



# Exploring Flexibility vs. Stability: A Biomechanical Study on Stand-Alone Cages vs. Unilateral and Bilateral Pedicle Screw Fixation in Multilevel Lateral Lumbar Interbody Fusion and the Impact on Slope Variations

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## Abstract

**Background Context:** Lateral lumbar interbody fusion (LLIF) is utilized to treat various lumbar spine conditions, including degenerative disc disease, spondylolisthesis, and spinal instability. Although pedicle screws and rods are commonly added for fusion stability, they pose risks such as adjacent facet joint issues and guidewire-related vascular problems. Previous research has identified a direct link between the level of instrumentation and a reduction in spinal flexibility, prompting a critical question: What's the ideal balance between spinal flexibility and stability for successful fusion, challenging the idea of completely restricting natural spinal motion?

**Methods:** Eight human cadaveric L1-L5 specimens were utilized, affixed to a universal testing machine (MTS 30/G) and subjected to optical motion-tracking technology for three-dimensional range of motion assessment. The specimens underwent testing under four conditions: 1) intact, 2) 26 mm lateral interbody stand-alone cages (stand-alone LLIF), 3) 26 mm lateral interbody cages with unilateral rod fixation at L1-L5 (LLIF + unilateral rod), and 4) 26 mm lateral interbody cages with bilateral rods fixation at L1-L5 (LLIF + bilateral rods).

**Results:** From the intact condition, stand-alone LLIF decreased the slope of flexion by 0.29, extension by 0.89, left lateral bending by 0.93, and right lateral bending by 0.18. Compared to the stand-alone cages, LLIF with unilateral rod and pedicle screw fixation further decreased the slope of flexion by 0.08-0.30. Conversely, the implementation of bilateral rods and pedicle screws decreased slope by an additional 0.24-0.42 compared to the stand-alone cages.

**Conclusions:** Our study found that the differences in ROM between stand-alone LLIF and using additional instrumentation amount to changes in slope below 1. This raises the question: Is the incremental decrease in ROM, often expressed in fractions, genuinely pivotal in the larger context of patient outcomes and overall well-being?

**Keywords:** bilateral pedicle screw fixation; unilateral pedicle screw fixation; stand-alone cage; biomechanical spinal stability; cadaveric spinal fixation; lateral lumbar interbody fusion

## Introduction

Lateral lumbar interbody fusion (LLIF) is a surgical technique employed to achieve spinal fusion in patients affected by diverse lumbar spine conditions, such as degenerative disc disease, spondylolisthesis, and spinal instability [1,2]. The primary clinical goals of LLIF include achieving spinal fusion, restoring disc height and alignment, and alleviating pain by addressing instability or neural compression. These outcomes are facilitated through indirect decompression, segmental stabilization, and biomechanical load redistribution by fusing two or more vertebral levels [3-5]. During the LLIF procedure, the surgeon skillfully removes the damaged disc and introduces a biocompatible interbody cage into the disc space, serving as a spacer to restore disc height and offer support to adjacent vertebrae [1]. The cage's design, often constructed from materials like titanium or polyetheretherketone, may feature porous surfaces to encourage bone growth in and around the cage, promoting fusion [6,7].

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When supplemental fixation is used, pedicle screws are inserted into the vertebral pedicles, and rods are secured to these screws to provide additional support and reduce micromotion at the fused segment. While supplemental internal fixation with pedicle screws and rods is a common practice in LLIF to enhance fusion stability, it carries risks like segment stiffness, adjacent facet joint violation and guidewire migration leading to vascular injury [8,9]. Patients with increased implantation face elevated complications, extended dissection, increased blood loss, longer surgeries, and higher costs [2,10]. In contrast, stand-alone LLIF without rods and screws offers a minimally invasive alternative, reducing tissue trauma, postoperative pain, and recovery time, potentially achieving comparable or superior fusion rates due to larger interbody cages [5, 11-14].

Previously, we examined spinal movement after introducing unilateral and bilateral instrumentation alongside stand-alone cages, finding that bilateral rods and screws increased stability, reducing movement an additional 1.1 to 2.77 degrees compared to stand-alone cages [15,16]. While these studies unveiled a direct correlation between the extent of instrumentation and the subsequent reduction in spinal flexibility, they also triggered an essential inquiry: Does the marginal decrease in ROM of 1-2 degrees justify the use of increased spinal instrumentation? What is the optimal balance between spinal flexibility and stability for successful fusion? This inquiry necessitates a nuanced examination of the trade-offs between biomechanical stability and preserving the spine's natural kinematics. While greater fixation is often advocated for improved spinal stability and fusion rates, emerging research suggests that excessive rigidity may negatively impact quality of life [17,18]. While there is no universally required level of spinal flexibility for all patients, the need for preserved motion varies based on individual factors such as age, activity level, and underlying pathology. Biomechanical ROM studies in cadaveric models are crucial in illustrating the mechanical effects of instrumentation, highlighting how small reductions in ROM can have a significant clinical impact. This raises a critical question: is the marginal gain in stability worth the potential compromise in long-term function and comfort for all patients? Our study adds to this conversation by demonstrating the biomechanical effects of different fixation strategies, reinforcing the importance of balancing stability with preserved motion to optimize patient outcomes.

This study aimed to appraise the biomechanical flexibility of broader 26 mm lateral cages in a multilevel fusion context spanning L1 to L5, encompassing flexion, extension, and lateral bending. Our investigation diverged from previous methods relying solely on angular measurements in degrees by utilizing slope alterations to assess stand-alone cages and unilateral and bilateral pedicle screw and rod fixation. Unlike measuring ROM in degrees, which provide precise angular

insights, slope measurements offer a more comprehensive assessment, quantifying both the degree of angular changes and changes in direction crucial for understanding spinal repositioning. This integrated approach in spine medicine presents opportunities for innovation, spanning personalized implant design, proactive scoliosis management, enhanced rehabilitation, advanced biomechanical research, and refined surgical planning. Our initial hypothesis posited that implementing 26 mm wide interbody cages would yield biomechanical flexibility akin to the traditional LLIF approach, aligning with the notion that additional instrumentation might not be imperative.

## Methods

### Specimen Preparation

We included eight freshly frozen human cadaveric specimens of L1–5. These specimens underwent preparation involving removing surrounding soft tissues and muscles while preserving the discs and spinal ligaments, such as the supraspinous, interspinous, facet capsules, posterior longitudinal ligament, and anterior longitudinal ligament. The average age of the specimens was  $66.5 \pm 11.5$  years, consisting of 7 males and 1 female. Their average body mass index was  $31.1 \pm 7.32$  kg/m<sup>2</sup>. Before testing, all specimens were carefully examined visually to ensure the absence of fractures, deformities, previous surgeries, or severe spondylosis.

A computed tomography (CT) scan using the GE Bright speed system in Boston, MA, USA, was performed on all specimens to investigate bone quality and determine the optimal implant size. The CT scan settings were 120 kV, 20 mA, and 0.62-mm resolution. The measurements obtained from the scans were utilized for implant size planning. Nondestructive testing was conducted on all specimens under various conditions, including flexion, extension, and lateral bending.

### Instrumentation

The lateral interbody cages were implanted while the specimen was positioned laterally, using the innovative LLIF surgical technique and specialized instruments (eXtreme Lateral Interbody Fusion, Nuvasive, San Diego, CA, USA). These cages boasted a 26 mm width (from front to back) and were constructed from polyetheretherketone material (CoRoent, Nuvasive, San Diego, CA, USA). Precise measurements of each implant's height (from top to bottom) and length (from side to side) were determined through meticulous CT scans and were fine-tuned as required.

With the specimen in the prone position, pedicle screws (Armada, Nuvasive, San Diego, CA, USA) were bilaterally inserted across all levels from L1 to L5, employing the standard freehand technique guided by anatomical

landmarks. The optimal size of the screws was diligently chosen based on CT scans and adjusted as deemed necessary. The team conducted meticulous tapping and probing of pilot holes and thorough visual inspections to ensure no breaches occurred. In cases necessitating posterior instrumentation, 5.5-mm titanium rods were carefully and bilaterally placed. For testing purposes, the specimens were evaluated with the screws in place but without the rods, both in their intact state and under stand-alone conditions.

## Biomechanical Testing

The specimens were affixed to a universal testing machine (MTS 30/G) utilizing custom holding jigs. To induce flexion, extension, and lateral bending, a 200 N load was gradually applied at a rate of 2 mm/sec to the loading arm connected to the thoracic end of the spin. In contrast, the sacral end was securely fixed to the base of the loading frame (Fig. 1a). A 50N preload (follower load) was applied from L1 to L5. Throughout the testing process, a sophisticated optical motion-tracking device (Optotrak, Northern Digital Inc., Waterloo, ON, Canada) captured the three-dimensional motion of the specimens.

The apparatus setup was designed to apply a compressive follower preload, emulating the physiological preload exerted on the lumbar spine to maintain its alignment. This preload was administered through bilateral cables, freely passing through guides anchored to each vertebra. Additional

compressive forces ranging between 200–300 N, with a lever arm of 1.5 cm, were applied for flexion and extension, generating a combined moment of 4.5–6 Nm. It is worth noting that most of the previous experiments employing the follower method utilized pure moment loads between 4–8 Nm.

## Order of Testing

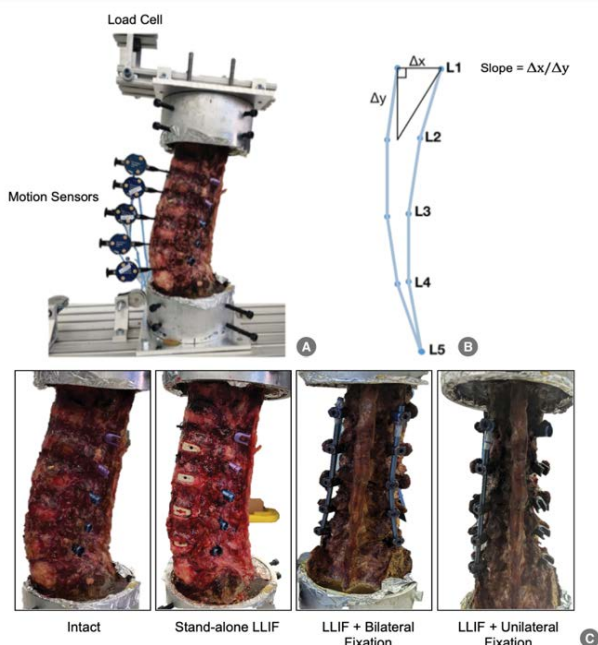
The test specimens underwent evaluation in four distinct conditions: 1) intact, 2) 26 mm lateral interbody stand-alone cages (stand-alone LLIF), 3) 26 mm lateral interbody cages with unilateral rod L1-L5 (LLIF + unilateral rod), 4) 26 mm lateral interbody cages with bilateral rods L1-L5 (LLIF + bilateral rods).

## Statistical Analysis

This study is a biomechanical cadaveric study, and patient-reported loss of flexibility was not directly assessed. However, ROM reductions in cadaveric models are often used as surrogates for clinical stiffness, as demonstrated in prior literature [17,18]. By tracking the positional shifts of the sensors during various spinal movements, we could calculate alterations in the inclination of the spine. Specifically, we calculated the change in the ROM following instrumentation as a percentage decrease from the intact specimen. ROM was determined by measuring the slope, which refers to the ratio of the vertical displacement to the horizontal distance between two specific points during spinal motion (flexion, extension, or lateral bending). The time points used for the vertical and horizontal measurements correspond to the spine's position before and after the motion in question. To clarify, the 'slope' described here is not simply a measure of stiffness (force applied/distance moved) but rather a geometric calculation representing the change in inclination of the spine during movement. For our analysis, we selected L1 as the reference point for measuring slope changes due to its central position in the lumbar spine and its characteristic alignment as the uppermost vertebra of the lumbar region. Changes in the slope of L1 relative to L5 were used as an indicator of overall spinal alignment, thus serving as a representative metric for evaluating the biomechanical effects of the interventions studied. The continuous variables' descriptive statistics are presented as mean  $\pm$  standard deviation. To compare ROM between instrumentation conditions and account for potential confounding effects, such as differences in bone quality among specimens, a paired t-test was employed. The statistical analyses were conducted using Microsoft Excel Version 2023, and significance was set at  $p < 0.05$ .

## Results

Bone quality determined using a previously described technique, CT scans [19], revealed an average Hounsfield unit (HU) of  $143 \pm 29.4$  (range, 84 to 169.4), with only one



**Figure 1:** Experimental configuration illustrating the load cell application (A). Optical motion sensors were strategically positioned from L1 to L5, enabling the spinal slope (B) computation. The configurations of the four conditions tested were generated by inserting rods and cages (C).

specimen falling below the suggested osteoporosis threshold of 110 HU [20]. Lateral interbody cages, standardized at 26 mm width, displayed varying heights (8 to 14 mm) and lengths (45 to 60 mm), with prevalent dimensions of 10 mm in height (n = 13) and 55 mm in length (n = 14). Pedicle screw sizes ranged from 6.5 mm to 8.5 mm in diameter and 40 to 60 mm in length, with 6.5 mm (n = 10), 7.5 mm (n = 45), and 8.5 mm (n = 25) being the most commonly employed diameters. As determined by CT scans, the screw diameter represented an average of  $72.3 \pm 14.4\%$  (median, 70.2%) of the pedicle's inner diameter. Comprehensive assessments of flexion/extension, lateral bending, and axial rotation were conducted across all eight specimens.

### Comparison with Intact Condition

Within the intact specimen, the mean ROM during spinal flexion was  $1.05 \pm 0.58$  (see Table 1). Following the introduction of a stand-alone cage, the slope during flexion was reduced by 0.29. This variation did not demonstrate statistically significant divergence from the intact ROM. When implementing the LLIF + unilateral rod approach, the slope of flexion decreased by 0.37 ( $p = .0033$ ). Using LLIF + bilateral rods further reduced the slope during flexion by 0.58 ( $p < 0.0001$ ).

Moreover, the mean ROM during spinal extension was quantified at  $1.52 \pm 0.33$ . Integration of a stand-alone cage reduced the slope during extension by 0.89. LLIF + unilateral rod yielded a reduction in slope by 0.93, and with the incorporation of LLIF + bilateral rods, the reduction escalated to 1.13. All three scenarios were statistically significant ( $p < 0.0001$ ).

In the context of left lateral bending of the spine, the mean ROM averaged  $1.75 \pm 1.16$ . With the introduction of a stand-alone cage, the slope during left lateral bending was reduced by 0.93. The LLIF + unilateral rod approach decreased the slope by 1.22, while the LLIF + bilateral rods decreased it by 1.23. All three deviations were statistically significant ( $p \leq 0.0001$ ).

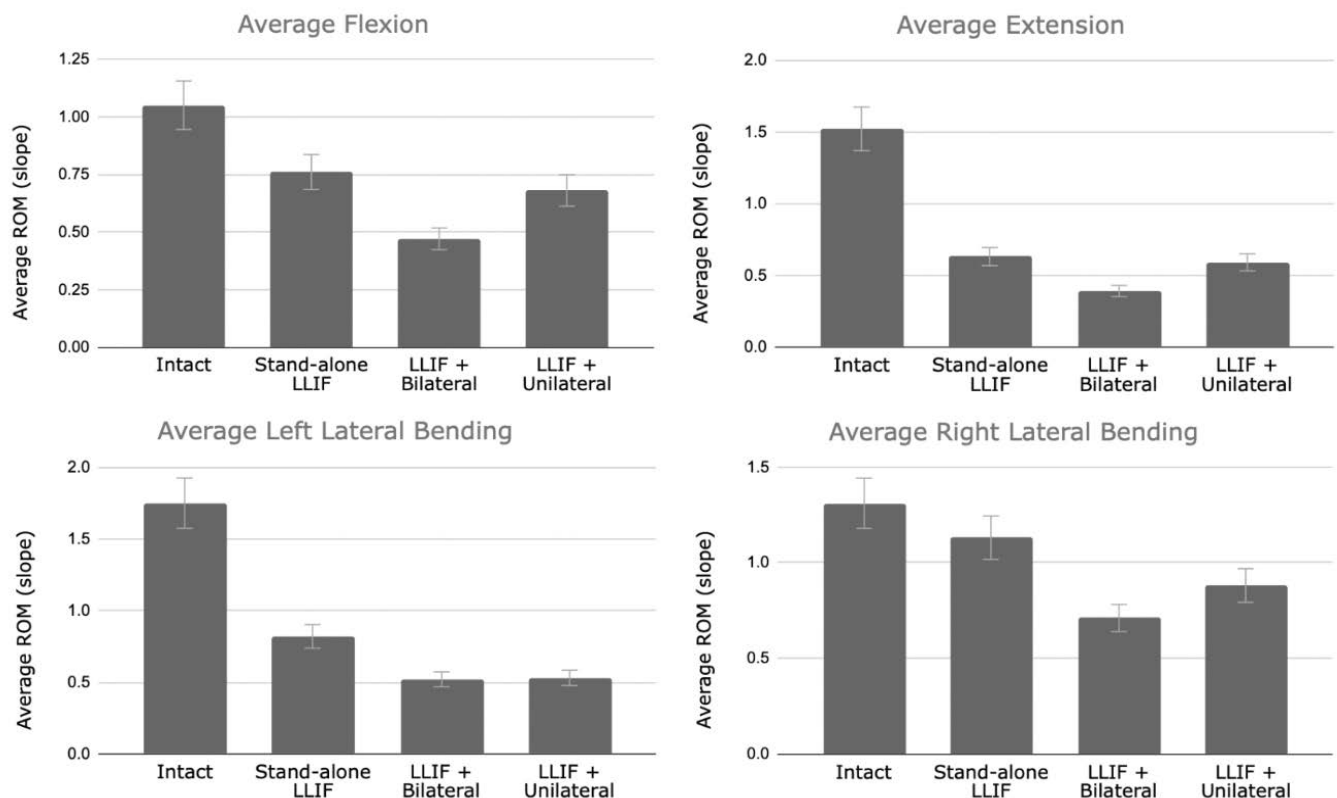
Furthermore, the mean ROM during right lateral bending of the spine was computed to be  $1.31 \pm 0.31$ . Using a stand-alone cage resulted in a decrease in slope by 0.18. This variance did not achieve statistical significance from the intact ROM. Implementing the LLIF + unilateral rod decreased the slope by 0.43, and the LLIF + bilateral rods reduced the slope by 0.60. These variations were statistically significant ( $p \leq 0.0001$ ). See Figure 2 for an alternative visualization of these results.

**Table 1:** Comparison of ROM of intact spine specimens with specimens after LLIF with stand-alone cages, as well as unilateral or bilateral pedicle screw and rod fixation.

Range of Motion (Slope)					
	Intact			Decrease in Slope from Intact	% Decrease from Intact
	Average	SD	p-value		
Flexion	1.05	0.58	-	-	-
Extension	1.52	0.33	-	-	-
Left Lateral Bending	1.75	1.16	-	-	-
Right Lateral Bending	1.31	0.31	-	-	-
	Stand-alone LLIF			Decrease in Slope from Intact	% Decrease from Intact
	Average	SD	p-value		
Flexion	0.76	0.61	0.0738	0.29	27.62%
Extension	0.63	0.13	< 0.0001	0.89	58.55%
Left Lateral Bending	0.82	0.13	0.0001	0.93	53.14%
Right Lateral Bending	1.13	0.38	0.0573	0.18	13.74%
	LLIF + Unilateral Rod			Decrease in Slope from Intact	% Decrease from Intact
	Average	SD	p-value		
Flexion	0.68	0.26	0.0033	0.37	35.24%
Extension	0.59	0.25	< 0.0001	0.93	61.18%
Left Lateral Bending	0.52	0.20	< 0.0001	1.23	70.29%
Right Lateral Bending	0.88	0.43	0.0001	0.43	32.82%
	LLIF + Bilateral Rod			Decrease in Slope from Intact	% Decrease from Intact
	Average	SD	p-value		
Flexion	0.47	0.09	< 0.0001	0.58	55.24%
Extension	0.39	0.09	< 0.0001	1.13	74.34%
Left Lateral Bending	0.53	0.51	< 0.0001	1.22	69.71%
Right Lateral Bending	0.71	0.22	< 0.0001	0.60	45.80%

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**Figure 2:** Bar graphs illustrate the ROM achieved by the intact spinal specimen and the specimens treated with various interventions, including LLIF with stand-alone cages and unilateral and bilateral pedicle screw and rod fixation.

### Comparison between Stand-alone LLIF and Unilateral and Bilateral Rods and Pedicle Screw Fixation

In evaluating slope variations between stand-alone LLIF and unilateral rod and pedicle screw fixation, a reduction of 0.8 in flexion and 0.4 in extension was observed when additional instrumentation was applied; however, these changes did not demonstrate statistical significance (see Table 2). In contrast, during lateral bending assessments, the slope was reduced by 0.30 during left lateral bending and 0.25 during right lateral bending. These changes exhibited statistical significance ( $p < 0.0001$  and  $p = 0.025$ , respectively).

When comparing the changes in ROM between stand-alone LLIF and bilateral rod and pedicle screw fixation, the slope was decreased by 0.29 during flexion, 0.24 decrease during extension, 0.29 during left lateral bending, and 0.42 during right lateral bending when additional instrumentation was applied. These four shifts demonstrated statistical significance ( $p = 0.0159$ ,  $p < 0.0001$ ,  $p = 0.0052$ , and  $p < 0.0001$ , respectively).

### Discussion and Conclusion

The primary aim of this investigation was to elucidate the potential merits inherent in using stand-alone LLIF cages as opposed to employing rods and pedicle screw

fixation. Our findings disclose a relatively lesser decrease in the ROM for stand-alone cages after multilevel LLIF, in contrast to the incorporation of bilateral rods and pedicle screws. The incorporation of a unilateral rod with pedicle screws contributed to a further reduction of the spine's overall ROM by 0.08-0.30 compared to utilizing stand-alone cages while the implementation of bilateral rods and pedicle screws reduced ROM by an additional 0.24-0.42 compared to using stand-alone cages. These findings prompt a pivotal inquiry: Is the substantial incorporation of such instrumentation within the body truly imperative, especially when the discerned differences in slope amount to fractions below 1? Our perspective becomes somewhat skewed when we encounter statistics presenting a conspicuous 38.16% reduction in flexion achieved by incorporating bilateral rods and pedicle screws in contrast to stand-alone cages. However, this 38.16% shift translates to a mere 0.29 reduction in ROM during flexion. This underscores the importance of examining the absolute numerical changes alongside the seemingly impressive percentages to better understand the clinical significance of these biomechanical alterations.

In 2016, Kretzer et al. conducted an investigation that revealed no statistically significant improvement in stability when facet screws and pedicle screws were introduced, in contrast to utilizing separate cages for stabilization [21].

Manzur et al. found that “stand-alone LLIF yields high fusion rates overall, with mean fusion noted in 85.6% of cases.”[22] Suk et al. and Fernandez-Fairen et al., independently concluded that there is no discernible variance in long-term radiographic or clinical outcomes between employing bilateral and unilateral instrumentation in posterolateral fusion [23,24]. As research continues to expand, advocating for the potential benefits of unilateral instrumentation over bilateral, it's crucial to acknowledge that our study did not uncover statistically significant changes in ROM during flexion and extension when comparing stand-alone LLIF with LLIF involving unilateral instrumentation. In essence, when tested biomechanically at time zero, employing stand-alone cages may impart similar stability as unilateral rods and pedicle screws. This challenges the notion that increased instrumentation is always synonymous with better stability.

Under all circumstances, incorporating increased spinal instrumentation (rods and pedicle screws) during fusion procedures diminishes the spine's flexibility, adversely affecting the patient's everyday activities. This reduced ROM can lead to challenges in performing routine tasks, compromised occupational functionality, limited engagement in recreational pursuits, altered posture, heightened risk of musculoskeletal issues, and psychological strain [25]. Bess et al. and Cappuccino et al. demonstrated that stand-alone cages, regardless of the presence or absence of supplemental fixation, induce a substantial reduction in ROM compared to the intact spine [26,27]. Although the research advocating for the preferential use of stand-alone cages over bilateral rods and screws is limited, emerging evidence suggests that the benefits of additional instrumentation should be carefully assessed, considering the potential downsides and complexity of increased surgical intervention. As research progresses, a focus on long-term outcomes, including fusion rates, biomechanical stability, and patient-reported results, is essential for assessing the effectiveness of multilevel stand-alone LLIF. Since this study captures an immediate post-surgery snapshot, future investigations should incorporate healing dynamics better to gauge the necessity of extensive instrumentation for spine stabilization. Moreover, exploring advancements in materials, techniques, and patient selection could further enhance the stand-alone approach's efficacy and applicability, contributing to refining spinal fusion strategies and ultimately enhancing patient well-being.

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## Conflict of Interest:

Author 1 & 6 disclose in-kind product donation by

Nuvasive. Author 6 discloses that he receives consulting fees and royalties from MiRus.

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