Biomechanical Comparison of Anterior Cervical Plate Fixation Versus Integrated Fixation Cage for Anterior Cervical Discectomy and Fusion

Timothy P. Murphy, MD,† Jeremy D. Tran, MD,*† Donald F. Colantonio, MD,*† Anthony H. Le, MS,‡ Donald R. Fredericks, MD,*† William B. Roach, MD,*† Joon Chung, BS,§ Alfred J. Pisano, MD,*† Scott C. Wagner, MD,*† and Melvin D. Helgeson, MD*†*

Study Design: Cadaveric, biomechanic study.

Objective: To compare the range of motion profiles of the cervical spine following one-level anterior cervical discectomy and fusion (ACDF) constructs instrumented with either an interbody cage and anterior plate or integrated fixation cage in a cadaveric model.

Summary of Background Data: While anterior plates with interbody cages are the most common construct of fixation in ACDF, newer integrated cage-plate devices seek to provide similar stability with a decreased implant profile. However, differences in postoperative cervical range of motion between the 2 constructs remain unclear.

Methods: Six cadaveric spines were segmented into 2 functional spine units (FSUs): C2-C5 and C6-T2. Each FSU was nondestructively bent in flexion-extension (FE), right-left lateral bending (LB), and right-left axial rotation (AR) at a rate of 0.5°/s under a constant axial load until a limit of 2-Nm was reached to evaluate baseline range of motion (ROM). Matched pairs were then randomly assigned to undergo instrumentation with either the standard anterior cage and plate (CP) or the integrated fixation cage (IF). Following instrumentation, ROM was then remeasured as previously described.

Results: For CP fixation, ROM increased by 61.2 ± 31.7% for FE, 36.3 ± 20.4% for LB, and 31.7 ± 19.1% for AR. For IF fixation, ROM increased by 64.2 ± 15.5% for FE, 56.7 ± 39.8% for LB, and 94.5 ± 65.1% for AR. There was no significant difference in motion between each group across FE, LB, and AR.

Conclusion: This biomechanical study demonstrated increased motion in both the CP and IF groups relative to the intact, uninstrumented state. However, our model showed no differences in ROM between CP and IF constructs in any direction of motion. These results suggest that either method of instrumentation is a suitable option for ACDF with respect to constructing stiffness at time zero.

Key Words: anterior cervical discectomy and fusion, integrated cage, cage plate

(*Clin Spine Surg* 2024;00:000–000)

Anterior cervical discectomy and fusion (ACDF) is considered the gold standard for the surgical treatment of many degenerative cervical spine pathologies.[1] Anterior cervical fusion accounts for up to 80.6% of cervical spine surgery in the United States, representing a significant expenditure of the healthcare system.[2,3] Interbody devices are placed between vertebral bodies after the removal of the intervertebral disk to restore disk height and decompress the neural foramen containing nerve roots. Anterior cervical plating has been shown to increase the rates of the second goal of ACDF, arthrodesis, or fusion.[4–6] The increased stability across instrumented segments with a plate likely contributes to the increased rates of arthrodesis.[4] Pseudoarthrosis, or failure of fusion, has consistently been shown to lead to suboptimal outcomes and high rates of revision surgery.[7,8] While pseudoarthrosis is decreased with the use of an anterior plate, other complications remain much more common. High incidences of dysphagia are seen despite the use of lower

Received for publication March 3, 2023; accepted March 7, 2024.

From the *Department of Orthopaedics, Walter Reed National Military Medical Center; †Department of Surgery, Uniformed Services University of the Health Sciences; ‡DoD-VA Extremity Trauma and Amputation Center of Excellence, Walter Reed National Military Medical Center, Bethesda, MD; and §Georgetown University School of Medicine, Washington, DC.

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This research was supported in part by an appointment to the Department of Defense (DoD) Research Participation Program administered by the Oak Ridge Institute for Science and Education (ORISE) through an interagency agreement between the U.S. Department of Energy (DoE) and the DoD. ORISE is managed by Oak Ridge Associated Universities under DoE contract number DE-SC00114664.

The authors declare no conflict of interest.

Reprints: Jeremy D. Tran, MD, Walter Reed National Military Medical Center, Department of Orthopaedic Surgery, 4494 Palmer Rd N, Bethesda, MD 20814 (e-mail: jeremy.d.tran2.mil@health.mil).

DOI: 10.1097/BSD.0000000000001630

profile plates relative to earlier designs.[9] Furthermore, implant failure and screw migration can occur with the potential to lead to catastrophic complications, including esophageal perforation.[10,11]

Anterior plate and screws with an interbody device are a common construct in current practice. The desire for an even lower profile device that would potentially decrease complications and minimize injury risk to vital structures overlying the anterior cervical spine led to the development of stand-alone interbody fusion devices. The integrated cage-plate device for anterior cervical fusion was developed based on a similar device created for lumbar fusion.[12,13] These integrated fixation devices typically lie completely within the intervertebral disc space, just dorsal to the anterior cortex of the vertebral body, with integrated cage and screw implants. By containing the device entirely within the disk space, this minimizes the implant's sagittal profile, with the potential benefit of decreasing dysphagia and implant-related complications seen with typical plates and screws.[14]

Biomechanical and clinical reports of the integrated fixation devices remain relatively limited. Scholz et al provide an early report comparing an integrated device containing a poly-ether-ether-ketone (PEEK) spacer and four diagonally oriented screws.[12] They found this integrated device provided equivalent biomechanical stability to the typical plate and interbody cage construct.[12] In a separate biomechanical study, Stein and colleagues found similar results in a device with a PEEK spacer and three integrated screws compared with a standard plate and cage for a single-level fusion.[15] Both studies reported decreased motion relative to the intact state with an integrated device that was comparable with the standard method of fixation.[12,15] Clinical results from early use of integrated fixation devices in one to 2-level fusions report comparable fusion rates to traditional anterior plating with potentially decreased rates of dysphagia.[14,16,17] As more of these devices come to market, appropriate biomechanical analysis and clinical data will be necessary to determine their potential benefits relative to anterior plating constructs.

Therefore, the purpose of this study was to perform a biomechanical comparison of a novel integrated fixation system and an anterior cervical plate and spacer construct in a 1-level ACDF cadaveric model. Our hypothesis was that the integrated spacer and plate would allow for a decreased range of motion (ROM) relative to the intact state but no difference when compared to more traditional instrumentation.

MATERIALS AND METHODS

Specimens

Six fresh-frozen human cadaveric cervicothoracic spines (C2-T2) were procured and stored at −30° C. Each specimen was screened at the time of harvest for deformities, evidence of prior injury, malignancy, or prior spinal instrumentation. The bone mineral density (BMD) of each specimen was measured at the center of the vertebral bodies through dual-energy x-ray absorptiometry (Discovery-A System, Hologic Mississauga, ON, CAN). Specimens were debrided of nonstructural soft tissue and dorsal musculature. Any spanning osteophytes present around the anterior and/or lateral aspect of the intervertebral disks were removed with a rongeur to allow for more physiologic motion. The ligaments, facet joints, transverse processes, spinous processes, and intervertebral disks were preserved. Specimens were then segmented into two functional spinal units (FSUs): C2-C5 and C6-T2. The purpose of this segmentation between upper-cervical and lower-cervical FSUs was to have each cadaveric spine undergo both treatments, serving as a control to account for the inherent variability in spine motion between specimens. FSUs were randomly assigned to one of two treatment groups: cage and anterior plate fixation (CP) or integrated fixation cage (IF) at the middle FSU level. To ensure rigid fixation to the materials testing system, most cephalad and caudad vertebrae of each FSU were potted using a 1:1 Bondo and fiberglass resin mixture (Bondo®, 3M Company, St. Paul, MN, USA). Screws were placed into the potted vertebrae to achieve better fixation in the resin base.

Biomechanical Testing

Specimens were thawed at room temperature and covered in 0.9% saline-soaked gauze prior to biomechanical testing.[18] Range of motion (ROM) was evaluated in each FSU in 3 different directions: flexion-extension (FE), right-left lateral bending (LB), and right-left axial rotation (AR) before and after instrumentation. Intact FSUs were first loaded onto a servohydraulic materials testing system augmented with a Spine Test Fixture (MTS 858 Mini Bionix II, MTS Systems Corp., Eden Prairie, MN, USA). The caudal pot was secured to a base mounted on an X-Y linear railing system to permit passive motion. The cephalad pot was secured on an upper base mounted to the Spine Test Fixture where bending rotations and torques were applied. Three-dimensional vertebral kinematics were recorded by infrared rigid body markers (Optotrak Certus, Northern Digital, Inc., Waterloo, Ontario, CA) attached to the instrumented level of the FSU (Fig. 1).

ROM was evaluated by nondestructively bending the specimens in FE, LB, and AR. Specimens were bent in each direction at a 0.5°/s rate under a constant 5 N axial compressive load until a predetermined 2 Nm limit was reached. This process was repeated two times in each direction to eliminate creep, and the ROM was recorded on the third iteration.[19] The same protocol was performed after the instrumentation of each FSU.

Experimental Design and Surgical Treatment

After native specimen ROMs were evaluated, each FSU was instrumented according to their randomized treatment group (CP or IF) to obtain matched pairs. Surgical treatment was performed by 1 of 2 fellowship-trained spine surgeons. In the C2-C5 and C6-T2 FSUs, instrumentation was performed at the C3-C4 and C7-T1

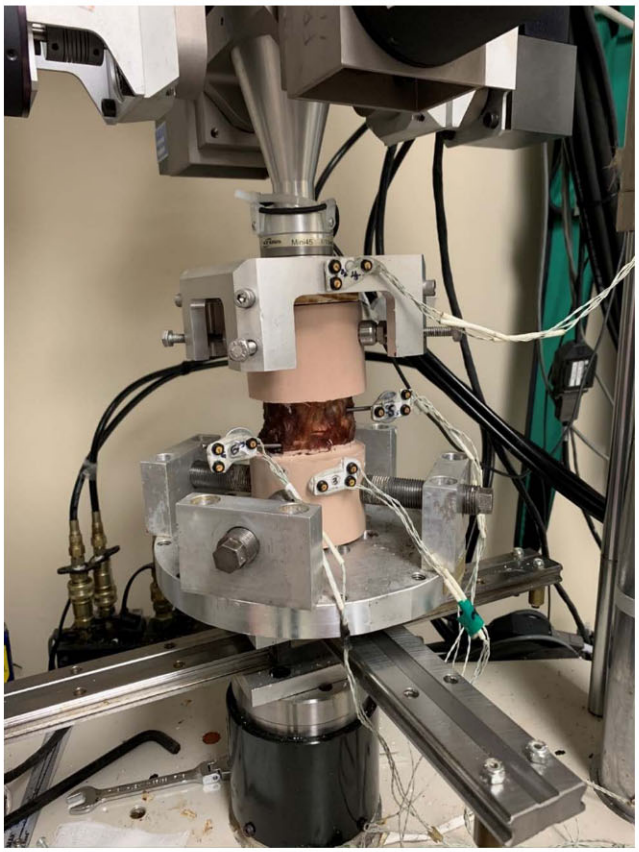

FIGURE 1. Biomechanical setup for functional spinal unit testing, including optical tracking marker placement. full color online

levels, respectively. For each group, the anterior longitudinal ligament was removed at the level to be instrumented. An incision was made in the annulus fibrosis, and a discectomy was performed. The posterior longitudinal ligament was preserved. In the CP group, a 1-level anterior cervical discectomy and fusion were performed using standard instruments and techniques. A four-hole RESONATE® anterior cervical plate (Globus Medical, Audubon, PA, USA) was used in conjunction with a COVERIS® anterior cervical spacer (Camber Spine, King of Prussia, PA, USA) (Fig. 2). In the IF group, the SPIRA®-C integrated fixation system was utilized (Camber Spine, King of Prussia, PA, USA). This device consists of a stand-alone interbody fusion cage with 2 integrated screws (Fig. 3).

Data Reduction

Three-dimensional segmental motions were processed and filtered using a fourth-order zero-lag Butterworth filter (fs = 100 Hz, fc = 1 Hz). Euler angles were then generated with custom MATLAB scripts (vR2020a, MathWorks Inc., Natick, MA, USA) and converted to vertebral ROMs in FE, LB, and AR.

Statistical Analysis

Segmental ROM at the instrumented level was calculated and normalized to their respective intact ROM as a percentage change relative to intact. One-way analysis of variance (ANOVA) compared ROM in FE, LB, and AR across treatment groups ($\alpha = 0.05$). Statistical analyses were performed using R (v4.0.2, Vienna, Austria) in RStudio (v1.3, RStudio, Inc., Boston, MA, USA) using the rstatix and lme4 packages.[20]

FIGURE 2. Specimen with an anterior cervical plate and interbody spacer (CP) construct, using the RESONATE® anterior plate and COVERIS® spacer. full color online

RESULTS

The mean BMD at C3 across the C2-C5 FSUs was 0.604 g/cm^3. In the C6-T2 FSUs, the mean BMD at C7 was 0.574 g/cm^3. No significant differences were seen between the 2 FSU groups ($P = 0.352$). In addition, no differences in the range of motion in any of the measured planes of motion were observed between the upper-cervical and lower-cervical FSU groups.

Flexion-Extension

Segmental ROM in each direction is shown in Figure 4. FE ROM increased from intact by 61.2 ± 31.7% and 64.2 ± 15.5% after CP and IF instrumentation, respectively. There was no difference in FE ROM between the CP and IF groups ($P = 0.840$).

Lateral Bending

LB ROM increased in both the CP and IF groups after instrumentation relative to intact specimens. ROM increased by 36.3 ± 20.4% in the CP group and 56.7 ± 39.8% in the IF group ($P = 0.300$).

Axial Rotation

AR ROM increased from intact specimens by 31.7 ± 19.1% after CP instrumentation and 94.5 ± 65.1% after IF instrumentation. These differences approached but did not reach statistical significance ($P = 0.065$).

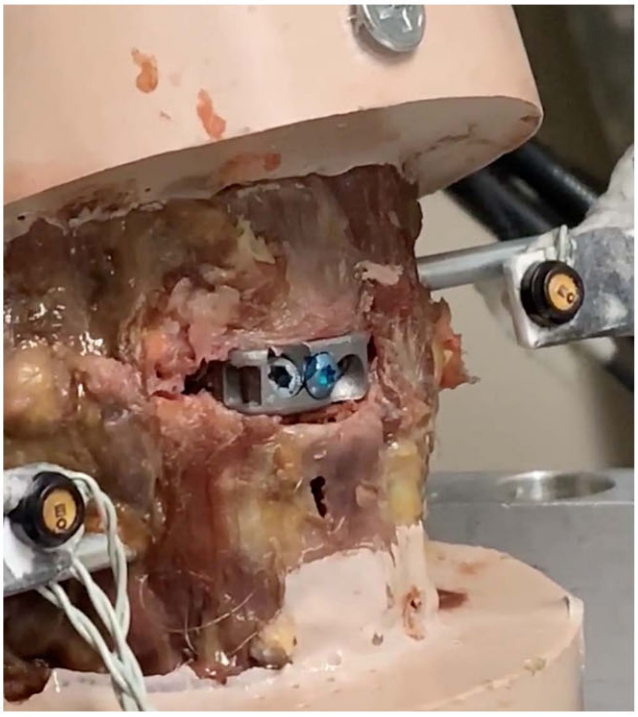

FIGURE 3. Specimen with an integrated fixation (IF) construct using the SPIRA-C® integrated fixation system. full color online

DISCUSSION

The purpose of this study was to compare the ROM of a new anterior cervical integrated spacer device with a conventional anterior cervical plating technique in a one-level ACDF. Our results demonstrated increased motion in both the CP and IF groups relative to the intact, uninstrumented state. There was no significant difference in motion between each group across FE, LB, and AR, with AR approaching but not achieving statistical significance.

ACDF is the gold standard for the treatment of a variety of degenerative conditions of the cervical spine.[1,21] Utilization of an anterior cervical plate increases fusion rates and modern, low profile plating systems reduce the risk of some of the catastrophic complications seen with earlier designs.[4,22] Despite these improvements, a number of complications remain associated with anterior cervical plating.[8,10,11] These implant-related complications prompted the development of integrated cage-plate devices designed to minimize problems seen with anterior plating through an even lower profile design. Prior biomechanical studies have demonstrated similar stability between integrated fusion devices and conventional anterior plating used for degenerative cervical spine conditions. Our findings differ from these previous studies in that all others observed decreased motion at instrumented segments.[12,15,23,24] Scholz et al performed a biomechanical analysis of the Zero-P® anchored spacer (DePuy Synthes Spine, Raynham, MA, USA) compared with other conventional methods of ACDF at C5-C6. In flexion, extension, bending, and rotation, they found a 60%, 65%, 74%, and 67% decrease, respectively, in ROM with the use of the integrated device relative to the intact state. With a cage and locking plate construct, they observed a 72%, 79%, 76%, and 67% decrease in flexion, extension, bending, and rotation, respectively, relative to the intact state.[12] While inducing bending moments up to 1.5 Nm without a compressive load, Stein et al observed similar findings in their in vitro comparison of various fusion constructs at C5-C6.[15] Relative to the intact state, they observed significant ROM reductions of 62%, 38%, 66%, and 50% in flexion, extension, LB, and AR, respectively, with the use of an anchored cage.[15] These prior studies contrast significantly with our finding of increased ROM in all directions of motion with both CP and IF constructs. However, no significant differences in ROM between integrated devices and conventional anterior cervical plating were observed in the present study or prior studies.[12,15,23,24]

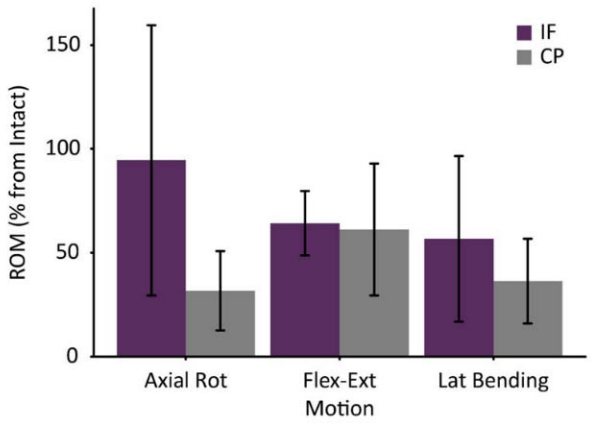

FIGURE 4. Percentage change in range of motion in various motion planes between the CP and IP constructs. full color online

The similar biomechanical profile and stability afforded by integrated cages and conventional anterior cervical plating are reflected in the clinical data. Radiologic and clinical outcomes with the use of the Zero-P® device have been comparable to conventional plate and spacer constructs at approximately 18 months postoperatively. Of 37 patients with primarily 1 and 2-level fusions, a 92.6% fusion rate was demonstrated.[17] Similar fusion rates have been reported with conventional ACDF.[21] Scholz et al observed similar findings at short-term follow-up with the same device. Chronic dysphagia in both retrospective studies was noted to be lower than reported with traditional plate and spacer instrumentation.[9,16,17] In a randomized controlled trial comparing an integrated spacer and a traditional plating construct for a single-level ACDF, comparable clinical and radiologic outcomes were found. Visual analog scale pain scores and neck disability index scores improved similarly in both groups.[25] The similar biomechanical and clinical profile between integrated devices and traditional anterior cervical plating for ACDF suggests it may be a viable option for single-level procedures.

Increased motion in this cadaveric model after performing a 1-level ACDF with the CP and IF techniques was an unexpected finding. Our hypothesis was that there would be decreased motion in both groups relative to the intact state

without any significant difference between groups. We observed screw loosening and cutting out in several samples, which were attributed to poor purchase in the specimens used. These specimens were included in our analysis, given the frequency at which we observed this finding. This likely contributed to increased motion after instrumentation. Disruption of the anterior longitudinal ligament and discectomy may also have influenced our results. Loss of the anterior tension band and removal of a degenerative disk can cause destabilizing effects on the spine.[26,27] However, our surgical dissection and technique did not greatly differ from previous reports examining IF versus CP instrumentation.[12,15]

There are several limitations of this study. The use of isolated cadaveric specimens may explain the unexpected findings of increased motion after instrumentation with CP and IF devices. The bone stock of these cadaveric specimens can be suboptimal and may have contributed to issues with screw purchase. This loss of fixation, despite proper instrumentation, could inadequately reflect the stability afforded by the various constructs studied. Furthermore, the dissection required for instrumentation and the use of isolated specimens disrupt the passive and active systems that provide spinal stability.[26,27] In a clinical setting, additional stability and decreased motion could be expected that is not replicable in a cadaveric study. A second limitation inherent to any biomechanical evaluation of spinal implants is the inability to account for changes in the bone-implant interface that occur over time.[19] The stiffness reported represents the initial stiffness at the time of surgery and does not account for the fusion that occurs between spinal levels. Nonetheless, the similar biomechanical profile of IF and CP constructs in this study and previously published studies suggest that integrated spacer devices are a viable alternative to traditional anterior cervical plating for ACDF. Another limitation in our study is that while FE and LB ROM did not demonstrate any significant difference between the 2 fixation strategies, differences in AR ROM appeared to approach, but not achieve, statistical significance. Our study likely lacked the necessary statistical power, resulting in the inability to reach significance.

Another limitation of our study is that we used only a select brand of implants for testing. This was done both for the ease of testing as well as the logistics of obtaining various implants from various manufacturers. While we understand that other implants are available and commonly used, the primary purpose of this study was to compare the biomechanical properties of the general principles of anterior cage and plate versus integrated fixation, not any one specific company or model. The implants selected were chosen with the goal of serving as a broad, generalizable comparison between the fixation strategies rather than a detailed analysis of that specific implant.

CONCLUSION

This biomechanical study showed no differences in ROM between CP and IF constructs in any direction of motion. Our results suggest that either method of instrumentation is a suitable option for ACDF with respect to construct stiffness at time zero. These findings should be interpreted with caution, however, as greater motion was seen at the instrumented level, where it would theoretically be expected to decrease. This is likely due to the destabilizing effects of a discectomy and lack of fusion in a biomechanical study. Further biomechanical and clinical studies are needed to assess the different methods of anterior cervical instrumentation.

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