

## Clinical Case Series

# Integrated intervertebral device for anterior cervical fusion: An initial experience

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### Abstract

**Objective:** To analyze the clinical and radiographic results following the use of integrated intervertebral implant in patients with cervical spine degenerative disease. **Background:** Though excellent results have been reported following anterior cervical discectomy and fusion using iliac crest autograft/allograft with plating, the morbidity associated with autograft harvest and small chances of complications with plating always exists. Recently, there has been development of a cervical stand-alone cage with integrated fixation for cervical fusion and stabilization with a possible low morbidity and optimal clinical outcome.

**Materials and Methods:** A retrospective study of 16 patients who underwent anterior cervical discectomy and fusion using the integrated intervertebral device was performed. Intra-operative parameters, clinical features [Neck Disability Index (NDI), visual analog scale (VAS) score for neck/arm pain], and presence or absence of dysphagia was recorded. Radiographs were evaluated for assessment of implant failure and fusion.

**Results:** Mean age of patients was 54 years (range: 38-84 years) with male: female ratio of 1:3. Follow-up ranged from 6 to 12 months (mean: 10 months). In the early postoperative period, 2 of the 15 patients (13%) patients had mild dysphagia that resolved during follow-up with no patient having complaints of dysphagia at 3-month follow-up. One of the patients with diffuse idiopathic skeletal hyperostosis (DISH) and severe preoperative dysphagia had significant improvement in swallowing function at 3-month follow-up that was stable at 1-year follow-up. There was no evidence of implant failure, with fusion occurring in 95% (19/20) of operated levels. Analysis of follow-up VAS and NDI scores showed significant reduction in VAS score for neck pain ( $P < 0.019$ ), radicular arm pain ( $P < 0.003$ ), and NDI score ( $P < 0.007$ ) in 77, 92, and 77% of patients, respectively, at a mean follow-up of 10 months (6-12 months). **Conclusions:** Our preliminary results with the use of this cervical stand-alone anterior fusion device with integrated screw fixation show its efficacy in anterior cervical decompression and fusion with stabilization with optimal clinical and radiographic outcome. Lower chances of dysphagia with no device-related complications are appealing, which needs to be verified in larger studies.

**Key words:** Cervical, degenerative, integrated, interbody cage, stand-alone, zero profile

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### INTRODUCTION

Anterior cervical discectomy and fusion (ACDF) is a well-established surgical procedure for the treatment of cervical degenerative disease. A radiographic fusion is aimed to obtain ideal clinical outcome. Though the use of internal fixation attempts to improve fusion rate, with other advantages like reducing/obviating the need of postoperative immobilization

and avoiding graft-related complications, led to its widespread use, especially in multilevel cases, its real necessity and clinical benefits are questionable, especially, in a single-level fusion.<sup>[1,2]</sup> Significant donor-site morbidity and complications associated with harvesting iliac crest autograft for fusion has been the impetus, leading to widespread use of several types of interbody fusion cages, osteoconductive materials, and allograft for ACDF in clinical practice.<sup>[3,4]</sup> Although studies have reported good clinical outcome without any orthotic/plating following the use of allograft and stand-alone cages for single level ACDF,<sup>[1]</sup> plating has become almost universal even after single-level anterior cervical fusion in the United States due to concerns for graft-related complications with the use of allograft or other osteoconductive materials.<sup>[5,6]</sup> The use of plating, however, is not without side effects and can be associated with increased chances of dysphagia, hardware-related complications, esophageal injury, higher incidence of adjacent-level degenerations, and heterotrophic ossification.<sup>[6-12]</sup>

Biomechanical studies using integrated screws with interbody spacer in lumbar spine have shown decreased torsional motion and more resistance to anterior displacement of the interbody device as compared to stand-alone cages that have been associated with suboptimal fusion rate in some studies.<sup>[13-15]</sup> In view of the equivocal need of anterior plating for single-level ACDF, with concerns for plating-related complications, there has been interest in the use of either stand-alone interbody cages,<sup>[16,17]</sup> use of anchoring clip,<sup>[18]</sup> or integrated fixation device<sup>[19]</sup> with interbody cage to ensure primary stabilization of the cage for cervical fusion. The oblique trajectory of the screws integrated with the interbody device traversing through the cortices adjoining the disc space provide strong fixation, obviating the need of anterior cervical plate.<sup>[20,21,22]</sup> Scholz *et al.*<sup>[19]</sup> recently reported the use of polyether ether ketone (PEEK) cages filled with b-tricalcium phosphate with integrated screws in a selective group of patients, providing encouraging results. We have been using a similar device recently for the treatment of cervical degenerative disease, and the present study was conducted to review our clinical experience in a group of 16 patients with cervical degenerative disease.

## MATERIALS AND METHODS

A retrospective chart review of patients who underwent ACDF, which involved placement of the anterior stand-alone device was conducted after obtaining institutional review board approval. A total of 20 levels were treated in 16 patients between June 2009 and November 2010 using the stand-alone device. Four patients had multi-level diseases and underwent two-level fusions each. All patients had symptomatic degenerative cervical spine disc disease between C3/C4 and C6/7 and failed non-operative treatment. The indications for surgery were either radiculopathy or myelopathy with/without functional/neurologic deficit with good clinic-radiological correlation as confirmed by magnetic resonance imaging (MRI) with or without computed tomography (CT). Two patients had an

associated diffuse idiopathic skeletal hyperostosis (DISH). One of the patients with severe DISH presented with severe dysphagia and required placement of gastrostomy tube due to severe difficulty in swallowing. Three patients had adjacent segment disease, two following previous fusion surgery and one with congenital Klippel-Feil disease. Degenerative disease was identified at the following levels: C3/4 (four), C4/5 (six), C5/6 (seven), and C6/7 (three). Figures 1-3 demonstrates the representative images of patients treated with the device in the present study.

## Technique

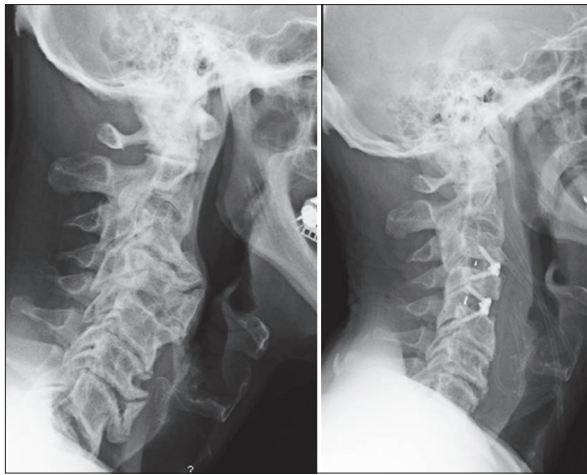
The patients were placed with a head extension in a supine position. To obtain the target disc space, a standard left side approach to the cervical spine was performed. A right-sided approach was used when necessary or in the presence of any contraindication to left-sided approach. After anterior decompression by the standard anterior cervical approach, trial spacers were used to determine the appropriate implant size. After the trial spacer was correctly fitted into the disc space, a corresponding stand-alone implant (COALITION; Globus Medical, Inc. Audubon, Pennsylvania, US) packed with b-tricalcium phosphate was inserted with an implant holder/aiming device. Correct position of the cage was ascertained using an image intensifier in lateral view.

## Description of the device

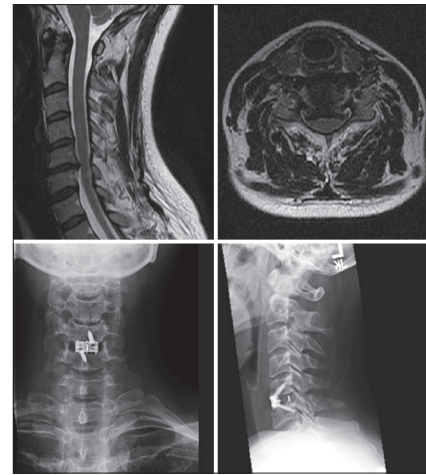
The device is made up of a PEEK body with tantalum markers along with a small plate containing two holes and internal screw threads [Figure 4]. After drilling the pilot hole through the aiming device, the first locking screw is inserted, followed by the second screw. The implant system contains screws of 14- and 16-mm length, which can be used depending on the overall bony anatomy of the patient. Due to anatomical obliquity, angled instruments for drilling, and inserting screws in the upper and lower may be required.

## Follow-up and statistical analysis

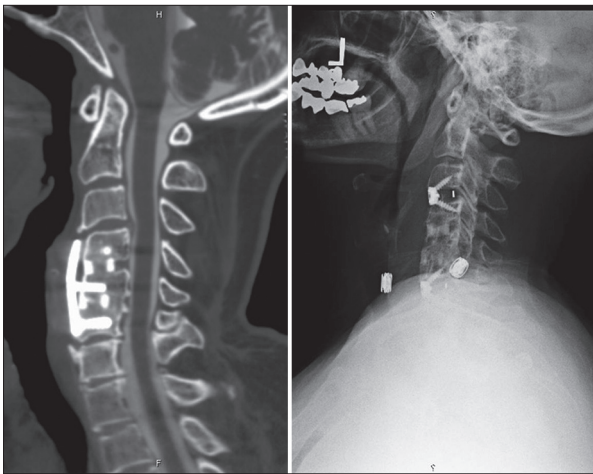
No orthosis/collars were used in any of the patients. Standard physical therapy was initiated after 6 weeks of surgery. Follow-up data consisted of clinical and radiographic evaluation at regular intervals. Patient's pre-operative visual analog scale (VAS) score for neck and radicular arm pain on 0-10 scales, with 0 representing no pain and 10 representing severe pain was compared with that at last follow-up. Also, assessment of functional outcome using the Neck Disability Index (NDI) score ranging from 0% to 100%, with a lower percentage being indicative of a better condition was done before surgery and at last follow-up. Presence or absence of dysphagia was subjectively assessed by the senior surgeon (JO) and classified as none (no episodes of swallowing problems), mild (rare episodes of dysphagia), moderate (occasional swallowing difficulty with specific food), and severe (frequent difficulty swallowing with majority of food) after surgery and at last follow-up.<sup>[7]</sup> Complications were recorded as implant-related, surgery-related, or general



**Figure 1:** Pre-operative (left) and post-operative (right) lateral X-ray of a patient with severe degenerative cervical spine disease and extensive DISH; the patient was treated with C3/4 and C4/5 fusion with resection of the osteophytes



**Figure 2:** T2-weighted sagittal (upper left) and axial MRI at C5/6 level (upper right) showing bilateral foraminal stenosis, resulting in radiculopathy. AP (lower left) and lateral (lower right) plain radiographs after decompression and fusion using integrated intervertebral device

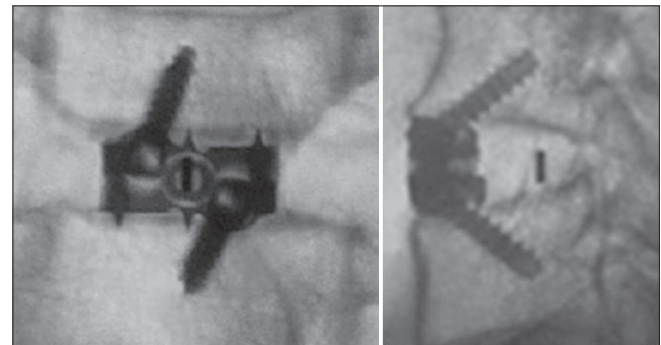


**Figure 3:** Pre-operative (left) and post-operative (right) lateral X-rays of a patient showing two level adjacent segment disease following previous two-level fusion, which was treated by performing fusion at the C3/4 and C6/7 level with removal of the previous instrumentation

(not directly implant or surgery related). Neutral and F/E radiographs were evaluated by both the authors (JO and MK) to look for graft subsidence, implant failure, and status of fusion. Fusion was defined as the absence of radiolucencies, evidence of bridging trabecular bone within the fusion area, and no differences in angulation ( $<2^\circ$ ) or interspinous process distance ( $<2$  mm) on F/E radiographs. The difference in VAS and NDI scores between pre-operative and at last follow-up was assessed using the *t*-test for paired samples and  $P < 0.05$  was considered significant.

## RESULTS

Mean age of patients was 54 years (range: 38-84 years) with a male: female ratio of 1:3. Follow-up ranged from 6 to 12 months (mean: 10 months). The average operation time



**Figure 4:** X-ray demonstrating the AP and lateral profile of the COALITION-integrated intervertebral device (Reprinted with permission from globus medical, inc., audubon, pennsylvania, US)

ranged from  $119 \pm 24$  min with average blood loss being 88 ml (range: 30-150 ml). Average length of stay in the hospital was 1.4 days (range: 1-3 days).

Before surgery, only 1 patient had complains of severe dysphagia, which required placement of gastrostomy tube for feeding [Figure 1]. In the early post-operative period, 2 of the 15 patients (13%) patients had mild dysphagia, which resolved during follow-up with no patient having complaints of dysphagia at 3-months follow-up. The patient with DISH and severe pre-operative dysphagia had significant improvement in swallowing function and came off his percutaneous endoscopic gastrostomy (PEG) tube at 3 months with stable swallowing at 1 year follow-up.

Eighty percent of operated levels had some evidence of graft subsidence at follow-up on radiographic assessment. None of them had a subsidence  $>2$  mm with the average graft subsidence being 1.1 mm (range: 0.4-2 mm). There was no evidence of any segmental collapse, graft migration, or detectable implant/screw loosening in any of the patients at last follow-up.

All patients had a follow-up of  $\geq 6$  months and were assessed for presence or absence of fusion; 95% of operated levels (19 of 20 levels) were defined as fused and 93% of patients (15/16) achieved solid fusion [Figure 5]. One patient who had an adjacent segment disease following a prior two-level fusion in the past developed symptomatic pseudoarthrosis at 12-month follow-up and underwent revision surgery. There were no surgery-related complications. One patient each had transient left upper extremity proprioceptive changes and urinary retention that resolved within 24 hours without any long-term sequel.

Analysis of follow-up VAS and NDI scores showed significant reduction in VAS score for neck pain ( $P < 0.019$ ), radicular arm pain ( $P < 0.003$ ), and NDI score ( $P < 0.007$ ) in 77, 92, and 77% of patients at a mean follow-up of 10 months (6-12 months) [Figures 6 and 7].

## DISCUSSION

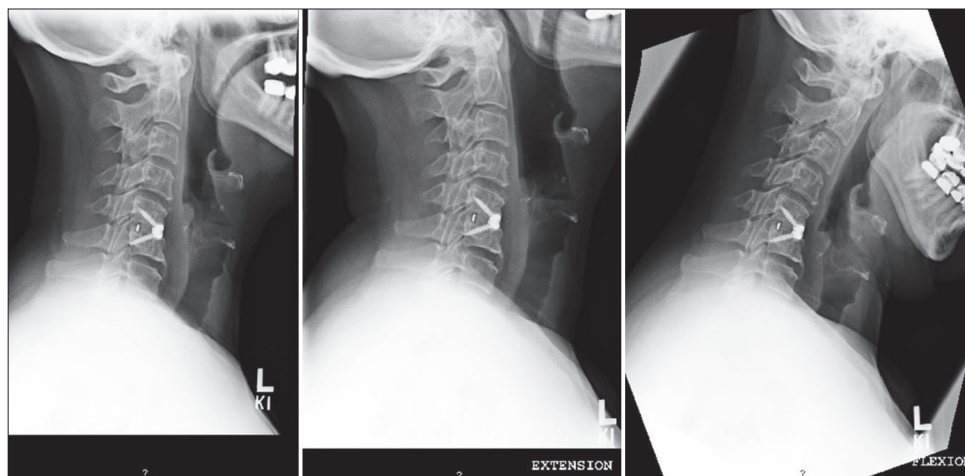
Anterior cervical discectomy with interbody fusion is well accepted for the surgical management of radiculopathy or myelopathy secondary to degenerative cervical disc disorders. Recognition of donor site morbidity has led to use of numerous graft options for anterior cervical fusion.<sup>[3,4]</sup> In patients treated without the plate, additional complications can include graft extrusion, collapse, and failure of fusion, leading to kyphosis and pseudoarthrosis.<sup>[1,16,17,23]</sup> The use of graft options other than autograft has resulted in frequent use of plating even after single-level fusion in order to increase the fusion rate, decrease graft-related complications, and avoid post-operative orthotic use.<sup>[5]</sup> In fact, as autograft/interbody cages have almost replaced use of autograft at most institutions in the United States, the use of anterior plate has become universal.

The addition of an anterior plate system reduces the problem of graft extrusion and collapse, but is itself associated with problems such as screw or plate dislodgement, dysphagia, and soft-tissue injury, higher incidence of adjacent-level degenerations, and

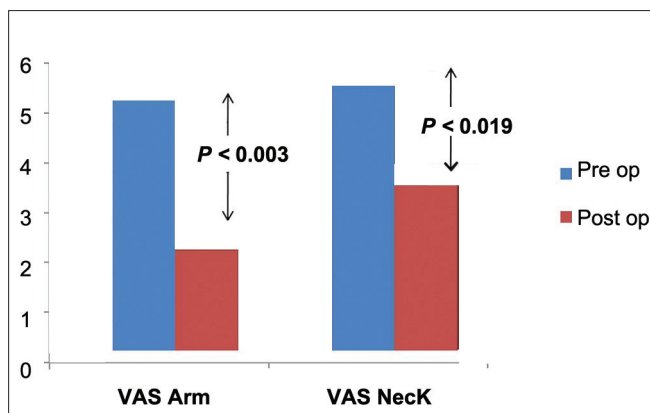
heterotrophic ossification.<sup>[6-10]</sup> Considering the equivocal benefit of plating in single-level anterior cervical fusion,<sup>[1,2]</sup> with small possibilities of plating-related complications, there has been a trend toward the use of stand-alone interbody cages to circumvent the complications associated with the use of both the iliac crest autograft as well as anterior cervical plating for single-level cervical diseases.<sup>[16-18,24-27]</sup> Interbody cages can be filled with iliac crest autograft bone or other osteoconductive material for fusion. A high incidence of subsidence has been reported in studies using stand-alone interbody cages in some studies.<sup>[16,17]</sup>

Due to concern for decreased biomechanical stability of interbody cages, especially in flexion/extension,<sup>[26]</sup> and higher chances of subsidence of stand-alone cages reported in the literature with possible misalignment and pseudoarthrosis,<sup>[16,17]</sup> there has been development of anterior cervical implant with screws integrated with the cage. The oblique trajectory of the screws associated with the integrated device engage the anterior cortex of the body and traverse through the strong cortices adjoining the disc space providing strong fixation, obviating the need of anterior cervical plate for a single and multi-level cervical fusion and was first described by Goel in 1997. Goel discussed a number of bicortical and tricortical combinations of using screws that employed the cortical surface adjoining the disc space.<sup>[20,21,22]</sup> There was no subsidence in the study using the zero profile device by Scholz *et al.*<sup>[19]</sup> Similarly, though 80% of our cases showed some evidence of implant subsidence, none of our patients had a segmental collapse or subsidence of  $> 2$  mm. Subsidence may be of more clinical importance in treating multi-level cervical degenerative disease rather than in surgery for single-level fusion.

Post-operative dysphagia after ACDF is a relatively common occurrence with a reported incidence of up to 70%, especially in early post-operative period.<sup>[6,7,11,12]</sup> Jagannathan *et al.*<sup>[11]</sup> reported a relatively lower incidence of dysphagia in their series of ACDF, without the use of any plating. Only 9% patients had dysphagia in the post-operative period with only 3% of



**Figure 5:** Lateral neutral (left), extension (middle), and flexion (right) X-rays of one of the patients at 6-month follow-up showing evidence of fusion

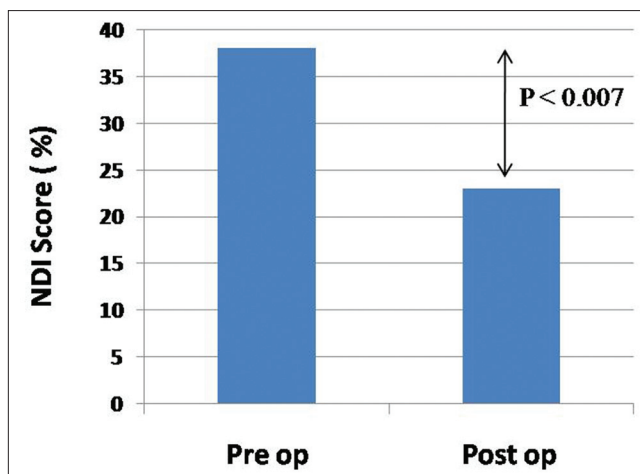


**Figure 6: Neck pain and radicular arm pain VAS scores preoperatively and at last follow-up**

patients complaining of dysphagia at 3-month follow-up. We had very low incidence of early postoperative dysphagia (13%) with 0% incidence of dysphagia at 3 months. Similarly, Scholz *et al.*<sup>[19]</sup> used a zero-profile device and reported a low incidence of dysphagia (3%) at 3-month follow-up. They however had very high incidence of early dysphagia (62%) in contrast to that in our study. Though the exact etiology of dysphagia after anterior cervical approach is unknown and multi-factorial, depending on the age of the patient, post-operative soft tissue edema, number of levels treated, esophageal injury, and post-operative hematoma, adhesions around cervical plates with plate prominence due to mechanical causes may be a contributing factor toward dysphagia.<sup>[1,6,7,11,28,29]</sup> Lee *et al.*<sup>[29]</sup> reported a lower incidence of dysphagia with use of thinner plates. The design of the implant used in the present study and also that reported by Scholz *et al.*<sup>[19]</sup> reduces the implant contact with mechanical irritation to the soft tissue, explaining the lower incidence of dysphagia with the use of stand-alone device. Also, reduced soft tissue dissection associated with the use of this low profile implant may contribute toward decreased chances of dysphagia.

Most of the patients in our series had significant improvement in their VAS score for arm and neck pain and NDI scores [Figures 6 and 7] after discectomy and fusion using the integrated device, which is consistent with the results reported in the literature. The overall operative time, blood loss, and length of hospital stay using the integrated intervertebral implant was comparable to that in other studies.<sup>[1,5]</sup> Also, there is no learning curve as the standard Smith Robinson technique is very familiar to all spine surgeons. However, there are certain limitations to this study. First, the study was a retrospective one and depended on the data available in the medical records with retrospective assessment of dysphagia, which may have underestimated the true incidence. Second, the number of patients with variable diagnosis was small.

However, the integrated intervertebral device described certain advantages. First, it requires less soft tissue dissection as compared to the standard cervical plating. Second, due to its low profile with location totally within the intervertebral disc space, the chances of dysphagia may be less and may be beneficial in



**Figure 7: Change in NDI score after surgery as compared to the pre-operative score**

patients who presents primarily with dysphagia due to severe DISH, reducing the theoretically risk of the plate acting as a mechanical cause for dysphagia. Also, treating skip level may be easier with the use of this device as was done in a couple of patients that would otherwise necessitate the use of longer cervical plates leading to more loss of normal mobility of the cervical spine. The less overall stiffness of the construct while preventing graft-related complications may lead to reduced chances of adjacent segment degeneration as compared to plating.<sup>[26]</sup> Also, the use of a PEEK cage filled with b-tricalcium phosphate avoids complications associated with autograft harvest.

To conclude, our preliminary results with the use of this cervical stand-alone anterior fusion device with integrated screw fixation shows its efficacy in anterior cervical decompression and fusion with stabilization with optimal clinical and radiographic outcome in a group of patients seen in the standard practice of a spine surgeon. Lower chances of dysphagia and no device-related complications with obviation of morbidly associated with autograft harvest are appealing, which needs to be verified in larger studies.

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