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Clinical and Radiologic Assessment for Anterior Cervical Interbody Fusion with Synthetic Cages

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Objective : This purpose of this study was to determine the clinical efficiency and applicability, and to analyze the radiologic findings of the anterior cervical approach using two synthetic cages for interbody fusion.

Methods : A total of 41 patients with cervical diseases underwent anterior discectomy and interbody fusion with the PEEK Solis™ cage in 21 patients and the carbon composite Osta-Pek™ cage in 20 patients. Outcome assessment was done using Odom's criteria. Radiological assessment was performed with respect to subsidence, bony fusion and lordosis. The mean follow-up period was 13 months.

Results : There were 34 (92.9%) successful cases. The average height of the disc space 12 months after surgery compared to the height before surgery was increased in 28 cases. The height of the disc space 12 months after surgery compared to the height just after surgery was decreased over 3mm in 4 cases, indicating severe subsidence. The use of these synthetic cages have provided the increase in postoperative cervical lordosis.

Conclusion : There were no significant differences between the Solis™ and Osta-Pek™ cages on clinical and radiologic outcomes. Both Solis™ and Osta-Pek™ cages showed low subsidences and complications associated with hardware with good clinical outcomes, high fusion rates, restored disc heights, and restored cervical lordosis.

KEY WORDS : Anterior cervical interbody fusion · Solis™ cage · Osta-Pek™ cage · Subsidence · Lordosis.

Introduction

Anterior cervical discectomy and fusion have undergone many technical modifications since their original description by Smith and Robinson[26] and then Cloward[6] in 1958. As a standard treatment for radiculopathy or myelopathy secondary to cervical spondylosis, modifications have largely been directed at minimizing the complications associated with interbody fusion[4,24,25].

The anterior approach to nerve root decompression and interbody fusion, a surgical treatment for the traumatic and degenerative cervical disease, enables a direct approach to remove a herniated disc and fuse bones to prevent recurrence and degenerative change; thus it is the most widely used surgical method especially in cases of monosegment, there have been many reports of successful autografts without the internal fixation[1,3,9-11,23].

More recently, this operation has undergone changes involving synthetic interbody cages with materials such as stainless steel, titanium, carbon fiber, and benzene ring polymers[18,25,29]. Cages have been used with iliac crest bone grafts or local autografts with bone substitutes, or no grafts at all[25]. However the use of metal cages has been associated with subsidence and loss of sagittal cervical spine balance, and radiologic confirmation of fusion is difficult.

This study was undertaken to determine the clinical efficiency and applicability and to analyze the radiologic findings of the anterior approach using a benzene ring polymer cage (Solis™) and a carbon fiber reinforced polymer cage (Osta-Pek™) for interbody fusion. We evaluated the clinical and radiologic outcomes according to cage type, site of cage placement, as well as the lordotic changes of the cervical spine curvature.

Materials and Methods

Between October 2003 to March 2005, 41 patients with cervical disease underwent anterior discectomy and inter-

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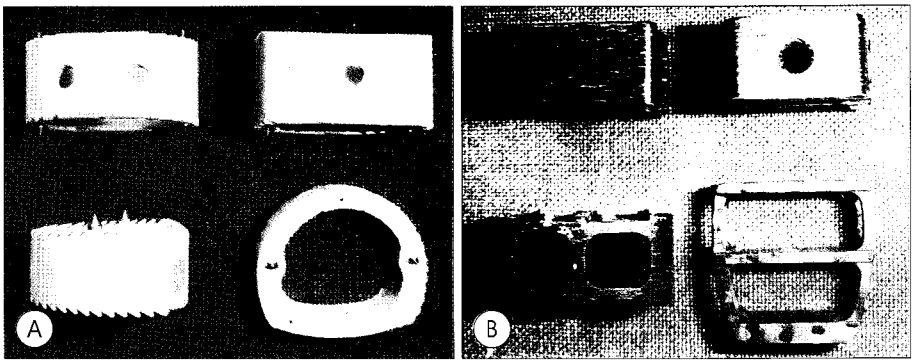

Fig. 1. A : The Solis™ cage has a hollow center, a convex superior surface, and 1mm titanium spikes bilaterally on both inferior and superior surfaces. B : The Osta-Pek™ cage has two hollow centers, but no bilateral spikes on either the inferior or superior surfaces. It is wedge-shaped where the anterior height of the cage is taller than its posterior height.

Table 1. Odom's criteria for assessment of clinical outcome

Result	Criteria
Excellent	All preoperative symptoms relieved
	Abnormal findings improved
Good	Minimal persistence of preoperative symptoms
	Abnormal findings unchanged or improved
Fair	Definite relief of some preoperative symptoms
	Other symptoms unchanged or slightly improved
Poor	Symptoms and signs unchanged or exacerbated

body fusion using the PEEK Solis™ cage (Stryker Spine, South Allendale, NJ) in 21 patients and the carbon composite Osta-Pek™ cage (Co-Ligne AG, Switzerland) in 20 patients. Indications for surgery included radiculopathy, myelopathy, and myeloradiculopathy.

Of the 41 patients, 28 were men and 13 were women. The mean age was 49 years (range 21-81 years). Thirty-three patients were presented with radiculopathy, 5 with myeloradiculopathy, and 3 with myelopathy. Single level fusion was accomplished in 24 patients, two-level fusion in 15 patients, and three-level fusion in 2 patients. The total accomplished fusion levels was 60 : C3/4 level in 5 levels (Solis™ 4 levels, Osta-Pek™ 1 level), C4/5 level in 15 levels (Solis™ 8 levels, Osta-Pek™ 7 levels), C5/6 level in 29 levels (Solis™ 14 levels, Osta-Pek™ 15 levels), C6/7 level in 11 levels (Solis™ 5 levels, Osta-Pek™ 6 levels).

In 21 cases, the Solis™ cervical interbody cage was used. This cage has a hollow center, a convex superior surface, and 1mm titanium spikes bilaterally on both inferior and superior surfaces. It is available with an internal anteroposterior diameter of 14 or 16mm and depths of 5, 6, or 7mm. The cage is radiolucent but has two markers to aid in identification of position on plain x-ray films (Fig. 1A).

In 20 cases, the Osta-Pek™ cage was used. This cage has two hollow centers, but no bilateral spikes on either the inferior or superior surfaces. It is wedge-shaped where the anterior height of the cage is taller than its posterior height. The OstaPek™ cage also has high radiolucency and has markers on plain x-ray films (Fig. 1B).

A standard anterior cervical discectomy was performed and the end plates were curetted to remove cartilage. The type of cage was selected randomly. Based on trial cages in the operative field, an appropriate-sized cage over disc space height was selected. To encourage bone union, an anterior iliac crest bone graft or local autograft with bone substitute (osteophyte) was performed randomly. The bone materials used to fill the cage were taken from the patients' anterior iliac crest and osteophytes around the involved disc space. The cages were then filled with bone dust by using an impactor and then inserted into the disc space.

All patients were followed up for at least 12 months and clinical data and radiological findings were analyzed retrospectively. The mean follow-up period was 13 months (range 12-24 months). Clinical assessment involved the use of Odom's criteria[21], which categorized the patients' status into excellent, good, fair, and poor (Table 1). Radiological images were taken before, just after and 12 months after each surgery to measure the degree of intervertebral disc height, cervical lordosis, and the site of cage placement. The height of the intervertebral disc was the distance between the mid-point of two end plates surrou-

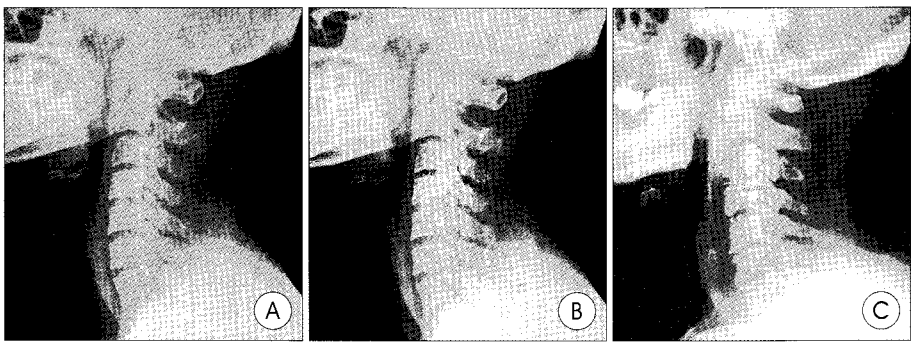

Fig. 2. A : The height of the intervertebral disc is the distance between the mid-point of two end plates surrounding the fusion site in the lateral cervical radiograph. B : The degree of cervical lordosis is measured by Profeta' s method, which uses the shortest distance from the posteroinferior side of the 4th cervical vertebra to a hypothetical line drawn from the posterior side of the second cervical vertebra to that of the 7th vertebra. C : 'Cage on the cortical bone' is defined when the distances from the anterior margin of the vertebral body to the cage were shorter than 2mm. 'Cage on the cancellous bone' is defined when the cage was placed more than 2mm inside the anterior cortical margin of the vertebral body.

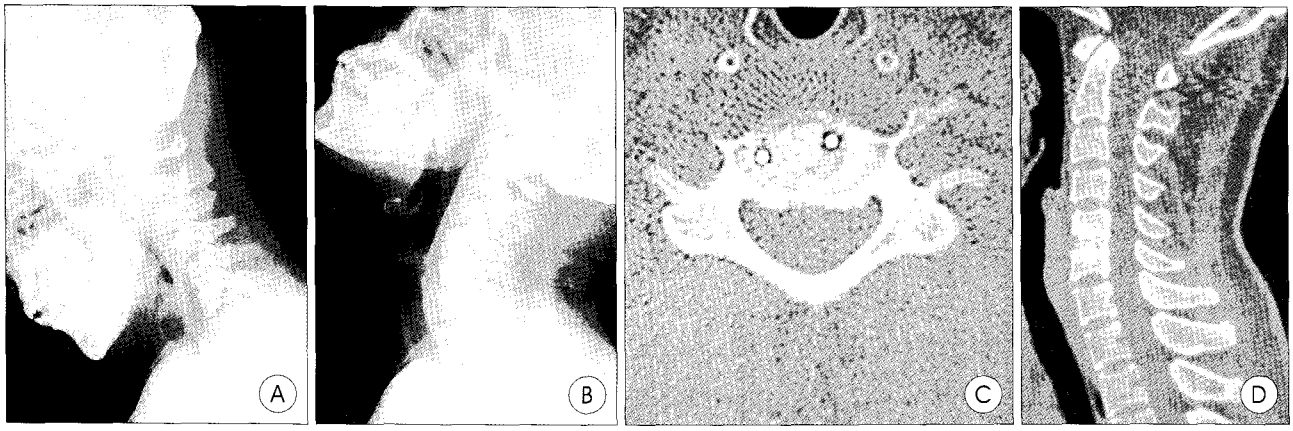

Fig. 3. A, B : There is no decrease in bone density on the margin between the graft and the vertebral body. C, D : There is an increase in bone density inside the cage with the axial and sagittal views of follow-up computed tomography.

Table 2. Changes of mean intervertebral disc height according to type of cage

Type of cage	Mean intervertebral disc height			Level No.
	Preoperative	Immediate postoperative	12 months postoperative	
Solis	6.46±1.25mm	8.47±1.05mm	7.32±1.60mm	31
Osta-Pek	5.87±1.03mm	8.02±1.35mm	6.30±2.00mm	29
Total	6.18±1.17mm	8.25±1.21mm	6.83±1.86mm	60

(p=0.009, RMA test)

nding the fusion site in the lateral cervical radiograph[15] (Fig. 2A). We defined 'severe subsidence' as a 3cm decrease in intervertebral disc height. The degree of cervical lordosis was measured by Profeta's method, which uses the shortest distance from the posteroinferior side of the 4th cervical vertebra to a hypothetical line drawn from the posterior side of the 2nd cervical vertebra to that of the 7th vertebra[22] (Fig. 2B). We defined 'cage on the cortical bone' when the distances from the anterior cortical margin of the vertebral body to the cage were shorter than 2mm. 'Cage on the cancellous bone' was defined when the cage was placed more than 2mm inside the anterior cortical margin of the vertebral body (Fig. 2C).

To determine radiographic bone fusion, dynamic flexion-extension plain images were taken 12 months postoperatively to confirm the mechanical stability of the cage, when there was no decrease in bone density on the margin between the graft and the vertebral body (Fig. 3A, B), and when there was sclerotic changes, or when a bridging formation was found with the coronal view of the follow-up computed tomography, and when there was an increase in bone density inside the cage with the axial and sagittal views of the follow-up computed tomography (Fig. 3C, D).

Results

The clinical outcome of the surgery was determined by Odom's criteria. Patients in either excellent or good categories were able to function normally at home and work, and thus were accepted as a successful group. There were 34 cases that fit into the excellent group, 5 cases of good, 1 case of fair and 1 case of poor, thus the success rate in clinical outcome was 92.9%. The success rate of the Solis™ cage was 95.2%. The success rate of the Osta-Pek™ cage was 95.0%. The Solis™ cage provided higher successful rates than the Osta-Pek™ cage in our study. However, there was no statistical significance between the different cage groups (p=1.000, Fisher's exact test).

The average height of disc space was 6.46±1.25mm (Solis™ cage) and 5.87±1.03mm (Osta-Pek™ cage) before surgery; 8.47±1.05mm (Solis™ cage) and 8.02±1.35mm (Osta-Pek™ cage) just after surgery; then it was progressively decreased to 7.32±1.60mm (Solis™ cage) and 6.30±2.00mm (Osta-Pek™cage) within 12 months (Table 2). The average height of the disc space 12 months after surgery compared to the height just after surgery showed more subsidence in the cases with the Osta-Pek™ cage than those with the Solis™ cage. However, there was no statistical significance between the different cage groups (p=0.009, Repeated Measure ANOVA test).

The average height of the disc space 12 months after surgery compared to the height before surgery was increased in 28 cases. The height of the disc space 12 months after surgery compared to the height just after surgery was decreased over 3mm in 4 cases, which indicates severe subsidence. Among these 4 cases, there were 3 cases that fit into the excellent group and 1 case in the poor group. There were 3 cases with the Solis™ cage and 1 case with the Osta-Pek™ cage. The average height of the disc space was 5.97±1.21mm (cage on cortical bone) and 6.38±1.12mm (cage on cancellous bone) before surgery; 8.03±1.18mm (cage on cortical bone) and 8.47±1.23mm (cage on cancellous bone) just after surgery; then it was progressively decreased to 6.80±1.67mm (cage on cortical bone) and 6.86±2.07mm (cage on cancellous bone) wi-

Table 3. Changes of mean intervertebral disc height according to site of cage placement

Site of cage placement	Mean intervertebral disc height (mm)			Level No.
	Preoperative	Immediate postoperative	12 months postoperative	
Cortical	5.97±1.21	8.03±1.18	6.80±1.67	30
Cancellous	6.38±1.12	8.47±1.23	6.86±2.07	30
Total	6.18±1.73	8.25±1.21	6.83±1.86	60

(p=0.261, RMA test)

Table 4. Changes of mean cervical lordosis by Profeta's method (p=0.258, T-test)

Type of cage	Preoperative lordosis (mm)	Postoperative lordosis (mm)	Changes of mean cervical lordosis (mm)
Solis	4.69±5.51	6.15±5.55	1.46±4.62
Osta-Pek	3.12±4.70	5.78±4.84	2.90±3.27

Table 5. Patients profile with severe subsidence (>3mm)

Number and age/gender	Type of cage	Level	Preop. Lordosis by Profeta (mm)	Postop. Lordosis by Profeta (mm)	Lordotic change	Odom's criteria
1 (21/M)	Solis	1	6.45	1.73	-5.00	Excellent
2 (81/F)	Solis	1	0.50	7.50	7.00	Excellent
3 (55/M)	Solis	2	-9.02	-4.35	4.70	Poor
4 (59/M)	Osta-Pek	2	6.30	1.80	-5.00	Excellent

thin 12 months. The average height of the disc space 12 months after surgery compared to the height just after surgery showed less subsidence in the cases with 'cage on cortical bone' than 'cage on cancellous bone' (Table 3). However, there was no statistical significance between the different groups (p=0.261, Repeated Measure ANOVA test).

The change in the cervical lordosis measured by Profeta's methods was 1.46±4.62mm in patients operated with the Solis™ cage and 2.90±3.27mm with the Osta-Pek™ cage (Table 4). The use of the Osta-Pek™ cage increased the postoperative cervical lordosis more than the Solis™ cage. However, there was no statistical significance between the different cage groups (p=0.258, T-test).

Bony fusion was confirmed in 40 patients. One patient with preoperative kyphosis showed subsidence on the radiograph taken 3 months after surgery. Due to the increased subsidence in the 5th month after first surgery, patient had to go through another surgery with corpectomy, iliac graft and plating. No bone fusion was found intraoperatively (Illustrative case).

Postoperative complications included 4 cases of severe subsidence (>3mm), and 1 case of hoarseness (Table 5). The patient who experienced hoarseness improved after 12 months.

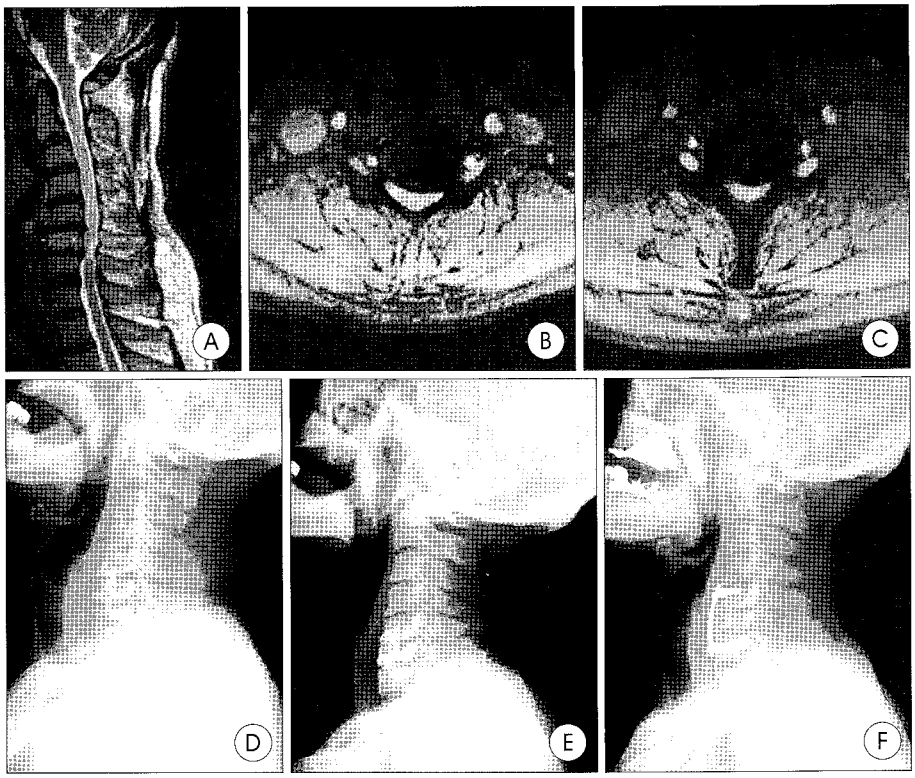

Fig. 4. A, B, C : T2-weighted magnetic resonance image of the cervical spine showing a high signal intensity lesion compatible with myelopathy at C6/7 level and herniated cervical disc materials at C5/6 and C6/7 levels. D : The herniated cervical disc materials at C5/6 and C6/7 levels have been treated with anterior interbody fusion and discectomy. The Solis™ cages and autografts were used in the fusion materials. E : The 3-month follow-up lateral cervical radiography revealing severe subsidence at C5/6 level. F : In the 12-month follow-up lateral cervical radiography after 2nd surgery, the fusion status is good with excellent clinical outcome was excellent.

Illustrative case

A 56-year-old man with left sided arm pain for 2 months was admitted in May 2004. T2-weighted MRI of the cervical spine showed a high signal intensity lesion compatible with myelopathy at C6/7 level and herniated cervical disc materials at C5/6 and C6/7 levels (Fig. 4A, B, C). The herniated cervical disc materials at C5/6 and C6/7 levels were treated with anterior interbody fusion and discectomy. The Solis™ cages and autografts were used for the fusion materials (Fig. 4D). The 3-month follow-up lateral cervical radiography revealed severe subsidence at C5/6 level (Fig. 4E). The patient complained of hand tingling sensations in both hands, with a poor outcome by Odom's criteria. We decided to reoperate and performed surgery with a corpectomy of C6 vertebral body, autologous iliac bone graft and plate fixation. Lateral cervical radiography taken at 12-month

follow-up after 2nd surgery showed good fusion status with good clinical outcome (Fig. 4F).

Discussion

Surgical treatment of a herniated intravertebral disc includes discectomy through the anterior approach, a combination of removal and interbody fusion methods, and laminectomy and laminoplasty through the posterior approach. Discectomy and interbody fusion using the anterior approach is a relatively easy approach with a small amount of blood loss, has a good operative visual field and less restraint on postoperative spinal mobility. Because of these advantages, the anterior approach is most commonly used nowadays[7,9,11].

Uninstrumented fusion with graft shows collapse, extrusion or resorption, followed by neural compression, instability and pseudoarthrosis[8]. To reduce these problems, anterior plating has been used in the past[8]. More recently, reports have claimed the advantages of stand-alone cervical cages over classic autologous bone graft with or without anterior plating[8,20,22]. Some cages are designed for use with local autografts[25]. Several authors have reported the placement of cages filled with bone substitute or even those that are empty[25]. There is evidence, however, that the autograft is associated with the best fusion rates[2,19,25].

Despite the fact that using autologous bone with interbody fusion demonstrates a high fusion rate, a low infection rate or pain at the donor site and longer operative times are problems to be noted; thus new methods using allografts, xenografts, and synthetic materials have been introduced[11]. However, allografts have risks of immune reaction and infection, while xenografts have lower rates of interbody fusion; thus the replacement material for the autografts with similar rates of fusion, lower risks of infection and maintenance of early spinal stability was studied. Thus, synthetic materials such as hydroxyapatite implants, bone morphogenic protein, polymethylmethacrylate, biocompatible osteoconductive polymer, titanium discs, and ceramics titanium or carbon were introduced[11,12,16,17,27].

There are some advantages of using a Solis™ cage filled with autografts collected in the form of bone dust. Donor site morbidity is eliminated and results in reduced postoperative pain[25]. The cage design in terms of its shape and the presence of titanium spikes minimizes the need for an anterior plate device and its associated complication[25]. Because the cage is composed of radiolucent polyetheretherketone, the bridging bone within the cage can be demonstrated on plain x-ray film, and thus new bone formation is easier to assess than in cases involving metal cages[25].

The Osta-Pek™ frame cage is composed of long fiber carbon with similar elasticity as the bone, thus, it is known to have stress shielding effects, stimulates bone formation, improves the quality of fusion[5,11,28], and in animal studies the cage enhanced the production of osteocalcin and the activity of alkaline phosphatase, as well as the growth of fibroblasts[11]. The carbon cage has higher radiolucency; thus it is easier than a metal cage to evaluate the interbody fusion postoperatively[11].

In our study, 34 of 41 (92.9%) patients operated on using the two types of synthetic cages showed good to excellent functional recovery. Radiological assessment confirmed the restoration of cervical-sagittal alignment with restoration of segmental height and reduction of kyphotic angles[25].

Up to now, many kinds of stand-alone cervical cages have been developed and widely used despite the reports on subsidence postoperatively using these cages. This study results have demonstrated the increase of intervertebral disc height in 40 cases just after surgery ($p<0.001$). However, 35 cases also had a tendency to decline in intervertebral disc height 12 months after surgery, compared to the height just after surgery ($p<0.001$). Also a severe decrease of intervertebral disc height compared to the height before surgery was observed in 4 cases.

Three of our patients with severe subsidence were aged over 50 years and had bad bone quality seen intraoperatively. In particular, One patient with severe cervical kyphosis preoperatively showed more severe subsidence postoperatively. His clinical outcome was not satisfactory and he subsequently underwent a reoperation 5 months after 1st surgery. The causes of subsidence may stem from the instability created by the discectomy, the postoperative cervical motion, the cage design, the end plate preparation, or the bone mineral density[8]. Thus, it seems to be mandatory to carefully evaluate for osteoporosis in elderly patients and severity of preoperative kyphosis may be corrected by wedge-shaped cage insertion followed by cervical plating. However, this still requires further studies.

It is still controversial whether the decline of intervertebral disc height itself has a large impact on the clinical outcomes. In our study, 3 of 4 cases with severe subsidence underwent operation with the Solis™ cage and the clinical symptoms were varied. Kim et al.[14] reported that the height of the disc space was decreased more after surgery with multisegments compared to that with a monosegment but it did not correlate with the clinical symptoms. Also, Cho et al.[5] reported that a decrease in the height of the vertebral disc after surgery did not affect the clinical outcomes.

This study also showed that the use of the Osta-Pek™ cage increased cervical lordosis more than the Solis™ cage ($p=0.258$, T-test). We suggested that the Osta-Pek™ cage should be wedge-shaped so that the anterior height of the cage can be higher than its posterior height, thus providing the spinal curvature to be more natural[11]. Some studies reported that by using the wedge-shaped carbon cage compared to the cage used in the Cloward procedure, the complication rate of kyphosis is lower, and the anterior disc height is higher. Vavruch et al.

reported similar results that the carbon cage in the anterior interbody fusion was better than autografts in maintaining the disc height[11]. For the case that showed severe kyphosis before surgery in our study, it seems to be a good idea to use the Osta-Pek™ cage followed by cervical plating to improve lordotic curve and prevent subsidence. It would be better if there were various products with wedge shapes like the Osta-Pek™ cage.

In generally, bone fusion can be expected 3 to 6 months after surgery. Some studies reported that both the Solis™ cage and the Osta-Pek™ cage showed high bone fusion rates as in pur cases[8,11]. Only 1 of 41 cases required additional surgery for non-union.

Conclusion

This study results show satisfactory clinical and radiologic outcomes with 41 patients by applying the Solis™ and Osta-Pek™ cages after anterior cervical interbody fusion. Both the Solis™ and Osta-Pek™ cages show less subsidences and fewer complications associated with hardware along with good clinical outcomes, high fusion rates, restored disc height, and restored cervical lordosis. Four cases that showed severe cervical kyphosis preoperatively presented severe subsidence (>3mm). It seems necessary to apply cervical plating for patients with severe kyphosis preoperatively and to merchandise products in wide ranges to improve the lordotic curve.

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Commentary

The anterior interbody fusion surgery method with use of a cage has become the standard procedure in cervical neck herniation. When using a synthetic cage, the type of cage has no impact on the prognosis in which selection is based on the surgeon's preference and familiarity. A metallic cylindrical cage has more subsidence than a synthetic cage. However, subsidence does not have a substantial amount of effect on the patient's outcome. Even when using a hollow empty cage, it has been reported that a small amount of bone dust does not have any effect on fusion. There has to be more study done on hollow empty as well as hydroxypatite cages in the near future.

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