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Basic Science

Biomechanics of lateral plate and pedicle screw constructs in lumbar spines instrumented at two levels with laterally placed interbody cages

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Abstract BACKGROUND CONTEXT: The lateral transposas approach to interbody fusion is gaining popularity because of its minimally invasive nature and resultant indirect neurologic decompression. The acute biomechanical stability of the lateral approach to interbody fusion is dependent on the type of supplemental internal fixation used. The two-hole lateral plate (LP) has been approved for clinical use for added stabilization after cage instrumentation. However, little biomechanical data exist comparing LP fixation with bilateral pedicle screw and rod (PSR) fixation.

> **PURPOSE:** To biomechanically compare the acute stabilizing effects of the two-hole LP and bilateral PSR fusion constructs in lumbar spines instrumented with a lateral cage at two contiguous levels.

STUDY DESIGN: Biomechanical laboratory study of human cadaveric lumbar spines.

METHODS: Eighteen L1–S1 cadaveric lumbar spines were instrumented with lateral cages at L3–L4 and L4–L5 after intact kinematic analysis. Specimens (n=9 each) were allocated for supplemental instrumentation with either LP or PSR. Intact versus instrumented range of motion was evaluated for all specimens by applying pure moments (\pm 7.5 Nm) in flexion/extension, lateral bending (LB) (left+right), and axial rotation (AR) (left+right). Instrumented spines were later subjected to 500 cycles of loading in all three planes, and interbody cage translations were quantified using a nonradiographic technique.

RESULTS: Lateral plate fixation significantly reduced ROM (p<.05) at both lumbar levels (flexion/extension: 49.5%; LB: 67.3%; AR: 48.2%) relative to the intact condition. Pedicle screw and rod fixation afforded the greatest ROM reductions (p<.05) relative to the intact condition (flexion/extension: 85.6%; LB: 91.4%; AR: 61.1%). On average, the largest interbody cage translations were measured in both fixation groups in the anterior-posterior direction during cyclic AR.

CONCLUSIONS: Based on these biomechanical findings, PSR fixation maximizes stability after lateral interbody cage placement. The nonradiographic technique served to quantify migration of implanted hardware and may be implemented as an effective laboratory tool for surgeons and engineers to better understand mechanical behavior of spinal implants. © 2013 Elsevier Inc. All rights reserved.

Keywords: Lateral transposas approach; Lateral interbody fusion cages; cage motion; Lateral plate; Pedicle screws/rods

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Introduction

Several health-related reports indicate low back pain as one of the main musculoskeletal disorders in the United States, affecting approximately 30 million people annually [1]. Almost 10% of low back pain cases are chronic, leading to disabling back pain [1,2]. Sources of pain could be a herniated or degenerated disc, facet joints, or a combination of both [3]. Conservative methods such as physiotherapy and medications are generally the primary treatment options, but surgical intervention is required when conservative treatments fail to alleviate pain for prolonged periods.

In patients who are refractory to nonoperative measures, an invasive neural decompression needs to be performed. This has been historically accomplished via laminectomy, facetectomy, and foraminotomy interventions. When resecting the bony and/or soft-tissue elements responsible for natural spinal stability, additional instrumentation and interbody spacers may be warranted to restore disc height, correct coronal and sagittal alignment, and fuse the operated motion segment. Operative approaches to the anterior column for stabilization of the thoracolumbar spine include posterior, transforaminal, anterior, and more recently, the lateral transpsoas, which minimizes the reported neural [4,5] and vascular [6,7] complications associated with posterior and anterior approaches, respectively. Although relatively new, emerging clinical reports [8] suggest that the lateral transpsoas approach to interbody fusion affords the necessary decompression for the treatment of spinal stenosis in a minimally disruptive way as measured by relief of both back and leg pain [9,10]. Additional advantages of the procedure to traditional approaches of anterior column fusion include the removal of an abundant amount of disc to accommodate a large interbody implant that spans the dense ring apophysis, affording a larger area for interbody fusion [10–12] and retention of the anterior and posterior longitudinal ligaments that function naturally to maintain spinal alignment and stabilization [13,14]. Also, retention of the indirect decompression is comparatively higher with the laterally placed interbody cage compared with other devices used for indirect decompression, such as the XSTOP (Medtronic Spine LLC, Sunnyvale, CA, USA) interspinous spacer [8,15].

Although early clinical reports indicate that alleviation of symptoms associated with lumbar spinal stenosis may be accomplished with stand-alone lateral cages [8], supplemental internal fixation, such as pedicle screws and lateral plates (LPs), may be added to increase the stability of the construct and assist the fusion process. Supplemental fixation may also be necessary after stand-alone cage placement if end plate fracture concomitant with persistent neurologic symptoms is noted postoperatively [8].

Lateral plate fixation offers the advantage of using the same incision to reinforce the anterior column for fusion. However, very little literature exists defining the stabilizing role of two-hole LP fixation with this procedure [16]. The goal of this biomechanical study was to quantify and compare the stability afforded by two-hole LP and bilateral pedicle screw and rod constructs in lumbar spines instrumented with the laterally placed cage at two levels. Interbody cage translations were also quantified using a novel non-radiographic technique. Current radiographic techniques such as computed tomography do not allow for real-time dynamic visualization, and accuracy is a function of scan resolution and image scatter from post-instrumentation scans. The advent of high-fidelity optical motion tracking systems can facilitate characterization of implant migration kinematics under applied loads in a laboratory setting, providing insight into implant motions that may be experienced in vivo. Although such approaches have been used to characterize implant migration patterns in hip arthroplasty [17,18], we believe this is the first report of quantifying interbody cage translations in a laboratory setting.

Materials and methods

This biomechanical study was investigator initiated. The authors were not contracted by industry to perform this work. Research support was provided by industry, but the sponsor gave up all rights to the data and was not involved in the writing or preparation of this manuscript.

Specimen preparation

Eighteen (n=18) lumbar specimens (L1–S1) were dissected from fresh-frozen cadaveric specimens (11 males and 7 females; average age: 57.7 years \pm 9.8; range: 30– 69 years). Anterior-posterior (AP) and lateral radiographs confirmed that the procured specimens were free of deformity, excessive degeneration, or prior instrumentation. Specimens were cleaned and denuded of musculature and adipose tissue taking care to retain all ligamentous structures. Bone mineral density (BMD) values at the L5 lumber level were assessed by dual-energy X-ray absorptiometry (Lunar Prodigy; GE Healthcare, Madison, WI, USA) using an approach previously described for assessing bone quality in cadaveric tissue specimens denuded of extraneous soft tissues published by Wähnert et al. [19].

Lumbar specimens were rigidly potted at the cephalad and caudal (L1 and S1) ends using interference screws and high-strength resin (Bondo Body Filler; 3M, St. Paul, MN, USA). Specimens were kept hydrated by regularly spraying with 0.9% saline. Before biomechanical testing, all specimens were thawed out overnight (8–10 hours) at room temperature (~25°C).

Kinematic evaluation

Nondestructive, pure moment loading was applied to each specimen through a system of cables, pulleys, and suspended weights in similar fashion to previously reported methods [20-22]. The kinematic testing frame allowed free movement at the cephalad end while rigidly fixing the caudal (S1) end. Using a 10" moment arm and slotted weights, moments were applied at 1.5 Nm increments up to a maximum of 7.5 Nm about the appropriate anatomical axes to induce six different motions: flexion, extension, left and right lateral bending (LB), and left and right axial rotation (AR). To overcome the spine's viscoelastic effects, before recording motion data for each loading scenario, three preconditioning cycles were applied to the specimen, and incrementally applied moments were maintained for approximately 30 seconds. Intervertebral range of motion (ROM) was obtained using an optoelectronic motion analysis system (Optotrak Certus; Northern Digital Inc., Waterloo, ON, Canada) with infrared light-emitting diode marker arrays rigidly coupled to each vertebral level. The lumbar specimens (n=18) were kinematically evaluated in the "intact" condition to determine baseline intervertebral ROM values.

Lateral interbody fusion constructs

After intact kinematic evaluation, the lumbar specimens were allocated to one of the following test conditions (Fig. 1): polyetheretherketone (PEEK) interbody cage implant (CoRoent; NuVasive Inc, San Diego, CA, USA) at L3-L4 and L4-L5, supplemented with a two-hole LP (XLP Plate; NuVasive Inc) with bicortical screw size range: 50–65 mm; plate size range: 8-14 mm) at each level (n=9); interbody cage implant at L3-L4 and L4-L5 supplemented with bilateral pedicle screws (range: 45-60 mm) and rods (diameter: 5.5 mm; length range: 60-85 mm) (SpheRx, DBR II; NuVasive Inc) at each level (n=9). An a priori power analysis for this cadaveric study was based on the mean and variance estimates of kinematic intervertebral ROM data from a similar study of single-level lumbar fusion constructs [16]. To detect a 20% difference in flexion-extension ROM between the instrumented constructs at a single level, a sample size of eight (n=8)afforded an experimental design powered at the 0.93 level. Using nine (n=9) specimens in each group powered the experiment at greater than the 0.95 level.

Hardware instrumentation was facilitated with fluoroscopy, and all procedures were performed by board certified spine surgeons experienced with the lateral approach technique. A total of 36 lumbar levels were instrumented with the lateral interbody cages. All cages were 18-mm wide and the lateral (range: 50–60 mm) and vertical height (10–14 mm) dimensions were determined by anatomy.



Fig. 1. (A and C) Lateral and (B and D) anterior-posterior radiographs of the lateral interbody fusion cage constructs (Top: Lateral Plate; Bottom: Pedicle Screws + Rods).

After cage placement and instrumentation, kinematic evaluation of the specimens was performed using the pure moment loading protocol as previously described to quantify ROM reductions afforded by both forms of fixation at the L3–L4 and L4–L5 vertebral levels.

Cage motion analysis

After kinematic evaluation, the lumbar specimens were mounted in an electromechanical biaxial testing machine (TestResources, Model 800L, Shakopee, MN, USA). The specimens were rigidly coupled to custom-designed fixtures that cycled the specimens in flexion-extension (4 Nm, with 400 N preload), LB (2 Nm) and AR (5 Nm) for 500 cycles at 0.5 Hz. Assuming the PEEK cages to be nondeforming rigid bodies, custom-designed marker flags (Fig. 2) were rigidly coupled into the laterally placed cages at the L3-L4 and L4-L5 levels using pre-existing threaded holes (used for cage implantation) and screws to quantify cage translations during cyclic loading in the AP, mediallateral, and inferior-superior directions (Fig. 3). Threaded holes were created in cages where access to pre-threaded holes was obstructed (as with the LP instrumentation). The translations for each cage were measured relative to its respective superior vertebral body (eg, cage translations at L3-L4 reported with respect to L3). Specifically, local coordinate systems were defined in both the vertebral body and interbody cage by rigidly coupling optoelectronic marker triads (Optotrak) to them. With the use of a digitizing pen, two points were defined on the right and left lateral aspects of the L3 and L4 inferior end plates at the vertebral body midline, which defined the +x axis. A single point was digitized on the anterior-most aspect of the body, defining the +z axis and, by default, the +y axis. Similarly, three points were digitized on the cage to define the interbody

cage's local coordinate system. Thus, any translations measured along the x, y, and z axes during cyclic loading were defined as interbody cage translations in the disc space. Care was taken to digitize points such that the x-z planes were parallel to one another. The loading sequence was randomized for each specimen, such that an equal number of specimens (3x) in each construct group underwent flexion/extension, LB, and AR as the starting loading mode. The average peak-to-peak displacement amplitudes at each level were derived from the last 10 cycles for each loading condition in both the LP and pedicle screw constructs after processing the raw data with a third order Butterworth filter.

Statistical analysis

Range of motion reductions relative to the intact condition afforded by two-level LP or pedicle screw augmentation were compared with a two-tailed, paired sample *t* test, and ROM comparisons between instrumentation groups were compared with a two-sample, two-tailed *t* test. Significance was set at the α =0.05 level, and all comparisons were performed with SYSTAT 13 (Systat Software, Inc.; Chicago, IL, USA).

Results

Of the n=36 lumbar levels implanted with the interbody cages, five (n=5; 13.9%) levels sustained end plate fracture during instrumentation (inferior: n=4, 80%; superior: n=1, 20%). Fracture occurred in one specimen (n=1) in the pedicle screw group and in four (n=4) LP specimens. End plate fractures were identified from postinstrumentation AP and lateral radiographs. In the five levels that sustained



Fig. 2. Quantification of interbody cage translation was facilitated by coupling custom-designed marker flags to the cage laterally as shown. Displacements were measured during cyclic loading of the entire lumbar construct.



Fig. 3. All cage translations were measured relative to the superior vertebral body (eg, C1 cage translations were measured relative to L3 vertebral body; C2 cage translations were measured relative to L4 vertebral body).

end plate fracture, the bone quality of the specimen was osteoporotic only in two instances. The remaining three end plate fractures occurred in specimens that were osteopenic (n=2) or normal (n=1) with regard to bone quality. In the post hoc review of the kinematic and cage translation data, we noted differences in the kinematic patterns and interbody cage translations at those lumbar levels in which end plate fracture was documented. As an example, in the pedicle screw+rod construct with end plate fracture, flexion-extension motion was reduced by only 32% relative to the intact condition. Minimal reductions in ROM in this specimen were associated with interbody cage translations greater than 3 mm along the define axes. Reductions in flexion-extension ROM in the LP specimens with end plate fracture averaged only 5% relative to the intact conditions with similar increases in cage translations of greater than 3 mm. This non representative ROM data as well as the associated cage translation data, were removed from further statistical analysis and are neither included nor presented in this article.

The mean spine BMDs, T-scores, and ages were 0.969 g/cm², -2.011, and 58.8 years, respectively, for the LP group and 1.022 g/cm², -1.622, and 58.0 years, respectively, for the pedicle screw group. These values were not significantly different (BMD, p=.584; T-score, p=.628; and age, p=.875).

Kinematics

In the intact test condition, no significant difference in ROM was identified between test groups at L3–L4 or L4–L5 in flexion-extension (p=.417 and p=.910, respectively), LB (p=.350 and p=.690, respectively) or AR (p=.839 and p=.508, respectively).

In flexion-extension, pedicle screw instrumentation significantly reduced ROM at the L3–L4 (p<.001) and L4– L5 (p<.001) levels relative to the intact condition (Fig. 4). At the two levels, ROM was reduced on average by 82.6% and 88.9%, respectively. Lateral plate instrumentation also significantly reduced ROM at the L3–L4 (p=.011) and L4–L5 (p=.015) levels by 52.3% and 47.1%, respectively. Range of motion reductions were significantly greater in the pedicle screw constructs relative to the LP constructs at both lumbar levels (p<.018).

In LB, pedicle screw instrumentation significantly reduced ROM at the L3–L4 (p<.001) and L4–L5 (p<.001) levels relative to the intact condition (Fig. 5). At the two levels, ROM was reduced by 89.8% and 93.2%, respectively. Lateral plate instrumentation also significantly reduced ROM at the L3–L4 (p=.002) and L4–L5 (p<.001) levels by 71.0% and 64.5%, respectively. Range of motion reductions were significantly greater in the pedicle screw



Fig. 4. Flexion-extension ROM results. All comparisons relative to intact case were significant ($p \le .015$). PSR, pedicle screw/rod; LP, lateral plate.



Fig. 5. Lateral bending ROM results. All comparisons relative to intact case were significant ($p \le .002$). PSR, pedicle screw/rod; LP, lateral plate.

constructs relative to the LP constructs at both lumbar levels (p < .026).

In AR, pedicle screw instrumentation significantly reduced ROM at the L3–L4 (p=.001) and L4–L5 (p<.001) levels relative to the intact condition (Fig. 6). At the two levels, ROM was reduced by 53.4% and 69.8%, respectively. Lateral plate instrumentation also significantly reduced ROM at the L3–L4 (p=.038) and L4–L5 (p=.012) levels by 45.3% and 50.4%, respectively. No significant difference in AR ROM reduction was identified between the pedicle screw and LP constructs (p>.678).

Interbody cage translations

In general, the largest total interbody cage translations (Table) were measured in AR at L3–L4 and L4–L5 for both LP and pedicle screw fixation. Interbody cage translations (ranges) were largest in magnitude in the AP direction in



Fig. 6. Axial rotation ROM results. All comparisons relative to intact case were significant ($p \le .038$). PSR, pedicle screw/rod; LP, lateral plate.

Table

Interbody cage translations (mm) along three axes measured during cyclic loading

	Averaged over L3-L4 and L4-L5 levels		
Fixation	AP	ML	IS
Flexion-extension			
Lateral plate	0.3 (0.2)	0.1 (0.1)	0.2 (0.4)
Pedicle screw/rod	0.4 (0.1)	0.1 (0.1)	0.2 (0.1)
Lateral bending			
Lateral plate	0.2 (0.1)	0.2 (0.4)	0.2 (0.2)
Pedicle screw/rod	0.2 (0.1)	0.1 (0.1)	0.2 (0.2)
Axial rotation			
Lateral plate	0.8 (1.0)	0.2 (0.3)	0.4 (0.4)
Pedicle screw/rod	0.8 (0.4)	0.3 (0.3)	0.2 (0.1)

AP, anterior-posterior; ML, medial-lateral; IS, inferior-superior.

Note: Lateral plate and pedicle screw/rod means and standard deviations (in parentheses) are derived from the n=14 and n=17 levels with intact end plates.

this loading mode. Data presented do not include the interbody cage translations of those levels in which end plate fracture was documented.

Discussion

Indirect decompression of the spinal canal using an interbody cage placed through the lateral, minimally invasive transpsoas approach avoids the need for an open or direct surgical intervention. Early clinical results using laterally placed cages are promising, with relief of both back and leg pain having been reported [8–10], and recent literature suggests that complications associated with the technique in the early postoperative timeframe are minimal [8]. Unlike alternative anterior and posterior approaches for fusion of the anterior spinal column, the lateral access approach spares the anterior and posterior longitudinal ligament and affords the placement of a large implant that spans the entire vertebral width. Taken together, these theoretical advantages suggest that a stable interbody construct is achievable.

The ROM reductions afforded by the interbody cage with two-hole LP fixation were significant relative to the intact case at both the L3–L4 and L4–L5 levels in all motion planes. Averaged over the L3–L4 and L4–L5 level, range of motion reductions in flexion-extension, LB, and AR were 49.5%, 67.3%, and 48.2%, respectively. In the bilateral posterior pedicle screw constructs, average range of motion reductions in flexion-extension, LB, and AR were 85.6%, 91.4%, and 61.1%, respectively. All ROM reductions in the pedicle screw constructs were significant relative to the intact condition. These data suggest that bilateral posterior pedicle screw and rod fixation maximizes stability after lateral interbody fusion compared with the two-hole LP.

To the authors' knowledge, two related biomechanical studies exist to which we can compare our findings [16,23]. In a biomechanical study of lumbar fusion

constructs instrumented with a single laterally placed cage at the L3-L4 level, Cappuccino et al. [16] implemented a pure moment loading protocol (±7.5 Nm in all loading planes) to compare the relative stability afforded by stand-alone implant followed by fixation with the LP as well as unilateral and bilateral pedicle screw fixation in 10 cadaveric spines. Intervertebral ROM at the instrumented level was significantly reduced in all loading modes at the L3-L4 level relative to the intact condition. Flexionextension ROM was reduced by 68.4%, 67.5%, 79.6%, and 87% for the stand-alone, LP, unilateral, and bilateral pedicle screw constructs, respectively. Significant reductions in ROM relative to the intact condition were also noted in LB (67.5%, 84.1%, 78.4%, 85.6%, and 85.6%) and AR (30.6%, 46.6%, 48.7%, 58.3%, and 58.3%) for the standalone, LP, unilateral, and bilateral pedicle screw constructs, respectively. In this one-level lateral lumbar interbody fusion (LLIF) study, the authors noted significantly greater reductions in ROM at L3-L4 level afforded by bilateral pedicle screw fixation relative to LP fixation in flexionextension, whereas in both LB and AR, LP and bilateral pedicle screw fixation afforded statistically equivalent reductions in ROM at the L3-L4 level.

Although exact comparisons of our study with the study by Cappuccino et al. are difficult because of differences in testing methodology and experimental design, our findings in two-level fusion constructs are, in general, numerically similar with significantly greater stability afforded by bilateral pedicle screw rod fixation compared with twohole LP fixation in flexion-extension. Furthermore, at both the L3-L4 and L4-L5 lumbar levels, we found that AR motion was on average reduced by 48.2% and 61.1% relative to the intact state for the LP and pedicle screw constructs, respectively, which are numerically similar to the reductions in ROM reported in the one-level study. Their report of significantly reduced AR ROM conferred by the pedicle screw constructs (58.3% vs. 46.6%) differs from our finding of statistically similar motion reduction conferred by both forms of fixation (61.1% vs. 48.2%) and may be explained by the higher statistical sensitivity of the repeated measures experimental design used in the one-level study.

The largest discrepancy between our findings and those of Cappuccino et al. is with regard to ROM reductions in LB afforded by two-hole LP fixation. In their study, LP fixation on average reduced bending ROM by 84.1%, whereas our results indicate that ROM is reduced on average by only 67.1%. Although no raw data are provided by Cappuccino et al., using our raw ROM data at the index lumbar levels, this discrepancy amounts to a difference of approximately 2.1° in LB ROM afforded by LP fixation between the two studies. Bess et al. [23], in a one-level XLIF lumbar fusion study in seven cadaveric lumbar specimens (L1–L5) instrumented with LP, reported an average decrease in LB ROM of 75.8% relative to the intact condition, which further supports the stabilizing effects of LP reported by Cappuccino et al. Their cadaveric repeated measures biomechanical study also included evaluation of supplemental bilateral pedicle screws, and their results in a one-level construct agree with our study findings that bilateral constructs significantly decrease ROM for flexionextension and LB compared with XLIF and two-hole LP fixation.

As a secondary outcome measure, we implemented an optoelectronic motion analysis technique to quantify interbody cage translations during physiologically relevant cyclic loading. Our results indicate that the cages translate along all three principle axes in all loading modes, with the largest average cage translations of 800 to 900 μ m occurring in the AP direction during AR loading. This finding appeared independent of supplementary fixation type. To our knowledge, this is the first in vitro report that has quantified interbody cage kinematics. Although the clinical significance of less than 1 mm interbody cage translation is unknown, this technique could be implemented as a high fidelity and comparative modality with which to quantify the movements of various interbody conditions.

As with the majority of other biomechanical studies on cadaveric specimens, ours share some common limitations. The nature of the moment loading test method implemented can only describe the acute kinematic effects of lateral interbody cage implantation and supplementary internal fixation. The results reported herein cannot take into account the biological changes that occur in vivo and therefore cannot be reasonably extrapolated to time periods beyond the immediate postoperative. Furthermore, all musculature was removed from the specimens; thus, the kinematic results reported here may be considered "worst case," given the lack of stabilizing effects afforded by muscles that would be present in vivo. The specimens enrolled in this study were of variable bone quality and presented with various levels of pre-existing disc degeneration. However, these conditions are realistic of the patient population undergoing such instrumentation procedures. The homogeneity between treatment groups in the current study with regard to BMD, donor age, and baseline ROM values at the instrumented levels, supports direct comparison of the acute stabilizing effects of the two-hole LP and bilateral pedicle screw constructs.

The authors are aware of the potential for research bias that may result from funding provided by industry sponsors and that sponsorship by industry may be associated with publication outcomes that are favorable to the sponsor. However, we believe that any bias that may be perceived in the current work is negated by two important factors. First, this was a comparative study of two devices made by the same company. Furthermore, the research presented here was investigator initiated. While we disclose that research support was provided by industry, the sponsor gave up all rights to the data and was not involved in the writing or preparation of this manuscript.

Conclusion

The lateral approach to interbody fusion is a relatively new technique advocated as a minimally invasive approach to anterior column fusion above the L5 level in patients with degenerative disc disease, complex spinal deformity, and spondylolisthesis. The lateral approach to the disc space that spares the anterior longitudinal ligament and posterior longitudinal ligament as well as the ability to place a large interbody spacer that spans the dense ring apophysis suggests that a stable interbody construct is achievable, and prior biomechanical work has demonstrated that stand-alone lateral interbody cage placement significantly reduces ROM relative to the intact lumbar spine. The current work suggests that two-hole LP and bilateral pedicle screw fixation both significantly limit ROM in all loading planes relative to the intact state and may be suitable when used in two-level lumbar fusion with laterally placed cages. Pedicle screw rod fixation resulted in the greatest reduction in ROM and may be a preferable fusion construct when rigid, motion-eliminating stabilization is required. Surgeons may evaluate these comparative forms of fixation and their effects on conferring stability over two contiguous lumbar levels and choose a fixation option that best suits the stability requirements of their patient.

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