ROI-C® Cervical Cage with VerteBRIDGE® Plating: Comparable Fusion with Lower Rates of Dysphagia & Secondary Surgery

The attached white paper was developed by the LDR Clinical Affairs Department. The following white paper discusses and compares the final outcomes from the retrospective study on ROI-C® Cervical Cage with Vertebridge® technology to published IDE data on ACDF. Data on file at LDR Spine.

This resource addresses the following topics:

- *Parameters of ROI-C study*
- *ROI-C outcomes compared to ACDF*
- *Information on adverse events*

KEY TAKE-AWAYS

- In a a multi-center study of 109 ROI-C patients, in standard of care settings, fusion rates were 99.1% compared to 82-98% reported in the literature for ACDF.
- Follow-up NDI and VAS Neck and Arm scores were within range of those reported for ACDF.
- Mean operative time, rates of dysphagia, and subsequent surgery for ROI-C show a trend toward being lower than ACDF.

ROI-C Cleared Indications for Use:

The *ROI-C Implant System* is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had 6 weeks of nonoperative treatment. The ROI-C Implant System is intended to be used with autogenous bone graft and implanted via an open, anterior approach. Supplemental internal fixation is required to properly utilize this system.

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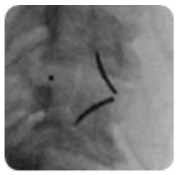
Introduction

Anterior cervical discectomy and fusion (ACDF) and cervical disc arthroplasty (CDA) are two effective surgical procedures for the treatment of radiculopathy and myelopathy stemming from cervical degenerative disc disease (DDD). For patients who do not meet the inclusion criteria for CDA, ACDF is still considered the gold-standard surgical option. ACDF treats the potentially debilitating effects of DDD by providing long-term stabilization and decompressing the neural elements. The use of anterior plating is the traditional practice in ACDF to stabilize the segment, improve outcomes, and avoid pseudoarthrosis. However, the use of anterior plating with its inherent prominence can cause complications such as dysphagia, which may be due to compression and irritation of the surrounding soft tissues.

The development of the ROI-C cervical cage with VerteBRIDGE Plating Technology has resulted in a stand-alone fusion device with efficient fixation fully contained within the intervertebral space. ROI-C with VerteBRIDGE was designed to provide all the benefits of traditional ACDF, without the drawbacks of plating or posterior instrumentation when used in accordance with FDA-approved indications*. Here, we evaluate the use of an ROI-C cervical cage with VerteBRIDGE for single-level ACDF in patients with symptomatic DDD.

The ROI-C Cervical Cage in the stand-alone configuration



12-month post-operative ROI-C radiograph

Patient Sample / Study Design

Surgical data and patient demographic information were collected from 109 retrospectively identified patients at 7 study centers. Inclusion criteria included a diagnosis of DDD at one level between C2 and T1 with radiculopathy and/or myelopathy confirmed by radiographic imaging and corresponding pain and/or neurologic deficit. All subjects were treated with the stand-alone configuration of the ROI-C device with VerteBRIDGE and autograft bone. Time points were pre-op, operative, and where available, at 2 and 6 months. The final visit was prospectively planned and conducted, at least 12 months postoperatively. Fusion status was determined using A/P, lateral, and flexion/extension radiographs at each time point, and was defined by the presence of bridging bone with less than 2° segmental motion in flexion/extension and less than 3 mm of A/P translation. Device integrity was assessed radiographically for subsidence, pseudoarthrosis and device-related complications. Neck disability index (NDI) and visual analog scale (VAS) neck and arm pain scores were recorded at the final follow-up visit. Patient-reported adverse events and dysphagia were also collected. Outcomes of this study were compared to the outcomes of the control ACDF treatment group in published, peer-reviewed studies.

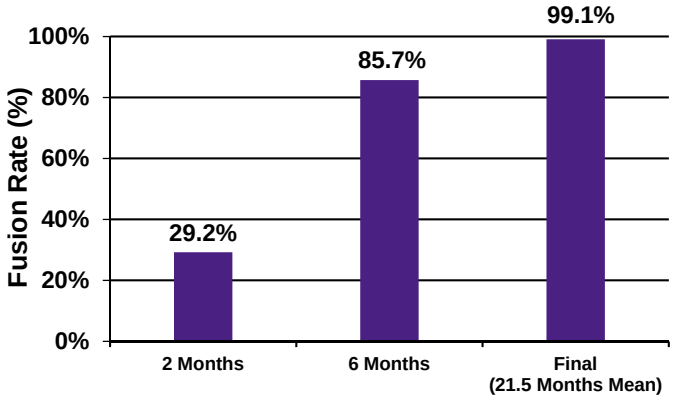
Results

The study population included 63 females and 46 males. The mean age was 52.0 ± 10.2 years. The mean follow-up time was 21.5 ± 8.8 months. The mean operation time was 1.13 hours. Operated levels included C3-C4 (13), C4-C5 (16), C5-C6 (40), C6-C7 (38), and C7-T1 (3). The criteria for fusion were met for 29.2% of patients at 2 months, 85.7% at 6 months, and 99.1% of patients at the final follow-up visit. Comparatively, FDA IDE clinical trials involving patients treated with ACDF with anterior plating and allograft bone had average operation times of 1.1 to 1.65 hours and fusion rates of 82% to 98.1% at 24 months[1-3,5,11,15].

Outcome	ROI-C with VerteBRIDGE® (Ave 21.5 mos)	ACDF[1-3,5,11,13,16] (12-24 mos)
NDI	17.9	11.8-23.1
VAS Neck	23.8	19.4-35.6
VAS Arm	11.1 (Right); 13.6 (Left)	1.2-26.9
Fusion	99.1%	82-98.1%
2° Surgery	0.91%	1.4-7.9%

Dysphagia	ROI-C with VerteBRIDGE®	ACDF[1-3,5,11,13,16]
2 Months	4.7%	2.5-32.2%
6 Months	8.2%	1.2-17.8%
12 Months	2.3%	3.7-12.5%

The mean NDI, VAS neck pain, VAS right arm pain, and VAS left arm pain scores at the final follow-up visit were 17.9, 23.8, 11.1, and 13.6, respectively. Treatment with ACDF with anterior plating and allograft bone by 12-24 months has shown comparable results[1-3,5,11,13,16]. Rates of dysphagia were 4.7%, 8.2%, and 2.3% at 2 months, 6 months, and 12 months respectively, and were comparable or lower than the results of ACDF (2 Months:2.5-32.2%; 6 Months: 1.2-17.8%; 12 Months: 3.7-12.5%)[1,4]. Secondary surgeries in the ACDF literature report a rate of 1.4-4.7% at 1 year and 3.5-7.9% at 2 years[5-16].



There was one instance of pseudoarthrosis (0.91%) and one instance of secondary surgery (0.91%). The first patient at 12 month follow-up had radiographically confirmed pseudoarthrosis resulting in device failure. This patient reported an overall NDI score of 4% and VAS neck and arm scores of 0 and did not undergo surgical treatment for the asymptomatic non-union. The second patient, with a diagnosis of cervical stenosis with myelopathy at multiple levels, had subsequent surgery after 8 months that included the level of the index surgery. The device was in place and fusion had occurred; the surgeon documented this reoperation as unrelated to the device.

Conclusion

Analysis of this retrospective study shows that the ROI-C Cervical Cage with VerteBRIDGE Plating Technology in a stand-alone construct is as effective as ACDF with anterior plating in patients with cervical DDD with shorter operative times, less dysphagia and fewer secondary surgeries. By the final time point, 99.1% of all ROI-C patients met the criteria for radiographic fusion. NDI and VAS pain scores were low and comparative with the traditional ACDF treatment with anterior plate.

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