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Clinical Study

Clinical and radiographic outcomes of cervical disc replacement with a new prosthesis

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Abstract

BACKGROUND CONTEXT: Anterior cervical discectomy and interbody fusion was a classical treatment for cervical degenerative disc disease (CDDD). However, the rigid fusion also leads to a reduction in normal cervical spine motion and to increased biomechanical stress at adjacent levels, which in turn accelerates degenerative changes of the discs at these levels. Cervical disc replacement (CDR) is a new technology with the aim of addressing the limitations of fusion procession and preserving motion at the treated level. Discover prosthesis (DePuy Spine, Raynham, MA, USA) is a new type artificial disc and there are few reports about it.

PURPOSE: The purpose of this study was to analyze the primary clinical and radiographic outcomes of CDR with Discover prosthesis to treat mono- or bi-segment CDDD in a Chinese population.

STUDY DESIGN: The study design was prospective and single-center clinical trial of the Discover prosthesis in the treatment of patients with mono- or bi-segment CDDD.

PATIENTS SAMPLE: Seventy-nine patients with 102 Discover prosthesis arthroplasty performed (56 mono-segment and 23 bi-segment) were evaluated.

OUTCOME MEASURES: Clinical outcomes based on Japanese Orthopaedic Association (JOA), visual analog scale (VAS) pain score, and Odom's scale and radiographic outcomes including the anterior disc heights (ADH), posterior disc heights (PDH), range of motion, and performance of heterotopic ossification (HO) of the operative segment were assessed.

METHODS: Clinical and radiographic follow-up was performed. Preoperative and postoperative ADH, PDH, and range of motion were measured from lateral and flexion-extension radiographs. The paired *t* test was used to assess the difference of clinical and radiographic outcomes before and after operation. The performance of HO was observed by two independent MD.

RESULTS: The mean follow-up time for all the patients was 31.6 months, ranging from 24 to 43 months. Mean preoperative JOA score was 9.5, and VAS overall pain score was 7.2. At 2-, 6-, 12-, and 24-month follow-up, the mean JOA score was 14.1, 14.7, 15.3, and 14.9, whereas the mean VAS overall pain score was 1.9, 1.7, 1.8, and 1.4, respectively. Mean JOA and VAS scores showed statistical improvements in the postoperative period. Seven patients had mild dysphagia within the first month after operation. According to Odom's scale, 52 patients had excellent outcomes, 25 patients had good outcomes, and 2 patients had fair outcomes at 2-year follow-up. The Mean preoperative ADH and PDH of the operative segment were 4.9 mm and 3.1 mm. Compared with

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preoperative, there were significantly increased and maintenance well at 2- (7.5 mm, 5.1 mm), 6- (7.5 mm, 5.0 mm), 12- (7.4 mm, 4.9 mm) and 24-month (7.2 mm, 5.0 mm) follow-up. Range of motion of the operative segment in the postoperative follow-up was slightly increased than the preoperative follow-up but not statistically significant. Heterotopic ossification was presented in six replaced levels at 1-year follow-up including 4 Grade I and 2 Grade II and 18 replaced levels at the follow-up more than 2 years including 8 grade I and 10 grade II. No prosthesis subsidence or excursion was identified.

CONCLUSIONS: The use of Discover prostheses in our study resulted in satisfactory clinical and radiographic outcomes. The prostheses can restore and maintain interbody height, while preserve the motion of the treated segment. Although the results of this study demonstrate initial safety and effectiveness in a Chinese population, we need further studies to know more about the impact of CDR with Discover prosthesis, especially on HO and adjacent segment degeneration.

Keywords: Cervical degenerative disc disease; Cervical disc replacement; Discover; Heterotopic ossification

Introduction

Since its development in the 1950s, anterior cervical discectomy and interbody fusion (ACDF) has proven to be a successful and versatile treatment for cervical degenerative disc disease refractory to conservative therapy [1–4]. The use of Cage and anterior plating have diminished pseudarthrosis and graft site complication [5]. However, the rigid fusion also leads to a reduction in normal cervical spine motion and increased biomechanical stress at spinal levels adjacent to the fusion, which in turn accelerates degenerative changes of the discs at these levels [6–8]. Hilibrand et al. [9] have documented the occurrence of symptomatic adjacent-segment disc degeneration at a relatively constant incidence of 2.9% per year on a cumulative basis, with a predicted prevalence at 10 years approximating 25%. It has been estimated that 7% to 15% of the patients ultimately require a secondary procedure at an adjacent level after ACDF [10].

Cervical disc replacement (CDR) is a relatively new technology in spine surgery with the aim of addressing the limitations of fusion procession and preserving motion at the treated level. There are a wide variety of artificial prosthetic discs available, among which Discover is a relatively new type with limited reports to date. We describe the preliminary clinical and radiographic outcomes from a prospective study of consecutive patients undergoing mono- or bi-segment CDR with Discover artificial discs. The primary efficacy was tested throughout the data analysis.

Materials and methods

Patients

A total of 79 patients (41 women and 38 men) of cervical degenerative disc disease who had 3-13 months' preoperative history of symptoms (23 cases with radiculopathy, 38 cases with myelopathy, and 18 cases with both radiculopathy and myelopathy) and did not respond to the conservative treatment were enrolled and treated by CDR with Discover prosthesis from March 2009 to November 2010. Inclusion criteria for enrollment were disc herniation with preserved mobility ($>3^\circ$ and $<11^\circ$) in the affected one or two segments. Exclusion criteria included ossification of the posterior longitudinal ligament, kyphotic deformity, trauma, or instability of the cervical spine. Further exclusion criteria were advanced osteoporosis, ankylosing spondylitis, and rheumatoid arthritis. Patients above the age of 60 years were also excluded from our study. The mean age of the cohort of patients was 41.3 years (range, 31–59 years). A total of 102 prosthesis were implanted with 56 mono-segment and 23 bi-segment (Table 1). The mean follow-up time was 31.6 months, ranging from 24 to 43 months.

Operation procedure

Patients acquired general anesthesia and were placed in supine position. A right lateral transverse cut was implemented to expose the surgical segments. The compressive materials including the posterior longitudinal ligament were removed. After testing the intervertebral height and width by fluoroscopy, appropriate prosthesis was implanted. Patients were asked to get off the bed 24 hours later. A neck collar was required to wear no more than 1 week.

Clinical evaluation

The clinical outcomes were evaluated using Japanese Orthopaedic Association score and visual analog scale (VAS) score before and after operations. Incidence of dysphagia-related symptoms was recorded using the system defined by Bazaz et al. [11] as a compensative index for clinical evaluation during the follow-up period. The Odom criteria [12] was used to evaluate the operation effect for each patient at 2 year's follow-up.

Radiological evaluation

Patients were required to take cervical x-ray imaging, computed tomography, and magnetic resonance imaging before operation. Additional x-ray imaging was also