Effect of preoperative segmental range of motion on patient outcomes in cervical disc arthroplasty

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Abstract

Background

Cervical disc arthroplasty (CDA) has been demonstrated in clinical trials as an effective and safe treatment for patients diagnosed with radiculopathy and/or myelopathy. However, the current CDA indication criteria based on the preoperative segmental range of motion (ROM), comprise a wide range of variability. Although the arthroplasty level preserved ROM averaged 7°-9° after CDA, there are no clear guidelines on preoperatively limited or excessive ROM at the index level, that could be considered as suitable for CDA in any given trials.

Methods

Patients who underwent CDA between January 2008 to October 2018 using Prestige-LP discs in our hospital, were reviewed retrospectively. They were divided into the small-ROM (≤5.5°) and the large-ROM (> 12.5°) groups according to preoperatively index-level ROM. Clinical outcomes, including the Japanese Orthopedics Association (JOA), Neck Disability Index (NDI), and Visual Analogue Scale (VAS) scores, were evaluated. Radiological parameters, including cervical lordosis, disc angle (DA), global and segmental ROM, disc height (DH), and complications were measured.

Results

One hundred and twenty-six patients, with a total of 132 arthroplasty segments were analyzed. There were 64 patients in the small-ROM and 62 in the large-ROM group. There are more patients diagnosed with cervical spondylosis in the small-ROM than in the large-ROM group (P=0.046). Patients in both groups had significantly improved in JOA, NDI, and VAS scores after surgery, but the intergroup difference was not significant. Patients in the small-ROM group increased dramatically in cervical lordosis, global and segmental ROM postoperatively (P < 0.001). However, global and segmental ROM paradoxically decreased in the large-ROM group postoperatively (P < 0.001). Patients in the small-ROM group had lower DH preoperatively (P=0.012), and a higher rate of heterotopic ossification (HO) postoperatively (P=0.037).

Conclusion

Patients with preoperatively limited or excessive segmental ROM could achieve satisfactory clinical
outcomes at 3 years postoperatively. Patients with limited segmental ROM had more, and severe HO and significantly increased segmental mobility, which decreased in patients with excessive segmental ROM after surgery.

Introduction

In recent decades, cervical disc arthroplasty (CDA) has been studied in many clinical trials as an alternative surgical treatment to anterior cervical discectomy and fusion (ACDF) due to a paradigm shift towards preserving motion and avoiding adjacent segment disease [1-7]. Segmental range of motion (ROM) has been commonly accepted as an indication for using CDA in published FDA-approved trials. These trials suggest that preoperative segmental ROM should range between 2° to 11° or 20° on lateral flexion-extension X-rays [4-9], presenting patients who have undergone CDA with a wide range of variability in segmental motion. There are no clear guidelines as to the optimal preoperative index-level ROM that could be considered amenable to CDA in any given trials; although the preoperative ROM at the index level averaged 7°-9°, and was successfully preserved the similar motion after surgery [10-14]. These observations raise a question for surgeons: whether limited or excessive preoperative ROM, other than the average one at the index level, could also achieve satisfactory clinical or kinematic outcomes.

There is limited data to answer the question above. Tu et al. [10] concluded that preoperatively less-mobile patients (ROM ≤5°) had similar clinical improvements, but a greater increase in segmental mobility than the more-mobile (ROM >5°) ones. However, some patients in the more-mobile group had excessive segmental ROM that may affect the results. To our knowledge, no clinical study on CDA has specifically analyzed patients with preoperatively excessive ROM at the index level. Patients’ selection is crucial to guarantee all the benefits of CDA. This study aims to investigate the influence of preoperative index-level ROM on postoperative ROM after CDA, and whether the patients with preoperatively limited or excessive segmental ROM are suitable candidates for arthroplasty.

Methods

Patients

Patients (312) who underwent CDA or hybrid surgery (HS) in our hospital, using Prestige-LP discs
between January 2008 and October 2018, were retrospectively reviewed. The surgical indications were intractable symptomatic radiculopathy and/or myelopathy caused by cervical degenerative disc disease (DDD) or spondylosis at 1-or 2-level from C3-C7. Exclusion criteria for arthroplasty were: 1) severe facet joint degeneration, 2) ossification of the posterior longitudinal ligament (OPLL), 3) segmental ROM < 2°, 4) segmental instability (>3.5 mm sagittal plane translation or >20° sagittal plane angulation), 5) intervertebral disc height loss more than 50% and, 6) less than 12 months follow-up period. ACDF was performed if radiographic signs of instability, bridging osteophytes, and severe facet degeneration were observed in the 2-level disease. The study protocol was approved by the institutional ethics committee, and all patients signed informed consent.

Cutoff values for preoperative segmental ROM

There is no consensus on cutoff values of relatively small or large ROM at the index level for surgery. Tu et al. [10] divided patients based on C5/6 preoperative ROM of ≤5° and >5°, without explanation. Kang et al. [15] defined cutoff values as 10°, to group patients according to the average segmental ROM at the last follow-up. In the current study, the mean and standard deviation (SD) of radiographic data of the segmental ROM at the index levels was calculated. Each target disc in 2-level CDA surgery was considered as an independent data point. The data were normally distributed around the mean of 9.01° with an SD of 3.47° (K-S test, P=0.200). Based on the raw data, the cutoff values for preoperative small ROM were defined as mean - SD, while large ROM was mean + SD. Therefore, the small-ROM and large-ROM groups were defined as the segmental ROM at the index level ≤5.5° (Fig. 1) and the large-ROM group as > 12.5°, respectively (Fig. 2).

Surgical techniques

All operations were performed by the same senior surgeon (H.L.). A standard right-sided anterior cervical approach was performed after general anesthesia. Thorough decompression was done at the index levels by removing the disc tissue, posterior longitudinal ligament, and osteophytes to achieve neural decompression. Appropriated Prestige-LP disc (Medtronic Sofamor Danek, Memphis, Tennessee) or Zero-P implant (Synthes, Oberdorf, Switzerland) was inserted into the intervertebral space after the endplates were well prepared. C-arm fluoroscopy was performed to verify the proper
placement of the implants. A drainage tube was inserted after irrigation and hemostasis before the closure of the incision.

Data collection
The clinical and radiographic outcomes of patients were routinely evaluated at regular intervals: before surgery, at one week, 3, 6, 12 months postoperatively, and at the last follow-up. Clinical outcomes were evaluated according to validated self-assessment questionnaires, including the Japanese Orthopedics Association (JOA), Visual Analogue Scale (VAS), and Neck Disability Index (NDI) scores. Radiological parameters including cervical lordosis, the disc angle (DA) of the arthroplasty segments, the ROM of C2 - C7 and the arthroplasty segments, and disc height (DH), were measured in lateral radiographs in neutral, extension and flexion views. Global and segmental ROMs were defined as the difference in respective Cobb angles between flexion and extension views. We applied McAfee classification system (Grades 0 to 4) to classify heterotopic ossification (HO) [16]. McAfee grades 0-2 were defined as low-grade HO and grades 3-4 as high-grade HO, based on impaired ROM criteria [17]. Adjacent segment degeneration (ASD) was evaluated based on narrowing of the disc space and new formation or enlarging of anterior osteophytes on lateral radiographs according to the classification system proposed by Goffin et al. [18]. Prosthesis subsidence was defined as > 2 mm height loss of anterior or posterior functional spinal unit (FSU) when compared with that of the immediate postoperative radiograph.

Statistical analysis
Statistical analyses were performed using SPSS software version 19.0 (IBM SPSS Inc, New York, USA). The results were presented as mean±SD or percentages. A paired t-test was used to compare preoperative and postoperative parameters. The independent t-test or the Mann-Whitney U test was used to compare continuous variables between the two groups. The Chi-square or Fisher’s exact test was used for inter-group categorical variables. Tests were two-tailed with p < 0.05.

Results
Demographic data
One hundred and twenty-six patients underwent 1-or 2-level surgery for a total of 132 arthroplasty
segments (Table 1). Sixty-four (male/female: 32/32) were placed in the small-ROM group, and 62 (male/female: 21/41) in the large-ROM group, with a mean follow-up of 37.12 months. The mean age was 46.11 years in the small-ROM and 43.81 years in the large-ROM group. Sixty-one patients (48.41%) underwent 1-level CDA, 26 (20.63%) 2-level CDA, and 39 (30.96%) 2-level HS. The most commonly operated level with CDA was C5/6 (n= 75), followed by C4/5 (n=36) then C6/7 (n=21). No patients underwent 2-level CDA distributed target levels in the different groups.

Clinical outcomes

Overall, JOA, NDI, and VAS scores showed significant improvement (P < 0.001) in both the small-ROM and large-ROM groups after surgery. However, there were no significant differences in the JOA, NDI, and VAS scores between the two groups at any follow-up point. The detailed information was summarized in Table 2.

Radiographic outcomes

Cervical lordosis and C2-C7 ROM

In the small-ROM group, the preoperative cervical lordosis values (6.25° ± 11.24°) had increased significantly at the last follow-up (10.45° ± 7.90°, P<0.001). In the large-ROM group, the corresponding values changed slightly in comparison (12.01° ± 12.62° and 12.06° ± 9.08°, respectively). Patients in the large-ROM group showed significantly greater cervical alignment before surgery (P=0.008), but there was no significant post-surgical difference between the two groups. The overall cervical motion increased significantly from admission to the last follow-up in the small-ROM group (37.85° ± 13.51° to 45.38° ± 12.14°, P < 0.001) and significantly decreased in the large-ROM group (59.79 ± 11.79° to 53.24° ± 12.56°, P < 0.001). The changes over the follow-up period are shown in Figure 3.

Radiographic changes at the arthroplasty level

The small-ROM group showed significantly less preoperative disc lordosis than the large-ROM group (1.19° vs. 4.09°, P <0.001), and tended to have less reduction (1.13° vs. 2.14°, P=0.125) at the last follow-up.

Preoperative segmental mobility significantly increased at the last follow-up in the small-ROM group
(4.05° ± 1.04° to 7.11° ± 3.43°) for an overall delta ROM (△ROM) of 3.05° ± 3.69° (P<0.001, Fig. 4). The large-ROM group yielded an opposite trend; ROM of the arthroplasty level remarkably decreased from 14.80° ± 1.82° to 10.02° ± 4.07° with a △ROM of -4.77° ± 4.22° (P<0.001). Although the differences between the two groups were narrow, the segmental mobility was significantly higher in the large-ROM group (P<0.001).

The average pre- and postoperative DH in the small-ROM group were 5.22mm ± 0.81mm and 6.40mm ± 0.70mm, respectively. The corresponding values in the large-ROM were 5.59mm ± 0.85mm and 6.60mm ± 0.77mm, respectively. There was a significant difference in DH between the two groups preoperatively (P=0.012).

Complications
Twelve patients (18.8%) in the small-ROM and 10 (16.1%) in the large-ROM group had degenerative radiographic changes (Table 4). The rate of HO development was significantly higher in the small-ROM than in the large-ROM group, as determined in the last follow-up (60.6% vs. 42.4%, p=0.037).

Although the proportion of levels with high-grade HO was higher in the small-ROM as compared to the large-ROM group, the difference was not significant (25.8% vs. 15.2%, P=0.131). We divided the arthroplasty levels into positive △ROM (A) and a negative △ROM subgroups (B). Fourteen levels with less mobile (≤5°) were in subgroup B; however, 11 of them (78.6%) developed high-grade HO (Fig. 5).

Throughout the follow-up period, two levels in the small-ROM and 3 levels in the large-ROM group occurred subsidence. No device-related complications, such as screw loosening or prosthesis migration, occurred.

Discussion
Many trials have substantiated the theoretical advantages of CDA over fusion in recent decades, such as preservation of motion through the operated segments; however, the documented ROM of CDA showed wide variability among patients. Several investigations suggest that the preoperative ROM scale attributes to the variability of ROM after CDA [19], but there is a shortage of data on whether limited or excessive segmental mobility should be considered as a suitable indicator for CDA. In the current study, patients were divided into the small-ROM (ROM≤5.5°) and large-ROM (> 12.5°) groups
according to their preoperative index-level mobility. There was a significant difference in the distribution of operated levels between the groups, where C4/5 was more prone to hypermobility before surgery. This observation could be a reflection of the relatively spared disc disease at C4/5 compared with other segments [20, 21]. Patient symptoms relieved after surgery regardless of preoperative segmental mobility; this may be attributed to the complete decompression of the spinal cord or nerve roots, as well as disc height restoring and reconstructing stability of the cervical spine.

Radiographic features were different between the two groups. Patients with limited segmental ROM showed significantly less global and segmental lordosis, and ROM and shorter DH. This may be due to the degenerative cascade concept; that loss of proteoglycans and water in the nucleus pulposus causes disc height loss, leading to excessive motion and instability at the early stage of disc degeneration and losing segmental ROM at the late stage. These patients also suffered from relatively severe cervical spine degeneration. △ROM significantly increased by 3.05° in discs with preoperatively limited ROM, which parallels the observations of a previous study [10]; however, unlike the current study, there were no clinical studies that had reported on the outcomes of CDA in discs with excessive motion. By contrast, the changes in ROM paradoxically decreased by 4.77° in discs with preoperative hypermobility. Many factors, such as overstretch of the surrounding soft tissue[21], prostheses design [10], the inconsistent axis of rotation [22], and development of HO [17], could lead to decreased ROM after CDA. These findings indicate that segmental ROM could be physiologically restored by CDA using Prestige-LP discs in some cases with loss of mobility and that the technique could partly reduce mobility in some degenerative segments with excessive motion, to achieve “dynamic” re-stability.

The key concern for patients who had excessive ROM preoperatively was that the associated hypermobility would cause increased stress loading on the facet joints and accelerate their degeneration leading to additional neck pain. However, based on the clinical and radiographic outcomes, we suggested that segmental mobility preservation at the index level and the maintenance of motion through the posterior elements did not place patients at risk of increased neck pain. Thus, we supposed that selected patients with preoperatively limited or excessive segmental ROM were
good candidates for CDA.

Although there is no consensus on the mechanism of HO, its development has been associated with variables such as age, sex, disc height, residual exposed endplate, and mismatch of the prosthesis [17, 23, 24]. We found that segments with preoperatively limited ROM has significantly less HO than those with excessive ROM at the last follow-up. This was in contrast to previous studies by Tu et al., who reported that HO was similar for patients in less-mobile and more-mobile groups [10]. For further analysis, some segments in the negative $\Delta$ROM subgroup were found to be more prone to severe HO, especially those with preoperatively limited ROM. One possible explanation could be that limit-ROM discs inherently degenerated more before surgery. Zhou et al. [25] reported that patients with more severe preoperative cervical spondylosis had higher rates of ossification formation after CDA with Bryan discs. Wu et al. [26] demonstrated that patients diagnosed with soft-disc herniation had significantly less HO (6.25%) than those diagnosed with spondylosis (58.33%). In the current study, 11 segments with preoperatively limited ROM developed HO in the negative $\Delta$ROM subgroup; however, 8 of them (72.7%) had been diagnosed with cervical spondylosis before surgery. This observation perhaps indicated that patients with preoperative cervical spondylosis are not optimal candidates for CDA if the index-level ROM is limited.

There were several limitations in the study. First, it was a retrospective study carried out at a single institution presenting inherent weaknesses and limited generalizability of the findings. Second, we evaluated the levels as long as they met the inclusion criteria before surgery. However, different surgery types or levels in subaxial cervical spine may affect outcomes. The small sample size did not present adequate-subgroup data to cover all potential factors. In the current study, factors such as age, sex, and primary cause did not have any significant effect on the results, other than a tendency between the two groups, which may also attribute to the small sample size. Third, the study was limited to the quantity of motion of Prestige-LP discs, whose FDA trials defined inclusion criterion of segmental ROM is in the range 2°-20°; thus, the results may not represent any other type of prostheses. Forth, HO formation was a time-dependent complication after CDA. Due to the extensive time span of the study and the relatively small sample of long-term follow-up cases, the results may
Conclusions

Clinical outcomes were not affected by the preoperative segmental ROM. Patients with preoperatively limited or excessive segmental ROM could achieve satisfactory symptom relief at 3 years postoperatively. However, patients with limited segmental ROM significantly increased segmental mobility and had more and severe HO, whereas patients with excessive segmental ROM paradoxically decreased segmental mobility. With proper patients selection, discs with limited or excessive mobility could benefit from CDA.

Abbreviations

CDA = cervical disc arthroplasty; ACDF = anterior cervical discectomy and fusion; HS = hybrid surgery; ASD = adjacent segment degeneration; ROM = range of motion; JOA = Japanese Orthopedics Association; NDI = Neck Disability Index; VAS = Visual Analogue Scale; DA = disc angle; DH = disc height; DDD = degenerative disc disease; HO = heterotopic ossification; CT = computed tomography; MRI = magnetic Resonance Imaging; SD = standard deviation

Declarations

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Availability of data and materials

Summarized data have been presented in this manuscript. The raw data for this study are located and protected at West China Hospital of Sichuan University. Sharing of the raw data is not suggested, because a secondary analysis is planned.

Authors’ contributions

TKW and HL contributed to the design of the study. TKW drafted the manuscript with the help from BYW, KKH, JBH and YH. JBH and KKH helped in the statistical analyses. Statistical analyses were discussed with TKW, CD and HL. TKW, XR and BYW contributed to the revision. All authors have read
and approved the final manuscript.

**Ethics approval and consent to participate**

The study protocol was approved by the institutional ethics committee of West China Hospital of Sichuan University, and all patients signed informed consent.

**Consent for publication**

Not applicable.

**Competing interest**

The authors declare that they have no competing interests.

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Tables

Table 1 Summary of the patient demographic data (Displayed as a number or mean±standard deviation).

| Variable                  | Small-ROM       | Large-ROM       | P  |
|---------------------------|-----------------|-----------------|----|
| No. of patients, n        | 64              | 62              | -  |
| No. of arthroplasty levels, n | 66              | 66              | -  |
| Age (range), years*       | 46.11 ± 7.87 (26 - 62) | 43.81 ± 7.99 (28 - 63) | 0.106 |
| Sex (M/F)‡                | 32/32           | 21/41           | 0.067 |
| BMI*                      | 23.67 ± 2.87    | 23.17 ± 3.11    | 0.354 |
| T-value*                  | 0.48 ± 1.16     | 0.45 ± 1.26     | 0.925 |
| Cause†                    |                 |                 | 0.051 |
| Disc herniation           | 43              | 53              |    |
| Spondylosis               | 23              | 13              |    |
| Surgery type†             |                 |                 | 0.996 |
| 1-level CDA               | 31              | 30              |    |
| 2-level CDA               | 14              | 13              |    |
| 2-level HS                | 20              | 19              |    |
| Level§                    |                 |                 | 0.008 |
| C4/5                      | 12              | 24              |    |
| C5/6                      | 38              | 37              |    |
| C6/7                      | 16              | 5               |    |
| Operative time (range), min* | 131.83 ± 36.95 (60 - 225) | 135.29 ± 38.53 (60 - 300) | 0.608 |
| Blood loss (range), ml*   | 56.11 ± 33.47 (5 - 150) | 66.69 ± 58.94 (10 - 350) | 0.216 |
| Follow-up (range), months*| 35.95 ± 23.26 (18 - 120) | 38.27 ± 23.13 (13 - 109) | 0.587 |

*Independent t test
†Chi-square test
‡Fisher exact test

Table 2 Clinical outcomes between small-ROM and large-ROM groups

|          | Small-ROM       | Large-ROM       | P  |
|----------|-----------------|-----------------|----|
| JOA *    |                 |                 |    |
| Pre-op   | 11.84 ± 1.48    | 11.85 ± 1.46    | 0.996 |
| Post-op  | 15.92 ± 0.80    | 15.84 ± 0.79    | 0.560 |
| NDI *    |                 |                 |    |
| Pre-op   | 29.48 ± 4.99    | 28.15 ± 3.37    | 0.079 |
| Post-op  | 7.58 ± 3.68     | 7.77 ± 3.39     | 0.757 |
| VAS *    |                 |                 |    |
| Pre-op   | 6.25 ± 1.41     | 6.29 ± 1.25     | 0.866 |
| Post-op  | 1.39 ± 1.06     | 1.39 ± 0.88     | 0.984 |

*Independent t test
†Chi-square test

Pre-op = preoperatively, Post-op = postoperatively, JOA = Japanese Orthopedic Association, NDI = Neck Disability Index, VAS = Visual Analogue Scale

Table 3 Radiographic outcomes between small-ROM and large-ROM groups
Cervical lordosis (°) *
Pre-op       6.25 ± 11.24       12.01 ± 12.62       0.008
Post-op      10.45 ± 7.90       12.06 ± 9.08       0.288
C2-C7 ROM (°) *
Pre-op       37.85 ± 13.51       59.79 ± 11.79       <0.001
Post-op      45.38 ± 12.14       53.24° ± 12.56°       <0.001
△ROM        7.53 ± 15.92°       -6.55° ± 13.48°       <0.001
Disc angle (°) *
Pre-op       1.19 ± 2.88       4.09 ± 4.09       <0.001
Post-op      1.13 ± 3.80       2.13 ± 3.75       0.125
Segmental ROM (°) *
Pre-op       4.05 ± 1.04       14.80 ± 1.82       <0.001
Post-op      7.11 ± 3.43       10.02 ± 4.07       <0.001
△ROM        3.05 ± 3.69       -4.77 ± 4.22       <0.001
Disc height (mm) *
Pre-op       5.22 ± 0.81       5.59 ± 0.85       0.122
Post-op (immediately) 6.40 ± 0.70       6.60 ± 0.77       0.368
△DH         1.18 ± 0.73       0.93 ± 0.60       0.034
ASD (%)†     12 (18.8%)        10 (16.1%)        0.698
HO formation (%) † 40 (60.6%)       28 (42.4%)        0.037
HO classification (%) † 0.131
Low-grade     49 (74.2%)       56 (84.8%)        0.035
High-grade     17 (25.8%)       10 (15.2%)        1.000
Subsidence (%)‡ 2               3               1.000

*Independent t test
†chi-square test
‡Fisher exact test
Pre-op = preoperatively, Post-op = postoperatively, ROM = range of motion, DH = disc height, ASD = adjacent segment degeneration, HO = heterotopic ossification

Table 4 Subgroup analysis

| No. of arthroplasty levels | Small-ROM | Large-ROM |
|----------------------------|-----------|-----------|
| +△ROM                      | 52        | 10        |
| -△ROM                      | 14        | 56        |
| P                          | 0.035     | <0.001    |

| HO formation (%) †         | 28 (53.8%) | 12 (85.7%) |
| HO classification (%) †    | 10 (100%)  | 10 (100%)  |
| Low-grade                  | 46 (88.5%) | 10 (100%)  |
| High-grade                 | 6 (11.5%)  | 0          |

†Fisher exact test
HO = heterotopic ossification

Figures
Figure 1

A patient underwent CDA at C6/7 using Prestige-LP discs in the small-ROM group. Preoperative segmental ROM was measured 3.48° at lateral flexion-extension X-rays (A and B), and preoperative MRI demonstrated disc herniation at C6/7 (C and D). X-rays at 50 months follow-up (E and F) showing increased segmental mobility (ROM = 9.50°) at the arthroplasty segment.

Figure 2

A patient in the large-ROM group underwent CDA at C5/6 using Prestige-LP discs. Preoperative segmental ROM was measured 17.19° at lateral flexion-extension X-rays (A and B), and MRI showed disc herniation at C5/6 (C and D). X-rays recorded at 50 months follow-up (E and F) showing decreased segmental mobility (ROM = 11.45°) at the arthroplasty segment.
C2-C7 ROM. Patients in the small-group significantly increased (P < 0.001) while they significantly decreased in the large-ROM group after surgery (P < 0.001). Asterisks (*) indicated a significant difference between the two groups (P< 0.05).
ROM at the arthroplasty levels. The index levels in the small-group significantly increased (P < 0.001) while they significantly decreased in the large-ROM group after surgery (P < 0.001). Asterisks (*) indicated a significant difference between the two groups (P < 0.05).
A 43-year-old male patient diagnosed with cervical spondylosis. The preoperative ROMs at C5/6 and C6/7 were 4.28° and 4.01°, respectively (A and B). The immediate postoperative X-ray (C) demonstrated the satisfactory location of Prestige-LP discs. The 87-month X-ray (D) and CT scans (E and F) showed high-grade HO developed at C5/6 and C6/7.