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Original Article

Comparison of anterior cervical discectomy and fusion with the zero-profile implant and cage-plate implant in treating two-level degenerative cervical spondylosis

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Abstract: Previous studies based on small sample sizes have reported the application of the Zero-P implant (Zero-P, Synthes GmbH, Switzerland) in single anterior cervical discectomy and fusion (ACDF) surgery with excellent outcomes. However, the safety and effectiveness of two-level ACDF with Zero-P implant still remains controversial. A retrospective study was conducted to compare the clinical outcomes and complications between Zero-P implant and conventional cage-plate implant in two-level ACDF for the treatment of degenerative cervical spondylosis. The Japanese Orthopedic Association (JOA) scale score, neck and arm visual analog scale (VAS), bony fusion rates and main complications were recorded. Dysphagia was evaluated according to the Bazaz grading system. A total of 67 consecutive patients in Zero-P group and 72 consecutive patients in Plate group were enrolled in this retrospective study. The total incidence of dysphagia in Zero-P group and Plate group were 40.00% and 55.56% at one week, respectively. Similar improvements were observed in the JOA and VAS pain scores in both groups at the final follow-up (P>0.05). There were no significant difference between two groups concerning other complications such as postoperative hematoma, recurrent laryngeal nerve palsy, cerebrospinal fluid leakage and pseudarthrosis. The Zero-P implant and the traditional titanium plate with cage are both effective treatments for two-level degenerative cervical spondylosis, but the Zero-P implant has a lower dysphagia incidence. Future prospective, randomized and controlled studies with larger sample size are needed.

Keywords: ACDF, Zero-P, degenerative cervical spondylosis, plate, anterior cervical discectomy and fusion

Introduction

Anterior cervical discectomy and fusion (ACDF) has been regarded as the gold-standard procedure in the treatment of degenerative cervical spondylosis for several decades [1, 2]. At first simple discectomy and fusion with iliac bone graft was performed and then intervertebral cages with or without an additional anterior cervical plate were widely applied in ACDF procedure. Anterior cervical plate can significantly increase interbody fusion rates compared ACDF without additional anterior cervical plate [3, 4]. In addition, anterior cervical plate can also increase cervical stability and maintain or ameliorate cervical sagittal alignment [5, 6]. However, previous studies have also reported that anterior cervical plate may increase some other complications such as increased dysphagia rates, perforation of esophagus, plate malposition, tracheoesophageal lesions, and accelerated adjacent disc degeneration [7-9].

In order to reduce the complications associated with traditional cervical anterior plate and maintain the advantages of traditional cervical anterior plate, a new zero-profile, stand-alone device (Zero-P, Synthes GmbH, Switzerland) for ACDF has been introduced in recent years [10-13]. Previous studies based on small sample sizes have reported the application of the Zero-P in single ACDF surgery with excellent clinical and radiographic outcomes [11, 14-16]. However, two-level ACDF with Zero-P has been little reported. The biomechanical stability and fusion rates of two-level ACDF with the Zero-P remains unknown. Results from a biomechanical 3-dimensional spine test showed that segmental sta-

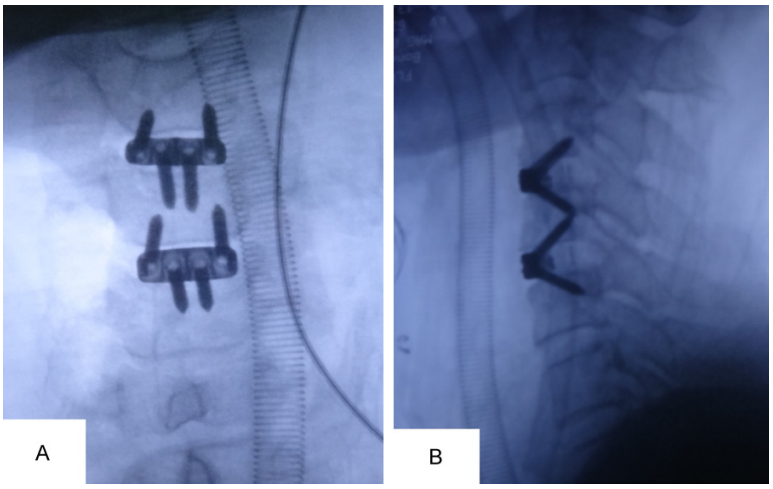

Figure 1. Intraoperative anteroposterior, lateral X-rays of two-level anterior cervical discectomy and fusion using the Zero-P implant.

Table 1. The Bazaz grading system

Severity	Liquid	Solid
0-None	None	None
1-Mild	None	Rare
2-Moderate	None or rare	Occasionally
3-Severe	None or rare	Frequent

bility decreases with the number of instrumented segments regardless of the used implant, but the locking plate and cage construct was stiffer in all test modes than the Zero-P devices in multilevel constructs [17]. However, whether this difference will have an impact on the clinical outcomes and fusion rates still remain unclear. A retrospective study was conducted in our hospital aimed to compare the clinical outcomes with radiographic data and complications between Zero-P implant and conventional cage-plate implant in two-level ACDF for the treatment of degenerative cervical spondylosis. To the best of our knowledge, this is the largest sample size with the longest available follow-up duration study concerning Zero-P and cage-plate implants in two-level ACDF in the literature.

Materials and methods

Patient inclusion and exclusion criteria

The current retrospective study was approved by Medical Ethical Committee of West China Hospital, Sichuan University. All of the patients provided informed consent for the analysis of their clinical data. All of the enrolled patients were treated and followed-up at the West China Hospital, Sichuan University in Chengdu city, China.

A total of 67 consecutive patients who underwent two-level ACDF using Zero-P implant (Zero-P group) and 72 consecutive patients who underwent two-level ACDF using conventional cage-plate implant (Plate group) between December 2011 and November 2014 were enrolled in this retrospective study. All patients operated on two-level ACDF during this period were included if they meet the following inclusion criteria: (1) signs and symptoms of degenerative cervical spondylosis which was unresponsive to conservative treatment more than six months; (2) two level degenerative cervical spondylosis confirmed by imaging such as computed tomography (CT) scan and magnetic resonance imaging (MRI); (3) age >18 years and (4) complete and continuous clinical and imaging data. Exclusion criteria consisted of severe osteoporosis of the cervical spine, presence of active infections, pathologic fractures of the vertebrae, patients with spinal deformity, ankylosing spondylitis or rheumatoid arthritis, continuous or combined ossification of the posterior longitudinal ligament (OPLL), developmental stenosis, patients who underwent ACDF not using an anterior plate or Zero-P device, and patients suffering from acute or chronic serious diseases which might increase the perioperative risk.

Surgical technique

All surgeries were performed via a classic right Smith-Robinson approach after induction of general anesthesia in a supine position [18]. With the help of fluoroscopy and metal markers, a horizontal right side skin incision was determined. The intervertebral disc and herniated nucleus pulpous were extirpated and then the posterior longitudinal ligament and along with osteophytes were resected. The subchondral endplate of each vertebral body was prepared with a high speed drill and curette while

Table 2. Patient demographic and baseline data for two groups

Group	Zero-P Group (N=60)	Plate Group (N=63)	P
Age (y): Mean SD	47.90±8.84	48.03±8.46	0.185
Gender (Female/Male)	24/36	28/35	0.618
JOA	9.6±2.1	9.4±2.2	0.351
VAS for neck	7.27±2.23	7.33±2.54	0.139
VAS for arm	7.18±2.04	7.31±2.29	0.125
Intraoperative time (min)	165.50±19.81	166.89±25.32	0.235
Estimated blood loss (ml)	100.59±39.35	108.49±34.23	0.156
Length of hospital stay (d)	12.44±4.19	12.78±3.56	0.129

Data were shown as mean ± SD.

the bony endplate was preserved as much as possible to prevent implant subsidence. After complete decompression and preparation of the endplate, the disc space was distracted and a trial implant of appropriate size was inserted under image control. Then appropriate Zero-P implant or cage filled with composite synthetic bone graft (β-tricalcium-phosphate) was implanted into intervertebral space. Lateral and anterior-posterior fluoroscopic images were performed and the correct position of the implant was adjusted. In Zero-P group, four locking screws were inserted using torque limitation after preparing the pilot hole oriented through the aiming device (**Figure 1**). In Plate group, the appropriate anterior plate was paced and adjusted with the help of fluoroscopic images. Similarly locking screws were inserted using torque limitation after preparing the pilot hole and the plate was implanted. Hemostasis is rechecked, and the skin was sutured subcutaneously. All the patients were obeyed to wear a cervical collar postoperatively for 12 weeks.

Clinical and radiographic evaluations

Charts and medical records of all patients were reviewed. The following data for each patient including age, gender, intraoperative time, estimated blood loss, length of hospital stay, operated levels, and kinds of instrumentation. Plain radiographs (including flexion/extension views) and MRI were performed before surgery. Neurological examination and functional assessment were recorded at 1, 3, 6, 12 and 24 months and at the latest follow-up assessment. The neurologic status was assessed using the Japanese Orthopedic Association (JOA) scale score. Neck and arm pain was evaluated using the 10-point visual analog scale (VAS). Dysphagia was evaluated according to the Bazaz grading system [19] which was widely used by many spinal surgeons (0-None; 1-Mild; 2-Moderate; 3-Severe; as listed in **Table 1**). The standard definition: evidence of continuous bridging bone between the adjacent endplates of the involved motion segment, radiolucent lines at 50% or less of the graft-vertebra interfaces in CT scan, and 2° or less of segmental rotation on lateral flexion/extension radiographs, was used for fusion evaluation [20]. Implant failure, including screw loosening or breakage was recorded. Screw loosening was defined as an initial halo sign, followed by a double halo sign on later plain radiographs or CT scans [21].

Statistical analysis

The data were analyzed using the Chi-square test, Student t-test and Mann-Whitney U test, when appropriate. The statistical program SPSS version 19.0 (SPSS Inc. for windows) was used for all statistical analysis. *P*-values of less than 0.05 were accepted as significant.

Results

The Zero-P group included 67 consecutive patients with a mean age of 47.90 years and a mean follow-up duration of 3 years. The Plate group included 72 consecutive patients with a mean age of 48.03 years and a mean follow-up duration of 3 years. There were seven patients in the Zero-P group and nine patients in the Plate group did not complete the final follow-up and these patients were excluded from the final analyses. The results are based on 60 patients in the Zero-P group and 63 patients in the Plate group. The Zero-P group had a mean intraoperative blood loss of 100.59±39.35 ml, a mean intraoperative time of 165.50±19.81 minutes and a mean length of hospital stay of 12.44±4.19 days. The Plate group had a mean intraoperative blood loss of 108.49±34.23 ml, a mean intraoperative time of 166.89±25.32 minutes and a mean length of hospital stay of 12.78±3.56 days. There were no significant difference between two groups concerning age, gender, VAS for neck, VAS for arm and JOA scores before surgery (all, P>0.05) as shown in **Table**

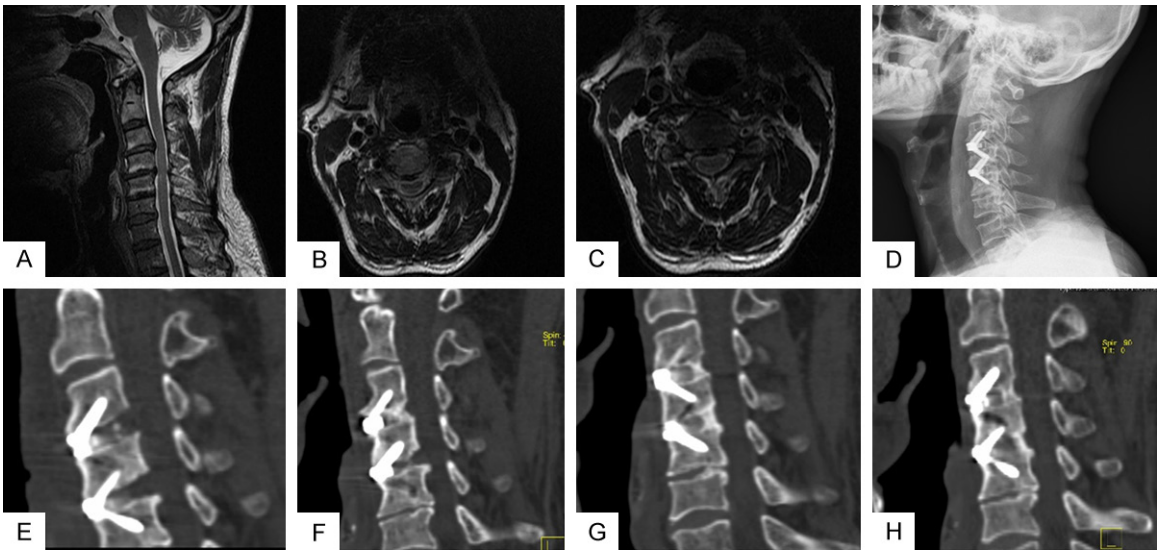

Figure 2. A 70-year-old male patient was operated on two-level anterior cervical discectomy and fusion using the Zero-P implant at segment of C3/4 and C4/5 because of herniation of intervertebral discs (A-C), one week post-operative X-rays and CT scan showed the good position of the implants (D, E), six months postoperative CT scan showed bony fusion at C3/4 but not at C4/5 (F), 12 months postoperative (G) and 18 months postoperative (H) CT scan showed bony fusion at C3/4 and C4/5.

2. The JOA and VAS pain scores in two groups were significantly improved after surgery (all, $P<0.05$). Similar improvements were observed in the JOA and VAS pain scores in both groups at the final follow-up ($P>0.05$). The zero-p group had a lower fusion rates at the 3, 6 months follow-up, but the fusion rates were found to be similar and satisfying in two groups at the 12 months follow-up and at the final follow-up (**Figure 2**). There were three patients in the Zero-P group and four patients in the Plate group did not reach bony fusion according to the standard definition listed above (**Figure 3**). Radiographic and clinical outcomes at the final follow-up between the two groups are listed in **Table 3**.

The total incidence of dysphagia in Zero-P groups was 40.00% at one week, 23.33% at one month, 18.33% at three months, 10.00% at six months, 8.33% at 12 months and 5.00% at the latest follow-up. The total incidence of dysphagia in Plate group was 55.56% at one week, 46.03% at one month, 33.33% at three months, 25.40% at six months, 17.46% at 12 months and 15.87% at the latest follow-up. The incidences of dysphagia for two groups are listed in detail in **Table 4**. There were no wound infection, esophageal perforation, instrumentation failure, nerve root injury, pulmonary embolism, perioperative cardiac event or other serious complications in two study groups. For other post-operative complications such as postoperative hematoma, recurrent laryngeal nerve palsy, cerebrospinal fluid leakage and pseudarthrosis, there were no significant difference between two groups (**Table 5**; all, $P>0.05$).

Discussion

ACDF for the treatment of degenerative cervical spondylosis has been introduced as a classical spinal procedure more than 60 years. Aimed to increase the immediate postoperative stability after bone grafting, avoid long time plaster immobilization and increase the fusion rates, anterior plate was developed in recent decades. However, the necessity and selectivity for additional instrumentation after decompression still remain controversial. Anterior cervical plate have been reported to reduce the incidence of the cage subsidence and displacement and increase the fusion rates but have also been reported to be associated with some relative complications and disadvantages. In order to overcome the disadvantages and limitations but maintain the advantages of anterior cervical plate, a new zero-profile, stand-alone device (Zero-P, Synthes GmbH, Switzerland) for ACDF has been developed in recent years and it has

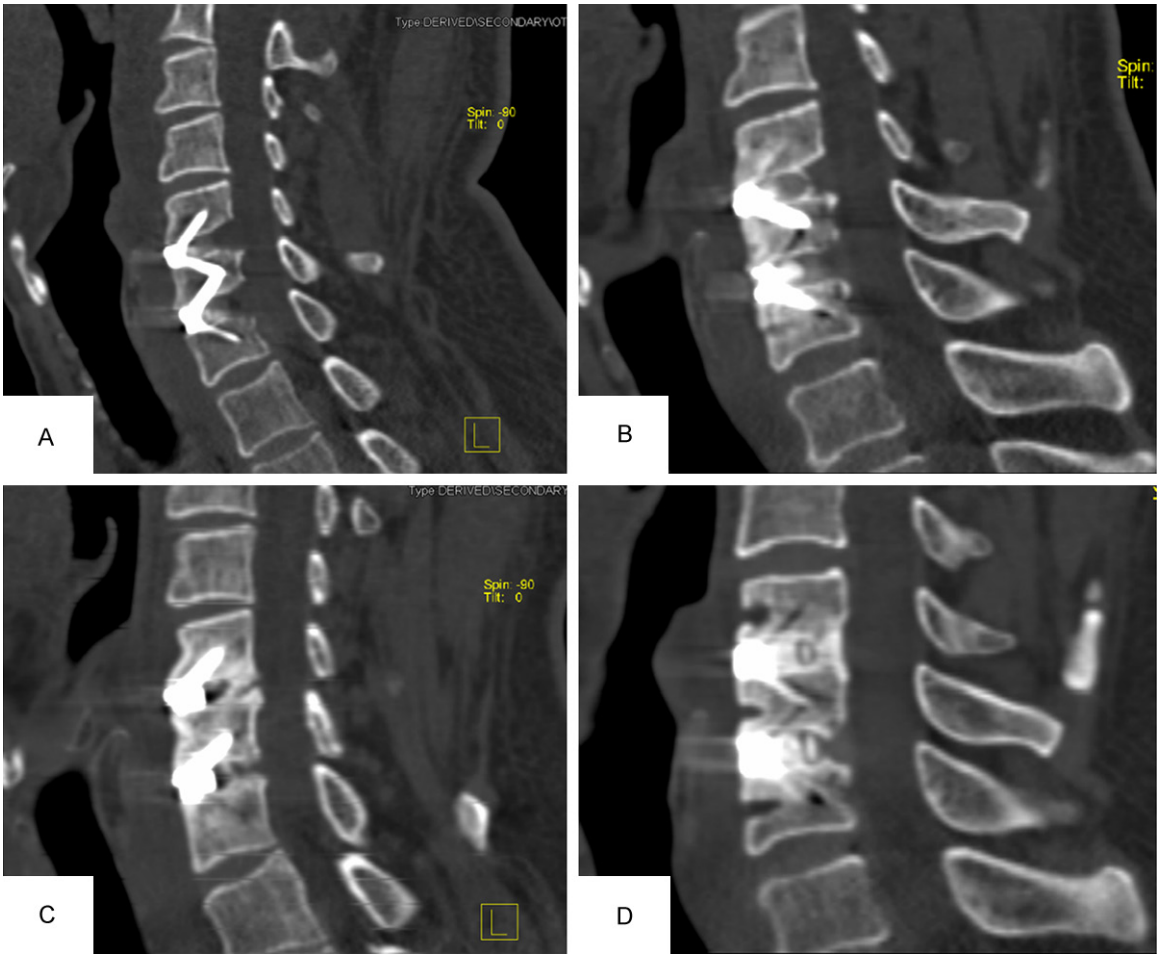

Figure 3. A 53-year-old female patient was operated on two-level anterior cervical discectomy and fusion using the Zero-P implant at segment of C5/6 and C6/7, one week postoperative CT scan showed the good position of the implant (A), 3 months postoperative showed no evidence of bony fusion (B), 6 months postoperative CT scan showed bony fusion at C5/6 but not C6/7 (C), 12 months postoperative CT scan showed bony fusion at C5/6 and C6/7 (D).

Table 3. Radiographic and clinical outcomes at the final follow-up

	Zero-P group (N=60)	Plate group (N=63)	P
JOA	14.5±1.1	14.6±1.2	0.381
VAS for neck	1.37±0.53	1.33±0.39	0.259
VAS for arm	1.18±0.41	1.25±0.44	0.287
Fusion rate	95.00%	93.65%	0.748

Data were shown as mean ± SD.

been also widely reported in previous studies in single level ACDF with excellent clinical outcomes. Results from a biomechanical 3-dimensional spine test showed that segmental stability decreases with the number of instrumented segments. So the safety and validity of two-level ACDF using Zero-P implant remains unclear. Aimed to compare the clinical outcomes with radiographic data and complications between Zero-P implant and conventional cage-plate implant in two-level ACDF for the treatment of degenerative cervical spondylosis, we conducted this retrospective study.

In this study, we observed that the overall clinical and radiographic results were similar in two groups. Three months after surgery the neck pain and arm pain VAS score in both groups were significantly decreased compared with preoperative VAS score. Previous studies have reported the rate of postoperative transient dysphagia following ACDF ranges from 2% to 67% [19, 22, 23]. Similarly the results from our study also indicated that the patients in Plate group had a much higher incidence of dyspha-

Table 4. The incidences of dysphagia for two-level ACDF using Zero-P and cage-plate

	Zero-P group (N=60)					Plate group (N=63)					
Time	None	Mild	Moderate	Severe	Total incidence	None	Mild	Moderate	Severe	Total incidence	P#
One week	36	18	5	1	40.00%	28	20	9	6	55.56%	0.035
One month	46	10	4	0	23.33%	34	18	7	4	46.03%	0.006
Three months	49	9	2	0	18.33%	42	12	6	3	33.33%	0.038
Six months	54	5	1	0	10.00%	47	10	4	2	25.40%	0.022
One year	55	4	1	0	8.33%	52	7	3	1	17.46%	0.003
The final follow-up	57	3	0	0	5.00%	53	7	2	1	15.87%	0.046

#Mann-Whitney U test.

Table 5. Postoperative complications of two-level ACDF using Zero-P and cage-plate

	Zero-P group (N=60)	Plate group (N=63)	P
Postoperative hematoma	1	3	0.333
Wound Infection	0	0	NA
Recurrent Laryngeal Nerve Palsy	1	2	0.589
Cerebrospinal fluid leakage	1	2	0.589
Esophageal Perforation	0	0	NA
Instrumentation Failure	0	0	NA
Pseudarthrosis	3	4	0.748

gia compared to patients in Zero-P group at each follow-up. Most of the dysphagia in two groups was found to be mild and gradually decreased in the following three months. Moderate or severe dysphagia was not common in two groups. However, in this study there were still 5% patients in Zero-P group and 15.87% patients in Plate group suffering from dysphagia at the latest follow-up. Lee *et al*. has demonstrated that design and thickness of anterior plates has an impact on postoperative dysphagia incidence [24]. Anterior plating is associated with higher rates of postoperative dysphagia in ACDF surgery [25, 26]. The Zero-P implant may decrease the incidence of dysphagia as it avoid the direct impinging as the anterior cervical locking plate is placed directly posterior to the esophagus [10, 27]. However, the exact pathophysiologic mechanism of dysphagia remains unknown, and the dysphagia is often regarded as a multi-factor result. Plate thickness or a zero-profile device is just one of the multiple factors which influence the incidence of post-operative dysphagia.

In our study, we also found an excellent fusion rate with good stability. The zero-p group had a lower fusion rates at 3, 6 months after surgery, but the fusion rates were also similar and satisfying in two groups at 12 months after surgery and at the final follow-up. The self-locking devices were reported to ensure excellent primary temporary stability of the implant and promote early bony fusion. In addition, the elastic modulus of the anchored cage is similar to that of bone, which theoretically helps to decrease stress shielding and increase bony fusion [11]. Of course, surgical techniques that include optimal preparation of the fusion bed and proper disc space distraction may also have an impact on fusion rate. There were no wound infection, esophageal perforation, instrumentation failure, nerve root injury, pulmonary embolism, perioperative cardiac event or other serious complications in two study groups. For other post-operative complications such as postoperative hematoma, recurrent laryngeal nerve palsy, cerebrospinal fluid leakage and pseudarthrosis, there were no significant difference between two groups. However, there are also some limitations in our study. First, the design of the study is a retrospective study. In addition, only 123 consecutive patients were included in this study. Thus, future prospective, randomized, controlled studies with larger sample size are needed.

In conclusion, the results of this study do not show significant differences between Zero-P implant and the traditional titanium plate with cage for degenerative cervical spondylosis in terms of improvement in JOA scores, VAS pain scores, fusion rate, and main complications. The Zero-P implant and the traditional titanium plate with cage are both effective treatments

for two-level degenerative cervical spondylosis, but the Zero-P implant was associated with a lower dysphagia incidence. Future prospective, randomized, controlled studies with larger sample size are needed.

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Disclosure of conflict of interest

None.

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