

# Comparison of the ROI-C cage and Zero-P device used in anterior cervical discectomy and fusion: a minimum 2-year follow-up study

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## Research article

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# Abstract

Background: Anterior cervical discectomy and fusion (ACDF) has been considered the gold-standard procedure for treating symptomatic cervical spondylosis refractory to conservative management. The aim of this study was to compare the clinical efficacies of anterior cervical discectomy and fusion (ACDF) with Zero-P and ROI-C devices in the treatment of cervical degenerative disc disease (CDDD). Methods: Between July 2014 and December 2014, 56 patients underwent ACDF with Zero-P or ROI-C. Pre-, intra-, and postoperative clinical and radiographic outcomes were compared between groups. Results: The visual analogue scale (VAS) pain score, Japanese Orthopaedic Association (JOA) score, neck disability index (NDI) score, cervical range of motion (CROM) angle, C2-7 Cobb angle, and disc height index (DHI) exhibited significant postoperative improvements in both groups ( $P < 0.05$ ). The successful treatment rates in both groups were 76% ( $P > 0.05$ ). In the Zero-P group, the duration for surgeries involving C3-4 or C6-7 was longer than for other surgeries ( $135.0 \pm 19.0$  vs.  $105.6 \pm 17.5$  min,  $P < 0.05$ ). The operative time for surgeries involving C3-4 or C6-7 was significantly shorter for ROI-C than for Zero-P ( $112.2 \pm 20.5$  min,  $P < 0.05$ ). There were no significant differences in the dysphagia or cage subsidence rates between the Zero-P and ROI-C groups ( $P > 0.05$ ). The last follow-up Cobb angle in the Zero-P group ( $24.4 \pm 4.5^\circ$ ) was significantly higher than that in the ROI-C group ( $18.1 \pm 2.3^\circ$ ) ( $P < 0.05$ ). Conclusion: ACDF with ROI-C showed comparable efficacy with the Zero-P device, with a shorter operation time for surgeries involving C3-4 or C6-7. However, ROI-C may cause more Cobb angle loss over time, which may lead to uncomfortable symptoms. Above all, the surgeon should take individual patient context and personal proficiency into consideration when choosing cage devices.

## Background

Cervical degenerative disc disease (CDDD) is a common spinal cord disorder affecting older populations [1]. Anterior cervical discectomy and fusion (ACDF), first described by Smith and Robinson in the 1950s [2], has been considered the gold-standard procedure for treating symptomatic cervical spondylosis refractory to conservative management [3]. The plate-cage construct (PCC) applied in ACDF has become the standard method of anterior reconstruction to allow complete immediate stability, thereby improving clinical outcomes [4]. However, PCC use is associated with complications [5, 6] such as dysphagia, tracheoesophageal injury, and plate and screw loosening. To minimize these issues, some authors have advocated for treatment involving some new anterior cervical interbody fusion and internal fixation systems [7, 8], such as the Zero-P and ROI-C devices.

Both the Zero-P and ROI-C devices involve a cage, but their fixation styles differ (Figure 3). The former fixation involves four screws, while the latter involves two clips. The Zero-P device is stand-alone anchored spacer (SAAS; Zero-P; Synthes GmbH, Oberdorf, Switzerland). This new device combines the advantages of a stand-alone cage and anchoring screw fixation, providing instant stability and preventing plate-related complications [4]. The ROI-C interbody cage (LDR Medical, Sainte-Savine, France), which also has a “zero-profile” structure, is a well-known system with the advantages of being

simple and compact. The cage design enables implantation into the vertebral space after discectomy, offering instant postoperative stability [9, 10].

Previous studies reported that the Zero-P or ROI-C implant achieves comparable outcomes with the PCC in terms of improvements in the NDI, JOA and VAS scores; and in the disc height index and C2-7Cobb angle [11,12]. But the Zero-P or ROI-C implant have lower rates of operation complications such as shorter operation time, dysphagia and cage subsidence [13,14].

Although recent reports have compared the Zero-P device and PCC or the ROI-C device and PCC, few studies have directly compared clinical outcomes and radiologic parameters between the Zero-P and ROI-C devices.

From July 2014 to December 2014, the patients in this study underwent ACDF with Zero-P or ROI-C for CDDD. The aim of this retrospective study was to ask which device (Zero-P or ROI-C) is more fit for patients with CDDD undergoing ACDF with better clinical outcomes and lower complication rates.

## Methods

### Patient population and study design

A total of 56 patients (27 males, 29 females) who underwent ACDF in our medical center (Zhujiang Hospital, Southern Medical University) from July 2014 to December 2014 were retrospectively included. The exclusion criteria were (1)  $\geq 3$  treated segments; (2) diagnosis of CDDD with other spinal diseases (e.g., ossification of the posterior longitudinal ligament, hypertrophic ligamentum flavum, spinal tumors, cervical spinal trauma, spinal infections, severe osteoporosis, etc.); (3) a history of previous cervical spine injury or surgical intervention; (4) follow-up period  $< 3$  years; and (5) non-contiguous affected segments. Eligible patients were separated into two groups based on the implant used. All patients had symptomatic CDDD and had not responded to at least 3 months of conservative treatment. Clinical manifestations were consistent with radiologic findings and physical examinations. The Zero-P group included 16 males and 14 females, with a mean age of 56.2 (range 35-65 years). The ROI-C group comprised 11 males and 15 females, with a mean age of 57.4 (range 36-67 years). Demographic and baseline characteristics were comparable between the two groups (Table 1). The patients were further subdivided according to the affected level. In group A, the treated levels included C3-4 or C6-7; patients in group B had other affected levels. We compared operative times between groups A and B (Table 2).

This study was approved by the Ethics Committee of Zhujiang Hospital, Southern Medical University, China. Patient consent was not required for this retrospective study as all the data were collected and analyzed anonymously.

### Surgical techniques

All patients were operated on by the same senior surgeon. Preoperative X-ray (anterior-posterior, lateral, and flexion-extension), computed tomography (CT, sagittal reconstruction) and magnetic resonance

imaging (MRI) scans were performed on every patient to confirm the affected level(s). A right-sided Smith-Robinson approach under general anesthesia was used for all patients. Intraoperatively, the X-ray machine was used to confirm the correct cervical segments, optimal cage depth, and suitable screw angles. After a complete discectomy, the cartilaginous portions of the cervical vertebral endplate were removed. The posterior longitudinal ligament and superfluous osteophytes were also resected if necessary. A suitable-sized Zero-P or ROI-C cage (filled with allograft cancellous chips) was implanted into the segmental interbody region according to the trial spacers. Finally, four screws were used to fix the Zero-P cage, while two individually designed cervical anchoring clips were inserted into the lower and upper vertebrae through the anterior portion of the ROI-C cage (self-locking system). Patients were allowed to ambulate 2 days after surgery, but they were required to wear a neck brace for 4-6 weeks to avoid cervical flexion-extension.

### **Outcome assessment**

The patients were followed-up for a minimum of 2 years. Clinical and radiological data were collected preoperatively and at 3, 6, 12, 24, and 36 months (when possible) after surgery. All patients were followed up for at least 2 years postoperatively. A visual analogue scale (VAS) was used to quantify neck and arm pain before surgery and at the final follow-up visit. The modified Japanese Orthopedic Association (JOA) scoring system was used to assess functional status before surgery and at the final follow-up visit. The recovery rate (%) at the final follow-up visit was calculated using the Hirabayashi [15] method:  $(\text{postoperative JOA score} - \text{preoperative score}) / (17 - \text{preoperative score}) \times 100\%$ . The final outcomes were classified as follows:  $\leq 25\%$ , poor; 25-49%, fair; 50-74%, good; and  $\geq 75\%$ , excellent. The neck disability index (NDI) was used to determine the degree to which neck pain interfered with patients' ability to manage activities of daily life. Cervical lordosis (CL) was measured as the C2-C7 Cobb angle. The cervical range of motion (CROM) was defined as the sum of the C2-C7 Cobb angle on lateral X-rays during flexion and extension. The disc height index (DHI) was the distance from the highest portion of the lower endplate of the cephalad vertebra to the closest portion of the upper endplate of the caudal vertebra. Subsidence was defined as height loss  $>3$  mm at any of the two measured disc heights [16]. Patients were evaluated for dyspepsia according to the subjective modified Bazaz Dysphagia Severity Grades [17] (Table 3). Successful fusion was defined as the presence of bone inside or outside the graft with no lucent lines, defined as lucencies extending  $>50\%$  of the graft-host interface [18]. All radiographs were read by two independent radiologists, and a third independent reading was conducted in cases of disagreement.

### **Statistical analysis**

Data are presented as mean $\pm$ standard deviation. SPSS for Windows version 25.0 (IBM, Armonk, NY, USA) was used for all analyses. Paired t tests were performed to identify significant group differences between pre- and postoperative JOA score, VAS score, NDI score, CROM, C2-C7 Cobb angle, and DHI. Independent-samples t tests were used to compare intergroup differences in JOA score, VAS score, NDI score, CROM,

C2-C7 Cobb angle, and DHI. For categorical data, Pearson's  $\chi^2$  test and Fisher's exact test were used. Differences were considered significant at  $P < 0.05$ .

## Results

The study included 56 patients (27 males, 29 females) with a mean age of 56.6 (34-65) years. Among them, 30 patients had 1 level, 26 patients had 2 levels, and no patients had  $\geq 3$  levels operated on during ACDF surgery.

The 56 patients were divided into the Zero-P and ROI-C groups (30 and 26 patients, respectively). There were no significant differences in age, sex, number of fused levels, surgery time, or blood loss between the Zero-P and ROI-C groups (all  $P > 0.05$ , Table 1). However, the comparison of surgery time between group A (including C3-4 or C6-7) and group B (not including C3-4 or C6-7) revealed a significant difference ( $P < 0.05$ , Table 2). There were significant postoperative improvements for JOA score, VAS score, NDI, DHI, and C2-7 Cobb angle in both groups ( $P < 0.05$ , Table 3). However, the final follow-up Cobb angle in the Zero-P group ( $24.4 \pm 4.5^\circ$ ) was significantly higher than that in the ROI-C group ( $18.1 \pm 2.3^\circ$ ) ( $P < 0.05$ ). Postoperatively, we identified 4 (4/56, 7.1%) patients with dysphagia and 1 (1/56, 1.7%) with cage subsidence. There was no significant difference between the Zero-P and ROI-C groups in the rates of dysphagia ( $P = 0.615$ ) or cage subsidence ( $P = 0.464$ , Table 2). Immediately after surgery, 3 and 1 patients had mild and severe dyspepsia, respectively. All 4 cases resolved within 3 months. The recovery rates in the Zero-P and ROI-C groups at the last follow-up were 76.6% and 76.9%, respectively (Table 5).

There were no neurological or vascular complications or wound infections. Radiographic examinations confirmed spinal fusion in all 56 patients.

## Discussion

Our results confirm that the devices (Zero-P and ROI-C) achieve similar clinical and radiographic outcomes after ACDF. However, the operation time of Zero-P is longer than ROI-C. The ROI-C may cause more C2-6 Cobb angle loss in the long run, which may lead to uncomfortable symptoms.

We observed significant postoperative improvements in the VAS, JOA, NDI, and DHI scores compared to the preoperative scores in both the Zero-P and ROI-C groups. The rates of successful treatment were 76.6% and 76.9%, respectively ( $P > 0.05$ ). All patients had evidence of bone fusion on the last follow-up CT scan. Overall, the efficacies of the Zero-P and ROI-C devices for ACDF are similar to each other and that obtained with the conventional plate system. For the reason that both devices restored the physical lordosis of cervical vertebral and foraminal height, basing on the discectomy.

This study shows that the dysphagia rate of Zero-P was higher than ROI-C, but with no significant difference ( $P = 0.615$ ). Patients who undergo longer time surgeries with ACDF may have greater risk of postoperative dyspepsia [19, 20]. Longer time surgeries require a greater duration of pulling the

esophagus in the supine position. The result that the operative time for Zero-P was longer than that for ROI-C could account for the dysphagia rate difference.

It was interesting to note that, the operative time in group A (including C3-4 or C6-7) was 20 minutes shorter for ROI-C than Zero-P, and the operative time for Zero-P in group A was longer than that in group B (not including C3-4 or C6-7). There were no differences between the two devices when the surgery did not involve C3-4 or C6-7. The reason for this result is in accordance with previous reports [4, 21]. That is, the ROI-C device only needs to be vertically hammered into the cervical vertebra through a cage without obstruction by the jaw or sternum, so it can save time when the treated levels include C3-4 or C6-7. Based on this result, we recommend using the ROI-C device if the operative segments include C3-4 or C6-7. This problem may also be solved by using a universal screwdriver.

Our results showed that the Cobb angles at the early follow-up significantly improved for both devices with no significant differences between groups immediately after surgery. Conversely, the last follow-up Cobb angle was higher in the Zero-P group compared to the ROI-C group ( $24.4\pm 4.5^\circ$  and  $18.1\pm 2.3$ , respectively;  $P < 0.05$ ). We propose that the postoperative Cobb angle improvements (with no significant difference between Zero-P and ROI-C) during early follow-up is mainly related to cage size, as the same surgeon operated on all patients using the same cage size standards.

However, our study showed that the Cobb angle decreased over time, and this was more evident in the ROI-C group. Cho et al. [22] compared the trend in Cobb angle changes 2 years after ROI-C and Zero-P device implantation and concluded that maintenance of normal cervical curvature was superior with Zero-P. Loss of CL after ACDF surgery is closely related to cage subsidence. We analyzed the reason for the decreased anterior Cobb angle in the ROI-C group is that the cross-sections of the two fixed clips are small and the shear force is large. Although the clips do not easily regress, they tend to go deeper, leading to subsidence. Conversely, the Zero-P device is tightly screwed to the fusion cage. As they are firmly screwed into the vertebra, the screws are unlikely to loosen, so the cage will remain in place [23]. In addition, 5 patients' postoperative Cobb angles were smaller than preoperative Cobb angle. This might be because preoperative cervical muscle stiffness resulted in neck hyperextension, and postoperative local segmental fusion decreased mobility. CL loss or kyphosis development can lead to cervical degeneration and cause pain, dysfunction, and other uncomfortable symptoms [24]. So we should consider the complication such as CL in the long run, when choosing cage devices for ACDF.

Our results should be considered in the context of the study's limitations. Firstly, this study had a small sample size and a short follow-up time. Secondly, we did not consider many factors that influence operation time. Thirdly, cage Stability between ROI-C and Zero-P should be done in biomechanics studies.

## Conclusions

In summary, clinical efficacy outcomes for ACDF with Zero-P were not significantly different compared to outcomes for ACDF with ROI-C. However, for ACDF with Zero-P, the duration of surgery involving levels C3-4 or C6-7 was significantly longer than with ROI-C. Therefore, ROI-C is a suitable device for reducing

surgery time if the operative level involves C3-4 or C6-7. However, ROI-C may cause more Cobb angle loss over time, which can cause uncomfortable symptoms. Above all, the surgeon should take individual patient context and personal proficiency into consideration when choosing cage devices.

## **Abbreviations**

ACDF, anterior cervical discectomy and fusion; CDDD, cervical disc degenerative disease; CL, cervical lordosis; CROM, cervical range of motion; DHI, disc height index; JOA, Japanese Orthopaedic Association; NDI, neck disability index; PCC, plate-cage construct; VAS: visual analogue scale.

## **Declarations**

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### **Authors' contributions**

AMJ conceived and designed the study, PHW and ADY collected the data, BCS and SXM analyzed the data, PHW and ADY wrote the paper. †Penghuan Wu and Aidong Yuan are equal contributors. All authors read and approved of the final manuscript.

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### **Availability of data and materials**

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

### **Ethics approval and consent to participate**

This study was approved by the Ethics Committee of Zhujiang Hospital, Southern Medical University, China. Patient consent was not required for this retrospective study as all the data were collected and analyzed anonymously.

### **Consent for publication**

Not applicable.

### **Competing interests**

The authors declare that they have no competing interests.

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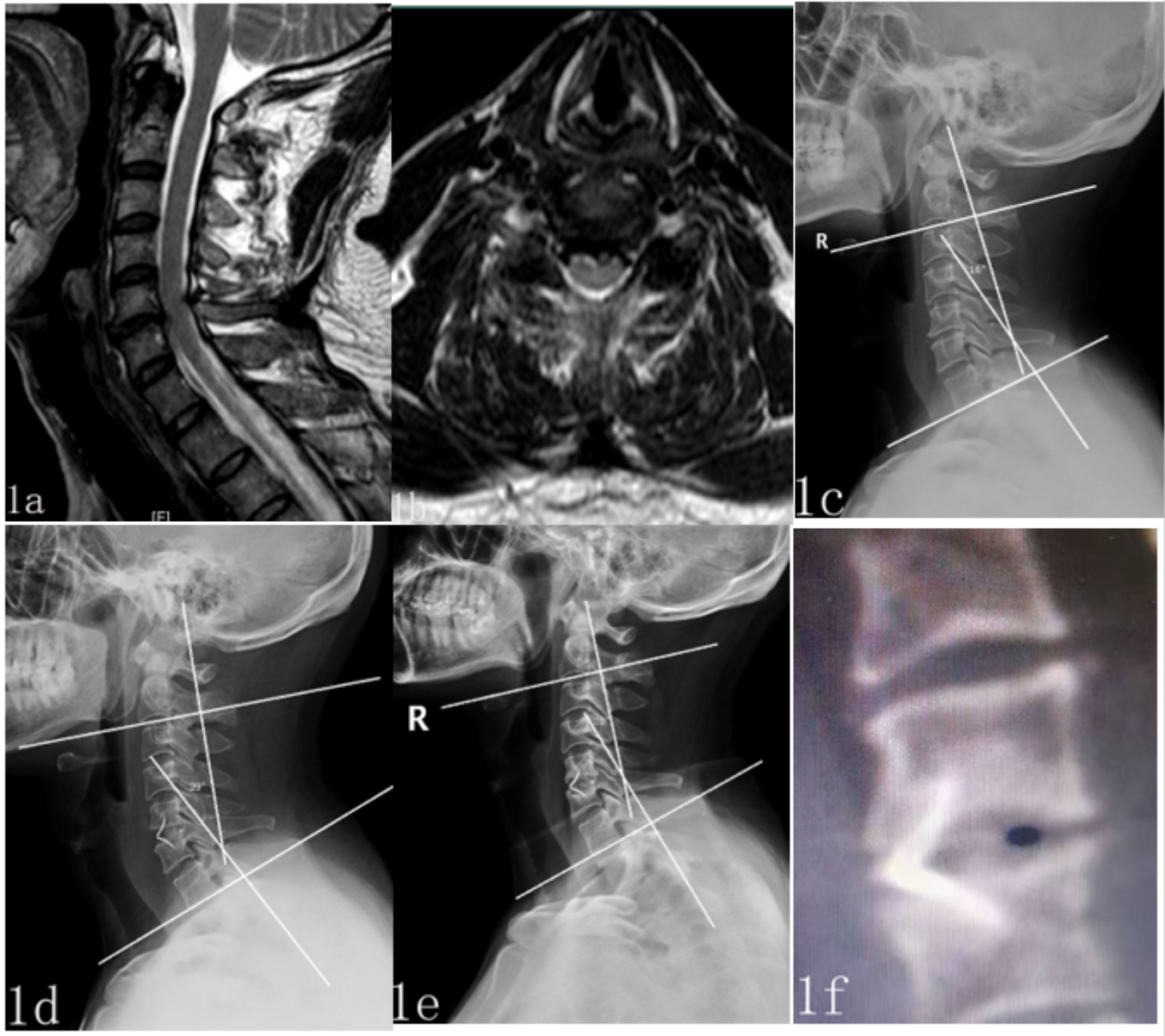
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## Tables

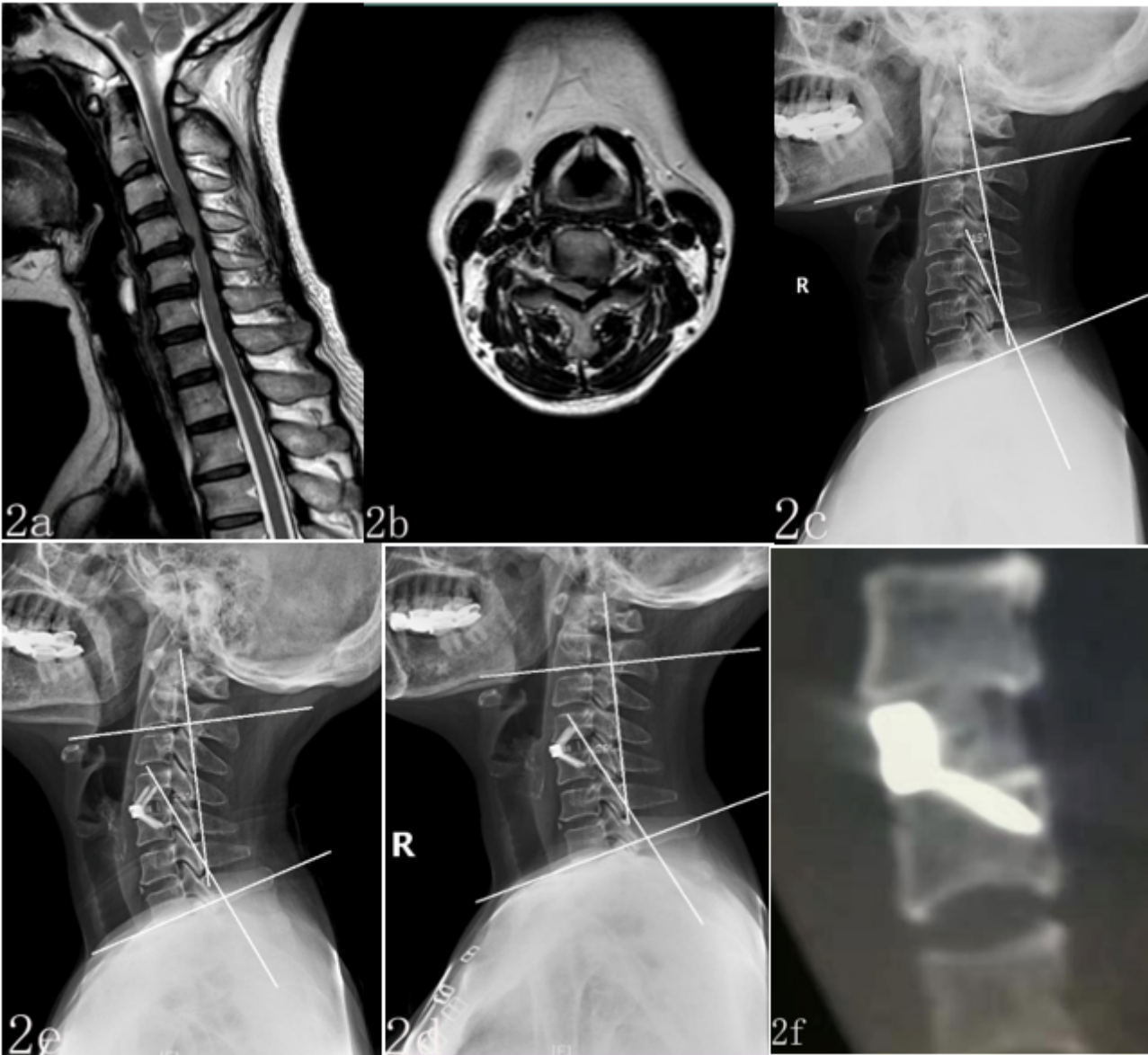
Due to technical limitations, tables are only available as a download in the supplemental files section.

## Figures



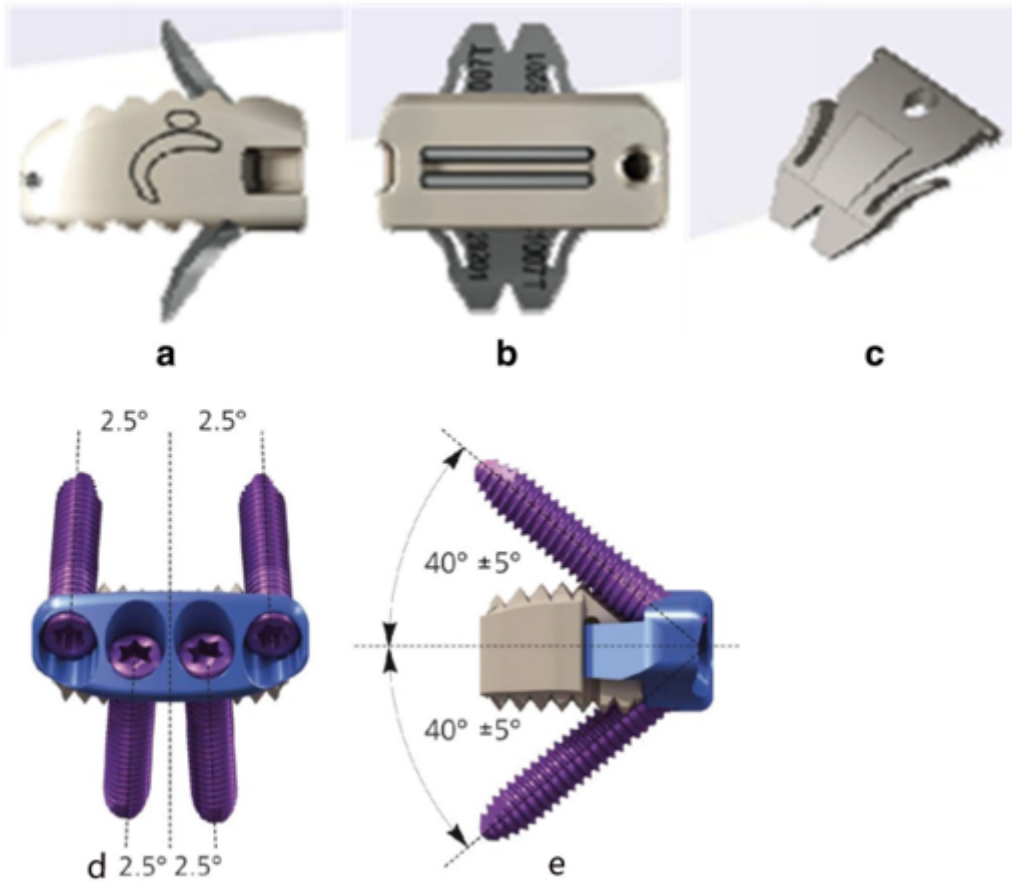
**Figure 1**

A 48-year-old man developed 1-level CDDD and underwent an ACDF operation using ROI-C. a. Preoperative MRI showing severe spinal cord compression of C5-6. b. Preoperative axial MRI images showing severe compression of C5-6. c. Preoperative lateral radiography revealed a C2-7 Cobb angle of 16°. d. Immediately after surgery, lateral radiography showed the C2-7 Cobb angle had increased to 29°. e. At 2.5 years, follow-up lateral radiography showed the C2-7 Cobb angle had decreased to 20°. f. CT examinations confirmed spinal fusion at last follow-up.



**Figure 2**

A 52-year-old woman developed 1-level CDDD and underwent an ACDF operation using Zero-P. a. Preoperative MRI showing severe spinal cord compression at C4-5 levels. b. Preoperative axial MRI images showing severe spinal cord compressions at C4-5. c. Preoperative lateral radiography revealed a C2-7 Cobb angle of 15°. d. Immediately after surgery, lateral radiography after ACDF with ROI-C, the C2-7 Cobb angle was 26°. e. At 3 years follow-up, lateral radiography showed the C2-7 Cobb angle had decreased to 25°. f. CT examinations confirmed spinal fusion at last follow-up.



**Figure 3**

Lateral (a) and anteroposterior (b) views of the ROI-C anchored spacer (LDR Medical, Sainte-Savine, France); (c) the integrated self-locking and self-directing clip; Coronal view (d) and Sagittal view (e) of Zero-P device (SAAS; Synthes GmbH, Oberdorf, Switzerland).

## Supplementary Files

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