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Original Article

The application of Zero-profile implant in two-level and single level anterior cervical discectomy and fusion for the treatment of cervical spondylosis: a comparative study

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Abstract: While the application of the Zero-P implant (Zero-P, Synthes GmbH, Switzerland) in two-level ACDF has been little reported, a retrospective study was conducted to compare the clinical outcomes with radiographic data and complications between two-level and single level ACDF using Zero-P. A total of 132 patients who underwent ACDF using Zero-P between September 2011 and December 2014 in our department were retrospectively reviewed. The Japanese Orthopedic Association (JOA) scale score, neck disability index (NDI), neck and arm visual analog scale (VAS), bony fusion rate and main complications were recorded. Dysphagia was evaluated according to the Bazaz grading system. The results are based on 74 patients in the single level group and 41 patients in the two-level group. There were no significant difference between two groups concerning age, gender, smoking, alcohol, diabetes mellitus, VAS for neck, VAS for arm, NDI and JOA scores before surgery (all, $P>0.05$). The JOA, NDI and VAS pain scores in two groups were significantly improved after surgery (all, $P<0.05$). Similar improvements were observed in the JOA, NDI and VAS pain scores in both groups each follow-up (all $P>0.05$). There was no significant difference in two groups concerning postoperative main complications (all $P>0.05$). In conclusion, no significant difference was observed between two groups in terms of clinical improvement, fusion rates and main complications. The Zero-P implant may be an effective and safe choice in two-level ACDF surgery. Future prospective, randomized, controlled studies with larger sample size are needed.

Keywords: ACDF, dysphagia, fusion, zero-profile, anterior cervical discectomy and fusion

Introduction

Since Simmons and Bhalla introduced anterior cervical discectomy and fusion (ACDF) in 1960s, it has been widely applied all over the world and regarded as the gold-standard procedure in the treatment of cervical spinal degenerative disease by most spinal surgeons [1-4]. Simple discectomy and fusion with iliac bone graft was often performed in early time with high risk of pseudarthrosis and donor site morbidity [5]. Intervertebral cages (fulfilled with autogenous or allograft bone) without or with additional anterior cervical plate were developed to achieve higher fusion rate, reduce donor site morbidity and patients' work stoppage time [6-10]. Anterior cervical plate can significantly increase fusion rates, cervical stability and maintain or improve cervical sagittal alignment [6, 8]. However, anterior cervical plate may also be associated with higher dysphagia rates, tracheoesophageal lesions, plate malposition and accelerated adjacent disc degeneration [11-13].

In an attempt to reduce the complications associated with traditional cervical anterior plating but maintain the advantages of traditional cervical anterior plating, a new zero-profile, standalone cage with integrated fixation for segmental stabilization (Zero-P, Synthes GmbH, Switzerland) has been developed in recent years [14-18]. The Zero-P is made up of three main components: a PEEK interbody spacer, a titanium alloy plate and locking head screws. The PEEK interbody spacer is made of medical

grade PEEK-OPTIMA (poly-etheretherketone) with characteristics of radiolucency and low elastic modulus. The zero-profile titanium alloy plate is reinforced within two cranial and two caudal locking screws. Entitative images of Zero-P and post-operative antero-posterior and lateral X-rays are shown in **Figure 1**.

Segmental stability decreases with the number of instrumented segments regardless of the used implant and the locking plate but cage combined with anterior plate was stiffer in all test modes than the Zero-P devices in multi-level constructs confirmed by a biomechanical 3-dimensional spine test. Previous studies have reported the application of the Zero-P in single level ACDF surgery with very excellent clinical and radiographic outcomes [15, 19-21]. However, two-level ACDF using Zero-P has been little reported, biomechanical stability and fusion rates also remains unclear. Soa retrospective study was conducted in our hospital in an attempt to compare the clinical outcomes with radiographic data and complications between two-level and single level ACDF using Zero-P for the treatment of degenerative cervical spondylosis.

Materials and methods

Patient search

A total of 132 patients who underwent ACDF using Zero-P between September 2011 and December 2014 in our department were enrolled in this retrospective study. Among them there were 83 patients underwent single level ACDF (single group) and 49 consecutive patients underwent two-level ACDF (two-level group). All patients underwent ACDF surgery using Zero-P during this period were included in this study. The study was approved by Medical Ethical Committee of West China Hospital, Sichuan University. All of the 132 patients provided informed consent for the analysis of their clinical and radiological data.

Inclusion and exclusion criteria

The inclusion criteria were: 1) patients who presented with radiculopathy or myelopathy from single-level or two-level degenerative cervical spondylosis; 2) no response to non-operative treatment at least 6 weeks; 3) radiographic results consistent with clinical signs and symptoms; 4) ACDF surgery C2-C7; 5) age >18 years old and 6) complete clinical and radiographic data. The main exclusion criteria were as followings: 1) severe osteoporosis; 2) presence of active infections; 3) combined with spinal cord diseases or motor neuron disease; 4) pathologic fractures of the vertebrae; 5) allergy to the implant material (titanium or polyether); 6) ankylosing spondylitis or rheumatoid arthritis; 7) patients with history of cervical spine surgery; 8) patients with spinal deformity and patients suffering from acute or chronic serious diseases which might increase the perioperative risk; 9) patients with preoperative dysphagia, a history of disorders in the central nervous system such as stroke and esophageal diseases.

Surgical technique

All the surgical procedures were performed by one senior spinal surgeon using a standard Smith-Robinson approach [22, 23]. With the help of fluoroscopy and metal markers, a horizontal right side skin incision was used in all patients. After intervertebral disc and herniated nucleus pulposus were extirpated, the posterior longitudinal ligament and along with osteophytes were removed. After discectomies and intervertebral decompression completed, foraminotomies are performed using a high-speed drill, curettes, and Kerrison cervical rongeurs when appropriate. The subchondral endplate of each vertebral body was prepared with a high speed drill and curette while the bony endplate was preserved as much as possible to prevent implant subsidence. After complete decompression and preparation of the endplate, a trial implant of appropriate size was inserted carefully under image control. Then appropriate Zero-P fulfilled with composite synthetic bone graft (beta-tricalcium phosphate, β-TCP, ChronOS; DePuySynthes, Paoli, CA, USA) was implanted into intervertebral space. Lateral and anterior-posterior fluoroscopic X-rays were performed and the correct position of the implant was adjusted. After confirmation of size and position, four locking screws were inserted using torque limitation after preparing the pilot hole oriented through the aiming device. The final implant position is verified once again in the anterior-posterior and lateral fluoroscopic X-rays (**Figure 2**). Hemostasis is rechecked, and the skin was sutured subcutaneously. All the patients were obeyed to wear a cervical collar for 6 weeks after surgery.

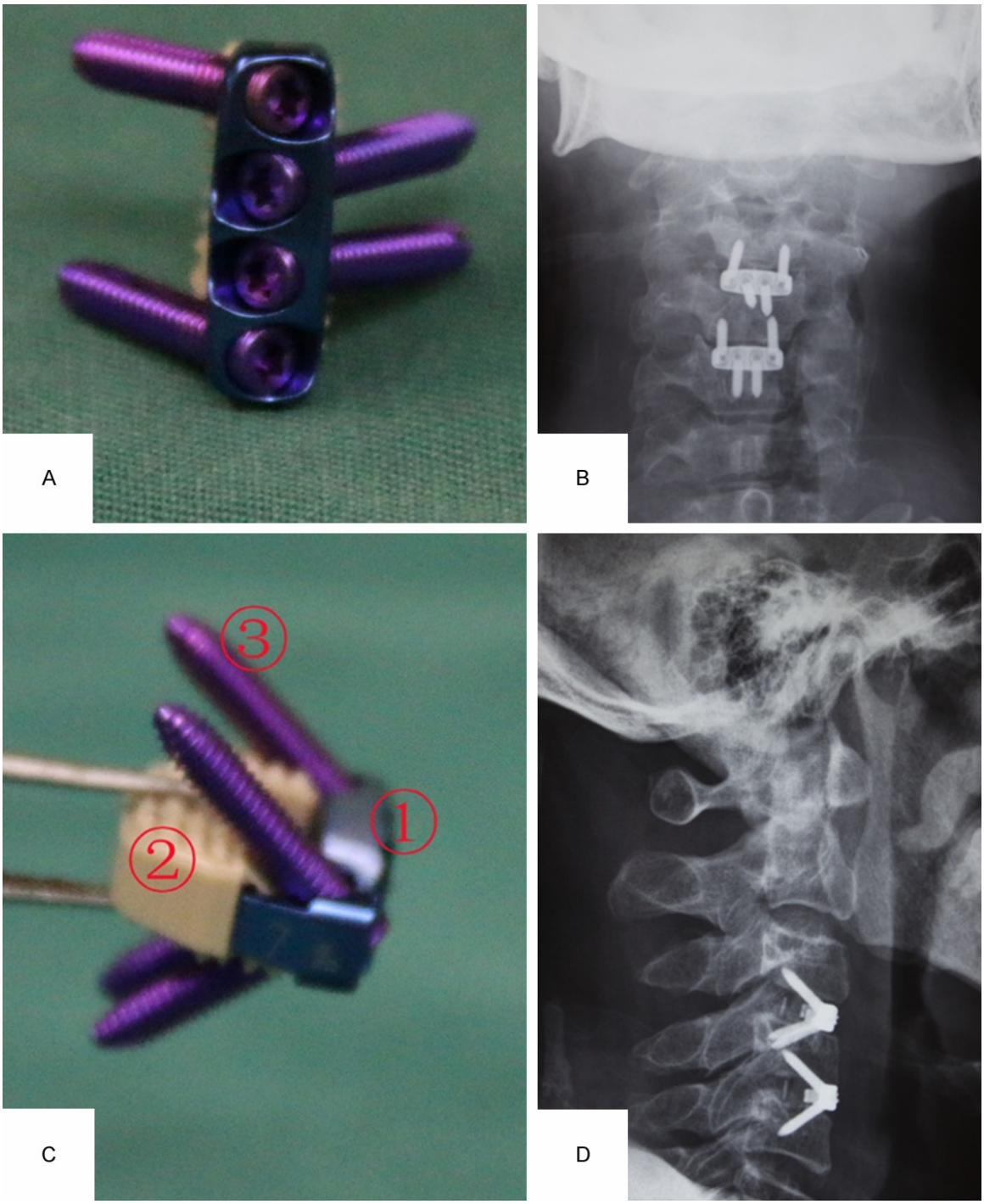

Figure 1. Entitative images of Zero-P (A and C) and postoperative anterior-posterior and lateral X-rays (B and D). (① titanium alloy plate, ② PEEK interbody spacer and ③ locking screws).

Clinical and radiographic evaluations

Charts and medical records of all patients were reviewed. Plain radiographs (including flexion/extension views), computed tomography (CT) and magnetic resonance imaging (MRI) were performed before surgery. Neurological examination and functional assessment were recorded at 3, 6, 12 months postoperatively and at the final follow-up. The neurologic status was assessed using the Japanese Orthopedic Association (JOA) scale score and neck disability

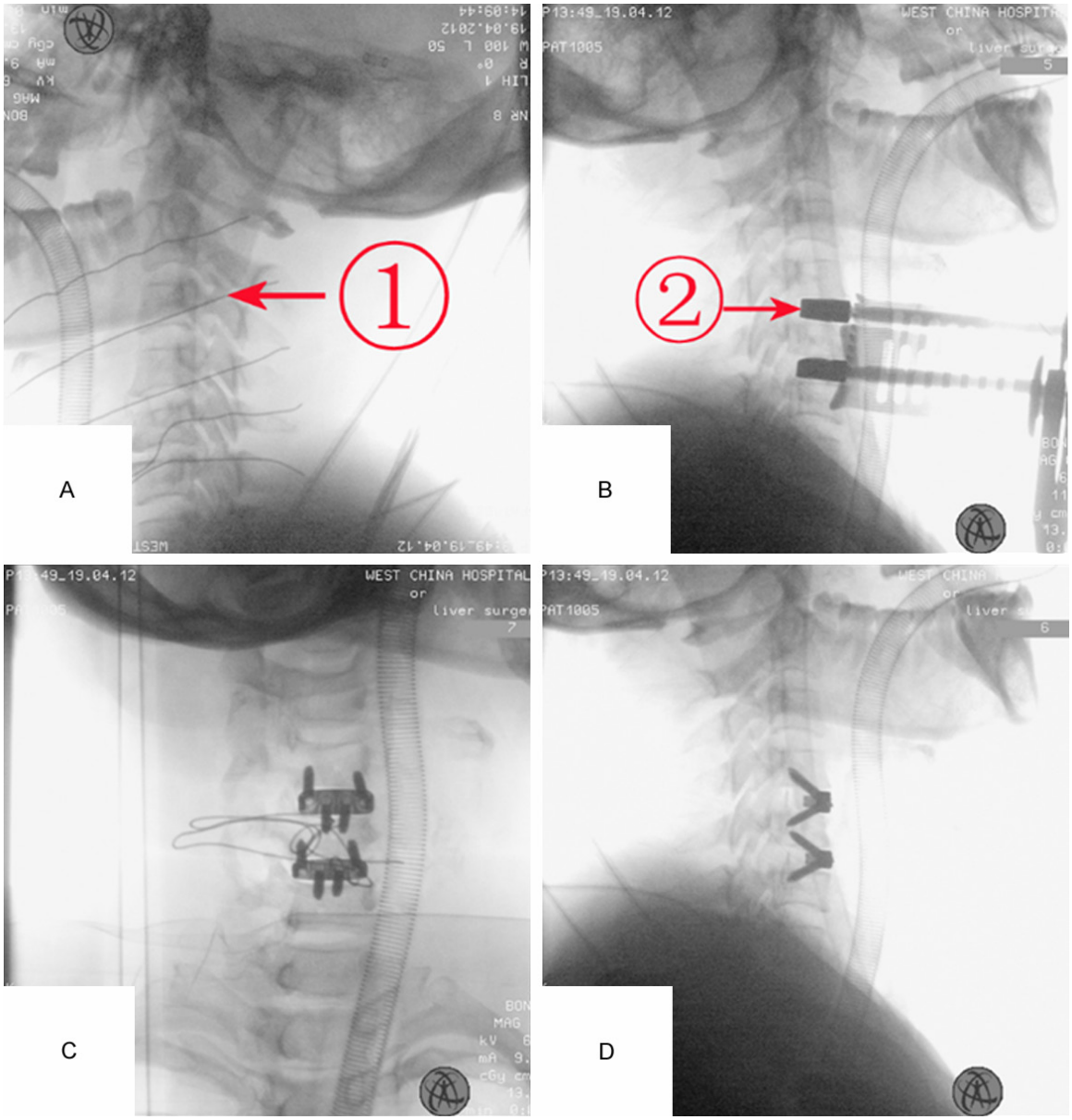

Figure 2. Intraoperative fluoroscopy (A. Determining skin incision with the help of fluoroscopy and metal markers; B. Inserting a trial implant of appropriate size; C and D. Confirming of final implant position in the anterior-posterior and lateral fluoroscopic X-rays).

Table 1. The Bazaz grading system for dysphagia

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

index (NDI). Neck and arm pain was evaluated using the 10-point visual analog scale (VAS). The severity of dysphagia was evaluated according to the Bazaz grading system [24] which was widely used in previous studies (0-None; 1-Mild; 2-Moderate; 3-Severe; as listed in **Table 1**). Fusion was evaluated by three dimensional reconstruction CT scan images according to the standard definition which was widely applied in previous studies: 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 [25]. Similarly 2° or less of segmental rotation on lateral flexion/extension

Table 2. Demographics of patients in two groups

Group	Single level group (N=74)	Two-level group (N=41)	*P*
Age (y): Mean SD	51.59 ± 13.13	49.30 ± 8.63	0.113
Gender (Female/Male)	29/45	14/27	0.592
Smoking	22	16	0.310
Alcohol	32	20	0.568
Diabetes mellitus	11	7	0.775
JOA	9.4 ± 2.2	9.5 ± 2.6	0.521
NDI	12.5 ± 2.1	12.7 ± 3.2	0.726
VAS for neck	7.29 ± 2.09	7.17 ± 2.16	0.229
VAS for arm	7.12 ± 2.25	7.44 ± 2.14	0.325
Intraoperative time (min)	141.76 ± 18.31	170.25 ± 24.93	0.021
Estimated blood loss (ml)	71.15 ± 19.54	109.50 ± 21.57	0.017
Length of hospital stay (d)	13.62 ± 4.34	14.18 ± 3.83	0.484

JOA, Japanese Orthopedic Association; NDI, neck disability index; VAS, visual analog scale.

X-rays were also regarded as fusion [26]. 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 computerized tomography scans [27]. Wound infection, esophageal perforation, nerve root injury, postoperative hematoma, recurrent laryngeal nerve palsy, cerebrospinal fluid leakage, pulmonary embolism, perioperative cardiac event or other serious complications were also recorded.

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 22.0 (SPSS Inc. for windows) was used for statistical analysis. *P*-values of less than 0.05 were regarded as significant.

Result

A total of 132 patients who underwent ACDF using Zero-P between September 2011 and December 2014 in our department were enrolled in this retrospective study according to the inclusion and exclusion criteria. However, there were nine patients in the single level group and eight patients in the two-level group did not complete the final follow-up and these patients were excluded from the final analyses. The results of this study are based on 74 patients in the single level group and 41 patients in the two-level group. The single level group had a mean age of 51.59 years and a mean follow-up duration of 2 years (range from 1 year to 4 years) while the two-level group had a mean age of 49.30 years and a mean follow-up duration of 2 years (range from 1 year to 4 years). In single level group there were 29 fem-ales and 45 males, and among them there were 22 patients with a history of sm-oking, 32 patients with a history of alcohol and 11 patients also suffering from diabetes mellitus. In two-level group there were 14 females and 27 males, and among them there were 16 patients with a history of smoking, 20 patients with a history of alcohol and 7 patients also suffering from diabetes mellitus. A total of 156 Zero-P devices were implanted in these 115 patients: 18 implants at C3/4, 36 implants at C4/5, 79 implants at C5/6 and 23 implants at C6/7.

The single level group had a mean intraoperative blood loss of 71.15 ± 19.54 ml, a mean intraoperative time of 141.76 ± 18.31 minites and a mean length of hospital stay of 13.62 ± 4.34 days. The two-level group had a mean intraoperative blood loss of 109.50 ± 21.57 ml, a mean intraoperative time of 170.25 ± 24.93 minutes and a mean length of hospital stay of 14.18 ± 3.83 days. The preoperative JOA score was 9.4 ± 2.2 in single level group and 9.5 ± 2.6 in two-level group (P=0.521). The preoperative NDI was 12.5 ± 2.1 in single level group and 12.7 ± 3.2 in two-level group (P=0.726). The preoperative VAS for neck was 7.29 ± 2.09 in single level group and 7.17 ± 2.16 in two-level group (P=0.229). The preoperative VAS for arm was 7.12 ± 2.25 in single level group and 7.44 ± 2.14 in two-level group (P=0.325). There were no significant difference between two groups concerning age, gender, smoking, alcohol, diabetes mellitus, VAS for neck, VAS for arm, NDI and JOA scores before surgery (all, P>0.05) as listed in **Table 2**. The JOA, NDI and VAS pain scores in two groups were significantly

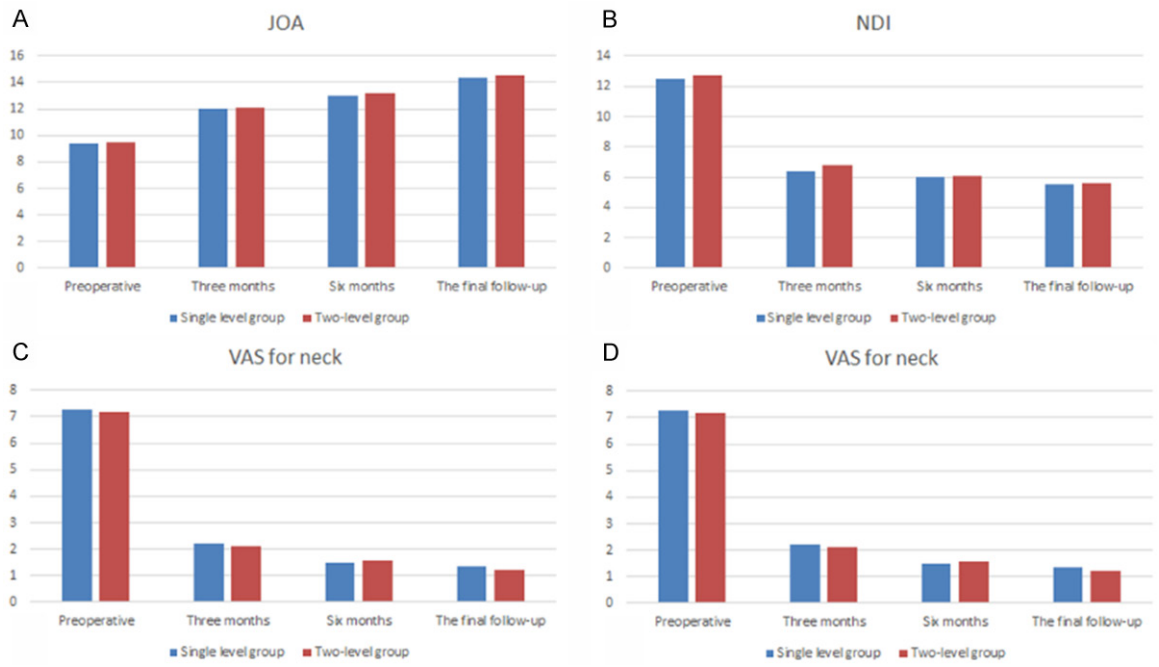

Figure 3. Clinical outcomes measured by the Japanese Orthopedic Association (JOA) scale score, neck disability index (NDI) and the 10-point visual analog scale (VAS) for neck and arm (All, P>0.05).

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

	Single level group (N=74)	Two-level group (N=41)	*P*
JOA	14.4 ± 1.2	14.5 ± 1.1	0.451
NDI	5.5 ± 1.3	5.6 ± 1.7	0.642
VAS for neck	1.34 ± 0.23	1.23 ± 0.28	0.427
VAS for arm	1.28 ± 0.43	1.29 ± 0.51	0.364
Fusion rate	94.59%	92.68%	0.683

JOA, Japanese Orthopedic Association; NDI, neck disability index; VAS, visual analog scale.

improved after surgery (all, P<0.05). Similar improvements were observed in the JOA, NDI and VAS pain scores in both groups at 3, 6 months after surgery and at the final follow-up, all P>0.05 (**Figure 3**). There were 70 patients in the single level group and 38 patients in two-level group reached bony fusion at the final follow-up according to the standard definition listed above. Radiographic and clinical outcomes at the final follow-up between the two groups are listed in detail in **Table 3**.

The total incidence of dysphagia in single level group was 32.43% at one week, 8.11% at three months, 5.41% at six months and 4.05% at the latest follow-up. The total incidence of dysphagia in two-level group was 43.90% at one week, 26.83% at three months, 12.20% at six months and 9.76% at the latest follow-up. The incidence of dysphagia (0-None; 1-Mild; 2-Moderate; 3-Severe) for two groups were similar at one week, six months after surgery and at the final follow-up but significantly higher in two-level group at three months after surgery. The incidences of dysphagia for two groups are listed in detail in **Table 4**. There were no patient suffered from wound infection, esophageal perforation, nerve root injury, pulmonary embolism, perioperative cardiac event or other catastrophic complications in two groups. There were 2 patients in single level group and 1 patient in two-level group suffered from postoperative hematoma, 2 patients in single level group and 2 patients in two-level group suffered from recurrent laryngeal nerve palsy, 2 patients in single level group and 3 patients in two-level group suffered from cerebrospinal fluid leakage, 4 patients in single level group and 3 patients in two-level group suffered from pseudarthrosis (all, P>0.05). There was no instrumentation failure patient in single level

Table 4. The incidences of dysphagia for two groups

	Single level group (N=74)					Two-level group (N=41)					
Time	None	Mild	Moderate	Severe	Total incidence	None	Mild	Moderate	Severe	Total incidence	*P*#
One week	50	18	5	1	32.43%	23	11	5	2	43.90%	0.157
Three months	68	5	1	0	8.11%	30	7	4	0	26.83%	0.006
Six months	70	4	0	0	5.41%	36	3	2	0	12.20%	0.180
The final follow-up	71	3	0	0	4.05%	37	3	1	0	9.76%	0.215

#Mann-Whitney U test.

Table 5. Postoperative main complications for two groups

	Single level group (N=74)	Two-level group (N=41)	*P*
Postoperative hematoma	2	1	0.932
Wound Infection	0	0	NA
Nerve root injury	0	0	NA
Pulmonary embolism	0	0	NA
Recurrent Laryngeal Nerve Palsy	2	2	0.544
Cerebrospinal fluid leakage	2	3	0.247
Esophageal Perforation	0	0	NA
Instrumentation Failure	0	1	NA
Pseudarthrosis	4	3	0.683

group, however, a 46-year-old malein two-level group suffered from instrumentation failure as six months postoperative X-ray and CT scan showed a locking screw at the segment C6/7 pulled out. Cons-idering the patient was asymptomatic, the cervical stability is reliable and no evidence of esophageal perforation, conservative treatment was recommended and the patient was followed up every six months. Postoperative main complications for two groups were in summarized in **Table 5**.

Discussion

ACDF, a classical spinal procedure, has been usedin the treatment of degenerative cervical disc diseases for more than 60 years [28, 29]. Anterior cervical plate was developed in recent decades in order to increase the immediate postoperative stability and fusion rate after bone grafting between vertebral bodies, reduce the occurrence of the cage subsidence and displacement. However, the necessity and selectivity for additional instrumentation after decompression still remains controversialasplate can also be associated with some relative complications such as higher dysphagia rates and plate malposition. In order to overcome the disadvantages and limitations but maintain the advantages of anterior cervical plate at the same time, a new zero-profile, stand-alone cage with integrated fixation for segmental stabilization (Zero-P, Synthes GmbH, Switzerland) has been developed in recent years and it has been also widely reported in previous studies in single level ACDF with excellent clinical outcomes. Wang et al. compared the Zero-P implant versus plate cage benezech implant (PCB) in the treatment of single-level cervical spondylotic myelopathy and they concluded that Zero-P implant and PCB implant are both effective in the treatment of cervical spondylotic myelopathy, but Zero-P implant has the advantages of easy operation, short operation time, less intraoperatve blood loss and less complications [21]. Cho et al. retrospectively reviewed 121 patients who underwent single level ACDF and compared the clinical and radiographic outcomes of stand-alone PEEK cage and Zero-P implant for single level ACDF with the conclusion that Zero-P implant has some advantage after cage for maintaining segmental lordosis and lowering subsidence rate [30]. Son et al. analyzed clinical and radiological outcomes of Zero-P implant and conventional cage-plate for single level ACDF and concluded that application of Zero-P may achieve favorable outcomes and reduce postoperative dysphagia in single level ACDF [20].

However, results from a biomechanical 3-dimensional spine test showed that segmental stability decreases with the number of instrumented segments andcage combined with anterior plate was stiffer than the Zero-P devices in multilevel constructs. So the safety and validity of two-level ACDF using Zero-P implant remains unclear. Chen et al. compared the

safety and efficacy of two-level ACDF using the Zero-P implant versus the plate method in patients with cervical spine spondylosis recently and they concluded that clinical results with the Zero-P implant used for two-level ACDF were satisfactory but prospective trials with more patients and longer follow-ups are required to confirm their observations [31]. Considering the little knowledge of this area, we conducted this retrospective study to explore the safety and efficacy of the Zero-P implant in two-level ACDF surgery.

The overall clinical and radiographic results were similar in two-level and single level ACDF patients. The neck pain and arm pain in both groups were significantly relieved three months after surgery. The JOA, NDI and VAS pain scores in two groups were significantly improved after surgery. The fusion rates were also similar and satisfying in two groups at the latest follow-up. We think the self-locking devices can also ensure excellent primary temporary stability of the implant and promote early bony fusion in two-level ACDF surgery. Second, the elastic modulus of the anchored cage is similar to that of bone, which theoretically helps to decrease stress shielding and increase bony fusion [15]. Third, surgical techniques that including optimal preparation of the fusion bed and proper disc space distraction may also have an influence on fusion rate. Last, the kind of bony graft can also have an impact on final fusion rate [32]. Autogenous iliac bone was still regarded as the gold standard graft material concerning fusion rate [33-35]. In this study beta-tricalcium phosphate (ChronOS; DePuySynthes, Paoli, CA, USA) was used for all patients and this may also have an impact on final fusion rate [36].

Compared with anterior plating, Zero-P implant was reported to have a lower incidence of postoperative dysphagia in ACDF surgery [13, 37, 38]. The overall incidence of dysphagia in our study in not high. Most of the dysphagia in two groups was mild and gradually decreased during the following months. Moderate or severe dysphagia was not common in two groups. However, there was still 4.05% patients in single level group and 9.76% patients in two-level group suffering from dysphagia at the latest follow-up. The incidence of dysphagia for two groups were similar at one week, six months after surgery and at the final follow-up but significantly higher in two-level group at three months after surgery. Levels may have an impact on postoperative dysphagia in ACDF surgery as multilevel surgery often means a much longer surgery time and more powerful traction to expose operative field which may irritate the esophagus more seriously [39-41]. However, the exact pathophysiologic mechanism of dysphagia remains unknown, and the dysphagia is often regarded as a multi-factor result. Number of surgical levels is only one of the multiple factors than have an impact on the incidence of postoperative dysphagia.

There were no patient suffered from wound infection, esophageal perforation, nerve root injury, pulmonary embolism, perioperative cardiac event or other catastrophic complications in our study. No significant difference was observed in two groups concerning postoperative hematoma, recurrent laryngeal nerve palsy, cerebrospinal fluid leakage and pseudarthrosis. A 46-year-old male in two-level group suffered from instrumentation failure as six months postoperative X-ray and CT scan showed a locking screw at the segment C6/7 pulled out but the patient was asymptomatic, the cervical stability is reliable and no evidence support an esophageal perforation.

Several limitations in our study must be discussed. First, the primary limitation of this study is the retrospective design. Second, we used the Bazaz Scale to assess these verity of dysphagia. The Bazaz Scale is a non-validated grading scale based on qualitative information even it was widely used by many spinal surgeons, it is not an accurate measurement method. Gold standard evaluation methods including instrumental assessment such as video-fluoroscopy or fiber optic endoscopic evaluation of swallowing, are recommended [42-44]. Third, the sample size is small as only 115 consecutive patients with were included in this study. Thus, future prospective, randomized, controlled studies with larger sample size are needed.

Conclusion

In conclusion, no significant difference was observed between two-level and single level ACDF surgery using Zero-P implant in terms of clinical improvement, fusion rates and main

complications. The Zero-P implant may be an effective and safe choice in two-level ACDF surgery. Future prospective, randomized, controlled studies with larger sample size are needed.

Disclosure of conflict of interest

None.

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