



Motion analysis of dynamic cervical implant stabilization versus anterior discectomy and fusion: a retrospective analysis of 70 cases

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Abstract

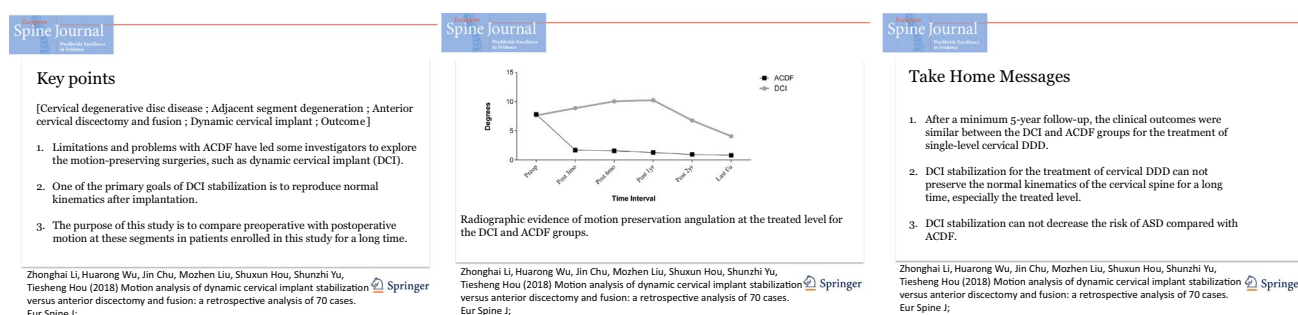
Purpose Retrospective kinematic analysis of treated level, adjacent levels, and overall cervical spine after single-level dynamic cervical implant (DCI) stabilization versus anterior cervical discectomy and fusion (ACDF).

Methods Between June 2009 and March 2013, 70 consecutive patients with a symptomatic single-level cervical degenerative disk disease (DDD) were enrolled in this study and divided into DCI ($n = 35$) group and ACDF ($n = 35$) group. All cases were followed up for more than 5 years. The study compared perioperative parameters; clinical outcomes; and radiological parameters. Kinematic analysis included range of motion (ROM) of treated level and adjacent level, overall ROM (C2–C7), and changes in adjacent disk spaces.

Results There were no significant differences between the DCI group and ACDF group in terms of improvement in the SF-36, VAS, NDI, and JOA scores. DCI stabilization resulted in better ROM of C2–C7 and the treated level than ACDF did. The ROM of treated level decreased significantly at 24 months after surgery and last follow-up in the DCI group, and the C2–C7 ROM showed different degrees of reduction after the 24 months after surgery. Radiological evidence of adjacent segment degeneration (ASD) at last follow-up was observed in 4/22 patients (18.2%) in the DCI group and 5/23 patients (21.7%) in the ACDF group which was not a significant difference between groups ($p > 0.05$).

Conclusions DCI stabilization for the treatment of cervical DDD cannot preserve the normal kinematics of the cervical spine for a long time, especially the treated level. DCI stabilization cannot decrease the risk of ASD compared with ACDF.

Graphical abstract These slides can be retrieved under Electronic Supplementary Material.



Zhonghai Li, Huarong Wu and Jin Chu contributed equally to the manuscript and should be considered co-first authors.

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Keywords Cervical degenerative disk disease · Adjacent segment degeneration · Anterior cervical discectomy and fusion · Dynamic cervical implant · Outcome

Introduction

Anterior cervical discectomy and fusion (ACDF) is an effective and safe treatment for patients with radiculopathy and myelopathy. However, in the untreated levels adjacent to a fusion, increased motion and elevated intradiscal pressures have been reported [1, 2]. Some investigators have postulated that these changes may lead to an increased risk of adjacent segment degeneration (ASD) [2–5]. Limitations and problems with ACDF have led some investigators to explore the motion-preserving surgeries, such as cervical total disk replacement (TDR) [6–11]. Although TDR has been shown to reduce adjacent-level intradiscal pressures and provide a more physiological overall cervical but also index- and adjacent-level range of motion (ROM) while maintaining sagittal alignment, recent studies have also highlighted the potential limitations of TDR [12, 13].

Dynamic cervical implant (DCI, Scient'x, Bretonneux, France) is a type of anterior decompression and cervical non-fusion implant that was initially conceived as a method to combine the potential advantages of fusion and TDR [14, 15]. The DCI is intended to provide controlled, limited flexion and extension—the primary motions in the subaxial cervical spine—that is greater than that seen with fusion, but less than that achieved with TDR. In contrast to other motion-preserving implants, the device functions as a shock absorber and allows for axial compression in flexion and limited extension and is protected from fatigue overload via its mechanical stop during maximal flexion.

The first-generation DCI products were developed in 2002, but the long-term clinical efficacy of these products has not been reported. In a recent comparative study, we reported that there were no significant differences between DCI stabilization and ACDF for cervical degenerative disk disease (DDD) in terms of improvement in clinical symptoms, blood loss, operation time, or improvement in disk height throughout their follow-up period of mean 32 months [14]. However, DCI stabilization was associated with better postoperative NDI scores than ACDF. DCI stabilization also resulted in better overall cervical ROM and segmental ROM at the treated level than ACDF.

One of the primary goals of DCI stabilization is to reproduce normal kinematics after implantation. We hypothesize that the DCI stabilization maintains spinal kinematics at both the treated, the adjacent levels, and overall cervical vertebra (C2–C7). Accordingly, the purpose of this study is to compare preoperative with postoperative motion at these segments in patients enrolled in this study for a long time.

Also results of the investigational treatment will be compared with patients treated by ACDF.

Materials and methods

Patient population

This was a retrospective clinical study. Between June 2009 and March 2013, 79 consecutive patients who underwent DCI stabilization or ACDF for cervical DDD in our spine surgery center took part in the study. Nine patients were lost to follow-up before 5 years were completed: 2 emigrated, 4 had another serious health condition (ongoing Parkinson disease, lymphoma or lung cancer), and 3 did not want to continue the full study after 24 months. All patients underwent X-ray radiographs, computed tomography (CT), and magnetic resonance imaging (MRI) to prove diagnosis before surgery. One-level symptomatic cervical disk disorder between C3–C4 and C6–C7 was included in our study. Cases of soft disk herniation with radiculopathy or myelopathy and spondylotic radiculopathy were included, but cases of cervical instability, severe facet joint degeneration, deformity, severe spondylosis, and spondylotic myelopathy that were determined by the dynamic X-rays and MRI were excluded. Ultimately, 70 patients (46 males and 24 females) were deemed eligible for inclusion in the study. The mean age of patients was 47.5 years (range 38–72 years), and the mean duration of symptoms was 27.8 months (range 12–56 months). The patients' demographic data are summarized in Table 1.

Surgical technique

Each patient received preoperative intravenous antibiotics. All procedures were performed through a transverse skin incision on the right side of the neck. Discectomy and decompression were performed using a surgical approach similar to that described by Smith and Robinson [16], with preservation of the uncovertebral joints to minimize soft tissue damage and bleeding and to avoid damage to the bony endplates. To reduce new bone formation at bleeding sites, soft tissue bleeding was meticulously controlled, and damaged bone was covered with bone wax. The posterior longitudinal ligaments were completely removed only when they were torn preoperatively. The cartilaginous endplate was removed completely to expose the cortical endplate. The bony endplate was preserved as such as possible to prevent implant subsidence. ACDF procedures were

Table 1 Patient demographic data

Variable	DCI group	ACDF group
Patients, <i>n</i>	35	35
Sex (male, female)	22, 13	24, 11
Age (years)	45.9 ± 7.1	49.1 ± 8.4
BMI (kg/m ²)	23.8 ± 3.2	24.6 ± 4.2
Active smokers	12	10
Patient with diabetes	7	8
Symptom of radiculopathy	17	19
Symptom of myelopathy	7	6
Combined symptoms ^a	11	10
Symptom duration (months)	26.8 ± 8.8	28.8 ± 8.6
Operated level		
C3–C4	3	2
C4–C5	13	14
C5–C6	17	18
C6–C7	2	1
Hospital stay (days)	8.7 ± 1.6	9.1 ± 1.5
Follow-up period (months)	73.2 ± 14.6	74.8 ± 14.4

ACDF anterior cervical discectomy and fusion, DCI dynamic cervical implant

^aCombined symptoms of radiculopathy and myelopathy

performed using a titanium mesh cage and Slim-Loc plate (DePuy Spine, Johnson & Johnson, Piscataway, NJ, USA). Operations were performed under fluoroscopic guidance. All patients were immobilized in a Philadelphia collar for 4 weeks postoperatively.

Data collection and outcome evaluations

The data collected included epidemiological data, operative segment, intraoperative blood loss, operation time, length of hospital stay, cost of index surgery, complications, and clinical and radiological parameters. Perioperative information was collected from the anesthesia records.

All outpatients visit at postoperative 3 months, 6 months, and every 6 months thereafter. Follow-up clinical examinations were obtained by a physician unrelated to the surgical procedures. All patients were asked to complete questionnaires before surgery and at each follow-up examination. The self-reported measures used were the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36) [17], Neck Disability Index (NDI) [18], and visual analog scale (VAS) scores. Myelopathy was graded using the Japanese Orthopedic Association (JOA) score [19].

Preoperative imaging included anterior–posterior (AP) and lateral X-rays, with flexion–extension views, CT and MRI. The cervical spine static and dynamic X-rays were obtained at each follow-up. The segmental (cephalad, treated, and caudal disk levels) and overall (C2–C7) ROM

were measured on the dynamic full flexion and extension lateral X-rays. Disk degeneration was graded on T2-weighted sagittal and axial images using the five-point scale as described by Miyazaki [20]. To correct for intra-observer and inter-observer differences in radiological measurements, three experienced observers independently evaluated radiological outcomes.

Statistical analyses

All analyses were performed using the Statistical Package for the Social Sciences for Windows, version 22.0 (SPSS Inc., Chicago, IL, USA). Quantitative data were expressed as the mean ± standard deviation. Intergroup comparisons were performed using the *t* test or Wilcoxon signed-rank test. Clinical and radiological data before and after surgery were compared using the mixed effect model. Any value of *p* < 0.05 was considered to indicate statistical significance.

Results

Perioperative parameters and clinical outcomes

All cases were followed up for more than 5 years postoperatively (range 60–116 months; average 74.1 months). There were no statistically significant differences for patient sex, age, BMI, smoke, diabetes, operative level, symptom duration, follow-up period, or hospital stay among the two groups (*p* > 0.05, Table 1). There were also no significant differences between the two groups in operation time (55.8 ± 9.3 min vs 59.3 ± 13.2 min, *p* > 0.05) or blood loss (35.6 ± 14.2 mL vs 39.3 ± 15.5 mL, *p* > 0.05) (Table 2).

The clinical outcomes of these patients are summarized in Table 2. The SF-36, VAS, NDI, and JOA scores of all patients, including both the two groups, were improved significantly at last follow-up (*p* < 0.05). There were no significant differences between the two groups in the SF-36, VAS, NDI, and JOA scores at last follow-up (*p* > 0.05).

Radiological outcomes

The radiological outcomes of these patients are summarized in Table 3. There were no significant differences between the two groups in the preoperative radiological parameters (all *p* > 0.05). In the DCI group, the ROM of treated level was 8.9° ± 2.9° 3 months after surgery, 10.1° ± 2.3° 6 months after surgery, 10.3° ± 2.0° 12 months after surgery, 6.8° ± 2.5° 24 months after surgery, and 4.1° ± 1.1° at last follow-up. The ROM of treated level was significantly increased at 3 months after surgery and 12 months after surgery (all *p* < 0.05). However, the ROM of treated level showed a significant reduction at 24 months after surgery

Table 2 Patient perioperative parameters and clinical outcomes

Variable	DCI group (<i>n</i> = 35)	ACDF group (<i>n</i> = 35)
Operation time (min)	55.8 ± 9.3	59.3 ± 13.2
Blood loss (mL)	35.6 ± 14.2	39.3 ± 15.5
Preoperative VAS for neck	3.5 ± 0.7	3.6 ± 0.8
VAS for neck at last follow-up	0.6 ± 0.6*	0.5 ± 0.6*
Preoperative VAS for arm	6.7 ± 1.8	6.8 ± 1.8
VAS for arm at the final follow-up	0.9 ± 0.7*	0.8 ± 0.5*
Preoperative NDI score	19.1 ± 9.1	20.1 ± 8.5
NDI score at last follow-up	4.5 ± 2.9*	5.1 ± 2.8*
Preoperative SF-36 score	26.6 ± 4.9	25.7 ± 4.7
SF-36 score at last follow-up	40.9 ± 6.9*	41.9 ± 6.6*
Preoperative JOA score	9.2 ± 1.9	8.9 ± 1.7
JOA score at last follow-up	14.1 ± 1.3*	14.3 ± 1.0*

ACDF anterior cervical discectomy and fusion, DCI dynamic cervical implant, NDI Neck Disability Index, VAS visual analog scale

**p* < 0.05 compared with preoperative

and last follow-up (all *p* < 0.05) (Fig. 1). In the ACDF group, the ROM of treated level significantly was decreased significantly at any time point after surgery (all *p* < 0.05). At any time point after surgery, no statistical differences were present in adjacent motions compared with preoperative motion in groups at both the cephalad and caudal level (all *p* > 0.05) (Fig. 2). There were no significant differences between the two groups in the ROM of adjacent levels at any time point after surgery (all *p* > 0.05). In the DCI group, the C2–C7 ROM was improved significantly at any time point after surgery (all *p* < 0.05). Although the C2–C7 ROM showed different degrees of reduction at the 24 months after surgery and last follow-up comparing 3 months, 6 months, and 12 months after surgery, no significant difference (all *p* > 0.05) was noted (Fig. 3). In the ACDF group, the C2–C7 ROM was decreased significantly at any time point after surgery (all *p* < 0.05). Radiological evidence of ASD was observed in 4/22 patients (18.2%) in the DCI group and 5/23 patients (21.7%) in the ACDF group, which was not a significant difference between groups (*p* > 0.05). A typical case of DCI stabilization is shown in Fig. 4.

Complications

Anterior migration of the prosthesis by 2 mm was detected in one patient in the DCI group at the 12-month follow-up. This was caused by a deficiency in the endplate milling process. This patient did not develop neurological or vascular complications or dysphagia. The prosthesis was noted to have regained stability at the 18-month follow-up and continued to be stable until the most recent follow-up at 49 months after surgery. Cage subsidence of more than 1 mm was observed in two patients in the ACDF group at the final follow-up. Prosthesis subsidence of more than

1 mm was observed in two patients in the DCI group after 12 months, respectively. The causes of prosthesis subsidence were not identified, but these prostheses were noted to have regained stability at later follow-ups. No other complications were observed in either group.

Discussion

ACDF is an effective and safe procedure for the surgical treatment of patients with radiculopathy and myelopathy. The goals of ACDF are to decompress the neural elements, provide permanent segmental stabilization, maintain the physiological lordosis, and preserve the anatomical disk-space height. However, increased motion and increased intradiscal pressure have been reported in the untreated levels adjacent to fused levels [1, 2]. Some investigators have postulated that these changes may lead to an increased risk of ASD [2–4, 6]. ACDF has a high rate of clinical success for the treatment of cervical DDD, but the rigid fixation may result in ASD. Hilibrand et al. [4, 21] reported that approximately 25% of patients who underwent single-level ACDF developed ASD within 10 years. Buttermann et al. [22] reviewed 159 consecutive patients undergoing ACDF and found that 29% of the patients required a second operation because of pseudarthrosis repair and symptomatic adjacent-level degeneration at the 10-year follow-up.

The limitations and problems associated with ACDF have led some investigators to explore motion-preserving surgery such as artificial cervical disk arthroplasty. DCI is one of the several stabilization systems currently being investigated for use in the cervical spine. The first-generation DCI products were developed in 2002, but the clinical efficacy of these products has not been reported. Paradigm

Table 3 Patient radiological outcomes

Variable	DCI group (<i>n</i> = 35)	ACDF group (<i>n</i> = 35)
Preoperative ROM (°)		
Treated level	7.6 ± 3.3	7.8 ± 3.2
Cephalad level	8.9 ± 2.9	9.1 ± 2.8
Caudal level	7.3 ± 3.2	7.5 ± 3.1
C2–C7	41.1 ± 6.6	42.3 ± 5.6
ROM at 3 months (°)		
Treated level	8.9 ± 2.9*	1.7 ± 1.1* [#]
Cephalad level	9.1 ± 2.7	9.2 ± 2.5
Caudal level	7.7 ± 2.9	7.8 ± 2.8
C2–C7	43.7 ± 4.7*	36.2 ± 5.4* [#]
ROM at 6 months (°)		
Treated level	10.1 ± 2.3*	1.6 ± 1.0* [#]
Cephalad level	9.4 ± 2.4	9.4 ± 2.4
Caudal level	8.1 ± 2.8	8.1 ± 2.8
C2–C7	45.4 ± 3.9*	37.1 ± 5.2* [#]
ROM at 12 months (°)		
Treated level	10.3 ± 2.0*	1.3 ± 0.9* [#]
Cephalad level	9.7 ± 2.2	9.9 ± 2.0
Caudal level	8.4 ± 2.6	8.5 ± 2.6
C2–C7	47.5 ± 3.6*	37.0 ± 5.3* [#]
ROM at 24 months (°)		
Treated level	6.8 ± 2.5	0.9 ± 0.8* [#]
Cephalad level	9.9 ± 1.8	10.0 ± 2.1
Caudal level	8.5 ± 2.5	8.6 ± 2.6
C2–C7	45.1 ± 3.2*	35.9 ± 4.9* [#]
ROM at last follow-up (°)		
Treated level	4.1 ± 1.1*	0.8 ± 0.7* [#]
Cephalad level	10.0 ± 1.8	10.1 ± 1.9
Caudal level	8.4 ± 2.5	8.4 ± 2.6
C2–C7	43.3 ± 3.2*	35.8 ± 4.9* [#]
Adjacent segment degeneration (%)	18.2 (4/22)	21.7 (5/23)

ACDF anterior cervical discectomy and fusion, DCI dynamic cervical implant, DHI disk height, ROM range of motion

**p* < 0.05 compared with preoperative, [#]*p* < 0.05 compared with the DCI group

spine made improvements to the first-generation products in 2005, and the second-generation of DCI products has been used in clinical practice since 2008. DCI stabilization has developed over the last two decades to enable normal motion and preserve biomechanics in an attempt to overcome the disadvantages of ACDF, while providing sufficient stability to restore normal segmental kinematics, control abnormal motion, enable greater physiological load transmission, and reduce or eliminate ASD. Although many of these systems have early outcome data, long-term outcome studies are still pending [14, 15, 23]. In this study, we described the clinical and radiographic outcomes of a retrospectively collected series of patients treated with the DCI and ACDF and followed up to a minimum 5-year after surgery. We asked whether the DCI would be able to maintain spinal

kinematics at both the treated, the adjacent levels and overall cervical vertebra, decrease the risk of ASD, and replace ACDF for the treatment of patients with cervical DDD.

DCI stabilization has not been widely used, and there are few reports describing this procedure in the literature [14, 15, 23–25]. Matgé et al. [23] reported the clinical and radiographic results of 47 patients who underwent DCI stabilization for the treatment of cervical disk disease with radiculopathy or myelopathy at a minimum of 24 months. In 47 patients with 58 operated levels, the radiographic assessment showed good motion (5°–12°) of the device in 57%, reduced motion (2°–5°) in 34.5%, and little motion (0°–2°) in 8.5%. Motion greater than 2° of the treated segment could be preserved in 91.5%, while 8.5% had a near segmental fusion. Wang et al. [15] compared the amount of motion

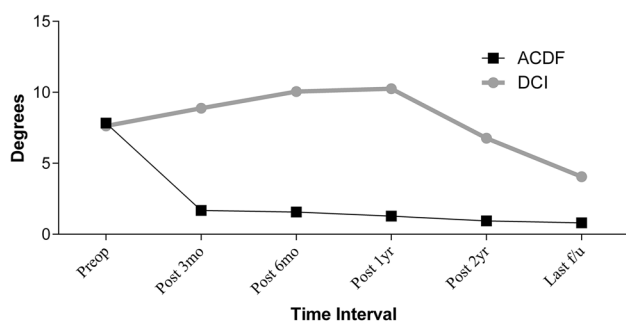


Fig. 1 Radiographic evidence of motion preservation angulation at the treated level for the DCI and ACDF groups. In the DCI group, the ROM of treated level was significantly increased at 3 months after surgery and 12 months after surgery. The ROM of treated level showed a significant reduction at 24 months after surgery and last follow-up. In the ACDF group, the ROM of treated level significantly were decreased significantly at any time point after surgery. ROM, range of motion; DCI, dynamic cervical implant; ACDF, anterior cervical discectomy and fusion; fu, follow-up

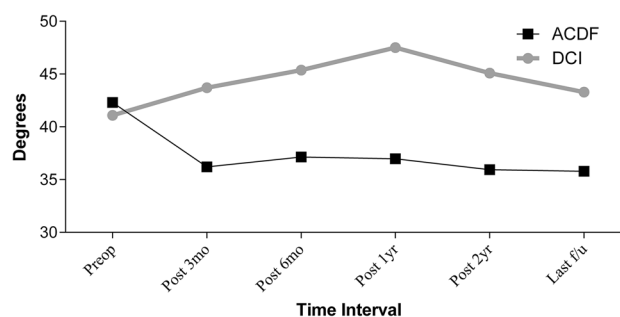


Fig. 3 Radiographic evidence of motion preservation angulation at overall cervical (C2–C7) ROM for the DCI and ACDF groups. In the DCI group, the C2–C7 ROM was improved significantly at any time point after surgery. Although the C2–C7 ROM showed different degrees of reduction at the 24 months after surgery and last follow-up comparing 3 months, 6 months and 12 months after surgery, no significant difference was noted. In the ACDF group, the C2–C7 ROM significantly were decreased significantly at any time point after surgery

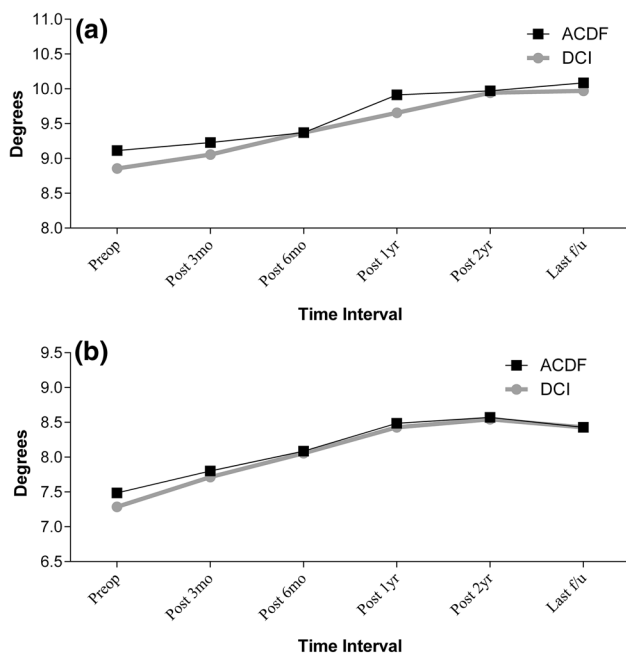


Fig. 2 Radiographic evidence of motion preservation angulation at both the cephalad (a) and caudal (b) level for the DCI and ACDF groups. At any time point after surgery, no statistical differences were present in adjacent motions compared with preoperative motion in groups. There were no significant differences between the two groups in the ROM of adjacent levels at any time point after surgery

of the adjacent vertebral endplate and the intrinsic motion of the DCI implant and calculated a correlation analysis. Results showed that DCI provided elastic dynamic stability for the targeted segment, and restored and sustained intervertebral space height and ROM of the cervical spine. Li et al. [14] found that DCI was associated with better postoperative

NDI scores and resulted in better overall cervical ROM and segmental ROM at the treated level than ACDF did. Zhu et al. [24] compared three anterior cervical surgeries (DCI, ACDF, and TDR) and concluded that DCI is an interbody fixed device between ACDF and TDR, which can partially keep the motion function of cervical surgical segments and achieve satisfactory short-term effect. However, these positive clinical and radiographic results of DCI in the studies mentioned above were observed during the short-term follow-up. In this study, we compared the clinical and radiological outcomes of DCI stabilization versus ACDF for the treatment of single-level cervical DDD with a minimal follow-up time of 5 years.

In contrast to ACDF, the goal of DCI implants is to provide increased stability while preserving ROM of the involved segment. Previous studies demonstrated that DCI can restore and maintain cervical ROM and simultaneously impose minimum influence on the adjacent soft tissues within 2 years of follow-up [14, 15, 23–25]. In our study, DCI resulted in better ROM of C2–C7 and the treated level than ACDF did at any time point after surgery. The clinical outcomes were similar between two groups. The ROM at treated level was maintained well during the first 2-year follow-up in the DCI group, but it decreased significantly at 24 months after surgery and last follow-up. In our opinion, the main reason for this change may be that HO formation resulted at the anterior or posterior border of the intervertebral space of the treated level.

One of the major concerns regarding ACDF is that it does not preserve the normal kinematics of the spine and might therefore result in ASD, which could eventually lead to a need for additional treatment. Theoretically, DCI stabilization should be associated with less stress at the adjacent levels, which may decrease the risk of ASD. However,

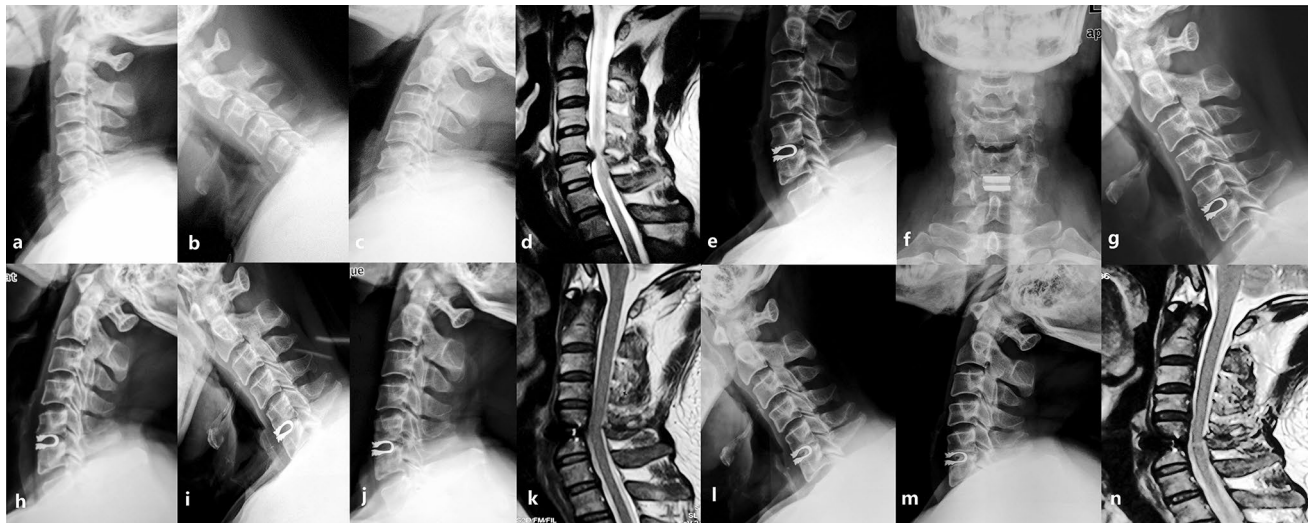


Fig. 4 A 47-year-old man presented with progressive numbness in her two hands and weakness in his four extremities for 2 years. **a** Preoperative lateral view X-ray. **b, c** Preoperative ROM of C4–C5, C5–C6 and C6–C7 was 7.9°, 7.3° and 7.5° on flexion-extension lateral view X-ray. **d** Preoperative T2-weighted midsagittal MRI images showed disc herniation in C5–C6, Miyazaki grade of C4–C5 was grade II, and C6–C7 was grade. **e, f** Lateral and posterior-anterior view X-ray at postoperative 3 months showed DCI was in good position. **g, h** The ROM of C4–C5, C5–C6 and C6–C7 was 8.0°, 7.5° and 7.9° on flexion-extension lateral view X-ray at postoperative 3

months. **i, j** The ROM of C4–C5, C5–C6 and C6–C7 was 8.1°, 7.7° and 8.1° on flexion-extension lateral view X-ray at postoperative 24 months. **k** T2-weighted midsagittal MRI images at postoperative 24 months, follow-up showed no change in disc degeneration at the lower level, worsening at the upper level by a grade (II to III). **l, m** The ROM of C4–C5, C5–C6 and C6–C7 was 7.6°, 7.5° and 7.8° on flexion-extension lateral view X-ray at postoperative 84 months. **n** T2-weighted midsagittal MRI images at postoperative 84 months, follow-up showed no change in disc degeneration at the adjacent levels comparing 24 months after surgery

this has not been shown in our study. In this study, the ROM of treated level and C2–C7 was significantly higher in the DCI group than in the ACDF group. However, the ROM of treated level decreased significantly at 24 months after surgery and last follow-up in the DCI group, and the C2–C7 ROM showed different degrees of reduction at the 24 months after surgery and last follow-up. There were no significant differences between the two groups in the ROM of the adjacent cephalad and caudal levels at any time point after surgery. Radiological evidence of ASD at last follow-up was observed in 4/22 patients (18.2%) in the DCI group and 5/23 patients (21.7%) in the ACDF group. We consider that DCI stabilization cannot preserve the normal kinematics of the cervical spine for a long time, especially the treated level. Therefore, DCI stabilization cannot decrease the risk of ASD compared with ACDF.

This study was limited by the small sample size and retrospective nature. In addition, we did not compare the surgical outcomes in patients with cervical DDD who underwent DCI stabilization with patients who underwent artificial cervical disk arthroplasty. However, we feel that this study provides useful information regarding the surgical treatment of cervical DDD because there are currently few reports describing long-term outcomes after DCI stabilization. Therefore, we need future prospective, randomized, and longitudinal studies with a larger number

of patients and longer follow-up period to evaluate the efficacy of DCI stabilization.

Conclusions

After a minimum 5-year follow-up, the clinical outcomes were similar between the DCI and ACDF groups for the treatment of single-level cervical DDD. DCI stabilization resulted in better ROM of C2–C7 and the treated level than ACDF did. However, the ROM at treated level decreased significantly in the DCI group at 24 months after surgery and last follow-up. The rate of ASD was similar after DCI stabilization and ACDF. Overall, the results show that DCI stabilization for the treatment of cervical DDD cannot preserve the normal kinematics of the cervical spine for a long time, especially the treated level. We consider that DCI stabilization can not decrease the risk of ASD compared with ACDF.

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Compliance with ethical standards

Conflict of interest All authors state that there is no actual or potential of conflicts of interest in relation to this article. All authors declare that there are no any financial and personal relationships with other people or organizations that could inappropriately influence (bias) our work.

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