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# Effectiveness of cervical zero profile integrated cage with and without supplemental posterior Interfacet stabilization

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# ABSTRACT

*Background:* Conditions requiring cervical decompression and stabilization are commonly treated using anterior cervical discectomy and fusion using an anterior cage-plate construct. Anterior zero profile integrated cages are an alternative to a cage-plate construct, but literature suggests they may result in less motion reduction. Interfacet cages may improve integrated cage stability. This study evaluated the motion reduction of integrated cages with and without supplemental interfacet fixation. Motion reduction of integrated cages were also compared to published cage-plate results.

*Methods*: Seven cadaveric (C2-T1) spines were tested in flexion-extension, lateral bending, and rotation. Specimens were tested: 1) intact, 2) C6-C7 integrated cage, 3) C6-C7 integrated cage + interfacet cages, 4) additional integrated cages at C3-C4 and C4-C5, 5) C3-C4, C4-C5 and C6-C7 integrated cages + interfacet cages. Motion, lordosis, disc and neuroforaminal height were assessed.

*Findings:* Integrated cage at C6-C7 decreased flexion-extension by 37% (P = .06) and C3-C5 by 54% (P < .01). Integrated + interfacet cages decreased motion by 89% and 86% compared to intact (P < .05). Integrated cages increased lordosis at C4-C5 and C6-C7 (P < .01). Integrated + interfacet cages returned C3-C5 lordosis to intact values, while C6-C7 remained more lordotic (P = .02). Compared to intact, neuroforaminal height increased after integrated cages at C3-C5 (P  $\leq$  .01) and at all levels after interfacet cages (P < .01).

*Interpretation:* Anterior integrated cages provides less stability than traditional cage-plate constructs while supplemental interfacet cages improve stabilization. Integrated cages provide more lordosis at caudal levels and increase neuroforaminal height more at cranial levels. After interfacet cages, posterior disc height and neuroforaminal height increased more at the caudal segments.

# 1. Introduction

Cervical fusion is a commonly performed procedure to treat symptoms of cervical spondylosis, disc herniation, and other conditions that require decompression and/or stabilization. The most commonly used cervical fusion technique is anterior cervical discectomy and fusion (ACDF) using an anterior interbody graft/cage with an anterior plate or a "plated-ACDF". Fusion success rates with plated-ACDF range from 50% to 100% depending on factors such as comorbidities, and the number of levels fused, but are typically 93%–97% for single level fusions (Fountas et al., n.d.; Fraser and Härtl, 2007; Veeravagu et al., 2014). Complications associated with plated ACDF include concerns over the plate thickness, soft tissue disruption, mobilization of the esophagus/trachea and major arteries, dysphagia, and dysphonia. Postoperative dysphagia in the literature varies greatly with 2%–70% of patients affected (Fountas et al., n.d.; Cho et al., 2013; Joaquim et al., 2014; Lee et al., 2005; McAffee et al., 2010; Rihn et al., 2011). Many of these cases resolve within a few weeks (Fountas et al., n.d.), while several reports describe an incidence of 10–14% at 1 year (Cho et al., 2013; Joaquim et al., 2014; Lee et al., 2005; Rihn et al., 2011).

Anterior integrated cages (AIC) also known as zero-profile cages, are an alternative to a plated-ACDF. These cages have integrated screws or other mechanisms to assist with fixation to the adjacent vertebral bodies. AIC have been found to require a less-invasive approach than plated-ACDF and evidence supports a decrease in dysphagia and dysphonia with their use (Grasso and Landi, 2018; Hofstetter et al., 2015;

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Lecture





Kasliwal and O'toole, 2012; Li et al., 2017). However, literature suggests AIC may have less motion reduction capabilities and greater subsidence rates compared to plated-ACDF (Kang et al., 2017; Lee et al., 2015). Lee et al. performed a retrospective cohort study to assess the postoperative motion stabilization and subsidence rates of cages with plates (plated-ACDF) and AIC. They concluded that AIC were less effective at stabilizing the motion segment compared to plated-ACDF and resulted in a lower fusion rate (Lee et al., 2015).

The question remains, in those patients in which AIC does not provide sufficient motion reduction, what can be done to reduce motion without the morbidity of an anterior revision or invasive open posterior screw and rod fusion surgery?

Posterior interfacet stabilization has been proposed as a technique to add supplemental fixation to an anterior cage construct (Kasliwal et al., 2016; Smith et al., 2017). To assess the motion limiting effectiveness of posterior supplementation of AIC, a biomechanical analysis was conducted. A zero-profile anterior integrated fusion cage (CAVUX\* Cervical Cage-L, Providence Medical Technology Inc.; Pleasanton, CA) with and without bilateral posterior interfacet cage supplementation (CAVUX\* Cage-B Cervical Posterior Cage with Ally<sup>™</sup> Bone Screw, Providence Medical Technology Inc.; Pleasanton, CA) was tested to observe the stabilizing effects of the implant systems and any change in segmental cervical alignment and neuroforaminal height (Fig. 1). To date, no studies have reported the biomechanical effects of an AIC with and without supplemental fixation using a posterior cervical stabilization system (PCSS) consisting of bilateral interfacet fusion cages.

This study compared one level (C6-C7) and two level (C3-C5) AIC cervical fusion constructs to AIC with supplemental PCSS. We hypothesized that supplemental PCSS stabilization would significantly improve the motion limiting properties of AIC in one and two-level fusion constructs. The effects that these constructs had on posture and indirect neuroforaminal decompression were also studied by evaluating the change in segmental lordosis, intervertebral disc height and neuroforaminal height. Finally, the motion reduction abilities of a standalone AIC and AIC with supplemental PCSS were compared to results from a previously published study on plated-ACDF (Voronov et al., 2016).

# 2. Methods

Seven fresh-frozen cadaveric cervical (C2-T1) spine specimens with mean (standard deviation) age 42 (7) years, (5 male, 2 female) were tested. Specimens were radiographically screened for osseous abnormalities and previous spinal surgery. Specimens were thawed and stripped of paraspinal musculature while leaving osteoligamentous structures, facet joint capsules and discs intact. Specimen specific motion analysis was used to non-invasively assess disc height, foraminal height and segmental disc angles during kinematic evaluation (Havey

et al., 2015). Fiducial markers were placed on each vertebral body in preparation for computed tomography (CT) based specimen specific 3-D motion analysis. Similar to 3-D surgical navigation, this spatial motion measurement technique combines vertebral body 3-D reconstructions from fine slice axial CT scans (< 0.63 mm), and motion tracking of the individual vertebral bodies using the Optotrak® Certus motion measurement system (Northern Digital Inc., Waterloo, Ontario, CA). The output of this technique is a digital 3-D animated representation of the individual vertebral bodies reconstructed from the CT scan moving in response to the forces and moments applied during testing. This technique makes it possible to accurately measure the relationship (lordosis, disc height, neuroforaminal height) between adjacent vertebral bodies throughout the specimen's motion. Individual specimens were then potted in aluminum cups with polymethyl methacrylate bone cement and fixed to a kinematic testing apparatus caudally, while the cephalad end was left unconstrained (Brody et al., 2014; Wojewnik et al., 2013).

The testing apparatus allowed continuous cycling of the specimen between specified maximum moment endpoints ( $\pm$  1.5 Nm) in flexionextension (FE), lateral bending (LB), and axial rotation (AR). Testing was performed in moment control mode and a six-component load cell (Model MC3A-6-1000, AMTI Inc., Newton, MA, USA) under the specimen measured the applied moments. Load-displacement data were collected until two reproducible load-displacement cycles were obtained (Brody et al., 2014; Wojewnik et al., 2013).

Each of the seven specimens (C2-T1) was tested sequentially in the following five conditions: 1) intact, 2) C6-C7 AIC, 3) C6-C7 AIC + PCSS, 4) addition of AIC at C3-C4 and C4-C5, 5) AIC + PCSS at C3-C4, C4-C5 and C6-C7 (Fig. 2). Cervical fusion using AIC was performed according to the manufacturer's surgical guidelines. Following AIC, a posterior approach was used to place cages bilaterally between the cervical facet joints of the target level according to the manufacturer's guidelines. Kinematic measures included: segmental range of motion (RoM) in FE, LB and AR, change in segmental lordosis, change in segmental disc height, and change in segmental neuroforaminal height in the neutral upright posture.

To determine if parametric statistical analysis was appropriate, Lilliefors tests based on the one sample Kolmogorov-Smirnov test were conducted on the range of motion, lordosis, disc height and neuroforaminal height data. Results showed the data was not different than the normal distribution signifying that parametric statistical analysis was appropriate. Segmental kinematics were analyzed using paired *t*-tests with Bonferroni correction for multiple comparisons, unless otherwise noted. Depending on the analysis, either two or three comparisons were made. Rather than adjust the level of significance (P < .025, P < .017), the Bonferroni corrected P values were obtained by taking the product of the number of comparisons and the uncorrected P value. This allowed the significance level to be alpha = 0.05 for all Bonferroni



Fig. 1. Surgical implants used in this study. A) Zeroprofile anterior integrated fusion cage (AIC) (CAVUX<sup>®</sup> Cervical Cage-L, Providence Medical Technology Inc., Pleasanton, CA, USA). B) Posterior interfacet fusion cage (CAVUX<sup>®</sup> Cage-B Cervical Posterior Cage with Ally<sup>™</sup> Bone Screw, Providence Medical Technology Inc., Pleasanton, CA, USA).



Fig. 2. Surgical and testing protocol: A) Intact, B) AIC at C6-C7; C) AIC + PCSS at C6-C7; D) addition of AIC at C3-C4 and C4-C5; E) AIC + PCSS at C3-C4, C4-C5 and C6-C7.

corrected comparisons. The following comparisons were conducted: intact vs AIC at one (C6-C7) and two-levels (C3-C5), and AIC vs AIC + PCSS at one and two levels. A stabilization intervention at any level is likely to alter RoM from intact conditions at adjacent spinal levels. Therefore, RoM values after each sequential step were used for continuing analysis. All comparisons were done separately for FE, LB and AR as no comparisons across load-types were intended.

# 3. Results

# 3.1. Segmental range of motion

Single level (C6-C7) integrated fusion with AIC significantly reduced motion in lateral bending and axial rotation compared to the intact conditions (P < .001). Flexion-extension motion decreased by 37% from a mean (standard deviation) of 9.3 (2.0) degrees intact to 5.9 (2.9) degrees after AIC, but statistical significance was not reached (P = .056). Two level (C3-C5) fusion using an AIC decreased RoM compared to the intact condition in all three modes of motion (P  $\leq$  .002) (Tables 1, 2). Compared to the intact condition, C3-C5 flexion-extension RoM only decreased by 54% from 20.4 (5.4) to 9.4 (6.9) degrees after stand-alone AIC (P = .002). In both one- and two-level implantations, posterior supplemental fixation (AIC + PCSS), further decreased segmental RoM in all modes of motion compared to

stand-alone AIC to at most 1.4 (1.8) degrees (P  $\leq$  .04) (Tables 1, 2).

#### 3.2. Change in segmental lordosis

The change in segmental lordosis with insertion of AIC was segment dependent, with larger increases seen in the more caudal segments. C3-C4 showed no significant change in lordosis after implantation of AIC compared to intact (Table 3). At C4-C5, AIC increased segmental lordosis on average by 3.5 (1.6) degrees (P = .004). At C6-C7 the increase in segmental lordosis from intact to AIC was 8.6 (2.6) degrees (P < .001).

Comparing AIC in a stand-alone setting to AIC with posterior supplementation (AIC + PCSS), the loss in segmental lordosis was significant at C3-C4 (P = .02) and C6-C7 (P < .001) with larger changes again seen at more caudal segments. Lordosis at C3-C4 and C4-C5 after AIC with addition of posterior supplemental fixation (AIC + PCSS) was not significantly different than the intact condition. At C6-C7 after AIC + PCSS, the motion segment remained 4.3 (2.7) degrees more lordotic than the intact condition (P = .018) but lost 50% of the lordosis gained from the anterior interbody construct.

#### 3.3. Change in anterior, middle and posterior disc height

At all three implanted levels, insertion of AIC increased anterior and

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# Table 1

Segmental range of motion (degrees) after each protocol step presented as mean (standard deviation).

	Intact	C6-C7	C6-C7	C3-C5	C3-C5
		AIC	AIC + PCSS	AIC	AIC + PCSS
C3-C4					
Flexion-extension	9.0 (2.9)	9.7 (3.0)	9.7 (3.1)	3.9 (3.0)	1.4 (1.8)
Lateral bending	10.0 (2.7)	11.3 (2.8)	11.0 (2.8)	1.8 (2.4)	0.2 (0.2)
Axial rotation	8.9 (2.4)	9.0 (2.4)	9.0 (2.4)	2.3 (1.5)	0.3 (0.2)
C4-C5					
Flexion-extension	10.1 (2.4)	10.8 (2.7)	10.7 (2.7)	5.6 (3.9)	1.4 (1.4)
Lateral bending	7.8 (2.4)	9.2 (2.3)	8.9 (2.2)	1.6 (1.2)	0.2 (0.1)
Axial rotation	9.7 (2.6)	9.9 (2.8)	10.1 (2.7)	3.8 (2.7)	0.4 (0.3)
63-65					
Flexion-extension	19.2 (4.9)	20.5 (5.2)	20 4 (5 4)	94(69)	28(31)
Lateral bending	17.8 (4.1)	20.5 (4.2)	19.9 (4.1)	3.4 (2.8)	0.4 (0.2)
Axial rotation	18.6 (4.8)	18.9 (5.0)	19.1 (5.0)	6.1 (3.7)	0.7 (0.4)
CE C6					
Elevion-extension	10.9 (2.5)	121 (29)	120(31)	122(31)	121(32)
Lateral bending	6.8 (1.8)	76 (20)	74(20)	79(25)	78(24)
Axial rotation	8 4 (2 4)	87(27)	86 (26)	87(28)	86(28)
	0.1 (2.1)	0.7 (2.7)	0.0 (2.0)	0.7 (2.0)	0.0 (2.0)
C6-C7					
Flexion-extension	9.3 (2.0)	5.9 (2.9)	1.0 (0.5)	1.0 (0.4)	1.0 (0.6)
Lateral bending	7.3 (1.6)	1.8 (1.3)	0.3 (0.1)	0.3 (0.1)	0.3 (0.1)
Axial rotation	5.8 (2.0)	2.7 (2.0)	0.5 (0.2)	0.4 (0.2)	0.4 (0.1)

#### Table 2

Statistical analysis of segmental range of motion between protocol steps. Statistical comparisons made using two-tailed paired t-test with correction for multiple comparisons. Statistical significance is shown by P  $\,<\,.05$ .

	Intact vs AIC	AIC vs AIC + PCSS
C3-C4		
Flexion-extension	P = .01	P = .02
Lateral bending	P < .01	P = .03
Axial rotation	P < .01	P = .02
C4-C5		
Flexion-extension	P < .01	P = .01
Lateral bending	P < .01	P = .03
Axial rotation	P < .01	P = .02
C3-C5		
Flexion-extension	P < .01	P = .01
Lateral bending	P < .01	P = .03
Axial rotation	P < .01	P = .01
C6-C7		
Flexion-extension	P = .06	P = .01
Lateral bending	P < .01	P = .03
Axial rotation	P < .01	P = .04

#### Table 3

Change in segmental lordosis (degrees) between protocol steps presented as mean (standard deviation). Statistical comparisons made using two-tailed paired t-test with correction for multiple comparisons. Positive change is an increase in lordosis. Statistical significance is shown by P < .05.

	Intact vs AIC		Intact vs AIC + PCSS		AIC vs AIC + PCSS	
C3-C4	1.3 (1.8)	P = .32	-0.5 (1.9)	P = 1.0	-1.7 (1.1)	P = .02
C4-C5	3.5 (1.6)	P < .01	1.4 (2.8)	P = .69	-2.1 (2.0)	P = .11
C6-C7	8.6 (2.6)	P < .01	4.3 (2.7)	P = .02	-4.3 (1.1)	P < .01

middle disc height compared to the intact condition (P  $\leq$  .01) (Table 4). While posterior disc height also increased at all implanted levels, the increase was significant at C3-C4 (P = .003) and C4-C5 (P = .002) but was not significantly different than intact at C6-C7 (P = .287).

Compared to AIC, supplemental posterior cages (AIC + PCSS) decreased anterior disc height at C3-C4 on average by 0.3 (0.3) mm

#### Table 4

Change in anterior, middle and posterior disc height (mm) between protocol steps presented as mean (standard deviation). Statistical comparisons made using two-tailed paired t-tests with correction for multiple comparisons. Positive change represents an increase in disc height. Statistical significance is shown by P < .05.

	Intact vs AIC		Intact vs AIC + PCSS		AIC vs AIC + PCSS	
Anterio	r					
C3-C4	1.2 (0.7)	P = .01	0.8 (0.7)	P = .05	-0.4 (0.3)	P = .03
C4-C5	1.6 (0.5)	P < .01	1.3 (0.6)	P < .01	-0.3 (0.4)	P = .23
C6-C7	2.4 (0.7)	P < .01	2.2 (0.6)	P < .01	-0.3 (0.4)	P = .40
Middle						
C3-C4	1.0 (0.5)	P = .01	0.9 (0.5)	P = .01	-0.2 (0.2)	P = .26
C4-C5	1.2 (0.4)	P < .01	1.1 (0.4)	P < .01	-0.1 (0.2)	P = .97
C6-C7	1.4 (0.5)	P < .01	1.6 (0.4)	P < .01	0.2 (0.5)	P = .94
Posterio	or					
C3-C4	0.9 (0.4)	P < .01	0.9 (0.4)	P < .01	0.0 (0.2)	P = 1.0
C4-C5	0.8 (0.3)	P < .01	0.9 (0.4)	P < .01	0.1 (0.2)	P = .39
C6-C7	0.4 (0.6)	P = .29	1.1 (0.4)	P < .01	0.7 (0.4)	P = .09

(P = .035) while having no significant effect on anterior disc height at C4-C5 or C6-C7. Middle and posterior disc heights did not change significantly after posterior supplemental fixation (AIC + PCSS) at all tested levels.

Compared to the intact condition, AIC + PCSS significantly increased anterior, middle and posterior disc heights at all implanted levels (P < .05). Posterior disc height between the intact condition and AIC + PCSS, increased by 0.9 (0.4) mm at C3-C4 (P = .003) and C4-C5 (P = .002) and by 1.1 (0.4) mm at C6-C7 (P = .001) (Table 4).

# 3.4. Change in neuroforaminal height (mm)

Like segmental lordosis, the change in neuroforaminal height was segment dependent, with cranial and caudal cervical segments behaving differently (Table 5). Neuroforaminal height significantly increased by 0.7 mm at C3-C4 (P = .005) and C4-C5 (P = .003) after AIC placement, while C6-C7 showed no change from intact. After supplemental fixation (AIC + PCSS), C3-C4 and C4-C5 showed a total increase in neuroforaminal height compared to the intact condition of 1.0 (0.2) mm (P < .001) and 1.1 (0.5) mm (P = .002) respectively. At C6-C7

### Table 5

Change in neuroforaminal height (mm) between surgical steps. Mean (standard deviation) of left and right foramen. Statistical analysis performed using two-tailed paired t-test with correction for multiple comparisons. Statistical significance is shown by P < .05.

	Intact vs AIC		Intact vs AIC + PCSS		AIC vs AIC + PCSS	
C3-C4	0.7 (0.4)	P = .01	1.0 (0.2)	P < .01	0.3 (0.3)	P = .08
C4-C5	0.7 (0.3)	P < .01	1.1 (0.5)	P < .01	0.4 (0.2)	P < .01
C6-C7	0.1 (0.5)	P = 1.0	1.0 (0.5)	P < .01	0.9 (0.7)	P = .03

the interfacet cages (AIC + PCSS) added 0.9 (0.7) mm of neuroforaminal height compared to AIC alone, resulting in a total increase of 1.0 (0.5) mm compared to the intact condition (P = .004).

#### 4. Discussion

It is generally accepted that cervical fusion with anterior integrated cages is a less complex surgery with shorter operative time, blood loss and soft tissue dissection than plated-ACDF (Hofstetter et al., 2015; Li et al., 2017). Studies in the literature have documented decreased dysphasia with AIC (Hofstetter et al., 2015; Joaquim et al., 2014; Kasliwal and O'toole, 2012; Scholz et al., 2011). However, Kang et al. and Lee et al. presented evidence that AIC provides less stability resulting in higher pseudarthrosis than plated-ACDF (Kang et al., 2017; Lee et al., 2015).

# 4.1. Supplemental use of PCSS

Biomechanical studies confirm that PCSS fixation mechanically locks translation of the interarticular facet surfaces contributing to a reduction of cervical segmental range of motion (Leasure and Buckley, 2014; Voronov et al., 2016). The current study is the first to evaluate the biomechanical role of PCSS placed in the facet joints as a supplement to an AIC at one and two levels. Study results show AIC with PCSS supplementation provides a significant reduction in range of motion compared to AIC alone. With this data we can affirm our hypothesis, and state that supplemental use of bilateral posterior interfacet cages can significantly improve immediate postoperative segmental stabilization of AIC at one and two levels.

The results of this biomechanical study support the clinical findings that there is a role for the use of bilateral posterior fusion cages when added stability is required, such as in patients with elevated risk of pseudarthrosis (multiple level fusion, smokers, etc.) (Kasliwal et al., 2016; Smith et al., 2017). If revision or supplemental fixation of an anterior fusion is necessary, common options include anterior revision or posterior screw and rod fixation (Balaram et al., 2014; Kaiser et al., 2009). Pseudarthrosis studies in the literature are not conclusive on the best revision approach for failed anterior fusion. Anterior reoperation has certain benefits including reduced morbidity and a more direct correction of the cause of pseudarthrosis. A posterior open approach eliminates the increased complexity of revision through scar tissue and the complications regarding esophagus mobilization and dysphagia

#### (Kaiser et al., 2009; Piazza et al., 2017).

The posterior open approach also provides effective stabilization, but it is technically demanding, requires longer hospital stays, has higher rates of morbidity and complications such as axial neck pain, infection, higher blood loss, and postoperative pain (Leckie et al., 2016; Memtsoudis et al., 2011). In cases in which anterior subsidence or height loss is not an issue, a posterior minimally invasive option may provide sufficient stabilization while decreasing surgical morbidity compared to an open posterior approach.

Options for posterior MIS supplemental cervical fixation are limited but include transfacet screws and interfacet spacers. Transfacet screws can be effective at stabilizing the motion segment, but their minimally invasive use is technically demanding with high rates of misplacement (Husain et al., 2016). Posterior fusion cages placed within the facet joints may offer an effective means of segmental fixation with a minimally invasive, tissue sparing approach (Kaiser et al., 2009; Kasliwal et al., 2016; Piazza et al., 2017; Smith et al., 2017). These posterior cervical cages have been shown to decrease range of motion at the index level and be effective in the treatment of radiculopathy (Goel and Shah, 2011; Leasure and Buckley, 2014; McCormack et al., 2013; Voronov et al., 2016). In a clinical study of nineteen symptomatic pseudarthrosis patients, Kasliwal et al. used cervical interfacet cages to supplement the preexisting anterior cervical discectomy and fusion construct (Kasliwal et al., 2016). While this study showed good outcomes, caution must be used when evaluating pseudarthrosis patients as candidates for PCSS since a load bearing anterior column is necessary for these interfacet cages to effectively reduce motion. Patients with compression fractures or cage/graft subsidence may not be candidates for this minimally invasive technique.

#### 4.2. AIC vs plated-ACDF

The findings of this study provide evidence that AIC is not as effective as published results of plated-ACDF at stabilizing cervical motion segments. In a previous study by Voronov et al. performed in the same laboratory using similar methodology, range of motion of plated-ACDF was compared to the intact condition and to ACDF with supplemental PCSS fixation (Table 6) (Voronov et al., 2016). Data from Voronov et al. (Voronov et al., 2016) after plated-ACDF was compared to data from this study using a two-tailed unequal variance t-test. Results of the two studies show that in flexion-extension in both one and two-level constructs, plated- ACDF provided significantly more motion reduction than stand-alone AIC. In lateral bending and axial rotation there was no significant difference between plated ACDF and standalone AIC in either one or two-level constructs. The lack of significance in lateral bending and axial rotation may be partially due to the smaller motions and larger variability in motion reduction in the AIC group as shown in Table 6.

Comparing AIC + PCSS to plated-ACDF shows that addition of PCSS results in greatly reduced motion over AIC alone, with motion reduction similar to or better than plated ACDF (Table 6). The significant reduction in RoM of AIC + PCSS compared to plated-ACDF may not be clinically relevant but does highlight the effectiveness of PCSS.

Table 6

Comparison of mean (standard deviation) range of motion (degrees) of plated ACDF and AIC fusion data sets. ACDF and ACDF + PCSS data is from Voronov et al. (Voronov et al., 2016). Statistical comparison was performed using a two-tailed, two-sample unequal variance t-test with correction for multiple comparisons. Statistical significance is shown by P < .05.

•	•					
	Fusion level	Plated ACDF	AIC	Plated ACDF vs AIC	AIC + PCSS	Plated ACDF vs AIC + PCSS
Flexion-extension	C6-C7	2.5 (0.8)	5.9 (2.9)	P = .04	1.0 (0.5)	P < .01
	C3-C5	1.7 (0.9)	9.4 (6.9)	P < .05	2.8 (3.1)	P = .76
Lateral bending	C6-C7	1.6 (0.7)	1.8 (1.3)	P = 1.0	0.3 (0.1)	P < .01
	C3-C5	1.7 (0.6)	3.4 (2.8)	P = .35	0.4 (0.2)	P < .01
Axial rotation	C6-C7	1.7 (0.4)	2.7 (2.0)	P = .47	0.5 (0.2)	P < .01
	C3-C5	2.1 (0.5)	6.1 (3.7)	P = .06	0.7 (0.4)	P < .01

Comparisons to the Voronov et al. data set provides evidence that supplemental posterior interfacet fixation using PCSS can stabilize a motion segment with an anterior integrated cage (AIC) at least as well as plated ACDF.

#### 4.3. Sagittal alignment and indirect decompression

Study results show that AIC and PCSS behave differently in the lower cervical spine (C6-C7) versus the upper cervical spine (C3-C5). AIC at C6-C7 had a large effect of increasing segmental lordosis which diminished at each cranial level. A similar response was seen with placement of PCSS, with a larger reduction in lordosis at C6-C7 signifying a 50% reduction in lordosis gained by AIC. Lordosis at the more cranial levels C4-C5 and C3-C4 was not significantly different than the intact condition after supplementation of AIC with PCSS.

These results were mirrored in the segmental disc height data where a small increase in posterior height was seen after AIC at C6-C7 and relatively larger increases in posterior height at the upper levels. These differential changes in disc height and lordosis after AIC and PCSS are likely driven by differences in vertebral body morphology and the location of the segmental axes of rotation. Bogduk and Mercer, as well as Hipp and Wharton presented data showing the location of the segmental center of rotation in the cervical spine moves caudally at more cranial segments (Bogduk and Mercer, 2000; Hipp and Wharton, 2008). This relationship is likely driven by the location of the facet joints relative to the disc space (Milne, 1991).

Studies in the literature have presented data on indirect neuroforaminal decompression with interfacet fusion (Goel and Shah, 2011; Leasure and Buckley, 2014; Siemionow et al., 2016). Results of this study provide additional evidence that use of PCSS moderately increases posterior disc height and neuroforaminal height in the immediate postoperative period and can cause a level dependent change in lordosis. Published clinical results of PCSS document a small decrease in lordosis of the treated segment, but no significant change in overall cervical lordosis (Kasliwal et al., 2016; McCormack et al., 2013; Siemionow et al., 2016; Tan et al., 2015). When indirect decompression is intended, special attention should be given to the interplay of lordosis provided by the interbody device and posterior disc height and neuroforaminal decompression provided by the posterior interfacet cages. Future clinical studies may offer an improved understanding of this interaction and appropriate indications at the different cervical levels to achieve optimal outcomes. As with any implant system, it is important to understand how sagittal alignment may be affected by single and multi-level instrumentation. Specimens studied in this work were without significant degenerative changes which would reduce disc height or change sagittal alignment. Clinically the degenerative process and bone quality may have varying effects on lordosis, disc height and indirect decompression. Future analysis of biomechanical data and validation with clinical findings will provide insight into the effects of the studied fusion techniques on sagittal balance at different cervical levels.

# 4.4. Limitations

The consequence of long-term cyclical loading experienced in vivo are not reflected in the in vitro evaluation of the tested constructs. Rather, the results presented provide evidence for the immediate postoperative effects of the implants. In vivo, compressive loads help to stabilize instrumented segments (Patwardhan et al., 2003). In this study, no compressive follower load was used in order to simulate a worst-case scenario for segmental motion.

C5-C6 is the most operated segment in the cervical spine. In this study C5-C6 was not implanted so there would be a free mobile disc between the one level (C6-C7) and two level (C3-C5) fusion constructs. In biomechanical evaluation, comparisons are best made before and after surgeries at the same level. This is because segmental kinematics

such as range of motion and axis of rotation vary between individual motion segments (Hipp and Wharton, 2008; Martin et al., 2011; White and Panjabi, 1978). Future studies can evaluate the response of C5-C6 to determine if its response is more similar to C6-C7 or the upper cervical spine.

Finally, this study was performed on donor specimens without significant sagittal deformity or degenerative changes. The postural consequences of PCSS on straight or kyphotic cervical spines should be considered, especially in multi-level use. Clinical studies may be able to address the relationship between anterior fusion cage height, interfacet fusion and resulting sagittal balance.

# 5. Conclusion

In cervical biomechanics the facet joints play just as pivotal a role as the intervertebral disc in segmental motion (Bogduk and Mercer, 2000; Jaumard et al., 2011; Milne, 1991). The results of this study provide evidence that an anterior column support such as an integrated fusion cage, combined with bilateral posterior interfacet cages intended to block facet translation, is an effective means of stabilizing a motion segment to promote fusion.

In the cervical spine there is an antagonistic relationship between indirect neuroforaminal decompression and segmental lordosis. Anterior interbody cages provide more lordosis at caudal levels than at cranial levels. As a result of the contrasting effects on lordosis, posterior disc height and neuroforaminal height increase more at cranial levels (C3-C4 and C4-C5) after AIC than at C6-C7.

As in previous clinical and biomechanical studies, this study shows that PCSS can increase posterior disc height and neuroforaminal height in the immediate post-operative period (Goel and Shah, 2011; Leasure and Buckley, 2014; Siemionow et al., 2016). This indirect decompression from PCSS results in a loss of lordosis at more caudal cervical levels. After PCSS the posterior disc height and neuroforaminal height increased more at the caudal segments than at cranial segments. These trade-offs between added lordosis with AIC and reduced lordosis with PCSS resulted in similar increases in posterior disc height and neuroforaminal height after AIC + PCSS at all cervical levels studied.

This and other studies show that stand-alone AIC can provide less stability than plated-ACDF in the immediate post-operative period (Kang et al., 2017; Lee et al., 2015). The data presented in this work provides evidence that in the immediate postoperative period, supplemental bilateral interfacet fusion cages can dramatically improve the motion reduction capabilities of anterior interbody constructs.

# **Declaration of Competing Interest**

The authors do not have a financial relationship with the industry research sponsor. The first and last authors have full control of all data.

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# References

Balaram, A., Ghanayem, A., O'Leary, P., Voronov, L., Havey, R., Carandang, C., Abjornson, C., Patwardhan, A., 2014. Biomechanical evaluation of a low-profile, anchored cervical interbody spacer device at the index level or adjacent to plated

fusion. Spine 39 (13), E763-E769.

Bogduk, N., Mercer, S., 2000. Biomechanics of the cervical spine. I: Normal kinematics. Clin. Biomech. 15, 633–648.

- Brody, M., Patel, A., Ghanayem, A., Wojewnik, B., Carandang, G., Havey, R., Voronov, L., Vastardis, G., Potluri, T., Patwardhan, A., 2014. The effect of posterior decompressive procedures on segmental range of motion after cervical total disc arthroplasty. Spine 39 (19), 1558–1563.
- Cho, S., Lu, Y., Lee, D., 2013. Dysphagia following anterior cervical spinal surgery: a systematic review. Bone Joint J. 95 (B), 868–873.
- K. Fountas, E. Kapsalaki, L. Nikolakakos, H. Smisson, K. Johnston, A. Grigorian, G. Lee and J. Robinson, "Anterior cervical discectomy and fusion associated complications," Spine, 32, 21, pp. 2310–17, (207).
- Fraser, J., Härtl, R., 2007. Anterior approaches to fusion of the cervical spine: a metaanalysis of fusion rates. J. Neurosurg. Spine 6 (4), 298–303.
- Goel, A., Shah, A., 2011. Facetal distraction as treatment for single- and multilevel cervical spondylotic radiculopathy and myelopathy: a preliminary report. J. Neurosurg. Spine 14, 689–696.
- Grasso, G., Landi, A., 2018. Long-term clinical and radiological outcomes following anterior cervical discectomy and fusion by zero-profile anchored cage. J. Craniovertebr. Junction Spine 9 (2), 87–92.
- Havey, R.M., Goodsitt, J., Khayatzadeh, S., Muriuki, M., Potluri, T., Voronov, L.I., Lomasney, L.M., Patwardhan, A.G., Jul 2015. Three-dimensional computed tomography-based specimen-specific kinematic model for ex vivo assessment of lumbar neuroforaminal space. Spine 40, E814–E822.
- Hipp, J., Wharton, N., 2008. Quantitative motion analysis (QMA) of motion-preserving and fusion technologies for the spine. In: Motion Preservation Surgery of the Spine. Saunders, Philadeplhia, pp. 85–96.
- Hofstetter, C., Kesavabhotla, K., Boockvar, J., 2015. Zero-profile anchored spacer reduces rate of dysphagia compared with ACDF with anterior plating. J. Spinal Disord. Tech. 28 (5), E284–E290.
- Husain, A., Akpolat, Y., Palmer, D., Rios, D., Criswell, K., Cheng, W., 2016. A comparison of open versus percutaneous cervical transfacet fixation. J. Neurosurg. Spine 25 (4), 430–435.
- Jaumard, N., Welch, W., Winkelstein, B., July 2011. Spinal facet joint biomechanics and mechanotransduction in normal, injury and degenerative conditions. J. Biomech. Eng, 133.
- Joaquim, A., Murar, J., Savage, J., Patel, A., 2014. Dysphagia after anterior cervical spine surgery: a systematic review of potential preventative measures. Spine J. 14, 2246–2260.
- Kaiser, M., Mummaneni, P., Matz, P., Anderson, P., Groff, M., Heary, R., Holly, L., Ryken, T., Choudhri, T., Vresilovic, E., Resnick, D., 2009. Management of anterior cervical pseudarthrosis. J. Neurosurg. Spine 11 (2), 228–237.
- Kang, D., Wagner, S., Tracey, R., Cody, J., Gaume, R., Lehman, R., 2017. Biomechanical stability of a stand-alone interbody spacer in two-level and hybrid cervical fusion constructs. Glob. Spine J. 7 (7), 681–688.
- Kasliwal, M., O'toole, J., 2012. Integrated intervertebral device for anterior cervical fusion: an initial experience. J. Craniovertebr. Junction Spine 3 (2), 52–57.
- Kasliwal, M., Corley, J., Traynelis, V., 2016. Posterior cervical fusion using cervical interfacet spacers in patients with symptomatic cervical pseudarthrosis. Neurosurgery 78 (5), 661–668.
- Leasure, J., Buckley, J., 2014. Biomechanical evaluation of an interfacet joint decompression and stabilization system. J. Biomech. Eng. 136.
- Leckie, S., Yoon, S., Isaacs, R., Radcliff, K., Fessler, R., Haid, R., Traynelis, V., 2016. Perioperative complications of cervical spine surgery: analysis of a prospectively gathered database through the association for collaborative spinal research. Glob. Spine J. 6, 640–649.
- Lee, M., Bazaz, R., Furey, C., Yoo, J., 2005. Influence of anterior cervical plate design on

Dysphagia: a 2-year prospective longitudinal follow-up study. J. Spinal Disord. Tech. 18 (5), 406–409.

- Lee, Y., Kim, Y., Park, S., 2015. Does a zero-profile anchored cage offer additional stabilization as anterior cervical plate? Spine 40 (10), E563–E570.
- Li, Z., Zhao, Y., Tang, J., Ren, D., Guo, J., Wang, H., Hou, S., 2017. Comparison of a new zero-profile, stand-alone Fidji cervical cage and anterior cervical plate for single and multilevel ACDF: a minimum 2-year follow-up study. Eur. Spine J. 26, 1129–1139.
- Martin, S., Ghanayem, A.J., Tzermiadianos, M.N., Voronov, L.I., Havey, R.M., Renner, S.M., Carandang, G., Abjornson, C., Patwardhan, A.G., Aug 2011. Kinematics of cervical total disc replacement adjacent to a two-level, straight versus lordotic fusion. Spine 36, 1359–1366.
- McAffee, P., Cappuccino, A., Cunningham, B., Devine, J., Phillips, F., Regan, J., Albert, T., Ahrens, J., 2010. Lower incidence of dysphagia with cervical arthroplasty compared with ACDF in a prospective randomized clinical trial. J. Spinal Disord. Tech. 23 (1), 1–8.
- McCormack, B., Bundoc, R., Ver, M., Ignacio, J., Berven, S., Eyster, E., 2013. Percutaneous posterior cervical fusion with the DTRAX facet system for single-level radiculopathy: results in 60 patients. J. Neurosurg. Spine 18, 243–244.
- Memtsoudis, S., Hughes, A., Ma, Y., Chiu, Y., Sama, A., Girardi, F., 2011. Increased inhospital complications after primary posterior versus primary anterior cervical fusion. Clin. Orthop. Relat. Res. 469 (3), 649–657.
- Milne, N., 1991. The role of zygapophysial joint orientation and uncinate processes in controlling motion in the cervical spine. J. Anat. 178, 189–201.
- Patwardhan, A.G., Carandang, G., Ghanayem, A.J., Havey, R.M., Cunningham, B., Voronov, L.I., Phillips, F.M., 2003. Compressive preload improves the stability of anterior lumbar interbody fusion cage constructs. J. Bone Joint Surg. Am. 85, 1749–1756.
- Piazza, B., Pace, G., Knaub, M., Bible, J., 2017. Anterior cervical discectomy and fusion pseudarthrosis posterior versus "redo" anterior. Clin. Spine Surg. 30 (3), 91–93.
- Rihn, J., Kane, J., Albert, T., Vaccaro, A., Hilibrand, A., 2011. What is the incidence and severity of dysphagia after anterior cervical surgery? Clin. Orthop. Relat. Res. 469 (3), 658–665.
- Scholz, M., Schnake, K., Pingel, A., Hoffmann, R., Kandziora, F., 2011. A new zero-profile implant for stand-alone anterior cervical interbody fusion. Clin. Orthop. Relat. Res. 469, 666–673.
- Siemionow, K., Janusz, P., Glowka, P., 2016. Cervical cages placed bilaterally in the facet joints from a posterior approach significantly increase foraminal area. Eur. Spine J. 25, 2279–2285.
- Smith, W., Gillespy, M., Huffman, J., Vong, V., McCormack, BM, 2017. Anterior cervical pseudarthrosis treated with bilateral posterior cervical cages. Operative Neurosurg. 14 (3), 236–242.
- Tan, L., Straus, D., Traynelis, V., 2015. Cervical interfacet spacers and maintenance of cervical lordosis. J. Neurosurg. Spine 22, 466–469.
  Veeravagu, A., Cole, T., Jiang, B., Ratliff, J., 2014. Revision rates and complication in-
- Veeravagu, A., Cole, T., Jiang, B., Ratliff, J., 2014. Revision rates and complication incidence in single- and multilevel anterior cervical discectomy and fusion procedures: an administrative database study. Spine J. 14 (7), 1125–1131.
- Voronov, L., Siemionow, K., Havey, R., Carandang, G., Phillips, F., Patwardhan, A., 2016. Bilateral posterior cervical cages provide biomechanical stability: assessment of stand-alone and supplemental fixation for anterior cervical discectomy and fusion. Med. Dev. 9, 223–230.
- White, A.A., Panjabi, M.M., 1978. Kinematics of the spine. In: Clinical Biomechanics of the Spine. J.B. Lippincott Company, Philadelphia, pp. 61–90.
- Wojewnik, B., Ghanayemm, A., Tsitsopoulos, P., Voronov, L., Potluri, T., Havey, R., Zelenakova, J., Patel, A., Carandang, G., Patwardhan, A., Jan 2013. Biomechanical evaluation of a low profile, anchored cervical interbody spacer device in the setting of progressive flexion-distraction injury of the cervical spine. Spine J. 22 (1), 135–141.