

Technical Reports

Interbody device endplate engagement effects on motion segment biomechanics

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Abstract

BACKGROUND CONTEXT: Stand-alone nonbiologic interbody fusion devices for the lumbar spine have been used for interbody fusion since the early 1990s. However, most devices lack the stability found in clinically successful circumferential fusion constructs. Stability results from cage geometry and device/vertebral endplate interface integrity. To date, there has not been a published comparative biomechanical study specifically evaluating the effects of endplate engagement of interbody devices.

PURPOSE: Lumbar motion segments implanted with three different interbody devices were tested biomechanically to compare the effects of endplate engagement on motion segment rigidity. The degree of additional effect of supplemental posterior and anterior fixation was also investigated.

STUDY DESIGN/SETTING: A cadaveric study of interbody fusion devices with varying degrees of endplate interdigitation.

OUTCOME MEASURES: Implanted motion segment range of motion (ROM), neutral zone (NZ), stiffness, and disc height.

METHODS: Eighteen human L23 and L45 motion segments were distributed into three interbody groups (n=6 each) receiving a polymeric (polyetheretherketone) interbody spacer with small ridges; a modular interbody device with endplate spikes (InFix, Abbott Spine, Austin, TX, USA); or dual tapered threaded interbody cages (LT [Lordotic tapered] cage; Medtronic, Memphis, TN, USA). Specimens were tested intact using a 7.5-Nm flexion-extension, lateral bending, and axial torsion flexibility protocol. Testing was repeated after implantation of the interbody device, anterior plate fixation, and posterior interpedicular fixation. Radiographic measurements determined changes in disc height and intervertebral lordosis. ROM and NZ were calculated and compared using analysis of variance.

RESULTS: The interbody cages with endplate spikes or threads provided a statistically greater increase in disc height versus the polymer spacer (p=.01). Relative to intact, all stand-alone devices significantly reduced ROM in lateral bending by a mean 37% to 61% (p≤.001). The cages with endplate spikes or threads reduced ROM by ~50% and NZ by ~60% in flexion-extension (p≤.02). Only the cage with endplate spikes provided a statistically significant reduction in axial torsion ROM compared with the intact state (50% decrease, p<.001). Posterior fixation provided a significant reduction in ROM in all directions versus the interbody device alone (p<.001). Anterior plating decreased ROM over interbody device alone in flexion-extension and torsion but did not have additional effect on lateral bending ROM.

FDA device/drug status: approved for this indication (Tapered threaded cage; PEEK interbody spacer; Modular spacer).

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CONCLUSION: The cages with endplate spikes or threads provide substantial motion segment rigidity compared with intact in bending modes. Only the cages with endplate spikes were more rigid than intact in torsion. All devices experienced increased rigidity with anterior plating and even greater rigidity with posterior fixation. It appears that the endplate engagement with spikes may be beneficial in limiting torsion, which is generally difficult with other “stand-alone” devices tested in the current and prior reports. © 2009 Elsevier Inc. All rights reserved.

Keywords: Biomechanical; Cadaveric; Endplate; Flexibility; Interbody; Lumbar

Introduction

Anterior lumbar interbody fusion (ALIF) may be achieved using a variety of techniques. Successful stand-alone ALIF is attractive because it avoids damage to the posterior lumbar musculature [1–4]. ALIF with autologous structural bone graft may result in morbidity to the donor site, whereas allografts, such as femoral cortical ring allografts (femoral ring allograft [FRA]) have limited availability, variable biomechanical properties, and risk disease transmission [5,6]. Alternatives include nonbiologic interbody devices or cages that give structural interbody support and are typically packed with morselized bone graft to obtain fusion.

Despite the appeal of stand-alone ALIF, the clinical success of stand-alone ALIF with structural bone or nonbiologic interbody fusion devices has been variable [7–20]. The clinical variability may be related to the interbody device design’s effect on motion segment stability, which may then influence the rate of obtaining a solid arthrodesis. Most cages are available in only limited sizes and lordosis angles, and there may be a lack of congruity of the device to the interbody space. The biomechanical stability of anterior interbody stand-alone devices, of which there are numerous designs, has been studied previously [21–27]. A common finding is the inability to limit torsion [22,25,27,28]. This includes threaded devices, in which the threads are oriented approximately tangent to the applied moment resulting in “rolling” of these cylindrical implants [16,22,29]. Tapered cages have been used in place of FRA or polymeric spacers as stand-alone devices or in combination with supplemental fixation [30]. Some devices have design features such as radiolucency that allows assessment of fusion, some have endplate interdigitation with serrations, screw threads, or spikes, and others are modular. Modular devices are able to accommodate a greater variety of disc space sizes and degree of lordosis, and therefore can be customized to a specific patients’ desired intervertebral geometry. Interbody spacers that penetrate the endplate with spikes may better resist torsion.

Additional interbody fusion construct stability may be achieved with supplemental fixation, such as anterior plating or posterior interpedicular fixation. It is unknown whether interbody devices combined with this supplemental fixation provides all interbody fusion techniques with variable or the same increase in rigidity, or whether

different interbody techniques will approach a common level of rigidity with supplemental fixation. To date, there has not been a published biomechanical study specifically comparing the stability of interbody device designs with different modes of endplate interdigitation (spacer, modular with spikes, and taper/threaded) with or without supplemental fixation.

The purpose of this study was to compare three interbody devices with different endplate engagement and insertion methods. The first device, a polymeric spacer, had minimal 0.5-mm ridges for endplate engagement, the second was a modular spacer with multiple 1.5-mm spikes, and the third was a tapered/threaded cage with 1.0-mm deep threads. They were compared in terms of their ability to decrease interbody motion, increase disc height, and maintain normal lordosis. Furthermore, the effect of supplemental posterior pedicle screw and anterior plate fixation on each device was investigated.

Materials and methods

Eighteen human L2–3 and L4–5 motion segments were distributed across three interbody device groups—polymeric cage (polyetheretherketone, FRA-type interbody spacer with 0.5-mm serrations in the coronal plane), modular interbody spacer (InFix; Abbott Spine, Austin, TX, USA) with 12 1.5-mm spikes per endplate and holes that allow bone to grow through, and tapered interbody cages (LT [Lordotic tapered] cage; Medtronic, Memphis, TN, USA) with 1.0-mm deep threads for endplate engagement (Fig. 1). Specimens were distributed such that each group contained three L2–3 and three L4–5 motion segments, and no group contained more than one motion segment from the same donor. All specimens were tested intact, after simulated anterior fusion surgery using “stand-alone” device (“ALIF”), after ALIF and supplemental posterior interpedicular fixation (Fig. 2, top), and after ALIF and supplemental anterior plate fixation (Fig. 2, bottom).

Specimen preparation

Fresh-frozen human cadaveric lumbar spines were obtained from donors aged 33 to 64 years. Donor tissue was free of bone metastasis, auto-fusion, or advanced spondylosis as evidenced by direct examination, radiographs, and

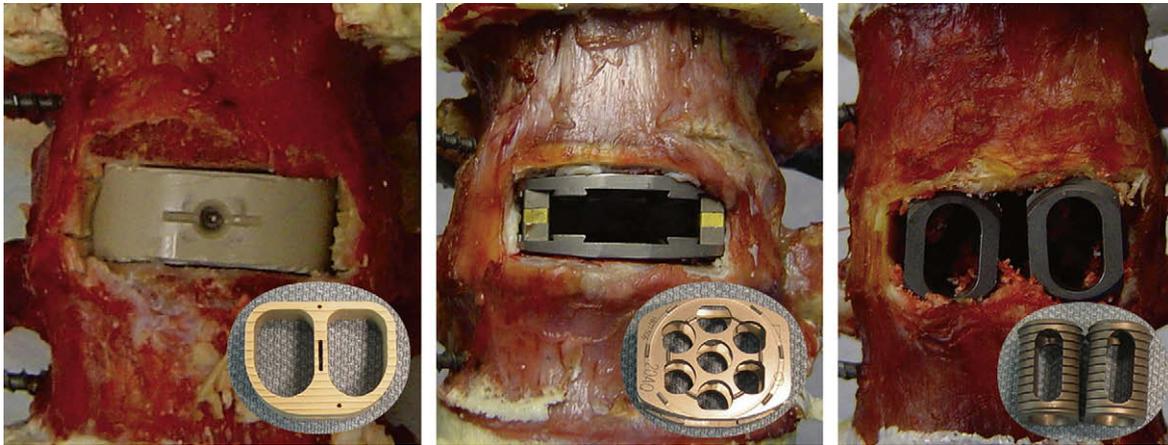


Fig. 1. (Left) Interbody spacer groups included a polymer interbody spacer, (Middle) a modular interbody spacer, and (Right) tapered/threaded interbody cages. Insets show top views of each device.

donor medical history. After obtaining the anteroposterior (AP) bone mineral density (BMD) scans (dual-energy X-ray absorptiometry [DXA]; GE Lunar Prodigy, Madison, WI, USA) of the lumbar spine, the spine was g-sectioned into nine L2–3 and nine L4–5 motion segments consisting of proximal and distal vertebral bodies, an intervening disc, and associated ligamentous structures. The AP BMD scores ranged from 0.83 to 1.42 g/cm² in this study. The mean \pm standard deviation BMD score was 1.04 \pm 0.22 g/cm² for the polymer spacer group, 1.08 \pm 0.12 g/cm² for the spiked cage group, and 1.16 \pm 0.05 g/cm² for the threaded cage group. There was no significant difference in the DXA value between groups as determined using analysis of variance ($p = .22$).

The proximal and distal vertebral bodies, augmented with wood screws for fixation, were potted in a urethane epoxy such that the disc remained in a horizontal orientation. To minimize specimen degradation, specimens were kept at room temperature for no more than 8 hours, and were refrigerated during overnight storage if required. Specimens were sprayed with saline throughout testing to maintain hydration.

Surgical technique

All subtotal discectomies and device implantations were performed by experienced spine surgeons. The discectomy procedure included the removal of the entire nucleus, the anterior (including the anterior longitudinal ligament) and anterolateral annulus, and the cartilaginous endplates. After discectomy, the disc space was manually distracted with a spreader and the interbody dimensions were measured. The goal was to maximize disc space height while maintaining lordosis. The appropriately sized interbody device was chosen based on surgeon experience and manufacturer's recommendation.

The polymer spacer height was chosen based on interbody space size under distraction and the height oversized by

1 mm (range, 10–16 mm height). Spacer sagittal dimension ranged from 23 to 27 mm, the transverse dimension ranged from 31 to 35 mm, and the lordotic angle was 4° ($n = 5$) or 8° ($n = 1$). The polymer spacers were inserted, impacted into place, and countersunk approximately 3 to 5 mm.

Modular interbody devices were composed of components that allowed the surgeon to adjust lordosis and intervertebral height. We selected struts and endplate components to reproduce and slightly increase the anterior disc height (ADH) and posterior disc height (PDH) measured after disc space distraction, and the device was then inserted using manufacturer's distraction and insertion tools. Briefly, the spiked device endplates are inserted into the disc space. A distraction instrument drives the spikes into the cortical bone of the vertebral endplates and vertical struts are then placed to maintain the distraction and act as a lateral side-wall for the cage (Fig. 1). The height of the device at its anterior margin ranged from 13.5 to 18 mm. The sagittal dimension ranged from 26.5 to 29.0 mm and the transverse dimension ranged from 32 to 35 mm. The lordotic angle of the implants was selected to reproduce lordosis of the intact motion segments (mean, approximately 7°); 3° ($n = 2$), 6° ($n = 3$), or 12° ($n = 1$).

Endplate preparation in the threaded cage group was conducted using reamers and guide tubes provided by the manufacturer. The cage size was based on ADH under manual distraction. The anterior height ranged from 17 to 22 mm, the sagittal length ranged from 20 to 26 mm, and the lordosis was measured to be approximately 7° for all devices. Two interbody cages were placed for each disc space.

Pedicle screw holes were prepared with a surgical drill and pedicle finder. Titanium alloy pedicle screws (InCompass; Abbott Spine, Austin, TX, USA) of appropriate diameter (5.5–6.5 mm) and length (45–55 mm) were then driven by hand until fully seated. When tested with interpedicular fixation, the proximal and distal screws were connected

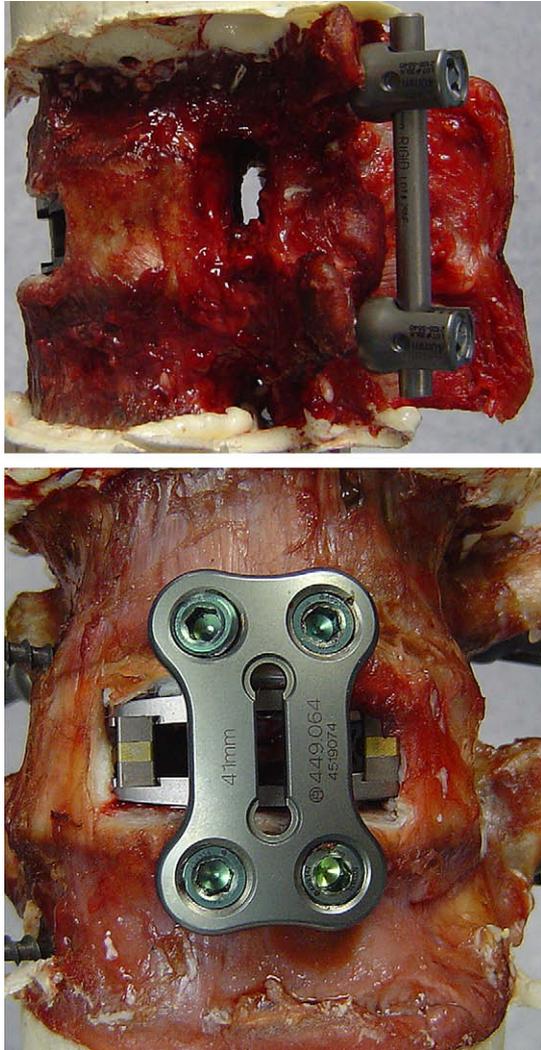


Fig. 2. (Top) Posterior interpedicular fixation, and (Bottom) anterior plating were used as supplemental fixation to the simulated interbody fusion.

bilaterally with a 5.5-mm titanium rod and locked into place with torque-specific breakaway set screws. The rods were removed after testing the posterior fixation groups, whereas the screws were left in place until the experiment was completed.

The anterior plate group received titanium plates (3.5-mm thick, and 37-, 41-, or 49-mm in length, ATB plate; Synthes Spine, West Chester, PA, USA) that were fixed with 5.5-mm diameter locking screws ranging from 20 to 28 mm in length. Plates were applied using manufacturer's instrumentation, so that the threaded screw head would fully seat in the threaded plate. Screws were tightened using the manufacturer's torque limiting driver.

Flexibility testing

Potted motion segments were mounted in a spinal loading fixture designed to apply unconstrained moments in each of the three anatomic planes (Enduratec, Eden Prairie, MN, USA). Specifically, 7.5-Nm moments were applied at

a moment-controlled rate of 0.5 Nm/s in flexion-extension, bilateral lateral bending, and bilateral axial torsion [31,32]. Three cycles were applied with the first two representing preconditioning cycles and data collection occurring only on the third cycle. All moments were applied in the presence of a 100-N preload applied to the proximal vertebra in a direction normal to the mid-disc plane. This load level was chosen to represent axial compression across the motion segment while minimizing the artifact that occurs with preload application [33]. Each vertebra had three reflective markers placed for motion measurements. Motions were tracked in six-degrees-of-freedom using a five-camera VICON motion measurement system (VICON Motion Systems, Oxford, UK), and were described using Euler angle formulations to within 0.25 degrees. Only motions in the plane of applied motion were evaluated in this fusion-device study.

Each motion segment was first tested intact and the pre-assigned interbody device was implanted. Motion segments were then tested with the interbody device alone, interbody device with anterior plate, and interbody device with pedicle screws and rods. To limit order-related effects, the test order was randomized such that all six surgical state test order permutations were performed in each of the three interbody groups.

Imaging

AP and lateral fluoroscopic images were acquired for each test construct of each motion segment. Once flexibility testing was complete, all supplemental fixation was removed and AP and lateral radiographs were acquired.

Intervertebral angle (IVA) and disc height were obtained from calibrated lateral radiographs using image measurement software (NIH Image; Scion Corporation, Frederick, MD, USA). This analysis was performed for the intact and stand-alone interbody device states only. The mean disc height was calculated as the average of the ADH and PDH. The IVA was calculated from these measurements as follows:

$$IVA = \tan^{-1} \left(\frac{ADH - PDH}{VB \text{ depth}} \right)$$

where *VB depth* was the sagittal dimension of the caudal vertebral body. This method correlated well with manual measurements using the Cobb method.

Data analysis

Range of motion (ROM), neutral zone (NZ) and stiffness (initial and elastic zone) were calculated about the axis of applied motion from the flexibility curves of each specimen. The ROM was calculated as the change in rotation between the maximum positive and negative moments. The NZ was calculated as the difference in rotation between the position after completion of the positive moment

loading and that after the completion of the negative moment loading. Stiffness was calculated for comparison in the low-stiffness (ie, NZ) and high-stiffness (ie, elastic zone) regions of the flexibility curves.

For each test direction, the effects of group and state on ROM and NZ were investigated using a two-way, repeated measures analysis of variance. Specifically, specimen was the repeated measure, and interbody device (polymer, spiked, and threaded cage) and test state (intact, ALIF, plate, pedicle screws) were factors with only test state repeated. A log transformation was used to correct for non-constant variance. Where global significance was noted ($p < .05$), post-hoc comparisons were made using the Student-Newman-Keuls method, and p -values below .05 were considered statistically significant. Because the stiffness measures were not independent from their respective NZ and ROM measures, they were not compared statistically. The effects of device on the change in IVA and disc space height were investigated before versus after implantation using a paired t test.

Results

Interbody device comparisons

The stand-alone interbody devices (ALIF) affected the ROM and NZ of the motion segments to various degrees (Figs. 3–5). Global differences ($p < .05$) were noted in the ROM data in each direction and in the NZ data in flexion-extension and lateral bending. The polymer spacer significantly reduced ROM in lateral bending to a mean \pm standard deviation $63\% \pm 44\%$ of the respective intact values ($p = .004$). The threaded cages provided a significant reduction in flexion-extension ROM to a mean $47\% \pm 19\%$ ($p < .001$) and NZ to $42\% \pm 16\%$ ($p = .02$) of the intact values, and decreased mean lateral bending ROM to

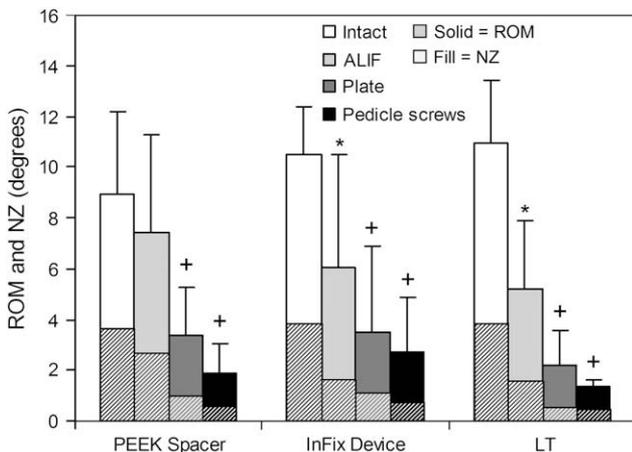


Fig. 3. Mean \pm standard deviation flexion-extension range of motion (ROM) and neutral zone (NZ). Significant differences ($p < .05$) are indicated between anterior lumbar interbody fusion (ALIF) and intact ROM (*) and between ALIF and respective supplemental fixation state ROM (+).

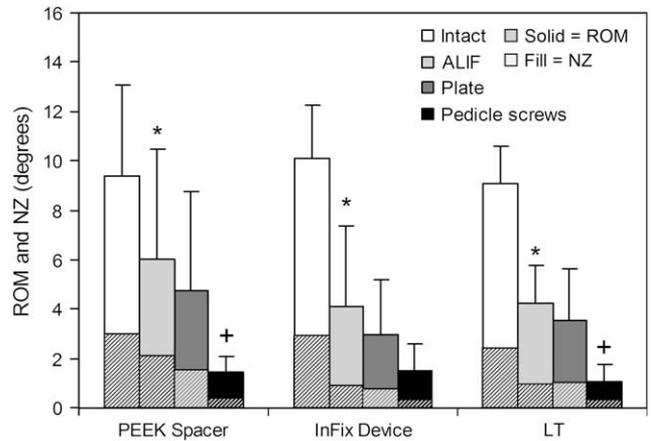


Fig. 4. Mean \pm standard deviation bilateral lateral bending range of motion (ROM) and neutral zone (NZ). Significant differences ($p < .05$) are indicated between anterior lumbar interbody fusion (ALIF) and intact ROM (*) and between ALIF and respective supplemental fixation state ROM (+).

$46\% \pm 12\%$ ($p < .001$) and NZ to $53\% \pm 48\%$ ($p = .01$) of the respective intact values. The spiked modular device significantly reduced mean flexion-extension ROM to $54\% \pm 32\%$, mean flexion-extension NZ to $43\% \pm 35\%$, mean lateral bending ROM to $39\% \pm 26\%$, and mean lateral bending NZ to $34\% \pm 31\%$ compared with the respective intact values (all at $p \leq .001$).

In axial torsion, only the spiked modular stand-alone device significantly reduced ROM compared with the respective intact values to a mean $48\% \pm 31\%$ of the intact value ($p < .001$); conversely, the mean torsion NZ increased to $127\% \pm 135\%$ of the intact value. The tapered threaded cages resulted in a marginally significant ($p = .052$) decrease in the mean torsional ROM to $74\% \pm 49\%$ of the intact value and a nonsignificant (NS) increase in the mean torsional NZ to $192\% \pm 138\%$ of the intact value. The polymer spacer increased the mean torsional ROM to $149\% \pm 144\%$ and increased the mean NZ to $333\% \pm 271\%$ of the respective intact values (both NS). Across-group differences did not reach statistical significance in any instrumented states with this sample size, possibly because of the underlying

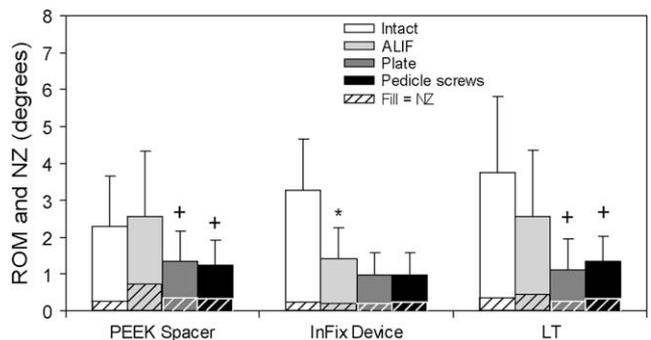


Fig. 5. Mean \pm standard deviation bilateral axial torsion range of motion (ROM) and neutral zone (NZ). Significant differences ($p < .05$) are indicated between anterior lumbar interbody fusion (ALIF) and intact ROM (*) and between ALIF and respective supplemental fixation state ROM (+).

Table 1
Mean \pm standard deviation primary (neutral zone) stiffness (Nm/°)

Device	Test direction	Intact	ALIF only	ALIF+plate	ALIF+postfixation
Polyetheretherketone spacer	Flexion-extension	1.0 \pm 1.0	1.1 \pm 1.2	2.8 \pm 2.8	13.4 \pm 12.5
	Lateral bending	0.8 \pm 0.9	3.7 \pm 3.8	6.3 \pm 7.4	13.9 \pm 6.2
	Axial torsion	8.9 \pm 9.4	9.4 \pm 9.3	14.1 \pm 7.3	17.9 \pm 10.9
Modular device (InFix)	Flexion-extension	0.5 \pm 0.1	3.3 \pm 3.4	6.7 \pm 5.5	13.3 \pm 16.7
	Lateral bending	2.3 \pm 4.8	6.8 \pm 7.0	8.0 \pm 7.8	14.0 \pm 12.1
	Axial torsion	5.8 \pm 2.2	12.7 \pm 5.9	19.0 \pm 12.5	27.3 \pm 24.0
Tapered cage (LT cage)	Flexion-extension	0.3 \pm 0.2	2.6 \pm 2.0	5.6 \pm 5.2	11.5 \pm 6.3
	Lateral bending	0.6 \pm 0.4	3.5 \pm 2.0	4.8 \pm 3.0	16.7 \pm 10.7
	Axial torsion	4.9 \pm 3.7	10.6 \pm 11.8	19.7 \pm 14.3	14.6 \pm 9.6

ALIF, anterior lumbar interbody fusion; LT, Lordotic tapered.

variability of the intact motion segments, which may make the different treatments more or less effective on a given segment (eg, concave vs. convex endplates, low vs. high bone density, short vs. tall discs, and so forth).

Supplemental fixation comparisons

All devices tended to approach a similar reduced level of motion in all test directions with increasingly rigid supplemental fixation. When compared with the stand-alone interbody devices, pedicle screw fixation and anterior plating significantly reduced ROM in flexion-extension to overall averages of 19% \pm 12% and 30% \pm 21% of the intact values, respectively (both $p < .001$ vs. stand-alone). The flexion-extension NZ was also decreased for both plates and pedicle screws ($p < .001$). In lateral bending, pedicle screws reduced the ROM compared with the stand-alone device to a mean 14% \pm 7% and NZ to a mean 15% \pm 9%, of the respective intact values overall ($p < .001$), whereas plated constructs had an overall mean ROM of 39% \pm 27% ($p = .026$ vs. stand-alone device) and a NZ of 54% \pm 63% ($p = \text{NS}$ vs. stand-alone device) of the respective intact states. In bilateral torsion the addition of pedicle screws reduced the ROM to 34% \pm 27% of the respective intact values with the modular device ($p = .2$ vs. stand-alone, $p < .001$ vs. intact), to 42 \pm 30% with tapered threaded cage ($p = .025$ vs. stand-alone, $p < .001$ vs. intact),

and to 65% \pm 44% with the polymer spacer ($p = .049$ vs. stand-alone and $.075$ vs. intact).

There was greater reduction in ROM and NZ for pedicle screw compared with anterior plate supplemental fixation. Differences between pedicle screws and anterior plates were statistically significant in lateral bending (ROM and NZ, both $p < .001$), but were also seen in flexion-extension (ROM only, $p = .003$). Plates and pedicle screws provided a similar reduction in ROM and NZ in axial torsion. For the spiked, modular cage, the addition of supplemental fixation led to significant additional decreased ROM in flexion-extension, but not in lateral bending or torsion.

Both primary and secondary stiffness followed the trends seen with respective ROM and NZ results for all constructs (ie, greater stiffness with less ROM, Tables 1 and 2). Statistics were not performed on stiffness values to limit the contrasts performed on the same data.

Radiographic results

Overall, the intact mean disc height was 7.9 mm (range was 5.5–11.5 mm). After discectomy and device implantation, the mean mid-disc height increased from 8.1 \pm 2.3 to 9.5 \pm 2.1 mm in the polymer spacer group ($p = .09$), from 8.6 \pm 1.1 to 12.2 \pm 1.7 mm in the spiked cage group ($p = .001$), and from

Table 2
Mean \pm standard deviation secondary (elastic zone) stiffness (Nm/°)

Device	Test direction	Intact	ALIF only	ALIF+plate	ALIF+postfixation
Polyetheretherketone spacer	Flexion	3.4 \pm 0.5	2.5 \pm 1.0	3.4 \pm 2.4	12.3 \pm .0
	Extension	8.8 \pm 7.9	7.7 \pm 4.0	6.8 \pm 0.7	11.5 \pm 13.7
	Lateral bending	2.9 \pm 0.8	4.1 \pm 2.0	7.2 \pm 6.7	13.9 \pm 6.2
	Axial torsion	10.4 \pm 9.0	10.5 \pm 8.5	14.1 \pm 7.3	17.9 \pm 10.9
Modular device (InFix)	Flexion	2.5 \pm 0.8	3.8 \pm 3.0	7.0 \pm 5.1	14.1 \pm 16.1
	Extension	4.3 \pm 2.4	5.0 \pm 2.5	17.8 \pm 26.7	13.3 \pm 16.2
	Lateral bending	4.2 \pm 3.9	7.3 \pm 6.6	8.4 \pm 7.5	14.0 \pm 12.1
	Axial torsion	5.8 \pm 2.2	12.7 \pm 5.9	19.0 \pm 12.5	27.3 \pm 24.0
Tapered cage (LT cage)	Flexion	3.0 \pm 0.9	3.3 \pm 1.4	4.3 \pm 2.6	12.6 \pm 6.2
	Extension	4.3 \pm 1.5	5.8 \pm 2.4	9.3 \pm 6.0	9.9 \pm 3.5
	Lateral bending	3.5 \pm 1.2	4.1 \pm 1.6	5.5 \pm 3.5	17.5 \pm 10.3
	Axial torsion	5.8 \pm 2.9	11.7 \pm 11.2	19.7 \pm 14.3	14.6 \pm 9.6

ALIF, anterior lumbar interbody fusion; LT, Lordotic tapered.

6.9±0.8 to 11.1±1.2 mm in the threaded cage group ($p<.001$). The mean lordosis was similar for all groups (7–8°) and was maintained after device implantation.

Discussion

Variable clinical results have been obtained with stand-alone interbody devices including dual threaded cages [10–18,34]. The variable results with threaded cages have been largely attributed to the poor ability to obtain and assess fusion, variable patient selection and variable cage placement techniques [13,35]. Because poor clinical success may be resulting from motion segment instability, such as excessive motion in torsion and extension [21], the present study investigated the biomechanical stability of three interbody devices that had substantially different designs pertaining to the device/bone interface. We found that only the design with multiple endplate spikes, with sufficient length to fully penetrate the cortical bone of the endplate, resisted torsion in the stand-alone configuration.

Our results compare favorably with previous studies evaluating intact motion segments and motion segments instrumented with polymer spacers or threaded cages. For the intact specimens, average ROM values and their standard deviations were similar in all directions to those found previously under similar protocols when corrected for the applied moment [25,27–29,36]. Similar to prior reports, ALIF with a polymer spacer alone did not decrease motion in torsion compared with the respective intact state, and reduced motion to a significant degree in lateral bending only [27,28,37]. As in previous studies, relative to the intact state, dual threaded cages reduced motion in lateral bending and somewhat in flexion–extension, but also did not decrease motion in torsion [29,38–41]. Our results thus give further support that torsion instability may be related clinical failure [16].

The spiked, modular cage evaluated in this study differed from the other devices studied in its method of endplate engagement and its effect on torsional rigidity. The spiked, modular cage significantly reduced motion in flexion–extension, lateral bending, and axial torsion compared with intact. Like the threaded cage, the modular device is designed to engage the endplates, but with spikes instead of threads. An additional difference is that the modularity of the spiked device allows the vertical stress within the disc space to be imparted after the spikes are positioned against the bony endplates. This differs from the threaded device that cuts troughs in the endplates as it is inserted. Leaving a trough in the endplates puts the device at risk of migration and has been observed in both threaded devices and nonmodular spiked devices that had fixed height and were impacted into the disc space creating troughs [19,42–44]. One prior study compared devices with various degrees of endplate coverage and engagement, including one-piece cages with small serrations or small spikes, or dual threaded cages [22]. Similar to our study they found

a decrease in flexion–extension and lateral bending ROM, but there was no reduction in axial rotation ROM. Another study evaluating the insertion of additional bone screws into an FRA-type implant supports the concept of optimizing endplate engagement as seen with the modular device [23]. Probably the reason that axial rotation rigidity was greater for the spiked modular device compared with the other two devices of this and prior studies may be because of the number, size, and shape of spikes and their peripheral arrangement to optimize engagement of the thickest region of the bony endplate.

Motion segment rigidity for interbody devices is influenced by a number of factors in addition to cage design, such as annular tension, device preload, and endplate strength. Vertebral bone quality affects fusion construct rigidity, and may do so to varying degrees with different implant designs and insertion techniques [45]. Endplate strength is lowest in its central portion and is greatly reduced with cortical bone removal [46,47]. In the present study, DXA scores were similar between groups indicating that intergroup differences in strength and rigidity were due largely to implant design and implantation methods. Tapered threaded cages aim to allow maintenance of the lordotic profile without excessive reaming, and allow greater anterior and posterolateral endplate engagement vs. their nontapered counterparts [30]. However, reaming is still necessary, and thus removal of some endplate cortical bone is unavoidable. In contrast, the spiked, modular implants used in the present study rely on distributed bony contact over the entire endplate, and engage their spikes into intact endplates without the creation of a trough on insertion. Subsidence risk may therefore be reduced and motion segment rigidity increased. Pilot testing in the present study suggests failure occurs by different modes—threaded cages tended to gradually subside with increasing loads, whereas the spiked, modular cage tended to fail at a higher, catastrophic load.

Construct rigidity may be also influenced by the degree of annular tensioning related to axial “oversizing” of the interbody implants at the time of insertion. Undersized cages along with annular tissue relaxation overtime may lead to device loosening [48,49]. Although an attempt was made to standardize the distraction force used in sizing and inserting the devices, the device design and implantation methods likely influenced the final degree of distraction. Insertion of the polymer spacer occurred relatively quickly and did not allow creep to occur in the annular tissues and did not significantly increase disc height in this study. Modular spacer insertion and threaded cage implantation occurred over a longer time period and entailed wedging/leveraging with the instrumentation or device shape and resulted in statistically significant gains in disc height.

Although the ability of supplemental fixation to reduce motion in this study was not surprising, the response of the interbody device constructs to supplemental fixation was of interest. As found previously, supplemental pedicle

screw fixation dramatically reduced motion versus the ALIF state [24–26,28,33,36,41,50–57]. The present study further found that with pedicle screw fixation the three interbody device constructs were brought to a similar mean level of rigidity in all test directions. This finding suggests that pedicular fixation overcomes the differences between various interbody devices. Plating had a similar effect on ALIF construct rigidity in flexion-extension and axial torsion but did little to limit motion in lateral bending. One difference among interbody device constructs is that the spiked, modular spacer, which already had the greatest reduction in torsion ROM, received only a minimal and non-statistically significant additional benefit in torsion rigidity with supplemental fixation. Clinically, if a surgeon suspects construct instability and is considering additional surgery our study suggests that in the late case a posterior spinal fusion should be performed regardless of the interbody device. In the acute case, during the anterior ALIF surgery, a polymer or threaded cage device is best salvaged with an additional posterior fusion procedure, whereas the spiked, modular device could be salvaged directly with an anterior plate. Avoiding a posterior procedure would be a considerable reduction in surgical costs. Potential scenarios are unexpected poor bone quality with potential for subsidence, or large disc space on distraction after discectomy, which is known to result in potential instability [48,58].

Limitations of the present study include the small number of specimens, and it is thus possible that some true differences between various constructs may not have reached statistical significance. One must also recognize that the present study only describes the immediate postoperative rigidity of each construct. The *in vivo* condition during fusion healing is probably better represented with dynamic cyclic testing, but in this study the variable of cyclic loading was excluded in the interest of a repeated measures design. Cyclic loading has been shown to increase ROM and NZ of ALIF constructs [29,41]. We suggest a future study to assess clinical failure using a load control cyclic test of the stand-alone devices in rotation about each major axis [41]. After initial flexibility tests, we suggest testing to 100k cycles and then repeating flexibility testing. Analysis could then compare the construct stiffness before and after cyclic testing. The radiographic analysis in this single-level study was limited because the surgeons aimed to maintain the existing lordosis rather than to increase lordosis as is often done clinically. Disc height and lordotic angle measurements obtained in this study would not necessarily be found clinically because of the lack of the whole-spine loading and patient positioning variables that are present intraoperatively.

Several clinically relevant observations can be made despite the above limitations. The threaded and spiked devices provided a reduction in motion segment rigidity in all anatomic planes in this study, and their use as stand-alone devices in selected patients may thus be more appropriate vs. polymer cages. The authors believe that limiting motion

in axial torsion, which was reduced significantly in only the spiked modular device, is particularly important because it seems to be a common mode of stress on the lumbar spine during activities of daily living, such as walking [59,60], and would place shear stress on a newly forming arthrodesis. Others have also suggested that a lack of axial torsion stability may result in clinical failure of spinal arthrodesis [16], and have pointed out that residual motion after device implantation occurs at the bone-implant interface [22]. The concept of axial rotation instability as a potential failure mode has been suggested in hip arthroplasty femoral stem fixation but has not been fully evaluated in spinal fusion [61–66]. When used with supplemental rod fixation, all interbody devices produced very rigid constructs with mean ROM below two to three degrees in all planes. These results indicate that supplemental fixation should be considered if less than optimal construct rigidity is noted intraoperatively during a stand-alone procedure (eg, the surgeon identifies unexpected osteopenia, endplate disruption, or excessive disc height/annular laxity).

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