Effectiveness comparison of Zero-profile interbody fusion implant and anterior cervical plate interbody fusion device: a clinical and radiological study

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Abstract

Purpose This study was to compare the clinical outcomes, radiographic parameters, and complications of anterior cervical discectomy and fusion (ACDF) with a Zero-profile implant (Zero-P) and traditional plate and cage. **Methods** There were 68 patients received ACDF of single level, 35 patients with Zero-profile implant (Zero-p group) and 33 patients with traditional plate and cage (Cage group), from C3–C7 during 2014 to 2016. Collecting and analyzing of clinical and radiological data were performed. Patients were followed-up at least 1 year after surgery. The operation time, blood loss, Japan Department of Orthopedics Association (JOA) score, pain Visual Analogue Score (VAS), Neck Disability Index (NDI) score and dysphagia score were recorded. Additionally, changes in cervical lordosis, fusion rate and adjacent segment degeneration were analyzed as well. **Results** For neurologic outcomes, the JOA, VAS and NDI were statistically equivalent between the two groups ($P>0.05$). For radiographic outcomes, there were no significant differences in the C2-7 Cobb angles, segmental Cobb angle and incidence of subsidence at the final follow-up ($P>0.05$). No degenerative changes was found in the Zero-p group, whereas 5 patients in the Cage group developed degeneration in adjacent segments ($P<0.05$). Also, the incidence of postoperative dysphagia is higher in Cage group than in Zero-p group at 3 months and 12 months ($P<0.05$). **Conclusions** Both Zero-profile implant and anterior cervical plate interbody fusion device were demonstrated to be effective and safe strategies in this study. Considering the lower incidences of dysphagia and degenerative changes, the Zero-profile implant is a good succedaneum.

Introduction

The cervical spondylosis is a neurological disease resulted from the stimulation or compression of adjacent spinal cord as a result of degenerative changes in the cervical spine. Symptoms include neck and arm pain associated with radiculopathy or myelopathy [16, 23, 31]. According to a correlating clinical symptoms and the evidence of root or spinal cord compression from recent radiological examination, the surgical intervention is indicated as below: 1. clinical symptoms are severe and progressive, which effect patients' normal life a lot; 2. conservative treatment is not effective [28]. As a golden standard, anterior cervical discectomy and fusion (ACDF) has been widely introduced in patients with cervical spondylosis disease since the 1950s. Some studies have suggested that the ACDF with cervical plates and intervertebral cages brings more satisfying fusion rates and a lower occurrence of failure [26], but a higher incidence of plate-associated complications such as postoperative dysphagia [3, 12, 24].

To prevent the issues, zero profile anchored spacer (Zero-P) has been advocated by some researchers (Synthes, Zuchwil, Switzerland). The advantage of Zero-P is likely to supply immediate stability. Moreover, it has been widely reported to be a promising strategy in reducing the occurrence of postoperative dysphagia [2, 25, 30]. The purpose of our study is to compare the clinical outcomes and radiologic results of patients receiving the Zero-P spacer with those using titanium plate and cage implants.

Materials And Methods

Patients:

A total of 68 patients were enrolled in this study from 2016 to 2018. The criterion for enrolling is that: 1. Patients have the symptoms of the cervical spondylosis. 2. Symptoms have had a deep influence on the normal life. 3. Symptoms are severe and progressive. 4. It's ineffective for at least 3 months conservative treatment. 5. The indication for surgery was according to the clinical symptoms correlated with recent radiological evidence of root or spinal cord compression.

Single level ACDF were performed for all patients. 33 operations were performed with a traditional plate and cage (Cage group), and the others were treated with Zero-P (Zero-P group). The indication of performing ACDF for these patients was the same and the device used in the operation was selected randomly.

Clinical outcomes

The data about surgical procedure (operation time, intraoperative blood loss) were recorded. All of the patients completed the questionnaires of JOA, VAS and NDI before the operation, 3 months and 12 months postoperatively. Additionally, complications were recorded, such as dysphagia, the looseness and pulling away of screws, and adjacent segment degeneration. The presence of dysphagia was assessed using the system designed by Bazaz [3] at 1 week, 3 months and 12 months postoperatively (Table 1).

Table 1
Bazaz grading system for dysphagia

Symptom severity	Liquid food	Solid food
None	None	None
Mild	None	Rare
Moderate	None or rare	Occasionally (only with specific food)
Severe	None or rare	Frequent (majority of solids)

Radiographic evaluations

The CT and MRI examinations were performed before the operation for all patients. Anteroposterior and lateral X-rays with the neck in neutral position, flexion and extension X-rays were taken before the operation and 1 week, 3 months and 12 months postoperatively.

Cervical alignment (Cobb C) was calculated by the Cobb angle between the lines perpendicular to the upper planes of the C2 vertebral body and the lower plane of the C7 vertebral body. The segmental angle (Cobb S) was evaluated with the angle between the lines perpendicular to the superior margin of the cranial vertebral body and the inferior margin of the caudal vertebral body involved in the operation level (Fig. 1). The Cobb C and Cobb S were obtained at preoperative, 3 months postoperative and final follow-up to evaluate the aggravation of kyphosis [5].

The criteria of bone fusion was defined as: 1. less than 10-degree movement on lateral flexion/extension views; 2. presence of trabecular bridging across the bone-graft interface; 3. less than 50% radiolucency in the perimeter surrounding the cage; and 4. no evidence of pullout of the device [5].

The total interbody height (TIH) of segmental level was measured preoperatively, 3 months postoperative, and at the final follow-up assessment to assess the subsidence of implants [14]. TIH was identified as the length from the midpoint of the upper end plate of the cranial vertebral body to the lower end plate of the caudal vertebral body on lateral X-ray views (Fig. 1). The occurrence of subsidence was defined as TIH in final assessment decreased > 2 mm from that 1 week postoperative on lateral X-ray views. Additionally, we also recorded the number of patients with bony spurs' formation, which is the indication of degenerative changes of the adjacent segment (Fig. 2).

Statistical analysis

The data was analyzed with SPSS for Windows Version 24.0 and expressed as means $\pm$ standard deviation. The quantitative data was analyzed by U-test. The qualitative data was analyzed by the Chi-square test. The P value < 0.05 was considered statistically significant.

Results

Surgical Details

Through the comparison, the difference of the age, gender, surgical level between the two groups were not significantly different ($P > 0.05$). The operative time and blood loss in the two groups were as showed in the Table 1. Though the mean operative time and mean blood loss in the Zero-p group was less slightly, obvious difference was observed only for operative time ($P < 0.05$) (Table 2).

Table 2
Demographic and Surgical Data

	Cage	Zero-p	P value
Patients number	33	35	
Sex(male/female)	17/16	20/15	0.641
Age	47.8 ± 11.0	49.6 ± 9.1	0.583
Surgical sites			0.809
C3-4	4	2	
C4-5	3	5	
C5-6	24	26	
C6-7	2	2	
Operation time(min)	162.0 ± 34.1	141.9 ± 23.9	0.006
Blood loss	30.8 ± 72.2	67.9 ± 95.6	0.280
Cage, the conventional cage-plate group; Zero-p, the Zero-p group.			

Clinical Outcome and Complications

The postoperative JOA, VAS and NDI at 3months, 12months postoperative were higher than their respective preoperative data in both groups, and the difference was different obviously ($P < 0.05$). Between the two groups, significant difference was not found for JOA, NDI and VAS at the every follow-up respectively ($P > 0.05$) but the JOA score at 12months postoperative ($P < 0.05$) (Table 3).

Table 3
Clinical outcomes

	Cage	Zero-p	P value
JOA			
Preoperative	12.46 ± 1.61	12.07 ± 2.34	0.830
Postoperative 3 months	14.62 ± 0.87	14.79 ± 1.48	0.375
Postoperative 12 months	15.61 ± 0.97	15.97 ± 0.86	0.103
NDI			
Preoperative	14.69 ± 7.543	16.00 ± 9.013	1.000
Postoperative 3 months	6.69 ± 4.922	4.00 ± 7.863	0.943
Postoperative 12 months	6.23 ± 5.862	4.43 ± 5.185	0.302
VAS			
Preoperative	5.31 ± 3.146	5.43 ± 3.251	0.981
Postoperative 3 months	2.23 ± 2.127	1.79 ± 2.293	0.650
Postoperative 12 months	1.38 ± 2.103	0.64 ± 1.216	0.402
Dysphagia			
Postoperative 1 week	7/33(21.2%)	5/35(14.3%)	0.453
Postoperative 3 months	6/33(18.2%)	1/35(2.3%)	0.038
Postoperative 12 months	4/33(12.1%)	0/35(0%)	0.034

At 1 week postoperatively, five patients in Zero-p group complained mild dysphagia and seven patients in Cage group complained mild (n = 6) or moderate (n = 1) dysphagia (P > 0.05). At the 3 month postoperatively, only one patient in Zero-p group still had mild dysphagia, which had been resolved completely by 12 months. In Cage group, six and four patients still had mild dysphagia at 3 and 12 months postoperatively respectively (Table 3). The occurrence of dysphagia was different significantly between the two groups 3 months and 12 months postoperatively (p < 0.05).

Radiographic Outcome

Compared with the preoperative value, the value of Cobb C and Cobb S was improved for both groups at the 3 months and 12 months postoperatively (P < 0.05). In Cage group, the Cobb C was 13.91 ± 4.43 at the 3-month postoperative, which was decreased to 11.40 ± 3.19 at the final follow-up. Meanwhile, Cobb C was 14.25 ± 3.56 and 12.30 ± 2.86 in the Zero-P group at the 3-month and final follow-up, respectively. Similarly, the Cobb S for the Cage group decreased from 7.08 ± 2.36 3 months after the operation to

postoperative assessment to 6.68 ± 2.65 at the final follow-up. In the Zero P group, Cobb S increased from 6.11 ± 2.27 at the 3-month postoperative assessment to 7.19 ± 1.74 at the final follow-up assessment. No significant difference was observed between two groups for both Cobb C and Cobb S at any time after surgery (Table 4).

Table 4
Radiographic outcomes

	Cage	Zero-p	P value
Cobb C (°)			
Preoperative	8.52 ± 3.16	9.15 ± 2.23	0.241
Postoperative 3 months	13.91 ± 4.43	14.25 ± 3.56	0.443
Postoperative 12 months	11.40 ± 3.19	12.30 ± 2.86	0.229
Cobb S (°)			
Preoperative	3.98 ± 1.49	3.50 ± 1.48	0.191
Postoperative 3 months	6.68 ± 2.65	6.11 ± 2.27	0.418
Postoperative 12 months	7.08 ± 2.36	7.19 ± 1.74	0.902
TIH (cm)			
Preoperative	3.18 ± 0.22	3.11 ± 0.19	0.466
Postoperative 3 months	3.45 ± 0.36	3.47 ± 0.26	0.180
Postoperative 12 months	3.31 ± 0.22	3.30 ± 0.19	0.141

Regarding the extent of TIH, the two groups had a significant increase of the distance between the vertebral bodies at 3months after surgery ($P < 0.05$). Through the observation of TIH, subsidence occurred in five patients of the Cage group and four patients of the Zero-p group at final follow-up. The occurrence rate about subsidence was not significantly different between the groups ($P > 0.05$) (Table 5).

Table 5
Radiological outcomes of Fusion rate, Subsidence and Bony spurs

	Cage	Zero-p	P value
Subsidence	5(15.2%)	4(11.4%)	0.651
Fusion (yes/no)(%)	32/1(97.0%)	35/0(100%)	0.299
Bony spurs (yes/no)(%)	4/29(12.1%)	0/35(0%)	0.034

In the follow-up, we didn't observe loosening and pulling away of screws. Bone fusion was found in 97% and 100% of the Cage group and the Zero-P group, respectively. No significant difference was detected about the fusion rate between two groups ($P > 0.05$) (Table 5).

The number of patients with bony spurs was four in Cage group and none in the Zero-p group, respectively (Fig. 2). The incidence of bony spurs was different significantly between the two groups ($P < 0.05$). Moreover, there was one patient formed a new cervical disc herniation with the evidence of MRI.

Discussion

ACDF is the standard surgical treatment for cervical spondylosis when conservative treatment failed [18]. With increasing experience, number of reports had authenticated the effectiveness of additional plate to treat degenerative spine disorders [9, 26, 27]. It was demonstrated that plate benefited the higher fusion rate and immediate postoperative stability, and decreased the occurrence of pseudarthrosis [1, 4]. It also prevented interbody cage dislocation and subsidence, which might occur after multilevel procedures [22]. Despite this treatment was widely accepted, it also had a number of drawbacks, one of which was dysphagia postoperatively [7, 11, 21].

Chronic dysphagia is a common complication of ACDF. It was reported that the incidence of this complication varied from 3% up to 21% [3, 13, 17, 25]. There are several potential reasons for dysphagia, such as soft tissue swelling, hematoma, esophageal injury, and adhesion formation around implanted cervical plates [8]. Additionally, adjacent segment degeneration is other complication accompanying with the implant of plate [15]. To solve these problems, stand-alone cages were introduced to be an alternative choice and it was proved to bring satisfying outcomes [21, 29]. However, stand-alone cages had a relatively high incidence of implant subsidence with secondary kyphotic deformity, which might lead to adjacent cervical segment disease in the long term [10]. Therefore, cage screw devices that can provide immediate biomechanical stability, as anterior cervical plates, have been developed (e.g., Zero-P by DePuy Synthes).

An integral part of the Zero-P spacer is a plate and screw system, eliminating the basic disadvantage of stand-alone cages, which is extension instability [14, 19, 21]. It was reported that either the Zero-P spacer or traditional titanium plate with cage has satisfying effect to improve the symptoms of cervical degeneration disease. However, less dysphagia was observed in the Zero-P group [30]. Additionally, it was inferred that utilization of the Zero-P spacer could decrease adjacent level spondylosis, potential mechanism of which was the less stress to adjacent level conveyed by Zero-P device. Similar conclusion was obtained in other studies [25, 30]. In this study, we also find the incidence of dysphagia in the zero-p group was lower than that in cage group at 3months and 12 months after surgery ($P < 0.05$). From all, we concluded that the zero-p can take a lower incidence of dysphasia.

Referring the clinical effectiveness appraised by JOA, VAS and NDI, both groups had a significant improvement in the respect of neurological function and symptom. The symptoms of cervical spondylosis are due to the stimulation or compression of the degenerative intervertebral disc. The

degenerative disc was removed thoroughly in both two groups. Thus, either the Zero-p or traditional plate and cage can contribute good clinical outcomes.

Adjacent segment degeneration (ASD) was confirmed when the adjacent intervertebral space developed a reduction of height, instability, or osteophyte formation. Cervical fusion results in increased stress on adjacent segments [6, 20]. Additionally, application of anterior plate results in irritation of the adjacent segment, leading to formation of bony spurs and degenerative changes [32]. Through the observation of lateral X-ray, there were none patient in zero-p group while 4 patients in cage group had bony spurs at final follow-up in this study. The difference is significant ($P < 0.05$). Moreover, one patient formed new cervical disc herniation in cage group after 12 months.

Conclusions

The results of this study showed a good result for both zero-p implant and traditional titanium plate with cage for cervical degenerative disc disease in terms of improvement in clinical outcomes (JOA scores, VAS scores, NDI scores, fusion rate) and correction of Cobb C and Cobb S. We concluded that either zero-p implant or the traditional titanium plate with cage was an effective treatment for single level cervical spondylosis. However, the incidence of adjacent segments degeneration and dysphagia are lower in zero-p group. In addition, the zero-p implant is associated with shorter operation time and relatively greater simplicity than the traditional titanium plate with cage. Therefore, the zero-p implant is a good succedaneum for traditional titanium plate with cage. However, a prospective trial with more patients and longer follow-ups are required to confirm these observations.

Declarations

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Availability of data and materials

The authors can not share the raw data and materials.

Authors' contributions

JZ, a resident, contributed to data analysis. XT, a senior radiologist, contributed to data collection. WX, a senior surgeon, contributed to data analysis. HW and CL, senior surgeons, drafted the manuscript. FL, a

senior surgeon, performed surgeries and drafted the manuscript. The final manuscript was read and approved by all the authors.

Ethics approval and consent to participate

This study was approved by the ethics committee of Tongji Hospital, HUST, Wuhan, China. The committee waived the informed consent from the patients.

Consent for publication

Not applicable. No individual data of patients were included in this article.

Competing interests

The authors declare that they have no competing interest

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Figures

Figure 1

The lateral X-rays of the cervical vertebra. Cobb C: the Cobb angle between the lines perpendicular to the upper planes of the C2 vertebral body and the lower plane of the C7 vertebral body. Cobb S: the angle between the lines perpendicular to the superior margin of the cranialis vertebral body and the inferior margin of the caudal vertebral body involved in the operation level. TIH: total interbody height.

Figure 2

Lateral X-Rays image of the cervical spine, obtained at 3months postoperative (A,C) and final follow-up (B,D), showing a new anterior bony spurs had formed from the tip of the plate to the upper adjacent level at the final follow-up in Cage group(D). We totally found 4 patients suffered bony spurs in cage group and none in the Zero-p group.