

# Comparison of the clinical effects of zero-profile anchored spacer (ROI-C) and conventional cage-plate construct for the treatment of noncontiguous bilevel of cervical degenerative disc disease (CDDD)

## A minimum 2-year follow-up

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### Abstract

Comparing the clinical and radiographic outcomes in anterior cervical discectomy and fusion (ACDF) using a zero-profile anchored spacer (ROI-C) or a conventional cage-plate construct (CPC) for treating noncontiguous bilevel of cervical degenerative disc disease (CDDD).

Overall, 46 patients with 2 noncontiguous segments of CDDD, treated with ACDF from January 2011 to October 2015, were included in this study. ROI-C was used in 22 patients (group A) and CPC in 24 patients (group B). The clinical and radiographic outcomes and complications were compared pre- and postoperatively. All patients were followed up for at least 24 months after surgery.

No significant difference was found in fusion rate, cervical curvature, height of fused segment (FSDH), intraoperative blood loss, and Japanese Orthopaedic Association (JOA), and Neck Disability Index (NDI) scores between the 2 groups. Group A had a shorter operation time and significantly lower incidence of dysphagia (3 and 24 months postoperatively) than group B ( $P < .001$  and  $P < .05$ , respectively). Moreover, group A had a higher loss of FSDH than group B, but with no difference between the 2 groups ( $P > .05$ ). Two cages developed subsidence in group A (4.5%) and 2 adjacent levels developed degeneration in group B (2.8%).

ACDF with ROI-C device was superior to CPC for noncontiguous bilevel of CDDD because it avoided postoperative dysphagia and required a shorter operation time. Moreover, the clinical outcomes were comparable. Prospective trials with larger samples and longer follow-up are required to confirm the results.

**Abbreviations:** ACDF = anterior cervical discectomy and fusion, ASD = adjacent segment degeneration, CDDD = cervical degenerative disc disease, CPC = cage-plate construct, FSDH = disc height of fused segment, IS = intermediate segment, JOA = Japanese Orthopaedic Association, MRI = magnetic resonance imaging, NDI = Neck Disability Index, PEEK = polyetheretherketone, ROM = range of motion.

**Keywords:** anterior cervical discectomy and fusion (ACDF), cervical degenerative disc disease (CDDD), noncontiguous, ROI-C, skip-level

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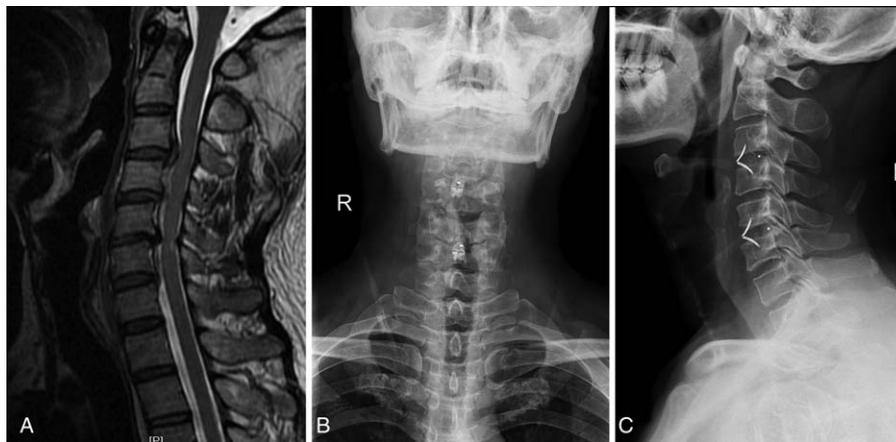
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## 1. Introduction

Anterior cervical discectomy and fusion (ACDF) is a worldwide accepted surgical procedure for treating cervical degenerative disc disease (CDDD).<sup>[1,2]</sup> The conventional cage-plate construct (CPC) has the advantages of immediate postoperative stability, higher fusion rate, and lower incidence of pseudarthrosis.<sup>[3,4]</sup> However, subsequent implant-related complications, such as screw loosening or breakage, plate dislodgement or fracture, dysphagia, soft-tissue injury, esophagus perforation, spinal cord or nerve injury, and adjacent segment ossification, may occur.<sup>[1,5–9]</sup> Stand-alone cages have been designed and put into clinical application to avoid these hardware-related complications. However, they were reported to have poor immediate stability due to the high incidence of subsidence, malalignment, and segmental kyphosis.<sup>[10,11]</sup> A ROI-C device (LDR, Troyes, France) of the cervical spine was developed and used clinically in single-level, double-level, or even in multilevel CDDD to overcome these disadvantages.<sup>[12–16]</sup>

The skip-level CDDD is one of the specific types of multilevel CDDD, including one or more normal segments between the lesion levels. Surgeons often perform operations on noncontiguous involved segments individually in clinical practice. The



**Figure 1.** A 53-year-old male. Sagittal plane of T2-weighted MRI scan (A) showed 2 noncontiguous segments of herniation (C3/4 and C5/6) compressed the posterior spinal cord, and the height of intervertebral space was reduced. The anteroposterior (B) and lateral (C) X-ray radiographs at 1 month postoperatively showed anterior cervical discectomy and fusion (ACDF) with zero-profile anchored spacers (ROI-C) at the corresponding levels.

therapy on patients of skip-level CDDD may aggravate complications such as dysphagia and adjacent segment ossification due to the use of prevertebral multiplate. The ROI-C device is a new type of stand-alone anchored spacer composed of a polyetheretherketone (PEEK) cage and 2 anchoring clips. The design of zero-profile implant allows the whole implantation of the cage into the intervertebral space, thereby providing adequate stability and avoiding implant contact with the anterior soft tissue. This results in a reduction in the occurrence of plate-related complications.<sup>[12]</sup> Theoretically speaking, the ROI-C device can preserve the normal motions of the intermediate segment (IS), while only dealing with the lesion levels in treating noncontiguous segments of CDDD.

In previous studies, ACDF with stand-alone anchored spacer (MC+ or Zero-P) achieved satisfactory clinical effect in treating noncontiguous levels of CDDD.<sup>[17–21]</sup> The present study compared the clinical and radiological results of the patients with noncontiguous bilevel of CDDD who underwent ACDF using the ROI-C device or the CPC. The aim was to determine whether the ROI-C device had theoretical efficacy for patients with 2 noncontiguous segments of CDDD.

## 2. Materials and methods

### 2.1. Patient population

The study was conducted as a retrospective investigation of 53 patients with 2 noncontiguous levels of CDDD who underwent ACDF from January 2011 to October 2015. The study was approved by the Medical Ethics Committees of The First Affiliated Hospital of Soochow University. Informed written consent was obtained from all individual participants. Among the 53 patients, 7 were lost to follow-up. Finally, a total of 46 patients (28 males and 18 females) were included in this retrospective study. The inclusion criteria were as follows: clinical presentation of myelopathy and/or radiculopathy; spinal cord or nerve root compression seen on recent magnetic resonance imaging (MRI) at 2 noncontiguous levels; and failure of conservative management for at least 6 months. The exclusion criteria were as follows: patients whose operative levels included C2/3 or C7/T1; those with severe cervical instability and developmental stenosis; those with continuous or combined ossification of the posterior

longitudinal ligament (OPLL); those with a history of previous cervical spine surgery, trauma, infection, tumor, severe osteoporosis, metabolic disease, and allergy to the implant material; those indicated for simultaneous anterior and posterior surgery; and those with a follow-up period of less than 24 months.

Among the 46 patients, 92 skip levels were treated, including C3/4+C5/6 in 34 patients, and C4/5+C6/7 in 12 patients. The patients were divided into 2 groups based on the different types of implants: 22 patients who underwent fusion using zero-profile anchored spacer (ROI-C, LDR, Troyes, France) implants were classified as group A (Fig. 1), and 24 patients who underwent fusion using conventional stand-alone PEEK cages and an anterior titanium plate (Medtronic, MN) served as group B (Fig. 2). In group A, the mean age and follow-up time were  $56.6 \pm 6.4$  years (range 46–70 years) and  $30.5 \pm 5.2$  months (range 24–42 months), respectively. The operated skip levels were C3/4+C5/6 in 15 patients and C4/5+C6/7 in 7 patients. In group B, the mean age and follow-up time were  $58.6 \pm 7.2$  years (range 44–72 years) and  $32.1 \pm 6.5$  months (range 24–46 months), respectively. The surgical noncontiguous segments were C3/4+C5/6 in 19 patients and C4/5+C6/7 in 5 patients. No statistically significant differences were found in age, sex, treated noncontiguous segments, and follow-up time between these 2 groups ( $P > .05$ ; Table 1).

### 2.2. Surgical procedure

All the surgeries were performed by 1 single senior spine surgeon. The patients were placed in the supine position after general anesthesia. The surgeries were performed using a standard right-sided anterior Smith–Robinson approach.<sup>[22]</sup> Extensive decompression was performed by removing the herniated disc, osteophytes, and posterior longitudinal ligament to expose the dura and relieve the compressions of spinal cord and nerve roots. The cartilage endplates were carefully removed with curettage. Care should be taken to preserve the bony layer of both adjacent endplates. The appropriate size of the cage was trialed and determined by both preoperative templating and intraoperative examination to avoid overdistraction of intervertebral space. All the cages were filled with excised local osteophytes and 0.25 mg of recombinant human bone morphogenetic protein (rhBMP-2; Pharmaceutical Group Investment Limited Corporation, Hangzhou, China).



**Figure 2.** A 44-year-old male. Lateral T2-weighted MRI scan (A) showed nonadjacent bilevel of disc herniation (C3/4 and C5/6) compressed the posterior spinal cord, and the height of intervertebral space was reduced. The anteroposterior (B) and lateral (C) radiographs at 1 month postoperatively showed anterior cervical discectomy and fusion (ACDF) with the traditional cage and plate at the corresponding segments.

In group A, proper-sized devices (ROI-C) were inserted with the aid of an impactor. Upper and lower anchoring clips of the device were placed in the cranial and caudal vertebral bodies, respectively, to fix the implant under the fluoroscopic guidance. In group B, stand-alone PEEK cages were inserted into the disc space along with anterior cervical plates immobilized by self-tapping screws. Operation time and intraoperative blood loss in the 2 groups were recorded.

Postoperatively, all patients were encouraged to get off the bed after 24 hours with a semi-rigid neck collar and resume their normal activities gradually. Attention should be paid to avoid excessive neck movement within the first 3 postoperative months. All patients were followed up at 1, 3, and 24 months postoperatively to conduct a clinical and radiological assessment after discharge.

**2.3. Clinical evaluation**

Clinical outcomes were assessed by the Japanese Orthopaedic Association (JOA) scoring system and the Neck Disability Index (NDI) scoring system preoperatively and at each follow-up time points. The postoperative dysphagia rate was evaluated according to the criterion defined by Bazaz et al.<sup>[5]</sup> The severity of dysphagia-related symptoms was graded as none, mild, moderate, and severe based on the patients’ statements (Table 2).

**2.4. Radiologic assessment**

The radiological outcomes were measured preoperatively and at each follow-up time point. Fusion was defined according to the

criteria of previous studies<sup>[2,11]</sup>: changes in the interspinous distance of the fused segments should not be more than 2 mm on lateral flexion-extension radiographs; no radiolucent gap should occur between the bone graft area and the endplate; and continuous bridging bony trabeculae should be present across the intervertebral space and its width should not be less than 3 mm on lateral radiographs. The cervical curvature was assessed using the Cobb angle method between the line parallel to the inferior border of the C2 and C7 vertebral bodies. The disc height of fused segment (FSDH) was ascertained as the mean value of the anterior and posterior disc height measured from the lower-endplate of the cephalad centrum to the upper-endplate of the caudal centrum of the fused segment.<sup>[15]</sup> Cage subsidence was defined as the sum distance between the superior and inferior parts of the vertebral body cage exceeding 3 mm,<sup>[10,11]</sup> approximately measured by the decrease of FSDH at the final follow-up compared with the value obtained at 1 month after surgery. Adjacent segment degeneration (ASD) was defined as the presence of enlargement of anterior osteophyte or new osteophyte formation, disc height loss ( $\geq 30\%$ ), and segmental instability on plain film radiographs, or decrease in disc signal intensity and intervertebral herniation at adjacent segments (cranial, caudal, or intermediate) on T2-weighted MRI.<sup>[23,24]</sup> All radiographs were evaluated twice using picture archiving and communication system software (PACS, Neusoft, Shenyang, China) with the same methods by an independent experienced radiologist not related to the process of therapy.

**2.5. Statistical analysis**

All statistical analyses were performed using SPSS 19.0 software (SPSS Inc., Chicago, IL). Continuous variables were expressed as mean  $\pm$  standard deviation (SD) and compared using the Student *t*

	Group A	Group B	P
Age, y	56.6 $\pm$ 6.4	58.6 $\pm$ 7.2	.424
Gender (male/female)	13/9	15/9	.813
Skip-level			
C3/4+C5/6	15	19	.718
C4/5+C6/7	7	5	
Follow-up, mo	30.5 $\pm$ 5.2	32.1 $\pm$ 6.5	.369
Blood loss, mL	79.1 $\pm$ 12.0	86.3 $\pm$ 15.8	.099
Operation time, min	121.1 $\pm$ 14.7	154.4 $\pm$ 12.3	.000

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)

**Table 3**

**Clinical and radiologic outcomes of patients receiving anterior cervical discectomy and fusion with zero-profile anchored spacer (ROI-C) or conventional cage-plate construct.**

	Group A	Group B	P
<b>JOA scores</b>			
Preop	10.0 ± 1.8	9.6 ± 1.5	.460
Postop 1 M	14.1 ± 1.4*	13.7 ± 1.3*	.298
Postop 3 M	14.8 ± 1.5*	14.3 ± 1.4*	.312
Final FU	14.9 ± 1.4*	14.6 ± 1.3*	.428
<b>NDI scores</b>			
Preop	32.3 ± 7.7	34.0 ± 7.1	.449
Postop 1 M	14.9 ± 4.9*	15.4 ± 4.7*	.770
Postop 3 M	13.4 ± 5.0*	13.7 ± 4.9*	.835
Final FU	13.1 ± 5.7*	12.7 ± 5.7*	.826
<b>Fusion rate</b>			
Postop 3 M	86.4% (38/44)	87.5% (42/48)	.872
Final FU	100%	100%	1.000
<b>Cervical curvature, °</b>			
Preop	10.2 ± 4.0	10.5 ± 4.4	.831
Postop 1 M	20.1 ± 4.6*	20.7 ± 4.8*	.688
Postop 3 M	17.6 ± 4.0*	18.1 ± 4.2*	.668
Final FU	15.9 ± 3.7*	16.3 ± 3.9*	.682
<b>FSDH, mm</b>			
Preop	5.5 ± 1.1	5.8 ± 1.1	.373
Postop 1 M	7.8 ± 1.4*	8.0 ± 1.1*	.730
Postop 3 M	7.0 ± 1.1*	7.3 ± 1.1*	.381
Final FU	6.4 ± 1.0†	6.9 ± 0.9	.101

FSDH = disc height of fused segment, FU = follow-up, JOA = Japanese Orthopaedic Association, M = month, NDI = Neck Dysfunction Index, Postop = postoperative, Preop = Preoperative.

\* P < .001 Statistical significance compared with preoperatively.

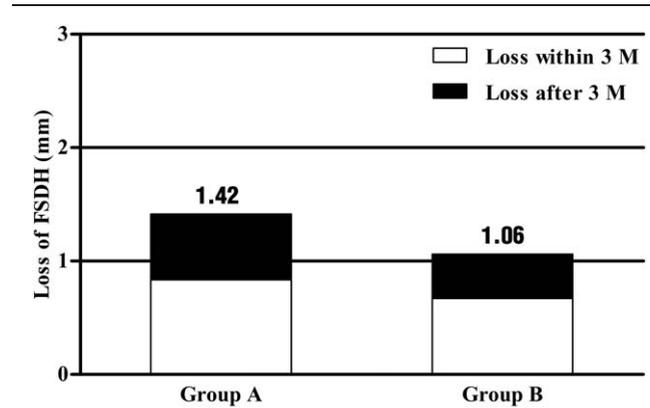
† P < .05 Statistical significance compared with preoperatively.

test. Categorical variables were expressed as number or percentages and compared using the Chi-square or Fisher exact test. All values of P < .05 were considered statistically significant.

**3. Results**

**3.1. Clinical outcomes**

No statistically significant difference was found in the intraoperative blood loss between the 2 groups (79.1 ± 12.0 vs 86.3 ± 15.8 mL, P > .05; Table 1). The surgical time of group A was significantly shorter than that of group B (121.1 ± 14.7 vs 154.4 ± 12.3 minutes, P < .001; Table 1). The JOA scores at the final follow-up increased significantly compared with the preoperative

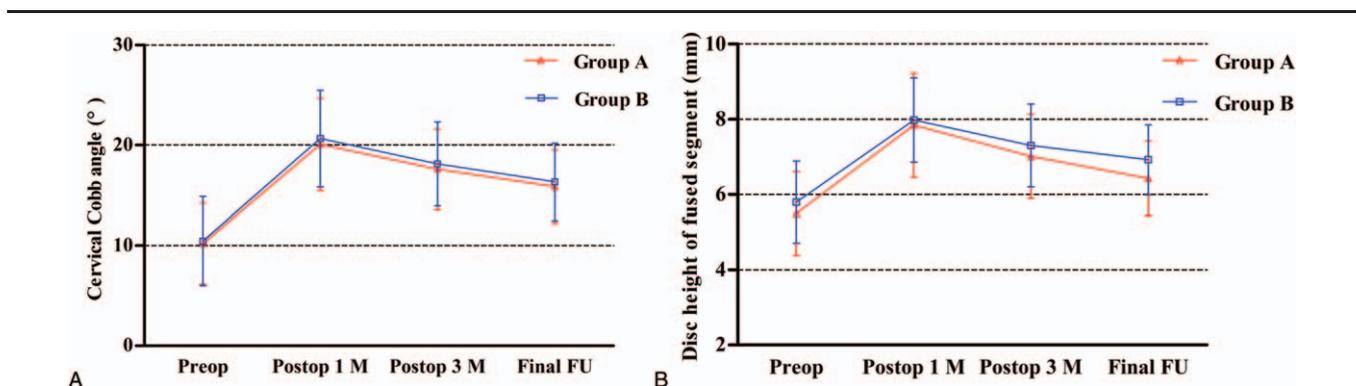


**Figure 4.** A stacked graph showed the loss of FSDH in group A and group B during the follow-up period. The white block indicated the loss of FSDH from 1 month to 3 months postoperatively, and the black block indicated the loss of FSDH from 3 months postoperatively to the final follow-up. FSDH = Disc height of fused segment; M = month.

values in 2 groups (P < .05; Table 3). The postoperative NDI scores at the final follow-up were significantly reduced compared with the preoperative values in the 2 groups (P < .05; Table 3). However, no statistical significance was found in the JOA and NDI scores at each follow-up time point between the 2 groups (P > .05; Table 3).

**3.2. Radiologic outcomes**

The cervical Cobb angle was improved pronouncedly from 10.2 ± 4.0° preoperatively to 20.1 ± 4.6°, 17.6 ± 4.0°, and 15.9 ± 3.7° at 1, 3, and 24 months postoperatively in group A, respectively, and from 10.5 ± 4.4° preoperatively to 20.7 ± 4.8°, 18.1 ± 4.2°, and 16.3 ± 3.9° at 1, 3, and 24 months postoperatively in group B, respectively. No statistical difference was found in the cervical lordosis between the 2 groups at each time point (P > .05; Table 3). Regarding FSDH, the values elevated from 5.5 ± 1.1 mm preoperatively to 7.8 ± 1.4, 7.0 ± 1.1, and 6.4 ± 1.0 mm at 1, 3, and 24 months postoperatively in group A, and from 5.8 ± 1.1 mm to 8.0 ± 1.1, 7.3 ± 1.1, and 6.9 ± 0.9 mm in group B, respectively. No significant difference was found in the FSDH values between the 2 groups at each time point (P > .05; Table 3). The variable tendency of cervical lordosis and FSDH are shown in Figure 3A, B, respectively. The loss of FSDH at the final follow-up relative to that of 1 month preoperatively was 1.42 ± 1.03 mm in group A and 1.06 ± 0.80 mm in group B (P > .05; Fig. 4). The descending



**Figure 3.** Line graphs showed comparisons of clinical and radiologic results between Group A (ACDF with ROI-C device) and Group B (ACDF with cage-plate construct). Variable tendency of cervical lordosis (A) and disc height of fused segment (B). ACDF = anterior cervical discectomy and fusion, FU = follow-up, M = month, Postop = Postoperative, Preop = Preoperative.

**Table 4**  
**Conditions of loss of FSDH and subsidence in 2 groups.**

	Group A	Group B	P
Total loss, mm	1.42 ± 1.03	1.06 ± 0.80	.206
Loss within 3 M, mm	0.84 ± 0.86	0.67 ± 0.67	.478
Loss within 3 M/Total loss	59.1%	63.4%	
Subsidence rate	4.5% (2/44)	0%	.226

FSDH = disc height of fused segment, M = month.

distance within the first 3 months postoperatively accounted for 59.1% of the total 2-year descending distances in group A and 63.4% in group B (Table 4). At the final follow-up, subsidence occurred in 2 cages of 2 patients in group A (4.5%), and none of patients had a loss of FSDH of more than 3 mm in group B. No correlation was found between these 2 groups ( $P > .05$ ; Table 4). The fusion rate at 3 months postoperatively was 86.4% (38/44) in group A and 87.5% (42/48) in group B. All patients achieved radiographic fusion at the final follow-up (Fig. 5).

**3.3. Complications**

Dysphagia was the most common postoperative complication. In group A, 3 patients (13.6%) complained of mild dysphagia at 1 month postoperatively and obtained complete remission at 3 months postoperatively. In group B, 9 patients (37.5%) complained of dysphagia (7 mild and 2 moderate) at 1 month postoperatively, 7 patients (5 mild and 2 moderate) at 3 months postoperatively, and 6 patients (all mild) at the final follow-up. A significant difference was found in the incidence of dysphagia at 3 months postoperatively ( $P = .010$ ) and the final follow-up between the 2 groups ( $P = .022$ ). One patient had hoarseness in group A, which finally disappeared after conservative treatments and appropriate nursing. ASD was observed in 2 segments of 2 patients without any clinical symptoms in group B. An anterior osteophyte was formed at the IS and cephalad adjacent segment. The incidence of complications is summarized in Table 5.

**Table 5**  
**Incidence of complications in 2 groups.**

	Group A	Group B	P
Dysphagia			
Postoperative 1 mo	13.6% (3/22)	37.5% (9/24)	.132
Postoperative 3 mo	0%	29.2% (7/24)	.010*
Final follow-up	0%	25.0% (6/24)	.022*
Hoarseness	4.5% (1/22)	0% (0/24)	.478
Adjacent segment degeneration	0% (0/66)	2.8% (2/72)	.497

\*  $P < .05$  Significant difference between the 2 groups.

**4. Discussion**

ACDF was firstly described by Smith and Robinson [22] and Cloward [25] in 1958, and since then, it has been considered as the standard operative treatment for CDDD after the failure of conservative treatment. [1,2] Skip-level CDDD is a rare, age-dependent degenerative disc disease, which severely impairs the life quality of patients. The conventional operation for the noncontiguous bilevel of CDDD is independent discectomy and plate fixation for both the levels, preserving the range of motion (ROM) of the IS disc. However, the 4 tips of the 2 plates obviously increase the risk of adjacent segment ossification and intervertebral disc degeneration. [6] Three-level fusion using only 1 plate has the advantage of removing the overloaded stress and excessive activity of IS with the aforementioned methods, avoiding high incidence of reoperation of normal IS. Nonetheless, it may result in a significant increase in the intradiscal pressure and segmental motion at the supra- and infra-adjacent segments. [26,27] A biomechanical study implemented by Finn et al [28] suggested that IS experienced modest augmentation of ROM after noncontiguous 2-level fusion, whereas supra- and infra-adjacent levels of tri-level fusion might suffer from a pronounced increase in ROM compared with the noncontiguous bilevel fusion. Bisson et al [29] reviewed the clinical data of 17 patients who underwent skip-level ACDF with 2 anterior plates and found improved overall neurological and clinical outcomes. Moreover, they discovered that only 2 patients suffered the osteophyte



**Figure 5.** A 53-year-old male. Lateral plain films showed anterior cervical discectomy and fusion (ACDF) with ROI-C device at C3/4 and C5/6 at 1 and 3 months postoperatively (A, B), respectively. Reconstructed sagittal CT scan (C) showed bony fusion at the final follow-up.

enlargement at the IS with no symptomatic ASD during the follow-up period.

Theoretically, the use of ROI-C device in the skip-level CDDD can not only reduce the incidence of donor site and screw plate related complications but also guide targeted therapy on lesion segments, especially for skip-level cervical spondylosis, which can keep its normal motion of IS. Several authors have applied other types of stand-alone anchored spacers with a similar fixation mechanism as the ROI-C device in the skip-level CDDD and achieved favorable clinical effects.<sup>[17–21]</sup> Wang et al<sup>[17]</sup> reported that 15 patients (93.8%) achieved solid fusion with an average follow-up period of 43.6 months in 2 noncontiguous levels of CDDD after ACDF with self-locking stand-alone cage (MC+). They found only 3 segments (6.25%) exhibiting radiological evidence of ASD with no postoperative neurological symptoms or implant failure. Shi et al<sup>[21]</sup> compared the clinical effects of stand-alone anchored spacer (Zero-P) and CPC in the treatment of 2 noncontiguous levels of CDDD and found no significant difference in the JOA scores, fusion rate, cervical alignment, and incidence of dysphagia between these 2 groups. They demonstrated that ACDF with stand-alone anchored spacer (Zero-P) was a reliable and effective method for skip-level cervical spondylosis with a little impact on IS.

To our knowledge, no direct comparison has been made between ROI-C device and CPC in the operative treatment of nonadjacent bi-segment of CDDD. The present study found no statistical differences in the postoperative fusion rate, JOA scores, and NDI scores between the 2 groups, suggesting that both techniques can achieve satisfactory therapeutic effect after surgery. However, group A consumed significantly less time compared with group B, which should be attributed to the use of self-locking structure of the ROI-C device. The surgical procedure and manipulation could be simplified using this device, so that surgeons could spare the use of plate and screw for fixation and reduce the exposure region and trauma to local soft tissue.

Dysphagia was one of the most common complications following ACDF. The early postoperative incidence can be up to 71%.<sup>[30]</sup> The majority of patients who complained about swallowing dysfunction recovered completely within the first 3 months, whereas about 12.5% to 35.1% still had the persistent symptoms for more than 3 months.<sup>[5]</sup> The detailed pathophysiological mechanisms related to dysphagia were multifactorial. Several researches have indicated that tracheal intubation, soft-tissue edema, esophageal injury, recurrent laryngeal nerve paralysis, and postoperative hematoma formation may be responsible for transient dysphagia after surgery, and development of fibrous adhesions and prevertebral osteophyte formation may account for the long-standing symptoms.<sup>[1,5,9,30,31]</sup> In previous studies of this stand-alone anchored spacer, Wang et al<sup>[14]</sup> showed a significantly lower risk of dysphagia in the ROI-C group than that in the anterior plate group (0% vs 27.3%) while treating 1- or 2-level CDDD at 3 months postoperatively. Liu et al<sup>[16]</sup> identified a higher incidence of dysphagia of 25% and 21.9% at 3 months after surgery and final follow-up with CPC, in contrast with that of 3.6% and 3.6% with ROI-C device for multilevel cervical spondylotic myelopathy, respectively ( $P=.02$  and  $P=.037$ ). Consistent with the aforementioned reports, our research also found a statistically significant difference between group A and group B at 3 months postoperatively (0% vs 29.2%;  $P=.010$ ) and final follow-up (0% vs 25.0%;  $P=.022$ ). This might be attributed to the design of zero-profile implant that allowed the whole implantation of the cage into the intervertebral space, thereby providing adequate stability and avoiding implant

contact with the anterior soft tissue. This resulted in a reduction in the incidence of postoperative dysphagia. Moreover, group B exhibited several adverse factors, such as longer static retraction time, excessive dissection of soft tissue, and installation of 2 prevertebral titanium plates, inevitably stimulating the anterior structures after operation.

A stand-alone cage is known to have a high tendency of subsidence, which might cause a loss of cervical alignment and kyphosis, and accelerate degeneration of adjacent segments.<sup>[32,33]</sup> Fujibayashi et al<sup>[11]</sup> reported a high incidence (44%) of cage subsidence ( $\geq 3$  mm), and loss of cervical lordosis ( $\geq 5^\circ$ ) existed in stand-alone cages despite the advantages of less invasiveness and donor-site morbidity. Gercek et al<sup>[10]</sup> found that 5 of the 9 fused segments had an anterior or posterior disc height loss exceeding 3 mm, with 1 patient suffering from recurrent radiculopathy after 6-month follow-up. In the present study, the loss of FSDH mainly (about 60%) occurred within the first 3 months, which was consistent the reports of previous studies.<sup>[11,32,34]</sup> The loss of FSDH was much higher in group A than in group B ( $1.42 \pm 1.03$  vs  $1.06 \pm 0.80$  mm) and subsidence was only observed in group A, whereas no statistical differences were found between the 2 groups. The possible explanations were as follows: elastic modulus of PEEK cage was equivalent to the normal human cortical bone, and superior and inferior sections of the self-locking anchoring clips contributed to the stability. Therefore, both the techniques could reduce the risks of displacement and subsidence and promote the bony fusion; the surgeons had excellent surgical techniques in preserving the bony endplate, selecting the appropriate size of cage, and avoiding overdistraction; and all patients had a normal bone mineral density and postoperative fixation of more than 3 months.

In the present study, most patients underwent assessment of ASD using x-ray films because of the lack of MRI images. Two patients of the CPC group had anterior osteophyte formation in the adjacent segments, one in the IS and the other in the supra-adjacent segment. The occurrence rate of ASD in IS was 4.2%, which was higher than that of the ROI-C group (0%). Shi et al<sup>[21]</sup> reported 3.7% of the patients who underwent skip-level fusion with 2 anterior cervical plates developed ASD at the IS, which was also higher than that in the zero-profile implant group (0%). The aforementioned results supported the findings of Yang et al<sup>[35]</sup> that zero-profile device could reduce the adjacent segment ossification compared with the anterior plate and cage. However, another study worked by Shi et al<sup>[20]</sup> on the MRI examination of ASD after skip-level fusion found that the zero-profile device still experienced a decreased signal intensity at the IS with a high rate of 20%. The possible reasons were that MRI was a more sensitive method than radiographs for evaluating ASD, and had a higher detection rate at the early stage of disc degeneration.

This study had some limitations. First, it had the inherent weaknesses and drawbacks of a retrospective study. Noncontiguous bilevel of CDDD was rare and thus only 46 patients were included in this study, with a short-term follow-up. Second, reliable computed tomography scan was not performed for partial equivocal radiographic data. Third, most patients in this study lacked imaging data, such as postoperative MRIs, and would be more sensitive to ASD at the IS. Evaluation of intervertebral disc degeneration may become more definitive by combining plain radiographs with MRIs.

## 5. Conclusion

Taken together, the results of the present study demonstrated that ACDF with ROI-C device for noncontiguous bilevel of CDDD

achieved satisfactory clinical and radiographic results compared with that using CPC. It preserved the motion of normal IS, consumed shorter time for operation, and showed lower occurrence of dysphagia and ASD. A multicenter, large sample, and long-term follow-up prospective randomized controlled clinical trial is required to further confirm the efficacy of skip-level ACDF with ROI-C in noncontiguous segments of CDDD.

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