



Implantation of an empty polyetheretherketone cage in anterior cervical discectomy and fusion: a prospective randomised controlled study with 2 years follow-up

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Abstract

Purpose To compare the clinical outcomes, radiographic results and fusion rate of ACDF between empty PEEK cages and PEEK cages packed with β -tricalcium phosphate.

Methods Forty-five patients were prospectively enrolled with cervical degenerative disc disease who requiring ACDF with a PEEK cage. 23 patients were randomised to the study group (empty cages) and 22 patients were in the control group (cages filled with β -tricalcium phosphate). Both patient groups were fixed with a cervical locking plate. A CT scan was performed 12 months postoperatively and 24 months if not confirmed fused at 12 months to evaluate the status of fusion. Clinical status was evaluated using the Japanese Orthopaedic Association (JOA) score, the Oswestry Disability Index (ODI) and the Visual Analogue Scale (VAS).

Results 46 levels (97.88%) in the study group and 44 levels (97.77%) in the control group were confirmed as fused at 24 months. There was no significant difference between the fusion rates observed in the study and control groups ($p = 0.82$). There was no significant difference in JOA, ODI, or VAS scores at 24 months follow-up. The results showed that the members of the non-fusion group tended to be older than the individuals in the fusion group at 12 months, but was not significant in statistics.

Conclusions Similar fusion rates and clinical outcomes were achieved when using ACDF with PEEK cages and instrumentation, regardless of whether the cage was filled with bone substitute at 24 months follow-up. Fusion rates improved over time and are comparable between both groups.

Graphical abstract These slides can be retrieved under Electronic Supplementary material.

The graphical abstract consists of three slides from a presentation. The first slide, titled 'Key points', lists: 1. Empty cage, 2. ACDF, 3. PEEK cage. The second slide, titled 'Figure 1', shows two views of a PEEK cage: (a) an empty cage and (b) a cage filled with a bone substitute. The third slide, titled 'Take Home Messages', states: 1. This prospective randomised controlled study is to compare the outcomes between ACDF using empty cages and cages filled with β -tricalcium phosphate. 2. ACDF with empty cages showed similar fusion rates and clinical outcomes. 3. Fusion rates improved over time and are comparable between both groups. Each slide includes a 'Springer' logo and a '[Citation]' placeholder.

Keywords Empty cage · ACDF · PEEK cage

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Introduction

Anterior cervical discectomy and fusion (ACDF) has been widely used in the treatment of cervical spinal disorders since the 1950s [1]. Various materials have been used in fusion such as autograft, allograft, and artificial materials. Fusion rates with these materials have been reported with satisfactory results [1–6]. Interbody fusion using cages filled with different materials, such as surgical-site bone, autograft, calcium sulfate, biphasic calcium phosphate, and β -tricalcium phosphate (β -TCP), and bone morphogenic protein (BMP) has been thoroughly investigated with satisfactory results [4, 5, 7–9]. Whereas autograft can involve issues related to donor site mobility, the use of a surgical-site bone graft can involve problems related to an insufficient supply. The excessive cost of using additional filling materials, such as calcium phosphate and BMP, is prohibitive.

Many different types of cages have been explored, ranging from the titanium cage and polymethylmethacrylate (PMMA) cage used previously until the recent development of bioabsorbable cages, carbon-fibre cages, polyetheretherketone (PEEK) cages, and silicon nitride spacer, etc [3, 10–16]. The advantages of the PEEK cage include increased radiolucency, biocompatibility and decreased stiffness [17].

In our experience, a bridging callus is found not only within the cage, but also anterior or posterior to the cage in patients with ACDF. Similar observations have been made by other authors [12]. It is unknown whether the biomaterial packed into the cage plays an important role or whether fusion occurs spontaneously even in the absence of any packing materials. The fusion rate achieved when using an empty PEEK cage in ACDF remains unclear. The purpose of this study is to compare the clinical outcomes, radiographic results and fusion rate of ACDF between empty PEEK cages and PEEK cages packed with β -tricalcium phosphate alone.

Methods

This study included patients with cervical degenerative disc disease causing myelopathy or radiculopathy requiring anterior cervical discectomy and fusion with a PEEK cage. Patients requiring posterior cervical surgery, anterior cervical corpectomy, or revision surgery were excluded. Patients who were chronic smokers or steroid users were also excluded.

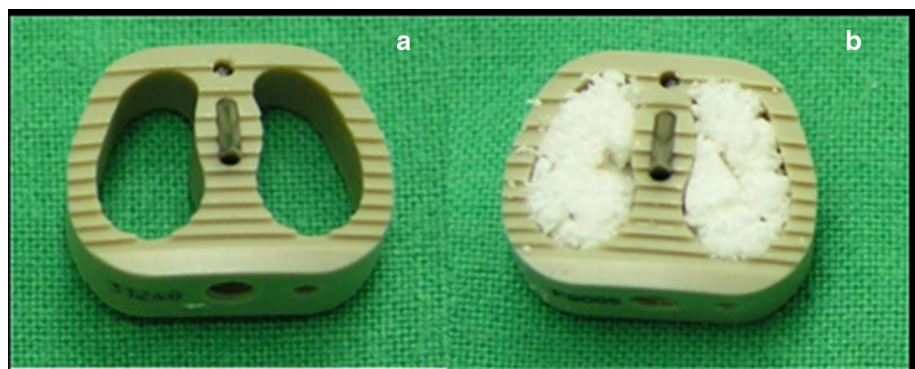
Patients were numbered consecutively in the order they were admitted to our hospital and randomised to either the study group or the control group using computer-generated random numbers.

Patients in the study group underwent fusion with an empty PEEK cage, and patients in the control group underwent fusion with a PEEK cage packed with β -tricalcium phosphate alone. Prior to randomisation, the patients were informed about the details of the surgical procedures involved in the two different groups. Randomisation was performed using a statistical program. The study was approved by the Institutional Review Board.

Surgical procedure

Anterior cervical discectomy was performed via a left-sided anterior approach, as described by Smith and Robinson [1]. The cervical disc was excised completely, and spurs were removed using a Kerrison rongeur and curettes. The posterior longitudinal ligament was removed to the greatest extent possible. The subchondral cartilage was curetted to expose the bony endplate prior to implantation of the PEEK cage (Fidji cervical cage, Zimmer spine, Bordeaux, France). In the study group, each individual was implanted with an empty PEEK cage. In the control group, the PEEK cage was packed with β -tricalcium phosphate (ChronOS, Synthes, USA) alone without bone graft (Fig. 1). Both patient groups were fixed with an appropriately sized cervical locking plate (CSLP, Synthes, USA) to stabilise the excision at all levels. Postoperative care was the same in both groups. A semirigid

Fig. 1 **a** Empty PEEK cage, **b** PEEK cage packed with β -tricalcium phosphate



neck collar was used for 2 months, and nonsteroidal anti-inflammatory drugs (NSAID) were avoided for 3 months.

Radiologic evaluation

Plain radiographs of the cervical spine (anterior–posterior view, lateral view, flexion–extension view) were taken at 1, 3, 6, 12, and 24 months postoperatively. A computerised tomography (CT) scan was taken 12 months after the operation to evaluate the status of fusion. If fusion is not confirmed at 12 months, another CT scan will be arranged at 24 months postoperatively. Fusion status was assessed in the window at a setting of 420/40, 120 kV, 60–200 mA (Toshiba, Aquilion, Tokyo, Japan) to optimise the trabecular bone detail.

The fusion was defined as follows: (1) rotation $< 4^\circ$ and < 1.25 mm translation [16] with the absence of motion adjacent to interspinous processes (> 3 mm) in the flexion–extension view [18] and (2) the presence of continuous trabecular bone bridging was revealed by CT scan in at least one of the following locations: anterior, within, or posterior to the PEEK cage. A radiologist and a senior spine surgeon evaluated the fusion status independently without any pre-conceptions regarding patients' clinical outcomes. A fused status was recorded only when both reviewers agree.

Outcome assessment

Clinical status was evaluated using the Japanese Orthopaedic Association (JOA) score, the Oswestry Disability Index (ODI) and the Visual Analogue Scale (VAS). Each patient's clinical status was evaluated preoperatively, 1 month postoperatively, 12 months and 24 months postoperatively. Evaluations were performed by an independent researcher who was not aware of whether the patient was assigned to the study group or the control group.

Statistical analysis

Patient demographics and fusion rates were analysed using Fisher's exact test. Clinical outcomes were analysed using a nonparametric Mann–Whitney test. Statistical significance was defined as $p < 0.05$. Interobserver reliability was evaluated using kappa coefficients (strength of agreement defined as < 0 poor, 0.01–0.2 slight, 0.21–0.4 fair, 0.41–0.6 moderate, 0.61–0.8 substantial, and 0.81–1 almost perfect).

Results

From May 2010 to March 2011, a total of 45 patients fulfilling the inclusion criteria underwent anterior cervical discectomy and fusion with a PEEK cage. In total, 23 patients

(10 male, 13 female) were assigned to the study group, and 22 patients (16 male, 6 female) were assigned to the control group. In the study group, the mean age was 64.3 years (range 33–88 years). One-level ACDF was performed in five patients, whereas two-level ACDF was performed in 12 patients, and three-level ACDF was performed in six patients. A total of 47 levels were treated, primarily at C4/5 and C5/6. Among these patients, 12 had radiculopathy, five had myelopathy, and six had radiculomyelopathy. In the control group, the mean age was 57.8 years (range 27–84 years). One-level ACDF was performed in four patients, two-level ACDF was performed in 13 patients, and three-level ACDF was performed in five patients. A total of 45 levels were treated, primarily at C4/5 and C5/6. Of these patients, eight had radiculopathy, seven had myelopathy, and seven had radiculomyelopathy (Table 1).

Radiographic evaluation

At postoperative 12 months follow-up, 39 levels (82.98%) in the study group and 37 levels (82.22%) in the control group were confirmed as fused. Eight levels (17.02%) in eight patients in the study group and eight levels (17.78%) in seven patients in the control group were not fused.

At postoperative 24 months follow-up, 46 levels (97.88%) in the study group and 44 levels (97.77%) in the control group were confirmed as fused (Table 2). There was one level in each group considered not fused.

No subsidence, collapse, extrusion or other cage-related complications were observed in either group. Trabecular bony bridging could be observed anteriorly, within and posteriorly to the cages. There was no significant difference between the fusion rates observed in the study and

Table 1 Patient characteristics and operative data

	Study group	Control group	<i>p</i> value
Number of patients	23	22	0.07
M:F	10:13	16:6	
Age	64.3	57.8	0.26
Treated levels (mean)	47 (2.04)	45 (2.05)	0.90
One level	5	4	
Two levels	12	13	
Three levels	6	5	
Symptoms			0.55
Myelopathy	5	7	
Radiculopathy	12	8	
Radiculomyelopathy	6	7	

Patient demographics were analysed using Fisher's exact test or Chi-square test. Age was analysed using nonparametric Mann–Whitney test

Table 2 Clinical outcomes and radiological evaluation

	Study group	Control group	<i>p</i> value*
Treated levels	47	45	
Fusion rate (1 year)	39/47 (82.98%)	37/45 (82.22%)	1.00
Fusion rate (2 years)	46/47 (97.88%)	44/45 (97.77%)	1.00
JOA score			
Preoperative	10.13	10.64	0.49
Postoperative (1 year)	13.52	13.86	0.60
Postoperative (2 years)	13.61	13.82	0.59
ODI score (%)			
Preoperative	46.88%	48.33%	0.52
Postoperative (1 year)	23.99%	21.21%	0.58
Postoperative (2 years)	23.26%	21.44%	0.66
VAS score			
Preoperative	6.30	6.32	0.94
Postoperative (1 year)	2.74	2.77	0.93
Postoperative (2 years)	2.65	2.64	0.94
VAS improvement (2 years)	3.65	3.68	0.89

Fusion rate was analysed using Fisher's exact test

*Patient clinical outcomes were analysed using nonparametric Mann–Whitney test

control groups at postoperative 1 year ($p = 1.00$) or 2 years ($p = 1.00$) (Table 2).

Clinical outcomes

Patients in both groups showed improvements in VAS, JOA and ODI scores during the 24-month follow-up. Patients in the control group had better improvement at both 12 and 24 months, although there was no significant difference. All outcome measures are illustrated in Table 2.

We sub-divided the patients into a fusion group and a non-fusion group at 12 months follow-up. If the patient exhibited at least one level without fusion, then the patient was placed in the non-fusion group. The clinical outcomes were analysed accordingly. The results show that the members of the non-fusion group at 12 months tended to be older than the individuals in the fusion group, but this trend was not significant in statistics. No significant difference was observed for any other clinical outcome (Table 3).

Discussion

Previous studies have shown that the fusion rate for cervical spine ACDF using strut autografts ranges from 56 to 100% with an average of 77% [15, 19, 20]. The wide range of fusion rates observed for ACDF when performed with an autograft may be related to the investigation of multiple

Table 3 Clinical evaluation of the fusion group and non-fusion group

	Fusion group	Non-fusion group	<i>p</i> value*
Number of patients	30	15	
M:F	16:14	10:5	0.53
Age	58.4	66.47	0.19
JOA score			
Preoperative	10.61	9.80	0.40
Postoperative [†]	13.86	13.40	0.41
JOA recovery rate	51.96%	46.10	0.52
ODI score (%)			
Preoperative	46.73%	49.11%	0.54
Postoperative [†]	22.32%	23.44%	0.89
ODI improvement	24.40%	25.67%	0.84
VAS score			
Preoperative	6.32	6.27	0.82
Postoperative [†]	2.75	2.80	0.90
VAS improvement	3.57	3.47	0.79

Patient clinical outcomes were analysed using nonparametric Mann–Whitney test

*Patient demographics were analysed using Fisher's exact test or Chi-square test

[†]Taken at 12 months postoperatively

levels and whether a plate was used. Some studies have shown that union rate was higher if plating was used at two or three levels [19, 20]. The fusion rate ranged from 39 to 100% when an artificial spacer was used, regardless of the material (e.g., hydroxyapatite, PEEK, titanium or PMMA) [15]. Recent studies showed ACDF performed with titanium cages and PEEK cages could achieve a fusion rate ranging from 87 to 100% [4–6, 12, 21–28]. This wide range of fusion rates achieved with artificial materials might be due to the different evaluation methods used by various authors and the mode of assessment.

It remains unclear whether packing filling materials into the cage can affect the fusion rate. We were able to find some studies that discussed the fusion rate after the implantation of an empty cage [12, 25, 29]. Pechlivanis reported 52 patients with 60 levels affected who had undergone ACDF using an empty PEEK cage (AMT, Nonnweiler, Germany). Bony fusion was present at 43 levels (71.7%). In the study, another 29 patients with ACDF treated with various types of empty PEEK cages (Pina, Signus, Germany) were retrospectively evaluated. Fusion was present at 30 levels (71.4%). Statistical analysis revealed no significant difference between the two groups that were treated with different types of empty PEEK cages. Zevgaridis compared titanium cages containing iliac crest autografts with empty titanium cages, and the results showed that the fusion rates of treated levels were 91 and 87%, respectively. There was no significant difference between the two groups ($p = 1.00$). Shiban

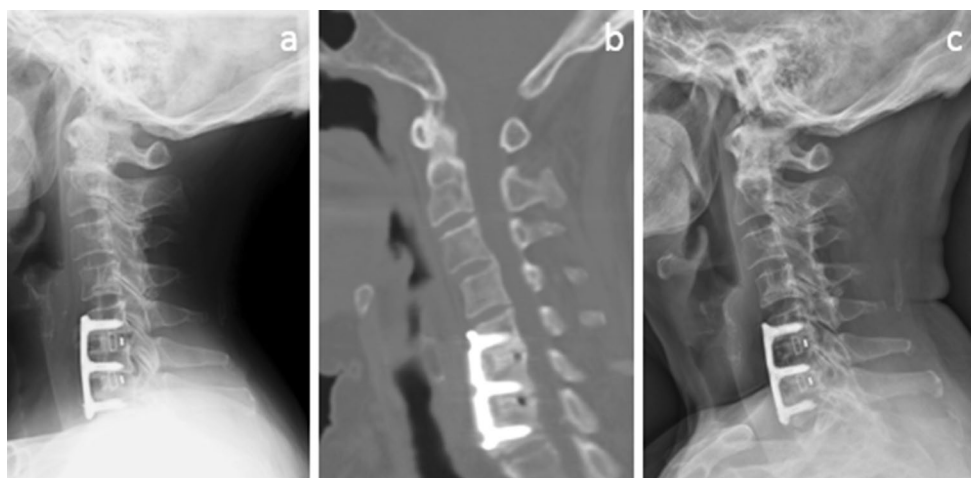


Fig. 2 Serial follow-up for an 84-year-old female who received C5/6 and C6/7 ACDF with PEEK cages packed with β -tricalcium phosphate. **a** 12 months postoperative lateral radiograph; **b** sagittal-view CT scan showing fused at 12 months; **c** 24 months postoperative lateral radiograph

et al. also reported very good fusion rate with stand-alone empty peek cage in one- and two-level ACDF in his studies with a minimum follow-up of 12 months [29]. In his study, fusion was achieved in 85, 95, and 94% of segments in one-, two-, and three-level surgeries, respectively.

The present study is a prospective randomised controlled study comparing individuals implanted with empty PEEK cages or PEEK cages filled with β -TCP alone. β -tricalcium phosphate is the only bone substitute could be used in our hospital and is covered by the national health insurance system. The results showed a fusion rate of 82.98% in the study group vs. 82.22% in the control group at 12 months, and 97.88% in the study group vs. 97.77% in the control group at 24 months. The relatively lower fusion rate at 1 year may have several explanations. First, our patients typically exhibited lesions at multiple levels (79.3% in the study group and 81.8% in the control group). Second, we used a CT scan as the primary method of assessment, whereas most studies used X-rays as the mode of assessment. Notably, the use of a CT scan to assess cervical fusion seems to be the most accurate approach with the best interobserver reliability [18].

The cervical spine has very good fusion potential. Even with no fusion technique performed after discectomy, fusion rate of 64–70% was achieved [30, 31]. A bridging callus formed not only within, but also around the cage. We assume that this is because in order to perform adequate nerve root decompression, part of the joint of Luschka was removed, similarly to the decortications necessary for the fusion procedure. Decortications of the joint of Luschka and the posterior margin of the vertebral body may have been the main cause of the high fusion rate in ACDF. Even the high occurrence rate of heterotopic ossification or spontaneous fusion after cervical artificial disc arthroplasty may be due to the same reason [32].

Cho et al. compared ACDF using PEEK cages containing iliac autografts (66 treated levels) with autogenous iliac crest autografts (58 treated levels). The fusion rates of the two groups were not significantly different (100 vs. 93.1%, $p = 0.18$) [26]. In another study, Cho et al. compared the results of using a PEEK cage containing a biphasic calcium ceramic with the use of a PEEK cage containing autogenous iliac bone graft. For both, the 6-month fusion rate was 100% [5]. These two studies demonstrate that the cage-filling materials may not influence the fusion rates of the ACDF. As mentioned before, Zevgaridis's study showed that the fusion rate was similar for titanium cages containing iliac crest autograft and empty titanium cages. These studies suggest that the fusion potential of the cervical spine is higher than we had thought and that the wide range of fusion rates observed for different ACDF techniques may be due to various authors' evaluation methods and modes of assessment.

Previous studies have shown that plating has no effect on single-level lesion [33]. However, instrumentation appears to be helpful for ACDF involving two or more levels [19, 20]. To achieve consistent external environments for every level, our study used plate immobilisation for even single-level ACDF. Our study shows high fusion rates at 24 months with no significant difference between the two groups (Figs. 2, 3). This might also indicate that the presence or absence of fusion materials is not as important as stability. However, further comparative studies on autologous bone grafting, which remains the gold standard for fusion, are needed in the future studies due to the relative low fusion rate in this study.

Another factor affecting fusion could be the duration of the follow-up interval. Many studies show that longer follow-up periods were associated with higher rates of fusion [5, 10, 13]. Theoretically, the fusion rate of the present study may have been higher if follow-up had continued for more

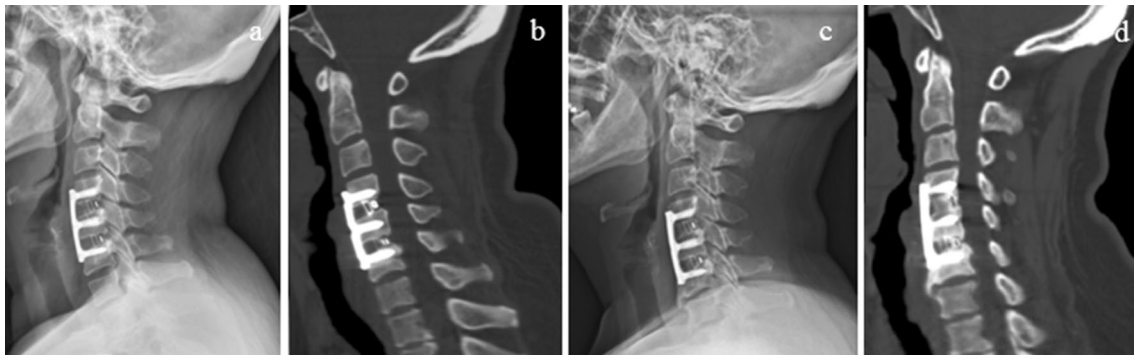


Fig. 3 Serial follow-up for a 52-year-old female who received C4/5 and C5/6 ACDF with empty cages. **a** 12 months postoperative lateral radiograph; **b** sagittal-view CT scan showing not fused at 12 months;

c 24 months postoperative lateral radiograph; **d** sagittal-view CT scan showing fused at 24 months

than 1 year. Thus, larger comparative studies with longer follow-up are needed to assess these results.

The present study showed that similar fusion rates and clinical outcomes were achieved when using ACDF with PEEK cages and instrumentation, regardless of whether the cage was filled with bone substitute. However, the study also demonstrated that the patients with solid fusion or non-union had similar functional results, which was similar to the results reported by previous studies [25, 30, 31].

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Compliance with ethical standards

Conflict of interest None of the authors has any potential conflict of interest.

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