Clinical and radiographic reports following cervical arthroplasty: a 24-month follow-up

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Abstract We reviewed patients with cervical disc prosthesis replacement for single-level cervical disc disease to evaluate its clinical effect and maintenance of cervical spine motion. Fifteen patients underwent Bryan artificial cervical disc replacement and were followed-up for at least 24 months. No neurological or vascular complications were observed during or after operation. JOA, VAS, and NDI scores showed statistical significant improvement in our follow-up. The procedure achieved an 87% (13/15) satisfactory rate at 24-month evaluations according to Odom's criteria. The range of motion (ROM) of the cervical spine, treated segment, adjacent segment, and functional spinal unit (FSU) decreased at early follow-up, but they recovered to the preoperative level at 12- and 24-month follow-up. Also, preoperative lordosis of the cervical spine and FSU were not only maintained but also even improved during the 24-month follow-up. No obvious degeneration of adjacent discs were found at MRI. There were no cases of prosthesis subsidence or extrusion. The cervical disc prosthesis showed a good clinical outcome; it also restored ROM of the cervical spine and reestablished cervical curvature in our 24-month follow-up. But to be sure of its long term effect, a longer follow-up is needed.

Résumé Nous avons revu les patients ayant bénéficié d'une prothèse cervicale de disque, placée à un seul niveau ceci afin d'évaluer le bénéfice clinique et la persistance de la mobilité cervicale. 15 patients ayant bénéficié d'une prothèse de disque de type Bryan ont été suivis avec un

minimum de 24 mois. Aucune complication neurologique ou vasculaire n'a été observée durant l'intervention. Le score de la JOA et le score douleur VAS et le score NDI ont montré de façon significative une amélioration au dernier suivi de ces patients, le taux de satisfaction étant de 87% (13/15) à 24 mois selon les critères de Odomi. La mobilité de la colonne cervicale (FSU) après une limitation passagère précoce est entièrement récupérée à un niveau identique au niveau pré-opératoire entre 12 et 24 mois de suivi. La lordose préopératoire de la colonne cervicale et la mobilité segmentaire FSU non seulement sont maintenues mais sont aussi améliorées durant ces 24 mois de suivi. Nous n'avons pas observé de dégénérescence des disques adjacents à la prothèse discale à l'IRM. Il n'y a pas eu de tassements ou d'extrusion de la prothèse discale. Cette prothèse et les disques cervicaux ont un bon devenir clinique qui permettent de restaurer la mobilité de la colonne cervicale, de rétablir la courbure cervicale à 24 mois de suivi, mais néanmoins, un suivi à long terme est nécessaire.

Introduction

Treatment of degenerative cervical disc disease with anterior cervical discectomy and interbody fusion (ACDF) has been the classic method, but fusion may result in the loss of range of motion (ROM) of the cervical spine and accelerate degeneration of the adjacent cervical disc. Artificial cervical disc replacement, as in arthroplasty elsewhere, could restore ROM of the treated segment. Theoretically, it could prevent accelerated degeneration of adjacent segments. Many authors have reported its clinical outcome, but ROM of the cervical spine and cervical curvature after cervical prosthesis replacement were minimally reported. We retrospectively reviewed 15 patients

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who had undergone cervical prosthesis replacement to study its clinical outcome and its effect on restoring ROM of the cervical spine.

Materials and methods

Fifteen patients with single-level degenerative disc disease from C3 to C7, ten males and five females, underwent Bryan disc prosthesis replacement (Medtronic Sofamor Danek, Memphis, TN). There were three C3/4 replacements, five C4/5, six C5/6, and two C6/7. The average age was 45.4 years, ranging from 35 to 63. The course of disease ranged from two to 22 months, with an average of 16.3 months. The operation time was 140 ± 30 minutes. All patients were asked to wear cervical support for one month. The average follow up time was 29.5 months, ranging from 24 to 35 months. All patients received systemic conservative treatment before operation, but the symptoms worsened gradually. Patients with kyphotic cervical spine were excluded the other factors that excluded patients from eligibility for this surgery, such as osteoporosis and osteopenia or other bone metabolic diseases, posterior facet arthropathy, severe myelopathy due to posterior vertebral body spinal cord compression, chronic infections, tumour, metabolic or systemic disease, or pertinent metallic allergies. All patients were evaluated preoperatively and at one, three, six, 12, and 24 months postoperatively. JOA, VAS, NDI, and Odom's criteria were used to assess clinical outcomes. Static and dynamic radiographs were measured to determine the ROM of the cervical spine, treated segment, adjacent segment, and functional spinal unit (FSU). CT and MRI were measured at 12 and 24 months

postoperatively to see if there were signs of prosthesis subsidence or extrusion, heterotopic ossification, and spinal cord or nerve root recompression.

Cervical curvature was calculated using the Cobb's angle method between the inferior margin of C2 and C7 vertebral bodies in a neutral position (Fig. 1). The ROM of the cervical spine was defined as the difference in the Cobb's angle between full flexion and extension. To analyse movement at the level of the proposed arthroplasty, we examined the FSU angle [19]. The FSU angle was formed by lines drawn at the superior margin of the superior vertebral body and at the inferior margin of the inferior body in a neutral position. ROM of the FSU was defined as the difference in the FSU angle between the full flexion and extension (Fig. 2). The treated segment angle was also used to analyse movement of the diseased segment. It was formed by lines drawn at the inferior margin of the superior vertebral body and at the superior margin of the inferior body, and postoperatively the margin was the shell of the cervical disc prosthesis. ROM of the treated segment was defined as the difference in the treated segment angle between full flexion and extension. Similar calculations were made for ROM of the adjacent segment. Paired *t* test was carried out with significance level of 0.05 using SPSS version 16.0.

Results

Clinical outcome

The average JOA score before operation was 8.6, with an average score of 12.0 one month postoperative, 14.4 at 12 months postoperative, and 14.9 at 24 months postoperative.

Fig. 1 The cervical lordotic angle and the FSU lordotic angle were measured on the lateral radiograph

Fig. 2 ROM of the cervical spine, FSU, treated segment, and adjacent segments were measured on the lateral dynamic radiographs

All differences had statistical significance between preoperative and one month, 12 months, and 24 months postoperative ($p < 0.05$ paired t test). The average VAS before operation was 7.0, with 4.2 at one month, 2.3 at 12 months, and 2.4 at 24 months postoperative. All differences had statistical significance ($p < 0.05$ paired t test) except between 12 and 24 months postoperative ($p > 0.05$ paired t test). The average NDI before operation was 23.0, at one month 16.8, at 12 months 9.6, and at 24 months postoperative 8.9. All differences had statistical significance ($p < 0.05$ paired t test) except between 12 and 24 months postoperative ($p > 0.05$ paired t test). According to Odom's criteria, six was scored as *excellent*, seven scored as *good*, two as *fair*, and zero as *poor* at 12-month follow-up. At 24-month follow-up, nine were scored as *excellent*, four scored as *good*, two as *fair*, and zero as *poor*.

Radiographic analysis

1. ROM of the cervical spine was $68.8 \pm 6.7^\circ$ preoperatively, $60.6 \pm 6.4^\circ$ one month postoperatively, $70.2 \pm 5.9^\circ$ 12 months postoperatively, and $69.6 \pm 4.8^\circ$ 24 months postoperatively. The ROM decreased at one-month follow-up ($p < 0.05$ paired t test), but recovered to the preoperative level at 12- and 24-month follow-ups ($p > 0.05$ paired t test).
2. ROM of the FSU was $13.0 \pm 2.2^\circ$ preoperatively, $9.8 \pm 1.3^\circ$ one month postoperatively, $12.8 \pm 1.7^\circ$ 12 months postoperatively, and $13.0 \pm 1.7^\circ$ 24 months postoperatively. The ROM decreased at one month follow-up ($p < 0.05$ paired t test), but recovered to the preoperative level at 12- and 24-month follow-ups ($p > 0.05$ paired t test).
3. ROM of the treated segment was $10.4 \pm 2.7^\circ$ preoperatively, $8.8 \pm 1.8^\circ$ one month postoperatively, $10.8 \pm 1.9^\circ$ 12 months postoperatively, and $10.9 \pm 2.0^\circ$ 24 months postoperatively. The ROM decreased at one month follow-up ($p < 0.05$ paired t test), but recovered to the preoperative level at 12- and 24-month follow-ups ($p > 0.05$ paired t test).
4. ROM of the upper and lower levels were $12.9 \pm 1.9^\circ$ and $11.8 \pm 1.4^\circ$ preoperatively, $9.8 \pm 1.4^\circ$ and $9.5 \pm 1.3^\circ$ one month postoperatively, $12.7 \pm 1.7^\circ$ and $11.5 \pm 1.7^\circ$ 12 months postoperatively, and $13.0 \pm 2.0^\circ$ and $11.8 \pm 1.5^\circ$ 24 months postoperatively. The ROM decreased at one month follow-up ($p < 0.05$ paired t test), but recovered to the preoperative level at 12- and 24-month follow-ups ($p > 0.05$ paired t test).
5. The cervical curvature was $17.2 \pm 6.9^\circ$ preoperatively, $20.6 \pm 7.7^\circ$ one month postoperatively, $30.4 \pm 9.9^\circ$ 12 months postoperatively, and $30.8 \pm 9.8^\circ$ 24 months postoperatively. The cervical lordotic angle increased postoperatively ($p < 0.05$ paired t test), but there were no obvious changes 12 months later and the differences between 12 and 24 months postoperative had no statistical significance ($p > 0.05$ paired t test). Thus, the change occurred shortly following operation.
6. The FSU angle was $5.5 \pm 2.4^\circ$ preoperatively, $7.2 \pm 2.3^\circ$ one month postoperatively, $10.7 \pm 2.9^\circ$ 12 months postoperatively, and $10.5 \pm 2.8^\circ$ 24 months postoperatively. The FSU angle increased postoperatively ($p < 0.05$ paired t test), but there were no obvious change 12 months later and the differences between 12 and 24 months postoperative had no statistical significance ($p > 0.05$ paired t test). Thus, this change also happened shortly following operation.

7. No prosthesis subsidence, extrusion or heterotopic ossification were found at 12- and 24-month CT. There was also no recompression of the spinal cord or nerve root at 12- or 24-month MRI.

Discussion

Treatment of cervical disc disease with anterior cervical decompression and fusion (ACDF) has been the classic method, but numerous authors suggest that ACDF may result in the loss of range of motion of the cervical spine and accelerate degeneration of the adjacent cervical discs. Patients who have undergone ACDF may display radiographic and clinical evidence of progressive degeneration. Long-term radiographic follow-up review in patients with ACDF has demonstrated hypermobility and degenerative changes in the nonfused segments of the spine, including disc space narrowing, endplate sclerosis, and osteophyte formation [4, 7, 10, 23, 24]. Weinhoffer et al. [22] found that about 73% and 45% increase in intradiscal pressure at levels cephalad and caudad to fusion segment, respectively. Hilibrand et al. [11] found that about 2.9% of patients needed a second operation each year due to complications with adjacent segments after anterior interbody fusion, with a predicted rate of 25.6% at ten years. Although several authors have demonstrated radiographic degeneration with no clinical correlation [6, 8, 12, 17], Gore and Sepic [10] found an association between recurrent cervical pain and progression of spondylosis.

Cervical disc prosthesis is designed to restore normal spinal motion after anterior discectomy and avoid degeneration of adjacent segments [2]. Different types of prostheses have been introduced, such as Prestige, Bryan, and ProDisc-C. The Bryan cervical disc prosthesis consists of a low-friction polyurethane nucleus surrounded by a polyurethane sheath and situated between two titanium alloy shells. The biarticulating metal-on-polymer disc exhibits elasticity and little compressibility and allows for unconstrained motion and translation through normal ROM. The prosthesis is axially symmetrical, allowing for similar ROM in sagittal plane motion and in lateral bending. In 2002, Goffin et al. [9] first reported that the Bryan disc was successfully used for treatment of cervical radiculopathy and achieved 85–90% satisfactory rate in 12-month follow-up. In that same study, sagittal plane motion was preserved in 88% of patients treated with single-level and 86% of patients with two-level prostheses after one year. Anderson et al. [3] studied this group of patients for a longer follow-up and reported that 45 of 73 (62%) single-level patients with two-year follow-up had *excellent* out-

comes, with seven patients scoring *good*, 13 *fair*, and eight *poor*. Sagittal plane motion remained present in 88% of patients after two years. Many other authors also have had encouraging reports [15, 18, 20, 21].

In our study, 100% of patients with single-level arthroplasty demonstrated a good clinical outcome. JOA, VAS, and NDI scores improved, and an 87% satisfactory rate was achieved at 24-month follow up. In fact, the early clinical improvements were mostly due to surgical decompression and recovery of function of the spinal cord and nerve root but not directly due to the Bryan cervical disc prosthesis or anterior cervical discectomy and fusion. But the effect of the prosthesis is necessary—it can help to restore ROM of the cervical spine and prevent accelerated degeneration of adjacent segments. Radiographic results show that ROM of the cervical spine, treated segment, adjacent segment, and FSU decreased one month postoperatively, and the differences had statistical significance. This may be because of neck pain or patients' noncompliance to the wearing of the cervical support. But with time, ROM recovered to preoperative levels ($p > 0.05$ paired t test) as seen at 12- and 24-month follow-ups. In terms of maintaining normal ROM of the cervical spine and its structure sharing the loads, the prosthesis would not change load distribution of the cervical spine and would not accelerate degeneration of adjacent segments. Chang et al. [5] reported that artificial cervical discs can maintain adjacent-level intra-discal pressure near preoperative values in all modes of motion through a cadaveric study. But there is still no adjacent intradiscal pressure measured in vivo.

Although the ROM is an important feature of an artificial disc, it is only a single measure of spinal biomechanics. Cervical curvature is another important feature. In 2001, Katsuura et al. [13] found that degeneration of adjacent levels was significantly associated with loss of physiological cervical lordosis. Cervical lordotic angle and FSU lordotic angle were larger postoperatively than preoperatively, and the difference had statistical significance. A cervical disc prosthesis helps to reestablish lordotic curvature of the cervical spine and FSU. No obvious postoperative kyphosis was seen in our study. Although the cervical disc prosthesis is not designed to correct kyphosis, it can help to reestablish cervical curvature. Yoon et al. [25] reported a good clinical outcome in late follow-up, and that ROM of the whole cervical spine, FSU, and adjacent segments were preserved. Also, the sagittal alignment of the cervical spine showed kyphosis after surgery but restored lordosis at a later time. They hypothesised that the postoperative kyphotic influencing factors included over-milling at the dorsal endplate, the angle of Bryan disc insertion, structural absence of lordosis in the Bryan disc, surgical procedure to remove the posterior longitudinal ligament, and preexisting kyphosis.

But to decompress completely, we always remove the posterior longitudinal ligament. Kim et al. [14] reported a good clinical outcome postoperative, but preoperative lordosis of the cervical spine and the FSU were partly maintained during follow-up. Our study shows that the preoperative lordosis of the cervical spine and the FSU were not only maintained but also even improved during the 24-month follow-up. Based on our observations, we presumed that the lordotic change of the cervical curve may be the result of the cervical disc prosthesis which is not designed to correct kyphosis through the three following paths.

1. Cervical pain relief after operation.

The main reason for the cervical spine becoming straight is spasm of cervical muscles responding to pain which drags the cervical vertebrae anteversion. NDI and cervical pain decreased sharply postoperatively relaxing the cervical muscles and decreasing the anteversion force.

2. Change of biomechanics of the cervical spine.

The degenerated disc protrudes into the vertebral canal, and the front of the inter-vertebral space is empty; thus, it cannot sustain the normal pressure. As compensation, the cervical spine becomes straight. The cervical disc prosthesis replaces the degenerated disc, and the biomechanics of the cervical spine recover to normal.

3. Keeping cervical flexion posture to relieve pain.

When the cervical spine is extended, the degenerated disc protrudes severely to the canal. But when the cervical spine is flexed, the disc returns to the inter-vertebral space and the compression of the spinal cord or nerve is decreased. After cervical disc arthroplasty, patients can flex and extend freely.

Heterotopic ossification (HO) following total disc prosthesis replacement is reported by many authors. Leung et al. [16] reported a 17.8% (16/90) HO rate, and found that male sex and older patients were two factors associated with development of HO. In our study, only one patient had HO, and it did not affect cervical prosthesis movement. Possible reasons for HO may include residual bone dust left at the operative site and muscle damage [1]. Thus, we should try our best to clean the operative site with normal saline and limit retraction damage to cervical muscles. NSAIDS may prevent HO, but have side effects and should be used with caution.

CT and MRI results did not show obvious cervical prosthesis subsidence or excursion nor recompression of the spinal cord or nerve root. Choosing appropriate prosthesis size and insertion position should prevent its subsidence or extrusion, because these affect stability of the prosthesis and alter the axis of rotation and load sharing. Osteoporosis is also an important reason for subsidence or extrusion. No obvious degenerative changes of adjacent segments were seen from the 12- and 24-month MRI results.

Our study has some limitations, it dose not have a control group, and the lateral bending and axial rotation are not analysed. Only single-level disc disease was included, and patients with cervical kyphosis were excluded. We still do not know its effect in those kyphotic patients. Adjacent level intradiscal pressure and facet joint force are not measured. In any event, the follow-up time is not long enough.

At 24-month follow-up, the artificial cervical disc prosthesis replacement not only had a good clinical outcome, but it also restored ROM of the cervical spine and cervical curvature and prevented accelerated degeneration of the adjacent segments. But to make sure of its long-term effect, a longer follow-up is needed.

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