

# THE MANAGEMENT OF CERVICAL DISC DISEASE BY USING AN ANTERIOR CERVICAL INTERBODY CAGE WITH INTEGRATED SCREWS

By

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## ABSTRACT

**Background:** Stand-alone anchored spacers aim at reducing complications associated with traditional plating while maintaining the functionality of interbody spacer and plating.

**Objective:** We prospectively followed up patients who underwent anterior cervical discectomy and fusion (ACDF) in single or multiple levels using the polyetheretherketone (PEEK) prevail cervical interbody device.

**Patients and Method:** Prospective study of 24 patients suffering from single or multiple level degenerative cervical disc diseases from C3-C4 to C7-T1, operated at Al-Agouza spine hospital, between September 2013 to August 2015. All patients underwent surgery using PEEK prevail device. Patients were evaluated using visual analogue score (VAS) for neck pain, VAS for arm pain, and neck disability index (NDI) scores. Clinical improvement was also graded by Odom's criteria at final follow up.

**Result:** The study showed a statistically significant difference between pre and post-operative as regard VAS for neck pain and arm pain of the study group. Also, there was a statistically significant difference between pre- and post-operative as regard neck disability index of the study group.

**Conclusion:** The use of stand-alone cages in anterior cervical decompression and fusion provided short time clinical improvement with minimal complication rates.

**Keywords:** VAS score, stand-alone cages, Odom's criteria.

## INTRODUCTION

Surgical treatment has been advocated for long in patients with cervical disc disease with radiculopathy and/or myelopathy in whom conservative treatment fails. ACDF with plating and bone grafting/ interbody cages has been an effective surgery with good early and late post-operative functional and radiological outcomes even in multi-level procedures (Song et al., 2009). Complications like dysphagia, trachea-esophageal injury, screw loosening with migration, soft tissue damage, adjacent level degeneration

especially in multi- level cases, and donor site morbidity with autologous iliac crest bone grafting were associated with this surgery. Thus, in the late past decade, zero profile stand-alone devices with screws were introduced for use in ACDF surgeries (Romano et al., 2013). These aim at reducing complications associated with traditional plating while maintaining the functionality of interbody spacer and plating (Patel et al., 2008).

In this study, we prospectively followed up patients who underwent ACDF in single or multiple levels using the (PEEK) prevail cervical interbody device.

## PATIENTS AND METHODS

Prospective study included 24 patients suffering from single or multiple level degenerative cervical disc disease from C3-C4 to C7-T1, operated at Al-Agouza spine hospital, between September 2013 to August 2015. Informed consents were obtained from all the patients. Ethical clearance was obtained from the ethical committee, Faculty of Medicine, Al-Azhar University. Patients included in the study were skeletally mature with unilateral or bilateral radicular pain with/without associated neck pain. All the patients had MRI done and confirmed single or multiple level cervical disc disease from C3-C4 to C7-T1, and had completed, at least, six weeks of conservative treatment without any improvement. The exclusion criteria were previous surgery at the diseased level, congenital or iatrogenic fusion of the adjacent level, patients needing more than three levels of surgery, developmental cervical stenosis, systemic or local infection, active rheumatoid arthritis, uncontrolled diabetes and other co morbidities compromising surgical outcome, severe osteoporosis, and known allergy to PEEK or titanium alloy. Nineteen patients had single level disease, and 5 patients had two or more level disease. All patients underwent surgery using PEEK prevail device. Patients were evaluated using VAS neck pain, VAS arm pain scores, and neck disability score. All patients were operated with a head extension in supine position. Post-operatively, patients were mobilised under supervision with Philadelphia collar support in the first post-operative day. No active physiotherapy of the neck was allowed for six weeks. Patients were

assessed at the time of discharge and then after one month, three months and six months thereafter. Clinical improvement was also graded by Odom's criteria at final follow up (Niu et al., 2010). Length and severity of post-operative dysphagia were recorded by Bazaz's criteria at each follow up. Implant related and surgery related complications were documented (Bazaz et al., 2002). Pre- and post-operative radiographic parameters were assessed. Two parameters namely interbody height and overall kyphotic angle were assessed radiologically in the pre-operative and post-operative follow up using the lateral radiographs. Pitzen's criteria were used to assess fusion which is defined as absence of radiolucencies and absence of bony sclerosis and evidence of bridging trabeculae within the fusion area (Jae et al., 2014). A decrease in more than two mm of interbody height during follow up was termed segmental collapse indicating implant subsidence.

**Statistical analysis:** Data were analyzed using Statistical Program for Social Science (SPSS) version 20.0. Quantitative data were expressed as mean  $\pm$  standard deviation (SD). Qualitative data were expressed as frequency and percentage. The following tests were done: Paired sample t-test of significance was used when comparing between related samples and probability (P-value).

## RESULTS

The patient population consisted of 20 males and 4 females, and the mean age was  $51.2 \pm 13.7$  years ranging from 28 to 72 years. A total 30 levels were operated (19 patients with single, 4 patients with double, and 1 patient with multilevel disease). The pain relief after ACDF using

this type of prosthesis was rapid and evident postoperatively. The pain relief was sustained for up to 12 months after the procedure.

There was marked improvement in functional outcome assessment using NDI score, denoted by improvement of neck disability index (NDI) score from mean  $21.88 \pm 6.88$  preoperatively to  $7.58 \pm 1.35$  postoperatively (Table 1).

**Table (1):** Pre- and post-operative values of the NDI.

State \ Score	Range	Mean±SD	Mean Diff.		Paired Sample t-test	
			Mean	±SD	T	p-value
Preoperative	12-34	21.88±6.80	14.29	5.60	12.505	<0.001
Postoperative	3-15	7.58±3.79				

This effect was shown by reduction of VAS score for neck pain from  $5.17 \pm 2.70$  preoperatively to  $2.5 \pm 1.74$  postoperatively (Table 2).

**Table (2):** Pre- and post-operative values of the VAS for neck pain.

State \ Score	Range	Mean±SD	Mean Diff.		Paired Sample t-test	
			Mean	±SD	t	p-value
Preoperative	0-10	5.17±2.70	2.67	1.55	8.423	<0.001
Postoperative	0-6	2.50±1.74				

This effect was shown by reduction of VAS score for radicular pain from  $7.58 \pm 1.35$  preoperatively to  $2.5 \pm 1.74$  postoperatively, and continuous decrease of VAS score points in all patients till 12 months follow-up (Table 3).

**Table (3):** Pre- and post-operative values as regard the VAS for arm pain.

State \ Score	Range	Mean±SD	Mean Diff.		Paired Sample t-test	
			Mean	±SD	t	p-value
Preoperative	5-10	7.58±1.35	5.04	1.94	12.702	<0.001
Postoperative	0-5	2.54±1.47				

According to Odom's criteria, 11 patients (45.8%) had good outcome, 11 (45.8%) patients had excellent outcome and 2 (8.4%) had fair outcome.

In this study, according to Bazaz dysphagia score, 3 patients complained of dysphagia (8.33%) post-operatively. All had mild dysphagia at one month follow-up and none of patients had dysphagia by 6 months follow-up.

## DISCUSSION

The major concern in standalone devices is whether they provide biomechanical stability enough to achieve fusion. Studies using anchored spacers with 4 screw construct, three screw construct, and two screw construct showed comparable biomechanical stability in flexion-extension, lateral bending and axial torsion with standard anterior plating (Stein et al., 2014).

The "I beam" shape of the cage and Nitinol locking mechanism increases the stability of screw implant interface. PEEK material used in our implant was radio-opaque allowing for better evaluation of fusion, and it was more rigid than autograft. Several studies have shown PEEK to provide 100% fusion rates with good to excellent clinical outcome with minimal subsidence maintaining foraminal decompression and sagittal alignment (Celik et al., 2007).

Hofstetter et al. (2015) evaluated post-operative radiographs for pre vertebral swelling, and found that patients operated with plates had significant post-operative pre-vertebral swellings that persisted for more than six months compared to patients who had zero profile device

fixation. Decreased incidence of midterm and late dysphagia, in our study, and other studies with zero profile devices, clearly support the hypothesis of hardware prominence and scarring associated with plating leading to prolonged dysphagia symptoms.

In our study, no patient had adjacent level ossification at final follow up X-rays which is the case with other studies with stand-alone cages (Sholz et al., 2011).

In our study, 90% of patients had excellent to good outcomes and 10 % had fair outcomes which are comparable to other studies with ACDF and plating and stand-alone cages (Matz et al., 2009).

Pitzen et al. (2009) reported an incidence of screw and plate loosening between 0% and 15.4%, screw breakage between 0% and 13.3%, plate breakage between 0% and 6.7%, plate and graft displacement (with or without graft fracture) between 0% and 21.4%, and implant malposition (screws in discs, plating of unfused segments, etc) between 0% and 12.5% for long segmental anterior plate fixation.

None of these complications were seen in our series indicating that the implant and the surgical technique give reproducible midterm results with minimal complications in single and two level surgeries. Similar results were demonstrated by other studies (Jayabalan et al., 2016).

There were several limitations in our study. These included the relatively small number of patients and the short follow up duration.

## CONCLUSION

The results from our prospective study indicated that use of standalone cages in anterior cervical decompression and fusion provided short time clinical and radiological improvement, with minimal complication rates. Further long-term studies are required to validate the usage of these devices, especially in multi-level disease.

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## علاج أمراض الغضروف العنقي باستخدام القفص العنقي ما بين جسم الفقرات المدمج به مسامير

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**خلفية البحث :** الأقفص العظمية العنقية ذات المسامير المدمجة تهدف إلى تقليل المضاعفات الناتجة عن استخدام الشرائح التقليدية، مع الاحتفاظ بوظيفة القفص العظمي و الشريحة العنقية.

**الهدف من البحث :** متابعة حالة المرضى الذين أجريت لهم جراحة الإستئصال الأمامي للغضروف العنقي، وتركيب قفص عظمي مدمج به مسامير سواء كان ذلك على مستوى واحد أو عدة مستويات.

**المرضى وطرق البحث :** اشتمل هذا البحث أربعة و عشرين مريضاً يعانون من مرض الإنتكاس الغضروفي العنقي بين الفقرات العنقية ، من الفقرة العنقية الثالثة وحتى الفقرة السابعة، أجريت الجراحة في مستشفى العمود الفقري بالعجوزة ، في الفترة الزمنية من شهر سبتمبر ٢٠١٣ إلى شهر أغسطس ٢٠١٥. تم استخدام القفص العظمي المدمج به مسامير في كل الحالات. تمت متابعة التحسن السريري للمرضى عن طريق مقارنة درجة الإحساس بالألم قبل الجراحة وبعدها. وتم قياس التحسن في نشاط المرضى عن طريق مقياس أودوم.

**النتائج :** أظهرت النتائج حدوث تحسن ملحوظ في حالة المرضى بعد إجراء الجراحة. وقد ظهر ذلك من خلال الفروق الظاهرة في تحسن درجة الألم في العنق وفي الطرف العلوي بعد إجراء الجراحة. كما أظهر البحث تحسناً ملحوظاً في نشاط المريض اليومي بعد إجراء الجراحة.

**الخلاصة :** إن استخدام القفص العظمي المدمج به مسامير في حالات الإستئصال الأمامي لغضروف العنق يقدم حلاً ناجحاً للمرضى المصابين بأمراض الإنتكاس الغضروفي العنقي. وقد ظهر ذلك من خلال التحسن السريري في حالة المرضى بعد إجراء الجراحة، وقلة حدوث المضاعفات.