

# Contiguous Two-Level Anterior Cervical Discectomy and Fusion Using Zero-P VA System: A Retrospective Study

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**Purpose:** The aim of this study was to explore short-term radiological findings after contiguous two-level ACDF with Zero-P VA devices.

**Methods:** Patients who underwent contiguous two-level anterior cervical discectomy and fusion (ACDF) from C3 to C7 with a Zero-P VA system were followed. Cervical anteroposterior and lateral X-rays and functional outcomes were assessed 3 months after surgery.

**Results:** Overall, 34.9% of patients had prosthesis subsidence and 74.6% screw loosening. Up to 46.8% of the patients with screw loosening also experienced prosthesis subsidence compared with 0 patients without screw loosening ( $p=0.0005$ ). The screw-loosening rate was 91.7% in patients with poor positioning of the screw/cage and 70.6% in patients without poor positioning of the screw/cage, but no statistical difference was found between the groups ( $p=0.267$ ). The subsidence rate was 50% in patients with poor positioning of the screw/cage and 31.4% in patients without poor positioning of the screw/cage, but no statistical difference was found between the groups ( $p=0.314$ ). VAS scores of patients with prosthesis subsidence were much higher than those without ( $p=0.031$ ), but this difference was not found for patients with or without screw loosening ( $p=0.116$ ). The NDI scale was much higher in patients regardless of screw loosening or subsidence.

**Conclusion:** Screw loosening and prosthesis subsidence happen frequently after contiguous two-level ACDF with Zero-P VA. Screw loosening seems to be the only risk factor for prosthesis subsidence.

**Keywords:** contiguous two-level ACDF, Zero-P VA, screw loosening, prosthesis subsidence

## Introduction

Anterior cervical discectomy and fusion (ACDF) is widely recognized as the gold standard for operation of patients with cervical disc disease.<sup>1,2</sup> An anterior cervical cage with plate construct (CP) is widely used in ACDF due to its outstanding clinical outcomes, excellent stability, high fusion rate, and satisfactory reconstruction and maintenance of segmental lordosis.<sup>3,4</sup> However, there are some unavoidable complications like dysphagia and tracheoesophageal injury because of the thickness of the plate.<sup>5</sup> A stand-alone cage has also been developed to avoid these soft-tissue compression-related complications, but the weaknesses of low fusion rate, high subsidence rate, and difficulty in reconstructing/maintaining cervical lordosis have limited its application.<sup>6</sup>

Accordingly, a zero-profile device (Zero-P) was developed with the advantages of both the CP and stand-alone cage, but avoiding their disadvantages, affording stability, but no soft-tissue compression-related complications. Many studies have reported satisfactory outcomes using the Zero-P system,<sup>7-9</sup> with lower rates of complications and competitive clinical and radiological outcomes compared to CP. The old version of the Zero-P system is designed with four screws to fix the two proximal vertebral bodies, demonstrating mechanical properties comparable to the CP system.<sup>10</sup> This version of the Zero-P device also has some shortcomings, most importantly the difficulty in placing the screws, especially for

contiguous two-level ACDF. It is too difficult to place four screws in a single small cervical vertebral body. Thus, the Zero-P system was modified to a new version (Zero-P VA [zero-profile variable angle], DePuy Synthes, Switzerland) with only two screws.<sup>1,11</sup> However, controversy continues about the biomechanical stability of this new version, as well as its influence on fusion rate, subsidence risk, and clinical outcomes, especially for multilevel ACDF. Few studies on the risks of prosthesis subsidence after contiguous two-level ACDF with the Zero-P VA system has been performed. Here, we aimed to explore short-term radiological findings after contiguous two-level ACDF with the Zero-P VA device.

## Methods

### Patient Population

The study followed patients who underwent contiguous two-level ACDF from C3 to C7 for degenerative cervical disc disease with the Zero-P VA system from August 2018 to July 2022 at Ruijin Hospital. Patients suffering from symptoms of radiculopathy and/or myelopathy and had failed with at least 6 months of conservative treatments were included in the study. All the patients were diagnosed according to clinical manifestations, physical examinations, and radiological findings by at least two experienced spine specialists. The operation indications and plan were also decided by at least two spine experts, and any discordance was solved by discussion. Exclusion criteria were prior cervical operation, follow-up <3 months, radiological parameters that could not be measured, additional posterior instrumentation after ACDF, or infection, tumor, or fracture. The study was approved by the Ethics Committee of Ruijin Hospital. Written informed consent was obtained from all participants.

### Surgical Procedure

All surgical procedures were performed by senior spinal surgeons in our department with a standard right-sided Smith–Robinson approach after the induction of general anesthesia. First, thorough decompression and removal of degenerated disc tissue, posterior longitudinal ligament, and osteophytes were performed. After preparation of the endplates, a suitable Zero-P VA implant (DePuy Synthes Spine, USA) filled with autogenous bone graft was inserted into the intervertebral space. Two locking head screws were screwed into place, and finally, anteroposterior and lateral fluoroscopies were performed to confirm the positioning of the implants. The second segment was handled with the same procedures.

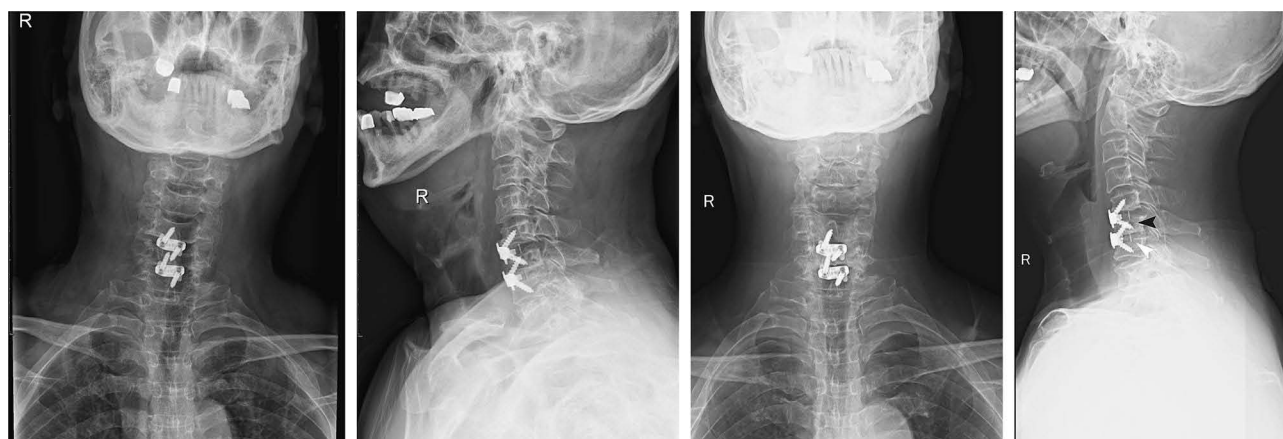
### Postsurgery Rehabilitation

All patients underwent the same rehabilitation program. The patients were **allowed to engage in outdoor activities** under the protection of a cervical collar for 4 weeks. The patients were allowed back to daily life (school or work) 1 month after surgery. Functional exercise of the scapular muscles started at 2 weeks after surgery, but exercise of the neck muscles was not allowed until radiological fusion of the surgical segments (at least 12 weeks after surgery).

### Follow-Up Evaluation

Plain X-rays, computed tomography, and magnetic resonance imaging were performed prior to operation for all patients to determine the diagnosis and surgery strategies. All patients received cervical anteroposterior and lateral plain radiography once the drainage tube was removed (about 1 or 2 days after surgery). After 3 months, the patients were asked to undergo another cervical anteroposterior and lateral plain radiograph to evaluate the implant status and other parameters. Functional outcome evaluations, including visual analogue scale (VAS) and neck disability index (NDI) scores were also collected during follow-up.

The segmental cervical angle (Cobb S) was evaluated between lines drawn parallel to the upper endplate of the most cranial vertebra and the lower endplate of the most caudal vertebra at the surgical level. The segmental cervical angle was measured immediately after surgery and 3 months postoperatively. The value of change in segmental cervical angle over time was calculated. Screw loosening was defined as a radiolucent zone of minimal thickness of  $\geq 1$  mm surrounding the screw on radiography and/or the “double halo” sign (Figure 1).<sup>12</sup> The prosthesis subsidence was defined by calculating the distance from the superior endplate of the upper vertebral body to the inferior endplate of the lower vertebral body at the level of the operation



**Figure 1** Having failed with 7 months of conservative treatment, a 76-year-old man suffering from C5–C6 and C6–C7 degenerative cervical spondylosis was treated with C5–C7 ACDF with the Zero-P VA system. The X-ray after 12 weeks demonstrated loosening of the C5–C6 downward screw (“double halo” sign, black arrow). Prosthesis subsidence did not occur in C5–C6, but did in C6–C7 without screw loosening (white arrow).

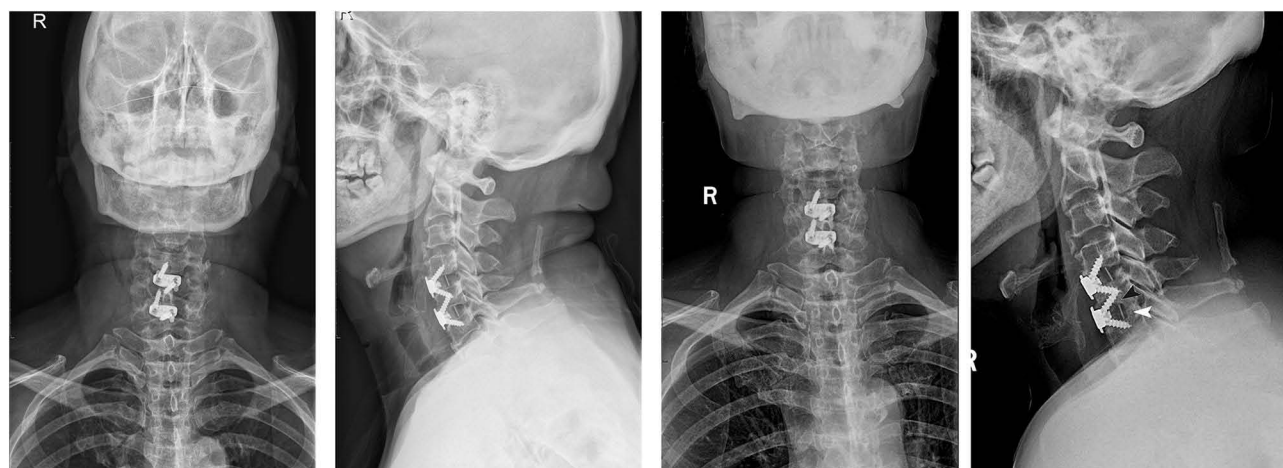
from the anterior and posterior borders of the vertebral bodies. As all included patients received contiguous two-level ACDF, the prosthesis subsidence was defined as a decline of more than 4 mm (three vertebra) between the images obtained immediately after surgery and at 3 months postsurgery (Figure 2).<sup>13</sup> Poor positioning of the prosthesis was defined as screw implanted into the disc, endplate cutting, screw degree less than 27°, or cage–endplate contact surface less than two-thirds of the cage.

## Statistical Analysis

The Statistical Package for Social Sciences (SPSS version 16.0, Inc., Chicago, Illinois, USA) for Windows was used for statistical analysis. The clinical data are presented as means  $\pm$  SD and were compared using Student’s *t*-test. Demographic data and radiological results were assessed with  $w^2$  tests. Stratified analysis was performed to determine the risk factors for screw loosening and cage subsidence, e.g., age, sex, and the position of the screw/cage.  $p < 0.05$  was considered a statistically significant difference.

## Results

A total of 148 patients who received contiguous two-level ACDF at our hospital were enrolled in this study, then 85 were excluded for reasons like no follow-up of 12 weeks or no measurable anteroposterior/lateral plain radiograph available.



**Figure 2** Having failed with 6 months of conservative treatment, a 62-year-old woman suffering from C4–C5 and C5–C6 degenerative cervical spondylosis was treated with C4–C6 ACDF with three Zero-P VA system. The X-ray after 12 weeks demonstrated loosening of the C5–C6 upward screw (black arrow) and prosthesis subsidence in C5–C6 (white arrow).

Thus, a total of 63 patients were finally included — 29 men and 34 women. The mean age was  $57.9 \pm 10.8$  (range 31–79) years. The average period between diagnosis and operation was 6.6 months.

There were 22 patients with prosthesis subsidence (34.9%) and 47 with screw loosening (74.6%), both rather high compared with published data on the CP system. The mean segmental Cobb angles were  $15.6^\circ \pm 7.0^\circ$  immediately after surgery and  $11.2^\circ \pm 8.2^\circ$  at 12 weeks postsurgery. The average difference in Cobb S between immediately postsurgery and 12 weeks postsurgery was  $4.4^\circ \pm 4.5^\circ$ . For patients with screw loosening, the average difference in Cobb S was  $5.4^\circ \pm 4.5^\circ$ , much higher than the non-loosening cases ( $0.9^\circ \pm 2.2^\circ$ ;  $p=0.0009$ ). For patients with prosthesis subsidence, the average difference in Cobb S was  $7.9^\circ \pm 5.2^\circ$ , also much higher than the non-subsidence cases ( $2.5^\circ \pm 2.6^\circ$ ;  $p<0.0001$ ). Therefore, both screw loosening and prosthesis subsidence are related to the loss of sagittal lordosis (Table 1).

We further investigated if the screw-loosening rate and subsidence risk were affected by sex or age. The loosening rate was 69.0% in men and 79.4% in women, with no significant difference ( $p=0.394$ ). The average age in the non-loosening group was 55.3 years and in the loosening group 58.8 years, with no significant difference either ( $p=0.267$ ). The subsidence rate was 31.0% in men and 38.2% in women, with no significant difference ( $p=0.604$ ). The average age was 56.3 years in the non-subsidence group and 60.8 years in the subsidence group, with no significant difference ( $p=0.116$ ). Therefore, age and sex are related to the incidence of screw loosening or prosthesis subsidence.

Regarding the doubts about the stability of the Zero-P system, we also set out to determine if poor positioning of the screw/cage or just a stability defect in the Zero-P VA system were related to the screw-loosening, prosthesis-subsidence, and Cobb S angle-loss risks. Overall, poor positioning of the screw/cage rate amounted to 19%. The screw-loosening rate was 91.7% in patients with poor positioning of the screw/cage and 70.6% in patients with good positioning of the screw/cage, with no significant difference between the groups ( $p=0.267$ ). The subsidence rate was 50% in patients with poor positioning of the screw/cage and 31.4% in patients without poor positioning of the screw/cage, with no significant difference between the groups ( $p=0.314$ ). Therefore, the position of the screw/cage has no relationship with the incidence of screw loosening or prosthesis subsidence either. Most importantly, up to 46.8% of the patients with screw loosening also had prosthesis subsidence compared with 0 patients without screw loosening having prosthesis subsidence ( $p=0.0005$ ), which means that cage subsidence may be directly related to screw loosening (Table 2).

Furthermore, we explored if screw loosening and prosthesis subsidence were related to clinical outcomes. VAS and NDI scores were measured 3 months after surgery. We found that VAS scores of patients with prosthesis subsidence was much higher than those without ( $p=0.031$ ), but this difference was not found for patients with or without screw loosening ( $p=0.116$ ). NDI scores were much higher in patients regardless of screw loosening or subsidence. This means that both screw loosening and prosthesis subsidence can affect clinical outcomes after surgery (Table 3).

## Discussion

Prosthesis subsidence mostly occurs in the anterior part of the segment, thus resulting in loss of segmental lordosis and even kyphosis, which may induce degeneration in the adjacent segment or recurrence of symptoms like radiculopathy or myelopathy. A stable fixation is needed for reconstruction of the segment and to avoid prosthesis subsidence, especially for multilevel fusion, as long-segment fusion is an independent risk factor for prosthesis subsidence. For the Zero-P VA system or other anchored cage, controversy continues regarding the questionable segmental stability provided and its fixation strength in multilevel ACDF. For example, some studies have reported a higher incidence of subsidence of

**Table 1** Influence of screw loosening and prosthesis subsidence on segmental Cobb angle

Average difference in Cobb S from immediately after surgery to 12 weeks postsurgery (degrees)		
Patients with screw loosening	Patients without screw loosening	<i>p</i>
$5.4 \pm 4.5$	$0.9 \pm 2.2$	0.0009
Patients with prosthesis subsidence	Patients with prosthesis subsidence	<i>p</i>
$2.5 \pm 2.6$	$7.9 \pm 5.2$	<0.0001

**Table 2** Analysis of risk factors for subsidence

		Screw loosening		p	Subsidence risk		p
Sex	Male	20 (69.0%)		0.394	9 (31.0%)		0.604
	Female	27 (79.4%)			13 (38.2%)		
Age		With	Without	0.2674	With	Without	0.116
		58.8	55.3		60.8	56.3	
Position of the screw/cage	Poor (12 cases, 19%)	91.7%		0.267	50.0%		0.314
	Good (51 cases, 81%)	70.6%			31.4%		
Screw loosening	With				46.8%		0.0005
	Without				0		

**Table 3** Influence of screw loosening and prosthesis subsidence on clinical outcomes

	Screw loosening		p	Subsidence risk		p
VAS	With	Without	0.116	With	Without	0.023
	3.4±1.3	2.3±1.0		3.9±1.3	2.7±1.1	
NDI	With	Without	0.031	With	Without	<0.001
	38.2%±10.3%	16.3%±7.9%		44.7%±12.5%	23.5%±8.6%	

anchored cages than the CP system,<sup>14,15</sup> but other studies did not confirm this finding.<sup>16–18</sup> An important fact is that most of the previous studies depended on single-level cases. Few studies of two contiguous levels or more have been reported, and those multisegment cases were more sensitive to minor changes in stability. More importantly, most of these studies used the old Zero-P system with four screws, but nowadays, the new Zero-P VA system with only two screws is more widely used. Does the so-called similar or minor difference of the stability provided by the two Zero-P versions influence the fixation effect of the two contiguous segments? No such studies have been performed.

The reported rates of subsidence range from 0 to 42.5% with the use of different interbody-fusion devices after ACDF.<sup>19–24</sup> Further research has been performed looking at different numbers of surgical segments or different implants. Shibani et al demonstrated that subsidence rates varied from 25% for one-level to 27% for two-level and 15% for three-level stand-alone PEEK ACDF cage procedures.<sup>25</sup> Ng et al noted that for 31 patients undergoing two-level stand-alone PEEK ACDF, the subsidence rate was 22.5%, but it did not negatively impact JOA scores or fusion rates.<sup>26</sup> Nakanishi et al further found subsidence in 11 (17.7%) of 62 cases, which was moderate in 14.5%, but severe in 3.2% of cases in single- to two-level **stand-alone titanium-coated PEEK** cage procedures.<sup>27</sup> Previous studies also compared the subsidence rates of different implants and most importantly the CP and Zero-P systems, but controversial results were found. Dhir et al report that subsidence happened in all cases of Zero-P implantation. In another study, the subsidence incidence of Zero-P VA cage was 56% at 12 months after the surgery.<sup>28</sup> In a meta-analysis comparing seven different implants, the CP group presented the lowest incidence of subsidence, significantly lower than that in the Zero-P group.<sup>29</sup> On the contrary, Guo et al found that the incidence of screw loosening in the Zero-P group (3.66%) was significantly lower than that in the PC group (15.43%).<sup>7</sup> Many studies have found no statistically significant difference between Zero-P and PC groups based on postoperative fusion cage subsidence rate.<sup>7</sup> Here, we demonstrated that 74.6% two-level ACDF with Zero-P VA patients experienced screw loosening, and up to 46.8% of those (34.9% of total patients) also had prosthesis subsidence.



It is important to figure out why the screw-loosening and subsidence rates are so high in two-level ACDF with the Zero-P VA system. In this study, we found that screw-loosening and subsidence rates had no relationship with sex, age, or the position of the screw. Prosthesis subsidence represents a breaking through of intervertebral disc replacement into the trabecular bone of adjacent vertebral bodies with a consecutive decrease in the height of intervertebral space and thus loss of sagittal lordosis. Few studies depending on two-level ACDF with Zero-P are available, but investigations into implant subsidence after single-level ACDF are a research hotspot. Multiple risk factors, including bone quality, extent of preoperative intervertebral space distraction, poor positioning, material, size of the implant, awful vertebral endplate treatment, and implant fixated by means of a ventral plate,<sup>19,30–33</sup> have been reported. We firstly investigated the role of bone quality, especially osteoporosis. It is better to use BMD as an indicator of bone quality, but unfortunately there are insufficient data on BMD. As such, sex and age were selected instead due to their close relationship with bone quality. However, no relationship was found in the present study. A reason is that in this study, all patients were strictly selected, i.e., mostly young patients (few old patients with normal BMD) with no osteoporosis and no severe instability. Thus, bone quality was good across the patients and could not be responsible for the loosening and subsidence. Also, all the surgeons in this study were experienced spine specialists, so surgical procedures like prosthesis implantation and vertebral endplate treatment were performed well. As a result, surgical procedure-related risks of prosthesis subsidence were negligible, and the statistical analysis also found that screw-loosening/subsidence rates had no relationship with the position of the screw. Consequently, it seems a stability defect in the Zero-P VA system may be the reason for screw loosening and subsidence in two-level ACDF.

The Zero-P VA system consists of a stand-alone cage and two variable-angle screws. The fixation strength and immediate stability of the implant are somewhat questionable, especially for multilevel cases or adjacent ACDF of a fused segment. The screw-loosening rate was very high (74.6%) and up to 46.8% of the patients with screw loosening also had prosthesis subsidence. The high incidence of screw loosening indicated the high instability of the segments. A stability defect in the Zero-P VA system may be the chief culprit, e.g., the absence of a locking mechanism for the screws, the limited bonding strength of the plate and cage sections, and weak fixation strength due to the limited number of the screws.

There are some limitations of the present study. First of these is the small sample and study design. Randomized controlled trials with larger samples are more suitable and provide higher levels of evidence. Also, setting a control group based on the CP system would have made the study stronger. Secondly, X-rays were used for follow-up evaluation, perhaps biasing measurement of the parameters, so computed tomography scan would be preferable. Also, a long-term follow-up is needed to explore the final subsidence and fusion rates. Thirdly, no biomechanical analysis was conducted, so the conclusion that a stability defect in the Zero-P VA system may be the chief culprit was just a supposition. Finally, there were insufficient clinical outcomes and a short follow-up period. The effect of screw loosening and prosthesis subsidence should be much clearer and thus guide applications in the clinic.

## Conclusion

Screw loosening and prosthesis subsidence happen frequently after contiguous two-level ACDF with the Zero-P VA. Screw loosening seems to be the only risk factor for prosthesis subsidence.

## Ethics Approval

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of Ruijin Hospital. Written informed consent was obtained from all participants.

## Consent to Publish

The authors affirm that human research participants provided informed consent for publication of the images.

## Disclosure

The authors declare that they have no conflicts of interest.

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