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Biomechanical Characteristics of an Integrated Lumbar Interbody Fusion Device

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Abstract

Introduction

We hypothesized that an Integrated Lumbar Interbody Fusion Device (PILLAR SA, Orthofix, Lewisville, TX) will function biomechanically similar to a traditional anterior interbody spacer (PILLAR AL, Orthofix, Lewisville, TX) plus posterior instrumentation (FIREBIRD, Orthofix, Lewisville, TX). Purpose of this study was to determine if an Integrated Interbody Fusion Device (PILLAR SA) can stabilize single motion segments as well as an anterior interbody spacer (PILLAR AL) + pedicle screw construct (FIREBIRD).

Methods

Eight cadaveric lumbar spines (age: 43.9±4.3 years) were used. Each specimen's range of motion was tested in flexion-extension (FE), lateral bending (LB), and axial rotation (AR) under intact condition, after L4-L5 PILLAR SA with intervertebral screws and after L4-L5 360° fusion (PILLAR AL+Pedicle Screws and rods (FIREBIRD). Each specimen was tested in flexion (8Nm) and extension (6Nm) without preload (0 N) and under 400N of preload, in lateral bending (±6 Nm) and axial rotation (±5 Nm) without preload.

Results

Integrated fusion using the PILLAR SA device demonstrated statistically significant reductions in range of motion of the L4-L5 motion segment as compared to the intact condition for each test direction. PILLAR SA reduced ROM from 8.9±1.9 to 2.9±1.1° in FE with 400N follower preload (67.4%), 8.0±1.7 to 2.5±1.1° in LB, and 2.2±1.2 to 0.7±0.3° in AR. A comparison between the PILLAR SA integrated fusion device versus 360° fusion construct with spacer and bilateral pedicle screws was statistically significant in FE and LB. The 360° fusion yielded motion of 1.0±0.5° in FE, 1.0±0.8° in LB (p0.05).

Conclusions

The PILLAR SA resulted in motions of less than 3° in all modes of motion and was not as motion restricting as the traditional 360° using bilateral pedicle screws. The residual segmental motions compare very favorably with published biomechanical studies of other interbody integrated fusion devices.

Introduction

Lumbar interbody fusion is an often performed and well described procedure. The most commonly utilized fusion construct involves anterior and posterior fixation (360° fusion) utilizing an interbody graft/spacer with posterior pedicle screws and rods which substantially increases the stability of ALIF construct[1, 2, 3, 4, 5, 6, 7, 8] and is associated with a significantly improved fusion rate[9,10]. An aggressive surgery by means of 360° fusion, although linked with higher fusion rates, is not always associated with a favorable clinical outcome[9]. Several clinical problems have been attributed to intraoperative damage of the posterior muscle groups. Numerous studies have shown that lumbar surgery through a posterior approach results in erector spinae muscle changes, demonstrated through clinical studies measuring extensor strength[11, 12], histologic studies[11, 13, 14, 15, 16, 17] and postoperative imaging studies by computed tomography (CT)[11] or magnetic resonance imaging (MRI).[18, 19] In addition erector spinae are detached from the paravertebral gutters then held laterally by self-retaining retractors during posterior lumbar surgery. Studies by Kawaguchi et al. suggest that pressure caused by self-retaining retractors leads to lesions of the erector spinae[13]. Results from biomechanical and clinical studies indicate that an anterior only approach utilizing an interbody spacer and anterior plate seem to provide stability comparable to that of a 360° (interbody + pedicle screw fixation) and less postoperative morbidity.[20] However, the anterior only standard of care is the use of an interbody device with an anterior plate which protrudes anteriorly from the vertebral bodies creating a raised profile which interferes with the great vessels which are also anterior and adjacent to the lumbar vertebral bodies. The profile of current plates for anterior fusion is lower than that of earlier designs, but they are still bulky and might lead to postoperative complications. The insertion of these plates is a time-consuming surgical procedure which requires wider surgical exposure, more tissue dissection, anterior muscle disruption, and higher post-op morbidity. During this procedure some anatomical structures on the anterior aspect of the lumbar spine, such as the great vessels, are endangered. Other disadvantages include screw migration with possible soft tissue damage, increased of risk of adjacent level ossification and difficulty in stacking plates for adjacent level surgery. As a further improvement of this anterior only concept, combination or integrated interbody spacers for zero- or low profile segmental stabilization have been developed to perform the role of the separate spacer and plate. The proposed benefit of these integrated devices is that they provide sufficient stabilization to promote biologic fusion while avoiding posterior soft tissue morbidity during the primary procedure. In addition, the concern for adjacent level ossification is less, and in cases of adjacent level disease, the integrated interbody device can be placed without interfering

with the previously operated segment nor requiring removal of the previously placed anterior plate. An additional benefit of these integrated devices is that they fit completely inside the disc space therefore limiting the exposure of the anterior spine column and potentially reduce complications such as vascular injury[21,22,23,24]. The objective of this study was to determine if an Integrated Interbody Fusion Device (PILLAR SA, Orthofix, Lewisville, TX) Figure 1A can stabilize single motion segments as effectively as an anterior interbody spacer (PILLAR AL, Orthofix, Lewisville, TX) Figure 1B + posterior instrumentation (pedicle screw construct) i.e. a 360° fusion construct. The following hypotheses were tested: (1) An Integrated Lumbar Interbody Fusion Device (PILLAR SA) will significantly reduce motion at the implanted level, relative to intact; (2) The PILLAR SA device will function biomechanically similar to a traditional anterior interbody spacer (PILLAR AL) plus posterior instrumentation (360° fusion construct).

Fig. 1A. Integrated interbody fusion device PILLAR SA, Orthofix, Lewisville, TX.

Fig. 1B. Anterior interbody spacer PILLAR AL, Orthofix, Lewisville, TX.

Materials and Methods

Specimens and Experimental Setup

Eight fresh frozen human cadaveric spine specimens (L1-S1) were used for this study (age: 43.9±4.3 years). Radiographic screening was performed to exclude specimens with fractures, metastatic disease, bridging osteophytes, osteoporosis, previous spine surgeries or other conditions that could significantly affect the biomechanics of the spine. Bone mineral density (BMD) of each specimen was determined using a peripheral Quantitative Computed Tomography (pQCT) (Norland Medical Systems, Inc). A rectangular area 10 by 10 mm in the middle of the T12 vertebral body was investigated with an exposure dose

of 200mA and 120 KVp. Based on the criteria proposed by WHO, specimens with normal BMD (BMD > 150 mg/cm^3) were used for the study.[25] Specimen demographics and pQCT values are presented in Table 1. The specimens were thawed and stripped of the paraspinal musculature while preserving the discs, facet joints, and osteoligamentous structures. The specimens were wrapped in saline soaked towels to prevent dehydration of the soft tissues. All tests were performed at room temperature. The specimens were fixed to the apparatus at the caudal end and free to move in any plane at the cephalad end Figure 2. A moment was applied by controlling the flow of water into bags attached to loading arms fixed to the L1 vertebra. The apparatus allows continuous cycling of the specimen between specified maximum moment endpoints in flexion, extension, lateral bending, and axial rotation. The load-displacement data was collected until two consecutive reproducible load-displacement loops were obtained. The angular motion of the L1 to S1 vertebrae were measured using an optoelectronic motion measurement system (Model 3020, Optotrak, Northern Digital, Waterloo, Ontario). In addition, bi-axial angle sensors (Model 902-45, Applied Geomechanics, Santa Cruz, CA) were mounted on each vertebra to allow real-time feedback for the optimization of the preload path. A six-component load cell (Model MC3A-6-1000, AMTI Multi-component transducers, AMTI Inc., Newton, MA) was placed under the specimen to measure the applied compressive preload and moments. Fluoroscopic imaging (GE OEC 9800 Plus digital fluoroscopy machine) was used in the neutral, flexed and extended postures during the kinematic testing and during surgical implantations to ensure correct implant placement.

Table 1. Specimen Demographics

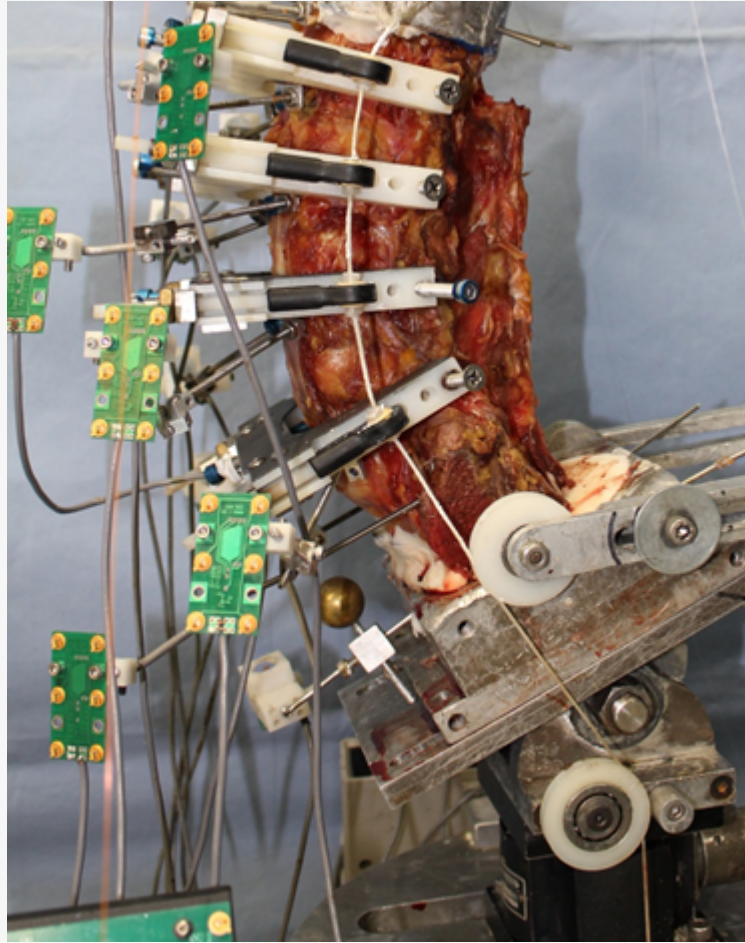| Specimen	Age (years)	Sex	pQCT (mg/cm^3)	
1	40	M	215	
2	38	M	210	
3	42	M	150	
4	45	F	211	
5	41	F	190	
6	50	M	205	
7	48	M	182	
8	47	F	189	
Mean	**43.9**	**5M/3F**	**194**	
SD	4.3		21.5	

Fig. 2. Experimental Setup.

Experimental Protocol

Each specimen's range of motion was tested in flexion-extension, lateral bending, and axial rotation Figure 3 under the following sequential conditions:

1. Intact spine;
2. Nucleotomy at L4-L5 (to simulate mechanical instability of disc degeneration);
3. PILLAR SA at L4-L5 (with intervertebral screws);
4. PILLAR SA + Pedicle Screws and rods at L4-L5 (FIREBIRD);
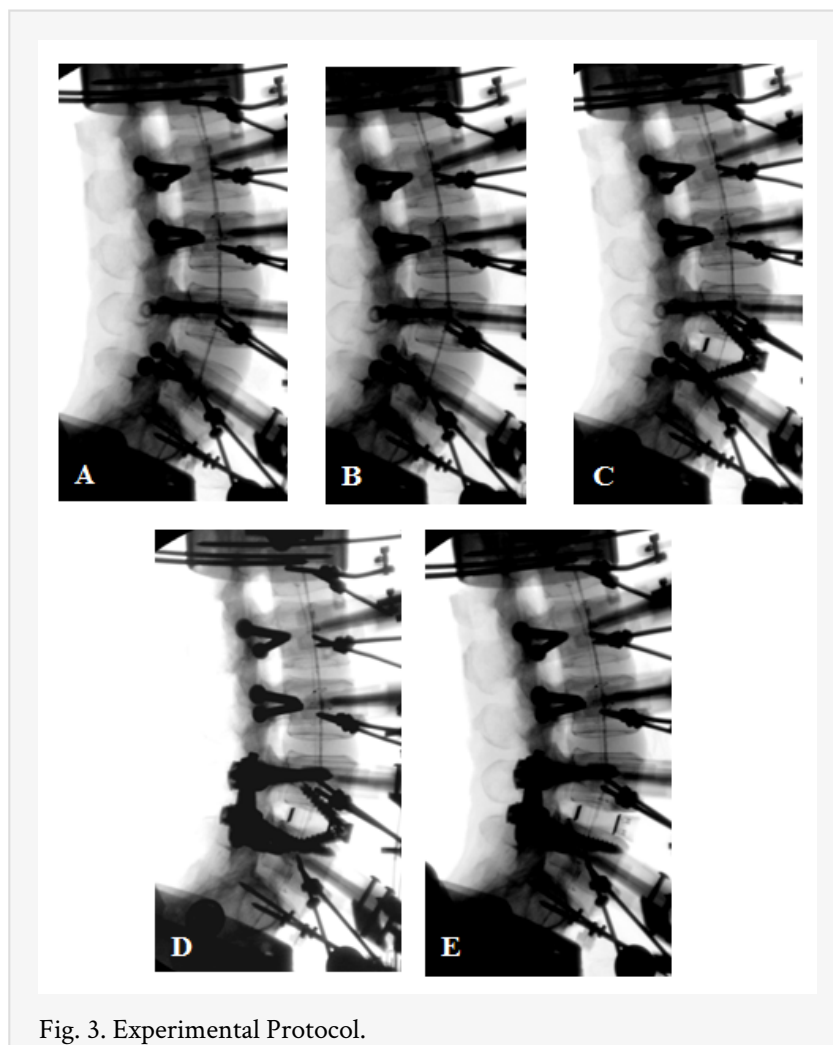5. PILLAR AL + Pedicle Screws and rods at L4-L5 (FIREBIRD).

Fig. 3. Experimental Protocol.

Each specimen was tested in flexion (8Nm) and extension (6Nm) without preload (0 N) and under 400N of follower preload. Each specimen was also tested in lateral bending (±6 Nm) and axial rotation (±5 Nm) without preload.[26,27,28,29]

Data Analysis

The applied moment versus angular motion data were used to calculate the range of motion values in all three modes. Range of motion values were analyzed using repeated measures analysis of variance with a post-hoc Bonferroni correction for multiple comparisons. The following comparisons were made:

1. 1 vs. 3 Intact vs. Integrated Cage
2. 3 vs. 4 Integrated Cage + Pedicle Screws & Rods vs. Integrated Cage
3. 3 vs. 5 Integrated Cage vs. 360 fusion with Spacer

These comparisons were done separately for flexion-extension, lateral bending, and axial rotation, since no comparisons across load-types were intended in the study design. The statistical data analyses were performed with use of the Systat 10.2 software package (Systat Software, Richmond, CA).

Results

Representative applied moment versus angular displacement graphs (Figure 4, Figure 5, Figure 6, Figure 7) depict the classic sigmoidal behavior of the L4-L5 motion segments in the intact condition, followed by nucleotomy, and stabilization using each of three constructs tested in this study.
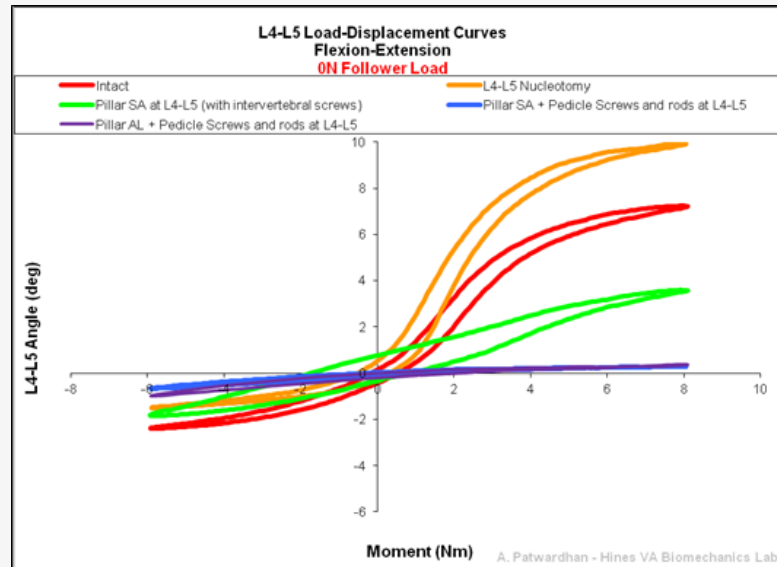
Fig. 4. Representative L4-L5 Load-Displacement Curves in flexion-extension 0N of preload.
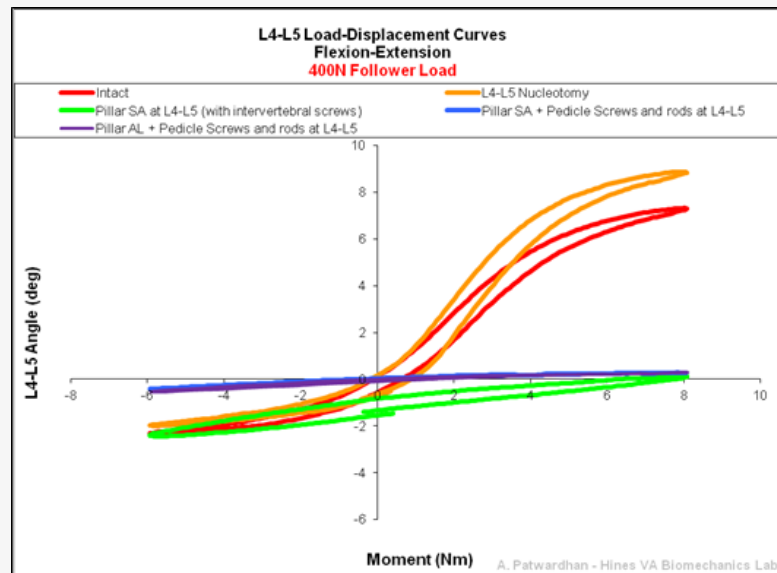

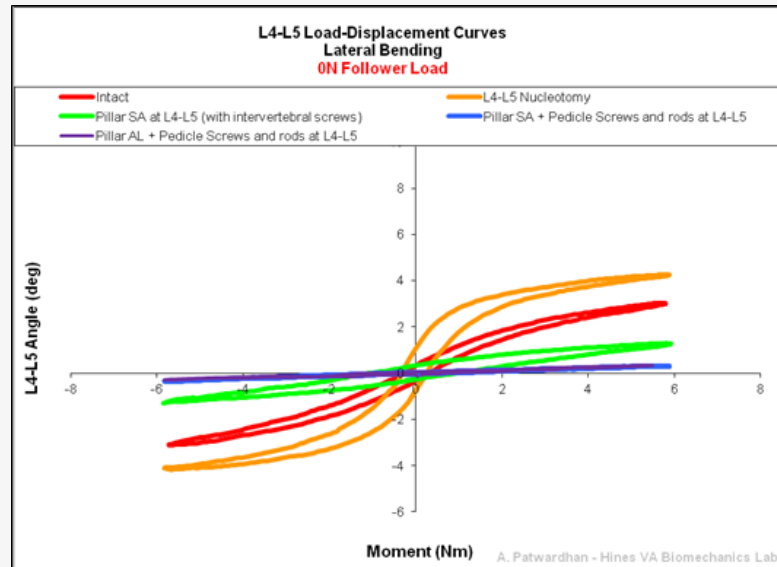Fig. 5. Representative L4-L5 Load-Displacement Curves in flexion-extension 400N of follower preload.

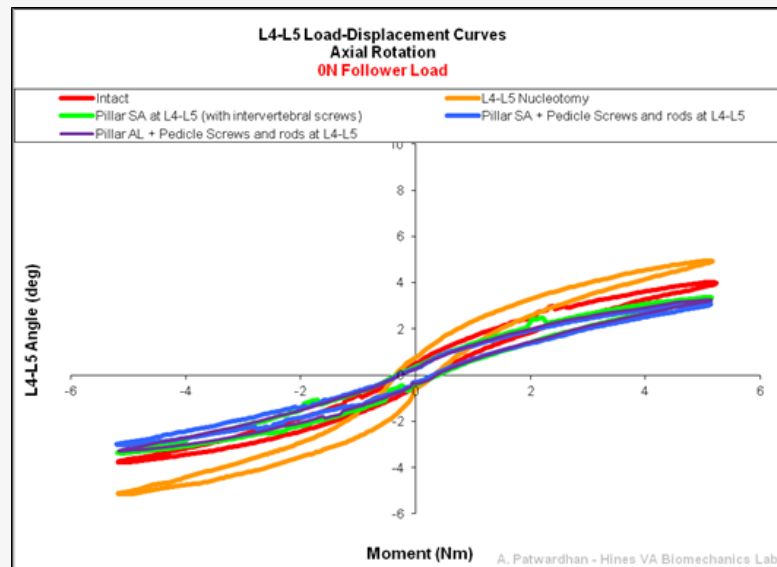Fig. 6. Representative L4-L5 Load-Displacement Curves in lateral bending 0N.

Fig. 7. Representative L4-L5 Load-Displacement Curves in axial rotation.

Range of Motion

Flexion-Extension

In the absence of a compressive preload, the intact spine had a total angular motion of 9.0±2.3 degrees in flexion-extension corresponding to the moments used in this study (0-8Nm flexion, 0-6Nm extension) Figure 8. The motion increased to 11.8±2.7 degrees after nucleotomy (p < 0.01, compared to intact), then decreased to 5.6±3.2 degrees after implantation of the integrated lumbar cage (PILLAR SA), a reduction of 39.5±24.9% (p < 0.01, compared to intact). The addition of bilateral pedicle screws and rods to the

integrated cage construct reduced the motion further, to 1.3±0.9 degrees (p < 0.01, compared to intact). The construct involving an interbody spacer (PILLAR AL) with supplemental bilateral pedicle screws and rods resulted in 1.7±1.2 degrees of angular motion at the L4-L5 segment, a reduction of 81.9±10.2% (p < 0.01, compared to intact). Application of a physiologic compressive preload of 400N caused a further decrease in motion of all fusion constructs(Figure 8). The angular motion of the construct utilizing the PILLAR SA implant was reduced to 3.4±1.7 degrees, a reduction of 64.5±12.7% from intact (p < 0.01, compared to 0 N preload). This is a significant improvement in the performance of the integrated cage due to the addition of physiologic compressive preload (64.5% vs. 39.5% reduction from intact motion). The 360° fusion yielded motion of 1.1±0.5 degrees in flexion-extension, which was significantly less than the motion in the construct using the integrated fusion device (p < 0.05). When the flexion and extension modes were analyzed separately, the integrated cage device, in the absence of a compressive preload, reduced motion in flexion (p < 0.01, compared to intact) but not in extension (p>0.9, compared to intact) (Figure 9 & Figure 10). With the addition of a 400 N compressive preload, the motion of the integrated cage construct further reduced in flexion and the motion in extension became significantly smaller than intact (p < 0.05).
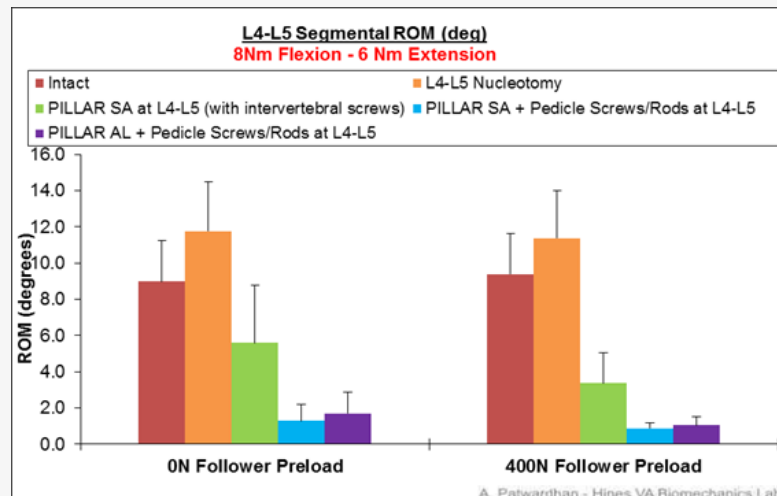
Fig. 8. L4-L5 segmental flexion-extension range of motion in degrees.
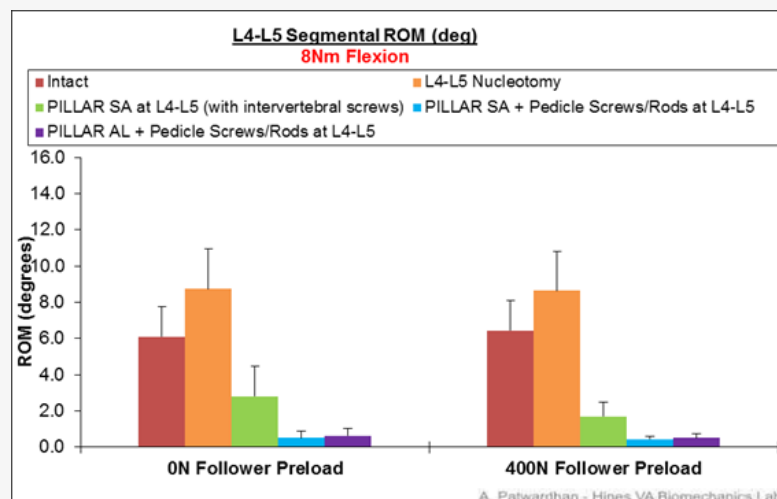

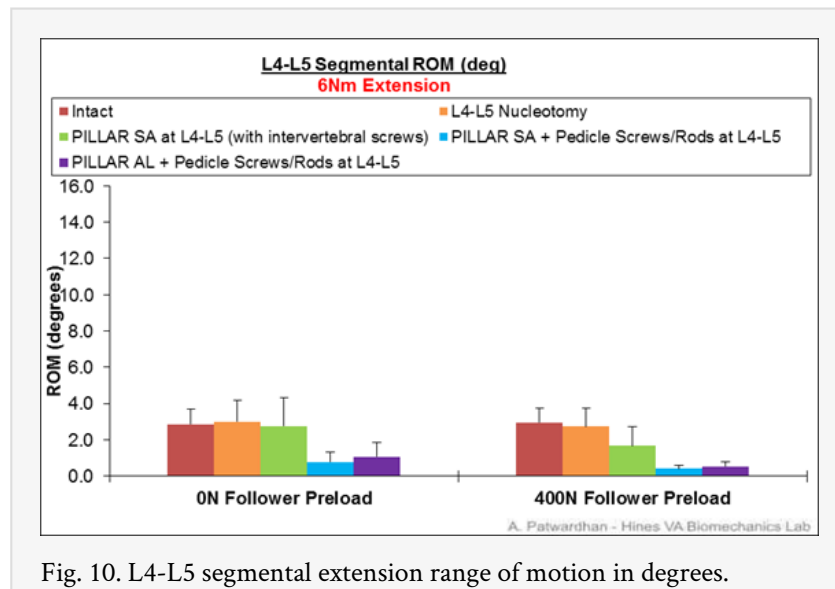Fig. 9. L4-L5 segmental flexion range of motion in degrees.

Fig. 10. L4-L5 segmental extension range of motion in degrees.

Lateral Bending and Axial Rotation

The intact spine had a total angular motion of 8.4±1.8 degrees in (right + left) lateral bending corresponding to the moments of ±6Nm Figure 11. The motion increased to 10.4±3.0 degrees after nucleotomy ($p < 0.05$, compared to intact), then decreased to 2.9±1.5 degrees after implantation of the integrated lumbar cage (PILLAR SA) ($p < 0.01$, compared to intact). The addition of bilateral pedicle screws and rods to the integrated cage construct reduced the motion further, to 0.8±0.5 degrees ($p < 0.01$, compared to intact). The construct involving an interbody spacer (PILLAR AL) with supplemental bilateral pedicle screws and rods resulted in 1.0±0.8 degrees of angular motion at the L4-L5 segment ($p < 0.01$, compared to intact). This 360° fusion construct yielded significantly less motion than the construct using the integrated fusion device ($p < 0.05$). Under moments of ±5Nm in axial rotation, the angular motion at L4-L5 was reduced from 2.4±1.2 degrees in intact to 0.8±0.5 degrees after implantation of the PILLAR SA ($p < 0.01$, compared to intact). The addition of bilateral pedicle screws and rods reduced the motion further, to 0.5±0.4 degrees ($p < 0.01$, compared to intact). The 360° fusion yielded motion of 0.7±0.4 degrees, which was statistically equivalent to the motion in the construct using the integrated fusion device ($p > 0.05$).
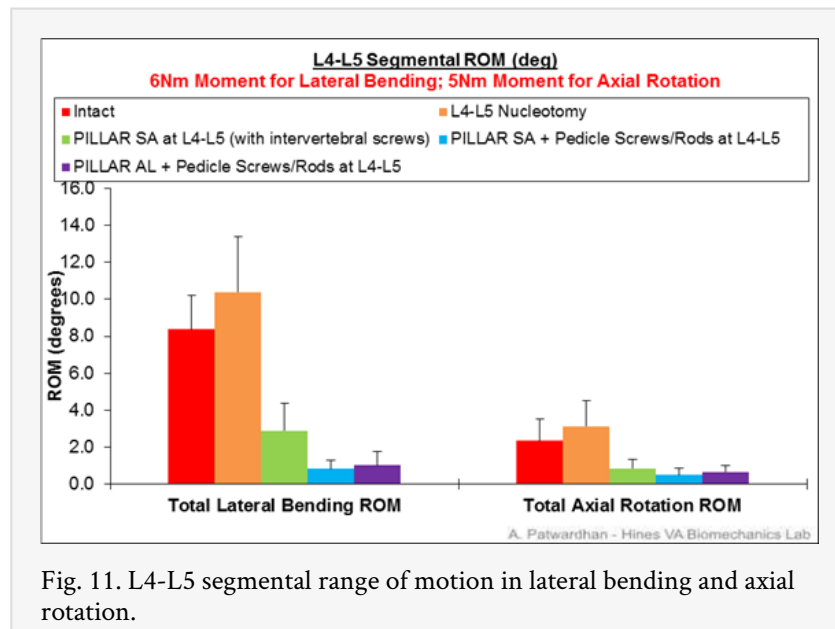
Fig. 11. L4-L5 segmental range of motion in lateral bending and axial rotation.

Discussion

This study was designed to evaluate and compare the biomechanical ability of an integrated lumbar interbody fusion device (PILLAR SA, Orthofix, Lewisville, TX) to a traditional anterior interbody spacer (PILLAR AL, Orthofix, Lewisville, TX) supplemented with posterior instrumentation (FIREBIRD, Orthofix, Lewisville, TX). As a further improvement of anterior only surgical fusion approach and as an alternative to the traditional cage and anterior plate construct to alleviate numerous complications, combination or integrated interbody spacers for zero- or low profile segmental stabilization have been developed to perform the role of the separate spacer and plate. Based on the clinical outcomes of current fusion options, complexity of certain surgical procedures (360º fusion, transarticular facet screws, etc.), excessive soft tissue dissection during anterior plating option, and technical difficulties in plate insertion during surgical procedures for adjacent segment degeneration cases led to the necessity for lumbar (as well as cervical) anterior cage devices with integrated screws. There are several publications reporting the biomechanical performance of such devices as a stand-alone construct or in conjunction with "traditional" fusion options. Kuzhupilly et al. have previously evaluated the stiffness of a femoral ring allograft (FRA) with and without integrated crossed anterior screws under ±4 Nm in flexion-extension and lateral bending and ±2.5 Nm in axial rotation with a compressive preload of 100-150 N.[30] The integrated FRA plus screws was surprisingly significantly less stiff than intact in flexion-extension and about the same as intact in lateral bending. The integrated screws significantly improved the stability of the femoral ring allograft spacers in extension with a trend toward increasing of stiffness in torsion. Cain et al. compared the stand-alone anterior integrated lumbar cage and "traditional" fusion constructs (cage with transarticular facet screws or pedicle screws) under ±6 Nm with a compressive preload of 50 N.[4] The integrated cage reduced the motion to 6.5 degrees in flexion-extension, 3.3 degrees in lateral bending, and 1.1 degrees in axial rotation. The construct using an interbody spacer and bilateral pedicle screws had uncharacteristically large residual motions of 5.9 degrees in flexion-extension, 3.2 degrees in lateral bending and 1.6 degrees in rotation. Schleicher

et al. compared two integrated cage implants – PEEK cage with integrated anterior titanium plate with four diverging locking screws and stand-alone anterior cage with four integrated screws – under ±6 Nm without a compressive preload [31]. Results of this study showed a significant stabilizing effect for both implants in all loading directions; the residual motions were about 2 degrees in flexion-extension and lateral bending and about 1 degree in axial rotation. It should be noted, however, that the native segments seemed to have smaller than normal ranges of motion; only 5.2 degrees in flexion-extension, 2.6 degrees in lateral bending and 2.2 degrees in axial rotation. Beaubien et al. evaluated a stand-alone cage with integrated screws under a moment of ±7.5 Nm with 100N compressive preload[3]. The motion after implantation of the integrated cage was 6.1 degrees in flexion-extension, 5.1 in lateral bending, and 1.8 in axial rotation. The construct with bone graft and pedicle screws was the most stable, with motions of less than 2 degrees in all three modes. Kornblum et al. evaluated the biomechanical stability of ALIF constructs by comparing those using a stand-alone integrated cage device with traditional ALIF supplemental fixation construct under ±7.5 Nm without a compressive preload[32]. These authors did not report the residual motion in degrees; instead they report the results as percent of intact motion. The integrated cage with 3 or 4 screws had residual motions of about 40% of intact in flexion-extension, about 30% in lateral bending and between 45% and 55% of intact in axial rotation. The construct with cage and bilateral pedicle screws was more rigid, with residual motions of about 15% of intact in flexion-extension and lateral bending, and about 35% on intact in axial rotation. In our study we reported biomechanical results using a follower preload of 400N as well as no preload option. The application of follower preload represents an attempt at simulating the "muscle involvement" and mimicking the in vivo scenario, while testing without preload represents a worst-case scenario, but gives a chance to compare our results with other investigators' published studies, where follower load testing was not used. Limitations of this current study as well as for all research studies using cadaveric tissue remain the same: inability to simulate biological fusion and show only acute tissue response and represent the immediate postoperative period. The PILLAR SA device differs from other lumbar integrated interbody devices in that it uses a 4-screw design with medial-oriented screw holes. In addition, its ovoid shape parallels the apophyseal ring of the vertebral body, while providing a wide central opening to hold a larger amount of potential graft material. Lastly, it has a cover plate that stops the possibility of screw back-out while maintaining a nearly zero profile. The PILLAR SA implantation resulted in motions of about 3° under physiologic loads in all modes of motion but was not as motion restricting as the traditional 360° construct using interbody spacer and bilateral pedicle screws. The residual segmental motions compare very favorably with published biomechanical studies of other lumbar interbody integrated fusion devices[3,4]. In addition, motions of about 3° in FE are considered to be sufficient to promote solid biological spinal fusion[33,34,35,36].

Conclusions

The PILLAR SA implantation resulted in motions of less than 3° in all modes of motion but was not as motion restricting as the traditional 360° using bilateral pedicle screws. The residual segmental motions compare very favorably with published biomechanical studies of other lumbar interbody integrated fusion devices. A physiologic compressive preload due to the action of the musculature in vivo acts to stabilize the interface between the interbody device and vertebral endplates, and therefore should be incorporated into

biomechanical test setup for interbody device assessment. The clinical impact of our results is additional information for clinicians who might previously have been apprehensive with respect to performing a lumbar fusion using a stand-alone device. Normally this concern might result in posterior instrumentation being added to the anterior device to ensure stability of the fusion site. However, performing a circumferential fusion adds additional surgical complications due to a secondary surgical site in addition to extending the duration of the entire surgery. The presented results indicate that although the PILLAR SA alone is not as motion-restrictive as the 360 fusion, the motion of the fusion segment is still restricted to a degree that will enable fusion to occur as compared to what is seen in the literature. Additional future studies should be randomized, prospective clinical trials to further support the evidence presented in this paper.

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Disclosures