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ZERO-PROFILE ANCHORED SPACER SYSTEM IN THE TREATMENT OF CERVICAL DEGENERATIVE DISEASE WITH A FOLLOW-UP OF 1 YEAR- OUR EXPERIENCE .

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ABSTRACT **Objects:** Anterior cervical plating decreases the risk of pseudarthrosis, increases rate of fusion following anterior cervical discectomy and fusion (ACDF). Dysphagia is a common complication of ACDF, with the anterior plate implicated as a potential contributor. A zero-profile, stand-alone interbody spacer has been postulated to minimize soft-tissue irritation and postoperative dysphagia, but studies are limited. We are reporting our findings in term of clinico-radiological outcomes following the use of such devices in the treatment of cervical spine degenerative diseases with a focus on the course of postoperative prevertebral soft-tissue thickness and the incidence of dysphagia. **Methods:** The authors conducted a prospective analysis of all patients who had undergone ACDF between December 2018 and December 2019. All patients received a Zero-P implant (DePuy Synthes Spine).The Neck Disability Index (NDI),Modified Japanese Orthopaedic Association Score(mJOA) and visual analog scale (VAS) scores for arm and neck pain were documented. Dysphagia was determined using the Bazaz criteria. Prevertebral soft-tissue thickness, spinal alignment, intervertebral disc height were assessed as well. The final outcome was assessed with Odom's criteria. **Results:** Total 30 patients were studied prospectively, and data were collected and analyzed. 17 male and 13 female consecutive patients, with a mean age of 48.28 ± 8.17 years, underwent ACDF with Zero-Profile spacer (42 total operated levels) in the defined study period. There were significant improvements in neck and arm VAS scores, the NDI and mJOA scores following surgery at last follow up. The neck VAS score improved from a mean 7.34 ±1.87 to 1.04 ± 0.09 ($p<0.01$) . The arm VAS score improved from 7.22±2.03 to1.03±0.10 at latest follow up. NDI score improved significantly from preoperative 31.94±6.73 to 12.87±5.24 and mJOAscore improved from preoperative 9.53±1.98 to 15.6±1.26 at last follow up. Immediate postoperative dysphagia was experienced by 36.67% of all patients. Complete resolution of dysphagia was demonstrated at the latest follow-up. Prevertebral soft-tissue thickness at postoperative 48 hrs decreased across all levels from a mean of 15.87 ±0.69 to 11.81 ± 0.53 mm at last follow up. Cervical alignment and intervertebral disc height were also improved significantly after surgery. Radiographic fusion was achieved in 100% of implants. No correlation was found between prevertebral soft-tissue thickness and Bazaz dysphagia score. Majority of the patients had excellent outcomes in odom's criteria. **Conclusions:** Zero-Profile device is a safe and effective alternative for the treatment of cervical degenerative diseases. Chronic dysphagia rates are comparable to or better than those for previously published case series.

KEYWORDS : ACDF-Anterior cervical discectomy and fusion , mJOA -Modified Japanese Orthopaedic Association Score , NDI- Neck Disability Index, VAS-Visual analogue scale , Zero-P- Zero-Profile, PEEK-Polyether ether ketone

INTRODUCTION:

Anterior cervical Discectomy and Fusion (ACDF), proposed by Smith and Robinson (1958)[1] remains the gold standard surgical approach for cervical spondylotic myelopathy with or without radiculopathy. The goal of surgical treatment is to provide neural decompression and segmental stability[2]. The ACDF treats the potentially debilitating effects of cervical degenerative disc disease (DDD) by providing long-term stabilization, maintaining disc space height and decompressing the neural elements[3,4,5].

Since its initial description, many technical modifications of ACDF have been done to reconstruct the discectomy defect including use of allograft bone and anterior plating, polyetheretherketone (PEEK) cages with anterior plating, and other interbody fusion devices.[6] Currently, the vast majority of surgeons use interbody spacer cage with anterior locking plates. An interbody spacer is used to increase the disc space and neuroforaminal height and restore cervical lordosis. An anterior plate is commonly added to enhance construct stability and reduce the rate of pseudarthrosis; however, this addition may be complicated by postoperative dysphagia, soft tissue injury, and hardware failure[7,8,9]. To avoid the drawbacks of plating , zero-profile anchored cage systems have been designed for stand-alone fusion[10]. Zero-profile stand-alone device (Zero-P, Synthes GmbH, Switzerland) for ACDF has been approved to use for patients with degenerative cervical disc disease by the United States Food and Drug Administration in 2008.[11] Previous studies based on small sample sizes have reported the application of the Zero-P in single ACDF surgery with excellent clinical and radiographic outcome[12].The zero-profile device or anchoring cage or stand-alone cage consists of a cage with angle controlled interbody locking screws, where screws could get into the adjacent vertebral body through the end plate, are attached to the front of the cage. The whole device can be implanted into the intervertebral space to avoid the implant contact to the front soft tissue of the cervical region.[13]. In this prospective study, we described the clinical and radiological outcomes of 30 consecutive patients who underwent ACDF with a Zero-profile, PEEK integrated interbody spacer implant. We also assessed postoperative prevertebral soft-tissue thickness as well as the incidence of early and late postoperative dysphagia.

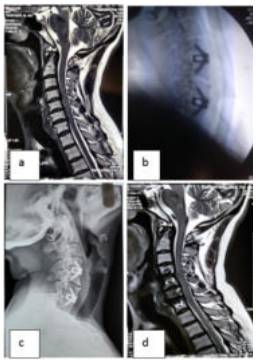

Figure1 showing (a) preop MRI with C4-C5&C6-C7 compression, (b) intraop C-arm after implantation (c) postop lateral x-ray C-spine,(d) postop MRI of same patient.

Materials and Methods: We conducted a prospective study of 30 patients operated with Zero-Profile spacer system(PEEK) for the treatment of cervical degenerative disease in our hospital between the duration of December 2018 and December 2019. The inclusion criterion of this study was patients with degenerative cervical spine presenting with radiculopathy or myelopathy not responding to conservative treatment. Patients with infections, tumors, traumatic fractures, and degenerative disease >2 levels involvement, patients requiring anterior cervical corpectomy and patient with long segment disease requiring laminectomy and fixation, patients with previous cervical spine surgery were excluded from our study. All the patients were operated by a standard left-sided Smith-Robinson approach to cervical spine under general anesthesia. After cervical discectomy and decompression at the desired level and after the preparation of endplate, a correct size Zero-Profile spacer cage was placed in the prepared disc space and fixed to upper and lower vertebral body with appropriate size locking screw system under C-arm guidance. Postoperatively, patients were advised with soft neck collar for 3 weeks along with physical therapy.

Clinical Evaluation: Demographic variables such as patient age, sex, BMI, and smoking habits were recorded. Clinical outcomes were collected preoperatively, at 1, 3, 6 and 12 months after ACDF. Dysphagia was recorded and graded according to the Bazaz scoring system (none /mild /moderate /severe). A numerical score ranging from 0 (no episodes of swallowing difficulty) to 3 (severe difficulty with the majority of food) was noted for each patient. Clinical outcomes were measured using the Neck Disability Index (NDI), the visual analog scale (VAS) and Modified Japanese Orthopaedic Association Scores(mJOA score). Intraoperative and postoperative complications were recorded.

Table1:**Summary of characteristics in 30 patients who underwent ACDF(Zero-P)**

CHARACTERSTICS	NO. (%)
Mean age at surgery in years	48.28 ± 8.17
Sex	
M	17(57.67)
F	13(43.33)
Hypertension	6(20)
Diabetes	4(13.33)
Smoking	2(6.67)
Intra-operative time(mean)	96.17 ± 17.68 min
Estimated-blood loss(mean)	98.32 ± 40.91 ml
Length of hospital stay(mean)	3.26 ± 1.23 days
No.of levels operated (total 42)	1-level- 18, 2-levels- 12
Level of surgery	
$C_3 – C_4$	4
$C_4 – C_5$	9
$C_5 – C_6$	13
$C_6 – C_7$	4

Radiological Evaluation: Antero posterior and lateral cervical radiological images were ideally obtained at 48hrs, 1, 3, 6, and 12 months after ACDF. At a minimum of 3 months, flexion and extension images were obtained as well. Preoperative, immediate postoperative, and latest follow-up radiographs were used to measure Cobb angles at the operated levels, subsidence, prevertebral soft-tissue thickness, and hardware failure or instability. Computed tomography scans were obtained at approximately 3, 6 and 12 months to evaluate radiological fusion. Cervical alignment (Cobb angle) measurements were made to track changes in spinal alignment at the operated levels and were determined between the upper endplate of the vertebral body above the fusion and the lower endplate of the vertebral body below the fusion. The height of the surgical motion segment was determined by measuring the distance from the upper endplate of the upper vertebral body to the lower endplate of the lower vertebral body from the anterior, middle, and posterior portions of the operated levels. Subsidence was calculated by subtracting the latest follow-up motion segment height from the immediate postoperative height and was defined as a loss of intervertebral height greater than 3 mm. The intervertebral disc height was measured on the lateral radiograph as the distance from the highest portion of the lower end-plate of the cephalad vertebra to the closest portion of the upper end-plate of the caudal vertebra Prevertebral soft-tissue thickness was determined by measuring the thickness of soft tissue from the anterior aspect of C3–7 vertebral bodies to the posterior aspect of the trachea. Radiographic fusion was defined by the presence of bony bridging across the intervertebral space on CT imaging. Postoperative MRI was done in all patients at 3 months and at 1 year and compared with preoperative MRI to see changes of canal diameter.

Statistical analysis: Statistical analysis was performed using the SPSS software version 16 (SPSS Inc. Chicago, IL 60606-6412) using the pair *t*-test for comparison, and $P < 0.05$ was considered statistically significant.

RESULTS:

Total 30 patients (17 males, 13 females) underwent ACDF with the Zero-P implant (42 operated levels). All patients had symptomatic degenerative cervical disc disease or disc herniation from level C3–4 to C6-7. The total number of operated levels were 42 (18 patients of single-level ACDFs and 12 patients of two-level ACDF). The most common level of surgery was C5–C6 (13 cases), followed by C4–C5 (9 cases), C6–C7 (4 cases), and C3–C4 (4 cases). The mean operating time was 96±17.68 mins, mean estimated blood loss was 98.32±40.91 ml and mean hospital stay was 3.26±1.23 days.

Clinical Outcomes: All patients underwent assessment of clinical and functional outcomes at preoperative period, at 1 month, at 3 month, 6 month and at 1 year of post- operative period using the neck and arm VAS , NDI criteria and mJOA score. At the latest follow-up, there was a statistically significant reduction in the mean VAS neck pain score from 7.34±1.83 to 1.04±0.09 ($p < 0.01$) and in the mean VAS arm pain score from 7.22±2.03 to 1.03±0.10 ($p = 0.01$). The mean NDI score statistically improved from 31.94 ± 6.73 preoperatively to 12.87 ± 5.24 at the latest follow-up ($p < 0.01$). Modified Japanese Orthopaedic Association Scores (mJOA score) was also significantly improved from preoperative 9.53±1.98 to 15.6 ±1.26 at the latest follow up ($p<0.01$).

Table -2: Summary of clinical measures in 30 patients who underwent ACDF

Mesures	Pre-op	Final followup	p- value
VAS- neck	7.34 ± 1.83	1.04 ± 0.02	<0.01
VAS- arm	7.22 ± 2.03	1.03 ± 0.10	<0.01
NDI	31.94±6.73	12.87± 5.24	<0.01
mJOA	9.53 ± 1.98	15.6 ± 1.26	<0.01

Radiological Outcomes: The cervical Cobb angle was also significantly improved from 12.61°± 5.7°, measured before surgery, to 17.1°± 5.2°at 1 week and 19.43°± 4.24°at 12 months following the implant ($P < 0.05$). Intervertebral disc height (DH) was increased significantly after surgery. The mean DH at the treated level was significantly restored after surgery in all the cases. Briefly, the height of intervertebral space was significantly improved from 5.8 ± 0.9 mm measured before surgery to 7.2 ± 1.03 mm at 1 week and 6.89 ± 1.02 mm at 1 year following the surgical treatment($p<0.05$). The most common device size was 7 mm (range 6–9 mm),which was implanted in 75% of levels. Prevertebral soft tissue thickness increased at 48 hours after surgery. After 6 month and 1 year of surgery, prevertebral soft tissue thickness is approximately similar to baseline value ($P>0.05$). Dysphagia at 48 hrs after surgery was experienced by 36.67% of patients, and 6.67% of patient experienced mild dysphagia at 3 month of follow up but at the latest follow-up no patient was found to have dysphagia. A lower fusion rate (10%) was found at 3 months after surgery, but at the final follow-up the fusion rate was 100%. Patient's satisfaction by Odom's criteria was excellent (16), good (11), fair (3),and poor(nil). Subsidence pseudoarthrosis, screw loosening etc were not detected at the last follow-up.

Table 3: Pre-vertebral soft tissue thickness(mm)

Pre-op	**12.19 ± 0.78**
Post-op (48hrs)	15.87 ± 0.69
6 month	12.56 ± 74
1 year	11.81 ± 0.53

Table 4: Comparison of dysphagia incidence. (Bazaz scoring)

	Dysphagia incidence(Bazaz score)				
Time interval	**None**	**Mild**	**Moderate**	**Severe**	**Incidence**
Post op 48hrs	19	7	3	1	36.67%
1 Month	22	5	3	0	26.67%

3 Month	28	2	0	0	6.67%
6 Month	30	0	0	0	-
1 Year	30	0	0	0	-

DISCUSSION:

Anterior cervical discectomy and fusion (ACDF) is a well-established technique for treatment of cervical myelopathy and radiculopathy. The technique aims at establishing neural decompression and providing segmental stability at the symptomatic cervical level. Since its initial description by Smith and Robinson (1958)[1] the technique has undergone extensive modifications. The current standard method combines an anterior locking plate with either a synthetic, allograft, or metallic interposition graft[14,15,16]. While the addition of an anterior plate enhances the biomechanical stability of the construct and leads to a higher fusion rate, it has also been associated with prevertebral soft tissue injury and dysphagia[17,18]. Several factors are assumed to have a role in the increased rates of dysphagia following ACDF with anterior plating, such as retraction, direct impingement of the esophagus, and irritation of surrounding soft tissue. A zero-profile implant may exert less of a mass effect on the esophagus. A previous study showed that zero-profile anchored spacers can lead to similar clinical and radiological outcomes as ACDF with plating, yet carry a lower risk for persistent dysphagia[19,20].

In the present study, we report our experience with Zero-Profile spacer cage system in the treatment of cervical radiculopathy/myelopathy requiring surgery. Significant improvement in VAS pain score for neck and arm, NDI score, Modified Japanese Orthopaedic Association Scores (mJOA score) was seen at last follow-up in all the patients. These findings were consistent with other literature[10,21,22]. Irrespective of implants used in ACDF

(e.g. Zero-Profile cage, plating or integrated screws, and cage spacer system) showed improvement in VAS , NDI score and mJOA score after surgery[23,24,25,26]. Significant improvement of cobb angle , intervertebral disc height has been seen in our study at latest follow up period from that of preoperative value. Similar findings has been reported by Takhelmayum, *et al* [26] Grasso *G et* al [27]. Though prevertebral soft tissue thickness increased at 48 hrs of postoperative period but it became similar with that of preoperative value at final follow up. Innocent Njoku et al [28] in their study revealed that immediately postoperative soft-tissue thickness was significantly greater than the preoperative prevertebral value across all vertebral levels ($p < 0.001$), and the latest follow-up prevertebral soft-tissue thickness was significantly smaller than the immediately postoperative values, however, they did not find any correlation between prevertebral soft tissue thickness and postoperative dysphagia. Suk *et al*[29] also reported similar decrease of prevertebral soft tissue thickness from immediate postoperative period to latest follow up. Similar to Innocent Njoku et al [28] we did not find any correlation between prevertebral soft tissue thickness and postoperative dysphagia both early and at last follow up. In our series, the fusion rate at 1year was 100%. Previous studies reported similarly high rates of bony fusion ranging between 95.2% and 100%.[12,27,31] When patients satisfaction was compared with other literatures available we found majority of the patients in excellent category of Odom's criteria at the latest follow up.[26] In the present study the total incidence of dysphagia was 36.67% at post op 48 hrs, 26.67% at 1 month ,6.67% at 3 months. At latest follow up of 1 year no patients were found to have dysphagia. Scholz et al[10] reported early postoperative dysphagia in 62% of their patients and after 6 months no patient was reported to have dysphagia.Their findings are consistent with our study though incidence of early postoperative dysphagia was higher than our findings. McAfee et al[31] also reported no patient with dysphagia after 3 months of surgery similar to our findings. Lee at al [32] ,Winslow et al [33] also mentioned that in the majority of cases postoperative dysphagia resolves within the first 3 months. however, in 12.5%–35.1% of patients dysphagia persists for >3 months[33,34] Cage with very low profile avoids an implant contact to the soft tissue in front of the cervical spine. This might avoid any mechanical irritation of the esophagus and may explain the low dysphagia rate, Grasso G *et al*[27]. In the postoperative period, other factors may contribute to dysphagia, such as esophageal irritation or ischemia, recurrent laryngeal nerve palsy, adhesions, and screw or plate migration in a small fraction of cases. Thus,other modifications in ACDF surgery, such as refinements to retractors, which would minimize retraction pressure on adjacent key soft-tissue structures, may be important in reducing postoperative dysphagia.[35].

CONCLUSIONS:

Zero-Profile implant device is a good option for treating cervical degenerative disease. Clinical outcomes, functional outcomes, and radiographic fusion rates that are comparable with those for standard ACDF plate and spacer implants, however, the chronic dysphagia rate following the use of this implant is comparable or decreased as compared with rates reported in the literatures. The relationship between prevertebral soft-tissue thickness and dysphagia after ACDF surgery may not be directly correlative. Thus, further study of the pathophysiology of dysphagia is needed, and additional refinements should focus on techniques or instruments that address other causes of dysphagia following ACDF.

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