

Patient Outcomes Following Posterior Lumbar Interbody Fusion for Adjacent Segment Disease Using VariLift® as a Standalone Expandable Interbody Device

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Abstract

Background: Adjacent segment disease (ASD) is a notable complication following lumbar fusion. Clinicians use various surgical techniques to correct progression of spine deterioration and reduce the risk of continued ASD. The aim of this retrospective case series is to describe patient outcomes following posterior lumbar interbody fusion (PLIF) using the VariLift® standalone expandable interbody device (without supplemental fixation) for the treatment of ASD.

Methods: Nine consecutive patients who underwent a single-level PLIF for the treatment of ASD were reviewed. Outcome measures included patient demographics, comorbidities, surgical complications, time to fusion, Visual Analog Scales for Pain (VAS), and overall patient-reported recovery of symptoms. Nine patients (8 males, 1 female) with a mean age of 62.3 (42 to 72) years underwent a single-level procedure. The standalone VariLift expandable interbody fusion system was used in all nine (9) sequential patients, regardless of the type of fusion/fixation instrumentation previously used. Surgical technique consisted of discectomy and generous bilateral laminotomies with medial facetectomies preserving midline ligamentous structures.

Results: Radiographic ASD was confirmed in all cases. Each patient had a history of a lumbar fusion. Preoperatively, 89% of patients reported 9-10 VAS back pain levels. All patients experienced symptomatic improvement. By 12 months postoperatively, average VAS back pain score was 2, a significant improvement from baseline ($p < 0.05$). Solid interbody fusion without implant failure was observed in all cases with averaged time to fusion at 346 days (min = 181 days).

Conclusions/Level of Evidence: Posterior lumbar interbody fusion using the VariLift device to treat symptomatic ASD offers significant clinical success and solid fusion rates without the need for supplemental fixation or extension of previous supplemental fixation. Level of evidence IV.

Clinical Relevance: This stand-alone expandable fusion device produced high fusion rates and symptomatic improvement in a sample of patients with severe back pain and ASD.

Keywords: Posterior lumbar interbody fusion (PLIF); Adjacent segment disease (ASD), standalone; VariLift; complications

degeneration at the adjacent level, where most surgical fusions occur (L3-S1) [3].

Introduction

Adjacent segment disease (ASD) is a notable spine surgery complication that can include instability, disc herniation, spondylolisthesis, stenosis, and/or vertebral compression fractures stemming from spinal fusion. The origin of adjacent level disease of the lumbar spine is a strongly debated topic in the spine literature. The concept is based on the theory that specific spine interventions increase the likelihood of spine degeneration compared to the natural rate of degeneration [1,2]. Studies note that the incidence of clinically symptomatic ASD following lumbar fusion ranges between 0.6-3.9% annually [1]. However, patients who experience symptomatic ASD report intractable back pain with a significantly decreased quality of life. Patient age, degree of debilitation, and chronic comorbidities are just a few of the various risk factors that can influence the rate of

Radiographic diagnosis of adjacent segment disease is based on the presence of instability, radiculopathy, or spinal stenosis above or below a previously fused level that causes clinical symptoms unresolved with conservative therapies such as physical therapy, medication, and/or steroid injections [4,5]. Current treatment of symptomatic ASD typically consists of decompression and stabilization, with an extension of existing pedicle screw hardware, which often results in added postoperative complications [4]. While the argument can be made that the use of supplemental posterior fixation with pedicle screws and rods ensures biomechanical stability, supplemental fixation is more technically demanding, increases operative time, and can cause further complications such as violation of the adjacent facet joint, which contributes to continued ASD. Various studies have reported that biomechanics and large torque application play a significant role in adjacent segment disease [6,7]. Some studies have explained that

patient specific risk factors such as age, comorbidities, and prior fusion results as well as the use of pedicle screws and rods accelerates ASD by further degenerating the intervertebral disc or progressing spondylolisthesis in the adjacent segments [1,4-8]. Therefore, it is important to find alternatives for symptomatic patients who may have had prior fusion using pedicle screws but may not present significant radiographic evidence of degeneration [2,4]. Many surgeons report that alternative decompression techniques, including laminoplasty, indirect decompression with interspinous spacers, and minimally invasive decompression and fusion with certain interbody devices may help decrease the risk of developing ASD postoperatively by preserving a certain amount of needed motion within the spine [2,4].

In this case series, we reviewed nine (9) patients who underwent a single-level PLIF using the VariLift-L device for the treatment of symptomatic ASD. The aim of this retrospective case series is to describe patient outcomes following posterior lumbar interbody fusion (PLIF) using the VariLift® standalone expandable interbody device (without supplemental fixation) for the treatment of ASD. The VariLift® Interbody Fusion System (VariLift® system) has been developed as a standalone solution to provide the benefits of intervertebral fusion cages without the requirement of supplemental fixation that has been shown to contribute to ASD [9].

Materials and Methods

This retrospective case series was based on a review of medical records for nine (9) consecutive patients treated surgically for single-level adjacent segment disease (ASD). From July 2013 to December 2015, these nine (9) patients were treated with a single-level PLIF using standalone VariLift-L by the same surgeon (BW) at one of two teaching facilities.

All patients returned for initial post spinal fusion visits that involved a radiographic assessment and clinical examination by the senior author. The development of new or persistent symptoms, work status, functional status, the use of pain medication, and the findings of a complete neurological examination were documented. Functional status was documented using a VA facility modified Oswestry scale that was documented descriptively in the clinical notes.

Prior to surgery, all patients were treated with conservative measures, including medication, activity modification, and physical therapy for at least 6 months. Indications for surgery included preoperative symptoms such as intractable back and leg pain, disabling intermittent claudication, and progressive neurological deficits attributed to spondylosis, stenosis, disc herniation or rupture, instability, or nerve impingement related to the adjacent segment above or below a previous lumbar fusion.

Radiographic diagnosis of adjacent segment disease was based on the presence of instability, radiculopathy, or spinal stenosis above or below a previously fused level causing clinical symptoms unresolved with conservative measures. Radiographs including x-rays, CT, or MRI of the lumbar spine were obtained in all patients. The operating surgeon's decision to use standalone VariLift-L was made during review of radiographs and discussion of options with each patient. The number of fusion levels and where the VariLift-L device was implanted was based on radiographic findings and disease presentation at time of surgery.

All patients underwent a single-level PLIF procedure with minimally-invasive implantation of the VariLift®-L interbody fusion

system (Wenzel Spine, Austin, TX USA). Surgical technique consisted of discectomy and generous bilateral laminotomies with medial facetectomies preserving midline ligamentous structures. In all cases, the VariLift device was implanted without supplemental posterior fixation, such as pedicle screws and rods. The surgeon used various grafting techniques for each case, including but not limited to a combination of milled autologous local bone admixed with Vitoss (Stryker®, Malvern, PA USA) bone graft substitute and bone marrow aspirate to pack the anterior disc space.

VariLift®-L is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had 6 months of nonoperative treatment [9,10]. The VariLift®-L is a titanium, standalone, expandable interbody fusion device (Figure 1).

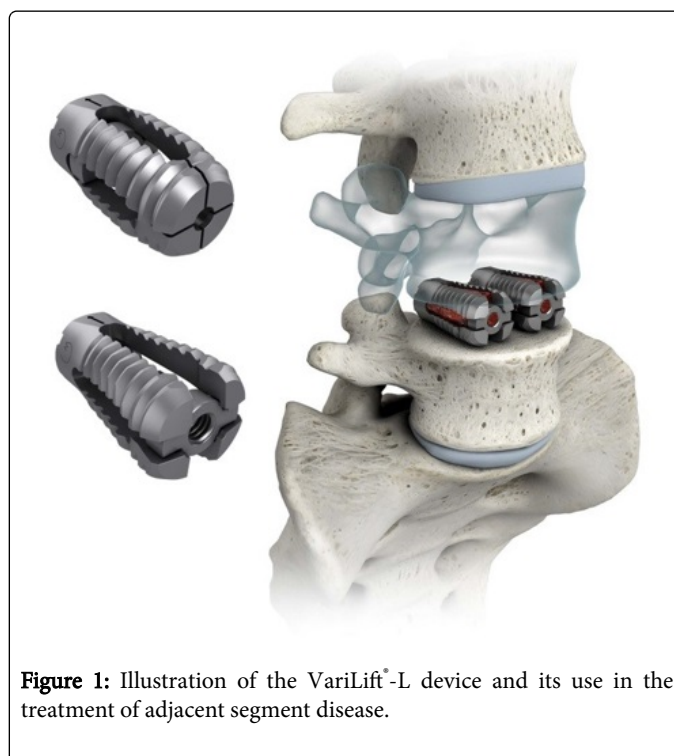


Figure 1: Illustration of the VariLift®-L device and its use in the treatment of adjacent segment disease.

The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease with up to grade I spondylolisthesis [9]. VariLift®-L is designed to be implanted bilaterally via a posterior (PLIF) approach or as a single device via a transverse (TLIF) approach [9,10]. The device may be implanted with or without supplemental fixation and intended for use with autograft to facilitate fusion. Prior to surgical implantation, the VariLift device is bulletted in design with a leading edge as small as 6mm. This standalone expandable device is grooved and self-tapping to reduce or eliminate impaction during insertion into the intervertebral space. The device is then expanded *in situ* by advancing a sliding expansion plate to lock and secure the device in proper anatomical position. The bone graft chamber and open architecture (fenestrations) on all four sides of the implant allow for bone graft contact with the endplates to promote intervertebral bony fusion [9]. The design characteristics, indications for use, operative technique and clinical experience with the VariLift® device have been published previously [9,10].

All patients were evaluated postoperatively at different follow-up time points on average at 3 weeks and months 3, 6, 12, 18, and/or 24 after surgery based on patient availability to return for clinical

assessment. Back pain intensity was assessed with the visual analog scale (VAS), and any leg symptoms were recorded with the clinical assessment. Radiographic follow-up was obtained routinely using plain radiographs, CT scans, and MRIs and compared against each other with the last follow-up to assess fusion status. Fusion parameters include the presence or absence of bridging bone, cage subsidence and vertebral osteolysis [11]. Solid interbody fusion was defined as trabecular bone growth across the disc space in and around the VariLift device (Figure 2,3).

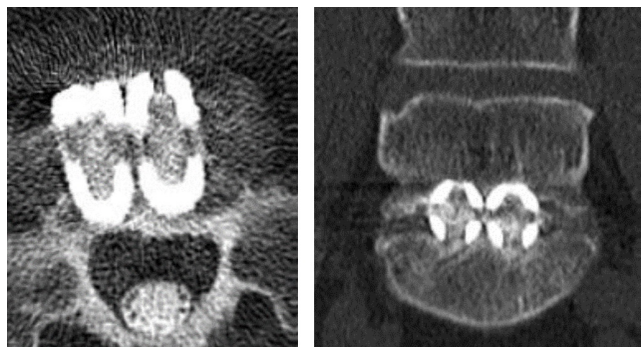


Figure 2: Axial and Coronal view of trabecular bone growth across the disc space in and around the VariLift device.



Figure 3: Lumbar CT at 12 months assessing fusion. At final follow-up, all patients reported minimal or no lumbar symptoms. Fusion is clearly documented by CT.

Follow-up review of levels above or below the VariLift fused level was conducted postoperatively by radiology to assess for continued ASD including development of additional surgical complications such as retrolisthesis, hypermobility, loss of disc height and/or disc degeneration.

Statistical Methods

The total study sample was nine (9) patients. Patient demographics, comorbidities, surgical complications, time to fusion, VAS, and overall

patient reported recovery of symptoms were used as outcome measures. Values for VAS were analyzed using descriptive statistics, including mean, standard deviation, and two-tailed t-test for P-value.

Results

In this case series, we reviewed nine (9) patients who underwent a single-level PLIF using the VariLift-L device for the treatment of symptomatic ASD. The patient characteristics are described in Table 1.

Characteristic	Value (N = 9)
Sex, n (%)	
Female	1 (11)
Male	8 (89)
Age, mean (range)	
	62.3 (42-72)
Ethnicity, n (%)	
Caucasian	5 (56)
African American	3 (33)
Other	1 (11)
Comorbidities, n (%)	
Cardiac History	4 (44)
Diabetes	2 (22)
Hyperlipidemia	5 (56)
Hypertension	8 (89)
Mental Health	4 (44)
Obesity	5 (56)
Smoking/Hx of Smoking	5 (56)

Table 1: Demographic characteristics of 9 patients treated with single-level PLIF using standalone VariLift-L interbody fusion device.

Each of the nine (9) consecutive patients (8 males, 1 female) with a mean age of 62.3 (42 to 72) years had ASD confirmed with radiographs.

Preoperatively, these nine (9) patients complained of intractable back pain with or without radiating leg pain, numbness, and/or tingling and a decrease in functional activities of daily living (ADLs). All nine (9) consecutive cases had a history of a lumbar fusion with some form of prior fusion with supplemental fixation. Postoperatively, all patients reported significant pain relief, functional improvement based on documented clinical assessment, and time to fusion was observed and noted following surgery (Table 2).

Characteristics	Value (N = 9)
VariLift Surgical Level, n (%)	
L2/L3	1 (11)
L3/L4	5 (56)

L4/L5	3 (33)
Estimated Blood Loss (ml)	
Mean, range	275 (100-400)
Hospital Days (days)	
Mean, range	3.7 (2-6)
Follow-up (mos)	
Mean, range	13 (6-24)
Time to Fusion (days)	
Mean, range	346 (181-833)

Table 2: Surgical Outcomes.

Solid interbody fusion without implant failure was observed in all cases with averaged time to fusion at 346 days (min = 181 days). Solid interbody fusion was defined as trabecular bone growth across the disc space in and around the VariLift device observed radiographically (Figure 3).

Preoperatively, 89% of patients (8 of 9) reported 9-10 VAS back pain levels. All nine (9) cases underwent a surgery for symptomatic ASD using a standalone VariLift interbody fusion system. All patients experienced symptomatic improvement and, by 12 months postoperatively, average VAS back pain scale for all patients was 2. The mean VAS scores are summarized in Table 3.

Variable	Value (N = 9)
Back Pain VAS	
Preop	9.3 ± 0.7
Final Postop	2.4 ± 2.6
VAS: visual analog scale	

Table 3: Clinical Outcomes.

Overall, pain scores improved significantly from baseline to 12 months ($p < 0.05$). In addition to improved pain, neurological clinical assessment and functional status after VariLift implantation described significantly improved or completely resolved patient symptoms and return to normal activities of daily living for all nine (9) patients.

There was no surgery-related mortality. One patient had an unintended durotomy that was repaired during surgery. The patient was kept flat in bed 24 hours postoperatively. One patient had a longer time to fusion (833 days) that appeared to be associated with a number of chronic comorbidities including but not limited to diabetes, obesity, vitamin D deficiency, and kidney disease. In addition, radiographic imaging was lacking between 12 and 24 months due to the patient not returning for follow-up to confirm fusion status. Fusion was confirmed when the patient returned for follow-up at 24 months and imaging was obtained. Postoperatively, there were 2 patients who reported mild pain (VAS 4-5). In both occasions, the patient explained to the clinician that they were experiencing cervical pain ranging from upper neck to mid back and were under conservative treatment for a cervical condition. VAS scores were not differentiated for neck or back pain during follow-up visits and were only recorded by the neurology

clinician (Physician Assistant or Nurse Practitioner) as 1 overall VAS score. All of these patients received appropriate clinical care for their conditions and did not report additional complications or negative outcomes.

Discussion

In this case series, only cases in which PLIF was performed using standalone VariLift for the treatment of ASD were selected. Each of these cases were further reviewed for completeness of data and available radiographs. The most common pattern of ASD was lumbar spondylosis with stenosis and neurogenic claudication at the level above a previously surgically-fused level (Figure 4a). Of the nine (9) consecutive cases, 7 treated patients had developed ASD above the surgical level that had undergone a previous PLIF procedure with supplemental fixation with pedicle screws and rods (Figure 4a, d-f). In one of the two treated cases in this series, the patient had a surgical intervention (L4-L5) with BAK cages in the early 1990s and developed symptomatic ASD at L3-L4 in 2013 (Figure 4b). In the second treated case, the pedicle fusion system was removed in a surgery prior to the PLIF using the VariLift device (Figure 4c).



Figure 4: The most common pattern of ASD was lumbar spondylosis (panel a). One patient developed ASD following use of BAK cages (panel b). In one patient, a pedicle fusion system was removed before PLIF using VariLift (panel c). Several patients developed ASD above a previous PLIF procedure (panels d-f).

When expanded, the large open architecture (fenestrations) allowed for adequate radiographic visualization of the developing fusion construct [12]. At the final follow-up evaluation, all patients reported minimal or no lumbar symptoms experienced preoperatively with fusion clearly documented (Figure 5 CT, and Figure 6 X-Ray).

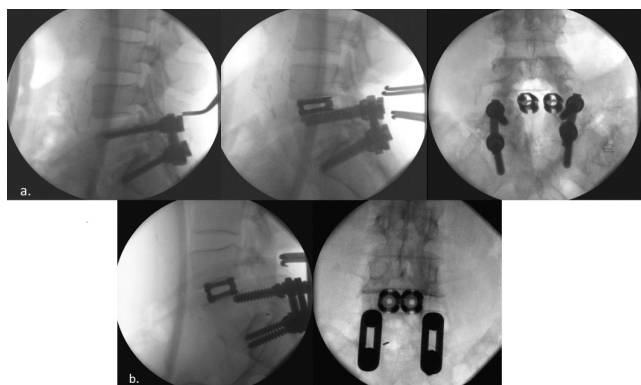


Figure 5: Surgical implantation of VariLift. In each case, 2 bilateral devices were implanted, providing maximal endplate contact (panels a and b).



Figure 6: Lumbar X-ray at 12 months assessing fusion. At final follow-up, all patients reported minimal or no lumbar symptoms. Fusion is clearly documented by X-ray.

Population size is a limitation of this case series. Arguably, a larger population with a diagnosis of symptomatic ASD who undergo a PLIF using standalone VariLift treated by multiple surgeons would need to be reviewed and analyzed. Additionally, mastery of a surgical technique that focuses on maintaining the integrity of the structures and adequately prepares the disc space in fusion surgery has long been argued as a significant measure in preventing continued ASD [8]. Frequent performance of PLIF procedures using a standalone VariLift device can only help to improve the comfort level of the surgeon,

adequate implantation of the device within the disc space, and continued positive patient outcomes. Finally, this case series did not address the cost-effectiveness of using the standalone VariLift device for the treatment of ASD compared to the use of an interbody cage with supplemental fixation. Further investigation would be warranted.

Conclusion

In conclusion, symptomatic ASD remains a significant cause of postoperative morbidity and reoperation following lumbar fusion. Employing a standard PLIF procedure provides decompression of neural structures and restores lordosis and foraminal patency. Moreover, our data suggests that a PLIF with use of the VariLift-L device without supplemental fixation for the treatment of ASD resulted in positive patient outcomes evidenced by a significant reduction in VAS scores and clinical symptoms. This surgical technique offered significant clinical success and high fusion rates, without the need for supplemental fixation or extension of current supplemental fixation.

Conflicts of Interest and Sources of Funding

Dr. Wohlfeld is a non-paid consultant for Wenzel Spine and has no conflict of interest regarding the publication of this paper. Dr. del Monaco is an employee of Wenzel Spine.

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