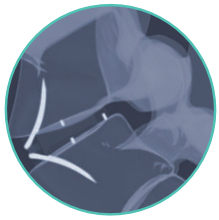
Review of Radiographic Fusion with the ROI-A® ALIF Cage

The ROI-A ALIF cage in the stand-alone configuration



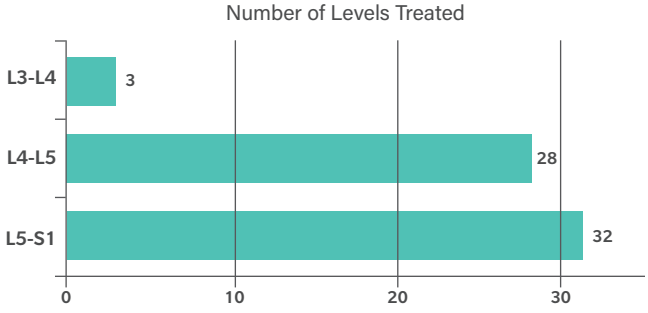
12-month post-operative ROI-A radiograph

Anterior lumbar interbody fusion (ALIF) is one of several surgical options available for the treatment of lumbar degenerative disc disease characterized by discogenic back pain and radiographic evidence of disc degeneration. The goals of ALIF surgery are to decompress neural elements, restore intervertebral disc space height and proper alignment of the lumbar spine, and to permanently fuse the motion segment. The ROI-A lumbar cage is an interbody fusion device that may be used with VerteBRIDGE® plating. The system is also designed to accommodate supplemental fixation, as required.* The goal of this study was to quantify the rate of fusion after ALIF with the ROI-A device with VerteBRIDGE® at one or two contiguous levels of the lumbar spine.

Patient Sample / Study Design

Prospective and retrospective data of 46 patients (30 retrospective and 16 prospective) was collected from six study centers. 69.6% (32/46) of patients were female and the average age was 53.3 ± 15.0 years. Contributing surgeons were: Drs. Jeffery Phelps, Kevin James, Robert Jackson, Khalid Sethi, Joseph Morreale, and Rajesh Arakal.

All subjects were treated with the ROI-A device and VerteBRIDGE plating for degenerative disc disease (DDD) with up to grade 1 spondylolisthesis at one or two levels between L3 and S1. Single level procedures were performed in 29 patients and 2-level procedures were performed in 17 patients. A total of 63 levels were treated. Patients were evaluated at 12 months post-operatively.

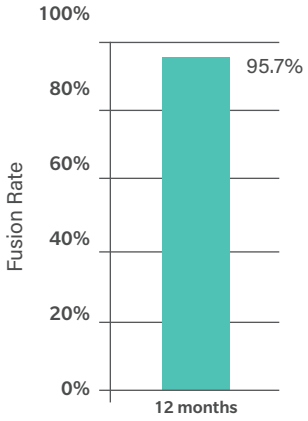


Outcome Measure

The outcome measure in this study was fusion status, as determined by the treating physician who reviewed AP, lateral, and flexion/extension x-rays. Physicians were instructed to use (1) less than 5° range of motion in flexion-extension and (2) the presence of bridging bone as criteria for fusion. Two-level patients had each level evaluated separately, and were only deemed a fusion if both levels were fused.

Results

95.7% (44/46) of patients at 12-month follow-up achieved successful fusion. The two patients who were not fused met at least one of the fusion criteria.



CONCLUSION

Reporting a 95.7% fusion rate at 12 months post-op, this study found the ROI-A ALIF cage with VerteBRIDGE plating to be an effective method for achieving radiographic fusion in patients with lumbar DDD at one or two levels of the lumbar spine between L3 and S1. The ROI-A ALIF cage, with or without VerteBRIDGE plating, is indicated for use with supplemental fixation.

*When used as an intervertebral body fusion device, the ROI-A Implant System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

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