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Subsidence Ratio after Anterior Cervical Interbody Fusion Using an Intraoperative Custom-made Cervical Cage

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Objective: The postoperative subsidence of anterior cervical interbody fusion for cervical degenerative diseases gives rise to segmental kyphotic collapse, screw loosening, and chronic neck pain. So, intraoperative custom-made polymethylmethacrylate (PMMA) C-cage has been developed to prevent subsidence following anterior cervical fusion.

Methods: A total of patients who underwent anterior cervical interbody fusion with a intraoperative custom - made cervical cage filled with local bone and demineralized bone matrix (group A) were analyzed prospectively from June 2004 to June 2005. These were compared with 40 patients who were treated with iliac bone graft (group B). We evaluated subsidence ratio, change of segmental angle, distraction length and segmental angle. Statistical analysis was performed using independent sample t-test and Pearson correlation coefficient.

Results : Group A had a statistically significant decrease in subsidence ratio $(0.64 \pm 0.43\%, p=0.00)$, distraction length $(2.42 \pm 1.25 \text{ mm}, p=0.02)$, and follow angle change $(1.78 \pm 1.69^{\circ}, p=0.01)$ as compared with Group B. However, there was no statistically significant difference in postoperative segmental angle change (p=0.66). On the analysis of the correlation coefficient, the parameters showed no interrelationships in the group A. On the other hand, subsidence ratio was affected by distraction length in the group B (Pearson correlation=0.448).

Conclusion: This operative technique would be contributed for the reduction of a postoperative subsidence after the anterior cervical interbody fusion procedure for cervical disc disease with moderate to severe osteoporotic condition and segmental loss of lordosis.

KEY WORDS: Subsidence · Cervical cage · Anterior cervical fusion.

Introduction

A nterior cervical discectomy and fusion is an effective surgical treatment of cervical degenerative diseases with a high percentage of good clinical outcomes⁹⁾. The goal of this treatment is to restore physiologic disc height and to achieve fusion for adequate stabilization. For this purpose, a central discectomy is performed, and the intervertebral space is filled with bone graft^{23,24)}, bone cement^{6,20)}, biodegradable polymers^{11,14,15,23)}, or interbody fusion cages^{2,4,13,17,27)}.

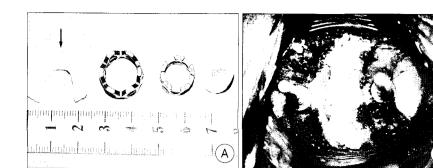
Although the current gold standard of bone graft materials in anterior cervical fusion is autogenous iliac crest, potential problems include donor site morbidity (pain, hematoma, infection, neuropraxia, etc.)^{5,12)}, kyphotic collapse and dislodgement of

donor bone^{8,28)}. In order to avoid inevitable complication of autograft, a variety of allografts and cervical fusion cages have been used in cervical spinal fusion. However, these substitutes have revealed several problems such as delayed union, nonunion, insufficient fusion surface or high cost^{15,25)}. Above all, the most complicating problems in the clinical course are graft collapse and nonunion. Authors have developed intraoperative custommade PMMA C-cage has to prevent subsidence and collapse following anterior cervical fusion.

The objective of this study is to report the efficacy of the intraoperative custom-made PMMA C-cage analyzing the subsidence ratio and the change of segmental angle of patients who underwent treatment with custom-made cage and patients who were treated with iliac bone graft.

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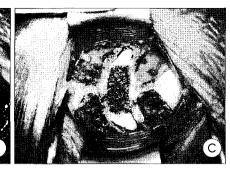


Fig. 1. Picture showing the polymethylmethacrylate cage remolded into C shape (black arrow) and variable cages (A), reinsertion into the disc space (B), bony powder and demineralized bone matrix mixture packed into hollow space of polymethylmethacrylate C-shaped cage (C).

Materials and Methods

Patient populations and Indications

This prospective study was conducted in our department from June 2004 to June 2005. Criteria for inclusion were unremitting radicular arm pain with or without neck pain, and/or a neurological deficit that correlated with appropriate level and side neural compression verified either on magnetic resonance imaging (MRI) or computed tomography (CT). Patients were not excluded because of age, sex, compensation claims, diabetes, obesity or other medical conditions that would not preclude surgery in general. We selected patients consistent with these indications and divided into two groups (Groups A and B). Group A included 35 patients who underwent treatment with intraoperative custom-made cervical cage. Group B consisted of 40 patients who were treated with iliac bone graft. In the group A, we enrolled 14 men and 21 women (age range, 53-80yr; mean age, 53.6yr); in the group B, we enrolled 18 men and 22 women (age range, 54-72yr, mean age, 60.6yr). The demographic data and levels of discectomy are shown in Table 1. We analyzed the subsidence ratio, the change of segmental angle and follow angle change between two groups.

Operative technique and Fusion device

A cervical transverse incision was made along the skin fold in a supine position. After dividing the platysma sharply in perpendicular line with the skin incision, the interval between the carotid sheath and the esophagus was developed bluntly, thereby exposing the anterior cervical spine. Once the correspondency operative vertebral level was identified, the affected discs were removed with pituitary forceps and curettes. Uncotomy or superior pediculotomy for foraminal decompression was added in a cervical spondylotic radiculopathy. After the anterior cervical discectomy was performed all the way to the posterior longitudinal ligament, all cartilaginous endplates were removed down to the level of bleeding subchondral bone with curettes

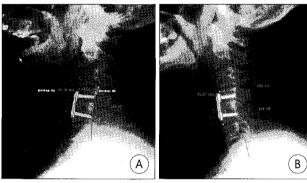


Fig. 2. Radiographs showing the method of measuring subsidence ratio, segmental height, and segmental angle on immediate postoperative (A) and 6-months postoperative (B) lateral films.

Table 1. Demographic data of cervical disc diseases

Characteristics	Group A (N=35)	Group B (N=40)
Male/Female	14/21	18/22
Radiculopathy	25	28
Myelopathy	5	8
Radiculomyelopathy	5	4
C3-4	1	1
C4-5	7	9
C5-6	23	30
C6-7	24	18
One level	24	30
Two level	15	18
Three level	1	2

or a high-speed burr. Two pieces of bone plate obtained with chiseling from the bony endplates were used as a bone graft material with demineralized bone matrix (DBM). After divergent insertion of distractive screw and centripetal distraction of vertebral body was performed for minimal stretching of capsular ligament and correction of segmental lordosis, the PMMA cage was constructed and cast in a mold of interbody space. The PMMA cage that became solid was removed and trimmed to fit the graft site and remodeled into C shape with high speed drill. After the cage was snugly filled into the disc space for fusion, subchondral cortical endplate was removed com-

pletely with high speed drill, cancellous bone of the vertebral body was exposed and bony powder made by cortical drilling was collected. The bony powder and DBM mixture were packed into hollow space of PMMA C-shaped cage and the

Table 2. Patient-related preoperative data

Characteristics	Group A (N=35)	Group B (N=40)
Age	61 ± 5.7	61 ± 7.9
BMD	-2.3 ± 0.4	-1.9 ± 0.4
Preoperative lordosis (°)	2.9 ± 5.6	4.4 ± 5.8
Preoperative height (mm)	40.6 ± 10.6	39.8 ± 8.9

Values represent the mean \pm SD. BMD: bone mineral density

Table 3. Independent Samples t-test for patient-related preoperative data

Characteristics	Significance (2-tailed)	Mean difference	Std. Error Difference
Age	0.190	2.201	1.657
BMD	0.000	-0.438	0.987
Preoperative lordosis (°)	0.263	-1.520	1.346
Preoperative height (mm	0.708	0.854	2.271

Table 4. Radiological outcome data in both groups

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Characteristics	Group A (N=35)	Group B (N=40)
Distraction length (mm)	2.42 ± 1.25	4.01 ± 1.25
Subsidence ratio (%)	0.64 ± 0.43	1.54 ± 1.34
Segmental angle change (°)	4.16 ± 6.10	4.74 ± 5.35
Follow angle change (\degree)	1.78 ± 1.69	2.94 ± 2.24

Values represent the mean \pm SD

Table 5. Independent Samples t-test for radiological outcome data

Characteristics	Significance (2-tailed)	Mean difference	Std. Error Difference
Distraction length	0.002	-1.593	0.522
Subsidence ratio	0.000	0.898	0.236
Segmental angle change	0.662	-0.585	1.334
Follow angle change	0.014	1.153	0.455

Table 6. Pearson correlation coefficient of group A(N=35)

	Distraction length	Subsidence ratio	Segmental angle change	Follow angle change
Distraction length	1	0.033(0.853)	0.190(0.274)	0.091(0.601)
Subsidence ratio	0.033(0.853)	1	-0.232(0.179)	-0.265(0.124)
Segmental angle change	0.190(0.274)	-0.232(0.179)	1	-0.229(0.187)
Follow angle change	0.091(0.601)	-0.265(0.124)	-0.229(0.187)	1

^{() =} Sig. (2-tailed)

Table 7. Pearson correlation coefficient of group B (N=40)

	Distraction length	Subsidence ratio	Segmental angle change	Follow angle change
Distraction length	1	0.448(0.004)*	0.303(0.057)	-0.083(0.609)
Subsidence ratio	0.448(0.004)*	1	-0.101(0.537)	-0.139(0.393)
Segmental angle change	0.303(0.057)	-0.101(0.537)	1	-0.009(0.957)
Follow angle change	-0.083(0.609)	-0.139(0.393)	-0.009(0.957)	11

^{() =} Sig. (2-tailed), * Correlation is significant at the 0.01 level

entrance was plugged with bony plates (Fig. 1). Finally, internal fixation was accomplished by using a titanium screw and plate system across the segments to be fused. In the group B, autograft was harvested from the anterior iliac crest.

Radiographic measurement and statistical analysis

Lateral plain-film radiographs were used to measure parameter values that need to be calculated. The parameters were included in subsidence ratio, change of segmental angle, distraction length and follow angle change. The formulas for these were introduced in following sentences; Subsidence ratio= $100 - (postop 0a \times postop 6b \times 100 / postop 0b \times postop$ 6a); Change of segmental angle (SA)=preop SA – postop 0SA; Distraction length=preop SH - postop 0SH; Follow angle change=postop OSA - postop 6SA; Postop 0a=anterior fixation plate length measured immediately after surgery; Postop 0b =segmental height measured immediately after surgery; Postop 6a=anterior fixation plate length measured after 6 months postoperatively; Postop 6b=segmental height measured after 6 months postoperatively; Postop OSA=segmental angle measured immediately after surgery; Postop 6SA=segmental angle measured after 6 months postoperatively; SH=segmental height (Fig. 2). Posterior vertebral body tangent method was used to measure the segmental angle. All angle measurements were analyzed in degrees, whereas distance measurements were analyzed in millimeters and converted to percentage with subsidence ratio formula. Statistical analysis was performed using independent samples t-test and Pearson correlation coefficient. A P value of 0.05 was considered significant.

Results

P atient-related preoperative data was presented in Table 2. In group A, the mean age was 61 years (range, 53 to 80)

and mean preoperative cervical lordosis was $2.9 \pm 5.7^{\circ}$. The average BMD for group A was -2.3 ± 0.4 and mean preoperative segmental height was 40.6 ± 10.6 mm. In group B, the mean age was 60 years (range, 54 to 72) and mean preoperative cervical lordosis was $4.4 \pm 5.8^{\circ}$. The average BMD for group B was -1.9 ± 0.4 and mean preoperative segmental height was 39.8 ± 8.9 mm. Except that the BMD score in group A was lower than that in group B, there was no statistically significant difference of age, preoperative lordosis and

preoperative height (Table 3).

Table 4 summarizes the radiographic outcome data. In group A, the mean distraction length was 2.42 ± 1.25 mm and mean subsidence ratio was 0.64 ± 0.43%. The average segmental angle change(increase in lordosis) for group A was 4.16±6.10° and mean follow angle change (decrease in lordosis) was 1.78 ± 1.69 °. In group B, the mean distraction length was 4.01 ± 1.25 mm and mean subsidence ratio was $1.54\pm1.34\%$. The average angle change (increase in lordosis) for group B was $4.74\pm5.35^{\circ}$ and mean follow angle change (decrease in lordosis) was $2.94\pm2.24^{\circ}$. The average volume of DBM in each level of group A was 1.84 ± 0.53 cc. We compared the results of Group A and Group B in Table 5. There were statistically significant differences between group A and B in distraction length (p=0.02), subsidence ratio (p=0.00), and follow angle change (p=0.01). Group A had a statistically significant decrease in subsidence ratio, distraction length and follow angle change as compared with Group B. However, there was no statistically significant difference in postoperative segmental angle change (p=0.66).

On the analysis of the correlation coefficient, there was no interrelationship in the group A parameters, which means that distraction and subsidence ratio have no affect on postoperative segmental angle and following angle change in the custom-made cage operation for group A (Table 6). On the other hand, subsidence ratio was affected by distraction length in group B (Pearson correlation=0.448). However, others were not correlative to each other (Table 7).

Discussion

nterior cervical fusion is an established surgical treatment A of cervical degeneration diseases and associated with high percentage of good clinical outcomes⁹⁾. It offers advantages including direct decompression of neural tissue, restoration of intervertebral spacing, enlargement of a stenotic neural foramen, and stabilization of the degenerative disc. From the first report of the use of a structural tricortical iliac crest graft for interbody cervical fusion in 1950s by Smith and Robinson¹⁹, the iliac crest autograft is considered the "gold standard" for cervical interbody spinal fusion procedure. The advantage of bone graft is that no foreign bodies need to be implanted, and complete bony fusion can be achieved. However, harvesting autogenous bone from the iliac crest can be associated with increased blood loss, limited supplies of donor bone, and postoperative pain at the graft site^{12,22)}. Sawin et al.²¹⁾ reported a 25.3% morbidity rate that included pain, hematoma, fracture, and meralgia paresthetica. As well, significant discomfort and residual pain may continue for as long as 12-24 months after surgery¹⁾.

The best method to avoid graft site morbidity is to avoid graft harvest. For this reason, some authors have advocated allograft or other interbody grafts for cervical interbody fusion procedure^{3,7)}. In addition, there have been advantages such as ready availability, easy storage, reduction in blood loss, and reduction of operation time. However, inherent problems with allograft are decreased union rate, delayed union, potential for disease transmission and lack of availability on worldwide basis. Delayed union and nonunion are certainly serious problems of the fusion processes thus surgeons are distressed by unsatisfying postoperative clinical results. Martin et al. 16) reported a fusion rate of 90% using freeze-dried allograft in one-level procedures, which declined to 72% with two-level fusions. Another alternative in cervical spinal fusion first described in the 1980s is the implantation of interbody fusion cages. These consist of titanium, carbon fiber, polyetheretherketone (PEEK), and are small, porous, hollow implants, either cylindrical or nearly cuboid in shape, that restore physiologic disc height and allow the growth of bone through the implant and bony fusion. However, cervical interbody fusion cages sometimes cause complications from subsidence into the adjacent vertebrae with collapse of the intervertebral space and kyphotic deformation of the affected segment. No perfect cage has been produced; subsidence, migration and structural failure of the cage have occurred.

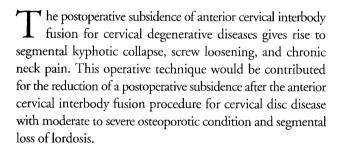
To prevent such complication, the custom-made PMMA C-cage has been developed. The advantage of custom-made PMMA C-cage in cervical fusion is to combine the benefits of bone graft (bony fusion) with those of bone cement (high immediate stability and the loss of donor side morbidity). In addition, its sufficient graft fusion surface enhances complete bony fusion and establishment of axial load transmission through the cage and strong cortical surface of apophyseal ring reduces the rate of subsidence. Moreover, the maintenance of segmental height and angle through it might guarantee postoperative clinical results. Regarding the bone graft material used in this cage, DBM can function as both an osteoinductive and osteoconductive material. Although not a replacement for autograft, DBM has the capability of extending or enhancing the activity of autograft. As an extender, DBM provides more grafting volume^{10,18,26)}.

Multiple reasons for loss of lordosis, subsidence, and diminution in foraminal height can be speculated such as inappropriate distraction(either over- or underdistraction), mismatch of donor bone with the patient's vertebral body density, excessive removal of densely cortical endplate, placement of a small intervertebral body spacer in the middle of the endplate (thus not contacting the stronger ring apophysis at the periphery of the endplate), or inadequate external bracing or internal

plate fixation. In this regard, anterior cervical fusion using intraoperative custommade PMMA C-cage could eliminate these multiple causes of subsidence with following merits: 1) unnecessary excessive distraction from centripetal interbody distraction allow the avoidance to stretch facet joint ligaments and capsule; 2) utility of local bone powder and cortical endplate fundamentally prevent donor site complications; 3) complete removal of densely cortical endplate at the central portion of the cage promote bony consolidation and fusion; 4) the placement of a precise and tight interbody spacer cast in a mold contact the strong ring apophysis at the periphery of the endplate and then enhance the axial load transmission and consequently reduce the rate of graft collapse and subsidence; and 5) strong segmental stabilization by adequate internal plate and bicortical screw fixation guarantee successful fusion.

There are several limitations to the current study. Foremost, short follow up periods with an average of 10.4 months is not sufficient to prove definitive postoperative clinical results and fusion rate. Furthermore, uneven spectrum of patient diagnosis and BMD scores for the selection of control group must be treated for the next study. Finally, methods that require the manual measurement on lateral radiograph may cause multiple sources of error: the exact definition of vertebral contours, the reproducibility of the radiograph tracing or making, and irregular shapes on cervical vertebrae.

Conclusion



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