Clinical Article

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Clinical Outcome Results of Stand Alone Anchored Spacer for Anterior Cervical Discectomy and Fusion

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Abstract

Background Data: Anterior cervical discectomy and fusion (ACDF) became the classic operation in treating degenerative cervical spondylosis. The application of anterior cervical plate helped fusion and stabilization; however, there were many reports of the complications, such as dysphagia and the possibility of adjacent segment degeneration that may develop after anterior cervical approach.

Purpose: The aim of this study is to assess the outcome of the standalone anchored cervical spacers in anterior cervical discectomy and fusion.

Study Design: This is a retrospective study included 30 patients suffering from degenerative cervical disc disease. The outcome measures were: the visual analogue score, Cobb's angles for sagittal and segmental alignment, the Japanese orthopedic association score, Nurick score for myelopathic patients and the occurrence of post-operative dysphagia.

Patients and Methods: 30 patients were included in this study. All these patients had an anterior approach for cervical discectomy. A standalone anchored cervical spacer was used for this purpose. All patients were regularly assessed through the follow up period of two years post surgical intervention.

Results: The study included 30 patients, 22 patients had single level, and 8 patients had two levels cervical discectomy. Postoperative improvement of radicular pain VAS were statistically significant (9.0 to 1.67) as well as the improvement in Cobb's angle (1.39±5.69 to 6.78±3.83) were statistically significant (P=0.001). Postoperative improvement in the JOA Score was significant (7.12 to 14.65). Nurick score for myelopathy improvement was statistically significant (2.6 to 0.83). Postoperative improvement in the fused levels' height was statistically significant (p=0.001)

Conclusion: Stand-alone anchored spacer has a good result regarding relief of symptoms, fusion, and is simple to insert with less post-operative dysphagia. (2018ESJ156)

Keywords: Anchored spacer; cervical plate; degenerative spine; cervical discectomy; dysphagia

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Introduction

In 1950s Smith and Robinson[33] and Cloward[9] reported the procedure of anterior cervical discectomy and fusion (ACDF) which later on become the standard operation in treating degenerative cervical disc disease. The application of anterior cervical plate has gradually made up for the disadvantages of single decompression and fusion. Plates help stabilizing the cervical spine, firmly fixing the bone grafting block and promoting fusion. Although the application of anterior plate reduces the complications caused by fusion meanwhile, other complications may occur, including throat discomfort, dysphagia and adjacent disc degeneration. Tortolani et al,[36] reported that after ACDF, 2-67% of patients suffered from dysphagia in the early period, which disappeared within few weeks, with most patients, but not all, recovering completely.[4] According to reports the incidence of chronic dysphagia after ACDF is about 3-21%.[25]

Traditionally, interbody allograft, autograft, or xenograft is inserted into the interbody space either alone or with the addition of an anterior cervical plate. Although the benefit of plating has been established with multiple-level fusions,[38] there is disagreement regarding the necessity of a plate, especially for single-level fusions.[7,30] Single-level ACDF fusion rates are high without plating; plate prominence may cause dysphagia and screws may extrude.[7,14] Proponents of plating claim that additional rigidity, higher fusion rates, and reduced kyphosis can be obtained with the use of cervical plates.[39] One proposed solution to graft containment and increased fusion construct rigidity may be to incorporate fixation into the graft itself. This method has been evaluated in the lumbar spine and may hold promise in the cervical spine as well.[6]

Patients and Methods

This is a retrospective study included a total number of 30 patients with symptomatic cervical spondylosis, who underwent anterior cervical discectomy and fusion using a stand-alone anchored cervical interbody polyetheretherketone (PEEK) spacer (PEEK PREVAIL™, Medtronic, Inc) (Figure 1) between January 2010 to January 2013. The study was done in Ain Shams University Hospitals.

Inclusion criteria were patients with symptomatic cervical disc degenerative compression causing either radiculopathy or myelopathy or both with failed medical treatment for at least six months in patients with radiculopathy symptoms. In all patients clinical evaluation was performed pre-operative, one week, two months, six months, one year, and two years post-operative using the visual analogue score (VAS) for radicular pain and the Japanese orthopedic association score (JOA) and Nurick score for myelopathic patients.[37]

Technical Note:

All patients underwent Smith-Robinson decompression with and opening of the posterior longitudinal ligament.[1] Some modifications were applied in the form of anterior vertebral body preparation once the discectomy is complete, a high-speed drill with a burr is used to carefully shape the inferior lip of the superior vertebral body and the superior lip of the inferior vertebral body to match the flanges found on both the trial and implant. This chamfer must be cut at an angle to allow each screw to be inserted at an angle into the vertebral bodies. It is important that the chamfer match the angle of the flange to ensure proper screw placement. Once the decompression and anterior vertebral body preparation are completed, a stand-alone anchored cervical interbody PEEK spacer is determined by selecting the trial that properly fits in the prepared disc space. Final end-plate preparation is carried out with minimal bone removal. Once the appropriate height is identified, the corresponding spacer loaded with artificial bone granules is inserted. After inserting the appropriate size spacer, the self-drilling screw length that is most appropriate for the patient's anatomy is selected. The screws should be inserted at an angle, perpendicular to the chamfered lip.

The heights of the fused levels were measured (from the upper endplate of the upper cervical vertebral body to the lower endplate of the lower vertebral body including the disc space in between) to evaluate the degree of maintenance of the operated disc (s) and vertebral body (ies) heights.

Also the occurrence of subsidence was measured and documented (Figure 2).

Statistical comparison was performed between the pre-operative and the second year post-operative values. Pre-operative MRI and dynamic x-rays were evaluated and post-operative x-rays were performed at three months intervals to evaluate the fusion and measure the global cervical spine angle (Cobb C), segmental angle of the treated level (s) (Cobb S), amount of segmental collapse.[8,19] The incidence of post-operative dysphagia was also reported.

Results

This study included 30 patients (21 males and 9 females). Patients' age ranged from 29 to 68 years with a mean of 50.53 years. Twelve patients were smokers, four patients had associated hypertension, and two patients had controlled diabetes mellitus. Twenty two patients had a single level discectomy (Figure 3) and eight patients had two levels discectomy (Figure 4); with the C 5-6 being the most commonly affected level seen in 16 (53 %) patients followed by C 6-7 level that was operated upon in 11 (36.7 %) patients. The mean operative time was 90±25 minutes. Thirteen patients suffered from radiculopathy, eight patients had myelopathy, and nine patients suffered from radiculomyelopathy (Table 1).

Changes in the Visual Analogue Score for radiculopathy were statistically significant; the mean pre-operative VAS was 9.0±0.743, which was reduced to 1.67±0.61 post-operatively (p=0.001). Changes in the Japanese orthopedic association score for myelopathy were statistically significant with a pre-operative mean of 7.12±3.77 (Range, 2.0-13.0) and a post-operative mean of 14.65±1.97 (Range 11.0-17.0) (P=0.001). In addition, the Nurick score for myelopathic patients showed a statistically significant change (P=0.001) with a pre-operative mean of 2.6±1.57 (Range, 1.0-5.0) and a post-operative mean of 0.83±0.913 (Range, 0.0-3.0).

All patients performed plain static X-ray assessment in the anteroposterior and lateral views. All patients had an evidence of fusion by the ninth month post operatively (Figure 4). The change in the fused levels' height between pre-operative and post-operative values was statistically significant (The mean pre-operative height was 33.42±10.81 mm and the mean post-operative height was 40.46±11.04 mm) (P=0.001) (Table 2). This increase in the fused levels' height was maintained throughout the follow up period and neither of the patients showed radiological evidence of subsidence.

The segmental angle (Cobb's S angle) measurements of the degree of segmental lordosis showed a statistically significant difference between the pre-operative and the post-operative values (The mean pre-operative angle was 1.39±5.69 degrees and the mean post-operative angle was 6.78±3.83 degrees) (P=0.001) (Table 2). While the measurement of the global cervical angle (Cobb's C) showed no significant change between the pre-operative and post-operative values (The mean pre-operative angle was 9.40±5.78 degrees and the mean post-operative angle was 12.75±2.15 degrees) (Table 2).

Thirteen patient (43.3%) suffered from immediate post-operative dysphagia, 12 of them showed rapid improvement within the first post-operative week. Only one patient had a residual mild dysphagia by the 12th post-operative month which disappeared by the second year post-operatively. None of the patients included in this study had an evidence of adjacent segment degeneration through the follow up period. There were no other reported complications throughout the follow up period.

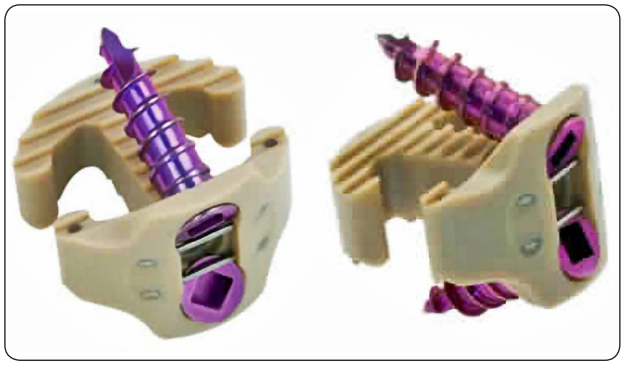

Figure 1. The (PEEK PREVAIL™, Medtronic, Inc) inter body cage.

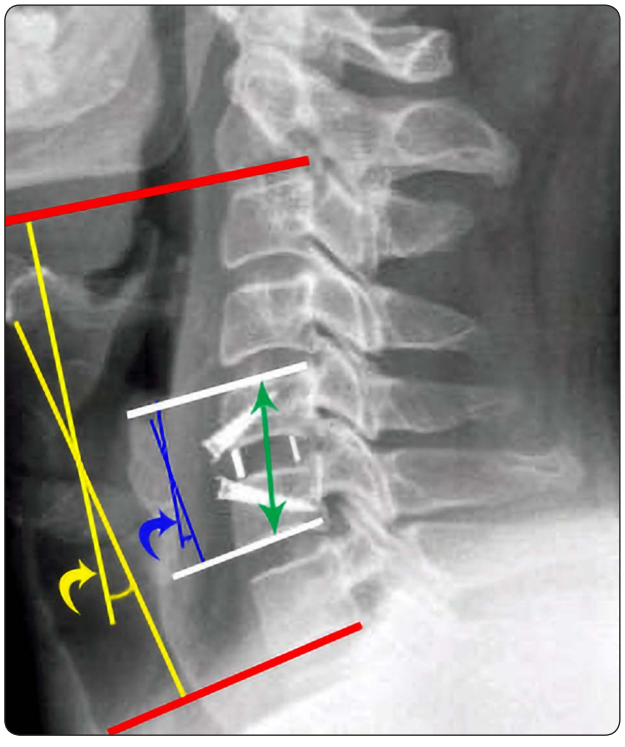

Figure 2. Demonstration of the measurements of the Cobb-C angle: yellowish arrow, Cobb-S angle: bluish arrow, and segmental height demonstrated by the double headed green arrow.

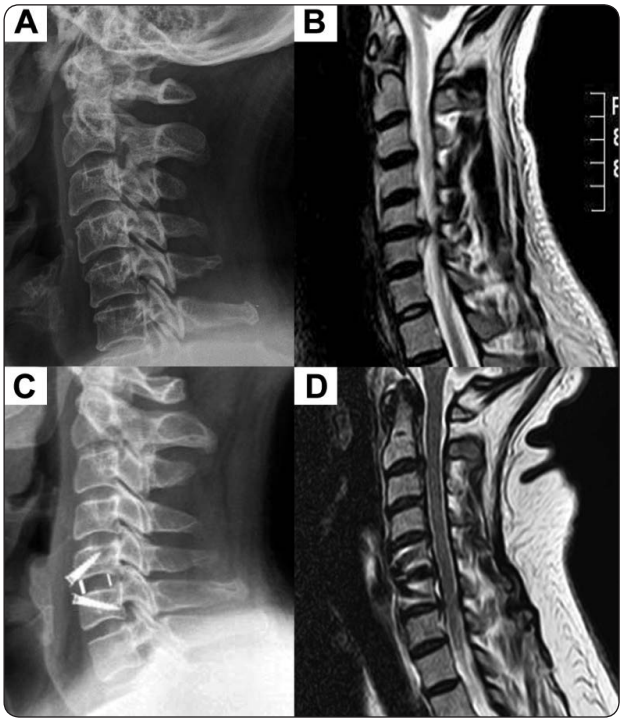

Figure 3. A: Pre-operative X-ray, B: Sagittal T2 MRI cervical spine showing C5-6 disc prolapse. C: Two months post-operative X-ray, D: Post-operative Sagittal T2 MRI.

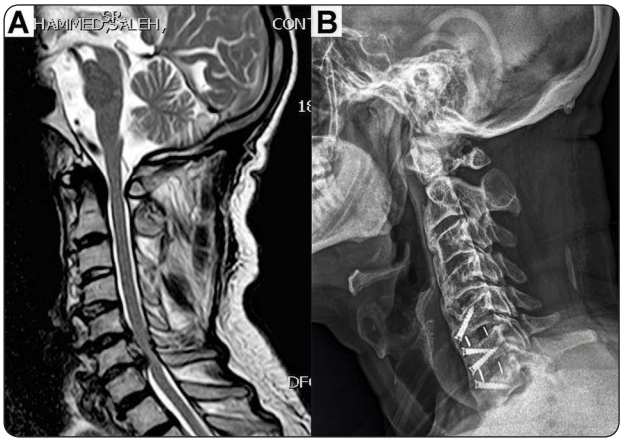

Figure 4. (A) Pre-operative sagittal T2 MRI cervical spine showing C5-6 & C6-7 disc prolapses. (B) Two years post-operative X-ray showing the two levels anchored spacers.

Table 1. Epidemiological and Clinical Data of our Study Patients (N=30)

Variable		Number	Percent
Age	Age/years	50.53±10.57	
Gender	Male/Female	21	70%
Comorbidity	Smoking	12	40%
	Hypertension	4	13.33%
	Diabetes mellitus	2	6.66%
Presentation	Radiculopathy	13	43.33%
	Myelopathy	8	26.66%
	Radiculomyelopathy	9	30%
	Single level discectomy	22	73.33%
	Double level discectomy	8	26.66%

Table 2. Radiological Outcomes of our Study Patients (N=30)

Group	Mean	SD	Min	Max	CI 95%*	df	t statistic	P value**
PreOp Fused Levels Height	33.42	10.81	23.5	56.4	29.55-37.29	29	-16.761	<0.001
PostOp Fused Level Height	40.46	11.05	30.1	60.9	36.51-44.41			
PreOp Cobb_S	1.39	5.69	-5.8	19.9	-0.64-3.43	29	-7.071	<0.001
PostOp Cobb_S	6.78	3.83	-0.3	13.1	5.41-8.151			
PreOp Cobb_C	9.40	5.78	-11.3	26.7	7.33-11.47	29	-3.385	0.002
PostOp Cobb_C	12.75	2.15	7.5	15.2	11.98-13.52			

*We are 95% certain that the true value of the mean is within this interval. But it could still lie anywhere outside of those bounds.

**If p is small, e.g. less than 0.01, or 0.001, you can assume the result is statistically significant i.e. there is a difference between at least two groups. Note: a statistically significant difference may not necessarily be of any practical significance.

Discussion

The use of a plate and cage has been shown to increase the rates of fusion, reduce the period of post-operative immobilization and improve clinical results in comparison with anterior fusion surgery without plate,[17] but the complications, such as dysphagia and the possibility of adjacent segment degeneration, require attention. The application of a plate may lead to soft-tissue damage, especially in multilevel procedures, and an oversized plate may affect the movement of the adjacent level and increase the risk of adjacent segment degeneration.[1,11,32] Stand-alone cages were introduced for anterior cervical fusion, with good results,[16,29] but subsidence of the cage, cervical malalignment, loss of lordosis, and pseudoarthrosis post-operatively have been reported.[13,15] Biomechanical studies have suggested that cervical cages should be supplemented with additional external or internal supports to prevent excessive movement in flexion–extension. Using an anterior cervical plate can significantly enhance the rate of fusion,[21] and reduce the rate of segmental kyphosis, loss of disc height, pseudarthrosis and the need for revision surgery.[35]

In this study; satisfactory fusion rate in all patients underwent ACDF with anchored spacers obtained. The rate of fusion and biomechanical stability with this device were comparable to other case series using a plate and cage construct, and both procedures corrected cervical kyphosis and improved cervical alignment.[21,32]

The stand-alone cages have issues of subsidence and local kyphosis at the index level.[3,13,24] The kyphosis at the index level may aggravate the degenerative change in adjacent levels.[22] Kim et al,[24] reported that even though the subsidence does not affect short-term outcome, it may be associated

with the acceleration of the degenerative change. Seventy seven percent of the patients with kyphosis at the fused segment showed a degenerative change in a long-term study. To minimize these problems, stand alone anchored spacer was produced. This method reduces the volume of the anterior plate so that it can decrease dysphagia while maintaining the benefits of anterior cervical plating.

Hyun et al,[20] compared the bone fusion rate in standalone cage with standalone anchored spacer; there was no significant different between the two groups. Also comparing the Cobb's angle of the whole cervical spine and the segmental area between the stand-alone cage group and the stand alone anchored spacer group. The initial Cobb-C was not significantly different. The immediately post-operative Cobb-C was improved in both groups, showing no significant difference between the groups. The lordotic curve of both groups was improved temporarily, but it worsened as time passed. The 24 month post-operative Cobb-C of the cage group was even worse than the pre-operative Cobb-C, while the stand alone anchored spacer group maintained a somewhat improved value compared the pre-operative Cobb-C value. However, the two groups were not statistically different. In our study, the comparison of pre-operative and post-operative Cobb-C showed improvement that was maintained on late follow up evaluation at the second year but it was not statistically significant in agreement with Hyun and colleagues.

In the same study; comparing the tendency of the Cobb-S between the two groups, it showed similar results to the Cobb-C; lordosis was improved temporarily and then gradually worsened. The comparison between the immediate post-operative and the 24-month post-operative was significant. The stand alone anchored spacer group showed significant maintenance of the segmental Cobb-S angle than that of the cage group.[20] Compared to our study; the changes between the pre-operative and second year post-operative measurement of Cobb-S were statistically significant. Taking this into consideration, the restoration of the lordotic angle may be beneficial to prevent the aggravation of degenerative changes. In this aspect, the stand alone anchored spacer can maintain the normal curvature of the cervical spine more than the stand-alone cage do.

We measured disc and vertebral body heights of the fused level (s) to evaluate the subsidence rate and the post-operative cervical alignment. In our study, there were no statistically significant changes between the immediate post-operative and the two years postoperative measurements. Additionally, the insertion of the stand alone anchored spacer does not need excessive dissection of the pre-vertebral soft tissue in comparison to the procedure of cervical plating. After ACDF, significant long-term complications are adjacent segment degeneration.[2]

Heino et al,[23] reported 54 patients with ACDF with nearly 7 years and found that 13 patients had spinal compression due to adjacent level disc degeneration, with one patient suffered cervical spondylotic myelopathy, and 15 patients with adjacent level instability which was considered to cause the increase of adjacent level degeneration after ACDF. Hilibrand et al,[18] reported that 25% of the patients who underwent single level ACDF developed adjacent level disc degeneration with more than 10 years follow-up. Hilibrand et al,[17] also reported 374 patients submitted for ACDF from 1973 to 1992 and were followed up for more than 10 years on average. They reported that the yearly symptomatic adjacent level disease incidence was about 2.9% and the 10 year incidence was nearly 25.6%. McGrory et al,[27] reported 42 patients with cervical vertebral injury undergoing ACDF and were followed up for more than 7 years on average, and found cervical spinal canal stenosis and osteophyte formation in 29% of non-fused levels.

Currently, the exact mechanism explaining adjacent level degeneration is unknown. It is not only related to the natural intervertebral discs degeneration, but also may be related to the increased mobility of upper as well as lower levels adjacent to post-operative fusion levels, which causes abnormal stress on adjacent intervertebral discs and zygapophyseal joints, leading to degeneration.[31] Park et al,[28] found that an anterior cervical fixed plate near to the adjacent intervertebral disc may cause adjacent level disc degeneration or surrounding bone formation, which may result in complications. In our study, we didn't report adjacent segment

degeneration through the follow up period of two years.

The incidence of dysphagia after anterior cervical fusion with plating is reported to vary between <1% and 47%.[5,34] The possible causes include: age, esophageal injury, soft tissue edema, hematoma and adhesion formation around the plate.[10,12,26] Lee et al,[25] compared the incidence of dysphagia in patients undergoing anterior cervical fusion using two different profiles of plate and found significantly less dysphagia with the smaller profile. In this study, dysphagia was noted in the first few days after surgery in 43% of patients. Only one patient had a residual mild dysphagia by the 12th post-operative month which disappeared by the second year post-operatively. This finding supported that the stand alone anchored spacers had a better outcome regarding the post-operative dysphagia in comparison to published studies using anterior cervical plating for fusion.

The small number of patients recruited this study that could be increased for better statistical accuracy represent and the absence of control group are the major limitations of our study.

Conclusion

Stand-alone anchored spacers had a good result regarding post-operative dysphagia, fusion, and segmental alignment. However, this outcome needs to be validated through more controlled trials with longer follow up

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الملخص العربي

النتائج الإكلينيكية لجراحات إستئصال الغضاريف العنقية من الأمام بإستخدام الأقفاص العنقية ذاتية التثبيت

البيانات الخلفيه: لقد أصبحت جراحات إستئصال الغضروف العنقى من الأمام هى الوسيلة الأساسية فى علاج أمراض الغضاريف العنقية. ولقد ساعد تركيب الشرائح العنقية من الأمام على الإلتحام الفقاري بين أجسام الفقرات ولكن العديد من الدراسات أثبتت تعدد الشكوى من الصعوبة المزمنة فى البلع و كذلك تعددت الدراسات التى تثبت حدوث تنكسات في المستويات المجاورة ما بعد تركيب الشرائح العنقية الأمامية والتى ربما يرجع أسباب هذه الشكاوى إلى تشريح العديد من الأنسجة الرخوة بالمنطقة الأمامية العنقية.

الغرض: تقييم نتائج وفائدة الجراحات الأمامية لإستئصال الغضاريف العنقية بإستخدام الأقفاص العنقية ذاتية التثبيت بدون إستخدام الشرائح العنقية.

تصميم الدراسة: هذه الدراسة كانت بأثر رجعي أجريت على ثلاثين مريضا يعانون من أمراض الغضاريف العنقية التنكسية. ولقد تم تقييم المرضى باستخدام المقاييس التالية: مؤشرات الألم البصرية، زوايا الإنحناء للعمود الفقري فى اتجاهات متعددة، مقياس إتحاد العظام اليابانى لأمراض النخاع الشوكي العنقي، وكذلك تقييم ظهور صعوبة البلع.

المرضى و الطرق: أجريت الدراسة على ثلاثين مريضا خضعوا لإجراء جراحة إستئصال غضروف عنقى من الأمام مع التثبيت بإستخدام الأقفاص العنقية ذاتية التثبيت. وتم تقييم المرضى كلهم فى خلال زيارات المتابعة التى امتدت لعامين.

النتائج: اشتملت عينة المرضى على اثنين وعشرين مريضا يعانون من انزلاق غضروفى في مستوي واحد، بينما عانى الثمانية الباقون من الإنزلاق الغضروفي فى مستويين. وكانت التغيرات الإحصائية فى قياسات التقييم كبيرة والتي شملت زوايا الإنحناء بالعمود الفقري وإرتفاع المستويات التي أجرى بها الجراحة.

الإستنتاج: لقد أثبتت الأقفاص العنقية ذاتية التثبيت أنها من التركيبات السهلة الإستخدام أثناء إجراء جراحات إستئصال الغضاريف العنقية الأمامية وتستطيع أن تحقق الإلتحام الفقاري المناسب مع حدوث نسبة أقل من صعوبة البلع بعد الجراحة.