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ORIGINAL ARTICLE

Single-level cervical arthroplasty with ProDisc-C artificial disc: 10-year follow-up results in one centre

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Abstract

Purpose The aim of this study was to evaluate the long-term clinical and radiographic outcomes of cervical arthroplasty using the ProDisc-C prosthesis.

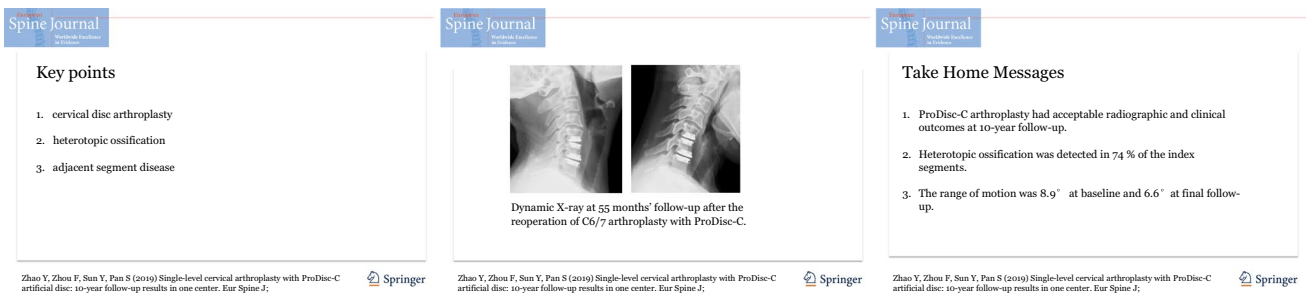
Methods Clinical and radiographic evaluations, including dynamic flexion–extension lateral images, were performed at baseline and at 10-year follow-up.

Results Twenty-seven patients who had single-level ProDisc-C arthroplasty were followed up for a mean period of 123 months. The range of motion at the operated level was 8.9° ± 3.9° at baseline and 6.6° ± 3.5° at final follow-up. Twenty of 27 levels (74%) developed heterotopic ossification. According to McAfee's classification, one level was classified as grade I, four levels were classified as grade II, 12 levels were classified as grade III and three levels were classified as grade IV. Three patients developed recurrent cervical radiculopathy or myelopathy due to adjacent segment disease and received the reoperations. The reoperations included two cases of cervical arthroplasty at adjacent segments and one case of cervical laminoplasty.

Conclusions ProDisc-C arthroplasty had acceptable clinical and radiographic results at 10-year follow-up. Heterotopic ossification was common after ProDisc-C arthroplasty, which decreased the range of motion.

Graphic abstract

These slides can be retrieved under Electronic Supplementary Material.



Keywords Cervical disc arthroplasty · Heterotopic ossification · Adjacent segment disease

Yanbin Zhao and Feifei Zhou contributed equally to this work.

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Introduction

Cervical arthroplasty was developed to preserve range of motion (ROM) and to prevent the accelerated degeneration of adjacent segments after cervical fusion. Five-year follow-up [1] results showed that cervical arthroplasty with ProDisc-C artificial disc was safe and effective treatments for single-level symptomatic cervical disc disease. Janssen et al. [2] reported

that clinical outcomes after cervical arthroplasty with ProDisc-C were similar to cervical fusion and patients treated with ProDisc-C had a lower probability of subsequent surgery at 7-year follow-up. This study aimed to evaluate the 10-year radiographic and clinical outcomes of cervical arthroplasty using ProDisc-C in one centre.

Methods

Clinical enrolment

Patient inclusion criteria were single-level cervical myelopathyor cervical radiculopathy, which had not responded to non-surgical treatment. Exclusion criteria were previous cervical spine surgery, marked cervical instability, severe spondylosis at the level to be treated, severe osteoporosis, ossification of the posterior longitudinal ligament and active infection. Severe spondylosis was defined as narrowing of the disc space > 50% compared to adjacent segment's disc space or segmental range of motion < 4 degree on dynamic flexion–extension X-ray.

ProDisc-C cervical disc arthroplasty was first performed in our centre in June 2006. Twenty-seven patients who received single-level ProDisc-C arthroplasty between June 2006 and November 2008 by the same surgeon gained around 10-year follow-up. The mean follow-up period was 123 months (110–142 months). The study group consisted of 16 men and 11 women. Their ages ranged from 30 to 58 years (mean 44 years). The levels of surgery included C3/4 (two levels), C4/5 (four levels), C5/6 (16 levels) and C6/7 (five levels). Thirteen of the 27 patients presented with myelopathy, 12 with radiculopathy and two with combined myelopathy and radiculopathy.

Radiographic evaluation

Radiographic evaluation included static and dynamic flexion–extension lateral images. Heterotopic ossification (HO) was evaluated by X-rays according to McAfee's classification [3]. ROM at baseline and final follow-up was measured using flexion–extension lateral X-rays according to White's method [4]. The radiologic evidence of adjacent segment degeneration on lateral X-rays included the presence of any of the following parameters [5]: (1) new anterior or enlarging osteophyte formation, (2) narrowing of the disc space by ≥ 30% or (3) calcification of the anterior longitudinal ligament.

Statistical analysis

Statistical analysis was conducted using paired *t* tests with SPSS version 13.0 software. A *P* value < 0.05 was considered to be statistically significant.

Results

Clinical outcomes

mJOA score The mJOA of 13 patients with myelopathy was 12.8 ± 2.1 at baseline and 15.9 ± 1.1 at final follow-up.

The VAS score The VAS arm of the 12 patients with radiculopathy was 5.4 ± 1.8 at baseline and 1.0 ± 1.7 at final follow-up. The VAS neck of the 12 patients was 4.8 ± 2.3 at baseline and 1.7 ± 1.7 at final follow-up.

Reoperation Three patients developed recurrent cervical radiculopathy or myelopathy due to adjacent segment disease and received the reoperations. The intervals between the initial surgery and reoperations were 54 months, 61 months and 94 months, respectively. The reoperations included two cases of cervical arthroplasty at adjacent segments and one case of cervical laminoplasty (Fig. 1).

Radiographic outcomes

Heterotopic ossification

Twenty of 27 levels (74%) developed heterotopic ossification. According to McAfee's classification, one level was classified as grade I, four levels were classified as grade II, 12 levels were classified as grade III and three levels were classified as grade IV.

ROM

X-ray examination revealed the ROMs of the 27 levels to be 8.9° ± 3.9° at baseline and 6.6° ± 3.5° at final follow-up, with a significant difference between them ($P < 0.05$, paired *t* test).

Adjacent segment degeneration

Fifty-four adjacent segments were evaluated by lateral X-rays, and four adjacent segments were excluded because of shoulder shadows. Twenty-five segments (50%) were found to have developed adjacent segment degeneration.

Discussion

Clinical outcomes after ProDisc-C arthroplasty

Cervical arthroplasty with ProDisc-C artificial disc was safe and effective treatments for single-level symptomatic cervical disc disease at 5- and 7-year follow-up [1, 2, 6]. Mehren et al. [7] followed up 38 patients for 10 years and found good

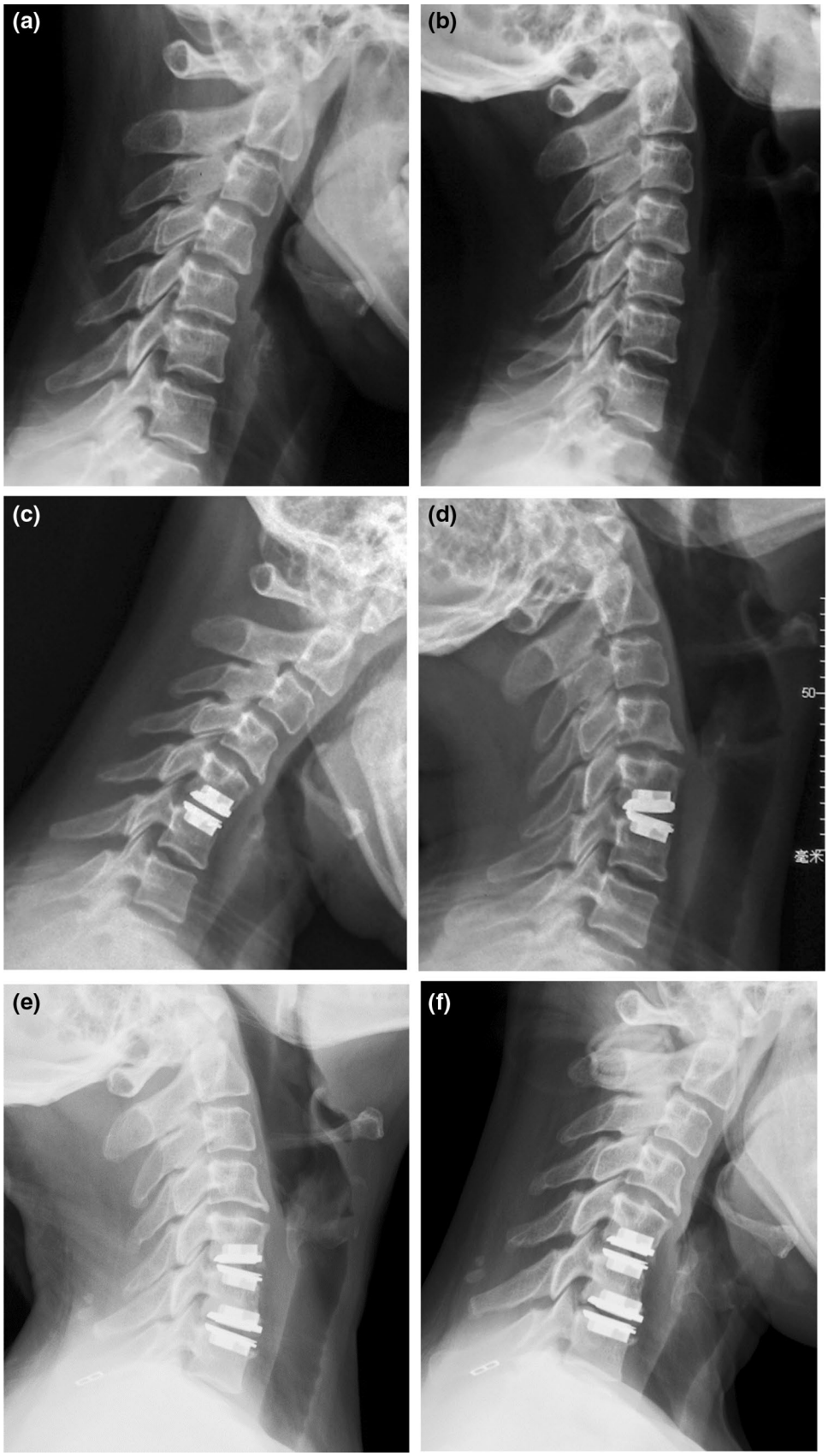

Fig. 1 **a**, **b** A 34-year-old female patient' preoperative dynamic extension–flexion X-ray. **c**, **d** Dynamic X-ray at 61-month follow-up after C56 arthroplasty with ProDisc-C, and the patient developed adjacent segment disease of C67. **e**, **f** Dynamic X-ray at 55-month follow-up after the reoperation of C67 arthroplasty with ProDisc-C

clinical outcomes and low rates of subsequent surgeries. In this study, the JOA score was 12.8 at baseline and improved to 15.9 at final follow-up. The VAS score for the patients with cervical radiculopathy also improved.

Three patients developed adjacent segment disease and received the reoperations in this study. Mehren et al. [7] reported three patients (7.9%) received conservative treatments for adjacent segment disease and none of the patients had to be re-operated at 10-year follow-up. Cervical arthroplasty with ProDisc-C had a lower probability of subsequent surgery [2, 6, 8]. But, large cohort studies are needed to evaluate the adjacent segment degenerations after cervical arthroplasty.

ROM after ProDisc-C arthroplasty

The goal of cervical arthroplasty was to prevent increased degeneration of adjacent segments by preserving motions. Results of the prospective multicentre investigational device exemption study [1, 2, 9] reported the follow-up of 103 patients with single-level ProDisc-C arthroplasty, and the average flexion–extension ROM was 8.5° at baseline, 9.4° at 2-year follow-up, 8.1° at 5-year follow-up and 8.1° at 7-year follow-up. Mehren et al. [7] reported the average flexion–extension ROM was 9.0° at baseline, declined to 7.7° at 5-year follow-up and 7.6° at 10-year follow-up after ProDisc-C arthroplasty.

In our study, the ROM was 8.9° at baseline and decreased to 6.6° at final follow-up. The decrease in motion may be related to the high rate of HO formation.

HO after ProDisc-C arthroplasty

McAfee et al. [3] classified HO into grades I–IV, and only grade IV HO segments lost motion. The mechanism for the formation of HO is not clear. Mehren et al. [7, 10] reported the HO rate was 65.2% at 1-year follow-up after ProDisc-C arthroplasty and the rate of HO increased to 90% at 10-year follow-up. Cho et al. [11] reported the HO rate was 56% at 1-year follow-up, 86% at 2-year follow-up and increased to 89% at 3-year follow-up. Our previous study [12] reported the HO rate was 65.4% at 5-year follow-up after ProDisc-C arthroplasty. The ProDisc-C arthroplasty seems to have a higher rate of HO and the rate of HO increased to 74% at 10-year follow-up in our centre. Most of the HOs were detected on the anterior margin of the vertebral body. Keel cuts were made on the midline of the vertebral body to fit the ProDisc-C prosthesis during the surgery, which may lead to the formation of HO on the anterior margins. Different types of cervical disc prosthesis had differences in the rates of HO formations due to variable design and biomechanical property [13, 14].

The ProDisc-C prosthesis was a small-radius ball and socket device with a fixed centre of rotation and the location of centre of rotation shifted forward after cervical arthroplasty [15]. This device can only simulate a part of the motion of the human cervical disc, which may contribute to the formation of HO due to physiologic compensation to iatrogenic instability after cervical arthroplasty [11].

Zhou et al. [16] performed a meta-analysis and found that the presence of HO is not associated with clinical outcomes after cervical arthroplasty. But, severe HO might block the ROM of prosthesis or cause foraminal stenosis at the index level [17]. Stricter inclusion criteria should be applied for cervical arthroplasty to decrease the rate of HO formation [17, 18].

ProDisc-C arthroplasty had acceptable radiographic and clinical outcomes at 10-year follow-up. HO was detected in 74% of the index segments which decreased the ROM. Large cohort studies are needed to evaluate the effects of HO after ProDisc-C arthroplasty. These are the results of a first-generation cervical disc prosthesis which is no longer in use in most of the countries.

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Compliance with ethical standards

Conflict of interest None.

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