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Review of Immediate Restoration of Lordosis and Disc Height in Transforaminal Lumbar Interbody Fusion: A review of a Novel Expandable Interbody Cage

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OBJECTIVE: Interbody cage implantation during Mini open or minimally invasive (MIS TLIF) surgery for transforaminal lumbar interbody fusion presents several challenges. Expandable cages when collapsed facilitate insertion; subsequent expansion in situ optimizes endplate contact and restores the intradiscal height. This retrospective report investigates the effects of an expandable interbody spacer in terms of satisfactory clinical radiographic outcomes while allowing for safe placement, improvement, and maintenance of foraminal and disc dimensions post-surgery with low risk of subsidence.

METHODS: Four (4) researchers performed a retrospective cohort study of 38 patients who were ≥18 years old and underwent one or two level TLIF procedures (58 operative levels) where the Lordotic ProLift® Expandable Spacer with Osseo-Loc™ surface modification (*Figure 1*) was combined with transpedicular posterior stabilization in either an Mini open or minimally invasive surgical approach. Clinical and radiographic records with device-related complications were obtained from 1 month of preliminary data. Primary outcome of interest was change in Anterior Disc Height (AH), Posterior Disc Height (PH), Midline Disc Height (DH), Foraminal Height (FH), Focal Lordosis (FL), and Global Lumbar Lordosis (GL) from preoperative values to those at 1 month postoperatively.

RESULTS: Mean patient age was 60.3 years (60.2 for females). In all, 47% (18 of 38) underwent 1-level fusion, and 53% (20 of 38) 2-level fusion. No intraoperative complications were reported for any of the procedures performed . Groups had similar baseline characteristics and were observed to be statistically significant (P <.001). For AH, median improvement was 5.58mm (6.06mm for MIS) at 1 month postoperatively. For PH, median improvement was 3.81mm (2.98mm for MIS). For DH, median improvement was 3.70mm (4.01mm for MIS) at 1 month postoperatively. For FL, median improvement was 5.20° (5.56° for MIS) at 1 month postoperatively, with GL median improvement was 5.20° (4.44° for MIS) at 1 month.

CONCLUSIONS: The expandable interbody cage led to improvement in radiographic outcomes after both Mini open and MIS TLIF procedures, including increased intervertebral disc height and lordosis, with no evidence of a collapse of the device or any significant subsidence. When compared to previously published studies [5,7,8], the ProLift Expandable Spacer compared favorably to noted radiographic outcomes.

Lumbar interbody fusion is commonly performed for the treatment of a wide variety of pathologies and clinically relevant conditions. Indications for fusion lumbar instability.[1] Although surgical goals differ on a patient-by-patient basis, general goals include restoration of biomechanical stability, foraminal decompression, and disc height restoration (anterior and posterior height).[2] Recently, focus has increased on the extent of disc height and lordotic correction that can be achieved with various operative procedures, particularly in patients in whom restoration is required.[3-8] By virtue of the surgical approach, posterior implants are constrained in height, footprint, and lordosis by the access corridor itself. Although use of static cages in TLIF procedures has shown favorable clinical results, complications such as cage migration, subsidence, as well as dural tears and transient neurologic deficits, have been reported.[9-11] Expandable interbody cages have been designed to be implanted at a minimized profile and expanded in situ, offering the potential advantages of a more optimized fit between vertebral endplates while avoiding the challenges and complications reported with static cages. The reduced profile of the contracted device requires less impaction during insertion, which may preserve the structural integrity of the vertebral endplates and reduced iatrogenic impact, require less nerve root retraction, and decrease the incidence of postoperative radiculitis.[8,12] With the availability of expandable cages increasing, the current investigation sought to review the utility of such devices by examining clinical and radiographic outcomes when an Mini open or minimally invasive TLIF approach was used to insert the ProLift Expandable Spacer.

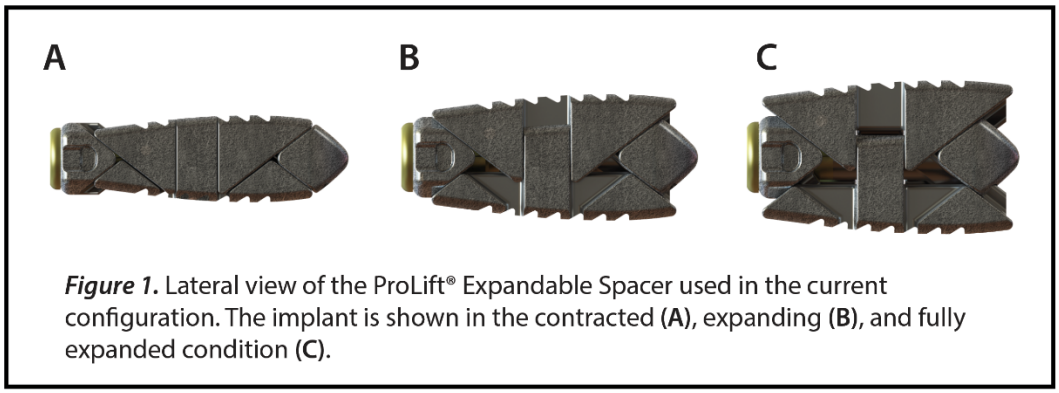


Figure 1. Lateral view of the ProLift® Expandable Spacer used in the current configuration. The implant is shown in the contracted (**A**), expanding (**B**), and fully expanded condition (**C**).

METHODS:

A total of 58 expandable cages were implanted in either a Mini open or with a minimally invasively approach in 38 patients by four surgeons at four different facilities between December 2017 and November 2019. The ProLift Expandable Spacer (Life Spine, Inc, Huntley Illinois USA) was included in this study as the primary reviewed expandable device and industry sponsored by Life Spine, Inc. The

minimum follow-up was 1 month radiologically. The preoperative patients' demographics are summarized in Table 1.

Patient's Demographics

Demographic	Mini Open	MIS
Procedure (n, %)	33 (87%)	5 (13%)
Mean Age (StD, Range)	60.3 (40-85)	65.6 (59 -73)
Gender (n, %)		
Female	17 (52%)	5 (100%)
Male	16 (48%)	0
Locations and Levels (n, %)		
1 Level	17 (52%)	1 (20%)
2 Level	16 (48%)	4 (80%)
L2 - L3	3 (6%)	
L3 - L4	14 (29%)	
L4 - L5	25 (51%)	5 (56%)
L5 - S1	7 (14%)	4 (44%)

The patients fulfilled the following criteria: persistent stenotic leg pain more than 6 months with failed conservative treatment; radiological evidence of foraminal stenosis and/or spondylolisthesis with presence of spinal canal stenosis; and complete medical records.

Data was collected retrospectively, using the preoperative hospital admission sheets, operative notes, postoperative follow-up, and outpatient clinic documentations. An Institutional Review Board approval and informed consent was obtained when required by the respective institution.

SURGICAL PROCEDURE:

The MIS TLIF technique was performed as described previously by Schwender et al.[17] After a complete unilateral facetectomy, a thorough discectomy was performed, with care taken to remove the endplate cartilage without breeching the endplate. The intervertebral disc space was dilated with a single trial for determination of initial implant size and lordosis. The implant was placed in an oblique fashion across the midline, such that the anterior aspect of the cage rested in the anterior portion of the apophyseal ring. An appropriately sized implant, with an expansion range equivalent to preoperative planning measurements, was inserted through the posterior annulotomy window. After in situ expansion, optimal endplate contact and positioning were verified through anteroposterior and lateral fluoroscopic views (Figures 2, 3). Autogenous or allogenic bone graft material was packed both within and around the implant to facilitate fusion. After expansion, flowable graft material was introduced in the posterior end of the cage to fill any gaps or voids caused by the expansion and allow for columnar fusion. Supplemental fixation was achieved with use of transpedicular screw and rod instrumentation at index

levels after implant insertion.

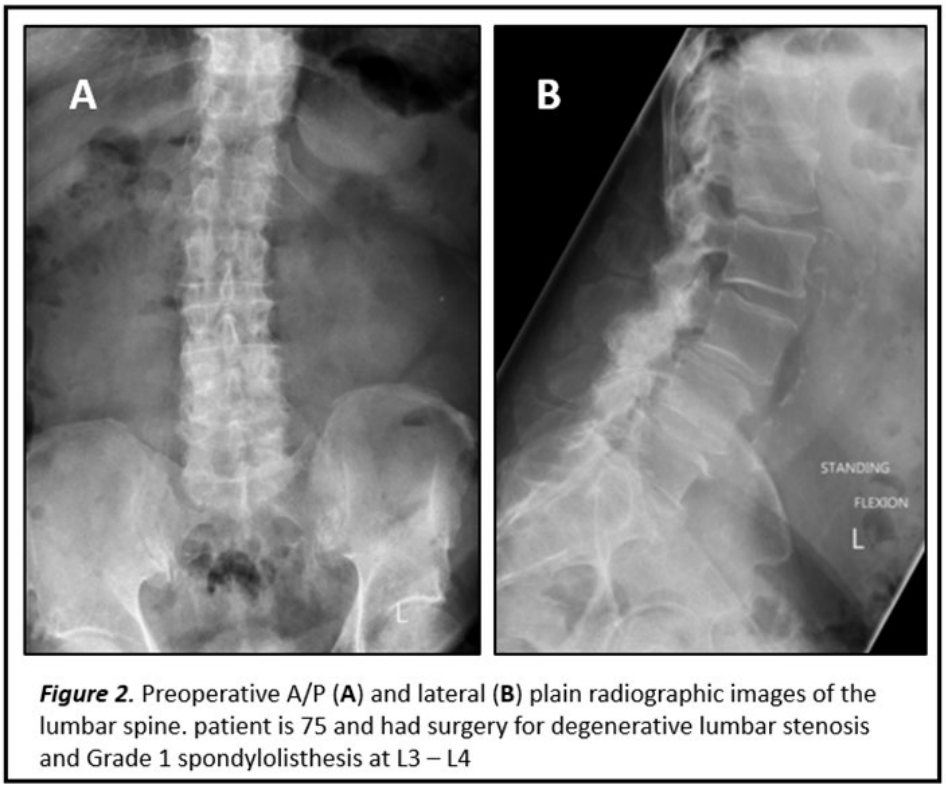


Figure 2. Preoperative A/P (**A**) and lateral (**B**) plain radiographic images of the lumbar spine. patient is 75 and had surgery for degenerative lumbar stenosis and Grade 1 spondylolisthesis at L3 – L4

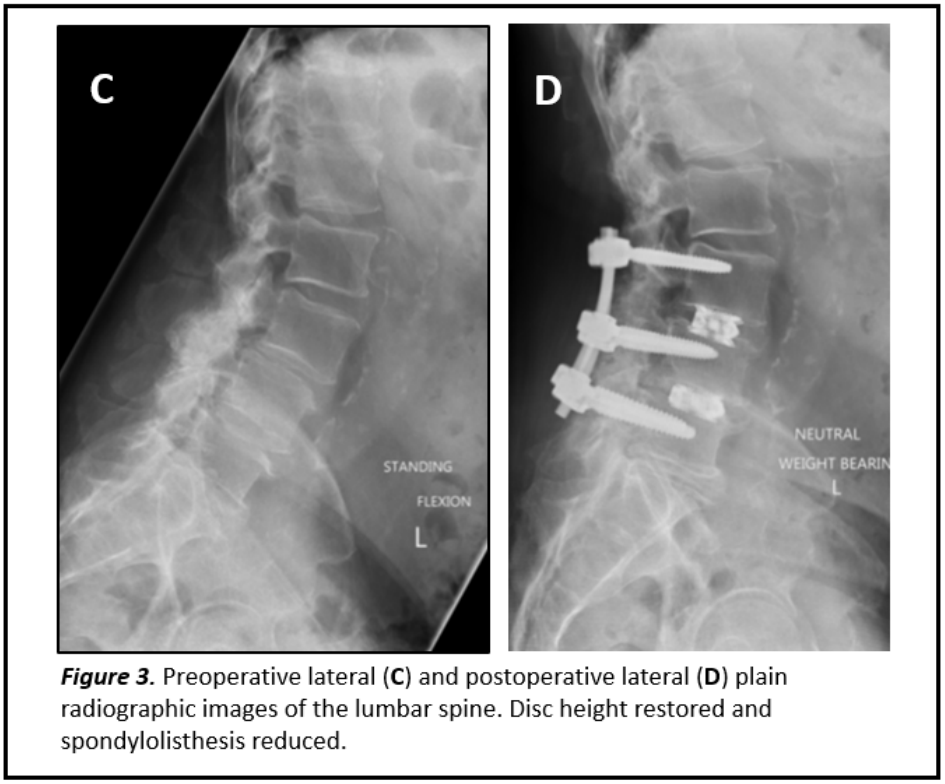


Figure 3. Preoperative lateral (**C**) and postoperative lateral (**D**) plain radiographic images of the lumbar spine. Disc height restored and spondylolisthesis reduced.

DATA COLLECTION AND OUTCOMES:

Data regarding patient demographics and medical history, including age at time of surgery, sex, and medical history, were recorded. Details regarding the TLIF procedures included operative date, surgical indication, approach (Mini open vs minimally invasive), and lumbar level treated.

The primary outcome of interest was change in AH, PH, DH, FH, FL and LL before and after cage insertion. FL was defined as the angle between the inferior and superior endplates of the fusion segment. GL was defined as the angle between the superior endplates of L1 and S1. FL and GL were measured from lateral upright radiographs of the spine preoperatively, at 1 month postoperatively. Disc height was measured as perpendicular distance between the two cartilaginous endplates in the middle of the vertebra above. Foraminal height was measured using line between the middle of the edge of superior and inferior pedicles. (Figure 4) Angle measurements were performed by a single independent reviewer utilizing multiple density and gradient standing plain film radiographs with Surgimap™ (115 East 23rd St, Suite #501, New York, NY 10010, USA.) Subsidence was also assessed and defined as a greater than 2-mm intrusion into the adjacent vertebral body by the cage.

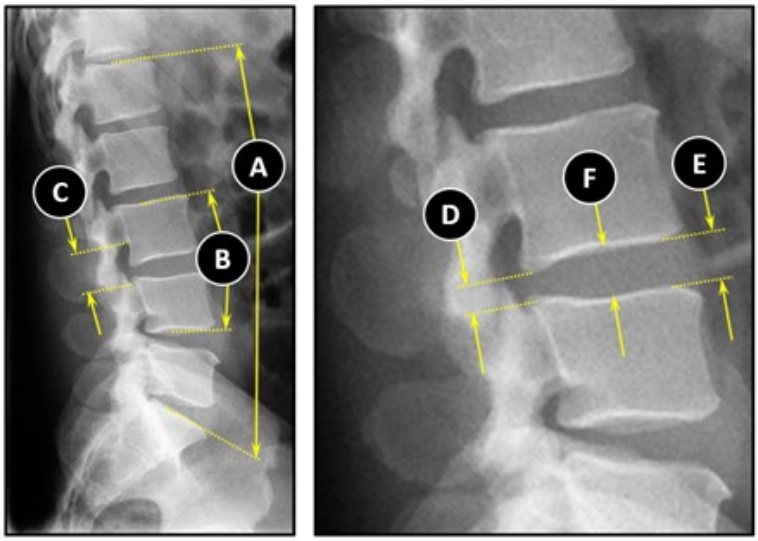


Figure 4. Plain film lateral radiographic images of the lumbar. (A) Lumbar Lordosis=LL, (B) Focal Lordosis=FL, (C) Foraminal Height=FH, (D) Posterior Disc Height=PH, (E) Anterior Disc Height=AH, (F) Disc Height=DH

STATISTICAL ANALYSIS

Paired samples two tail t-tests were also conducted to investigate whether there was a statistical difference in radiographic assessments (AH, PH, DH, FH, FL and LL) between pre-surgery and post-surgery, respectively).

RESULTS

The data collected from 38 patients (58 fusion levels, as some patients had more than one level fused) who were surgically managed with the ProLift Expandable Spacer were analyzed. No significant intraoperative or perioperative complications (neurologic, infectious, or vascular) were reported for the 38 patients included in the current review, and no patients required reoperation at index or adjacent levels. Furthermore, no evidence of cage migration or breakage was observed at any operative level. There was no significant difference in radiographic improvement between MIS and Mini open surgery, 33 vs 5 respectively.

RADIOLOGICAL OUTCOMES

Radiological assessment from the follow-up in 38 patients (58 levels) was as follows: Radiographic subsidence (2mm endplate subsidence)[13-16] was noted in 3 of 58 (5%) operative levels with no clinical complications or requiring reoperation. All 3 noted levels still restored disc height and lordosis irrespective of radiographic subsidence. (Figure 8). Focal lordosis increased by 5.2 degrees, and intervertebral disc heights changes were noted as 3.70mm (3.52 MIS). These changes compared favorably to previously reported studies for expandable and static cages (Figure 5 and 6).

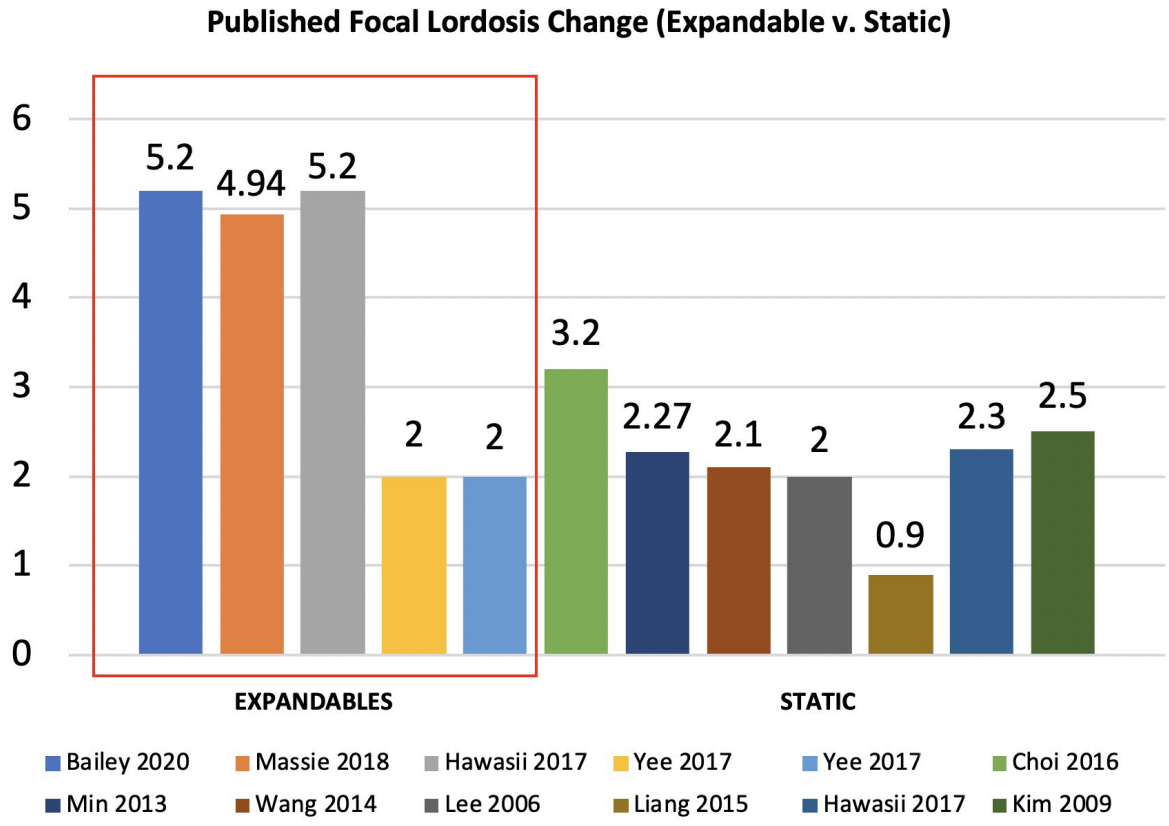


Figure 5

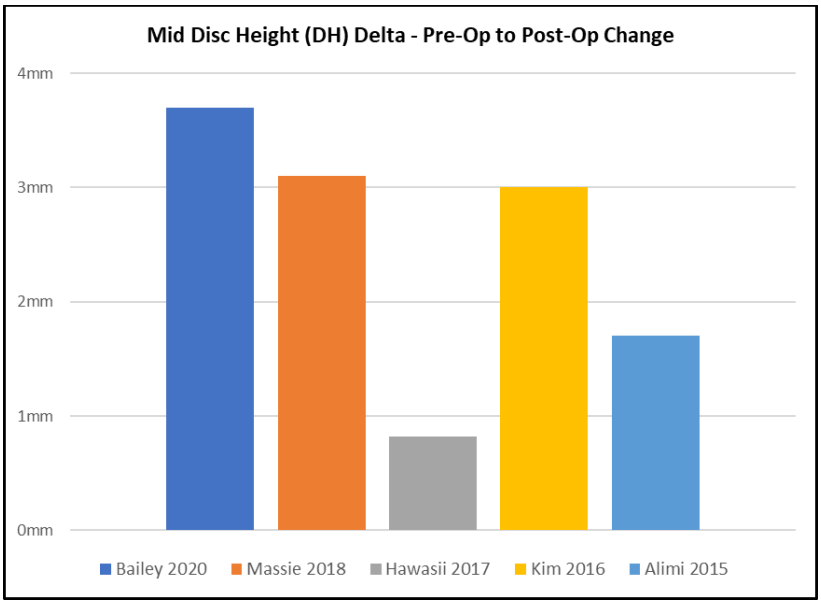
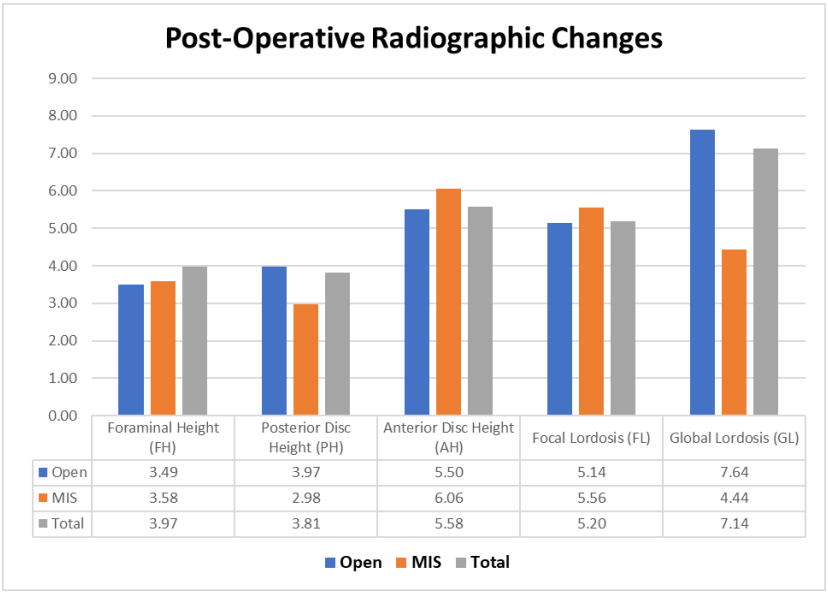


Figure 6

Additional changes to foraminal height (FH), anterior disc height (AH), posterior disc height (PH), and global lordosis (GL) are noted in Figure 7 for Mini open, minimally invasive, and total cases reviewed. Global Lordosis was compared to published literature for both static and expandable cages and compared favorably to the ProLift Expandable Spacer (Figure 9)



	Foraminal Height (FH)	Posterior Disc Height (PH)	Anterior Disc Height (AH)	Focal Lordosis (FL)	Global Lordosis (GL)
Open	3.49	3.97	5.50	5.14	7.64
MIS	3.58	2.98	6.06	5.56	4.44
Total	3.97	3.81	5.58	5.20	7.14

Patient's Demographics

Demographic	**Mini Open**	**MIS**
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Figure 7

Published Subsidence Rates

Expandable	Total	Subsidence	Rate
Bailey 2020	58	3	5%
Massie 2018	44	3	7%
Yee 2017	41	3	7%
Kim 2016	50	0.5	1%
Alimi 2015	49	4	8%
Non-Expandable			
Choi 2016	21	7	33%
Lee 2008	27	5	19%
Kim 2009	46	0.5	1%
Kepler 2012	45	3	7%
Yee 2017	48	2	4%

Figure 8

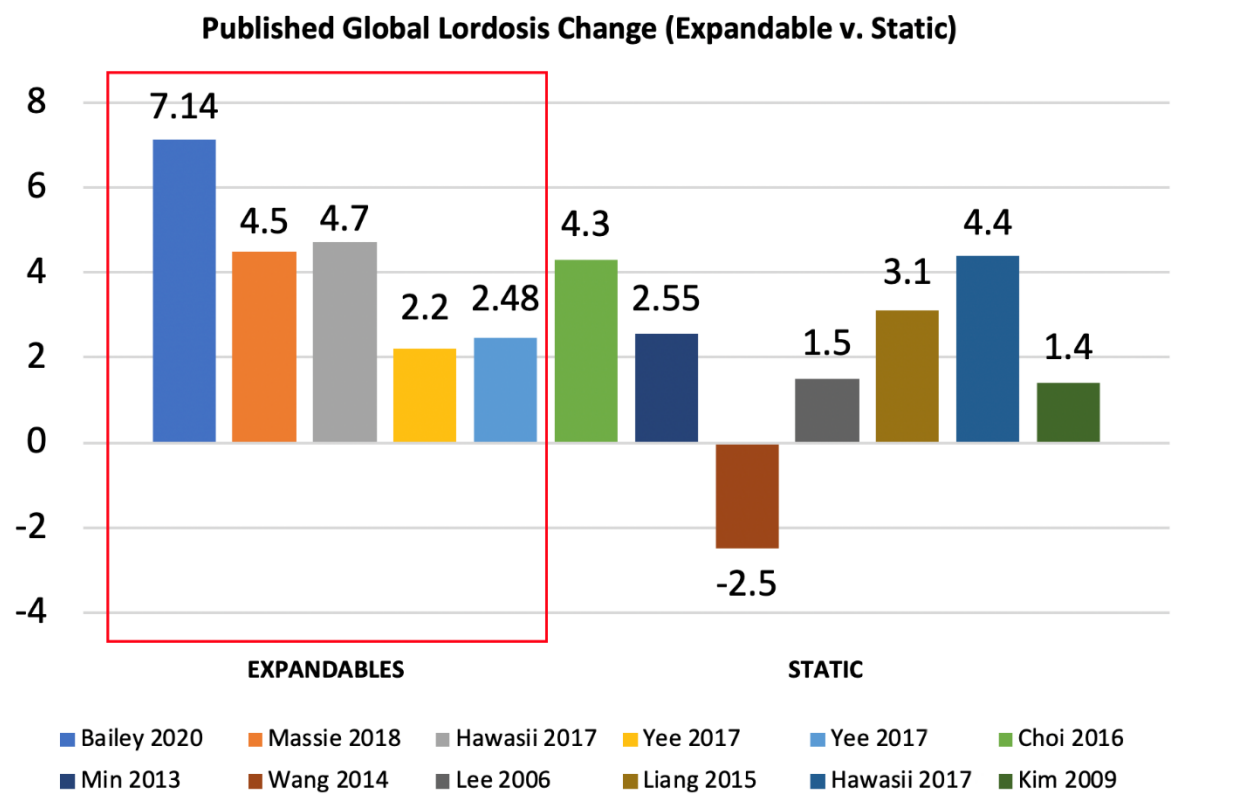

Figure 9

LIMITATIONS TO THE STUDY

The study was performed retrospectively with lack of control group, as well as no long term follow up for this early radiographical study. Computerized tomography scanning would provide more accurate information regarding fusions rates but would subject the patient group to increased radiation which we

felt unnecessary in patients with no clinical indication to be scanned. Additionally, patient pain and outcome scores (VAS and ODI) will be included as another parameter for successful outcomes with this novel device.

CONCLUSIONS

Findings of the current review show that use of an expandable interbody device for Mini open and MIS TLIF procedures resulted in improved radiographic outcomes, restoration of intervertebral disc height, than reported with static devices.

DISCLOSURES

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