. Radiopaque images in the lung parenchymal greater than 1 mm were considered cement emboli.

RESULTS

In this study, 688 cement-augmented PSs were inserted into 55 patients (40 female, 15 male). The mean follow-up was 45 months (range, 24–116 months). The average cement augmented PSs for each patient was 12.5 screws (range, 10–18 screws). Interbody fusion was applied in 37 patients at all levels. All screws were supported with 1 mL of cement in the thoracic region and 2 mL cement in the lumbar region.

Radiologic evaluations performed by CT showed that 10 screws (1.4%) in 7 (12.7%) patients had loosened. Among these 7 patients with loose screws, 5 had T scores under -4.0, and 2 had T scores between -3.2 and -4.0. All screw loosenings occurred

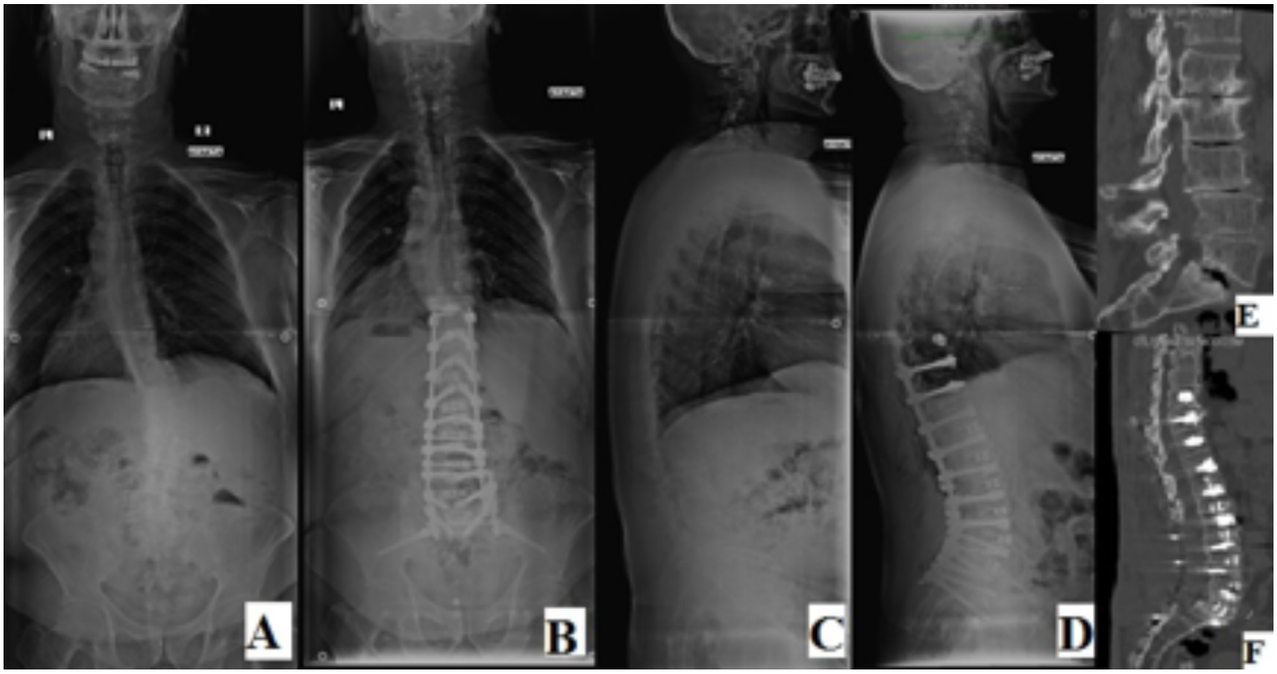

Fig. 1. — a) Preoperative standing anterior-posterior spine radiograph; b) Postoperative standing anterior-posterior spine radiograph; c) Preoperative standing lateral spine radiograph; d) Postoperative standing lateral spine radiograph; e) Preoperative computer tomography (CT_ sagittal scan; and f) Postoperative CT sagittal scan revealing screw loosening in the topmost level

in the levels that had not undergone interbody fusion (Figure 1), except in one patient who was postoperatively diagnosed with pseudoarthrosis.

There were no cement leaks to the neural canal or cases of myelopathy or radiculopathy; however, 7 (12.7%) patients had cement extravasation. All cement leaks were detected as dots or streaks, indicating where the cement leaks were located in relation to the small vessels around the vertebral body. There were no neurovascular injuries.

Three patients (5.4%) had cement emboli present on postoperative chest radiographs; however, these patients were asymptomatic, and according to the medical records, their postoperative vital signs were within normal limits (Figure 2).

There were no fractures in vertebral bodies at the levels that received cement-augmented PS insertions.

Deep wound infection developed in 3 patients (5.4%) with diabetes mellitus, including 1 patient who underwent revision surgery. Bacterial cultures showed Staphylococcus epidermis in 2 patients and Escherichia coli in 1 patient. A six-week course of antibiotics was prescribed after debridement and irrigation. These patients healed without the need for implant removal.

Bone fusion was achieved in all patients except for 2, and none of the patients developed an osteoporosis-dependent deformity in the neighboring segments. The rod fractured in 1 patient who developed pseudoarthrosis, and the patient underwent revision surgery (Figure 3).

DISCUSSION

Increased life expectancy results in an increased number of patients with severe osteoporosis, and this consequently increases the frequency of PS fixation use in spinal operations. In severe osteoporotic patients, the force that anchors the transpedicular screw to the bone and its resistance against forces that may cause micro-motion is very low; thus, new procedures for improving the PS fixation to severe osteoporotic bone are required by spinal surgeons. The risk of PS loosening in osteoporotic patients may be due to these low anchoring and resistive strengths. The key for long-term positive performance of PSs

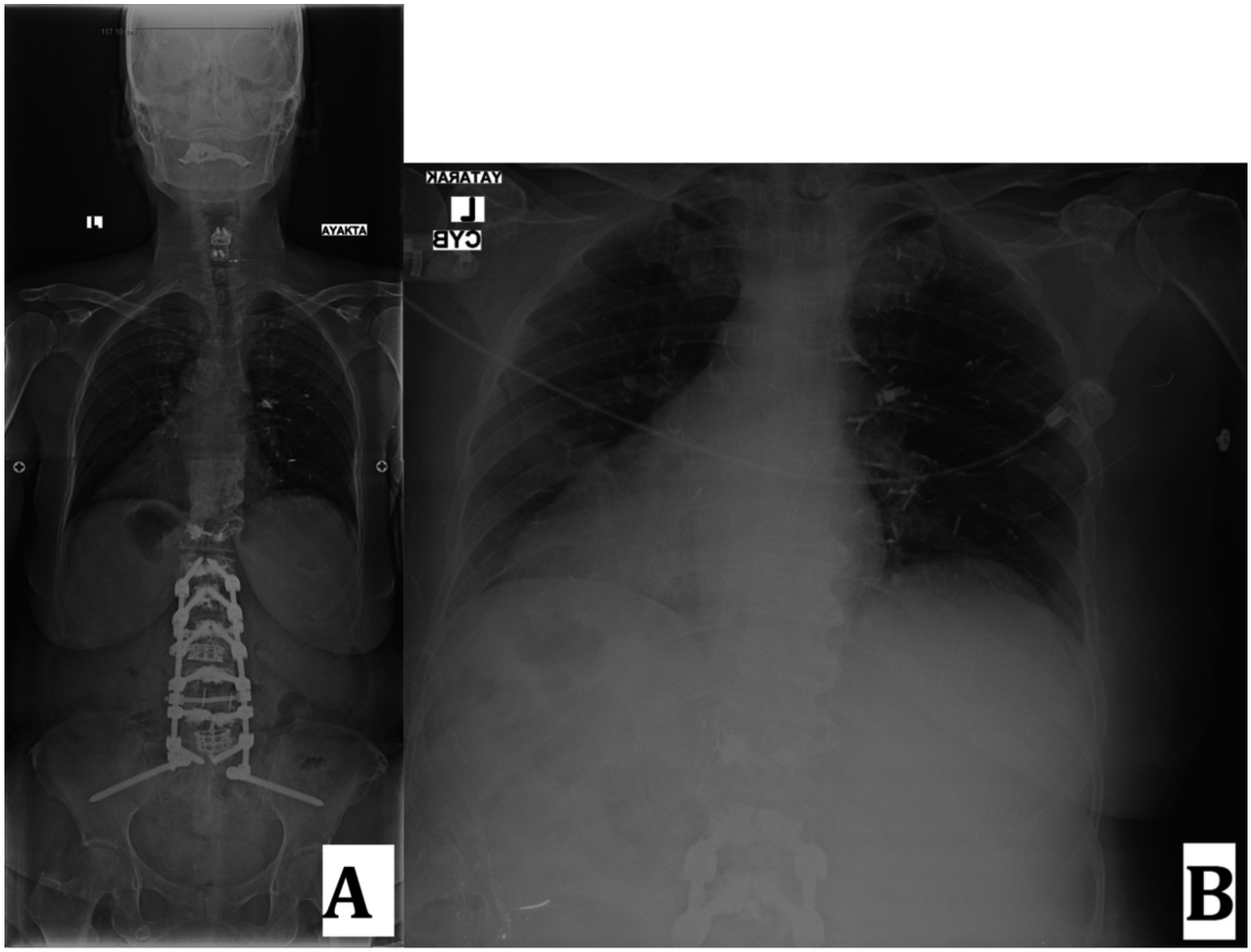

Fig. 2. — a) Postoperative standing anterior-posterior spine radiograph indicating cement embolism; and b) Postoperative chest radiograph indicating cement embolism

is the anchoring power between the bone and the implant. However, previous experimental studies report that osteopenia negatively affects the success of screw fixation *(13,14,23,28).*

The use of cement was demonstrated to increase the anchoring force between the bone and prosthesis; therefore, cement began to be used in arthroplasties during the 1960s *(3, 24).* This was followed by an increased use of cement-augmented PSs in spinal surgery *(2,9,18,25)*.

In our patient group, interbody fusion was applied to all levels in 37 patients by using allogeneic graft and a titanium mesh cage. A radiologically observed loosening was detected in 10 cement-augmented PSs of 7 patients. All of these screws were in the levels that had not been treated with interbody fusion. According to our clinical observations, interbody fusion decreases the possibility of screw loosening.

The cement extravasation rate is reported to be 27–74% in the literature *(5,11,16,20,21)*. Our rate was 12.7%, and none of the patients had an extravasation that could result in neurologic deficit or injury to the neighboring soft tissues. We believe that our low extravasation rate was caused by our injection technique, which involves a cement consistency that is neither very hard nor liquid, no exaggerated pressure, fluoroscopic control with meticulous surgery, and a low mean amount of cement injection for each pedicle.

The incidence of pulmonary cement embolism after a vertebroplasty procedure ranges from 3–23% *(1,4,7)*. The reason for passing the cement into the

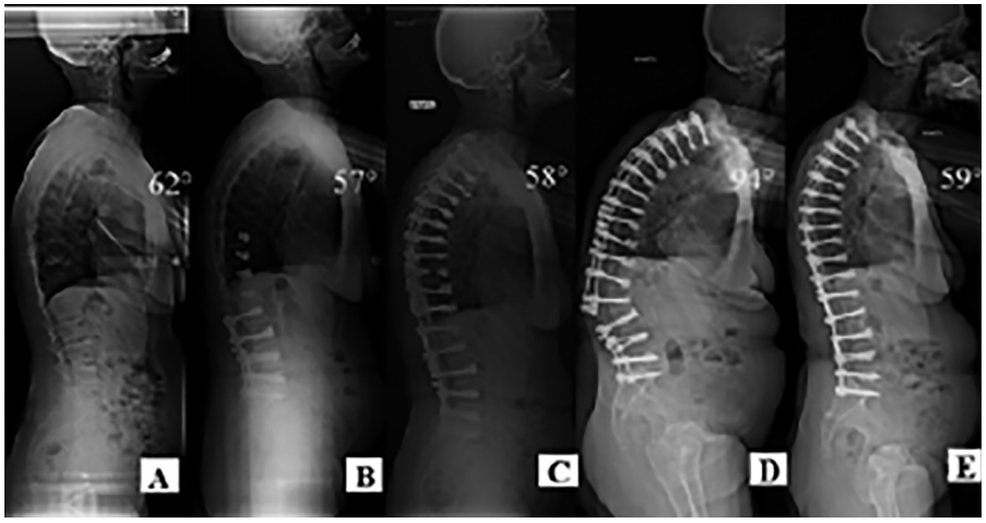

Fig. 3. — a) Preoperative standing lateral spine radiograph; b–c) Early postoperative standing lateral spine radiograph; d) Rod breakage due to pseudoarthrosis at one-year follow-up; and e) Eighteen-month follow-up after revision surgery

venous system is due to the absence of valves in the vertebral venous system. The pulmonary cement embolism rate in our patients was 5.4%, which is within the reported range. However, the rate is expected to increase when the level of cementing is considered *(7)*. We believe that the relatively lower rates are the result of paying attention to the consistency of the cement and mechanical aspiration of the vertebral body prior to the injection.

Similar to other studies, we observed that a lower bone mineral density (BMD) may lead to screw loosening *(19)*. Seven of the 10 screws that loosened in our study occurred in patients with severe osteoporosis (BMD $\leq$ -4.0); whereas, the other 3 screws occurred in patients with moderate to severe osteoporosis (BMD >-4.0 and BMD $\leq$-3.2, respectively). We believe that the BMD value may play a role in screw loosening in PS fixation and union problems at the fusion site.

CONCLUSION

Based on our study's findings, we believe that the cement-augmented PS is the method of choice in osteoporotic patients. Cement-related complications may be minimized with a meticulous surgical technique, and interbody fusion plays a key role in preventing long-term screw failure.

The effect of cement on PS fixation may be better understood in the future with prospective randomized studies.

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