Biomechanical Analysis of an Interspinous Process Fixation Device with In Situ Shortening Capabilities: Does Spinous Process Compression Improve Segmental Stability?

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Biomechanical Analysis of an Interspinous Process Fixation Device with In Situ Shortening Capabilities: Does Spinous Process Compression Improve Segmental Stability?

Christopher Wagener[1], Anup Gandhi[2], Chris Ferry[3], Sam Farmer[2], Ryan DenHaese[4]

■ OBJECTIVE: **The objective of this study was to characterize the biomechanical implications of spinous process compression, via in situ shortening of a next-generation interspinous process fixation (ISPF) device, in the context of segmental fusion.**

■ METHODS: **Seven lumbar cadaveric spines (L1-L4) were tested. Specimens were first tested in an intact state, followed by iterative instrumentation at L2-3 and subsequent testing. The order followed was 1) stand-alone ISPF (neutral height); 2) stand-alone ISPF (shortened in situ from neutral height; shortened); 3) lateral lumbar interbody fusion (LLIF) + ISPF (neutral); 4) LLIF + ISPF (shortened); 5) LLIF + unilateral pedicle screw fixation; 6) LLIF + bilateral pedicle screw fixation. A 7.5-Nm moment was applied in flexion/extension, lateral bending, and axial rotation via a kinematic test frame. Segmental range of motion (ROM) and lordosis were measured for all constructs. Comparative analysis was performed.**

■ RESULTS: **Statistically significant flexion/extension ROM reductions: all constructs versus intact condition ($P < 0.01$); LLIF + ISPF (neutral and shortened) versus stand-alone ISPF (neutral and shortened) ($P < 0.01$); LLIF + USPF versus ISPF (neutral) ($P = 0.049$); bilateral pedicle screw fixation (BPSF) versus stand-alone ISPF (neutral and shortened) ($P < 0.01$); LLIF + BPSF versus LLIF + unilateral pedicle screw fixation (UPSF) ($P < 0.01$). Significant lateral bending ROM reductions: LLIF + ISPF (neutral and shortened) versus intact condition and stand-alone ISPF (neutral) ($P < 0.01$); LLIF + UPSF versus intact condition and stand-alone ISPF (neutral and shortened) ($P < 0.01$); LLIF + BPSF versus intact condition and all constructs ($P < 0.01$). Significant axial rotation ROM reductions: LLIF + ISPF (shortened) and LLIF + UPSF versus intact condition and stand-alone ISPF (neutral) ($P \leq 0.01$); LLIF + BPSF versus intact condition and all constructs ($P \leq 0.04$).**

■ CONCLUSIONS: **In situ shortening of an adjustable ISPF device may support increased segmental stabilization compared with static ISPF.**

INTRODUCTION

Instrumented intervertebral fusion is a well-accepted intervention when treating pain secondary to lumbar spine degeneration and/or instability. Although open posterior screw fixation remains the most readily practiced and proven means to providing robust supplementary stabilization, increased consideration is being given to modified approaches (i.e., percutaneous) and/or hybrid techniques (i.e., midline cortical bone trajectory) in which soft tissue disruption and boney invasion are diminished.[1-41] However, despite continued clinical success with screw-based techniques, alternative posterior fixation modalities continue to be explored in an attempt to expand the breadth of

Key words
- Biomechanics
- Cadaveric
- Interspinous process fixation
- Lateral lumbar interbody fusion
- Pedicle screw fixation
- Posterior fixation

Abbreviations and Acronyms
ALIF: Anterior lumbar interbody fusion
AR: Axial rotation
BPSF: Bilateral pedicle screw fixation
FE: Flexion/extension
ISPF: Interspinous process fixation
LB: Lateral bending
LLIF: Lateral lumbar interbody fusion
PH: Post height
PSF: Pedicle screw fixation
ROM: Range of motion
UPSF: Unilateral pedicle screw fixation

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device feasibility and mechanical attributes. Rigid interspinous process fixation (ISPF) is one such alternative modality, receiving consideration with both posterolateral and interbody fusion applications.[3,5,11-14,17,18,30,31,33,36-40]

Placed through a singular midline incision, ISPF uses the cortical bone mass of the laminar junction to achieve rigid fixation, avoiding dissection down to the pedicles and/or facet joints, and largely preserving paraspinal structures. Accordingly, decreased intraoperative blood loss, incision lengths, operative time, and fluoroscopic exposure have all been attributed to ISPF compared with traditional screw fixation.[36,38] However, despite such intraoperative advantages and robust sagittal stability, reservations remain around ISPF regarding stability in the axial and coronal planes.[11-14,17,18,30,33,40] To address these reservations, a next-generation adjustable ISPF device has been developed that permits axial shortening/extension in situ (**Figure 1**). This capability is believed to provide additional leverage necessary to achieve greater circumferential stability and segmental lordosis with ISPF.

The objective of this study was to biomechanically assess this adjustable ISPF device as a function of segmental stability and segmental lordosis, considering both neutral and in situ shortened conditions. A standard cadaveric in vitro lumbar model was used, with and without lateral lumbar interbody fusion (LLIF) present. Unilateral pedicle screw fixation (UPSF) and bilateral pedicle screw fixation (BPSF) cohorts were implemented as controls.

METHODS

Specimen Preparation

Seven fresh frozen human cadaveric lumbar spines (L1-L4) were tested (3 women, 4 men; age, 54 ± 4.8 years). Each spine was thawed at room temperature and the lumbosacral specimens were dissected out. Ligamentous structures were maintained. Residual musculature and adipose tissue were removed. All specimens were received from the same accredited tissue bank service and were indicated to have had no known clinical history of spinal disease (Science Care, Inc., Phoenix, Arizona, USA). In addition, standard anteroposterior and lateral radiographs were obtained of all specimens and assessed for any evidence of lumbosacral surgery, excessive degeneration, or anatomic discrepancy. No specimen showed radiographic evidence of intervertebral disc degeneration or facet joint degeneration. Furthermore, no discrepancies were observed on specimen inspection after gross dissection. Bone mineral density evaluations were performed by dual-energy X-ray absorptiometry. Mean bone mineral density and T scores were 0.835 g/cm^2 (range, 0.71−0.997) and −2.2 (range, −0.5 to −3.3), respectively.

Standard wood screws were placed in the cephalad and caudal vertebral bodies, followed by anchoring in high-strength resin (Bondo Body Filler [3M, St. Paul, Minnesota, USA]) for subsequent test apparatus attachment. Potted specimens were then sealed in plastic bags and maintained frozen at −20°C until approximately 10 hours before testing, at which time they were allowed to thaw at room temperature (approximately 25°C).

Specimens were then instrumented with custom-made optoelectronic triad markers in each vertebral body. Screw placement did not obstruct any fixation construct. The vertebral bodies were assumed to be rigid.

Each specimen was then subjected to pure moment flexibility testing (as described in the Testing Protocol section) in the following order:

1) Stand-alone ISPF (neutral height)
2) Stand-alone ISPF (shortened in situ from neutral height; "shortened")
3) LLIF + ISPF (neutral) (**Figure 2**)
4) LLIF + ISPF (shortened) (**Figure 2**)
5) LLIF + UPSF
6) LLIF + BPSF.

All references to the term "shortened" (regarding the ISPF device) are indicative of in situ shortening of the ISPF device (Alpine XC Adjustable Fusion System [Zimmer Biomet Spine, Broomfield, Colorado, USA]) once affixed to the spinous processes. Device indications, per manufacturer surgical technique guide, include:

—Use at a single level in the noncervical spine (T1-S1)

—Use in posterior, noncervical pedicle and nonpedicle spinal fixation, to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion

—Indicated disease includes degenerative disc disease, spondylolisthesis, trauma, spinal stenosis, deformities or curvatures, tumor, pseudarthrosis, and failed previous fusion

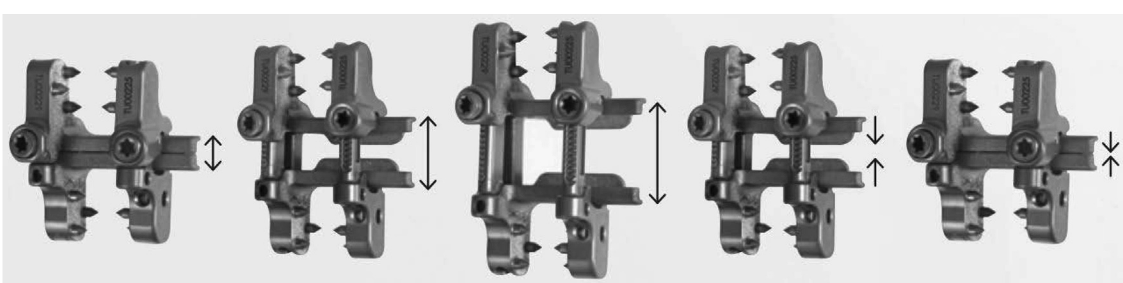

Figure 1. Next-generation interspinous process fixation device that can be shortened/extended in situ.

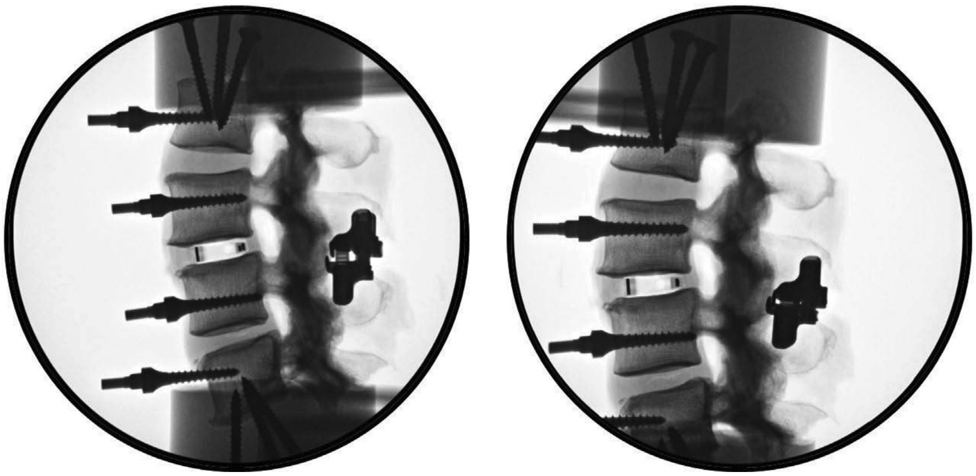

Figure 2. Lateral fluoroscopic images of cadaveric test specimen with lateral interbody cage and interspinous process fixation device at neutral post height (*left*) and in situ shortened post height (*right*).

—Use intended with bone graft material (autograft or allograft); not intended for stand-alone use.

After intact condition testing, the interspinous and supraspinous ligaments were resected. The ISPF device was then implanted at a neutral post height (PH) deemed appropriate by the performing surgeon. The post is considered the adjustable (axial) portion of the device that sits within the interspinous space. The ISPF device used in this study possessed a maximum PH of 18 mm and minimum PH of 6 mm. Device placement was as far anterior and as close to the laminar junction as possible. After the desired implantation PH was established, definitive device fixation to the spinous processes was performed via medial compression, effectively seating the device spikes into the spinous process bone mass (**Figure 3**). Maximal compression was performed by the investigating surgeons based on tactile feedback, ensuring good bone-plate apposition without risk of weakening or crushing of the cortex.

After ROM testing of the ISPF (only) construct at neutral PH, the ISPF device was then shortened in situ (**Figure 4**). A target shortening length of 3 mm was predefined in accordance with previous work by Gandhi et al.,[42] which showed that 3 mm of compression with the same ISPF device resulted in approximately 100 N of applied force to the spinous processes. The 100 N value is below mean spinous process fracture values from previous studies (339—493 N), providing a factor of safety

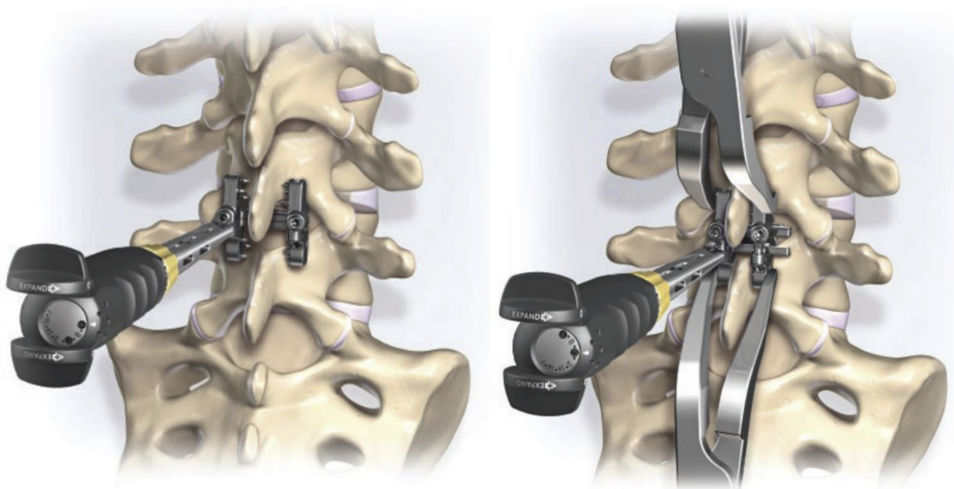

Figure 3. Next-generation interspinous process fixation device placed with interspinous space (*left*) and then after medial compression of the device, seating the device spikes within the cortex (*right*).

>3.[43,44] Mean PH shortening was 3.1 mm for both stand-alone and LLIF application.

After stand-alone ISPF device testing, the ISPF device was removed and a standard lateral discectomy (L2-3) was performed. The posterior annulus was left intact, with the intervertebral access window centered in the anterior half of the disc space. The end plates were preserved. The rationale to use L2/3 as the level of instrumentation was a low rate of degeneration traditionally observed at this level. We considered that this rationale would best ensure native physiologic range of motion (ROM) across all test specimens at baseline. A standard LLIF cage (Timberline Lateral Fusion System [Zimmer Biomet Spine, Broomfield, Colorado, USA]) was then inserted. Cage footprint was determined specific to specimen anatomy. Selection of LLIF as the most pertinent interbody fusion technique was made in accordance with current literature trends, which support the ideal that ISPF may be most appropriate with a large lateral cage.[11-14,30] After cage placement, the specimen was re-instrumented with the ISPF device at a neutral PH. Medial compressive loading of the device to the spinous processes was again determined based on the tactile feedback of the investigating surgeons. As with previous placement (without interbody cage present), care was taken to ensure adequate bone-plate apposition without compromising the cortex. Furthermore, visual inspection of the spinous processes was performed before device placement and after device removal to determine whether device spikes migrated/translated within the bone mass during loading cycles. Migration suggests boney compromise that could diminish the quality of subsequent fixation. However, visual inspection showed no evidence of boney compromise throughout the duration of testing. Additional contributing factors to bone preservation included robust specimen bone quality, low-profile device spikes, and minimalized repeated instrumentation (device removed and re-affixed only once). ROM testing was then performed, followed by subsequent in situ shortening (target, 3 mm) and ROM testing. The ISPF device was then removed and the specimen received UPSF instrumentation, followed by ROM testing, and then conversion of UPSF to BPSF with subsequent ROM testing. Pedicle screw fixation (PSF) was performed via standard technique (Silverton Spinal Fixation System [Zimmer Biomet Spine, Broomfield, Colorado, USA]). Selection of PSF as a control was in accordance with current literature trends, which indicate UPSF and BPSF as a standard of care in supplementing LLIF.[44]

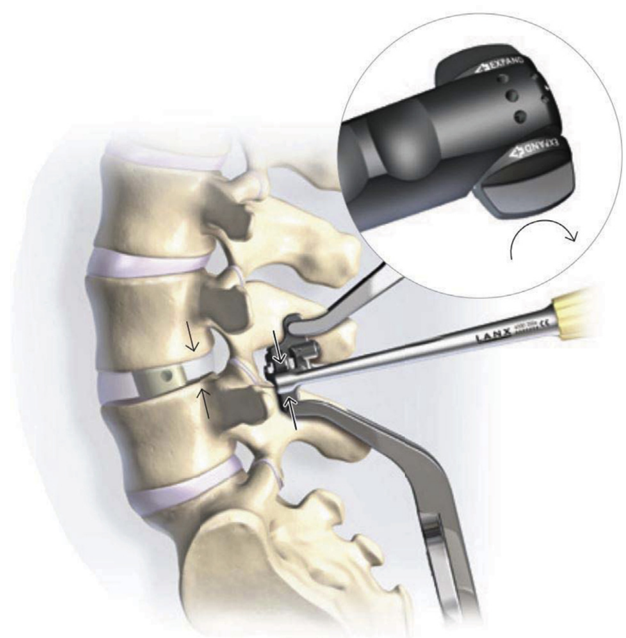

Figure 4. Next-generation interspinous process fixation device with adjustment instrument attached. Device shortening/extending achieved via turning of instrument handle knob (*top right*).

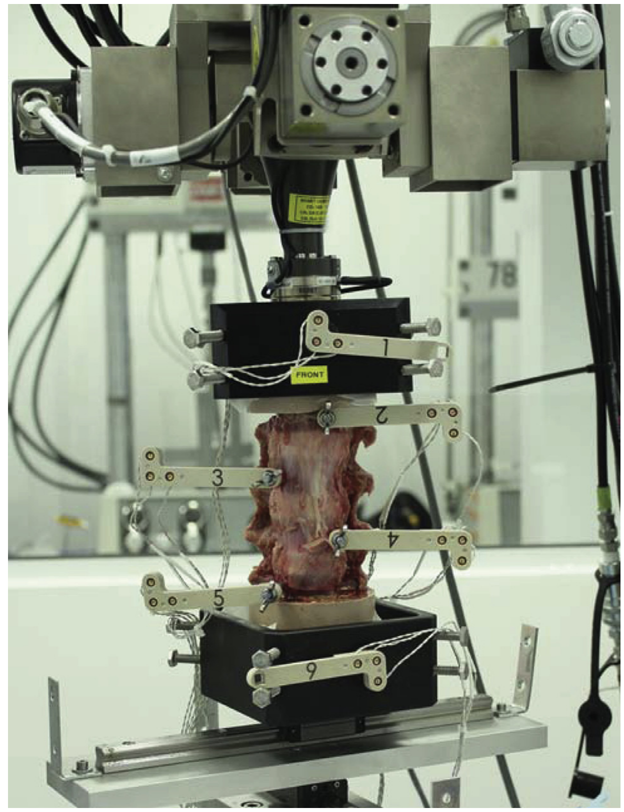

Figure 5. 6° of freedom kinematic testing machine (Bionix Spine Kinematics System [MTS Corporation, Eden Prairie, Minnesota, USA]) with intact specimen attached.

Lateral and anteroposterior fluoroscopic imaging was used to ensure proper device placement. Specimens were covered in saline-soaked gauze during all intermittent testing periods.

Testing and Motion Analysis Protocol

A 6° of freedom kinematic testing machine (Bionix Spine Kinematics System [MTS Corporation, Eden Prairie, Minnesota, USA]) was used to apply nonconstraining, nondestructive, pure moment loading in the 3 principal motion directions (**Figure 5**).

Specimens were rigidly mounted within the test apparatus. The caudal attachment afforded free translation in the x-y plane via a translating table. A maximum loading moment of ±7.5 Nm was applied in flexion/extension (FE), left/right lateral bending (LB), and axial rotation (AR) at a rate of 1°/second for 3 cycles. We acknowledge that a compressive follower load was not used; this strategy was chosen to assess device performance within a worst-case environment. Furthermore, as shown by Dreischarf et al.,[45] nonoptimized follower load paths and poorly defined starting conditions can diminish the comparability of studies and make drawing conclusions more challenging.

Three-dimensional motion of each vertebral body was recorded, in all cycles, relative to their adjacent levels (L1-2, L2-3, L3-4), as well for the cumulative specimen (L1-4) using an optoelectronic motion measurement system (Optotrak [Northern Digital Inc., Waterloo, Ontario, Canada]). Each optoelectronic triad maker was coupled to its respective level to establish a local coordinate system. In addition, 2 optoelectronic markers were rigidly attached to the static test frame to define the +x and +y axes, and subsequently the +z axis. Data acquired during the third test cycle were used for statistical analyses, as recommended by Wilke et al.[46]

Subsequent study metrics included mean ROM reduction relative to intact conditions and segmental lordosis (L2/3). Lordotic angles were measured using the Cobb method.

Statistical Analysis

A repeated measures analysis of variance and Bonferonni post hoc tests ($P < 0.05$) were performed to determine significance in ROM reductions and segmental lordosis between constructs (GraphPad Prism Software, La Jolla, California, USA). Pair-wise comparisons were made between all constructs.

RESULTS

ROM and segmental lordosis outcomes data are summarized in Table 1.

FE

All constructs showed significant ROM reduction from the intact state in FE ($P < 0.01$) (Figure 6). All LLIF cage constructs showed significantly greater FE ROM reduction than that of the stand-alone ISPF construct at neutral height ($P \leq 0.04$). Similarly, all LLIF cage constructs, except for LLIF + UPSF ($P = 1.0$), showed significantly greater FE ROM reduction than that of the stand-alone ISPF construct under in situ shortened conditions. No significant differences existed between LLIF constructs ($P \geq 0.06$). No significant differences existed when comparing ISPF (neutral) versus ISPF (shortened) and LLIF + ISPF (neutral) versus LLIF + ISPF (shortened) ($P = 1.0$). ISPF device shortening in stand-alone application yielded a 4.5% increase in FE ROM reduction ($P = 1.0$), whereas ISPF device shortening in LLIF application yielded a 1.2% increase in FE ROM reduction ($P = 1.0$). In addition, ISPF device shortening in stand-alone and LLIF application yielded increases in segmental lordosis of 1.4° and 1.7°, respectively.

LB

All LLIF constructs showed significant ROM reduction in LB from the intact state ($P \leq 0.01$); however, stand-alone ISPF application (neutral and shortened) did not achieve statistically significant reduction from intact conditions ($P \geq 0.46$) (Figure 7). Furthermore, all LLIF cage constructs expressed significantly greater LB ROM reduction than that of the stand-alone ISPF construct at neutral height ($P \leq 0.01$); however, only the LLIF + UPSF and LLIF + BPSF constructs showed significantly greater LB ROM reduction compared with the stand-alone ISPF constructs ($P \leq 0.01$). No significant differences in LB ROM reduction were

Table 1. Summary of Raw Segmental Range of Motion and Segmental Lordosis Data

Construct	ISPF Post Height (mm) (Mean ± SD)	Range of Motion (% Intact Condition) Flexion/Extension (Mean ± SD)	Range of Motion (% Intact Condition) Lateral Bending (Mean ± SD)	Range of Motion (% Intact Condition) Axial Rotation (Mean ± SD)	Mean Segmental Lordosis (% Intact Condition) (Mean ± SD)
ISPF (neutral)	9.7 ± 1.3	32.1 ± 22.4*	90.8 ± 8.8	94.0 ± 15.2	99.2 ± 22.6
ISPF (shortened)	6.6 ± 1.2	27.6 ± 24.0*	74.6 ± 19.3	78.1 ± 18.0	115.2 ± 35.0
LLIF + ISPF (neutral)	10.9 ± 2.0	13.2 ± 4.4*†‡	56.8 ± 16.9*†	77.0 ± 28.2	99.5 ± 25.6
LLIF + ISPF (shortened)	7.8 ± 2.1	12.0 ± 3.8*†	54.5 ± 19.3*†	63.3 ± 29.2*†	126.7 ± 22.3†
LLIF + UPSF	—	18.4 ± 4.3*†‡	41.6 ± 15.8*†‡	48.7 ± 17.8*†	138.1 ± 18.7†
LLIF + bilateral pedicle screw fixation	—	10.8 ± 4.4*†‡§	15.2 ± 4.7*†‡§‖¶	33.5 ± 16.4*†‡§‖¶	139.1 ± 33.9†‖

SD, standard deviation; ISPF, interspinous process fixation; LLIF, lateral lumbar interbody fusion; UPSF, unilateral pedicle screw fixation.
*Versus intact ($P < 0.05$).
†Versus ISPF (neutral) ($P < 0.05$).
‡Versus ± ISPF (shortened) ($P < 0.05$).
§LLIF + UPSF ($P < 0.05$).
‖Versus LLIF + ISPF (neutral) ($P < 0.05$).
¶Versus LLIF + ISPF (shortened) ($P < 0.05$).

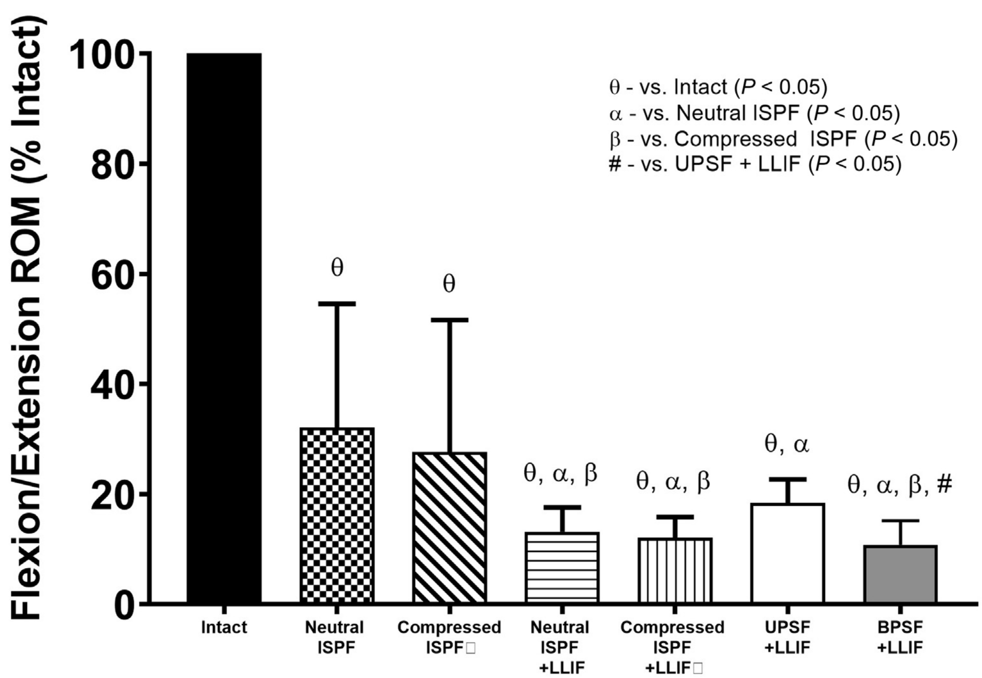

Figure 6. Mean range of motion (ROM), relative to intact conditions, when loaded in flexion-extension under a pure moment of 7.5 Nm. Bars represent the mean and error bars are standard deviation. Symbols denote significant differences ($P < 0.05$) between groups according to a repeated measures analysis of variance with Bonferonni correction for multiple comparisons. BPSF, bilateral pedicle screw fixation; ISPF, interspinous process fixation; LLIF: lateral lumbar interbody fusion; UPSF, unilateral pedicle screw fixation.

observed between the LLIF + ISPF constructs and LLIF + UPSF condition ($P \geq 0.48$); however, LLIF + BPSF significantly exceeded both LLIF + ISPF constructs, as well as the LLIF + UPSF construct ($P \leq 0.01$). ISPF device shortening in stand-alone application yielded a 16.2% increase in LB ROM reduction ($P = 1.0$), whereas ISPF device shortening in LLIF application yielded a 2.3% increase LB ROM reduction ($P = 1.0$).

AR

LLIF + UPSF, LLIF + BPSF, and LLIF + ISPF (shortened) conditions resulted in significant ROM reduction in AR from the intact state ($P \leq 0.01$); however, stand-alone ISPF (neutral and shortened) and LLIF + ISPF (neutral) application did not ($P \geq 0.41$) (**Figure 8**). Neither LLIF + ISPF condition achieved significantly greater AR ROM than that of the stand-alone ISPF shortened condition ($P \geq 0.86$); however, the LLIF + ISPF (shortened) condition did support significantly greater reduction that that of the stand-alone ISPF construct at neutral height ($P = 0.01$). AR ROM reduction with LLIF + UPSF exceeded all ISPF conditions ($P \leq 0.01$), except for LLIF + ISPF (shortened) ($P = 1.0$), whereas LLIF + BPSF application exceeded all other conditions, including LLIF + UPSF ($P \leq 0.04$). ISPF device shortening in stand-alone application yielded an 11.9% increase in AR ROM reduction ($P = 1.0$), whereas ISPF device shortening in LLIF application yielded a 13.7% increase AR ROM reduction ($P = 1.0$).

Segmental Lordosis

Significant differences in segmental lordosis were observed between stand-alone ISPF (neutral) and the LLIF + ISPF (shortened), LLIF + UPSF, and LLIF + BPSF conditions ($P \leq 0.01$) (**Figure 9**). In addition, segmental lordosis of LLIF + BPSF was significantly greater than that of LLIF + ISPF (neutral) ($P = 0.01$).

DISCUSSION

Biomechanical Outcomes

Spinous process compression via in situ device shortening resulted in increased segmental stability in both constructs (stand-alone ISPF and LLIF + ISPF) and in all principal motion directions (FE, AR, and LB). Collectively, outcomes after in situ compression were most advantageous in the axial plane, with the stand-alone and LLIF constructs showing additional ROM reductions of 15.9% and 13.7%, respectively. The greatest relative increase in segmental stability after compression was observed in LB in stand-alone application (16.2%); however, only a 2.3% increase was observed with an LLIF cage present. However, these contrasting outcomes are not unanticipated, because the inherent stability of an LLIF cage provides considerably more stability at baseline, as

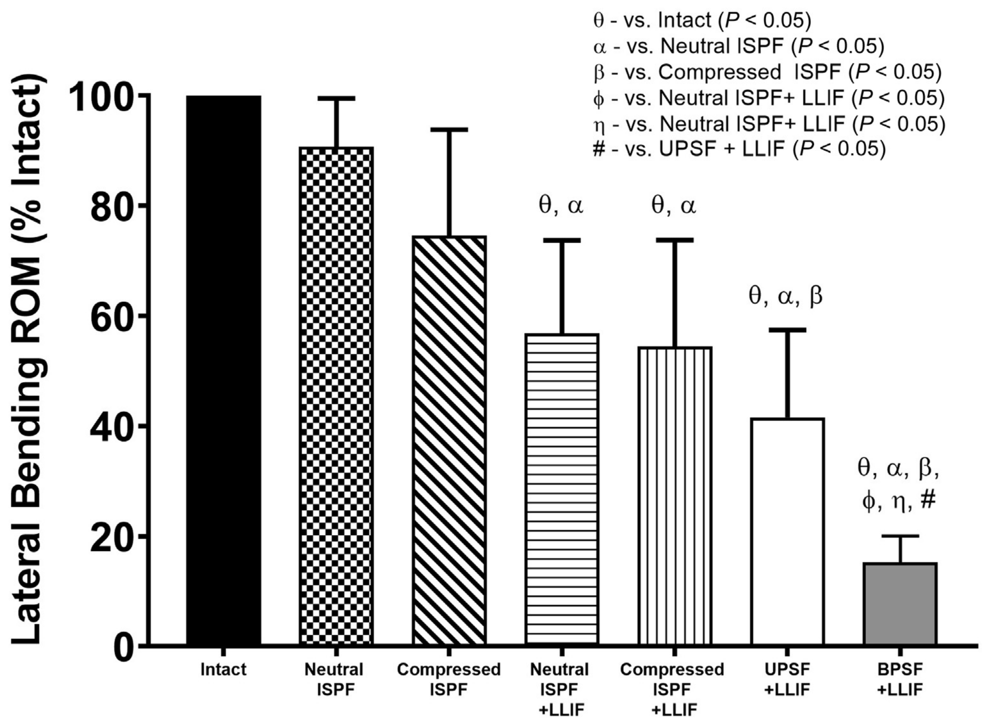

Figure 7. Mean range of motion (ROM), relative to intact conditions, when loaded in lateral bending under a pure moment of 7.5 Nm. Bars represent the mean and error bars are standard deviation. Symbols denote significant differences ($P < 0.05$) between groups according to a repeated measures analysis of variance with Bonferonni correction for multiple comparisons. BPSF, bilateral pedicle screw fixation; ISPF, interspinous process fixation; LLIF, lateral lumbar interbody fusion; UPSF, unilateral pedicle screw fixation.

shown by the 34.0% difference in initial ROM between neutral stand-alone and LLIF constructs.

Although the differences between neutral and shortened conditions were not of statistical significance in LB and AR, the trends support the concept that in situ spinous process compression may afford greater middle and posterior column stability, specifically at the facet joints. The usefulness of facet joint stabilization in resisting axial and coronal motion has been particularly well substantiated in the literature, with facet screw fixation/wedging in LLIF application supporting motion reduction up to 81.9% in AR and up to 88.1% in LB.[4,10,15,19] Future work in which facet joint stability/pressure is characterized as a function of spinous process compression may be warranted.

Relative changes in FE stability after ISPF device shortening (stand-alone, 4.5%; LLIF, 1.2%) were marginal and not to the same extent as in AR and LB. However, total FE ROM reduction in both constructs (stand-alone, 72.4%; LLIF, 88.0%) exceeded that seen in AR and LB, performing similarly compared with PSF (UPSF, 81.6%; BPSF, 89.2%). In situ ISPF device shortening produced mild increases in segmental lordosis in both stand-alone (+1.4°; 8.3°) and LLIF (+1.7°; 8.6°) application, however, less than that observed with PSF (UPSF, +2.0 °, 9.3°; BPSF, +2.4°, 9.6°). These findings are particularly notable because they suggest that the offset loading of the anterior column (via 3 mm of ISPF device shortening) does not drastically alter segmental lordosis, as may be expected given the potential moment arm of the spinous processes about the interbody space. Although this study cannot address the exact mechanics of this phenomenon, it does suggest that ISPF device shortening, when placed and performed adjacent to the laminar junction, exerts its affects more so at the facet joints than about the interbody space/cage. Greater stability/locking at the lumbar facet joints would inherently decrease AR, whereas motion in the sagittal plane would be affected less after compression. Outcomes in this study are suggestive of this theory, because relative ROM reduction in AR (13.7%—15.9%) was notably greater than that in FE (1.2%—4.5%). Hence, when using ISPF device compression/shortening, close consideration should be given to the integrity of the facet joints, with less anticipation of FE ROM reduction.

ISPF construct outcomes reported in this study were consistent with those reported in the literature for both stand-alone and adjunctive LLIF application. Karahalios et al.,[18] Kaibara et al.,[17] and Gonzalez-Blohm et al.[14] assessed segmental stability with ISPF as a stand-alone technique, reporting

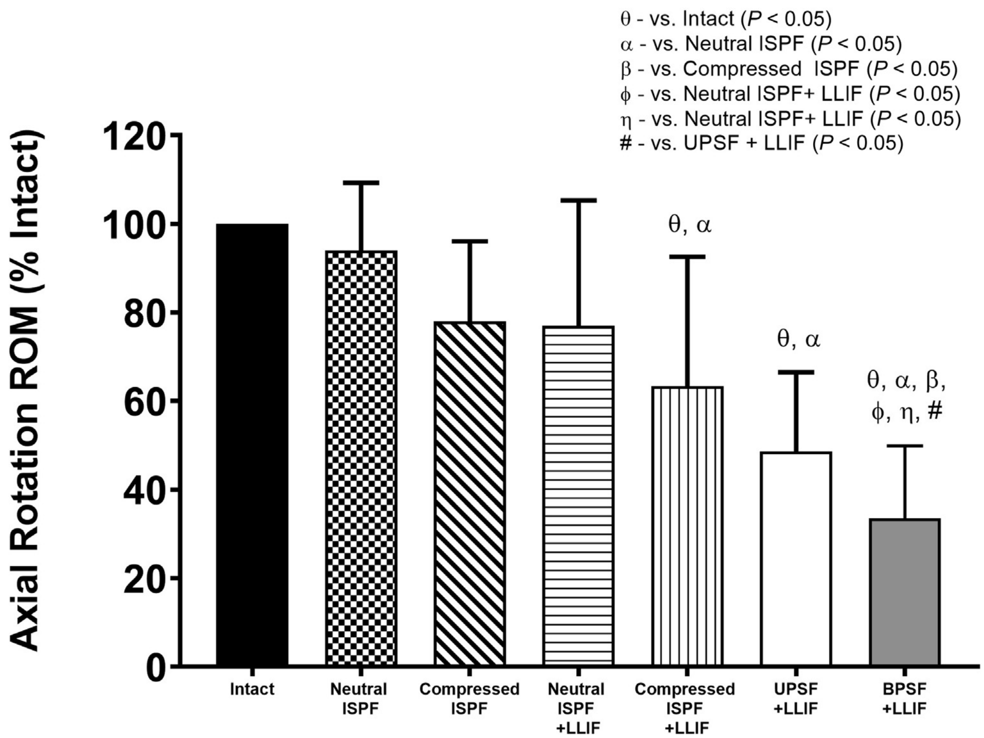

Figure 8. Mean range of motion (ROM), relative to intact conditions, when loaded in axial rotation under a pure moment of 7.5 Nm. Bars represent the mean and error bars are standard deviation. Symbols denote significant differences ($P < 0.05$) between groups according to a repeated measures analysis of variance with Bonferonni correction for multiple comparisons. BPSF, bilateral pedicle screw fixation; ISPF, interspinous process fixation; LLIF, lateral lumbar interbody fusion; UPSF, unilateral pedicle screw fixation.

motion reduction (relative to intact) ranges of 17.9%–33.3% in FE, 70.9%–123.0% in LB, and 61.9%–110% in AR, respectively. Furthermore, Fogel et al.,[13] Doulgeris et al.,[11] and Reis et al.,[30] assessing associated motion reduction (relative to intact) of ISPF as an adjunct to LLIF, reported outcomes of 10.4%–32.5% in FE, 40.0%–47.4% in LB, and 44.4%–85% in AR, respectively. Although these outcomes are difficult to differentiate because of cross-study variability, the general trends reiterate the benefit of ISPF in resisting FE ROM. The extent to which the study investigators sought segmental compression with ISPF was not indicated, and this may be a primarily contributor to the variation in outcomes observed in LB and AR. As shown by Gandhi et al.,[42] just 2 mm of axial compression on the spinous processes can increase interbody load by 50%, whereas compression of 4 mm and 6 mm can result in relative increases of >100% and >200%, respectively. Although the relationship between interbody load and segmental stability is not directly established, these findings suggest that axial compression beyond 3 mm (current study) may have increased biomechanical implications. Furthermore, the trends shown by Gandhi et al. speak to the importance that implantation height (ISPF PH) may have on subsequent stability and lordosis. If the PH is oversized or placed in distraction against the interspinous space, subsequent shortening results in less compressive loading of the facet joints and interbody space. These trends do not necessarily explain the lack of significant findings in the current study; however, they generate conversation as to what is a clinically appropriate amount of compression. In the current study, 3 mm of compression/shortening was not definitive in improving ROM reduction; however, it is unknown whether further shortening would improve stability without compromise to device/segmental stability. It is also unknown as to at what shortening distance the facet joints experience the greatest/optimal loading engagement, versus that of the interbody space. There may exist a pendulum in which more loading at the facets results in less loading at the interbody and vice versa. At best, the current study suggests that ISPF device shortening/compression does not provide significant ROM reduction when ≤3 mm; however, future efforts across multiple ISPF device PHs are warranted. In addition, the current study suggests that ROM reduction may not be universal in all motion directions, with the axial plane more prone to relative reduction at initial shortening lengths.

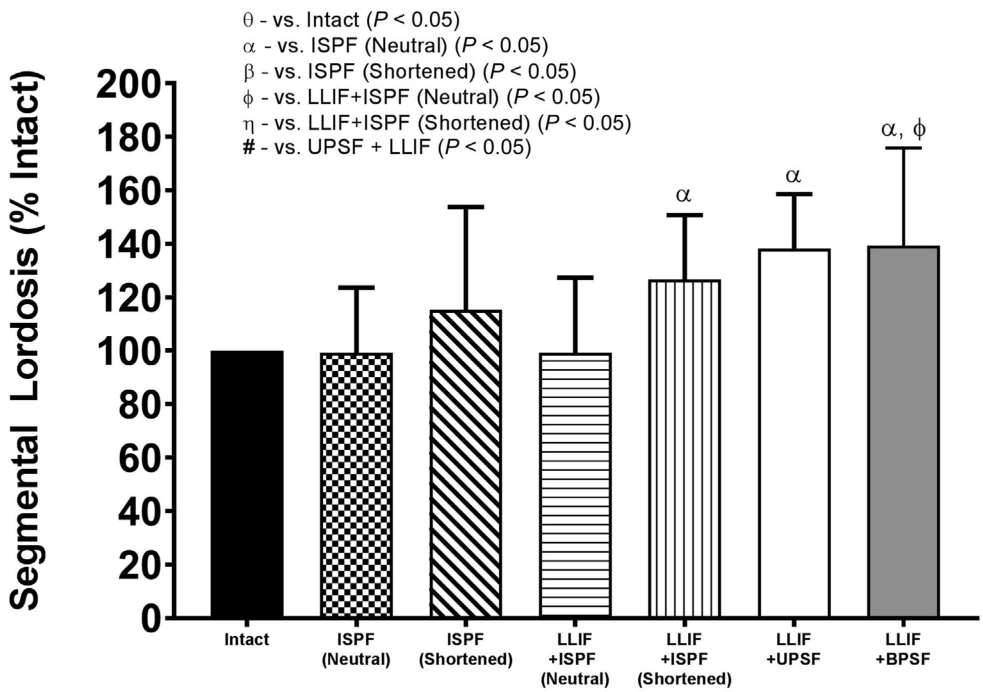

Figure 9. Segmental lordosis as measured via lateral fluoroscopic imaging and normalized to intact conditions. Bars represent the mean and error bars are standard deviation. Symbols denote significant differences ($P < 0.05$) between groups according to a repeated measures analysis of variance with Bonferonni correction for multiple comparisons. BPSF, bilateral pedicle screw fixation; ISPF, interspinous process fixation; LLIF, lateral lumbar interbody fusion; UPSF, unilateral pedicle screw fixation.

Clinical Extrapolations

Although the current study focuses on construct rigidity, the clinical usefulness of a posterior fixation device is not purely a function of rigidity. Segmental stabilization and subsequent fusion of the affected level(s) is necessitated by the desire to diminish pathologic motion and force loading; however, careful consideration must also be given to segmental alignment and neural decompressive attributes. It is important to consider these implications within the context of current ISPF technologies, as well as relevance within the collective minimally invasive posterior fixation paradigm.

Although expansion of the spinous processes is often possible given the ability to readily distract against the interspinous space, compression of the spinous processes is challenging. Drilling/tapping and pinning of the spinous process bone masses has traditionally been the only means to achieve the leverage needed to compress axially. This technique is burdensome intraoperatively and predisposes the spinous processes to fracture. Finite control of compression is also limited and may require multiple iterative efforts to achieve or preserve a desired degree of lordosis. The data presented herein show that more nuanced application of ISPF is attainable when using an adjustable device.

As spine surgery continues to shift toward less disruptive techniques, particularly in arthrodesis, the necessity/extent of posterior stabilization remains of considerable debate and diverse philosophy. Within this debate, much deliberation has been focused on patients with short segment spondylolisthesis (low-grade) and/or degenerative disc disease, in whom significant reduction and restoration can often be achieved through use of a stand-alone/integrated anterior lumbar interbody fusion (ALIF)/LLIF device alone.[1,35] However, when abnormal motion/instability and/or sagittal imbalance are present, adjunctive posterior stabilization remains advantageous. Given the proven inherent stabilizing capabilities of ALIF/LLIF in AR and LB, the sagittal stability and lordotic correction afforded by ISPF helps create a biomechanically synergistic construct.[4,6,8,10-15,18-20,23,25,27,30,35,39] Recent prospective randomized controlled work by Kim et al., comparing adjunctive ISPF with PSF in ALIF/LLIF, has substantiated the clinical value of such a construct, reporting significantly less intraoperative blood loss, operative time, incisions lengths, and fluoroscopy time posteriorly for patients undergoing ISPF and has also showed no significant differences in patient-reported or radiographic outcomes up to 2 years.[47] These clinical data, coupled with the increasing body of biomechanical evidence around ISPF, serve as indication that ISPF is a distinctly unique adjunct within the continuum of instrumented spinal arthrodesis.

Limitations

A primary limitation of this study was the extent to which the novel ISPF device was compressed. In each construct, the device was shortened approximately 3 mm. However, the device affords up to 12 mm of compression when affixed at its maximum PH of 18 mm. Work of Gandhi et al.[42] showed that compression/shortening up to 8 mm with the same novel ISPF device was capable of producing a pure linear increase in interbody load. It is possible that compression beyond 3 mm would have resulted in further reduction in ROM. However, the overarching purpose of this study was to show that a clinically conservative amount of compression would provide a clinically relevant increase in stability. Further work is warranted in which greater compression/shortening of the ISPF device is used.

Although this study does aim to bring comparison with other ISPF devices in the literature, a key limitation of any such comparison is device design. Variation in ISPF device profile, bulk, and spike pattern should all be considered unique contributors of performance and assessed accordingly when considering clinical use.

This study also possessed several inherent limitations consistent with those previously reported in the literature.[4,6,8,10-15,18-20,23,25,27,30,39] The iterative testing sequence was not randomized; however, this strategy was followed to ensure consistent bone composition/surface quality across each iteration and specimen. Furthermore, the cadaveric model did not replicate degenerative changes or instability at the index or adjacent levels. Although this strategy was followed to best ensure consistency across specimens, outcomes are inherent to the model alone and may not be representative of performance in an altered/pathologic biomechanical environment. Degenerative changes, although typically problematic in the context of pathologic motion/reduced motion, can also be challenging with respect to the placement of fixation devices. Facet arthropathy in particular can alter the posterior boney structures required for fixation and potentially require further resection for adequate bone purchase. These limitations of the study model and device performance should be considered accordingly when considering clinical adoption. Similarly, study conclusions are also limited in their scope of generalizability because of the use of a singular test level (L2/3). The instrumented level (L2/3) was specifically chosen because it afforded intact adjacent levels cranially (L1/2) and caudally (L3/4) in all procured specimens, as recommended by Wilke et al.[46] However, as established in the literature, segmental lumbar motion and force distribution are unique at each discrete level, and therefore the performance of any fixation device must be considered in the context of the level for which it was tested.[48] This dynamic is further complicated by the absence of supporting musculature, absent weight loading by the torso, and a lack of simultaneous multiplanar force/motion application. Accordingly, we emphasize that the outcomes of the current study should be considered only in the context of the study model used and that clinical extrapolations should be made only with supporting clinical evidence and experience relative to the patient of interest. Future efforts evaluating performance across all lumbar segments are warranted. In addition, the quality of bone specimen is an inherent limitation of outcome extrapolation in any cadaveric biomechanical study. Although the specimen bone stock in this study was good (mean T score: 0.835 g/cm^2), bone quality in the clinical setting may not be so accommodating because many patients present with disadvantageous osteogenic changes. Constructs may behave differently in lesser quality bone. Future work may be warranted in which pathologic variables are incorporated in the model.

CONCLUSIONS

In situ shortening of an adjustable ISPF device, with or without a lateral interbody cage placed, may support mechanical outcomes not typically achievable with static ISPF devices. However, although stability in AR and LB seemed to improve under ISPF compression, outcomes with traditional bilateral PSF were still notably pronounced. Future studies are warranted in which greater ISPF device shortening/axial compression is performed to determine whether a threshold exists for which statistically significant reduction is achieved.

CRediT AUTHORSHIP CONTRIBUTION STATEMENT

Christopher Wagener: Conceptualization, Methodology, Investigation, Writing - review & editing, Supervision, Visualization. **Anup Gandhi:** Conceptualization, Methodology, Software, Investigation, Validation, Formal analysis, Resources, Data curation, Writing - review & editing, Supervision, Funding acquisition. **Chris Ferry:** Methodology, Investigation, Formal analysis, Data curation, Writing - original draft, Writing - review & editing. **Sam Farmer:** Methodology, Software, Investigation, Validation, Formal analysis, Resources, Data curation, Writing - review & editing. **Ryan DenHaese:** Conceptualization, Methodology, Investigation, Writing - review & editing, Supervision, Visualization.

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