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 processes 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

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


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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.

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.
acquired at 2 days postoperation and 2-, 6-, 12-, 24-month follow-up, respectively. On the standing lateral cervical x-ray, anterior disc heights and posterior disc heights were measured to determine the heights at the operative segment before and after operation, whereas the range of motion (ROM) of the operative segment was calculated by the difference of interbody angle on flexion-extension lateral x-ray imaging using the Cobb technique (Fig. 1). The performance of heterotopic ossification (HO) was observed by two independent MD in the follow-up.

Statistical analysis

Data were analyzed using SAS version 9.2 (SAS Institute Inc., Cary, NC, USA). The paired t test was used to assess the difference of aimed outcomes before and after operation. A p value of <.05 was considered as significant.

Table 1
Distribution of segments implanted with Discover prosthesis

<table>
<thead>
<tr>
<th>Cervical segments</th>
<th>No. of Discover prosthesis (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>C3–C4</td>
<td>5 (5)</td>
</tr>
<tr>
<td>C4–C5</td>
<td>32 (31)</td>
</tr>
<tr>
<td>C5–C6</td>
<td>48 (47)</td>
</tr>
<tr>
<td>C6–C7</td>
<td>17 (17)</td>
</tr>
<tr>
<td>Total</td>
<td>102 (100)</td>
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</tbody>
</table>

Table 2
Operation effect at 2-year follow-up according to the Odom criteria

<table>
<thead>
<tr>
<th>No. of patients (%)</th>
<th>Score</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>52 (65.8)</td>
<td>Excellent</td>
<td>All preoperative symptoms relieved. Neurologic deficits improved.</td>
</tr>
<tr>
<td>25 (31.6)</td>
<td>Good</td>
<td>Minimal persistence of preoperative symptoms. Neurologic deficits unchanged or improved.</td>
</tr>
<tr>
<td>2 (2.5)</td>
<td>Fair</td>
<td>Some preoperative symptoms improved. Others unchanged or slightly improved.</td>
</tr>
<tr>
<td>0 (0)</td>
<td>Poor</td>
<td>Preoperative symptoms unchanged or exacerbated.</td>
</tr>
</tbody>
</table>
1-year follow-up, including 4 Grade I and 2 Grade II. The occurrence of HO became common at the follow-up more than 2 years that we found HO performance in 18 replaced levels, including 8 Grade I and 10 Grade II. We observed no prosthesis displacement and had no revision surgery. Typical imaging are shown in Figs 3 and 4.

Discussion

Fernstrom spherical endoprostheses have been the first artificial discs implanted in humans in the 1960s. Fernstrom reported the use of these devices in the cervical [13]. Modern cervical artificial disc replacement first made its debut in 1991, with the Bristol/Cummins disc, the first of numerous articulating CDR devices. The original devices were implanted by Cummins in 20 patients, who later reported that some continued to function well, up to 12 years after implantation [14]. The past 10 years has seen the development of CDR in an attempt to overcome some of the shortcomings of ACDF. Despite the relative short-term outcomes documented in the literature, the increasing acceptance of CDR is primarily supported by the concept that maintaining treated segment and cervical spine mobility could achieve, with time, better protection of adjacent levels than fusion. Overall results of CDR implantations are satisfactory and promising. Level I and Level II evidences suggest equivalence in clinical results between CDR and ACDF. Furthermore, Level I evidence suggests lower revision rates and quicker return to work with CDR versus ACDF. Mummaneni et al. [15] reported on the Prestige ST prospective, randomized, multicenter IDE trial. In total, 541 patients with mono-segment disease were enrolled, with 276 patients receiving CDR with Prestige ST and 265 patients treated with ACDF. In total, 80% of the investigational patients and 75% of the fusion patients were available for follow-up at 2 years. The study showed better clinical results in the CDR group, although they did not reach clinical significance. There was a statistically significant lower rate of surgery for adjacent segment disease, with 1.1% of disk replacement patients requiring surgery versus 3.4% of the ACDF patients. The patients of CDR group were able to return to work sooner compared with

Fig. 2. Evolution of the flexion/extension range of motion at the operative segment preoperatively and more than 2 years of postoperative follow-up. Results are expressed as mean±SEM at each time-point. SEM, standard error of the mean.
the ACDF patients. Nabhan et al. [16] evaluated 49 patients who either underwent Prodisc-C disc replacement or ACDF in a randomized, controlled series. After 1 year’s follow-up, both groups improved clinically with no statistical significance, and both groups lost some cervical segmental ROM, with ACDF patients losing significantly more segmental motion. Murrey et al. [17] reported the results from the ProDisc-C IDE study. In total, 209 patients were enrolled, with 103 receiving the disk replacement and 106 undergoing ACDF. From both groups, we obtained similarly improved NDI scores and VAS scores showing neurologic successes. A significant difference was observed in reoperation rates: with 8.5% in the ACDF patients versus 1.8% in the disc replacement group. The primary clinical results in our series of 79 patients treated with Discover prosthesis are similar to published studies on CDR. We believe that removing the compressive materials thoroughly is the most important factor to improve the symptoms. We not only removed the herniated disc of the target segment but also resected the posterior longitudinal ligament as regular. Another explanation is that resection of posterior longitudinal ligament may increase ROM in CDR [18,19].

Rebuilding the intervertebral disc height after discectomy is an important factor to restore the cervical lordosis. In this study, the preoperative intervertebral disc height was more than 3 mm and was significantly higher after CDR. There was no prosthesis subsidence and shifting in the follow-up. Peng et al. [20] advocated that patients with greater disc collapse of less than 4 mm preoperative disc height benefit more in ROM after CDR, but the optimal postoperative disc height range to maximize ROM is between 5 and 7 mm.

A heightened awareness of the risk of dysphagia after anterior approach to the cervical spine arose during the past decade. Segebarth et al. [21] evaluated patients for dysphagia who were enrolled in the ProDisc-C IDE study. There were 38 patients in the CDR group and 38 in the ACDF group. After 1 year’s follow-up, the incidence of dysphagia was much lower in the CDR group than that of the ACDF group (15.8% vs. 42.1%). Although the etiology of dysphagia is multifactorial, the anterior plate used in ACDF was thought to be an important risk factor. Recent studies evaluating plate design suggest that a lower, smoother anterior profile may correlate with reduced incidence of dysphagia following ACDF [22,23]. The Discover prosthesis has no profile, which could avoid stimulating the esophagus directly and mitigating the adhesions of the esophagus. The incidence of dysphagia in this study was lower than that of ACDF from the published articles, and no patient had chronic dysphagia. Another important factor may be the retraction pressure differences existing between ACDF and CDR. In a cadaveric study, intraesophageal pressure was significantly higher during insertion of anterior cervical plate compared with the insertion of the cervical disc prosthesis [24].

Ongoing data collection and increasing number of studies describe HO resulting in decreased mobility of the prosthesis. The McAfee classification of HO is widely used to
describe hyperostotic changes in the cervical spine [25]. In the published studies, the frequency of HO was varied with the different prosthesis and the length of follow-up period. Bertagnoli et al. [26] reported results of 27 ProdiscC patients with 1-year follow-up without any appearance of fusion. Later, the same author [27] observed a 9.4% incidence of HO among 117 patients treated with the same prosthesis and followed-up for more than 2 years. Leung et al. [28] described a 17.8% overall rate of HO occurrence with 6.7% being Grade 2 or 3 at 1-year follow-up evaluation of 90 of 100 available patients with single-level procedures in a multicenter series of Bryan disc implantations. The incidence of HO in our study was relatively low. Age is one of the important factors contributing to the low HO incidence, as older age has been reported as a risk factor for the development of HO [27]. In addition to this, the design characteristics of the Discover prostheses may also play an important role. Because of the short follow-up period and relatively small number of similar studies, the verdict that Discover results in a lower HO rate than other commonly used prostheses is yet to be determined.

Conclusion

The use of Discover prostheses in our study resulted in satisfactory clinical outcomes. The prostheses can be inserted safely in the process of CDR, restoring and maintaining interbody height, while preserving the motion of the treated segment. The incidence of postoperative dysphagia was low. Further studies are demanded to better understand the impact of CDR with Discover prosthesis, especially on the HO and adjacent segment degeneration, although the results reported in this article clearly showed initial safety and effectiveness from our patient sample.

References