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# Anterior Cervical Discectomy and Fusion—Can a Standalone Zero-Profile Titanium Cage a Better Alternative Option to Traditional Cervical Plate-Titanium Cage Combination?: A Prospective Observational Study

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## Abstract

**Introduction** Anterior cervical plating in anterior cervical discectomy and fusion (ACDF) has inherent drawbacks like plate loosening, screw pullout, breakage, tracheaesophageal irritation and fistula, increased operation time, and increased duration of hospital stay. Due to low profile and in-built screw fixation slots, Zero-profile (Zero-P) cages are becoming popular among spine surgeons since they are supposed to minimize drawbacks that are associated with anterior cervical plates.

**Aims** In our study, we evaluated two different fixation methods: (1) anterior cervical plate plus titanium cage and (2) zero-P titanium cages with respect to duration of surgery, length of hospitalization, rate of fusion, and postoperative complications.

**Materials and Methods** This was a comparative prospective observational study with a sample size of 30 patients. Patients with cervical compressive disease (-radiculopathy/myelopathy or combined symptoms) who require ACDF and fit in inclusion criteria were divided in two groups: group A—anterior cervical plate and titanium cage and group B—Zero-P titanium.

**Statistical Analysis Used** Mann–Whitney U test was used for the duration of stay, and Student's *t*-test was used for the duration of surgery.

**Results** C4–5 level was most commonly involved followed by C5–C6 level and C3–C4 level. The mean duration of surgery in group A was 141.3 minutes and group B was 111.3 minutes. The mean duration of stay in group A was 4.40 days and group B was 2.0 days. Two patients in group A and one patient in group B had dysphagia. One each in both groups had developed hoarseness of voice after surgery. Two patients in group A and one in group B had persistent donor site pain till 6 weeks to 2 months. One patient each of both groups had cage subsidence. Almost all patients in both groups achieved fusion by 6 months.

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**Keywords** 

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Thieme Medical and Scientific Publishers Pvt. Ltd., A-12, 2nd Floor, Sector 2, Noida-201301 UP, India **Conclusion** ACDF with standalone Zero-P cage is equally good. Duration of surgery and duration of stay were shorter in standalone Zero-P cage group. We feel it is good for patients and healthcare since it reduces overall financial burden.

## Introduction

Disabling neck pain is one of the increasing conditions in the adult population with prevalence that extends from 2 to 13.5%. However, cervical radiculopathy is not that common with a prevalence of 3.3 cases per 1,000 people.<sup>1–4</sup> Aging-associated degeneration of the cervical spine is pronounced in ~50% of the middle-aged population.<sup>5</sup>

The common symptom of cervical radiculopathy is radiating pain to one or both upper limbs with or without tingling numbness. The common symptoms of cervical myelopathy are gait imbalance, tingling and numbness in hands and lower limbs, loss of hand dexterity, hand grip weakness, loss of fine motor functions of hands, and bowel/bladder involvement in advanced stage.<sup>6</sup>

Anterior cervical discectomy and fusion (ACDF) is gold standard procedure for almost all degenerative cervical pathologies involving one or two level.<sup>7</sup> ACDF attains fusion of two consecutive vertebrae and is highly effective and comparatively safe procedure with outstanding results.<sup>8</sup>

Standalone strut graft has high rate of complications such as graft subsidence, dislodgement, nonunion and donor site morbidities. Anterior cervical plating also has inherent drawback like plate loosening, screw pullout, breakage, trachea-esophageal irritation and fistula, increased operation time, and increased duration of hospital stay.<sup>9,10</sup>

Recently, standalone titanium/polyetheretherketone (PEEK) cages, also called as Zero-profile (Zero-P) cages, have been developed that have slots for fixing screws into adjacent vertebral bodies and space for filling autologous cancellous iliac crest bone graft. Due to low profile and above advantages, Zero-P cages are supposed to minimize drawbacks that are associated with anterior cervical plates as mentioned in above paragraph.

In our study, we evaluated two different fixation methods: (1) anterior cervical plate plus titanium cage filled with autologous cancellous iliac crest bone graft (ACG) versus (2) Zero-P titanium cages filled with ACG with respect to duration of surgery, length of hospitalization, rate of fusion, and postoperative complications recorded postoperatively at regular follow-up of 6 weeks, 3 months, 6 months, and 1 year.

# **Materials and Methods**

This was a comparative prospective observational study with a sample size of 30 patients. All patients were admitted under orthopaedics department at our institute with the complaints of radiculopathy and/or myelopathy and not responding to conservative trial of 6 weeks (in case if patient is having normal motor power). In case of motor deficit or myelopathy Nurick grade > or = grade III, patients were advised surgery immediately and admitted. The study was approved by the Institutional Ethical Committee. The present study was carried during the year October 2017 to October 2019. Sampling was done by using simple random sampling by lottery system for randomization of patients in two groups. Thirty patients with cervical compressive disease who require decompression and fits in inclusion criteria were divided in two groups.

**Group A**: Anterior cervical plate and titanium cage filled with ACG.

Group B: Zero-P titanium cage filled with ACG

#### Inclusion Criteria

- 1. Radiculopathy  $\pm$  axial neck pain.
- 2. Myelopathy  $\pm$  axial neck pain.
- 3. Single level involved.
- 4. Not responding to conservative trial of 6 weeks.

#### **Exclusion Criteria**

- 1. Malignancy, inflammatory joint disease, or psychiatric disorder.
- 2. Previous cervical spine surgery.
- 3. Traumatic cervical spine injuries.
- 4. Multiple levels involved.
- 5. Ossified posterior longitudinal ligament.
- 6. Patients who were lost to follow-up or died before the fracture union.
- 7. Patient who did not give consent for the procedure.

#### Methods

The patients having complaints of radiculopathy and/or myelopathy with or without axial neck pain were examined by senior orthopaedic spine surgeon of our institute. Data was collected using predesigned proforma and questionnaire. Appropriate investigations required were performed including anteroposterior and lateral radiographs of cervical spine and magnetic resonance imaging of cervical spine with screening of whole spine. The patients who had symptoms less than 6 weeks and with normal neurology were advised conservative trial with medicines, physiotherapy, and rest. Patients who did not respond to conservative trial or who had motor weakness and myelopathy Nurick grade 3 or more were advised surgery. A detailed informed consent was taken from all the patients enrolled in this study. The preanesthetic checkup and fitness for operative procedure were performed. As per protocol for degenerative cervical disc disease patients were evaluated by detailed history, clinical examination, Nurick grading for myelopathy, and neck disability index.



Fig. 1 Postoperative X-ray of one of the patients of group A.

#### **Postsurgery Care**

Two doses of inj. cefuroxime 1.5 g were given 12 hours apart. Immediate postoperative X-rays were taken as soon as patient was comfortable (**-Figs. 1** and **2**). Patient was discharged as soon as he was well and with minimal pain. Usual protocol is to discharge patient after drain removal and first check dress. Patient was asked for dressing removal on day 15. The patients were reviewed at 6 weeks, 3 months, 6 months, and 1 year. Philadelphia collar was continued till 6 weeks and after that isometric neck exercises were started.

Following comparison was done between group A and B:

- 1. Duration of surgery.
- 2. Duration of hospital stay.
- 3. Rate of fusion.
- 4. Demography.
- 5. Complications.

**Statistical Analysis Used**: Mann–Whitney U test was used for the duration of stay, and Student's *t*-test was used for the duration of surgery.

### Results

In our study, most cases were in the age group of fourth and fifth decade. In addition, 21 (70%) patients were males showing male predominance of cervical disc disease over females. Fifteen (50%) patients were farmers showing heavy work involved in field which might be the cause of increased prevalence of cervical degenerative disease in this population. C4–5 level was most commonly involved (10 patients [33.33%]) followed by C5-C6 level (9 patients [30%]) and C3-C4 level (6 patients [20%]. Eighteen patients (60%) had soft disc prolapse and remaining 12 (40%) patients had cervical canal stenosis secondary to disc osteophyte complex and flavum hypertrophy.

The mean duration of surgery in group A was  $141.3 \pm 12.9$  standard deviation (SD; minutes) and group B was  $111.3 \pm 16.0$  SD (minutes). The difference is statistically significant with *p*-value 0.000 (<0.05) (**~Table 1**).

The average duration of stay (days) in group A was  $4.40 \pm 0.242$  SD (days) and group B was  $2 \pm 0.845$  SD (days). This difference was also found to be statistically significant with *p*-value 0.000 (<0.05) (**-Table 2**).

Two out fifteen (13.33%) patients in group A and one out of 15 patients (6.66%) patient in group B had dysphagia. One patient each in both groups had developed hoarseness of voice after surgery. However, both cases got improved on their own by postoperative day 15. Both these cases were done at C6–7 level. Two (6.66%) patients in group A and one (3.33%) patient in group B had persistent donor site pain even after wound healing for a period of 6 weeks to 2 months. All these patients were thin built and with poor pain tolerance.

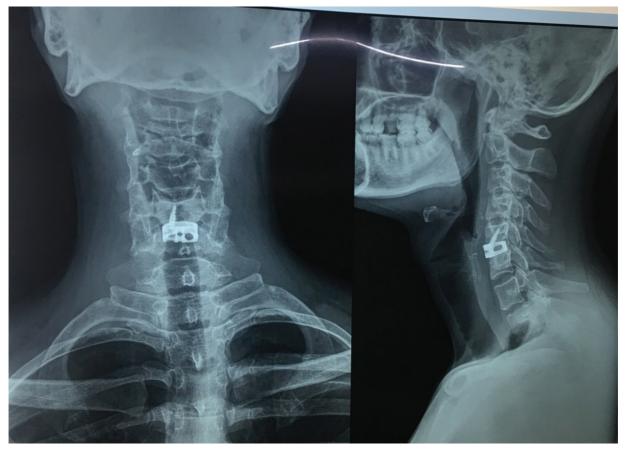


Fig. 2 Postoperative X-ray of one of the patients of group B.

	Table 1	Comparison of	duration of surge	ry (in minutes)	) between two groups
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Duration of surgery	Group A	Group B	t-Value	p-Value
	<i>n</i> = 15	<i>n</i> = 15		
Mean $\pm$ SD	141.3±12.9	111.3±16.0	5.66	0.000 <i>p</i> < 0.05 significant

Abbreviation: SD, standard deviation.

Test: Student's *t*-test (data follow normal distribution).

Table 2 Comparison of duration of stay (in days) between two groups

Duration of stay	Group A	Group B	Z-Value	p-Value	
	<i>n</i> = 15	<i>n</i> = 15			
Median	05	02	3.9196	0.000	
IQR (Q3-Q1)	04–05	01–03	p <	<i>p</i> < 0.05 significant	
$Mean\pmSD$	$4.40 \pm 1242$	$2.00\pm0.845$			

Abbreviations: IQR, interquartile range; SD, standard deviation. Test: Mann–Whitney U test (data do not follow normal distribution).

With respect to late complications, one patient each of both groups had cage subsidence seen on follow-up X-rays done at 6 weeks. However, both these patients fused nicely without any further symptoms. Two (13.33%) cases each of both groups had developed adjacent segment degeneration in follow-up X-ray done at 1 year interval. This was confirmed on follow-up magnetic resonance imaging scan. At 12 to 16 weeks, group A had 33.33% fusion, whereas group B had 26.66% fusion. At 16 to 20 weeks, group A had 46.66% of fusion, whereas group B had 40% of fusion. At 20 to 24 weeks of duration, group A had remaining 20% of fusion, whereas group B had 33.33% of fusion. Around 9% patients in both groups achieved fusion by 6 months.

## Discussion

ACDF is gold standard procedure for degenerative cervical pathologies, cervical trauma, infective spondylodiscitis and neoplastic lesion and provides remarkable results. The use of implant like anterior cervical plate along with titanium/PEEK cages filled with allograft/autograft enhances fusion of two adjacent vertebrae, maintains height, and provides stability. Anterior cervical plate has inherent drawbacks like plate loosening, screw pullout, trachea-esophageal irritation and resultant dysphagia and fistula, and increased operation time.<sup>9,10</sup>

Recently, Zero-P cages (titanium/PEEK) have been developed that have slots for fixing screws into adjacent vertebral bodies and space for filling ACG. Due to low profile and above advantages, Zero-P cages are supposed to minimize drawbacks associated with anterior cervical plates as mentioned in above paragraph.

We evaluated two different fixation methods in this study: (1) anterior cervical plate plus titanium cage filled with ACG versus (2) Zero-P titanium cages filled with ACG with respect to duration of surgery, length of hospitalization, rate of fusion and postoperative complications recorded postoperatively at regular follow-up of 6 weeks, 3 months, 6 months, and 1 year.

In this study, 10 (33.33%) patients had compression at C4– 5 level followed by C5–C6 (9 patients [30%]), C3–C4 level (6 patients [20%]) and C6–C7 level (5 patient [16.66%]). Islam et al<sup>6</sup> operated 16 patients of which 4 patients (25%) were at the level of C4–C5, 8 patients (50%) were at the level of C5–C6 level, 3 patients (18.75%) were at the level of C6–C7 level, and 1 patient was operated at the level of C3–C4. Thomé et al<sup>11</sup> operated 36 patients out of which 3 (8.33%) patients at C3–C4 level, 16 patients (44.44%) at C5–C6 level, 8 patients (22.22%) at C6–C7 level, and 4 patients (11.11%) at C4–C5 level.

In our study, 18 patients (60%) were diagnosed with cervical disc disease and 12 patients (40%) with cervical canal stenosis. Kanayama et al<sup>12</sup> had 24 cases in their study. Twelve patients (50%) had soft disc herniation and 11 patients (45.83%) had disc osteophytes and resultant stenosis. Kepler and Rawlins<sup>13</sup> had 37 patients. There were 30 patients (81%) who had radiculopathy due to disc prolapse.

The average duration of surgery in group A was  $141.3 \pm 12.9$  minutes and in group B the average duration of surgery was  $111.33 \pm 16.0$  minutes. Islam et al<sup>6</sup> et al observed the average duration of surgery for ACDF with plate and titanium cage was 150 minutes that is nearly same as group A in our study. Thomé et al<sup>11</sup> observed that titanium cage group had shorter duration of surgery, that is,  $129 \pm 29$  minutes and  $158 \pm 41$  minutes in iliac crest group.

The average duration of stay in group A was  $4.40 \pm 0.242$  days and in group B the average duration of surgery was  $2.00 \pm 0.845$  days. Islam et al<sup>6</sup> kept ACDF with plate and cage patient group in hospital for an average period of 3 days. Majd et al<sup>14</sup> postoperatively observed the patients for 1 to 8 days with average of 1.9 days. Thomé et al<sup>11</sup> postoperatively observed iliac crest graft group for  $6.4 \pm 3.8$  and  $4.8 \pm 2.0$  days in titanium cage group. The reference studies show plating with

titanium cage group had hospital stay comparable to our study. This is mainly because patients in group A had either more drain collection or more pain in immediate postoperative period that increases duration of stay.

At 12 to 16 weeks, group A had 33.33% fusion, whereas group B had 26.66% fusion. At 16 to 20 weeks, group A had 46.66% of fusion, whereas group B had 40% of fusion. At 20 to 24 weeks of duration, group A had remaining 20% of fusion, whereas group B had 33.33% of fusion. Around 99% patients in both groups achieved fusion by 6 months. However, this difference was statistically not significant. Islam et al<sup>6</sup> operated 16 patients in which average rate of fusion was 3.5 months and which ranged from 3 to 9 months. In Kanayama et al<sup>12</sup> study, 23 cases (96%) achieved a solid fusion, whereas the average time to fusion was 6.2 months. Majd et al<sup>14</sup> found 97% of patients achieved fusion in a follow-up of 6 months.

In our study, we found three patients (10%) from both groups suffered from dysphagia that resolved on its own within 2 days. Dysphagia was probably because of pressure effect over esophagus due to blades of retractor intraoperatively and not because of any damage/perforation. Islam et al<sup>6</sup> found two patients (12.50%) had mild and self-limiting type of dysphagia. Majd et al<sup>14</sup> found one patient was suffered from dysphagia immediately after surgery. Goz et al<sup>15</sup> observed that 0.33% of patient operated with synthetic cage suffered from dysphagia and 0.64% of patient operated with structural allograft suffered from dysphagia.

Two patients in group A and 1 patient in group B (10%) had persistent donor site pain even after wound healing for a period of 6 weeks to 2 months. All these patients were thin built and with poor pain tolerance. None of these patients had local site infection or hematoma. Silber et al<sup>16</sup> observed 35 patients (26.1%) suffered from pain at bone graft harvest site. Kepler and Rawlins<sup>13</sup> observed four patients (10.5%) had donor site pain for 6 weeks that was relieved at ~3 months. Low incidence of donor site pain in our patients might be because small incision was required to harvest cancellous bone graft in comparison to incision required to harvest tricortical iliac crest bone graft in reference studies.

In our study, two patients (6.66%) one each from group A and B suffered from hoarseness of voice. However, both cases improved on their own by postoperative day 15. Both these cases were done at C6–7 level and we believe the complication might have happened because of neuropraxia of right-sided recurrent laryngeal nerve.

Two patients (6.66%) in our study one each from group A and group B had cage subsidence seen on follow-up X-rays done at 6 weeks. Both patients were elderly and got excess end-plate removal during discectomy. We feel this should be the reason for titanium cage subsidence in our study. We advise to protect end-plates while doing discectomy in elderly population. However, both patients did well in follow-up. Thomé et al<sup>11</sup> reported that on radiological evaluation 8 (22.22%) patients suffered with graft subsidence in titanium group with no clinical symptoms.

In our study, no patient had any recurrence of symptoms, cage dislodgement, pseudoarthrosis, or required revision of surgery.

## Conclusion

The purpose of this study was to know if Zero-P cage alone can be used in ACDF surgery. We concluded that ACDF with standalone Zero-P cages are equally good when compared with anterior cervical plating and titanium cages. Duration of surgery and duration of stay were shorter in Zero-P cages group with respect to cervical plate group. We feel it is good from patient's point of view since it reduces overall stay and burden on healthcare. However, sample size was less in our study and we feel more studies will come in future with larger sample size and similar results.

Conflict of Interest None declared.

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