

# Comparison of the long-term efficacy of ROI-C and conventional cage-plate in treatment of spinal cord injury without fracture or dislocation: a retrospective study

**Hui Lu**

Suzhou Hospital of Integrated Traditional Chinese and Western Medicine

**Renjie Li**

Suzhou Dushu Lake Hospital

**Cailin Wang**

The People ' s Hospital of SND

**Mei Fang**

Suzhou Hospital of Integrated Traditional Chinese and Western Medicine

**Jianxue Qian**

Suzhou Hospital of Integrated Traditional Chinese and Western Medicine

**Bin Qian**

Suzhou Hospital of Integrated Traditional Chinese and Western Medicine

**Yi Song**

Suzhou Hospital of Integrated Traditional Chinese and Western Medicine

**Xinchao Jiang**

Suzhou Hospital of Integrated Traditional Chinese and Western Medicine

**Jie Chen** (✉ [taiguwangba@126.com](mailto:taiguwangba@126.com))

The First Affiliated Hospital of Soochow University

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## Research Article

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# Abstract

## Background

The self-locking cage (ROI-C, LDR, Troyes, France) has been clinically applied in treating cervical degenerative disc disease (CDDD). However, only a few long-term clinical and radiographic studies have been performed in the treatment of spinal cord injury without fracture or dislocation (SCIWFD) so far. A comparison between ACDF with either ROI-C or CCP was performed to determine the better treatment for SCIWFD.

## Methods

A total of 83 patients who underwent ACDF using either ROI-C or CCP were reviewed for radiological and clinical outcomes. There are 60 males and 23 females, aged between 32 and 88 years old, with an average age of 58.23 years. All patients had symptoms of nerve injury, including limb numbness, muscle weakness, hypoesthesia or urinary dysfunction. Preoperative ASIA classification of spinal nerve function: 7 cases of grade A, 23 cases of grade B, 34 cases of grade C and 19 cases of grade D were included in the study.

## Results

48 patients underwent ACDF with ROI-C and 35 patients with conventional cage-plate. They were studied with a follow-up of  $28.63 \pm 17.41$  months and  $29.48 \pm 15.43$  months respectively. No significant difference was found in blood loss, JOA and ASIA between the two groups. No significant difference was found in cervical lordosis (CL) ( $P > 0.05$ ). Statistical difference was found in disc height of fused segment and T1 slope between the two groups ( $P < 0.05$ ). No statistical difference was in the incidence of cage subsidence ( $P > 0.05$ ). There was significant difference in the incidence of dysphagia. Both of two groups achieved bony fusion at final follow-up.

## Conclusion

Our study demonstrated that ROI-C has the same efficacy as CCP in improving the cervical stability in treatment of SCIWFD. The migration of cage didn't occur in ROI-C group at final follow-up, showing steadily fixed in cervical column. Moreover, the ROI-C does have the advantages of good therapeutic effect, mis-invasive, shorter operation time and fewer complications.

## Introduction

Spinal cord injury without fracture or dislocation (SCIWFD) is a group of clinical symptoms of cervical pain, spinal cord and nerve root injury caused by direct or indirect violence to the cervical intervertebral

disc and its surrounding tissues, which protrudes into the spinal canal and causes compression on the spinal cord or nerve root<sup>[1, 2]</sup>. For the clinical treatment of SCIWFD, surgeons used to choose anterior titanium plate or combined posterior approach to enhance the stability of cervical spine injured segments. However, the high incidence of dysphagia and the influence on the function of adjacent segments should not be neglected. Besides, the method had some unavoidable shortcomings, such as difficulty in precise matching of titanium plate radian and excessive dissection of prevertebral tissues. With the continuous progress of invasive treatment technology, ROI-C has gradually been used in clinical treatment and become an effective method for the treatment of SCIWFD.

In this study, we retrospectively analyzed the clinical and radiologic data of patients with SCIWFD treated in our hospital to compare the efficacy of ROI-C and conventional cage-plate (CCP) in patients with spinal cord injury.

## Materials and Methods

### Patient population

The study was conducted as a retrospective investigation of 83 patients with SCIWFD who underwent ACDF from January 2013 to October 2018. 35 patients who underwent fusion using PEEK cages and anterior plates served as the conventional cage-plate (CCP) group. 48 patients who used self-locking cage were classified as the ROI-C group. In all patients we concluded typical symptoms which included limited cervical movement with pain, decreased sensation, hyporeflex of biceps and triceps tendons, tenderness of spinous process. Lateral X-ray shows that cervical curvature has been straightened or even reversed. MRI showed the stenosis of intervertebral space and foramen. 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. The inclusion criteria were as follows: (1) symptoms of spinal cord injury; (2) X-ray and computed tomography (CT) showed no fracture or dislocation and magnetic resonance imaging (MRI) showed signal change of spinal cord; (3) history of neck trauma; (4) those with poor conservative treatment; (5) approved by Hospital Ethics Committee. The exclusion criteria were as follows: (1) Spinal cord injury caused by fracture or dislocation; (2) History of cervical vertebra surgery or tumor; (3) Clinical presentation of myelopathy and/or radiculopathy. There was no significant difference in age, sex or fusion segment between the ROI-C and CCP group.

Among 83 patients, there are 60 males and 23 females, aged between 32 and 88 years old, with an average age of 58.23 years. All patients had symptoms of nerve injury, including limb numbness, muscle weakness, hypoesthesia or urinary dysfunction. Preoperative ASIA classification of spinal nerve function: There were 7 cases of grade A, 23 cases of grade B, 34 cases of grade C and 19 cases of grade D (Table 3). All X-ray films were displayed, showing no obvious fracture and dislocation. MRI showed disc herniation and signal change of spinal cord. Among these patients, the levels to be treated included C5-7(six patients.), C4-6(ten patients), C4-7(five patients), C3-4(eighteen patients), C3-4+C5-7(three patients), C3-6(four patients), C5-6(twenty patients), C4-5+C6-7(four patients), C3-5(three patients), C4-5(seven

patients), C6-7(three patients). Compression of spinal cord was obvious in the herniated part of the intervertebral disc. All patients underwent cervical bracing, dehydration, detumescence and nerve nourishing. Confirmed no contraindication that before we perform the surgery.

## Surgical technique

### ACDF with ROI-C group

The patients were administered general anesthesia and were placed in the supine position. The basic procedures include exposure, discectomy, and decompression. The surgeries were performed using a standard right sided anterior Smith Robinson approach<sup>[3]</sup>. The discectomy was performed with pituitary forceps after confirmation of the surgical level. Scraping of intervertebral discs and osteophytes with a curette and file at each edge of the vertebral body. Opening the posterior longitudinal ligament and removing other compressive elements to ensure adequate dural and neural decompression. Great care was taken to remove the cartilaginous tissue, but preserve the bony endplate to prevent cage subsidence. Each appropriate-sized cage was packed with 0.25 mg of recombinant human bone morphogenetic protein (rhBMP-2, pharmaceutical group investment limited corporation, Hangzhou, China). The local osteophytes were excised and placed in the center of ROI-C device. Then the cage was implanted into the intervertebral space. Under the guidance of C-arm machine, cage was placed into the intervertebral space and displayed well on the lateral and anteroposterior views. Two cervical anchoring clips were placed into the lower and upper vertebrae through the anterior part of the cage to ensure primary stabilization by self-locking function of the anchoring clips. After exact hemostasis, the wound was closed in a layer-by-layer fashion after drainage insertion. Antibiotics were used prophylactically within 3 days. Patients are encouraged to exercise their limbs early. Cervical collar was fixed for 6 weeks (Fig 2).

### ACDF with CCP group

The early-stage operative procedure was the same as ROI-C group. The stand-alone PEEK cages were inserted into the disc space along with anterior cervical plates immobilized by self-tapping screws (Fig 3).

## Outcomes assessment

All the patients were informed to make a return visit at 1 month, 3 months, 6 months after surgery. Clinical and radiological results obtained by physicians who were blinded to the assessment of each other.

### Clinical and radiological outcomes

### Functional evaluation

Functional evaluation was performed by using the Japanese Orthopaedic Association (JOA) and American Spinal Injury Association Impairment Scale (ASIA) for SCIWFD preoperative and at each follow-

up (Table 3).

### Radiological evaluation

The definitions of parameters are defined as following: (1) cervical lordosis (CL) is defined as the Cobb angle of C2-7 on lateral film; (2) the disc height of fused segment (FSDH) was ascertained as the mean value of the anterior and posterior disc height measured from the lower-plate of the cephalad centrum to the upper-plate of the caudal centrum of the fused segment<sup>[4]</sup>. (3) sagittal vertical axis (SVA) is from C2 plumb line to posterior margin of upper-plate of C7<sup>[5]</sup>. (4) T1 slope (T1S) is the angle between the superior end-plate of T1 and the horizontal line<sup>[5]</sup> (Table 4).

### Statistical analysis

The students t-test was used to analyze the numerical data obtained within a normal distribution. The results were presented as the mean±standard deviation. The results were considered significant when P was less than 0.05. Data analysis was performed by Microsoft Excel 2016 (Microsoft, Seattle, WA) and SPSS 19.0 (SPSS, Chicago, IL).

## Results

Clinical indicators are as follows:

No significant difference existed in age, gender and follow-up times between the two groups (P 0.05) (Table 1). The blood loss in ROI-C group was much less than that of CCP group (Table 2). Statistically significant difference was found in the intraoperative blood loss between two groups in patients for single level (P 0.05). Statistical difference was found in operative time between two groups (P<0.05) (Table 2). No significant differences in terms of JOA score and ASIA were observed at baseline between the two groups. During the follow up period, the JOA and ASIA were significantly increased compared with the baseline measurements. After surgery, none of the patients suffered from neurological deterioration. The dysphagia occurred in 10 cases of the ROI-C group and 13 cases of the CCP group. 1 case and 7 cases of dysphagia were found in two groups at final follow-up respectively (Table 5).

Imaging indicators are as follows:

The radiological outcomes were measured preoperatively and at each follow-up time. PA and lateral X-ray films of cervical spine were taken at each follow-up. The CL was improved pronouncedly from  $9.20\pm 3.13$  preoperatively to  $20.29\pm 3.39$ ,  $19.29\pm 2.85$  and  $19.06\pm 2.81$  at 1, 3 months and final follow-up postoperatively in ROI-C group, respectively, from  $8.29\pm 4.40$  preoperatively to  $20.9\pm 2.72$ ,  $19.90\pm 2.69$  and  $19.67\pm 2.53$  at 1, 3 months and final follow-up postoperatively in CCP group. Meanwhile, the T1S significantly increased from  $19.7\pm 9.2$  to  $23.8\pm 6.9$  after surgery and became  $23.7\pm 7.1$  at the final follow-up. The T1S was significantly lower in the CCP group than in the ROI-C group both postoperatively and at the final follow-up. The fusion rate at 3 months postoperatively was 83.3% (40/48) in ROI-C group and

82.9% (29/35) in CCP group. All cases in the two groups achieved fusion at the time of the final follow-up, and there was no difference in rate of fusion between the two groups (Table 4) (Fig 1).

## Discussion

ACDF is standard treatment method when the conservative treatment of SCIWFD fails. Niu et al.<sup>[6]</sup> concluded that patients undergoing ACDF in combination with a PEEK interbody spacer and anterior fixation had a high rate of fusion success, for the fusion rates were reported to be unacceptably low after multi-level ACDF without plating<sup>[7, 8]</sup>. However, the use of additional plate is associated with various complications, including increased risks of hardware failure and postoperative dysphagia. Besides, the plate was difficult to match the cervical spine precisely. The stress blocked by titanium plate will affect the Interbody fusion in the future<sup>[9]</sup>. To avoid the potential complications caused by titanium plates, a self-locking cage has been introduced in treating SCIWFD.

SCIWFD includes two crucial characteristics of this injury-spinal cord injury and no fracture or dislocation. Due to unstable cervical spine caused by lesions to ligaments, surgeons used to implant titanium plate to strengthen spinal stability. Spinal stability is one of the main factors in affecting bony fusion. Sharma et al.<sup>[10]</sup> concluded from animal mechanics experiments that bony fusion is the final phase of cage subsidence and it decreases the incidence of cage subsidence. The ROI-C consists of two anchoring clips and a cage, which can combine interbody support and supplemental fixation into a single device. The unique structure offers a fixation mechanism that is similar to the function of titanium plate, improving the spinal stability after operation. In addition, to increase the rates of fusion, the ROI-C device features an enclosed chamber that may be filled with autologous or allogenic bone graft. Bony fusion means that no light transmission was found in the upper and lower end-plants. Sagittal CT reconstruction of cervical vertebra could be performed to confirm the fusion status. Continuous bone trabecular growth was observed in the cage and adjacent vertebral endplates. Iampreechaku et al.<sup>[11]</sup> reported that there is no significant difference was found in fusion rate between ROI-C and PCC groups. Xiong et al.<sup>[12]</sup> reported that satisfactory clinical results have been obtained in the treatment of cervical degenerative diseases. In our study, all cases in two groups achieved fusion at the time of the final follow-up, and there was no difference in the rate of fusion between the two groups. No backward movement of cage was found in all patients. No statistical difference was found in cage subsidence in two groups.

Postoperative X-ray showed that both cervical curvature and intervertebral height were restored. Normal lordotic alignment is one of the crucial factors related to good function and motion of the cervical spine. The recovery of cervical lordosis relieves axial pain, improving the long-term efficacy<sup>[13]</sup>. The restoration of intervertebral height is to enlarge the area of the canal, so that the nerve root is free from compression. In our study, the intervertebral height and cervical lordosis were significantly improved and maintained at the last final follow-up in two groups.

Adjacent segment disease (ASD) is a common long-term complication in ACDF for sacrificing the range of motion of diseased segments and increasing mobility of upper and lower levels adjacent to fusion

levels. The mal-positioning of titanium plate and disturbance of implantation to adjacent intervertebral discs are important factors that can't be ignored (Fig. 4). Wei et al.<sup>[14]</sup> reported that ROI-C device decreases the incidence of adjacent segment ossification compared with the titanium plate. The incidence of cases reported increased by 2.9% per year<sup>[15]</sup>. Salari et al.<sup>[16]</sup> demonstrated that the rigidity of ROI-C internal fixation is less than that of anterior titanium plate, and the cushioning effect of vertical compressive stress protects adjacent discs from excessive stress. That's why ROI-C decreases the probability of disc degeneration at adjacent segments. In ROI-C group, only the fascia of the operative segment should be exposed to reduce the interference to adjacent discs. Song et al.<sup>[17]</sup> concludes that ROI-C improve the loss of range of motion in operative segment and increase of ROM in adjacent segment to a certain extent.

Postoperative dysphagia and foreign body sensation are the most well-known complications. In ROI-C group, 10 patients (20.8%) complained of mild dysphagia at 1 month postoperatively and obtained nearly complete remission at 3 months postoperatively. In Cage-plate group, 13 patients (37.1%) complained of dysphagia (9 mild and 4 moderate) at 1 month postoperatively, 8 patients (7 mild and 1 moderate) at 3 months postoperatively, and 7 patients (all mild) at the final follow-up. A significant difference was found in the incidence of dysphagia at 3 months postoperatively ( $P = 0.002$ ) and the final follow-up between the 2 groups ( $P = 0.006$ ). No esophageal injury was found in all patients. In order to prevent pulmonary infection caused by cough, gastric tube was inserted in some elderly patients. Postoperative soft tissue swelling, intra-incision hematoma, esophageal injury and scar tissue are all possible causes of dysphagia. A report demonstrates that dysphagia (> 3 months) rates following ACDF with anterior plating have been estimated range between 12.5 and 35.1%<sup>[18, 19, 20]</sup>. In the current study we demonstrate that ROI-C device allows for similar clinical and radiographic outcomes compared to ACDF with anterior plating. Avoidance of using titanium plate may decrease the incidence of postoperative dysphagia<sup>[21]</sup>. The migration of anchoring clips didn't happen after implantation, which theoretically decreases the risk of long-term esophageal injury caused by screw loosening and displacement of the implant.

## Limitations

However, it should be pointed out that traumatic and degenerative cervical disc herniation may exist at the same time, which is difficult to distinguish between clinical symptoms and imaging. Therefore, the homogeneity of the samples in this study may affect the accuracy of the conclusion.

## Conclusion

The study demonstrated that ROI-C has the same efficacy as CCP in improving cervical stability in SCIWFD. The migration of cage didn't occur in ROI-C group at final follow-up, showing steadily fixed in cervical column. What's more, the ROI-C does have the advantages of good therapeutic effect, mis-invasive, shorter operation time and fewer complications. ACDF with ROI-C is a reliable min-invasive surgical treatment, which is worthy of clinical promotion.



# Abbreviations

SCIWFD:Spinal Cord Injury WithoutFracture or Dislocation; CDDD:Cervical Degenerative Disc Disease; ACDF:Anterior Cervical Discectomy and Fusion; CCP:Conventional Cage-plate.

# Declarations

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## Authors' contributions

J.C. and M.F. contributed to the design, H.L. and R.L. and C.W. helped in statistical analysis, participated in most of the study steps. H.L. and J.C. and R.L. and C.W. prepared the manuscript. J.Q. and B.Q. and Y.S. and X.J. assisted in designing the study. All authors have read and approved the content of the manuscript.

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## Availability of data and materials

Datasets are available through the corresponding author upon reasonable request.

## Ethics approval and consent to participate

This is a systematic review. The First Affiliated Hospital of Soochow University Research Ethics Committee has confirmed that no ethical approval is required.Informed consent was obtained from all individual participants included in the study.

## Consent for publication

This is a system review and meta-analysis so it does not involve the interests of patients.

## Competing interests

The authors have no relevant financial or non-financial interests to disclose.

## Author details

<sup>1</sup>Department of Pain, Suzhou Hospital of Integrated Traditional Chinese and Western Medicine, Suzhou, Jiangsu Province, China. <sup>2</sup>Department of Orthopaedic Surgery, Suzhou Dushu Lake Hospital, Suzhou, Jiangsu Province, China. <sup>3</sup>Department of Orthopaedic Surgery, The People's Hospital of SND, Suzhou, Jiangsu Province, China. <sup>4</sup>Department of Orthopaedic Surgery, The First Affiliated Hospital of Soochow University, Suzhou, Jiangsu Province, China.

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## Tables

Table 1 Patient demographic of both groups.

Patient demographic	ROI-C group	Cage-plate group	P-value
Number	48	35	—
Gender (male/female)	35/13	25/10	0.071
Age (years)	57.14±10.1	60.71±12.3	0.218
Follow-up (months)	28.63±17.41	29.48±15.43	0.850

Table 2 Operative details including blood and operative time of both groups.

Operative details	ROI-C group	Cage-plate group	P-value
Blood loss (ml)			
one-level	49.76±12.77	84.17±11.33	<0.001 <sup>***</sup>
two-level	87.19±68.67	104±4.89	0.609
three-level	97.27±16.01	140±0	0.298
Operative time (min)			
one-level	94.95±25.07	127.73±65.54	0.049 <sup>*</sup>
two-level	121.69±15.84	149.75±20.63	0.002 <sup>**</sup>
three-level	164.82±10.02	216±0	0 <sup>***</sup>

\*: P 0.05; \*\*: P 0.01; \*\*\*: P 0.001 (statistically significant difference).

Table 3 Comparison of clinical parameters including ASIA and JOA scores between two groups.

Parameters	ROI-C group	Cage-plate group	P-value
ASIA			
Pre-operation (A/B/C/D)	3/15/21/9	4/8/13/10	0.479
Post-3m (A/B/C/D)	3/10/20/15	4/6/14/11	0.477
Final follow-up (A/B/C/D)	3/7/15/23	4/6/10/15	0.544
JOA scores			
Pre-operation	4.4±3.9	4.0±1.6	0.557
Post-3m	12.6±0.9	12.2±1.8	0.165
Final follow-up	13.4±2.6	13.3±1.6	0.530

ASIA: American Spinal Injury Association Impairment Scale; JOA: Japanese Orthopaedic Association.

Table 4 Radiological parameters evaluation of two groups.

Parameters	ROI-C group	Cage-plate group	P-value
CL (°)			
Pre-operation	9.20±3.13	8.29±4.40	0.263
Post 1 m	20.29±3.39	20.9±2.72	0.473
Post 3 m	19.29±2.85	19.90±2.69	0.413
Final follow-up	19.06±2.81	19.67±2.53	0.407
FSDH (mm)			
one level			
Pre-operation	5.31±1.26	6.65±1.31	0.005**
Post 1 m	9.21±1.78	10.78±1.44	0.010*
Post 3 m	8.65±1.40	10.31±1.24	0.001**
Final follow-up	8.60±1.45	10.00±1.44	0.009**
two levels			
Pre-operation	9.19±1.91	9.83±2.57	0.580
Post 1 m	16.04±1.65	17.97±2.92	0.081
Post 3 m	15.39±2.08	17.28±2.75	0.136
Final follow-up	14.59±2.00	16.68±2.58	0.087
three levels			
Pre-operation	13.98±1.67	20.35±0	—
Post 1 m	23.07±2.44	27.39±0	—
Post 3 m	22.09±2.90	26.8±0	—
Final follow-up	21.13±2.65	25.98±0	—
C2-7 SVA (mm)			
Pre-operation	11.9±7.5	12.3±8.1	0.871
Post 1 m	12.7±7.2	12.1±7.5	0.783
Post 3 m	13.4±6.8	11.9±7.2	0.492
Final follow-up	13.3±6.4	11.8±7.3	0.584
T1 slope (°)			
Pre-operation	19.7±9.2	20.3±8.7	0.573

Post 1 m	23.8±6.9	18.8±7.2	0.022*
Final follow-up	23.7±7.1	18.6±7.4	0.013*
Fusion rate (%)			
Post 3 m	83.3 (40/48)	82.9 (29/35)	0.955
Final follow-up	100 (48/48)	100 (48/48)	1
Sedimentation			
Final follow-up	6.25% (3/48)	5.71% (2/35)	0.691

CL: cervical lordosis; FSDH: the disc height of fused segment; SVA: sagittal vertical axis. \*: P 0.05; \*\*: P 0.01 (statistically significant difference).

Table 5 Incidence of dysphagia in two groups.

Incidence of dysphagia	ROI-C group	Cage-plate group	P-value
Post 1m	20.8% (10/48)	37.1% (13/35)	0.104
Post 3m	2.08% (1/48)	22.9% (8/35)	0.002**
Final follow-up	2.08% (1/48)	20.0% (7/35)	0.006**

\*\* : P 0.01 (statistically significant difference).

## Figures

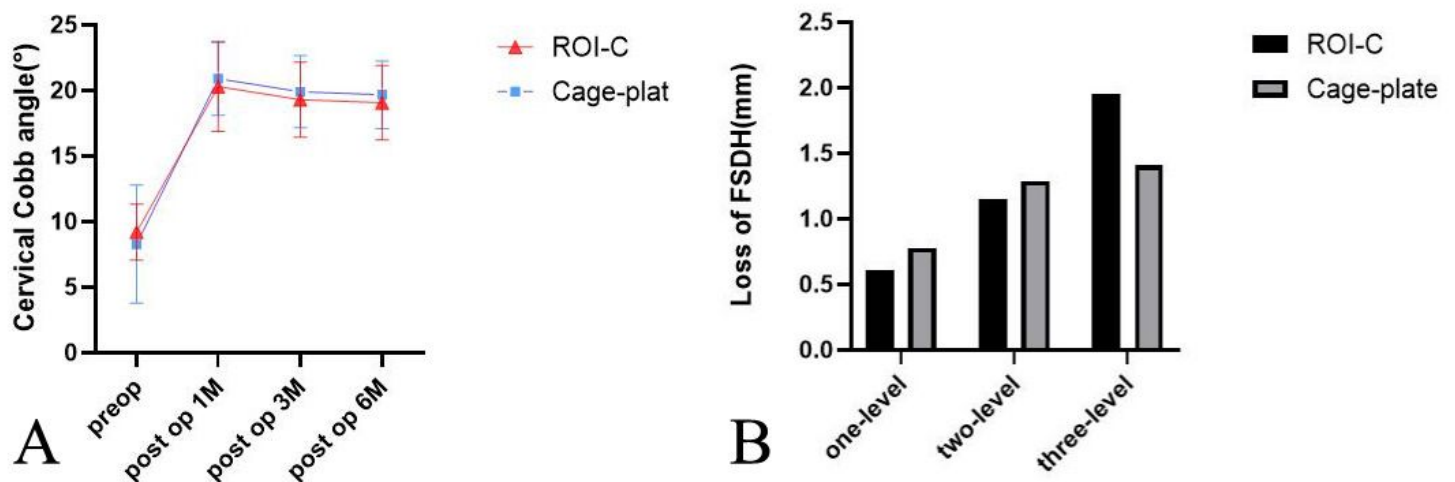


Figure 1

Two graphs showed comparisons of radiologic results between ROI-C group and Cage-plate group, including variable tendency of cervical lordosis (A) and loss of FSDH (B). M =month, Post op = Postoperative, Pre op = Preoperative. FSDH=fusion segment disc height.

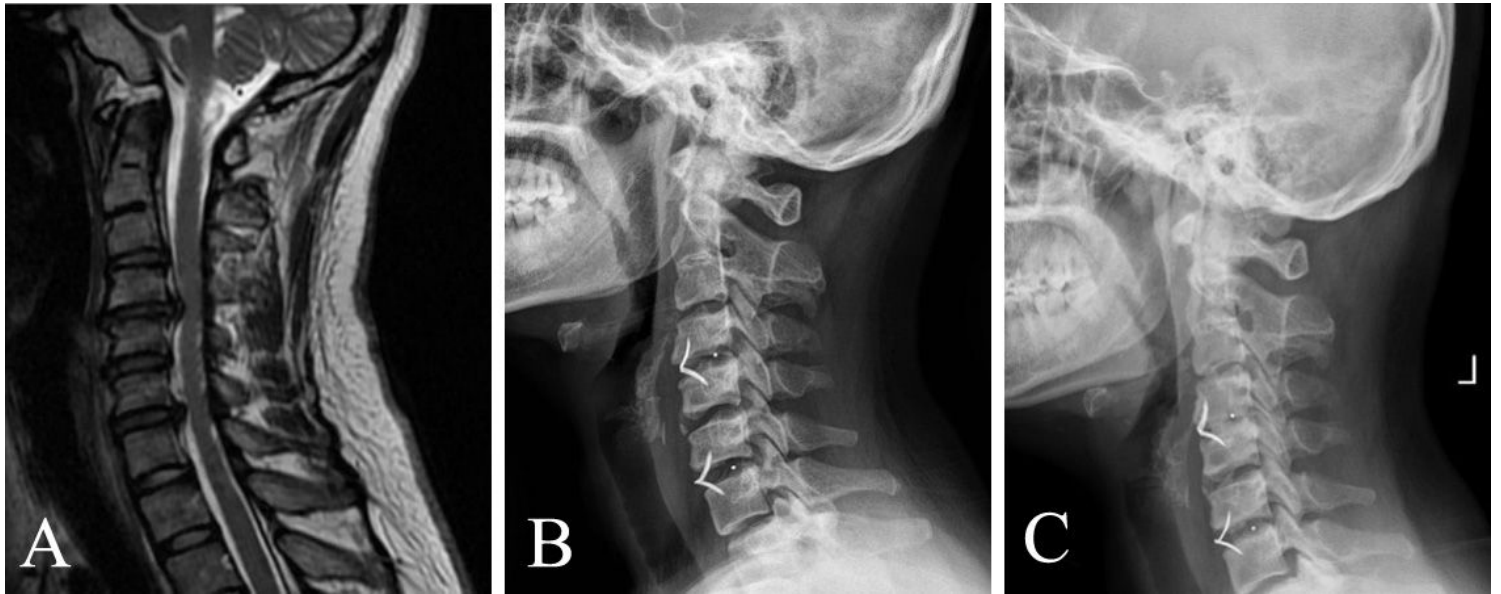


Figure 2

A 32-year-old female of sagittal T2-weighted MRI scan (A) showed that herniation of intervertebral disc (C4-5 and C6-7) compressed the posterior spinal cord. The lateral radiographs at postoperative 1 month (B) and postoperative (C) showed anterior cervical discectomy and fusion (ACDF) with zero-profile anchored spacers (ROI-C) at the corresponding levels.

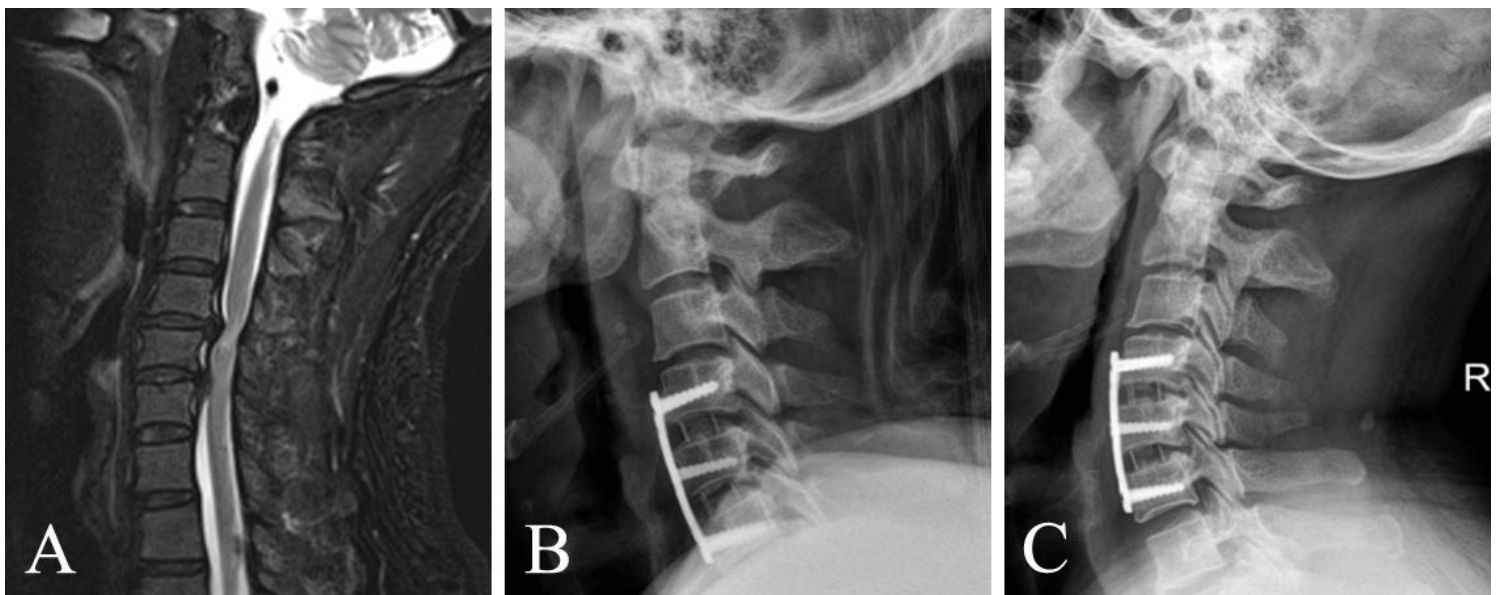


Figure 3



A 44-year-old male of sagittal T2-weighted MRI scan (A) showed that herniation of intervertebral disc (C4-5 and C5-6) compressed the posterior spinal cord accompanied by high intensity signal changes. The lateral radiographs at postoperative 1 month (B) and postoperative 6 months (C) showed anterior cervical discectomy and fusion (ACDF) with conventional cage-plate (CCP) at the corresponding levels.

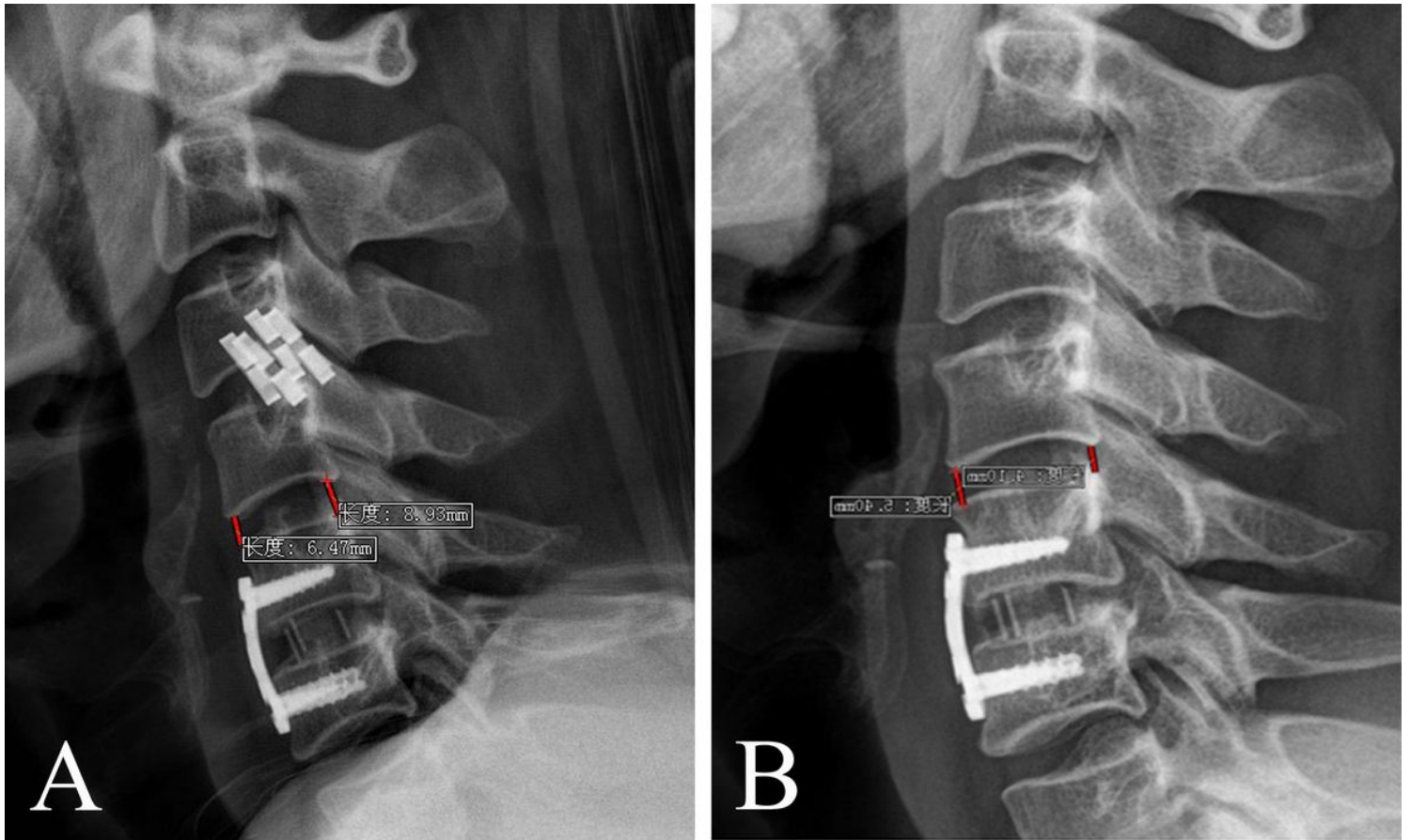


Figure 4

A 37-year-old male of the lateral radiographs at postoperative 1 month (B) and postoperative 6 months (C) showed the loss of fusion rate of disc height (FSDH) at the adjacent segment (C4-5).