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# Clinical Efficacy of Autogenous Vertebrae-Filled PEEK Cage in Anterior Cervical Discectomy and Fusion with Instrumentation

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#### Abstract

This study aimed to investigate the clinical efficacy of the autologous vertebral-filled polyetheretherketone (PEEK) cage in anterior cervical discectomy and fusion with instrumentation (ACDFI). The clinical data of 368 patients who received ACDFI from September 2012 to September 2017 were retrospectively analyzed. Based on the material that filled PEEK cage during the surgery, the patients were divided into two groups, the autologous vertebrate group (n =185) and the autologous iliac group (n = 183). The operative time, operative blood loss, postoperative complications in the two groups were recorded and analyzed. The bone graft fusion and postoperative functional outcomes, including scores of modified Japanese Orthopedic Association score (mJOA), Neck Disability Index (NDI), and Visual Analog Scale (VAS) were compared. Patients were followed-up for 14.04  $\pm$ 0.98 months. At 6-months follow-up, the rate of spinal fusion was 96.29% (178/185) in the vertebral group and 95.94% (176/183) in the iliac group, with no significant difference between the two groups (p > 0.05). The postoperative VAS, mJOA, and NDI scores were also not significantly different between two groups during the follow-up (p >0.05). The operative time and blood loss in the vertebral group were significantly less than that of the iliac group (p < 0.01). All patients in the iliac group suffered pain at the iliac donor site, 65 patients suffered numbness, 12 patients had fat liquefaction at donor incision. Meanwhile, all the patients in the vertebral group had no postoperative complications. This study concluded that the autologous vertebrae-filled PEEK cage could achieve the same clinical outcome as the autologous iliac, but have the advantages of shorter operative time, less intraoperative blood loss, and postoperative complications.

#### Keywords

Autologous; Vertebrae; Iliac; PEEK cage; ACDFI

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## 1 Introduction

Anterior cervical discectomy and fusion with instrumentation (ACDFI) have been widely used in the treatment of the degenerative disease or traumatic instability of the cervical spine<sup>1,2</sup>. In the past, the autologous iliac crest (AIC) was considered to be the best material for intervertebral support and bone graft fusion. However, absorption and displacement of the grafted bone are one of the long-term complications<sup>3</sup>. The issue of alternative techniques other than using iliac bone grafts has been occurring so long in the medical field. The intervertebral polvetheretherketone (PEEK) cage is a material with excellent biocompatibility as it could immobilize not only the unstable motion segment but also maintain the intervertebral height effectively<sup>4</sup>. Currently, autologous iliac bone is the most commonly used bone graft material for filling the PEEK cages<sup>5</sup>. However, it requires an additional surgical incision which may lead to complications at the donor site<sup>6</sup>. Autogenous vertebrae without osteophytes collected during decompression can be an ideal material for filling intervertebral cage7. However, its longterm efficacy still needs to be confirmed<sup>8</sup>. This study aimed to investigate the clinical efficacy of autologous vertebrae-filled PEEK cage in ACDFI, thus, exploring the feasibility of autologous vertebrae bone as the bone graft fusion material.

# 2 Methodology

# 2.1 Patients and Study Design

The inclusion criteria were as follows: (1) Patients with single-segment cervical disc herniation who failed conservative treatment for more than three months, without spinal stenosis or instability of other segments;

(2) Patients with a degenerative disease that caused a single segmental cervical spondylotic radiculopathy;

(3) Patients suffered from singlesegment intervertebral instability caused by trauma, along with abnormal signals of the spinal cord in MRI, with or without neurological symptoms;

(4) Patients with cervical hyperextension injury and MRI showed an interruption of the anterior longitudinal ligament, and a mixed-signal change in the intervertebral disc. Patients were excluded if they have severe osteoporosis, tumour of the cervical spine, a history of cervical surgery, acute spinal infections, and systemic infections.

The clinical data of 368 patients were retrospectively reviewed. Based on the bone graft materials used in filling the PEEK cage, the patients were divided into two groups, autogenous vertebrae-filled PEEK cage group (Group A; n = 185) and autologous iliac bone-filled PEEK cage group (Group B; n = 183). All patients received single-segment anterior cervical discectomy and decompression with instrumentation (ACDFI). The interverbal space was supported by a PEEK cage filled with bone graft (vertebrae or iliac bone) and fixed by instrumentation. This retrospective study was approved by the Research Ethics Committee of the General Hospital of Ningxia Medical University (Approval Number: 2019-043). Informed consent (written) was obtained from all patients for this study. All patients agreed to participate in the study. The general information of the patients is shown in Table 1.

Table 1. General information of patients in two groups.

Croupo	n	Age ±	Gender		Segment				Diseases	
Groups		SĎ	Male	Female	C3-4	C4-5	C5-6	C6-7	Degeneration	Trauma
Autologous vertebrate	185	53.1 ± 5.01	95	90	29	58	64	34	137	48
Autologous iliac	183	$\begin{array}{c} 52.9\pm\\ 4.87 \end{array}$	90	93	26	56	66	35	141	42

#### 2.2 Surgical Procedure

All the surgical procedures were performed by the same orthopaedic surgeon. After general anaesthesia, patients were placed in a supine position. A standard right sided ACDFI was performed through a transverse incision. By cutting the platysma horizontally and revealing the pre-vertebral fascia after blunt separation along the vascular sheath and the visceral sheath, the vertebral body, and intervertebral disc were exposed carefully. The segment of the lesion was confirmed by intraoperative fluoroscopy, and discectomies were performed. Osteophytes and soft tissues around the intervertebral space were removed for the fixation of the titanium plate and the preparation of bone graft materials. The intervertebral space was opened by using a Casper disc expander, and then the upper and lower endplate annulus fibrosus and cartilage endplate tissue were scraped. The posterior longitudinal ligament was then incised. Once the dural and intervertebral foramen were adequately decompressed, the cage and anterior locking plate ware placed.

#### 2.3 Preparation of PEEK Cage-Filled Bone Graft Material

For the autologous vertebral group, after clearing the anterior cervical soft tissue, the osteophytes of the anterior and posterior margin of the vertebral body (the red area in Figure 1) were all removed. The normal vertebral bone tissues in the anterior and posterior margins of the upper and lower vertebral bodies were obtained, including part of the cancellous bone (green area in Figure 1) without osteophytes.

For the autologous iliac group, a right anterior superior iliac incision was made, and the cancellous iliac bone was scraped with a spoon after cortical fenestration.

Patients were allowed to attend an offbed exercise on the first day after the operation. The drainage was removed when the amount was less than 5 ml, and the dressings of the surgical site were changed regularly to observe the healing of the incisions. The patients were inspected daily for postoperative complications at the donor site or cervical operative site.



Figure 1. (A) A sketch map of the excision of autologous vertebrae. (B) Autologous vertebrae excised from intervertebral space. (C) Cage filled with autologous vertebrae.

#### 2.4 Assessment of Outcomes

The clinical and radiographic evaluations were performed preoperatively and at 6-12 months after surgery. The operative time, intraoperative blood loss, postoperative hospital stays, and postoperative complications were recorded. The VAS score was used to identify the pain level of the neck and upper arms, and the mJOA score and NDI score were used to evaluate the neurological function. Radiological outcomes including bone fusion rate, lordosis of the cervical spine, and subsidence of cage were assessed by radiographs and CT scans. The standard criteria of radiological bone graft fusion<sup>9</sup> was as follows:

(1) There was no clear shadow between cage and endplate, and trabecular bone grows through the interface;

(2) There was a bone bridge between the upper and lower endplates, whether the bone bridge was located inside or outside the cage;

(3) Translucent bands were not seen in the fusion cage or intervertebral space.

The radiological evaluation was determined independently by two orthopaedic surgeons who were blinded to the design of the research (Figure 2).



Figure 2. Patient female, 45 years old, cervical 4-5 disc herniation. The vertebrae space was filled by autologous vertebrae-filled PEEK cage. (A) A preoperative cervical lateral radiograph (X-ray).
(B) Preoperative MRI showed cervical 4-5 disc herniation, compression of the dural sac spinal cord.
(C) Postoperative X-ray of the cervical vertebrae. (D) Six months after the operation, X-ray of the cervical vertebra showed continuous trabecular bone in the cage. (E) The cervical vertebra reconstruction was performed 12 months after surgery. Visible continuous bone bridge formation. (F)-(G) 12 months after surgery CT axial scan showed good bone graft fusion.

#### 2.5 Statistical Analysis

IBM SPSS (Version 22.0) software was used for statistical analysis. One-way analysis of variance (ANOVA) was used to compare functional scores between two groups at the same time; the LSD-*t* test was used to compare functional scores between groups at different time points. Data were expressed as mean  $\pm$  standard deviation ( $\bar{x} \pm$  SD) or percentages (%). P < 0.05 was considered to be statistically significant.

#### 3 Results

#### 3.1 Clinical Outcomes

There was no statistically significant difference between the vertebrae-filled group (Group A) and the iliac bone-filled group (Group B) in terms of gender, age, segment of disease, operative segments, pre-operative VAS score, mJOA score, and NDI score (p > 0.05). The operative time in Group A was significantly shorter than that of Group B (p < 0.01). The blood loss in group A was significantly fewer than that of group B (p < 0.01). There was no significant difference in postoperative hospitalization days between the two groups (Table 2). No

postoperative complications occurred in patients of group A, while all patients in group B complained of pain in the iliac donor region. A total of 65 patients in group B suffered numbness in the skin around the donor region, and 12 patients suffered fat liquefaction at the iliac donor incision.

The patients were followed-up at 6-12 months after surgery. All the patients reported to experience significant relieve of neck pain with gradual reductions of symptoms. The VAS score, mJOA score, and NDI score were significantly improved at 6- and 12-months post-surgery compared to preoperative data (p < 0.01). There were no significant differences in VAS scores, mJOA scores, and NDI scores between the two groups at 12 months (p > 0.05) (Table 3).

**Table 2.** Comparison operative data and postoperative complications between the two groups.

	Gro	oup				
	Autologous vertebrate (mean ± SD)	Autologous iliac (mean $\pm$ SD)	t	q		
Operative time (mins)	$94.45\pm10.87$	$106.75 \pm 16.13$	-3.658	0.001		
Blood loss (ml)	$34.24 \pm 8.21$	$62.73 \pm 12.19$	-14.410	0.000		
Postoperative hospital stays (days)	$6.36 \pm 0.74$	$\textbf{6.67} \pm \textbf{1.14}$	-1.670	0.110		

Note: *t* refers to students' *t*-test. *p* refers to *p*-value.

**Table 3.** Comparison of function score of the two groups.

		Gr	oup		
		Autologous vertebrate (mean ± SD)	Autologous iliac (mean $\pm$ SD)	t	p
VAS	Preoperative	$\textbf{6.09} \pm \textbf{0.69}$	$6.00\pm0.62$	0.90	0.370
	6 months	$\textbf{3.12} \pm \textbf{0.82}^{*}$	$\textbf{3.36} \pm \textbf{0.86}^{*}$	-1.76	0.090
	12 months	$1.82\pm0.58^{\#}$	$1.97\pm0.59^{\#}$	-1.41	0.170
m-JOA	Preoperative	$\textbf{7.30} \pm \textbf{1.26}$	$\textbf{7.63} \pm \textbf{1.19}$	-1.00	0.330
	6 months	$13.97 \pm 0.15^{*}$	$13.70 \pm 0.17^{*}$	1.77	0.088
	12 months	$15.23 \pm 1.57^{\#}$	$15.07 \pm 1.41^{\#}$	0.80	0.430
NDI	Preoperative	35.33 ± 1.54	$\textbf{35.23} \pm \textbf{1.38}$	0.42	0.680
	6 months	$\textbf{7.27} \pm \textbf{0.91}^{*}$	$\textbf{7.33} \pm \textbf{1.09}^{*}$	-0.24	0.810
	12 months	$3.40\pm1.07^{\#}$	$3.67 \pm 1.12^{\#}$	-1.49	0.150

Note: *t* refers to students' *t*-test. *p* refers to *p*-value. \* means using LSD-test the mean function score at this time was statistically different with the mean preoperative function score. # means using LSD-test, the mean function score at this time was statistically different with the mean function score at 6 months.

# 3.2 Radiological Evaluation

At a 6-months follow-up, the fusion rate in group A and group B was 77.14% (143/185)and 75.76% (139/183),respectively, and there was no significant difference between the two groups (p > 0.05). The fusion rate in the two groups at 12-months follow-up was 94.29% (174/185)and 93.94% (172/183),respectively, and there was no significant difference (p > 0.05).

# 4 Discussion

Anterior cervical discectomy and fusion (ACDF) was considered a standard surgical procedure for degenerative and traumatic cervical diseases. However, clinical efficacy is closely related to the efficacy of intraoperative decompression and postoperative intervertebral fusion<sup>[10</sup>. To achieve satisfying intervertebral fusion, it is crucial to select a suitable interbody fusion material<sup>11</sup>. The commonly used materials mainly include autologous iliac bone, allogeneic bone, and synthetic materials. The autologous iliac bone is the material with the highest bone fusion rate, but an additional incision is required, and donor site complications could not be avoided. The cost for allogeneic bone is high and patients are at risks of bone graftrelated complications<sup>12</sup>. The use of cage filled with allogeneic bone or synthetic materials could avoid these disadvantages, but its bone fusion rate and reliability are still controversial<sup>7,13,14</sup>.

In 2000, a prospective, randomized, multicenter clinical study focusing on the beneficial use of the cervical Spine cage was published in the Spine journal. Since then, the intervertebral cage was widely used in ACDFI<sup>15</sup>. The innovation and improvement of the intervertebral cage have greatly enhanced the development of ACDFI. The types of intervertebral cage included stainless-steel cage, titanium alloy cage, and PEEK cage<sup>16</sup>. PEEK cage has good biomechanical properties, and its elastic modulus is close to the vertebral body. The height of intervertebral space can also be maintained effectively. In addition, the PEEK cage has the advantages of X-ray penetrability, and its hollow design

can be filled with bone graft material to improve the fusion rate<sup>17</sup>. A lot of research articles on PEEK cage were published and it was reported to achieve promising results in ACDFI, which is now the most popular intervertebral fusion material<sup>18,19</sup>.

An ideal PEEK cage filled bone grafting materials should be excellent in conductivity, induction, and osteogenesis of bone. Moreover, the materials should be convenient and cheap<sup>20</sup>. Autologous bone is currently recognized as an ideal bone graft material. It has been reported that the intervertebral fusion rate of single-segment ACDFI using cortical iliac bone filled PEEK cage was over 95%, and the improvement rate of neurological symptoms was close to 80%<sup>21-23</sup>. However, since an additional surgical incision is needed, patients are at higher risks of postoperative complications such as pain, bleeding, infection, disruption of femoral lateral cutaneous nerve and ilioinguinal nerve, and fracture of iliac<sup>24-26</sup>. It was reported that the incidence of donorsite related complications ranged from 9.4% to 49.0%<sup>25,27,28</sup>. Furthermore, the clinical applications of allogeneic bone, artificial bone, and other materials are limited due to their high price and low fusion rate.

The osteophytes extracted from local bites during anterior surgical decompression can be used as filling materials<sup>29,30</sup>, but its clinical efficacy is limited. It was difficult to completely remove the soft tissue and fibrous tissue attached to the surface of osteophytes, the effect of bone graft fusion would be affected by the low levels of osteoblasts<sup>31</sup>. A study had been conducted to compare the proliferation and ossification of bone marrow stem cells in autogenous vertebrae and autologous iliac bone, it was found that the proliferation and ossification of bone marrow stem cells were similar<sup>32</sup>. In this study, autogenous vertebrae were used as the bone graft material to fill the PEEK cage. Based on the anatomy of the cervical vertebral body, the lower endplate of the cervical vertebra is concave, while the anterior and lower margin of the vertebral body is lip shaped. The degeneration of the intervertebral disc and the proliferation of osteophytes in the anterior margin of the vertebral body results in obvious narrowing of the

vertebral space. To achieve sufficient decompression the in anterior and posterior intervertebral space and the vertebral canal, the osteophyte and the labial structure of the vertebral body were usually removed intraoperatively to expand the operative field. The anterior and posterior vertebrae of the upper and lower vertebral bodies were removed without causing significant damage to the upper and lower endplates, and the preparation of bone graft beds was also not affected.

The clinical benefits of autogenous vertebrae mainly include:

(1) No additional iliac bone extraction was performed during the operation; the operative time was significantly shortened;

(2) The intraoperative blood loss was significantly fewer because no additional incision was needed;

(3) Postoperative complications on donor site can be fully avoided;

(4) The vertebral extracted from the body is convenient and cheap compared to allogeneic bone;

(5) At the 12-months follow-up, the bone fusion rate and functional outcomes were excellent, indicating that the autologous vertebrate-filled PEEK cage can achieve a satisfying clinical outcome.

# 5 Conclusion

summary, the application In of autologous vertebral filled with PEEK cage could achieve satisfactory bone graft fusion and functional outcomes, and it is convenient and cheap, which may be an ideal bone graft material in ACDFI. The authors acknowledge that this study has some limitations of it being a retrospective study with a short time of follow-up. A prospective, randomly controlled study, with long-term follow-up should be performed in the future.

# **Conflict of Interest**

The authors declare that there is no conflict of competing financial and non-financial interests.

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## **Author Contribution**

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