Abstract: This case report demonstrates the successful use of the VariLift-L Expandable Interbody Fusion System for the treatment of degenerative grade I spondylolisthesis at L4-5. The VariLift-L system was designed to restore disc space height, reestablish foraminal patency, and achieve solid interbody fusion. The devices are placed via a minimally-invasive posterior approach in a stand-alone capacity, without supplemental pedicle screw fixation. This application is only indicated for Grade I spondylolisthesis patients without pars interarticularis defects. For these patients, we propose that the VariLift-L System offers a simplified method of achieving solid intervertebral stability that preserves the posterior native anatomy and maintains facet micro-motion post-operatively.

Introduction

In patients with degenerative spondylolisthesis for whom non-operative treatments have failed, spinal decompression and fusion is the indicated method of treatment. Various surgical approaches and different types of instrumentation for this treatment plan have been thoroughly described in the literature, including posterior lumbar interbody fusion (PLIF). Generally, the goals of surgical treatment with fusion are to decompress the neural elements, re-establish and maintain foraminal patency, and stabilize the subluxation of the involved vertebral bodies. Here we report on a case of degenerative Grade I spondylolisthesis treated with the stand-alone VariLift-L Interbody Fusion Device via a PLIF approach.

Case Summary

This patient was a 58-year-old male diesel truck mechanic who underwent L2-S1 decompression 15 years previously for removal of a large intradural neurofibroma. Twelve years post-operatively, he was noted to have developed L4-5 disc space narrowing with an early Grade I spondylolisthesis. Two years later, he fell in the shower and developed low back pain which radiated into his hips and legs bilaterally. On physical examination, range of motion at his waist was restricted by 50%. Straight-leg raising was very positive at 60° bilaterally, and he had developed a 30% weakness of his right foot dorsiflexors.

Plain radiographs, with flexion and extension views, and a lumbar MRI scan revealed severe disc space narrowing, bilateral foraminal stenosis, and a Grade I spondylolisthesis at L4-5. The L4-5 disc was significantly protruded posteriorly causing cauda equina compression. Significant instability was noted on bending films. (Figure 1 on the following page) A lumbar myelogram/CT scan confirmed the above findings. During the myelogram, his alignment at L4-5 reduced to almost normal position on extension, but subluxed to 16 mm on forward flexion, with cauda equina compression.

In the operating room no pars inter-articularis defects were present, and stand-alone posterior lumbar interbody fusion at L4-L5 was performed utilizing VariLift-L Expandable Interbody Fusion Devices (Figure 2 on the following page). This titanium-alloy (Ti6Al4V) device includes a novel expansion feature, which provides a secure anatomic fit within the disc space. The device is cylindrical in shape, with flattened sides, a grooved surface, a hollow inner chamber, and wide fenestrations on each of the four sides. After implantation, an inner locking expansion washer is advanced anteriorly, opening the device into a...
wedge shape and creating a 12˚ angle of lordosis in the anterior end of the disc space. This expansion securely locks the grooves of each device into the vertebral endplates, stabilizing the interspace and preventing device migration. (Figure 3)

After accessing the L4-5 disc space via a minimally-invasive posterior midline surgical approach, bilateral exploration and decompression was performed at L4-5, with lysis of epidural adhesions. No recurrent tumor was noted on pre-op studies or during surgery. The L4-5 disc was removed in a standard bilateral fashion. Significant instability with severe bilateral foraminal narrowing and bilateral L4 and L5 nerve root compression was present.

A ring curette was used to remove the cartilaginous plates from the vertebral body surfaces, thus preparing the end-plate for direct graft-to-bone contact. Care was taken to preserve the structural integrity of the weight-bearing vertebral endplates, as this is key to avoiding future subsidence of the VariLift-L devices. A bullet spacer was placed into one side of the disc space, slightly distracting the vertebrae. On the contra-lateral side of the disc space, a sizing drill was used to select the device diameter and prepare the posterior opening of the disc space. In this patient, a 13-mm VariLift-L device was selected and screwed into proper position in the disc space via fluoroscopy. The inner locking expansion washer was then advanced anteriorly with the expansion wrench, expanding the VariLift-L device and locking it into position in the disc space. The bullet spacer was removed from the contra-lateral side of the disc space. The second 13-mm VariLift-L device was then inserted into the contra-lateral side of the disc space, parallel to and at the same depth as the first device. The second device was then expanded and locked into position in the disc space.

After bilateral placement and expansion of the VariLift-L devices, the disc space and the VariLift-L devices were copiously flushed with an antibiotic solution. The devices and disc space were then packed with morselized locally-acquired bone graft, obtained from the spinous processes.
and lamina arches. The endcaps were then threaded into place, compacting the bone graft securely inside the VariLift-L devices. Surgical blood loss of 200 ml was noted.

The patient had immediate relief of his severe pre-operative low back and leg pain. He gradually ambulated, and was discharged home 3 days post-surgery. Plain radiographs taken 6 months post-operatively indicated excellent position of the VariLift-L devices at L4-5 with fusion in progress. Flexion and extension views at that time showed no instability.

Discussion

The device and procedure employed in this case have been used clinically for over 15 years. In 2002, Dr. David Attia, the inventor of the VariLift-L device, reported his 5-year results, noting a greater than 90% fusion rate with minimal complications, 79% of patients had pain reduce from high to low/moderate, and early recovery.8,9,10 A single center, multi-surgeon retrospective study of 638 consecutive patients with up to a 2-year follow-up demonstrated significant pain score improvement.11 Radiographic analysis of this series showed a 95.9% fusion rate and with significant (more than 3 mm) device subsidence and migration observed in 3.54% (11/311) and 0.64% (2/311), respectively.11 Other reports12,13 have also verified the clinical viability of the VariLift-L system.

Because the VariLift-L System was designed to achieve immediate stability with stand-alone use, the additional need for supplemental pedicle screw fixation can be avoided in most patients. This permits a smaller incision, but also allows for the preservation of much of the native posterior anatomy, including micro-motion in the facet joints. This is especially important in cases of spondylolisthesis, where the posterior anatomy is pre-operatively compromised. Thus, the VariLift-L system can offer the benefits of a minimally invasive operative technique along with benefits of an open exposure (i.e. a bilateral view of the disc space after decompression allowing for easy device insertion, with minimal retraction of the neural elements).

Note that the use of the VariLift-L System in a stand-alone capacity is not indicated for patients with spondylolisthesis of greater than Grade I or in those patients with bilateral pars interarticularis defects. In Dr. Neely’s experience, VariLift-L combined with posterior pedicle screw and posterior-lateral fusion is a very effective method of treating patients with subluxations of greater than Grade I.

Conclusion

This case demonstrates the successful use of VariLift-L Expandable Interbody Fusion Devices in a stand-alone capacity for the treatment of degenerative Grade I spondylolisthesis. This is a straight-forward bilateral PLIF approach that provides immediate solid interbody stability and foraminal patency, while preserving facet anatomy and micro-motion.
Treatment of Grade I Spondylolisthesis Using the Stand-Alone VariLift-L Expandable Interbody Fusion System: A Two-year Retrospective Review

Materials/Methods:
Retrospective cohort study
- 104 consecutive patients
- Diagnosis of Grade I Spondylolisthesis without pars interarticularis defects
- 29 men, 75 women
- Mean age 65.8 year (41 to 86)
- Minimally-invasive midline PLIF approach
- Bilateral placement of stand-alone VariLift-L devices

Results:

<table>
<thead>
<tr>
<th>Complications</th>
<th>12- and 24-Mo Radiographic Outcomes:</th>
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<tbody>
<tr>
<td>Deep Infection 0.00%</td>
<td>Fusion Rate 95.9%</td>
</tr>
<tr>
<td>Adjacent Level Disease 2.91%</td>
<td>12-Mo Migration* 2.38% (2/84)</td>
</tr>
<tr>
<td>Adjacent Level Disease Disease</td>
<td>24-Mo Migration 4.26% (2/47)</td>
</tr>
<tr>
<td>Return to OR for Supplemental Fixation 0.00%</td>
<td>12-Mo Subsidence* 0.00% (0/84)</td>
</tr>
<tr>
<td>Return to OR for VariLift-L Reposition 0.00%</td>
<td>24-Mo Subsidence 4.26% (2/47)</td>
</tr>
</tbody>
</table>

* Positional change < 3 mm is considered stable. Percentage based on number of levels.

Conclusions
- Significantly improved pain scores
- A high rate of bony fusion
- Low rate of subsidence
- No re-operation or revisions

References