

ACDF with a PEEK cage clinically provides a good outcome with minor donor site morbidity despite unsatisfactory radiological findings —A prospective cohort study of a PEEK cage in stand-alone usage—

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Abstract:

Study Design: A prospective cohort study was conducted on patients with anterior cervical decompression and fusion (ACDF) with a polyetheretherketone cage (PEEKc).

Background: Advantages of a PEEKc have been proposed in the study. However, benefits of using a PEEKc in ACDF are still controversial.

Objective: To investigate the advantages of a PEEKc in ACDF.

Materials and Methods: A total of 27 patients was enrolled in the study. The mean age of patients was 55 ± 10 years (mean $\pm$ standard deviation). The mean duration of symptoms was 17 ± 21 months. Surgery was conducted at C3/4 in 1, C4/5 in 3, C5/6 in 11, C6/7 in 9, C7/T1 in 2, and C5/6/7 in 1 patient. The mean follow-up period was 2.1 ± 1.3 years. Clinical outcomes were analyzed by the Japanese Orthopedic Association Scores (JOA scores) and its recovery rate. Perioperative complications were also investigated. Radiologically, studies were conducted on interbody lordotic angle (IBLA), interbody height (IBH), and bone fusion rates.

Results: The JOA score was 14.7 ± 1.4 preoperatively and 16.3 ± 1.3 at the final follow-up. A significant improvement was observed ($p < 0.05$). The mean recovery rate of JOA scores was $74.0 \pm 25.0\%$. The preoperative IBLA was $0.5 \pm 6.1^\circ$. The mean IBLA at the final follow-up was $1.9 \pm 5.6^\circ$. The preoperative IBH was 34.2 ± 3.5 mm. The mean IBH at the final follow-up was 34.3 ± 3.5 mm. No significant improvement in IBLA and IBH was observed. A complete union rate at 1 year and 2.3 years (range, 2.0-6.0) after surgery was 29% (8/28 segments) and 61% (11/18 segments). No major complications were observed.

Conclusions: Despite an unsatisfactory bone union rate and no significant improvement in IBLA and IBH at the final follow-up, ACDF with a PEEKc clinically provided a stable outcome with less surgical invasion and minor donor-site morbidity.

Keywords:

Anterior Cervical Decompression and Fusion, Polyetheretherketone Cage, Stand Alone Usage, Sagittal Alignment

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Introduction

Mixter and Barr first disclosed the ruptured intervertebral disc with the involvement of the cervical spinal canal as a ventral vertebral disc chondroma in the cervical spine, and noted an instability after laminectomy for the removal of the

ruptured cervical intervertebral disc in 1934¹⁾. To overcome the instability after laminectomy, Robison et al. developed an original procedure of anterior cervical decompression and fusion (ACDF) for cervical radiculopathy caused by the foraminal spur in 1954²⁾. Cloward also started ACDF for the ruptured cervical disc and reported a good surgical result in

1958³⁾. There is no doubt that ACDF using autogenous iliac bone (AIB) is a golden standard procedure at present, almost 60 years after the studies conducted by Robinson and Cloward. Although ACDF with AIB is widely indicated for degenerative disorders and trauma in the cervical spine, it needs a technical demand for bone harvesting and grafting. Furthermore, it is being associated with a possibility of collapsing of the grafted bone that may lead to a non-union, donor-site morbidity, including persistent pain, hematoma, infection, and meralgia paresthetica. These problems cannot be completely resolved by surgical skill alone. If ACDF can be performed without these problems, then it may prove to be quite beneficial for both patients and spinal surgeons.

In the late 1990s and early 2000s, various types of intervertebral devices (IBD) in the cervical spine, which provided solid anterior column support of the functional spinal unit, were introduced and used *in vivo*. IBD has considerably improved the biomechanical stability immediately after surgery. In particular, some polyetheretherketone (PEEK) was introduced to the orthopedic sphere in the late 1990s and has been used for a type of interbody device materials^{4,5)}. PEEK is a biocompatible and radiolucent material. Moreover, it has a construct stiffness (4.1 ± 0.3 GPa in Young's modulus) similar to that of a bone tissue, which is expected to provide a better and earlier bone fusion⁶⁾. This is the main reason why a PEEK cage (PEEKc) is widely preferred for IBD, especially in ACDF. A PEEKc in ACDF also proposes a simple surgical technique, no material collapse, and minimal or no donor-site morbidity as compared to ACDF with AIB. Furthermore, it has an excellent MRI compatibility.

Despite these biomechanical and surgical advantages of a PEEKc in ACDF, its clinical and radiological benefits are still controversial⁷⁻¹¹⁾. Therefore, it is necessary to assess whether a PEEKc provides a better clinical and radiological result in ACDF. This study aims to investigate the clinical and radiological advantages of using a PEEKc in ACDF.

Materials and Methods

A prospective cohort study was conducted on patients with ACDF with a stand-alone cage for degenerative cervical disorders. This study was approved by our medical ethics board according to the 1964 Helsinki Declaration (approval number 22).

Diagnosis

The diagnosis of myelopathy and radiculopathy included clinical and neurological examinations. Plain radiograms and MRI in the cervical spine were routinely conducted. Myelography, CT-myelogram, and CT-discography were conducted for further evaluation if necessary.

Inclusive criteria for surgery

1. Progressive myelopathy.
2. Radiculopathy with motor weakness (MMT ≤ 3).
3. Radiculopathy with severe pain and/or persistent numb-

ness after a failed conservative treatment at least for 6 weeks.

4. Findings, which explain subjective symptoms and neurological disturbances, on MRI, myelogram, CT-myelogram, and CT-discogram.

Exclusive criteria for surgery

1. Developmental canal stenosis, continuous ossification of the posterior longitudinal ligament.
2. Previous anterior spine surgery.
3. Severe osteoporosis, infection, and neoplasm.

Surgical procedure and care after surgery

A standard ACDF was performed via an anterolateral approach. Surgery was mandatory and was conducted with the assistance of a microscope. The herniated disc, spur, and posterior longitudinal ligament, which compressed the neural tissue, were completely removed after distraction by 2 screws placed in the affected vertebral bodies. The cartilaginous endplate was resected with curettage and/or air drilling without damaging the bone endplate. The spinal canal was decompressed with a width of minimal 18 mm to maximal 20 mm. A hollow PEEKc (CeSpace PEEK[®], Aesculap[®] B/BRAUN Germany) was used. A PEEKc with an appropriate size was carefully implanted at the decompressed intervertebral space. The size of a PEEKc was determined using a trial device to check the initial stability. After insertion of a PEEKc, distraction was released. Postoperatively, a soft collar was braced for a week. Ambulant was allowed on the following day of surgery. No limitation of ADLs was informed all patients of, but heavy working and contact sports activities were prohibited for 6 weeks and 12 weeks, after surgery.

Clinical and radiological assessments

With regard to clinical assessment, the Japanese Orthopaedic Association (JOA) score for cervical myelopathy was used. The JOA score was calculated by a perfect score of 17 points (8 for upper and lower motor function, 6 for sensory function, and 3 for urinary and bowel function). The recovery rate of JOA score was determined by a formula, (postoperative JOA score - preoperative JOA score) $\times 100 / (17 - \text{preoperative JOA score})$ %. The preoperative duration of symptoms was also evaluated. As surgical parameters, surgical time, blood loss in surgery, perioperative complications were analyzed. Plain radiograms on the anteroposterior and lateral views were routinely checked preoperatively, on the day of surgery, at 2 weeks, 6 weeks, 3 months, 6 months, 1 year after surgery, and at the final follow-up. Lateral radiograms in flexion and extension were also taken, preoperatively, at 6 weeks, 3 months, 6 months, 1 year to surgery, and at the final follow-up. Radiological assessment was performed in the radiograms preoperatively, at 2 weeks, one year after surgery, and at the final follow-up. Segmental kyphosis and height were investigated using interbody angle (IBLA) and interbody height (IBH) proposed by Park HW et al. (Fig. 1)⁹⁾. If no movement was observed on the lateral



Figure 1. Measurement of Interbody Lordotic Angle (IBLA) and Interbody Height (IBH). Showing IBLA and IBH is 3.94° and 32 mm, respectively.

view in the flexion-extension of the fixed segment and continuity of the trabecular bone bridging was observed at the fixed interbody space on the lateral radiogram, then it was termed as “complete union.” If any movement was observed on the lateral view in the flexion-extension of the fixed segment, then it was termed as “non-union.” If continuity of the trabecular bone bridging around the cage was vague despite no movement of the fixed segment, then it was termed as “probable union”^[12]. In case the fused segment was not clearly observed on the lateral radiogram, such as C6/7, C7/T1 segment in an obese patient, reconstructed CT was referred to assess IBLA, IBH, and the trabecular bone bridging. Consensus of the bone fusion assessment was obtained through a radiological conference with 7 orthopedic doctors, including 5 doctors who were completely independent to the surgery.

Statistic Analysis

A paired t-test was used to compare preoperative and postoperative values. The Pearson correlation coefficient was applied to determine the relationship between clinical and radiological results. Data were described as mean $\pm$ standard deviation and p value <0.05 was considered as significant.

Results

A total of 31 consecutive patients was informed and enrolled from October 2010 to December 2015. However, 3 out of 31 patients dropped out because of no contact within 1 year after surgery. A patient with a posterior fusion due to iatrogenic spondylolisthesis at C4/5 was also excluded.

Table 1. Demographic Characteristics of Patients.

Characteristics	Patient Numbers (%)
Male/Female	14/13
Age (years)	55 $\pm$ 10 years
BMI*	24.2 $\pm$ 4.2 kg/m ²
Duration of Symptoms	17 $\pm$ 21 months
Smoker	11 (41)
Radiculopathy	16 (59)
Myelopathy	11 (41)
Operated Level (n=28)	
C3/4	1
C4/5	3
C5/6	11
C6/7	9
C7/T1	2
C5/6/7	1

BMI*: Body Mass Index

Therefore, 27 patients were included in this study. Surgery was conducted on 13 females and 14 males with the mean age of 55 $\pm$ 10 years. The mean duration of symptoms was 17 $\pm$ 21 months. A total of 16 and 11 patients was presented with radiculopathy and myelopathy, respectively. Surgery was conducted at C3/4 in 1, C4/5 in 3, C5/6 in 11, C6/7 in 9, C7/T1 in 2, and C5/6/7 in 1 patient. The mean follow-up period was 2.1 $\pm$ 1.3 years (range, 1.0-6.0). Of them, 17 patients with 18 affected segments could be followed up for more than 2 years (average, 2.3 years. range, 2.0-6.0). The percentage of smokers was 41% (11/27) of patients. The mean body mass index (BMI) was 24.2 $\pm$ 4.2 kg/m². Patient demographics were summarized in Table 1. In 8 segments (29%), a small amount of cancellous bone from the anterior iliac crest was grafted in the hollow of the cage. In 18 segments (64%), collagen hybrid hydroxyapatite, hydroxyapatite, and/or the resected local bone was grafted in the hollow of the cage without bone harvesting. In 2 segments (7%), an empty PEEKc was used (Table 2).

Surgical parameters and complications

Blood loss during surgery was averaged at 36.3 $\pm$ 92.0 grams per fused segment. The average surgery time was 2.0 $\pm$ 0.4 hours per fused segment. There were no major complications in all patients. However, massive epidural bleeding (400 grams), partial tear of the dura mater, and mild dysphagia, which spontaneously recovered within 3 months after surgery, were observed in 1, 1, and 2 patients. Transient and extremely mild pain at the bone-harvested site was present in 2 patients.

Clinical outcome and radiological outcomes

The mean JOA score was 14.7 $\pm$ 1.4 preoperatively and 16.3 $\pm$ 1.3 at the final follow-up. A significant improvement was observed between the scores ($p < 0.05$). The mean recovery rate of the JOA score was 74.0 $\pm$ 25.0%. The mean

Table 2. Demography of Grafted Materials in a PEEKc.

Material	Fused Segments (%)
Iliac Bone	8 (29)
Resected Local Bone	1 (4)
Collagen Hybrid HA*	6 (21)
HA*	1 (4)
Collagen Hybrid HA* & Resected Local Bone	10 (35)
None	2 (7)

HA*: Hydroxyapatite

Table 3. Outcome of ACDF with a PEEK Cage.

Parameter	Pre-op	Post-op 2ws ¹	Final Follow-up
JOA score ²	14.7±1.4		16.3±1.3
Recovery rate			74.0±25.0 %
IBLA ³	0.5±6.1° *	4.9±4.8 ° **	1.9±5.6° ***
IBH ⁴	34.2±3.5 [#]	36.0±2.9 mm ^{##}	34.3±3.5 mm ^{###}

1. Two weeks following surgery

2. Japanese Orthopaedic Association Score

3. IBLA: Interbody Lordotic Angle (°)

4. IBH: Interbody Height (mm)

Significant difference between *and ** (P<0.05)

Significant difference between #and ## (P<0.05)

No significant difference between *and ***

No significant difference between #and ###

IBLA was $0.5 \pm 6.1^\circ$ preoperatively. It significantly improved to $4.9 \pm 4.8^\circ$ at 2 weeks after surgery ($p < 0.05$) and was $1.9 \pm 5.6^\circ$ at the final follow-up. No significant difference was found between the preoperative and the IBLA at the final follow-up. The mean IBH was 34.2 ± 3.5 mm preoperatively. It was 36.0 ± 2.9 mm at 2 weeks after surgery and 34.3 ± 3.5 mm at the final follow-up. There was a significant difference between the preoperative and the IBH at 2 weeks after surgery, but no significant difference was found between the preoperative and the IBH at the final follow-up. The complete union rate at 1 year and 2.3 years (range, 2.0-6.0) after surgery was 29% (8/28 segments) and 61% (11/18 segments), respectively. The probable union rate at 1 year and 2.3 years (range, 2.0-6.0) after surgery was 46% (13/28 segments) and 6% (1/18 segments), respectively (Table 4). The non-union rate at 1 year and 2.3 years (range, 2.0-6.0) after surgery was 25% (7/28 segments) and 33% (6/18 segments), respectively. No breakage of the PEEKc was observed on the radiograms at the final follow-up. There was no correlation among IBLA, IBH, and the recovery rate of JOA scores. The clinical and radiological outcomes were summarized in Table 3, 4.

Case Presentation

A 65-year-old female with myelopathy at C5/6.

The preoperative JOA score was rated to be 11.5 points. The preoperative lateral radiogram showed that IBLA and IBH were 0° and 33 mm at C5/6 (Fig. 2-A). ACDF using a PEEKc, with a small amount of the cancellous bone from

Table 4. Bone Union Rate.

	1 year after surgery	2.3 years after surgery (range, 2.0-6.0)
Complete union	29% (8/28 segments)	61% (11/18 segments)
Probable union	46% (13/28 segments)	6% (1/18 segments)
Non- union	25% (7/28 segments)	33% (6/18 segments)

the anterior iliac bone, was performed. The lateral radiogram at 2 weeks after surgery showed that IBLA and IBH were 0° and 35 mm (Fig. 2-B). The lateral radiogram at 3 years after surgery demonstrated a trabecular bone formation in and around the cage, which suggested a complete union, and IBLA and IBH were restored as much as the preoperative stage (Fig. 1-C). The JOA score was rated to be 16 points at the final follow-up.

Discussion

Wrought titanium 6Al-4V ELI alloy in an interbody device is corrosion-resistant, strong enough to obtain the immediate stability of the fixed segment in the cervical spine, and has biologically an intimate affinity to the bone tissue. Thus, it enhances bone ingrowth around the alloy itself^{6,12,13}. However, wrought titanium 6Al-4V ELI alloy has a considerably high construct stiffness to the cortical (18 GPa in Young's modulus) or cancellous bone (1 GPa in Young's modulus). This higher construct stiffness has a side effect of stress shielding that would develop absorption of the grafted bone within the cage or around the spacer. Therefore, the bone ingrowth within and around a titanium cage is questionable¹⁴. On the contrary, PEEK has a construct stiffness (4.1 ± 0.3 GPa in Young's modulus) similar to that of the bone tissue⁶. From the viewpoint of biomechanical characteristics, a better bone fusion with a PEEKc is expected than a titanium cage in ACDF. This is probably the main reason why a PEEKc is widely preferred to a titanium cage in ACDF. In this study, the bone union rate at 1 year and 2.3 years (range, 2.0-6.0) after surgery was 29% (8/28 segments) and 61% (11/18 segments), respectively. The bone union rate of the present result is relatively lower than that of other studies of ACDF with a PEEKc^{8,11}, but this may have attributed to our strict criteria for bone fusion. In general, it is reported that PEEK has no bone conductivity itself *in vitro*⁶. Sinclair et al. have already noted that a scar tissue, which is barely seen around a titanium cage, is present around a PEEKc in the cervical spine of the gout model in 2012¹⁵. This disadvantage of a PEEKc results in a lack of bone ingrowth on the surface of the cage, which may lead to the subsidence of the cage and non-union in ACDF^{7,11}. Meanwhile, in this study, 2 patients using an empty PEEKc radiologically obtain bone fusion as well. The complete fusion of the 2 cases is not in agreement with the no bone conductivity of a PEEK. The bone conductivity of a PEEK *in vivo* still needs to be discussed¹³. The lack of bone ingrowth, which reduces resistance to shear force between a

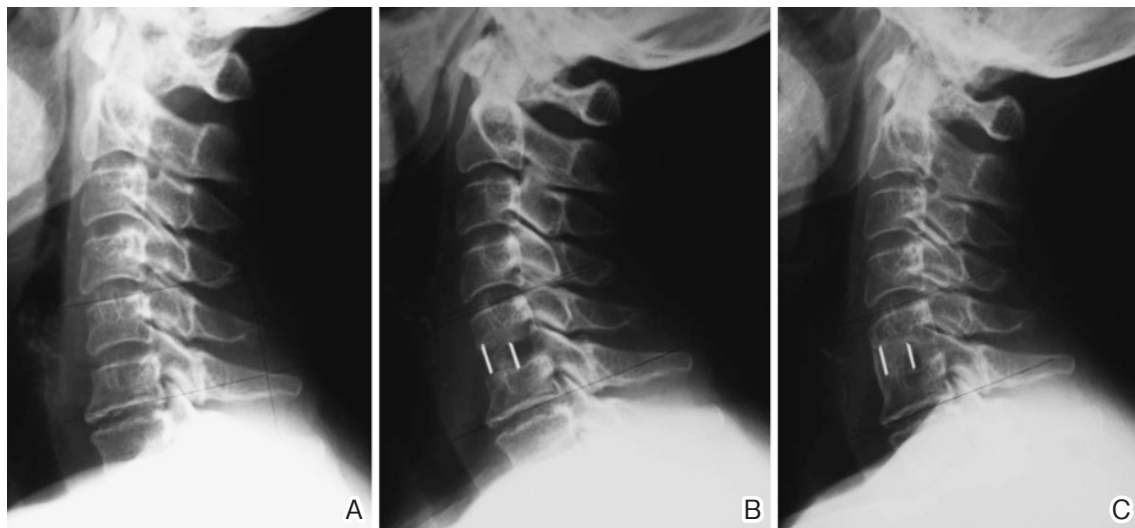


Figure 2. A 65-year-old female with myelopathy at C5/6

A, The preoperative lateral radiogram.

B, The lateral radiogram at 2 weeks following surgery.

C, The lateral radiogram demonstrating a union 3 years after surgery.

PEEKc surface and the vertebral end-plate, may play another role in the development of non-union^{6,16}. A relatively higher risk of non-union is not neglected in ACDF using a PEEKc. Further detailed studies are expected to disclose the issue at present. Application of a PEEKc with surface coating or carbon fiber has the potential to resolve these problems^{17,18}.

It is generally believed that physiological lordosis of the fused segment is crucial to gain the better dorsal shifting of the decompressed spinal cord in ACDF. However, clinical data that support the importance of cervical lordosis is rarely observed. Wu et al. have disclosed that the recovery rate of the JOA score was significantly related to the C2-C7 Cobb angle of 57 patients in whom ACDF with a stand-alone cage was performed¹¹. In the lumbar spine, it is also noted that a degenerative change would be accelerated in the adjacent segment to the kyphotic fusion in the long term^{19,20}. In this study, no correlation was found between IBLA and the recovery rate of JOA at the final follow-up. Our result does not agree with the commonly held option for the cervical lordosis. However, Vavruch et al. have demonstrated a weak but significant correlation between a decreased segmental lordosis and improvement after ACDF using the Cervical Spine Functional Score. In their discussion, they have attributed the unusual result to the fact that the kyphosis results in a disengagement of the facet joints and thereby in better pain relief than lordosis, which may compress and induce symptoms from the degenerated facet²¹. A better lordosis of the fused segment in ACDF provides less degeneration in the adjacent segment? A long-term follow-up should be conducted.

The morbidity of harvesting graft bone from the ilium is quite significant. Yonger et al. reported complications of donor site in detail²². The major complications that they mentioned included deep infection, prolonged wound drainage,

sensory loss, chronic severe pain, etc. In particular, donor site pain is quite persistent and irritable for patients. If ACDF is performed without graft bone harvesting, then it proves to be a great advantage. In this study, donor-site minor morbidity was observed only in 2 patients who needed a small amount of bone packing in the hollow of a PEEKc. Indeed, no donor-site morbidity was reported from patients in whom an artificial and/or a resected local bone was being packed into the hollow of a PEEKc.

The benefit of a PEEKc in ACDF is already proposed in recent studies. Park HW et al. have demonstrated the efficacy of a PEEKc filled with demineralized bone matrix in 2009⁹. In 2010, Lied et al. stated their preference of using a PEEKc to AIB because of the absence of donor-site morbidity and a similar clinical result between the 2 groups⁸. In 2015, Xie et al. also reported a prospective randomized comparison of a PEEKc containing calcium sulphate or demineralized bone matrix with autograft in ACDF. In their study, the fusion rate and the recovery rate of JOA score between the 2 groups were quite similar, and the advantage of less operative blood loss and fewer complications at the donor site in ACDF with a PEEKc was mentioned¹⁰. The present study has also demonstrated that ACDF with a PEEKc provides a significant clinical improvement. At last, I would like to stress that ACDF with a PEEKc provided a good clinical outcome with less surgical invasion and a minor donor-site morbidity, including MRI compatibility, although an unsatisfactory bone union rate and no radiological improvement in the sagittal alignment were gained at the final follow-up.

Limitations

- For clinical evaluation, the JOA score was introduced in the present study. A JOA score cannot assess neck

pain in its items; thus, a different clinical result may be obtained if another scoring tool, such as the Cervical Spine Functional Score, was used.

- Cost-effectiveness of a PEEKc was not evaluated. The PEEKc used in this study costs approximately ¥174000/piece in Japan. It is questionable to justify the usage of a PEEKc given its high cost.
- Clinical evaluation while the follow-up was performed by the first author who mainly participated in the surgery. This methodology may cause a positive or negative bias of the surgical outcome. The inter-observer test of the criteria for the bone union rate was not conducted. A relatively low union rate may be attributed to the stringent radiological assessment according to our criteria.
- A total of 17 patients with 18 affected segments could be followed up for more than 2 years (average, 2.3 years, range, 2.0-6.0). The number of patients and the follow-up period is quite small. Furthermore, several types of materials were grafted in the hollow of a PEEKc. These are the weak points of this study. A cohort study with several patients with the same grafting material in the hollow of a PEEKc and a longer follow-up by independent observers is expected.

Conflicts of Interest: The manuscript submitted here does not contain information about medical devices or drugs. No benefit in any form has been or will be received from a commercial party related directly or indirectly to the subject of this manuscript.

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