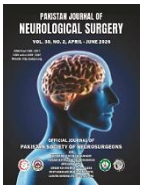

PAKISTAN JOURNAL OF NEUROLOGICAL SURGERY (QUARTERLY) – OFFICIAL JOURNAL OF PAKISTAN SOCIETY OF NEUROSURGEONS

Original Research

Evaluating the Safety and Efficacy of Stand-Alone Locking Cage in Single- and Multi-Level Anterior Cervical Discectomy and Fusion in the hands of a young Neurosurgeon: A Retrospective Study of 125 Cases

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ABSTRACT

Objective: Cervical degenerative spondylosis often requires surgical intervention after failed conservative management. Zero-profile stand-alone cages for anterior cervical discectomy and fusion (ACDF) offer stability with reduced implant bulk. This study evaluates clinical outcomes, fusion success, and determinants of outcomes following single- and multi-level ACDF using this technique.

Materials and Methods: This retrospective cohort Study of 125 patients undergoing ACDF with a zero-profile stand-alone cage was conducted at Swat Medical Complex Teaching Hospital and Swat Medical College, Swat, KPK. Clinical outcomes (Neck Disability Index, Visual Analogue Scale for pain, modified Japanese Orthopaedic Association score) and radiological fusion were assessed preoperatively and at 3, 6, and 9 months. Predictors of fusion failure and functional improvement were identified using multivariable regression analyses.

Results: Mean age was 49.2±8.7 years; 55.2% were male. Significant improvements occurred across all measures ($p<0.001$). Fusion rates were 90.1%, 80.0%, and 66.7% for single-level, two-level, and three-level procedures, respectively (trend $p=0.015$). Independent predictors of fusion failure were current smoking (odds ratio 3.35), multi-level surgery (odds ratio 3.74), and osteoporosis (odds ratio 4.66). Multi-level surgery was associated with significantly less Neck Disability Index improvement (3.21 points, $p=0.002$). The overall complication rate was 17.6%.

Conclusion: Zero-profile stand-alone cage ACDF is effective and safe, yielding high fusion rates and significant clinical improvement. Success is influenced by smoking, multi-level surgery, and osteoporosis, emphasizing the importance of patient selection and preoperative optimization.

Keywords: Anterior cervical discectomy and fusion; cervical spondylosis; fusion rate; neck disability index; stand-alone cage; zero-profile cage.

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Date of Submission: 07-02-2026
Date of Revision: 10-06-2026
Date of Acceptance: 11-06-2026
Date of Online Publishing: 16-6-2026
Date of Print: 30-6-2026

DOI: 10.36552/pjns.v30i2.1200

INTRODUCTION

The cervical spine is a complex anatomical structure designed to balance mobility with the protection of neural elements. The complex relations and intricate interplay between ligamentous structures, uncovertebral and facet joints, and intervertebral discs make it susceptible to age-related deterioration and degeneration.[1,2] A pathologic cascade is triggered over time by osteophytic proliferation at the spinal endplates, disc desiccation, and height loss.[3] Nerve roots or the spinal cord itself may be mechanically compressed as a result of these degenerative alterations, gradually narrowing the spinal canal and neural foramina.[1,2] The primary clinical syndromes of degenerative cervical spondylosis, cervical radiculopathy (characterized by radiating pain and sensory/motor deficits in a dermatomal distribution), and cervical myelopathy (characterized by gait instability, hand clumsiness, and potential long-tract signs) are fundamentally caused by this direct compression.[1-3] Degenerative cervical spondylosis imposes a substantial global health burden, with neck pain alone affecting an estimated 579.1 per 100,000 individuals annually and a point prevalence of 2,696.5 per 100,000 population, particularly among women and those aged 45–74 years.[1,2] This burden is projected to rise with aging populations, underscoring the growing demand for effective surgical interventions.[2] Conservative measures, including physical therapy, analgesics, and nerve root injections, serve as first-line treatment for cervical radiculopathy and myelopathy. However, surgery becomes necessary when patients exhibit progressive neurological deficits, refractory pain, or evidence of severe cord compression.[3] Anterior cervical discectomy and fusion (ACDF), first described by Smith and Robinson in the 1950s, remains the gold standard for surgical management, offering direct decompression of neural elements and restoration of segmental stability [2,3]. In multi-level constructs, the addition of anterior cervical plates provides a tension band effect that reduces non-union rates, prevents graft extrusion, and facilitates faster recovery with minimal external immobilization.[4,5] Implant technology advancements targeted at maximizing fusion success and reducing approach-related morbidity have characterized the evolution of ACDF. Although successful, traditional designs that use a distinct anterior cervical plate and cage have been linked to issues such as soft tissue irritation, postoperative dysphagia, and sporadic hardware failure.[4,6] As a result, stand-alone (ST) cages were created, which combine fixation functions into a single interbody apparatus. ST cages have sparked worries about a higher risk of cage sinking and migration, despite the fact that they streamline the process.[4] Zero-profile (ZP) cage systems have been developed more recently to overcome these drawbacks. These implants attach to the vertebral bodies with an integrated, low-profile anterior fixation, usually with screws. By decreasing prevertebral mass and offering initial stability comparable to a plate construct, the ZP design seeks to improve cervical lordosis and disc height preservation and may lower the risk of dysphagia.[3-7] Comparative analysis of implant performance is essential to optimize surgical outcomes, given the high prevalence of cervical degenerative disease. While available literature, such as the study by Mu et al, (2022), provides valuable insights into surgical outcomes of two-level ACDF with stand-alone cages versus zero-profile devices,[3] there remains a need for broader investigations that

consider the impact of patient-specific comorbidities (e.g., smoking, osteoporosis) and longer-term radiographic integrity with multi-level surgery.

MATERIALS AND METHODS

Study Design, Setting, and Period

This retrospective cohort study was conducted at the Neurosurgery Department, Swat Medical Complex Teaching Hospital, Swat, KPK, Pakistan, where anterior cervical discectomy and fusion (ACDF) using a zero-profile stand-alone locking cage is a routinely performed procedure. The cohort included all consecutive patients operated on between January 1, 2020, and February 5th, 2026. The study proposal and protocol were discussed, reviewed, and approved by the Institutional Review Board / Ethics Committee, Swat Medical Complex Teaching Hospital / Swat Medical College, Swat, and Saidu Group of Teaching Hospital / Saidu Medical College, Saidu Sharif, Swat, KPK, Pakistan under Ethical Approval No: 004-ERB/SMC/STMC/026 dated January 12th, 2026. Due to the retrospective nature of the study and anonymized clinical data, informed consent was waived. The study was conducted and reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.

Sample Size Justification

A post-hoc power analysis was performed using G*Power 3.1. Based on the observed overall fusion rate of 86.4% in this cohort, and the clinically significant difference in fusion success between single- and multi-level procedures reported in prior literature, the study's sample size of 125 patients provided 88% statistical power (α=0.05) to detect a 15% absolute difference (e.g., 90% vs. 75%) in fusion rates between these groups, which is considered a relevant clinical margin.

STUDY POPULATION

Inclusion Criteria

This retrospective cohort included 125 consecutive adult patients who had anterior cervical discectomy and fusion (ACDF) using a zero-profile stand-alone locking cage.

The **inclusion criteria** were (1) Age 18 years or older; (2) clinically significant symptoms of cervical radiculopathy (sensory deficit, arm pain, or motor weakness in a dermatomal/myotomal distribution); (3) corresponding degenerative pathology (osteophyte formation, anterior disc herniation or cord compression) confirmed on preoperative MRI; (4) failure of at least three months of structured conservative management, including pharmacologic therapy and supervised physiotherapy; (5) patients with a diagnosis of osteoporosis based on a DEXA scan (T-score ≤ -2.5) were included as long as they had no documented history of fragility fractures.

Exclusion Criteria

Exclusion criteria comprised: Acute trauma, tumors, or active infections causing cervical pathology; ossification of the posterior longitudinal ligament (OPLL); prior cervical spine surgery history; severe osteoporosis with a history of fragility fractures; concurrent systemic malignancy or a medical condition that precludes elective surgery.

Pre-operative Assessment

All patients had a standardized evaluation before surgery, which included recording their baseline neurological and functional condition, comorbidities such as diabetes and smoking status, demographics, and symptom duration. The Visual Analogue Scale (VAS) for pain, the Neck Disability Index (NDI), the modified Japanese Orthopaedic Association (mJOA) score, and the Nurick grade were all part of the preoperative clinical evaluation. Every patient had an MRI, and

when instability was indicated, flexion-extension radiographs were taken.

Surgical Technique

All surgical procedures were performed using the anterior cervical approach (Smith–Robinson Approach). Microsurgical discectomy was carried out with decompression of the bilateral neural foramina and removal of the posterior longitudinal ligament when indicated. Endplate preparation was standardized. A zero-profile stand-alone titanium/polyetheretherketone (PEEK) cage integrated with an internal locking screw mechanism was filled with autologous bone graft harvested during decompression and inserted based on trial sizing. Fluoroscopy was used to confirm level identification and implant positioning. The number of levels addressed—single, two, or three was determined by clinic radiological correlation. Postoperatively, all patients received routine antibiotic prophylaxis and analgesia, and a cervical collar was used selectively according to bone quality and the number of levels fused.

Postoperative Protocol and Follow-up

Patients were followed postoperatively at three, six, and nine months. Clinical outcomes (mJOA, VAS, NDI, and Nurick grade) were assessed at each patient visit. Evaluation of Radiological fusion was carried out at six and nine months using dynamic lateral radiographs (X-ray Cervical Spine in Dynamics), with the 9-month assessment designated for the primary comparative analysis. The presence of bridging trabecular bone across the interspace, accompanied by <2° of angular motion or <1 mm of translational motion on flexion–extension films, was defined as fusion. Reduction of ≥3 mm in intervertebral height or evidence of endplate violation was defined as cage subsidence. Complications were categorized as early (≤30 days) or late (>30 days) based on their initial appearance postoperatively. Clinical documentation for symptomatic events (hoarseness, dysphagia, infection) and radiographic follow-up for cage subsidence determined the complication timings. Except for cage subsidence detected at the 6-month radiographic follow-up, all other complications occurred within the early postoperative period (≤30 days).

Data Collection and Management

Data were extracted by two independent reviewers blinded to clinical outcomes, using operative logs, electronic health records, and imaging archives. Radiographic assessments were performed by a senior radiologist blinded to clinical data. Missing data were handled under the missing-at-random (MAR) assumption. Variables with <10% missing data underwent pairwise deletion; others were imputed using multiple imputation by chained equations (MICE, 10 imputations), including all demographic, surgical, and outcome variables. Sensitivity analysis comparing complete-case and imputed datasets confirmed robustness.

Statistical Analysis

Continuous variables are reported as mean ± standard deviation (SD) with 95% confidence intervals (CI); categorical variables as frequencies and percentages. The normality of continuous data distributions was assessed. Pre- to postoperative comparisons of clinical outcomes (VAS, NDI, mJOA) were performed using paired t-tests. Group comparisons (e.g., across surgical levels) employed chi-square or Fisher's exact tests for categorical variables and one-way ANOVA or Kruskal–Wallis tests for continuous variables, as appropriate. Predictors of fusion failure (binary outcome) were analyzed using multivariable logistic regression, with model fit assessed by the Hosmer–Lemeshow test, Nagelkerke R^2, and the area under the receiver operating characteristic curve (AUC-ROC). Predictors of the change in Neck Disability Index (ΔNDI) were analyzed using multivariable linear

regression. Multicollinearity among predictor variables was assessed, with variance inflation factors (VIF) confirmed to be < 5. A two-sided *p*-value < 0.05 was considered statistically significant. All analyses were performed using SPSS Statistics version 26 and R software version 4.1.

Outcomes

The primary outcomes of interest were radiographic fusion success rate at nine months and the magnitude of improvement in the Neck Disability Index (NDI) between baseline and the nine-month follow-up. Secondary outcomes included the temporal profile of clinical recovery assessed by modified Japanese Orthopaedic Association (mJOA) scores at 3, 6, and 9 months postoperatively, changes in Visual Analog Scale (VAS) for pain, shifts in Nurick grade, and the overall postoperative complication profile (including rates of hoarseness, dysphagia, and surgical site infection). Radiographic secondary outcomes included the rate of cage subsidence at follow-up and the need for any reoperation related to the index procedure.

RESULTS

Illustrative Case

A representative case among the 125 operated cases included a female patient (45-year-old) who presented with a three-month history of progressive worsening neck pain, bilateral hand clumsiness, along with intermittent numbness, and significant gait disturbance (including frequent tripping and unsteadiness). Cervical myelopathy was graded as Nurick grade 3 with an mJOA score of 13 on clinical examination. Magnetic resonance imaging preoperatively (Fig. 1A) demonstrated severe spinal cord compression due to disc-osteophyte complexes at the Spinal levels C5-C6 and C6-C7. The patient underwent a two-level anterior cervical discectomy and fusion (ACDF) using the standardized zero-profile PEEK cage surgical technique as described in the Methodology section of this article.

***Note**: Written informed consent was obtained from the patient for publication of this case and any accompanying images/Scans (Figures 1- 4). The patient has permitted the use of anonymized radiological scans and clinical images in this article.*

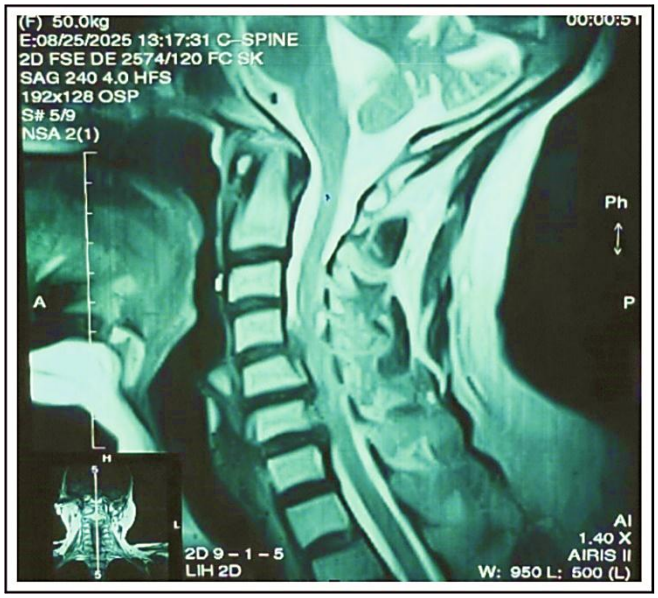

Figure 1A: *Cervical Spine preop MRI Sagittal view.*

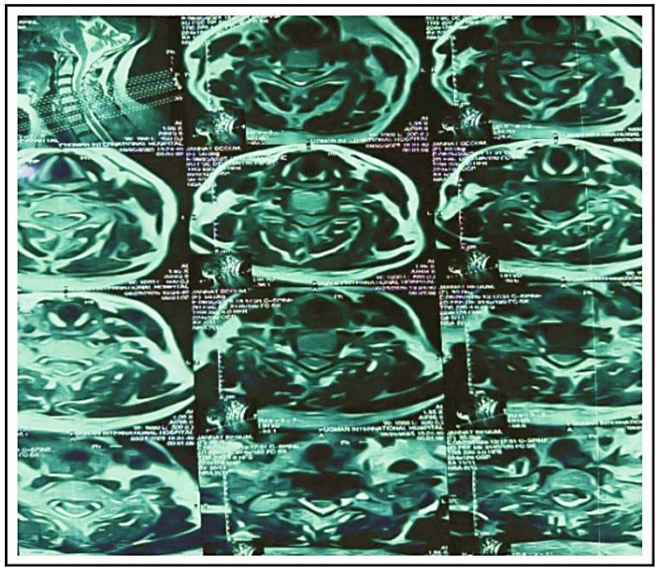

Figure 1B: *Cervical Spine preop MRI Axial view.*

Clinical Outcome of the Illustrative Case

The patient demonstrated significant neurological improvement postoperatively. A follow-up MRI scan at nine months (Fig. 1B) confirmed proper implant position with adequate decompression of the spinal canal. At the final follow-up, her functional status had improved to a Nurick grade of 1 and an mJOA score of 16.

Figures 1A and 1B: Cervical Spine preop MRI showing severe spinal cord compression due to disc-osteophyte complexes at the Spinal levels C5-C6 and C6-C7. (images used with permission from the patient).

The study included 125 patients (55.2% male; mean age 49.2 years, 95% CI: 47.7–50.7). Clinical presentations were cervical radiculopathy (56%), myelopathy (24%), and radiculomyelopathy (20%). Single-level ACDF predominated (65%), followed by two-level (28%) and three-level (7%) procedures (χ^2=58.67, p<0.001). Significant clinical improvement was observed across all measures (Table 4). VAS improved from 8.1 ± 1.2 to 2.4 ± 1.1 (mean difference: 5.7; p<0.001), NDI from 31.6 ± 4.8 to 15.9 ± 3.6 (mean difference: 15.7; p<0.001),

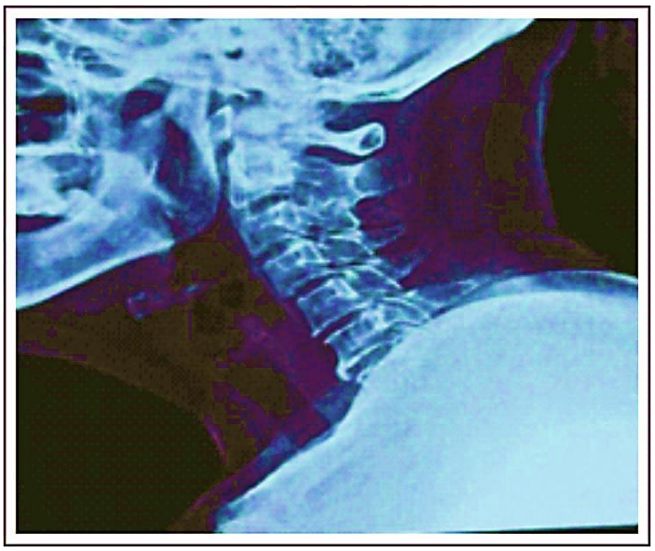

Figure 2: *Preoperative X-ray Lateral View of Cervical Spine. (image used with permission from the patient).*

and mJOA from 13.3 ± 1.5 to 16.7 ± 1.2 (mean difference: 3.4; p<0.001). Radiological fusion at nine months was achieved in 90.1% of single-level, 80.0% of two-level, and 66.7% of three-level procedures (Cochran-Armitage p=0.015). Independent predictors of fusion failure were multi-level surgery (OR=3.74, p=0.014), current smoking (OR=3.35, p=0.037), and osteoporosis (OR=4.66, p=0.030). Multi-level procedures were

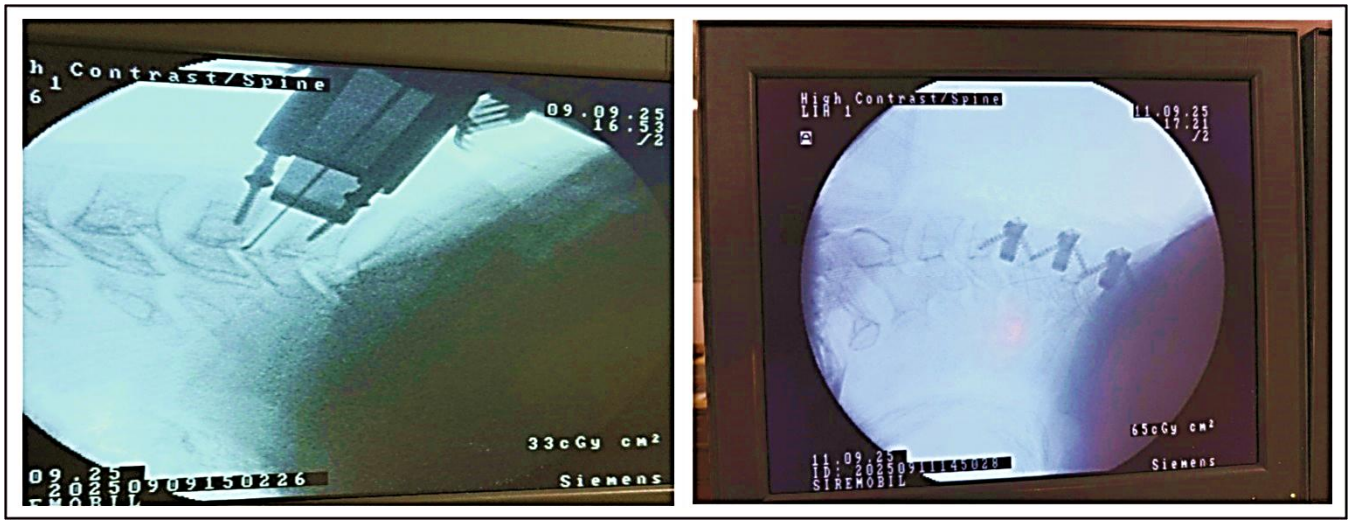

Figure 3A: *Assessment and Removal of Posterior Osteophytes.* **Figure 3B:** *Three-Level ACDF at the end of surgery.*
Figure 3: *Per Op Images showing the implant positioning in the cervical spine. (images used with permission from the patient).*

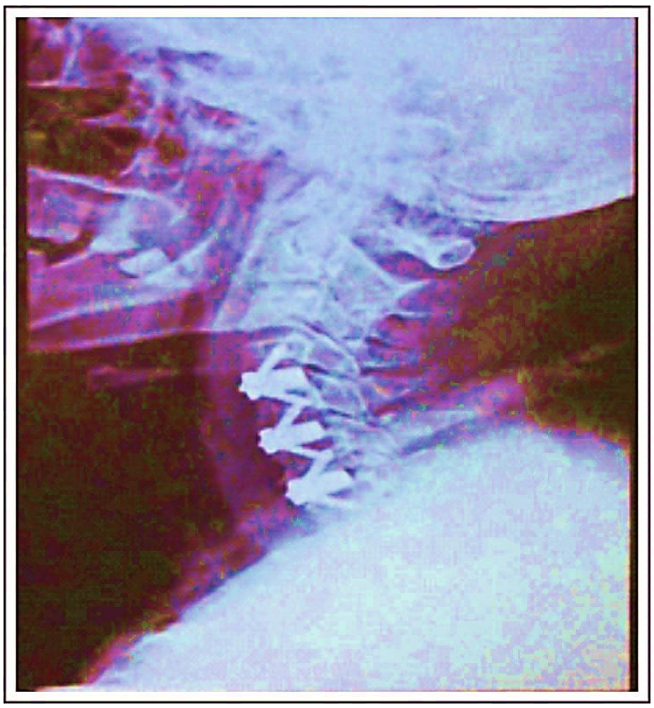

Figure 4: *Post Op X ray Cervical Spine in dynamics. (image used with permission from the patient).*

associated with 3.21 points less NDI improvement than single-level surgery (p=0.002). The overall complication rate was 17.6% (95% CI: 12–25%), with transient dysphagia (8%), hoarseness (4%), cage subsidence (3%), and superficial wound infection (2%) being most common. No mortality occurred, and no independent predictors of complications were identified ($\chi^2(6)=9.84$, p=0.132). Sensitivity analysis confirmed internal consistency (all p>0.05). Overall, ACDF with a zero-profile cage provided significant clinical improvement, high fusion rates, and a low complication burden, with outcomes influenced by smoking status, number of levels fused, and bone quality.

Cohort Demographics and Clinical Profile

Demographic and comorbidity data are presented in Table 1. The mean age was 49.2 years (95% CI: 47.7–50.7), with 55.2% male. Current smokers comprised 22.4%, while osteoporosis and diabetes mellitus were present in 11.2% and 16.8%, respectively.

Clinical Presentation and Surgical Characteristics

Table 2 displays the distribution of surgery levels and preoperative diagnosis. The most frequent presentation was cervical radiculopathy (56%). The majority of procedures were single-level ACDF (65%), a distribution significantly skewed toward single-level surgery ($\chi^2=58.67$, p<0.001), followed by two-level (28%) and three-level fusions (7%).

Table 1: *Demographic and Clinical Profile of the Cohort.*

Variable	Category	n (%) or Mean ± SD	95% CI
Age (years)		49.2 ± 8.7	47.7 – 50.7
Sex	Male	69 (55.2%)	46.4 – 63.8%
	Female	56 (44.8%)	36.2 – 53.6%
Smoking Status	Current Smoker	28 (22.4%)	15.8 – 30.5%
	Former Smoker	18 (14.4%)	9.1 – 21.8%
	Never Smoked	79 (63.2%)	54.3 – 71.4%
Diabetes Mellitus	Yes	21 (16.8%)	11.0 – 24.5%
	No	104 (83.2%)	75.5 – 89.0%
Osteoporosis(DEXA T-score ≤ -2.5)	Yes	14 (11.2%)	6.6 – 18.1%
	No	111 (88.8%)	81.9 – 93.4%
Hypertension	Yes	37 (29.6%)	22.1 – 38.2%
	No	88 (70.4%)	61.8 – 77.9%

Preoperative Myelopathy Severity

Table 3 describes the preoperative functional condition based on the Nurick grade. Before surgery, the majority of the patients (56%) had moderate or early myelopathy, as evidenced by the fact that they came with Nurick grade 0 (root symptoms only).

Table 2: *Clinical Presentation and Surgical Levels.*

A. Clinical Presentation (N=125)	Number of Patients	Percentage (%)(95% CI)
Cervical Radiculopathy	70	56% (47 – 65%)
Myelopathy	30	24% (17 – 32%)
Radiculomyelopathy	25	20% (14 – 28%)
Total	125	100%
B. Surgical Levels	**Number of Patients**	**Percentage (%)(95% CI)**
Single-level ACDF	81	65% (56 – 73%)
Two-level ACDF	35	28% (21 – 36%)
Three-level ACDF	9	7% (4 – 13%)
Multi-Level (Two and Three-Level Combine)	44	35% (27 – 44%)
Total	125	100%

Clinical Outcomes Following Surgery

Table 4 compares preoperative and postoperative clinical outcomes. Significant, progressive improvement was observed across all measures at each follow-up interval. At nine months, VAS improved from 8.1 ± 1.2 to 2.4 ± 1.1 (mean difference: 5.7; 95% CI: 5.3–6.1; p<0.001), with similar gains observed in NDI and mJOA scores.

Paired t-tests were used to compare preoperative scores with 9-month postoperative scores for each outcome measure. All improvements were statistically significant ($p < 0.001$).

Table 3: *Preoperative Functional Status (Nurick Grade).*

Nurick Grade	Number of Patients	Percentage (%)(95% CI)
0	70	56% (47 – 65%)
1	25	20% (14 – 28%)
2	19	15% (10 – 22%)
3	11	9% (5 – 15%)
Total	125	100%

Table 4: *Clinical Outcomes at Preoperative, 3, 6, and 9 Months Postoperative.*

Outcome Measure	Preoperative Mean ± SD	3 Months Postop Mean ± SD	6 Months Postop Mean ± SD	9 Months Postop Mean ± SD	Overall Improvement (Preop to 9M)	t-value	p-value
VAS	8.1 ± 1.2	4.2 ± 1.3	3.1 ± 1.2	2.4 ± 1.1	5.7 (5.3–6.1)	32.45	<0.001
NDI	31.6 ± 4.8	22.3 ± 4.2	18.1 ± 3.9	15.9 ± 3.6	15.7 (14.5–16.9)	28.12	<0.001
mJOA	13.3 ± 1.5	14.8 ± 1.4	15.8 ± 1.3	16.7 ± 1.2	3.4 (3.0–3.8)	18.93	<0.001

Postoperative Complication Profile

Table 5 summarizes the safety profile. The overall complication rate was 17.6% (22/125; 95% CI: 12–25%), with transient dysphagia (8%, n=10), hoarseness (4%, n=5), cage subsidence (3%, n=4), and superficial wound infection (2%, n=3) being most common. Early complications (≤30 days) accounted for 18 of 22 events; subsidence was the sole late complication. No deaths or reoperations occurred. Multivariable logistic regression identified no significant independent predictors of complications ($\chi^2(6)=9.84$, $p=0.132$). The morbidity rate aligns with published benchmarks (Table 9).

As shown in Table 5, the majority of complications (18 of 22, 81.8%) occurred within the early postoperative period (≤30 days). Cage subsidence, detected at the 6-month radiographic evaluation, was the only late complication observed.

Table 5: *Postoperative Complications.*

Complication Type	Number of Patients (n)	Percentage % (95% CI)	Timing	Onset/Detection
Transient Dysphagia	10	8.0% (4–14)	Early (≤30 days)	Within the first two weeks
Hoarseness	5	4.0% (2–9)	Early (≤30 days)	Within the first week
Cage Subsidence	4	3.2% (1–8)	Late (>30 days)	6-month follow-up
Superficial Infection	3	2.4% (0.5–7)	Early (≤30 days)	Within 2 weeks
Total Morbidity	22	17.6% (12–25)	18 Early, 4 Late	

Table 6: *Fusion Success by Number of Surgical Levels.*

Surgical Levels	Fused (n)	Not Fused (n)	Total Patients (n)	Fused/Total	Fusion Rate % (95% CI)
Single-level	73	8	81	73/81	90.1% (82.3–95.5%)
Two-level	28	7	35	28/35	80.0% (65.2–90.0%)
Three-level	6	3	9	6/9	66.7% (35.4–88.7%)
Multi-level (combined)	34		44	34/44	77.3% (63.8–86.9%)
Total	107		125	107/125	85.6% (78.4–90.9%)

Statistical Note: *Cochran-Armitage test for trend: $\chi^2=5.89$, $p=0.015$.*

Radiographic Fusion Success by Surgical Levels

Radiological fusion at nine months was achieved in 90.1% of single-level (73/81), 80.0% of two-level (28/35), and 66.7% of three-level (6/9) ACDF procedures (Table 6). When combined, multi-level procedures (two- and three-level) demonstrated a 77.3% fusion rate (34/44), showing a significant inverse trend with increasing surgical levels (Cochran-Armitage p=0.015).

Table 7: *Predictors of Fusion Failure – Multivariable Logistic Regression.*

Variable	Adjusted OR (95% CI)	p-value
Multi-level (vs. Single)	3.74 (1.30 – 10.76)	0.014
Current Smoking	3.35 (1.08 – 10.41)	0.037
Osteoporosis	4.66 (1.16 – 18.74)	0.03
Age (per 10-year increase)	1.36 (0.88 – 2.10)	0.158
Diabetes	1.95 (0.59 – 6.45)	0.271
Sex (Female)	0.75 (0.28 – 2.02)	0.571

Model Fit: *Nagelkerke $R^2=0.28$; Hosmer-Lemeshow $\chi^2(8)=6.42$, $p=0.598$; AUC-ROC=0.72.*

Table 8: *Predictors of Functional Improvement (ΔNDI) – Multivariable Linear Regression.*

Variable	β (95% CI)	Standardized β	p-value
Multi-level (vs. Single)	-3.21 (-5.23 – -1.19)	-0.28	0.002
Baseline NDI	0.45 (0.23 – 0.67)	0.32	<0.001
Age (years)	-0.08 (-0.18 – 0.02)	-0.12	0.112
Diabetes	-1.89 (-4.35 – 0.57)	-0.12	0.131
Smoking	-2.12 (-4.45 – 0.21)	-0.14	0.075
Sex (Female)	0.87 (-1.07 – 2.81)	0.07	0.376

Model Summary: $R^2=0.31$, Adjusted $R^2=0.27$; $F(6,118)=8.76$, $p<0.001$.

Independent Predictors of Fusion Failure

Multivariable logistic regression (Table 7) identified multi-level surgery (OR=3.74, p=0.014), current smoking (OR=3.35, p=0.037), and osteoporosis (OR=4.66, p=0.030) as independent predictors of fusion failure, with moderate predictive accuracy (Nagelkerke $R^2=0.28$, AUC-ROC=0.72).

Table 9: *Complication Rate Comparison with Published Meta-Analytic Benchmarks.*

Complication	Our Study Count (n)	Our Study Rate % (95% CI)	Literature Benchmark % (Range)	Key Reference (Meta-Analysis/Review)
Transient Dysphagia	10	8.0% (4–14)	9.5% (8–12)	Lu et al, Spine, 2020
Hoarseness	5	4.0% (2–9)	3.8% (2–6)	Jiang et al, Eur Spine J, 2018
Cage Subsidence	4	3.2% (1–8)	4.2% (3–6)	Scholz et al, Eur Spine J, 2021
Superficial Infection	3	2.4% (0.5–7)	1.5% (1–3)	Yao et al, Spine, 2020
Total Morbidity	**22**	**17.6% (12–25)**	**16.8% (15–20)**	Aggregate from above

Predictors of Functional Improvement (ΔNDI)

Multivariable linear regression (Table 8) showed multi-level surgery was associated with 3.21 points less NDI improvement than single-level surgery (95% CI: -5.23 to -1.19, p=0.002), with the model explaining 27% of the variance (Adjusted R^2=0.27).

Table 10: *Sensitivity Analysis – Complete Cases vs. Imputed Data.*

Outcome	Complete Cases	Multiple Imputation	Difference (p-value)
Fusion Rate	90.70%	89.60%	0.712
Mean ΔNDI	15.7 ± 4.1	15.4 ± 4.3	0.589
Complication Rate	17.80%	17.60%	0.941

Table 11: *Subgroup Analysis – Fusion Rates by Smoking Status and Surgical Levels.*

Group	Fused/Total	Fusion Rate % (95% CI)	OR vs. Reference (95% CI)	p-value
Non-Smokers (Single-level)	56/59	94.9% (87.0–98.5)	Reference	—
Smokers (Single-level)	17/22	77.3% (57.7–89.8)	0.21 (0.06–0.79)	0.015
Non-Smokers (Multi-level)	22/26	84.6% (67.0–94.0)	0.30 (0.07–1.25)	0.09
Smokers (Multi-level)	12/18	66.7% (43.8–84.0)	0.10 (0.02–0.45)	0.002

Cochran-Mantel-Haenszel Test for Trend: χ^2=12.37, p<0.001.

Complication Rates in the Context of Published Literature

The overall complication rate was 17.6% (22/125; 95% CI: 12–25%), with transient dysphagia (8%, n=10), hoarseness (4%, n=5), cage subsidence (3%, n=4), and superficial wound infection (2%, n=3) being most common. No mortality or reoperations occurred. Multivariable logistic regression identified no significant independent predictors of complications ($\chi^2(6)$=9.84, p=0.132).

Table 9 places these observed complication rates in context by contrasting them with accepted standards from recent systematic reviews and meta-analyses. The 17.6% overall morbidity rate and the rates of specific complications, such as infection (2.4%), subsidence (3.2%), hoarseness (4.0%), and dysphagia (8.0%), are all within the limits documented in recent literature.

Sensitivity Analysis for Missing Data

Sensitivity analysis (Table 10) comparing complete-case (n=118) and multiply imputed (n=125) datasets revealed no significant differences in fusion rates, mean ΔNDI, or complication rates (all p>0.05), confirming the robustness of the findings.

Interaction of Smoking and Surgical Extent on Fusion

Table 11 presents a subgroup analysis examining the interaction between surgical extent and smoking status on fusion success. Smokers

undergoing multi-level ACDF had a significantly lower fusion rate (66.7%) compared to non-smokers with single-level surgery (94.9%) (OR=0.10; 95% CI: 0.02–0.45; p=0.002), demonstrating a compounded risk. A significant inverse trend between smoking, increasing surgical levels, and reduced fusion success was confirmed (Cochran–Mantel–Haenszel test, p<0.001).

DISCUSSION

In this cohort of 125 patients, ACDF with a zero-profile stand-alone cage resulted in significant clinical improvement across all measures, with high fusion rates and a favorable safety profile. These findings align with the growing body of evidence supporting zero-profile devices as a safe and effective alternative to traditional cage-and-plate constructs.[8,9] However, our results also reveal important outcome stratification based on surgical extent and patient-specific risk factors, which warrant closer examination. Mean VAS scores improved from 8.1 to 2.4, exceeding the minimal clinically important difference (MCID). Similarly, NDI scores decreased from 31.6 to 15.9, reflecting a transition from "severe" to "mild" disability. Neurological recovery was further evidenced by an increase in mJOA scores from 13.3 to 16.7, particularly among the 44% of patients presenting with myelopathy or myeloradiculopathy. These findings are consistent with the broader literature on zero-profile devices. Similar levels of improvement in NDI and VAS ratings have been found in a meta-analysis by Lu et al,[8] and prospective investigations by Barbagallo et al,[9,] confirming that the immediate clinical efficacy of decompression is unaffected by the absence of an anterior plate. In the early postoperative phase, the locking screws' instant stability seems to be enough to reduce pain related to micro-instability. Nonetheless, a nuanced result emerged from our multivariable linear regression analysis (Table 8): multi-level surgery was substantially linked to reduced improvement in NDI (β = - 3.21, p=0.002). This implies that although multi-level patients do experience improvement, their functional recovery is less pronounced than that of single-level individuals. Greater surgical trauma, altered global kinematics due to increased cervical column stiffness, or possibly sub-clinical micromotion at the fusion sites that hinders full resolution of neck pain[10] could be the cause of this. The study's most notable conclusion is the notable decline in fusion rates for three-level procedures (66.7%) as opposed to single-level procedures (90.1%) (Table 6). This dramatic drop is consistent with a body of research that casts doubt on the biomechanical suitability of standalone structures for major cervical restorations. Our data confirms the more cautious perspective of researchers like Yang et al,[8] and Zhang et al,[11] who contend that the stability offered by segmental fixation alone may not be enough to counteract the increased bending moments and shear forces present in long-segment constructs.[12] This is in contrast to some authors, like Barbagallo et al, who have reported fusion rates exceeding 90% in multi-level zero-profile ACDF.[9] By limiting extension and rotation across the instrumented segment, the plate in a conventional plated ACDF serves as a bridge tension band, therefore "sharing" the load and safeguarding the graft-endplate interface.[13] On the other hand, zero-profile devices are totally dependent on the cage's inherent stability and the purchase of the integrated screws inside the vertebral body.[14] These clinical findings have been supported by biomechanical investigations using cadaveric models and finite element analysis (FEA). Stand-alone cages have been shown to allow more micromotion in extension and rotation than plate-reinforced structures, but to a dramatically lower range of motion (ROM) when compared to the intact spine.[15] This difference is exacerbated as the number of fused layers increases. This biomechanical susceptibility is highlighted by our discovery that multi-level surgery is an independent predictor of fusion failure (OR=3.74)

(Table 7). Even in the absence of overt hardware failure, the discrepancy in NDI progress can be a clinical symptom of this subtle instability or inadequate consolidation. Therefore, while zero-profile devices are highly effective for single and perhaps two-level disease, the addition of supplemental fixation (such as posterior instrumentation) or the use of an anterior plate should be strongly considered for three-level pathology to ensure adequate immobilization.[16] Postoperative dysphagia, a well-recognized complication of anterior cervical surgery with reported rates of 2% to over 70%,[3] was the primary impetus for developing zero-profile devices. By housing fixation entirely within the intervertebral space, these implants eliminate the anterior prominence of traditional plates (which can protrude 2–3 mm) and reduce mechanical esophageal irritation.[3,8,17] Our observed transient dysphagia rate of 8.0% (Table 5) compares favorably with plated ACDF benchmarks of 15–20% and aligns with meta-analyses by Lu et al, and Yang et al, which confirm significantly lower dysphagia risk with zero-profile constructs at both early and late follow-up.[8,18] Notably, all cases were transient, with no permanent swallowing dysfunction, reinforcing the utility of this implant for patients at high risk for dysphagia, including those with pre-existing swallowing difficulties or professional voice users (the latter also benefiting from the low 4% hoarseness rate).[19] Despite literature reports of subsidence rates as high as 20–30% for stand-alone cages,[3,20] our study observed a low 3.2% rate, likely attributable to meticulous endplate preservation, PEEK material properties, and specific measurement thresholds.[21] However, osteoporosis (OR=4.66) remains a significant predictor of failure, as low bone density compromises screw purchase and invites micromotion,[22] warranting consideration of supplemental fixation in this population.[23] Similarly, smoking (OR=3.35) impairs revascularization and osteoblast function,[24] with subgroup analysis revealing a compounded risk in smokers undergoing multi-level ACDF (fusion rate 66.7% vs. 94.9% in non-smokers with single-level surgery; Table 11). This interaction suggests smoking may be a relative contraindication for multi-level zero-procedures, necessitating stringent preoperative cessation or additional fixation [25,26]. Superficial surgical site infection occurred in 2.4% of patients, slightly above the 0.1–1.6% range reported in large databases[27] but within acceptable safety margins, likely reflecting sample size or reporting variations. No deep infections occurred, reinforcing the reduced dead space advantage of zero-profile implants over bulky plates.[3] While subclinical infections (e.g., *Cutibacterium acnes*) have been reported in 17–55% of cervical discs,[28] their clinical relevance remains debated, and zero-profile devices do not appear to increase infection risk.[11] Collectively, these findings validate the zero-profile stand-alone cage as an excellent option for single- and two-level disease in patients with good bone quality, offering high fusion rates and superior clinical outcomes with minimized dysphagia risk compared to traditional plating.[29,30] However, its use in three-level constructs or high-risk patients warrants careful deliberation.

LIMITATIONS

This study has several limitations. Its retrospective design is inherently susceptible to information and selection bias, and the absence of a control group precludes definitive conclusions regarding superiority over alternative constructs. All surgeries were performed by a team of young neurosurgeons (age less than 40 years) at a single tertiary center, limiting generalizability despite ensuring surgical homogeneity. The 9-month follow-up, while adequate to assess early fusion and complications, is insufficient to evaluate long-term outcomes such as adjacent segment degeneration or delayed pseudoarthrosis. Fusion was assessed on dynamic radiographs rather than CT, which may overestimate true bony union.

Although robust for a young surgeon series, the sample size (N=125) was underpowered for subgroup and multivariable analyses, particularly for rare complications. Additionally, data on key confounders, including bone mineral density, BMI, and socioeconomic status, were incompletely recorded, and the absence of a formal a priori sample size calculation warrants cautious interpretation of non-significant findings. Despite these limitations, this study provides valuable real-world evidence on the safety and efficacy of this implant in the hands of an early-career surgeon, with a large consecutive cohort, standardized protocol, and systematic use of validated outcome measures.

FUTURE DIRECTIONS

Future research should prioritize large-scale, prospective, randomized controlled trials comparing zero-profile devices against cage-and-plate constructs specifically in the context of multi-level (3+) surgery to definitively settle the stability controversy. Additionally, the integration of advanced preoperative planning tools, such as MRI-based Vertebral Bone Quality (VBQ) scores, could refine risk stratification for subsidence and non-union better than DEXA scans alone.[23]

From a materials science perspective, the continued evolution of 3D-printed porous titanium cages, which may offer superior osseointegration compared to PEEK, warrants investigation in stand-alone applications.[3] Finally, long-term longitudinal studies are essential to validate whether the reduction in dysphagia and the preservation of the anterior profile truly translate into a reduction in adjacent segment pathology over the course of a decade or more.

CONCLUSION

Anterior cervical discectomy and fusion (ACDF) utilizing a zero-profile stand-alone cage is a safe and effective procedure, offering a significant clinical improvement, high fusion rates, and a favorable safety profile comparable to traditional techniques. Its reduced implant profile provides a distinct advantage in potentially lowering the risk of postoperative dysphagia. However, the long-term success of this construct is not universal and is critically dependent on both procedural and biological factors. This study confirms that multi-level surgery, active smoking, and osteoporosis are strong, independent predictors of fusion failure, with multi-level procedures also correlating with diminished functional recovery. Consequently, while this technique represents an excellent option for appropriately selected single- and two-level cases, its application in three-level constructs or in patients with compromised healing potential (smokers, osteoporotic) requires careful deliberation. A tailored surgical strategy—emphasizing meticulous patient selection, rigorous preoperative optimization (smoking cessation, bone health management), and consideration of more rigid fixation for complex multi-level pathology in high-risk hosts—is paramount to ensuring that the benefits of a low-profile implant are not offset by an increased risk of long-term instability.

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Additional Information

Disclosures: No conflicts of interest are reported by the authors.
Ethical Review Board Approval: Approved by ERB Saidu Medical College/Saidu Group of Teaching Hospital Saidu Sharif Swat and ERB Swat Medical College Swat (Ref no: 004-ERB/SMC/STMC/026)
Human Subjects: Every patient and volunteer in this study gave their informed consent.
Conflicts of Interest: All authors affirm the following in accordance with the ICMJE uniform disclosure form: Financial Relationships: Each author has stated that they have no financial relationship to any organizations that might be interested in the submitted work, either now or within the last three years.
Other Relationships: Each author has stated that the submitted work was not impacted by any other relationships or activities.
Data Availability Statement: For data sharing, interested researchers can contact the corresponding author.
Funding: None.

AUTHORS CONTRIBUTIONS

Sr.#	Author's Full Name	Intellectual Contribution to Paper in Terms of:
1.	Adnan Khaliq	1. Study design and methodology, Manuscript writing, Supervision, Final Approval, & Accountable for Work.
2.	Mian Iftikhar Ul Haq	2. Manuscript writing and Review, Study Design, Final Approval, & Accountable for Work.
3.	Ubaid Ullah Mian	3. Data collection and Analysis, Manuscript Writing and Revision, Study Design, Final Approval, & Accountable for Work.
4.	Adil Ahmed	4. Analysis of data and interpretation of results, Manuscript Writing, Final Approval, & Accountable for Work.
5.	Suleman Khan	5. Literature review and referencing, Manuscript Revision, Final Approval, & Accountable for Work.
6.	Haider Ali	6. Editing and quality insurer, Manuscript Writing, Final Approval, & Accountable for Work.
7.	Alishba Hameed & Touba Azeem	7. Literature review and referencing, Manuscript Revision, Final Approval, & Accountable for Work.