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Original Research Article

Incidence and Clinical Outcomes of Hardware Failure After MIS-ATP Guided Multilevel Posterior Percutaneous Fixation in Adult Spinal Deformity: A Prospective Analysis

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Abstract:

Background: Minimally invasive surgical techniques are gaining acceptance for adult spine deformity treatment with the hopes of decreasing perioperative morbidity and improving recovery. The minimally invasive antepsoas (MIS-ATP) approach has been regarded as a reasonable alternative for multilevel posterior percutaneous fixation due to the soft tissue disruption it offers along with postoperative spinal stability. Hardware failure, including screw loosening, rod fracture, or construct instability is not well studied in the adult spine deformity population. **Objective:** Determine incidence of hardware failure in adult deformity receiving multilevel posterior percutaneous fixation via MIS-ATP with exploration of risk factors and clinical outcomes.

Methods: This was a single center, exceptional prospective observational study at Department of Orthopedics, Adesh Medical College and Hospital, Haryana, India that included a total of 128 adult patients with spine deformity undergoing multilevel posterior percutaneous fixation from January 2023 to December 2023, with a minimum follow up of 12 months. Hardware failure was defined as any radiographically confirmed loosening, breakage, or migration of a fixation. Clinical measures were gathered by Visual Analog Scale (VAS) for pain, Oswestry Disability Index (ODI), and radiographic corrections of deformity.

Results: Nineteen patients (14.8%) experienced hardware failure during follow-up. Loosening of the screw was the most common failure type (52.6%), followed by fracture of the rod (31.5%) and failure of the construct migration (15.9%). Increased body mass index (BMI), osteoporosis and number of instrumented levels were significant factors associated with hardware failure (p < 0.05). Patients with hardware failure had higher mean VAS and ODI scores than patients without failure, indicating worse functional outcomes. However, revision surgery restored stability and improved pain symptoms in the majority of patients.

Conclusion: Hardware failure is a clinically relevant complication following MIS-ATP guided multilevel posterior percutaneous fixation in adult spine deformity, with an incidence of approximately 15%. Patient-specific risk factors, particularly osteoporosis and obesity, significantly influence outcomes. Careful preoperative patient selection, optimization of bone quality, and construct planning are essential to reduce the risk of hardware-related complications.

Keywords: Adult Spine Deformity, MIS-ATP Approach, Multilevel Posterior Percutaneous Fixation, Hardware Failure, Screw Loosening, Rod Fracture, Minimally Invasive Spine Surgery.

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Introduction

Adult spine deformity (ASD) consists of a heterogeneous collection of spinal malalignment disorders, both sagittal and coronal, that commonly include chronic pain, neurological symptoms, and disability. ASD prevalence has increased in recent years due to both an aging community and recognition of spinal alignment as a determinant of overall function [1]. Although traditional open techniques for deformity correction are effective in

restoring alignment, their associated morbidity includes substantial blood loss, long operations, delayed recovery and/or paraspinal muscle injury. As a result, there is a progression to consider minimally invasive surgical (MIS) methods for selected patients [2]. Among these minimally invasive alternatives, the minimally invasive antepsoas (MIS-ATP) technique is a viable option for deformity correction. One benefit of the MIS-

ATP approach is that a retroperitoneal, antepsoas corridor allows for direct access to the vertebral column while minimizing damage to the psoas muscle or lumbar plexus. When paired with posterior percutaneous fixation, MIS-ATP develops lasting multilevel constructs with less tissue disruption and faster recovery profiles compared to open approaches [3]. There is also considerable literature supporting that it can achieve deformity correction and concurrently have decreased perioperative morbidity while improving patientreported outcomes. Regardless of these benefits, the durability of MIS-ATP constructs for long-term fixation remains a concern. Hardware-related complications, including screw loosening, rod fracture or breakage, and construct migration, are anticipated risks that adversely affect the stability and efficacy of surgical correction [4]. These complications can affect both functional and radiographic outcomes and often require revision, increasing the cost of care and patient morbidity. Previously, in open deformity surgery, rates of hardware failure have been in a range of 10% to 25%, however, large-scale outcomes data exist regarding these rates with MIS-ATP multilevel posterior percutaneous fixation [5]. Risk factors for hardware failure are multifactorial and include patient-related parameters such as age, bone quality, obesity, and comorbidities, as well as surgical factors including construct length, screw density, and rod contouring techniques. It is important to identify these predictors in the MI approach for surgical planning, as both patient selection and optimizing modifiable risk factors may significantly reduce complication rates. Moreover, it will refine perioperative counseling as well as influence postoperative surveillance strategies, considering the clinical impact of hardware failure, its effect on pain and disability, and its contribution to function recovery [6].

The purpose of this study was to prospectively explore the incidence, mechanisms, and clinical implications of hardware failure in adult spine deformity patients who receive multilevel posterior percutaneous fixation using the MIS-ATP method. Challenges and outcomes were recorded over a twelve-month period at a tertiary care hospital in India, and the study aimed to analyze radiographic as well as functional outcomes and explore predictor values important for hardware complications. The results should begin to address the gaps in the literature and provide support for spur of report surgical decision making and highlighting the safety and effectiveness of minimally invasive mechanisms in complex spinal deformity surgery.

Materials and Methods

Study Design and Setting: This study was a yearlong longitudinal observational study for one year conducted in the Department of Orthopedics, Adesh

Medical College and Hospital, Haryana, India. The study involved patients undergoing multilevel posterior percutaneous fixation for adult spine deformity by way of the minimally invasive antepsoas (MIS-ATP) approach.

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Study Population

A total of 128 consecutive patients were enrolled in the study. Inclusion criteria were:

- 1. Adults aged 18 years and above.
- 2. Radiographically confirmed diagnosis of adult spinal deformity (scoliosis, kyphosis, or combined deformities) requiring multilevel fixation.
- 3. Patients planned for MIS-ATP guided posterior percutaneous fixation involving at least three motion segments.
- 4. Ability to provide informed consent and willingness to adhere to follow-up protocol.

Exclusion criteria included:

- 1. History of previous spinal fusion or instrumentation at the intended levels.
- 2. Active infection, systemic malignancy, or metabolic bone disease other than osteoporosis.
- 3. Severe medical comorbidities precluding surgery.
- 4. Patients lost to follow-up before 12 months.

Preoperative Evaluation: Baseline demographic and clinical data were collected, including age, sex, body mass index (BMI), comorbidities, bone mineral density (BMD), and neurological status. Radiographic evaluation consisted of standing whole-spine anteroposterior and lateral radiographs, magnetic resonance imaging (MRI), and computed tomography (CT) scans to assess deformity parameters, spinal alignment, and bone quality. Functional status was measured using the Visual Analog Scale (VAS) for back pain and the Oswestry Disability Index (ODI).

Surgical Technique: All procedures were performed under general anesthesia with the patient in the lateral decubitus position. The MIS-ATP approach involved retroperitoneal dissection via the antepsoas corridor to access the intervertebral space. Appropriate discectomy and interbody fusion were performed where indicated. Posterior percutaneous fixation was achieved using multilevel pedicle screws and rods, introduced under fluoroscopic guidance. Rods were contoured as per deformity correction requirements, and final tightening was performed with attention to preserving alignment stability. construct Intraoperative neuromonitoring was used in all cases to minimize neurological complications.

Postoperative Care and Follow-up: All patients received standardized postoperative care, including pain management, early mobilization, and

prophylaxis for deep vein thrombosis. Serum calcium and vitamin D supplementation were provided in patients with osteoporosis. Follow-up evaluations were scheduled at 6 weeks, 3 months, 6 months, and 12 months postoperatively. At each visit, clinical assessment, VAS, ODI, and standing radiographs were obtained. CT scans were performed at 12 months or earlier if hardware failure was suspected.

Definition of Hardware Failure

Hardware failure was defined as any radiologically confirmed complication involving the instrumentation, including:

- 1. Pedicle screw loosening (radiolucent zone >2 mm around screw).
- 2. Rod fracture or breakage.
- 3. Construct migration or loss of fixation. Cases of screw pullout without clinical symptoms were also categorized under hardware failure.

Outcome Measures: Primary outcomes were the incidence and types of hardware failure during the 12-months follow-up. Secondary outcomes included identification of risk factors for failure and the clinical impact on pain, disability, and deformity correction.

Statistical Analysis: Data were analyzed using SPSS software (version 26.0). Continuous variables were expressed as mean \pm standard deviation, and categorical variables as frequencies and percentages. Chi-square or Fisher's exact test was

used to compare categorical data, while independent t-test or Mann–Whitney U test was used for continuous data. Logistic regression was employed to identify independent predictors of hardware failure. A p-value <0.05 was considered statistically significant.

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Results

A total of 128 patients with adult spine deformity underwent multilevel posterior percutaneous fixation using the MIS-ATP approach and were followed for at least 12 months. The mean age of the cohort was 58.2 years, with a slight female predominance. Most patients had underlying comorbidities such as osteoporosis and hypertension, and the average number of levels instrumented was 4.8.

Hardware failure occurred in 19 patients, accounting for an overall incidence of 14.8%. Screw loosening was the most frequent complication, followed by rod fracture and construct migration. Patients who experienced hardware failure were more likely to have higher body mass index, reduced bone mineral density, and a greater number of instrumented levels. Functional outcomes, measured by VAS and ODI, showed significantly poorer improvement in the hardware failure group compared to those without failure. Revision surgery was required in 12 of the 19 patients with hardware failure, while the remaining were managed conservatively with bracing and medical optimization.

Table 1: Demographic characteristics of the study population

Variable	Value (n = 128)
Mean age (years)	58.2 ± 10.6
Age range (years)	35–78
Sex (Male/Female)	56 / 72
Mean BMI (kg/m²)	27.4 ± 3.9
Osteoporosis (n, %)	42 (32.8%)
Hypertension (n, %)	37 (28.9%)
Diabetes mellitus (n, %)	29 (22.6%)

Table 2: Surgical characteristics

Variable	Value (n = 128)
Mean instrumented levels	4.8 ± 1.3
Range of levels instrumented	3–7
Interbody fusion performed	98 (76.5%)
Mean operative time (minutes)	210 ± 35
Mean blood loss (mL)	280 ± 90
Intraoperative complications	5 (3.9%)

Table 3: Incidence and types of hardware failure

Type of hardware failure	Number of patients	Percentage (%)
Screw loosening	10	52.6
Rod fracture	6	31.5
Construct migration/loss	3	15.9
Total	19	14.8

Table 4: Risk factors associated with hardware failure

Risk factor	Hardware failure (n=19)	No failure (n=109)	p-value
Mean age (years)	61.4 ± 9.2	57.7 ± 10.8	0.18
Mean BMI (kg/m²)	29.2 ± 4.1	27.0 ± 3.6	0.04
Osteoporosis (n, %)	12 (63.2%)	30 (27.5%)	0.01
Instrumented levels ≥ 5 (n, %)	13 (68.4%)	42 (38.5%)	0.02

Table 5: Functional outcomes comparison (12 months follow-up)

Outcome measure	Hardware failure (n=19)	No failure (n=109)	p-value
VAS score baseline	7.8 ± 1.2	7.6 ± 1.3	0.62
VAS score at 12 months	4.9 ± 1.1	2.6 ± 0.9	< 0.001
ODI baseline	58.2 ± 10.4	56.7 ± 9.8	0.49
ODI at 12 months	38.5 ± 7.2	24.1 ± 6.3	< 0.001

Table 6: Management of hardware failure

Management approach	Number of patients	Percentage (%)
Revision surgery	12	63.2
Conservative (brace, medical)	7	36.8

Table 7: Radiographic outcomes (Cobb angle correction)

Measurement	Preoperative (mean ± SD)	Postoperative (mean ± SD)	12 months follow-up
Cobb angle (degrees)	42.5 ± 9.6	15.2 ± 6.3	17.1 ± 6.9
Sagittal vertical axis (mm)	62.4 ± 18.7	28.6 ± 10.4	30.1 ± 11.2

Table 1 highlights the mean age of 58.2 years with a slight female predominance and frequent comorbidities, notably osteoporosis. Table 2 shows that the average number of instrumented levels was 4.8, with interbody fusion performed in most patients. Table 3 indicates an overall hardware failure rate of 14.8%, with screw loosening as the most common event. Table 4 demonstrates that higher BMI, osteoporosis, and longer constructs were significant predictors of hardware failure. Table 5 shows that patients with hardware failure had poorer VAS and ODI outcomes at 12 months compared to those without failure. Table 6 reveals that most hardware failures required revision surgery, though some were managed conservatively. Table 7 confirms that deformity correction was effectively achieved postoperatively, but slight loss of correction was observed in patients with hardware failure.

Discussion

This prospective research assessed the occurrence, risk variables, and clinical effects of hardware malfunctions after multilevel posterior percutaneous fusion with a minimally invasive antepsoas (MIS-ATP) approach for adult spinal deformity. We observed a hardware malfunction rate of around 15% of the cohort, with screw loosening being the most common. Rod fracture and malposition were the next most frequent causes, which demonstrates the influence of patient-specific risk factors such as obesity, osteoporosis, and construct length on the durability of MIS-based instrumentation [5]. The hardware malfunction rates in this investigation are

in agreement with complication rates historically reported for open posterior deformity- correction surgeries, where rates have traditionally ranged between 10% and 25%. Although minimally invasive approaches were created to decrease surgical trauma and recovery times, when extensive constructs are required, the incidence of hardwarerelated complications appears substantial. The MIS-ATP offers unique perioperative benefits compared to traditional methods such as reduced blood loss, a shorter length of stay, and less muscle dissection, however, the issue of durability of fixation for correction of a major deformity must be addressed [6]. Screw loosening, which is noted as greater than 50% of the hardware failures in the study, is also closely tied to osteoporosis. The loss of bone mineral density leads to difficulty with screw anchorage and eventually cause loosening over time. Bone quality should be optimized prior to surgery. Through medical management of calcium, vitamin D, and anti-resorptive or anabolic agents, coupled with intraoperative input like cement augmentation, will contribute in any way to mitigate this complication [7]. The second most prevalent mode of failure that was noted was rod fracture, which is related to biomechanical stresses also experienced with long constructs during the deformity corrections. There may be stress concentration at junctional zones that may impart fatigue failure, but especially in patients classified as obese or with larger deformities. The3 are strategies to mitigate this, including multi-rod constructs, transitional rods, and following appropriate restoration of sagittal alignment. Intraoperatively, it is also

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important to contour rods further to tie in with the physiological curvature of the spine, to lessen focal stress points that can lead to rod failure [8].

Migration and loss of fixation, while less frequently observed, were meant to be clinically significant because they were associated with instability and surgical revision in almost all patients. The burden of longer constructs (≥5 levels) in this group of patients is notable given the mechanical instability extensive instrumentation. associated with Techniques to biomechanically reinforce constructs, such as higher screw density or supplemental fixation at the lumbosacral junction, can be considered prior to instrument migration/fixation loss [9]. From a clinical perspective, hardware failure correlated with worse pain relief and improved functionality in our cohort, as demonstrated by significantly higher VAS and ODI scores at 12 months, compared to patients who did not experience hardware failure. This, once again, emphasizes how a patient's quality of life can be directly affected by instrumentation integrity, thus underscoring the importance of careful planning in regards to surgical approach and instrumentation to mitigate these complications. Although revision surgery was successful in restoring stability and improving symptoms for most patients, revising the surgical procedure increased treatment burden (overall), cost, and morbidity [10]. This article helps to address the gap in literature on hardware outcomes with MIS-ATP directed deformity correction. As a study purely on the perspective of MIS-ATP, the results help to highlight the positive aspects of its use—while acknowledging the limitations of the application in a practical, humanscale setting. Reformatted in this study, MIS-ATP can accomplish positive deformity correction, and minimizes surgical morbidity, hardware related complications—in particular, in a patient population with poor bone quality, obesity, or multilevel disease—remains an important concern [11]. There are important clinical implications in a study such as this, first is patient selection in regard to biological factors. Patients with severe osteoporosis, or with high BMI may not be appropriate candidates for long segment fixation while as a surgical team, we are not using preoperative optimization. The implants must be planned for the biomechanical environment when they are going to be put; especially related to the use of multi-rod constructs, screw density, and additional fixation as indicated. Lastly, part of the positive outcome was directly related to frequent follow up radiographs, which helped identify early implant failure and transition the surgical patient to an intervening strategy, prior to qualitative clinical deterioration [12].

The merits of the study include its prospective study design, standardized methodology, and sustained follow-up should include radiographic and functional outcomes. Nonetheless, limitations should also be discussed. While the 12-month follow-up is sufficient to detect most of the early failures, it is not enough time frame to analyze late complications, such as rod fatigue, which can occur at any time, but particularly over the one-year period. The study was also done at one tertiary care center, which may preclude the generalizability of the findings. Finally, while revisions were successful, no cost analysis was a part of this study, which would show the costs related to hardware failure.

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In summary, this study concludes MIS-ATP is a favorable option for minimally invasive management of adult spine deformity, but hardware failure is a significant clinical issue, especially in patients with obesity, osteoporosis, and large constructs. The patient factors must be improved, operative planning should be advanced, and biomechanical fixation should be further implemented to enhance long-term results.

Conclusion

This prospective study shows that hardware failure is a clinically relevant complication after multilevel posterior percutaneous fixation via the MIS-ATP approach in adults with spine deformities. The annual failure rate of 14.8% emphasizes the fact that although this is a minimally invasive technique, there is still a considerable risk of mechanical failure. The most common type of mechanical failure was screw loosening, followed by rod failure and construct migration. Important patient-specific traits including osteoporosis and obesity, as well as surgical factors such as the number of instrumented levels, were statistically strong predictors of hardware failure. Functional outcome measures including VAS and ODI were noted to be worse in patients who experienced hardware failure, although most patients noted improvement of symptoms after revision. Careful surgical patient selection, optimal bone health considerations, and thoughtful construct planning are important modifiable factors to reduce the risk of hardware failure in future cases and ultimately improve functional long-term outcomes.

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