

A comparison of the bridge-type ROI-C interbody fusion cage system and ACDF with plating and cage system in 2-level anterior cervical discectomy and fusion: A retrospective study

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Abstract

Objective: A study was conducted to explore the clinical efficacy and radioactive results of the bridge-type ROI-C interbody fusion cage (ROI-C) and anterior cervical discectomy and fusion with plating and cage system (ACDF) for cervical spondylopathy.

Methods: From January 2014 to January 2018, 45 patients who underwent operations were retrospectively analyzed, including 24 cases of ROI-C (group A) and 21 cases of ACDF (group B). The operation time, blood loss, Neck Disability Index (NDI), Japanese Orthopaedic Association score (JOA), postoperative complications, imaging results including cervical Cobb angle, and fusion were compared between groups.

Results: All patients were successfully treated with surgery. No cerebrospinal fluid leakage, esophageal fistula, or hoarseness occurred after the surgery. The operation time and blood loss in group A were lower than those in group B ($P < 0.05$). During the follow-up period, JOA score increased and NDI score decreased after the operation ($P < 0.05$), but no significant difference was found between the groups ($P > 0.05$). In group A, the incidence of postoperative dysphagia was 12.5%, which returned to normal after 1 month. In group B, the incidence of postoperative dysphagia was 38.1%, which was 19% after 1 month and 4.8% at the final follow-up. In group A, the fusion rate was 83.3% at 3 months after surgery and 100% at the last follow-up. The rate of adjacent level ossification development was 12.5%. In group B, the fusion rate was 85.7% at 3 months after surgery and 100% at the last follow-up. The rate of adjacent level ossification development was 23.8%.

Conclusion: Both ROI-C and ACDF achieved satisfactory results, but ROI-C had a shorter operation time, less bleeding, and lower incidence of dysphagia in the short term.

Introduction

Cervical spondylosis is a common clinical degenerative disease. Cervical spondylosis incidence has been increasing year by year due to the change in people's lifestyles^[1]. Spinal cord dysfunction caused by cervical spondylosis seriously affects the quality of life of patients^[2]. With the continuous improvement of medical technology and medical equipment, surgical treatment methods for cervical spondylopathy, including anterior discectomy and fusion internal fixation and posterior laminectomy or plastic surgery, have become increasingly diverse. Anterior cervical surgery is accepted by an increasing number of patients because it leads to less small trauma and has fast recovery and definite curative effect^[3,4]. ACDF is often used in the operation of two-level cervical spondylosis. This operation is an effective treatment method, but some complications still exist. Complications, such as dysphagia, esophageal injury, bone nonunion, screw loosening and plate displacement, are common^[5,6]. Therefore, reducing postoperative complications on the premise of adequate decompression, firm fixation, and bone graft fusion has become an important research direction in the treatment of cervical spondylosis.

ROI-C is a new surgery that is composed of a PEEK box and two self-locking clips. It has been successfully applied in clinical practice. It provides a stable biomechanical environment and avoids contact between the implant and the anterior vertebral soft tissue. In this study, 45 patients with cervical spondylosis were retrospectively analyzed. We compared the curative effect and complications of patients with cervical spondylosis treated with the bridge-type ROI-C interbody fusion cage system and titanium mesh graft with titanium plate fixation.

Materials And Methods

General information

From January 2014 to January 2018, 24 patients were placed in the ROI-C group (group A), as follows: 9 males and 15 females aged 51–71 years old (average, 60.59 ± 8.21 years old). 21 patients were placed in the ACDF group (group B), as follows: 8 males and 13 females, aged 52–70 years old (average, 60.15 ± 7.52 years old). The inclusion criteria were as follows: (1) cervical spondylosis showed corresponding symptoms, such as neck and shoulder pain, numbness, limb weakness and walking instability; (2) cervical X-ray film, computed tomography (CT), or magnetic resonance imaging (MRI) showed compression of adjacent two-level spinal cord or nerve root. Exclusion criteria included the following: (1) developmental stenosis and ossification of the posterior longitudinal ligament; (2) history of cervical surgery, tumor, or any serious disease; (3) cervical fracture dislocation or severe cervical instability.

Surgical procedures

All operations were performed by two experienced surgeons in the same treatment group. The patients were administered general anesthesia and were placed in the supine position. In group A, trial spacers were used to determine the appropriate size of the anchored intervertebral fusion cage. After the implantation of the cage, two cervical anchoring clips were placed into the lower and upper vertebrae through the anterior part of the cage to ensure primary stabilization through the self-locking function of the anchoring clips. In group B, the appropriate size for the cage was determined by intraoperative evaluation using two cages. Self-tapping screws were used to fix the anterior cervical plate.

Clinical evaluation

The following were recorded: the operation time; the bleeding during the operation; and postoperative complications, including the incidence of dysphagia, the duration of symptoms, and whether or not these symptoms disappeared. JOA ^[7] and NDI ^[8] scores were used to evaluate the clinical outcomes before and after surgery. The effect of operation was determined by Odom's score ^[9], and the grades were as follows: excellent, symptoms and signs disappeared after operation; good, most symptoms and signs were

relieved, and normal function was restored; general, symptoms and signs were partially improved, but the person could not operate normally; and poor, symptoms and signs were basically the same as before the operation. According to the Bazaz score^[10], the degree of dysphagia was divided into four grades, as follows: none, no dysphagia; mild, almost no dysphagia; moderate, occasional dysphagia; and severe, severe dysphagia.

Radioactivity evaluation

The imaging data included preoperative and postoperative imaging examination. If all the following conditions are satisfied, then radiologic fusion is achieved: a) The displacement of adjacent vertebrae < 2° in flexion and extension of neck; b) height of the intervertebral space was unchanged; and c) no transparent line was seen between the grafted bone and the upper and lower endplates of vertebral body. The evaluation criteria of adjacent level ossification development (ALOD) were as follows: grade 0, no ALOD formation; grade 1, ALOD extends across less than 50% of the disc space; grade 2, ALOD extends greater than or equal to 50% of the disc space; and grade 3, complete bridging of the adjacent discspace. The Cobb angle is measured in the sagittal position of the cervical spine, which is formed between the perpendicular line of the inferior end plate of the C2 and C7 vertebral bodies.

Statistical treatment.

All statistical analyses were performed using SPSS 19.0 software (SPSS Inc., Chicago, USA). Student t test was used to analyze the clinical and radiological outcomes among both groups. Chi-square test was used to assess rate of dysphagia, ALOD, and fusion. All $P < 0.05$ values were considered statistically significant.

Results

Clinical evaluation

All patients were successfully treated with surgery, and no cerebrospinal fluid leakage, esophageal fistula, or hoarseness occurred after surgery. The 45 patients were divided into two groups. Group A comprised 24 patients who underwent fusion using ROI-C (**Figs. 1 and 2**). Group B comprised 21 patients who underwent fusion using ACDF (**Figs. 3 and 4**). In group A, the patients were 60.59 ± 8.21 years old, the follow-up time was 25.6 ± 3.3 months, the operation time was 101 ± 22 min, and blood loss was 150 ± 46 ml (**Table 1**). JOA score increased from preoperative 9.6 ± 1.7 to postoperative 13.8 ± 2.2 and was finally maintained at 14.5 ± 1.5 . NDI score decreased from preoperative 32.1 ± 7.9 to postoperative 15.9 ± 4.7 and finally maintained at 13.7 ± 4.6 (**Table 2**). One month after surgery, three patients had complications of dysphagia, but the symptom soon disappeared (**Table 3**). In group B, the patients were 60.15 ± 7.52 years old, the follow-up time was 26.1 ± 3.5 months, the operation time was 118 ± 29 min, and the blood loss was 185 ± 58 ml (**Table 1**). JOA score increased from preoperative 9.4 ± 1.5 to postoperative 14.1 ± 1.6 and was finally maintained at 14.6 ± 1.8 . NDI score decreased from preoperative 30.5 ± 8.6 to postoperative 15.1 ± 4.9 and was finally maintained at 13.1 ± 4.4 (**Table 2**). One month after the operation,

eight patients had dysphagia complications; these disappeared in four patients 3 months after the operation. One patient still had dysphagia at the last follow-up (**Table 3**). The operation time and blood loss in group A were lower than those in group B ($P<0.05$). During the follow-up period, JOA score increased and NDI score decreased after operation ($P<0.05$), but no significant difference was found between the groups ($P>0.05$). The incidence of dysphagia in group A was lower than that in group B at 1 and 3 months after operation ($P<0.05$), but the final follow-up results showed that no significant difference in the incidence of dysphagia was found between the two groups ($P>0.05$).

Table 1. General information

	Group A	Group B	<i>P</i> value
Number	24	21	
Gender			
Male	9	8	
Female	15	13	
Age (year)	60.59±8.21	60.15±7.52	0.853
Level			
C3-C5	3	2	
C4-C6	14	12	
C5-C7	7	7	
Follow-up (months)	25.6±3.3	26.1±3.5	0.625
Operation time (minute)	101±22	118±29	0.031
Blood loss (ml)	150±46	185±58	0.029

P value is given for comparison between group A and group B
 $P<0.05$, statistically significant.

Table 2
Clinical and radiologic data evaluated before surgery and during follow-up (mean \pm SD)

	Group A	Group B	P value
JOA scores			
Preoperative	9.6 \pm 1.7 ^a	9.4 \pm 1.5 ^a	0.680
Postoperative 1 month	13.8 \pm 2.2 ^b	14.1 \pm 1.6 ^b	0.608
Last follow-up	14.5 \pm 1.5 ^b	14.6 \pm 1.8 ^b	0.840
NDI scores			
Preoperative	32.1 \pm 7.9 ^a	30.5 \pm 8.6 ^a	0.519
Postoperative 1 month	15.9 \pm 4.7 ^b	15.1 \pm 4.9 ^b	0.579
Last follow-up	13.7 \pm 4.6 ^b	13.1 \pm 4.4 ^b	0.658
<i>JOA</i> Japanese Orthopedic Association, <i>NDI</i> Neck Disability Index			
^a P value is given for comparison between group A and group B			
^b P < 0.05 comparing with preoperative value			

Table 3
Incidence of dysphagia.

	Group A	Group B	P value
Dysphagia	12.5% (3/24)	38.1% (8/21)	0.046
One month postoperatively	0% (0/24)	19% (4/21)	0.025
Final follow-up	0% (0/24)	4.8% (1/21)	0.280
P value is given for comparison between group A and group B			
P < 0.05, statistically significant.			

Radioactivity evaluation

In group A, Cobb angle increased from preoperative 13.5 \pm 10.3 to postoperative 18.9 \pm 9.4 and was finally maintained at 17.9 \pm 9.8. The fusion rate was 83.3% at 3 months after surgery and 100% at the last follow-up. The rate of adjacent level ossification development was 12.5%. In group B, Cobb angle increased from preoperative 12.5 \pm 9.4 to postoperative 17.5 \pm 10.4 and was finally maintained at 17.1 \pm

10.6. The fusion rate was 85.7% at 3 months after surgery and 100% at the last follow-up. The rate of adjacent level ossification development was 23.8% (Table 4).

Table 4
The mean outcomes of radiological parameters measured before operation and during follow-up(mean \pm SD)

	Group A	Group B	P value
Cervical lordosis			
Preoperatvie	13.5 \pm 10.3 ^a	12.5 \pm 9.4 ^a	0.737
Postoperative 1 month	18.9 \pm 9.4 ^b	17.5 \pm 10.4 ^b	0.638
Last follow-up	17.9 \pm 9.8 ^b	17.1 \pm 10.6 ^b	0.794
Fusion rate			
Postoperative 3 month	83.3% (20/24)	85.7% (18/21)	0.826
Final fusion	100%	100%	
Adjacent segment degeneration	12.5% (3/24)	23.8%(5/21)	0.322
^a P value is given for comparison between group A and group B			
^b P < 0.05 comparing with preoperative value			

Discussion

After conservative treatment was ineffective, surgical intervention became the first choice for treatment [11]. ACDF is the standard surgery for the treatment of cervical degenerative disc disease. It can restore the physiological radian of the cervical vertebra to the maximum extent, has high intervertebral fusion rate, can maintain the stability of cervical spine, and has remarkable surgical effect [12]. In our study, the postoperative cervical cobb angle of the two surgery was significantly larger than the preoperative cervical cobb angle, which indicated that both surgeries can correct cervical kyphosis. Therefore, the fusion and biomechanical stability of ROI-C are equal to those of ACDF; satisfactory surgical results of both surgery have been achieved [13]. The results of this study showed that JOA and NDI scores of both groups improved, and good operation effect was maintained during the follow-up period, which demonstrated that the two surgeries can relieve spinal cord and nerve compression and improve the quality of life of patients.

The ROI-C had the following advantages. First, the operation wound was smaller, and less bleeding was observed. Although ROI-C surgery did not reduce skin incision, it was not necessary to consider the

placement of plate fixation and extensive exposure of adjacent vertebral body. Only the exposure of the target intervertebral space was needed for convenience. Second, the operation time was relatively short, and the operation was simple. In group A, the cage was directly fixed with self-locking clip, which could save operation time. Third, the incidence of dysphagia was reduced after the operation. Dysphagia is a common complication after ACDF, and the underlying mechanism has not been explained clearly [14,15]. This complication may be related to the following factors. First, during anesthesia, the stimulation of pharynx and trachea may cause dysphagia. Some scholars suggest that atomization after operation can partly relieve dysphagia symptoms. Dysphagia caused by this reason can be recovered within one month. Second, postoperative soft tissue adhesion may lead to dysphagia. To expose the target position, the soft tissue in front of the vertebral body needed to be stripped. In group A, only the intervertebral space needed to be exposed to facilitate the operation, whereas in group B, the plate fixation was placed in front of the vertebral body, resulting in a wider range of exposure and more bleeding, thereby increasing the possibility of postoperative adhesion. Third, the incidence of dysphagia increases with the use of the anterior cervical plate [16]. A large number of clinical studies have shown that after plate fixation, the plate will protrude from the surface of cervical body, which causes a slight compression on the esophagus [17,18]. Some scholars reported that the use of thinner plate fixation will reduce the incidence of dysphagia [19]. Previous studies have also shown that the use of zero-profile anchored spacer can significantly reduce the incidence of dysphagia. In the present study, we found that the ROI-C was completely implanted in the intervertebral space, and no compression on the esophagus occurred. The incidence of dysphagia in group A was lower than that in group B. The difference was statistically significant at one month and three months after operation, which indicated that the use of ROI-C can reduce the incidence of early dysphagia.

The effect of ACDF depends on the degree of decompression, the recovery of Cobb angle, and the stability of fusion. Anterior plate fixation is often used in ACDF to improve the speed of interbody fusion and enhance the stability of cage. Only after bone fusion can kyphosis and spinal canal stenosis be effectively prevented, thereby preventing the compression of the spinal cord and nerve root [20]. Wang et al. [21] and Grasso et al. [22] reported a fusion rate of 100% in patients with ROI-C who were followed up for 2 years. Hofstetter et al. [12] reported that the fusion rate of ROI-C was 95.2% after an average follow-up of 13.9 months. Our results show that the two groups have achieved satisfactory results of bone fusion, and no significant difference was found between the two methods.

The mechanism underlying adjacent level ossification development is unclear. It is related to the natural degradation of adjacent joints and to the increase of the adjacent upper and lower joint activities caused by abnormal fusion [23]. Lee et al. [24] believed that the use of short plates with oblique screw tracks can significantly reduce the incidence and severity of ALOD. A short plate length leads to the low incidence of ossification of the adjacent vertebral body, which may be related to the separation of the soft tissue in

front of the vertebral body [25,26]. In group A, three patients had adjacent level ossification development. In group B, five patients had adjacent level ossification development. In the last follow-up, no patient needed surgical intervention. We will continue to investigate and further evaluate whether the bridge-type ROI-C interbody fusion cage can help reduce the incidence of adjacent level ossification development and the need for reoperation.

This study has some limitations. First of all, this is a retrospective study, and the level of evidence is limited. Second, there may be measurement errors. To minimize these errors, three orthopedic surgeons measured the X-ray data separately. Finally, the number of cases in this study is small, and the follow-up time is short, which may lead to selective bias. Robust randomized multi-center prospective studies with long-term follow-up are needed to confirm these findings.

Conclusion

Both ROI-C and ACDF can achieve satisfactory results, but ROI-C has a shorter operation time and results in less bleeding and a lower incidence of dysphagia in the short term.

Abbreviations

ROI-C: the bridge-type ROI-C interbody fusion cage; **ACDF:** anterior cervical discectomy and fusion with plating and cage system; **JOA:** Japanese Orthopaedic Association score; **NDI:** Neck Disability Index; **ALOD:** adjacent level ossification development; **MRI:** magnetic resonance imaging; **CT:** computed tomography

Declarations

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Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request

Authors' contributions

All authors made substantive intellectual contributions to this study to qualify as authors. QZ, WY and CK contributed to study design, acquisition of data, analysis of data, and interpretation of results. ZC and ZX

contributed to study coordination. SX, ZC and WS contributed to statistical analysis. HS and ZZ contributed to manuscript preparation. All authors read and approved the final manuscript.

Ethics approval and consent to participate

This study was approved by the Institutional Ethics Committee of Soochow University. Written informed consent was obtained from all participants.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

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Figures

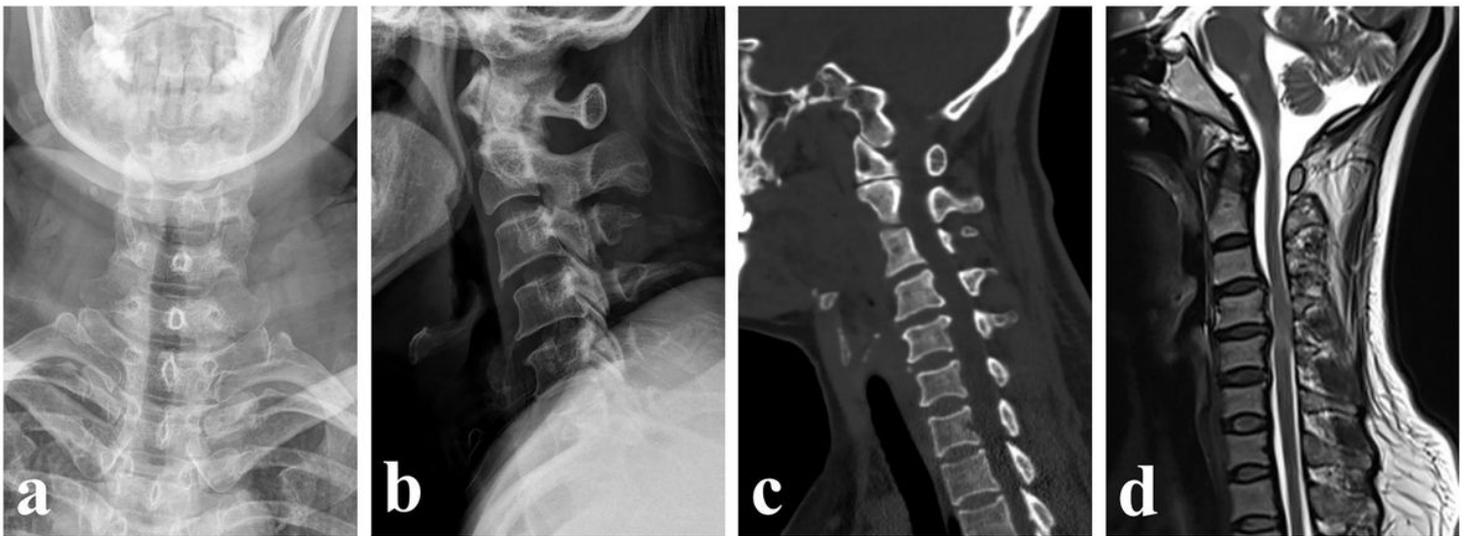


Figure 1

A 65-year-old woman with cervical spondylosis was admitted to our hospital due to numbness and weakness of both upper limbs: (a, b) Preoperative X-ray showed the disappearance of cervical vertebrae radian; (c) Preoperative CT showed cervical degeneration, loss of physiological radian and hyperosteoegeny; (d) Preoperative MRI indicated C3-C4 and C4-C5 cervical disc herniation and spinal cord compression.

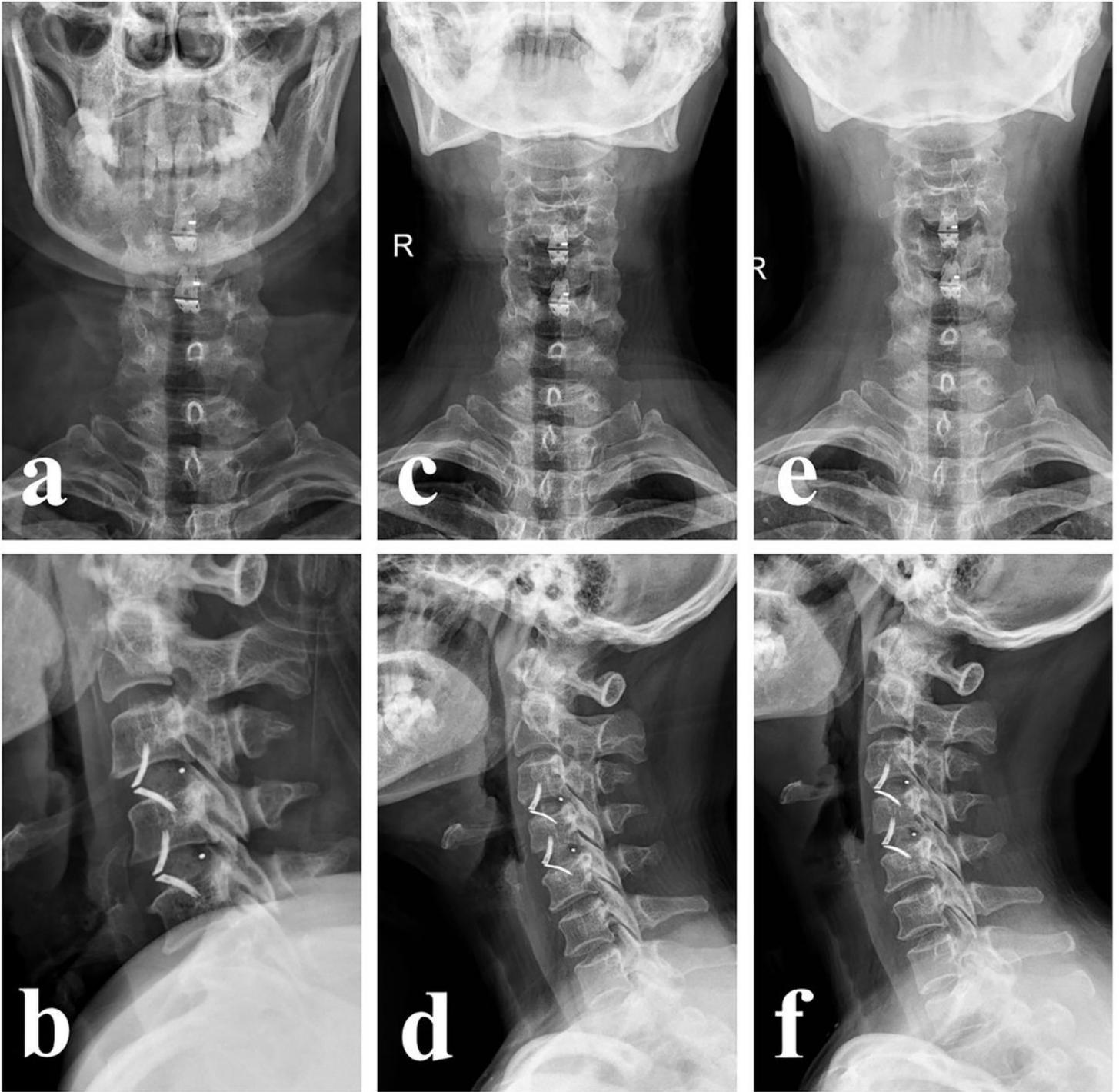


Figure 2

(a, b) Three days after operation, X-ray showed that C3-C4 and C4-C5 cervical discectomy and the positions of bridge-type ROI-C interbody fusion cages were good; (c, d) One year after operation, X-ray showed that C3-C4 and C4-C5 cervical fusion and the positions of bridge-type ROI-C interbody fusion cages were good; (e, f) Two years after operation, X-ray showed that C3-C4 and C4-C5 cervical fusion and the positions of bridge-type ROI-C interbody fusion cages were good.

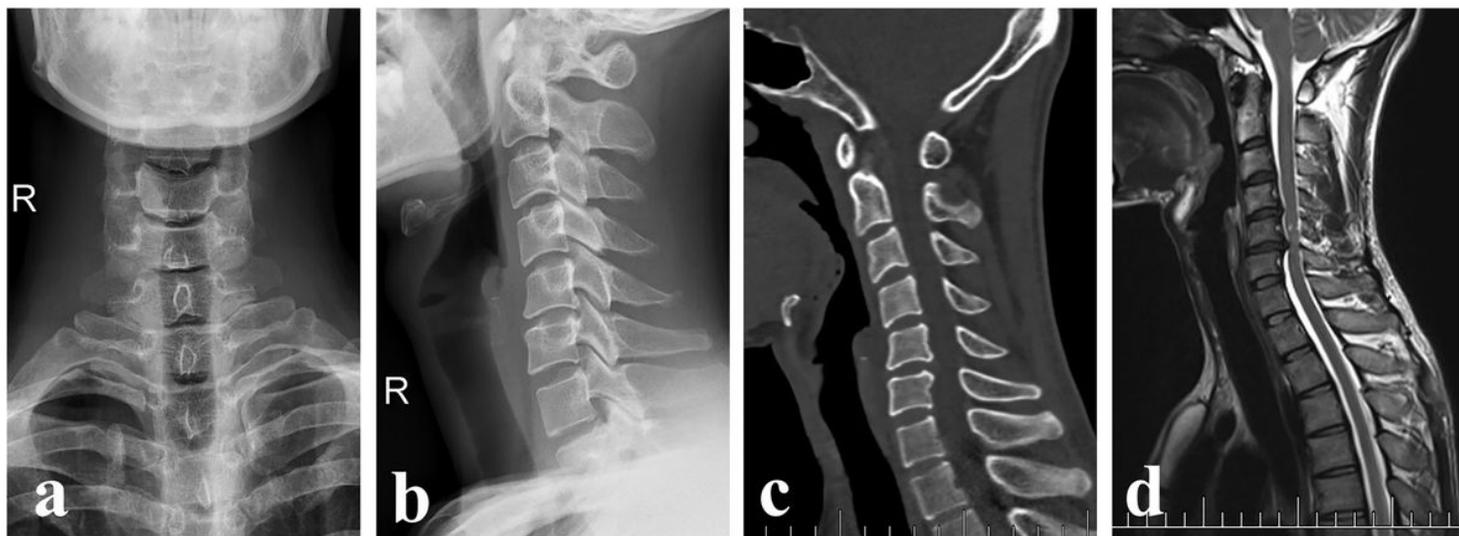


Figure 3

A 67-year-old man with cervical spondylosis was admitted to our hospital due to numbness and weakness of both upper limbs. (a, b) Preoperative X-ray showed the disappearance of cervical vertebrae radian; (c) Preoperative CT scan showed the disappearance of cervical vertebrae radian and the change of intervertebral space; (d) Preoperative MRI showed C4-C5 and C5-C6 cervical disc herniation and spinal cord compression.

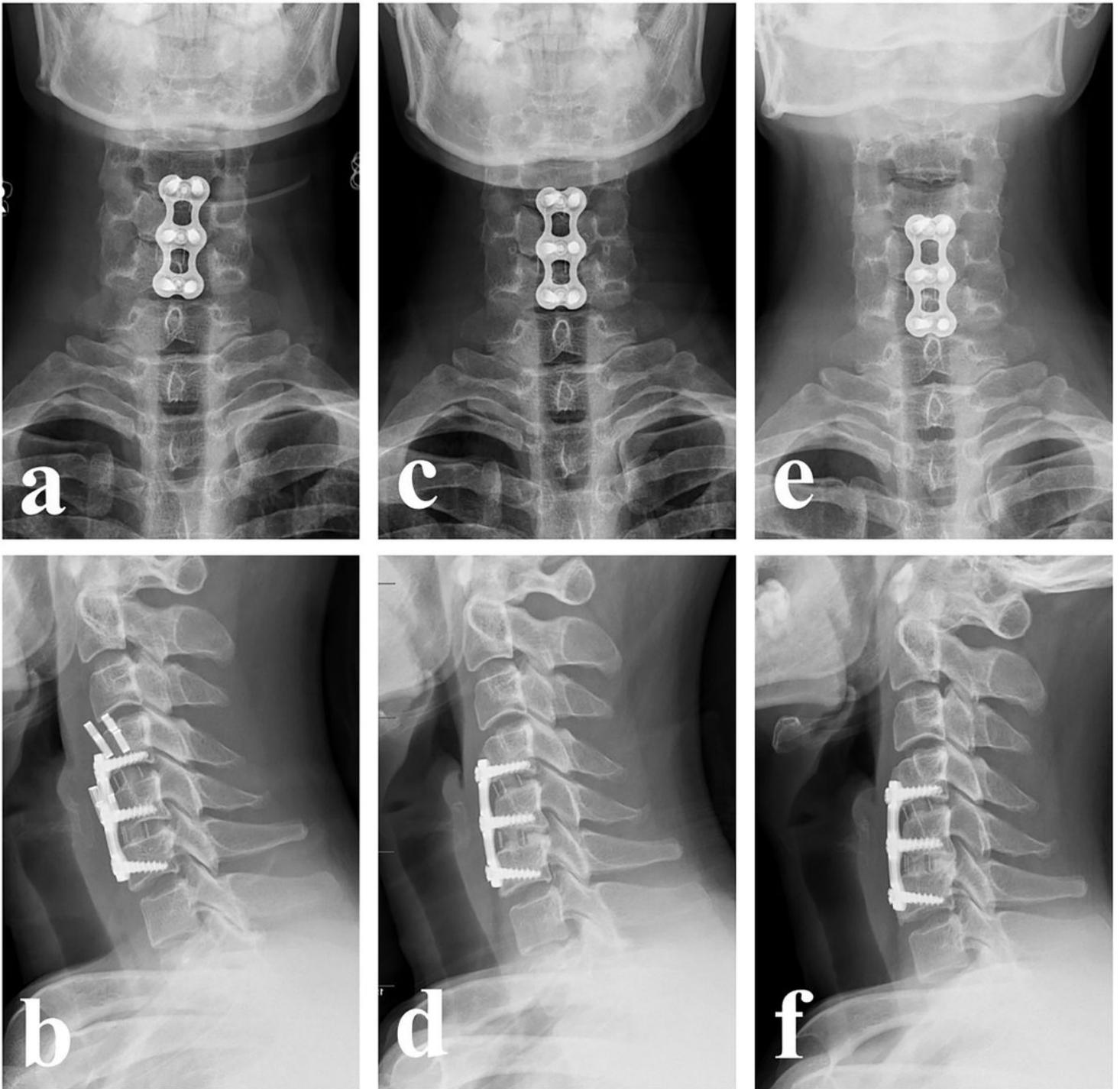


Figure 4

(a, b) Three days after operation, X-ray showed that C4-C5 and C5-C6 cervical discectomy and the positions of cages and plate were good; (c, d) One year after operation, X-ray showed that C4-C5 and C5-C6 cervical fusion and the positions of cages and plate were good; (e, f) Two years after operation, X-ray showed that C4-C5 and C5-C6 cervical fusion and the positions of cages and plate were good.