Cadaveric Evaluation of the ROI-A® ALIF Cage with VerteBRIDGE® Plating Technology

Introduction

- Lumbar spinal fusion aims to limit pain by decompression and to obtain long-term stability with solid intervertebral fusion. Anterior lumbar interbody fusion (ALIF) provides excellent fusion results.
- ALIF 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-A, 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 pedicle screw fixation or anterior hardware that protrudes beyond the vertebrae.
- The aim of this study is to gain a better understanding of how the ROI-A construct compares biomechanically to conventional anterior dual threaded cages and popular stand-alone PEEK constructs that feature integrated screws.

Figure 1: The ROI-A® ALIF cage with VerteBRIDGE® Plating Technology

Hypotheses

- The ROI-A ALIF construct will increase stability versus the intact spine in all anatomic directions.
- The ROI-A ALIF construct will perform similarly to previously tested stand-alone ALIF devices with 3 integrated screws in flexion-extension and lateral bending.
- The ROI-A ALIF construct will have as good as or better resistance to pullout forces than published data for similar stand-alone ALIF devices and anterior dual threaded cages without pedicle screws.

Methods

Model

- L2-3 and L4-5 cadaveric motion segments were acquired, DEXA scanned, 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 7.5 Nm in flexion, extension, and bilateral lateral bending were applied with a 50 N machine-applied axial preload.

Test Methods – Pullout

- Pullout testing was used to compare resistance to expulsion.
- Force was applied at 10mm/min under a 400 N axial preload.
- The vertebrae were allowed to rotate during testing (Figure 2).

Outcome Measures

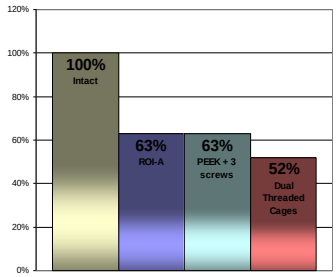
- Flexibility: Range of motion (ROM)
- Pullout: Peak extraction loads

Results

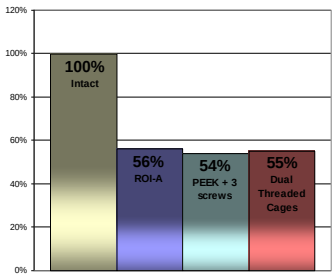
Flexibility

- The ROI-A construct reduced the range of motion in all directions versus the intact state.

Flexion-Extension (as % of Intact ROM)



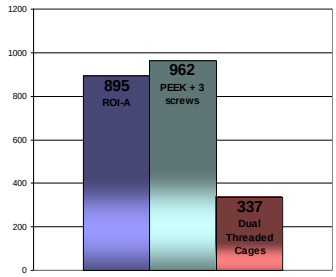
Lateral Bending (as % of Intact ROM)



Pullout

- Pullout failure of the ROI-A occurred due to plowing of the device and opening (lordosing) of the segment. Failure loads were greater than the expected physiologic loads.

Pullout Force (N)



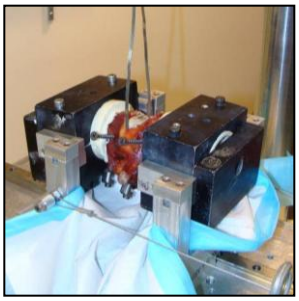


Figure 2: Pullout fixture

Conclusions

- In flexion-extension and lateral bending range of motion, and in pullout force, the ROI-A construct tested in this *in vitro* study was comparable to the published data[1] of a similar stand-alone PEEK-spacer ALIF device with 3 integrated screws.
- The pullout force of the ROI-A was markedly greater than the published data[1] for anterior dual threaded cages without pedicle screws.
- When additional resistance to expulsion versus a spacer alone is desired, the ROI-A construct may be a suitable alternative to anterior dual threaded cages or comparable stand-alone PEEK-spacer ALIF devices with integrated screws.

References

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

[1] Beaubian BP, Freeman AL, Turner JL, et al. Comparative Biomechanical Evaluation of a Lumbar Spacer with Integrated Screws. Poster 1712, presented at: 55th Annual Meeting of the Orthopaedic Research Society; February 22-25, 2009; Las Vegas, NV.

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