

65. Multilevel Kinematic Assessment of Immediate and Simulated Long-Term Stabilization of Novel Inline Cervical Interbody Devices with Intervertebral Screw, Anchor, or Blade Fixation

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BACKGROUND CONTEXT: Anterior cervical discectomy and fusion (ACDF) remains the gold standard for cervical spondylotic myelopathy and radiculopathy. Stand-alone multi-level ACDF with screw fixation has become more widely adopted to reduce retraction, dysphagia, and irritation to paravertebral soft tissue associated with the use of anterior cervical plates. However, the relatively aggressive intervertebral screw trajectory requires an increased operative incision compared to traditional plating. More recently, novel intervertebral anchors or bladed devices have been introduced to provide fixation in-line with the operative disc, usually inserted via a curvilinear trajectory, to minimize the surgical corridor. Nevertheless, the immediate and long-term biomechanical efficacy of these alternative intervertebral fixation techniques in stand-alone multilevel construction is unknown.

PURPOSE: To biomechanically quantify immediate stability and fixation following simulated in vivo fatigue of two-level integrated ACDF with anchor or blade intervertebral fixation compared with integrated ACDF with traditional screw fixation. The comparison groups were (a) traditional intervertebral body screws (MIS-S), (b) a novel cylindrical anchor (MIS-A) fixation design, and (c) self-guided flat blade fixation design (MIS-B).

STUDY DESIGN/SETTING: An in vitro human cadaveric study using six-degrees-of-freedom spine flexibility testing.

PATIENT SAMPLE: Fifteen cadaveric specimens.

OUTCOME MEASURES: Range of motion.

METHODS: Fifteen cadaveric lumbar specimens (C2-C7) were divided in three groups (MIS-S, MIS-A, MIS-B) such that bone mineral density (BMD) was equivalent between groups. Operative constructs (C4-6) include: 1) intact, 2) integrated stand-alone device (ISA), and 3) ISA following simulated in vivo fatigue. Load control (± 1.5 Nm) testing was performed in flexion-extension (FE), lateral bending (LB), and axial rotation (AR) and max motion of the operative levels was recorded and normalized to the mean injured condition. Simulated in vivo fatigue of ISA devices included displacement control protocol on a MTS 858 to produce maximum FE, LB, and AR motions for 1,000 cycles at 0.5 Hz. Comparisons were made between groups (significance at $p < .05$).

RESULTS: BMD of MIS-S, MIS-A, and MIS-B treatment groups were 0.70, 0.70, and 0.76 g/cm², respectively. Across all fixation groups (MIS-S, MIS-A, MIS-B) ISA reduced motion in all planes ($p < .05$). In FE, ISA reduced motion to 47%, 67%, and 60% of intact (MIS-S, MIS-A, MIS-B, respectively). In LB, ISA reduced motion to 29%, 43%, and 35% of intact. In AR, ISA reduced motion to 43%, 65%, and 57% of intact. Simulated in vivo fatigue significantly increased motion of MIS-S, MIS-A, and MIS-B groups, in FE (74%, 95%, 82%), LB (53%, 62%, 66%) and AR (71%, 82%, 74%), respectively, of intact (all $p < .05$). No significant differences in both immediate and long-term fixation were observed in ISA treatment groups, in all planes of motion ($p > .05$).

CONCLUSIONS: The present study provided the first biomechanical data of in-line minimally invasive ACDF devices for the treatment of multilevel cervical degenerative pathologies. Both immediate and long-term stability followed the general trend: anchors (least stable) > blades > screws (most stable). Nevertheless, both experimental anchor and blade fixation methods provided statistically equivalent fixation compared to traditional intervertebral screws. Multicenter longitudinal studies are needed to establish clinical equivalency between fixation techniques.

FDA DEVICE/DRUG STATUS: COALITION MIS (Globus Medical) (Not approved for this indication), ROI-C (Zimmer) (Not approved for this indication)

<https://doi.org/10.1016/j.spinee.2017.07.083>

Refer to onsite annual meeting presentations and postmeeting proceedings for possible referenced figures and tables. Authors are responsible for accurately reporting disclosure and FDA device/drug status at time of abstract submission.

66. Effect of Posterior Cervical Cages Supplemental to Anterior Cervical Integrated Cage Fusion on Lordotic Alignment, Foraminal Height, and Intersegmental Space

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BACKGROUND CONTEXT: Anterior cervical integrated cage fusion (ACICF) has been shown to provide less motion reduction as compared to conventional plated ACDF while providing increased segmental lordosis at the implanted segment. Posterior cervical cages (PCC) implanted in the interfacet space are intended to reduce motion between vertebrae. PCC is known to provide some interfacet distraction which may affect the cervical sagittal alignment, and may also provide indirect foraminal decompression. The change in lordosis and magnitude of foraminal decompression has not been previously studied. This study's aim is to evaluate the effect of PCC on foraminal height (FH), segmental lordosis and disc height following ACICF.

PURPOSE: To assess the effect of PCC as a supplement to ACICF on cervical alignment and foraminal height in neutral posture.

STUDY DESIGN/SETTING: Cadaveric laboratory study.

PATIENT SAMPLE: Seven cadaveric cervical C2-T1 specimens (mean age 42 \pm 7 years).

OUTCOME MEASURES: Sagittal segmental lordosis, foraminal height and intersegmental distraction (disc height).

METHODS: Kinematic flexion-extension range of motion was performed on cervical cadaveric specimens (± 1.5 Nm). During kinematic testing the three dimensional (3D) position of the cervical spine vertebral bodies was captured using specimen specific 3D modeling technology. This technology uses CT-scan of each specimen and 3D reconstruction combined with motion measurement of each vertebra. The result is an animation of the reconstruction providing precise anatomical measurements including: lordosis, foraminal height and disc height. Specimens were tested intact, after ACICF and ACICF+PCC. Testing was performed with: 1) one-level C6-7 fusion, 2) two-level C3-5 fusion. The left PCC was implanted before the right PCC for all specimens. Adjusted two-tailed paired t-tests were performed for all comparisons.

RESULTS: C6-7 fusion results: Segmental wedge angle (sagittal angle between adjacent endplates) increased after ACICF (6.2 \pm 3.0 to 14.8 \pm 3.9 $^\circ$, $p < .05$) and decreased after PCC to 10.5 \pm 3.9 $^\circ$ ($p < .05$). Right FH changed from 9.0 \pm 1.0 to 9.3 \pm 1.2 mm with ACICF and to 9.9 \pm 1.1 mm after PCC. Left FH changed from 8.7 \pm 1.1 to 8.6 \pm 0.8 mm with ACICF, and to 9.8 \pm 0.8 mm ($p < .05$) after PCC. Middle disc height increased after ACICF (4.6 \pm 0.8 to 6.1 \pm 1.0 mm, $p < .05$) and to 6.3 \pm 0.7 mm after PCC. C3-C4 two-level fusion results: Segmental wedge angle changed (5.5 \pm 4.4 to 6.8 \pm 4.0 $^\circ$) with ACICF and to 5.0 \pm 4.2 $^\circ$ ($p < .05$) after PCC. Right FH changed (8.5 \pm 1.5 to 9.4 \pm 1.7 mm, $p < .05$) after ACICF and to 9.6 \pm 1.6 after PCC. Left FH showed no change (8.2 \pm 1.2 to 8.7 \pm 1.5 to 9.1 \pm 1.2 mm). Middle disc height changed significantly after ACICF (5.0 \pm 0.4 to 6.0 \pm 0.8 mm, $p < .05$) and to 5.8 \pm 0.7 mm after PCC. C4-5 two-level fusion results: Segmental wedge angle changed from 8.0 \pm 5.4 to 11.5 \pm 5.2 $^\circ$ ($p < .05$) after ACICF and to 9.4 \pm 5.5 $^\circ$ after PCC. Right FH changed (8.8 \pm 1.0 to 9.4 \pm 0.9 mm) after ACICF and to 10.1 \pm 0.7 mm ($p < .05$) after PCC. Left FH changed (8.6 \pm 1.6 to 9.4 \pm 1.5, $p < .05$) and to 9.5 \pm 1.5 mm after PCC. Middle disc height changed (4.7 \pm 0.6 to 5.9 \pm 0.8, $p < .05$) after ACICF and to 5.8 \pm 0.8 after PCC.

CONCLUSIONS: The difference between the right and left foraminal height changes may be related to the order of the surgery, as well as the asymmetric anatomy of the facets. Overall, ACICF tended to increase wedge angle by 4.5 degrees, disc height by 1.2 mm and foraminal height by 0.5 mm. Following PCC, there was a decrease in wedge angle of 2.7 degrees, no change in disc height and an additional increase in foraminal height of 0.5 mm.