Comparative Study between Implantation of an Empty Polyethylethylketone Cage versus Cage with Bone Graft in Anterior Cervical Discectomy and Fusion

Yasser Ahmed Mashal*, Mohamed Ahmed Samir, Ahmed Ali Morsy, Hosny Hassan Salama
Department of Neurosurgery, Faculty of Medicine, Zagazig University, Sharkia, Egypt
***Corresponding author:** Yasser Ahmed Mashal, **Mobile: (**+20) 01201524694, **Email:** yasser.mashal30@gmail.com

ABSTRACT

Background: Cervical spondylosis is a chronic degenerative process of the cervical spine that affects the vertebral bodies and intervertebral discs of the neck and may progress into disc herniation, bone spur formation, compression of the spinal cord. The majority of cervical spine disorders are self-limited and may be treated non-operatively.

Objective: To compare implantation of empty polyethylethylketone cage versus cage with bone graft in Anterior cervical discectomy and fusion regarding clinical improvement & radiological fusion rate and cage subsidence.

Patients and Methods: 48 patients suffering from 2 levels or more cervical degenerative disc disease who were unresponsive to medical treatment were divided into 2 groups: Group A: Included 17 patients who underwent ACDF with an empty cage. Group B: Included 15 patients who underwent the same procedure with cages with bone grafts.

Results: The mean operative time in our study in group A was 128.3±11.63 while in group B was 125.77±14.16 with no significant difference between the 2 groups (p=0.00**). The mean amount of blood loss in group A was 178.11±11.63 while in group B was 172.77±14.16 with no significant difference between the 2 groups (p=0.00**). The mean VAS of neck pain improved in group A from 6.71±0.78 preoperatively to 2.2±0.7 postoperatively, and also improved in group B from 5.11±0.78 preoperatively to 0.77±0.62 postoperatively, there was a significant improvement in both groups. **Conclusion:** Interbody cage-based fusion with or without plate fixation in two levels or more cervical discectomies achieved good stability and neurological outcome.

Keywords: Implantation, Empty Polyethylethylketone Cage, Cage with Bone Graft, Anterior Cervical Discectomy, Fusion.

INTRODUCTION

Cervical spondylosis is a chronic degenerative process of the cervical spine that affects the vertebral bodies and intervertebral discs of the neck and may progress into disc herniation, bone spur formation, and compression of the spinal cord [(1)].

Chronic cervical degeneration is the most common cause of progressive spinal cord and nerve root compression. Spondylotic changes are frequently found in many asymptomatic adults, resulting in stenosis of the spinal canal, lateral recess, and foramina. Radiculopathy is a result of intervertebral foramina narrowing. Spinal canal stenosis can lead to spinal cord compression, ultimately resulting in cervical spondylosis myelopathy [(2)].

Cervical disc herniation occurs when the nucleus in the center of the disc pushes out of its normal space. The nucleus presses against the annulus, causing the disc to bulge outward. Gradually, the nucleus herniates completely through the annulus and crushes the disc, compressing the spinal canal or nerve roots. Additionally, the nucleus releases chemicals that can irritate the surrounding nerves causing inflammation and pain [(3)].

Prolonged cord compression from cervical spondylosis can result in irreversible histological spinal cord changes such as intradural fibrosis, ischemia, destruction of the blood-spinal cord barrier, demyelination, and neuronal apoptosis within the spinal cord [(1)]. Decompressive surgery may rescue these changes and halt or even reverse the deterioration in myelopathy patients and contribute to an improvement in functional and neurological status [(4)].

The current radiological modality of choice to assess the severity of cervical myelopathy is magnetic resonance imaging (MRI). It provides information about the etiology of canal stenosis, the degree of cord compression, and pathological changes within the cord [(3)]. **Bailey and Badgley** measured canal compromise on computed tomographic (CT) and T1- and T2-weighted MR images, as well as cord compression on T1- and T2-weighted MR images from patients with spinal cord injury [(5)].

Anterior cervical discectomy and fusion have first introduced for degenerative diseases of the cervical spine. To overcome the graft-related complications (e.g., graft compression fracture, graft resorptions or dislocation, and pseudoarthrosis) anterior plating to the treated segment is highly recommended [(6)].

Anterior plate and screw constructs provide enhanced stability and maintenance of deformity correction, and lordotic curvature and increase the stability and probability of fusion, compared to no plates and it may eliminate the need for rigid collar immobilization postoperatively [(7)].

This study aimed to compare between implantation of empty polyethylethylketone cage versus cage with bone graft in anterior cervical discectomy and fusion regarding clinical improvement & radiological fusion rate and cage subsidence.

PATIENTS AND METHOD

This was a prospective randomized study conducted on 48 cases who were admitted to Neurosurgery Department, Zagazig University Hospital for 4 months

Received: 22/12/2021
Accepted: 21/02/2022

from 12 / 2020 and followed up for 1 year from 4/2021 to 4/2022.

Inclusion criteria: Age: above 18 years, single level or multiple levels between C3 – T1, stable cervical spine i.e. no marked angulation, no dislocation, and clinical signs of radiculopathy or myelopathy.

Exclusion criteria: Age: if <18 years, Unfit patients for surgery, Osteoporosis., Cervical trauma, Cervical neoplasia, Ongoing cervical infection, Previous operation, Cervical instability or kyphosis, Incomplete follow-up records.

Tools: Medical records.

Technique" This was an interventional comparative study (the results were compared in a prospective randomized study) (groups were randomized & operated on according to surgeon preference).

The patients were classified into 2 groups: Group (A): included 17 patient who was operated on by empty cages only, and **Group (B):** included 15 patients who were operated on by cages with bone grafts.

The steps included:

Pre-operative Assessment:

1. **Full medical history:** The patient's history was taken to assess age, sex, job, onset, and course of symptoms.
2. **Clinical examination:** motor, sensory system examination and assessment of sphincteric manifestations, Pain visual analog scale of neck pain and arm pain, neck disability index & Odom's criteria.

   Pain visual analog scale:

   Using a ruler, the score is determined by measuring the distance (mm) on the 10-cm line between the "no pain" anchor and the patient's mark, providing a range of scores from 0–to 100(M). A higher score indicates greater pain intensity. Based on the distribution of pain VAS scores in post-surgical patients who described their postoperative pain intensity as none, mild, moderate, or severe, the following cut points on the pain VAS have been recommended: no pain (0–4 mm), mild pain (5-44 mm), moderate pain (45–74 mm), and severe pain (75–100 mm). Normative values are not available. The scale has to be shown to the patient otherwise it is an auditory scale, not a visual one [7].
3. **Radiological Assessment:** Plain X-ray on cervical spine: AP view, Lateral view, and dynamic films.
4. **Full laboratory evaluation:** CBC, LFT, KFT, and coagulation profile
5. **Consent** is taken from all cases included in the study.

Operative Assessment:

All the patients in this study were operated on at the Neurosurgery Department, Zagazig University Hospital under the supervision of our senior stregardinggard for the best decision making a consultation.

All the patients were operated on by open surgery via anterior approach (Smith Robinson technique) in the same way regardless of using empty cages or cages with bone grafts.

Anterior approach to the cervical spine: (Smith Robinson technique)

The level is determined, and the skin incision is approximately 4–5 cm horizontally **Fig (1)**, centered on the sternomastoid muscle. Mright-handednded surgeons prefer operating from the right side of the neck, although the risk to the recurrent laryngeal nerve (RLN) is lower w it aleft-decided approach (the RLN lies in a groove between the esophagus and trachea). The skin may be undermined off the platysma to permit a vertical incision in the platysma in the same orientation as its muscle fibers. Alternatively, some incise the platysma horizontally with scissors. Dissect in tissue plane medial to sternomastoid muscle. Sweep omohyoid medially (to stay out of it and to protect the RLN). The trachea and esophagus are retracted medially. The carotid sheath and sternomastoid muscle are retracted laterally. After verification of level with a lateral C-spine x-with spinal needle in the interspace, bipolar the prevertebral fascia and medial edges of the longus coli muscles longitudinally in the midline. Self-retaining retractor blades are inserted underneath the fascia to retract the longus coli muscles laterally. The anesthesiologist is asked to deflate the cuff of the endotracheal tube and then reinflate it using a minimal leak technique to reduce the risk of compression injury from the retractor. The disc space is incised with a 15-scalpel blade. The discectomy is performed with curettes and pituitary rongeurs; a vertebral body spreader aids the exposure. The posterior longitudinal ligament is incised, one technique is to elevate it with a sharp nerve hook and then incise it w with an 11 scalpel. The subligamentous space is probed with a blunt nerve hook. The posterior lip of the VB above and below is removed w with a Kerrison rongeur with a small foot-plate. Decompression of the roots is verified with the blunt nerve hook. Fusion is performed at this time if desired by placing the graft in the interspace [8].

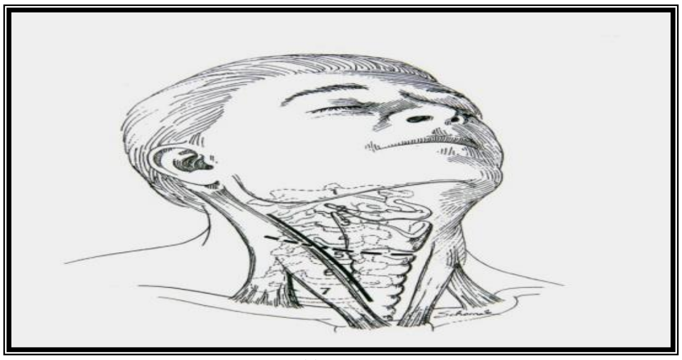

Figure (1): Skin incision [8].

The application of cages and plates was performed under C-Arm guidance.

Classification of cages:

There are two basic types of cages, threaded hollow cylindrical cages (Cloward type procedure) and rectangular cages (Smith-Robinson type procedure). The threaded cages are introduced and screwed through the endplates of the vertebral bodies, whereas the rectangular cages mimic the intervertebral space dimensions and are following the anatomy of the endplates [(9)].

Titanium, carbon fiber, and Polyetheretherketone (PEEK) are the most commonly used materials for cage production. The use of a titanium cage may lead to vertebral body collapse if the end plate is over degraded during discectomy. In addition, radiological metallic artifacts may complicate imaging. Furthermore, radiotransparent carbon fiber cages have been used widely, but synovitis and the lymphatic spread of fiber debris may be found after intra-articular procedures.

Ethical consent:

An approval of the study was obtained from Zagazig University Academic and Ethical Committee. Every patient signed an informed written consent for acceptance of participation in the study. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical analysis

The collected data were coded, processed, and analyzed using the SPSS (Statistical Package for Social Sciences) version 22 for Windows® (IBM SPSS Inc, Chicago, IL, USA). Quantitative data were expressed as the mean, median (range), and qualitative data expressed as Absolut frequencies (number) & relative frequencies (percentage). Quantitative data were expressed as mean ± SD (Standard deviation). Percentage of categorical variables were compared using the Chi-square test or fissures exact test when inappropriate. A risk assessment by relative risk (RR) and confidence interval 95 % (CI 95%). All tests were two-sided. P-value < 0.05 was considered statistically significant (S). P-value < 0.001 was considered highly statistically significant (HS) and P-value ≥ 0.05 was considered statistically insignificant (NS).

RESULTS

This table shows that the average age of the cage with bone graft was lesser than the empty PEEK cage but this difference was not statistically significant between the two studied groups, also sex was not statistically significant between the two studied groups (matched groups). The commonest co-morbidity in the past history was hypertension (35 % of patients) **(Table 1)**.

Table (1): Age and sex characteristics, as well as the Co-morbidities among the studied groups

Variables	Cage with bone graft No=17	Empty PEEK cage No=15	Test	p-value
Age (years) Mean ± SD Median	51.1±7.6 51	45.9±10.1 50	T=0.6	0.5
Sex Male Female	9 (52.9%) 8 (47.1%)	7 (46.7%) 8 (53.3%)	χ^2=0.5	0.4
The Co-morbidities among the studied groups				
Co-morbidities	N		%	
D.M	6		30	
Hypertension	7		35	
Ischemic heart disease	3		15	
Asthma / COPD	4		20	

This table shows that there was no statistically significant difference between the two studied groups regarding preoperative data and also shows that there was no statistically significant difference in operative duration and blood loss and postoperative hospital stay between the two studied groups among cage with bone graft and empty PEEK cage group (**Table 2)**.

Table (2): Comparing preoperative and peri-operative data between the two studied groups

Variables	Cage with bone graft No=17	Empty PEEK cage No=15	t-test	p-value
	Mean ± SD Median (Range)	Mean ± SD Median (Range)		
VAS neck	7.1±0.9 7 (6-8)	6.7±1.1 7 (5-8)	1.1	0.3
VAS arm	6.9±2.1 8 (3-9)	6.8±0.86 7 (6-8)	0.2	0.8
NDI	37.2±3.02 38 (30-40)	38.4±3.5 40 (30-42)	1.01	0.3
Operative duration (Minutes)	128.3±14.5 123 (110-155)	125.5±15.6 120 (105-145)	5.1	**0.001**
Blood loss amount (cc)	178.7±31.3 190 (100-220)	172.3±45.4 186 (90-215)	4.1	**0.001**
Post-operative hospital stays (Days)	2.2±0.53 2 (1.5-3)	2.3±0.52 2 (1.5-3)	0.5	**0.6**

This table shows that there was a highly statistically significant decrease in VAS arm and neck and NDI among the cage with bone graft group postoperatively than preoperative and also shows that there was a highly statistically significant decrease in VAS arm and neck and NDI among the empty PEEK cage group postoperatively than preoperative. While regarding C2_7_cobb_angle, segmental angle, and height, they were statistically significantly increased postoperatively than preoperative among the empty PEEK cage group (**Table 3)**.

Table (3): Comparing pre-and post-operative data among the cage with bone graft and the empty PEEK cage group

Variables	Pre-operative No=17	Post-operative No=15	Paired t-test	p-value
	Mean ± SD Median (Range)	Mean ± SD Median (Range)		
The cage with bone graft group				
VAS neck	7.1±0.9 7 (6-8)	1.9±0.79 2 (1-3)	23.9	**0.001****
VAS arm	6.9±2.1 8 (3-9)	1.9±0.7 2 (1-3)	7.8	**0.001****
NDI	37.2±3.02 38 (30-40)	5.5±1.3 5 (4-8)	33.6	**0.001****
The empty PEEK cage group				
VAS neck	6.7±1.1 7 (5-8)	2.2±0.77 2 (1-3)	12.2	**0.001****
VAS arm	6.8±0.86 7 (6-8)	2.3±0.7 2 (1-3)	13.4	**0.001****
NDI	38.4±3.5 40 (30-42)	6.06±1.7 5 (4-8)	34.9	**0.001****

VAS arm and neck and NDI were decreased more among the cage with bone graft group postoperatively than the empty PEEK cage group **(Table 4)**.

Table (4): Comparing post-operative data between the two studied groups

Variables	Cage with bone graft No=17	Empty PEEK cage No=15	t-test	p-value
	Mean ± SD Median (Range)	Mean ± SD Median (Range)		
VAS neck	1.9±0.79 2 (1-3)	2.2±0.77 2 (1-3)	0.9	0.3
VAS arm	1.9±0.7 2 (1-3)	2.3±0.7 2 (1-3)	1.3	0.2
NDI	5.5±1.3 5 (4-8)	6.06±1.7 5 (4-8)	1.1	0.3

Most cases operated with a cage with bone graft were Excellent according to Odom's criteria more than Excellent results in cases with an Empty PEEK cage. The study also shows more rapid radiological fusion in cases with cages with bone grafts than in cases with Empty PEEK cages **(Table 5)**.

Table (5): Comparing post-operative data according to Odom's criteria and the radiological fusion between the two studied groups

Odom's criteria	Cage with bone graft No=17		Empty PEEK cage No=15	
Excellent	10	58.8 %	8	53.3 %
Good	4	23.5 %	5	33.3 %
Fair	2	11.8 %	1	6.7 %
Poor	1	0.06 %	1	6.7 %
Radiological fusion				
Fusion	12	70.6 %	10	66.7 %
Incomplete fusion	5	29.4 %	5	33.3 %

Two cases (13.3%) of the cage with bone graft group had mild dysphagia while one case (6.7%) of the empty PEEK cage group had moderate dysphagia, one case (6.7%) had mild hoarseness of voice and other had mild superficial infection among the empty PEEK cage group with no statistically significant difference between the two groups **(Table 6)**.

Table (6): Comparing post-operative complications among the two studied groups

Post-operative complications	Cage with bone graft No=15	Empty PEEK cage No=15	χ^2	p-value
New deficit	0 (0.0%)	0 (0.0%)	1.8	0.4
Superficial infection Mild	0 (0.0%)	1 (6.7%)		
Dysphagia Mild Moderate	2 (13.3%) 0 (0.0%)	0 (0.0%) 1 (6.7%)		
Hoarseness of voice Mild	0 (0.0%)	1 (6.7%)		

DISCUSSION

In our study, the mean age of patients in group A was 51.1±3.45 while in group B was 45.9±4.42 there is no significant difference between 2 groups as regards age (p=0.351), and **Feng *et al.*** [10] series, the mean of age of patients in group A (empty cage) was 51.1± 7.6 while in group B(cages With a bone graft) was 45.9 ± 7.10.1 there is no significant difference between the 2 groups as regard age (p= 0.076).

In our study, in group A, there were 9 males and 8 females and in group B, there were 7 males and 8 females with a total of 16 males and 16 females. There is no significant difference between 2 groups regarding sex (p=**0.77**) while, Male predominance was found in **Feng *et al.*** [10] series as, in group A, there were 31 males and 25 females and in group B, there were 11 males and 11 females with a total of 42 males and 36 females.

The mean operative time in our study in group A was 128.3±11.63 while in group B was 125.77±14.16 with no significant difference between 2 groups (p=0.00**), while In **Feng *et al.*** [10] series, the mean operative time in group A was 146.34 ± 46.10 while in group B was 154.55 ± 40.59 with no significant difference between 2 groups (P = 0.323).

The mean amount of blood loss in group A was 178.11±11.63 while in group B was 172.77±14.16 with no significant difference between the two groups (p=0.00**). In **Elkazaz *et al.*** [11], the amount of blood loss in group A was 62.50±45.85 while in group B was 85.41±45.79 with no significant difference between the two groups(p=0.23).

The mean hospital stay in group A was 2.2±0.83 while in group B was 2.35±0.72 with no significant difference between 2 groups (p=0.555) while, In **Feng *et al.*** [10] series, the mean hospital stay in group A was 2.30 ± 0.54 while in group B was 2.41 ± 0.59 with no significant difference between 2 groups (P = 0.414)

In our study; the mean VAS of neck pain improved in group A from 6.71±0.78 preoperatively to 2.2±0.7 postoperatively, and also improved in group B from 5.11±0.78 preoperatively to 0.77±0.62 postoperatively, there was a significant improvement in both groups. this coincides with **Hwang *et al.*** [12] series, as the mean VAS of neck pain, improved in group A from 8.8 ± 0.9 preoperatively to 3.1 ± 2.1 postoperatively, and also improved in group B from 8.5 ± 1pre operatively to 2.8 ± 1.8 postoperatively, there was a significant improvement in both groups.

In our study; the mean VAS of arm pain improved in group A from **5.58±0.97**pre operatively to **1.2±0.62** postoperatively, and also improved in group B from **7.1±0.87** preoperatively to **1.9±0.42** postoperatively, there was a significant improvement in both groups. In the **Liu *et al.*** [13] series, the mean postoperative VAS arm pain score was 2.5 ± 1.5 compared with a preoperative score of 7.9 ± 1.1 in 25 non-plated patients. In the **Song *et al.*** [14] series, the mean postoperative VAS arm pain score was 3.93 ± 1.78 compared with a preoperative score of 6.74 ± 1.09 in patients with cages with bone grafts.

the mean NDI improved in group A from 38.4±3.16 preoperatively to 6.06±1.87 postoperatively, and also improved in group B from 37.37±3.15 preoperatively to 5.5±1.73 postoperatively, there was a significant improvement in both groups, while, In **Feng *et al.*** [10] series, the mean NDI improved in group A from 38.42 ± 23.14 preoperatively to 6.06 ± 11.69 postoperatively, and also improved in group B from 37.37 ± 24.49 preoperatively to 5.5 ± 8.59 postoperatively, there was a significant improvement in both groups, but more in group B.

In our study, 0 patients in group A and also 0 patients in group B developed a new neurological deficit postoperatively with no significant difference between the two groups, while in **Habba *et al.*** [15] series: only 1 patient in group B group developed new neurological deficit.

Postoperatively, 1 patient in group A and no patients in group B developed a wound infection that improved with medical treatment. there was no significant difference between the 2 groups (p=1.0), also in the **Feng *et al.*** [10] series, 1 patient in group A and no patients in group B developed wound infection that improved with medical treatment.

No patients in group A and also 2 patients in group B developed dysphagia. There was a non-significant difference between the 2 groups (p=0.03*). Dysphagia was mild in all these patients and lasted only for a few days, while In **Feng *et al.*** [10] series, 2 patients in group A and also 2 patients in group B developed dysphagia.

No patients in group A and 1 patient in group B developed hoarseness of voice with no significant difference between the 2 groups (p=0.02*) .this may be due to the long duration of traction on RLN. this case improved after a few days while in **Habba *et al.*** [15] series 1 patient in group A and also 1 patient in group B developed hoarseness of voice with no significant difference between 2 groups.

CONCLUSION

Interbody cage-based fusion with or without plate fixation in two levels or more cervical discectomies achieved good stability and neurological outcome. The addition of anterior cervical plate fixation resulted in improvement in cervical lordosis than non-plated patients at 3 m follow-up examination. However, the difference between both groups was not statistically significant. On the other hand, patients managed by anterior cervical plate showed a significantly higher complication rate than patients managed by interbody fusion cages alone However, the difference between both groups was not statistically significant. In addition, adding plate fixation required longer operative time, more blood loss, and higher cost than patients managed by interbody fusion cages alone. The difference between both groups was statistically significant.

Transient dysphagia, and was the most common postoperative complication encountered in our study.

Conflict of interest: The authors declare no conflict of interest.
Sources of funding: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.
Author contribution: Authors contributed equally to the study.

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