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CLINICAL CASE SERIES

Lateral Lumbar Interbody Fusion in Ambulatory Surgery Centers

Patient Selection and Outcome Measures Compared With an Inhospital Cohort

Kingsley R. Chin, MD,[*,†] Fabio J. R. Pencle, MB, BS,[†] André V. Coombs, MB, BS,[‡] Morgan D. Brown, BS,[§] Kasey J. Conklin, BS,[*] Andew M. O'Neill, BS,[*] Michael J. McGarry, BA,[*] Jason A. Seale, MB, BS,[†] and Elijah A. Hothem, MD[†]

Study Design. Comparative analysis.

Objective: To evaluate the safety and outcomes of moving lateral lumbar interbody fusion (LLIF) surgeries to an outpatient setting.

Summary of Background Data. LLIF has been popularized as a less invasive lumbar fusion surgery as an alternative approach to anterior lumbar interbody fusions, posterior lateral interbody fusion, and transforaminal lateral interbody fusion (TLIF). Lumbar fusions have been traditionally performed in a hospital setting because of the potential blood loss, length of surgery, and need for longer recovery. There is a movement to transition spine surgeries to outpatient settings with many benefits afforded by less invasive techniques and technologies.

Methods. The medical records of 70 consecutive patients with prospectively collected data were retrospectively reviewed. Two cohort groups, inpatients (40 patients) and outpatients (30 patients), were created. Patient demographics, risk factors, and body mass index (BMI) were evaluated to determine inclusion criteria for study.

Result. A total of 34 males and 36 females, age range (31–71) average 59.3 ± 2.3 years. Average BMI was 29.6 ± 1.1 kg/m^2. The most common level operated on being L3-L4 in both groups (63%). Mean preoperative inpatient Oswestry Disability Index (ODI) increased from 48.5 ± 3.0 to 55.5 ± 3.2 compared with outpatient preoperative ODI means reduced from 45.2 ± 5.1 to 39.1 ± 4.6. There was no statistically significant change in VAS scores between groups. There was however significant improvement in outpatient preoperative VAS scores from 7.3 ± 0.5 to 4.1 ± 0.5, $P = 0.045$.

Conclusion. The outcomes of the present study have shown that patients who had LLIF performed in the outpatient setting had statistically significant improvement in ODI scores compared with the inpatient setting ($P = 0.013$). Fusion was achieved in all patients and there was no evidence of implant failure or subsidence. Complications were transient in both settings. We conclude that outpatient LLIF improves patients' outcomes with similar safety profile as the hospital setting.

Key words: inpatient, lateral lumbar interbody fusion, outpatient fusion, outpatient surgery, retroperitoneal.

Level of Evidence: 3

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Degenerative diseases of the lumbar spine are a common cause of chronic lower back pain and are responsible for creating a significant strain on the health care system in the United States.[1–5] Many treatment strategies exist that aim to reduce pain and limit the progression of the underlying pathology.[1–7] Spinal arthrodesis is one effective treatment option for patients whom have failed conservative therapy for a minimum of 6 to 12 months, and meet all requirements needed for surgical clearance.[6–8]

Traditionally performed in a hospital setting, various approaches and techniques of lumbar arthrodesis for the treatment of degenerative disc disease (DDD) have been reported in the literature with variability in both clinical and radiological success rates.[1–3] The lateral lumbar interbody fusion (LLIF) technique (otherwise known as the direct lateral, extreme lateral, or transpsoas approach) has been popularized as a viable and minimally invasive alternative approach to the lumbar spine.[9–12] Since its introduction by Ozgur *et al*, indications for the lateral approach to the

From the [*]Charles E. Schmidt College of Medicine, Florida Atlantic University, 777 Glades Road, Boca Raton, FL 33431; [†]Less Exposure Surgery Specialists Institutes (LESSi), 1100 W. Oakland Park Blvd, Ste#3, Fort Lauderdale, FL, 33311; [‡]Less Exposure Suregery(LES) Society, 3217 NW 10th Terrace, Ste 307, Fort Lauderdale, Fl 33309; and [§]University of Florida, Gainesville, FL 32611.

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Address correspondence and reprint requests to Kingsley R. Chin, MD, Affiliate Professor of Clinical Biomedical Sciences, Charles E. Schmidt College of Medicine at Florida Atlantic University, Attending Spine Surgeon, Less Exposure Surgery Specialists Institute (LESS Institute), 1100 W. Oakland Park Blvd. Suite #3, Fort Lauderdale, FL 33311; E-mail: kingsleychin@gmail.com.

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lumbar spine have expanded. Originally, they were limited to low back pain secondary to DDD without severe canal stenosis. LLIF indications now, however, include patients with Grade I or II spondylolisthesis, trauma, infection, and degenerative scoliosis.[13–15]

At the turn of the millennium,[15,16] many authors have concluded that the benefits of LLIF entail avoidance of anterior and posterior approach related complications. LLIF evades major vessel and bowel injury anteriorly, dural, and nerve injury posteriorly,[15–17] and can be safely performed in an outpatient setting.

The procedure involves direct transpsoas access of the lumbar spine through the use of specialized retractors and dilators. Consequently, unique adverse effects implicated by this surgical approach may involve transient injury to the lumbosacral plexus, which traverses this muscle, with an incidence of up to 60% in the literature.[18,19] Rarely, however, do permanent neurological deficits occur.[9,10,16]

We wanted to know what the success rate for outpatient LLIF procedure was in order to determine which patient and/or surgical parameters were considered most safe. We, however, found no studies that compared outcomes in the inpatient *versus* outpatient settings. The authors thus conducted a retrospective review of similar prospective cases done in both settings to determine whether there were any statistically significant differences in patient reported and surgical outcomes, complications, and reoperation rates. Based on our findings, we have also provided a list of parameters, which were associated with better clinical and radiologic outcomes in both settings.

MATERIALS AND METHODS

We performed a comparative analysis of 70 adult patients identified from multiple institutions who underwent single-level LLIF with supplemental posterior fixation at each lumbar level from L1-L5. Two groups were assigned, Group 1 in which LLIF was performed in the hospital setting, and Group 2 where LLIF was performed in the ambulatory surgery center (ASC). Patient selection was randomized depending on institution seen originally whether hospital or surgeon's private practice then operation performed at hospital or outpatient setting respectively. All operations were done by a single surgeon, who was experienced in performing LLIF in academic and private hospitals as if it were in an outpatient setting, before commencing in an outpatient setting. Data regarding these groups were collected from medical records and operative notes. IRB approval was obtained for the present study for our institution. Indications for surgery included chronic and disabling lower back pain without radiculopathy for at least 3 months and inability to perform normal daily activity before start of symptoms, secondary to DDD and low-grade (Grade I) spondylolisthesis (Figure 1 A and B). All included patients had failed a minimum of 6 months of conservative therapy, which comprised anti-inflammatory medications, physical therapy, and radiofrequency rhizotomies for patients with suspected facet-mediated axial back pain. Informed patient preference and surgeon discretion prompted the decision to operate *via* a lateral approach.

Inclusion Criteria Used in the Present Study

1. BMI $< / =$ 42.[20,21]
2. All patients with chronic medical illnesses must be stable and be cleared by their family practitioner and/or specialist where applicable.[20,22]
3. Patients with a history of heart disease must be cleared through cardiologist evaluation including echocardiogram and/or stress test.[20,22]
4. Low-to-moderate anesthesia risks (ASA criteria 1–3).[20,23]

Exclusion Criteria Used in This Study

1. Patients with a history of malignant tumors, spinal infections, congenital diseases.

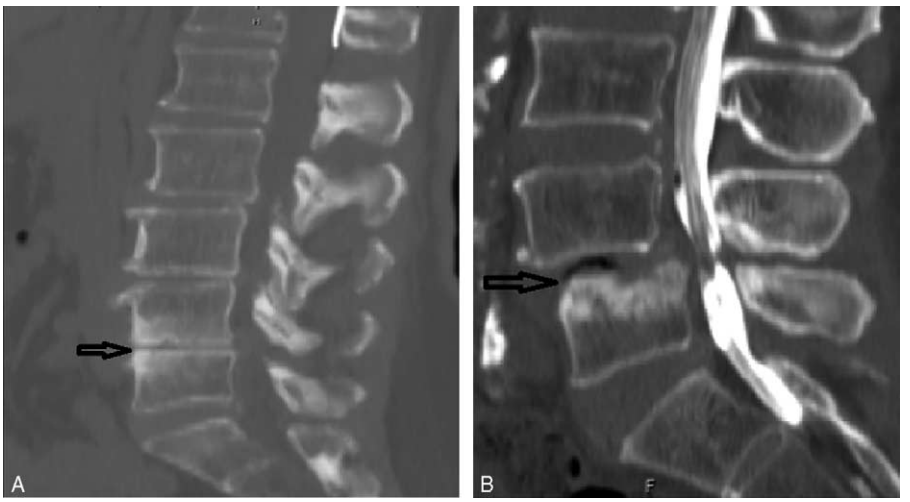

Figure 1. (**A**) Sagittal magnetic resonance imaging (MRI) demonstrating degenerative disc disease (arrow). (**B**) Sagittal MRI demonstrating spondylolisthesis (arrow).

2. Patients with history of major acute traumas, major deformities (severe scoliosis, ankylosing spondylitis *etc.*), and pulmonary embolism.
3. Patients who had previous lumbar spine surgery.

Demographics and Functional Outcomes

Demographic data and functional outcome measures were collected from 2009 to 2014. Pre- and postoperative outcome evaluation executed at 3, 6, 12, 18, and 24 months. Demographic data included age, sex, BMI, and pathological level affected. Functional outcomes included patient numeric rating scale or visual analog scale (VAS) for lower back pain (0–10), Oswestry Disability Index (ODI), surgeon operative time, blood loss, and complication rates.

Fusion

Fusion was aided with interbody polyetheretherketone cages assessed radiologically using fluoroscopy for evidence of interbody placement. In addition, bone grafts were used to aid fusion and included demineralized bone matrix, allograft cancellous chips, and autograph laminectomized bone. All patients received supplemental posterior fixation with the use of transfacet pedicle screws and/or standard pedicle screws and rods.

Less Exposure Surgery Technique

After being intubated by the anesthesia team, the patient was placed left side up in the lateral position with the top of the iliac crest at the level of the break. The table was flexed to open the space between the iliac crest and the ribs, the operative level was identified, endplates aligned, and the table was tilted to bring the operative level into optimal orthogonal alignment. Under fluoroscopic guidance the target disc space was identified and a single incision was made in the mid-axillary line. The retroperitoneal space was entered through blunt dissection and a guide wire placed under fluoroscopic guidance. A series of dilators and expanding retractors were used to expose the anterior 2/3 of the disc space while maintaining hemostasis. Neuromonitoring equipment used included Cadwell-Cascade Elite Cadwell Industries, Inc. Washington, USA and XLTEL Protektor, Natus Medical Inc., California USA, IBM Corp., New York. After confirmation by the neuromonitoring team that it was safe to proceed, an annulotomy was performed followed by discectomy to bleeding endplates. An interbody polyetheretherketone cage was appropriately trialed and inserted with packed demineralized bone matrix bone graft. We then removed the retractors, ensured adequate hemostasis, and confirmed our cage position fluoroscopically before closure (Figure 2). The patient was then placed prone for posterior instrumented fixation of the target level. During the study period there was no change in technique and implants from the same company utilized.

Statistical Analysis

Statistical analysis was performed using SPSS v22 (IBM Corporation, New York). An independent sample Student *t* test was used to compare groups for continuous data and chi-squared used for categorical data. Continuous data comparisons were expressed as means with standard error. Tests were considered significant if $P < 0.05$. Power analysis performed based on means using VAS and ODI scores to achieve a power of 0.8 and α of 0.05, a total sample size of 40 patients is necessary.[24,25]

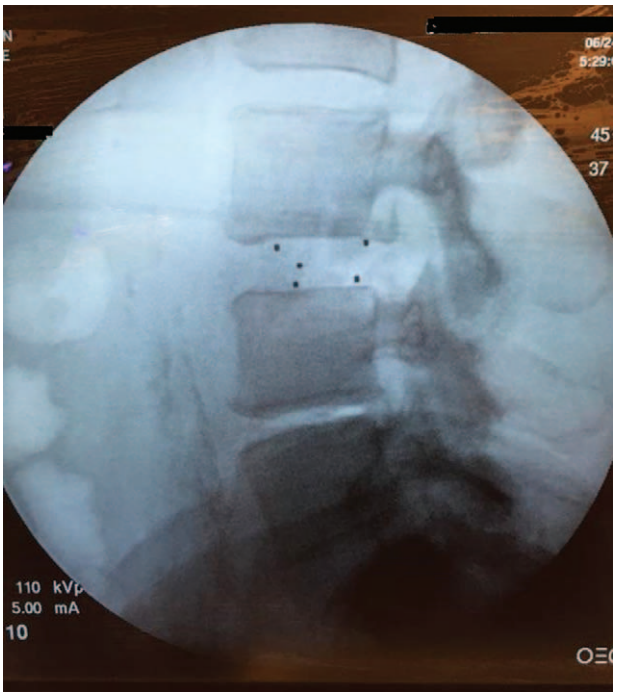

Figure 2. Fluoroscopic image confirming cage placement.

RESULTS

Demographics

Patient demographics are presented in Table 1. A total of 70 patients were evaluated, we then separated them into two groups. Group 1 comprised 40 patients in the hospital setting and Group 2 consisted of 30 patients in the ASC. Females represented 52% of patients overall; however, there was no difference in sex between groups, $P = 0.147$. Overall age and BMI was 59.3 ± 2.3 years and 29.6 ± 1.1, respectively. Mean age of Group 1 was 60.7 ± 2.1 and Group 2 was 57.9 ± 2.5 ($P = 0.076$). Mean BMI for Groups 1 and 2 were 28.4 ± 0.7 and 30.7 ± 1.4, respectively, $P = 0.7$.

Functional Outcomes

Group 1 mean preoperative VAS back pain scores improved from 7.8 ± 0.3 to 4.8 ± 0.8 at final follow-up, $P = 0.004$. Mean preoperative ODI score however increased from 48.5 ± 3.0 to 55.5 ± 3.2 at final follow-up, $P = 0.398$. In Group 2, the preoperative VAS score improved from 7.3 ± 0.5 to 4.1 ± 0.5, $P = 0.045$. Preoperative ODI means reduced from 45.21 ± 5.1 to 39.1 ± 4.6, $P = 0.368$. Statistical comparison of final follow-up outcomes between Groups 1 and 2 showed no statistical difference in VAS scores ($P = 0.503$), but a significant improvement in ODI scores $P = 0.013$. Outcome scores are summarized in

TABLE 1. Demographic Characteristic of Patients Who had LLIF in the Hospital and LLIF in the ASC

Variable	LLIF in Hospital (Group 1)	LLIF in ASC (Group 2)
Age (years)	57.9 ± 2.5	60.7 ± 2.1
BMI (kg/m^2)	30.7 ± 1.4	28.4 ± 0.7
Female	24	12
Male	16	18
Pathological level		
L1-L2	4	2
L2-L3	6	5
L3-L4	25	19
L4-L5	5	4

ASC indicates ambulatory surgery center; BMI, body mass index; LLIF, lateral lumbar interbody fusion.

Figures 3 and 4. The most common level operated on being L3-L4 in both groups (63%). The subsets of patients who saw the greatest improvement in VAS and ODI scores in Groups 1 and 2 were those who had surgery at the L2-L3 and L3-L4 levels, respectively (Table 3).

Analysis of Group 1 and Group 2 surgical times revealed a statistically significant decrease in the outpatient group with operative times of 224 ± 103 minutes and 97 ± 49 minutes, respectively $P = 0.005$. This was also true for estimated blood loss, Group 1 resulting with 143 ± 39 mL lost and Group 2 with 56 ± 10 mL ($P = 0.038$).

Follow-Up

Sagittal and axial CT radiographs were evaluated by the authors (K.R.C., F.J.R.P., and E.A.H.) to look for graft subsidence, implant failure, and status of fusion. Fusion was defined as the absence of radiolucency's, evidence of bridging trabecular bone within the fusion area (Figure 5 A and B). Fusion was achieved in 100% of patients. There was no evidence of implant failure nor signs of nonunion in the groups.

Complications

Overall complication rates were higher in Group 1 for both neurological and non-neurological complications (Table 2). All complications were new onset postoperative complaints. The most common complication overall observed in both groups was dermatome numbness (20% and 7% in Groups 1 and 2, respectively). The level affected most commonly in each group was L4-L5. Weakness was noted by three patients in hospital cohort with average grade 3/5. Only one patient complained of inability to walk in this study that lasted for 6 weeks. Average time to resolution of neurological symptoms was approximately 6 ± 1 month in Group 1 and 3 ± 0.75 months in Group 2.

DISCUSSION

The present study aimed to directly compare the relative safety and procedural outcomes of LLIF performed in both the hospital and surgery center settings. Overall, a statistically significant improvement in ODI scores was observed for those in the outpatient *versus* inpatient setting. Although the difference in VAS scores between both groups was not significant, surgical time and estimated blood loss was statistically lower for outpatient group. In addition the overall number of complications was higher for LLIFs performed in the inpatient *versus* outpatient setting.

The specialty of spine surgery continues to evolve with the development and success of less invasive surgical

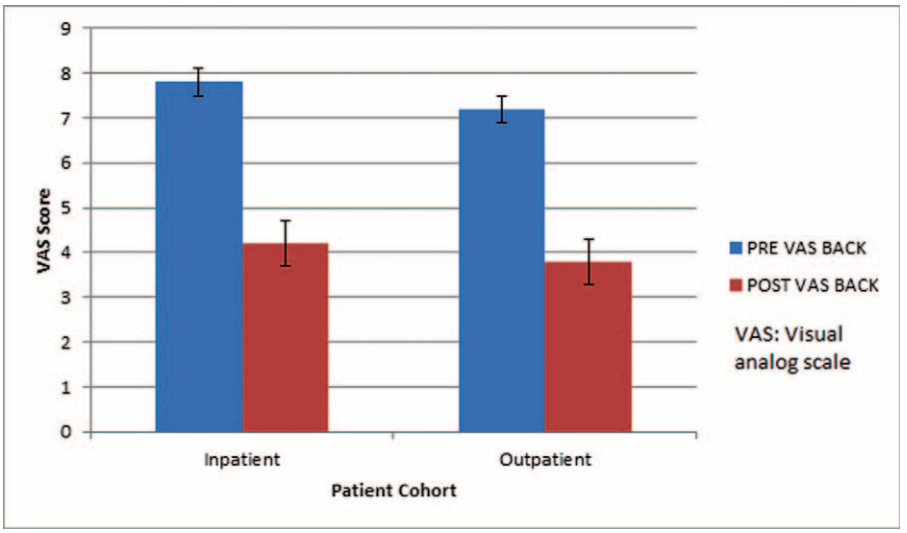

Figure 3. Bar graph of preoperative and postoperative visual analog scale (VAS) scores in the inpatient and outpatient groups.

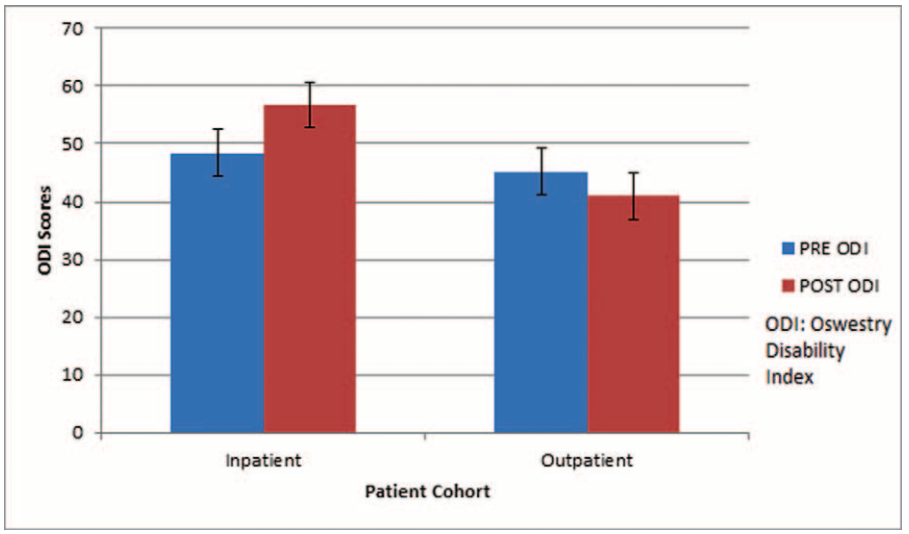

Figure 4. Bar graph of preoperative and postoperative Oswestry Disability Index (ODI) scores in the inpatient and outpatient groups.

techniques and instruments in parallel to the incidence of many procedures occurring in the outpatient setting.[26,27] There are now an estimated 6000 actively operating ASCs across the United States[28,29] and this number is expected to rises with the burgeoning awareness of the general benefits of same day surgery, regardless of specialty. In this single surgeon study LLIF has been performed in the outpatient setting since 2012 after gaining experience in the hospital. Because of the relatively high rate of neurological complaints (such as transient anterior thigh numbness) and complications (such as overt lumbar plexopathies) as reported in the literature,[30,31] the authors decided to do a comparative review of the outcomes of the procedure done in both settings.

Evaluation of single-level fusions only revealed that the most approach-related complications occurred at L4-L5. Possible explanations for this finding may be that the L4-L5 intervertebral disc space is a common location for lumbar disc herniation and the intimate anatomic relation with the lumbosacral plexus.[19,32,33] Despite these unique complications associated with the LLIF, additional benefits garnered include less postoperative pain, shorter operative times, shorter hospital stays, and faster recovery and return to satisfactory quality of life.[10,17,34] Overall, patients in the outpatient group experienced superior results in improved VAS and ODI scores, with fewer complications and approach-related adverse effects.

Strengths and Limitations

The authors report no biases or conflict of interest. The authors note the following strengths and limitations.

The main strengths of the present study are adequate sample size, random selection of patients based on inclusion criteria. The outcomes assessed include patient and surgeon factors that were independently analyzed.

Limitations of the present study include the fact that it was a single-surgeon investigation. The preent study was also a retrospective review of data collected in two cohort populations prospectively. Outcomes were collected for all data point except for three patients from the hospital cohort with missing surgeon time and estimated blood loss.

Recommendations

A few points for surgeons considering performing LLIF in the ASC based on the trends found in this series include avoidance of L5-S1 LLIF[15] in the outpatient setting. Patient

TABLE 2. Postoperative Complications of LLIF in ASC and LLIF in the Hospital

Complication	LLIF in Hospital	LLIF in ASC
Dermatome numbness	4 (10%)	2 (7%)
L1-L2	0%	0%
L2-L3	1 (2.5%)	0%
L3-L4	0%	0%
L4-L5	3 (7.5%)	2 (7%)
Weakness	3 (7.5%)	0%
Inability to walk	1 (2.5%)	0%
Total	8 (20%)	2 (7%)

ASC indicates ambulatory surgery center; LLIF, lateral lumbar interbody fusion.

TABLE 3. Pre- and Postoperative VAS and ODI Scores for L2-L3 and L3-L4 Levels

Scores	Group 1 L2-L3		Group 2 L3-L4	
	Preoperative	Postoperative	Preoperative	Postoperative
VAS score	7.4 ± 0.8	4.6 ± 1.0	7.7 ± 0.8	4.3 ± 2.2
ODI score	55 ± 4.3	47 ± 6.6	41.8 ± 8.7	21.5 ± 5.9

ODI indicates Oswestry Disability Index; VAS, visual analog scale.

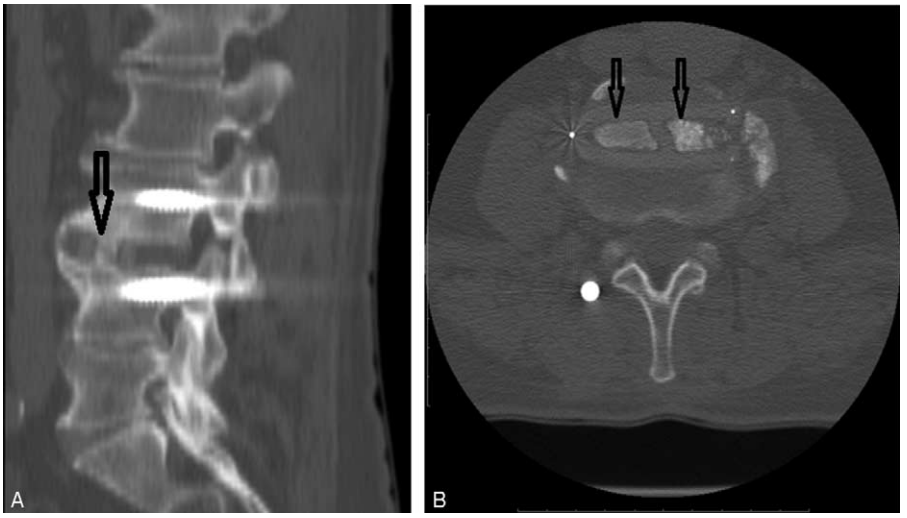

Figure 5. (**A**) Sagittal CT demonstrating fusion with bridging bone (arrow). (**B**) Axial CT demonstrating fusion with bone formation (arrow) within cage.

selection is of paramount importance in minimizing complications associated with the procedure, particularly in the ASC where postoperative monitoring does not occur beyond 24 hours.[20] A BMI of 42 should be the maximum considered for outpatient surgery [20,21] and an operation limited to one level only. Patients who do not meet these basic criteria should have their surgery in the hospital in anticipation of difficult, extended, or delicate surgery.

The present article provides the groundwork for the safety, feasibility, and improved results of outpatient lateral lumbar interbody fusions. Further studies and continued clinical investigations are needed as the expansion of outpatient spine surgery evolves.

CONCLUSION

Using prospective collection of surgical data and retrospective review of two cohorts, the present study has evaluated the safety and outcomes of LLIF surgeries performed in both the hospital and surgical center settings. Overall, fusion was achieved for all patients, however, LLIF performed in the outpatient setting showed a significant improvement in ODI scores ($P = 0.013$), operation time ($P = 0.005$), and blood loss ($P = 0.038$) when compared with the inpatient setting. In addition, a lower rate of complications (both neurological and non-neurological) was observed in the outpatient group. Results of the present study support not only the viability of LLIF as a minimally invasive procedure but also the merit of the procedure in the outpatient setting.

➢ Key Points

- ❑ Lateral lumbar interbody fusion technique has been popularized as a viable and minimally invasive alternative approach to the lumbar spine.
- ❑ Procedure involves direct transpsoas access of the lumbar spine through the use of specialized retractors and dilators.
- ❑ Most common level operated on was L3-L4.
- ❑ There was significant improvement in Oswestry Disability Index in outpatient group compared with inpatient group.
- ❑ Fusion was achieved in all patients.

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