



Case Report:

Treatment of Adjacent Level Disease with the Stand-Alone Expandable VariLift® -C Cervical Interbody Fusion Device

Abstract:

The treatment of adjacent level disease subsequent to cervical fusion often involves a complex surgical procedure. This case report demonstrates that the stand-alone VariLift-C Cervical Interbody Fusion Device can provide a straightforward and clinically successful solution for these patients.

Introduction:

Anterior cervical discectomy and fusion (ACDF) is a widely accepted treatment for patients with failed conservative treatment of neck and arm pain associated with degenerative disc degeneration and disc herniation. However, a noted finding after this procedure is the development of degenerative disc disease and disc herniations at an adjacent disc space level (ALD), with rates reported in the literature of greater than 25% within 10 years following surgery.^(1,2) There is no consensus regarding the precise etiology of ALD, whether caused by biomechanical effects of the fusion, the natural progression of previously existing degenerative disease, or by some combination.⁽³⁾ Treatment of these patients often involves a difficult and invasive surgical procedure, requiring removal and revision of the patient's hardware. Here we report on using the zero-profile VariLift-C Cervical Interbody Fusion Device, in a stand-alone fashion, for the treatment of a patient with cervical ALD.

Case Summary:

A 44 year old female presented with significant neck and right arm pain three years following an ACDF at C6-7 with a cadaver interbody bone plug, anterior plate and screws. Her pain was confined to her right posterior neck, shoulder and arm. Her neurological examination revealed hypesthesia in the right C6 nerve root distribution and a 40% weakness of her right biceps and brachioradialis motor groups. Her right biceps deep tendon reflex was absent. MRI scans of her cervical spine revealed a large central and right sided disc herniation, with spinal cord and right C6 nerve root compression. Plain x-rays with flexion and extension views and a CT scan of her cervical spine indicated a slightly incomplete, but stable fusion at C6-7.

(Figure 1)

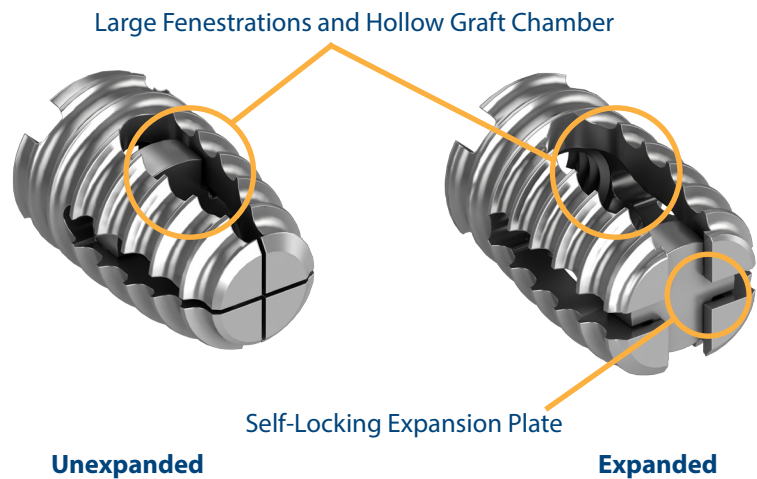


(Figure 1)

Pre-operative MRI showing the C5-C6 disc herniation and previous ACDF at C6-C7

Case Summary Cont.:

The patient underwent C5-6 anterior cervical discectomy and fusion (ACDF) utilizing the VariLift-C expandable interbody fusion device, in a stand-alone fashion. The anterior plate and screws from the C6-C7 fusion procedure were solid and were not removed. Intra-operative spinal cord monitoring was utilized in performing the C5-6 discectomy with spinal cord and bilateral C6 nerve root decompression. Following disc removal, attention was turned to stabilization. Two 9mm VariLift-C interbody fusion devices were inserted into the disc space, one on either side of the midline, and slightly counter-sunk below the anterior edges of the vertebral bodies. After insertion, each device was expanded and locked into position in the end-plates of the C5 and C6 vertebrae, respectively.

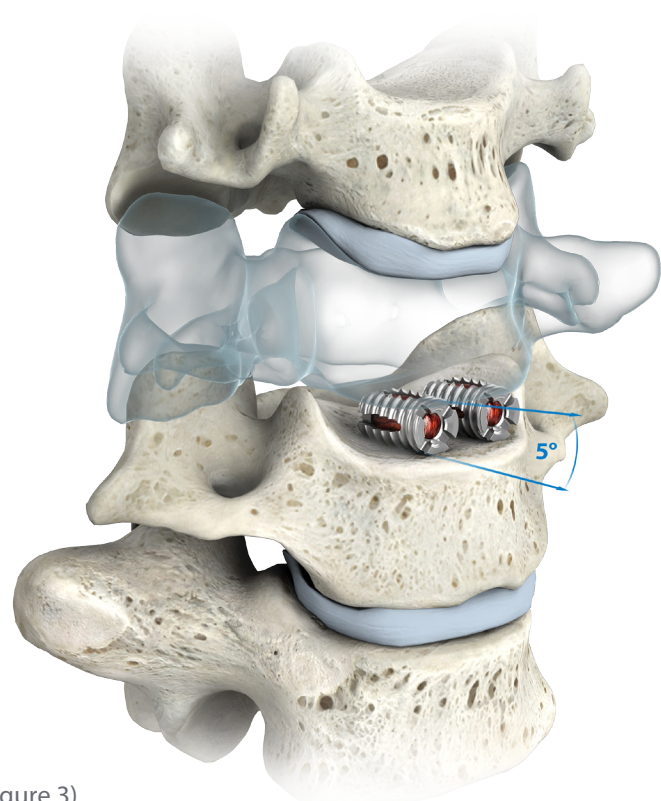


(Figure 2)

The VariLift-C device is composed of medical grade titanium-alloy (Ti6Al4V) which provides strength and durability. The device includes a novel expansion feature, which provides a secure anatomic fit within the disc space. The unexpanded device is a tapered wedge shape with a grooved surface, a hollow inner bone graft chamber and wide fenestrations on each of the four sides. (Figure 2) After implantation, an inner locking expansion plate is advanced to the posterior end of the device, expanding the device and locking the grooved edges into the vertebral end-plates. This immediately stabilizes the disc space and reduces the incidence of device migration. The final wedge shape of the expanded VariLift-C device imparts 5 degrees of lordosis into the anterior aspect of the disc space. (Figure 3)

Surgical Technique:

Following exposure of the anterior cervical spine at C5-6, disc removal and decompression of the spinal canal was performed using a Caspar retractor. The Caspar pins were placed in the midline of each vertebra. During disc removal, the vertebral endplates were carefully preserved so as to function as the weight bearing surfaces for the VariLift devices and the cartilaginous plates were removed to ensure proper bone graft to vertebral body contact. The 7.5 and 9.0mm taps were used as sizing devices to assist in selecting the proper implant size. The VariLift-C devices are self-tapping, and do not require the disc space to be tapped prior to insertion. Two VariLift-C devices were inserted bilaterally into the prepared disc space. The first VariLift was screwed into place with no impaction on one side of the midline using the insertion wrench. The device was counter-sunk into the center of the disc space for stabilization and sagittal balance of the cervical spine. Intermittent fluoroscopy confirmed the position and depth of the VariLift device. Once positioned in the disc space, the VariLift-C was expanded using the expansion



(Figure 3)

The surface ridges grip into the bone and provide immediate stability and resistance to migration over time. The large fenestrations provide a clear view into the graft chamber

Surgical Technique Cont.:

wrench to engage the ridges on the surface of the device to the vertebral endplates. The second device was then inserted and expanded on the ipsilateral side of the disc space in a similar fashion. The final position of each VariLift placed the large fenestrations in contact with the vertebral endplates for bone graft to vertebra contact. Final intra-operative imaging was completed to verify proper zero-profile device placement.

The disc space and VariLift devices were then irrigated and filled with locally acquired bone graft. Bone wax was placed over the anterior end of each device to secure the bone graft inside the graft chambers. Following wound closure, the patient was immobilized in a collar for six weeks. Post-operative recovery was uneventful with complete resolution of the patient's pre-operative symptoms and neurological deficits. Clinical follow-up was uneventful with no complications over a 1 year period. Follow-up radiographs indicate a stable interbody fusion at C5-6 with no change in her C6-7 interspace. (Figure 4)

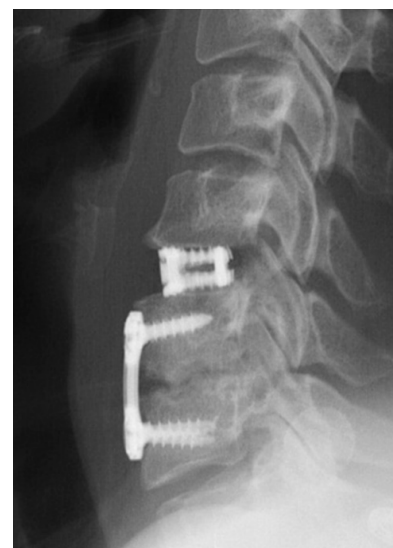
Discussion:

The VariLift-C device has been used in Europe for 15 years and received clearance from the FDA in Jan 2013 for use as a stand-alone interbody device for use in cervical spine. Insertion of the device is straightforward and, due to the grooved surfaces on the inferior and superior surfaces, it provides immediate stability without the need for supplemental fixation.⁴ These features allow the VariLift-C to be implanted in patients with ALD with no disruption to the existing hardware. Its zero profile design leaves nothing anterior to the vertebral bodies which potentially decreases the risk for potential post-operative complications such as migrating screws or chronic dysphagia.^(5,6) Each device has a large bone graft chamber and wide fenestrations providing excellent graft to vertebra contact. When used stand-alone, micro-motion is preserved in the facet joints of the fused interspace, thus possibly lessening the future breakdown of adjacent disc spaces.

(A)



(B)



(Figure 4)

One year follow-up radiographs (a) A/P neutral, (b) Lateral flexion

Conclusion:

ALD following spinal fusion is a frequent complication that can pose many technical challenges in its surgical treatment. This case report demonstrates that the stand-alone VariLift-C Cervical Interbody Fusion Device can provide a simple and straightforward solution in the treatment of Adjacent Level Disease associated with previous cervical fusion.

References:

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