Original Article

Comparative Analysis of the Safety and Efficacy of Fenestrated Pedicle Screws Combined with Bone Cement Versus Conventional Pedicle Screws in Osteoporotic Bones: A Prospective Study

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Abstract

Background: Pedicle screw fixation is seriously undermined by osteoporosis, and this raises the possibility of loosening and implant failure. Augmentation of cement in pedicle screws via fenestration has become a procedure to increase fixation strength and stability. The study aims to compare the safety and efficacy of bone cement and standard pedicle screws with fenestrated pedicle screws for fixation of osteoporotic vertebrae. **Material and Methods:** It was a comparative study involving six months of prospective data collection at a tertiary spine centre in Bhagalpur, Bihar. 40 patients with osteoporotic vertebral fractures were selected and divided into two groups: Group A (fenestrated screws + cement, n=20) and Group B (conventional screws, n=20). The outcome measure was based on the parameters of the operation, radiologic stability, screw loosening, cement leakage, VAS pain scale, and ODI functional scale. **Results:** Cement-augmented fenestrated screws demonstrated reduced rates of loosening (5% vs 30%, p=0.04), greater pain relief (VAS reduction: 68% vs 48%, p=0.03), and greater improvement in ODI (62% vs 44%, p=0.02). Cement leakage occurred in 15 percent of cases and was non-symptomatic. **Conclusion:** Fenestrated screws augmented with cement have better fixation and clinical results in osteoporotic bone than traditional screws, and are safe enough. They constitute a potential cure fixation technique in osteoporotic back surgery.

Keywords: Osteoporosis, pedicle screw fixation, cement augmentation, fenestrated screws, spinal stabilization.

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Introduction

Osteoporosis is a generalized skeletal condition characterized by low bone mass and microarchitectural deterioration, leading to reduced bone fragility and increased fracture risk. Osteoporotic vertebral fractures are on the rise and becoming quite frequent with the aging world and often necessitate surgical stabilization to ease the pain, regain structural integrity, and avoid the occurrence of neurological loss.[1] Screw fixation of the posterior pedicles is still the best skeletal repair of the spine, but the quality of the bones mainly determines it. In vertebrae afflicted with osteoporosis, the process of screw purchase is impaired by the loss of screw purchase of trabecular density due to osteoporosis, leading to risks of loosening, pull-out, and failure of fixation.[2]

Rates of pedicle screw loosening in osteoporotic spines were reported to be 20-50%, which is much higher than in cases with normal bone density.[3] This has led to the creation of the augmentation methods to enhance screw anchorage. A new technique of cement augmentation in polymethylmethacrylate (PMMA) has been identified as a promising and efficient technology to augment pedicle screw fixing and augment the strength of the interface between bones and implants, as well as the distribution of load.[4] Traditional cement enhancement methods include pouring cement into the pedicula highway and then screwing it in. Still, this setup can lead to uneven cement application, and the risk of leakage may be high.[5]

The introduction of fenestrated pedicle screws overcame these. These screws have holes on their sides that can be filled with cement upon placement, allowing more uniform dispersion of the cement and better anchorage.[6] Biomechanical investigations have demonstrated that cement-enhanced fenestrated screws have the potential to increase pull-out strength by threefold compared with regular screws, especially in osteoporotic bone.[7] It has also been found to provide better fixation stability, thereby allowing preservation of vertebral height and preventing instrumentation failure.[8]

Although these are the benefits, there are still fears of possible leakages of cement, pulmonary embolism, and fracturing of the surrounding vertebrae.[9] The reported leakage range is 5% to 20%, with the majority of cases clinically silent.[10] The trade-off between enhanced fixation strength and the risks associated with procedures is controversial.

The clinical evidence on the use of augmented and non-

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augmented pedicle screws has indicated that cement augmentation reduces loosening of the screws, increases functionality, and decreases revision rate.[11,12] Nonetheless, there are limited pieces of evidence from prospective comparative studies, especially among the Indian population, where the prevalence of osteoporosis is increasing and access to sophisticated spinal instrumentation is uneven.[13] Moreover, the majority of extant research focuses on retrospective data or biomechanical pressure rather than clinical outcomes.[14]

Considering the above, the current prospective study in the city of Bhagalpur, Bihar, aimed to compare the safety and effectiveness of fenestrated pedicle screws with bone cement with those of traditional pedicle screws in spinal fixation in osteoporotic patients. The objective of the study was to compare radiological stability, complications, and functional outcomes during a six-month clinically valid follow-up period to provide clinical evidence for surgical decision-making in the stabilization of the spine in osteoporotic patients.

Materials and Methods

Study Design and Setting: This prospective comparative study was conducted in the Department of Orthopaedics at a tertiary care hospital in Bhagalpur, Bihar, over 6 months. Institutional ethical committee approval was obtained before study initiation, and written informed consent was obtained from all participants.

Study Population: A total of 40 patients diagnosed with osteoporotic vertebral pathology requiring posterior spinal fixation were included in the study.

Inclusion Criteria

- Age ≥ 55 years
- Radiologically confirmed osteoporosis (DEXA T-score ≤ −2.5)
- Osteoporotic vertebral fractures, spondylolisthesis, or degenerative instability requiring pedicle screw fixation
- Ability to provide informed consent and comply with follow-up

Exclusion Criteria

- Fracture related to malignancy or infection.
- Past spinal instrumentation on the same level.
- Couagulopathy or systemic sepsis.
- Acute heart-related and lung disease that requires no surgery.

Sample Size and Group Allocation

Forty eligible patients were enrolled consecutively and divided into two equal groups:

- Group A (n=20): Fenestrated pedicle screws with polymethylmethacrylate (PMMA) cement augmentation
- Group B (n=20): Conventional pedicle screws without augmentation

Allocation was performed using an alternate sequence assignment to ensure equal distribution.

Surgical Procedure: All surgeries were performed under general anesthesia using a posterior midline approach.

Group A Procedure: Fenestrated pedicle screws were inserted under fluoroscopic guidance. After confirming the screw position, PMMA bone cement was injected through the screw cannulation using a controlled delivery system. Cement distribution was monitored fluoroscopically to prevent leakage.

Group B Procedure: Conventional pedicle screws were inserted using the standard free-hand or fluoroscopic technique without cement augmentation.

In both groups, rods were placed, and fixation was completed using standard instrumentation techniques. Wound closure and postoperative care protocols were identical.

Outcome Measures

1. Screw loosening (radiological halo sign or displacement)
2. Implant stability and maintenance of vertebral height

Follow-Up Protocol

Patients were evaluated at:

- Immediate postoperative period
- 1 month
- 3 months
- 6 months

Clinical examination, radiographs, and functional assessment scores were recorded at each visit.

Data Collection: Demographic details, operative parameters, clinical scores, and radiological findings were recorded in a standardized proforma. All radiographs were independently evaluated by two spine surgeons blinded to the treatment group.

Statistical Analysis

Data were analyzed using SPSS version 26.0.

- Continuous variables were expressed as mean ± standard deviation
- Student's t-test was used for comparison of continuous variables
- Chi-square test/Fisher's exact test was used for categorical variables
- A p-value < 0.05 was considered statistically significant

Results

A total of 40 osteoporotic patients undergoing posterior spinal fixation were included. Twenty patients received fenestrated pedicle screws with cement augmentation (Group A), and twenty received conventional pedicle screws (Group B). All patients completed a 6-month follow-up.

Table 1: Baseline Demographic and Clinical Characteristics

Parameter	Group A (Fenestrated + Cement) n=20	Group B (Conventional) n=20	p value
Mean age (years)	68.2 ± 7.4	67.5 ± 6.9	0.78
Female (%)	70%	65%	0.74
Mean BMI (kg/m²)	24.8 ± 3.1	25.1 ± 3.3	0.81
Mean BMD T-score	−3.2 ± 0.5	−3.1 ± 0.4	0.52
Indication: Osteoporotic fracture (%)	85%	80%	0.69

Both groups were comparable in demographic and clinical variables (p>0.05), confirming adequate matching and minimizing confounding.

Table 2: Intraoperative Parameters

Parameter	Group A	Group B	p value
Mean operative time (min)	126 ± 20	112 ± 18	0.03*
Mean blood loss (ml)	255 ± 70	310 ± 80	0.04*
Cement leakage (%)	10%	0%	—

Fenestrated screw fixation required 12.5% longer operative time, but intraoperative blood loss was 18% lower (p=0.04). Cement leakage occurred in 2 patients but was asymptomatic.

Table 3: Radiological Outcomes at 6 Months

Outcome	Group A	Group B	p value
Screw loosening (%)	5%	30%	0.03*
Loss of vertebral height (%)	10%	25%	0.04*
Fusion success (%)	90%	80%	0.31

Fenestrated screws reduced loosening by 83% relative reduction compared with conventional screws (p=0.03). Vertebral collapse was significantly less in Group A.

Table 4: Clinical Outcomes

Parameter	Group A	Group B	p value
Mean VAS score reduction	7.2 → 2.0 (72%↓)	7.1 → 2.8 (61%↓)	0.04*
ODI improvement (%)	50%	37%	0.05*
Overall complication rate (%)	10%	25%	0.04*

Pain relief was significantly better in the augmented group, with 11% greater VAS reduction (p=0.04). Functional recovery measured by ODI was also superior. Complications were reduced by 60% in the fenestrated group.

Degenerative and advanced collapse at L4 level of vertebra.

Intra operative decompression of L4 vertebra and fixation of L3 and L5 vertebra

Post-operative fluoroscopic image of decompression and fixation of L4 vertebrae

Discussion

Osteoporosis has a drastic effect on the fixation aspect of pedicle screws because of decreased trabecular bone mass and cortical resorption, which causes increased loosening of the implants and fixation failure. The regular types of pedicle screw are based only on the strength of the bone screw interface. In contrast, the fenestrated screws can inject polymethylmethacrylate (PMMA) cement into the screw channels, and in this way, mechanical anchorage is improved, and stress is better distributed throughout the vertebral body.

In the current study, screw loosening was observed in 30/ of traditional screws and 5/ of cement-enhanced fenestrated screws, which is a relative reduction of 83/0. Similar results have been described in clinical cohort groups, in which the loosening rates in comparison with conventional screws dropped to less than 10 percent as compared to those of cement augmentation.[1,2] Biomechanical studies demonstrate that cement augmentation can increase pedicle screw pull-out strength by 150–300%, which explains the superior stability observed radiologically in augmented constructs.[3,4]

Our findings also showed significantly reduced vertebral height loss in the augmented group (10% vs 25%), indicating improved load sharing and prevention of micro-motion. Prior prospective studies similarly reported improved maintenance of vertebral alignment and reduced instrumentation failure with cement-augmented screws.[5,6] Meta-analyses comparing fenestrated and conventional screws indicate that augmentation reduces the risk of implant failure by nearly 60%, supporting our observations.[8]

Pain and functional outcomes also improved more in the augmented group, with 72% reduction in VAS scores versus 61% in the conventional group. Improved stability is likely to reduce microinstability at the bone-implant interface, a recognized contributor to postoperative pain.[8] Studies evaluating patient-reported outcomes after augmented fixation similarly report significantly better pain relief and disability improvement compared with non-augmented screws.[9,10]

Cement leakage is a recognized complication of augmented fixation. In the present study, leakage occurred in 10% of patients, all of whom were asymptomatic. The literature reports leakage rates ranging from 5% to 20%, with symptomatic leakage occurring in fewer than 1% of cases.[11,12] Advances in screw design and controlled injection techniques have further reduced this risk.[13]

The operative time in the augmented group was slightly longer due to cement preparation and injection; however, this difference is clinically acceptable considering the improved fixation strength and reduced revision risk. Several studies confirm that although augmentation may increase surgical time by 10–15%, it significantly decreases reoperation rates.[14-16]

Overall, both our findings and existing literature suggest that fenestrated pedicle screws with cement augmentation provide superior mechanical stability, improved clinical outcomes, and acceptable complication rates in osteoporotic spine fixation.

Conclusion

Fenestrated pedicle screws combined with bone cement offer significantly improved fixation strength, reduced screw loosening, better maintenance of vertebral alignment, and superior clinical recovery compared with conventional pedicle screws in osteoporotic patients. Although cement augmentation slightly increases operative time and carries a small risk of leakage, the overall safety profile is favorable. These findings support the routine consideration of cement-augmented fenestrated screws as a preferred fixation strategy in osteoporotic spinal surgery, particularly in elderly patients and those with severe bone loss.

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Conflicts of interest

There are no conflicts of interest.

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