Basic Science

Do stand-alone interbody spacers with integrated screws provide adequate segmental stability for multilevel cervical arthrodesis?

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Abstract

BACKGROUND CONTEXT: Some postoperative complications after anterior cervical fusions have been attributed to anterior cervical plate (ACP) profiles and the necessary wide operative exposure for their insertion. Consequently, low-profile stand-alone interbody spacers with integrated screws (SIS) have been developed. Although SIS constructs have demonstrated similar biomechanical stability to the ACP in single-level fusions, their role as a stand-alone device in multilevel reconstructions has not been thoroughly evaluated.

PURPOSE: To evaluate the acute segmental stability afforded by an SIS device compared with the traditional ACP in the setting of a multilevel cervical arthrodesis.

STUDY DESIGN: In vitro human cadaveric biomechanical analysis.

METHODS: Thirteen human cadaveric cervical spines (C2–T1) were nondestructively tested with a custom 6 df spine simulator under axial rotation, flexion-extension, and lateral bending loading. After intact analysis, eight single-levels (C4–C5/C6–C7) from four specimens were instrumented and tested with ACP and SIS. Nine specimens were tested with C5–C7 SIS, C5–C7 ACP, C4–C7 ACP, C4–C7 ACP + posterior fixation, C4–C7 SIS, and C4–C7 SIS + posterior fixation. Testing order was randomized with each additional level instrumented. Full range of motion (ROM) data were obtained and analyzed by each loading modality, using mean comparisons with repeated measures analysis of variance. Paired t tests were used for post hoc analysis with Sidak correction for multiple comparisons.

RESULTS: No significant difference in ROM was noted between the ACP and SIS for single-level fixation (p > 0.05). For multisegment reconstructions (two and three levels), the ACP proved superior to SIS and intact condition, with significantly lower ROM in all planes (p < 0.05). When either the three-level SIS or ACP constructs were supplemented with posterior lateral mass fixation, there was a greater than 80% reduction in ROM under all testing modalities (p < 0.05), with no significant difference between the ACP and SIS constructs (p > 0.05).

CONCLUSIONS: The SIS device may be a reasonable option as a stand-alone device for single-level fixation. However, SIS devices should be used with careful consideration in the setting of multilevel cervical fusion. However, when supplemented with posterior fixation, SIS...
devices are a sound biomechanical alternative to ACP for multilevel fusion constructs. Published by Elsevier Inc.

Keywords: Stand-alone cervical interbody spacer; Integrated screws; Anchored interbody spacer; Biomechanical stability; Multilevel cervical arthrodesis; Cervical

Introduction

Anterior cervical discectomy and fusion (ACDF) was first described in 1955 by Robinson and Smith [1] for the treatment of degenerative spondylotic conditions and is considered one of the most successful spine procedures performed in last several decades. Patients following ACDF have reported greater than 90% rate of relief of radicular complaints and improvement of myelopathic symptoms [2,3]. However, complications can occur, and dysphagia has been increasingly recognized after ACDF [4–6]. Reported rates of dysphagia vary from 2% to 67%, occurring most commonly in the early postoperative period, with most patients reporting mild symptoms and complete recovery without the need for further intervention [5]. However, not all patients improve from their swallowing problems, with recent studies suggesting the incidence of chronic dysphagia may be as high as 13.6% with persistent symptoms for over 2 years after the index procedure [6]. Risk factors contributing to chronic dysphagia include revision surgery and multiple fusion levels; however, recent literature has identified that plate profile and volume significantly contribute to this problem [6,7].

Recent advances include the development of a low-profile interbody spacer with integrated screws (SIS) for application in the cervical spine. This device has been proposed to reduce the risk of dysphagia associated with traditional anterior or plating because of its smaller anterior profile and decreased operative exposure and time for instrumentation [8,9]. These implants are potentially promising in the setting of revision surgery and multilevel fusions, where wide surgical exposure and increased operative time incrementally increase the risk for perioperative morbidity [6]. Additionally, the SIS may be advantageous in the treatment of adjacent segment disease (ASD), obviating the need for a wide operative exposure to remove a previously placed anterior plate. There has also been report of the SIS used as part of a “hybrid” multilevel construct adjacent to a cervical disc replacement and may be particularly useful with the Prestige cervical disc replacement (Medtronic Sofamor Danek, Memphis, TN, USA) that requires screw fixation into a plate-like structure that overhangs the anterior aspect of the vertebral body [10,11]. Even for a physician-directed use in multilevel disc arthroplasty, this particular device design precludes it being placed next to another Prestige.

Despite these proposed advantages, SIS constructs have only recently been introduced, and thus have limited biomechanical [12–15] and clinical [8–11] data to guide their use. Consequently, the primary aim of this investigation was to evaluate acute segmental stability afforded by an SIS compared with the traditional anterior plate fixation in the setting of a multilevel cervical arthrodesis.

Materials and methods

Specimen preparation

Thirteen (n=13) fresh-frozen cadaveric spines were harvested from human cadavers. Bone mineral density (BMD) measurements were obtained by dual-energy radiographic absorptiometry using a Hologic QDR-2000 scanner (Bedford, MA, USA), with measurements taken from lateral image of the cervical spine vertebral body. The average measured BMD was 0.65 g/cm² (range, 0.42–0.91 g/cm²). Specimens with BMD below 0.900 g/cm² were considered osteoporotic [16]. Each specimen was then carefully disarticulated at the C1–C2 level proximally and the T2–T3 level distally, with care to preserve all native osseous anatomy. The spines were carefully dissected free of surrounding soft tissue attachments, while leaving osteoligamentous structures intact. Additionally, all specimens were inspected both visually and radiographically to identify the presence of preexisting fracture or compromised osseous integrity. All specimens were stored at −20°C until further testing ensued. To prepare the specimen for biomechanical testing, all specimens were allowed to appropriately thaw to room temperature. Specimens were then secured at their proximal and distal ends to a fixation jig using a polyester resin supplemented by additional screws. Care was taken to avoid encasing any of the remaining testable specimen and motion analysis markers with the resin to prevent inaccurate data collection.

Before instrumentation, all specimens were tested first in the intact state as a control. All specimens then received either a single- or multilevel discectomy, followed by the appropriate instrumentation. All surgical procedures were performed by a fellowship trained spine surgeon. The discectomies were performed by careful removal of the disc material with the use of sharp curettes and a high-speed burr. Meticulous technique was used to ensure preservation of the disc end plates, and the posterior longitudinal ligament was carefully resected. Any preexisting osteophytes were carefully removed with a Rongeur to allow access to the intervertebral disc space.

After the appropriate level-specific discectomy, the specimens were randomly assigned to receive an anterior plate with a standard interbody spacer versus a stand-alone spacer with integrated screws. All implants were individually sized to restore the appropriate disc height and reestablish cervical
lordosis. All specimens underwent fluoroscopic evaluation after instrumentation to ensure appropriate seating and alignment of the implants and to evaluate for any iatrogenic fracture before biomechanical testing. Implants were trialed and appropriately sized based on each cadaveric specimen’s intervertebral space height, and the footprint of the interbody device of the Prevail SIS (width, 14 mm × length, 11 mm) and standard polyetheretherketone (PEEK) spacer (width 16 mm × length, 13 mm) were comparable. The same size (height) interbody spacer (range, 5–8 mm height) was used between comparison groups (SIS vs. standard PEEK spacer with anterior cervical plate [ACP]) for each level in the tested specimens (ie, if a 6 mm SIS device was inserted at a specific level, then a 6 mm standard PEEK spacer was placed for the ACP). To alleviate the effect of screw loosening, rescue screws were used during reinstrumentation for the three-level constructs (SIS rescue screw diameter 4.5 mm, standard screw 4.0 mm) for each level in the tested specimens (ie, if a 6 mm SIS device was inserted at a specific level, then a 6 mm standard PEEK spacer was placed for the ACP). To alleviate the effect of screw loosening, rescue screws were used during reinstrumentation for the three-level constructs (SIS rescue screw diameter 4.0 × 15 mm, standard screw 3.5 × 13 mm; ACP rescue screw diameter 4.5 × 15 mm, standard screw 4.0 × 13 mm).

Four specimens underwent single-level discectomy and fusion at two noncontiguous levels (C4–C5 or C6–C7), thus providing us with a sample size of eight (n = 8) for single-level comparisons. Specimens were instrumented and tested with the following devices, randomized across the levels.

1. ACP (Atlantis Cervical Plating System, Titanium Alloy; Medtronic Sofamor-Danek, Memphis, TN, USA; dimensions = height, 25 or 27.5 mm depending on specimen size × width, 20 mm × length, 2.5 mm); with PEEK interbody spacer
2. SIS (PEEK Prevail; Medtronic Sofamor-Danek, Memphis, TN, USA)

Nine specimens were then subsequently tested in the following configurations across multiple levels, with the order of reconstructions randomized within two- and three-level comparisons (Figs. 1–4).

3. C5–C7 ACP (Medtronic, Minneapolis, MN, USA) (dimensions = height, 40, 42.5, 45 mm depending on specimen size × width, 20 mm × length, 2.5 mm)
4. C5–C7 SIS
5. C4–C7 ACP (dimensions = height, 60, 62.5, 65 mm depending on specimen size × width, 20 mm × length, 2.5 mm)
6. C4–C7 SIS
7. C4–C7 ACP with posterior lateral mass screw fixation (3.5 mm × 12–14 mm, Vertex titanium screws and 3.2 mm titanium rods)
8. C4–C7 SIS with posterior lateral mass screw fixation

Biomechanical testing

Biomechanical evaluation was carried out using the MTS 858 MiniBionix II system configured with a custom 6 df Spine Simulator (MTS Systems, Inc., Minneapolis, MN, USA). Motion analysis was carried out with the use of specialized markers comprising infrared light emitting diodes that were placed individually on the anterior aspect of all vertebral levels from C4 to C7. Light emitting diode 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 three planes of spinal motion: axial rotation (y-axis, ± 1.5 Nm), flexion/extension (x-axis, ± 1.5 Nm), and lateral bending (z-axis, ± 1.5 Nm). We used the flexibility method for assessment of stability, with a nonconstrained pure moment bending load applied for three loading and unloading cycles in each plane, with data analysis based on the final cycle.

Data and statistical analysis

Data obtained from the final load/unload cycle were used for final data analysis. The peak range of motion (ROM) for each simulated loading moment was calculated using Euler angles through the OptoTrack Certus software as the sum of motion observed in the neutral (NZ) and elastic (EZ) zones. Angular ROM (ROM = NZ + EZ) was reported for the whole construct (C4–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. Neutral zone displacement was limited to moment readings of ±0.5 Nm in each plane, whereas EZ was calculated as a difference between segmental ROM recorded at peak load and NZ limit in each loading direction. The two values obtained in this manner (eg, right and left) were then averaged for each loading modality.

All data were shown as mean ± 1 standard deviation. A repeated measures analysis of variance was used 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

Single-level fusion

No significant differences in ROM (p > .05) were noted for all planes of motion between the ACP and SIS for single-level fusion and this relationship was present regardless of fusion level at C4–C5 or C6–C7. Both devices significantly reduced ROM in all planes of motion when compared with the intact condition (p < .05). (Fig. 5; Table)

Two-level fusion

The ACP significantly reduced ROM (p < .05) for all three loading moments when compared with both the SIS
and intact spine. However, although the SIS construct provided slightly more stability than the intact condition, it was not statistically significant (p > .05) for all planes of motion. (Fig. 6; Table)

**Discussion**

The primary aim of the present investigation was to evaluate the biomechanical stability of an SIS device compared with the traditional ACP. Our results suggest that the SIS is biomechanically equivalent to the ACP for a single-level fusion. However, in multilevel fusion constructs, the stand-alone SIS construct provides significantly less segmental stability compared with the anterior plate in all planes of motion. For three-level fusion constructs supplemented with posterior fixation, there was no difference in segmental stability between the SIS and ACP groups.

For a single-level fusion construct, our findings are similar to a previously performed biomechanical study by Scholz et al. [14] that demonstrated no significant
difference in segmental stability comparing the Zero-P (Synthes Spine, Paoli, PA, USA) anchored cervical interbody spacer with conventional ACP fixation, using either a locking or dynamic plate. In that study, all three fixation techniques significantly decreased the ROM in all motion planes and no statistically significant difference was noted between the devices [14]. Another study by Wojewnik et al. [15] evaluated the use of two different low-profile interbody devices, with either locked or variable angle integrated screws for single-level cervical fusion in the setting of progressive flexion-distraction injury. The authors found that the locked screw device significantly reduced segmental motion compared with the intact specimen, even with progressive flexion-distraction injury, whereas the variable angle screw device did not provide sufficient stabilization [15]. The authors were the first to recognize

Fig. 3. Fluoroscopic images (anteroposterior and lateral) of cadaveric specimen with second-level anterior cervical plate with standard spacer fusion construct.

Fig. 4. Fluoroscopic images (anteroposterior and lateral) of cadaveric specimen with third-level interbody spacers with integrated screws fusion construct.
the importance of device design in regard to the stabilizing potential of SIS device and recommended against the use of variable angle screw SIS devices in the setting of cervical flexion-distraction injury. Another study also evaluated the biomechanical properties of a single-level SIS device (Coalition; Globus Medical, Audubon, PA, USA) in the setting of ASD, comparing the stability of a three–level hybrid construct (two-level C4–C6 ACP with C3–C4 SIS) with a three-level ACP (C3–C5 ACP) [12]. The authors found no statistically significant difference between the two constructs and concluded that a single-level Coalition SIS device in a hybrid setting provides equivalent stability compared with a three-level ACP [12].

Although an SIS device may be useful for a single-level construct and in the setting of single-level ASD, another potential beneficial use of the SIS may be in the setting of a multilevel fusion, where the device may prove most effective in decreasing postoperative morbidity. However, an important finding of our study was a significantly greater segmental ROM for multilevel fusion using the Prevail SIS as a stand-alone construct compared with the ACP construct; but when supplemented with posterior fixation, there was no significant difference in segmental stability between the SIS and ACP constructs. These findings suggest the SIS may not provide adequate stability when used as a stand-alone device for two- and three-level fusions and may necessitate posterior fixation to achieve optimal acute fixation and stability. To our knowledge, there is only one other study evaluating the biomechanical role of SIS devices used as a stand-alone multilevel fusion construct. In contradiction to our results, this study by Clavenna et al. [13] using the Coalition SIS

Table
Stand-alone interbody spacer and anterior cervical plate ROM for one, two, and three levels

<table>
<thead>
<tr>
<th>Single Level Anterior Fixation</th>
<th>AR</th>
<th>FE</th>
<th>LB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single-level anterior fixation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intact</td>
<td>4.91±2.85</td>
<td>10.01±3.39</td>
<td>4.71±1.74</td>
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<tr>
<td>Stand-alone spacer</td>
<td>4.44±2.77</td>
<td>7.44±4.89</td>
<td>3.79±2.53</td>
</tr>
<tr>
<td>Anterior plate</td>
<td>3.50±2.63</td>
<td>4.96±2.32</td>
<td>3.24±2.08</td>
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<tr>
<td>Two-level anterior fixation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intact</td>
<td>11.38±3.42</td>
<td>18.90±5.59</td>
<td>12.98±4.55</td>
</tr>
<tr>
<td>Stand-alone spacer</td>
<td>9.80±4.93</td>
<td>18.38±9.31</td>
<td>11.73±4.30</td>
</tr>
<tr>
<td>Anterior plate</td>
<td>4.94±3.17</td>
<td>7.42±5.42</td>
<td>5.56±3.10</td>
</tr>
<tr>
<td>Three-level anterior fixation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intact</td>
<td>22.07±5.71</td>
<td>29.82±2.02</td>
<td>20.23±5.32</td>
</tr>
<tr>
<td>Stand-alone spacer</td>
<td>18.42±7.02</td>
<td>24.80±3.52</td>
<td>17.84±6.13</td>
</tr>
<tr>
<td>Anterior plate</td>
<td>10.30±2.73</td>
<td>13.30±1.92</td>
<td>10.56±4.26</td>
</tr>
<tr>
<td>Three-level anteroposterior fixation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intact</td>
<td>22.07±5.71</td>
<td>29.82±2.02</td>
<td>20.23±5.32</td>
</tr>
<tr>
<td>Stand-alone spacer</td>
<td>3.98±1.13</td>
<td>4.34±3.46</td>
<td>2.09±1.08</td>
</tr>
<tr>
<td>Anterior plate</td>
<td>3.84±2.59</td>
<td>2.33±2.80</td>
<td>2.14±1.37</td>
</tr>
</tbody>
</table>

ROM, range of motion; AR, axial rotation; FE, flexion-extension; LB, lateral bending.
device (Coalition; Globus Medical, Audubon, PA, USA) found a significant reduction in segmental ROM for two- and three-level stand-alone SIS constructs in all planes of motion compared with the intact condition and comparable stability to traditional ACP construct. The authors also interestingly found that the addition of posterior instrumentation induced more biomechanical stability, but significance was only observed in three-level fixation when compared with the ACP construct.

The apparent difference between our results and the findings of the study by Clavenna et al. [13] may be a function of implant design. While the Coalition SIS device has an anchored portion with torsional stabilizers that enhance rotational stability and allows for the placement of two contralateral lag screws with a blocking set screw, the Prevail SIS device used in our investigation has two midline screws that do not provide lag compression and a Nitinol wire locking mechanism (Medtronic, Minneapolis, MN, USA). These particular screws do not lock into the device and are secured underneath a thin Nitinol wire that may be subject to inappropriate seating, bending of the wire, or even breakage. Without secure integration of the screws into the interbody spacer, decreased segmental stability is expected, and as previously mentioned in the setting of flexion-distraction injury, an SIS device with locked/fixed angle screws may provide significantly better stability compared with a variable angle device [15]. However, the optimal stability of a fusion construct remains unknown, and screw integration as a fixed angle device may not provide an ideal fusion environment by restricting appropriate dynamization and compression across the interbody spacer. Furthermore, we hypothesize that the inferior results seen with the tested Prevail SIS device in multilevel fusion constructs may arise from the fact that a stress riser is created from a large void of cancellous bone formed by the convergence of the midline integrated screws (ie, inferior screw from C4–C5 spacer is directly adjacent to superior screw from C5–C6 spacer), and this phenomenon may even be worsened by screw impingement, with placement of larger diameter and longer rescue screws.

One inherent weakness and limitation of this investigation was demonstrated by the equivalent findings seen between the two devices, with the addition of posterior fixation. For the two- and three-level fusions, the plate clearly demonstrated significantly greater stability when compared with the stand-alone SIS construct. Moreover, no difference was seen between the construct with the spacer and the intact spine, which may be explained by the spondylotic cadaveric specimens that may have induced increased motion after removal of osteophytes and posterior longitudinal ligament during preparation of the disc space. However, this finding may also suggest the possible presence of implant-bone interface failure (ie, integrated screw failure/cutout) or an unrecognized compromise of the cadaveric specimen. Interestingly, when posterior fixation was added, the two devices provided similar biomechanical stability. It could be inferred that the contribution provided by posterior fixation was significant, and therefore, the spine should have been tested with posterior fixation only to provide a basis for comparison, although previous studies have demonstrated circumferential fusion with anterior plating and segmental posterior cervical fixation provides significant stability compared with anterior plating alone for multilevel cervical fusion constructs after both discectomy and corpectomy [17].

Another limitation of our study was the repeated use of each cadaveric specimen for various testing constructs, with the removal and reinsertion of screws for both the SIS and ACP. To minimize the impact of this potential confounding factor, we randomized the order of placement between the SIS and ACP for both the two-level constructs, and then the three-level constructs, with the use of a larger/longer rescue screw during repeat screw insertion. Despite this, the repeated use of each screw hole may have inadvertently reduced fixation strength and potentially confounded our results. We were aware of this potential problem during the instrumentation process and took great care to limit screw removal/reinsertion to no more than two times per level and ensure the insertion trajectories of each screw did not cross because the SIS devices used in our study had a midline screw going cephalad and one caudad, whereas the plates had two screws on each side that were placed in a slightly convergent trajectory but were well outside the screw path of the SIS device. The advantage of testing various constructs on a single specimen is that each specimen serves as its own control in regard to the intact ROM and overall specimen quality. However, similar to other biomechanical studies, we were limited by the availability of high quality human cadaveric specimens, and testing the two- and three-level constructs in different specimens would have required double the number of specimens.

Although translation of biomechanical studies to their impact on clinical practice and their relevance to true in vivo performance remains unknown, the present study suggests the use of the SIS device in multilevel fusion constructs may not be ideal for immediate stability. However, in terms of clinical outcomes, a study by Scholz et al. [9] evaluated the Zero-P (Synthes Spine, Paoli, PA, USA) anchored spacer in 38 patients, with 15 one-level, 20 two-level, and 3 three-level ACDF. The authors reported radiographic evidence of fusion for all operated levels at the 6-month follow-up, good improvement in clinical outcome measures (visual analog scale and neck disability index), and low rate of complications [9]. Given the high rate of radiographic fusion present within their study, one can extrapolate that the multilevel SIS construct provided enough segmental stability to prevent pseudoarthrosis. In a similar prospective, short-term follow-up study by Miao et al. [8], the Zero-P anchored spacer (n=39) compared with ACP (n=50) was found to have a significantly lower rate of chronic dysphagia
(0% vs. 4% at 12-month follow-up), with no difference in clinical outcomes. Another study by Hofstetter et al. [18] also compared ACP with zero-profile anchored implants and found a significant difference in chronic dysphagia rate (2.9% vs. 20%), with no differences in fusion rate (~95% for both groups) and clinical outcomes. The various clinical reports on the use of SIS for multilevel fusion have been small, with short-term follow-up, and their conclusions should be interpreted carefully before the routine use of SIS devices as a stand-alone construct for multilevel fusions.

Overall, based on our finding, we recommend the SIS be used with caution for multilevel anterior cervical fusion surgery, given the limited biomechanical and clinical evidence to date. Although the application of this device has been shown to be equivalent in one-level arthrodesis, it may not merit use in the treatment of multilevel cervical disease, despite the possibility that the utilization of the SIS may be more clinically relevant and advantageous with increasing fusion levels to minimize the complications associated with implant bulkiness and increased operative time. Variations in plate design and screw integration may serve to enhance fixation strength for multilevel constructs and should be an area of further investigation. Although not tested in our study, another area of investigation may be the difference in stability, comparing consecutive one-level plates with consecutive SIS devices, which is a more equivalent comparison in place of a multilevel plate that provides a single, rigid link over the entire multilevel segment that inherently provides greater stability. Also, although supplemental posterior fixation was shown to provide equivalent stability between the two groups for three-level fusion constructs, further investigations would be necessary, given the inferior results seen with multilevel fusion with the SIS as a stand-alone construct compared with an ACP. Also, in the clinical setting, supplemental posterior fixation should also be performed with careful consideration and planning, given the significant increase in cost, operating room time, and infection risk.

**Conclusion**

An SIS device provides similar segmental stability to anterior plating for single-level cervical fusion constructs. However, the SIS should be avoided as a stand-alone device in multilevel cervical fusion constructs unless supplemented by posterior fixation. Further biomechanical and clinical investigations of the SIS device are warranted to determine the long-term clinical outcomes, particularly for their use in multilevel cervical fusion constructs.

**References**


