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Clinical and Radiological Analysis of Bryan Cervical Artificial Disc Replacement for “Skip” Multi-Segment Cervical Spondylosis: Long-Term Follow-Up Results

Authors' Contribution:
Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

ABCEF 1,2 **Zikun Shang**
ABF 1,2 **Yingze Zhang**
BCEF 1,2 **Di Zhang**
BCD 1,2 **Wenyuan Ding**
ADE 1,2 **Yong Shen**

1 Department of Orthopedic Surgery, The Third Hospital of Hebei Medical University, Shijiazhuang, Hebei, P.R. China
2 The Key Laboratory of Orthopedic Biomechanics of Hebei Province, The Third Hospital of Hebei Medical University, Shijiazhuang, Hebei, P.R. China

Corresponding Author: Yong Shen, e-mail: drsypine@hotmail.com, shangzikun2011@163.com
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Background: The aim of this study was to retrospectively analyze the clinical and radiological efficacy of Bryan cervical artificial disc replacement (ADR) for “skip” multi-segment cervical spondylosis (SCS).





Material/Methods: We enrolled 49 patients with SCS treated with either Bryan cervical ADR (18 cases) or ACDF (31 cases). Each case was evaluated preoperatively and at more than 48 months postoperatively in follow-up using the JOA, NDI, and VAS. Cervical sagittal curvature, total cervical ROM, and degree of middle segments of motion were also evaluated. MRI was used to assess adjacent segment degeneration (ASD), spinal cord compression, and signal changes.

Results: The JOA, NDI, and VAS scores in the 2 groups improved significantly postoperatively. At the last follow-up, the results of Group Bryan were better than those of Group ACDF with respect to the incidence of axial symptoms (11.1% and 45.2%, respectively), VAS, ROM, and the degree of middle segments of motion. The ROM in Group Bryan was $38.2 \pm 4.6^\circ$ and in Group ACDF was $25.3 \pm 4.6^\circ$. The middle segments of motion were $8.4 \pm 2.0^\circ$ in Group Bryan and $12.2 \pm 2.2^\circ$ in Group ACDF. There were no patients with ASD in Group Bryan. In Group ACDF, 1 case with an internal fixation device developed dislocation, and 2 cases developed degeneration, but there was no need for reoperation.

Conclusions: ADR for SCS can effectively improve neurological function and retain the overall activity of the cervical, thereby reducing ASD and the incidence of postoperative axial symptoms.

MeSH Keywords: **Cervical Vertebrae • Intervertebral Disc Degeneration • Neck Pain • Total Disc Replacement**

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Background

“Skip” cervical spondylosis (SCS) is a multi-segment section of discontinuous cervical disease, with 1 or more normal discs interspersed between lesion segments. Few SCS treatment modalities have been reported in the literature, and treatment is not uniform. Anterior cervical decompression and fusion (ACDF) has widely been used for the treatment of cervical spondylosis [1]. However, Hilibrand et al. [2] found that approximately 2.9% of patients every year reported symptomatic adjacent segment degeneration (ASD), with a 10-year cumulative incidence of 25%. Artificial disc replacement (ADR) with non-fusion technology retains the cervical spine, thereby reducing the incidence of complications related to fixation; it has irreplaceable fusion advantages. Currently, a comparative study of both techniques for the clinical treatment of SCS is lacking.

The present study retrospectively analyzed the clinical data of 2 groups of patients with SCS preformed with different surgeries. Our evaluation of these patients occurred preoperatively and at more than 48 months postoperatively. We compared the clinical effects of the 2 surgical procedures and imaging outcomes. The aims of our study were: 1) to investigate the surgical procedures selecting for SCS; 2) to evaluate the efficacy of Bryan ADR for SCS; and 3) to investigate the use of Bryan ADR to prevent related complications.

Material and Methods

General information

This study was approved by the Institutional Review Board of No. 3 Hospital of Hebei Medical University. From February 2002 to May 2012, according to the preoperative inclusion and exclusion criteria [3], a total of 49 SCS patients (29 males and 20 females) who were treated with Bryan cervical ADR (Group Bryan) or ACDF (Group ACDF) completed the final assessment. All of the patients were asked to participate in the study; those who did not wish to participate were not enrolled. Radiographic and functional evaluations were performed preoperatively and postoperatively at 24 months and the last follow-up visit.

Eighteen patients were in the Bryan group, including 10 males and 8 females. Thirty-one patients were in the ACDF group, including 19 males and 12 females. In Group ACDF, there were 5 isolated-type OPLL, 6 cases of cervical vertebral osteophyte formation, and 2 cases of yellow ligament hypertrophy (Table 1).

We examined the cervical spine X-ray, lateral dynamic X-ray, and cervical MR and CT electromyography (EMG) scans preoperatively for each patient.

The surgical method

All surgeries were performed by the same group of surgeons. Patients were treated with general anesthesia. The surgical approach was through the Smith-Robinson approach. The lesioned intervertebral disc of the patients in Group Bryan were completely removed. Then, the surgeon completely removed the posterior longitudinal ligament, the vertebral osteophyte, and tissues that caused the compression of the spinal cord. Based on the CT scan, we used the template of different magnification factors to predict the diameter of the implanted artificial cervical disc prosthesis (Medtronic Sofamor Danek, Memphis, TN, USA) and implanted it [3]. The other pathological disc was managed in a similar way.

In Group ACDF, the lesioned intervertebral disc, intervertebral osteophytes, and the vertebral ossification of the posterior longitudinal ligament were also completely removed. Three patients had dural ossifications with severe adhesions or dural ossifications. The surgeon used surgery flotation, with free grinding ossification, under direct vision to observe the dural sac floating forward [4]. A correspondingly-sized polyetheretherketone (PEEK) cage (Medtronic Sofamor Danek, Memphis, TN, USA) filled with bone was placed in the intervertebral space and a titanium plate with a similar curvature was applied (Medtronic Sofamor Danek, Memphis, TN, USA). The surgery was performed in a similar method on the other disc.

Follow-up and evaluation criteria

Blood loss, operation time, and hospital costs were recorded. The Japanese Orthopedic Association (JOA) 17-point score system was used to evaluate neurological function. According to the Neck Disability Index (NDI), we assessed the improvement of axial symptoms after surgery. A visual analogue scale (VAS) was used to assess the degree of pain in the neck and upper limbs [5,6].

We judged whether the fusion of the bone graft was standard as proposed by Song et al. [7]. We performed a lateral cervical X-ray and measured the cervical sagittal curvature (C2~C7 angle), the total cervical range of motion (ROM), and the degree of motion of the middle segments on flexion-extension stress lateral radiographs [2]. Lateral X-ray and MRI T2-weighted images were used for the determination of ASD and cervical heterotopic ossification [5]. Adjacent segment degeneration (ASD) was defined by the presence of at least 1 of the following on X-ray: calcification of the anterior longitudinal ligament; narrowing of the disc space with or without posterior osteophytes; or new anterior or enlarging osteophyte formation.

Measurements were made using Synapse (PACS) image software (Fujifilm Inc., Japan) for each angle of the cervical spine.

Table 1. Demographic baseline data and surgical information.

Demographics	Group Bryan (18 cases)	Group ACDF (31 cases)	Statistical value	P value
Age [year]	48.7±6.1	49.3±8.6	t=-0.257	P=0.799
Sex				
Male	10 (55.6%)	19 (61.3%)	$\chi^2=0.155$	P=0.768
Female	8 (44.4%)	12 (38.7%)		
Type				
Radiculopathy	7 (38.9%)	13 (41.9%)	$\chi^2=0.004$	P=0.539
Myelopathy	11 (61.1%)	18 (58.1%)		
Operation segment				
C3-C4, C5-C6	8 (44.4%)	11 (35.5%)	$\chi^2=0.385$	P=0.559
C4-C5, C6-C7	10 (55.6%)	20 (64.5%)		
Preoperative history [months]	14.2±10.6	14.3±7.1	Z=-0.773	P=0.439
Amount of bleeding [ml]	143.2±35.8	135.1±44.7	Z=-1.074	P=0.283
Operation time [min]	137.1±20.8	147.5±30.3	Z=-0.864	P=0.388
Surgical costs [million yuan]	8.5±0.5	6.6±0.5	t=13.5	P<0.001
Follow-up time [months]	79.5±20.1	74.5±15.6	t=-0.953	P=0.345
Incidence of axial symptoms	16 (88.9%)	17 (54.8%)	$\chi^2=6.004$	P=0.025
Not present	2 (11.1%)	14 (45.2%)		
Present				

To ensure accurate measurements, 2 independent radiologists evaluated these images, and each image was measured 3 times on average. All X-ray and MRI images were used to assess the adjacent segment degeneration, and the evaluator was blinded to the treatment groups.

Statistical methods

The SPSS (Version 19.0, Chicago, IL, USA) statistical software package was used for data analysis. Data are presented as $x \pm s$. Measurement data were compared using the independent two-samples *t* test or nonparametric rank sum test; ratios or rates were compared using the chi-square test and Fisher exact test. A two-sided α value of 0.05 was used.

Results

In our study, 49 patients were followed for more than 48 months and up to 110 months. The average postoperative follow-up time of Group Bryan patients was 79.5 ± 20.1 months; Group ACDF patients were followed for an average of 74.5 ± 15.6

months. Differences in demographic and baseline data in the 2 groups of patients were not statistically significant (Table 1).

Surgical results

The 2 groups of patients successfully completed surgery. There was no significant difference in the amount of bleeding or the operation time between the 2 groups ($P > 0.05$, Table 1).

Clinical function and imaging evaluation

The incidence of axial symptoms in Group Bryan was 11.1% (2 cases), and the incidence in Group ACDF was 45.2% (14 cases); the difference between the 2 groups was statistically significant (Table 1). The JOA, NDI and VAS scores were significantly improved after the operation in the 2 groups; the differences in the VAS scores between the 2 groups at 24 months and at the end of the follow-up period were statistically significant ($P=0.000$ and $P=0.005$, respectively). The differences in the JOA and the NDI scores between the 2 groups at the same time points were not statistically significant (Table 2). However, we found that in Group ACDF, the NDI score at 24 months was significantly different from the score at the final

Table 2. Clinical efficacy results.

Group		JOA score	NDI score	VAS score
Group Bryan	Preoperative	6.7±1.7	43.1±3.7	7.3±1.5
	2-year follow-up	15.9±0.8	6.2±1.4	1.6±0.8
	Last follow-up	16.1±1.0	4.9±1.4	1.4±1.0
Group ACDF	Preoperative	7.5±1.8	41.5±3.8	6.7±2.3
	2-year follow-up	16.0±1.5	6.1±1.4	2.7±1.2
	Last follow-up	16.3±1.0	5.2±1.3	2.3±0.9
Statistical values	Comparison of the two groups preoperatively	Z=-1.774 P=0.076	t=-1.592 P=0.111	Z=-0.586 P=0.558
	Comparison of the two groups after two years' follow-up	Z=-1.269 P=0.205	Z=-0.272 P=0.786	Z=-3.540 P=0.000
	Comparison of the two groups at the end of the follow-up	Z=-0.826 P=0.409	Z=-0.637 P=0.524	Z=-2.836 P=0.005
	Comparison of preoperative and 2-year data in Group Bryan	Z=-5.173 P=0.000	Z=-5.203 P=0.000	Z=-5.181 P=0.000
	Comparison of preoperative and final data in Group Bryan	Z=-5.184 P=0.000	Z=-5.162 P=0.000	Z=-5.163 P=0.000
	Comparison of 2-year and final data in Group Bryan	Z=-0.704 P=0.482	Z=-2.562 P=0.010	Z=-0.496 P=0.521
	Comparison of preoperative and 2-year data in Group ACDF	Z=-6.858 P=0.000	Z=-6.879 P=0.000	Z=-6.107 P=0.000
	Comparison of preoperative and final data in Group ACDF	Z=-6.884 P=0.000	Z=-6.814 P=0.000	Z=-6.468 P=0.000
	Comparison of 2-year and final data in Group ACDF	Z=-0.665 P=0.506	Z=-2.543 P=0.011	Z=-2.385 P=0.017

follow-up visit (P=0.011), and the same results were found in Group Bryan. The JOA score changes did not follow this pattern. We also observed that in Group ACDF, the VAS score at 24 months was significantly different from the score at the end of the follow-up period (P=0.017), but Group Bryan did not exhibit these results.

According to the imaging data, the sagittal curvature at the last follow-up visit was significantly different between the 2 groups (P=0.024) but was not significantly different between groups preoperatively (Table 3). At the last follow-up visit, the ROM in Group Bryan and Group ACDF was 38.2±4.6° and 25.3±4.6°, respectively, and the degree of middle segment motion in Groups Bryan and ACDF was 8.4±2.0° and 12.2±2.2°, respectively, which represented a statistically significant difference (P<0.05, Table 3). With prolonged postoperative recovery time, the cervical sagittal curvature in Group ACDF tended to return to preoperative levels, which led to a significant increase in middle segment activity. Although this trend also occurred in Group Bryan, there was no significant increase in intermediate segment mobility.

As shown in this group of photos, including preoperative (Figure 1A–1C) and 68 months postoperative (Figure 1D–1F) X-ray and MR images, a 31-year old patient suffered from C3–C4 and C5–C6 cervical spondylosis. The postoperative images demonstrate that the middle segment of the disc did not degenerate, and the cervical curvature and mobility remained good.

Complications

After surgery, the 2 groups each included 5 cases of immediate pharyngeal pain and swallowing difficulties and 1 case of hoarseness and cough. These patients received atomization inhalation treatment; after 1 week, the symptoms significantly improved, and after 1 month the symptoms disappeared. Cerebrospinal fluid leakage occurred in 2 cases in Group Bryan and in 4 cases in Group ACDF. Similar treatment was provided during and after the operation [5]. All patients healed well.

At the last follow-up visit, there was no heterotopic ossification or prolapse in Group Bryan, and MRI images of the intervertebral disc in the adjacent segment, especially the middle segment,

Table 3. Imaging results.

Group		Cervical sagittal curvature (°)	Total cervical spine range of motion (ROM, °)	Degree of middle segment motion (°)
Group Bryan	Preoperative	11.5±4.1	30.6±7.8	8.7±1.8
	2-year follow-up	14.5±3.5	35.5±5.9	7.3±1.4
	Last follow-up	14.7±1.9	38.2±4.6	8.4±2.0
Group ACDF	Preoperative	10.9±4.3	29.3±7.5	8.7±2.2
	2-year follow-up	13.3±3.9	24.5±6.2	10.1±1.6
	Last follow-up	12.6±3.6	25.3±4.6	12.2±2.2
Statistical values	Comparison of the two groups preoperatively	t=0.481 P=0.632	Z=-0.809 P=0.418	Z=-0.283 P=0.777
	Comparison of the two groups after two years' follow-up	Z=-0.977 P=0.329	t=6.135 P=0.000	Z=-5.104 P=0.000
	Comparison of the two groups at the end of the follow-up	t=2.329 P=0.024	t=9.380 P=0.000	Z=-6.056 P=0.000
	Comparison of preoperative and 2-year data in Group Bryan	t=-2.345 P=0.025	Z=-2.058 P=0.040	Z=-2.127 P=0.033
	Comparison of preoperative and final data in Group Bryan	t=-3.052 P=0.006	Z=-3.070 P=0.002	t=0.494 P=0.625
	Comparison of 2-year and final data in Group Bryan	t=-0.259 P=0.797	t=-1.543 P=0.132	Z=-1.485 P=0.138
	Comparison of preoperative and 2-year data in Group ACDF	t=-2.308 P=0.024	t=2.789 P=0.007	Z=-2.456 P=0.014
	Comparison of preoperative and final data in Group ACDF	t=-1.709 P=0.093	Z=-2.130 P=0.033	Z=-5.011 P=0.000
	Comparison of 2-year and final data in Group ACDF	t=0.724 P=0.472	t=-0.630 P=0.531	Z=-3.604 P=0.000

exhibited no change from preoperative images. However, there was 1 patient with internal fixation device dislocation in Group ACDF at 6 months after surgery (Figure 2A, 2B). We did not reoperate until intervertebral fusion occurred. The fusion rate was 100%. In Group ACDF, 2 cases of adjacent segment degeneration occurred, all of which were in the middle segment, but no obvious clinical symptoms were present, and no reoperation was performed. As shown in 2 MRIs of a 63-year-old female patient preoperatively (Figure 3A) and 66 months after (Figure 3B) ACDF surgery, the intervertebral disc prior to surgery appeared degenerated and prominent.

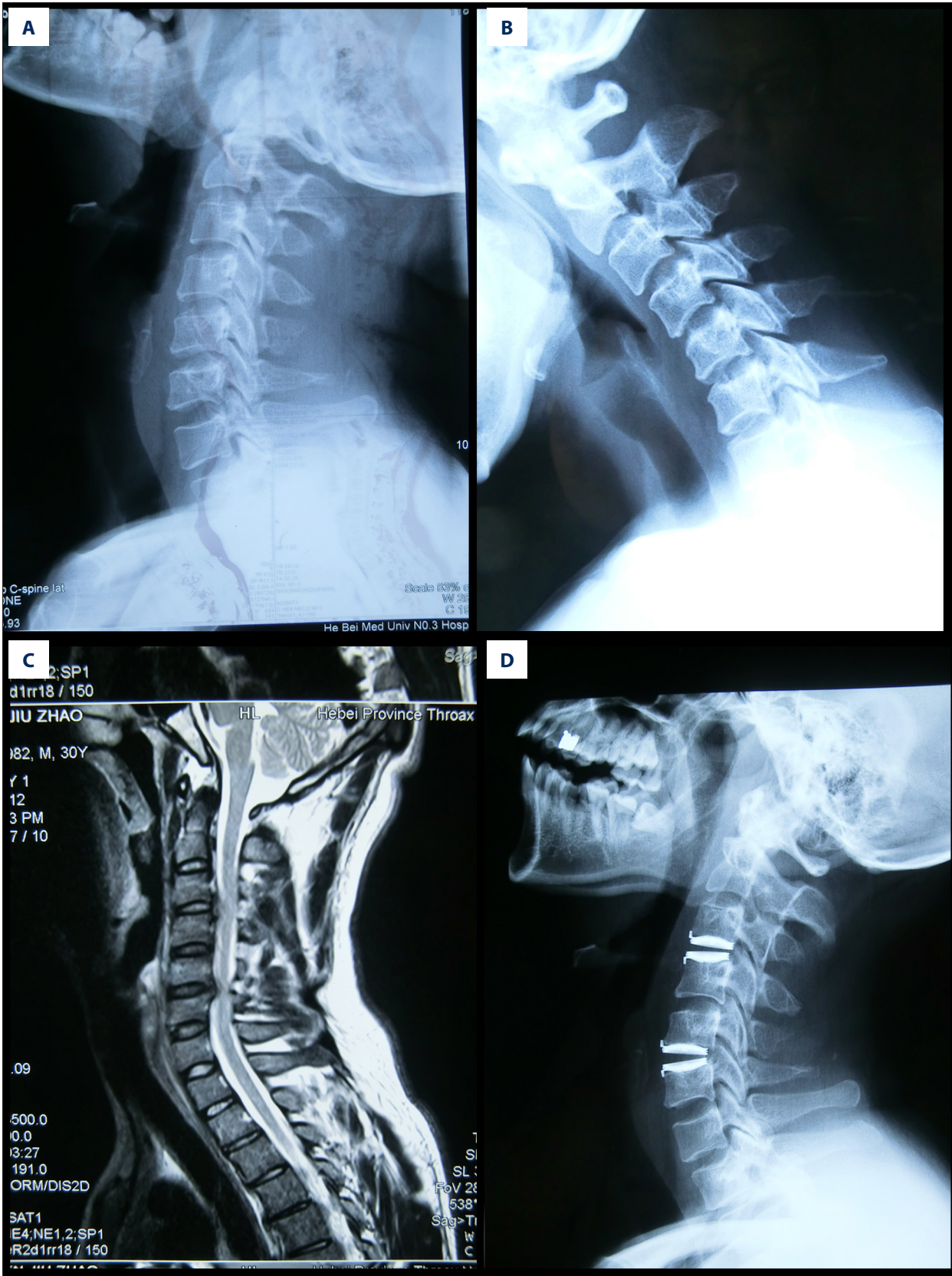
Discussion

The anterior surgical method

SCS is a special type of multi-segment cervical spondylosis. Previous studies demonstrated that the long-term curative rate

of ACDF operation is very high, as is the long-term effect [5,8]. Some studies have used the same skipping fusion approach as in our study [9,10], and patient neurological function recovered well. The results of this study demonstrate that patients undergoing ACDF exhibited good neurological recovery at the time of the last follow-up visit. However, based on our follow-up results, ACDF surgery resulted in greater postoperative pain and a significant increase in the activity of the non-surgical intervertebral disc.

In 2002, Goffin [11] first described 60 patients who underwent single-segment artificial disc implantation. In these patients, neurological symptoms were relieved, and only 2 cases of implant displacement occurred. With the improvement of artificial disc prostheses and the improvement in surgical techniques, the patients in Group Bryan achieved good neurological functional recovery at the last follow-up visit. The imaging findings demonstrated that the operative segment did not exert pressure and did not exhibit abnormal cervical



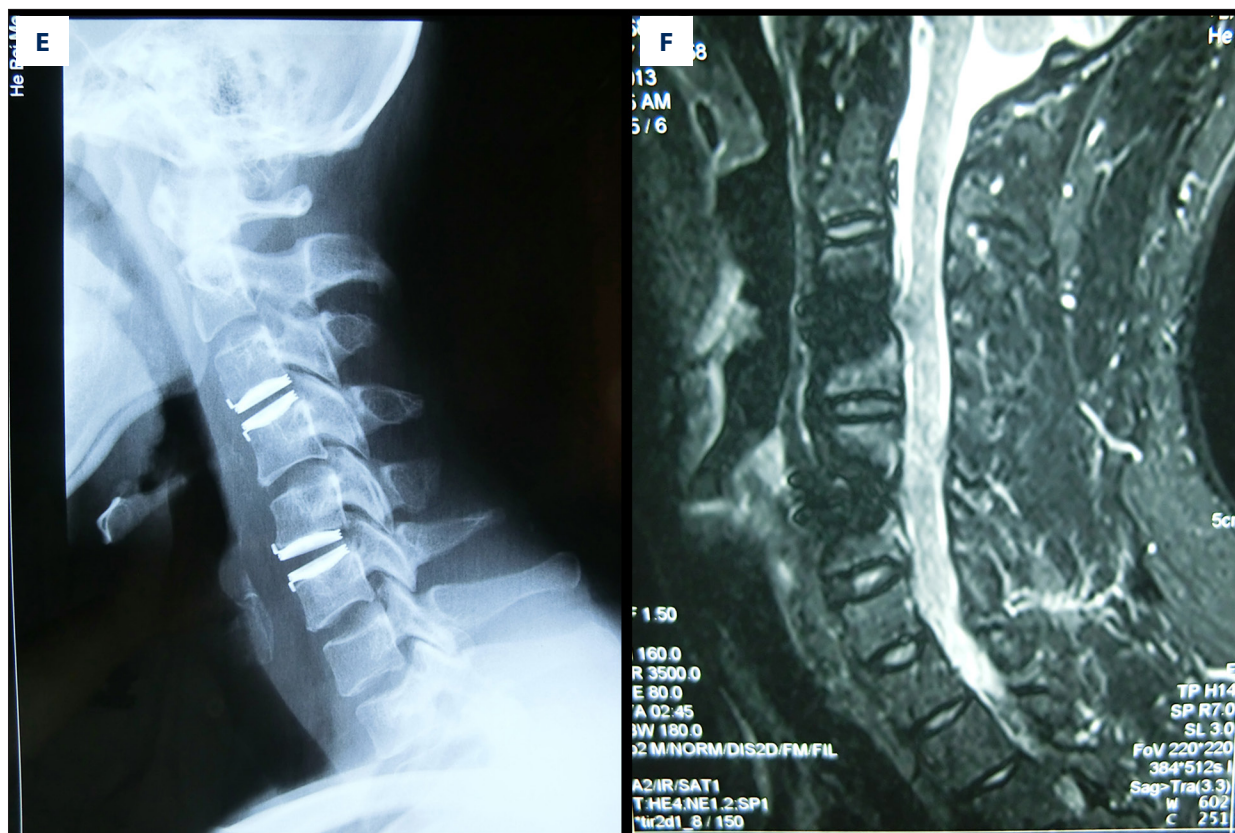


Figure 1. As shown in this group of photos, including preoperative (A–C) and 68-month postoperative (D–F) X-ray and MR images, a 31-year-old patient had C3–C4 and C5–C6 cervical spondylosis. The postoperative images demonstrate that the middle segment of the disc did not degenerate, and the cervical curvature and mobility remained good.

curvature or prosthesis displacement. The application of ADR in the treatment of SCS can reduce the probability of implant failure. We found that good intraoperative decompression of the intervertebral space and spinal cord and nerve root release for postoperative nerve rehabilitation are particularly important. Improved intervertebral disc implantation can provide a better intervertebral disc implantation angle and position [3], so that the artificial intervertebral disc can ensure appropriate surgical decompression.

In this study, the differences in postoperative neurological improvement of the 2 groups were not statistically significant. This suggests that the key to improving neurological function in patients with SCS is decompression, independent of the specific implant.

Maintaining cervical spine curvature and activity

Anterior cervical surgery to restore the normal physiological curvature of the spine to maintain long-term stability and recovery of the cervical biomechanical environment is important. A biomechanical study by Finn et al. [12] found that a two-segment jump fixation adjacent to the intervertebral disc resulted

in a 35% increase in the activity range, and three-segment fixation increased the activity range by approximately 72%. This result is consistent with the trend in the overall postoperative cervical motion in our Group ACDF. However, due to individual differences in patients, this group of patients presented with an overall cervical motion of more than 45°, which is not entirely consistent with previous studies. In the ACDF group, the overall degree of cervical spine surgery is due to the increased activity of the non-surgical segments, which is similar to the results of previous studies [13]. The postoperative cervical lordotic angle is associated with failure of internal fixation syndrome [14]; when the angle of lordosis is greater, the risk of failure of internal fixation is higher. There was only 1 case of internal fixation failure syndrome in Group ACDF, which was associated with strong intervertebral fusion or the implantation of appropriate fusions. We postulate that this situation was due to osteoporosis in the patient and the stress concentration after fusion.

A study by Liu et al. [15] found that the severity of cervical axial symptoms was related to abnormal cervical curvature. The ACDF group exhibited no fusion kyphosis, but the incidence of axial symptoms was significantly higher than that in the Bryan

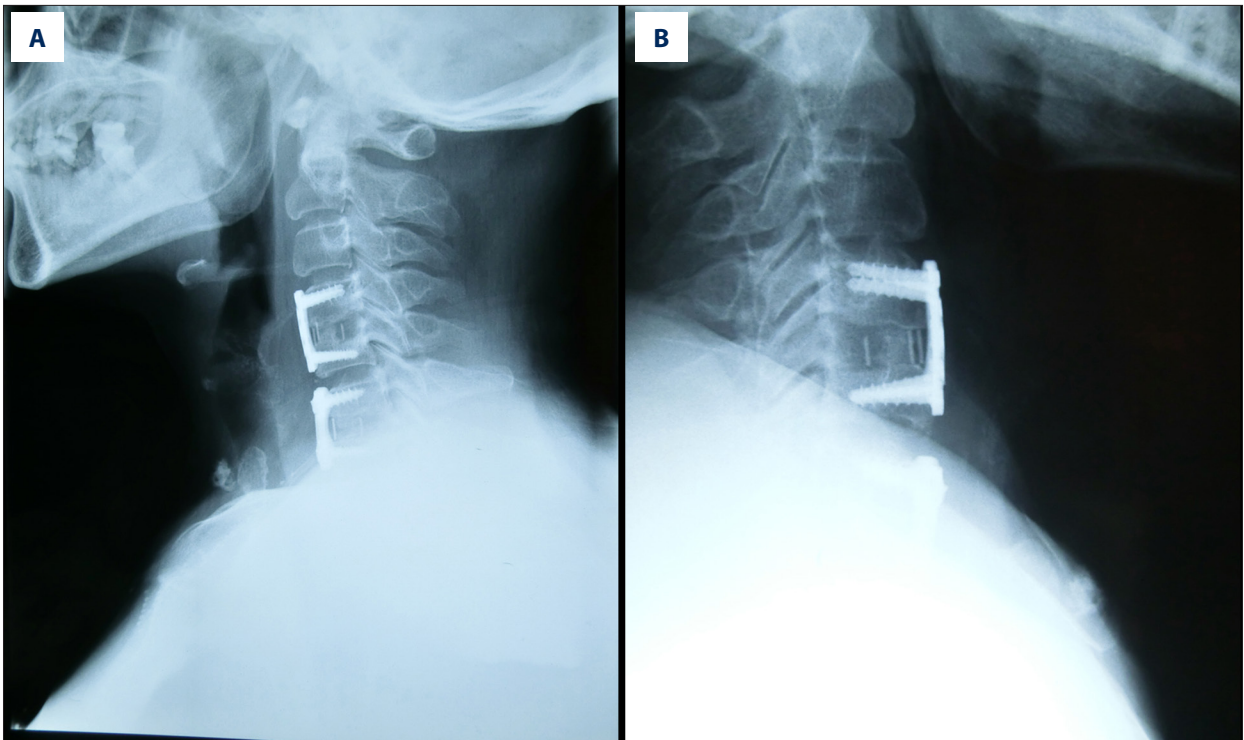


Figure 2. Two X-ray films of a 56-year-old female patient 1 week (A) and 6 months (B) after ACDF surgery demonstrate the loosening of the internal fixation between C4 and C5.

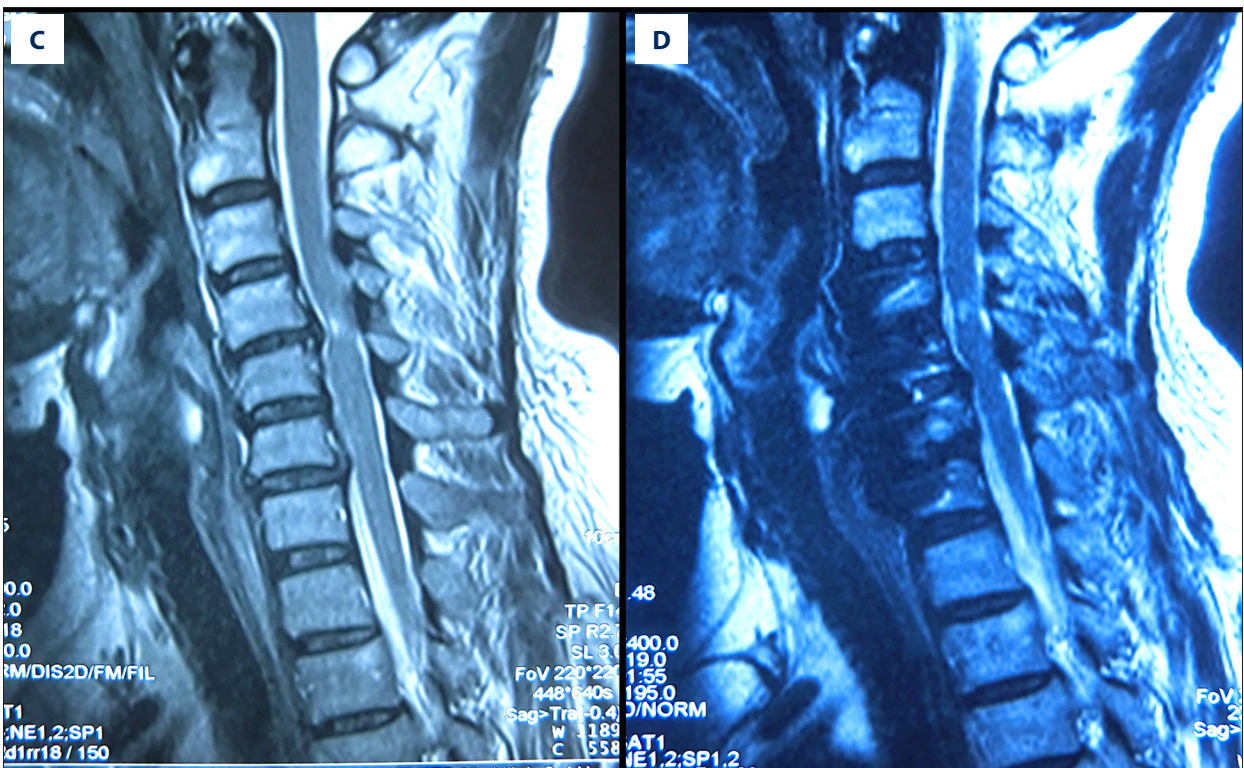


Figure 3. As shown in 2 MRIs of a 63-year-old female patient before (A) and 66 months after (B) ACDF surgery, the intervertebral disc prior to surgery appeared degenerated and prominent of the internal fixation between C4 and C5.

group. We believe that this result may be associated with a reduction in the degree of postoperative cervical spine mobility in patients with surgical fusion. Patients in Group Bryan exhibited well-maintained postoperative cervical physiological curvature and activity, which is important in the rehabilitation of neurological function and the reduction of postoperative neck axial pain.

Reducing the incidence of adjacent segment degeneration

ASD after spinal surgery has been a concern of spine surgeons. ACDF surgery due to the loss of segmental motion results in adjacent segmental disc stress, an increased load, and local biomechanical environment changes, all of which can easily lead to degenerative changes in the adjacent disc and a series of clinical symptoms [16]. Studies by Acikbas et al. [17] have indicated that ASD is not completely related to anterior surgery on muscle, ligament injury, or ligament ossification. Some authors have also developed age-based cervical degenerative animal models [18]. Finn et al. [12] reported that in the skip segment fusion after surgery, especially in the middle segment, activity and stress increased, which may have led to the acceleration of non-surgical segment disc degeneration. Park et al. [19] confirmed the biomechanical results of the former study. In our study, 2 patients in the ACDF group presented with adjacent segmental degeneration, and all the affected areas were intermediate segments. This result demonstrates that over a very long period of time after surgery, patients will experience middle intervertebral disc degeneration secondary to disc stress concentration and increased load.

Some reports indicate that when patients are followed for 2 to more than 5 years, the probability of reoperation after a single level ACDF is 11.1–11.3%, and the incidence of reoperation after 2-level ACDF is 11.4–16.2% [20–22]. In our study, there was no need for reoperation, which may be because SCS does not cause excessive stress in other discs after surgery. Few studies have assessed the mobility and stress changes

in the middle segment of the postoperative multilevel segmental cervical spondylopathy. Our study found that the average angle of activity in the middle segment in Group Bryan was $8.7 \pm 1.8^\circ$ preoperatively and $8.4 \pm 2.0^\circ$ postoperatively; in Group ACDF, the average angle was $8.7 \pm 2.2^\circ$ preoperatively and significantly increased postoperatively to an average of $12.2 \pm 2.2^\circ$. In Group ACDF, intermediate activity was found to be greater at the time of the last follow-up visit than at 2 years after surgery, possibly due to compensation. Compared with Group ACDF, the intervertebral disc motion was not significantly increased after artificial disc implantation in Group Bryan, which reduced the possibility of accelerated disc degeneration in adjacent segments.

Limitations and shortcomings of the study

The number of cases in this study was relatively small, and the number of patients in the 2 groups was not balanced. In the follow-up study, we will design a multi-center, randomized, prospective study with a larger sample size to further compare ADR with ACDF surgery in the treatment of SCS. In addition, this study was a retrospective clinical study; in future work, we will also be more rigorous with SCS biomechanical research and three-dimensional finite element analysis.

Conclusions

Bryan ADR can improve neurological function and effectively retain the overall activity of the cervical spine, reducing the activity of the non-surgical segment and thereby avoiding ASD and decreasing the incidence of postoperative axial symptoms in the treatment of "skip" multi-segmental cervical spondylosis.

Conflict of interest

None.

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