

Anterior Cervical Interbody Fusion with the Carbon Composite Osta-Pek Frame Cage in Degenerative Cervical Diseases

Kwang Wook Han, M.D., Joon Soo Kim, M.D., Kyu Hong Kim, M.D.,
Yong Woon Cho, M.D., In Chang Lee, M.D., Sang Do Bae, M.D.

Department of Neurological Surgery, Masan Samsung Hospital, School of Medicine, Sungkyunkwan University, Masan, Korea

Objective : Different types of interbody fusion cages are available for use in the surgical treatment of degenerative cervical diseases. The purpose of this study is to assess the technical feasibility, clinical efficacy and radiological results of intervertebral fusion with a carbon composite Osta-Pek frame cage (Co-Ligne AG, Switzerland) following anterior cervical discectomy.

Methods : 41 patients (25 males and 16 females) with minimum 6 months follow-up were included in the study. Disc height, cervical lordotic angle, segmental angle, and fusion rate were assessed by lateral radiographs. In this retrospective analysis, clinical outcome was assessed as evaluated according to Odom's criteria.

Results : Fifty-four cages were implanted in 30 single-level, 9 two-level, and 2 three-level procedures. The mean disc height, cervical lordosis angle, segmental angle were 4.2 ± 1.8 mm, $23.5 \pm 7.2^\circ$, $2.3 \pm 3.3^\circ$ pre-operatively and 5.3 ± 2.1 mm, $24.2 \pm 8.3^\circ$, $3.8 \pm 3.5^\circ$ at 6 months after the surgery. Six months after surgery, there was radiographic evidence of fusion in 92.7% (38/41) of the patients. According to Odom's criteria, 37 of 41 (90.2%) patients experienced good to excellent functional recovery.

Conclusion : These clinical and radiological results suggest that the carbon composite Osta-Pek frame cages are safe and effective alternative to autologous bone graft after anterior cervical discectomy for treatment of degenerative cervical disease.

KEY WORDS : Interbody fusion · Carbon cage · Osta-Pek · Anterior cervical discectomy.

Introduction

The anterior approach to nerve root decompression and interbody fusion, a surgical treatment for the degenerative cervical disease, enables direct approach to remove herniated disc and fuse bones to prevent recurrence and degenerative change thus it is the most widely used surgical method and especially in cases of monosegment, there has been many reports of successful autograft without the internal fixation^{1,6,13,15,29}.

However, reports of displacement or collapse of graft fragment, change in the cervical angle, or pain from the donor site lead to many studies to find a stable material to obtain sufficient disc space and spinal stability and reduce donor site related complications^{2,14,28,34,36}.

This study analyzes radiological findings and shows the clinical efficiency and applicability of the anterior approach using a carbon composite Osta-Pek frame cage, as a bone replacement, for the interbody fusion.

Materials and Methods

Between October 2001 to March 2004, 55 patients with degenerative cervical disease to underwent anterior discectomy and interbody fusion with carbon composite Osta-Pek frame cage (Co-Ligne AG, Switzerland). Among them, 41 patients could be follow up for at least 6 months thus able to report their cases to be analyzed using clinical data, and radiological findings in this retrograde study. Radiological images were taken before, just after, a month, 3 months and 6 months after each operation to measure the degree of cervical lordosis, segmental lordosis, and disc space height. The gore angle was used to determine the degree of the cervical lordosis, which is created by two hypothetical lines drawn from the posterior side of the second cervical vertebra to that of the 7th vertebra¹³. The height of disc space was the distance between

- Received : October 29, 2004 • Accepted : January 24, 2005
- Address for reprints : Joon Soo Kim, M.D., Department of Neurosurgery, Masan Samsung Hospital, School of Medicine, Sungkyunkwan University, 50 Hapseong 2-dong, Masan 630-522, Korea
- Tel : +82.55-290-6183, Fax : +82.055-290-6899
- E-mail : nkalzabi@netian.com

the mid-point of two endplates surrounding the fusion site in the lateral cervical radiograph. The degree of segmental lordosis was measured by the angle drawn that two perpendicular lines of the upper and lower endplates of fused segment.

Six months After the operation, the lower density between the bone graft and vertebra, existence of trabecular bridging ossification, the mobility of space in flexion-extension radiographs were taken to determine the successfulness of the bony fusion (Table 1).

All the cases were done in Smith-Robinson method and the size of cage to be inserted were determined by that length measured from the radiograph. To encourage the bone union, in initial 17 cases, the bone material used to fill the cage were taken from the patient's own iliac crest, the later 24cases used commercialized allograft to avoid graft-site complications. The patients started walking on 2nd to 3rd day of the operation wearing soft prosthetics for 3months. The clinical outcome of the surgery were measured using the Odom's criteria and were categorized into excellent, good, fair, and poor²⁵⁾ (Table 2).

Results

Clinical findings

The age distribution was from 34 to 70years old with mean age of 47.5. There were 25cases of male and 16cases of females. There were 14 cases each from 30's and 50's then over 60', 40's and there were no one under 30. At the time of admission, 28 cases were diagnosed as cervical radioculopathy, 9cases of myelopathy and 4cases with both of the symptoms. There were 30cases of monosegment which was the most common type, 9cases of bisegments, and 2cases of trisegments out of 54 total number of segments. In 28cases, the surgery was performed the C5-6 level.

Radiological results

The average height of disc space was 4.2 ± 1.8 mm before the surgery, 6.7 ± 1.6 mm, an increase in 159%, just after the surgery, then progressively decreased to 6.2 ± 1.8 mm at 1month, 5.8 ± 1.9 mm at 3months, and 5.3 ± 2.1 mm, an overall increase in 126% compared to the height before the surgery at 6 months after the surgery

The average angle of the cervical lordosis was $23.5 \pm 7.2^\circ$ before the surgery and decreased to $20.3 \pm 5.1^\circ$ just after the surgery, and then progressively increased to $22.8 \pm 7.5^\circ$ at 1month, $23.2 \pm 7.7^\circ$ at 3months, and $24.2 \pm 8.3^\circ$, an overall increase in 103% compared to the angle before the surgery at 6months after the surgery.

The average angle of the segmental lordosis was $2.3 \pm 3.3^\circ$

Table 1. Criteria of fusion status

Good : No motion on flexion/extension radiographs, no radiolucent zones between the graft and vertebrae, and trabecular bridging at both endplates
Average : No motion on flexion/extension radiographs, no radiolucent zones between the graft and vertebrae
Poor : Motion on flexion/extension radiographs, radiolucent zones between the graft and vertebrae, and no trabecular bridging at both endplates

Table 2. Criteria of clinical results (by Odom. et al²⁵⁾)

Excellent : Complete relief of symptoms with full activity
Good : Partial relief of symptoms with full activity
Fair : Improvement but limitation of activity
Poor : No Improvement or deterioration after surgery

before the surgery, $5.3 \pm 2.1^\circ$, an increase in 230%, just after the surgery, then progressively decreased to $4.9 \pm 2.8^\circ$ at 1month, $4.6 \pm 2.9^\circ$ at 3months, decreased to $3.8 \pm 3.5^\circ$, an overall increase in 165% compared to the angle before the surgery at 6 months after the surgery.

We decided the surgery to be successful if scored Good or Average and there were 24cases that scored good and 14cases of average, and 3cases of poor thus fusion rate was 92.7%.

Clinical results

The clinical outcome of the surgery was determined by the Odom's criteria and patients with either excellent or good categories were able to function normally at home and work thus accepted as a successful group. There were 21cases (51.2%) that fit into excellent group, 16cases (39.0%) of good, 3cases (7.3%) of fair and 1case with trisegments of poor group thus the successful rate was 90.2%.

Complications

Post-operative complications included 1case of temporary dysphagia, 1case of mild graft migration, 2 out of 3cases of hoarseness later improved but 1cases did not. Four cases out of 17cases which received autograft complained of pain at the donor site but alleviated within 6months. There were 5 cases of the transplanted cage sunk into the vertebra body which only occurred in patients with multisegments.

Discussion

Herniated intravertebra disc is a result of the age related degeneration, that is intravertebral disc undergo biological and morphological changes causing cervical pain, neurological symptoms, or dysfunctional spine and there are two types of treatments. There are conservative treatments such as rest, physical therapy, or administration of non steroid anti-inflammatory drugs and surgical treatment. Surgical treatment include only disectomy through the anterior approach, combination of

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removal and inter-body fusion method, and laminectomy and laminoplasty through the posterior approach. Especially disectomy and interbody fusion using the anterior approach is relatively easy approach with less amount of blood loss, good operative field and less restraint on post-operative spinal mobility are some of the advantages to the approach thus the most common method to be used^{11,33}.

Since the introduction of the anterior approach to the cervical spine in 1955 by Smith and Robinson³², the procedure was continuously modified by Cloward¹⁰, Bailey² and other authors. However, in the case of cervical fracture, anterior approach by itself result in migration of graft material, developed kyphotic deformity thus Bohler et al⁵ performed internal fixation using H-shaped plate. During 1970s, Orozco and Liovert²⁶ used H-shaped plate to fixate internally and in 1986 Morscher et al²³ attempted fusion used cervical spine locking (CSLP) system. Currently various types of metal are being introduced. Comparing the internal fixation using an metal plate with bone graft without plate fixation, advantages are immediate stability to the spine, maintain normal cervical curvature, shortening the fusion time, prevent graft deformity however, there are complications including a screw loosening, recurrence of the instability due to screw fracture, esophageal perforation, swallowing difficulty or pain, soft tissue or nerve damage during the surgery, delay the surgical time, and limited post-operative spinal motion^{4,27,30}.

Some of the authors in case of degenerative cervical spondylosis and disc herniation involving a monosegment, did not perform the interbody fusion but just the disectomy and its result compared with ones with the interbody fusion method were not much difference in the clinical symptom while lowering the risk of complication thus denied the need for the metal plates^{16,38}. However, when performing disectomy without the interbody fusion, there is delayed complication of kyphotic deformity causing neck pain lasting long period of time, and narrowed vertebral disc, causing recurrence symptoms related to the narrowed neural foramen thus became less favorable and currently it is common to limit the treatment to soft disc herniation of monosegment²⁴.

Authors have different opinion as to whether or not performing the bone graft is necessary during the anterior approach to the degenerative cervical spondylosis but currently it is accepted that interbody fusion with bone graft regardless of the type of the graft material should be performed. These bone grafts was first attempted in early 1950s by Bailey & Badgely² by collecting the autograft from the iliac crest and Cloward¹⁰ used dowel type graft, Smith & Robinson³² used Tricortical iliac crest graft, Vail and Urbaniak³⁵ used fibular bone graft for the interbody fusion.

Despite the fact that using the autologous bone in interbody fusion demonstrates high fusion rate, infection or pain at the donor site, longer operative time are problems to be noted thus new methods using allograft, xenograft, and synthetic material were introduced. However, allograft has risk of immune reaction and infection, xenograft have lower rate of interbody fusion, thus replacement for the autograft with similar rate of fusion, lower risk of infection and maintain early spinal stability were studied thus synthetic materials such as hydroxyapatite implants, bone morphogenic protein, polymethylmethacrylate, biocompatible osteoconductive polymer, titanium discs, and ceramics titanium or carbon were introduced^{17,19,21,31,34}. In this study, the Osta-Pek frame cage which is a medical grade composite composed of long fiber carbon encapsulated in a PEKEKK (polyetherketone-therketoneketone) matrix were used during the surgery.

Carbon cage consisted of similar elasticity as the bone thus it is known to have stress shielding effect, and stimulated bone formation and improving the quality of fusion^{8,37} and in the animal studies, the cage enhanced the production of osteocalcin and activity of alkaline phosphatase, growth of fibroblast²⁰. In addition, the carbon cage is a wedged shaped which the anterior side of the cage is higher then its posterior side thus improving the spinal curvature to be more natural and have more high radiolucency thus it is easier than metal cage to determine the post-operative evaluation of interbody fusion.

Latest studies reported that the wedged shaped carbon cage compared to cage used in the cloward procedure the complication rate of kyphosis is lower, and higher anterior disc height³ and Vavruch et al³⁶ argued that the Carbon cage in the anterior interbody fusion were better then autograft in maintaining the disc height.

This study also showed that the degree of cervical lordosis increased when comparing before (average of 23.5) and 6 months (average of 24.2°) after the surgery. The height of the disc space increased from the initial average height of 4.2mm just after the surgery but decreased to 5.3mm 6months after the surgery, that is the height increased by 1.4mm on average. The fusion rate was 92.7% and in 3cases where the fusion did not occur but the symptom did not aggravate. According to Odom's criteria, 37 of 45 (90.2%) patients experienced good to excellent functional recovery thus should expect a good clinical result.

Hacker et al¹⁴ used only BAK/C cage which the success rate was similar to that of autograft with plate but reported that the surgical complication occurred as half as many (11.8% vs. 20.4%) and donor site complication was 3% compared to 67% that of autograft. Also Bartels et al³ reported that in patients with

monosegmental degenerative cervical spondylosis only used the cage without filling it with to prevent donor site complication which resulted in fairly good clinical outcome and maintained stability as well.

In addition, the procedure that used only the interbody fusion cage did not affect adjacent organs such as the esophagus thus were able to decrease the post-operative complications such as dysphagia.

The post-operative complications in this study include 1 case of dysphagia, 1 case of graft migration, 3 cases of hoarseness, and 4 cases out of 17 cases which received autograft complained of pain at the donor site but all were alleviated within 6 month period.

Kim et al¹⁸⁾ reported the height of disc space to be decreased more after the surgery in multisegments compared to monosegment but did not correlate with the clinical symptoms, and also Choe et al⁹⁾ reported that decreased in the height of the vertebral disc after the surgery did not affect the clinical outcomes after the surgery.

However, in this study there were 5 cases with partial descent of the cage at the graft-site and all went through multisegment operations and clinical symptom of one of them worsened. Therefore, when the operation must be performed on multisegments, the replacement material should be seriously examined and studied, and the need for additional use of internal fixation should be further studied in the future.

Conclusion

The authors concluded that by using the carbon composite Osta-Pek frame cage in anterior interbody fusion, the disc height is reserved while not requiring an additional internal fixation, and it has high fusion rate, and less donor site complications thus it is an effective therapy for the degenerative cervical diseases.

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