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Original Article

Clinical and radiologic evaluation of the IntraSPINE non-fusion technique for lumbar degenerative disease

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Abstract: Objective: To compare the clinical and radiographic outcomes of the non-fusion IntraSPINE technique with patients receiving traditional lumbar fusion. Methods: A prospective study was conducted on patients with lumbar degenerative disease who failed to respond to conservative treatment. Clinical and radiologic evaluations were performed preoperatively and at 7 days, 6 months, and 12 months postoperatively. Clinical outcomes were assessed using the Japanese Orthopaedic Association (JOA) score, Visual Analogue Scale (VAS), and Oswestry Disability Index (ODI). Radiographic parameters included range of motion (ROM), posterior disc height (PDH), and foraminal height (FH) at the treated and adjacent segments. Results: Both groups demonstrated significant postoperative improvements in VAS, JOA, and ODI scores. However, the fusion group demonstrated complete loss of motion at the treated segment and increased motion at adjacent segments. In contrast, the non-fusion group retained partial ROM at the treated segment while maintaining adjacent segment motion close to preoperative levels. PDH and FH remained stable in the non-fusion group, whereas the fusion group experienced significant reductions in these measures at the adjacent segments. Conclusion: The IntraSPINE non-fusion technique yields clinical outcomes comparable to those of lumbar fusion, while preserving ROM, PDH, and FH in both the treated and adjacent segments. This preservation may reduce the risk of adjacent segment degeneration, supporting the use of IntraSPINE as a viable alternative to traditional fusion surgery.

Keywords: Degenerative disease of the lumbar spine, non-fusion, lumbar fusion, IntraSPINE dynamic stabilization system

Introduction

With the rapid aging of the global population, lumbar degenerative diseases have become a leading cause of lower back and leg pain, particularly among middle-aged and elderly individuals [1-3]. Although conservative treatment is generally the first-line approach, surgical intervention is often required when non-operative management fails to provide sufficient symptom relief [4-6]. Lumbar fusion surgery is currently considered the gold standard for treating lumbar degenerative conditions [6-8]. However, despite its clinical efficacy, lumbar fusion is associated with several limitations, including loss of segmental motion and an increased risk of adjacent segment degeneration (ASD) [8-10].

To overcome these limitations, the IntraSPINE non-fusion dynamic stabilization system was developed as an alternative surgical option. This technique is designed to restore disc function, maintain or improve lumbar mobility and biomechanical stability, and reduce the risk of ASD, thereby avoiding some of the complications associated with conventional fusion surgery [11-13]. The IntraSPINE system has seen increasing adoption in spinal surgery, with several studies reporting favorable clinical outcomes [14, 15].

In this study, we conducted a comprehensive evaluation of clinical efficacy, with a particular focus on the IntraSPINE system's ability to preserve or restore the range of motion (ROM) in both treated and adjacent segments.

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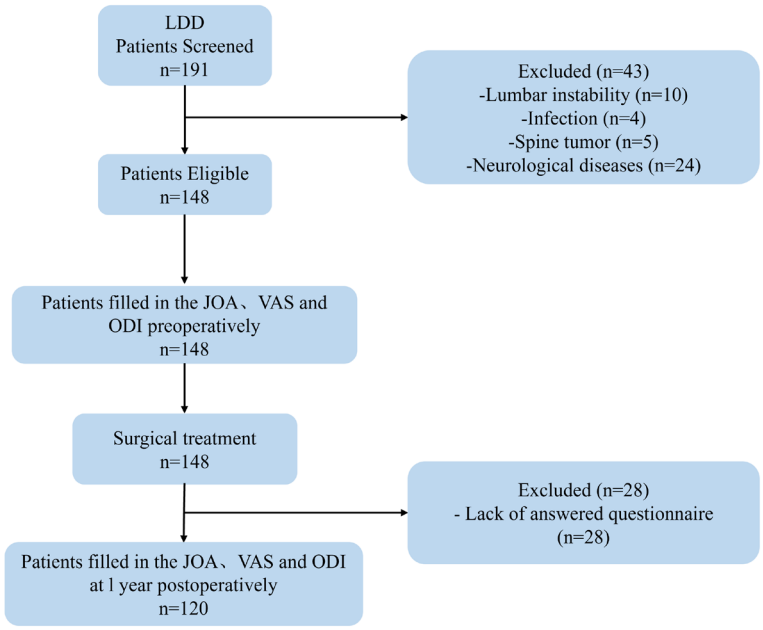

Figure 1. Flowchart illustrating the patient selection process for this study (LDD: Lumbar degenerative disease; JOA: Japanese Orthopaedic Association scores; VAS: Visual Analog Scale scores; ODI: Oswestry Disability Index scores).

Additionally, we assessed its effects on posterior disc height (PDH) and foraminal height (FH).

Materials and methods

Human ethics and consent to participate declaration

This prospective study was approved by the Medical Ethics Committee of the First Affiliated Hospital of Shandong First Medical University (Approval No. S368) and registered at clinicaltrials.gov (Registration No. NCT06075966). Written informed consent was obtained from all participants prior to enrollment. Patient confidentiality and anonymity were strictly maintained throughout the study [16].

Study design

This prospective cohort study was conducted between January 2020 and June 2021 at the Department of Spinal Surgery, First Affiliated Hospital of Shandong First Medical University. A total of 191 patients diagnosed with lumbar degenerative disease were initially screened. After applying the inclusion and exclusion criteria, 43 patients were excluded, resulting in 148 eligible participants.

Participants were assigned into two groups based on the surgical approach: Non-fusion group (n = 77): treated with the IntraSPINE dynamic stabilization system. Fusion group (n = 71): underwent traditional lumbar fusion surgery.

Group allocation was determined according to the following criteria: (1) Preoperative surgical indication confirmed by at least three spinal surgeons holding the title of Associate Chief Physician or above; (2) Patient preference after detailed counseling regarding the risks and benefits of both procedures; (3) Surgical feasibility assessed by preoperative imaging studies.

All procedures were performed by the same primary surgeon to ensure consistency. Decompression was conducted on the symptomatic side in all cases.

During follow-up, 28 patients were excluded due to incomplete questionnaire responses, leaving a final cohort of 120 patients for analysis, with 60 cases in each group.

None of the patients had a history of previous lumbar spine surgery. All had received at least three months of standardized conservative treatment, including nutritional support, hydration, physical therapy, massage, traction, acupuncture, herbal medicine, and non-steroidal anti-inflammatory drugs, without satisfactory symptom relief.

A detailed flowchart of the patient selection and enrollment process is presented in **Figure 1**.

Inclusion and exclusion criteria: Inclusion criteria: Patients were eligible if they met all of the following conditions: (1) Clinical symptoms, physical examination, and imaging findings consistent with a diagnosis of lumbar degenerative disease [17]; (2) Inadequate symptom relief after at least three months of standardized conservative treatment; (3) Preoperative

imaging confirmed single-segment disc protrusion or herniation causing segmental stenosis; (4) Indication for surgery localized to the L4-L5 segment; (5) All procedures were performed by the same primary surgeon to ensure consistency. Exclusion criteria: Patients were excluded if they met any of the following conditions: (1) Lumbar instability or spondylolisthesis of grade II or higher; (2) Severe osteoporosis, spinal tuberculosis, or spinal tumors; (3) Psychiatric disorders, poor compliance, or inability to complete follow-up assessments.

Clinical data: All patients were followed for a minimum of 12 months, with follow-up durations ranging from 12 to 15 months. Clinical and radiographic evaluations were conducted at baseline (preoperatively), at 7 days postoperatively, and during follow-up visits at 6 and 12 months.

Preoperative imaging assessments included anteroposterior and lateral lumbar spine X-rays, dynamic flexion-extension X-rays, computed tomography (CT), and magnetic resonance imaging (MRI) scans. Postoperative evaluations consisted of anteroposterior lumbar spine X-rays and CT scans performed at 6 and 12 months postoperatively. MRI scans were additionally performed in selected cases based on clinical indications.

Clinical parameters and radiographic measurements were systematically collected at each time point to evaluate surgical outcomes, segmental stability, and device performance.

Clinical evaluation method: Clinical outcomes and patient improvement were assessed using the Japanese Orthopaedic Association Lumbar Function Score (JOA) [18], the Visual Analogue Scale (VAS) [19], and the Oswestry Disability Index (ODI) [20].

The JOA score is a widely used tool for assessing neurologic function in patients with lumbar degenerative disease, evaluating motor function, sensory deficits, and bladder function. It measures neurological recovery by comparing preoperative scores with those at postoperative time points (7 days, 6 months, 12 months).

The VAS score quantifies subjective pain perception on a 0-10 scale, reflecting the efficacy of pain relief. A higher preoperative score indicates severe pain, while a progressive reduction postoperatively demonstrates the effectiveness of surgical intervention. It is particularly useful for assessing both short-term (e.g., 7 days) and long-term (e.g., 12 months) pain outcomes.

The ODI score evaluates the impact of lumbar disease on functional disability, including standing, walking, and sleeping. A high preoperative score indicates significant functional impairment, whereas a gradual postoperative decline reflects improvements in daily activities and overall quality of life.

Radiographic evaluation method: Radiologic assessments were done using lateral lumbar spine X-rays in neutral, hyperextension, and hyperflexion positions. Key measurements included the surgical gap and Cobb angle, which were measured at both the operative and adjacent segments to determine the ROM.

PDH was defined as the vertical distance between the inferior endplate of the upper vertebral body and the superior endplate of the lower vertebral body, measured in the neutral position. FH was defined as the vertical distance between the inferior margin of the upper vertebral pedicle notch and the superior margin of the lower vertebral pedicle notch.

Measurements of ROM, PDH, and FH were performed at four time points: preoperatively, and at 7 days, 6 months, and 12 months postoperatively. These evaluations allowed for a comprehensive analysis of segmental mobility, intervertebral height preservation, and angular changes, offering critical insight into the biomechanical outcomes of the procedure.

Statistical analysis

All preoperative and postoperative data were carefully collected and validated for accuracy prior to statistical processing. Analyses were conducted using SPSS version 26.0 (IBM Corp., Armonk, NY, USA).

Independent samples t-tests were used to compare demographic and clinical variables between groups, including age, duration of disease, duration of conservative treatment, operative time, screw/device placement time, intraoperative blood loss, hospital stay, VAS scores,

Table 1. Comparison of baseline characteristics between groups

	Non-fusion group (n = 60)	Fusion group (n = 60)	x^2/t	*P*
Gender (n)			< 0.001	> 0.999
Male	22	22		
Female	38	38		
Age (year)	52.37 ± 11.74	60.18 ± 9.21	-4.06	< 0.001*
Process (month)	38.57 ± 33.01	40.22 ± 30.32	-0.29	0.78
Conservative treatment (month)	7.07 ± 1.70	6.88 ± 2.35	0.49	0.63
Time of operation (min)	72.42 ± 15.95	82.12 ± 14.06	-3.53	0.001*
Time of screw/device placement (min)	15.53 ± 3.34	27.82 ± 6.23	-13.46	< 0.001*
Amount of bleeding (ml)	65.50 ± 16.84	82.15 ± 17.05	-5.38	< 0.001*
Length of stay (day)	9.23 ± 4.26	11.12 ± 4.72	-2.30	0.02*

*P < 0.05.

JOA scores, ODI scores, ROM, PDH, and FH. The Chi-square test was used to compare gender distribution between the groups. All values were expressed as mean ± standard deviation (SD).

Within-group comparisons of VAS, JOA, ODI, ROM, PDH, and FH across different time points were analyzed using repeated measures analysis of variance (ANOVA). A *p*-value < 0.05 was considered significant.

Results

Comparison of baseline characteristics

The baseline characteristics of the fusion and non-fusion groups showed both similarities and differences. Gender distribution was identical in both groups, with 22 men and 38 women (P > 0.05), and the average illness duration as well as the mean duration of prior conservative treatment were comparable between the two groups (both P > 0.05). However, the fusion group had a significantly higher mean age and a longer mean hospital stay compared to the non-fusion group (both P < 0.05).

After undergoing adequate decompression and nucleus pulposus removal, 60 patients in each group were respectively treated with lumbar fusion surgery (posterior lumbar interbody fusion [PLIF] or transforaminal lumbar interbody fusion [TLIF]) and the IntraSPINE dynamic stabilization system. In terms of treatment - related metrics, the fusion group had a significantly longer operative time and screw/device placement time compared to the non-fusion group (both P < 0.05). Additionally, intraoperative blood loss was significantly higher in the fusion group than in the non-fusion group (P < 0.05). See **Table 1**.

Comparison of clinical outcomes

Both groups demonstrated significant postoperative improvements in JOA, VAS, and ODI scores compared to baseline (all P < 0.05) (**Table 2**; **Figure 2**).

Notably, VAS scores showed marked reductions in postoperative pain in both groups; however, at 12 months, the non-fusion group exhibited significantly better pain relief compared to the fusion group (P < 0.05).

Comparison of radiographic outcomes

Radiographic evaluations confirmed that all patients underwent decompression at the L4-L5 level, with pedicle screw-rod fixation in the fusion group and IntraSPINE implantation in the non-fusion group (**Figure 3**). All patients were diagnosed with lumbar degenerative disease at the L4-L5 segment and underwent decompression surgery at this level. Following decompression, patients in the non-fusion group received IntraSPINE prosthesis implantation, while those in the fusion group underwent pedicle screw-rod fixation. Representative radiographic images, including neutral position MRI and dynamic lateral radiographs, are shown in **Figure 3**.

Postoperatively, ROM at both the operative and adjacent segments decreased at 7 days in both groups (**Table 3**; **Figure 4**). By 6 and 12 months,

Table 2. Comparative analysis of clinical outcomes: non-fusion vs. fusion groups

	Non-fusion group (n = 60)	Fusion group (n = 60)	*t*	*P*
Japanese Orthopaedic Association (JOA) scores				
Pre-op	13.02 ± 2.00	13.00 ± 1.90	0.05	0.96
7 days	20.43 ± 2.21	20.72 ± 2.15	-0.71	0.48
6 months	25.80 ± 2.21	26.27 ± 1.43	-1.38	0.17
12 months	26.37 ± 2.16	26.82 ± 1.54	-1.32	0.19
Visual analog scale (VAS) scores				
Pre-op	7.80 ± 0.88	7.68 ± 0.93	0.71	0.48
7 days	2.67 ± 1.07	2.97 ± 1.03	-1.57	0.12
6 months	1.45 ± 0.98	1.53 ± 0.89	-0.49	0.63
12 months	0.63 ± 0.74	0.95 ± 0.83	-2.21	0.03*
Oswestry Disability Index (ODI) scores				
Pre-op	55.45 ± 5.00	55.62 ± 5.15	-0.18	0.86
7 days	41.77 ± 5.09	42.72 ± 4.89	-1.04	0.30
6 months	13.22 ± 4.05	14.37 ± 3.94	-1.58	0.12
12 months	12.27 ± 4.23	12.73 ± 3.39	-0.66	0.51

*P < 0.05.

ROM at the operative segment was completely eliminated in the fusion group, while adjacent segment ROM significantly increased (P < 0.05). In contrast, the non-fusion group demonstrated partial recovery of operative segment ROM and stable adjacent segment mobility without significant changes from baseline (P > 0.05).

PDH at the operative segment improved significantly in both groups postoperatively. However, in the fusion group, PDH at the upper adjacent segment significantly decreased at 6 months, and PDH at the lower adjacent segment was further reduced at 12 months compared to the non-fusion group (P < 0.05) (**Table 3**; **Figure 5**).

FH at the operative segment increased after surgery in both groups. Nevertheless, the fusion group consistently exhibited significantly lower FH values at 7 days, 6 months, and 12 months compared to the non-fusion group (P < 0.05). Moreover, at 6 and 12 months, FH at the upper adjacent segment, and at 12 months at the lower adjacent segment, were reduced in the fusion group relative to the non-fusion group (P < 0.05) (**Table 3**; **Figure 6**).

Discussion

The prevalence of lumbar degenerative diseases has been steadily increasing, particularly among younger individuals, due to occupational demands and sedentary lifestyles [21]. In response, there is growing emphasis on standardizing and optimizing treatment strategies for this condition. Management typically follows a stepwise approach, wherein conservative therapy is prioritized for patients with mild symptoms and shorter disease duration, while surgical intervention is reserved for those with more severe pathology and prolonged disease courses [22]. Currently, lumbar fusion surgery remains the gold standard for treating lumbar degenerative disease, primarily due to its effectiveness in restoring spinal stability [23]. However, despite its clinical benefits, lumbar fusion significantly alters spinal biomechanics. It increases facet joint loading and intervertebral disc pressure in adjacent segments, thereby elevating the risk of ASD [24]. Previous studies have shown that fusion surgery can reduce ROM at the operative segment by 80.8%-90.9%, while increasing ROM at adjacent segments by 12.6%-28.9%, thus significantly raising the likelihood of ASD development [25]. In a study of 97 patients who underwent fusion surgery, Ouchida et al. reported that 19 cases (19.6%) developed ASD within two years postoperatively [26]. Given the substantial clinical effect of ASD, preventing or delaying its onset has become a key objective in the surgical management of lumbar degenerative diseases.

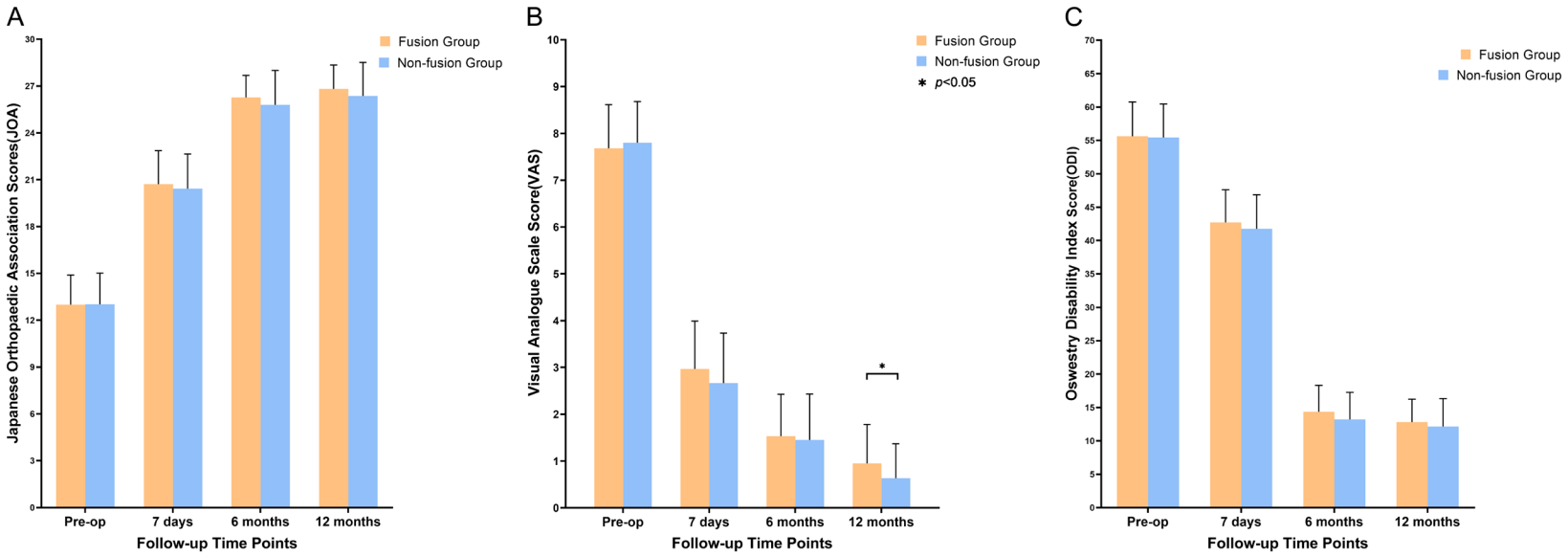

Figure 2. Comparison of clinical outcomes (JOA: Japanese Orthopaedic Association scores; VAS: Visual Analog Scale scores; ODI: Oswestry Disability Index scores). The JOA scores (A), VAS scores (B) and ODI scores (C) for the lumbar fusion group (60 patients) and the IntraSPINE dynamic stabilization system group (60 patients) were evaluated over time. The mean JOA scores, VAS scores, and ODI scores before and after the surgery (at 7 days, 6 months, and 12 months) were calculated for all 120 patients. Data are presented as mean ± standard deviation for each time point (*P < 0.05).

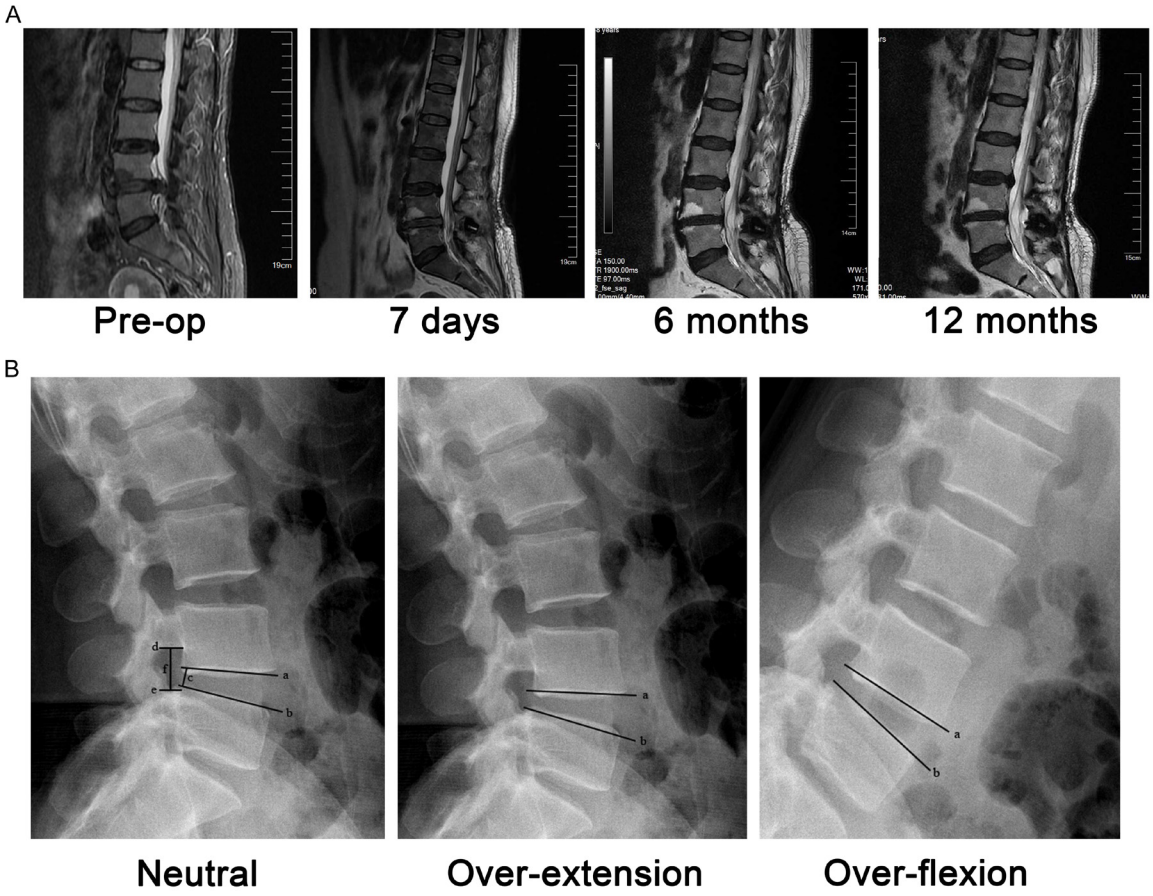

Figure 3. Original and typical radiographic images. A. Neutral MRI images (From left to right: Preoperatively, 7 days postoperatively, 6 months postoperatively, 12 months postoperatively). B. Lateral X-rays images (From left to right: Neutral, Hyperextension and Hyperflexion). (a) Inferior endplate of the superior vertebral body. (b) Superior endplate of the inferior vertebral body. Range of motion (ROM): Angular difference between the line connecting the inferior endplates of superior vertebrae (a) and the line connecting the superior endplates of inferior vertebrae (b) during hyperextension-flexion motion at a single spinal segment. (c) Posterior disc height (PDH)-Vertical distance between the posteroinferior margin of the superior vertebral body and the posterosuperior margin of the inferior vertebral body on neutral lateral radiographs. (d) Inferior pedicle notch of the superior vertebral body. (e) Superior pedicle notch of the inferior vertebral body. (f) Foraminal height (FH)-Vertical distance between the inferior pedicle notch of the superior vertebral body and the superior pedicle notch of the inferior vertebral body on neutral lateral radiographs.

Dynamic stabilization systems were introduced to mitigate adjacent segment degeneration while preserving segmental mobility and redistributing spinal loads to support intervertebral disc self-repair [11]. The main non-fusion stabilization devices currently in clinical use are interspinous process devices, including static systems such as X-STOP and Wallis, and dynamic systems like Coflex and the Device for Intervertebral Assisted Motion. Although these devices are widely used in managing mild to moderate lumbar degenerative conditions, they are associated with several limitations. Reported complications include spinous process fractures, technical difficulties in implanting devices at the L5-S1 level, and recurrence of postoperative pain symptoms [27-29]. These limitations highlight a need for further innovation and refinement in interspinous process stabilization technologies.

The IntraSPINE dynamic stabilization system, developed by Italian researchers Guizzardi and Morichi [30], was designed to overcome these limitations. Its anterior component is composed of medical-grade silicone and polymers, allowing implantation between the laminae to restore intervertebral height and achieve decompression by distracting the superior and inferior laminae. The posterior component,

Table 3. Comparative analysis of radiographic outcomes: non-fusion vs. fusion groups

	Non-fusion group (n = 60)	Fusion group (n = 60)	*t*	*P*
Range of motion (ROM) of upper segment (°)				
Pre-op	5.52 ± 1.60	5.08 ± 1.79	1.40	0.16
7 days	2.50 ± 1.03	2.97 ± 1.63	-1.88	0.06*
6 months	5.55 ± 1.44	6.47 ± 1.82	-3.06	0.003*
12 months	5.87 ± 1.42	8.38 ± 1.65	-8.96	< 0.001*
ROM of operative segment (°)				
Pre-op	6.35 ± 1.57	6.60 ± 1.54	-0.88	0.38
7 days	1.13 ± 0.89	0.28 ± 0.45	6.58	< 0.001*
6 months	3.40 ± 1.18	0.25 ± 0.44	19.37	< 0.001*
12 months	3.43 ± 1.08	0.22 ± 0.42	21.54	< 0.001*
ROM of lower segment (°)				
Pre-op	6.82 ± 1.44	6.73 ± 1.67	0.29	0.77
7 days	2.18 ± 1.02	3.12 ± 1.20	-4.61	< 0.001*
6 months	6.73 ± 1.45	8.63 ± 1.44	-7.21	< 0.001*
12 months	7.03 ± 1.57	9.67 ± 1.35	-9.85	< 0.001*
Posterior disc height (PDH) of upper segment (mm)				
Pre-op	9.75 ± 1.67	9.73 ± 1.46	0.07	0.94
7 days	9.75 ± 1.67	9.71 ± 1.47	0.15	0.88
6 months	9.73 ± 1.68	9.11 ± 1.39	2.21	0.03*
12 months	9.78 ± 1.71	8.20 ± 1.33	5.65	< 0.001*
PDH of operative segment (mm)				
Pre-op	6.71 ± 1.75	7.83 ± 1.61	-3.63	< 0.001*
7 days	8.71 ± 1.36	8.90 ± 1.44	-0.75	0.45
6 months	8.69 ± 1.38	8.88 ± 1.44	-0.74	0.46
12 months	8.72 ± 1.37	8.80 ± 1.43	-0.33	0.74
PDH of lower segment (mm)				
Pre-op	9.42 ± 1.62	9.67 ± 1.36	-0.93	0.35
7 days	9.41 ± 1.59	9.58 ± 1.34	-0.62	0.54
6 months	9.39 ± 1.58	9.13 ± 1.35	0.97	0.33
12 months	9.30 ± 1.60	8.11 ± 1.46	4.27	< 0.001*
Foraminal height (FH) of upper segment (mm)				
Pre-op	18.80 ± 2.21	18.37 ± 1.78	1.16	0.25
7 days	18.81 ± 2.23	18.32 ± 1.79	1.31	0.19
6 months	18.57 ± 2.20	16.81 ± 2.02	4.57	< 0.001*
12 months	18.39 ± 2.24	15.38 ± 2.27	7.33	< 0.001*
FH of operative segment (mm)				
Pre-op	13.19 ± 2.01	13.52 ± 1.75	-0.95	0.34
7 days	17.69 ± 1.93	14.71 ± 1.77	8.79	< 0.001*
6 months	17.61 ± 1.93	14.69 ± 1.76	8.65	< 0.001*
12 months	17.56 ± 1.93	14.72 ± 1.79	8.36	< 0.001*
FH of lower segment (mm)				
Pre-op	17.02 ± 2.03	17.37 ± 1.92	-0.96	0.34
7 days	16.94 ± 2.03	17.30 ± 1.91	-1.01	0.32
6 months	16.79 ± 2.04	16.90 ± 1.92	-0.32	0.75
12 months	16.68 ± 2.04	15.47 ± 1.99	3.27	0.001*

*$P < 0.05$.

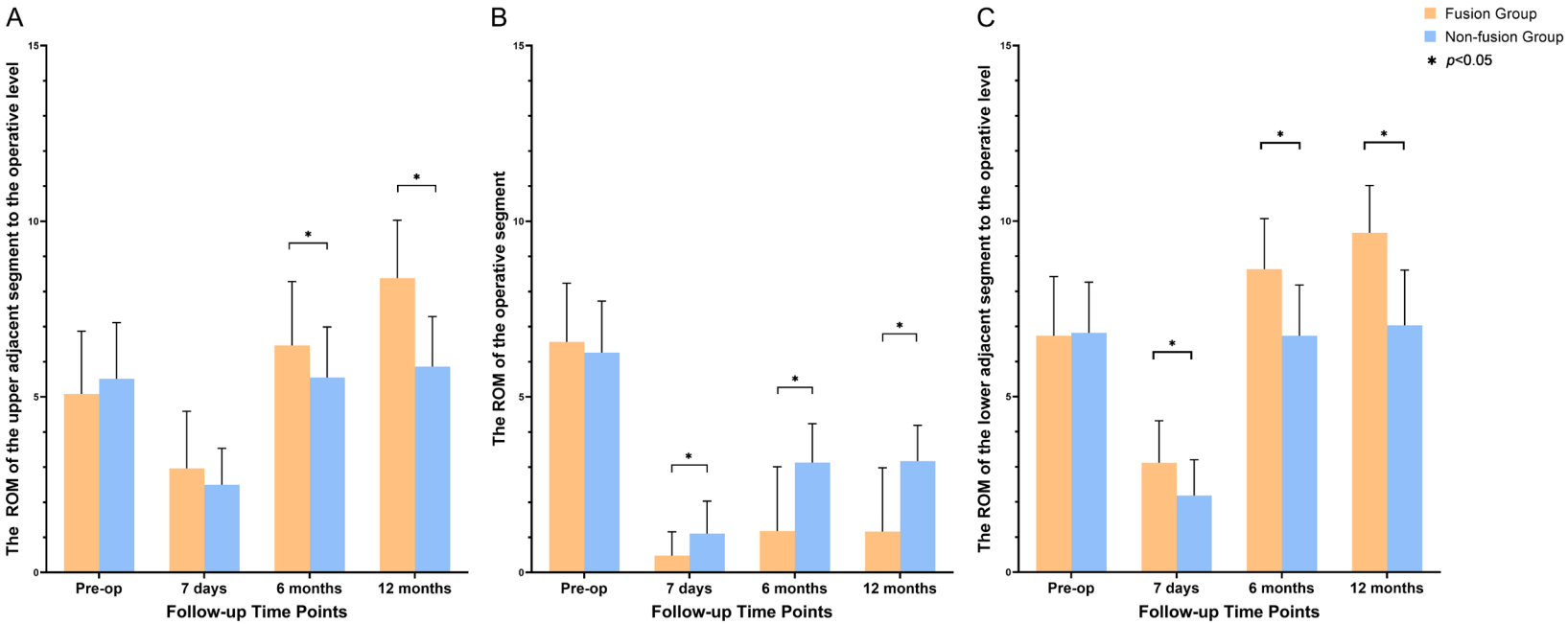

Figure 4. The range of motion (ROM) of the operative segment and adjacent segments. The ROM of the operative segment (B) and adjacent segments (A, C) was evaluated over time for both the lumbar fusion group (60 patients) and the IntraSPINE dynamic stabilization system group (60 patients). Data are presented as mean ± standard deviation for each time point (*P < 0.05).

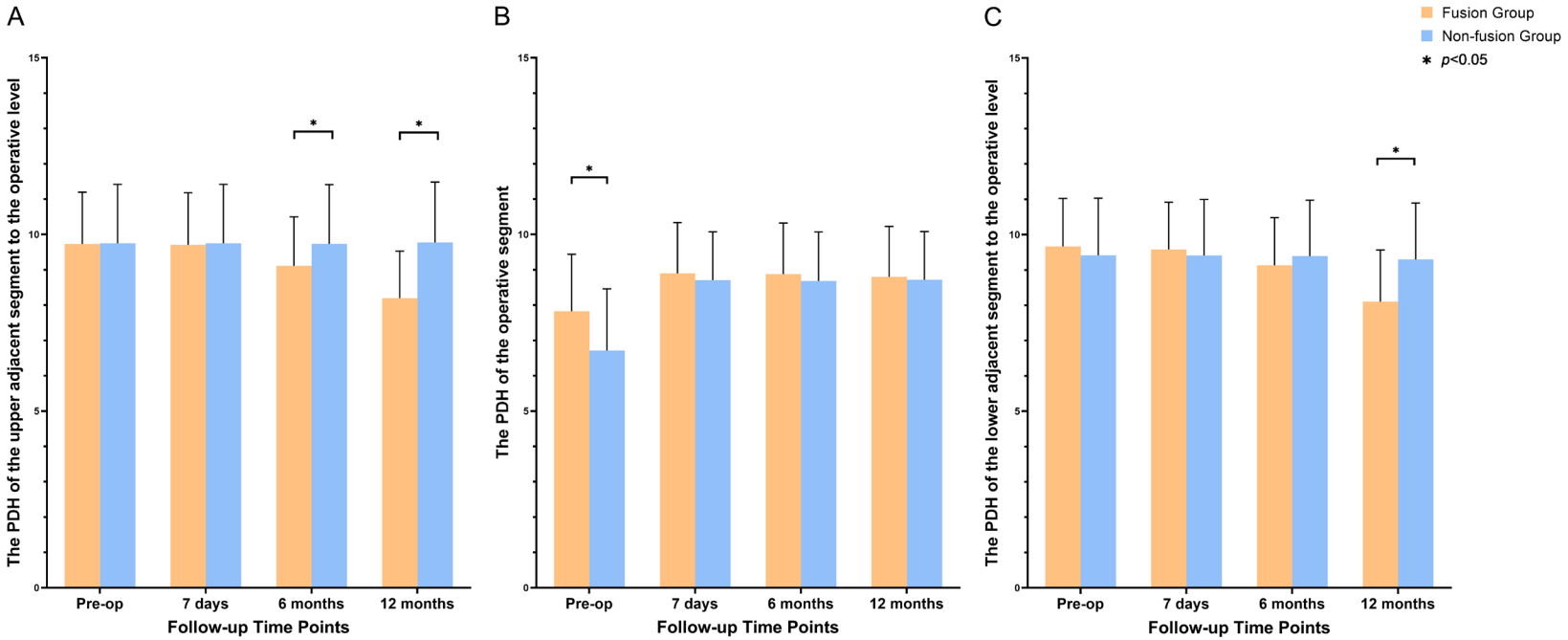

Figure 5. The posterior disc height (PDH) of the operative segment and adjacent segments. The PDH of the operative segment (B) and adjacent segments (A, C) was measured over time for both the lumbar fusion group (60 patients) and the IntraSPINE dynamic stabilization system group (60 patients). Data are presented as mean ± standard deviation for each time point (*P < 0.05).

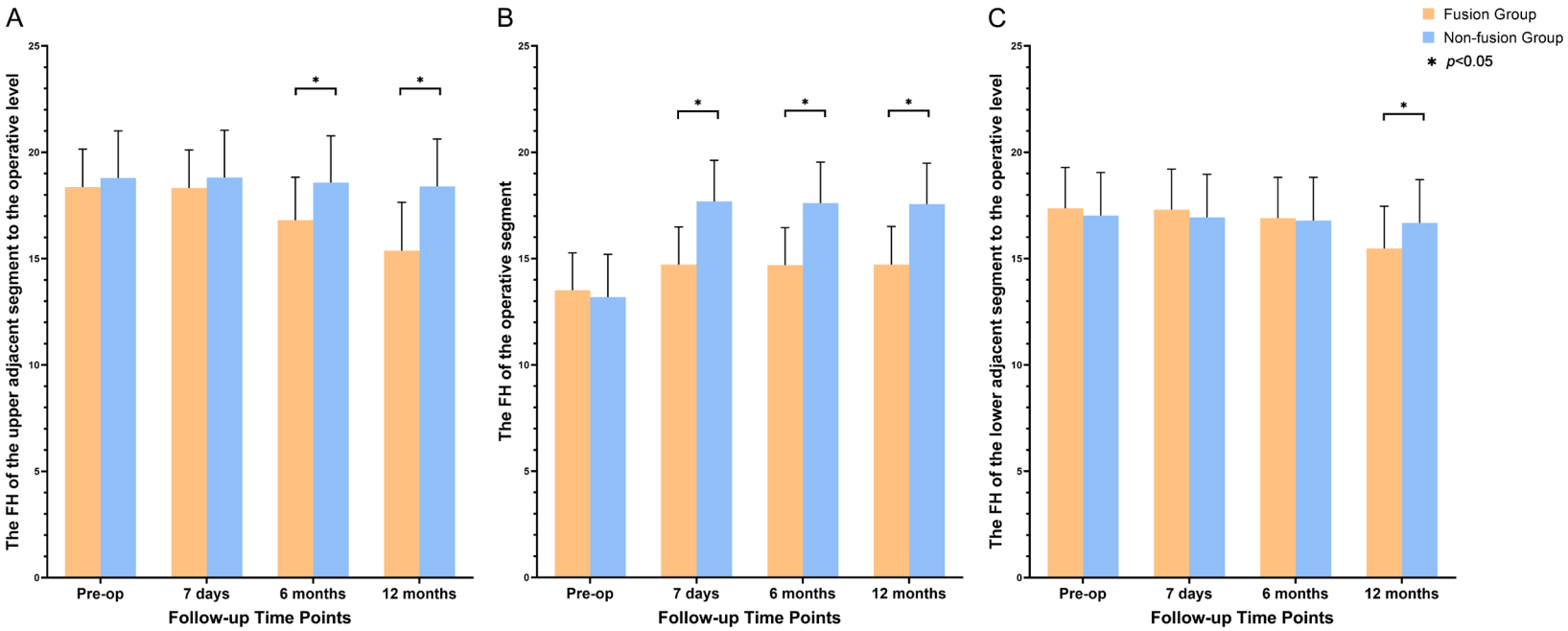

Figure 6. The foraminal height (FH) of the operative segment and adjacent segments. The FH of the operative segment (B) and adjacent segments (A, C) was measured over time for both the lumbar fusion group (60 patients) and the IntraSPINE dynamic stabilization system group (60 patients). Data are presented as mean ± standard deviation for each time point (*P < 0.05).

which is placed between the spinous processes, is made of highly compressible soft silicone. During implantation, it can be compressed to facilitate insertion and then rebound to its original shape upon removal of surgical tools, thereby simplifying the procedure.

Biomechanically, spinal movement is centered around the instantaneous axis of rotation. Compared to traditional interspinous process devices, the IntraSPINE system aligns more closely with the physiological IAR, reducing localized spinal stress and minimizing excessive loading on the spinous processes. This design advantage lowers the risk of postoperative spinous process fractures and osteolysis [15]. Functionally, the IntraSPINE system is intended to preserve physiologic spinal flexion and extension while limiting excessive flexion and improving rotational control. When used alone, it effectively reduces disc pressure during hyperextension. When combined with a strapping band, it further reduces disc pressure during both hyperextension and flexion [30]. These effects are attributed to the redistribution of spinal loads. In a normal spinal unit, the anterior column bears the majority of the mechanical load. The IntraSPINE implant helps redistribute this load, thereby reducing stress on the operative segment, enhancing stability, limiting excessive motion, and protecting the intervertebral disc. This load redistribution may slow or even reverse disc degeneration, making the IntraSPINE system a viable alternative to conventional fusion techniques.

The introduction of IntraSPINE as a novel dynamic stabilization system offers clinicians a promising alternative for the treatment of lumbar degenerative diseases. The primary source of pain in these patients is nerve root compression. Both lumbar fusion and the IntraSPINE non-fusion procedure effectively decompress the nerve root canal by removing disc material and posterior osteophytes, thereby achieving favorable clinical outcomes. However, unlike fusion surgery - which restricts motion at the operative segment - the IntraSPINE system aligns more closely with the physiological instantaneous axis of rotation. This biomechanical advantage facilitates the restoration of intervertebral foramen height while preserving lumbar mobility at both the treated and adjacent segments, possibly slowing or even reversing disc degeneration [11].

In this study, 120 patients diagnosed with degenerative spinal disorders underwent surgical treatment using either the IntraSPINE dynamic stabilization system or lumbar fusion. Compared to the fusion group, the non-fusion group had significantly shorter operative times, reduced device placement durations, lower intraoperative blood loss, and shorter hospital stays. Both groups showed significant improvements in JOA, ODI, and VAS scores at all postoperative time points compared to baseline. Notably, at the 12-month follow-up, the non-fusion group demonstrated significantly greater improvement in VAS scores, likely due to the less invasive nature of the IntraSPINE procedure, which minimizes soft tissue disruption and promotes faster recovery.

Radiographic findings revealed distinct biomechanical outcomes between the two groups. In the fusion group, patients experienced a near-complete loss of ROM in the operated segment within 7 days postoperatively, with minimal recovery observed at 6 and 12 months. Although adjacent segment ROM initially decreased, it exceeded preoperative levels by 6 and 12 months, indicating compensatory hypermobility. In contrast, the IntraSPINE group exhibited an initial reduction in operated segment ROM at 7 days postoperatively, with partial recovery observed at 6 and 12 months, reflecting preserved segmental mobility. Adjacent segment ROM in this group remained comparable to preoperative values throughout follow-up.

In addition, the fusion group showed a significant decrease in PDH and FH of the upper adjacent segment at 6 months postoperatively, and of the lower adjacent segment at 12 months. By contrast, the non-fusion group maintained PDH and FH at adjacent segments near preoperative levels throughout the study period.

These findings suggest that fusion surgery results in substantial loss of motion at the treated segment, with compensatory overloading and increased motion at adjacent levels, thereby promoting ASD. In comparison, the IntraSPINE system preserves spinal biomechanics by maintaining partial ROM at the operative segment and preventing abnormal stress on adjacent levels, thus reducing the risk of ASD.

At final follow-up, radiographic signs of ASD were observed in eight patients from the fusion group, three of whom required revision surgery. In the non-fusion group, two patients showed increased T2-weighted MRI signal in the intervertebral disc, indicative of a potential "rehydration" phenomenon. This may reflect a redistribution of mechanical stress conducive to disc self-repair, thereby slowing or even reversing degeneration [30].

The IntraSPINE dynamic stabilization system mimics the physiological IAR of the spine, reducing stress on adjacent segments and lowering ASD risk. In contrast, while fusion stabilizes the diseased segment, it increases motion in adjacent segments, possibly accelerating their degeneration [31]. At 12 months postoperatively, the IntraSPINE group showed partial recovery of ROM at the operative segment and stable adjacent segment motion, whereas the fusion group exhibited significantly increased adjacent segment ROM. These findings support existing evidence that dynamic stabilization better preserves spinal biomechanics. By maintaining segmental motion, dynamic systems reduce postoperative stiffness and pain, thereby enhancing short-term quality of life [32]. Conversely, while fusion achieves immediate stabilization, it may compromise long-term outcomes due to progressive ASD [27, 30].

In summary, both the IntraSPINE and fusion groups achieved significant improvements in VAS, JOA, and ODI scores at 7 days, 6 months, and 12 months postoperatively. However, the IntraSPINE system demonstrated superior preservation of adjacent segment function and radiographic measurements, suggesting that dynamic stabilization can offer comparable clinical efficacy to fusion while better maintaining spinal function.

No cases of recurrence were observed in the non-fusion group. However, in the fusion group, two patients (excluded post-inclusion) required revision surgery within one year postoperatively due to ASD. Additionally, no instances of prosthesis loosening, subsidence, or displacement were detected in the non-fusion group. These findings suggest that proper postoperative functional rehabilitation and accurate implant sizing may help maintain prosthesis stability and prevent complications such as loosening, subsidence, and displacement. Compared with lumbar fusion, the non-fusion approach may be more suitable for younger patients. Indications for IntraSPINE include: (1) relatively young patients with degenerative disc disease; (2) low back pain associated with disc or facet joint degeneration; (3) soft foraminal stenosis; (4) intractable low back pain due to facet joint syndrome; and (5) prevention of disc collapse following discectomy. Contraindications include: (1) large lumbar disc herniation or prolapse; (2) severe bony foraminal stenosis; (3) advanced osteoporosis; and (4) lumbar instability or spondylolisthesis of grade II or higher.

While this study provides valuable comparative insight into the effectiveness of the IntraSPINE dynamic stabilization system versus traditional lumbar fusion, several methodologic limitations must be considered:

Non-randomized patient allocation introduced potential selection bias, as surgical decision-making was based on clinical suitability and the preferences of surgeons and patients rather than randomization. Although baseline demographic and clinical characteristics were similar between groups, unmeasured confounders - such as differences in disease progression, psychosocial factors, or preoperative function - may still have influenced outcomes.

The sample size was determined based on patient availability rather than a formal *a priori* power calculation. Although post hoc analyses indicated sufficient statistical power to detect differences in primary outcomes, future studies should include prospective sample size estimations based on expected effect sizes and power levels (e.g., 80-90%).

The relatively short follow-up duration (12-15 months) limits the evaluation of long-term outcomes, especially ASD, which typically manifests over a longer period. Additionally, the single-center design and reliance on a single surgeon, although advantageous for procedural consistency, may limit the generalizability of the findings across other institutions, populations, or surgical teams.

Despite these limitations, assets of the study were strict inclusion/exclusion criteria, standardized surgical procedures, and comprehensive longitudinal data collection. The prospec-

tive design and direct comparison between dynamic stabilization and the gold-standard fusion technique offer a strong foundation for further investigation. Larger, multicenter randomized controlled trials with longer follow-up durations are warranted to validate these findings and further explore the long-term biomechanical and clinical outcomes of the IntraSPINE system.

Conclusion

Both lumbar fusion procedures (TLIF or PLIF) and the IntraSPINE dynamic stabilization system resulted in significant clinical improvement. However, compared to fusion, the IntraSPINE system offered several advantages, including less surgical trauma, shorter operative duration, and reduced intraoperative blood loss. Radiographic assessments showed that the IntraSPINE group had better preservation of ROM, PDH, and FH at both the treated and adjacent segments. These superior radiologic outcomes suggest that dynamic stabilization better preserves spinal biomechanics and limits structural deterioration at adjacent levels.

Furthermore, the preservation of motion at the operated segment and the minimal changes observed in adjacent segments in the IntraSPINE group may contribute to delaying the onset of ASD and reducing the need for subsequent revision surgeries.

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Disclosure of conflict of interest

None.

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