An Eight-Year Follow-Up Study on the Treatment of Single-Level Cervical Spondylosis Through Intervertebral Disc Replacement and Anterior Cervical Decompression and Fusion

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Objective: To compare the efficacy and safety of the postoperative long-term effect of the treatment of single-level cervical spondylosis through anterior cervical discectomy and fusion (ACDF) and artificial cervical disc replacement (ACDR).

Methods: This is a retrospective contrastive study, which was conducted for the period of January 2007 and January 2009 at the Department of Spine Surgery of the First Affiliated Hospital of Xinjiang Medical University. A total of 113 patients were divided into two groups depending on the operation method: ACDF group (fusion group, n = 66) and ACDR group (replacement group, n = 47). The ACDR group comprised of 23 males and 24 females. The age of these patients ranged from 31–60 years, with an average age of 42.89 ± 6.30 years. The ACDF group comprised of 38 males and 28 females. The age of these patients ranged from 28–73 years old, with an average age of 49.38 ± 9.89 years old. The evaluation index included the visual analogue scale (VAS), neck disability index (NDI), range of motion, dysphagia, adjacent vertebral disease, and related complications (prosthesis displacement, heterotopic ossification, etc.).

Results: A total of 113 patients met the inclusion criteria, and these patients receive more than 96 months of follow-up. The VAS and NDI of these two groups of patients significantly improved, when compared with those before the operation. In the last follow-up visit, the range of motion in the ACDR group and ACDF group was 43.22 ± 3.58 and 32.54 ± 2.82, respectively, and both are significantly different comparing to the values measured before the operation (P < 0.05). The dysphagia incidence of the ACDR group was higher than that of the ACDF group at the 36th month, but was lower than that of the ACDF group in other points time. In the last follow-up visit, six patients (12.77%) in the ACDR group and 18 patients (27.27%) in the ACDF suffered from adjacent segment degeneration (ASD). The general complication rate in the replacement group and fusion group was 38.31% and 37.88%, respectively, but the difference between the two groups was not statistically significant (P > 0.05).

Conclusion: Overall, the clinical efficacy and related complication rate of single-level cervical spondylosis after an anterior cervical approach operation was superior in the ACDR group when compared to the ACDF group.

Key words: Anterior cervical decompression and fusion; Cervical spondylosis; Intervertebral disc replacement; Long-term complication rate

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Introduction

For nearly a century, cervical spondylosis has become one of the most common and frequently occurring diseases, and anterior cervical disectomy and fusion (ACDF), as one of the standard operation methods for the treatment of cervical spondylosis, has become the gold standard for the treatment of cervical disc degenerative disease. This surgery relieves neural compression and improves spinal stability by fusion of the affected segments. ACDF has a wide range of applications, but there are more and more problems with this surgery due to the continuous increase in operation cases and extension in follow-up time. In recent years, biomechanics and clinical research have revealed that ACDF can accelerate adjacent segment degeneration (ASD), which requires additional surgical intervention in the long term. Furthermore, other postoperative problems, such as pseudarthrosis with recurrent pain at the operated level, must be taken into account. Due to ASD, the revision rates and revision surgery procedures have been extensively reported during the past decades.

In recent years, the anterior cervical disc replacement (ACDR), as the optional replacement treatment of ACDF, has been widely applied in the field of spine surgery. It was designed to perform neural decompression in a manner similar to that performed in ACDF, to preserve motion of the index disc, to restore and/or maintain mobility, to reconstitute disc height and spinal alignment, and, theoretically, to avoid accelerating degeneration of the adjacent segment. Previous studies have shown that ACDR could not only reach the same clinical efficacy of ACDF, but also effectively reserve the physiological activity and biomechanical environment of the cervical vertebra, thereby reducing the occurrence of ASD and avoiding other related complications of the fusion.

Although ACDR was associated with less ASD, some specific complications including subsidence, migration, and malposition required subsequent surgical intervention. Scholars have put forward that ACDR induces an adverse influence on ASD, and some patients even need to take the fusion again. During the past years, the need for subsequent surgery after ACDR has been attracting the attention of the investigators.

On this premise, scholars have repeatedly evaluated the efficacy and safety of the ACDF and ACDR operation methods. On the premise that these two operation methods reach the same curative effect, the determination of which operation method can reduce the related complication rate more effectively remains in dispute. A previous study on these two operation methods focused more on intraoperative comparison and postoperative short- and medium-term prognosis, and follow-up reports on the long-term complications of these two operation methods are few. The present study aims to: (i) discuss the efficacy of ACDR and ACDF for the treatment of single-level cervical spondylosis in the long-term follow-up; and (ii) compare the difference of these two groups in terms of VAS, NDI, range of motion, dysphagia, ASD, and other related complications (prosthesis displacement, heterotopic ossification, etc.).

Patients and Methods

Design
This is a retrospective contrastive analysis and study.

Time and Place
The study was conducted for the period of January 2007 and January 2009 at the Department of Spine Surgery of the First Affiliated Hospital of Xinjiang Medical University.

Inclusion and Exclusion Criteria

Inclusion Criteria
The inclusion criteria are as follows: (i) patients verified to suffer from spinal cord or nerve root compression according to imageological examination, and has classical symptoms or signs; (ii) the single intervertebral disc segment suffers from the lesion in C3-T1; (iii) more than 3 months of the formal and conservative treatment before the operation was ineffective; (iv) the post-operation follow-up time was ≥96 months, and the clinical data was complete; and (v) the patient provided an informed consent for the treatment and testing program, and was approved by the Ethics Committee of the hospital.

Exclusion Criteria
The exclusion criteria are as follows: (i) patients who have poor physical condition and suffer from serious osteoporosis, rheumatoid arthritis, and other orthopaedic diseases; (ii) patients who received an operative treatment for cervical vertebra, or suffer from serious organic diseases; (iii) patients who have trauma, infection, tumor, dysphagia and other related symptoms before the operation; and (iv) patients with a follow-up time less than 96 months.

Patients
A retrospective analysis was conducted on 154 patients who suffered from single-level cervical spondylosis and were admitted to the Department of Spine Surgery of the First Affiliated Hospital of Xinjiang Medical University from January 2007 to December 2009. Among these patients, 41 patients were lost to follow-up. Hence, 113 patients were included in the study. These patients were divided into two groups, according to the different treatment method: artificial intervertebral disc replacement group (n = 47) and anterior cervical decompression and fusion group (n = 66). The inclusion and exclusion criteria are presented in Table 1.
realize the hyperextension of the cervical vertebra. Then, routine disinfection and surgical draping was carried out, the C-arm machine located the object’s intervertebral space, the right anterior incision was taken, the skin and fascia membrane was cut open layer by layer, the anterior longitudinal ligament was excised using an electrotome, and the periosteal detacher was used to strip the muscle to both sides. Afterwards, the Casper opener was fixed by the screw to open the intervertebral space, the fiber ring and nucleus pulposus in the target space were excised, and the Lusaca joint and posterior hyperplasia osteophyte were excised by the spatula, but the posterior longitudinal ligament was not excised. Next, the anterior cervical fuser was placed in the decompression intervertebral space, and the bone-grafting rod was fixed firmly using the anterior cervical plate (provided by AO Company). The C-arm machine was used to determine whether the position of the implant was good through fluroscopy. Then, flushing, placement, and drainage were carried out, and the wound was sutured layer by layer.

**ACDF Group**

After the general anesthesia took effect, the patient was placed in the spinal position with the shoulders raised in order to realize the hyperextension of the cervical vertebra. Then, routine disinfection and surgical draping were carried out, the C-arm machine located the object’s intervertebral space, the right anterior incision was taken, the skin and fascia membrane was cut open layer by layer, the anterior longitudinal ligament was excised using an electrotome, and the periosteal detacher was used to strip the muscle to both sides. Afterwards, the Casper opener was fixed by the screw to open the intervertebral space, the fiber ring and nucleus pulposus in the target space were excised, and the Lusaca joint and posterior hyperplasia osteophyte were excised by the spatula, but the posterior longitudinal ligament was not excised. Next, the anterior cervical fuser was placed in the decompression intervertebral space, and the bone-grafting rod was fixed firmly using the anterior cervical plate (provided by AO Company). The C-arm machine was used to determine whether the position of the implant was good through fluroscopy. Then, flushing, placement, and drainage were carried out, and the wound was sutured layer by layer.

**TABLE 1 The inclusion and exclusion criteria**

| Inclusion criteria                                      | Exclusion criteria                                      |
|--------------------------------------------------------|---------------------------------------------------------|
| 1. Patients verified to suffer from spinal cord or nerve root compression according to the patient’s imageological examination, and has classical symptoms or signs; | 1. Patients who have poor physical condition and suffer from serious osteoporosis, rheumatoid arthritis and other orthopedic diseases; |
| 2. The single intervertebral disc segment suffers from the lesion in C3-T1; | 2. Patients who received an operative treatment for cervical vertebra, or suffer from the serious organic diseases; |
| 3. More than three months of the formal and conservative treatment before the operation was ineffective; | 3. Patients who have trauma, infection, tumor, dysphagia and other related symptoms before the operation; |
| 4. The post-operation follow-up time was ≥96 months, and the clinical data was complete. | 4. Patients with a follow-up time less than 96 months. |

**Operation Methods**

**ACDF Group**

After the general anesthesia took effect, the patient was placed in the spinal position with their shoulders raised to

suffered from mixed type cervical spondylosis (spinal type + nerve root type). Operation segment: C3-4, three patients; C4-5, eight patients; C5-6, 29 patients; C6-7, seven patients. The follow-up time of all patients was ≥96 months, and the average time was 104.34 ± 8.59 months.

Fusion (ACDF) group: This group comprised of 38 males and 28 females. The age of these patients ranged from 28–73 years old, with an average age of 49.38 ± 9.89 years. Among these patients, 42 patients suffered from nerve root type cervical spondylosis, 12 patients suffered from spinal type cervical spondylosis, and 12 patients suffered from mixed type cervical spondylosis (spinal type + nerve root type). Operation segment: C3-4, five patients; C4-5, 11 patients; C5-6, 50 patients; C6-7, 10 patients. The follow-up time for all patients was ≥96 months, and the average time was 104.06 ± 8.19 months.

All patients: took the C-spine anterior posterior and lateral (AP & LAT), hyperextension and hyperflexion X-ray film and cervical vertebra magnetic resonance imaging (MRI) plain scan before the operation; received the same basic treatment and nursing during the operation; and accepted regular follow-ups for 3 months, 6 months, and 12 months after the operation, and every year thereafter. These patients filled in the relevant questionnaire during the follow-up, routinely took the C-spine AP & LAT, hyperextension and hyperflexion X-ray film, and took the cervical vertebra MRI plain scan during the last follow-up. All patients provided a signed informed consent, and the present study was approved by the Ethics Committee of the hospital.

**Postoperative Treatment**

The patient received antibiotics, anti-inflammatory and neurotrophy medicines through intravenous injection at 3 days after the operation, the volume of drainage and character of drainage objects were closely observed, and the drainage tube was removed when the volume of drainage was <30 mL/24 h. The patient wore a hard cervical collar when walking at 24 h after the operation. Then, when the patient took off the cervical collar, cervical back muscle functional rehabilitation exercises were performed after 1 month.
Furthermore, regular reexaminations were performed at 3 months, 6 months, and 12 months after the operation, and every year thereafter.

**Observation Indicator**

**VAS and NDI**
The patient took the reexamination in the Department of Spine Surgery of our hospital at 3 months, 6 months, and 12 months after the operation, and every year thereafter. These patients filled in the VAS pain questionnaire and NDI questionnaire. The VAS was used to evaluate the degree of pain, which was self-assessed by the patients, and the scale ranged from 0 (no pain) to 10 (very severe pain). The NDI covers 10 dimensions of neck-specific disability, namely pain intensity, personal care, lifting, reading, headache, concentration, work, driving, sleeping, and recreation. Each dimension is assessed with one item, measured on a 6-point scale from 0 (no disability) to 5 (full disability). The sum score out of all 10 items is multiplied by 2 to obtain a score out of 100.

**ASD and Other Complications (Prosthesis Displacement, Heterotopic Ossification, Etc.)**
It was determined whether there was ASD and other related complications through the imageological examination. The ASD was defined as follows: protrusion of the intervertebral disc, degeneration, spinal canal stenosis, and subluxation or instability of the adjacent segment with or without symptoms. The heterotopic ossification is judged according to the method of McAfee.

**Cervical Vertebra Range Of Motion (ROM)**
The patient took the reexamination in the Department of Spine Surgery of our hospital at 3 months, 6 months, and 12 months after the operation, and every year thereafter. The range of motion was calculated through the Cobb angle, which was the sum of the intersection angle of the tangent line between the C2 centrum inferior margin and C7 centrum inferior margin in the cervical hyperextension and hyperflexion X-ray film.

**Dysphagia**
The patient filled in the swallowing questionnaire (blocking of dry, liquid, or large pieces of food; asthenia and bucking during swallowing; sensation of choking on object; burning; etc.), and it was evaluated whether the patient has dysphagia after the operation according to the Bazaz standard. The dysphagia incidence of the patient at 3 months, 6 months, and 12 months after operation, and every year thereafter, was recorded.

**Statistical Methods**
The SPSS 22.0 statistical software (IBM Inc., New York, USA) is used for the statistical analysis. And the t-test was used for changes in VAS, NDI, and range of motion during the preoperative and postoperative follow-up. A P-value of <0.05 (two-tailed) was considered significant in all analyses.

**Results**

**Comparison of Basic Data of the Two Groups of Patients**
A total of 113 patients met the inclusion criteria, and these patients receive more than 96 months of follow-up. The basic population statistics data are presented in Table 2.

**The Results of VAS and NDI**
The VAS change trend at every follow-up time point is presented in Fig. 2. In the replacement group, VAS decreased from 6.55 ± 1.21 before the operation to 1.45 ± 0.72 after the operation, and was 2.12 ± 1.09 in the last follow-up. In the fusion group, VAS decreased from 6.44 ± 1.10 before the operation to 1.74 ± 0.75 after the operation, and was 2.47 ± 1.29 in the last follow-up (P > 0.05). The VAS values measured at the last follow-up (96 months) between the two groups were significant difference (2.12 ± 1.09 vs 2.47 ± 1.29, P < 0.05). Furthermore, for male patients, the VAS values measured at the last follow-up between the two groups were also significantly different (1.96 ± 0.77 vs 2.42 ± 1.22, P < 0.05). But for female patients, the VAS values measured at the last follow-up between the two groups were not significant difference (2.08 ± 1.34 vs 2.53 ± 1.40, P > 0.05).

In the replacement group, the NDI decreased from 26.17 ± 5.35 before the operation to 7.31 ± 3.70 after the
operation, and was 9.83 ± 6.05 at the last follow-up. In the fusion group, the NDI decreased from 25.76 ± 5.50 before the operation to 7.88 ± 3.27 after the operation, and was 11.70 ± 7.01 at the last follow-up (P > 0.05). The change trend at every point in time is presented in Fig. 3. The NDI values measured at the last follow-up between the two groups were significantly different (9.83 ± 6.05 vs 11.70 ± 7.01, P < 0.05). For male patients, the NDI values measured at the last follow-up between the two groups were also significantly different (8.60 ± 4.35 vs 12.00 ± 6.57, P < 0.05). But for female patients, the NDI values measured at the last follow-up between the two groups were not significantly different (11.00 ± 7.23 vs 11.28 ± 7.64, P > 0.05).

These two operation methods significantly improved the patients’ clinical symptoms, and the patients maintained a good state, basically throughout the entire eight-year follow-up.

**The Results of Cervical Vertebra ROM**

In the replacement group, the range of motion decreased from 38.38 ± 1.83 before the operation to 28.19 ± 2.74 after the operation, and was 43.22 ± 3.58 at the last follow-up. In the fusion group, this decreased from 39.88 ± 2.05 before the operation to 26.93 ± 1.98 after the operation, and was 32.54 ± 2.82 at the last follow-up. The cervical motion of these two groups of patients was significantly limited after the operation, and presented a trend of gradual recovery with the extension of follow-up time. When the follow-up time was ≥12 months, the cervical vertebra ROM in the replacement group obviously recovered, and this was higher than before the operation, while recovery in the fusion group is not obvious. The change trend at every point in time during the follow-up period is presented in Fig. 4. Three typical cases in this study are shown in Figs 5–7.

**Dysphagia**

According to the Bazaz swallowing function marking system, the total incidence of dysphagia for patients in the ACDR group and ACDF group at 3 months, 6 months, and 12 months after the operation, and every year thereafter, was 23.40% vs 36.36%, 21.28% vs 24.24%, 12.77 vs 24.24%, 10.64% vs 18.18%, 10.64% vs 6.06%, 4.26% vs 6.06%, 4.26% vs 6.06%, 2.13% vs 6.06%, and 2.13% vs 6.06%, respectively. The results of the analysis revealed that the dysphagia incidence of patients in the replacement group was slightly higher, when compared to that in the fusion group, in the 36th month during the follow-up, and this is lower than that in the fusion group at the other time points (Fig. 8).

**Related Complication Assessment**

In the last follow-up, six patients (12.77%) in the replacement group suffered from ASD, while 18 patients (27.27%) presented a trend of gradual recovery with the extension of follow-up time. When the follow-up time was ≥12 months, the cervical vertebra ROM in the replacement group obviously recovered, and this was higher than before the operation, while recovery in the fusion group is not obvious. The change trend at every point in time during the follow-up period is presented in Fig. 4. Three typical cases in this study are shown in Figs 5–7.
in the fusion group suffered from ASD. In terms of postoperative ASD incidence after treatment of single-level cervical spondylosis, ACDR was obviously superior to ACDF, and the difference was statistically significant ($P < 0.05$). In the ACDR group, two patients suffered from prosthesis antedisplacement (>3 mm), while 10 patients suffered from heterotopic ossification. In the ACDF group, two patients suffered from pseudarthrosis, while five patients suffered from heterotopic ossification. The first patient who suffered from postoperative long-term complications was found at the 36th month in the replacement group and at the 24th month in the fusion group after the operation. The complication incidence of these two groups of patients at each follow-up time point is presented in Fig. 9.

Discussion

With the popularity of computers and mobile phone, approximately 80% of people suffer from cervical pain in their life. Regardless of whether it is a traffic accident or change of lifestyle, cervical spondylosis has become a common clinical disease that seriously affects quality of life. For single-level patients whose conservative treatment is ineffective for more than 3 months and the symptoms are severe, ACDF or ACDR can produce a good curative effect in clinic. The present study indicates that there is no statistical difference between the replacement group and fusion group in terms of VAS and NDI, and both produce a good clinical curative effect during the eight-year follow-up period. The difference is that the range of motion in the replacement group was significant improved than fusion group during 96 months after operation. The ACDR not only removes the

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Discussion

With the popularity of computers and mobile phone, approximately 80% of people suffer from cervical pain in their life. Regardless of whether it is a traffic accident or change of lifestyle, cervical spondylosis has become a common clinical disease that seriously affects quality of life. For single-level patients whose conservative treatment is ineffective for more than 3 months and the symptoms are severe, ACDF or ACDR can produce a good curative effect in clinic. The present study indicates that there is no statistical difference between the replacement group and fusion group in terms of VAS and NDI, and both produce a good clinical curative effect during the eight-year follow-up period. The difference is that the range of motion in the replacement group was significant improved than fusion group during 96 months after operation. The ACDR not only removes the
pathological intervertebral disc and realizes sufficient decompression, but also avoids the fusion of operation segments through the implantation of an artificial intervertebral disc, thereby reserving the range of motion of the cervical vertebra furthest. Therefore, the selection of cervical intervertebral disc replacement appears to conform more to the biomechanics of cervical vertebra, thereby reducing the degeneration of the adjacent segment20,21.

Although the anterior approach operation has a certain advantage, it can easily lead to dysphagia, hematoma, and other complications22 due to the complex anatomical structure of the anterior cervical approach, and the involvement of the nerve and other important structures. The dysphagia can be divided into functional, nervous, and structural dysphagia, according to the occurrence reason. The dysphagia is the result of the combined influence of multiple factors, and any stimulation of the esophagus would be deemed as the reason leading to an increase in dysphagia incidence. However, the specific mechanism still needs to be further studied. At present, the recognized influencing factors of dysphagia include the following: gender, age, operation segment (C4-6), Smith-Robinson right-side approach, intraoperative esophagus traction time or excessive traction, application hormone, etc.23.

According to the study by Rihn et al.24, the dysphagia incidence is as high as 70% after an anterior cervical operation. In the last follow-up, the dysphagia incidence of patients in the fusion group was obviously higher than that in the replacement group. Meanwhile, in existing study results and the present study, it was indicated that the dysphagia incidence of patients in the replacement group was slightly superior to that in the fusion group.

ACDF has a wide range of applications, but the related clinical and biomechanical study in recent years shows that adjacent segment stress will change after the operation. This would allow the ASD to be accelerated, and the occurrence of pseudarthrosis, bone grafting non-fusion and other complications25 after fusion. Compared with ACDF, ACDR can reserve the height of the intervertebral space, maintain the range of motion of the neck, and improve the stress distribution of the adjacent segment. Therefore, it has been expected that ACDR can become an operation method replacing ACDF. However, whether the natural degeneration process of the adjacent segment after fusion would accelerate due to fusion, and whether the maintenance of range of motion of the corresponding segment after the replacement operation can change the degeneration rate of the adjacent segment, still lacks clinical evidence3,26.

Yin et al.27 pointed out that ACDR can reserve the range of motion of the operation segment, but these two operation methods have no difference in terms of range of motion.
Fig. 7 A case of a 47-year-old man. He had been diagnosed as C5-C6 cervical disc herniation, and was enrolled in the anterior cervical disc replacement (ACDR) group. He had underwent an ACDR surgery in October 2008. The preoperative images were shown in Fig. 7A,B. And Fig. 7C,F were the images taken at the last follow-up, indicating the cervical vertebra ROM was obviously recovered. ROM, range of motion.

Fig. 8 The dysphagia incidence in each group. The dysphagia incidence in the anterior cervical disc replacement (ACDR) group was slightly higher than that in the anterior cervical discectomy and fusion (ACDF) group at the 36th month. But for other time points, the dysphagia incidence in the ACDR group was much lower.
motion of the adjacent segment. It was reported that the risk factor of ASD after ACDR and ACDF is basically equal27,28.

In the present study, the ASD incidence in the replacement group was 12.77%, which was obviously superior to 27.27% in the fusion group. This also indicates that the advantage of ACDR is postponing the occurrence of ASD along with the extension of follow-up time. However, the heterotopic ossification incidence was higher in the replacement group, and the correlation between the related biomechanics theory and clinical prognosis still needs to be further discussed29.

The limitations of this study include its retrospective nature, small number of patients, and the biases inherent in retrospective analyses. Furthermore, the subgroup analysis was not performed in this study. So, the influence of age and the related biomechanics theory on clinical complications still needs to be further studied.

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