

Clinical Perspective

Decompression and Fusion with the Valeo® TL Transforaminal Interbody Fusion Device

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Summary

This case reports on a 51 year old female diagnosed with facet cyst and grade I spondylolisthesis at L4-L5. She underwent an interbody fusion using the Valeo® TL Transforaminal Interbody Fusion Device (Amedica Corporation, Salt Lake City, UT). The Valeo TL implant is made of MC2® Silicon Nitride Ceramic, an advanced biomaterial developed and engineered for spinal fusion procedures.

Diagnosis

A 51-year-old female presents with severe left leg pain and back pain. She has been diagnosed with a facet cyst and grade I spondylolisthesis at L4-L5 (Figures 1-3). After attempting conservative measures including injections, physical therapy, oral analgesics, rest and observation, she presents for surgical consultation.

Her physical exam reveals weakness and decreased sensation in the L5 distribution on the left side. Otherwise, she is neurologically intact. She shows normal gait patterns and minimal pain to palpation over the lumbar spine.

After thorough description of surgical and non-surgical options, informed consent was obtained for a posterior L4-5 decompression, facet cyst excision, and instrumented interbody and posterolateral fusion.

Procedure

A midline exposure was made to the L4-5 level and confirmed radiographically. Standard decompression was performed and the facet cyst was resected en bloc. The L4-5 transforaminal space was then decompressed allowing access to the intervertebral disc space. A traditional posterior interbody discectomy and disc preparation was performed.



Figure 1



Figure 2

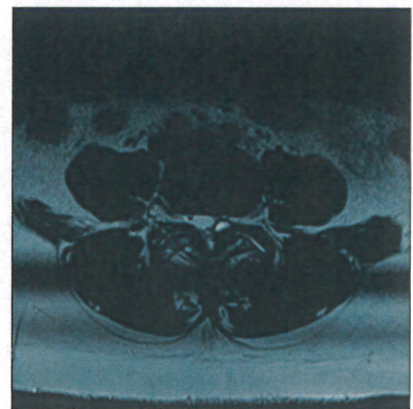


Figure 3

The intervertebral space was trialed to a 12 mm implant – Valeo® TL (Amedica Corporation, Salt Lake City UT, USA). The intervertebral space and implant were then filled with a combination of local autograft bone,

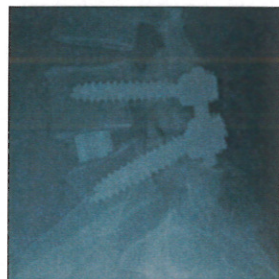


Figure 4

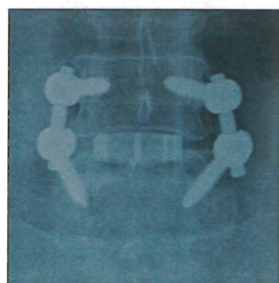


Figure 5

morselized allograft bone and bone-morphogenetic protein (rh-BMP²).* After placement of the intervertebral device, posterior pedicle screw instrumentation was positioned at L4 and L5 with connecting rods being applied and tightened. Standard wound closure over a suction drain was performed.

The patient reported complete relief of leg pain within 24 hours and discharged from an uneventful hospitalization 3 days after surgery (Figures 4, 5).

Results

The patient noted gradual reduction in back pain and continued reduction in leg pain. At one-year follow-up, CT imaging confirmed complete fusion of the interbody space with bridging bone through and around the device, as well as bone on-growth onto the device (Figures 6, 7). At her latest follow-up (25 months), she had continued leg and back pain relief.



Figure 6



Figure 7

Conclusion

The Valeo TL Interbody Fusion Device is made of MC²® Silicon Nitride, a contemporary biomaterial created specifically for spinal implants. The findings from this clinical review demonstrate that MC²® Silicon Nitride promotes complete fusion, as well as bony on-growth. Furthermore, the superior imaging qualities of the material, including no MRI or CT artifacts, facilitate both implant positioning and post-operative assessment of outcomes.

The U.S. Food and Drug Administration (FDA) has cleared the Amedica/US Spine Valeo® Spacer System as an Interbody Fusion Device to be used with autograft in skeletally mature patients.

Amedica/US Spine, and others acting on our behalf, do not recommend, or make any claim, that the Valeo Spacer System is safe and effective for any other indication or use. However, these restrictions do not prevent a physician from choosing to use the Valeo Spacer System for off-label use, if it is deemed to be appropriate for a specific patient. For additional information, please refer to the Indications-for-Use section of the Valeo Spacer System package insert.

For additional questions, please contact Amedica/US Spine at 801-839-3500 or customerservice@amedica.com.