IN VIVO *40*: 1637-1644 (2026)
doi: 10.21873/invivo.14314

Evaluation of Cement Leakage and Complications After Cement-augmented Pedicle Screw Fixation: A Retrospective Case Series

RICHARD ZACCARIA, NICK FETTKE, WOLFGANG BOECKER, KENNY HAGAR, CARL NEUERBURG, BIANKA RUBENBAUER, SIMON WEIDERT and EDUARDO M. SUERO

Department of Orthopaedics and Trauma Surgery, Ludtwig-Maximilians-University (LMU) Munich, Munich, Germany

Abstract

Background/Aim: Pedicle screw fixation is a standard technique for vertebral fractures but shows high loosening and pull-out rates, especially in osteoporotic bone. Cement augmentation can improve the screw-bone interface and construct stability. However, cement leakage rates of up to 94% have been reported, with rare but potentially serious complications such as pulmonary cement embolism. This study aimed to retrospectively evaluate the rate of cement leakage and serious complications after polymethylmethacrylate (PMMA)-augmented pedicle screw fixation.

Patients and Methods: We retrospectively reviewed 96 patients treated for thoracolumbar fractures with posterior stabilization and cement-augmented pedicle screws at LMU University Hospital Munich between July 2012 and August 2018. Demographic, operative, and imaging data were analyzed. Cement leakage detection rates were compared between intraoperative fluoroscopy, postoperative radiographs, and computed tomography.

Results: The cohort included 37 men (39%) and 59 women (61%). Most patients were ASA III (71%). Instrumentation involved two levels in 64% and four levels in 26% of cases. Mean operative time was 118±56 min. Cement leakage was identified in 71/93 patients (76%) on postoperative imaging. Intraoperative fluoroscopy detected leakage in 43% of cases, showing low sensitivity but high specificity. Postoperative radiographs detected leakage in 63%, while computed tomography showed the highest detection rate (91%). Increasing age was significantly associated with higher leakage risk (p=0.0109).

Conclusion: Cement leakage after PMMA-augmented pedicle screw fixation is common on postoperative imaging but was not associated with serious clinical complications in this cohort. Intraoperative fluoroscopy detects less than half of leakages, indicating limited sensitivity. Advanced intraoperative imaging techniques such as 3D imaging may improve detection.

Keywords: Cement augmentation, pedicle screw fixation, cement leakage, PMMA, thoracolumbar fractures, osteoporosis.

Richard Zaccaria, MD, Department of Orthopaedics and Trauma Surgery, Ludwig-Maximilians-University (LMU) Munich, Marchioninistrasse 15, 81377 Munich, Germany. Tel: +49 894400511687, e-mail: richard.zaccaria@med.uni-muenchen.de

Received February 9, 2026 | Revised March 5, 2026 | Accepted March 10, 2026

Introduction

Osteoporosis is a common condition among the elderly population and its prevalence continues to rise. According to the World Health Organization (WHO), osteoporosis is among the ten most common diseases worldwide and is therefore considered a widespread public health issue. In Germany, approximately six million people are affected by osteoporosis (1).

For spine surgeons, it is, therefore, becoming part of their surgical routine to treat osteoporotic patients in need of instrumented fusion. Posterior instrumentation with pedicle screw placement has long been the primary surgical treatment of unstable fractures of the thoracic lumbar spine that result from high-energy trauma, as well as of unstable fractures caused by bone insufficiency in the setting of, *e.g.*, osteoporosis or tumors. Currently, fluoroscopy-guided percutaneous placement of pedicle screws is the preferred operative technique. This method avoids extensive soft-tissue disruption and has demonstrated excellent results.

However, various studies have shown that the performance of pedicle screws depends on bone quality, indicating that patients with osteoporosis may be more susceptible to higher failure rates of posterior internal fixation systems (PIFS) (2, 3).

Cement augmentation of the pedicle screws has demonstrated improved biomechanical stability in low-quality bone. Multiple studies have shown improved pull-out strength and lower loosening rates with cemented screws (4-10).

As clinical evidence supporting the accuracy of pedicle screw fixation using spinal navigation continues to grow, adverse events related to cement leakage can increasingly be avoided (11-13). However, cement augmentation is associated with a risk of extravasation and leakage (14, 15). While extravasation into the surrounding musculature or into the intervertebral space is relatively innocuous, leakage into the spinal canal could lead to neurologic injury, and leakage into the nearby vessels could result in pulmonary embolism. In some studies, the use of thoracic computed tomography (CT) has been described as an important tool for the detection of pulmonary cement embolism (PCE), demonstrating high sensitivity and specificity of over 83% (16).

In the current study, we aimed to quantify the risk of cement leakage after cement-augmented pedicle screw placement in the setting of osteoporotic thoracolumbar fractures. We reviewed a series of 96 patients who underwent cement-augmented pedicle screw placement for various types of vertebral fractures.

Patients and Methods

Patients. We retrospectively reviewed the medical records of 96 patients who were treated for thoracolumbar fractures with posterior stabilization and cement augmentation of pedicle screws at the University Hospital of Ludwig Maximilian University (LMU) Munich between July 2012 and August 2018. Patients were eligible for inclusion if they were 18 years of age or older. The included cohort had an age range of 18 to 96 years, with a median age of 80 years. Demographic and clinical data were collected for all patients.

Available intraoperative fluoroscopic images, postoperative radiographs, and postoperative CT scans were reviewed to assess the presence and anatomical distribution of cement leakage following pedicle screw augmentation. To evaluate the diagnostic performance of intraoperative fluoroscopy for detecting cement leakage, sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy were calculated using postoperative radiographs and CT scans as reference standards. Logistic regression analysis was performed to identify independent risk factors for cement leakage. The following variables were included as covariates: patient age, sex, body mass index (BMI), spinal region, and the number of cement-augmented screws. All statistical analyses were performed using R (R Foundation for Statistical Computing, Vienna, Austria).

*Human ethics and consent to participat*e. This retrospective study was conducted in accordance with the ethical

standards of the institutional research committee and with the 1964 Declaration of Helsinki and its later amendments. Ethical approval was obtained from the Ethics Committee of the Medical Faculty of LMU Munich. Due to the retrospective nature of the study, the requirement for informed consent to participate was waived by the local ethics committee.

Polyaxial cannulated and fenestrated screw. Polyaxial cannulated and fenestrated pedicle screws were used in all cases. In total, 496 pedicle screws were implanted, of which 460 screws were cement-augmented. Cement augmentation was performed by injecting 1-3 ml of polymethylmethacrylate (PMMA) cement per screw through the fenestrations into the vertebral body under continuous lateral fluoroscopic control.

The majority of screws were from the CD Horizon system [Medtronic, Minneapolis, MN, USA (17)], including CD Horizon Longitude (69%) and CD Horizon Sextant II (4%). The Viper Prime system [VIPER MIS Spine System, DePuy Spine, Johnson & Johnson, Raynham, MA, USA (18)]; was used in 23% of cases, while other screw systems accounted for the remaining 4%. Bone cement was injected into the vertebral body through the fenestrations of the screws. For minimally invasive thoracic and lumbar instrumentation, two intraoperative C-arms (Ziehm Vision, Ziehm Imaging, Nuremberg, Germany) were routinely used to ensure accurate screw placement and controlled cement application. Computer-assisted navigation was employed in 6 patients (6%).

Cement injection technique. After insertion of the cannulated, fenestrated pedicle screws, the corresponding empty cement injection cannulas were inserted into the polyaxial screw heads. PMMA-based bone cement (PMMA; Vertecem V, Synthes GmbH, Oberdorf, Switzerland) was prepared and loaded into the injection cannulas, each with a capacity of 1.5 ml. To prevent uncontrolled cement flow into the screw heads –which could interfere with later rod insertion– the filled cannulas were only inserted after the screw heads had been sealed. Cement application was performed during the toothpaste-like phase of polymerization. Approximately 2 ml of cement was injected per screw. Cement distribution was continuously monitored using fluoroscopy after every 0.5 ml of injection. In the event of any signs of undesirable extravasation, the injection was immediately stopped.

PMMA-based bone cement. PMMA has been widely used since the 1960s due to its good biocompatibility, relatively low complication rates over the long term, and cost-effectiveness. Vertecem V+ is a PMMA-based, radiopaque bone cement designed for use in vertebroplasty and for pedicle screw augmentation. It offers good biocompatibility, rapid setting, and intraoperative stability. However, due to its bioinert nature, bone remodeling and osseointegration are limited. The kit includes a polymer powder containing zirconium dioxide and hydroxyapatite, as well as a monomer liquid; polymerization occurs *via* an exothermic reaction (19). Indications include osteoporotic fractures, osteolysis, and metastatic lesions. Contraindications include infections, spinal canal stenosis, and known allergies to any of the components. Major risks include cement extravasation, cardiovascular reactions, and thermal tissue damage. Despite the development of newer low-viscosity alternatives, PMMA often demonstrates superior results in biomechanical studies in terms of pull-out strength and resistance to failure (20).

Radiographic and complication assessment. We analyzed all available intraoperative fluoroscopic images, postoperative radiographs, CT scans to assess the occurrence and anatomical distribution of cement leakage following pedicle screw cement augmentation. To evaluate the diagnostic performance of intraoperative fluoroscopy in detecting cement leakage, we calculated its sensitivity, specificity, PPV, NPV, and overall accuracy, using postoperative radiographs and CT scans as reference standards. In addition, logistic regression analysis was performed to identify independent risk factors associated with cement leakage. The model included the following covariates: patient age, sex, BMI,

spinal region involved, and the number of augmented screws. All statistical analyses were conducted using R (R Foundation for Statistical Computing, Vienna, Austria).

Results

A total of 96 patients were analyzed (Table I). There were 59 female (62%) and 37 male (39%) patients. The mean age was 78±8 years. The mean BMI was 27±24 kg/m^2. A total of 69 patients (72%) had received a diagnosis of osteoporosis. The average operation time was 118±56 min, and the average radiation time was 5±3 min. Mean intraoperative blood loss was 180±204 ml; only one patient (1%) experienced blood loss exceeding 1000 ml. According to the ASA Physical Status Classification System, 15 patients (16%) were classified as ASA II; 67 patients (71%) as ASA III; 11 patients (12%) as ASA IV; and the one patient (1%) as ASA V.

A total of 496 pedicle screws were implanted, with 460 of them receiving cement augmentation (Table II). In terms of the implants and systems used, Medtronic CD Horizon Longitude was employed in 69% of cases, DePuy Synthes Viper in 23% of cases, Medtronic CD Horizon Sextant in 4%, while a different system was used in the remaining 4% of cases. Computer navigation was used in six patients (6%).

The thoracic spine was instrumented in 37 patients (39%); the lumbar spine in 52 patients (55%): and the thoracolumbar section was instrumented in six patients (6%). In terms of the number of levels that were instrumented, 61 patients (64%) received instrumentation across two levels: six patients (6%) across three levels; 25 patients (26%) across four levels; and three patients (3%) across five levels (Table III).

Complications. There was one intraoperative complication involving cardiorespiratory insufficiency in a patient in whom no leakage was detected. Two patients died within 30 days of surgery (2%) (in one case due to complications of aspiration and cardiorespiratory failure; in another case, after cardiorespiratory resuscitation with resulting hypoxic brain injury due to ARDS and sepsis). Surgical revision was conducted in four patients (4%): three hematoma evacuations and one wound debridement. No revisions were implant- or cement-related (Table IV).

Cement leakage. Cement leakage was detected in intraoperative fluoroscopy images in 43% of patients (33 of 76 patients with available images). Postoperative

Table I. *Patient demographics and surgical data.*

Variable	Value
Total patients, n	96
Age, years (mean±SD)	78±8
Sex, n (%)	
Female	59 (62%)
Male	37 (39%)
BMI, kg/m^2 (mean±SD)	27±24
Diagnosed with osteoporosis, n (%)	69 (72%)
Surgery duration, min (mean±SD)	118±56
Radiation time, min (mean±SD)	5±3
Blood loss, ml (mean±SD)	180±204
Use of computer navigation, n (%)	6 (6%)

SD: Standard deviation; BMI: body mass index.

Table II. *Instrumentation and implant systems used.*

Variable	Value
Total pedicle screws placed, n	496
Cement-augmented screws, n	460
Implant systems used, %	
Medtronic CD Horizon Longitude	69%
DePuy Synthes Viper	23%
Medtronic CD Horizon Sextant	4%
Other system	4%
Instrumented spinal regions, n (%)	
Thoracic spine	37 (39%)
Lumbar spine	52 (55%)
Thoracolumbar junction	6 (6%)

Table III. *Number of instrumented levels.*

Levels instrumented	n (%)
2 levels	61 (64%)
3 levels	6 (6%)
4 levels	25 (26%)
5 levels	3 (3%)

Table IV. *Complications in patients (n=96) with thoracolumbar fractures treated with posterior stabilization and cement augmentation of pedicle screws.*

Complication	n (%)
Intraoperative cardiopulmonary insufficiency	1 (1%)
30-day mortality	2 (2%)
Surgical revisions	4 (4%)
Hematoma evacuation	3
Wound debridement	1
Implant- or cement-related revision rate	0%

Table V. *Cement leakage by imaging modality.*

Imaging modality	Leakage rate
Intraoperative fluoroscopy	43% (33/76 patients)
Postoperative X-ray	63% (54/86 patients)
Postoperative CT	91% (39/43 patients)
Combined (X-ray+CT)	76% (71/93 patients)

Table VI. *Diagnostic performance of intraoperative images.*

	vs. Postop CT n=32	*vs.* Postop X-rays n=66	*vs.* Postop X-rays+CT n=73
Sensitivity	0.46	0.63	0.55
Specificity	1.00	0.96	0.94
	vs. Postop CT n=32	*vs.* Postop X-rays n=66	*vs.* Postop X-rays+CT n=73
PPV	1.00	0.96	0.97
NPV	0.21	0.58	0.39
Accuracy	0.53	0.74	0.64

radiographs showed a leakage rate of 63% (54 of 86 patients). The rate of leakage in postoperative CT scans was 91% (39 of 43 patients). The leakage rate in all postoperative images combined (radiographs and CT scans) was 76% (71 of 93 patients) (Table V). The diagnostic performance of intraoperative fluoroscopy for detecting cement leakage is summarized in Table VI. Logistic regression analysis revealed age as a significant risk factor for cement leakage (p=0.0109). Sex, BMI, instrumented spinal region and the number of cemented screws were not significant predictors of leakage (p>0.05).

Discussion

The aim of the present study was to evaluate the rate of cement leakage and associated complications following cement-augmented pedicle screw instrumentation in thoracolumbar fractures. The main findings of this retrospective analysis of 96 patients include a comparatively low rate of severe complications despite a high incidence of cement leakage, as well as the identification of age as the only independent risk factor for cement extravasation.

Cement leakage. A comparison with previous studies. The analysis revealed a cement leakage rate of 76% in the available postoperative imaging (X-ray+CT), which is consistent with the existing literature. Previous studies have reported leakage rates between 30% and 94% for augmented screws (21, 22).

Interestingly, despite the relatively high incidence of radiologically detectable cement extravasation in our cohort, no serious cement-associated complications such as neurological deficits or pulmonary cement embolism occurred. This finding underscores the important distinction between radiological leakage and clinically relevant leakage. The majority of documented extravasations were asymptomatic, which is consistent with previous data (23). This suggests that not every radiologically visible leakage has clinical relevance, provided the cement application protocol is strictly followed.

Explanation for the low rate of serious complications. The low rate of severe complications in our study may be attributable to several factors: (i) Strict intraoperative control using lateral fluoroscopy: Each cement injection was carefully monitored in 0.5 ml increments – an approach that likely allowed for early detection and immediate cessation of injection upon the first signs of leakage; (ii) Toothpaste-like consistency of the PMMA cement: The use of high-viscosity PMMA (Vertecem V+, Synthes) has been

shown to reduce the rate of cement migration beyond the screw fenestrations (24); (iii) Technical details of the implants: The use of cannulated and fenestrated screws with controlled cement application into the screw shaft allows for targeted cement distribution within the vertebral body (iv) Experienced surgical team: All procedures were performed at a university-level tertiary care center, indicating a high degree of standardized technique and surgical expertise (25).

Diagnostic accuracy of intraoperative fluoroscopy. An important methodological aspect was the analysis of the diagnostic accuracy of intraoperative fluoroscopy. The sensitivity was only 43%, meaning that more than half of the leakages were not detected intraoperatively. This finding indicates that intraoperative fluoroscopy alone is not sufficiently sensitive for detecting cement leakage– especially in the case of small or ventrally directed extravasations (26). Postoperative CT was found to be significantly more sensitive and should therefore be included in routine follow-up when there is clinical suspicion of a relevant leakage.

Risk factors for cement leakage. Multivariate regression analysis identified advanced age as a significant predictor for cement leakage (p=0.0109). This can be explained by the increasingly porous architecture of osteoporotic vertebrae with age, which increases the risk of cement migration. Neither sex, nor the region of instrumentation, nor the number of augmented screws showed a significant influence.

Limitations. First, its retrospective design carries an inherent risk of selection bias and limits the ability to establish causal relationships. Second, the sample size was relatively small, particularly for navigated procedures, which restricts statistical power and limits the generalizability of the findings. Third, the use of different imaging modalities –namely intraoperative fluoroscopy, postoperative radiographs, and CT scans– with varying sensitivities may have introduced variability in the detection of cement leakage. Additionally, the study was conducted at a single tertiary care center with an experienced surgical team, which may limit applicability to other institutions with different levels of expertise.

Conclusion

The present study confirms that cement augmentation for osteoporotic thoracolumbar fractures is a safe and effective technique–especially when standardized application techniques and careful intraoperative imaging are employed. Despite a high rate of radiological leakage, the rate of clinically relevant complications was extremely low. These findings further emphasize the need for a differentiated view of radiological *versus* clinical leakages and highlight the limited utility of intraoperative fluoroscopy alone for reliably detecting such events.

Conflicts of Interest

The Authors declare that they have no competing interests in relation to this study.

Authors' Contributions

Richard Zaccaria conceived and designed the study, collected and analyzed the data, and drafted the manuscript. Eduardo Suero contributed substantially to study conception and design, supervised the project, and critically revised the manuscript for important intellectual content. The remaining authors contributed to data collection and interpretation and critically reviewed the manuscript. All Authors approved the final version of the manuscript.

Artificial Intelligence (AI) Disclosure

During the preparation of this manuscript, a large language model ChatGPT (OpenAI, San Francisco, CA, USA) was used solely for language editing and stylistic improvements in select paragraphs. No sections involving the generation,

analysis, or interpretation of research data were produced by generative AI. All scientific content was created and verified by the authors. Furthermore, no figures or visual data were generated or modified using generative AI or machine learning-based image enhancement tools.

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