Cadaveric Biomechanical Evaluation of the ROI-C™ Cervical Cage with VerteBRIDGE™ Plating Technology

Introduction

- Cervical spinal fusion aims to limit pain by neurologic decompression and to obtain long-term stability with solid intervertebral fusion. Anterior cervical decompression and fusion (ACDF) accomplishes both goals with excellent fusion results.
- ACDF plus supplemental fixation improves the fusion rate, but can introduce complications, especially if the supplemental fixation protrudes outside the vertebrae, or requires greater exposure or increased operative time to install.
- The ROI-C, a PEEK interbody cage with a zero-profile plating system (Figure 1), was developed so additional fixation and resistance to graft extrusion could be provided without utilizing anterior hardware protruding beyond the vertebral margins.
- The aim of this study is to gain a better understanding of how the ROI-C construct compares biomechanically to conventional bone grafts with anterior plating as well as to increasingly popular stand-alone PEEK cages with integrated screws.

Figure 1: The ROI-C Cervical Cage with VerteBRIDGE Plating Technology

Hypotheses

- The ROI-C construct will increase stability versus the intact spine in all anatomic directions.
- The ROI-C construct will perform similarly to previously tested stand-alone PEEK cages with two integrated screws.
- The ROI-C construct will have a pullout force comparable to that published for a conventional bone graft with cervical plate construct.

Methods

Model

- C2-3, C4-5, and C6-7 cadaveric motion segments were acquired, evaluated, and potted in epoxy.

Test Methods – Flexibility

- The flexibility protocol (i.e., application of pure moments) was chosen to provide a direct comparison to the intact specimens, as well as to published data.
- Constructs were tested using a hydraulically actuated spinal loading system.
- "Pure" moments of 2.5Nm in flexion-extension, bilateral lateral bending and axial torsion were applied with a 20N machine-applied axial preload to maintain compression of the segment.

Test Methods – Pullout

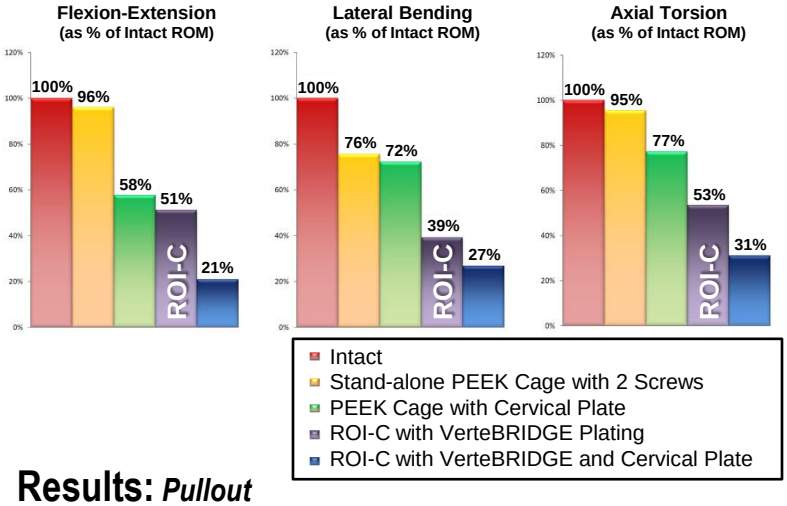
- Pullout testing was used to compare resistance to expulsion.
- Force was applied at 10mm/min under a 50N axial preload.
- The vertebrae were allowed to rotate during testing (Figure 2).

Outcome Measures

- Flexibility: Range of motion (ROM)
- Pullout: Peak extraction loads

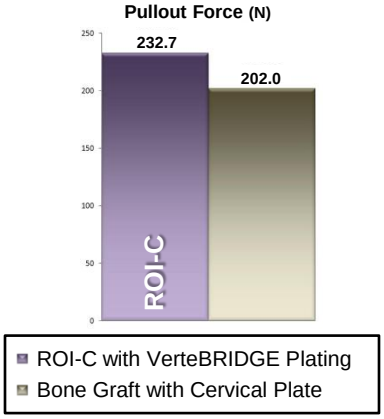
Results: *Flexibility*

- The ROI-C construct significantly reduced the range of motion in all directions versus the intact state. It also compares favorably to a stand-alone PEEK cage with two screws as well as to a traditional PEEK cage with cervical plate construct. The addition of a conventional cervical plate to the ROI-C construct further reduces the range of motion and may be appropriate to address cases of greater vertebral instability.



Results: *Pullout*

- Pullout failure of the ROI-C occurred due to plowing of the device through the bone and opening (lordosing) of the segment. Average pullout loads were greater than reported pullout loads for a conventional cervical plate, which are well above the expected physiologic loads.



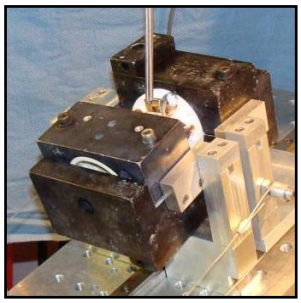


Figure 2: Pullout fixture

Conclusions

- In flexion-extension, lateral bending, and axial torsion, the ROI-C with VerteBRIDGE Plating showed lower ROM than published data[1] of a similar stand-alone PEEK Cage with two integrated screws and a conventional construct comprised of a PEEK cage and metal cervical plate.
- The pullout resistance of the ROI-C with VerteBRIDGE Plating is comparable to published data[2] of a bone graft with cervical plate and screws.
- When additional resistance to expulsion versus a cage alone is desired, the ROI-C with VerteBRIDGE Plating may be a viable option.

References

All testing was performed by the Excelen Center for Bone & Joint Research and Education, Minneapolis, MN, in September 2009.

[1] Freeman AL, Beaubien BP, Castro CA, Turner JL, Richardson V, Armstrong W, Dryer RF. Biomechanical Evaluation of a New Stand-alone Cervical Interbody Device versus Traditional Fixation Techniques. Poster 1711, presented at: 55th Annual Meeting of the Orthopaedic Research Society; February 22-25, 2009; Las Vegas, NV.

[2] Ames CP, Crawford NR, Chamberlain RH, Deshmukh V, Sadikovic B, Sonntag VKH. Biomechanical Analysis of a Resorbable Anterior Cervical Graft Containment Plate. *Spine* 2005;30:1031-1038.

REF: IR-C T 1 EN 10.2009 A US