Indirect decompression and vertebral body endplate strength after lateral interbody spacer impaction: cadaveric and foam-block models

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OBJECTIVE The lateral transpsoas approach to the lumbar spine is a well-defined procedure for the management of discogenic spinal pathology necessitating surgical intervention. Intervertebral device subsidence is a postoperative clinical risk that can lead to recurrence of symptomatic pathology and the need for surgical reintervention. The current study was designed to investigate static versus expandable lateral intervertebral spacers in indirect decompression for preserving vertebral body endplate strength.

METHODS Using a cadaveric biomechanical study and a foam-block vertebral body model, researchers compared vertebral body endplate strength and distraction potential. Fourteen lumbar motion segments (7 L2–3 and 7 L4–5 specimens) were distributed evenly between static and expandable spacer groups. In each specimen discectomy was followed by trialing and spacer impaction. Motion segments were axially sectioned through the disc, and a metal stamp was used to apply a compressive load to superior and inferior vertebral bodies to quantify endplate strength. A paired, 2-sample for means t-test was performed to determine statistically significant differences between groups (p ≤ 0.05). A foam-block endplate model was used to control simulated disc tension when a spacer with 2- and 3-mm desired distraction was inserted. One-way ANOVA and a post hoc Student Newman-Keuls test were performed (p ≤ 0.05) to determine differences in distraction.

RESULTS Both static and expandable spacers restored intact neural foramen and disc heights after device implantation (p > 0.05). Maximum peak loads at endplate failure for static and expandable spacers were 1764 N (± 966 N) and 2284 N (± 949 N), respectively (p ≤ 0.05). The expandable spacer consistently produced greater desired distraction than was created by the static spacer in the foam-block model (p ≤ 0.05). Distraction created by fully expanding the spacer was significantly greater than the predetermined goals of 2 mm and 3 mm (p ≤ 0.05).

CONCLUSIONS The current investigation shows that increased trialing required for a static spacer may lead to additional iatrogenic endplate damage, resulting in less distraction and increased propensity for postoperative implant subsidence secondary to endplate disruption.

http://thejns.org/doi/abs/10.3171/2015.10.SPINE15450

KEY WORDS endplate strength; subsidence; lateral interbody spacers; iatrogenic trauma; neural foramen height; disc height; distraction

L UMBAR interbody arthrodesis is a commonly used surgical procedure that provides clinical advantages in restoring segmental rigidity, increasing intervertebral disc space height, and improving sagittal plane alignment.[1,16,19] The process of interbody spacer trialing and impaction may induce iatrogenic endplate damage and potential complications. Expandable interbody spacers developed for lateral and posterior approaches offer controlled height restoration, minimal impaction during insertion, and less trialing, compared with static spacers. The lateral transpsoas surgical approach confers definitive advantages over traditional posterior or transforaminal lumbar interbody procedures by increasing the available area for bone graft, preserving pertinent ligamentous structures, and making surgical access less disruptive.[7] Both lateral and posterior reconstruction techniques can be augmented with transpedicular screw and rod fixation for additional segmental stability.

Interbody spacer subsidence is a clinical complication that can lead to loss of indirect neural foraminal decompression and recurrence of symptoms.[4,6,7,11] Evidence suggests that spacer design may prevent subsidence that occurs iatrogenically or postoperatively through natural biological responses and endplate contact.[5,17]

In a retrospective study of 104 patients undergoing transforaminal lumbar interbody spinal arthrodesis, a 14.8% incidence of cage subsidence (18 of 112 spacers) was reported.[6] Although a larger spacer provides benefit, subsidence remains a clinical concern when a lateral approach is used. In a retrospective review of 140 patients who underwent lateral interbody fusion, Le et al. found that 14.1% (19 of 135) of the 18 mm–wide spacer group showed evidence of radiographic subsidence, while only 1.9% subsidence (2 of 103) was seen in the 22 mm–wide implant group.[7] These findings were corroborated by other clinical publications concluding that interbody spacers with larger surface area reduce the risk of implant subsidence.[13] Furthermore, Marchi et al. found evidence of subsidence in 42% (41 of 98) of stand-alone instrumented lumbar levels using a subsidence classification scale. The lateral technique has also been used to surgically manage low-grade degenerative spondylolisthesis, with favorable results.[12]

It remains unclear whether implant subsidence occurs as a result of intraoperative trialing and spacer impaction, or secondary to postoperative ambulation and restoration of normal activities. An expandable spacer can potentially reduce the amount of iatrogenic morbidity caused by trialing and impaction, while achieving height restoration goals. No in vitro biomechanical studies have investigated the extent of indirect decompression or the level of endplate strength after insertion of static versus expandable interbody spacers.

The primary objective of this study was to determine whether implant trialing and impaction of a static lateral spacer, CoRoent (NuVasive Inc.), can result in reduced endplate strength compared with that achieved by insertion of an expandable lateral spacer, CALIBER-L (Globus Medical, Inc.). Using an in vitro cadaveric model, investigators quantified neural foraminal height, disc height, spacer surface-area coverage, and vertebral endplate strength, and compared these measurements when instrumented with static versus expandable spacers.

Methods

Cadaveric Model

Specimen Preparation

A total of 14 lumbar motion segments from 7 cadaveric specimens (L2–3, n = 7; L4–5, n = 7) were used in this study (average age 64 ± 7 years; 4 men, 3 women). Motion segments from the same specimen were divided into 2 groups to control for similar bone quality. Anteroposterior and lateral plain radiographs were taken to confirm lack of major degeneration or other significant osseous pathology. Dual-energy x-ray absorptiometry (DEXA) scans were obtained to quantify differences in bone quality between groups using a Discovery DXA System (Hologic). Specimens were stored in double plastic bags at –20°C before biomechanical testing. Spines were dissected by carefully

denuding the paravertebral musculature while avoiding disruption of pertinent osteoligamentous structures and the intervertebral disc. Each motion segment was potted in a 3:1 mixture of Bondo Auto Body Filler and fiberglass resin (Bondo/MarHyde Corp.) and was copiously moistened throughout the testing period using 0.9% saline in an attempt to preserve its viscoelastic properties. Intact disc height varied and motion segments were randomly assigned between groups.

Surgical Technique

A custom-built fixture was used to apply a 240-N compressive axial load to the operative vertebral motion segment to replicate the in vivo intraoperative axial load in the lateral position, as documented in a previous investigation (Fig. 1).[15] A lateral radiograph of the intact specimen was obtained, and the intervertebral disc height at the center of the vertebra was measured to determine spacer height.

The anatomical left lateral anulus was excised with a No. 10 blade scalpel and a rongeur to create an anular window of approximately 18 mm. A pituitary rongeur was used to perform a complete nucleotomy, which was followed by insertion of a Cobb elevator to penetrate the contralateral anulus. A ring curette was used to remove cartilaginous layers and excess intervertebral disc material from the vertebral endplates. A postdiscectomy lateral radiograph was obtained. When spacers were inserted, the height of the implant was selected to restore intervertebral disc height to the intact condition after the discectomy. For the static group, trials starting at 5 mm were inserted at 1-mm increments until the desired height was achieved; this was followed by impaction of the spacer. For the expandable group, trials starting at 5 mm were inserted at 1-mm increments until the smallest starting-height expandable spacer that was capable of restoring the desired intervertebral disc height could be inserted. The spacer was then inserted in a collapsed position and was expanded by counting the num-
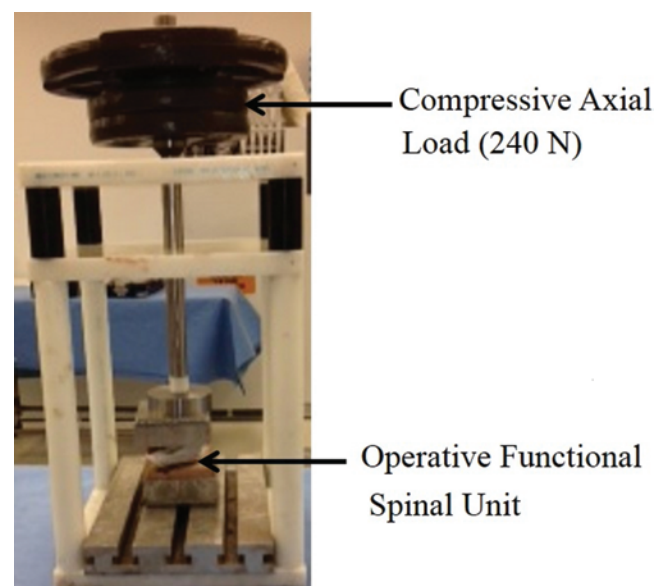

FIG. 1. Lateral view of the operative motion segment with 240 N of compressive axial load. Figure is available in color online only.

ber of setscrew revolutions to the intact disc height, which was confirmed radiographically. Figure 2 shows the algorithm used for spacer implantation.

Endplate Strength Testing

After inserting the final spacer, investigators used a scalpel to section the anulus and operative motion segment ligamentous structures. They removed the implants, leaving superior and inferior vertebral endplates exposed. This resulted in a sample size of 14 endplates per group. A metal stamp with the same geometric footprint as the interbody spacers (18 mm wide, 60 mm long) was used to apply an axial load to superior and inferior endplates at a rate of 5 mm/min to displacement of 3 mm, and the MTS 858 Mini Bionix (MTS Systems) test machine was used (Fig. 3). The stamp was not allowed to rotate.

Data Analysis

Researchers measured neural foraminal and sagittal plane midline disc heights using ImageJ software (US National Institutes of Health) with a rod of known length in the fluoroscopic image for calibration. Resolution was less than 0.1 mm. They calculated neural foramen and disc height restoration as postimplantation height minus discectomy height and quantified a straight line connecting inferior and superior pedicular landmarks of the foramen. Investigators calculated the percentage of vertebral body surface area covered by the spacers, using axial photographs of the sectioned vertebral bodies with a distance marker and ImageJ.

For the current study, subsidence was defined as 3 mm of endplate displacement.[10,14] Study authors used the force at 3 mm from the load displacement graphs to quantify the strength of the endplates, and when the endplate failed before 3 mm of displacement, they used maximum force. A paired 2-sample for means t-test was performed to determine statistically significant differences between groups ($p \leq 0.05$).
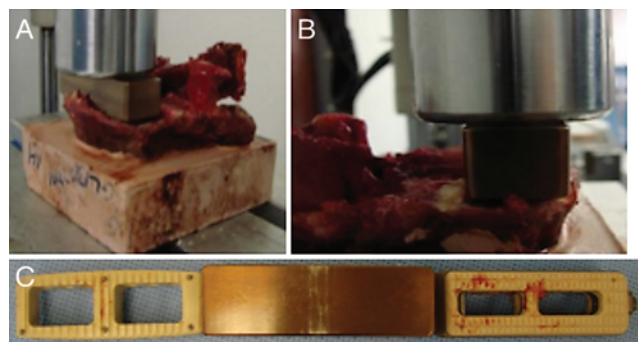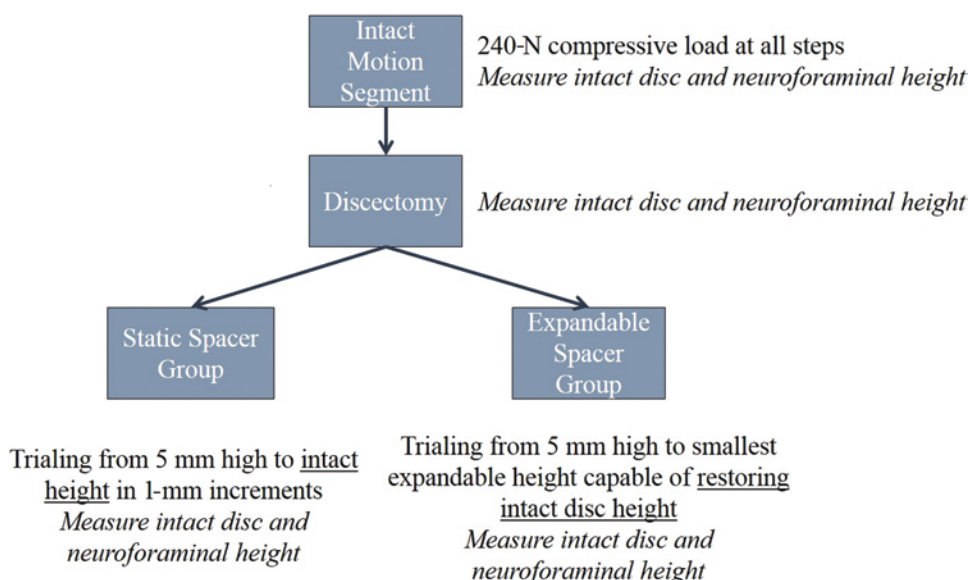

FIG. 3. Compression testing images. Oblique (**A**) and lateral (**B**) views of compression testing. Metal stamp used for compression testing *(center)* with static spacer *(left)* and expandable spacer *(right)*. All spacers (**C**) have a width of 18 mm and were selected to span the apophyseal ring. Figure is available in color online only.
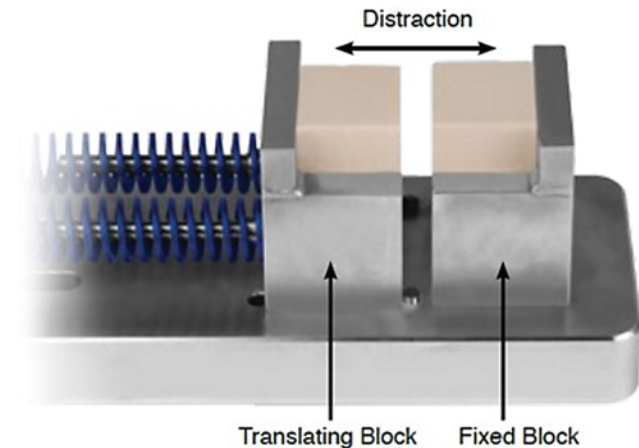
Foam-Block Model

Testing Setup

Two rectangular foam blocks (55 × 35 × 30 mm) were used to mimic vertebral bodies. The foam blocks consisted of a 2-mm outer layer of 40 pounds per cubic foot (PCF) foam bonded to soft 15 PCF foam (Sawbones Inc.) to model the cortical and cancellous bone of the vertebral body. Foam blocks are a commonly accepted model for human bone and are currently used to test implants for US Food and Drug Administration review.[2,3,9] One of the blocks was fixed; the other was allowed to translate with respect to the first block. A compressive load was applied by 2 springs, forcing the carriages toward one another and inhibiting distraction (Fig. 4).

Static spacers were impacted into the disc space between the 2 foam blocks to provide the desired distraction (Fig. 5). Expandable spacers were inserted into a gap equal to the spacer height and then were expanded to desired distraction.

Intact Motion Segment → 240-N compressive load at all steps *Measure intact disc and neuroforaminal height*

Discectomy *Measure intact disc and neuroforaminal height*

Static Spacer Group — Trialing from 5 mm high to <u>intact height</u> in 1-mm increments *Measure intact disc and neuroforaminal height*

Expandable Spacer Group — Trialing from 5 mm high to smallest expandable height capable of <u>restoring intact disc height</u> *Measure intact disc and neuroforaminal height*

FIG. 2. Algorithm used for interbody spacer trialing. Figure is available in color online only.

FIG. 4. Foam blocks seated in carriages of test fixture. The carriage on the *right* is fixed. Figure is available in color online only.

Impact Testing

Static and expandable interbody spacers were compared for intraoperative distraction. For all testing, a 10-mm high/18 × 55–mm static spacer and a 9- to 13-mm high/18 × 55–mm expandable spacer were used.

The goal for each test was to create 2 mm or 3 mm of distraction. For the static spacer, to create 2 mm of distraction, a 10-mm spacer was impacted into an 8-mm gap; to achieve 3 mm of distraction, a 10-mm spacer was impacted into a 7-mm gap. For the expandable spacer, a 9-mm spacer was inserted into a 9-mm gap and was expanded 2 mm or 3 mm to provide identical distraction. The magnitude of spacer distraction was determined by the number of setscrew revolutions. The expandable spacer was fully expanded between blocks. This procedure was repeated 5 times at 240 N resistance. After spacer insertion, the final distance between blocks was measured, and the distraction achieved was calculated by subtracting the starting height from the final height. Maximum expansion was achieved when the system limit of the expandable spacer was reached.

Distraction was calculated by subtracting initial block height from final block height. To determine statistical significance, 1-way ANOVA and a post hoc Student Newman-Keuls test were performed ($p \leq 0.05$).

Results

Cadaveric Model

Table 1 shows parameters measured during cadaveric testing. The mean (± SD) bone mineral density of the vertebral bodies used in static and expandable groups was 0.831 g/cm² (± 0.158 g/cm²) and 0.819 g/cm² (± 0.162 g/cm²), respectively, with no significant difference noted between groups ($p > 0.05$). Normalized neural foramen heights were 100.21% (± 5.12%) and 100.63% (± 5.34%) for static and expandable groups, respectively ($p > 0.05$). Mean normalized disc heights for static and expandable spacers were 95.43% (± 14.12%) and 107.03% (± 9.30%) of the intact disc heights, respectively ($p > 0.05$). Both static and expandable spacers successfully restored neural foramen height and disc height to the intact condition.
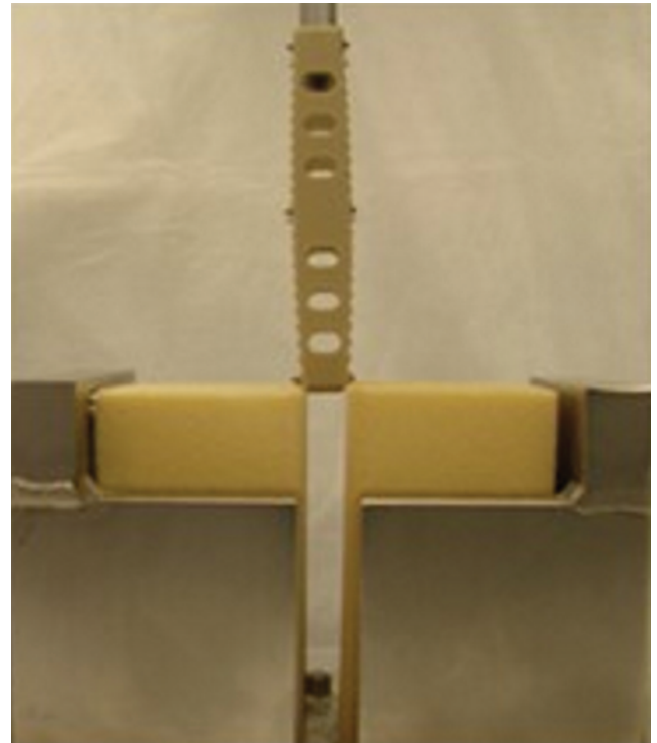
FIG. 5. Static spacer impacted into the disc space to provide distraction. Figure is available in color online only.

The mean percentage of surface area covered in static and expandable groups was 41.52% (± 1.97%) and 44.13% (± 3.32%), respectively ($p \leq 0.05$). In both groups, the mean final implant height was at least 10 mm.

The mean maximum load at endplate "subsidence" was 1764 N (± 966 N) and 2284 N (± 949 N) for static and expandable spacers. The specimen in the expandable group exhibited 30% greater endplate strength compared with endplates in the static group ($p \leq 0.05$).

Foam-Block Model

Figure 6 shows measured distraction for static and expandable spacer groups under 240 N of resistance at various desired distraction goals in the foam-block model. At 2 mm of desired distraction, static and expandable spacers provided means (± SD) of 1.11 mm (± 0.08 mm) and 1.57 mm (± 0.10 mm) of distraction, respectively ($p \leq 0.05$). The 3 mm desired distraction showed a similar trend, with means of 1.93 mm (± 0.04 mm) and 2.37 mm (± 0.11 mm) of distraction for static and expandable implants, respectively ($p \leq 0.05$). At maximum expansion, the expandable spacer provided a mean 3.24 mm (± 0.05 mm) of distraction. Distraction created by fully expanding the expandable spacer was significantly greater ($p \leq 0.05$) than that created by the static spacer and by 3 mm desired expandable spacer distraction.

Discussion

Summary of Study Objectives

Clinical use of interbody spinal arthrodesis techniques

TABLE 1. Summary of measured parameters during cadaveric testing*

Parameter	Static	Expandable	Difference	p Value†
BMD (g/cm^2)	0.831 ± 0.158	0.819 ± 0.162	0.012 ± 0.042	0.305
Neural foramen height (% intact)	100.21 ± 5.12	100.63 ± 5.34	0.42 ± 8.28	0.897
Disc height (% intact)	95.43 ± 14.12	107.03 ± 9.30	11.59 ± 20.59	0.187
% VB SA	41.52 ± 1.97	44.13 ± 3.32	2.61 ± 2.54	**0.002**
Endplate strength (N)	1764 ± 966	2284 ± 949	521 ± 871	**0.043**

BMD = bone mineral density; % VB SA = percentage of vertebral body surface area.
* Data are given as mean ± SD unless otherwise indicated.
† Boldface type indicates statistical significance.

is rapidly expanding. Intervertebral device subsidence is a postoperative clinical risk that can lead to recurrence of symptomatic pathology and the need for surgical reintervention. Appropriately choosing interbody implants and techniques may help control factors affecting subsidence. Expandable interbody devices are believed to induce minimal iatrogenic damage upon insertion, thereby preserving endplate integrity, minimizing the incidence of subsidence, and improving the chance that interbody spinal fusion will be successful. The current study was designed to determine cadaveric vertebral body endplate strength when instrumented with static and expandable spacers after the same distraction goals had been achieved. In a clinical scenario, the intervertebral disc would be degenerated and the surgical objective would be to attain height greater than prediscectomy height. Axial load during trialing mimicked degenerative disc height. To prevent oversizing of the spacers, prediscectomy height was used as the height restoration goal. Clinically, an expandable spacer may preserve the endplates better than a static spacer, as can be seen in the current in vitro setup.

Cadaveric Setup

Findings of the current investigation indicate that the static spacer requires additional trialing, which increases the likelihood that iatrogenic endplate trauma may create a trough along the vertebral body endplates. This observation was corroborated by endplate strength results of compression testing. In contrast, an expandable spacer can be inserted at a minimum height, reducing damage to the endplates, and can be expanded in situ to achieve the desired intervertebral height. The presence of a trough, which could occur during trialing of spacer impaction, could lead to loss of immediate indirect decompression. Furthermore, as a result of impaction damage to the endplate, the expandable group exhibited 30% greater endplate strength than was seen in the static group (p ≤ 0.05), which correlated with an increase of 520 N at the same displacement. The metal stamp allowed control of material differences between groups during compression testing. Specimens used in the expandable spacer group were slightly more osteoporotic as seen on DEXA scans but were not significantly different from specimens in the
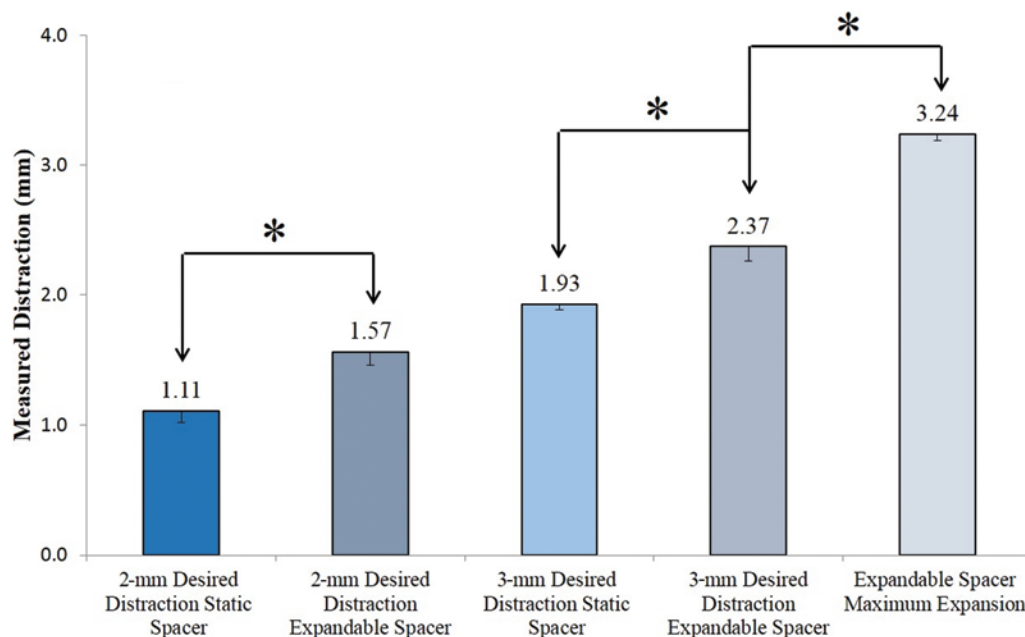

FIG. 6. Measured versus desired distraction of static and expandable spacers at 240-N resistance. *p ≤ 0.05. Figure is available in color online only.

static spacer group; therefore, specimen bone quality did not appear to influence the results.

Both static and expandable spacers were successful in restoring neural foramen and disc heights compared with intact values. Although the static spacer restored disc height to 95.43% of the intact value, no significant difference (p > 0.05) was noted when the static spacer was compared with the expandable spacer, which restored disc height to 107.03% of the intact value. The difference in restored height can be attributed to the fact that the static spacer caused physical damage to the inferior vertebral body. The expandable spacer group did cover a greater percentage of vertebral body surface area than was covered by the static spacer group. Although this finding achieved statistical significance (p ≤ 0.05), the difference of 2.61% is negligible and is not the principal variable in endplate strength.

Foam-Block Setup

The foam-block model was used to eliminate variability in bone quality while allowing focus on the effect of the distraction potential of the interbody spacer. After impaction of the static spacer, evidence showed damage to the foam blocks caused by spikes on either side of the spacer. This injury can potentially damage the cortical shell of the vertebral bodies, predisposing the motion segment to subsidence. The expandable spacer consistently resulted in significantly (p ≤ 0.05) greater desired distraction than was attained with the static spacer in the foam-block model. Although this is an intuitive result, the magnitude of the benefit was not previously identified. The foam-block results suggest that the expandable spacer allows for greater distraction than the static spacer, while preserving endplate integrity. In previous clinical studies, the extent of lumbar interbody spacer subsidence was reported to be as much as 1.35 mm and 1.05 mm for superior and inferior endplates, respectively.[8]

Clinical Relevance

The importance of endplate integrity is difficult to quantify clinically. Tohmen et al. compared radiographic implant subsidence and described a trend toward clinical outcomes that were inferior to those achieved with no radiographic subsidence.[18] Another potential source of endplate damage is the propagation of microtrauma to the endplate. Vertebral endplate trauma can potentially be exacerbated by multiple passes during implant trialing. To further preserve endplate integrity, a single expandable trial and implant may provide a viable alternative to conventional static implants by reducing the need for excessive trialing and minimizing propagation of iatrogenic endplate damage during implant insertion. Decreased postoperative endplate strength can be a contributing factor to implant subsidence and postoperative outcomes.

Conclusions

Both expandable and static spacers were capable of restoring neural foramen and disc heights to the intact condition. Furthermore, endplates in the expandable group were able to withstand an additional 520 N of compression at the same displacement. The increased trialing required for a static spacer may lead to additional iatrogenic endplate damage, which could result in less indirect decompression, predisposing the implant to subsidence at the operative level.

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Disclosures

Author Contributions

Conception and design: all authors. Acquisition of data: Moldavsky, Salloum. Analysis and interpretation of data: Moldavsky. Drafting the article: Moldavsky, Kwon, Hunter, Bucklen. Critically revising the article: Kwon, Hunter, Bucklen. Reviewed submitted version of manuscript: Moldavsky, Kwon, Hunter, Bucklen. Approved the final version of the manuscript on behalf of all authors: Moldavsky. Statistical analysis: Moldavsky, Bucklen. Administrative/technical/material support: Bucklen. Study supervision: Bucklen.

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