

Stability and Decompression Mechanics of Several MIS Lumbar Fixation Technologies: A Biomechanical Study

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Study Design: Several minimally invasive lumbar fixation systems were compared in situ using a multidirectional bending flexibility test and a custom axial compression test.

Objective: The goal of our study was to investigate the biomechanical properties of a minimally invasive surgery (MIS) lateral interspinous fixation device (IFD). We aimed to compare the stability, ability to distract the foramen, and effects on adjacent level facet loading to other MIS fixation systems. We hypothesized the direct lateral interbody fusion (DLIF) cage with lateral IFD would provide stability comparable to DLIF with supplemental pedicle or facet screws (DLIF+PS or DLIF+FS), would effectively distract the foraminal space, and would load the adjacent facets comparable to pedicle screws.

Summary of Background Data: There is a lack of biomechanical evidence on the effectiveness of the subject interspinous technology in conjunction with lateral interbody cages in comparison to other minimally invasive fixation technology.

Methods: Six human cadaver specimens were prepared and tested in the following states: 1) Intact; 2) IFD standalone; 3) DLIF with IFD (DLIF+IFD); 4) DLIF with bilateral pedicle screws (DLIF+biPS); 5) DLIF with unilateral pedicle screws (DLIF+uniPS); and 6) DLIF with facet screws (DLIF+FS). Motion capture markers were attached to L2, L3, L4, and L5 vertebral levels. Multidirectional bending flexibility tests were performed for flexion/extension, lateral bending, and axial rotation motion. Pressure measurement films were then placed in the articular spaces of L2/L3, and foramen position markers were placed about the L2/L3 foraminal space. Custom axial compression plus flexion and extension tests were conducted and data was collected under the neutral compressive load and under maximum bending moments.

Results: The intact group showed statistically significant differences in relative motion when compared to all other test groups ($p < 0.05$). The DLIF+IFD and DLIF+uniPS test groups showed statistically similar effects on relative motion ($p > 0.05$). There were no statistically significant differences in foraminal height between test groups.

Conclusions: Our results indicate that when used with DLIF, the minimally invasive lateral IFD provides rigid stability to the spine comparable to pedicle screws and greater than facet screws. Furthermore, the interspinous fixation device is effective in the distraction of the neuroforamen and maintains that distraction during motion. When used with DLIF, the IFD may offer an alternative to pedicle and facet screw systems.

KEYWORDS: Biomechanics, lumbar fusion, lumbar decompression, percutaneous, minimally invasive spine surgery, interspinous fixation device, facet screw, pedicle screw, lateral interbody.

Minimally invasive surgery for the lumbar spine has been shown to result in favorable outcomes such as quicker recovery times and earlier return to work for a number of procedures compared to their open approach counterparts (Hofstetter 2015 World J Orthop). Many biomechanical experts theorize effective fusion of the spine occurs when the anterior and posterior columns of load transmission are stabilized (Panjabi 2001 Spine J).

Until recently, stabilization of these columns was only achieved through multiple open approaches including posterior pedicle screws and anterior lumbar interbody cages. The transforaminal interbody cage can be delivered from a posterior approach; however, the introduction of the direct lateral approach interbody cage allowed for a large footprint in addition to a minimally invasive approach (Malham 2015 Eur Spine J). Since its introduction, the direct lateral approach interbody cage has been shown to exhibit superior biomechanics and clinical outcomes. Supplementing these lateral interbody cages can be achieved with many different options including traditional pedicle screws, transfacet fusions screws, or interspinous fixation devices. Pedicle screw technologies exist which deliver the implants minimally invasively; however, surgery time, ease of implantation, and the need to reposition the patient when used in conjunction with direct lateral interbody cages continue

to be an area of development. Transfacet screws (FS) may be delivered minimally invasively as well; however, decompression and patient repositioning when used with direct lateral interbody cages are challenges that need to be overcome. Previous interspinous technologies can only be delivered in open posterior approaches which increase surgical times and decrease clinical outcomes. A minimally invasive interspinous fixation device has been developed (Minuteman G3, Spinal Simplicity) which promises a direct lateral approach using blunt dilation, quick implantation time and rigid fixation.

There is a lack of biomechanical evidence on the effectiveness of this interspinous technology in conjunction with lateral interbody cages and in comparison to other minimally invasive fixation technologies (Fogel 2014 JNS and Wang 2006 Eur Spine J). If this technology can be delivered under these clinical parameters and exhibit comparable stabilization as well as the ability to decompress the neuroforaminal space, supplementation of the direct lateral cage with this technology would provide surgeons with a competitive option for treatment.

The goal of our study was to investigate the biomechanical properties of a newly developed MIS lateral IFD. Our first aim was to compare the stability of this technology to other MIS systems. Our second aim was to compare the ability to distract the foramen. We hypothesized the DLIF with MIS lateral IFD would provide stability comparable to DLIF with PS and DLIF with FS, it would effectively distract the foraminal space, and would load the adjacent facets comparable to PS.

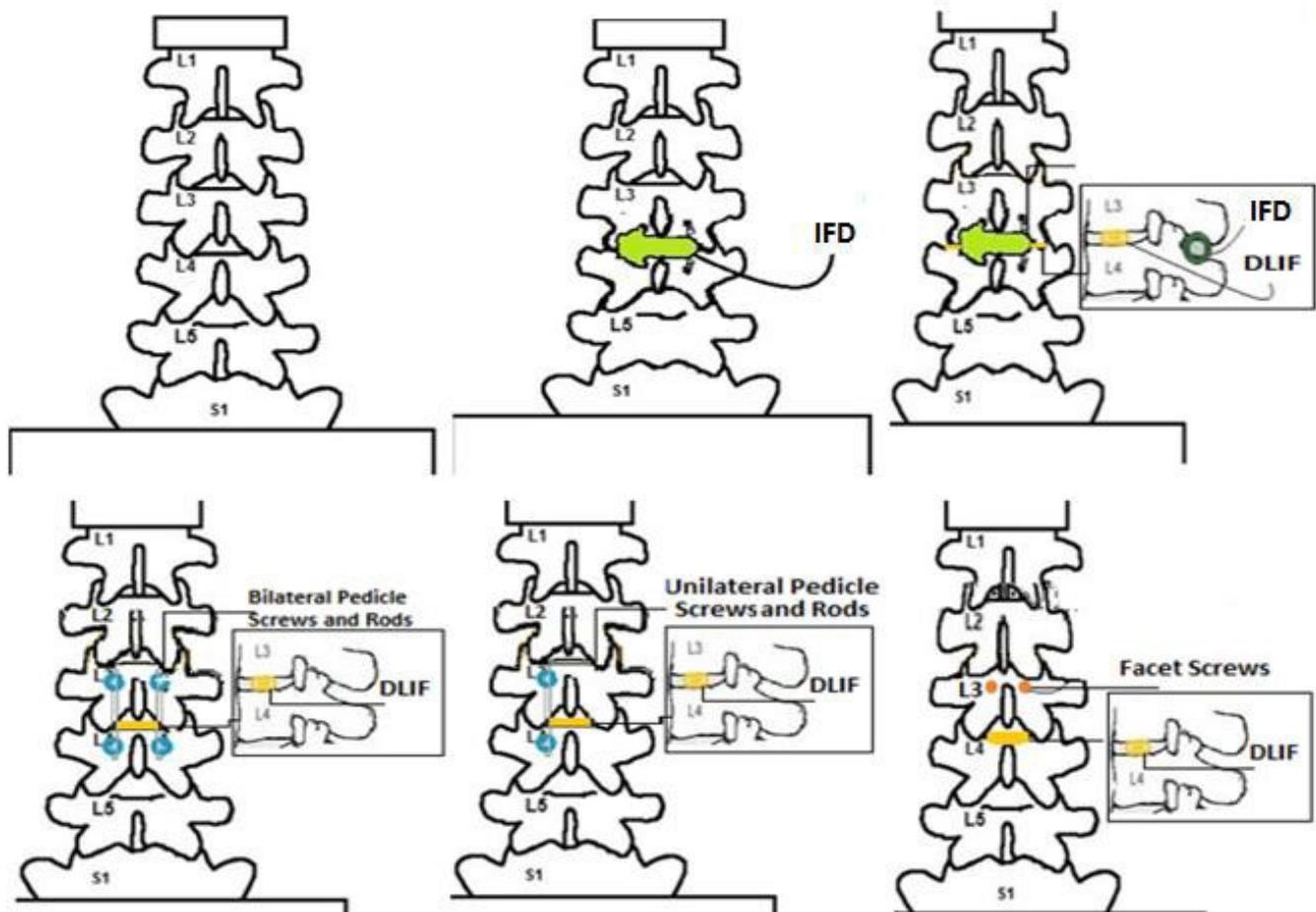


Figure 1. Diagrams of each test group including (from top to bottom, left to right) intact (INTACT), interspinous fixation device (IFD), IFD with direct lateral interbody cage (DLIF+IFD), DLIF with bilateral pedicle screws (DLIF+biPS), DLIF with unilateral pedicle screws (DLIF+uniPS), and DLIF with facet screws (DLIF+FS).

METHODS

Specimen Selection and Preparation

Six cadaver lumbar spines (L1-Sacrum) were acquired for testing from a local tissue bank. The ages were between 40 and 80 years old and both male and female donors were included. Donors with a history of spine surgery or abdominal surgery were excluded. Specimens were imaged for assessment of any signs of deformity or prior spine surgery before inclusion into the study. The cadaver spinal columns were cleaned of musculature and soft tissue with care taken not to disrupt any ligaments connecting the vertebrae. Each specimen was potted at L1 and S1 with epoxy resin.

Test Groups

Six test groups were prepared for mechanical testing according to various configurations of fixation implants in a repeat-measures study design with all cadaver specimens receiving all treatment groups. Diagrams of each construct are displayed in Figure 1. The first group was intact and did not receive any preparation beyond the removal of musculature and soft tissues (INTACT). The second group received an interspinous fixation

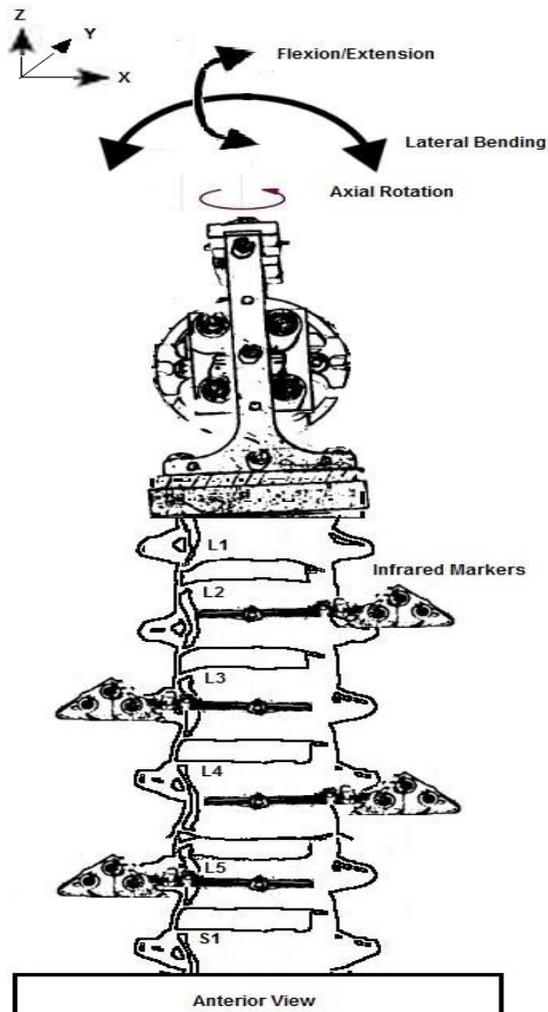


Figure 2. Diagram of the multi-directional bending flexibility. The arrows in diagram show where the pure moment is applied to induce flexion, extension, left/right axial rotation, and left/right lateral bending as well as infrared markers used for calculation of relative motion.

device (Minuteman G3, Spinal Simplicity) at L3/L4 (IFD). This group received a lateral approach rasping of the interspinous ligament, decortication of the cranial and caudal spinous processes followed by implantation of the device. Distraction of the neuroforamen was achieved by sizing the implant equal to the interspinous distance measured on fluoroscopy. The third group received a direct lateral interbody cage in the L3/L4 disc space in addition to the interspinous fixation device (DLIF+IFD). This group received a unilateral annulotomy and discectomy followed by a contra-lateral release of the annulus to allow for distraction of the disc space. Distraction of the neuroforamen was achieved by sizing the implant equal to the interbody distance measured on fluoroscopy. The fourth group received a direct lateral interbody cage in the L3/L4 disc space in addition to bilateral trans-pedicular fixation screws at L3 and L4 followed by connecting fusion rods (DLIF+biPS). This group received pilot holes with a standard point awl followed by pedicle screw insertion. No tap was utilized for pilot hole preparation. Distraction of the neuroforamen was achieved by locking the caudal pedicle screw blockers to the rods, followed by a 2mm distraction of the cranial screws using a standard distractor instrument. The fifth group received a direct lateral interbody cage in the L3/L4 disc space in addition to unilateral trans-pedicular fixation screws at L3 and L4 followed by a connecting fusion rod (DLIF+uniPS). A similar 2mm distraction was applied to the single fusion rod and screw construct. The sixth group received a direct lateral interbody cage in the L3/L4 disc space in addition to trans-facet fusion screws between L3 and L4 (DLIF+FS). This group received a pilot hole using a powered drill bit in a caudal-lateral direction from the inferior facet of L3 to the superior facet of L4.

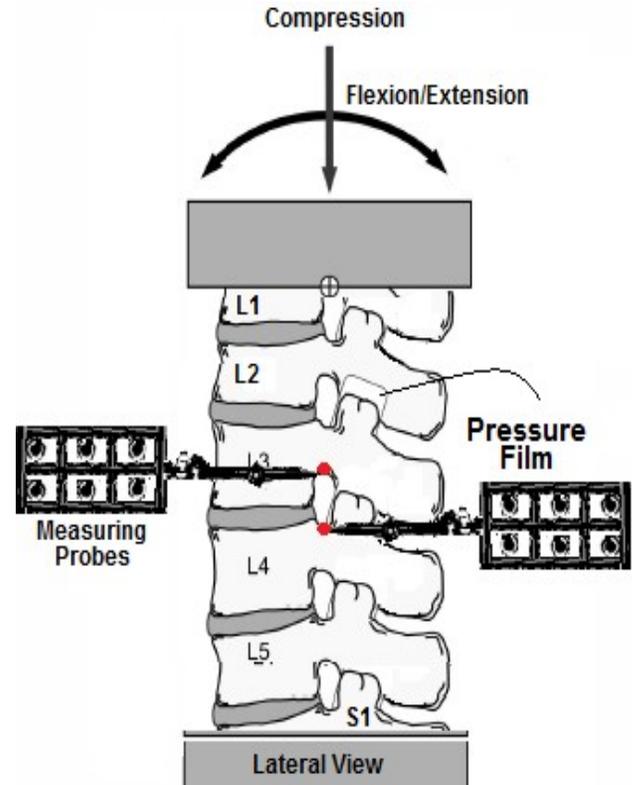


Figure 3. Diagram of combined axial compression plus flexion and extension. The arrows in the diagram show where the axial compression is applied in combination with the pure moment as well as foraminal height markers and facet pressure films.

Mechanical Testing

A 3-D motion tracking system, Optotrak 3020, utilized motion capture markers that were attached to L2, L3, L4, and L5 vertebral levels as seen in Figure 3. Relative motions between L2/L3, L3/L4, and L4/L5 functional spinal units were measured during testing. Six motions were described from the data collected during the experiments: flexion, extension, left lateral bend, right lateral bend, left axial rotation, and right axial rotation. The instantaneous axis of rotation at the final steps of loading was calculated for all three functional spinal units. Specimens were loaded up to 7.5 Nm in 1.5 Nm increments.

Custom axial compression plus flexion and extension tests were conducted in accordance with previous studies (Lindsey 2003 SPINE, Swanson 2003, Lazaro 2010, and Wilson 2006 J Biomech). Pressure measurement films were placed in the articular spaces of L2/L3 as seen in Figure 3. Peak force was collected under neutral and maximum loading. Foraminal height was measured at L3/L4 using the rigid body methods described by Lazaro 2010 JNS. Foraminal height was collected under neutral and maximum loading. Specimens were loaded with a combination of 700 N axial compression and 7.5 Nm of extension and flexion.

Outcome measures from bending flexibility testing were the relative motions at the index and adjacent levels and axis of rotation at the index level. Likewise, outcome measures from compression flexion/extension testing were peak pressure, peak force, total force, contact area, and center of pressure at the index and adjacent levels under neutral and max loading. Also measured were foraminal height at the index and adjacent levels under neutral and max loading. Comparison of outcome measures between the test groups was performed using standard one-way ANOVA methods and alpha equal to 0.05.

RESULTS

Multi-directional Bending: Flexibility & Instantaneous Axis of Rotation

Flexion/Extension relative motion between L3/L4 was decreased in all test groups as compared to the intact test group as seen in Figure 5 and Table 1. IFD standalone stabilized comparable to that of Intact; however, supplementing IFD with DLIF further stabilized the spine. DLIF+IFD stability was comparable to that of DLIF+uniPS and DLIF+FS. DLIF+biPS was the most stabilizing treatment group.

During Axial Rotation, we observed a decrease in all treatments groups compared to that of Intact. Supplementing DLIF with IFD had an insignificant effect on stability. We observed similar trends to that of Flexion/Extension, where DLIF+biPS was the most stabilizing treatment group and DLIF+IFD was comparable to that of DLIF+uniPS and DLIF+FS.

During Lateral Bending, we observed a decrease in all treatment groups compared to that of Intact. Supplementing DLIF with IFD further stabilized the spine compared to IFD standalone. Also, we observed similar trends to that of Flexion/Extension and Axial Rotation, where DLIF+IFD was comparable to DLIF+uniPS and DLIF+FS, but no groups were as stabilizing as the DLIF+biPS.

Two groups experienced an anterior shift in the instantaneous axis of rotation compared to Intact: DLIF+IFD and DLIF+uniPS. These shifts were not statistically significantly different ($p > 0.05$). Two groups experienced a cranial shift in the instantaneous axis of rotation compared to Intact: IFD and DLIF+FS. DLIF+IFD exhibited comparable shifts in the cranial-caudal direction to that of both pedicle screw group as seen in Table 1 and Figure 4.

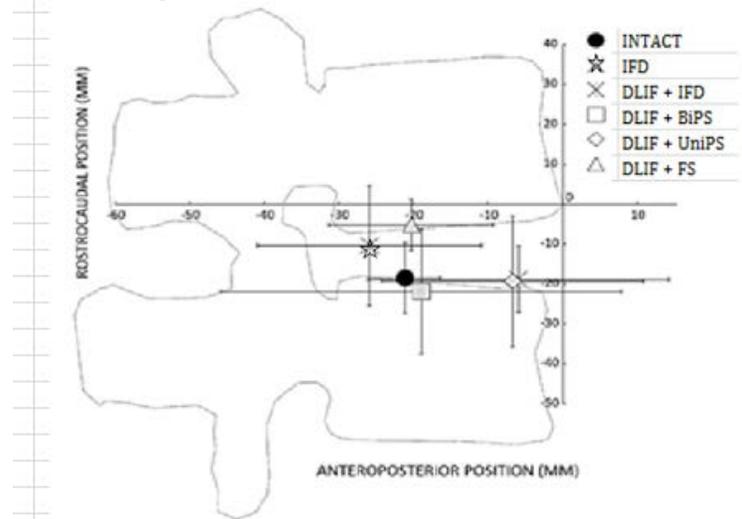


Figure 4. Average center of motion for each treatment group during Flexion-Extension testing.

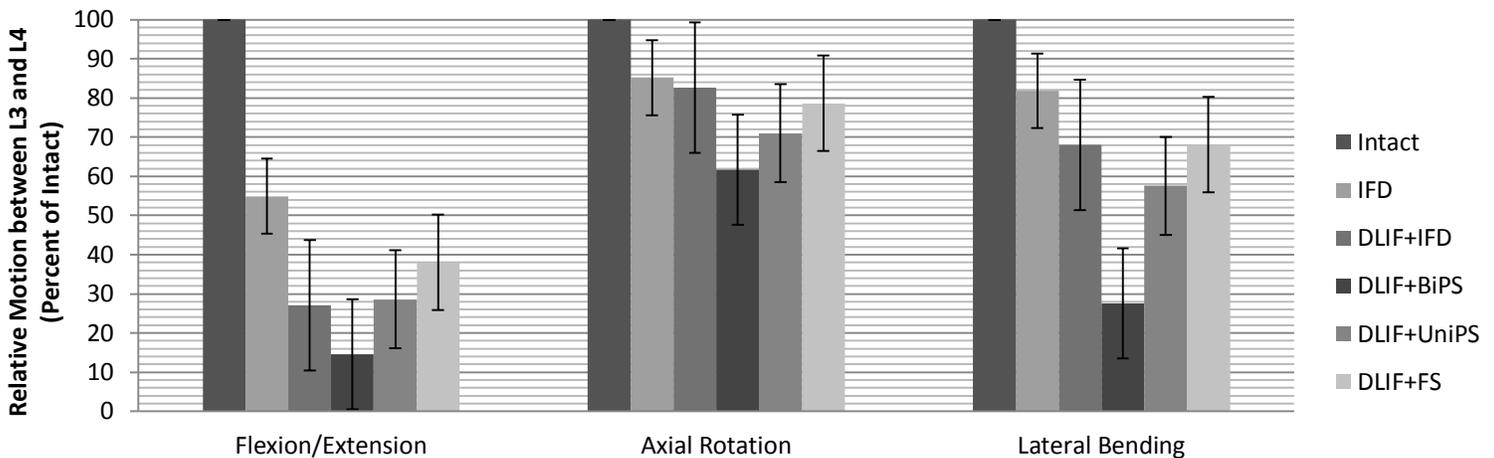


Figure 5. Total relative motion between L3 and L4. All data are represented as mean ± standard deviation.

Table 1. Data summary results off range of motion during multidirectional flexibility bending tests and instantaneous axis of rotation measurements. All data are represented as mean ± standard deviation.

Group	Range of Motion			Instantaneous Axis of rotation	
	Flexion/Extension Mean ± StDev (deg)	Axial Bending Mean ± StDev (deg)	Lateral Bending Mean ± StDev (deg)	Anteroposterior Mean ± StDev (mm)	Cranial/Caudal Mean ± StDev (mm)
INTACT	7.0 ± 0.9	4.4 ± 1.8	5.7 ± 1.7	-21.1 ± 4.8	-18.5 ± 8.9
IFD	3.9 ± 1.4	3.7 ± 0.8	4.7 ± 1.9	-25.9 ± 15.0	-10.3 ± 16.0
DLIF + IFD	1.9 ± 1.3	3.6 ± 1.7	3.9 ± 2.4	-5.9 ± 20.2	-18.7 ± 8.3
DLIF + BiPS	1.0 ± 0.4	2.7 ± 0.7	1.6 ± 0.6	-19.0 ± 26.9	-21.9 ± 15.6
DLIF + UniPS	2.0 ± 1.0	3.1 ± 0.9	3.3 ± 1.1	-6.7 ± 17.5	-19.2 ± 16.4
DLIF + FS	2.7 ± 2.2	3.5 ± 1.3	3.9 ± 2.7	-20.3 ± 11.0	-5.2 ± 6.4

Custom Axial Compression with Flexion/Extension: Foraminal Height

Deployment of the IFD and DLIF+IFD increased foraminal height under no load by 10% and 4%, respectively. Under flexion/extension moments, intact specimens demonstrated decreases in foraminal height of the greatest magnitude. During extension, foraminal height decreased by 8% in the intact group, but was maintained by the IFD and DLIF+IFD groups. Specimens in the DLIF+uniPS group demonstrated a decrease in foraminal height under flexion/extension moments. All other test groups maintained foraminal height under flexion/extension moments as seen in Table 2.

Table 2. Percent (%) of foraminal height in neutral compression in Extension and Flexion.

Group	Extension	Flexion
INTACT	94 ± 14	97 ± 13
IFD	101 ± 8	100 ± 8
DLIF + IFD	101 ± 5	102 ± 8
DLIF + BiPS	102 ± 4	105 ± 8
DLIF + UniPS	99 ± 2	98 ± 8
DLIF + FS	100 ± 4	102 ± 7

Facet pressures were measured in one specimen as seen in Table 3. Peak force was highest in the DLIF+FS group.

Table 3. Peak force measured in the facet joint in one representative specimen.

Group	No Load	Compression	Compression + Flexion	Compression + Extension
INTACT	0.7	2	2.2	4.6
IFD	0.9	1.4	0.3	2.4
DLIF + IFD	0.2	1	0.2	5.3
DLIF + BiPS	1.7	3	1.4	8.6
DLIF + UniPS	5.4	7.9	10.4	6.3
DLIF + FS	7.4	15	15.4	14

DISCUSSION

Our results indicate the minimally invasive lateral interspinous fixation device in conjunction with a lateral interbody cage provides stability to the spine comparable to that of competitive technologies such as pedicle screws and facet screws. Furthermore, the interspinous fixation device is effective in the distraction of the neuroforamen and maintains that distraction during motion.

Biomechanical investigations into lumbar fixation technologies are varied and plentiful; however, the work by Wang et al and Fogel et al present methods which are most directly comparable to the current study (Wang 2006 JNS and Fogel 2014 JNS). Wang compared 11 lumbar spine fixation techniques in a similar pure moment multidirectional bending flexibility including: interspinous fixation device as standalone, interspinous fixation device with anterior interbody cage, anterior cage with facet screws, and anterior cage with unilateral and bilateral pedicle screws. In large part our results are corroborated by Wang et al who reported superior stability with the interspinous/interbody combination compared to both facet and pedicle fixation. Fogel et al is a more recent investigation comparing 7 lumbar spine fixation techniques in similar pure moment flexibility including: interspinous with lateral interbody cage, bilateral screws with lateral interbody cage, and unilateral pedicle screws with lateral interbody cage. Their group’s results again corroborate many of our results with interspinous/interbody cage combination comparable to unilateral screws plus interbody cage. Neither of these studies investigated the ability of the interspinous fixation device to distract the neuroforamen. Lazaro et al conducted an investigation into distraction of the neuroforamen with an interspinous technology. This group compared 2 groups, intact and interspinous standalone in a flexion/extension neuroforamen height test. This group’s results corroborate our findings of the interspinous fixation device’s ability to maintain distraction during motion; however, the amount of distraction we observed with the deployment of the interspinous fixation device was much more pronounced. Strengths of our study include the results from many repeated test specimens in a controlled laboratory environment with all specimens undergoing standardized and controlled surgical treatments, receiving similar standardized mechanical loading and highly accurate and repeatable measurement sensors. We performed our investigation in a cadaver model which allowed for us to control for many factors which may have influenced the ability to measure motion or distraction accurately in a human subject model. Finally, a primary strength of our study is the direct comparison of the latest lumbar fixation technologies including minimally invasive lateral interbody cages, interspinous fixation devices, minimally invasive pedicle screws, and minimally invasive facet screw technologies. These implants represent the state of the art in spine treatment and have yet to be compared in a highly controlled biomechanical model. Our study was not without limitations. As with many cadaver-based biomechanical experiments, sample size was limited due to economic factors; however, we were able to perform statistical comparisons between some groups which proves beneficial in understanding the nuances between these technologies.

The clinical implications of this work provide surgeons with a

competitive option for the treatment of lumbar spine pathology.

CONCLUSION

The results indicate the Minuteman G3 fixation device, when used in conjunction with a lateral interbody cage, provides biomechanical stability and decompression comparable to pedicle screws and superior to facet screws. Three modes of testing were performed: bending flexibility, foraminal distraction during motion, and adjacent facet pressures during motion. Several different fixation construct designs were evaluated including the Minuteman G3 with and without an interbody fusion cage, an interbody fusion cage with facet screws, and an interbody fusion cage with pedicle screws.

The flexibility results indicate the Minuteman G3 with interbody cage stabilizes the spine comparable to alternative options such as pedicle screws and facet screws (both with interbody supplementation). Our results indicate the Minuteman G3 as a standalone stabilizes the spine in all directions compared to intact.

The foraminal distraction results indicate the Minuteman G3 achieves distraction of the foraminal space comparable to pedicle screws and maintains this distraction far better than unilateral pedicle screws.

DISCLOSURE

Sponsored by Spinal Simplicity, LLC.

KEY POINTS:

Minimally invasive, lateral interspinous technology has been developed to work in combination with direct lateral interbody cages.

This technology stabilizes and decompresses the lumbar spine comparable to other competitive supplemental implants. Clinical implications related to surgery time, recovery time, and patient satisfaction.

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