Biomechanical analysis in a human cadaveric model of spinous process fixation with an interlaminar allograft spacer for lumbar spinal stenosis

Laboratory investigation

**Ben B. Pradhan, M.D., M.S.E.,1 Alexander W. L. Turner, Ph.D.,2 Michael A. Zatushsky, M.D.,2 G. Bryan Cornwall, Ph.D.,2 Sean S. Rajaee, M.S.,3 and Hyun W. Bae, M.D.4**

1Risser Orthopaedic Group, Pasadena; 2NuVasive, Inc., San Diego; and 3The Spine Institute, Santa Monica, California

Object. Traditional posterior pedicle screw fixation is well established as the standard for spinal stabilization following posterior or posterolateral lumbar fusion. In patients with lumbar spinal stenosis requiring segmental posterior instrumented fusion and decompression, interlaminar lumbar instrumented fusion (ILIF) is a potentially less invasive alternative with reduced morbidity and includes direct decompression assisted by an interlaminar allograft spacer stabilized by a spinous process plate. To date, there has been no biomechanical study on this technique. In the present study the biomechanical properties of the ILIF construct were evaluated using an in vitro cadaveric biomechanical analysis, and the results are presented in comparison with other posterior fixation techniques.

Methods. Eight L1–5 cadaveric specimens were subjected to nondestructive multidirectional testing. After testing the intact spine, the following conditions were evaluated at L3–4: bilateral pedicle screws, bilateral laminotomy, ILIF, partial laminectomy, partial laminectomy plus unilateral pedicle screws, and partial laminectomy plus bilateral screws. Intervertebral motions were measured at the index and adjacent levels.

Results. Bilateral pedicle screws without any destabilization provided the most rigid construct. In flexion and extension, ILIF resulted in significantly less motion than the intact spine (p < 0.05) and no significant difference from the laminectomy with bilateral pedicle screws (p = 0.76). In lateral bending, there was no statistical difference between ILIF and laminectomy with unilateral pedicle screws (p = 0.11); however, the bilateral screw constructs were more rigid (p < 0.05). Under axial rotation, ILIF was not statistically different from laminectomy with unilateral or bilateral pedicle screws or from the intact spine (p > 0.05). Intervertebral motions adjacent to ILIF were typically lower than those adjacent to laminectomy with bilateral pedicle screws.

Conclusions. Stability of the ILIF construct was not statistically different from bilateral pedicle screw fixation following laminectomy in the flexion and extension and axial rotation directions, while adjacent segment motions were decreased. The ILIF construct may allow surgeons to perform a minimally invasive, single-approach posterior decompression and instrumented fusion without the added morbidity of traditional pedicle screw fixation and posterolateral fusion.

For the treatment of lumbar spinal stenosis with, for example, spondylolisthesis, direct decompression with segmental posterolateral instrumented fusion using pedicle screws has a long track record of clinical use2,18,28,33,48 and has demonstrated improved clinical outcomes7,17,21,32,55. Direct decompression through laminectomy can be somewhat varied in terms of bony resection.

**Key Words** • lumbar spine • spinal fusion • spinal stenosis • biomechanics • posterior lumbar fixation • spinous process plate

*Current**, spinal arthrodesis is the gold standard in the surgical management of degenerative lumbar diseases with instabilities, including spinal stenosis, spondylolisthesis, and degenerative disc disease.2,21,28,42,48,49 Among the variety of surgical techniques for spinal fusion, those most frequently used include instrumentation and posterolateral fusions.

*Abbreviations used in this paper:* bL = bilateral laminotomy; bPS = bilateral pedicle screw; ILIF = interlaminar lumbar instrumented fusion; pL = partial laminectomy; ROM = range of motion; uPS = unilateral pedicle screw.

This article contains some figures that are displayed in color online but in black-and-white in the print edition.
(lamina, facet joints, and so forth). Biomechanical studies indicate that the progressive removal of anatomical structures significantly increases the level of iatrogenic destabilization. Pedicle screw fixation is the most widely used instrumentation technique used for stabilizing the spine with the purported benefit of improving arthrodesis rates. However, pedicle screw fixation also carries a substantial amount of morbidity and is associated with a high rate of medical complications, including screw misplacement and neural injury. There is no consensus on how much stability is needed to create an environment that promotes fusion; however, the rigidity of the instrumentation should probably be balanced against the degree of instability to minimize adjacent-level hypermobility where possible.

Considering the pedicle screw–related clinical and biomechanical factors, coupled with the rising prevalence of degenerative spondylolisthesis, increased attention has been devoted to the exploration of alternative techniques for minimally disruptive decompression and internal fixation of the lumbar spine. Multiple fixation techniques have been developed utilizing a variety of instruments, including wires, clamps, plates, and screws. While each of these techniques has intrinsic advantages, there is still no consensus on the most effective strategy with the least amount of morbidity.

In 1911 Hibbs first described the technique of interlaminar arthrodesis in the treatment of degenerative conditions of the spine. In the current study we present a variation of Hibbs’ interlaminar fusion with the so-called interlaminar lumbar instrumented fusion (ILIF) technique. This technique was developed to overcome the potential shortcomings of the current standard of treatment for lumbar spinal stenosis by avoiding pedicle screw fixation and using a minimally disruptive surgical technique. The procedure includes direct decompression via bilateral laminotomy with a distraction laminoplasty technique similar to that described by O’Leary and McCance, which serves to maximize bone preservation. The decompression is assisted by a Hibbs-style interlaminar allograft spacer, which also serves as an extension block, and the construct is stabilized by a spinous process plate (Fig. 1).

In the current study, evaluation of the initial biomechanical stability of the ILIF construct was performed for the first time in a multisegmental cadaveric model by using the hybrid testing protocol described by Panjabi, which allows evaluation of both index- and adjacent-level motions. The ILIF construct was compared with a more traditional posterior laminectomy with pedicle screw fixation, which is clinically used today. Our hypothesis in this study was that the ILIF construct would provide index-level stability comparable to that following a laminectomy with pedicle screw fixation, while reducing stress at the adjacent levels.
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trectional testing using a LabVIEW-controlled (National Instruments Corp.) custom-built, 6-df spine testing system. Three cycles of unconstrained pure-moment flexion and extension, lateral bending, and axial rotation were performed, with data evaluation from the third cycle. No compressive preload was applied. While a follower load may provide more physiological sagittal plane motion, the applicability to lateral bending and axial rotation has not been established. Furthermore, the test setup can be susceptible to artifact given the positioning of the follower load cables. Forces and moments were continuously measured by a 6-df load cell (Delta, ATI Industrial Automation) mounted at the cranial end of the specimen.

Panjabi’s hybrid protocol was used to quantify both index- and adjacent-level motions. Under this method, the intact, untreated spines were first tested in load control to ±7.5 Nm in each direction, and the global L1–5 ROMs were measured. For subsequent test conditions, the L1–5 intact motions were replicated in displacement control. A decrease or increase in motion at the index level as a result of surgical intervention was then redistributed to, or subtracted from, the unaltered levels, respectively. Intervertebral motions were assessed using the Optotrak system mentioned above. After testing the intact spine, the following 6 test conditions were evaluated at L3–4 (Fig. 2): bilateral pedicle screw (bPS) fixation, bilateral laminotomy (bL), ILIF construct, partial laminectomy (pL), partial laminectomy plus unilateral pedicle screw (pL + uPS) fixation, and partial laminectomy plus bilateral pedicle screw (pL + bPS) fixation.

This order of testing was maintained for all specimens since the specimens were progressively destabilized. All surgical treatments were performed by a single orthopedic surgeon (B.B.P.). Specimens were irrigated with a 0.9% saline solution during testing to prevent dehydration.

Description of Surgical Techniques

Interlaminar Lumbar Instrumented Fusion Construct. The ILIF construct condition included a bilateral laminotomy (see below) assisted by an interlaminar allograft spacer (ExtenSure H2, NuVasive, Inc.) and stabilized by a spinous process plate (Affix, NuVasive, Inc.; Fig. 1). The allograft spacer was placed between the laminae of the cephalad and caudal vertebrae and provided structural stability by functioning as an extension block in addition to potentially promoting fusion. The spinous process plate was applied across the spinous processes to stabilize the spine. The plate system consists of 2 plates with medial teeth designed for maximum fixation and lamina/spinous process preservation, connected by a post. The plates were clamped to the spinous processes and locked to the post using an integrated ratcheting mechanism that facilitates closure and restricts opening. Although outside the scope of the current study, in clinical usage, additional bone graft material can be added between the spinous processes to encourage fusion.

Bilateral Laminotomy. In the bL test condition, a small semicircular portion (approximately 6–8 mm in width and height) of the lamina adjacent to the base of the spinous process on both sides was removed using a high-speed bur. In preparation for the subsequent ILIF condition, removal of the supraspinous and interspinous ligaments was also performed to allow for the post of the spinous process plate. Underlying ligamentum flavum was excised using a Kerrison rongeur to expose the dura mater. In ILIF surgery, the field of decompression can be expanded by distracting the spinous processes prior to application of the allograft spacer and spinous process plate.
Partial Laminectomy. The pL was an expansion of the existing bilateral laminotomies and was achieved using a Kerrison rongeur and a high-speed bur to create an approximately rectangular opening. It involved both the removal of the inferior aspect of the lamina and base of the spinous process in the cephalad direction until the point of insertion of the ligamentum flavum, and a partial resection of the superior aspect of the next level caudally. The lateral margins of the opening were defined by removing the medial aspects of both articular processes, while maintaining the integrity of the facet joints. The ligamentum flavum was completely excised, and the space was cleared from any debris to expose the dura.

Data Analysis

The ROMs at the index and adjacent levels were calculated for each loading direction (flexion and extension, lateral bending, and axial rotation) from the load-displacement curves. Range of motion was defined as the difference in the extremes of motion across the loading cycle. It was expressed as raw angular values, and the means and standard errors of the means were calculated. Repeated-measures ANOVA and Holm-Sidak multiple paired comparisons identified significant differences between conditions, with a level of significance at 0.05. The percent changes in ROM from the intact condition were also evaluated at the adjacent levels (L2–3 and L4–5).

Results

Among all test conditions, the most rigid construct in all directions was the bPS without any destabilization (Fig. 3 and Table 1). The destabilized conditions without instrumentation (bL and pL) were less rigid than the intact spine but not significantly in flexion and extension or lateral bending (bL: p = 0.800 and p = 0.967; pL: p = 0.600 and p = 0.960, respectively; Table 2). In axial rotation, the pL was significantly less rigid than the intact spine (p < 0.001).
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In flexion and extension (Fig. 3A), the condition with the greatest mean limitation in ROM was bPS at 1.4°, although no statistically significant difference existed when compared with ILIF at 1.8° (p = 0.727) and pL + bPS at 1.5° (p = 0.832). Adjacent-level motion (Fig. 4A) was increased for all fixation conditions. Bilateral pedicle screws provided the highest adjacent-level motion at L2–3 (bPS: 15.1% more than intact, pL + bPS: 12.9%) and L4–5 (bPS: 15.6% more than intact, pL + bPS: 18.0%). The ILIF condition led to an increase in adjacent-level motion of 12.1% at L2–3 and 9.6% at L4–5, which was similar to the pL + bPS condition at L2–3 (12.9%), and the pL + uPS condition at L4–5 (9.8%). The destabilized conditions showed a tendency for decreased motion at the adjacent levels.

In lateral bending (Fig. 3B), there was no statistically significant difference between the ROM for ILIF at 5.6° and pL + uPS at 5.0° (p = 0.113). Both conditions displayed reduced motion compared with the intact spine (p < 0.001). The bPS (2.3°) and pL + bPS (2.5°) conditions were not statistically different (bPS vs pL + bPS: p = 0.899), and both were more rigid than the ILIF and pL + uPS conditions (p < 0.001). Adjacent-level motion was increased by 19.0%–19.7% at L2–3 and 20.8%–21.3% at L4–5 for the bPS conditions. In contrast, the less rigid ILIF condition increased motion by only 5.1% at L2–3 and 6.8% at L4–5, which was comparable with pL + uPS (6.9% at L2–3 and 9.6% at L4–5). Again, there was a small decrease in adjacent-level motion with the non-instrumented laminotomy and laminectomy conditions (Fig. 4B).

Under axial rotation (Fig. 3C), the ROM for ILIF was 1.7°, which was significantly different from bPS (1.1°, p = 0.004) but not significantly different from pL + uPS (1.8°, p = 0.744) or pL + bPS (1.4°, p = 0.291). Furthermore, none of the fixation conditions were significantly different from intact (ILIF: p = 0.852, pL + uPS: p = 0.970, and pL + bPS: p = 0.070) with the exception of bPS (p < 0.001). The bL condition had 2.0° of motion, which was not statistically different from intact (1.8°; p = 0.843). The partial laminectomy condition increased axial rotation motion significantly compared with intact (pL: 2.5°, p = 0.001). At the adjacent levels, the largest changes were reductions in motion associated with the laminotomy and laminectomy conditions (Fig. 4C). The pL condition displayed a reduction in ROM at L2–3 of 14.9% and 13.3% at L4–L5. Interlaminar lumbar instrumented fusion produced a change in ROM of 4.8% less than intact at L2–3 and 7% less than intact at L4–5. All other conditions also tended to be within 10% of the intact adjacent-level motion.

### Discussion

Pedicle screw fixation is the most frequently used mode of instrumentation for facilitating spinal fusion, but several complications are associated with screw implantation. Nerve root injury, neurapraxia, screw malposition, CSF leakage, and their sequelae are all well-known complications associated with the procedure.\(^4,14,18,24,30,44\) In an attempt to reduce the morbidity of bilateral pedicle screw fixation, attention has been driven toward the development of alternative techniques, including unilateral pedicle screw placement, transfacet or translaminar screw fixation, anterior fusion methods, and spinous process fixation.\(^26\)

Spinous process fixation for facilitating fusion is not a...
novel concept, as the method has been studied for over 40 years.\textsuperscript{5,9,16,46,47} The procedure avoids many of the potential complications and morbidities associated with pedicle screw fixation since the spinous process plate is secured above the level of the lamina, away from the neural elements. Multiple studies have shown that interspinous plates provide adequate biomechanical strength in vitro when compared with other contemporary instrumentation techniques.\textsuperscript{25,26,47} Wang and coworkers\textsuperscript{47} demonstrated that a spinous process plate competed strongly with pedicle screw fixation and alternative fixation techniques. The plate provided the greatest limitation in flexion and extension over uni- or bilateral pedicle screw constructs and was also equivalent to unilateral screws in axial rotation. In 2010 Karahalios et al.	extsuperscript{26} and Kaibara et al.\textsuperscript{25} demonstrated the biomechanical stability of spinous process fixation in anterior lumbar interbody fusion and transforaminal lumbar interbody fusion constructs, respectively, with the most substantial reductions in movement in the flexion and extension plane.

In the present study, biomechanical stability of a Hibbs-style interlaminar block with adjunctive spinous process fixation (ILIF) was investigated in a cadaveric model at the L3–4 level. The interlaminar allograft block used in this procedure is unique because it contributes to stabilization of the spine by acting as an extension block and potentially promotes fusion, although clinical data are required to support the latter notion. Biomechanical testing demonstrated that the ILIF technique significantly reduces motion, particularly in flexion and extension, as compared with the normal spine. In flexion and extension, ILIF was not statistically different from bilateral pedicle screws. In lateral bending, ILIF was not different from partial laminectomy with unilateral pedicle screws, whereas in axial rotation, ILIF was not different from partial laminectomy with unilateral or bilateral

\begin{figure}[h]
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\includegraphics[width=\textwidth]{fig4.png}
\caption{Bar graphs showing the mean percent change in adjacent-level ROM with respect to the intact spine in response to loading in each direction: flexion and extension (A), lateral bending (B), and axial rotation (C). Error bars show \pm 1 SEM.}
\end{figure}
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pedicle screws. Motion at the levels adjacent to L3–4 was also examined. Under the hybrid test method, a reduction in motion at the surgically treated level will lead to redistribution of this motion across the unaltered levels; conversely, an increase in motion at the index level will lead to less motion at the adjacent levels. This was seen in the current study in which the more rigid constructs at L3–4 (for example, those with bilateral pedicle screws) tended to increase the adjacent-level motion, whereas destabilizing treatments (for example, laminectomy) had the opposite effect. In general, the ILIF condition displayed adjacent-level motions similar to those in the partial laminectomy condition stabilized with unilateral pedicle screws and less motion than that in the bilateral screw conditions, except at L2–3 in flexion and extension where they were similar. While it is generally agreed that fusion changes the biomechanics (ROM, disc pressure, and facet loads) of an adjacent segment, it is not clear if this biomechanical change necessarily leads to adjacent segment degeneration or if it is the natural progression of disc degeneration with age. Nevertheless, the ILIF construct does produce less adjacent-level hypermobility compared with bilateral pedicle screws under this test method and also removes the possibility of superior-segment facet violation by the pedicle screws.

As with most cadaveric biomechanical studies, there are limitations to the current investigation. Cadaveric tissue is inherently variable, and a sample size of only 8 specimens was used. Interpretation of the results should take this sample size into consideration, since the study may be underpowered to detect small differences. The spinal specimens were also relatively healthy to allow for consistency; therefore, the findings may not translate directly when applied to degenerated spinal segments. This study applied pure moments to the L1–5 spinal segments without compressive loading. Lack of musculature around the excised spine renders it unable to support the amount of axial compressive load that might be expected in vivo. Tangential follower loads have been implemented by some investigators to improve the load-carrying capacity; however, their application in lateral bending and axial rotation is not established. In flexion and extension, the follower load typically increases the stability of the spine (reduces ROM); therefore, relative comparisons in the absence of a follower load are expected to be similar, although probably with higher ROM values across all conditions. While the loading implemented in this study does not precisely replicate the in vivo loading environment, it does provide a method for evaluating different surgical treatments under repeatable conditions. The hybrid protocol used here makes assumptions about the redistribution of motion to neighboring segments of the spine, while it is possible that loss of motion after fusion is compensated for by other mechanisms. Finally, this type of investigation only provides information about the immediately postoperative period and does not consider longer term adaptation that may occur at the implant-bone interfaces or the effects of interlaminar fusion.

Conclusions

Biomechanical testing has indicated that the ILIF technique is a potential viable alternative for rigid fixation of the destabilized spine. It provides comparable stability to pedicle screw–instrumented laminectomy in flexion and extension and axial rotation but with reduced risks such as neurological injury. The ILIF technique provides surgeons with the ability to perform a minimally invasive, single-approach posterior decompression, fusion, and fixation procedure without the added morbidity of traditional pedicle screw fixation. Adjacent-level motions with ILIF were lower than those associated with bilateral pedicle screw fixation, suggesting that the risk of adjacent-segment degeneration may be lessened. The ability to implant the interspinous plate quickly with minimal surgical dissection also contributes to the appeal of the ILIF technique. Clinical studies evaluating the long-term stability of spinous process plating and fusion outcomes are needed and will be described in forthcoming studies.

Disclosure

Support for this study was provided by NuVasive, Inc. Dr. Turner owns stock in and is an employee of NuVasive, Inc. Dr. Zatushevsky owns stock in and is an employee of NuVasive, Inc. Dr. Cornwall is an employee of, owns stock in, and holds a patent with NuVasive, Inc. Dr. Bae holds a patent with NuVasive, Inc.

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Address correspondence to: Hyun W. Bae, M.D., Spine Research Foundation, Spine Institute at Saint John’s Health Center, Santa Monica, California 90404, email: baemd@me.com.