

# Does a Zero-Profile Anchored Cage Offer Additional Stabilization as Anterior Cervical Plate?

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**Study Design.** Retrospective cohort study.

**Objective.** This study aimed to compare 3 different surgical methods of single-level anterior cervical interbody fusion consisting of stand-alone cages (SCs), cages with plates (CPs), and anchored cages (ACs) (zero-profile). It focused on postoperative retention and motion stabilization.

**Summary of Background Data.** Several authors reported the radiological and clinical results of ACs, which seem similar to plates. However, it remains unclear whether ACs offer additional stabilization like plates.

**Methods.** Between 2005 and 2011, SCs (n = 60) and CPs (n = 18) were used to surgically treat patients with single-level cervical degenerative diseases. From January 2012 to June 2013, ACs were used (n = 23). We compared retention (cervical alignment, segmental angle, and segmental height) and motion stabilization (change of segmental angle and distance of interspinous process in flexion/extension). We also investigated subsidence, fusion rates, and clinical outcomes. The mean follow-up period was 19.9 months.

**Results.** The CP and AC groups showed significantly more retention at 12 months after surgery than the SC group ( $P < 0.05$ ). The CP group had significantly greater motion stabilization than the SC group ( $P < 0.05$ ). However, there was no statistically significant difference between the AC and SC groups. The subsidence rates of the SC, AC, and CP groups were 40.0%, 21.7%, and 11.1%, whereas the fusion rates were 83.3%, 87.0%, and 100.0%, respectively. Arm and neck visual analogue scale scores and Odom criteria showed superior results in the CP and AC groups than in the SC group ( $P < 0.05$ ).

**Conclusion.** The AC displayed similar retention and clinical outcomes to those of the CP. However, the AC was inferior to the CP in motion stabilization, subsidence prevention, and fusion rate.

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Therefore, for patients who require strong postoperative motion stabilization, CPs rather than ACs should be used.

**Key words:** anchored cage, zero profile, stand-alone cage, cage with plate, stabilization.

**Level of Evidence:** 4

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A zero-profile (Zero-P) anchored cage (AC) was approved by the United States Food and Drug Administration in 2008. Because an AC has an additional anchoring function compared with existing stand-alone cages (SCs), it has the advantage of immediate postoperative stabilization just like an anterior plating system.<sup>1</sup> Unlike with an anterior plating system, the instrument does not protrude in front of the vertebral body, which can reduce the occurrence of postoperative dysphagia.<sup>2,3</sup> Because these shortcomings of the SC and anterior cervical plate (ACP) are being improved upon, the use of ACs is gradually increasing.<sup>1–5</sup>

Most authors have indicated that radiological and clinical outcomes of ACs are similar to those of cages with plates (CPs) and have particularly emphasized the point about the decreased occurrence of postoperative dysphasia.<sup>1–6</sup> ACs maintained comparable stability with CPs in one biomechanical study, but ACs showed a higher range of motion in flexion/extension<sup>7</sup>; in contrast, other articles reported that ACs lack multilevel stability.<sup>8</sup>

In our study, using SCs in patients with single-level cervical disc disease for comparison, the degree of additional stability provided by the fixation devices of an AC was determined on the basis of comparisons and analyses of the postoperative retention of cervical alignment and motion stabilization.

## MATERIALS AND METHODS

The present study included a total of 101 patients with single-level cervical degenerative diseases of the subaxial cervical spine (C3–C7) who underwent surgery for neck pain and radiculopathy without improvement after more than 6 months of conservative therapy. Patients with trauma or infection and those who underwent cervical spine surgery were excluded.

From 2005 to 2011, SCs (n = 60) and CPs (n = 18) were used. Moreover, from 2012 to 2013, ACs (n = 23) were used to treat the same disease. The subjects were divided into the SC, CP, and AC groups.

## Surgical Procedure

The right-sided Smith-Robinson anterior cervical approach was used in all patients. To prevent excessive retraction, the distraction pins were distracted for 2 to 3 clicks with resistance. Complete discectomy, osteophyte removal, and careful endplate preparation were then performed. With the use of a trial spacer, appropriate implant shape and size were decided. In the SC and CA groups, a polyetheretherketone cage, Solis (Stryker, Allendale, NJ) or Cervious (Synthes, West Chester, PA), was used; along with an anterior plate, an Atlantis plate (Medtronic Sofamor Danek, Memphis, TN) was used. The Zero-P (Synthes, Zuchwil, Switzerland) was used in the AC group. The Zero-P consists of a polyetheretherketone cage and 4 titanium screws that can affix the top and bottom of a vertebral body to the integrated titanium and titanium plates in the front. For all patients, a cage filled with DBX putty (Musculoskeletal Transplant Foundation, available through Synthes, Paoli, PA) was used as bone graft substitute. The surgical procedures were performed by 2 senior spinal surgeons.

Subsidence is defined as a reduction in disc height for more than 2 mm due to implant migration into adjacent endplates. Fusion was evaluated using the Bridwell fusion grading system<sup>9</sup> and flexion/extension radiographs<sup>10</sup>; we defined grades 1 to 2 and motion (<3 mm) on flexion/extension radiographs as fusion.

Screw loosening is defined by more than 1-mm radiolucent zone surrounding screw on the basis of the anteroposterior and lateral plain radiography.<sup>11</sup>

## Clinical Evaluation

For clinical outcome, preoperative, postoperative, and 12-month postoperative neck and arm visual analogue scale scores were compared and the 12-month postoperative clinical outcome was evaluated using the Odem criteria.

## Radiological Evaluation

Cervical alignment was defined by the Cobb angle that formed between the lower vertebral body of C2 and the upper vertebral body of C7. The segmental angle was defined as the Cobb angle of the vertebral bodies adjacent to the involved

disc. Segmental height was determined by measuring the distance from the upper endplate of the upper vertebral body to the lower endplate of the lower vertebral body that form the anterior and posterior portions of the operated levels. The interspinous process distance was defined as the distance between the adjacent spinous processes of the involved disc (Figure 1).

For cervical alignment and segmental angle, the angle (°) that formed after surgery was used as the reference and the 3- and 12-month postoperative changes in angles in the 3 groups were compared. Using the same method, for anterior and posterior segmental height, the segmental height (mm) that formed after surgery was used as the reference and the measured values were compared to evaluate the retention in the 3 groups. Moreover, measurements of differences in segmental angle and interspinous process distance on a flexion/extension radiograph were taken at preoperative, postoperative, and 12-month postoperative points to compare the motion stabilization in the 3 groups.

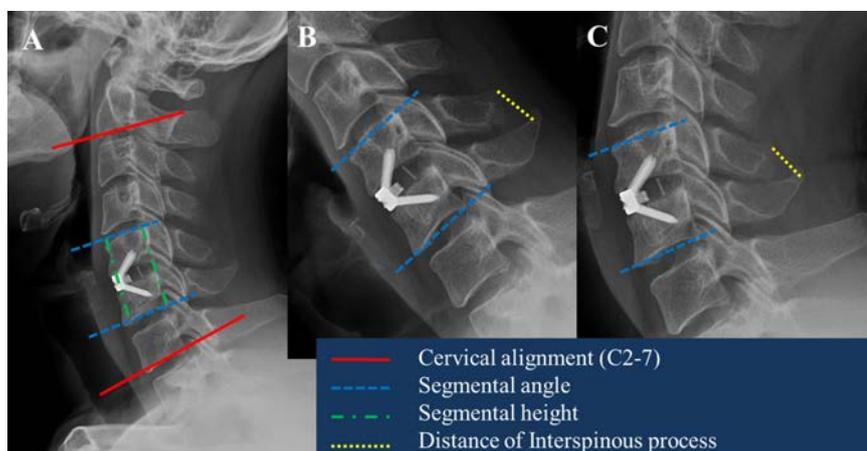
The images were saved in DICOM format for the picture archiving and communication system. Because the C-spine is a small-sized structure, the images were enlarged by 100% and then assessed. The measurements and evaluations based on radiography were initially performed by 1 surgeon, whereas 2 other surgeons independently reviewed and confirmed all of the radiological measurements.

## Statistical Analysis

For the 3 groups, analysis of variance, the Kruskal-Wallis *H* test, and the  $\chi^2$  test were used for comparison, and the degree of change in radiological outcome was compared using repeated measures analysis of variance. A *post hoc* comparison was also performed. *P* values of less than 0.05 were considered statistically significant. Statistical analyses were performed using SPSS software version 18.0 (SPSS Inc., Chicago, IL).

## RESULTS

There were no differences among the 3 groups in terms of age, sex, surgical site, or bone mineral density. Preoperative



**Figure 1.** Measuring method for cervical alignment, segmental angle, segmental height, and interspinous process distance on lateral plain radiographs.

**TABLE 1. Comparison of the Stand-alone Cage, Anchored Cage, and Cage With Plate Groups**

|  | Stand-alone Cage | Anchored Cage  | Cage With Plate | P      |
|--|------------------|----------------|-----------------|--------|
| Number   | 60               | 23             | 18              |        |
| Age (yr), mean ± SD                                | 53.62 ± 11.47    | 57.26 ± 13.28  | 52.89 ± 7.71    | 0.361  |
| Sex (male/female)                                  | 30/30            | 11/12          | 11/7            | 0.656  |
| Level  |                  |                |                 |        |
| C3–C4  | 3                | 4              | 1               | 0.377  |
| C4–C5  | 11               | 2              | 4               |        |
| C5–C6  | 39               | 13             | 9               |        |
| C6–C7  | 7                | 4              | 4               |        |
| Cage height, mean ± SD                             | 5.95 ± 0.81 mm   | 7.87 ± 0.63 mm | 6.70 ± 1.16 mm  | <0.001 |
| Anterior segmental height change, mean ± SD        | 2.77 ± 2.06 mm   | 3.05 ± 1.66 mm | 2.84 ± 2.09 mm  | 0.695  |
| Posterior segmental height change, mean ± SD       | 2.31 ± 1.10 mm   | 2.56 ± 1.35 mm | 2.44 ± 1.88 mm  | 0.934  |
| Cervical alignment, mean ± SD                      | 5.18 ± 10.72°    | 6.54 ± 10.60°  | 7.67 ± 14.13°   | 0.665  |
| Segmental angle, mean ± SD                         | 0.68 ± 5.08°     | 1.51 ± 5.83°   | 1.57 ± 5.79°    | 0.735  |
| Preoperative anterior segmental height, mean ± SD  | 31.70 ± 4.58°    | 32.14 ± 3.53°  | 32.77 ± 3.23°   | 0.572  |
| Preoperative posterior segmental height, mean ± SD | 31.63 ± 3.37°    | 31.46 ± 3.70°  | 32.48 ± 3.25°   | 0.642  |
| BMD, mean ± SD                                     | −0.49 ± 1.38     | −0.74 ± 1.83   | −0.36 ± 1.5     | 0.456  |
| Follow-up (mo), mean ± SD                          | 18.98 ± 10.30    | 12.57 ± 2.09   | 28.89 ± 20.24   |        |

BMD indicates bone mineral density.

cervical alignment, segmental angle, and anterior and posterior segmental height did not differ significantly among the 3 groups. The cage height used in the SC, CP, and AC groups was  $6.95 \pm 0.81$ ,  $6.70 \pm 1.16$ , and  $7.87 \pm 0.63$  mm, respectively, showing a statistical difference ( $P < 0.001$ ), whereas the amount of change in anterior and posterior segmental height from prior to surgery to immediately after surgery, that is, the postoperative increase in disc height, showed no statistically significant difference ( $P = 0.395$ ,  $0.934$ ). Furthermore, the mean follow-up periods of the SC, CP, and AC groups were 18.9, 28.9, and 15.6 months, respectively (Table 1).

### Subsidence

The subsidence of the SC, CP, and AC groups was 40.0% (24/60), 11.1% (2/18), and 21.7% (5/23), respectively (Figure 2). The occurrence of subsidence between the SC and CP groups was significantly different ( $P = 0.025$ ), whereas that between the SC and AC groups was not ( $P = 0.133$ ). To determine the factors that influence subsidence, a multivariate logistic regression analysis was performed at which time age ( $P < 0.001$ ), cervical alignment ( $P = 0.004$ ), bone mineral density ( $P = 0.032$ ), and CP ( $P = 0.020$ ) displayed statistical significance, whereas the AC ( $P = 0.055$ ) did not show statistical significance (Table 2). Furthermore, screw loosening was observed in 4 of 5 patients with subsidence in the AC group. However, the occurrence of subsidence in the CP group did not include screw loosening.

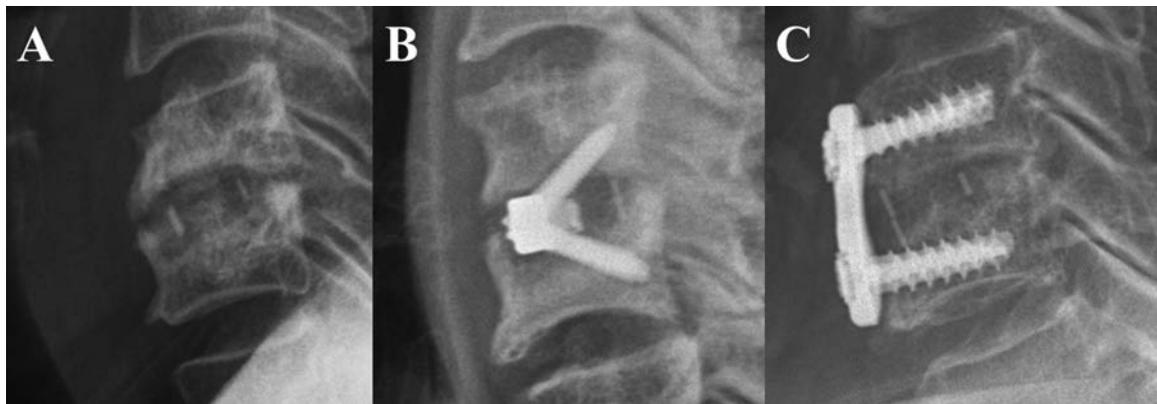
### Fusion Rate

At 12 months postoperative, the occurrence of fusion was investigated. Using grade 1 or 2 Bridwell fusion classification as the fusion standard, the results were 83.3% (50/60) in the SC group, 87.0% (20/23) in the CP group, and 100% (18/18) in the AC group. Using an interspinous process distance of less than 3 mm on flexion/extension radiograph as the fusion standard, the results were 63.3% (38/60) in the SC group, 82.6% (19/23) in the CP group, and 94.4% (17/18) in the AC group (Table 3).

### Radiological Outcomes

Postoperatively formed cervical alignment, segmental angle, and segmental height were investigated to determine the retention of each surgical method. Cervical alignment that formed after surgery decreased at 12 months postoperative, with the SC group going from  $13.01 \pm 8.30^\circ$  to  $6.50 \pm 11.08^\circ$ , the CP group going from  $14.34 \pm 5.98^\circ$  to  $12.73 \pm 6.71^\circ$ , and the AC group going from  $15.47 \pm 7.52^\circ$  to  $12.33 \pm 8.27^\circ$ . Comparisons of the decreases in cervical alignment showed statistical significance in the SC group compared with the CP and AC groups ( $P = 0.008$ ,  $0.048$ ) (Figure 3).

The segmental angle that formed after surgery also showed decreases at 12 months postoperative, with the SC group going from  $6.31 \pm 5.23^\circ$  to  $1.95 \pm 7.01^\circ$ , the CP group going from  $6.11 \pm 3.67^\circ$  to  $4.98 \pm 4.69^\circ$ , and the AC group going from  $6.41 \pm 3.67^\circ$  to  $3.65 \pm 4.37^\circ$ . Comparison of the decreases



**Figure 2.** Subsidence of the stand-alone cage (A), anchored cage (B), and cage with plate (C). Subsidence in the cage with plate did not demonstrate screw loosening, whereas screw loosening was observed in the anchored cage.

in segmental angle for each group were similar to those of cervical alignment because the SC group showed statistically significant decreases compared with the CP and AC groups ( $P = 0.013, 0.037$ ) (Figure 3).

For segmental height, retention in the 3 groups was compared with the height that formed after surgery being set as the baseline. The anterior segmental heights of the SC, CP, and AC groups at 12 months postoperative were 91%, 95%, and 96%, respectively, whereas the posterior segmental heights were 93%, 96%, and 97%, respectively; both showed retention. The CP and AC groups displayed statistically significantly higher retention than the SC group ( $P < 0.05$ ) (Figure 3).

Motion stabilization was investigated by the differences in segmental angle and interspinous process distances on dynamic radiography. Difference of segmental angle and interspinous process distance showed no statistical differences between preoperative and immediately after surgery.

However, comparing the SC group with the CP and AC groups at 12 months postoperative, the CP group showed statistically significant motion stabilization compared with the SC group ( $P = 0.023, 0.001$ ), but the AC group showed no statistical difference with the SC group ( $P > 0.05$ ) (Figure 4).

**Clinical Outcomes**

Postoperative neck and arm visual analogue scale scores immediately after surgery showed equivalent improvement in all 3 groups, whereas at 12 months postoperative, the SC group showed poorer outcomes than the CP and AC groups, with Odom criteria showing similar results (Figure 5).

**DISCUSSION**

In patients with cervical degenerative disc disease as well as neck pain and radiculopathy, when conservative therapy fails, anterior cervical discectomy and fusion (ACDF) are the standard treatment methods. However, decisions on surgical

| TABLE 2. Subsidence Rate and Logistic Regression Analysis of Risk Factors for Postoperative Subsidence of the Stand-alone Cage, Anchored Cage, and Cage With Plate Groups |                     |               |                     |
|---|---------------------|---------------|---------------------|
|   | Subsidence          | Nonsubsidence | Subsidence Rate (%) |
| Stand-alone cage  | 24                  | 36            | 40.0                |
| Anchored cage   | 5                   | 18            | 21.7                |
| Cage with plate   | 2                   | 16            | 11.1                |
|   | Odds Ratio (95% CI) |               | P                   |
| Age*  | 1.104 (1.045–1.168) |               | <0.001              |
| Cervical alignment*   | 0.928 (0.883–0.976) |               | 0.004               |
| BMD*  | 1.558 (1.038–2.337) |               | 0.032               |
| OP methods  |                     |               |                     |
| Stand-alone cage  | 1                   |               |                     |
| Anchored cage   | 0.261 (0.066–1.029) |               | 0.055               |
| Cage with plate*  | 0.138 (0.026–0.728) |               | 0.020               |

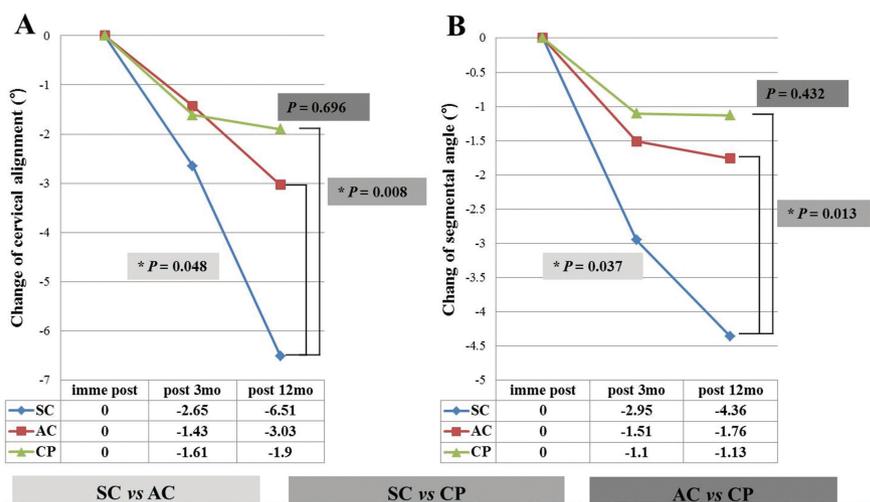
\*Statistically significant difference ( $P < 0.05$ ).

CI indicates confidence interval; BMD, bone mineral density; OP, operative.

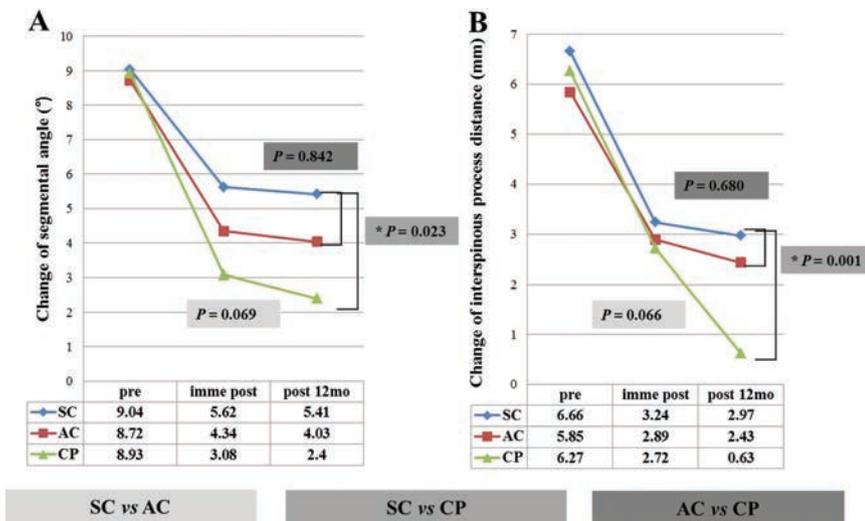
| TABLE 3. Fusion Rates of the Stand-alone Cage, Anchored Cage, and Cage With Plate Groups |           |        |                 |
|--|-----------|--------|-----------------|
| Distance of Interspinous Process (<2 mm)   | Nonfusion | Fusion | Fusion Rate (%) |
| Stand-alone cage   | 22        | 38     | 63.3            |
| Anchored cage  | 4         | 19     | 82.6            |
| Cage with plate  | 1         | 17     | 94.4            |
| Bridwell Fusion Classification (Grades 1 and 2)  | Nonfusion | Fusion | Fusion Rate (%) |
| Stand-alone cage   | 10        | 50     | 83.3            |
| Anchored cage  | 3         | 20     | 87.0            |
| Cage with plate  | 0         | 18     | 100.0           |

techniques for ACDF remain unclear.<sup>12</sup> One of the most representative methods among these is the autologous bone grafting and anterior plating system. Autologous bone grafting more effectively achieves fusion than the use of a cage.<sup>12</sup> Moreover, the use of an anterior plating system increases interbody fusion rates and stability<sup>13</sup> and can maintain or improve cervical sagittal alignment and prevent interbody graft dislocation or subsidence.<sup>14</sup> However, the use of an autologous bone graft can

lead to donor site morbidity and complications including neurological injury, hematoma formation, infection, and pain.<sup>15</sup> Furthermore, use of the anterior plating system can result in hardware failure and postoperative dysphagia and accelerate degenerative changes in adjacent segments.<sup>16,17</sup> Therefore, surgical methods using SCs without the use of additional plates are widely used.<sup>18-20</sup> However, the SC has the shortcomings of possible subsidence and/or kyphotic deformity changes.<sup>19,21,22</sup>



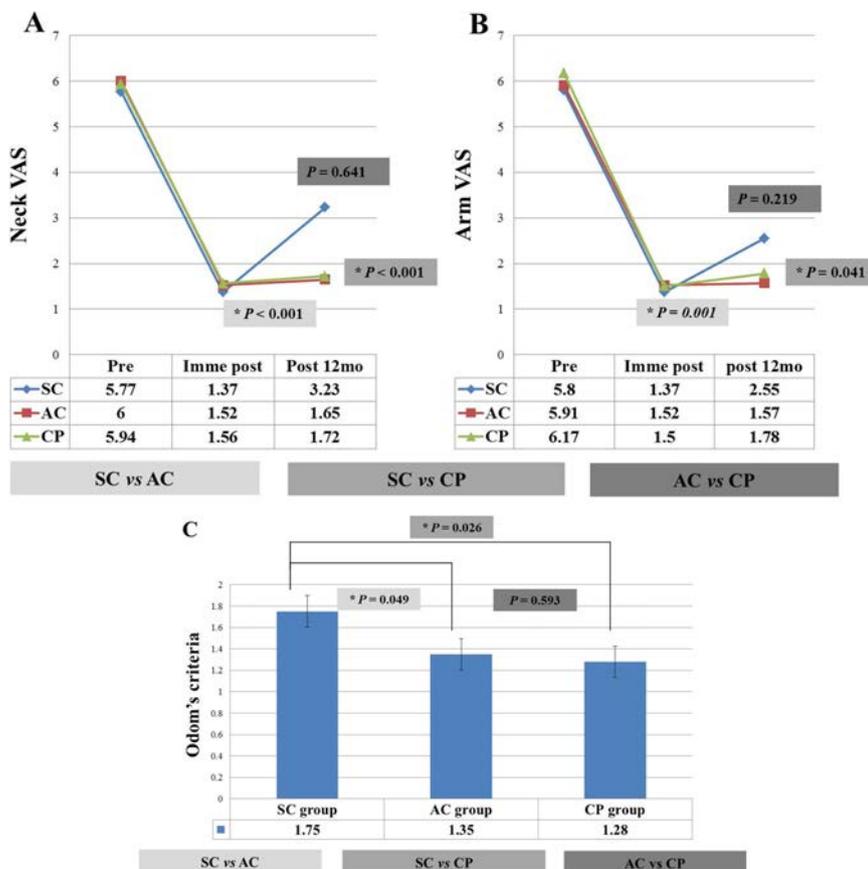
**Figure 3.** Evaluation of changes in cervical alignment (A), segmental angle (B), anterior and posterior disc height (C, D), and retention from immediately after surgery to the 3- and 12-month postoperative points. \*Statistically significant difference ( $P < 0.05$ ). SC indicates stand-alone cage; AC, anchored cage; CP, cage with plate.



**Figure 4.** Evaluation of motion stabilization based on surgical method from change of segmental angle and interspinous process distance from preoperative to immediately and 12 months postoperative. \*Statistically significant difference ( $P < 0.05$ ). SC indicates stand-alone cage; AC, anchored cage; CP, cage with plate.

The AC, which supplements the advantages and disadvantages of the aforementioned CP and SC, is gradually becoming more widely used.<sup>1-6</sup> Vanek *et al*<sup>1</sup> conducted a minimal 2-year prospective comparative study on the Zero-P spacer. Compared with the CP, there were no differences between the 2 groups for neck disability index, Cobb coronal value, and the presence of dysphagia; although the Cobb sagittal values differed up to 6 weeks, no differences were reported beyond

that point. As a result, the Zero-P showed similar biomechanical conditions to those of the CP. Another article reported that the AC promotes reduced clinical aspects and postoperative dysphagia from more than just radiological aspects.<sup>2,23-25</sup> In most articles, given that CP and AP are a surgical method that generally produces a good outcome, whereas the AC shows a lower dysphagia rate than the plate because there are no protrusions in front of the vertebral body. This study



**Figure 5.** Neck and arm visual analogue scale score, Odom criteria of stand-alone cage, anchored cage, and cage with plate group preoperative, immediately postoperative, and 12 months postoperative. \*Statistically significant difference ( $P < 0.05$ ). VAS indicates visual analogue scale; SC, stand-alone cage; AC, anchored cage; CP, cage with plate.

examined whether the AC can actually maintain firm stabilization like a plate to prevent subsidence, increase the fusion rate, retain the postoperative alignment, and provide motion stabilization. Moreover, for minute differences that were not seen in previous studies on direct comparisons between ACs and CPs, a study was conducted on how much influence ACs and plate screws have on stabilization using SCs, that is, without additional fixation.

Reports on the occurrence rate of subsidence after ACDF have varied from 5.4% to 55.6% depending on surgical method.<sup>2,18–21</sup> Njoku *et al*<sup>2</sup> reported a subsidence rate of the Zero-P of 22.7% (15 of 66 operated levels). Our study also indicated a similar subsidence rate of 21.7% for ACs, which meant a reduced subsidence rate compared with the SCs, but it was still not as effective as CPs. Moreover, screw loosening was observed in 4 of 5 patients treated with an AC who developed subsidence. With the screw loosening, any additional stabilization effects by the addition of more AC screws were eliminated, which led to motion instability. With subsidence comes a tendency for decreased fusion rate.<sup>21</sup> ACs showed fusion rates in the 82.6% to 87.0% range, which is somewhere between the SC and CP ranges.

An *in vitro* biomechanical study of the AC was conducted by Scholz *et al*<sup>7</sup> on SCs, ACs (Zero-P), and interbody CPs. Compared with CPs for flexion, extension, lateral bending, and axial rotation, ACs provided similar biomechanical stability. Although there was no statistical difference, the ACs showed lower stabilization than CPs in flexion and extension. Furthermore, Paik *et al*<sup>8</sup> also reported on biomechanical stabilization from the stand-alone interbody with integrated screw (SIS) and ACP. Although the range of motion in all directions at the single level showed no significant differences, an intact flexion and extension showed 10.01° whereas SIS and ACP showed 7.44° and 4.96°, respectively, thus indicating that SIS showed slightly less stability than ACP. Moreover, because ACP maintained better stabilization (with statistical significance) in multilevel treatment than SIS, using multilevel SIS was said to require serious consideration. The biomechanical studies mentioned previously performed measurements within a short period of time after implant insertion, whereas in our case, retention and motion stabilization of the AC was evaluated after 12 months. In our study, which used the SC group as the reference, the CP and AC groups showed good postoperative retention in cervical alignment, segmental angle, and segmental height, whereas in flexion/extension, motion stabilization in the AC group was less effective than that in the CP group. These differences in stabilization are thought to be the result of increased motion of the AC compared with the plate from loss of the additional motion stabilization due to elapsed follow-up time after surgery and screw loosening seen in 4 patients with an AC.

The present study has several limitations. The follow-up period was short. However, considering the fact that subsidence and fusion did occur within 12 months, it was sufficient for evaluating retention and motion stabilization. However, a longer follow-up period would be needed to investigate adjacent segment degeneration and long-term stabilization.

Although this was not a prospective randomized study, because an AC was used after a certain period of time, the study was conducted on the same patient groups. A future randomized prospective study is needed.

## CONCLUSION

The AC (Zero-P) may be a more reasonable option than the SC in single-level ACDF. However, the AC showed similar retention and clinical outcomes as those of the CP, although additional stabilization effects comparable with the plate were not seen in subsidence rate, fusion rate, or motion stabilization. Therefore, the CP rather than the AC should be used in patients who require strong postoperative motion stabilization.

## ➤ Key Points

- ❑ The anchored cage may be a more reasonable option than the stand-alone cage in single-level anterior cervical discectomy and fusion.
- ❑ The anchored cage showed similar retention and clinical outcomes as those of the cage with plate, although additional stabilization effects comparable with the plate were not seen in subsidence rate, fusion rate, or motion stabilization.
- ❑ The cage with plate rather than the anchored cage should be used in patients who require strong postoperative motion stabilization.

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