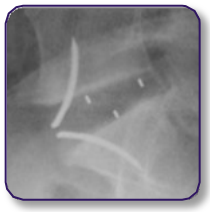
Review of Radiographic Fusion with the ROI-A® ALIF Cage

Introduction

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 in cases where a stand-alone* interbody fusion construct is appropriate. The system is also designed to accommodate additional supplemental fixation, as needed.* 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.

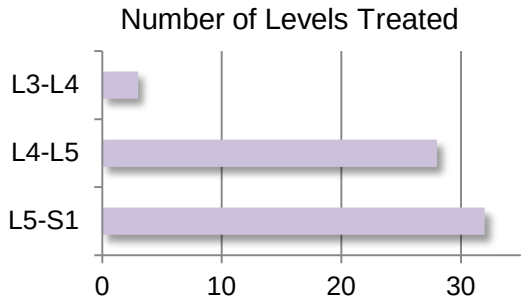
The ROI-A ALIF cage in the stand-alone configuration



12-month post-operative ROI-A radiograph

Patient Sample / Study Design

Prospective and retrospective data from 46 patients (30 retrospective and 16 prospective) was collected from six study centers. 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 for degenerative disc disease (DDD) with up to grade 1 spondylolisthesis at one or two levels between L3 and S1. Patients were evaluated at 12 months post-operatively. Single level procedures were performed in 29 patients and 2-level procedures were performed in 17 patients. A total of 63 levels were treated.

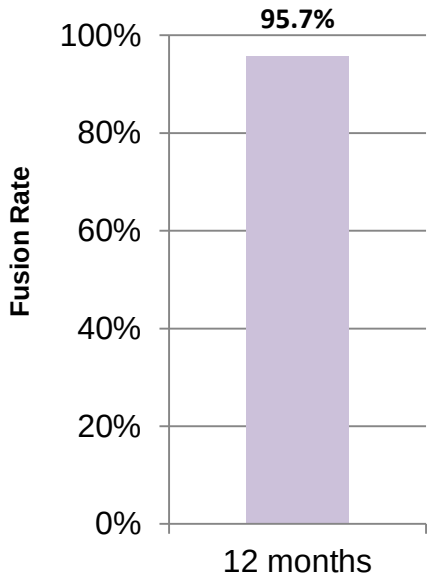


Outcome Measure

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

Results

This study includes results of forty-six patients: 32 females and 14 males. The average age was 53.3 ± 15.0 years.



The rate of patients achieving successful fusion measured at the 12-month timepoint was 95.7% (44/46). Both subjects that were not fused, had met at least one of the fusion criteria.

Conclusion

Based on this sample, the use of the ROI-A ALIF cage with VerteBRIDGE plating is an effective method for achieving radiographic fusion at affected motion segments at 12 months in patients with lumbar degenerative disc disease at one or two levels of the lumbar spine between L3 and S1.

***** 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.

CN 0561
Effective Date: March 27, 2013
REF: IR-A CP 2 Rev A 03.2013