Novel Titanium Cages for Minimally Invasive Lateral Lumbar Interbody Fusion: First Assessment of Subsidence

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Abstract:

Introduction: Implant subsidence is a potential complication of spinal interbody fusion and may negatively affect patients subjected to procedures relying on indirect decompression such as minimally invasive transpsoas lateral lumbar interbody fusion (LLIF). The porous architecture of a recently developed titanium intervertebral cage maximizes bone-to-implant contact and minimizes stress shielding in laboratory experiments; however, its subsidence rate in patients has not yet been evaluated. The goal of this current study was to evaluate implant subsidence in patients subjected to LLIF.

Methods: Our institutional review board-approved single-center experience included 29 patients who underwent 30 minimally invasive LLIF from July 2017 to September 2018 utilizing the novel 3D-printed porous titanium implants. Radiographs, obtained during routine postoperative follow-up visits, were reviewed for signs of implant subsidence, defined as any appreciable compromise of the vertebral endplates.

Results: Radiographic subsidence occurred in 2 cases (6.7%), involving 2 out of 59 porous titanium interbody cages (3.4%). Both cases of subsidence occurred in four-level stand-alone constructs. The patients remained asymptomatic and did not require surgical revision. Ten surgeries were stand-alone constructs, and 20 surgeries included supplemental posterior fixation.

Conclusions: In our patient cohort, subsidence of the porous titanium intervertebral cage occurred in 6.7% of all cases and in 3.4% of all lumbar levels. This subsidence rate is lower compared to previously reported subsidence rates in patients subjected to LLIF using polyetheretherketone implants.

Keywords:

Titanium, intervertebral cage, lateral lumbar interbody fusion, subsidence

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Introduction

Interbody fusion of the lumbosacral spine is a surgical treatment strategy for patients with low back pain or instability refractory to conservative care. It entails removal of degenerative disc material, preparation of vertebral endplates, and placement of interbody cages or spacers filled with bone graft. The goal of this procedure is to restore disc height and physiological spinal alignment as well as to stimulate bone growth between two vertebral segments, thereby eliminating motion as a possible pain generator.

Interbody fusion can be achieved through anterior, anterolateral, lateral, or posterior approaches to the disc space. Minimally invasive transpsoas lateral lumbar interbody fusion (LLIF), also known as extreme lateral interbody fusion (ELIF or XLIF), is a safe and effective operation resulting in at least equivalent clinical improvements with lower procedural morbidity, compared to conventional open anterior or posterior interbody techniques[1-5]. Minimally invasive LLIF is performed by using atraumatic tissue dilators and an expandable retractor system under real-time neuromonitoring to ensure safe dissection through the psoas muscle and exposure of the lateral disc space. This approach avoids disruption of stabilizing spinal ligaments and facilitates indirect decompression of neural elements through restoration of disc height and ligamentotaxis[6-8]. However, a particular concern of LLIF is cage subsidence, leading to decrease in disc space height and reversal of indirect decompression. Factors believed to promote subsidence include stand-alone intervertebral cages without supplemental posterior transpedicular

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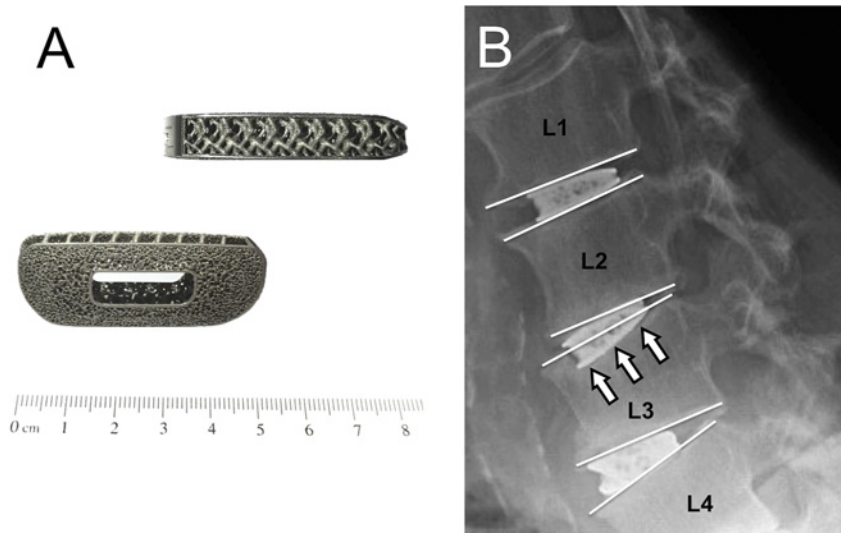

Figure 1. (A) Photograph of the 3D-printed titanium cage (Modulus; NuVasive, San Diego, CA). (B) Representative close-up view of a lateral postoperative radiograph demonstrating stand-alone 3D-printed titanium cages at L1/2, L2/3, and L3/4, with cage subsidence into the superior endplate of L3 (arrows). Endplates are exemplified by white lines.

instrumentation, overdistraction of the disc space leading to endplate damage, as well as the use of stiff narrow cages[9-11].

Material stiffness is a physical property described as Young's modulus (E) that measures the amount a specific material will deform under given stress. The stiffness of solid titanium alloys (E of 110,000 MPa) and polyetheretherketone (E of 2,000-4,000 MPa), materials commonly used for intervertebral cages, is higher than the stiffness of cancellous bone (E 20 to MPa)[12,13]. Laboratory studies demonstrated that porous intervertebral cages resulted in a substantial decrease of stress at the bone-hardware interface[12]. Consequently, a novel 3D-printed porous titanium cage has been developed with the purpose of mimicking the biomechanical properties of the bone, thereby minimizing stress shielding and subsidence (Fig. 1A, B). In March of 2017, this specific titanium cage has been cleared by the Food and Drug Administration for the use in patients. The subsidence rate of this novel titanium interbody cage has not yet been investigated. Therefore, the objective of this current study is to demonstrate radiographic subsidence rates of this specific cage in patients within 1 year after minimally invasive LLIF.

Materials and Methods

The current study was approved by our institutional review board. A retrospective chart review of prospectively collected data was conducted on all patients who underwent minimally invasive transpsoas LLIF, from July 2017 to September 2018, implementing novel 3D-printed titanium cages (Modulus; NuVasive, San Diego, CA). All surgeries were performed by one of three neurosurgeons at our academic, tertiary hospital. Common indications for surgery included degenerative disc disease with mild-to-moderate central and/or foraminal stenosis, symptomatic spondylolisthesis, degenerative scoliosis, and adjacent segment failure (Fig. 2A-C).

Surgery was performed as previously reported[1,14]. Briefly, after induction of endotracheal general anesthesia, the patient was placed in a true lateral position, which was confirmed by anterior-posterior and lateral fluoroscopy. After outlining the tentative incision, the patient was prepped and draped in the usual sterile fashion. A horizontally (for single level) or vertically oriented (for multiple levels) skin incision was made, followed by blunt dissection through subcutaneous tissue, the external and internal oblique, as well as the transversus abdominis muscles, thereby entering the retroperitoneal cavity. Under fluoroscopic guidance, a small dilator was placed through the psoas muscle onto the posterior third of the disc space. Neuromonitoring (NeuroVision; NuVasive, Sad Diego, CA) was used to ensure ample distance to the exciting nerve roots. Next, a K-wire was placed through the hollow dilator into the disc space. Dilators with progressively increasing diameter were used under 360° neurostimulation to bluntly dissect the psoas muscle. An expandable self-retaining retractor (MaXcess; NuVasive, San Diego, CA) was then placed over the dilators and anchored in the disc space. The discectomy was carried out as follows: An annulotomy knife was used to incise the lateral aspect of the disc. Under fluoroscopic guidance, a Cobb periosteal elevator was carefully advanced along the endplates just past the contralateral annulus. Box cutter, disc shavers, and pituitary rongeurs were used to remove disc material. The endplates were further prepared with curettes and rasps. The appropriate cage size was determined either by using a cage template or based on preoperative imaging. The final 3 D-printed titanium cage was packed with bone cellular matrix allograft (Osteocel Plus; NuVasive, San Diego, CA) and

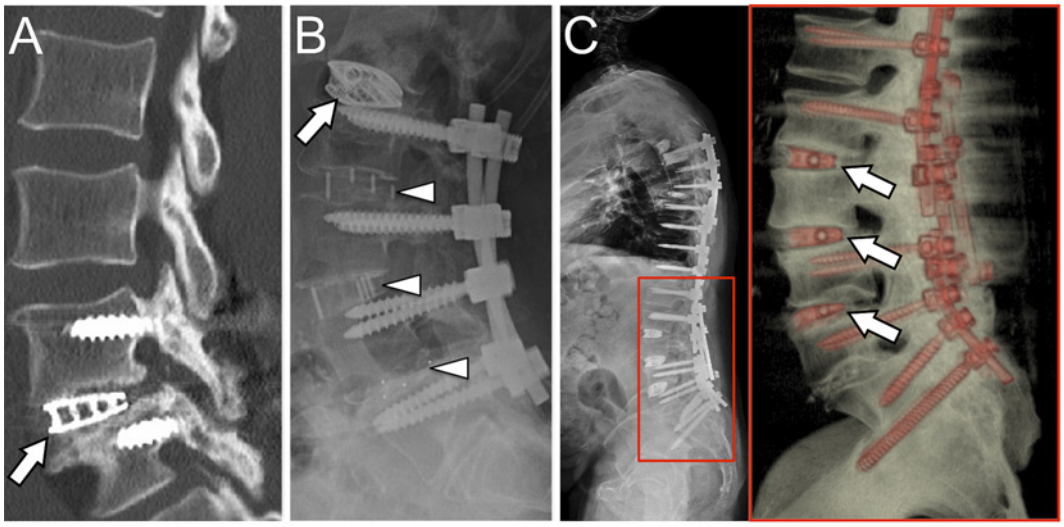

Figure 2. (A) Representative close-up view of a lateral postoperative computed tomography showing a single-level titanium cage at L4/5 (arrow) with supplemental posterior spinal instrumentation. (B) Representative lateral postoperative radiograph showing a stand-alone single-level titanium cage at L1/2 (arrow) for adjacent segment failure in a patient with prior placement of L2 to L5 interbody polyetheretherketone cages (arrow heads) and supplemental posterior spinal instrumentation from L2 to L5. (C) Lateral scoliosis radiograph and close-up view of 3D reconstruction of thoracolumbar hardware following computed tomography, depicting implementation of laterally placed titanium cages at L2/3, L3/4, and L4/5 (arrows) in a long-segment thoracolumbar construct for degenerative scoliosis.

Table 1. Demographic Characteristics.

Demographic characteristics	Frequency or mean (M)	Percentage or range
Age (years)	65.5 (M)	52-82
Gender		
Male	16	55.2%
Female	13	44.8%
Race		
White, non-Hispanic	23	79.4%
Black, non-Hispanic	3	10.3%
Hispanic	3	10.3%
Other	0	
BMI (kg/m^2)	32.4 (M)	21.1-66.7
Smoking history	19	63.3%

advanced into the disc space.

Collected data included patient demographics, operative characteristics (number of implants, duration of surgery, blood loss, type of supplemental fixation), as well as clinical characteristics (postoperative deficits, length of stay, and discharge location). Successful radiographic fusion was determined based on previously established criteria including (1) presence of bone formation through the cage or disc space, (2) absence of mobility (greater than 2 mm) of the fusion segment on flexion and extension lateral radiographs, and (3) absence of radiolucency around the pedicle screws[15]. The main outcome measurement was radiographic evidence of cage subsidence, which we defined as any compromise of either endplate on postoperative imaging (lumbar radiographs, long-cassette scoliosis films, or lumbar computed tomography), utilizing a GE Centricity 3.0 viewing station (GE Healthcare, Waukesha, WI). Postoperative imaging was obtained immediately after surgery as well as during routine 1-month, 3-month, 6-month, and 1-year follow-up appointments. We also reviewed unplanned clinic and hospital visits during which lumbar spine imaging was obtained.

Because of the low incidence of cage subsidence within our patient population, statistical group comparison was not feasible. For that reason, we implemented descriptive statists only.

Results

From July 2017 to September 2018, a total of 29 consecutive patients (16 male and 13 female) underwent 30 single- or multilevel minimally invasive transpsoas LLIF using novel 3D-printed porous titanium cages. Demographic characteristics are summarized in Table 1. Our patient population was pronominally white (79.4%) with a mean BMI of 32.4 kg/m^2, ranging from 21.1 to 66.7 kg/m^2. Prior to surgery, cessation of tobacco consume was requested in those with a known smoking history (63.3%). Operative characteristics are summarized in Table 2. One third of all patients were subjected to previous lumbar spine surgeries and 30% presented with a history of prior lumbar instrumentation. A total of 59 titanium cages were placed during 30 surgeries. Twelve patients (40%) received 1, 11 patients (36.7%) received 2, 3 patients (10%) received 3, and 4 patients (13.3%) received 4 titanium cages. One patient underwent two LLIF surgeries, first a one-level followed by a two-level lateral fusion approximately 6 months apart. The distribution

Table 2. Operative Characteristics.

Operative characteristics	Frequency or mean (M)	Percentage or range
Radiographic subsidence	2/30	6.7%
Subsidence per implant level	2/59	3.4%
Radiograph signs of fusion	37/59	62.7%
Previous L-spine surgeries	10	33.3%
Previous L-spine fusions	9	30%
Number of cages		
1	12	40%
2	11	36.7%
3	3	10%
4	4	13.3%
Spinal levels		
T12/L1	1	1.7%
L1/L2	12	20.3%
L2/L3	15	25.4%
L3/L4	15	25.4%
L4/L5	16	27.1%
Supplemental fixation		
None (stand-alone)	10	33.3%
Percutaneous pedicle screws	8	26.7%
Open pedicle screws	12	40%
Length of construct (levels)		
1	11	36.7%
2	2	6.7%
3	3	10%
4	6	20%
5	5	16.7%
8	1	3.3%
10	2	6.7%
Duration of surgery (minutes)	260 (M)	44-696
Blood loss (ml)	243 (M)	20-900

Table 3. Clinical Characteristics.

Clinical characteristics	Frequency or mean (M)	Percentage or range
Postoperative motor deficit	0	
Postoperative sensory deficit	1	3.33
Length of stay (days)	8 (M)	0.5-29
Discharge location		
Home	19	63.3%
Home with outpatient PT	1	3.3%
Inpatient rehabilitation	7	23.3%
Skilled nursing facility	3	10%
Last follow-up (months)	11.6 (M)	3-23

PT: Physical therapy

of lateral interbody instrumentation for each level was as follows: T12/L1, 1 (1.7%); L1/2, 12 (20.3%); L2/3, 15 (25.4%); L3/4, 15 (25.4%); and L4/5, 16 (27.1%). Ten patients (33.3%) underwent lateral instrumentation only (stand-alone), whereas 8 (26.7%) and 12 (40%) patients underwent percutaneous or open transpedicular fixation, respectively. The length of lumbar or thoracolumbar final construct ranged from one level to ten consecutive levels. The mean duration of surgery was 260 minutes, ranging from 44 to 696 minutes. The mean estimated intraoperative blood loss was 243 ml, ranging from 20 to 900 ml. Clinical characteristics are summarized in Table 3. No patient suffered a new postoperative motor deficits; however, one patient developed new-onset unilateral anterior thigh numbness after surgery, which resolved on postoperative day 2. The average hospital stay was 8 days, ranging from 0.5 to 29 days. Discharge location was the patient's own home for 19 (63.3%), the patient's own home combined with outpatient PT for 1 (3.3%), an inpatient rehabilitation facility for 7 (23.3%), and a skilled nursing facility for 3 (10%) patient/patients. The mean follow-up was 11.6 months, ranging from 3 to 23 months after the initial LLIF. Two patients were lost to follow-up after the 3-month clinic appointment. We found radiographic signs of fusion across 37 vertebral segments (62.7%).

The main outcome measurement of this study was radiographic evidence of cage subsidence. We found 2 cases of cage subsidence after 30 surgeries (6.7%) utilizing a total of 59 titanium implants (3.4%), (Fig. 3A, B). The first patient suffering from cage subsidence was an 82-year-old white female with a BMI of 35.6 kg/m^2 who presented with debilitating back pain secondary to degenerative disc disease between L1 and L5. The patient underwent a four-level stand-alone LLIF using 3D-printed titanium interbody cages. Upright X-rays of the lumbar spine obtained at 3 weeks after surgery demonstrated approximately 6 mm subsidence of the L2/3 cage (8 × 22 × 50 mm) into the superior endplate of L 3 (Fig. 1B). The patient endorsed improvement of her presenting symptoms. The last documented follow-up of this patient was 18 months after surgery. There was no evidence of symptom aggravation within this time period. The second patient was a 60-year-old white male with a BMI of 32.0 kg/m^2 who presented with lower back pain, bilateral leg pain, and neurogenic claudication secondary to degenerative disc disease between L1 and S1, scoliosis, and flat back syndrome. He underwent a staged surgery consisting of L1 to L5 LLIF with anterior column releases at L2/3 and L4/5. 20° hyperlordotic polyetheretherketone cages measuring 8 × 22 × 60 mm were placed at L2/3 and L4/5, and 3D-printed titanium interbody cages were placed at L1/2 and L3/4. Five days after the LLIF, the patient was taken back to the operating room for a L4/5 Grade 2 osteotomy, L5/S1 transforaminal interbody fusion, and L1 to ilium posterior instrumentation. A CT scan of the lumbar spine obtained 2 days after stage 1 demonstrated approximately 6 mm subsidence of the L3/4 cage (8 × 22 × 50 mm) into the superior endplate of L4 (Fig. 3B). The patient's presenting symptoms improved; however, he required inpatient rehabilitation because of general deconditioning. This patient was lost to follow-up after his 3-month clinic appointment.

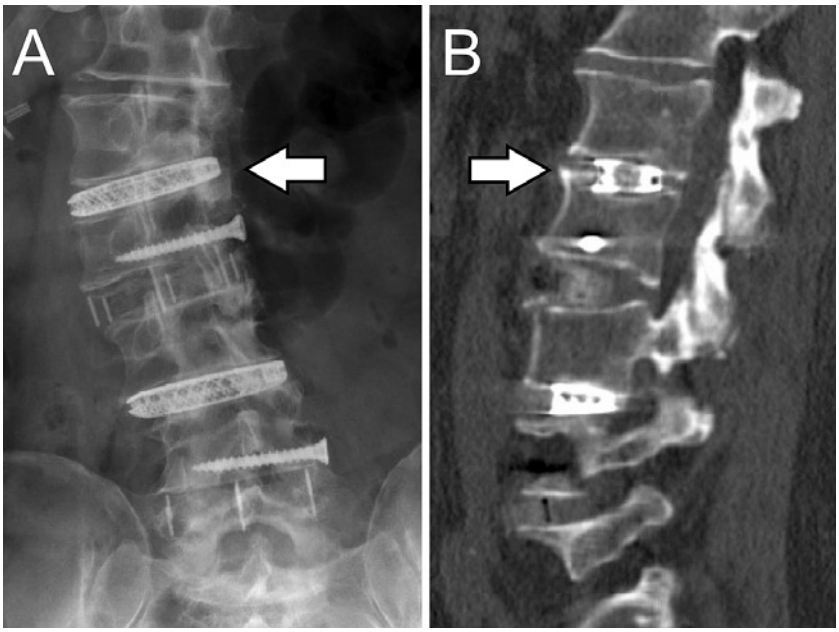

Figure 3. Close-up view of anterior-posterior radiograph (A) and lateral computed tomography (B) of the lumbar spine following stage 1 of a front-back thoracolumbar instrumentation demonstrating polyetheretherketone cages with lateral screw fixation following anterior column release at L2/3 and L4/5 as well as titanium cages at L1/2 and L3/4 with subsidence of the L1/2 cage (arrow) into the superior endplate of L2.

Discussion

Minimally invasive transpsoas LLIF is a safe and effective operation for patients suffering from diverse spinal pathologies including degenerative disc disease with mild-to-moderate central and/or foraminal stenosis, symptomatic spondylolisthesis, degenerative scoliosis, and adjacent segment failure. This approach demonstrated comparable postoperative clinical and radiographic improvements when compared to conventional open anterior or posterior lumbar interbody fusions; however, it is generally associated with a substantially lower procedural morbidity[2-5]. Disadvantages of the LLIF include limited accessibility of the L5/S1 motion segment because of the iliac crest as well as the risk of irritation or injury of sensory and motor nerves of the lumbosacral plexus[16,17]. Minimally invasive LLIF, especially when not combined with additional posterior surgery such as lumbar laminectomy/foraminotomy, relies merely on indirect decompression of neural elements by restoration of disc space height and ligamentotaxis[6-8]. Consequently, cage subsidence may reverse indirect decompression, result in progressive deformity, reduce the chance of successful fusion, and ultimately require a reoperation[14]. The cause of cage subsidence is likely multifactorial and may be related to operative techniques, bone quality, as well as size and material of the intervertebral cage[9-11]. Indeed, the bone-hardware interface must function as a distinct biomechanical unit in resisting axial loading stress in order to prevent subsidence[18]. Laboratory studies suggested that maximizing the bone-hardware interface area and creating implants with a texture and porosity similar to cancellous bone could minimize stress shielding and subsidence[12]. This theory led to the development of a novel porous 3D-printed titanium interbody cage, which we recently implemented for minimally invasive LLIF. The subsidence rate in our series of 29 patients, 30 LLIF procedures, and 59 implanted titanium cages was 6.7% per surgery and 3.4% per implant. This subsidence rate was found to be considerably lower than previously reported subsidence rates of static polyetheretherketone cages for minimally invasive LLIF ranging from 10.0 to 16.1%[8,11,14]. We have previously evaluated the subsidence rate of polyetheretherketone cages at our institution and found radiographic subsidence in 14.3% of patients subjected to LLIF; however, only 2.1% of patients were found to be symptomatic[14]. Both patients in our series demonstrated radiographic compromise of the superior endplate, which goes in hand with previous research stating that inferior lumbar endplates are 40% stronger than superior ones[19]. This finding was consistent with and comparable to polyetheretherketone intervertebral cages. Both patients in our series developed subsidence at upper levels of the construct, which is consistent with the concept that lumbar endplate strength is weaker in upper levels[18]. Furthermore, the epiphyseal plates of the inferior endplates have a larger surface area than those of the superior endplates in the lumbar spine[20]. It remains debatable whether or not multilevel stand-alone constructs are more prone to implant subsidence. One recent study demonstrated a higher subsidence rate in stand-alone LLIF[9]; however, others did not find a significant difference in cage subsidence between stand-alone constructs

and those with supplemental posterior fixation[6]. Comparing stand-alone constructs and those with supplemental posterior fixation remains difficult because the former are generally shorter constructs that are utilized less frequently. In our series, only ten patients underwent stand-alone LLIF. Interestingly, cage subsidence was found in two patients with a four-level stand-alone construct (one patient underwent supplemental posterior fixation after cage subsidence was found following the initial LLIF). Overdistraction of the disc space may lead to endplate damage and consequent subsidence[11]. As previously reported, it remained our practice to provide only between 2 and 4 mm of distraction per affected level[14]. We accomplished this by using titanium cages with heights of 8 and 10 mm and did not implement those with a height of 12 mm to avoid overdistraction. The selection of cage length was dependent on the width of the adjacent vertebral bodies. We attempted to always advance the cage just past the lateral margins of the endplates on both sides. As stated above, poor bone quality and increased implant stiffness may contribute to subsidence[12]. Porous materials have shown to reduce stress at the bone-hardware interface, which may be a possible improvement of this newly developed titanium cage. For this study specifically, we have defined subsidence as any endplate compromise on available postoperative imaging. Others have graded subsidence based on the amount of endplate destruction or loss of disc height, which makes a comparison with currently available data more challenging[2,9]. The fusion rate described in this current is lower when compared to other studies, although those have generally a more extended follow-up[2,11]. While our intraoperative characteristic such as duration of surgery and blood loss is well comparable and in line with previous reports, we have demonstrated improved intraoperative clinical outcomes, with no patient having developed a new motor deficit and only one having developed an intermittent sensory deficit[8]. A previous study evaluating clinical outcome following LLIF found new postoperative motor deficits in 2.9% and sensory changes in 17.5% of all patients[2]. This could be explained by advances in neuromonitoring for minimally invasive LLIF.

Limitations of this current study include that it was performed as a retrospective single-center study, and as such, a comparative analysis of cage material, length of construct, and stand-alone versus LLIF with supplemental posterior comparison was not possible. Because we found only two cases of implant subsidence, a statistical analysis between patients experiencing subsidence and those who do not was also not feasible. The novel porous titanium cage, we elected to evaluate, only recently received approval by the Food and Drug Administration for the use in patients. Thus, our study has a comparatively low patient number when compared to other investigations evaluating cage subsidence. Lastly, our study is lacking long-term clinical follow-up such as patient self-assessment questioners including the visual analog scale and Oswestry Disability Index. Despite these shortcomings, we found a promising reduction in subsidence rates with the novel porous titanium intervertebral cage following LLIF.

In conclusion, minimally invasive LLIF through a retroperitoneal transpsoas approach is a safe and effective technique for patients with diverse spinal pathologies. The novel porous 3D-printed titanium cage demonstrated lower subsidence rate when compared to previous studies using polyetheretherketone intervertebral cages. Further multicenter prospective investigations comparing implant material and subsidence are needed.

Conflicts of Interest: The authors declare that there are no relevant conflicts of interest.

Author Contributions: PRK, BO, GR collected and analyzed patient data including radiographic studies. ACV and PA designed the study and supervised data collection and analysis. All authors contributed in the preparation of the manuscript.

Informed Consent: Informed consent was waived because of the retrospective nature of this study.

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