

## Original Article

# Clinical outcome of a New Zero-profile Implant used in patients with cervical spondylosis: a retrospective study with a maximum of 43 months' follow-up

Ge Chen<sup>1</sup>, Wenjie Wu<sup>2</sup>, Jingtong Lyu<sup>2</sup>, Zhou Xiang<sup>1</sup>

<sup>1</sup>Department of Orthopaedic, Spine Center, West China Hospital, Sichuan University, Chengdu 610041, China;

<sup>2</sup>Department of Orthopaedic, Honghui Hospital, Xi'an Jiaotong University, Shanghai, China

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**Abstract:** This study aims to analyze collected clinical and radiological data in patients who underwent single- or multilevel anterior cervical discectomy and fusion using newly designed zero-profile interbody spacer. Fifty-six patients with cervical spondylosis undergoing anterior cervical discectomy and fusion used new implant (Zero-p plate). Ultimately, 51 patients applied this experimental study and accomplished follow-up. Japanese Orthopaedic Association score (JOA) and visual analogue scale score (VAS) were recorded. Postoperative dysphagia was assessed using the Bazaz-Yoody sphagia index. Imaging included X-rays and CT, were taken to evaluate prosthesis sank, lordotic curvature of cervical spine at level of operation and alignment of whole cervical spine. In addition, fusion state and time were measured. All 51 patients who were followed-up unabridged time levels had significant amelioration in JOA and VAS score at 6 months compared with pre-operation ( $P < 0.05$ ). Three patients at 1 month and 1 patient at 6 months complained about mild dysphagia-related symptoms (7.8%). A 96.1% and 94.1% fusion rate respectively can be demonstrated by X-rays and CT at last follow-up visit. Lordotic curvature of cervical spine at the level of operation have markedly increase in the immediately after operation and the first month. Alignment of whole cervical spine in the post-operative days increased to a maximum in follow-up periods at 3 month. Zero-profile Implant not arise significant subsiding at last following-up visits ( $P > 0.05$ ). And that no device-related complications occurred and no vertebrae cervicales. In conclusion, the New Zero-profile Implant allows decompress and fuse with safely and efficiently, even in multi-level cases.

**Keywords:** Zero-profile implant, cervical spondylosis, retrospective study

## Introduction

Anterior cervical discectomy and fusion had first been reported by Bailey and Badgley [1], Smith and Robinson [2], and Cloward [3] in 1950s and 1960s. Although there were tiny difference among each methods [4, 5], all the methods reported had severe complications such as the graft dislodgement, pseudarthrosis and kyphotic deformity. In order to resolve the complications due to the implants, reinforced plate had been widely used [6, 7].

The use of plating systems enhanced fusion rates, improved initial stability, reduced need for re-operation, decreased complications from graft migration, and decreased hospital stays [8-10]. Nevertheless, other complications may be occurred, including throat discomfort, dys-

phagia and adjacent level degeneration. In the early postoperative period, 2% to 67% of the patients may complain of dysphagia [11]. Which disappeared within 3 months, with most patients, but not all, recovering completely [12, 13]. At the same time, pseudarthrosis are among the most worrying complications [14, 15]. Further, Park et al. [16] reported a higher incidence of adjacent-level degenerations when fusion segments were fixed using a titanium plate. Yang et al. [17] demonstrating a lower rates of adjacent-level degeneration performing ACDF without plates. Based on these results, Low-profile angle-stable spacer Zero-P (Synthes, Switzerland) was approved by the United States Food and Drug Administration in 2008 and has been gradually clinically applied (Figure 1). The zero-p device can be implanted



**Figure 1.** CT scanning of Zero-P implant.

**Table 1.** Baseline characteristics of the subjects

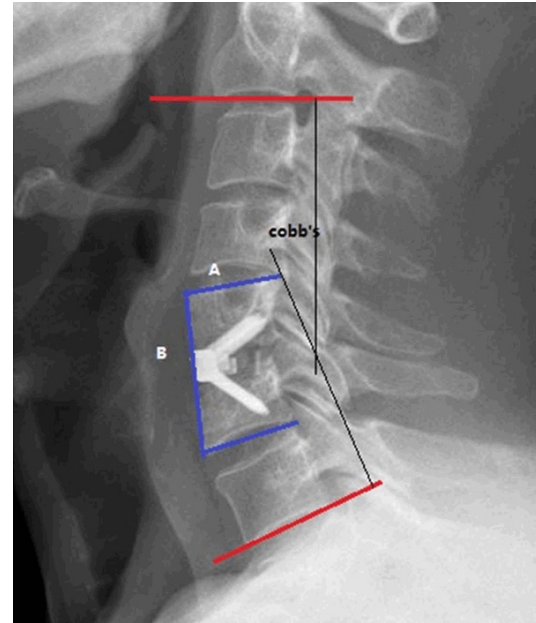
Characteristics	Zero-P
Mean age (yr.)	54.1±11.16
No. patient (M/F)	51
Cervical spondylotic myelopathy	31
Cervical spondylotic radiculopathy	14
Mixed cervical spondylotic	6
Course of disease (mon.)	25 (1, 140)
Follow-up (mon.)	18 (12, 43)

into the intervertebral space. This provides adequate stability and avoids the implant violate the front soft tissue [18]. One biomechanical study showed similar stability making the zero-p plate comparison to cage and cervical plate constructs [19]. The zero-p plate can be prevented dysphagia to achieve a balance between Low-profile angle-stable spacer Zero-P and the necessity of a thick plate by providing secure constrained screw fixation [19].

## Materials and methods

### Patients

From July 2009 to February 2013, 56 patients underwent cervical spondylosis was treated in our hospital. At the end of following periods, 51 of the patients were assigned to undergoing anterior cervical discectomy and fusion using the new implant. There were 31 of the patients who were diagnosed as cervical spondylotic myelopathy (CSM), 14 of them were cer-



**Figure 2.** Technique of Cobb's Angle and relative height of segment measurement.

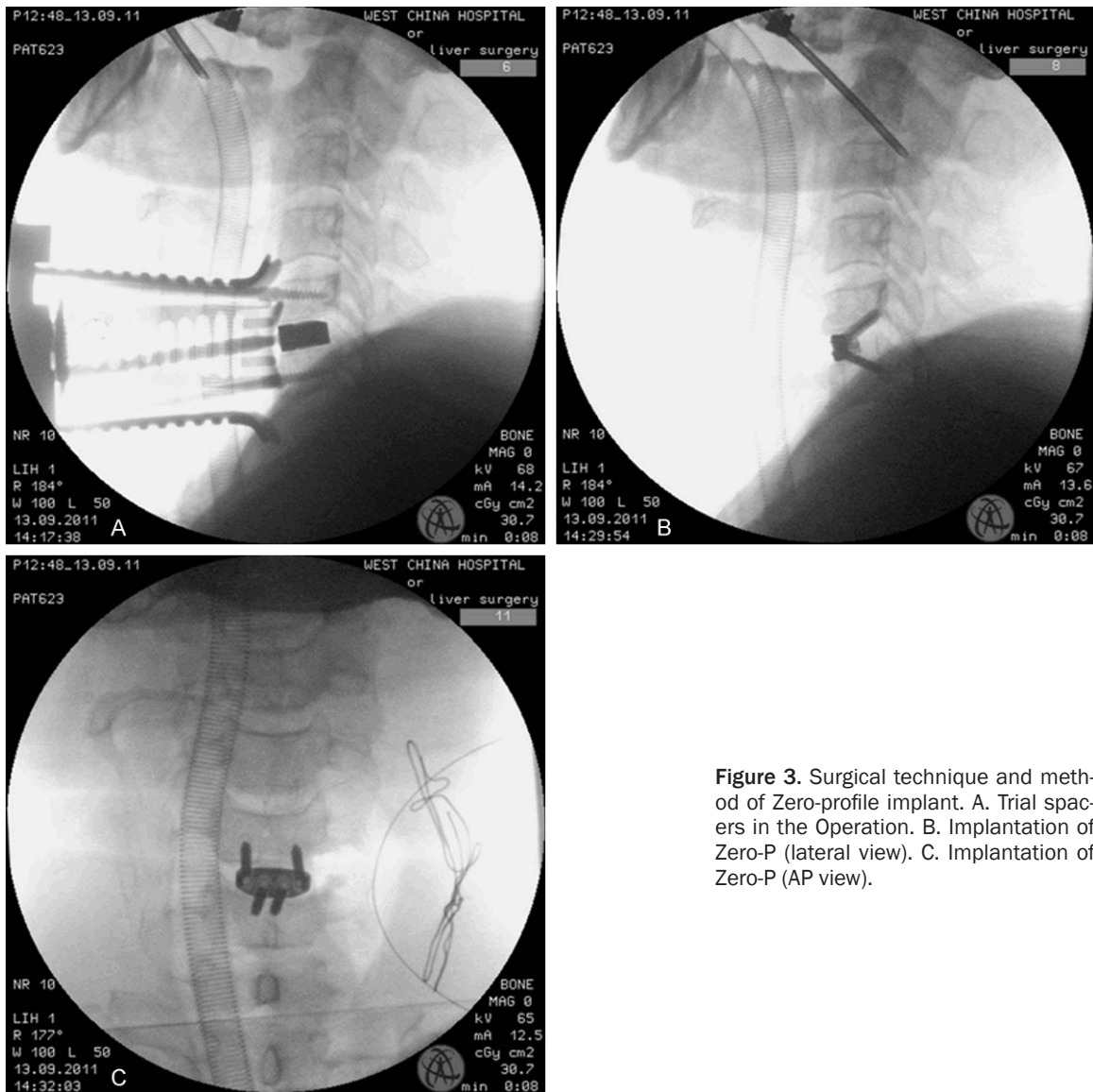
vical spondylotic radiculopathy, and the other 6 patients were classified to mixed cervical spondylotic. There were 28 males and 23 females in this study, which were average 54.1±11.16 years old (range of 44-75 years old). The course of disease were 1 to 140 months (average 25 months), with 12 to 43 months' follow-up (**Table 1**). All the patients had been definitely diagnosed after detailed history taking and physical examination as well as necessary accessory examination.

The exclusion criteria were summarized as follows: (1) previous posterior cervical surgery; (2) bone fusion in adjacent level of the cervical spine; (3) suit for the artificial cervical disc replacement and were prepared for the surgery; (4) severe osteoporosis; (5) severe rheumatoid arthritis; (6) active or suspected infection; (7) known malignancy.

### Measurement method

In order to make sure the location, character, the grade of spinal cord injury and the level of surgery, all the patients received the X-ray of antero-posterior and lateral film and lordotic kyphotic position film and CT, MRI examinations before the surgery. Japanese Orthopaedic Association score (JOA) and visual analogue scale score (VAS) and postoperative dysphagia

## Zero-profile Implant application in cervical spondylosis patient



**Figure 3.** Surgical technique and method of Zero-profile implant. A. Trial spacers in the Operation. B. Implantation of Zero-P (lateral view). C. Implantation of Zero-P (AP view).

addition were records pre-operation, immediately after surgery and 1, 6, 12 month and the last follow up.

To fusion state and time were measured at 6, 12 month and last following time, Sinking prosthesis were measured at 3, 6, 12 month and last follow time. Local cervical angle (C2-C7) was measured before, immediately after surgery and the last follow up.

Solid fusion was defined as the presence of all of the following radiographic features: an absence of lucency or halo formation around the screws or cage-bone interfaces, a lack of translation and  $<5^\circ$  of motion in the flexion-extension radiographs, and osseous continuity

through and/or around the cages on the follow-up sagittal reconstruction CT scan [20]. The degree of cervical curvature was measured by the Cobb method. Sink: at postoperative 3, 6, 12 month and at the time of the last follow-up. With respect to a standardized measurement of the segment Height. This was calculated as a ratio of the upper endplate size to the segment height measured in parallel to the anterior spine (B/A) (Figure 2) [21].

### *Surgical technique*

All patients had implantation of a zero-plate by anterior approach operation with completely decompression. The patients were instructed to walk a day after the operation and got out of

**Table 2.** Outcomes on JOA, VAS in the follow-up

Time	JOA	VAS
Pre-operation	9.35 (1.21)	7.05 (1.21)
6 Mon	15.13 (1.08)	1.21 (0.83)
12 Mon	15.21 (1.12)	1.17 (0.76)
24 Mon	15.19 (1.21)	1.11 (0.73)

the hospital 5 to 7 days, they need to wear a hard collar for 3 months with appropriate physical exercise. After anterior decompression, trial spacers were used to determine which implant shape would be used (**Figure 3A**). After choosing the trial spacer correctly, a corresponding Zero-P implant filled with  $\beta$ -tricalcium phosphate (Synthes GmbH, Oberdorf, Switzerland) was inserted with an implant holder/aiming device. Correct position of the cage was confirmed by using a C-arm in lateral and AP views. The device should be placed 2 mm behind the anterior vertebral border in the lateral view (**Figure 3B**) and in the center of the intervertebral space in the AP view (**Figure 3C**). After drilling the hole by the aiming device, the first locking screw was inserted. The other three holes were drilled by the same way. After the aiming device was removed, the three remaining screws were inserted. When the Zero-P implant is completely inserted, its zero-profile characteristic can be seen [18, 22].

#### Statistical analysis

The mean and standard deviation (SD) were determined for quantitative data such as degree of cervical alignment and the JOA, VAS score and sank, between preoperative and postoperative time points and during further follow-up using the t test for paired samples if a normality test was passed or a Wilcoxon signed-rank test if a normality test was failed and *P* values < 0.05 were considered statistically significant. All the statistical analysis was performed with SPSS19.0.

#### Results

Overall, the average time of operation was 115 minutes, the average amount bleeding was about 82.8 ml (60 ml-100 ml). Until the last follow-up, there were no patients who experienced neurological deterioration, deep infection or cardiopulmonary insufficiency. There

were no surgery-related complications such as screw fracture, screw loosening happened after surgery or during the period of follow-up. All the 51 patients showed an improvement in their clinical symptoms and 49 patients solid bony fusion without pseudo-articulation formation at 1 year.

#### Clinical outcome

All 51 patients who were followed-up unabridged time levels had significant amelioration in JOA and VAS score at 6 months compared with pre-operation (*P*<0.05). However, in apparent change during further following-up (*P*>0.05) (**Table 2**), 4 patients at 1 month and 1 patient at 6 months complained about mild dysphagia-related symptoms (7.8%). In the follow-up, we observed no implant displacement and vertebral instability.

#### Radiological outcome of solid fusion situation

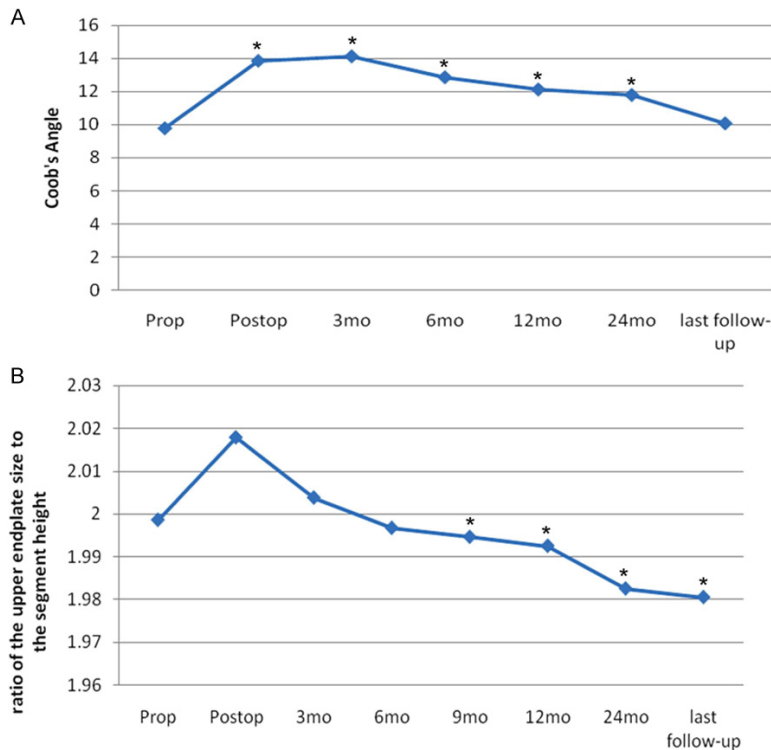
There were 39 (76.5%) of the 51 patients who achieved solid fusion 6 months after surgery, and 49 (96.1%) of the patients achieved solid fusion 1 year after surgery. Healing one X-ray observation, CT prompts suspicious. At the end of the 3 cases of incomplete healing of patients were follow-up for 1 year.

#### Measurement of regional cervical angle and sank

Radiologic evaluations revealed the mean local cervical angles to be -9.81 ( $\pm$ 3.54) degrees (a negative value corresponds to a lordotic angle and a positive value indicates the presence of kyphosis) comparing to -13.84 ( $\pm$ 4.41) after the operation. There were significant difference before and after operation (*P*<0.05). The local cervical angle in final follow-up declined comparing to postoperative local cervical angles but improved comparing to pre-operation (**Figure 4A**). Zero-profile Implant not arise significant subsiding at last following-up visits (*P*>0.05). But when assessing the whole patient group, the time effect was significant (*P*<0.05). Mean increase in the height of the treated segments was 3.9% in the first postoperative visit. This value then decreased gradually with time reaching 95% of preoperative state by the 12-month follow-up visit. Reaching 93% of preoperative state by the last following-up visit (**Figure 4B**).



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**Figure 4.** Development of radiological parameter Cobb's angle and ratio of the upper endplate size to the segment height. A. Development of radiological parameter Cobb's angle during follow-up. B. Development of radiological parameter ratio of upper endplate size to the segment height. \* $P < 0.05$  represents the value in the post-operation group compared to the pre-operation group.

### Discussion

Anterior cervical discectomy and fusion (ACDF) surgery is a common and successful method for treating degenerative. In last 30s years, more and more cervical plate applied to clinical. After anterior cervical bone graft fusion, attach a piece of steel plate, it can effectively prevent graft shift or out, and increase the safety of postoperative, simultaneously maintain cervical physiological curvature, promote bone graft fusion [23]. However, along with the increase in applications, complications of steel plate are more and more cause the attention of scholars. Static plate provide strong fixed, at the same time, the stress shelter phenomenon exists, have adverse effect on bone graft fusion [24, 25]. To solve this problem, a new dynamic steel plate arises at the historic moment. It can provide angular variational the screw or overall settlement of plate. The dynamic plate achieves the effect of dynamic pressure, and reduces stress blocking effect to

promote the fusion of bone graft [26]. Plate for either static or dynamic, however, they are all has certain thickness. It can stimulate the structure which is in front of the vertebral bodies, to produce the corresponding complications. The presence of a plate itself in the anterior cervical spine and its contact with the esophagus is considered to be a possible cause of postoperative dysphagia [27, 28]. This phenomenon might also be explained by the lower incidence of postoperative dysphagia inpatients after cervical arthroplasty as compared with patients who was treated with additional a cervical plate [25].

Because of above reasons, some scholars advocate to use single gap cage, avoid related complications of plate [29, 30]. However, using alone cage fusion, there are a series of complications.

For example: loss of cervical lordosis, cage sinking problem [31, 32]. As is known to all, it is important for normal cervical spine function and movement to maintain postoperative cervical physiological curvature. Cervical sagittal curvature loss may cause the occurrence of axial symptoms, neuropathic pain, which is lead to an adverse effect on postoperative function recovery. Cage sinking produce to the missing of disc height, thus causing cervical sagittal curvature changed. This phenomenon is mainly due to the single gap Cage fixation, and lack of strong and reliable screw. Postoperative micromotions between the endplate and the cage, eventually lead to cage sinking, pseudarthrosis formation.

Zero-P plate design concept is to avoid the above phenomenon, it connects the vertebral body by four screws. It includes the cage, fixed titanium alloy plate, intervertebral screw structure of three parts. Titanium alloy plate fixed with inter vertebral fusion, its unique groove

structure make the stress of fixed plate separated from cage, and avoided sinking. Because of without complementary with steel plate in intra operative, vertebral soft tissue disturbance is small, which can reduce the number of adjacent segment degeneration. Zero-P the design of the stator and the anatomic shape characteristics of fusion can make the cervical vertebra to achieve immediate stability, allowing patients with early postoperative activities. Some scholars have reported the fine properties of the Zero-P in biomechanics and clinical research [19, 21, 31, 33]. Our research shows that patients with postoperative JOA score and VAS scores significantly improved. Lordotic curvatures of the cervical spine at the level of operation have markedly increased in the immediately after operation and the first month. Nevertheless, these values decreased gradually again in later periods, still higher than the pre-operation. The alignment of the whole cervical spine in the post-operative days increased to a maximum in the follow-up periods at 3 month, and these values decreased again mildly in further follow-up visits, however, increased than that before operation. Zero-profile Implant not arise significant subsiding at last following-up visits ( $P>0.05$ ).

ACDF, as the gold standard for treatment of cervical spondylosis, bone graft fusion is the ultimate goal of it. Only stable bony fusion can avoid the happening of protrusion deformity after, and obtain good therapeutic effect. Some literature reports, the use of steel plate fusion rate is higher than that of without. Recent reports in the literature of the Zero-P, patients who used Zero-P plate obtained satisfactory fusion rates (91.3%, 100%) [34-36]. In our research, there were 39 (76.5%) of the 51 patients who achieved solid fusion 6 months after surgery, 49 (96.1%) of the patients achieved solid fusion 1 year after surgery.

Dysphagia is commonly phenomenon by patients after ACDF and often ascribed to soft-tissue swelling related to the surgery. Lee et al. [13] found that there was an association between dysphagia and plate thickness. When thinner plates were used, dysphagia incidence was decreased [13]. Some scholars have reported that the relation of postoperative prevertebral soft tissue swelling and dysphagia. They think the soft tissue swelling increased the risk of dysphagia. A certain thickness of the plates can stimulate prevertebral soft tissue,

or direct damage to the esophagus, causing corresponding symptoms [37, 38]. However, Kepler's research has found that the width of soft tissue in front of the cervical spine does not correlate with postoperative dysphagia [39].

Compared with a slightly thick and less smooth plate, the placement of a thinner and smoother plate may reduce the occurrence of dysphagia by a lower profile and milder scar formation. The Zero-P implant is remarkable on account of less influence to the anterior soft tissue, and especially to the esophagus. This might avoid any mechanical irritation of the esophagus and may be the possible reason of low dysphagia rate in patients. In our research, 3 patients at 1 month and 1 patient at 6 months complained about mild dysphagia-related symptoms (7.8%). The incidence of dysphagia in our study is similar to the study of Scholz [18]. They used Zero-P plate in 38 patients with a very low incidence of dysphagia after the following periods and is much lesser than the incidence reported by other scholars [40, 41].

In conclusion, our research has proved that the zero-P device in ACDF surgery has a good therapeutic effect. Clinical effect is satisfied, and the low incidence of dysphagia was occurred. No implant-related complications were observed. Due to the short follow-up period, adjacent segment degeneration not can be seen during follow-up periods. However, the major deficits of this study is that the nature of this analysis was retrospective and don't have control group for comparison, which may be associated with biases, the number of evaluated patients is small at the same time. Nonetheless, this research confirms the safety and efficacy of the Zero-P device in patients who treated at single and multiple levels and with a median follow-up. In future, a multi-center prospective randomized controlled trial with more patients and longer following-up are necessary to test and verify these observations.

### Disclosure of conflict of interest

None.

**Address correspondence to:** Dr. Zhou Xiang, Department of Orthopaedic, Spine Center, West China Hospital, Sichuan University, Guoxue Lane 37, Chengdu 610041, China. E-mail: liuhao6304@yeah.net

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