Biomechanical analysis of an interspinous fusion device as a stand-alone and as supplemental fixation to posterior expandable interbody cages in the lumbar spine

Laboratory investigation

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Object. In this paper the authors evaluate through in vitro biomechanical testing the performance of an interspinous fusion device as a stand-alone device, after lumbar decompression surgery, and as supplemental fixation to expandable cages in a posterior lumbar interbody fusion (PLIF) construct.

Methods. Nine L3–4 human cadaveric spines were biomechanically tested under the following conditions: 1) intact/control; 2) L3–4 left hemilaminotomy with partial discectomy (injury); 3) interspinous spacer (ISS); 4) bilateral pedicle screw system (BPSS); 5) bilateral hemilaminectomy, discectomy, and expandable posterior interbody cages with ISS (PLIF-ISS); and 6) PLIF-BPSS. Each test consisted of 100 N of axial preload with ± 7.5 Nm of torque in flexion-extension, right/left lateral bending, and right/left axial rotation. Significant changes in range of motion (ROM), neutral zone stiffness (NZS), elastic zone stiffness (EZS), and energy loss (EL) were explored among conditions using nonparametric Friedman test and Wilcoxon signed-rank comparisons (p ≤ 0.05).

Results. The injury increased ROM in flexion (p = 0.01), left bending (p = 0.03), and right/left rotation (p < 0.01) and also decreased NZS in flexion (p = 0.01) and extension (p < 0.01). Both the ISS and BPSS reduced flexion-extension ROM and increased flexion-extension stiffness (NZS and EZS) with respect to the injury and intact conditions (p < 0.05), but the ISS condition provided greater resistance than BPSS in extension for ROM, NZS, and EZS (p < 0.01). The BPSS increased the rigidity (ROM, NZS, and EZS) of the intact model in lateral bending and axial rotation (p ≤ 0.01), except in EZS for left rotation (p = 0.23, Friedman test). The incorporation of posterior cages marginally increased (p = 0.05) the EZS of the BPSS construct in flexion but these interbody devices provided significant stability to the ISS construct in lateral bending and axial rotation for ROM (p = 0.02), in lateral bending for NZS (p = 0.02), and in flexion/axial rotation for EZS (p ≤ 0.03); however, both PLIF constructs demonstrated equivalent ROM and stiffness (p ≥ 0.16), except in lateral bending where the PLIF-BPSS was more stable (p = 0.02). In terms of EL, the injury increased EL in flexion-extension (p = 0.02), the ISS increased EL for lateral bending and axial rotation (p ≤ 0.03), and the BPSS decreased EL in lateral bending (p = 0.02), with respect to the intact condition. The PLIF-ISS decreased lateral bending EL with respect to the ISS condition (p = 0.02), but not enough to be smaller or, at least, equivalent, to that of the PLIF-BPSS construct (p = 0.02).

Conclusions. The ISS may be a suitable device to provide immediate flexion-extension balance after a unilateral laminotomy, but the BPSS provides greater immediate stability in lateral bending and axial rotation motions. Both PLIF constructs performed equivalently in flexion-extension and axial rotation, but the PLIF-BPSS construct is more resistant to lateral bending motions. Further biomechanical and clinical evidence is required to strongly support the recommendation of a stand-alone interspinous fusion device or as supplemental fixation to expandable posterior interbody cages.

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Key Words • energy loss • in vitro • posterior lumbar interbody fusion • range of motion

Abbreviations used in this paper: BPSS = bilateral pedicle screw system; EL = energy loss; EZS = elastic zone stiffness; ISS = interspinous spacer; NZS = neutral zone stiffness; PLIF = posterior lumbar interbody fusion; ROM = range of motion; TLIF = transforminal lumbar interbody fusion.

Neurogenic claudication is one of the most common degenerative conditions of the spine. Treatments for this condition include open decompression with or without fixation.16 Spinal surgery is continuously evolving, and the necessity for less invasive techniques...
and instrumentation is an important factor in the design constraints and approaches of fusion implants. A variety of interspinous spacers (ISSs) have been proposed as minimally invasive devices that are promoted as either “dynamic” stabilization or as fusion devices after specific decompression surgeries. Different models and materials are available, but the shared goal is to create a natural distraction between spinous process (inducing segmental kyphosis), which in turns restricts extension (induces flexion) in the treated segment.1,6 Short-term advantages such as reduced morbidity, blood loss, operative time, and less hardware are intrinsic benefits of a minimally invasive procedure, such as those of the ISS. However, the success of long-term clinical outcomes, and/or even the need of this type of fixation after specific decompression techniques, are still controversial. Some surgeons advocate the use of the ISS device as a backup for minimal decompression surgeries such as laminotomies, while others suggest limiting their application to supplemental fixation (that is, posterior fixation to interbody cages). Superior clinical outcomes have been reported for bilateral decompression alone when compared with stand-alone ISS without decompression in the treatment of lumbar spinal stenosis with neurogenic claudication.1 However, surgical revision due to spinal instability has also been observed in cases of decompression without fixation, especially in cases of spondylolisthesis, but implantation of a bilateral pedicle screw system (BPSS) may be an excessive correction for microdecompression surgery and could potentially generate unnecessary risks.23 Thus, the ISS may be a suitable alternative in certain decompression procedures or as supplemental fixation to interbody cages. Furthermore, ISS implantation after unilateral decompression has shown satisfactory clinical outcomes in patients suffering from mild to moderate central and unilateral stenosis, where the decompression before interspinous device implantation was performed to avoid insufficient nerve root release by indirect decompression of the ISS.16 The concept of expandable interbody cages in posterior lumbar interbody fusion has gained popularity due to their inherent advantages such as less tissue disruption, more controlled distraction, and less nerve retraction; however, their application may be limited to further posterior fixation such as that of pedicle screws.2 To our knowledge, the performance of expandable posterior interbody cages with an interspinous fusion device has not been investigated. The purposes of this in vitro biomechanical investigation were 1) to evaluate the stand-alone performance of an interspinous fusion device after spinal decompression; 2) to compare its performance with that of the gold standard, BPSS; and 3) to compare the 2 constructs (ISS and BPSS) in a posterior lumbar interbody fusion (PLIF) model using expandable cages.

Methods

Specimen Preparation

Nine cadaveric lumbar spines were dissected into L3–4 functional spinal units without compromising the ligaments, synovial capsules, or intervertebral discs. Sex and age information was available for 7 of the specimens (males, mean age 70 ± 14 years), but all 9 specimens met the inclusion criteria of no previous spinal trauma or surgery, which was confirmed through fluoroscopic images.

Self-tapping screws (2 in) were installed into the vertebral bodies (L-3 and L-4) and then affixed in a mixture of Bondo auto body filler (Bondo Corp.) and fiberglass resin (3M).21 The vertebral bodies were centered and aligned using a series of leveling tools and customized potting frames to ensure proper force transmission to the functional spinal units while testing. Dissection and testing of each specimen were performed at room temperature (21 ± 2°C) for no longer than 48 hours. Specimens were coated with petroleum jelly during testing to minimize dehydration,22 and they were wrapped with 4 × 4-in gauze sponges moistened with 0.9% NaCl solution when not being tested.5

Biomechanical Testing

Flexibility tests were performed using a customized 4-df machine. The testing apparatus consisted of a servo hydraulic machine (MTS 858 MiniBionix modified by Instron) that allows axial rotation translation, and two custom-made frames (superior and inferior) that allow bending moments (in one direction) through pulley systems, as described in previous publications.5 Specimens were subjected to 100 N of axial preload and ±7.5 Nm of controlled torque for flexion-extension, right/left bending, and right/left axial rotation.4 Six cycles of axial rotation torque (±0.1 Nm) were dynamically applied at a rate of 0.125 Hz, while 3 cycles of quasistatic bending moments (flexion, extension, and right/left bending) were performed in increments of 1.5 Nm. The quasistatic loads were separated by 10 seconds, of which the last 5 seconds was used for recording. The number of cycles selected was based upon the delivery method and motion direction. Since flexion-extension and lateral bending were manually loaded by adding/removing weights to the pulley systems, and because these motions heavily rely on the disc space, a reduced rate and number of cycles were used in flexion-extension to minimize creep effects throughout the study. Conversely, a larger number of cycles were used in dynamic axial rotation to provide a higher factor of safety on measurements repeatability. Completion of flexion-extension, lateral bending, and axial rotation motions was considered a testing round and only the last 2 cycles of each test were averaged and analyzed.

Angular displacements (±0.1°) were optoelectronically tracked (Optotrak 3020, Northern Digital, Inc.) by infrared light–emitting diode sensors affixed to the frames connected to the L-3 and L-4 vertebral bodies (Fig. 1). Load-displacement curves were used to estimate range of motion (ROM), neutral zone stiffness (NZS), elastic zone stiffness (EZS), and energy loss (EL) among the different conditions. Stiffness was calculated as the inverse of the loading slope (Nm°/Nm) around the neutral posture (0–3 Nm) for NZS and the inverse of the unloading slope around the maximum load (7.5–4.5 Nm) for the EZS.23 The EL (Nm°/Nm) was estimated from the hysteresis loop using trap-
oped screws implanted (no rods).

Electrode before flexion-extension testing for the PLIF-ISS condition, with 2 of the 9 specimens.

 were compromised during interbody cage implantation in PLIF conditions was reduced to 7 because the endplates were used to simulate surgical scenarios, where excessive extension during ISS implantation was prevented to avoid spino process fracture.11 The BPSS (5.5-mm-diameter and 45-mm-long screws; Zodiac, Ti, Alphatec Spine) construct was always performed after the ISS (36–40 mm [width] × 8–10 mm [height]; Axle Interspinous Fusion System, X-Spine Systems, Inc.) condition; however, the testing order of the PLIF (CALIBER, Globus Medical, Inc.) conditions was randomly alternated. When the ISS-PLIF condition was tested after the BPSS-PLIF condition, the BPSS rods were removed and the pedicle screws were left implanted, which was assumed to have a negligible effect on the measurements. The interbody cages were expanded using surgical instrumentation until 2 Nm of expansion was reached. The sample size for the PLIF conditions was reduced to 7 because the endplates were compromised during interbody cage implantation in 2 of the 9 specimens.

2 Nm of expansion was reached. The sample size for the PLIF conditions was reduced to 7 because the endplates were compromised during interbody cage implantation in 2 of the 9 specimens.

The ROM, NZS, EZS, and EL were checked for normality using a Shapiro-Wilk test. A nonparametric approach for repeated measures was used for the statistical analysis. A Friedman test follow by post hoc Wilcoxon signed-rank paired comparisons were explored at a p ≤ 0.05 significance level.12 Two statistical analyses in all variables were performed to compensate for the unbalanced data:

1) Effects of injury and posterior constructs. The first 4 treatments (intact, injury, ISS, and BPSS) were statistically compared (n = 9) for each motion (flexion-extension, lateral bending, and axial rotation). If the Friedman test suggested differences among conditions, post hoc Wilcoxon signed-rank tests were performed among paired comparisons. Since the injury was unilateral, left and right lateral bending and axial rotation were analyzed separately for ROM, NZS, and EZS.

2) Effects of interbody cages on posterior constructs. All 6 treatments were statistically compared for each motion (flexion-extension, lateral bending, and axial rotation) among the specimens that underwent the PLIF conditions (n = 7). If Friedman tests suggested differences, the test was repeated only for the last 4 conditions (ISS, BPSS, ISS-PLIF, and BPSS-PLIF). If the second test suggested differences, paired comparisons were established among these 4 conditions using post hoc Wilcoxon signed-rank tests. The main focus of this analysis was to investigate the contribution of PLIF to the posterior constructs; thus, left and right lateral bending and axial rotation were grouped (measurements summed for ROM and averaged for stiffness).

All simulated treatments were performed by skilled surgeons using standard techniques/tools, according to manufacturers’ specifications. Appropriate implant sizes were used to simulate surgical scenarios, where excessive extension during ISS implantation was prevented to avoid spinous process fracture.11 The BPSS (5.5-mm-diameter and 45-mm-long screws; Zodiac, Ti, Alphatec Spine) condition was always performed after the ISS (36–40 mm [width] × 8–10 mm [height]; Axle Interspinous Fusion System, X-Spine Systems, Inc.) condition; however, the testing order of the PLIF (CALIBER, Globus Medical, Inc.) conditions was randomly alternated. When the ISS-PLIF condition was tested after the BPSS-PLIF condition, the BPSS rods were removed and the pedicle screws were left implanted, which was assumed to have a negligible effect on the measurements. The interbody cages were expanded using surgical instrumentation until 2 Nm of expansion was reached. The sample size for the PLIF conditions was reduced to 7 because the endplates were compromised during interbody cage implantation in 2 of the 9 specimens.

All statistical analyses were performed using the “raw” data, but graphics are presented as normalized percentages with respect to the intact condition (100%); p values were not adjusted for multiple comparisons since this was an explorative study.

Results

Range of Motion

All ROM data are summarized in Table 1 and are graphically presented as normalized values with respect to the intact condition in Fig. 3. The injury (left laminotomy and partial discectomy) condition increased median ROM in all motions with respect to the intact condition, but significance was only observed for flexion, left (injured side) lateral bending, and right/left axial rotation motions. The ISS and BPSS conditions significantly reduced flexion and extension ROM with respect to the intact and injury conditions (Table 2), whereas the median extension ROM was also significantly smaller in the ISS condition with respect to the BPSS condition. The BPSS condition significantly reduced right/left lateral bending and right/left axial rotation ROM of the injured and intact models, and these reductions were also significant with respect to the ISS construct. The incorporation of expandable cages (PLIF) to the posterior constructs reduced flexion, lateral bending, and axial rotation ROM of the PLIF-ISS and PLIF-BPSS conditions with respect to the ISS and BPSS conditions, respectively, and also ex-
tension of the PLIF-BPSS construct with respect to the BPSS condition, but changes were only significant in the PLIF-ISS construct for lateral bending and axial rotation (Table 2). Both PLIF constructs performed equivalently for all motions except for lateral bending, where the PLIF-BPSS showed greater rigidity (smaller ROM).

**Stiffness**

All stiffness data are summarized in Table 3 and are graphically presented as normalized values with respect to the intact condition in Figs. 4 and 5. The NZS was significantly reduced by the injury in flexion \( p = 0.01 \) and extension \( p < 0.01 \), but there was not enough evidence \( p \geq 0.10 \) to show any effect of this injury around the maximum load region (EZS) in any motion. Moreover, the BPSS construct increased both the NZS \( p \leq 0.04 \) and EZS \( p \leq 0.02 \) of the intact condition in all motions except in left rotation \( p = 0.23 \), Friedman test) for EZS. On the other hand, the ISS condition increased flexion and extension \( p \leq 0.03 \) NZS and EZS. A median increase in right/left lateral bending NZS was observed for the ISS condition with respect to the injury condition (not significant, \( p > 0.10 \)), but this represented a reduction in left (injured side) lateral bending NZS with respect to the intact condition \( p = 0.03 \). The incorporation of cages to the ISS construct significantly increased stability in the neutral region (NZS) for lateral bending \( p = 0.02 \) and in the elastic region (EZS) for flexion \( p = 0.03 \) and axial rotation \( p = 0.02 \). On the

**Fig. 2.** Fluoroscopic images of a potted L3–4 spinal segment under the intact (A), left laminotomy and partial discectomy (B, injury [circle]), ISS (C), BPSS (D), PLIF-ISS condition (with pedicle screws implanted, no rods) (E), and the PLIF-BPSS condition (F). Images A and B are posterior views; C–F are lateral views.
Lumbar interspinous fusion

Other hand, the PLIF-BPSS condition showed a marginal ($p = 0.05$) increase in EZS for flexion with respect to that of the BPSS construct. The 2 PLIF constructs (PLIF-ISS and PLIF-BPSS) provided comparable stiffness to the spinal segment for both neutral and elastic zones in flexion, extension, and axial rotation ($p \geq 0.30$), but the PLIF-BPSS construct was stiffer in lateral bending ($p = 0.02$).

**Energy Loss**

The instability triggered by the injury was also mani-

### Table 1: Median values for ROM and EL*

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Median (range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROM ($)</td>
<td>Extension</td>
</tr>
<tr>
<td>intact</td>
<td>1.9 (0.8–4.0)</td>
</tr>
<tr>
<td>injury</td>
<td>1.8 (0.8–4.3)</td>
</tr>
<tr>
<td>ISS</td>
<td>0.6 (0.3–1.3)</td>
</tr>
<tr>
<td>BPSS</td>
<td>0.8 (0.5–2.2)</td>
</tr>
<tr>
<td>PLIF-ISS†</td>
<td>0.7 (0.2–1.2)</td>
</tr>
<tr>
<td>PLIF-BPSS†</td>
<td>0.5 (0.2–1.4)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EL (Nm**)</th>
<th>Flexion-Extension</th>
<th>Bending</th>
<th>Rotation</th>
</tr>
</thead>
<tbody>
<tr>
<td>intact</td>
<td>4.6 (1.0–10.7)</td>
<td>6.2 (4.7–10.0)</td>
<td>5.4 (1.5–9.6)</td>
</tr>
<tr>
<td>injury</td>
<td>5.8 (1.4–12.2)</td>
<td>7.4 (5.1–10.7)</td>
<td>5.9 (2.3–9.2)</td>
</tr>
<tr>
<td>ISS</td>
<td>2.9 (0.4–8.5)</td>
<td>11.2 (5.8–17.5)</td>
<td>6.2 (2.7–9.8)</td>
</tr>
<tr>
<td>BPSS</td>
<td>4.9 (0.6–8.3)</td>
<td>4.8 (1.6–9.8)</td>
<td>3.9 (2.1–9.7)</td>
</tr>
<tr>
<td>PLIF-ISS†</td>
<td>2.8 (0.4–5.3)</td>
<td>5.8 (2.2–7.3)</td>
<td>6.2 (2.2–7.3)</td>
</tr>
<tr>
<td>PLIF-BPSS†</td>
<td>1.9 (0.6–6.5)</td>
<td>2.8 (0.6–5.0)</td>
<td>5.1 (2.2–5.5)</td>
</tr>
</tbody>
</table>

* injury = left laminotomy and partial discectomy.
† n = 7.

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![Graph](image-url)

**Fig. 3.** Range of motion values (median) normalized with respect to the intact condition. Error bars represent the interquartile range. The median values were estimated from 9 samples, except for the PLIF conditions (n = 7).
fested in terms of the energy lost, estimated from the hysteresis loops of all conditions under each motion (Fig. 6). The energy EL are summarized in Table 1, and percentages here discussed are with respect to the intact condition (100%), unless otherwise stated. The energy lost by the segment increased after the injury for flexion-extension (122%), lateral bending (107%), and axial rotation (112%), although significance was only achieved for flexion-extension ($p = 0.02$). The BPSS condition did not reduce EL for flexion-extension (84%) ($p = 0.50$) and axial rotation (83%) ($p = 0.32$), but it did for lateral bending (78%) ($p = 0.02$). On the other hand, the ISS slightly reduced flexion-extension EL (55%) ($p = 0.07$), but increased axial rotation EL (117%) ($p \leq 0.03$) and lateral bending EL (154%) ($p \leq 0.01$) with respect to the intact condition ($p \leq 0.03$). The increase in lateral bending (154%) was also significant with respect to all

### Table 2: Probability values from Wilcoxon signed-rank tests for L3–4 ROM at 7.5 Nm*

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Extension</th>
<th>Flexion</th>
<th>Bending</th>
<th>Rotation</th>
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</thead>
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<td>RtLt</td>
<td>RtLt</td>
<td>RtLt</td>
<td>RtLt</td>
</tr>
<tr>
<td>intact (ref)</td>
<td>0.36</td>
<td>0.01</td>
<td>&gt;0.99</td>
<td>0.03</td>
</tr>
<tr>
<td>injury</td>
<td>0.02</td>
<td>0.01</td>
<td>&lt;0.01</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>ISS</td>
<td>&lt;0.01</td>
<td>&lt;0.01</td>
<td>0.55</td>
<td>0.05</td>
</tr>
<tr>
<td>BPSS</td>
<td>0.02</td>
<td>0.01</td>
<td>&lt;0.01</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>injury (ref)</td>
<td>0.02</td>
<td>0.01</td>
<td>0.71</td>
<td>0.66</td>
</tr>
<tr>
<td>ISS (ref)</td>
<td>&lt;0.01</td>
<td>&lt;0.01</td>
<td>0.71</td>
<td>0.66</td>
</tr>
<tr>
<td>BPSS (ref)</td>
<td>0.02</td>
<td>0.01</td>
<td>&lt;0.01</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

* Comparisons of PLIF conditions with respect to the intact and injury conditions were not explored. Values in boldface represent differences statistically significant ($p \leq 0.05$). ref = reference.

† $n = 7$.

### Table 3: Stiffness median values [Nm/°] for the NZS and EZS

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Extension</th>
<th>Flexion</th>
<th>Lt Bending</th>
<th>Rt Bending</th>
<th>Lt Rotation</th>
<th>Rt Rotation</th>
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<tbody>
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<td>NZS</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>intact</td>
<td>2.7 (1.2–9.2)</td>
<td>1.9 (0.6–9.6)</td>
<td>1.5 (0.4–2.3)</td>
<td>1.4 (0.5–2.2)</td>
<td>2.8 (1.3–11.0)</td>
<td>3.0 (1.4–9.4)</td>
</tr>
<tr>
<td>injury</td>
<td>2.0 (0.7–8.9)</td>
<td>1.4 (0.4–6.7)</td>
<td>0.7 (0.4–2.7)</td>
<td>0.8 (0.5–2.3)</td>
<td>2.4 (1.3–9.8)</td>
<td>2.6 (1.4–7.4)</td>
</tr>
<tr>
<td>ISS</td>
<td>10.6 (2.6–24.0)</td>
<td>7.4 (3.0–18.6)</td>
<td>1.2 (0.3–1.6)</td>
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<td>2.9 (1.8–9.3)</td>
<td>3.3 (1.7–9.1)</td>
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<tr>
<td>BPSS</td>
<td>6.7 (2.2–12.0)</td>
<td>7.5 (2.4–11.7)</td>
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<tr>
<td>PLIF-ISS*</td>
<td>9.6 (3.0–26.1)</td>
<td>9.7 (2.6–25.8)</td>
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<td>PLIF-BPSS*</td>
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<td>6.8 (3.0–11.1)</td>
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<tr>
<td>EZS</td>
<td></td>
<td></td>
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<td>7.5 (4.1–12.3)</td>
<td>4.7 (2.2–8.1)</td>
<td>5.9 (4.2–9.6)</td>
<td>6.4 (3.7–12.3)</td>
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<td>9.0 (5.0–11.8)</td>
</tr>
<tr>
<td>injury</td>
<td>7.2 (4.5–11.2)</td>
<td>5.4 (0.7–9.6)</td>
<td>6.4 (4.4–12.3)</td>
<td>5.9 (3.4–8.5)</td>
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<tr>
<td>ISS</td>
<td>16.7 (12.3–29.8)</td>
<td>13.9 (6.6–22.9)</td>
<td>5.9 (4.6–7.7)</td>
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<td>6.8 (5.5–12.1)</td>
<td>7.2 (5.5–10.0)</td>
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<tr>
<td>BPSS</td>
<td>12.3 (6.2–18.6)</td>
<td>10.7 (6.4–14.9)</td>
<td>12.4 (8.5–22.4)</td>
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<td>8.9 (7.0–8.6)</td>
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<td>PLIF-ISS*</td>
<td>14.9 (12.4–29.8)</td>
<td>14.9 (12.3–25.3)</td>
<td>7.5 (4.9–9.6)</td>
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<td>9.7 (6.7–12.7)</td>
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<tr>
<td>PLIF-BPSS*</td>
<td>18.1 (9.3–33.9)</td>
<td>14.8 (9.4–26.2)</td>
<td>14.9 (9.6–22.4)</td>
<td>18.6 (10.4–22.4)</td>
<td>9.5 (8.2–12.8)</td>
<td>9.9 (7.5–14.1)</td>
</tr>
</tbody>
</table>

* $n = 7$.
other conditions (injury, PLIF-ISS [77%] and PLIF-BPSS [33%]; p ≤ 0.02). The incorporation of expandable cages (PLIF) only affected the ISS construct in lateral bending (p = 0.02), by reducing 77% the energy lost by the PLIF-ISS construct when compared with that of the ISS condition (154%). However, this reduction was not enough to prevent the lateral bending EL of the PLIF-ISS construct to be greater than that of the PLIF-BPSS construct (p = 0.02).

### Discussion

**Effects on ROM**

Laminotomies (unilateral or bilateral) are common procedures for degenerative lumbar conditions and surgeons may or may not use fixation to counteract any possible instability triggered by the decompression. The immediate increase in ROM after a unilateral laminotomy (and partial discectomy) can be significant in flexion, lateral bending at the injured side, and axial rotation (Fig. 3), which may suggest the need for some (posterior) fixation. The instrumentation requirement after unilateral decompression has been observed in clinical studies, such as that performed by Son et al., where 6.5% of patients treated with unilateral laminotomy without fixation required revision surgery.

Clinical and in vitro studies corroborate our findings of an ISS significantly restoring and stabilizing flexion-extension motion (Fig. 3). Kibbara et al., for example, reported significant restriction of flexion-extension ROM after implantation of an ISS in an intact model (no injury was simulated). On the other hand, our findings suggest that the ISS can immediately restore flexion-extension stability after unilateral decompression. However, the biomechanical comparison between unilateral decompression alone and unilateral decompression with an interspinous fusion system is intended to show the immediate effects of these surgical treatments. Further clinical investigations including patients with unilateral decompression with and without (control) an interspinous fusion system will indeed determine the clinical need and benefits of an ISS after unilateral decompression.

The significant contribution of BPSS in lateral bending and axial rotation ROM restriction (Table 2) are validated by previous biomechanical studies, but deciding if BPSS is a better option than an interspinous fusion device involves considering other factors such as blood loss, operative time, and postoperative complications.

Clinical evaluation of the need for posterior fixation after decompression has also been documented. Ritcher et al. conducted a prospective study in which outcomes (12 months of follow-up) of 1- to 2-level posterior decompression (partial laminotomy, removal of ligamentum flavum, and undercutting facetectomy) with and without Coflex (dynamic) ISSs were compared; no statistical differences between the control group (n = 30, decompression without instrumentation) and the treated group (n = 30, decompression with Coflex) were stated. However, this device is meant to provide “dynamic” stabilization,
which differs from interspinous fusion devices, such as the one used in this investigation, since dynamic devices are not meant to be used to promote postoperative fusion, although the incidence (80%) of arthrodesis was reported in a 13-year (mean) follow-up after Wallis (dynamic) ISS implantation.20

When posterior constructs were used as supplemental fixation to expandable posterior cages (PLIF), it was observed that ISS provided comparable stability to that of the BPSS for flexion-extension and axial rotation but not for lateral bending ROM (Table 2). Similar findings have been reported when comparing interspinous fusion devices with BPSS in transforminal lumbar interbody fusion (TLIF), where both posterior constructs provided equivalent immediate stability in flexion-extension and the TLIF-BPSS condition showed smaller lateral bending and axial rotation ROM.7, 24 One possible explanation for equivalent axial rotation ROM between the PLIF-ISS and the PLIF-BPSS construct, not observed in a TLIF model, may be related to the interbody spacer contribution; the bilateral implantation of posterior cages may provide slightly greater resistance to torsional motion than a single transfomaminal cage, which may have allowed the contribution of the ISS to make both the PLIF-ISS and the PLIF-BPSS constructs equivalent in axial rotation. This hypothesis can be also supported by the results of Kettler et al.,8 where axial rotation ROM was smaller (although not significant) in a PLIF construct than in a TLIF construct, using polyetheretherketone cages.

Interspinous fusion devices as posterior instrumentation to PLIF have been also clinically evaluated. Kim et al.10 concluded that the PLIF-ISS (using nonexpandable cages and a similar interspinous fusion device, Spire) and the PLIF-BPSS (using nonexpandable cages) constructs had comparable outcomes after at least 12 months of follow-up, but a higher incidence of adjacent degeneration was observed in the PLIF-BPSS group (36.1% vs 12.5%).

Changes in Regional Stiffness

Determining the location (that is, around the neutral posture or for greater loads) of the immediate instability/stability triggered by a surgical procedure can provide meaningful information to predict short-term clinical outcomes. In terms of biomechanics, the injury was expected to affect the stiffness around the neutral region, especially for flexion-extension motion, since the intervertebral disc (middle portion) and the lamina are important elements for the stability around the neutral posture (Fig. 4). On the other hand, ligament contributions under maximum loads are more significant to the EZS, which explains why the effects of this injury were minimal for that region (Fig. 5).

Changes in the NZS may be a better predictor of critical instability/stability created by spinal decompression/instrumentation than EZS since patients commonly exert micromotions to overcome vital activities of daily living after surgery (motion around the neutral posture) and are
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warned to avoid activities that imply great effort in terms of spinal loading (motion around the elastic zone). Thus, the NZS findings suggest that unilateral decompression creates immediate flexion-extension instability after surgery around the neutral posture, and an ISS may be sufficient to provide some sort of posterior fixation to this type of injury, especially in flexion-extension. However, the ISS is only suitable for particular spinal conditions and is not as stable as BPSS in lateral bending and axial rotation, which could lower the chances of bony fusion and increase the risk of failure from fatigue. Even though some designs of ISS are only meant to provide natural distraction of spinous processes, others, such as the one used in the current study, are intended to promote fusion.

The addition of expandable posterior cages (PLIF) to the ISS and BPSS constructs was expected to increase stiffness for all motions (Figs. 4 and 5) because it incorporates middle column stabilization to the posterior column. The contribution of the cages in increasing lateral bending stability around the neutral posture (NZS) and limiting excessive flexion and rotation (flexion and axial rotation EZS) was evident for the PLIF-ISS construct when compared with the ISS in the stand-alone model. Both PLIF constructs showed equivalent stiffness in the neutral and elastic regions, except for lateral bending, where the PLIF-BPSS construct had significantly greater stiffness.

Previous biomechanical investigations reveal that BPSS is required when implanting posterior expandable interbody cages, since these can be even more destabilizing than the intact condition, especially in flexion-extension. Thus, an interspinous fusion device may be a suitable option to provide additional stability, especially in flexion-extension motion, to a PLIF construct. On the other hand, favorable results of stand-alone posterior expandable cages after unilateral facetectomy were reported in a 24-month follow-up study; however, cage subsidence occurred in 10 of the 34 patients, and 2 patients presented with recurrent pain, which may require later revision surgery. This incidence of cage subsidence in posterior expandable cages could be related to the ability of expanding them after they have been inserted, since this could potentially increase the chance of over-expanding the device when compared with a static cage.

Preservation of Balance

Previous investigations have used the EL concept to help interpret biomechanical data. Energy loss indicates the probability of the segment maintaining the (corrected) balance in a specific plane, which in turn translates to the chances of segmental micromotions that could inhibit bony fusion. Clinically, EL can be interpreted as the likelihood of preserving sagittal (flexion-extension), coronal (lateral bending), and axial (axial rotation) balance. The importance of the EL concept can be illustrated by the effects of the different conditions in the EL (Fig. 6). Clinical investigations suggest that ISS can conveniently alter sagittal balance, which goes in line with our EL find-

Fig. 6. Representation of the load-displacement curve (hysteresis loop) under all conditions. Energy loss values for each condition are shown in the legend as condition (EL [Nm°]). B = bending; R = rotation.
ings (reduction of flexion-extension EL by 66% of the ISS construct with respect to the injury condition). However, the ISS does not restrict lateral bending motion; thus, an external lumbar brace may be an appropriate option when coronal balance needs to be preserved. The significant reduction of approximately 30% and 23% in lateral bending EL for the BPSS condition with respect to the injury and the intact condition, respectively, confirms the effectiveness of BPSS in maintaining segmental coronal balance. Moreover, the bilateral placement of posterior cages significantly improves the chance of maintaining segmental coronal (lateral bending) balance in the ISS condition, by reducing lateral bending EL for the PLIF-ISS condition in approximately 77% with respect to the ISS condition.

Clinical Complications of Interspinous Spacers

Some possible complications from ISS implantation are spinous process fracture, implant dislocation, and reoperation due to persistent pain (ineffective implant); however, these incidences seem to be sporadic and have been related specifically to dynamic ISSs, which are not promoted as fusion devices. The selection of an interspinous fusion spacer as a suitable option needs to be carefully evaluated since the incidence of complications may be associated with the device’s indication. For example, Kim et al. observed an association between spinous process fracture recurrence and degenerative spondylolisthesis. Even though their study included 2 dynamic spacers (X-STOP Titanium, X-STOP polyaryletheretherketone) and 1 interspinous fusion device (Aspen), an association between fractures and device design could not be established; however, this study only included 8 patients treated with the interspinous fusion device (of 38 patients total), which limits the analysis of dynamic versus fusion devices. Further clinical investigation in terms of interspinous fusion devices complications should be conducted.

Study Limitations

Even though the analysis under in vitro conditions is limited and the biomechanical effects of all surgical conditions here tested can be considered “small,” the behaviors were reproducible among specimens, which allowed establishing statistical (explorative) differences. However, extrapolating these findings to clinical scenarios can be challenging. The interbody cages alone were not tested; thus, quantifying the contribution of the BPSS or the ISS to the PLIF condition was based on the differences between the constructs with and without the interbody cages. Sequential testing of the BPSS after ISS removal has been reported in previous biomechanical studies and was assumed to have negligible effects in the biomechanical performance of the BPSS in the current investigation since implantation/removal of the ISS only compromised the interspinous ligament; however, this hypothesis was not investigated. The EL estimations were measured under a small number of cycles and did not take fatigue into account. The limited information available in the performance of expandable posterior interbody cages and ISSs only allowed us to compare our findings with similar publications that involved different (nonexpandable) cages and ISS designs, which we acknowledge could have an effect on the results. Also, the effects of reimplanting the ISS after interbody cages could have created bias results toward BPSS, although this effect was assumed to be negligible but was not investigated.

Conclusions

An interspinous fusion device may be a suitable construct to maintain segmental sagittal balance after a unilateral laminotomy. Biomechanical data suggest that interspinous and bilateral pedicle screws as supplemental fixation to expandable posterior interbody cages may provide similar immediate stability in flexion-extension and axial rotation, but posterior expandable cages with a pedicle screw construct provide greater coronal (lateral bending) balance. The new designs and techniques for interspinous devices suggest that more clinical and biomechanical evidence is needed to strongly support the recommendation of an interspinous fusion device as a stand-alone or as supplemental fixation to expandable posterior interbody cages in the lumbar spine.

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