

Implant complications after one-level or two-level cervical disc arthroplasty

A retrospective single-centre study of 105 patients

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Abstract

The aim of study was to investigate the complications of cervical disc arthroplasty (CDA) and to discuss the factors affecting the mobility of the prosthesis and the measures to prevent these complications. Hundred and five patients who underwent CDA between 2009 and 2016 were enrolled. The clinical and radiographic outcomes were used to assess and the complications were recorded as well.

All the patients were followed-up with an average of 41.30 ± 16.90 months with an average age of 47.90 ± 9.22 years. The visual analogue scale (VAS), neck disability index (NDI), and Japanese Orthopaedic Association (JOA) scores improved significantly at the final follow-up (FU) compared with the preoperative values. At the final FU, the overall incidence of heterotopic ossification (HO) was 51.42%. The distribution of different grades of HO was low-level HO (53.7%) and high-level HO (46.3%). No significant differences were found in the NDI, VAS, or JOA scores between patients with HO and those without HO ($P > .05$). In the high-level HO patients, the range of mobility (ROM) was significantly reduced compared with the low-level HO patients and those without HO ($P < .05$). The anterior displacement, subsidence, and instability were observed in 1 patient respectively and the segmental kyphosis, adjacent segment degeneration in 3 patients respectively. The patient of CDA instability also suffered severe neck pain and the revision surgery was performed.

Postoperative complications in CDA such as HO, segmental kyphosis, and prosthesis displacement are prone to occur, affecting prosthesis mobility. Surgical indications should be strictly controlled, and intraoperative and postoperative treatments should be given great attention in order to reduce prosthesis-related complications.

Abbreviations: ACDF = Anterior cervical discectomy and fusion, CDA = cervical disc arthroplasty, FU = follow up, HO = heterotopic Ossification, JOA = Japanese Orthopaedic Association, NDI = neck disability index, ROM = range of mobility, VAS = visual analog scale.

Keywords: cervical spine, complications, disc arthroplasty

1. Introduction

Anterior cervical discectomy and fusion (ACDF) is considered the gold-standard treatment for cervical degenerative lesions such as radiculopathy and myelopathy, providing reliable decompression

and maintaining good cervical alignment.^[1] However, the loss of motion in surgical level and acceleration of adjacent-level disc degeneration still remains unignorable for both surgeons and patients,^[2,3] especially in multiple-level of ACDF.

In recent years, a large number of researches have demonstrated that cervical disc arthroplasty (CDA) has been recommended as an alternative treatment for cervical degenerative disc diseases, preserving mobility, and avoiding adjacent segment degeneration.^[4–8] However, many studies have reported different incidences of heterotopic ossification (HO) formation after CDA, ranging from 7.7% to 94.1%,^[9–11] but the mechanism of HO formation remains unclear, and postoperative biomechanical changes may induce HO after CDA.^[12,13] The complications resulting from CDA have been reported, such as HO, migration of the prosthesis, subsidence of the prosthesis into the bone, and occurrence of spontaneous fusion, which can affect the range of mobility (ROM) of the prosthesis.^[14,15] The study aims to investigate the complications of the CDA patients and to discuss the factors affecting the mobility of the prosthesis and to discuss the measures to prevent these complications.

2. Materials and methods

2.1. Patients population

This study was a retrospective study and the study was approved by the Institutional Review Board of the First Affiliated Hospital

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The datasets generated during and/or analyzed during the present study are not publicly available, but are available from the corresponding author on reasonable request.

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of Chongqing Medical University (2019-075) and was conducted according to the principles of the Declaration of Helsinki. All the patients provided their written informed consent to participate in our study prior to the storage of their data in the hospital database. The patients who underwent CDA between January 2009 and January 2016 were reviewed. The inclusion criteria were as follows: patients who only had one-level or two-level cervical myelopathy or radiculopathy, who failed to undergo conservative treatment and who had a minimum FU of 2 years. The exclusion criteria were as follows: ossification of the posterior longitudinal ligament, cervical instability, previous cervical spine surgery, ankylosing spondylitis, rheumatoid arthritis, tumors, and infections.

All surgeries were performed by the same senior surgeon using a standard surgical technique. The clinical and radiographic data of all patients were routinely recorded preoperatively; immediately postoperatively; 3, 6, and 12 months postoperatively, and then annually.

2.2. Outcome assessments

For all patients, the following data were observed preoperatively, 3, 6, and 12 months postoperatively and at the final follow-up (FU):

1. the operation time, surgical haemorrhage, hospitalization time;
2. visual analogue scale (VAS), neck disability index (NDI), and Japanese Orthopaedic Association (JOA).
3. HO was assessed by the McAfee classification (Fig. 1).
4. the ROM of the index level was measured on full flexion and extension radiographs.
5. the subsidence was defined as a decrease in the segment height (SH) at the final FU greater than 3 mm compared with that immediately postoperatively, and displacement was defined as displacement at the final FU >2 mm compared with that immediately postoperatively.

The radiographic assessments were made by 2 senior independent Spine surgeons.

2.3. Statistical analysis

The statistical analysis was performed using the Statistic Analysis System (SAS Institute Inc, Cary, NC). Quantitative variables were described as the mean \pm SD. A repeated measures ANOVA was used for the statistical analysis of the differences in mean values, and the chi-squared test was used for categorical data. Differences with a P -value $<.05$ were considered.

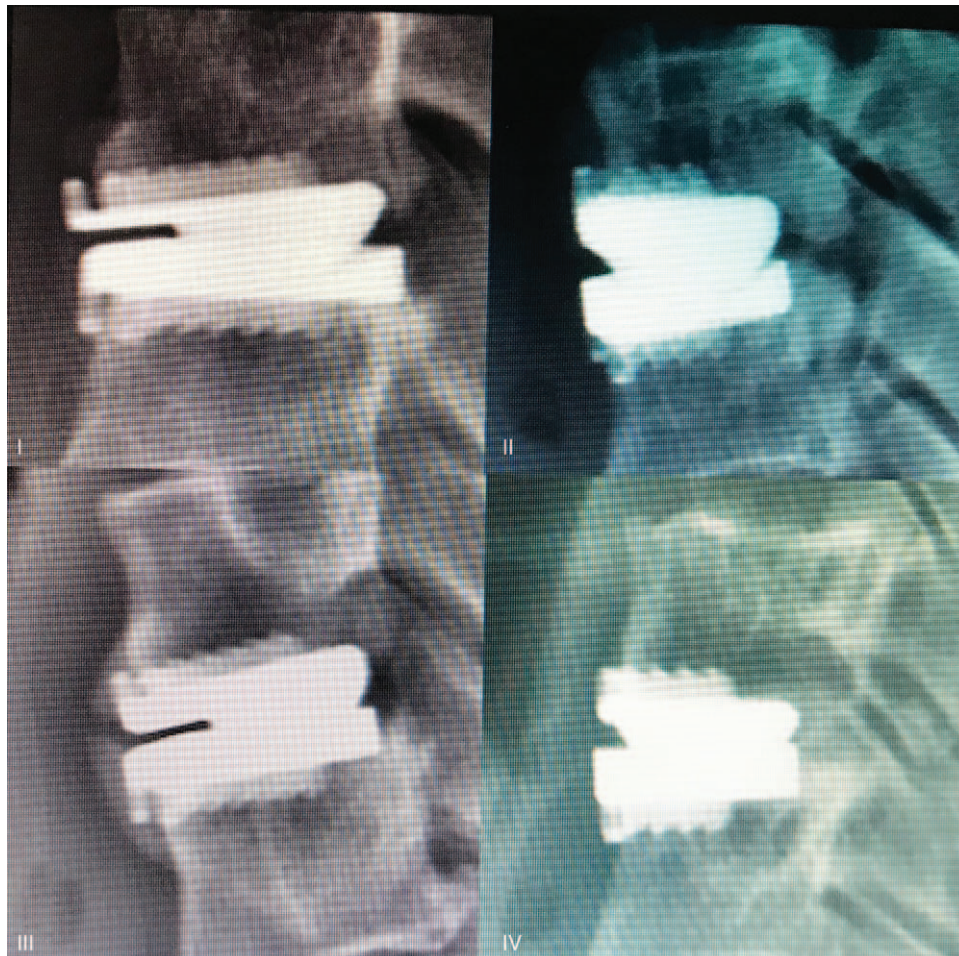


Figure 1. HO was assessed with the McAfee classification.

Table 1
Demographic characteristics of the patients.

Parameter	
No. of patients (n)	105
Male/female (n)	62/43
Mean age (years)	47.90±9.22
Mean FU (years)	41.30±16.90
Total levels	
One-level	95
Two-level	10
Intervertebral levels (n)	
C3-4	25
C4-5	31
C5-6	40
C6-7	19

FU= follow up.

3. Results

3.1. Demographics

A total of 105 patients were enrolled. Discover prostheses were used in 10 patients, while Prestige LP was used in 95 patients. The patients were followed up for an average of 41.30±16.90 months with an average age was 47.90±9.22 years (Table 1). The mean amount of surgical bleeding, surgical time, and hospitalization time were 58.00±15.17 mL, 94.00±28.86 min, and 5.60±0.94 days, respectively.

The VAS, NDI, and JOA scores improved significantly at the final FU compared with the preoperative values (Table 2). The statistical analysis showed significant differences between pre-operation values and the values at the final FU (Table 2).

3.2. Complications

At the final FU, the overall incidence of HO was 51.42% (55/105) (Table 3). The incidence of HO in each type of prosthesis is demonstrated in Figure 2. The distribution of different grades of HO in the prosthesis is shown in Table 3. No significant differences were observed in NDI, VAS, or JOA scores between patients with HO and those without HO (*P* > .05). However, in the high-level HO patients, at the final FU, the ROM was significantly reduced compared with the low-level HO patients and those without HO (*P* < .05).

The anterior displacement was observed in 1 patient (Fig. 2), but at the final FU, X-rays showed that the prosthesis fused

Table 2
Clinical outcomes between groups.

Parameter	Low HO	High HO	Control group	<i>P</i>
No. of patients (n)	29	25	51	
Preoperative ROM	7.71±1.68	6.57±2.05	6.99±1.62	.1357
Final FU ROM	7.75±1.76	3.91±1.05*	7.05±1.24	<.0001
Preoperative VAS	6.15±0.93	6.15±0.99	6.50±1.05	.4413
Final FU VAS	1.25±0.85*	1.25±0.55*	1.45±0.83*	.6284
Preoperative JOA	11.60±1.27	11.95±1.43	12.40±1.19	.1591
Final FU JOA	15.75±0.85v	15.85±0.75*	15.95±0.76*	.3994
Preoperative NDI	37.85±3.63	36.85±4.08	37.35±4.72	.9086
Final FU NDI	6.50±3.91*	6.60±1.70*	6.45±1.93*	.9771

* Preoperative treatment vs final FU, *P* < .05.

JOA=Japanese Orthopaedic Association, NDI=neck disability index, ROM=range of mobility, VAS=visual analog scale.

Table 3
The incidence of complications related to the implant.

Parameter	
Heterotopic ossification	51.42% (54/105)
HO 1	19
HO 2	10
HO 3	20
HO 4	5
Implant subsidence	1
Implant displacement	1
Segmental kyphosis	3
Adjacent segment degeneration	3
Instability	1

HO=heterotopic Ossification.

completely and that it had good stability. The subsidence was observed in 1 patient (Fig. 2), segmental kyphosis in 3 patients (Fig. 3), and adjacent segment degeneration in 3 patients (Fig. 4). One patient experienced instability, suffered severe neck pain, and the revision surgery was performed (Fig. 5).

Other complications such as vascular injury, dural injury, surgical site infection, increased pain, cerebrospinal fluid leak, etc were not observed.

4. Discussion

ACDF and CDA are the most commonly used surgical methods for the treatment of cervical degenerative diseases.^[1-5,16-22] With the popular application of CDA, many common anterior cervical surgical complications, such as dysphagia and neck haematoma, have been reported, including prosthesis-related complications such as displacement.^[14,15] In our study, one patient had a translucent area between the upper endplate of the prosthesis and the lower endplate of the vertebral body segment at the 3-month FU, but the patient did not complain of discomfort, and the size and position of the prosthesis were good. At the 2-year FU, the prosthesis was displaced forward by 3mm, but the translucent area had disappeared, suggesting that the bone had grown and the X-ray suggested that the prosthesis was stable. We considered that the reason for this outcome was early hyperactivity and overload of the patient's neck, which could lead to bone growth problems and could cause the rotation center and local force of the prosthesis to change due to displacement assessed at the long-term follow-up, thus causing segment instability and HO generation. Zhang reported that 5.5% of patients had displacement of 2 to 3 mm at the 1-year and 2-year follow-ups^[12] which is related to postoperative cervical hyperactivity. We believe that although there were two inverted tooth-shaped fixations on the upper and lower endplates of the prosthesis to provide good postoperative immediate stability, the ultimate stability of the prosthesis depends on bone growth. Therefore, it is still necessary for patients to wear neck collars early after surgery.

In the present researches, CDA patients showed good recovery postoperatively, indicating positive effects of the CDA. Although the incidence of prosthesis subsidence or kyphosis after CDA is low, mostly due to intraoperative injury of the bone endplate or to osteoporosis. Previous study reported that 20 patients who underwent Prestige LP and who were followed for 1 year showed an increase in the kyphosis angle of 2.2°.^[13,16,23] In our study, 3 patients had segmental kyphosis and 1 had subsidence who had



Figure 2. (A) At the 3-month FU, the prosthesis was normal. (B) demonstrates 3 mm of forward displacement. (C) Shows the HO at the 1-year FU, and subsidence can be observed in (D).



Figure 3. As shown by lateral X-rays (A and B), the spinous processes were not in line, and the cervical axis was not corrected. C4-5 and C5-6 radiculopathy were indicated for CDA. (D and E) shows that the two levels of the prosthesis rotation centre were not on the same axis. (F–I) At the final follow-up, the axis was exaggerated, a C4-5 prosthesis was implemented, and kyphosis as well as the mobility of the C4-5 prosthesis were decreased.



Figure 4. (A) A 51-year-old male patient with superior disc degeneration. (B) At the 1-month FU, the superior disc demonstrated few osteophytes. (C–F) At the final 5-year FU, there was still some activity of the prosthesis. However, ossification of the anterior longitudinal ligament was observed, and superior disc degeneration and intervertebral instability were exaggerated.

no new symptoms, but prosthesis activity was significantly affected. The 4 patients all underwent early operations performed before 2011, considering the reasons for neck hyperextension and unskilled endplate preparation. Afterwards, the position of the neck and the endplate preparation were more proficient, and no cases of kyphosis or subsidence occurred in our study. It has been suggested that the learning curve of CDA is relatively long and that the improvements in surgical techniques can help to reduce the occurrence of complications related to this type of prosthesis. At the same time, according to our experience, Prestige LP has a limited effect on reconstructing cervical curvature compared with a prosthesis with parallel endplates.

Prestige LP prosthesis replacement should be carefully selected for patients with poor preoperative cervical alignment.^[17–19] In addition, although there were two kinds of prostheses used in our study, the Discover prosthesis could not be applied in the early stage because of the hospital policy and additionally, the number of patients was small.

HO is common after CDA. It is well-known that the core idea of CDA is to preserve activity at the replacement level as much as possible, thus decreasing the occurrence of adjacent segment degeneration. However, present researches show that HO may affect the activity of the replacement level. As reported in other CDA clinical trials, the incidence of HO varies from 2.4% to



Figure 5. (A) A 50-year-old female patient was treated with CDA for C5-6 radiculopathy. (B–D) The ROM increased at the 3-month FU (6.9), at the 2-year FU (13.3), and at the 4-year FU (15.6), and the patient suffered severe neck pain. MRI and CT were performed in (E and F). (G) The patient underwent C5 corpectomy. (H and I) At the 3-month and the 1-year final FU, bony fusion was observed, and the patient was satisfied.

94.1% despite the different types of artificial disc prostheses.^[14,20,21] In our study, the HO incidence was 51.42%. The incidence of postoperative HO was higher in our study than in other studies, which may be due to the longer follow-up and the non-prophylactic use of NSAIDs for 2 weeks after surgery. The patients with HO had no clinical symptoms, and there were only 5 cases of grade IV HO and 20 cases of grade III HO. In the high-level HO patients of our study, the ROM was significantly reduced compared with the low-level HO patients and those without HO. There were axial symptoms of the cervical spine, but after conservative treatment, neck stiffness, and pain were significantly improved. Although the reason for HO remains unclear, the incidence certainly increases with time, which is the most common and inevitable complication after CDA. Some studies have suggested that patients with mild degeneration and ossification of the posterior longitudinal ligament should be treated before surgery. During the operation, the protection of the longissimus dorsi muscle should be given more attention, and the surgical segment should be fully flushed to reduce residual bone debris. Taking NSAIDs during the week and strict control of indications as well as an emphasis on intraoperative and perioperative management could reduce the incidence of HO.^[22,24]

Whether the process of adjacent disc degeneration is altered by CDA has not been addressed.^[25–29] At the final FU, 3 of 105 patients had radiographic adjacent segment degeneration without symptoms, and the incidence rate was 2.8%, which may be associated with a high incidence of postoperative prosthesis-related complications. However, it can be seen from

Figure 4 that in the case where the segmental activity was well preserved, the superior disc still degenerated. In this case, the superior disc had degenerative manifestations of anterior epiphyseal hyperosteoecy and anterior longitudinal ligament calcification, suggesting that CDA may not have protective effects on adjacent segments that have undergone degeneration. In addition, the influence of biomechanical factors and the degeneration of adjacent segments also play an important role in the natural process.^[30,31]

The present study has some limitations. First, the retrospective nature of our study may be associated with bias. Second, the prosthesis types included in our study were limited. There were only two kinds of prostheses discussed in the study, and there was a number difference in two, so no comparison was observed. Third, due to the limited number of the patients and the FU time, the study may be associated with bias and need longer FU to confirm the results. Fourth, the patients of three level or multi-level CDA were not enrolled and further study will be needed.

5. Conclusion

Our study indicated that the postoperative complications in CDA such as HO, segmental kyphosis and prosthesis displacement are prone to occur, affecting prosthesis mobility. Surgical indications should be strictly controlled, and intraoperative and postoperative treatments should be given great attention in order to reduce prosthesis-related complications. However, the study was a small-sample retrospective study, and prospective, randomized studies with long-term follow-up periods are needed.

Author contributions

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