A Comparison Of The Bridge-Type Roi-c Interbody Fusion Cage System And Titanium Mesh Graft With Titanium Plate Fixation In 2-Level Anterior Cervical Discectomy And Fusion With Plating And Cage System: A Retrospective Study

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Abstract

Objective: 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 undergoing ACDF 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, and no cerebrospinal fluid leakage, esophageal fistula, or hoarseness occurred after 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 operation ($P<0.05$), but there was no significant difference between the groups ($P>0.05$). The incidence of dysphagia in group A was lower than that in group B at 1 month and 3 months after operation ($P<0.05$), but the final follow-up results showed that there was no significant difference in the incidence of dysphagia between the two groups ($P>0.05$). In group A, the fusion rate was 83.3% 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% 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 can achieve satisfactory results, but ROI-C has shorter operation time, less bleeding and lower incidence of dysphagia in the short term.

Introduction

Cervical spondylosis is a common clinical degenerative disease. With the change of people's lifestyles, the incidence of cervical spondylosis increases year by year [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 are becoming more and more diverse, including anterior discectomy and fusion internal fixation and posterior laminectomy or plastic surgery. Anterior cervical surgery is accepted by more and more patients due to its small trauma, fast recovery and definite curative effect [3, 4]. ACDF is often used in the operation of 2-level cervical spondylosis. This operation has been proved to be an effective treatment method, but there are still some complications. It was reported that the complications are common such as dysphagia, esophageal injury, bone nonunion, screw loosening and plate displacement [5, 6]. Therefore, how to reduce postoperative complications on the premise of adequate decompression, firm fixation and bone graft fusion has been an important research direction in the treatment of cervical spondylosis.

ROI-C, a new surgery, that is composed of PEEK box and two self-locking clips has been successfully applied in clinical practice, which provide a stable biomechanical environment and avoid the implant contact with 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, there were 24 patients in ROI-C group (group A), including 9 males and 15 females, aged 51-71 (60.59 ± 8.21) years old; 21 patients in ACDF group (group B), including 8 males and 13 females, aged 52-70 (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, walking instability, cotton feeling and other symptoms; (2) cervical X-ray film, computed tomography (CT) or magnetic resonance imaging (MRI) showed compression of adjacent 2-level spinal cord or nerve root. Exclusion criteria included: (1) developmental stenosis and ossification of the posterior longitudinal ligament; (2) previous cervical surgery, tumor or any serious disease history; (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 the group A, trial spacers were used to determine the appropriate size of the anchored intervertebral fusion cage. After 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 by self-locking function of the anchoring clips. In the group B, the appropriate size for the cage was determined by intraoperative evaluation using a trial cage□Self-tapping screws were used to fix the anterior cervical plate.

Clinical evaluation

Record the operation time, the bleeding during the operation, and observe the postoperative complications, including the incidence of dysphagia, the duration of symptoms and whether they are disappeared. JOA score [7] and NDI score [8] were used to evaluate the clinical outcomes before and after surgery. The effect of operation was determined by Odom's score [9], and its grades were as follows: excellent, symptoms and signs disappeared after operation; good, most symptoms and signs were relieved and normal function was restored; generally, symptoms and signs were partially improved, but could not operate normally; poor, symptoms and signs were basically the same as before operation. According to the Bazaz score [10], the degree of dysphagia was divided into four grades: none, no dysphagia; mild, almost no dysphagia; moderate, occasional dysphagia; severe, severe dysphagia.

Radioactivity evaluation

The imaging data included preoperative and postoperative imaging examination. If all the following conditions are satisfied, it is considered that 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; 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 body.

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 2 groups: Group A (24 patients), who underwent fusion using ROI-C (Figs. 1 and 2); and Group B (21 patients), who underwent fusion using ACDF (Figs. 3 and 4). In group A, the patient was 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 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, 3 patients had complications of dysphagia, but the symptom soon disappeared (Table 3). In group B, the patient was 60.15 ± 7.52 years old, the follow-up time was 26.1 ± 3.5 months, the operation time was 118 ± 29 min and blood loss was 185 ± 58 ml (Table 1). JOA score increased from preoperative 9.4 ± 1.5 to postoperative 14.1 ± 1.6, and finally maintained at 14.6 ± 1.8. NDI score decreased from preoperative 30.5 ± 8.6 to postoperative 15.1 ± 4.9, and finally maintained at 13.1 ± 4.4 (Table 2). One month after the operation, 8 patients had dysphagia complications, of which 4 patients disappeared at 3 months after operation, and 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 there was no significant difference between the groups ($P > 0.05$). The incidence of dysphagia in group A was lower than that in group B at 1 month and 3 months after

operation (P < 0.05), but the final follow-up results showed that there was no significant difference in the incidence of dysphagia between the two groups (P > 0.05).

Table 1
General information

	Group A	Group B	*P* value
Number	24	21	
Gender			
Male	9	8	
Female	15	13	
Age (year)	60.59 ± 8.21	60.15 ± 7.52	0.853
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 ± SD)

	Group A	Group B	*P* value
JOA scores			
Preoperatvie	9.6 ± 1.7[a]	9.4 ± 1.5[a]	0.680
Postoperative 1 month	13.8 ± 2.2[b]	14.1 ± 1.6 [b]	0.608
Last follow-up	14.5 ± 1.5[b]	14.6 ± 1.8[b]	0.840
NDI scores			
Preoperatvie	32.1 ± 7.9 [a]	30.5 ± 8.6 [a]	0.519
Postoperative 1 month	15.9 ± 4.7 [b]	15.1 ± 4.9 [b]	0.579
Last follow-up	13.7 ± 4.6 [b]	13.1 ± 4.4 [b]	0.658
JOA Japanese Orthopedic Association, *NDI* 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 ± 10.3 to postoperative 18.9 ± 9.4, and finally maintained at 17.9 ± 9.8. The fusion rate was 83.3% 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 ± 9.4 to postoperative 17.5 ± 10.4, and finally maintained at 17.1 ± 10.6. The fusion rate

was 85.7% 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 ± SD)

	Group A	Group B	*P* value
Cervical lordosis			
Preoperatvie	13.5 ± 10.3 [a]	12.5 ± 9.4 [a]	0.737
Postoperative 1 month	18.9 ± 9.4 [b]	17.5 ± 10.4 [b]	0.638
Last follow-up	17.9 ± 9.8 [b]	17.1 ± 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 [11]. ACDF is the standard surgery for the treatment of cervical degenerative disc disease, which can restore the physiological radian of cervical vertebra to the maximum extent, have high intervertebral fusion rate, maintain the stability of cervical spine, and have remarkable surgical effect [12]. In our study, the postoperative cervical cobb angle of the two surgery was significantly bigger than the preoperative cervical cobb angle, which indicated that both surgery can correct cervical kyphosis. Therefore, the fusion and biomechanical stability of ROI-C are equal to those of ACDF, and satisfactory surgical results of both surgery have been achieved [13]. The results of this study showed that JOA score and NDI score of both groups were improved, and good operation effect was maintained during the follow-up period, which demonstrated that the two surgery can relieve spinal cord and nerve compression, and improve the quality of life of patients.

This study found that the ROI-C has the following advantages: 1. The operation wound is smaller and less bleeding. Although ROI-C surgery can't reduce skin incision, it is not necessary to consider the placement of plate fixation and extensive exposure of adjacent vertebral body, only need to expose the target intervertebral space, which is convenient for operation. 2. The operation time is relatively short and

the operation is simple. In group A, the cage was directly fixed with self-locking clip, which could save operation time. 3. The incidence of dysphagia was reduced after operation. At present, dysphagia is a common complication after ACDF, whose mechanism has not been explained clearly [14, 15]. It may be related to the following factors: 1. 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. 2. Postoperative soft tissue adhesion may lead to dysphagia. In order to expose the target position, the soft tissue in front of the vertebral body needs to be stripped. In group A, only the intervertebral space needs to be exposed to facilitate the operation, while in group B, the plate fixation is placed in front of the vertebral body, resulting in a wider range of exposure and more bleeding, which increased the possibility of postoperative adhesion. 3.The incidence of dysphagia will be increased by using anterior cervical plate [16]. A large number of clinical studies have shown that after plate fixation is fixed, the plate will protrude from the surface of cervical body, which cause 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 this study, we found that the ROI-C was completely implanted in the intervertebral space, and there was no compression on the esophagus. 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 cervical lordosis 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, so as to prevent compression of 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 there is no significant difference between the two methods.

So far, the mechanism of adjacent joint degeneration is not clear. It is not only related to the natural degradation of adjacent joints, but also to the increase of adjacent upper and lower joint activities caused by abnormal fusion [23, 24]. Lee et al. [25] believe that the use of short plates with oblique screw tracks can significantly reduce the incidence and severity of ALOD. Many studies have shown that the shorter the plate length, the lower the 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 [26, 27]. In group A, 3 patients had adjacent vertebral degeneration, and 5 patients in group B had adjacent vertebral degeneration. In the last follow-up, no patient needed surgical intervention. In the future, we will continue to investigate and further evaluate whether the bridge-type ROI-C interbody fusion cage can help reduce the incidence of adjacent vertebral degeneration and the need for reoperation.

Of course, this study also has some limitations: first of all, this study is a retrospective study, and the level of evidence is limited. Secondly, there may be measurement errors. In order 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. In the future, 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 shorter operation time, less bleeding and 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 ZZcontributed 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

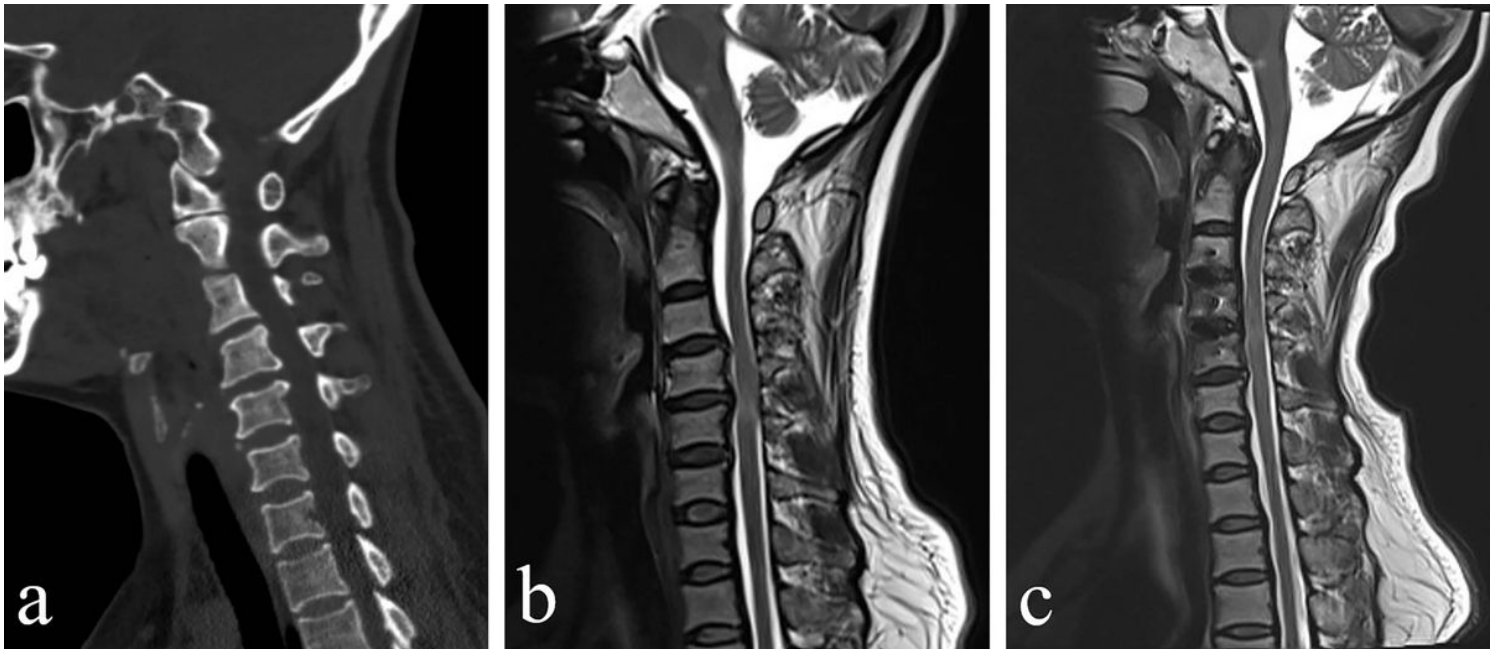

Figure 1

A 65-year-old woman with cervical spondylosis was admitted to our hospital due to numbness and weakness of both upper limbs: (a) Preoperative CT showed cervical degeneration, loss of physiological radian and hyperosteogeny; (b) Preoperative MRI indicated C3-C4 and C4-C5 cervical disc herniation and spinal cord compression; (c) Postoperative MRI noted that the spinal cord compression and the symptoms were relieved.

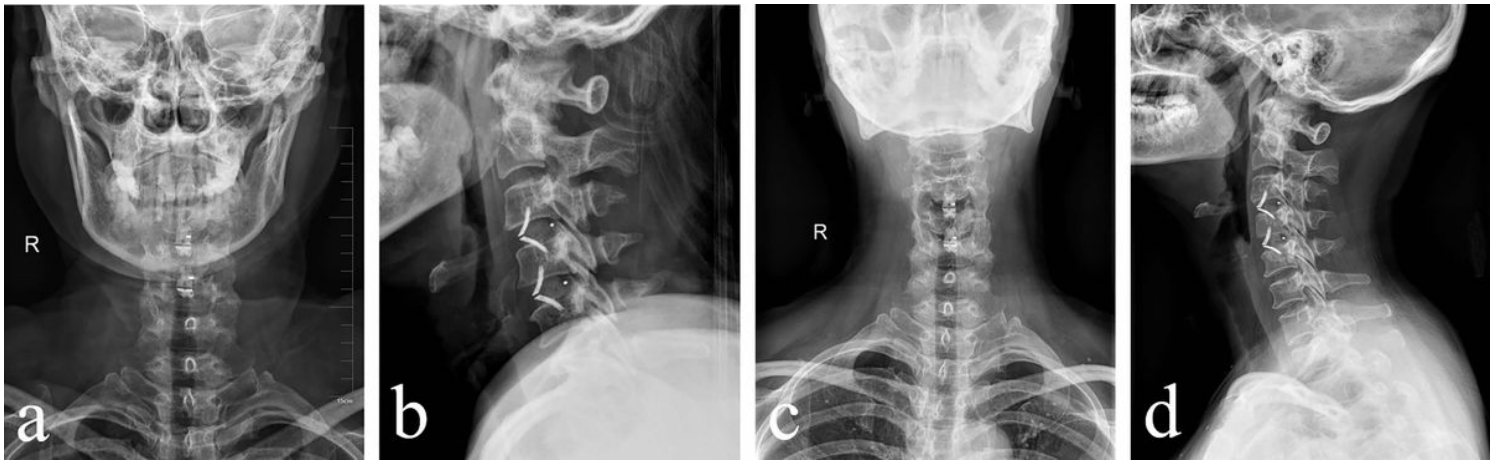

Figure 2

(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.

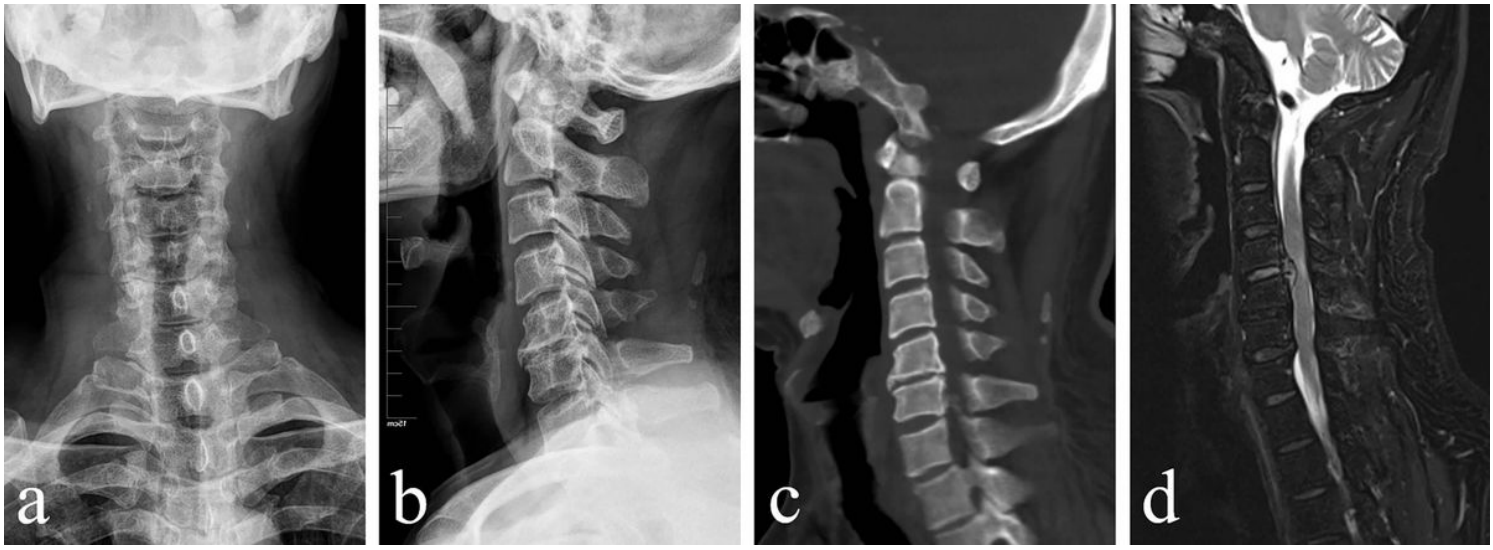

Figure 3

(a, b) Preoperative X-ray showed the disappearance of cervical vertebrae radian and hyperosteogeny; (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.

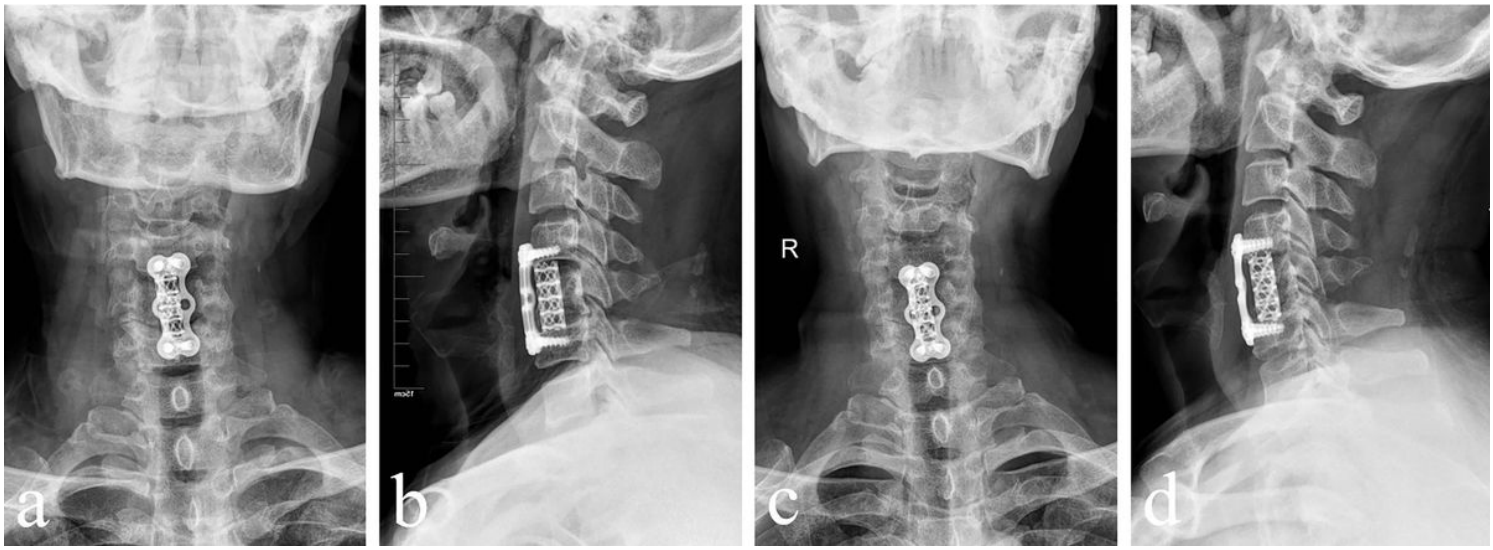

Figure 4

(a, b) Three days after operation, X-ray showed that C4-C5 and C5-C6 cervical discectomy and the positions of titanium mesh 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 titanium mesh and plate were good.