Lordosis Angle and Indirect Foraminal Decompression Following Interspinous Process Fixation with an Expandable Device

A Cadaveric Radiographic Analysis

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Abstract

Interspinous process (ISP) fixation devices are used in spinal constructs to allow for stabilization of the spinal segment and indirect decompression of the neural elements. A lordotic, expandable ISP implant may allow for better decompression than traditional non-lordotic ISP devices, given its ability to maximize spinous process distraction while maintaining optimal spinal alignment. The purpose of this study is to compare lordosis and indirect neuroforaminal decompression between a ratcheting ISP (ISP R), a static barrel ISP (ISP B), and AERIAL™ (Globus Medical, Inc., Audubon, PA, USA), an expandable ISP device (ISP EXP), used in conjunction with a lateral lumbar interbody fusion spacer (LS) and lateral plate (LP) construct.

Five L3-L4 spinal segments were instrumented with each ISP device in a randomized order. Micro-chromatography (microCT) scans were taken of each construct and the following parameters were analyzed: lordosis angle, anterior disc height, posterior disc height, interspinous process distance, neuroforaminal area, and neuroforaminal height. No significant change in lordosis was found for any treatment group ($p>0.05$). All three ISP constructs provided trending ($0.05\leq p<0.10$) or significant ($p<0.05$) increases in neuroforaminal decompression parameters relative to the injured condition. While no significant differences were seen between the three ISP groups in the decompression parameters tested, the ISP EXP group showed the largest increase in foraminal height and area in comparison to ISP R and ISP B, while maintaining lordosis angle.

Although statistical differences were not seen, the AERIAL™ expandable ISP device, when used in conjunction with a lateral spacer and lateral plate, achieved improvements in neuroforaminal height and area while maintaining the lordosis angle in the lumbar spine. An expandable ISP device such as AERIAL™ offers the added benefits of optimization to individual patient anatomy with minimum insertion height, which may improve surgeon workflow and by avoiding impaction, may reduce spinous process fracture risk in comparison to traditional ISP devices.

Introduction

A loss in flexibility, elasticity, and height of the intervertebral disc is a natural part of the aging process and is characterized as degenerative disc disease (DDD). DDD affects a majority of the population, and is often the precursor to more severe conditions such as the formation of osteophytes, spondylolisthesis, and spinal stenosis that can cause pain or numbness in the back or lower extremities [1, 2]. Spinal decompression and fusion are common surgical treatment options for these types of conditions to remove pressure on the involved neural elements and eliminate motion in the affected segment that may be causing pain.

ISP devices are used in spinal constructs to allow for both stabilization of the spinal segment, as well as indirect decompression of the neural elements [3]. It is believed that these devices help to unload the facet joints, restore foraminal height, and provide stability to ultimately improve clinical outcomes. More scientific research is needed to determine the capability of these devices to achieve indirect decompression.

Expandable interbody devices have been shown to offer numerous benefits over static devices in spinal decompression, endplate contact, fusion, and patient outcomes in a wide array of applications [4-6]. Expandable devices have been demonstrated to require less operating time, provide optimal fit, and allow for indirect decompression [4]. A lordotic, expandable ISP device may provide additional benefits than a traditional non-lordotic, static ISP device. A comparison study between expandable and static ISP devices has yet to be performed. The purpose of this study is to compare lordosis and indirect neuroforaminal decompression between a ratcheting ISP (ISP R), a static barrel ISP (ISP B), and an expandable ISP device (ISP EXP) such as AERIAL™ (Globus Medical, Inc., Audubon, PA, USA) used in conjunction with a lateral lumbar interbody fusion spacer (LS) and lateral plate (LP) construct.

Materials and Methods

Specimen Preparation

Five fresh-frozen human cadaveric L3-L4 spinal segments were utilized in this investigation. Specimens were radiographed in the anteroposterior and lateral planes to confirm the absence of fractures, deformities, degeneration, and other significant osseous pathologies. Paravertebral musculature was carefully denuded, avoiding disruption of pertinent osteoligamentous structures, joint capsules, and intervertebral discs. Bone mineral density (BMD) of the vertebrae was evaluated by dual-energy X-ray absorptiometry scans obtained from Lunar Prodigy Scanner 8743 (GE Medical Systems, Madison, WI, USA). All specimens were double-wrapped in plastic bags and stored at -20°C prior to biomechanical testing.

Surgical Constructs

All specimens underwent a lateral discectomy performed at L3-L4 followed by the insertion of a lateral static interbody spacer (TransContinental®, Globus Medical, Inc.) and a lateral plate [(PLYMOUTH®, Globus Medical, Inc.) (LS+LP)]. A lateral discectomy alone was used to mimic a degenerated spine and was considered the injured condition. Following the surgery, all specimens were instrumented with each ISP device in a randomized order, resulting in a final construct consisting of a lateral static cage with a lateral plate and an ISP device (LS+LP+ISP). Figure 1 shows the surgical constructs and the sequence of study procedures used to build the construct.

C-arm fluoroscopy was used throughout the technique to ensure consistent placement and sizing of implants across the specimens. When implanting the expandable ISP EXP, images were taken during expansion to verify that maximum expansion was achieved without compromising sagittal profile.

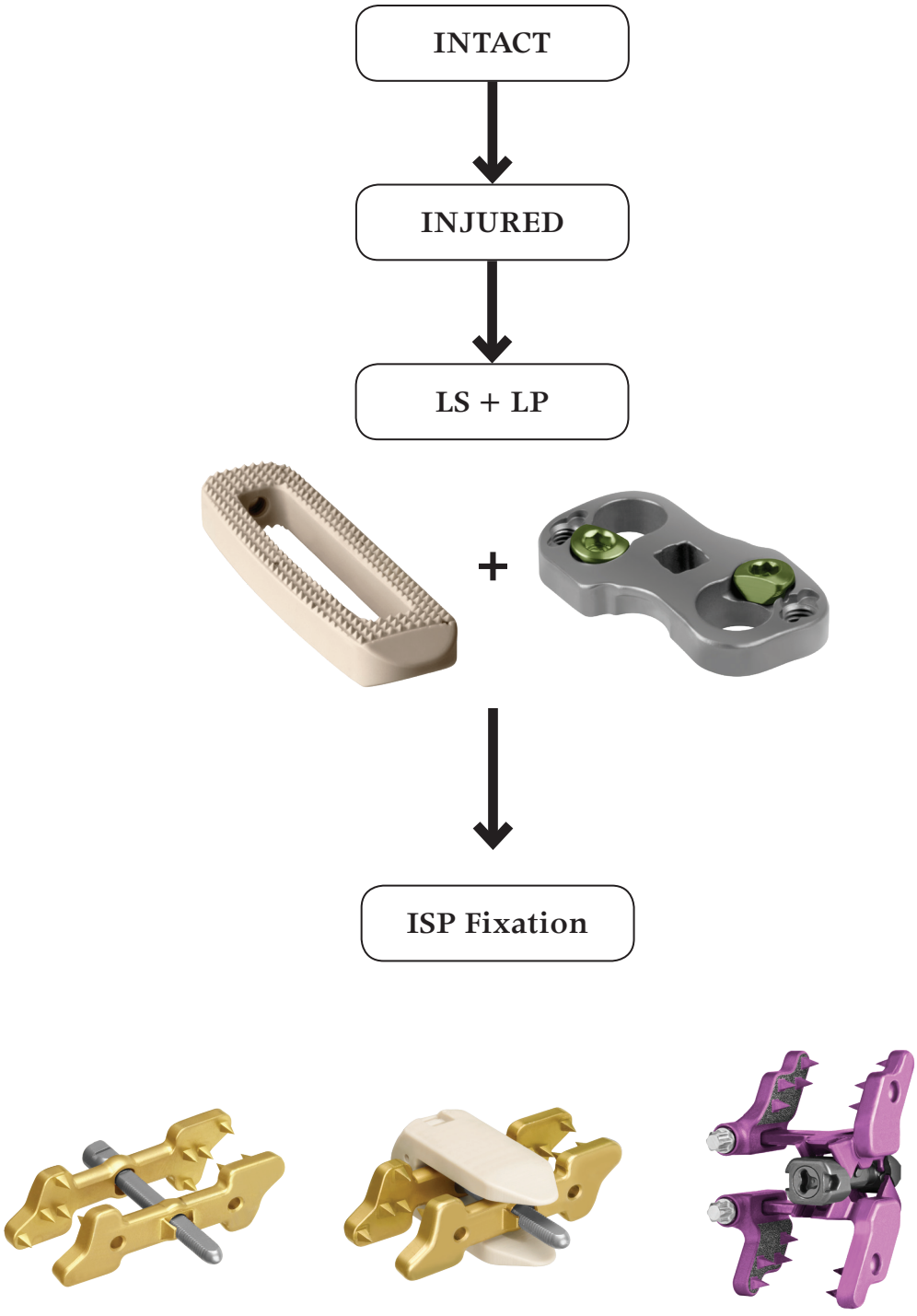


Figure 1: Sequence of building surgical constructs.
LS=lateral spacer, LP=lateral plate, ISP=interspinous process.

Radiographic Analysis

MicroCT images were taken of each specimen in the injured and instrumented conditions, and transferred to imaging software for analysis. Parameters of interest included lordosis of the lumbar motion segment (Fig. 2A), the distance between spinous processes (Fig. 2B), intervertebral height (Fig. 2B), and neuroforaminal area (Fig. 2C) at the treated level. The neuroforaminal area was recorded bilaterally in the sagittal plane where neuroforaminal height was the largest and clear bone borders were visible. All other measurements were taken in the mid-sagittal plane.

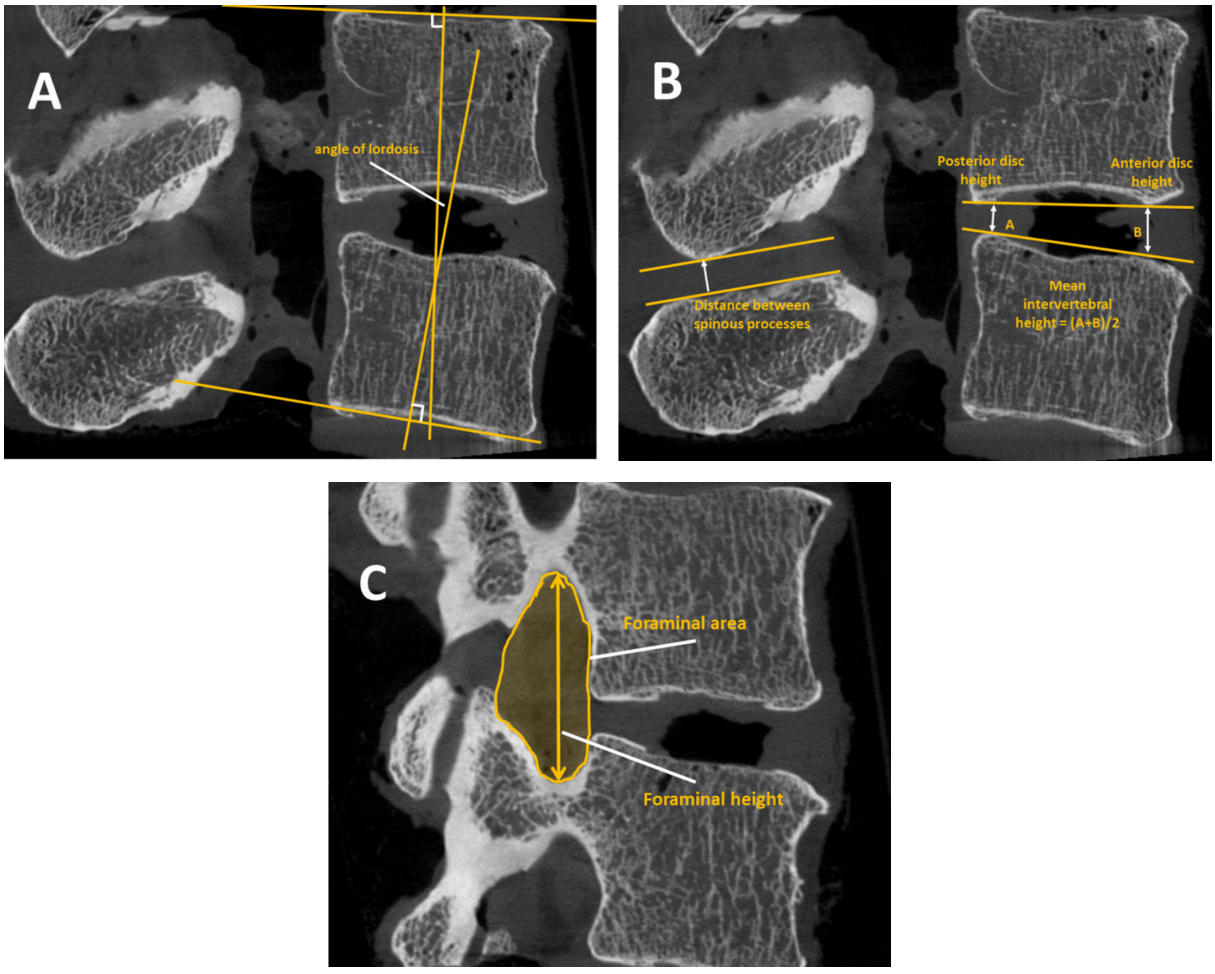


Figure 2: Measurements of interest included: (A) segmental lordosis of the lumbar motion segment, (B), distance between spinous processes, anterior and posterior intervertebral disc height, (C) neuroforaminal area, and height at the treated level. A and B views are mid-sagittal. C view is parasagittal at the largest neuroforaminal height.

Statistical Analysis

Statistical analyses were performed with MATLAB R2017b, Statistics and Machine Learning Toolbox™ (MathWorks, Inc., Natick, MA, USA). One-way analysis of variance with repeated measures was performed to assess within- and between-group differences in the outcome variables of interest between surgical constructs. Statistical significance was indicated at $p<0.05$, and trending parameters were indicated at $0.05<p<0.10$.

Results

Imaging analysis was conducted on microCT images of each surgical construct (injured, LS+LP+ISP R, LS+LP+ISP B, LS+LP+ISP EXP) for five specimens (BMD: -0.8±1.6).

Table 1 shows the percentage change in decompression parameters from the injured condition to the given construct. Trending ($0.05<p<0.10$) or significant ($p<0.05$) increases were observed in all decompression parameters when using the ISP devices in conjunction with a lateral spacer and a lateral plate, relative to the injured condition.

Radiographic Decompression Parameter Results			
	ISP R	**ISP B**	**ISP EXP**
Parameter	**% Change from Injured Condition**		
Anterior Disc Height	10.2±7.6*	11.8±4.0*	10.8±3.7*
Posterior Disc Height	36.0±10.8*	38.3±9.4*	41.3±13.9*
Neuroforaminal Area	16.2±8.6*	18.0±9.3*	19.2±11.1*
Neuroforaminal Height	9.1±5.2*	9.4±6.0*	10.4±4.4*
Spinous Process Distance	86.1±64.0*	94.0±38.8*	118.9±51.7*
Lordosis	-6.6±13.6	1.6±11.1	-12.9±21.9

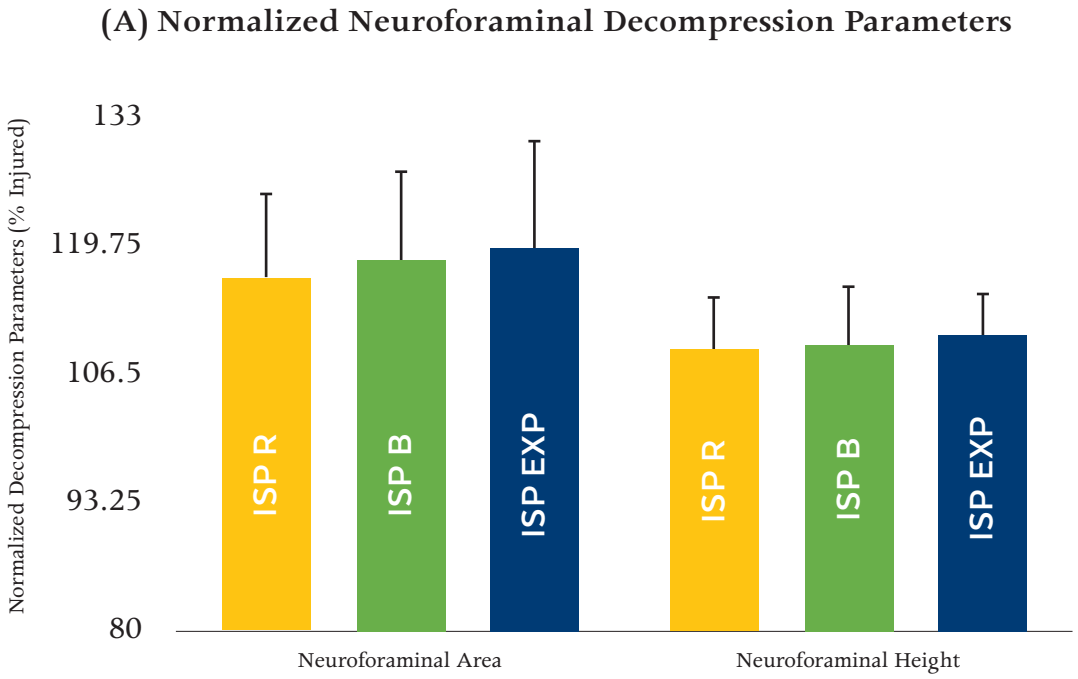
Table 1: Radiographic decompression parameter results. Results are expressed as the percentage change from the injured condition. *Indicates a significant difference ($p<0.05$) from the injured condition.

The expandable interspinous device used in conjunction with a lateral spacer and lateral plate led to the largest average percent increase in posterior disc height, neuroforaminal height, neuroforaminal area, and distance between the spinous processes. Additionally, the amount of decompression for each construct, normalized to injured, for the primary decompression variables is shown in Figure 3. All disc height and neuroforaminal decompression parameters were significantly increased from the injured condition ($p<0.05$). The expandable ISP device had the largest average increase in neuroforaminal height, neuroforaminal area, and posterior disc height (10.4%, 19.2%, and 41.3% increased from injured, respectively).

Discussion

This study investigated three different types of ISP devices used in conjunction with a lateral spacer and lateral plate following a lateral discectomy, and examined their effect on lordosis and indirect decompression. A significant increase in disc height, as well as in neuroforaminal height and area, were observed for all three ISP constructs (ISP R, ISP B, ISP EXP) relative to the injured condition. There was no significant difference in segmental lordosis found between any of the ISP constructs and the injured condition.

No significant differences in decompression parameters were observed between the constructs, suggesting that the three ISP devices provided comparable indirect decompression and the majority of the decompression observed was likely accomplished through the lateral spacer. This result was expected, as the primary purpose of a lateral cage is to increase disc height and distract the two endplates, whereas the purpose of an ISP device is to provide the motion segment with additional stability [7, 8].



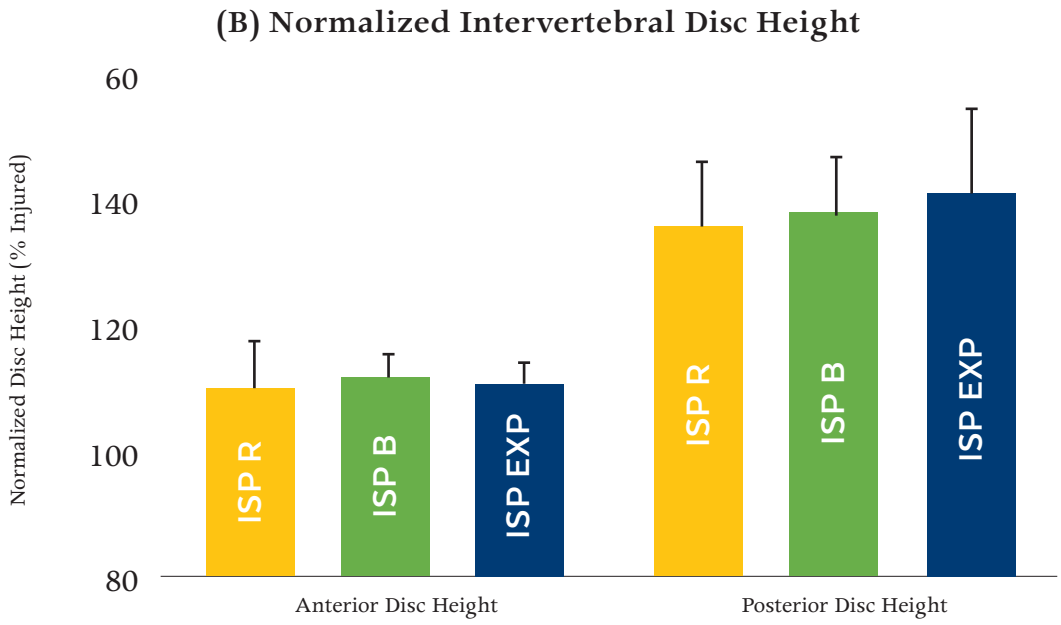


Figure 3: (A) Average disc height and (B) neuroforaminal decompression measurements for each construct, normalized to injured. All parameters are significantly increased from the injured condition ($p<0.05$).

Only recently have engineers begun to design new ISP devices, such as an expandable barrel ISP device, that have a secondary purpose of providing additional indirect decompression beyond the interbody construct. This study found that using the AERIAL™ expandable ISP device with the lateral spacer and lateral plate resulted in the largest average posterior disc height, average neuroforaminal area, and average neuroforaminal height when compared to surgical constructs with static ISP devices. This can likely be attributed to the expandable capability of AERIAL™ that allows for optimal interspinous height for each specimen.

In addition to optimized indirect decompression, expandable interbody devices have many benefits over static interbody devices [6,9]. The ability to insert an expandable device at a minimized profile and then expand *in situ* decreases trialing and thus potentially reduces bony damage associated with impaction in comparison to static devices [6]. This is especially advantageous when using ISP devices, since the spinous process is vulnerable to damage and its fracture rate following implantation of these devices has been reported up to 22% [10,11]. Avoidance of overloading and/or damaging the spinous process during trialing or impaction of the ISP device is expected to reduce fracture risk.

The loss of lordosis is a common concern when using a device designed to increase the distance between two adjacent spinous processes. This study found that no significant change in lordosis occurred from the injured condition with any of the three ISP devices. The lateral spacer likely played a large part in the maintenance of segmental lordosis by resisting a decrease in anterior disc height with an increased interspinous height.

Conclusion

The AERIAL™ expandable ISP device, when used in conjunction with a lateral spacer and lateral plate, achieved substantial neuroforaminal decompression without compromising lordosis. This type of expandable ISP device, when compared to a static barrel ISP device, may help to reduce damage to the spinous processes during insertion, as it can be inserted at a minimized profile and then expanded to an optimal fit, thereby potentially reducing fracture risk. Future studies should further investigate the clinical outcomes and potential spinous process fracture rate when using expandable ISP devices.

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