Biomechanical evaluation of a low profile, anchored cervical interbody spacer device in the setting of progressive flexion-distraction injury of the cervical spine

Bartosz Wojewnik · Alexander J. Ghanayem · Parmenion P. Tsitsopoulos ·
Leonard I. Voronov · Tejaswy Potluri · Robert M. Havey · Julia Zelenakova ·
Alpesh A. Patel · Gerard Carandang · Avinash G. Patwardhan

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Abstract

Introduction Anterior cervical decompression and fusion is a well-established procedure for treatment of degenerative disc disease and cervical trauma including flexion-distraction injuries. Low-profile interbody devices incorporating fixation have been introduced to avoid potential issues associated with dissection and traditional instrumentation. While these devices have been assessed in traditional models, they have not been evaluated in the setting of traumatic spine injury. This study investigated the ability of these devices to stabilize the subaxial cervical spine in the presence of flexion-distraction injuries of increasing severity.

Methods Thirteen human cadaveric subaxial cervical spines (C3–C7) were tested at C5–C6 in flexion–extension, lateral bending and axial rotation in the load-control mode under ± 1.5 Nm moments. Six spines were tested with locked screw configuration and seven with variable angle screw configuration. After testing the range of motion (ROM) with implanted device, progressive posterior destabilization was performed in 3 stages at C5–C6.

Results The anchored spacer device with locked screw configuration significantly reduced C5–C6 flexion–extension (FE) motion from 14.8 ± 4.2 to $3.9 \pm 1.8^\circ$, lateral

bending (LB) from 10.3 ± 2.0 to 1.6 ± 0.8 , and axial rotation (AR) from 11.0 ± 2.4 to 2.5 ± 0.8 compared with intact under ($p < 0.01$). The anchored spacer device with variable angle screw configuration also significantly reduced C5–C6 FE motion from 10.7 ± 1.7 to $5.5 \pm 2.5^\circ$, LB from 8.3 ± 1.4 to 2.7 ± 1.0 , and AR from 8.8 ± 2.7 to 4.6 ± 1.3 compared with intact ($p < 0.01$). The ROM of the C5–C6 segment with locked screw configuration and grade-3 F-D injury was significantly reduced from intact, with residual motions of 5.1 ± 2.1 in FE, 2.0 ± 1.1 in LB, and 3.3 ± 1.4 in AR. Conversely, the ROM of the C5–C6 segment with variable-angle screw configuration and grade-3 F-D injury was not significantly reduced from intact, with residual motions of 8.7 ± 4.5 in FE, 5.0 ± 1.6 in LB, and 9.5 ± 4.6 in AR.

Conclusions The locked screw spacer showed significantly reduced motion compared with the intact spine even in the setting of progressive flexion-distraction injury. The variable angle screw spacer did not sufficiently stabilize flexion–distraction injuries. The resulting motion for both constructs was higher than that reported in previous studies using traditional plating. Locked screw spacers may be utilized with additional external immobilization while variable angle screw spacers should not be used in patients with flexion-distraction injuries.

Keywords Cervical spine · Cervical interbody spacer device · Biomechanics

Introduction

Anterior cervical discectomy and fusion (ACDF), as first described by Smith and Robinson, has been used for the treatment of many spine conditions including cervical

B. Wojewnik · A. J. Ghanayem · P. P. Tsitsopoulos ·
L. I. Voronov · R. M. Havey · A. A. Patel ·
A. G. Patwardhan (✉)
Department of Orthopaedic Surgery and Rehabilitation,
Loyola University Medical Center, 2160 S. First Avenue,
Maywood, IL 60153, USA
e-mail: apatwar@lumc.edu

A. J. Ghanayem · P. P. Tsitsopoulos · L. I. Voronov ·
T. Potluri · R. M. Havey · J. Zelenakova ·
A. A. Patel · G. Carandang · A. G. Patwardhan
Musculoskeletal Biomechanics Laboratory, Department of
Veterans Affairs, Edward Hines Jr. VA Hospital, Hines, IL, USA

spondylotic myelopathy, degenerative disc disease, as well as traumatic injuries including unstable flexion-distraction injuries [1, 2]. An interbody graft and plate construct is often used to achieve stability and promote fusion. This common procedure does have its complications; some of which have been attributed to plate design and additional anterior dissection [3, 4].

In order to address some of the potential plate-related problems, such as more extensive dissection and hardware prominence, anchored spacer devices have been developed. These devices include low-profile components which are attached to an interbody spacer and use fixation that secures the spacer directly through the endplate (Fig. 1). The anchored spacer devices have been shown to provide biomechanical stability comparable to constructs that use an anterior plate to supplement an interbody cage in the presence of intact posterior soft tissue and bony structures [5, 6]. However, the biomechanical stability of anchored cervical spacers has not been evaluated in a flexion-distraction trauma model.

The purpose of this study was to evaluate the biomechanical stability of both fixed- and variable-angle anchored cervical spacers in the setting of progressive flexion-distraction traumatic cervical spine injury.

Fig. 1 Synthes Zero-P anchored cervical spacer: **a** locked screw version, **b** variable-angle screw version, **c** schematic of the implanted locked screw version

Materials and methods

Specimens and experimental setup

A total of 13 fresh human cadaveric subaxial cervical spines (C3–C7) were tested. Radiographs were taken to exclude severe degeneration, trauma, tumor, or significant osteoporosis. Specimens were divided randomly into two groups to be tested with different implants. Locked-angle device was tested in 6 specimens (3 male, 3 female, mean 42.3 ± 12.5 , range 27–59 years) and variable-angle device was tested in 7 specimens (3 male, 4 female, mean age 56.4 ± 9.0 , range 37–63 years). The specimens were sealed in plastic bags and frozen at -20°C . Specimens were thawed and cleaned the day of testing. Muscle tissue was removed preserving the osteoligamentous structures important for stability.

Each specimen was anchored in aluminum cups using k-wires and bone cement at the C7 and C3 vertebrae. The specimen was then mounted on a 6-component load cell (Model MC3A-6-250, AMTI Multi-component transducers, AMTI Inc., Newton, MA, USA) through the previously attached caudal base. The specimen was allowed to move freely at the proximal end. A moment was applied by controlling the flow of water into bags attached to the loading arms which were fixed to the C3 cup. This setup allowed for continued cycling of the specimen between specified moment endpoints in flexion–extension, lateral bending, and axial rotation. The experiment was performed at room temperature and tissue hydration was carefully maintained by wrapping the specimens in saline-soaked gauze.

A compressive preload of 150 N was applied to the specimen during flexion–extension testing to account for the physiologic compressive preload in the cervical spine produced by the action of muscles in balancing the weight of the head. The preload was applied along the path of the cervical spine lordotic curve to help support physiologic compressive preloads without damage to the specimen. The details of this methodology have been previously described [7, 8] (Fig. 2).

The motions of C3, C4, C5, C6 levels were measured in three-dimensions relative to the static C7 vertebra attached to the base plate. The measurements were obtained using an optoelectronic motion measurement system (Optotrak, Northern Digital Inc., Waterloo, Ontario, Canada). In addition, biaxial angle sensors were mounted on each vertebra to allow real-time feedback for the optimization of the preload path.

Experimental protocol

Initial range of motion (ROM) was determined in flexion–extension, lateral bending, and axial rotation in a load-control mode under ± 1.5 Nm moments. Flexion–extension

Fig. 2 X-Ray of specimen and experimental setup with follower load application

was tested with and without follower preload of 150 N. Load–displacement data were collected until 2 reproducible load displacement loops were obtained. This required three to four loading cycles.

After testing the intact spine, anterior cervical discectomy was performed at the C5–C6 level. During discectomy, the lateral annulus and posterior longitudinal ligament were left intact. The endplates were prepared by removing cartilage down to the cortical bone. This was followed by implantation of either locked anchored spacer ($n = 6$; Zero-P, Synthes, West Chester, PA, USA) or variable-angle anchored spacer ($n = 7$; Zero-P VA, Synthes, West Chester, PA, USA). Poly-ether-ether-ketone (PEEK) interbody spacers were used with both variable-angle- and fixed-angle devices and implanted according to instruction manual provided by the manufacturer. We standardized the screw length to 16 mm, given that screw length could influence stability and force necessary for loosening. Range of motion testing was repeated.

Next, progressive destabilization was performed in 3 stages at C5–C6 level to reproduce progressive stages of flexion distraction injury as described by Allen and further shown using MRI imaging by Vaccaro et al. [9, 10]. First stage (F-D grade-1 injury) included transection of supraspinous and interspinous ligaments and ligamentum

flavum. Second stage (F-D grade-2 injury) included transection of single facet capsule (left vs. right randomized) and ipsilateral inter-transverse ligament [11]. The final stage (F-D grade-3 injury) included transection of the contralateral facet capsule, inter-transverse ligament, and the posterior longitudinal ligament (Fig. 3). Load versus displacement data were obtained in all three test directions after each simulated stage of injury.

Statistical analysis

Load versus angular motion data corresponding to 1.5 Nm moments were statistically analyzed using Bonferroni adjustment for multiple comparisons. A total of four comparisons were made. We compared intact ROM with implantation and then implantation ROM with subsequent destabilization steps. If there was a significant difference after a specific destabilization step this new value was used to look for additional significant increases in ROM with further destabilization. The level of significance was set at $\alpha = 0.01$ to account for comparison of five groups (intact, ACDF with intact posterior ligamentous complex, grade-1, grade-2, and grade-3 injury). Data was analyzed for both preloads of 0 and 150 N in flexion–extension testing and with zero preload for lateral bending and axial rotation. Analysis was performed separately for fixed- and variable-angle implants. The statistical software Systat (version 10.2, Richmond, CA, USA) was used for the analysis.

Results

The ACDF construct using the locking screw anchored spacer significantly reduced motion in flexion–extension without a preload and with 150 N preload, and in lateral bending and axial rotation compared with intact (Table 1, $p < 0.01$). Grade-1 injury caused small but significant increase in flexion–extension, with or without preload, compared with the motion at the fusion construct with intact posterior ligamentous structures ($p < 0.01$). Grade-1 injury did not significantly increase motion of the construct in lateral bending or axial rotation. Grade-2 injury did not cause further significant increase in motion when compared with the motion after grade-1 injury. Grade-3 injury significantly increased motions in flexion–extension compared with grade-1 injury, but had no significant effect on lateral bending or axial rotation motions. After grade-3 injury the average motions in flexion–extension were 5.5 and 5.1° for no preload and with preload cases, respectively, 2.0° in lateral bending, and 3.3° in axial rotation. These ROM values remained significantly smaller than the motion of the intact segment (Table 1, $p < 0.01$).

Fig. 3 Illustration of all cuts performed at the last step simulating grade-3 flexion distraction injury: **a** coronal view, **b** sagittal view, **c** oblique view

The ACDF construct using the variable-angle anchored spacer also significantly reduced motion in flexion–extension, lateral bending, and axial rotation compared with intact (Table 2, $p < 0.01$). Grade-2 injury significantly increased flexion–extension, lateral bending, and axial rotation motions when compared with the fusion construct with intact posterior ligamentous structures, and also compared with grade-1 injury. After grade-3 injury, the motion in flexion–extension was 13.8 and 8.7° for no

preload and with preload cases, respectively, 5.0° in lateral bending, and 9.5° in axial rotation. These ROM values were not significantly smaller than the motion of the intact segment (Table 2, $p = 0.19$).

Discussion

Since the initial description of ACDF, significant advancements both in fixation and fusion rates have been made. Addition of anterior plating to the interbody fusion construct added stability to increase the fusion rate and decrease graft-related complications [12, 13]. Nevertheless, multiple complications including dysphagia and dysphonia have been described with anterior plating, some of which could be due to retraction of the soft tissues or plate bulkiness [4, 14, 15]. Case reports of dysphagia following ACDF with pharyngo-esophageal junction erosion have also been reported [14, 16]. Even though the cause of those complications is multifactorial, prominent hardware is thought to contribute to some of the cases [3, 17]. Adjacent level disease has also been described in multiple studies with anterior cervical discectomy and fusion with prevalence of 7–17 % [18, 19]. Hilibrand et al. [20] reported on 374 patients that underwent one to four level ACDF and identified a 2.9 % yearly incidence of symptomatic adjacent level disease with 25 % prevalence over a 10-year period. While there continues to be debate, potential causes of adjacent segment degeneration include surgical injury of adjacent discs during dissection, plate prominence or proximity [21], altered biomechanics, or a progression of a natural disease process.

Integrated cervical interbody spacer fusion devices have been developed to provide stability while trying to prevent some of the complications seen with anterior cervical plating. A reported benefit of these integrated devices is that they do not require the same degree of soft tissue mobilization during the primary procedure, limiting dissection around the adjacent levels. Studies have shown that reducing soft tissue dissection and instrumenting more than 5 mm away from adjacent disc can minimize the incidence of adjacent level disease [2, 21, 22]. The integrated cervical interbody-plate fusion device (Zero-P, Synthes Spine, West Chester, PA, USA) has been shown to create equivalent stability to anterior plating while limiting soft tissue disruption and irritation [5]. The primary indication for this device is fusion for degenerative disc disease. Notably, this device has not been evaluated in traumatic flexion-distraction injury of the cervical spine.

Flexion distraction injuries account for 10 % of lower cervical spine injuries and are most commonly caused by motor vehicle accidents [9]. Possibilities for treatment include anterior fusion, posterior fusion or the combination

Table 1 Fixed-angle implant—ROM data

	Intact	ACDF + intact PLC	Flexion distraction injury		
			Grade-1	Grade-2	Grade-3
Flexion–extension (0 N)	16.2 ± 4.5	4.0 ± 2.1*	4.5 ± 2.3 ^{*,†}	4.7 ± 2.4*	5.5 ± 2.3 ^{*,†,¥}
Flexion–extension (150 N)	14.8 ± 4.2	3.9 ± 1.8*	4.3 ± 2.0 ^{*,†}	4.5 ± 2.1*	5.1 ± 2.1 ^{*,†,¥}
Lateral bending	10.3 ± 2.0	1.6 ± 0.8*	1.6 ± 0.8*	1.7 ± 0.9*	2.0 ± 1.1*
Axial rotation	11.0 ± 2.4	2.5 ± 0.8*	2.3 ± 0.9*	3.0 ± 0.9*	3.3 ± 1.4*

PLC posterior ligamentous complex

* $p < 0.01$ compared with intact ROM

† $p < 0.01$ compared with ACDF with intact posterior ligamentous complex

¥ $p < 0.01$ compared with grade-1

Table 2 Variable-angle implant—ROM data

	Intact	ACDF + intact PLC	Flexion distraction injury		
			Grade-1	Grade-2	Grade-3
Flexion–extension (0 N)	12.0 ± 1.5	6.6 ± 2.3*	7.4 ± 2.5 ^{*,†}	8.1 ± 2.6 ^{*,†,¥}	13.8 ± 7.1
Flexion–extension (150 N)	10.7 ± 1.7	5.5 ± 2.5*	6.0 ± 2.8*	6.5 ± 2.7 ^{*,†,¥}	8.7 ± 4.5
Lateral bending	8.3 ± 1.4	2.7 ± 1.0*	3.0 ± 1.1*	3.8 ± 1.2 ^{*,†,¥}	5.0 ± 1.6 ^{†,¥}
Axial rotation	8.8 ± 2.7	4.6 ± 1.3*	5.2 ± 2.1*	6.5 ± 2.3 ^{†,¥}	9.5 ± 4.6 [¥]

PLC posterior ligamentous complex

* $p < 0.01$ compared with intact ROM

† $p < 0.01$ compared with ACDF with intact posterior ligaments

¥ $p < 0.01$ compared with grade-1

of both. The grading system of flexion distraction injury takes into account progressive destabilization of the spine with each increasing grade. Grade-1 includes injury to the posterior ligamentous structures including supraspinous ligament, interspinous ligament, ligamentum flavum and presents on radiographs as facet subluxation or widening of the space between the spinous processes. Grade-2 and 3 injuries signify higher trauma with unilateral and bilateral facet dislocation, respectively. Grade-4 injury is a complete dislocation [9].

Paxinos et al. [11] have shown that anterior cervical locked plating can stabilize grade-3 flexion distraction injury of subaxial cervical spine as described by Allen et al. [9]. In this study application, preload was used to account for muscle stabilizing effect of the cervical spine. Even though other biomechanical studies show mixed results with anterior plating and better stability with posterior devices [23–25], good results have been published in multiple clinical studies with anterior plating alone [25–32]. ACDF has been used for posteriorly unstable cervical spine injuries with lower complication rates compared with posterior surgery as described by Garvey et al. [33, 34] and possibly improved sagittal alignment [40].

In this study, we evaluated the biomechanical properties of two anchored spacers in the setting of progressive

destabilization of the cervical spine up to grade-3 of flexion-distraction injury. We tested the ability of the anchored spacer to stabilize the spine as the injury progressively increased. We also evaluated the difference between locked-angle and variable-angle option devices. By using a similar model, Paxinos et al. have shown that anterior plating was able to stabilize grade-3 injury down to 2.6° in flexion–extension from their average intact motion of 13.7°. This was an 81 % decrease in motion from intact, even with grade-3 injury. In our study, the locked screw anchored spacer device was able to limit the flexion–extension motion to 5.1° with a grade-3 injury. This was a 66 % reduction when compared with intact motion. In contrast, the variable screw angle device was not able to stabilize the cervical spine well in a setting of any grade of injury. Grade-1 injury already had a higher flexion–extension motion with the variable angle screw fixation than locked screw device (6.0 vs. 4.3°, $p = 0.22$). After grade-3 injury this range of motion increased to 8.7° which was only a 20 % decrease from intact.

Clearly, when used alone, a variable-angle device allowed larger motions in all modes of testing, which may be inadequate for good fusion and would risk implant displacement in a trauma setting. The large discrepancy between the two devices is likely due to the fact that

variable screw angle device has only 3 screws compared with locked screw device which uses 4 screws. Also each variable angle screw has free motion due to the variable-angle design which could allow the implant to function like a free spacer within this specific unrestrained range. Finally, the higher age of the specimens used for the variable-angle screw implant may have also contributed to a weaker bony purchase and hence less stability of the construct.

The locked screw implant was able to stabilize the spine well biomechanically although not as well as a plate construct. It is unknown, however, if the additional motion allowed by the locked screw implant would negatively affect arthrodesis. Given the findings of this study, additional external immobilization after surgery would be recommended for patients with flexion-distraction injuries treated with this integrated fixation device [35]. The variable angle construct should not be used in isolation to stabilize flexion-distraction injuries to the cervical spine. We theorize that it could be used in combination with posterior cervical instrumentation and that, given the motion allowed after implantation, it may serve a role in facet dislocations requiring an anterior discectomy followed by a posterior reduction and fusion. This scenario would need to be mechanically or clinically assessed.

There are limitations in our study. First, our study groups were limited to six and seven cadavers, respectively. This caused the groups to be uneven in age as well as initial range of motions. The average age in the variable-angle group was 14 years more than that in the locked screw group. This was statistically significant ($p = 0.04$). Although the cadaveric specimens were randomly assigned the small group size may have contributed to some of the observed differences. Despite this, both groups had relatively young specimens with the average of the older group being less than 60 years of age. Older patients might have decreased bone density which might contribute to implant subsidence and screw loosening, thus increasing the ROM. We did not notice this in our specimens when evaluating them after the experiment as no screws appeared loose. The second limitation is that this is a biomechanical study on cadaveric specimens. Even though we tried to account for stabilizing action of the muscles with the follower load model, this was only used for flexion–extension testing in our study due to engineering limitations. It is, therefore, unknown if these findings would translate to a clinical setting in a patient with cervical spine injury. Finally, the study reflects immediate postoperative stability and does not reflect stability with cycling loading until fusion is established. Good results rely on establishment of solid fusion by appropriate preparation of endplates and bone grafting around and inside the spacer [36]. Larger cadaveric studies and further clinical studies should be

considered to better delineate the role for anchored spacer devices in cervical trauma settings.

Conclusions

In a flexion-distraction cervical injury model, the locked screw anchored spacer was able to stabilize the cervical spine after grade-3 injury with reduction of motion by 66 % from intact spine in flexion–extension. The variable screw angle spacer did not provide adequate stabilization after traumatic injury with reduction of motion at only 20 % compared with intact spine in flexion–extension. Previous mechanical studies on traditional plate-screw fixation revealed less motion in a similar injury model. Until clinical data are available, patients with flexion-distraction injuries treated with locked screw spacers should be supplemented with external immobilization. Patients with flexion-distraction injuries should not be treated with variable angle screw spacers.

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Conflict of interest None.

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