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Evaluation of Two Novel Integrated Stand-Alone Spacer Designs Compared with Anterior and Anterior-Posterior Single-Level Lumbar Fusion Techniques: An *In Vitro* Biomechanical Investigation

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Study Design: *In vitro* biomechanical investigation.

Purpose: To compare the biomechanics of integrated three-screw and four-screw anterior interbody spacer devices and traditional techniques for treatment of degenerative disc disease.

Overview of Literature: Biomechanical literature describes investigations of operative techniques and integrated devices with four dual-stacked, diverging interbody screws; four alternating, converging screws through a polyether-ether-ketone (PEEK) spacer; and four converging screws threaded within the PEEK spacer. Conflicting reports on the stability of stand-alone devices and the influence of device design on biomechanics warrant investigation.

Methods: Fourteen cadaveric lumbar spines were divided randomly into two equal groups (n=7). Each spine was tested intact, after discectomy (injured), and with PEEK interbody spacer alone (S), anterior lumbar plate and spacer (AP+S), bilateral pedicle screws and spacer (BPS+S), circumferential fixation with spacer and anterior lumbar plate supplemented with BPS, and three-screw (SA3s) or four-screw (SA4s) integrated spacers. Constructs were tested in flexion-extension (FE), lateral bending (LB), and axial rotation (AR). Researchers performed one-way analysis of variance and independent *t*-testing ($p \leq 0.05$).

Results: Instrumented constructs showed significantly decreased motion compared with intact except the spacer-alone construct in FE and AR ($p \leq 0.05$). SA3s showed significantly decreased range of motion (ROM) compared with AP+S in LB ($p \leq 0.05$) and comparable ROM in FE and AR. The three-screw design increased stability in FE and LB with no significant differences between integrated spacers or between integrated spacers and BPS+S in all loading modes.

Conclusions: Integrated spacers provided fixation statistically equivalent to traditional techniques. Comparison of three-screw and four-screw integrated anterior lumbar interbody fusion spacers revealed no significant differences, but the longer, larger-diameter interbody spacer with three-screw design increased stabilization in FE and LB; the diverging four-screw design showed marginal improvement during AR.

Keywords: Intervertebral disc degeneration; Lumbar region; Range of motion; Equipment design

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Introduction

Anterior lumbar interbody fusion (ALIF) is a surgical technique that is used to treat patients with a wide range of destabilizing pathologies, including degenerative disc disease (DDD), spondylolisthesis, and adjacent segment disease [1]. The anterior approach facilitates direct access and complete removal of the symptomatic disc, restores disc height while indirectly decompressing nerve roots, and provides increased surface area for fusion compared with posterior and transforaminal approaches [2-7]. Traditionally, supplemental fixation in the form of bilateral pedicle screws, an anterior plate, or circumferential fixation has been required to further stabilize the motion segment and prevent implant migration [2,8]. However, the iatrogenic trauma associated with posterior paraspinal muscle dissection can result in longer operative periods, increased postoperative pain due to multiple incision sites, and prolonged hospital stays [9].

Alternatively, zero-profile stand-alone ALIF spacers with integrated plate and interbody screws are commercially available and were designed to alleviate the need for posterior fixation while stabilizing the motion segment with the goal of promoting fusion without the profile of an anterior plate. Although the extent of immediate stabilization required for spinal fusion is uncertain, the consensus is that increased stiffness is necessary for fusion to occur [10,11]. In their comprehensive review of clinical outcomes following fusion techniques, Wang et al. noted that circumferential fixation led to lower nonfusion rates, significantly lower rates of pseudarthrosis, and higher rates of successful clinical outcomes [11]. Although biomechanical data have validated the properties of integrated stand-alone devices compared with a wide variety of operative constructs [12-15], direct comparisons between stand-alone devices and circumferential fixation have not been reported in the literature.

The aforementioned biomechanical literature describes investigations of operative techniques such as an integrated locking plate design with four dual-stacked, diverging interbody screws (SynFix-LR, DePuy Synthes, West Chester, PA, USA) [12,13]; an integrated device with four alternating, converging screws through a polyether-ether-ketone (PEEK) spacer (Pillar SA, Orthofix, Lewisville, TX, USA [15]; Stalif, Centinel Spine, West Chester, PA, USA [16]); and an integrated device with four converging screws threaded within the PEEK spacer (Brigade, NuVasive, San Diego, CA, USA) [14]. In situ analysis reveals biomechanical differences between alternatively designed integrated ALIF devices [16].

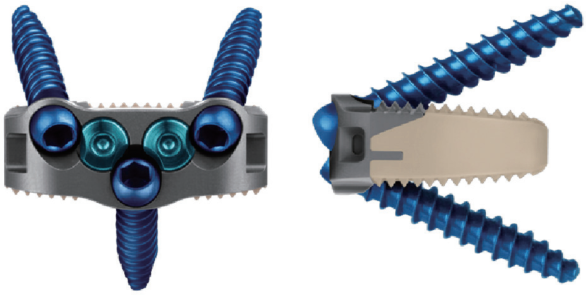

Fig. 1. Coronal and sagittal views of the three-screw integrated stand-alone polyether-ether-ketone spacer.

The objectives of the present study are twofold: (1) to compare stabilization characteristics of two uniquely integrated ALIF spacer and plate designs versus established surgical interventions (ALIF supplemented with pedicle screws, anterior plate, or circumferential fixation), and (2) to evaluate the biomechanical impact of design differences between a three-screw integrated device and a commercially available four-screw integrated lumbar spacer. The authors hypothesized that (1) integrated spacers would provide stability comparable with that of an anterior plate construct or a posterior fixation construct, and (2) the three-screw design would provide fixation equivalent to the four-screw industry standard, despite the use of three rather than four interbody screws (Fig. 1).

Materials and Methods

1. Specimen preparation

Fourteen fresh human cadaveric lumbosacral spines (L3–S1) were used in this study (age, 65.4±4.6 years). All specimens were radiographed in both anteroposterior and lateral planes to avoid specimens with gross pathology. Exclusion criteria included spinal trauma, malignancy, deformity, and fractures that would otherwise affect kinematics of the lumbosacral region. Specimens were carefully denuded of paravertebral musculature, while spinal ligaments, joints, and disc spaces were preserved. Spines were potted at the cranial-most and caudal-most vertebrae—L3 and S1, respectively—in a 1:1 mixture of auto body filler (Bondo, Bondo/MarHyde Corp., Atlanta, GA, USA) and fiberglass resin (Home Solutions All Purpose, Bondo/MarHyde Corp.). After they had been dissected and prepared, specimens were double-wrapped in plastic bags and stored at –20°C. Saline (0.9%) was used throughout testing to preserve the viscoelastic properties of the spine to prevent desiccation.

2. Surgical constructs

Fourteen spines were divided randomly into two equal groups (n=7) and were instrumented at L4–L5. Tested implants included an anterior interbody spacer, 6.5-mm-diameter titanium (Ti) polyaxial posterior screws and 5.5-mm-diameter Ti rods (Revere, Globus Medical, Inc., Audubon, PA, USA), and an anterior plate (Citadel, Globus Medical, Inc.). Integrated stand-alone PEEK spacers tested included a zero-profile, box-shaped PEEK spacer with integrated plate and three 5.5-mm-diameter interbody screws (two at L4 and 1 at L5, between 30 mm and 40 mm long, shown in Fig. 1; Independence, Globus Medical, Inc.), and a commercially available spacer-plate system (SynFix-LR, DePuy Synthes) with four 4-mm-diameter diverging interbody screws (two at L4 and two at L5; 30 mm in length). All implants were inserted by a trained surgeon and by laboratory personnel. Both integrated devices have been approved by the Food and Drug Administration and are currently available on the market.

The present study aimed to compare a three-screw integrated spacer versus traditional techniques used to remedy DDD, including a four-screw PEEK spacer and an integrated plate (currently available on the market). In each group, the following constructs were tested: (1) intact; (2) after discectomy (injured); (3) PEEK interbody spacer

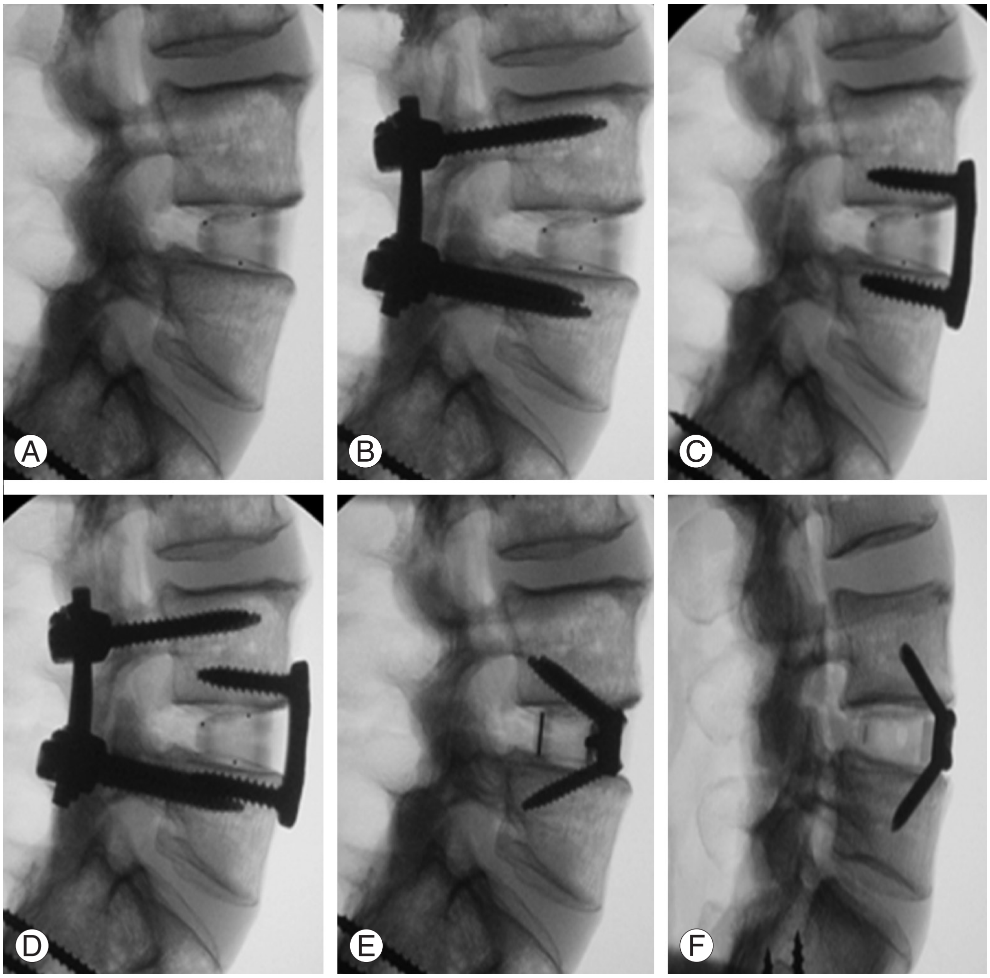

Fig. 2. Radiographs show the following. **(A)** Interbody spacer. **(B)** Bilateral pedicle screws with spacer. **(C)** Anterior plate with spacer. **(D)** Spacer and anterior lumbar plate supplemented with bilateral pedicle screws. **(E)** Integrated three-screw anterior lumbar interbody fusion (ALIF) (SA3s). **(F)** Integrated four-screw ALIF (SA4s).

alone (S); (4) anterior lumbar plate and spacer (AP+S); (5) bilateral pedicle screws and spacer (BPS+S); (6) circumferential fixation with spacer and anterior lumbar plate supplemented with bilateral pedicle screws (BPS+AP+S); and (7) three-screw (SA3s) or four-screw (SA4s) integrated spacers (in groups 1 and 2, respectively). Sagittal radiographic images of tested constructs are shown in Fig. 2.

Integrated spacers were tested in separate groups to prevent compromise of integrated screw trajectories. While intact and injured conditions were tested sequentially due to the destructive nature of the discectomy, the order of testing was randomly assigned to reduce the bias of the testing sequence. Implant footprints and heights were properly sized per specimen, and implantation was carried out as recommended by respective technique manuals.

3. Biomechanical testing

Each specimen was thawed overnight and was affixed to a six-degrees-of-freedom spine simulator. All constructs were tested in flexion-extension (FE), lateral bending (LB), and axial rotation (AR) for three cycles, with a continuous, pure-moment load of ±7.5 Nm applied to the L3 vertebra at a rate of 1.5°/sec [17]. Because of the viscoelastic properties of the spine, each loading mode was performed for a total of three load/unload cycles; the first two cycles were used to precondition the specimen, and data analysis was performed on the third cycle only. Plexiglass markers, each with three infrared light-emitting diodes, were secured to vertebral bodies both superior and inferior to the spacer, via bone screws, to track motion with the Optotrak Certus (Northern Digital Inc., Waterloo, ON, Canada) motion analysis system. Markers (denoting a rigid body) were aligned approximately sagittally along the curvature of the spine. The Optotrak Certus software superimposed the coordinate systems of two adjacent vertebral bodies to inferentially determine relative Eulerian rotations in each of the three planes, with accuracy of 0.1 mm and resolution of 0.01 mm [18].

4. Statistical methods

SPSS software (ver. 24.0, IBM Corp., Armonk, NY, USA) was used for all statistical analyses. Data analysis was carried out on relative motion at L4–L5 and was normalized to the average mean of intact. One-way analysis of variance with repeated measures and Bonferroni post hoc analysis were performed to assess differences in stability between all constructs within each group (significance found at $p \leq 0.05$). Additionally, an independent *t*-test was performed to elucidate differences between integrated ALIF designs (significance found at $p \leq 0.05$).

Results

A summary of biomechanical results is shown in Table 1 and in Figs. 3–5. All percentage data are reported as percentage of mean intact motion.

1. Group 1: traditional fixation versus three-screw integrated spacer and plate (SA3s)

The average age of cadaveric specimens in group 1 was 67.0±1.2 years of age (6 male, 1 female). Range of motion (ROM) was normalized to intact for all constructs tested in group 1 (SA3s); significant differences are shown in Table 1 and Fig. 3. All instrumented constructs significantly reduced ROM compared with intact ($p \leq 0.05$), as well as injury in all loading modes, except for the interbody spacer-alone (S) construct in FE and AR. When compared

Table 1. Normalized range of motion for all constructs in all loading modes with integrated three-screw ALIF (SA3s), %

Modes	Intact	Injured	S	BPS+S	AP+S	BPS+AP+S	SA3s
FE	100±18	164±26	89±21	17±10	40±20	7±6	24±15
LB	100±8	147±24	69±16	14±5	46±11	11±3	26±18
AR	100±27	196±61	116±77	39±20	45±25	21±16	42±22

Values are presented as mean±standard deviation.

ALIF, anterior lumbar interbody fusion; S, interbody spacer alone; BPS+S, bilateral pedicle screws and spacer; AP+S, anterior lumbar plate and spacer; BPS+AP+S, spacer and anterior lumbar plate supplemented with bilateral pedicle screws; SA3s, three-screw integrated interbody fusion; FE, flexion-extension; LB, lateral bending; AR, axial rotation.

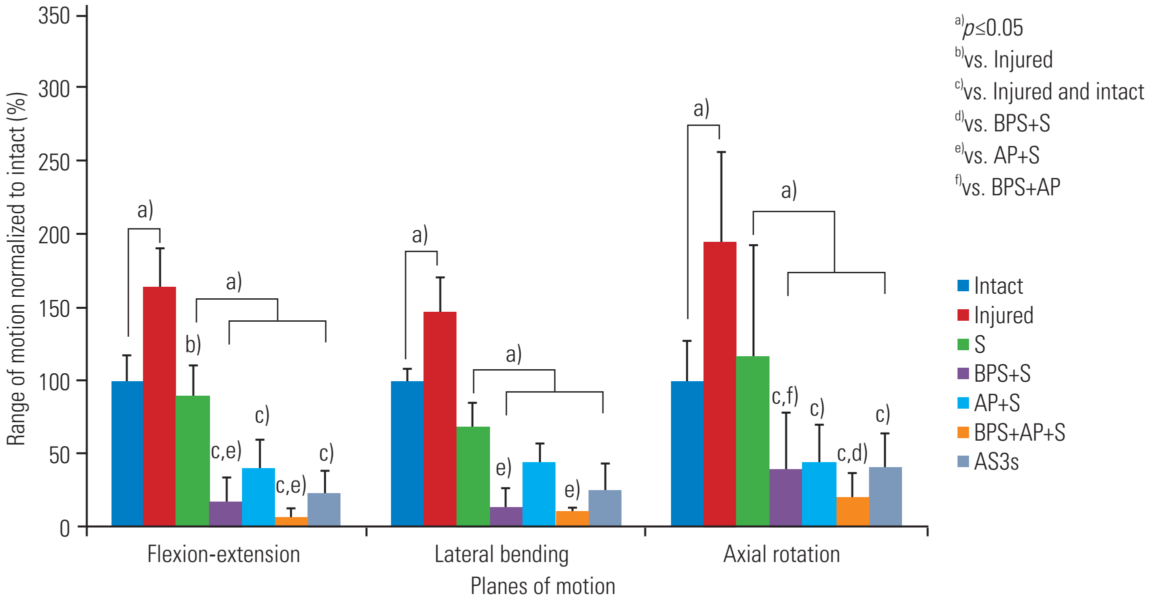

Fig. 3. Range of motion at L4–L5 for integrated three-screw anterior lumbar interbody fusion (SA3s) compared with traditional fixation. S, interbody spacer alone; BPS+S, bilateral pedicle screws and spacer; AP+S, anterior lumbar plate and spacer; BPS+AP+S, circumferential fixation with spacer and anterior lumbar plate supplemented with bilateral pedicle screws.

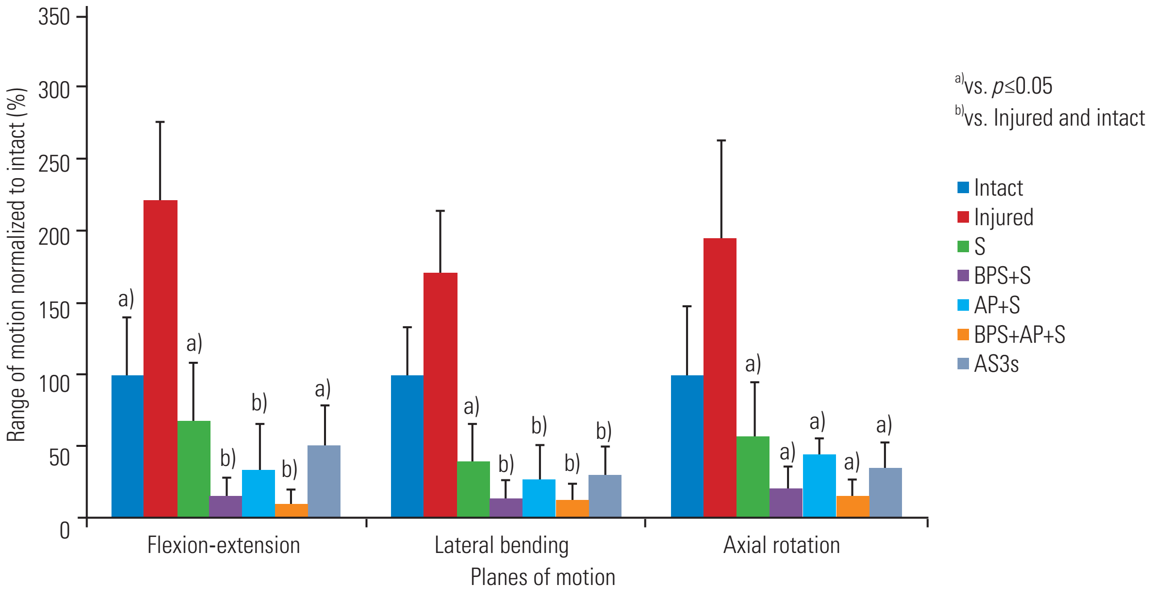

Fig. 4. Range of motion at L4–L5 for integrated four-screw anterior lumbar interbody fusion (SA4s) compared with traditional fixation. S, interbody spacer alone; BPS+S, bilateral pedicle screws and spacer; AP+S, anterior lumbar plate and spacer; BPS+AP+S, circumferential fixation with spacer and anterior lumbar plate supplemented with bilateral pedicle screws.

with the interbody spacer-alone construct, all surgical constructs significantly reduced ROM in FE, LB, and AR ($p\leq 0.05$). During FE and LB, BPS+S (17% and 14%), and BPS+AP+S (7% and 11%) constructs significantly reduced ROM compared with AP+S (40% and 46%) ($p\leq 0.05$). Bilateral pedicle screws in combination with an anterior plate and spacer (BPS+AP+S) provided the most rigid fixation in FE, LB, and AR (7%, 11%, and 21%, respectively). In all planes of motion, no statistically significant differences were found between BPS+AP+S and SA3s (24%, 26%, and 42%, respectively) ($p\geq 0.05$).

2. Group 2: traditional fixation versus four-screw integrated spacer and plate (SA4s)

The average age of cadaveric specimens in Group 2 was

Table 2. Normalized range of motion for all constructs in all loading modes with integrated four-screw ALIF (SA4s), %

Modes	Intact	Injured	S	BPS+S	AP+S	BPS+AP+S	SA4s
FE	100±41	221±56	69±39	15±14	35±32	10±11	50±29
LB	100±33	171±42	40±26	14±12	28±23	12±11	30±19
AR	100±48	195±67	37±37	21±15	32±24	16±12	35±19

Values are presented as mean±standard deviation.
ALIF, anterior lumbar interbody fusion; SA4s, four-screw integrated interbody fusion; S, interbody spacer alone; BPS+S, bilateral pedicle screws and spacer; AP+S, anterior lumbar plate and spacer; BPS+AP+S, spacer and anterior lumbar plate supplemented with bilateral pedicle screws; FE, flexion-extension; LB, lateral bending; AR, axial rotation.

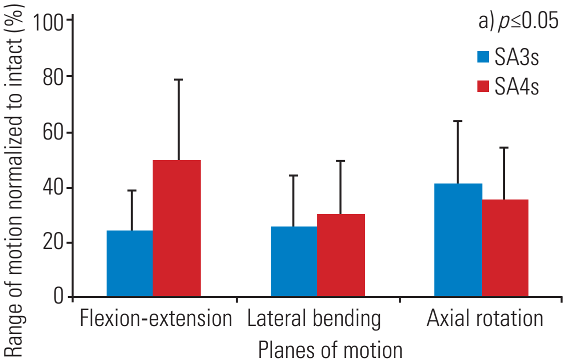

Fig. 5. Range of motion at L4–L5 for polyether-ether-ketone spacers for integrated three-screw anterior lumbar interbody fusion (ALIF) (SA3s) and integrated four-screw ALIF (SA4s). No significant differences were found ($p \geq 0.05$).

63.7±6.1 years of age (5 male, 2 female). Range of motion was normalized to intact for all constructs tested in group 2 (SA4s); significant differences are shown in Table 2 and Fig. 4. Overall, trends closely followed those seen in group 1; however, no statistically significant differences were found in the comparison between all instrumented constructs requiring fixation ($p \geq 0.05$). In FE, investigators noted that BPS+S, AP+S, and BPS+AP+S significantly reduced motion relative to both intact and injured states ($p \leq 0.05$), whereas S and SA4s significantly reduced motion relative to the injured state only ($p \leq 0.05$). In LB, researchers observed that BPS+S, AP+S, BPS+AP+S, and SA4s significantly reduced motion relative to both intact and injured states ($p \leq 0.05$), and the spacer alone significantly reduced motion relative only to the injured state ($p \leq 0.05$). Last, in AR, all instrumented constructs significantly reduced motion relative to the injured state ($p \leq 0.05$) but not to intact. Similar to the SA3s group, bilateral pedicle screws coupled with anterior plate and spacer (BPS+AP+S) provided the most rigid fixation in FE, LB, and AR (10%, 12%, and 16%). In all planes of motion, no statistically significant differences were found between BPS+AP+S and SA3s (50%, 30%, and 35%) ($p \geq 0.05$).

3. Integrated spacer device comparisons

Motion in all three planes normalized to intact per group is shown in Fig. 5. No statistically significant difference was found in all planes of motion ($p \geq 0.05$). Still, in FE, SA3s reduced intact motion to 24.3%—for twice as much fixation as SA4s (50.1%) ($p=0.057$). Furthermore, during LB, SA3s reduced intact motion to 25.8% and SA4s reduced motion to 30.4% ($p=0.651$). However, SA4s provided the greatest stability in AR (35.2% vs. 41.7%) ($p=0.323$).

Discussion

In the event that conservative management fails, lumbar discectomy with fusion is an established surgical procedure that can be used to alleviate chronic pain associated with DDD through removal of the symptomatic disc and restoration of foraminal height [2-7]. Nonetheless, the optimal surgical intervention remains controversial.

The anterior approach is advantageous for complete discectomy and endplate preparation, yet a fixation method is required to prevent spacer migration while bony growth between vertebrae is promoted [2,8]. Conversely, the ALIF approach is also associated with some noted disadvantages which include injury to the great vessels and to the presacral plexus resulting in retrograde ejaculation and sterility [19-21]; furthermore, anatomic variance of the iliac vessels may contribute to intraoperative complications [22,23]. In response, zero-profile integrated ALIF spacers with integrated screws have been developed to minimize surgical morbidity while providing sufficient stability (in spite of removal of the anterior tension band) to achieve fusion reliably [24,25].

Few studies have investigated biomechanical differences between the aforementioned anterior techniques, and a variety of results have been reported [12,14,26]. The earliest cadaveric study assessed the stabilizing characteristics of single femoral ring allografts with two integrated crossed anterior screws [26]. Kuzhupilly et al. [26] found that although anterior fixation significantly reduced FE compared with intact, it did not provide sufficient stability in LB nor in AR 21. Recent designs aim to improve lateral and axial stability by increasing the number of interbody screws. Both Cain et al. [12] and Kornblum et al. [14] investigated the stabilizing effects of four anterior interbody screws in integrated devices. Although Cain et al. [12] reported no statistically significant differences between SA4s and BPS+S ($p \geq 0.05$), Kornblum et al. [14] found significantly increased fixation with BPS+S compared with SA4s in both FE and LB ($p \leq 0.05$).

To address conflicting reports, investigators in the present study sought to compare two unique, commercially available integrated ALIF devices versus traditional surgical techniques that incorporate an anterior interbody spacer. In all planes of motion, circumferential fixation (with spacer and anterior lumbar plate supplemented with bilateral pedicle screws BPS+AP+S) provided the greatest stability, followed by BPS+S, three-screw and four-screw integrated interbody spacers (SA3s and SA4s), and AP+S. Broad trends among constructs for each motion plane were observed across both groups. Trends in ROM reported here are consistent with the findings of Kornblum et al. [14], although statistically significant differences between types of instrumentation were not found in the present study. Results from both groups suggest biomechanical equivalency between tested integrated devices and ALIF constructs supplemented with posterior instrumentation.

To the authors' knowledge, only one study to date has compared differing integrated ALIF spacer designs. Schleicher et al. [16] used a cadaveric model to compare the stability of two integrated ALIF designs—(1) SynFix-LR, a biconvex box-shaped PEEK spacer with a threaded integrated titanium plate and four duel-stacked diverging screws, and (2) Stalif, a semicircular wedge-shaped PEEK-only spacer with four alternating converging screws—and load distributions through a finite element model [16]. Researchers found that SynFix-LR designed with four diverging interbody screws marginally improved stability in FE and AR and significantly reduced LB motion compared with Stalif. Finite element evaluated stress profiles of SynFix-LR during flexion loading revealed that the PEEK spacer withstands nearly all stress, which is quickly transferred to the interbody screw and the plate-screw junction during extension. Overall results highlight the biomechanical impact of nuanced design differences between integrated spacers and plate implants.

As a result of the paucity of cadaveric biomechanical literature on this subject, investigators in the present study sought to biomechanically validate a new three-screw integrated design through comparison with the four-screw integrated spacer tested in previous studies. Although significant differences between SA3s and SA4s were not found, the SA3s construct was noted to increase achieved fixation by 51.5% during FE and by 15.1% during LB compared with SA4s. Conversely, additional vertebral body fixation and the medial screw trajectory in the SA4s construct improved stability in AR by 15.6% compared with the SA3s design. These results directly conflict with those of previous comparisons described in the literature, whereby a three-screw construct was simulated through removal of one of the superior interbody screws of a four-screw design [14]. This resulted in a marginal decrease in stability in the three-screw operational construct, possibly caused by asymmetry between alternating, converging screws that was not observed with the three-screw design used in this study.

Integrated ALIF spacers tested in the present study have several important differences that may affect their stability, most notably, interbody screw trajectory and diameter. As was mentioned previously, the SA4s design features a biconvex box-shaped PEEK spacer with an integrated plate and four dual-stacked diverging screws. The pair of stacked interbody screws angulates 42° cephalad-caudally and 15° laterally. When placed at the center of the disc, the trajectories of the screws are directed at the lateral corners of the cortical shell. According to the screw trajectory and the number of screws used, the SA4s device can accommodate 4.0-mm-diameter screws up to 30 mm in length. Screw trajectories of the SA3s design are shallower, with 35° cephalad-caudal and 12° lateral divergent screw trajectories. As the superior level utilizes one screw, lateral divergence correlates only with the inferior level. The shallow trajectory angle directs the interbody screw toward the posterior cortical shell, accommodating a longer screw (up to 40 mm in length). Additionally, using fewer screws allows use of larger 5.5-mm-diameter interbody screws.

Although these design considerations did not lead to statistically significant differences in rigidity, larger screw diameter with shallower trajectory enabling use of longer screws tends to improve fixation during FE and marginally during LB. Alternatively, use of four interbody screws diverging into the lateral cortical shell slightly improves stability during AR compared with the single superior interbody three-screw design. Biomechanical data presented here suggest that the combination of larger-diameter interbody screws and a shallow trajectory projecting through the entirety of the vertebral body obviates the requirement for a fourth screw. This study had several limitations. For financial and practical reasons, the sample size was limited to seven spines per group. Data were normalized to intact to minimize variability due to anatomic differences in cadaveric tissue. Each spine was used to sequentially test multiple constructs. The potential of anterior plate screws intersecting with existing screw trajectories of the integrated spacer construct (and vice versa) existed and could affect the biomechanical stability provided by either construct; however, fluoroscopy was used during insertion of all instrumentation to avoid previous screw paths and a randomized testing protocol was implemented to minimize the effect of intersecting trajectories, if it were to occur. Biomechanical data do not reflect the fact that patient factors such as overall health and osseous fusion can affect the performance of implants. An inherent limitation of all cadaveric biomechanic studies, data reported are pertinent to only results immediately following surgery and cannot account for patient factors such as bone healing and contributions of the fusion mass; furthermore, body weight and muscle forces were not replicated. Therefore, it is difficult to assess the long-term stability of the various constructs; such an assessment will be needed to further differentiate implant devices.

Conclusions

Cadaveric biomechanical investigation found circumferential fusion with bilateral pedicle screws, anterior spacer, and anterior plate provided the greatest stability, but additional benefits were not significant when compared with both three-screw and four-screw integrated spacer designs. Comparison of commercially available three-screw and four-screw integrated ALIF spacers revealed no significant differences, but the longer, larger-diameter interbody spacer with three-screw design increased stabilization in FE and lateral bending, and the diverging four-screw design showed marginal improvement during axial rotation. Long-term multicenter studies of the presented ALIF constructs are needed to determine clinically relevant differences between techniques.

Conflict of Interest

Travel fare and materials for the study were provided by Globus Medical, Inc. C.A.K. did not receive funds related to his participation in this study. C.A.K. has nothing to disclose. J.A.H., M.M.H., A.M., B.S.B., and S.K. are paid employees of Globus Medical, Inc.

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