

Biomechanical Stability of a Stand-Alone Interbody Spacer in Two-Level and Hybrid Cervical Fusion Constructs

Daniel G. Kang, MD¹, Scott C. Wagner, MD², Robert W. Tracey, MD², John P. Cody, MD², Rachel E. Gaume, BS², and Ronald A. Lehman Jr, MD³

Abstract

Study Design: In vitro human cadaveric biomechanical analysis.

Objective: To evaluate the segmental stability of a stand-alone spacer (SAS) device compared with the traditional anterior cervical plate (ACP) construct in the setting of a 2-level cervical fusion construct or as a hybrid construct adjacent to a previous 1-level ACP construct.

Methods: Twelve human cadaveric cervical spines (C2-T1) were nondestructively tested with a custom 6-degree-of-freedom spine simulator under axial rotation (AR), flexion-extension (FE), and lateral bending (LB) at 1.5 N m loads. After intact analysis, each specimen underwent instrumentation and testing in the following 3 configurations, with each specimen randomized to the order of construct: (A) C5-7 SAS; (B) C5-6 ACP, and C6-7 SAS (hybrid); (C) C5-7 ACP. Full range of motion (ROM) data at C5-C7 was obtained and analyzed by each loading modality utilizing mean comparisons with repeated measures analysis of variance with Sidak correction for multiple comparisons.

Results: Compared with the intact specimen, all tested constructs had significantly increased segmental stability at C5-C7 in AR and FE ROM, with no difference in LB ROM. At C5-C6, all test constructs again had increased segmental stability in FE ROM compared with intact ($10.9^\circ \pm 4.4^\circ$ Intact vs SAS $6.6^\circ \pm 3.2^\circ$, $P < .001$; vs Hybrid $2.9^\circ \pm 2.0^\circ$, $P = .005$; vs ACP $2.1^\circ \pm 1.4^\circ$, $P < .001$), but had no difference in AR and LB ROM. Analysis of C6-C7 ROM demonstrated all test groups had significantly greater segmental stability in FE ROM compared with intact ($9.6^\circ \pm 2.7^\circ$ Intact vs SAS $5.0^\circ \pm 3.0^\circ$, $P = .018$; vs Hybrid $5.0^\circ \pm 2.7^\circ$, $P = .018$; vs ACP $4.4^\circ \pm 5.2^\circ$, $P = .005$). Only the hybrid and 2-level ACP constructs had increased stability at C6-C7 in AR ROM compared with intact, with no difference for all test groups in LB ROM. Comparison between test constructs demonstrated no difference in C5-C7 and C6-C7 segmental stability in all planes of motion. However, at C5-C6 comparison between test constructs found the 2-level SAS had significantly less segmental stability compared to the hybrid ($6.6^\circ \pm 3.2^\circ$ vs $2.9^\circ \pm 2.0^\circ$, $P = .025$) and ACP ($6.6^\circ \pm 3.2^\circ$ vs $2.1^\circ \pm 1.4^\circ$, $P = .004$).

Conclusions: Our study found the currently tested SAS device may be a reasonable option as part of a 2-level hybrid construct, when used below an adjacent 1-level ACP, but should be used with careful consideration as a 2-level SAS construct. Consequences of decreased segmental stability in FE are unknown; however, optimal immediate fixation stability is an important surgical principle to avoid loss of fixation, segmental kyphosis, interbody graft subsidence, and pseudarthrosis.

Keywords

hybrid construct, adjacent segment disease, stand-alone cervical interbody spacer, anchored interbody spacer, zero-profile spacer, biomechanical stability, multilevel cervical fusion

Introduction

Multilevel anterior cervical decompression and fusion (ACDF) constructs with anterior cervical plate (ACP) fixation prevent interbody graft extrusion and have demonstrated reduced pseudarthrosis rates, earlier healing, less kyphotic deformity, and improved patient-reported outcomes compared with fusion

¹ Madigan Army Medical Center, Tacoma, WA, USA

² Walter Reed National Military Medical Center, Bethesda, MD, USA

³ The Spine Hospital, Columbia University Medical Center—New York Presbyterian, New York, NY, USA

Corresponding Author:

Daniel G. Kang, Department of Orthopedic Surgery, Madigan Army Medical Center, 9040 Jackson Avenue, Tacoma, WA 98431, USA.
Email: daniel.g.kang@gmail.com



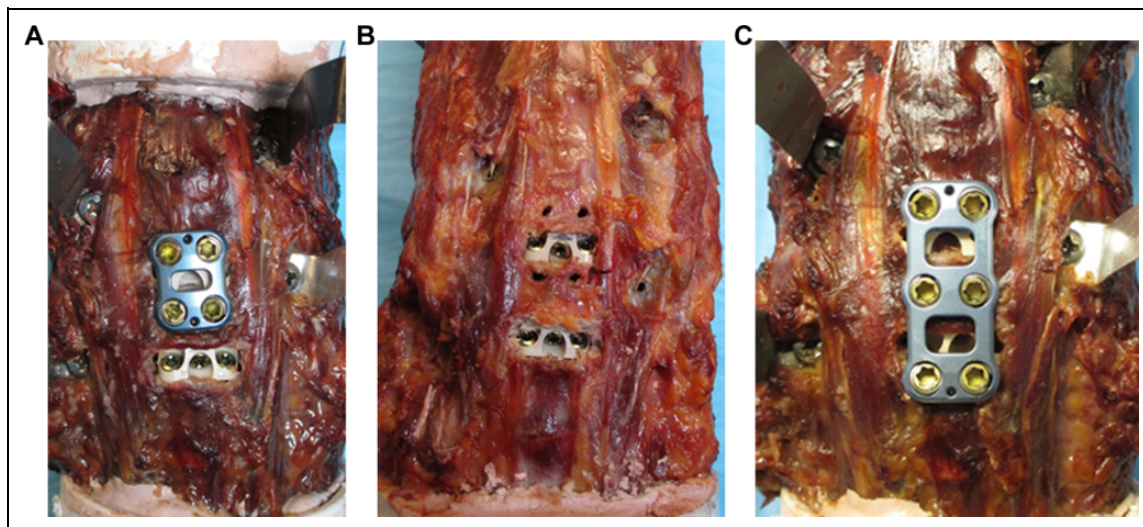


Figure 1. Images of biomechanical testing set-up and instrumented specimens: (A) Hybrid construct with C5-6 spacer with anterior cervical plate (ACP) and C6-C7 stand-alone spacer (SAS); (B) C5-7 stand-alone spacer (SAS) construct; (C) C5-7 spacer with 2-level ACP.

constructs without plate fixation.¹⁻⁵ However, ACP fixation has been associated with increased rates of dysphagia, with risk factors, including plate profile/volume, multilevel construct, and revision surgery.^{3,6-15} Additionally, ACP fixation is a risk factor for adjacent level ossification, particularly with plate migration.⁸ Several “low-profile” stand-alone spacers (SAS) with integrated screws have been developed to potentially reduce the various problems associated with ACP constructs.^{16,17} In particular, SAS devices may be advantageous in the setting of revision surgery for treatment of adjacent segment disease (ASD), obviating the need for a more extensive operative exposure to remove a previously placed ACP, with exposure of only the adjacent level and placement of the SAS device used as a hybrid construct above or below an existing anterior cervical plate.

Despite the purported advantages of the SAS device, there have been limited biomechanical¹⁸⁻²³ and clinical^{17,24,25} data to guide their use and optimal indications. While SAS devices have demonstrated successful clinical outcomes and similar biomechanical stability compared with a single-level ACP construct, their biomechanical stability in multi-level and hybrid constructs (SAS device adjacent to an ACP construct) has not been fully established. Therefore, we set out to investigate the immediate segmental biomechanical stability of an SAS device with integrated screws compared to traditional ACP in the setting of a 2-level cervical fusion construct and as a hybrid construct.

Materials and Methods

Specimen Preparation

Twelve ($n = 12$) fresh-frozen human cadaveric spines were harvested, with each test specimen carefully disarticulated from C1-C2 proximally and at T2-T3 distally, with careful attention to preserve all native osseous and ligamentous

anatomy. Additionally, all specimens were inspected both visually and radiographically (anterior-posterior and lateral fluoroscopic images) to ensure normal anatomy and absence of preexisting fracture, destructive bone lesions or compromised osseous integrity. All specimens were stored at -20°C , and on the day of biomechanical testing the specimens were allowed to appropriately thaw to room temperature. Once thawed, the specimens were moistened using 0.9% sodium chloride irrigation solution every 15 minutes throughout testing. Specimens were then secured/potted at their proximal (C2) and distal (T2) levels using polyester resin in a poly(vinyl chloride) plastic polymer casing, and fixed with additional screws. Care was taken to avoid encasing the remaining testable specimen and motion analysis markers with the polyester resin to prevent inaccurate motion analysis.

Prior to instrumentation, all specimens were tested first in the intact state as a control. Following intact testing, a fellowship trained spine surgeon performed all surgical procedures and instrumentation. Discectomy was performed by careful removal of the disc material and meticulous technique was utilized to ensure preservation of the disc endplate. Following the appropriate level-specific discectomy, the specimens were randomly assigned to undergo instrumentation and testing with the following construct groups (Figure 1):

- A. C5-7 SAS (2-level SAS construct)
- B. C5-6 ACP with C6-7 SAS (hybrid construct)
- C. C5-7 ACP (2-Level ACDF construct)

All SAS implants (Stalif-C, Centinel Spine, West Chester, PA) were individually sized to restore the appropriate disc height and alignment. In order to maintain similar interbody spacer footprint and material properties, the SAS interbody device without integrated screws was used as the interbody device for the ACDF constructs. Anterior cervical plates were sized appropriately for one and two-level fusion constructs, using a static

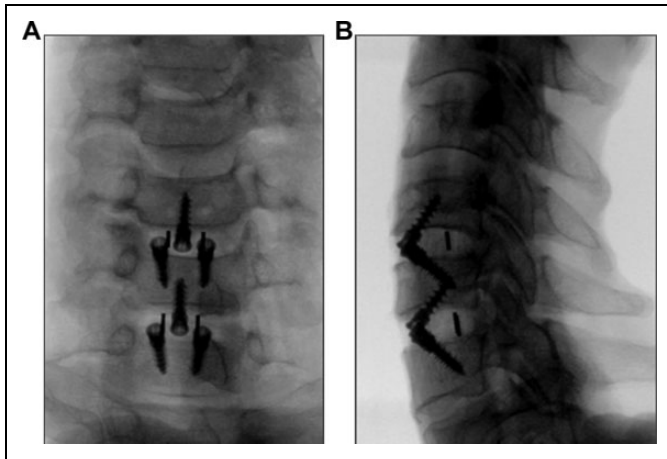


Figure 2. (A) Anteroposterior and (B) lateral radiographs of 2-level stand-alone spacer (SAS) construct.

titanium plate with fixed angle screws (Eagle Anterior Cervical Plate, Depuy Spine, Raynham, MA). Also, depending on the order of testing, we used larger diameter and longer “rescue” screws when instrumenting previously used screw holes for either the stand-alone device or ACP construct to maintain adequate screw fixation. All specimens underwent fluoroscopic evaluation following instrumentation to ensure appropriate seating and alignment of the implants and to evaluate for any iatrogenic fracture prior to biomechanical testing (Figure 2).

Biomechanical Testing

Biomechanical evaluation was performed with the MTS 858 MiniBionix II system configured with a custom 6-degree-of-freedom Spine Simulator (MTS Systems, Inc. Minneapolis, MN). Motion analysis was measured using specialized markers comprised of infrared light emitting diodes (LED), which were placed individually on the anterior aspect of all vertebral levels from C4-C7. LED rotations in space were tracked using an optoelectronic motion analysis system (OptoTrak Certus, Northern Digital Inc, Waterloo, Ontario, Canada). Specimens were then exposed to nondestructive testing in all 3 planes of spinal motion: axial rotation (AR, y -axis, ± 1.5 Nm), Flexion-Extension (FE, x -axis, ± 1.5 Nm), and lateral bending (LB, z -axis, ± 1.5 Nm). Nonconstrained pure moment bending was applied for 3 loading and unloading cycles in each plane, with data obtained from the final load/unload cycle was utilized for final data analysis.

Data and Statistical Analysis

Data was analyzed during the third/final cycle only, because the spines required preconditioning (“stretching”) during the initial testing cycles. This was necessary because of the viscoelastic properties of the ligaments and articulating joints in the spinal column. The peak range of motion for each loading mode was calculated as the sum of motions observed in the

neutral (NZ) and elastic (EZ) zones at the final loading cycle ($ROM = NZ + EZ$). Angular ROM ($ROM = NZ + EZ$) was reported for the fusion construct (C5-C7). The NZ was considered the displacement at the zero-load point from the neutral position, and the EZ was the displacement from the zero-load point to the maximum load point. Range of motion data was directly compared between the experimental groups. All data was shown as mean ± 1 standard deviation (SD). Statistical analysis was performed by the SPSS version 20.0 software (IBM Corp, Armonk, NY). A repeated-measures analysis of variance (ANOVA) was utilized to allow for mean comparisons. A test of simple effects combined with the Sidak correction for multiple comparisons was used for post hoc analyses. Significance was defined as statistical results with $P < .05$.

Results

C5-C7 Range of Motion Analysis

Comparison of Intact Specimen to All Test Groups. When compared with the intact specimen, all test groups had significantly reduced ROM at C5-C7 in AR and FE planes of motion, with no difference in LB plane of motion (Table 1).

Comparison Between Test Groups. The 2-level SAS construct compared to the 2-level hybrid construct demonstrated no difference in segmental ROM at C5-C7 in all planes of motion (AR $6.7^\circ \pm 3.7^\circ$ vs $5.1^\circ \pm 2.1^\circ$, $P = .777$; FE $11.6^\circ \pm 4.6^\circ$ vs $7.9^\circ \pm 3.4^\circ$, $P = .416$; LB $8.6^\circ \pm 6.0^\circ$ vs $6.7^\circ \pm 4.2^\circ$, $P = .968$).

The 2-level SAS construct compared with the 2-level ACP construct demonstrated no difference in segmental ROM at C5-C7 in all planes of motion (AR $6.7^\circ \pm 3.7^\circ$ vs $5.7^\circ \pm 2.7^\circ$, $P = .959$; FE $11.6^\circ \pm 4.6^\circ$ vs $6.5^\circ \pm 5.9^\circ$, $P = .112$; LB $8.6^\circ \pm 6.0^\circ$ vs $6.3^\circ \pm 4.6^\circ$, $P = .930$).

The 2-level hybrid construct compared to the 2-level ACP construct had no difference in segmental ROM at C5-C7 in all planes of motion (AR $5.1^\circ \pm 2.1^\circ$ vs $5.7^\circ \pm 2.7^\circ$, $P = .959$; FE $7.9^\circ \pm 3.4^\circ$ vs $6.5^\circ \pm 5.9^\circ$, $P = .986$; LB $6.7^\circ \pm 4.2^\circ$ vs $6.3^\circ \pm 4.6^\circ$, $P = 1.000$) (Table 2, Figure 3).

C5-6 Range of Motion Analysis

Comparison of Intact Specimen to All Test Groups. When compared with the intact specimen, all test groups had significantly reduced ROM at C5-C6 in FE ($10.9^\circ \pm 4.4^\circ$ Intact vs SAS $6.6^\circ \pm 3.2^\circ$, $P < .001$; vs Hybrid $2.9^\circ \pm 2.0^\circ$, $P = .005$; vs ACP $2.1^\circ \pm 1.4^\circ$, $P < .001$), with no difference in AR or LB planes of motion (Table 3).

Comparison Between Test Groups. The 2-level SAS construct compared with the 2-level hybrid construct demonstrated significantly greater segmental ROM at C5-C6 in FE ($6.6^\circ \pm 3.2^\circ$ vs $2.9^\circ \pm 2.0^\circ$, $P = .025$), with no difference in AR ($P = .990$) and LB ($P = .773$) planes of motion.

The 2-level SAS construct compared to the 2-level ACP construct demonstrated significantly greater segmental ROM

Table 1. Comparison of Range of Motion at C5-C7 Between Intact Specimen Versus Different Cervical Fusion Constructs.^a

	AR (deg)	P	FE (deg)	P	LB (deg)	P
Intact	10.5 ± 4.2		20.5 ± 6.2		12.0 ± 8.2	
Stand-alone spacer	6.7 ± 3.7	.040 ^b	11.6 ± 4.6	.001 ^b	8.6 ± 6.0	.672
Hybrid construct	5.1 ± 2.1	.001 ^b	7.9 ± 3.4	<.001 ^b	6.7 ± 4.2	.190
Anterior cervical plate	5.7 ± 2.7	.004 ^b	6.5 ± 5.9	<.001 ^b	6.3 ± 4.6	.139

Abbreviations: AR, axial rotation; FE, flexion-extension; LB, lateral bending.

^aWhen compared with the intact specimen, all test groups had significantly reduced range of motion at C5-C7 in AR and FE planes of motion, with no difference in LB plane of motion.

^bDenotes significant difference $P < .05$.

Table 2. Comparison of Range of Motion at C5-C7 Between Different Cervical Fusion Constructs.^a

	AR	FE	LB
2-Level SAS vs hybrid	.777	.416	.968
2-Level SAS vs ACP	.959	.112	.930
Hybrid vs ACP	.959	.986	1.000

Abbreviations: SAS, stand-alone spacer; ACP, anterior cervical plate; AR, axial rotation; FE, flexion-extension; LB, lateral bending.

^aThere was no difference in segmental ROM at C5-C7 between the different constructs in all planes of motion.

at C5-C6 in FE ($6.6^\circ \pm 3.2^\circ$ vs $2.1^\circ \pm 1.4^\circ$, $P = .004$), with no difference in AR ($P = .980$) and LB ($P = .925$) planes of motion.

The 2-level hybrid construct compared with the 2-level ACP construct had no difference in segmental ROM at C5-C6 in all planes of motion (AR $P = 1.000$; FE $P = .989$; LB $P = 1.000$) (Table 4).

C6-C7 Range of Motion Analysis

Comparison of Intact Specimen With All Test Groups. When compared to the intact specimen, all test groups had significantly reduced ROM at C6-C7 in FE ($9.6^\circ \pm 2.7^\circ$ Intact vs SAS $5.0^\circ \pm 3.0^\circ$, $P = .018$; vs Hybrid $5.0^\circ \pm 2.7^\circ$, $P = .018$; vs ACP $4.4^\circ \pm 5.2^\circ$, $P = .005$). Compared with the intact specimen, the 2-level hybrid ($3.8^\circ \pm 1.8^\circ$ vs $1.1^\circ \pm 2.4^\circ$, $P = .002$) and 2-level ACP ($3.8^\circ \pm 1.8^\circ$ vs $1.7^\circ \pm 1.4^\circ$, $P = .030$) constructs had significantly reduced ROM at C6-C7 in AR. The intact specimen demonstrated no difference in AR plane of motion compared with the 2-level SAS construct ($P = .073$), as well as no difference in LB plane of motion between the intact specimen and all test groups (SAS $P = .571$; Hybrid $P = .609$, ACP $P = .236$) (Table 5).

Comparison Between Test Groups. The 2-level SAS construct compared with the 2-level hybrid (AR $P = .770$; FE $P = 1.000$; LB $P = 1.000$) and 2-level ACP (AR $P = 1.000$; FE $P = .999$; LB $P = .995$) constructs had no difference in segmental ROM at C6-C7 in all planes of motion. The 2-level hybrid construct compared to the 2-level ACP (AR $P = .937$; FE $P = .999$; LB $P = .993$) construct also had no difference in segmental ROM at C6-C7 in all planes of motion (Table 6).

Discussion

The primary objective of the current study was to evaluate the immediate biomechanical stability of a stand-alone interbody spacer with integrated screws as a hybrid and 2-level construct. Our study found all constructs had significant increase in stability compared with the intact specimen in FE and AR, but no difference in LB. Our data suggests that the SAS device used in a 2-level construct and as a hybrid construct adjacent to a 1-level ACP construct has no difference in biomechanical stability in all planes of motion over the 2-level segment compared with a 2-level ACP construct. However, individual functional spinal unit (FSU) analysis found that the SAS device at the cephalad level in a 2-level construct offered less stability in FE ROM only, when compared with the hybrid (which utilized a ACP at the cephalad level) and traditional 2-level ACP constructs. Although the association of biomechanical in vitro cadaveric data to in vivo clinical performance remains unknown, our study suggests the use of a 2-level SAS construct may not provide optimal immediate stability in FE at the cephalad segment.

In terms of clinical outcomes, a recent meta-analysis by Dong et al¹⁷ found 10 studies with 719 patients, and pooled data found SAS devices compared with ACP had no difference in fusion rates, but demonstrated decreased operative time and blood loss, decreased rates of early (6 weeks) and late post-operative dysphagia, as well as better improvement of Japanese Orthopaedic Association (JOA) score, neck disability index (NDI), and pain on visual analogue scale (VAS). The current available clinical reports on multilevel SAS fusion constructs are limited by small sample size, study design (mostly retrospective), and short-term follow-up²⁴⁻²⁹; therefore the efficacy and safety of using SAS devices as stand-alone multilevel fusion constructs remain unclear.

Despite the theoretical advantages and good outcomes reported in small clinical reports, SAS devices for cervical fusion constructs have limited biomechanical data to guide their use. Several studies evaluating the use of various SAS devices for single-level fusion constructs, the only current Food and Drug Administration–approved application of this device, have consistently demonstrated no difference in biomechanical stability compared with single-level ACP.^{22,25,30}

There have only been limited biomechanical studies regarding hybrid SAS construct, and the biomechanical consequence of such an application remains incompletely understood. Healy

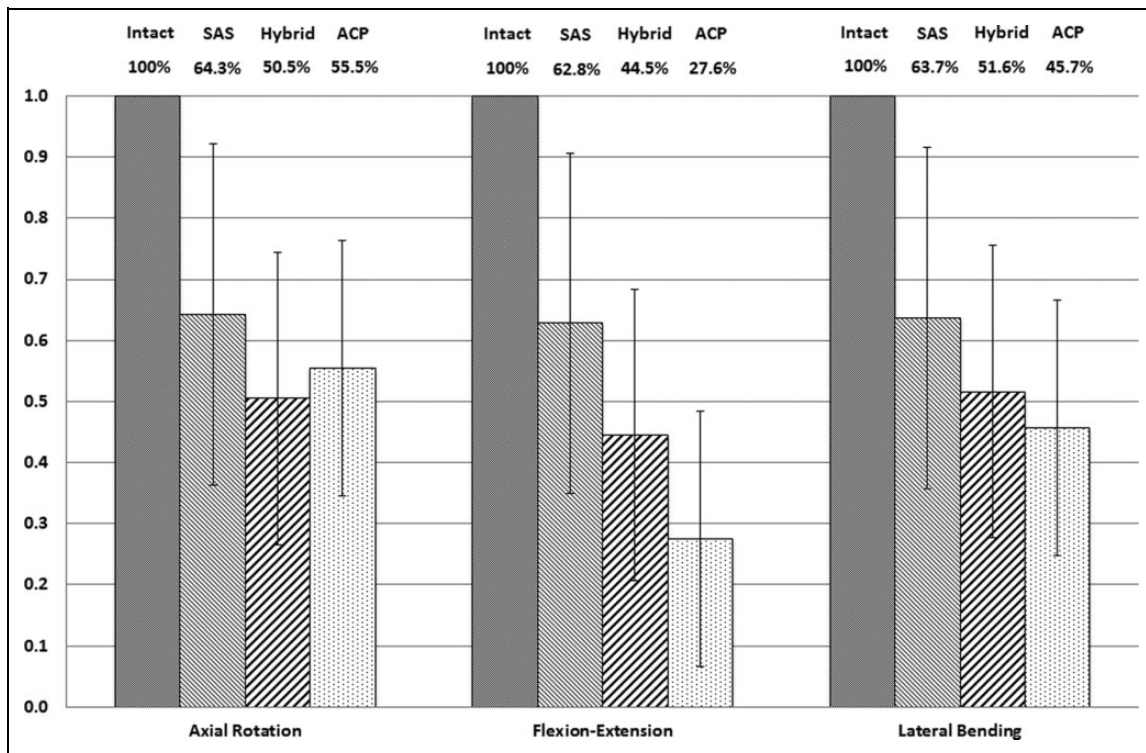


Figure 3. Chart comparing normalized segmental range of motion at C5-C7 for two-level SAS, two-level hybrid and two-level ACP fusion constructs.

Table 3. Comparison of Range of Motion at C5-C6 Between Intact Specimen Versus Different Cervical Fusion Constructs.^a

	AR (deg)	P	FE (deg)	P	LB (deg)	P
Intact	6.7 ± 3.4		10.9 ± 4.4		6.1 ± 7.0	
Stand-alone spacer	4.8 ± 2.8	.522	6.6 ± 3.2	<.001 ^b	2.9 ± 2.0	.445
Hybrid construct	4.0 ± 3.3	.171	2.9 ± 2.0	.005 ^b	2.9 ± 1.2	.971
Anterior cervical plate	3.9 ± 1.7	.142	2.1 ± 1.4	<.001 ^b	3.4 ± 1.9	.264

Abbreviations: AR, axial rotation; FE, flexion-extension; LB, lateral bending.

^aWhen compared with the intact specimen, all test groups had significantly reduced range of motion at C5-C6 in FE, with no difference in AR or LB planes of motion.

^bDenotes significant difference $P < .05$.

Table 4. Comparison of Range of Motion at C5-C6 Between Different Cervical Fusion Constructs.^a

	AR	FE	LB
2-Level SAS vs hybrid	.990	.025 ^b	.773
2-Level SAS vs ACP	.980	.004 ^b	.925
Hybrid vs ACP	1.000	.989	1.000

Abbreviations: SAS, stand-alone spacer; ACP, anterior cervical plate; AR, axial rotation; FE, flexion-extension; LB, lateral bending.

^a2-Level SAS v. Hybrid and 2-Level SAS v. ACP had significantly greater ROM for FE only, with no difference in AR and LB. There was difference in ROM for Hybrid versus ACP in all planes of motion.

^bDenotes significant difference $P < .05$.

et al³¹ compared a 2-level hybrid SAS construct with a 2-level ACP construct, using a 40-N preload, and found no difference in stability between constructs in all planes of motion. Beutler

et al¹⁹ evaluated the placement of an SAS device at C3-4 adjacent to a 2-level ACP at C4-C6, and when compared with a 3-level ACP at C3-C6, the authors found no difference in segmental stability between the 2 constructs. More recently, Balaram et al³² biomechanically tested a 3-level hybrid SAS construct from C4-C7, which involved a 2-level SAS next to an ACP, with the ACP randomly placed either at C4-5 or C6-C7. The authors found the SAS device at C5-6 had no difference in segmental ROM, whether the ACP was placed at C4-C5 or C6-C7.

In contrast, studies regarding the biomechanical stability of multilevel SAS constructs have not provided consistent findings. Clavenna et al¹⁸ evaluated 2- and 3-level SAS constructs, and found no difference in segmental stability compared with traditional multilevel ACP constructs. In contrast, Paik et al²² demonstrated 2- and 3-level SAS constructs compared with

Table 5. Comparison of Range of Motion at C6-C7 Between Intact Specimen Versus Different Cervical Fusion Constructs.^a

	AR (deg)	P	FE (deg)	P	LB (deg)	P
Intact	3.8 ± 1.8		9.6 ± 2.7		5.9 ± 3.4	
Stand-alone spacer	2.0 ± 1.2	.073	5.0 ± 3.0	.018 ^b	3.7 ± 3.4	.571
Hybrid construct	1.1 ± 2.4	.002 ^b	5.0 ± 2.7	.018 ^b	3.8 ± 3.7	.609
Anterior cervical plate	1.7 ± 1.4	.030 ^b	4.4 ± 5.2	.005 ^b	2.9 ± 3.4	.236

Abbreviations: AR, axial rotation; FE, flexion-extension; LB, lateral bending.

^aWhen compared with the intact specimen, all test groups had significantly reduced range of motion (ROM) at C6-C7 in FE plane of motion. Compared with intact, the hybrid and ACP constructs had significantly reduced ROM at C6-C7 in AR plane of motion. There was no difference in LB plane of motion between intact and all test groups.

^bDenotes significant difference $P < .05$.

Table 6. Comparison of Range of Motion at C6-C7 between DIFFERENT Cervical Fusion Constructs.^a

	AR	FE	LB
2-Level SAS vs hybrid	.770	1.000	1.000
2-Level SAS vs ACP	1.000	.999	.995
Hybrid vs ACP	.937	.999	.993

Abbreviations: SAS, stand-alone spacer; ACP, anterior cervical plate; AR, axial rotation; FE, flexion-extension; LB, lateral bending.

^aThere was no difference in segmental range of motion at C6-C7 between the different constructs in all planes of motion.

ACP constructs had significantly decreased segmental stability in all planes of motion, but found no difference in stability for all multilevel constructs with the addition of supplemental posterior fixation. Nayak et al³³ evaluated the Stalif-C (Centinel Spine, West Chester, PA) SAS device and found that 2-level SAS compared with 2-level ACP construct had less segmental stability in the sagittal plane (FE), with no difference in AR and LB. However, our study only demonstrated higher segmental ROM in FE at the cephalad SAS device in a 2-level SAS compared with 2-level ACP construct, whereas Nayak et al³³ found increased ROM at both levels in the 2-level SAS construct. Other notable differences from our study include evaluation of 2-level reconstruction at C4-C6, compared with C5-C7 in our study, as well as no evaluation of a hybrid construct. In addition, the authors also evaluated and compared the various fusion constructs with an interbody spacer alone, which was not evaluated in our study or in the study by Calvanna et al.¹⁸ Difference between our results and other biomechanical studies regarding immediate stability of multilevel SAS versus ACP constructs may be due to various confounding factors,^{21,34} as there were undoubtedly differences in implant design, investigator preferences for surgical technique (eg, amount of disc space/end plate preparation, resection of the posterior longitudinal ligament), as well as testing methodologies (eg, different levels tested, application of preload, loading rate,

preconditioning of specimens) making comparison between studies difficult.

A primary weakness of our study is the limited scope of the conclusions and potential clinical relevance to the specific SAS device tested and testing methodology. The SAS device used in the current study utilizes three integrated screws with each screw having a lag effect allowing for compressive fixation, and midline convergence of each screw. Other SAS implants have variable designs, including devices with 2, 3, or 4 integrated screws, some having locked screws, others with variable or fixed angle trajectories with or without lag effect, as well as various screw locations within the device (centrally located, peripherally located), with different horizontal inclination angles and midline convergence angles of the screws. We also used the SAS device without screws as an interbody device in the ACP construct to remove an additional confounding variable from our methodology in terms of interbody spacer size/footprint, shape, and material properties. Our study may have been more clinically representative using a similar sized/shaped PEEK (polyetheretherketone) interbody spacer or an allograft interbody graft for the ACP construct group. In addition, the current experiment only evaluated a hybrid construct with the SAS device used below a previous 1-level ACP, therefore, the biomechanical stability of the SAS device when used above a previous 1-level ACP remains unknown. Also, we used a static ACP because the current analyzed SAS device does not have dynamic capabilities, and we assumed the static ACP was most comparable in terms of biomechanical characteristics, although this has not been previously studied. Brodke et al,³⁵ in a biomechanical analysis found that with an appropriately sized interbody spacer, there were no significant difference in the abilities of the static compared with a dynamic ACP to share load or limit motion. In addition, a retrospective analysis by DuBois et al³⁶ of patients following 2- and 3-level ACDF did not find any significant difference in clinical outcomes between static and dynamic plate design, with a higher rate of nonunion in the dynamic plate group.

Another inherent limitation is the use of a human cadaveric specimen with absence of dynamic, in vivo muscular forces and loads that in the clinical setting may affect implant stability and performance. Also, our experimental design did not evaluate biomechanical properties of the various fusion constructs following repetitive, cyclic loading, and thus only represents immediate postoperative segmental stability. To our knowledge, no previous study has evaluated optimal segmental stability to obtain solid arthrodesis in the cervical spine; however, previous authors have theorized interfragmentary strain above 2% may hinder direct bone formation during extremity fracture healing.³⁷⁻³⁹ Therefore, the optimal segmental stability for a multilevel fusion construct remains unknown, and whether a statistically significant difference in segmental ROM of 5° to 6° between the multilevel SAS and ACP constructs would be clinically significant for altering the fusion environment.^{1,40} The approximate 40% to 50% reduction in ROM afforded by a multilevel SAS construct compared with the intact spine may be a reasonable trade-off to the increased stability, but

consequently increased morbidity of an anterior cervical plate. Also, the difference in stability and the possible implication on adjacent segment degeneration between the ACP and SAS constructs remains unclear, as the current study did not analyze adjacent segment disc pressures or disc strain.

Additional biomechanical and clinical investigations regarding the use of SAS devices for multilevel constructs are needed.

Conclusion

Our study found that the currently tested SAS device may be a reasonable option as part of a 2-level hybrid construct, when used below an adjacent 1-level ACP, but should be used with careful consideration as a 2-level SAS construct. Consequences of decreased segmental stability in FE are unknown; however, optimal immediate fixation stability is an important surgical principle to avoid loss of fixation, segmental kyphosis, interbody graft subsidence, and pseudarthrosis.

Authors' Note

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Declaration of Conflicting Interests

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