

## Original Article

# Application of Zero-P on anterior cervical decompression and bone fusion

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**Abstract:** Objective: To investigate the application value of anterior cervical zero-profile interbody fusion device (Zero-P) on anterior cervical decompression and bone fusion, by comparing the effect differences of Zero-P and anterior cervical plate cage benezech (PCB) in treating cervical spondylopathy. Methods: 120 patients with cervical spondylopathy (from February 2014 to January 2016) were selected and randomly divided into experimental group and control group of 60 cases in each. Experimental group performed operation with Zero-P while control group with PCB. The outcomes, such as operation time and intraoperative hemorrhage volume, the time of bone graft fusion, Japanese Orthopaedic Association (JOA) score, visual analogue scale (VAS), Neck Disability Index (NDI), short form 36 questionnaire (SF-36), cervical curvature (Cobb angle) were compared between these two groups. Results: In the experimental group, the excellent rate of curative effect in final follow-up visit was 93.3%, which was significantly higher than that of control group (80%) ( $P=0.029$ ). 18.3% patients in the experimental group presented with postoperative dysphagia, which was obviously lower than that of control group (28.3%) ( $P=0.001$ ). Besides, operation time and intraoperative hemorrhage volume in the experimental group were also significantly lower than those of control group ( $P=0.000$ ,  $P=0.001$ ). After treatment, the improvements of JOA, VAS score and NDI in the experimental group were significantly better than control group ( $P=0.000$ ,  $P=0.000$ ,  $P=0.000$ ). And there were no significant differences between two groups in SF-36, the time of bone graft fusion and Cobb angle ( $P=0.368$ ,  $P=0.563$ ,  $P=0.452$ ). Conclusion: Zero-P, with a simple operative procedure and low incidence of postoperative dysphagia, had a better curative effect in treating cervical spondylopathy. And it could effectively improve of cervical curvature, making the early clinical efficacy satisfactory.

**Keywords:** Anterior cervical spine surgery, Zero-P, intervertebral fusion, cervical spondylopathy

### Introduction

Cervical spondylopathy is a disease which has a serious impact on human health and quality of life. Surgical treatment should be performed in time when cervical intervertebral disc degeneration or secondary compression of adjacent vertebral artery, nerve root, and spinal cord occur. Currently, anterior cervical decompression and bone fusion operation, which has a certain curative effect, is regarded as a standard surgery of treating cervical spondylopathy [1, 2]. Anterior cervical plate cage benezech (PCB) has often been adopted in anterior cervical spine surgery, but it has several postoperative disadvantages such as poor stability of cervical spine biomechanics, high incidence of dysphagia, postoperative pain and so on. Therefore, the clinical treatment of cervical

spondylopathy has been in badly need of a new system, which can not only decrease postoperative complications like dysphagia, but also relieve postoperative pain and achieve intervertebral fusion [3, 4].

In recent years, with the development of anterior cervical fusion technique, anterior cervical zero-profile interbody fusion device (Zero-P) has been gradually used in the clinical treatment of cervical spondylopathy [5, 6]. Different from PCB, Zero-P can be placed in intervertebral space after decompression without the anterior cortex being protruded, and its interference to the adjacent intervertebral space is smaller [7, 8]. Besides, after being inserted, Zero-P can calibrate automatically, and its fixed screw is one-step-locking, which is easy to operate [9, 10].

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**Table 1.** Comparison of basic information between the two groups

Group	Gender (male/female)	Age (year)	Duration (month)	Disease segment (cases)				Disease type (cases)		
				C <sub>3-4</sub>	C <sub>4-5</sub>	C <sub>5-6</sub>	C <sub>6-7</sub>	CSR	TCP	CSM
E group	33/27	42.7±5.3	10.2	12	26	14	8	14	33	13
C group	35/25	43.2±4.9	10.4	13	24	16	7	16	32	12

Note: E group, Experimental group; C group, Control group; CSR, Cervical spondylotic radiculopathy; TCP, Traumatic cervical disc protrusion; CSM, Cervical spondylotic myelopathy.

Nowadays, there have been few researches about the effect of Zero-P on anterior cervical decompression and bone fusion. To get more insight into the stability of Zero-P and to compare its effect with traditional PCB system, Zero-P and PCB were used in this study for treating the patients with cervical spondylopathy. Indexes like postoperative complications, improvement of cervical function and recovery of postoperative pain were evaluated between the two groups. Meanwhile, observation and follow-up visits were performed and the clinical efficacy was analyzed after the surgery, in order to provide experimental and clinical data for the application of Zero-P on anterior cervical decompression and bone fusion.

### Materials and methods

#### *Clinical materials*

One hundred and twenty subjects were selected from patients who were diagnosed as cervical spondylopathy from January 2014 to February 2016. Inclusion criteria: Patients who had the lesion of one segment and no history of cervical vertebrae surgery; no tumour or vertebral fractures, no serious osteoporosis and infection. The clinical manifestations and symptoms of all patients were consistent with the imaging. Exclusion criteria: Patients who had pathological changes of Guillain-Barre syndrome and demyelination and other relevant surgical contraindications. There were 25 cases having pathological changes in the segment of C<sub>3-4</sub>, 50 cases in C<sub>4-5</sub>, 30 cases in C<sub>5-6</sub>, and 15 cases in C<sub>6-7</sub>. Among them, there were 30 cases of cervical spondylotic radiculopathy (CSR), 65 cases of traumatic cervical disc protrusion and 25 cases of cervical spondylotic myelopathy. Of all the enrolled patients were aged from 38 to 61 years, 68 were males and 52 were females. Imaging examination confirmed that intervertebral disc of all patients had different degrees of compression on vertebral artery, nerve root and spinal cord.

These patients were divided into experimental group and control group of 60 cases in each via random number sequence. The experimental group had 33 males and 27 females, with average age of (42.7±5.3) years and mean disease duration of 10.2 months. While there were 35 males and 25 females in the control group, with average age of (43.2±4.9) years and mean disease duration of 10.4 months. The basic information of two groups, such as age, gender and so on, was shown in **Table 1**, and the differences we not statistically significant, suggesting comparability of these data. This study had been approved by the ethics committees and all the patients and their families had signed informed consent.

#### *Research methods*

The experimental group was treated with Zero-P, while the control group was treated with PCB. They were followed up for 6 months after surgery.

#### *Zero-P*

All patients were in a supine position after general anesthesia, and the surgical segment was fully revealed from the right side of the neck. C-arm x-ray medical equipment was used for the localization of intervertebral space, which was widened by vertebral body distraction device. Then, intervertebral disc was cleared completely and the rongeur was used to remove the posterior marginal osteophytic of cervical vertebra so that a thorough decompression could be achieved. Appropriate Zero-P (produced by Johnson and Johnson, the American company) and the artificial bone and autologous bone chips were selected to ram in the correct position, which could be confirmed by c-arm x-ray medical equipment. The criteria of correct position were as follows: the anterior edge in the lateral position should not exceed that in vertebral body over 2 mm, and the posterior edge should be within 5 mm in the front of vertebral posterior, while the screw should be locked in

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the middle of vertebral body. Under the navigation of aiming device, fixed screws were used to embed the upper and lower vertebral body, and it should make sure that the length of screw was between 2/3 region of front and posterior edges and locked. At last, took out of aiming device and orthopedic retractor and sutured the incision after making sure there was no active bleeding by routine examination. Neck collar was used for neck protection for about 3 months after surgery.

### *PCB*

After general anesthesia, patients were treated with the same way as Zero-P to decompress intervertebral space entirely and fully. And the proper PCB cage (produced by Synthes, Swiss), was selected and closely fitted to the intervertebral space. Under the fluoroscopy of c-arm x-ray medical equipment, the cage was precisely fixed by screws. Meanwhile, the artificial bone and autologous bone chips were compressed after being embedded into the hollow vertebral body stents through foramen ovale. Then, suture the incision after routine examination. Neck collar was used for neck protection for about 3 months after surgery.

### *Observational index*

The spinal function table of the Japanese Orthopaedic Association (JOA) which has been widely used and it can objectively reflect the function and status of spinal cord. It was adopted in this study. The table was scored according to patients' upper limb function (0-4), lower limb function (0-4) and level of sensitivity (upper and lower limbs and body scores are 0-2 in respective, 0-6 in total) and bladder function (0-3). The improvement rate of the Japanese Orthopaedic Association (JOA score) = ((scores after treatment - scores before treatment)/(17 - scores before treatment)) \* 100%. It could be classified into excellent (>75%), good (50%-75%), medium (25%-50%) and bad (<25%). Then, Bazaz dysphagia scoring standard was applied to assess postoperative dysphagia. And SF-36 health questionnaire was used to evaluate the patients' quality of life after surgery while cervical curvature was measured and represented by Cobb angle. Besides, patients' cervical function was evaluated by Neck Disability Index (NDI). Furthermore, visual analogue scale (VAS) was applied to evaluate pain recovery of patients. Patients selected a

number in the 11 figures to represent their pain severity: 0 point corresponded to no pain at all; 1 to 3 points represented mild pain which could still be tolerated; 4 to 6 points represented the pain which affected sleep but tolerable; 7 to 10 points represented the pain which was gradually intensified, unbearable and affected their sleep and appetite. At last, the bone graft fusion time, operation time and intraoperative hemorrhage volume were compared between two groups.

### *Statistical analysis*

SPSS17.0 software was used to analyze experimental data. Count data was presented by percentage and its comparison between two groups was demonstrated by  $\chi^2$  test; measurement data was presented by mean and standard deviation ( $\bar{x} \pm SD$ ) and the comparison of two groups was expressed by t test.  $P < 0.05$  was considered statistically significant.

## **Results**

### *Comparison of excellent rate and dysphagia rate of two groups after treatments*

In the end of follow-up visit, the improvement rate of experimental group, evaluated by Japanese Orthopaedic Association, including the excellent 38.3% (23 cases), the good 55% (33 cases), the medium 3.3% (2 cases) and the bad 3.3% (2 cases). The excellent rate was 93.3%, which was significantly higher than control group (80%) ( $P = 0.029$ ). The distribution of improvement rate in control group was that the excellent 33.3% (20 cases), the good 46.7% (28 cases), the medium 13.3% (8 cases) and the bad 6.7% (4 cases). However, the dysphagia rate of the experimental group was 18.3% (11/60) within the 6 months follow-up period, including 8 cases of mild dysphagia and 3 cases of moderate dysphagia. In control group, 12 cases of mild dysphagia and 5 cases of moderate dysphagia occurred, accounting for 28.3% (17/60). The difference was statistically significant ( $P = 0.001$ ) (Table 2).

### *Comparison of two groups in operation time and hemorrhage volume*

In experimental group, operation time and hemorrhage volume were (71 $\pm$ 16.8) min and (50.2 $\pm$ 16.6) ml, respectively, which were significantly lower than those in control group

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**Table 2.** Comparison of excellent rate and dysphagia rate after treatment (cases, %)

Group	Cases	The rate of excellent and good	Chronic dysphagia
Experimental group	60	93.3%*	11 (18.3)*
Control group	60	80%	17 (28.3)
$\chi^2$ value	-	4.418	10.524
P value	-	0.029	0.001

Note: Compared with control group, \*P<0.05.

**Table 3.** The comparison of two groups in operation time and hemorrhage volume (cases,  $\bar{x} \pm s$ )

Group	Cases	Operation time (min)	Hemorrhage volume (ml)
Observation group	60	71±16.8*	50.2±16.6*
Control group	60	88.2±20.8	66.7±24.5
T value	-	4.124	3.602
P value	-	0.000	0.001

Note: Compared with control group, \*P<0.05.

((88.2±20.8) min (P=0.000) and (66.7±24.5) ml (P=0.001)) (Table 3).

### Comparison of scores of JOA, NDI and VAS of two groups before and after treatment

There was no significant difference in scores of JOA, NDI and VAS before treatment. The postoperative scores of JOA, NDI and VAS in experimental group were significantly better than the scores of pretherapy and that of control group. The difference was statistically significant (Table 4).

### Comparison of bone graft fusion time, SF-36 and Cobb angle of two groups

Bony fusion was achieved in both groups. The fusion time were respectively (12.6±7.9) weeks and (13.2±7.2) weeks (P=0.452). There was no significant difference in SF-36 and Cobb angle between the two groups (P=0.368, P=0.563). However, the improvement of SF-36 and Cobb angle after treatment in the experimental group were obviously better than those in pretherapy (P=0.001, P=0.000) (Figure 1).

## Discussion

With the aging of population, the incidence of cervical disease has been increasing year by year, most of which is caused by pathological changes of degenerative cervical spine and the

main clinical symptom is neck and shoulder pain. Anterior cervical decompression and bone fusion surgery is an effective treatment for cervical disease [11, 12]. The application of steel plate for anterior cervical surgery increases the incidence of intervertebral fusion, as well as effectively avoids the formation of pseudarthrosis and promotes the success rate of operation [13, 14], but the results during long-term follow-up indicates that auxiliary plates has some deficiencies. After PCB operation, there are plates fracture and screws loosening due to bone nonunion or absorption, leading to complications like adjacent vertebral degeneration. Besides, there are some problems such as dysphagia and esophageal fistula due to anterior plate [15, 16].

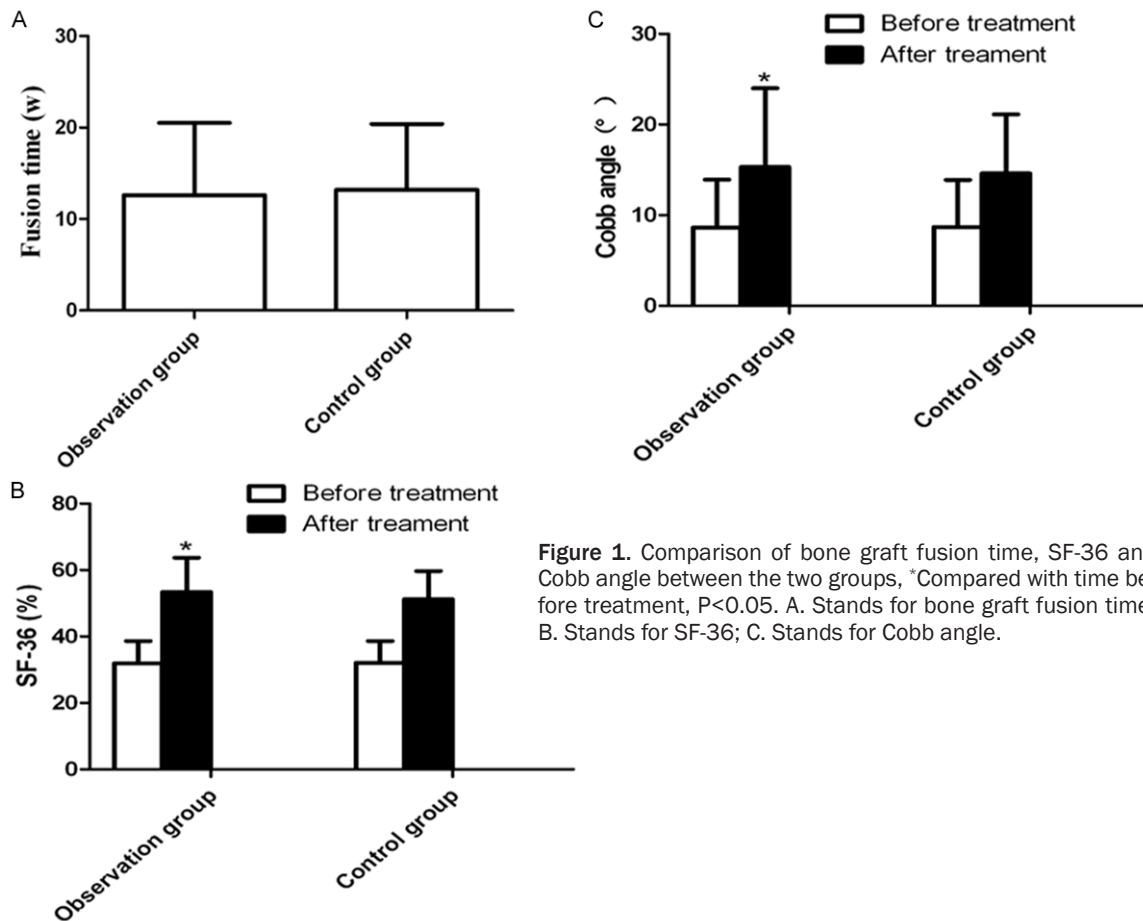
With the development of internal fixation system in spinal surgery, Zero-P, a new internal fixation system, is applied to clinic in order to decrease postoperative complications of anterior cervical decompression and fusion surgery. Zero-P consists of titanium alloy fixing plate, interbody fusion cage and intervertebral screw and has the advantage of both anterior cervical plate and interbody fusion cage [17]. Zero-P is the internal fixation system of zero profile, and can effectively reduce the postoperative complications of dysphagia. Some studies showed that the highest incidence of dysphagia after anterior cervical surgery could reach 67%, which was mainly related to the placement of plate and inflammatory adhesion in structures like prevertebral cervical fascia, esophagus and trachea. The symptom of dysphagia of some patients could disappear after active treatment, but about 21% of the patients still had chronic dysphagia [18, 19]. In Zero-P internal fixation system, materials are implanted into intervertebral space and the anterior edge of vertebral body is not prominent, which can reduce the irritation of the esophagus and then the postoperative complications of dysphagia can be reduced. In this study, compared with PCB surgery for cervical disease, the excellent rate of Zero-P reached 93.3% (Table 2, P=0.029), while the postoperative dysphagia rate was 18.3%, significantly lower than PCB surgery (Table 2, P=0.001). The result showed that Zero-P had a certain curative effect intreating cervical disease, and could significantly reduce the incidence of postoperative dysphagia, which was

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**Table 4.** The comparison of JOA, NDI and VAS of two groups before and after treatment (cases,  $\bar{x} \pm s$ )

Evaluation index	Time	Observation group (n=60)	Control group (n=60)	T value	P value
Evaluation of JOA (score)	Before treatment	8.6±2.8	8.7±2.9	0.149	0.786
	After treatment	15.2±4.9* <sup>#</sup>	10.1±4.1	5.357	0.000
Evaluation of VAS (score)	Before treatment	5.7±1.9	5.6±1.8	0.228	0.821
	After treatment	1.7±0.68* <sup>#</sup>	4.7±1.65	10.127	0.000
Evaluation of NDI (%)	Before treatment	39.4±12.78	39.7±12.69	0.112	0.896
	After treatment	12.8±7.87* <sup>#</sup>	28.2±10.89	6.503	0.000

Note: Compared with control group, \*P<0.05; compared with pretherapy, <sup>#</sup>P<0.05.



**Figure 1.** Comparison of bone graft fusion time, SF-36 and Cobb angle between the two groups, \*Compared with time before treatment, P<0.05. A. Stands for bone graft fusion time; B. Stands for SF-36; C. Stands for Cobb angle.

consistent with the research result at home and abroad. Moreover, Zero-P internal fixation system, having no need for plate, does small harm to prevertebral soft tissues and can reduce the degeneration of adjacent centrum. The result of this study showed that Cobb angle of cervical curvature imaging was significantly improved in patients treated by Zero-P during long term follow-up, compared with pretherapy. And it had the statistical significance. To some extent, it indicated that Zero-P

could reduce the occurrence of adjacent segment degeneration.

Having finished the overall pre-installation of Zero-P, the adjustment and pre-bending process of steel plate needn't to be carried out, thereby reducing the operation procedure and surgical trauma [20, 21]. This study also showed that compared with the patients treated with PCB, operation time and hemorrhage volume were significantly reduced in patients

treated with Zero-P (**Table 3**). Moreover, the improvement of experimental group was obviously better than control group after treatment in term of scores of JOA, VAS, NDI and SF-36 (**Table 4**). It meant that applying Zero-P to treat cervical disease could significantly improve the neural function, greater ease the pain and prominently promote patients' life-quality. Having analyzed its causes, this study believed that it probably due to the similarity of elasticity between the intervertebral fusion cage and human body, which not only could promote fracture healing and increase the fusion, but also could avoid the subsidence of fusion device. Thus, it had a better effect on human body's pain relief and the transformation of neural function, and had no influence on patients' life quality after operation. However, the number of cases selected in this study was limited, and a further observation was required for its long-term curative effect.

In summary, Zero-P is a good and new method for treating single segment cervical disease. It has a certain curative effect and convenient operation procedure, and can reduce the incidence of postoperative dysphagia, efficiently improve the cervical curvature and postoperative pains. At the same time, cervical function and life quality can be well recovered, and the early clinical effect is satisfying.

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### Disclosure of conflict of interest

None.

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