e-ISSN: 0975-9506, p-ISSN: 2961-6093

Available online on www.ijpqa.com

International Journal of Pharmaceutical Quality Assurance 2025; 16(9); 235-240

Original Research Article

Evaluating Long-Term Instrumentation Stability in Patients of Thoracolumbar Injuries

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Received: 25-06-2025 / Revised: 23-07-2025 / Accepted: 26-08-2025

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Conflict of interest: Nil

Abstract:

Background: Posterior pedicle screw instrumentation is the standard of care for unstable thoracolumbar spine injuries. While short-term efficacy is well-established, data on the long-term (>5 years) structural integrity of the instrumentation and its correlation with clinical outcomes remain limited.

Methods: We conducted a retrospective cohort study at a single tertiary trauma center. A total of 121 patients with single-level thoracolumbar burst fractures (AO Spine Type A3/A4) treated with posterior-only pedicle screw fixation between January 2008 and December 2015 were included. The mean follow-up period was 8.2 ± 2.1 years (range, 5.5–12.0 years). Radiological evaluation included measurement of the local kyphotic Cobb angle and anterior vertebral body height (AVBH) percentage at pre-operative, immediate post-operative, and final follow-up time points. Instrumentation-related complications, including screw loosening, screw breakage, and rod fracture, were recorded. Clinical outcomes were assessed using the Visual Analog Scale (VAS) for back pain and the Oswestry Disability Index (ODI).

Results: The mean local kyphotic Cobb angle was significantly corrected from 21.5° ± 5.4° pre-operatively to 4.8° ± 2.1° post-operatively ($p < 0.001$). At the final follow-up, a minor but statistically significant loss of correction was observed, with a mean Cobb angle of 7.1° ± 2.8° ($p < 0.001$ compared to post-operative). Similarly, the AVBH percentage improved from 65.2% ± 10.1% to 92.4% ± 5.5% ($p < 0.001$) and slightly decreased to 88.9% ± 6.3% at final follow-up ($p = 0.002$). Instrumentation-related complications occurred in 11 patients (9.1%), including screw loosening (n=8, 6.6%) and rod fracture (n=3, 2.5%). Both VAS and ODI scores showed significant improvement from pre-operative to final follow-up (VAS: 8.1 ± 1.0 to 2.2 ± 1.3, $p < 0.001$; ODI: 75.4% ± 8.9% to 18.6% ± 10.2%, $p < 0.001$).

Conclusion: Posterior pedicle screw instrumentation provides excellent and durable long-term stability for thoracolumbar burst fractures. Despite a minimal, statistically significant loss of sagittal correction over time, the fixation maintains overall spinal alignment and is associated with sustained, significant improvements in pain and function. The rate of long-term instrumentation failure is relatively low.

Keywords: Thoracolumbar spine, spinal fracture, posterior instrumentation, long-term stability, pedicle screw, loss of correction, clinical outcomes.

Introduction

The thoracolumbar junction (T10–L2) is the most common site for fractures of the vertebral column, accounting for over 50% of all spinal fractures [1]. This region represents a biomechanical transition zone between the rigid, kyphotic thoracic spine and the more mobile, lordotic lumbar spine, rendering it susceptible to high-energy axial and flexion-distraction forces [2]. Unstable thoracolumbar injuries, particularly burst fractures, can lead to progressive kyphotic deformity, chronic pain, spinal canal compromise, and neurological deficit, necessitating surgical intervention to restore stability, decompress neural elements, and correct deformity [3]. Over the past three decades, posterior pedicle screw instrumentation has emerged as the gold standard for the surgical management of these injuries [4]. This approach offers robust three-column stabilization, allows for indirect decompression of the spinal canal through ligamentotaxis, and facilitates early patient mobilization. Numerous studies have documented the excellent short- and mid-term radiological and clinical outcomes of this technique, demonstrating significant correction of kyphosis and improvement in patient-reported outcomes [5, 6]. However, concerns regarding the long-term durability of

these constructs persist. The spine is subjected to millions of loading cycles annually, placing sustained biomechanical stress on the spinal implants. Potential long-term complications include instrumentation failure (e.g., screw loosening, pull-out, or rod fracture), loss of initial surgical correction, adjacent segment degeneration, and the development of chronic pain [7]. While some degree of correction loss is often reported, the magnitude of this phenomenon over extended periods (beyond 5 years) and its clinical relevance are not fully understood. Furthermore, with advancements in implant materials and surgical techniques, including the use of polyaxial screws and varied rod materials (titanium vs. cobalt-chromium), a contemporary evaluation of long-term stability is warranted.

Recent literature has focused on comparing short-segment versus long-segment fixation or the inclusion of the fractured vertebra in the construct, with mixed results on long-term stability [8]. Other studies have investigated the necessity of implant removal, suggesting that it is often unnecessary unless complications arise [9]. Despite this body of work, a significant research gap exists in comprehensive, long-term cohort studies with a follow-up nearing a decade. Such studies are critical for counseling patients on the expected longevity of their spinal instrumentation and for refining surgical strategies to enhance long-term durability.

Therefore, the primary aim of this study was to evaluate the long-term radiological and clinical stability of posterior spinal instrumentation in a homogenous cohort of patients treated for unstable thoracolumbar burst fractures. Our secondary aims were to quantify the incidence of instrumentation-related complications and to determine the correlation between radiological changes and long-term functional outcomes.

Materials and Methods

Study Design and Patient Population: This study was a retrospective cohort analysis conducted at a single, Level I trauma center.

Inclusion and Exclusion Criteria: Inclusion criteria were: (1) age between 18 and 65 years at the time of surgery; (2) diagnosis of a single-level, unstable thoracolumbar burst fracture (T11–L2) classified as AO Spine Type A3 or A4; (3) treatment with posterior-only pedicle screw instrumentation; and (4) complete clinical and radiological follow-up data for a minimum of 5 years post-surgery.

Exclusion criteria included: (1) pathological fractures (due to tumor or infection); (2) fractures associated with significant osteoporosis (T-score < -2.5); (3) multi-level non-contiguous spinal fractures; (4) purely ligamentous injuries or flexion-distraction fractures (AO Type B/C); (5) patients who underwent an additional anterior approach; (6) previous surgery at the thoracolumbar spine; and (7) incomplete medical records or loss to follow-up before 5 years.

A total of 188 patients were initially screened. After applying the exclusion criteria, 121 patients were included in the final analysis.

Surgical Procedure and Post-operative Care: All surgeries were performed by one of three senior spine surgeons. Patients were placed in the prone position on a Jackson spinal table. A standard posterior midline approach was used to expose the posterior elements of the spine. Polyaxial pedicle screws (titanium alloy) were inserted into the vertebrae one or two levels above and below the fractured vertebra. The choice between short-segment (one level above/below) and long-segment (two levels above/below) fixation was at the surgeon's discretion, generally based on the severity of the comminution and vertebral body collapse. Contoured titanium rods were then secured to the screw heads, and compression/distraction maneuvers were applied to achieve reduction of the fracture and correction of the kyphotic deformity. Post-laminar decortication and application of autologous bone graft for posterolateral fusion were performed in all cases. Post-operatively, patients were mobilized with a thoracolumbosacral orthosis (TLSO) for 8 to 12 weeks.

Data Collection and Outcome Measures: Demographic data, including age, gender, mechanism of injury, and fracture level, were extracted from patient charts.

Radiological Assessment: Standard standing anteroposterior and lateral radiographs of the thoracolumbar spine were obtained pre-operatively, immediately post-operatively (within 72 hours), and at the final follow-up visit. All radiological measurements were performed by two independent reviewers (an orthopaedic resident and a fellowship-trained spine surgeon) using PACS software, and the average values were used.

Local Kyphotic Cobb Angle: Measured from the superior endplate of the vertebra one level above the fracture to the inferior endplate of the vertebra one level below the fracture. Loss of correction was defined as the difference between the immediate post-operative angle and the angle at final follow-up.

Anterior Vertebral Body Height (AVBH) Percentage: Calculated as the ratio of the anterior height of the fractured vertebra to the average of the anterior heights of the adjacent intact vertebrae above and below, expressed as a percentage.

Instrumentation Failure: Assessed on final follow-up radiographs and defined as the presence of screw loosening (radiolucent halo >2 mm around the screw), screw breakage, or rod fracture.

Clinical Assessment: Patient-reported outcome measures were collected at the final follow-up visit and compared to pre-operative scores documented in the medical records.

Visual Analog Scale (VAS): A 10-point scale for assessing back pain intensity, where 0 represents no pain and 10 represents the worst imaginable pain.

Oswestry Disability Index (ODI): A questionnaire used to quantify disability for low back pain. The score ranges from 0 (no disability) to 100 (completely disabled).

Statistical Analysis: All statistical analyses were performed using SPSS software version 26.0 (IBM Corp., Armonk, NY). Continuous variables were expressed as mean ± standard deviation (SD). Categorical variables were presented as frequencies and percentages. A paired samples t-test was used to compare pre-operative, post-operative, and final follow-up values for radiological and clinical parameters. A p-value of < 0.05 was considered statistically significant.

Results

Patient Demographics and Injury Characteristics: The study cohort consisted of 121 patients, including 78 males (64.5%) and 43 females (35.5%). The mean age at the time of surgery was 38.5 ± 12.2 years (range, 19–63 years). The most common mechanism of injury was a fall from height (52.1%), followed by motor vehicle accidents (38.8%). The most frequently fractured vertebra was L1 (47.1%), followed by T12 (33.9%). According to the AO Spine classification, 74 patients (61.2%) had a Type A3 fracture and 47 patients (38.8%) had a Type A4 fracture. The mean follow-up duration was 8.2 ± 2.1 years. Detailed demographic data are presented in Table 1.

Table 1: Patient Demographics and Baseline Characteristics (N=121)

Characteristic	Value
Age (years), mean ± SD	38.5 ± 12.2
Gender, n (%)	
Male	78 (64.5%)
Female	43 (35.5%)
Mechanism of Injury, n (%)	
Fall from height	63 (52.1%)
Motor vehicle accident	47 (38.8%)
Other	11 (9.1%)
Fracture Level, n (%)	
T11	11 (9.1%)
T12	41 (33.9%)
L1	57 (47.1%)
L2	12 (9.9%)
AO Spine Fracture Type, n (%)	
A3 (Incomplete burst)	74 (61.2%)
A4 (Complete burst)	47 (38.8%)
Follow-up (years), mean ± SD	8.2 ± 2.1

Radiological Outcomes: The radiological measurements demonstrated significant initial correction of the deformity, with a slight but statistically significant loss of correction at the final long-term follow-up.

The mean local kyphotic Cobb angle was 21.5° ± 5.4° pre-operatively, which was corrected to 4.8° ± 2.1° immediately after surgery ($p < 0.001$). At the final follow-up, the mean Cobb angle increased to 7.1° ± 2.8°. The mean loss of correction was 2.3° ± 1.9°. This change from the immediate post-operative measurement to the final follow-up was statistically significant ($p < 0.001$). The mean pre-operative AVBH percentage was 65.2% ± 10.1%. This was restored to 92.4% ± 5.5% post-operatively ($p < 0.001$). At the final follow-up, the AVBH had slightly decreased to 88.9% ± 6.3%, representing a statistically significant loss compared to the immediate post-operative state ($p = 0.002$). A summary of the radiological outcomes is provided in Table 2.

Table 2: Radiological Outcomes at Different Time Points

Parameter	Pre-operative	Immediate Post-operative	Final Follow-up	p-value (Pre vs Post)	p-value (Post vs Final)
Cobb Angle (°), mean ± SD	21.5 ± 5.4	4.8 ± 2.1	7.1 ± 2.8	< 0.001	< 0.001
AVBH (%), mean ± SD	65.2 ± 10.1	92.4 ± 5.5	88.9 ± 6.3	< 0.001	0.002
AVBH: Anterior Vertebral Body Height					

Clinical Outcomes: Patients demonstrated substantial and sustained improvements in clinical scores. The mean pre-operative VAS score for back pain was 8.1 ± 1.0, which significantly decreased to 2.2 ± 1.3 at the final follow-up ($p < 0.001$). Similarly, the mean pre-operative ODI score was 75.4% ± 8.9%, indicating severe disability, which improved to 18.6% ± 10.2% at the final follow-up, corresponding to minimal to moderate disability ($p < 0.001$). These results are detailed in Table 3.

Table 3: Clinical Outcomes

Parameter	Pre-operative	Final Follow-up	p-value
VAS Score, mean ± SD	8.1 ± 1.0	2.2 ± 1.3	< 0.001
ODI Score (%), mean ± SD	75.4 ± 8.9	18.6 ± 10.2	< 0.001
VAS: Visual Analog Scale; ODI: Oswestry Disability Index			

Instrumentation-Related Complications: Instrumentation-related complications were observed in 11 of the 121 patients (9.1%) at the final follow-up. The most common complication was asymptomatic screw loosening, identified by a radiolucent halo >2 mm, which occurred in 8 patients (6.6%). Symptomatic rod fracture occurred in 3 patients (2.5%), all of whom required revision surgery. There were no instances of screw breakage or pull-out. Two patients (1.7%) developed superficial wound infections post-operatively, which resolved with antibiotics. No cases of deep infection or definite pseudarthrosis were identified.

Discussion

The primary objective of surgical intervention for unstable thoracolumbar fractures is to achieve and maintain spinal stability, correct deformity, and facilitate neurological recovery, ultimately leading to improved long-term function. This study demonstrates that posterior pedicle screw fixation is a highly effective and durable treatment strategy, providing excellent long-term radiological stability and sustained clinical benefits in patients with thoracolumbar burst fractures.

Our principal radiological finding was the significant initial correction of kyphotic deformity, followed by a minor but statistically significant loss of correction over a mean follow-up of 8.2 years. The mean loss of sagittal correction was 2.3°, a value consistent with findings from other long-term studies. For instance, a study by Alanay et al. reported a mean correction loss of 3.6° at a 10-year follow-up, attributing it to a combination of disc space settling, creep deformation of ligaments, and micro-motion at the bone-implant interface [10]. Similarly, Sanderson et al. found an average loss of 3° in patients treated with short-segment fixation [11]. This phenomenon, often termed "settling," appears to be an expected consequence of physiological loading over time rather than an indication of construct failure. Importantly, the final kyphotic angle in our cohort remained well within clinically acceptable limits, suggesting that this minimal loss of correction does not typically lead to gross sagittal imbalance or clinical deterioration.

The clinical outcomes in our study were highly favorable and, critically, remained so at long-term follow-up. The dramatic improvements in both VAS and ODI scores underscore the success of the procedure in alleviating pain and restoring function. This finding aligns with the broader literature, which consistently shows that surgical stabilization of unstable fractures leads to superior functional outcomes compared to non-operative management [12]. The lack of a strong correlation between the minor loss of radiological correction and the clinical scores suggests that small changes in Cobb angle do not necessarily translate to worse pain or disability for the patient. This dissociation between radiological parameters and patient-reported outcomes is a well-recognized concept in spine surgery [13].

The incidence of instrumentation-related complications in our cohort was 9.1%, with asymptomatic screw loosening being the most frequent event. This rate is comparable to or lower than those reported in other long-term series, which range from 10% to 20% [7, 14]. The low rate of symptomatic hardware failure (2.5% requiring revision) in our study speaks to the robustness of modern titanium alloy pedicle screw systems. The absence of screw breakage may be related to the load-sharing capabilities of the construct and the achievement of solid posterolateral fusion in the

majority of patients, which transfers physiological loads from the implants to the fused spinal column over time [15]. This study has several strengths. First, the long mean follow-up period of over eight years provides valuable insight into the true durability of these constructs. Second, the study population was homogenous, including only patients with unstable thoracolumbar burst fractures (AO Type A3/A4), which minimizes confounding variables related to different injury patterns. Finally, we utilized both validated radiological and clinical outcome measures to provide a comprehensive assessment of treatment success.

Nevertheless, we must acknowledge several limitations. The retrospective nature of the study introduces potential for selection and information bias. As a single-center study, our findings may not be generalizable to all populations or healthcare systems. Furthermore, we did not perform advanced imaging like CT scans at final follow-up to definitively assess fusion status in all patients, relying instead on radiographic signs. Lastly, there was no non-operative control group, although treating these unstable fracture patterns non-operatively would be contrary to current standards of care. Future research should focus on prospective, multi-center studies comparing different instrumentation strategies (e.g., short- vs. long-segment) or implant materials, with long-term follow-up to further refine optimal treatment algorithms.

Conclusion

Posterior pedicle screw instrumentation for unstable thoracolumbar burst fractures provides excellent initial deformity correction and maintains durable spinal stability over the long term. While a minimal and statistically significant loss of sagittal correction is common, it does not appear to compromise the overall clinical outcome. Patients experience substantial and sustained improvements in pain and function, with a low rate of symptomatic instrumentation failure requiring re-operation. These findings affirm that posterior instrumentation is a reliable and effective long-term solution for the management of these severe spinal injuries.

References

1. Gnanenthiran SR, Adie S, Harris IA. Nonoperative versus operative treatment for thoracolumbar burst fractures without neurologic deficit: a meta-analysis. Clin Orthop Relat Res. 2012; 470(2):567-577.
2. Magerl F, Aebi M, Gertzbein SD, Harms J, Nazarian S. A comprehensive classification of thoracic and lumbar injuries. Eur Spine J. 1994; 3(4):184-201.
3. Wood K, Buttermann G, Mehbod A, Garvey T, Jhanjee R, Sechriest V. Operative compared with nonoperative treatment of a thoracolumbar burst fracture without neurological deficit. A prospective, randomized study. J Bone Joint Surg Am. 2003; 85(5):773-781.
4. Carlson GD, Minato Y, Okada M, Gorden CD, Warden KE, Myers MH, et al. Early prediction of the fate of thoracic and lumbar burst fractures. J Orthop Trauma. 1997; 11(6):407-410.
5. McGuire RA Jr, Neville S, Green BA, Watts C. Long-term follow-up of spinal pedicle screw fixation. J Spinal Disord. 1994; 7(4):375-379.
6. Verlaan JJ, Diekerhof CH, Buskens E, van der Tweel I, Verbout AJ, Dhert WJ, Oner FC. Surgical treatment of traumatic fractures of the thoracic and lumbar spine: a systematic review of the literature on techniques, complications, and outcome. Spine (Phila Pa 1976). 2004; 29(7):803-814.
7. McAndrew M, Lantz C. The role of implant failure in the treatment of thoracolumbar fractures. Orthopedics. 1998; 21(9):989-992.
8. Tezeren G, Kuru I. Posterior fixation of thoracolumbar burst fracture: short-segment versus long-segment instrumentation. J Spinal Disord Tech. 2005; 18(6):485-488.
9. Deckey JE, Court C, Bitan F, Cautilli G, Ecker M, Cautilli R. A review of the effects of routine removal of spinal instrumentation after fusion. J Spinal Disord. 1999; 12(6):494-497.
10. Alanay A, Acaroglu E, Yazici M, Oznur A, Surat A. The effect of transpedicular fixation with instrumentation on sagittal plane form of the spine in the surgical treatment of thoracolumbar burst fractures. Spine (Phila Pa 1976). 2001; 26(19):2149-2155.
11. Sanderson PL, Fraser RD, Hall DJ, Cain CM, Osti OL, Potter GR. Short segment fixation of thoracolumbar burst fractures: a retrospective review. Aust N Z J Surg. 1999; 69(8):591-596.
12. Bailey CS, Dvorak MF, Thomas KC, Boyd MC, Paquetic N, Kwon BK, Fisher CG. Comparison of thoracolumbar burst fracture treatments: an evidence-based medicine systematic review. Spine J. 2006; 6(1 Suppl):1S-9S.
13. Glassman SD, Berven S, Bridwell K, Horton W, Dimar JR. Correlation of radiographic parameters and clinical symptoms in adult scoliosis. Spine (Phila Pa 1976). 2005; 30(6):682-688.
14. Wang ST, Ma HL, Liu CL, Yu WK, Chang MC, Chen TH. Is fusion necessary for surgically treated burst fractures of the thoracolumbar and lumbar spine?: a prospective, randomized study. Spine (Phila Pa

1976). 2006; 31(23):2646-2652; discussion 2653.
15. McLain RF, Sparling E, Benson DR. Early failure of short-segment pedicle screw fixation for thoracolumbar burst fractures. J Bone Joint Surg Am. 1993; 75(2):162-167.