

Two or More Levels Anterior Cervical Discectomy and Fusion (ACDF) Using Stand-Alone PEEK Cages Filled With Bone Graft Substitute

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Abstract

Background Data: Anterior cervical discectomy and fusion (ACDF) has become a standard and a highly successful procedure for degenerative cervical disc disease associated with radiculopathy or myelopathy. In addition to graft complication, multilevel cervical discectomy is often combined with plate fixation to maintain the spinal curvature, and increasing the graft fusion rate but this also may carry risk of complications.

Study Design: Prospective descriptive clinical case study

Purpose: To evaluate the safety and efficacy of standalone PEEK cages filled with bone graft substitute in treatment of multi-level cervical disc disease.

Patients and Methods: Ninety one patients underwent multiple levels ACDF for a total of 239 levels. Mean follow-up was 24 months. Clinical outcomes were evaluated using Visual Analogue Scale (VAS) and Oswestry Disability Index (ODI); cervical lordosis and cervical fusion status was assessed on X-ray. Statistical analysis was performed using a dependent t-test using SPSS V.12.0 ($P < 0.05$).

Results: The fusion rate was 97.9% (234 out of total 239 levels operated). Clinically, the mean ODI scores were 50.49 (Range, 30 to 69) preoperatively and 16.89 (Range, 0 to 38) postoperatively ($P = 0.000$). All patient have significant pain reduction with mean VAS scores decreases from 6.52 (Range, 4 to 9) preoperative to 1.87 (Range, 0 to 5) postoperatively ($P = 0.000$). Cervical lordosis was preserved and neurological status was improved. No cage migration or cage breakage happened.

Conclusion: ACDF using standalone PEEK cages filled with Calcium triphosphate bone graft substitute is a safe and efficient method for treatment of multiple levels cervical disc disease. It preserves cervical lordosis and obviates the complications related to iliac crest grafting and screw-plate fixation. (2013ESJ045)

Key Words: cervical spine, Multi-level cervical disc disease, ACDF, PEEK cage.

Introduction

Anterior cervical discectomy and interbody fusion (ACDF) has become a standard and a highly successful surgical procedure for degenerative cervical disc disease. Since it was first introduced by Smith-Robinson²⁴ and Cloward⁸ in the 1950s, it has been considered the procedure of choice for the treatment of degenerative diseases of the cervical spine. The success of this procedure relies on a thorough decompression and development of a solid osseous fusion.^{5,27,28} In multilevel discectomy, the success rate declines as the number of levels increase.¹⁰

In cervical degenerative diseases, the literature supports a consistent rate of 10 to 12% pseudoarthrosis for single level anterior discectomy and autogenous bone fusion, 20 to 27% for 2-level, and approximately 30 to 56% for 3-level fusions.^{5,10,30} Even with solid fusion graft collapse and kyphosis of spinal curve often develops in multilevel discectomies with autogenous iliac crest graft (AICG) fusion.¹⁴ Additionally, morbidity due to bone graft harvest remains high and can compromise the satisfactory results of ACDF.^{2,31}

Multilevel cervical discectomy is often combined with plate and screw fixation to maintain the spinal curvature, and increasing the graft fusion rate. However, plates and screws may cause many complications.¹⁶ Stand-alone interbody fusion cages represent an alternative for anterior cervical fusion. Cage-assisted ACDF can restore physiologic disc height, provide immediate load bearing support to the anterior column,^{13,32} facilitate fusion and avoid many graft and plates related complications. Clinical outcomes have been encouraging in one- and two-level procedures^{21,26} and even in three- and four-level surgeries.¹¹

The aim of this study is to evaluate the effectiveness, safety and long term outcome of standalone Polyetheretherketone (PEEK) cages filled with calcium triphosphate bone graft substitute for treatment of multiple levels cervical degenerative disc diseases.

Patients and Methods

This prospective study have been carried out between January 2008 and December 2012, 102 patients with mean age of 57.3 years (range, 31-79) underwent multilevel ACDF using PEEK

cages (Polyetheretherketone is a non-absorbable biopolymer that has been used in a variety of medical devices. It is biocompatible, radiolucent and has modulus of elasticity similar to the bone)¹⁷ packed with calcium triphosphate bone graft substitute (OstIN–basic healthcare-India) mixed with autologous blood. Eleven patients were lost during follow up while 91 patients (33 women and 58 men) were followed up with mean follow up of 2 years and minimal follow up 1 year. (Table 1)

Only patients operated for treatment of degenerative cervical disc disease were included in this study. Patients with trauma, infection and neoplasms were excluded. Indication for operation was intractable radiculopathy, myelopathy, or radiculomyelopathy after confirmation by Magnetic Resonance Imaging (MRI) findings for every patient.

All patients were given detailed information on the operation, the follow-up protocol and radiological investigations, and their consent was obtained conforming to international ethical standards.

Operative Procedure:

A transverse skin incision was used in patients with two levels cervical discs while a longitudinal skin incision was used when three or four levels of cervical discs were approached. The anterior cervical disc was approached using the method described by Smith-Robinson.²⁴ A Caspar screw distractor was used to allow distraction of the disc space throughout the procedure. The upper and lower endplates were prepared by removing the overlying cartilage and preserving the subchondral bone. The disc, posterior longitudinal ligament and the posterior osteophytes were removed in microscopic assisted fashion. Adequate decompression of neural structures was verified using a blunt probe. An optimal PEEK cage was selected and the inner cavity of the cage was filled with calcium triphosphate bone graft substitute mixed with autologous blood. The cage was impacted into disc space for fusion. A check intraoperative lateral view images were taken using Image Intensifier to ensure optimum position of the cage which has been selected variably according to the preoperative cervical lordosis angle. Patients with hypolordosis, putting the cage posterior as much as possible will increase lordosis while in patient with hyperlordosis or normal lordosis we try to centralize the cage. The wound was closed in two layers over a suction drain. After surgery, all patients were

protected by wearing a rigid collar for 3 weeks and a soft collar for another 3 weeks. Neck exercises were initiated 6 weeks after surgery and a normal activity level was progressively resumed. Plain AP and lateral cervical spine radiographs were taken after surgery.

Outcome Measures:

Clinical and radiological follow-up was performed at the 3rd, 6th, 12th, and 24th months postoperatively. In addition to standard neurological examination, outcomes were assessed with Visual Analogue Scale⁹ and Oswestry Disability Index (ODI)³ preoperatively and postoperatively at final follow up.

We evaluated spinal curves, mobility and fusion status with X-ray. Four planes cervical radiographs were used including AP, and lateral in neutral, flexion and extension views. The criteria for bone fusion were either crossing bony specula across the fusion level in X-rays or no change in position of the fused levels on dynamic views (flexion and extension).

Spinal curve was evaluated using lateral X-rays preoperatively and postoperatively. The Ishihara Curvature Index (ICI) was used for this evaluation.¹² A straight line was drawn from the posterior border of the Dens to the posterior border of C7. Another line was drawn from the posterior border of C4 perpendicular to the first line, in which the intersected length was measured in millimeters as the degree of spinal curvature. A positive intersected length indicates the degree of lordosis. If the intersected length is negative, it indicates kyphosis. When the intersected length is zero, the spinal curve is referred to as straight.

Statistical analysis was performed to compare preoperative and postoperative scores using dependent t-tests using SPSS V.12.0 (SPSS Inc., Chicago, IL, USA).

Results

In this series, 91 patients (33 women and 58 men) with mean age of 57.3 years (Range, 31 to 79 years) underwent multilevel ACDF using standalone PEEK cages packed with calcium triphosphate bone graft substitute with mean follow up of 2 years (range, 12 to 59 months) and minimal follow up 1 year.

The mean operation time was 110 min (range, 90 to 180 min), estimated blood loss was below 100 ml in all patients. Forty-nine patients underwent two-level discectomy, twenty-seven patients underwent three-level discectomy and fifteen patients underwent four-

level discectomy with total 239 discs were operated. (Table 1, Figure 1,2,3)

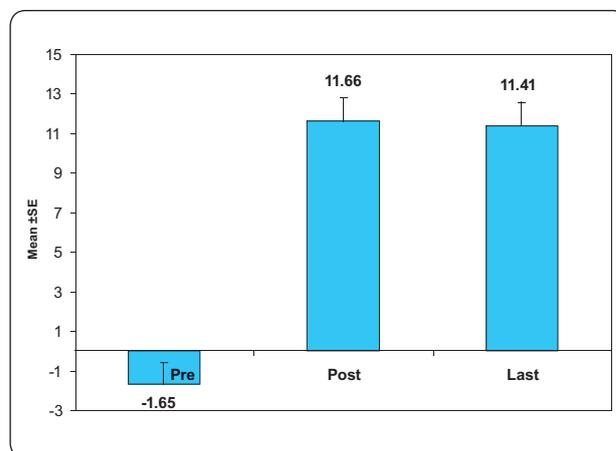
After surgery, none of the patients suffered neurological deterioration. There were no complications during the immediate postoperative period, and X-rays confirmed appropriate positioning of the cages, and all patients were discharged in the next postoperative day.

Clinically, the mean ODI scores were 50.49 (Range, 30 to 69) preoperatively and 16.89 (Range, 0 to 38) postoperatively. Patients were significantly better (P=0.000). All patient with root pain or neck pain have significant pain reduction with mean VAS scores decreases from 6.52 (Range, 4 to 9) preoperative to 1.87 (Range, 0 to 5) post operatively (P=0.000). (Table 2)

The mean preoperative ICI was 10.6±3.74 while postoperative the mean ICI was 10.2±3.16. The difference was insignificant (P=0.09). The cervical preoperative lordosis was preserved at the final follow up. (Graph 1)

At the final follow-up, the fusion rate was 97.9% (confirmed in 234 out of 239 levels operated). There were three patients with non-fusion levels:(two non-fusion levels in one patient with a four-level operation (C5-6 and C6-7 levels) two non-fusion level in one patient with a four-level operation (C3-4 and C4-5 level); and one level in one patient with a three-level operation (C2-3 level).

In long-term follow-up, imaging showed no cage breakage or dislodgement in these patients so reoperation for non-fusion was not necessary. In addition, no mobility was seen on dynamic X-ray films at any operated segments.



Graph 1. Radiological results (ICI) of our patients.

Table 1. Demographic Data of our Patients.

Number	91	
Age	57.3(31-79)yrs	
Sex	Male	33
	Female	58
Surgical indication	Radiculopathy	18
	Mylopathy	20
	Radiculomylopathy	53
levels treated	2-level (49 patients)	98 levels
	3-level (27 patients)	81 levels
	4-level (15 patients)	60 levels
	(Total 91 patients)	239 levels

Table 2. Clinical Outcome of our Patients.

	Pre	Latest	P value
VAS	6.52 (range, 4 to 9)	1.87 (range, 0 to 5)	0.000*
ODI	50.49 (range, 30 to 69)	16.98 (range, 0 to 38)	0.000*

Wilcoxon Signed Ranks test

*Statistical significant difference (P<0.05)



Figure 1. Male patient 47 years old with 2 levels ACDF, A: Preoperative MRI, B: 6 weeks postoperative Lateral view, C: 4 years postoperative lateral X rays showing solid bony fusion.

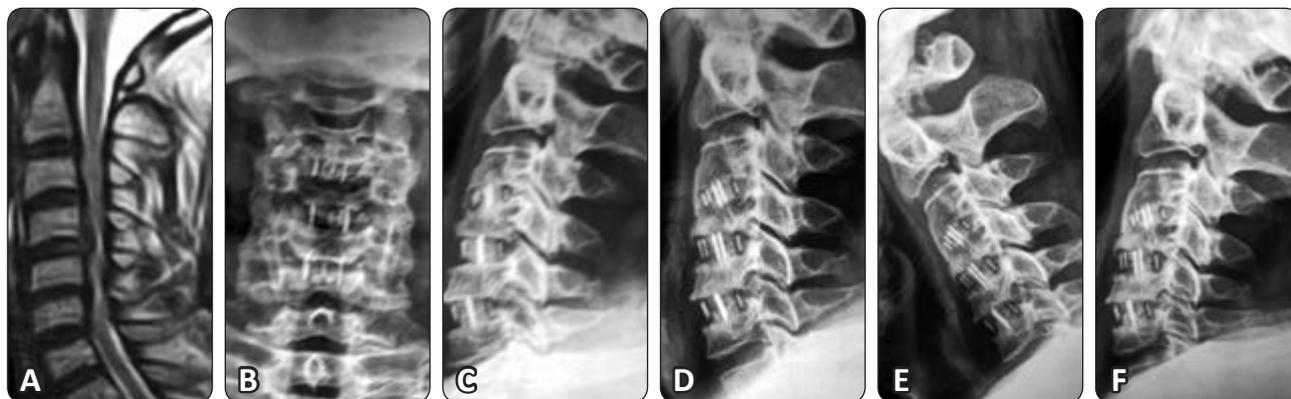


Figure 2. Female patient 49 years old had 3-level ACDF, A: Preoperative MRI, B: 3 months follow up radiograph in AP and C: lateral views. 18 month follow up lateral radiographs in D: neutral, E: flexion, and F: extension views.

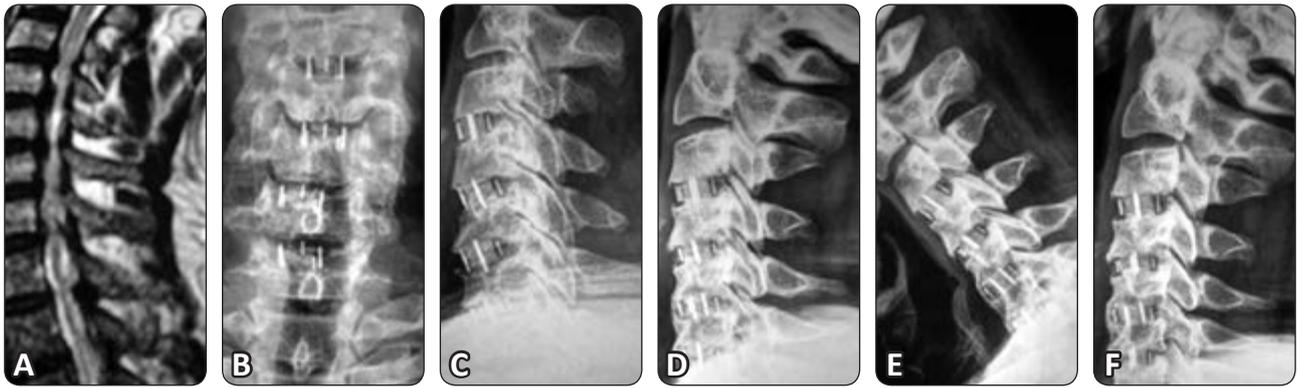


Figure 3. Male patient 56 years old had 4-level ACDF, A: preoperative MRI B: 12 months postoperative AP view and C: lateral view radiographs show no cage failure with preserved lordosis. 18 month follow up lateral radiographs in D: neutral, E: flexion, and F: extension views.

Discussion

Anterior cervical discectomy and interbody fusion is an efficient procedure used to treat a variety of cervical spinal disorders, including spondylosis, myelopathy, herniated discs, trauma, infection and degenerative disc disease. The success of this procedure relies on thorough decompression and development of a solid osseous fusion.^{26,6}

Although arthrodesis with autologous iliac crest graft is considered as the biological and biomechanical standard in anterior cervical reconstruction,³⁰ the morbidity of the iliac bone harvest can often limit these results.^{9,20,21} Silber et al,²³ observed that 26.1% of patients reported pain at the donor site. Summer et al,²⁵ also reported chronic pain in the donor site in 25% of 290 patients. According to Arrington et al,² in addition to the minor complications of the donor site (superficial infections, hematoma, cosmetic problems, etc.) there were major complications in 5.8% of cases, requiring therapeutic modifications, surgical revision and prolongation of hospitalization. In addition to the donor site problems, the graft complication rate in autogenous bone graft can be high.^{10,30,7,6} Matge¹⁸ reviewed patients who had undergone autogenous bone fusion procedures and found that there were many graft-related complications, including migration (2.1–4.6%), kyphosis (3–10%) and pseudoarthrosis (1–3%).

Multilevel anterior cervical discectomy and fusion still remains a difficult problem. Autogenous bone does not maintain spinal stability in multilevel discectomy very well and the graft complication rate in autogenous bone graft in multilevel fusion is

higher than at the single level.^{10,30} Graft collapse with autogenous bone is reported in 20–30% of multilevel fusions.^{14,22} Moreover, it has been reported that even with solid fusion, kyphosis often develops in multilevel discectomies with autogenous iliac crest graft fusion.¹⁴ The literature also reports a consistent rate of 10–12% non-fusion for single-level anterior discectomy and autogenous bone fusion, 20–27% for two-level, and approximately 30–56% for three-level fusions.³⁰ It is clear that the success rates decline as the number of levels increase.

In the light of these reports, in multilevel ACDF procedures, augmentation with plate fixation may seem to be preferable. Plate fixation may decrease the micro-movement of the cervical spine, enhance the fusion rate, and correct spinal curve to physiologic lordosis.²³ In ACDF, additional plate fixation has been reported to result in a higher fusion rate, lower reoperation rate, and better pain relief.^{22,30}

However, Plate complications include screw pullout,^{16,21} screw breakage,¹⁶ injury of the laryngeal nerve,¹⁰ injury of esophagus, injury of spinal cord or root, injury of vertebral artery, and wound infection.¹⁶ Additionally, the operative time is usually longer and the costs are higher with plate usage.

These complications of classical fusion procedures favored ongoing development of cage technology. Because of the advantages of these devices, the use of cages in ACDF operations has been increasing in popularity. Parallel with this, there are several different types of interbody fusion cages commercially available.^{26,7,25} Cage assisted ACDF has proven to be a safe and effective procedure for the treatment of degenerative disc disease. It has been

reported that the cage achieves excellent fusion rates ranging from 93.1–100%.^{21,26,7,18}

Bartels et al,⁴ reported that the cervical cage effectively increased foraminal height even after 1 year, which contributed to decompression of the nerve root. The wedge shape of the device may contribute to restoration of lordosis. In accordance with the current study, they showed that the cage resulted in preservation of the preoperative lordosis. There are numerous types of cages developed for ACDF including titanium, carbon fiber, and PEEK cages. Metallic cages used in ACDF can provide mechanical support, maintain initial disc height, and sagittal lordosis. Clinical results are satisfactory and donor site complications can be prevented.²⁰ But cage subsidence or migration was also observed resulting in disc height collapse and kyphotic deformity.²⁰ Furthermore, metallic cages are radio-opaque, which prevents the observation of trabecular bone formation, and radiographic determination of fusion has been debated.

In this study, we preferred to use PEEK cages for multilevel fusion, because of the lower reported complication rates.⁶ PEEK is a semi-crystalline polyaromatic linear polymer that provides a combination of strength, stiffness, toughness, and environmental resistance.⁷ In laboratory studies, this device demonstrated excellent resistance to compression, It is also biocompatible.²⁹ The cage has been shown to have a stimulatory effect on the protein content of osteoblasts.¹⁹

Also, the cage structure (two titanium spikes on the upper and bottom frame, in addition to the retention teeth on the surface of the upper and bottom frame) offers a fixation mechanism which is similar to the functions of a plate and screws.^{7,6} Additionally, bone fusion can be evaluated easily by examining X-rays, because the PEEK cage is radio-transparent. It is also possible to evaluate postoperative MRI or CT scans, because artifacts are negligible.⁷ Lastly, the PEEK cage is more elastic than the other cages which are made of metal, reducing the possibility of graft subsidence into the vertebral body.¹⁵ Many of the complications associated with autologous tricortical iliac crest have been reduced significantly with the use of the cage.

Autogenous iliac bone grafts, local bone grafts, sterilized allografts, and bone substitutes (such as hydroxyapatite grafts), and bone morphogenetic proteins have all been used to fill into the cage to

achieve bony fusion. According to literatures, usage of a cage with an autogenous iliac bone graft achieves the best fusion outcome, whereas allografts have relatively low fusion rates.

Recombinant human bone morphogenetic protein-2 is an osteoinductive protein significant for consistent new bone formation.³¹ However, its use in ACDF is limited due to its local inflammatory reaction, increased incidence of dysphagia, higher cost, and good success with a cheaper alternative.

The results of using bone substitute in cervical interbody fusion seemed to be encouraging. Agrillo et al,¹ reported a series study of 45 patients with cervical soft disc herniation who received anterior cervical fusion with cage implants containing granulated coralline hydroxyapatite. This fusion result is quite promising in terms of bone substitute usage.

Follow up study of fusion stated that 75.3% of operated levels showed bony fusion in less than six months postoperatively, while 21.3% required about one year to fuse. However bony fusion could be anticipated after one year postoperatively as 1.3% of the levels fused up to two years postoperatively. The high rate of fusion within the first six months may be due to stability produced by the cage or the assumed stimulatory effect of bone graft substitute on bone growth or both.

In our series, the fusion rate was 97.9 %, comparable to the related literature. There were three patients with non-fusion. Although these non-fusions were seen in three and four-level operated patients no clinical signs or radiographic mobility of pseudoarthrosis were observed during the follow-up period. No cage breakage or migration was encountered, even in patients who underwent fusion at more than two levels. The use of the cage as standalone spacer supporting the anterior spinal column was found to preserve the spinal lordosis and the height of the foramina throughout the follow up period.

Conclusion

Our conclusion from this study is that the use of standalone PEEK cages filled with calcium triphosphate bone graft substitute in multiple levels degenerative cervical disc diseases achieves fusion and stability of the anterior cervical column with avoidance of the dilemma of autogenous graft and plate complications.

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الملخص العربي

استئصال وتثبيت مستويين أو أكثر من الفقرات العنقية باستخدام أقفاص بيك مملوئة ببديل العظام الخلفية العلمية: أصبح استئصال الغضروف العنقي وتثبيت الفقرات جراحة ناجحة لعلاج اعتلال الغضروف العنقي المصاحب باعتلال جذور الاعصاب او النخاع الشوكي. بالإضافة الى مضاعفات الرقعة العظمية. استئصال عدة مستويات من الغضروف العنقي يصاحب غالباً بتركيب شريحة عنقية للحفاظ على انحناء الفقرات العنقية. وتدعيم لحام الرقعة العظمية ولكنه أيضاً يزيد من احتمالية حدوث المضاعفات. تصميم الدراسة: دراسة استشرافية سريرية وصفية.

الغرض: لتقييم سلامة وكفاءة استخدام اقفاص بيك العنقية المحشوة ببديل العظام لعلاج اعتلال الغضاريف العنقية متعدد المستويات.

المرضى والطرق: تم عمل الجراحة لـ ٩١ مريض وتم عمل ٢٣٩ مستوى. وتم متابعة الحالات لمدة متوسطها ٢٤ شهر. تم تقييم النتائج باستخدام المقياس المرئي التناظري. وتقييم الاشعة العادية للرقبة.

النتائج: كانت نسبة الحام الناجح ٩٧.٩%. وتم تحسن الالم من ٦.٥٢ الى ١.٨٧ على المقياس. وبتقييم الاشعة وجد المحافظة على انحناء العمود الفقري العنقي وتحسن الاعتلال العصبي. لم يتم كسر او انزلاق للقفاص.

الاستنتاج: يعتبر استئصال الغضروف العنقي وتثبيت الفقرات باقفاص بيك المحشوة ببديل العظام وسيلة آمنة لعلاج اعتلال الغضاريف العنقية متعددة المستويات. وهي تحافظ على انحناء العمود الفقري العنقي وتجنب المضاعفات التي قد تحدث نتيجة استخدام الرقع العظمية من الحوض او استخدام الشرائح والمسامير العنقية.