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Expandable vs Static Interbody Devices for Lateral Lumbar Interbody Fusion

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ABSTRACT

Lateral lumbar interbody fusion (LLIF) has paved a way for minimally invasive surgical treatment of a wide variety of spine pathologies. Interbody devices are used to stabilize painful disc levels, provide indirect decompression of neural elements, correct deformity, restore lordosis, and provide a sound durable fusion. Through the years, new static and expandable interbody devices have been developed in an attempt to improve radiographic and clinical outcomes in lumbar spine surgery. The purpose of this article is to explore the advantages and disadvantages between static and expandable interbody devices when used in LLIF. Specifically, this article addresses the differences in subsidence, indirect decompression, restoration of lumbar lordosis, complications, patient-reported outcomes, and cost between static and expandable interbody devices.

Lumbar Spine

Keywords: LLIF, device, spacer, cage, interbody, expandable, static

INTRODUCTION

The modern lateral lumbar interbody fusion (LLIF) was first performed by Pimenta in 1998 and further described by Ozgur et al in 2006. Through a muscle sparing dissection with minimal soft tissue retraction, operative time and postoperative pain are both reduced with LLIF. In addition, the approach provides increased ability to place an interbody device that spans the cortical apophysis of the end plates. There is also potential to place larger devices as there is no impedance from the posterior neural elements. However, limitations to LLIF exist, including reduced ability to access the L5/S1 disc space due to the iliac crest, risk of lumbar plexus injury, and postoperative transient thigh pain due to dissection through the psoas muscle. 4-6

Interbody devices for anterior column support were first introduced as autografts in 1936. They were historically designed to improve fusion between vertebral end plates, recreate lumbar lordosis, and restore intervertebral and foraminal height. Currently, structural devices are used in lieu of bone autograft spacers. Initial structural devices were static in design; however, expandable devices are now available in an attempt to provide more individuality with correction of spinal alignment and potentially improve radiographic and clinical outcomes. Insertion of expandable devices at minimal height allows for reduced impaction force and preservation of the end plate, thus theoretically mitigating the risk of end plate violation and device subsidence. In

addition, insertion in a compressed state allows for less soft tissue disruption possibly reducing risk of lumbar plexus injury and postoperative thigh pain. Compared to traditional vertically expanding devices, newer devices with horizontal expansion also allow for an increased footprint and end plate coverage. Today, some devices have the ability to expand vertically, expand horizontally, and, in lordosis, allow for more individualized patient-specific corrections in sagittal alignment. However, these potential benefits are mostly theoretical as the true clinical benefits of expandable devices are lacking due to the paucity of current literature.

The purpose of this article is to explore the advantages and disadvantages between static and expandable interbody devices when used in LLIF. Specifically, this article will address the differences in subsidence, indirect decompression, restoration of lumbar lordosis, complications, patient-reported outcomes, and cost between static and expandable interbody devices.

MATERIAL PROPERTIES AND GEOMETRIC NATURE OF LLIF DEVICES

Static interbody devices are traditionally made of polyetheretherketone (PEEK) or titanium whereas expandable devices are traditionally made of titanium and occasionally in combination with PEEK. Static devices come in a range of fixed heights, widths, lengths, shapes, and lordotic angles. In addition, these devices can be prefilled with graft prior to insertion. Expandable

devices come in a compressed state at minimal size and can expand in either height, width, length, or a combination of the 3. In addition, expandable devices can come in either fixed or customizable lordotic angles. Because each company has different expansion mechanisms, the amount of expansion and initial dimension of each device differs significantly (see Table). Similar to static devices, expandable devices can be prefilled with graft prior to insertion. Due to the expansion mechanism, the initial graft window is small. However, once expanded the graft window enlarges and the device can be back filled with additional graft. Unfortunately, it is difficult to completely fill the expanded graft window via back filling. Table outlines various different expandable interbody devices designed for the LLIF.

SUBSIDENCE

Subsidence is the phenomenon of interbody device "settling" through the superior and/or inferior end plates of the adjacent vertebral bodies. Low-grade subsidence (<2 mm) is a common postoperative occurrence. Alternatively, high-grade subsidence (>2 mm) is a complication of interbody device placement that can result in adverse events, such as inadequate indirect decompression, increased stenosis, failure to correct deformity, decreased disc height, and need for revision surgery. One goal of introducing expandable interbody devices was to mitigate risk of subsidence.

High-grade device subsidence in lateral static devices is a known potential complication and has been reported between 6% and 32%. However, several studies have shown a significant decrease in the device subsidence rate when using lateral expandable devices. In a study by Frisch et al, there was 0% subsidence in the expandable group and 16% subsidence in the static group. Li et al found similar results, with a 2-year subsidence rate of 6.7% in the expandable group and 16% in the static group. Several possible explanations exist to explain these findings.

The density and thickness of the vertebral end plates in the lumbar spine have been shown to increase from center to periphery and from anterior to posterior. Thus, it is thought that placement of interbody devices that span the lateral borders of the end plate and are located more posterior than anterior may help reduce subsidence. Although there are no comparative studies utilizing expandable LLIF, in an in vitro cadaver transforaminal lumbar interbody fusion(TLIF) study, Alkalay et al implanted static TLIF interbody devices (bilateral linear devices, single anterior conformal devices, or single unilateral oblique devices) at various

locations in the disc space.¹⁸ They found that anterior conformal devices had the highest subsidence rate (10%–30%) and concluded that placement of interbody devices at the stronger peripheral subchondral bone of the apophyseal ring would help prevent subsidence. Thus, regardless of static or expandable device, LLIF has an advantage compared to TLIF or posterior lumbar interbody fusion (PLIF) in terms of subsidence due to the surgeon's ability to preferentially and reliably place the device across the strong apophyseal ring.

A different study by Antoine et al evaluated the effect of LLIF device size on subsidence.¹⁹ They looked at clinical and radiographic data from 140 consecutive patients who underwent LLIF and were implanted with static PEEK intervertebral devices ranging between 40 and 60 mm in length, 8 and 16 mm in height, and either 18 or 22 mm in width. They found that taller device height, narrower device width, and shorter device length were significantly associated with increased risk of device settling of more than 4 mm at 12 months postoperatively. In addition, they found a 6.8 times greater risk of subsidence of >4 mm at 12 months with narrower devices. Therefore, it makes hypothetical sense that expandable interbody devices that allow customizable height, width, and length may provide a decreased risk of subsidence. In a systematic review, Macki et al reviewed 21 publications and found subsidence in 141 of 1362 patients (10.3%) and a reoperation rate for subsidence of 2.7% confirming that expandable interbody devices may mitigate the risk of subsidence.²⁰ This hypothesis has yet to be proven clinically in a randomized controlled trial.

Risk of subsidence has also been theorized to relate to implant insertional forces. With greater insertional force, increased iatrogenic damage to end plates may occur leading to increased risk of subsidence. To our knowledge, this has not been directly shown in an in vivo LLIF model; however, a study by Torretti et al looked at 10 L5-S1 cadaveric specimen and implanted expandable (n = 5) and static (n = 5) TLIF devices in conjunction with TLIF procedure.²¹ Total insertional force for placement of both trials and final interbody device was 330 N for expandable and 635 N for static devices. As a secondary outcome, they evaluated distraction of the intervertebral disc annulus during implant insertion and found a significant increase in overdistraction of the anterior and posterior disc with placement of static devices vs expandable devices. As there is no known amount of optimal distraction to assist with indirect decompression, caution should be taken to prevent overdistraction of the disc space. Expandable devices

Table. Various expandable interbody devices on the market and their specifications, including starting width, length, height, lordosis, and direction of expansion.

Release Date	Material	Starting Width (A-P)	Starting Length (M-L)	Starting Height	Starting Lordosis	Direction of Expansion	Back Filling	Literature
Titanium PEEK/titanium	nium	23 mm 16, 18, or 22 mm	50, 55, or 60 mm 40–60 mm	4, 6, 8, 10 mm Parallel expansion 7, 9, or 11 mm 6° Expansion range 8 mm 10° Expansion range	10°, 6°, or 10°	Lordosis, 10–30° Height, up to 5 mm	Yes No	NA Frisch et al ⁸
PEEK/titanium	<u>E</u>	18 or 22 mm	40–60 mm	Parallel expansion 7 or 10 mm 6° Expansion range 8 mm 10° Expansion range 10° Expansio	0°, 6°, or 10°	Height, up to 7 mm	Yes	Huang et al ⁹ Li et al ¹⁰
Titanium		20 mm	40–65 mm	Parallel expansion 7 or 10 mm 6° Expansion range 8 mm 10° Expansion range 10° Expansion range 10 mm	0°, 6°, or 10°	Height, up to 7 mm	Yes	Brady et al''
Titanium		20 mm	40-65 mm	5°-20° Expansion range 8 mm 15°-30° Expansion	5° or 15°	Height, up to 9 mm Lordosis, 5°–20° or 15°–30°	Yes	NA A
Titanium		20 mm	40–65 mm	Parallel expansion 7 or 10 mm 6° Expansion range 8 mm 10° Expansion range	0°, 6°, or 10°	Height, up to 7	Yes	V. V.
PEEK with 6% barium & tantalum markers		14 or 16 mm	Various	8 mm	0° or 6°	Height expansion in 1 mm increments	No	Alimi et al ¹²
Titanium		21.5 mm	42–58 mm	8.4 mm	°0	Height, 8.4–17.1 mm Lordosis. 0°–30°	Yes	NA
Titanium		18 or 22 mm	40–60 mm	18 mm width 6, 8, or 10 mm 22 mm width 7 or 10 mm	0°, 6°, or 10°	Height, up to 7	Yes	NA
PEEK Titanium		15 mm	45–60 mm	9–15 mm	0° or 7°	Width, 27 mm full expanded width	Yes	NA
Titanium		14 mm	45-60 mm	8 mm 10 mm 11 mm	5° 10° 15°	Height, up to 5 mm increase Width, either 21 or 24 mm	Yes	N.

Abbreviations: A-P, anterior to posterior; M-L, medial to lateral; NA, not available; PEEK, polyetheretherketone.

allow surgeons to judge distraction with tactile feedback, which may help reduce overdistraction in addition to using fluoroscopy to judge the amount of "appropriate" expansion that is achieved. While there is a paucity of biomechanical and clinical data, expandable devices that require less insertional force and allow for manual distraction may reduce end plate damage, thus helping to explain their decreased rate of subsidence. This controlled expansion may be more applicable in the lateral environment than TLIF/PLIF situation as the end plates of the device are much wider and bigger and can share the distribution of force over a much larger surface area. Again, it should be noted these theories have not been proven in the lateral environment as the literature is lacking. Additionally, although expandable and static devices can be used in TLIF/PLIF and LLIF, the surgical approach differs. Furthermore, the dimension and size of the device, which affect the ability to distract the disc space and alter the distraction force needed to expand the device, differ drastically between TLIF/ PLIF and LLIF. For these reasons, generalized conclusions should be tempered.

The material stiffness of static and expandable devices also has an influence on subsidence. The stiffness of titanium (E of 110,000 MPa), PEEK (E of 2000-4000 MPa), and cancellous bone of vertebral end plates (E of 20–1080 MPa) is vastly different.²² Because of the mismatch in stiffness between titanium and bone, there were concerns of increased subsidence with titanium devices. However, the true benefit of titanium over PEEK is titanium's property of excellent corrosion resistance, low density, and an ability to enhance cell adhesion and osseointegration.²³ In attempts to create devices with more favorable profiles, multimaterial devices made of PEEK and titanium have become available. Novel porous titanium devices have also been developed to decrease stress shielding at the bonehardware interface and match the stiffness of the device closer to bone. In an LLIF study, Krafft et al found that the use of 3-dimensional printed porous titanium devices resulted in radiographic subsidence in 3.4% of all implanted lumbar levels. ²⁴ In comparison, their institution previously published a subsidence rate of 14.3% with use of PEEK devices.²⁵ Thus, modern expandable and porous devices made of PEEK and titanium may be mechanically advantageous to reduce subsidence.

INDIRECT DECOMPRESSION

Indirect decompression of the nerve roots as they exit their foramina can be achieved with lumbar interbody fusion. Replacing a degenerative disc with an interbody

device restores disc height and increases the foraminal and thecal sac cross-sectional area. In a study by Oliveira et al, 43 levels were treated with stand-alone extreme lateral interbody fusion with 18-mm wide static PEEK devices.²⁶ Postoperative central and foraminal decompression was significant (P < 0.05), with an average 41.9% increase in disc height, 24.7% increase in foraminal area, and 33.1% increase in central canal diameter. In a systematic review by Kirnaz et al, 1166 levels underwent LLIF approach with varying static devices.²⁷ Of 9 included studies, the average increase in disc height, foraminal height, axial central canal area, and sagittal central canal diameter was 68%, 19%, 15%, and 32%, respectively. While interbody devices placed via LLIF provide indirect decompression of neural elements, current literature suggests there is no difference between static and expandable devices regarding indirect decompression.

In studies by Frisch et al and Li et al, there was no statistically significant difference between static and expandable devices in increasing neuroforaminal height. In the study by Frisch et al, the final intervertebral disc height after implant placement in the static group was about 4 mm more than that of the expandable group, suggesting that the static devices were possibly oversized. This alters the validity of the results because had the static devices been properly sized, the neuroforaminal area may have been significantly smaller in the static compared to the expandable group. Regardless, based on current limited LLIF research, it appears that both expandable and static devices are capable of providing equivalent indirect decompression of both the foramens and central canal.

LUMBAR LORDOSIS

Restoration of sagittal balance is one of the most important corrections that influences patient-reported outcomes in spinal deformity cases. As lumbar lordosis is a key component of sagittal balance, restoration of lumbar lordosis is an important goal of spine surgery. The literature has shown that device design and shape may have an effect on lumbar lordosis.

Using the LLIF approach, Sembrano et al compared lumbar lordosis in 61 consecutive lumbar levels after placement of nonlordotic (n = 30) and 10° lordotic PEEK devices (n = 31). They found a 2.8° improvement in segmental lordosis when lordotic devices were used compared to a 0.6° improvement with nonlordotic devices.

Furthermore, some studies evaluated how release of the anterior longitudinal ligament (ALL) affects lumbar lordosis after interbody device placement using the LLIF approach. A study by Melikian et al found that use of 10° devices did not increase segmental lordosis while a 30° device with ALL release increased segmental lordosis by 10.5°.29 Uribe et al looked at segmental lordosis with placement of 10° device without ALL release and 10°, 20°, and 30° devices with ALL release. 30 Placement of a 10° device without ALL release resulted in a 0.9° ± 2.5° increase in lordosis while with ALL release there was $4.1^{\circ} \pm 2.7^{\circ}$ increase. The largest correction came from placement of the 30° device with ALL release, resulting in $11.6^{\circ} \pm 3.6^{\circ}$ increased lordosis. While these studies evaluate changes in lordosis after placement of static devices, they emphasize that increasing lordotic angle with or without ALL release can improve lumbar lordosis.

In addition to ALL release with placement of lordotic devices, adding Schwab modifiers 1 (inferior facet and joint capsule removal) or 2 (inferior and superior facet removal with additional removal of posterior elements) can further increase segmental lordosis. 31,32 However, these techniques are used in cases requiring restoration of sagittal imbalance and thus not routinely used in single- or double-segment degenerative cases. We recommend for the surgeon to look at overall sagittal balance in all cases and utilize these deformity correction maneuvers as needed; however, this is beyond the scope of this review. It is also important to note that ALL release further destabilizes the spinal segment; thus, expandable devices are designed with modular or built side plates for the placement of end plate screws to prevent device migration. Ultimately, using the minimally invasive LLIF approach to release the ALL provides a tool for further improving sagittal balance.

Lordosis correction can also be achieved with the use of expandable devices. In 2020, Li et al compared the radiographic outcomes in 62 patients with degenerative disc disease after insertion of a static (n = 27)or expandable (n = 35) device through an LLIF. ¹⁰ In the expandable group, the segmental lordosis improved from baseline at all timepoints (6 weeks, 3 months, 6 months, 12 months, and 24 months) and increased by a mean of 23% by 24 months. In the static group, the segmental lordosis improved significantly from baseline only at 24 months and increased by a mean of 17%. A second study by Li et al looked at radiographic outcomes after placement of expandable devices with adjustable lordosis during LLIF.³³ In their 24 patients, segmental lordosis improved from baseline by a mean of 81.8% at 24 months while lumbar lordosis improved by a mean of 16.9% at 24 months. To our knowledge, this is the only study looking at radiographic parameters with use of an expandable interbody device with adjustable lumbar lordosis.

Together, these studies show that lordosis can be corrected with both static and expandable devices. Taking all the above into consideration, lumbar lordosis can be best restored by use of the LLIF approach with an ALL release and placement of an expandable interbody device with adjustable lordosis. Devices with expansion in multidirectional planes have significant potential to best correct spinal deformities.

SPECIFIC ACCESS AND IMPLANT-RELATED COMPLICATIONS

The LLIF provides some safety benefits compared to other lumbar interbody fusion approaches. While clinical outcomes are similar between LLIF and direct approaches, ³⁴ there is a reduction in length of hospital stay, decreased blood loss, and increased likelihood of rapid postoperative mobilization due to the limited muscle-splitting approach of the LLIF. ^{4,35} However, the LLIF is not without its own complications.

The LLIF approach requires dissection through the psoas muscle, which can lead to anterior thigh pain, psoas weakness, quadriceps weakness, and numbness. 36-41 There are numerous nerves at risk during dissection of the psoas muscle including the lumbar plexus, ilioinguinal, iliohypogastric, genitofemoral, lateral femoral cutaneous, and subcostal nerves. 40,42,43

Pseudarthrosis is another potential complication of LLIF. However, does implantation of expandable devices reduce the risk of pseudarthrosis and neural injury in patients who undergo LLIF?

Regarding pseudarthrosis, few studies have found no difference in rates of fusion between expandable and static devices. There is a theoretical concern that expandable devices have a smaller graft window size due to the expansion mechanism and are more difficult to back fill with graft, leading to lower fusion rates. However, Frisch et al showed 100% fusion at 2 years in 32 patients who received expandable devices and 31 patients who received static devices using the LLIF approach. It is important to note that all procedures were combined with supplementary transpedicular posterior fixation. Additionally, increased subsidence in the static group did neither lead to pseudarthrosis nor did it lead to different clinical outcomes between the static and expandable groups.

Finally, neural injury is a common complication after LLIF. In a systematic review by Hijji, there was

a 39% risk of transient neurological and 3.98% risk of permanent neurological complications. 44 Most of these injuries are thought to occur during dissection, use of retractors, and implant placement. While we are unaware of any studies comparing the rates of neural injury when using expandable vs static implants, expandable devices may provide reduced risk of injury. Muscle dissection and retraction of neural elements can be minimized with expandable devices as they are implanted in a fully compressed state. This reduced dissection and retraction may be enough to lower risk of nerve damage. With less dissection, muscle weakness may also be decreased, potentially leading to improved patient outcomes. Due to a paucity of data, further studies are warranted to test these hypotheses.

PATIENT-REPORTED OUTCOMES

Lateral expandable devices have good patientreported outcome scores. In a retrospective study by Huang et al, 37 patients were treated with lateral expandable interbody devices. They showed a significant improvement in the Oswestry Disability Index (ODI) and visual analog scale (VAS) scores of their patients. However, when comparing patient outcomes in expandable vs static groups, the literature is mixed. In a study by Frisch et al, 56 patients were treated with a lateral lumbar interbody device.⁸ Twenty-nine patients received a static device, and 27 patients received an expandable device. They found that at 2-year follow-up, the VAS scores and ODI scores improved in both static and expandable groups, but they did not differ from each other. These findings varied from those of Li et al, where they studied 62 consecutive patients treated with an expandable (n = 35) or a static (n = 25) lateral lumbar interbody device. 10 At 24 months postsurgery, the expandable group showed significantly greater improvements in VAS back and leg pain and ODI compared to the static group. These 2 studies suggest that patients who undergo LLIF with expandable interbody devices have equivalent if not better clinical outcomes compared to those who receive static devices.

COST

Lumbar interbody fusions are increasing in popularity with more than 923,038 performed in the United States between 2001 and 2010.⁴⁵ A metanalysis by Calvachi-Prieto et al revealed that expandable interbody devices are associated with shortened length of hospital stay.⁴⁶ They found the mean length of stay was 2.4 days with use of an expandable device and 6.4 days with use

of a static device. This metanalysis comprised studies in which TLIF and PLIF were performed; however, these results may translate over to the LLIF. Thus, expandable devices may be advantageous in reducing total costs of lumbar interbody fusions by decreasing length of stay—but they also may not decrease costs as many LLIFs are done as outpatient procedures already. The price of an expandable device is also significantly higher than that of a static device. While based on hospital and industry contracts, expandable devices have a premium of 30%–50% over static devices, equating to an increased cost of thousands of dollars. Future studies that investigate the cost savings between static and expandable devices due to a reduction in surgical time, length of hospital stay, revision rates due to implant failure and subsidence, and indirect costs due to early return to work would be beneficial.

CONCLUSION

The LLIF approach has paved a way for minimally invasive surgical treatment of a wide variety of spine pathology. Through the years, new static and expandable devices have been developed in an attempt to improve fusion and clinical outcomes while reducing complications. The utilization of expandable lateral devices is early in practice, and clinical studies are beginning to appear. Current studies suggest that expandable devices appear to have potential for ease of implantation, decreased subsidence, and more individualized restoration of spinal malalignment as compared to static devices. However, clinical outcomes are largely similar between static and expandable devices, and overall costs are likely increased with expandable devices. As lumbar interbody devices continue to be studied and developed, we will likely see a paradigm shift toward selection of devices that allow for the easiest implantation and superior clinical outcomes while maintaining an acceptable cost.

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