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Clinical Study

Cervical kinematics and radiological changes after Discover artificial disc replacement versus fusion

Yang Hou, MD, Yang Liu, MD, PhD, Wen Yuan, MD, PhD*, Xinwei Wang, MD, PhD, Huajiang Chen, MD, PhD, Lili Yang, MD, PhD, Ying Zhang, MD, PhD

Department of Orthopaedic Surgery, Changzheng Hospital, No. 415 Feng Yang Rd, Shanghai 200003, China

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Abstract

BACKGROUND CONTEXT: The cervical disc arthroplasty has emerged as a promising alternative to the anterior cervical discectomy and fusion (ACDF) in patients with radiculopathy or myelopathy with disc degeneration disease. The advantages of this technique have been reported to preserve the cervical mobility and possibly reduce the adjacent segment degeneration. However, no studies have compared the clinical outcomes and radiological results in patients treated with Discover artificial disc replacement to those observed in matched group of patients that have undergone ACDF.

PURPOSE: We conducted this clinical study to compare the cervical kinematics and radiographic adjacent-level changes after Discover artificial disc replacement with ACDF.

STUDY DESIGN: Analysis and evaluation of data acquired in a comparative clinical study.

PATIENT SAMPLE: The number of patients in the Discover and ACDF group were 149 and 196, respectively.

OUTCOME MEASURES: The Neck Disability Index (NDI) and visual analog scale (VAS) pain score were evaluated. The range of movement (ROM) by the shell angle, the functional segment unit and global angles were measured, and the postoperative radiological changes at adjacents levels were observed.

METHODS: A total of 149 patients with symptomatic single or two-level cervical degenerative diseases received the Discover cervical artificial disc replacement from November 2008 to February 2010. During the same period, there were a total of 196 patients undergoing one or two-level ACDF. The average follow-up periods of the Discover disc group and ACDF group were 22.1 months and 22.5 months, respectively. Before surgery, patients were evaluated using static and dynamic cervical spine radiographs in addition to computerized tomography and magnetic resonance imaging. Static and dynamic cervical spine radiographs were obtained after surgery and then at 3- and 6-month follow-up. Then, the subsequent follow-up examinations were performed at every 6-month interval. The clinical results in terms of NDI and VAS scores, the parameters of cervical kinematics, postoperative radiological changes at adjacent levels, and complications in the two groups were statistically analyzed and compared. No funding was received for this study, and the authors report no potential conflict of interest–associated biases in the text.

RESULTS: Although the clinical improvements in terms of NDI and VAS scores were achieved in both the Discover and ACDF group, no significant difference was found between the two groups for both single- (VAS p=.13, NDI p=.49) and double-level surgeries (VAS p=.28, NDI p=.21). Significant differences of cervcial kinematics occurred between the Discover and the ACDF group for both the single- and double-level surgeries at the operative segments (p<.001). Except the upper adjacent levels for the single-level Discover and ACDF groups (p=.33), significant increases in

FDA device/drug status: Investigational (The DISCOVER Artificial Cervical Disc).

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The authors YH and YL contributed equally to this work and should be considered as co-first authors.

* Corresponding author. Department of Orthopaedic Surgery, Changzheng Hospital, No. 415 Feng Yang Rd, Shanghai 200003, China. Tel.: (86) 13501726651; fax: (86) 021-63520020.

E-mail address: yuanwenspine@163.com (W. Yuan)

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adjacent segment motion were observed in the ACDF group compared with the minimal ROM changes in adjacent segment motion noted in the Discover group, and the differences between the two groups for both single and double-level procedures were statistically significant ($p<.05$). There were significant differences in the postoperative radiological changes at adjacent levels between the Discover and ACDF groups for the single-level surgery ($p<.001$, $\chi^2=18.18$) and the double-level surgery ($p=.007$, $\chi^2=7.2$). No significant difference of complications was found between the Discover and ACDF groups in both single ($p=.25$, $\chi^2=1.32$) and double-level cases ($p=.4$, $\chi^2=0.69$).

CONCLUSIONS: The adjacent segment ROM and the incidence of radiographic adjacent-level changes in patients undergoing ACDF were higher than those undergoing Discover artificial disc replacement. The cervical mobility was relatively well maintained in the Discover group compared with the ACDF group, and the Discover cervical disc arthroplasty can be an effective alternative to the fusion technique.

Keywords: Cervical arthroplasty; Anterior cervical discectomy and fusion; Discover artificial disc prothesis; Comparative clinical study; Cervical degenerative disease

Introduction

The cervical total disc replacement is designed to preserve segmental motion, and this technique is becoming more and more popular as an alternative to the so-far gold standard in the surgical treatment of degenerative disc disease, for example, anterior cervical discectomy and fusion (ACDF) [1,2]. The primary disadvantage of ACDF is that it converts a functionally mobile, mechanically stable spinal unit into a fixed, nonfunctional unit. Analysis of the strain distribution of intervertebral discs after anterior cervical disc fusion has shown an increase in longitudinal strain, most frequently at the levels immediately adjacent to the fused segment [3]. Many reports have shown evidence of the development of junctional degeneration adjacent to fused levels due to increased biomechanical stress [3–7] and the compensatory increase in motion at the adjacent level resulting from the reduced physiologic motion of the spine after fusion [8,9]. In addition to the adjacent-segment degeneration, other complications such as nonunion graft migration and kyphotic malunion have also been reported [10–13].

Compared with ACDF, cervical disc arthroplasty offers several theoretical and obvious advantages [14] and has gained attention as an alternative to traditional arthrodesis. The cervical artificial disc prosthesis can be used to restore and maintain mobility and function of the involved cervical spinal segments [15,16]. The Discover artificial cervical disc (DePuy Spine, Raynham, MA, USA) is an advanced, unconstrained prosthesis that is designed to allow motion similar to the normal cervical spine functional unit, following surgery for symptomatic cervical disc disease (Fig. 1). It consists of two end plates constructed from titanium alloy and a polyethylene core and has a fixed core ball-and-socket design with objectives to provide sufficient implant range of motion and maintain physiologic range of motion at treated level.

Results of biomechanical study have shown that the Discover disc at two levels can provide near-normal mobility at both levels without destabilizing the implanted segments or affecting adjacent segment motions [17]. In addition, good clinical and radiological results have been reported in a series of 25 patients, who underwent cervical arthroplasty using Discover disc, with an average follow-up period of 15.3 months [18]. However, the clinical efficacy of the Discover disc cannot be definitively determined without comparing with ACDF group and the small number of patients in this study may decrease the power of test. Therefore, we conducted this novel study to compare the clinical and radiologic outcomes of ACDF and Discover cervical disc arthroplasty in single and bi-level cases. We also aim to answer the question whether cervical artificial disc replacement is more efficacious and safer than the fusion in patients with clinical symptoms due to disc degeneration.

Materials and methods

This clinical study has been approved by the institutional review board of our hospital and every patient has signed the consent form before participating in this study.

In our study, patients inclusion criteria include symptoms of radiculopathy and/or myelopathy, not responding to conservative treatment for greater than or equal to 6 weeks and objective evidence of cervical disc disease at one or two vertebral levels between C3–C7. Exclusion criteria include congenital or post-traumatic deformity, infection, tumor, metabolic bone disease, severe multilevel cervical disc degeneration, medical history of fusion procedure at any level (C1–C7), allergy to the metal alloy or polyethylene, and any serious general illness (eg, heart failure, HIV) and a follow-up period less than 12 months.

The eligible patients were allocated into different treatment groups according to the patient's conditions. The patients with cervical instability (translation >3 mm and/or >11° rotational difference to that or either adjacent level), facet joint degeneration, severe spondylosis (bridging osteophytes, disc height loss >50%, and absence of motion <2°), and osteoporosis/osteopenia were considered inappropriate for the artificial disc replacement and were treated with fusion surgery.

Before surgery, patients were evaluated using static and dynamic cervical spine radiographs in addition to computerized tomography and magnetic resonance imaging. Static