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Evaluation of outcome of zero-profile implant for anterior cervical discectomy and fusion in traumatic cervical sub-axial disc injury in Indian population: A prospective study

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Abstract
Objective: The zero-profile implant (Zero-P) is accepted for use in anterior cervical fusion for the treatment of degenerative cervical disease in last decade.However, evidence pertaining to its efficiency and safety in traumatic cervical injury is largely insufficient. The purpose of this study was to assess the overall outcome of Zero-Profile implant for ACDF in traumatic cervical sub-axial three columnar injury with disc prolapse.
Methods: 20 patients with post-traumatic sub-axial three columnar cervical injury with single level disc prolapse and subsequent neural compression were underwent ACDF with Zero-profile implant and followed up for a minimum of one year. Apart from per-operative parameters, Cobb angle, operative segmental angle, fusion rate and subsidence were assessed radiologically. Clinical outcomes were evaluated using the Japanese Orthopaedic Association (JOA) score and Odom's criteria.
Results: Fusion rate at the end of one year was 90% (19/20). Mean Cobb angles and operative segmental angles increased by 3.6 degrees and 5.5 degrees respectively, over the preoperative value. Cage subsidence occurred in 3 cases (15%). Mean pre-operative JOA score was 13.4, improved post-operatively to 15.2. According to Odom's criteria, 13 patients (65%) had belonged to Excellent and Good category, five patients (25%) in Fair category and two patients (10%) remained in Poor category.
Conclusion: Zero-profile implants are effective in treating three columnar post-traumatic sub axial cervical disc prolapse in performing ACDF as it is biomechanically stable, restores the radiological parameters and can produce functional improvement.

Keywords: Cervical trauma, cervical disc prolapse, zero-profile implant, zero-p

Introduction
Anterior cervical decompression and fusion (ACDF) is an effective method for the treatment of trauma to the mid and lower cervical spine because neurologic compressions often occur anteriorly. In addition, it is simple to perform, allows misalignment correction and can be done without significant blood loss [1, 2]. After the initial description by Smith & Robinson, various techniques have been implemented; from traditional iliac crest bone grafting to anterior plating to stand-alone cages [3, 4, 5]. Although anterior cervical plating with autogenous bone grafting has been the most accepted procedure till date, it has been associated with numerous complications including donor site morbidity, esophageal injury, screw pull-out, plate migration and adjacent level ossification [6, 7, 8].
The zero-profile interbody fusion device, Zero-P (Synthes GmbH, Oberdorf, Switzerland) was invented to reduce plate-related complications. It consists of an interbody spacer and locking screws that can be fixed in the intervertebral space. It has been shown to provide similar biomechanical stability to the use of a cage and an anterior plating system [9]. The same conclusion was drawn from a study involving patients with degenerative pathology, and the Zero-P has been used in ACDF for the treatment of degenerative cervical disease [10]. However, these previous studies did not provide sufficient evidence on the efficacy or safety of Zero-P in traumatic cervical disc injury.

There have been only a few preliminary studies on the outcomes of ACDF using Zero-P in sub axial cervical spine trauma [11, 12].

In the present study, we performed a prospective analysis regarding outcome of clinical and radiological parameters achieved with ACDF using Zero-P for traumatic cervical sub axial spinal injury.

Materials & Methods

Ethics statement, Patient anonymity and Informed Consent

This study was approved by the institutional review board of Our Hospital (CZ-2015-N016).All subjects provided written informed consent. Research was conducted in accordance with the research principles mentioned in the Declaration of Helsinki.

Patient Population

A prospective study was conducted in 20 patients who presented at our Institution from January 2017 to July 2019. The inclusion criteria were traumatic injuries of the middle and lower cervical spine involving three columns with disruption of posterior ligamentous complex (PLC), presence of unilateral or bilateral facet subluxation with kyphotic deformity and traumatic disc degeneration with anterior neural compression [Fig-1a and 1b].

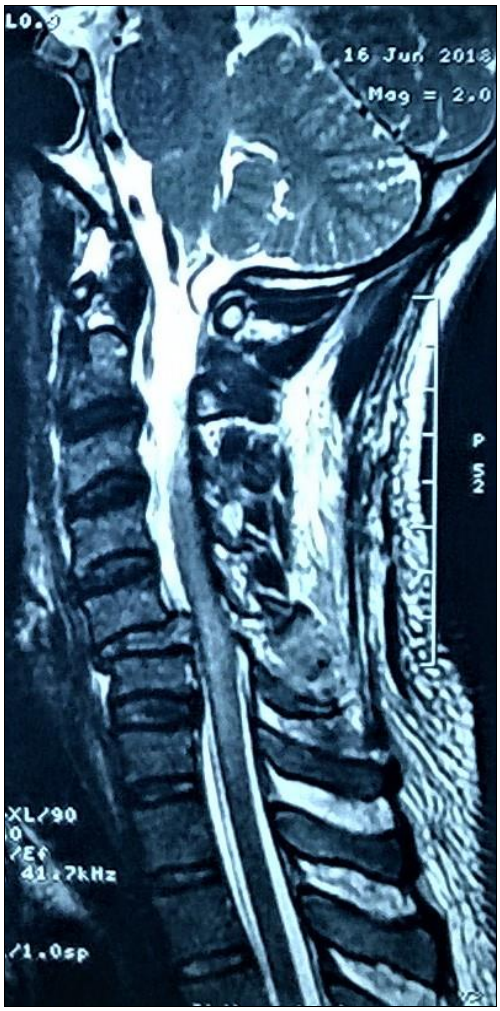


Fig 1a: [T2 weighted MRI sagittal image]

Traumatic posterior disc prolapse at C5/6 with presence of Hyper-intensity signal at cervical cord suggestive of cord oedema.

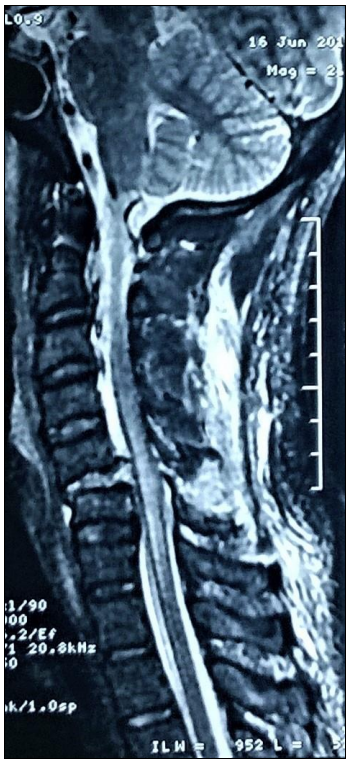


Fig 1b: [STIR sequence MRI sagittal image]

Traumatic posterior disc prolapse at C5/6 with presence of Hyper-intensity signal at cervical cord suggestive of cord oedema. Presence of Injury at supraspinous and Interspinous ligaments.

Presence of bony fracture, facet dislocation, kyphotic deformity requiring posterior stabilization and patients with history of prior surgery were excluded from this study. Clinico-radiological evaluation by Sub-axial Cervical Spine Injury Classification System (SLICS) was done in every patient [13]. All these cervical injuries were quite different in injury mechanism and fracture pattern, but they all needed an anterior cervical discectomy and fusion.

Plain radiographs, 1-mm thin-slice computed tomography scan (CT scan) of the injured cervical segment, and a cervical magnetic resonance imaging (MRI) were performed preoperatively.

Surgical techniques

For ACDF using Zero-P, the patient was placed in the supine position under general anaesthesia. Fluoroscopy was used to confirm the target level. A horizontal incision was made along the skin crease in the neck that correlated to the target cervical disc. After removal of the intervertebral disc with a careful endplate preparation, generous decompression of the bilateral neuroforamen was performed. A Kerrison punch and a high-speed electric drill were used to decompress the nerve roots by removing the osteophyte overgrowth on the uncovertebral joint and posterior lips of the vertebral body. Extensive saline irrigation was performed during drilling of the osteophytes and milling of the endplates.

After anterior decompression and reduction of the lesion if necessary to obtain a physiologic alignment, trial spacers were used to determine which implant shape would be used. The implant has different configurations: parallel-shaped, convex shaped, and lordotic-shaped end plates. After the trial spacers, stabilization was achieved with the application of a Zero-P implant and 4 Zero-P screws under intraoperative fluoroscopic control. After the release of a Casper distractor, a

manual pull out test was conducted to confirm the stability of the segments. All the cages were packed with locally harvested bone and osteophytes. Correct position of the cage was controlled by using an image intensifier in the lateral and anteroposterior views. The device should ideally be placed 2 mmbehind the anterior column in the lateral view and in the centre of the disc space in the anteroposterior view. When the Zero-P implant is completely inserted, its zeroprofile characteristic can be visualised.

After surgery, all patients were instructed to wear a Philadelphia neck brace for 6 weeks. After 6 weeks both passive and active neck mobilization were started under supervision. At discharge, patients with neurologic deficits were referred to departments of physical medicine for proper rehabilitation therapy.

Radiological evaluation

Apart from calculating operative time (OT) and intra-operative Blood loss (BL), Radiological images were assessed pre-operation and at follow- ups that occurred approximately 3, 6, and 12 months postoperativelyusing cervical X-rays and cervical computed tomography scans (CT scans).

The cervical Cobb angle was measured as the acute angle constructed by the lines running along each inferior vertebral endplate of the C2 and C7 vertebral bodies on a lateral X-ray. The operative segmental angle was measured as the acute angle constructed by the lines running along the superior and inferior vertebral endplates of the operated vertebral body. The difference between the pre-operative and 12-month postoperative follow-up angles for each parameter was designated as the delta (Δ) value [Fig. 2].

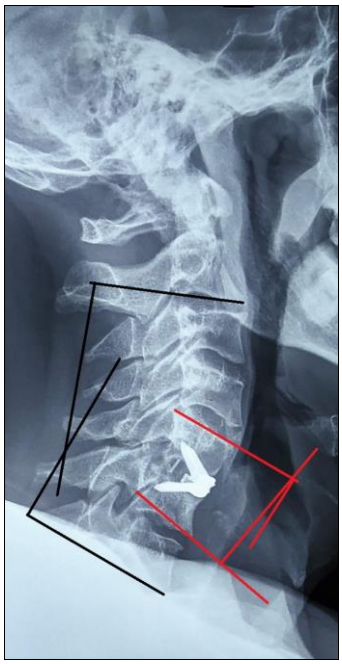


Fig 2:
Measurement of cervical sagittal alignment
Angle in Black line: Cervical Cobb's angle
Angle in Red line: Operative segmental angle

The evaluation of fusion was determined using dynamic cervical X-ray and CT sagittal reconstruction 12 months postoperatively. Fusion was defined: 1. Changes in the interspinousdistance of the fused segments should not be more than 2mm on lateral flexion-extension radiographs, 2. no radiolucent gap should be present between the cage and the endplate, and 3. Continuous bridging bony trabeculae should be present across the intervertebral space [14, 15].

Cage subsidence was defined as a decrease in interbody height >3 mm on a plain radiograph 12 months postoperatively. The difference in subsidence was based on the length between the centre of the upper and lower endplates in a lateral X-ray.

Screw loosening is defined by more than 1-mm radiolucent zone surrounding screw on the basis of the anteroposterior and lateral plain radiography [16].

Clinical Evaluation

The clinical outcomes were evaluated pre- and postoperatively and at the last follow-up using the Japanese Orthopaedic Association (JOA) score. The improvement rate of the Japanese Orthopaedic Association (JOA score) = ((scores after treatment - scores before treatment)/ (17 - scores before treatment)) * 100%. It could be classified into excellent (>75%), good (50%-75%), medium (25%-50%) and bad (<25%) [17]. The postoperative dysphagia rate was evaluated according to the criterion defined by Bazaz et al at one month and three months postoperatively [18]. The severity of dysphagia-related symptoms was graded as none, mild, moderate, and severe based on the patients' statements (Table 1). At the last follow-up, patients were assessed according to Odom's criteria, which ranged from ratings of excellent to poor [19].

Statistical Analysis

Patient characteristics and clinical outcomes were assessed using descriptive analyses, with the mean (standard deviation) and median (interquartile range) presented for quantitative variables and the frequency (percent) presented for qualitative variables. p-values are presented for all statistically significant variables. All statistical analyses were performed using the SPSS software package for Windows version 19.0 (IBM, Chicago, IL, USA). All tests were 2-sided, and p-values <0.05 were considered to indicate statistical significance.

Results

Assessment of the Demographic data [Table: 1] shows that among the 20 patients, the M:F distribution was 18:1. Mean age was 41 years (30-60 years). Maximum involved vertebral segment was C6/7 (no: 9) followed by C5/6 (no: 8), C4/5 (no: 2) and C3/4 (no: 1). Fall from height was the commonest mode of injury (70%) and the rest were due to road traffic accident. Unilateral and/or bilateral facet sub-laxation were present in 80% cases (16/20) and presence of diffuse hyper intensity signal (T2 / STIR sequence) in cervical cord was noted in 35% cases (7/20). The SLICS score was six points in seven patients (35%), with five points occurring most frequently (65%).

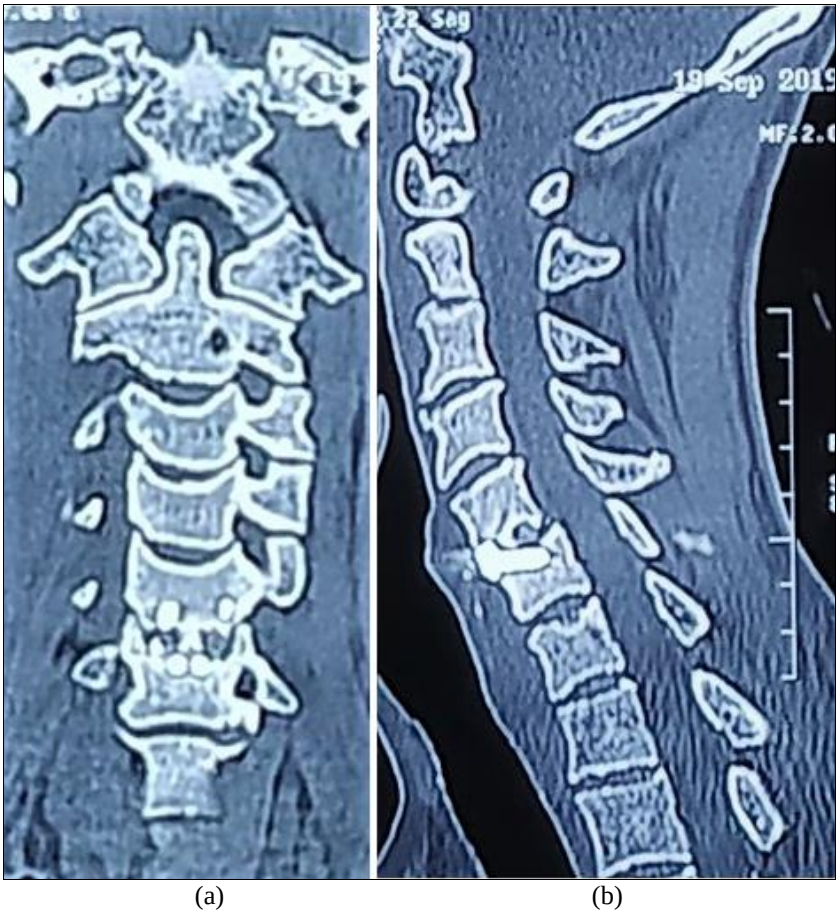
Table 1: Assessment of Demographic Data of the patients

No.	Sex/Age (years)	Level	Presence of PLC injury	Presence of Facet Subluxation	Presence of Cord signal change	SLIC Score
1	M/35	C5/6	P	P	P	5
2	M/52	C6/7	P	P	A	6
3	M/32	C5/6	P	P	P	6
4	F/35	C4/5	P	P	P	5
5	M/40	C6/7	P	P	A	5
6	M/45	C3/4	P	A	P	5
7	M/38	C6/7	P	P	A	6
8	M/32	C5/6	P	P	A	5
9	M/45	C6/7	P	A	P	6
10	M/52	C6/7	P	P	A	5
11	M/40	C6/7	P	P	P	6
12	M/42	C5/6	P	P	A	5
13	M/55	C6/7	P	P	A	5
14	M/30	C5/6	P	P	A	5
15	M/40	C6/7	P	P	A	5
16	M/60	C5/6	P	A	A	6
17	F/40	C4/5	P	P	A	5
18	M/42	C5/6	P	P	P	6
19	M/35	C6/7	P	P	A	5
20	M/30	C5/6	P	A	A	5

Regarding per-operative results, authors did not face any technical difficulty in implantation except in case of approaching C3/4 level in one case; which required a greater amount of soft tissue retraction. The average surgical time was 65 minutes (50-100 minutes) and the estimated average blood loss was 55 ml (40-90 ml). No patient experienced neurologic worsening after surgery.

All patients were followed up for a minimum of one year (mean 14 months; range 12-28 months). No patients were lost to follow-up during study.

Regarding the radiological outcome, the fusion rate at the end of one year was 90% (19/20) [Fig 3a and 3b]. The mean Cobb angles and operative segmental angles increased by 3.6 degreesand 5.5 degrees respectively, over the preoperative value [Table: 2]. Cage subsidence occurred in 3 cases (15%). No incidence of screw loosening and other instrumentation related complications. No incidence of surgical site infection, post-operative haematoma and re-operation.



(a) (b)

Fig 3: [CT coronal (a) and sagittal (b) images]

Signs of additional new bone formation with bony bridging across the disc space indication of fusion.

Table 2: Radiological assessment

No.	C2-7 Cobb Angle (Deg)			Operative Segmental Angle (SA)(Deg)		
	Pre-op	Post-op	(Δ) Cobb	Pre-op	Post-op	(Δ) SA
1	16	22	6	3 (K)	4 (L)	7
2	18	24	6	2 (K)	6 (L)	8
3	20	23	3	3(K)	4(L)	7
4	16	20	4	2(K)	5(L)	7
5	17	20	3	2(K)	3(L)	5
6	18	20	2	2(K)	2(L)	4
7	20	24	4	2(K)	5(L)	7
8	22	24	2	3(K)	4(L)	7
9	16	20	4	2(K)	2(L)	4
10	18	22	4	2(K)	3(L)	5
11	20	24	4	3(K)	2(L)	5
12	18	22	4	4(K)	2(L)	6
13	17	20	3	3(K)	1(L)	4
14	22	26	4	2(K)	3(L)	5
15	20	24	4	3(K)	3(L)	6
16	20	23	3	1(K)	4(L)	5
17	17	20	3	2(K)	1(L)	3
18	18	22	4	2(K)	4(L)	6
19	22	25	3	3(K)	2(L)	5
20	22	24	2	2(K)	2(L)	4

K: Kyphosis Angle; L: Lordosis Angle

All patients exhibited an improvement in functional outcome till the last follow-up. The mean pre-operative JOA score was 13.4, it improved post-operatively as mean JOA score was 15.2 [Table: 3].

Table 3: Assessment of Japanese Orthopaedic Association (JOA) Score

No	Pre-op JOA Score	Post-op JOA Score	Improvement Ratio (%)
1	14	15	33.33
2	12	14	40
3	11	12	16.66
4	12	14	40
5	14	16	66.66
6	12	14	40
7	14	17	100
8	15	17	100
9	11	12	16.66
10	12	15	60
11	10	12	28.57
12	14	16	66.66
13	14	17	100
14	15	16	50
15	16	17	100
16	15	17	100
17	14	16	66.66
18	12	14	40
19	16	17	100
20	15	16	50

Improvement Ratio

- **Excellent:** 6/17 (35.29%)
- **Good:** 6/17 (35.29%)
- **Medium:** 6/17 (35.29%)
- **Bad:** 2/17 (11.76%)

According to Odom's criteria, 13 patients (65%) had belonged to Excellent and Good category. Five patients (25%) in Fair category and two patients (10%) remained in Poor category ant the end of one year [Table: 4].

Table 4: Demography on Odom's Criteria

Odom's Criteria	
Clinical Outcome	**Number of Patients**
Excellent	6 (30%)
Good	7 (35%)
Fair	5 (25%)
Poor	2 (10%)

Regarding complications like dysphonia and hoarseness of voice, two patients experienced it for a transient period of timeafter which it improved shortly with steam inhalation [Table: 6]. At the end of post-operative one month, 5 patients had complained about dysphagia of mild to moderate degree. The dysphagia improved in the next two months when only two patients remained with a mild degree of dysphagia [Table: 5].

Table 5: Demography on Dysphagia Grading system (Bazaz et al [17])

Dysphagia Severity	Post-operative One month	Post-operative Three months
None	15	18
Mild	3	2
Moderate	2	0
Severe	0	0

Table 6: Complications

Complications		No. of Patients
Dysphagia	Early (up to 4 weeks)	5 (25%)
	Late (up to 12 weeks)	2 (10%)
Hoarseness	Transient	2 (10%)
	Permanent	Nil
Re-operation	Surgical site Infection	Nil
	Instrumental failure	
	Post-operative Haematoma	
CSF Leakage	Major	2 (10%)
	Minor	

Discussion

Indications for surgery in traumatic cervical spine injury namely, for the prevention of additional functional loss, for

the maintenance of neurological function, and for the restoration of spinal stability with bony union have already been established [20, 21]. ACDF with or without posterior instrumentation has become the most conventional surgery for traumatic cervical injury till date. The advantage of the cage-plate system in ACDF is that it requires only minimal external bracing and the return to normal activities is much earlier than with those who undergo cervicalfusion surgery without plating. Additional theoreticalbenefits, such as initial stability, improved bony fusion, prevention of bone graft collapse, or extrusion and maintenance of sagittal alignment have also been demonstrated in literature for decades. However, plate-related complications, such as oesophagus injury, postoperative dysphagia and dysphonia have always been a concern [22, 23].

Zero-P implants feature a design that fixes the existing stand-alone cage onto the vertebral body with four screws, thereby imparting anterior stand-alone stabilization and reduces the plate-related complications. Biomechanical stability of this device has been proven to create equivalent stability to anterior plating while limiting soft tissue disruption and irritation [9]. Efficacy of the Zero-P implant in terms of clinical (low rates of neck disability, post-operative dysphagia) and radiological (fusion time, restoration and maintenance of cervical lordosis) parameters have also seen to be comparable those with a plate cage system [24, 25]. But all of these studies have assessed the postoperative outcomes of ACDF using Zero- P in degenerative cervical spondylosis [10, 24, 25, 26, 27]. Based on these previous studies, we used Zero-P as an anchored inter-disc spacer for ACDF in selected patients with traumatic cervical three columnar flexion distraction injurywith traumatic posterior disc prolapse who had no bony fracture, no severe segmental instability, and no kyphotic deformity requiring posterior instrumentation.

A major concern of ACDF using Zero-P in traumatic injury is the risk of cage subsidence, pseudo-arthrosis, and sagittal malalignment. In our series, we objectively focused on objectively comparing these values with the available literature.This stand-alone cage with four angle controlled screws provides adequate immediate stability through the cervical motion segment and in the long run bony fusion across the PEEK cage stabilizes the segment. In this study, we had achieved a fusion rate of 90% at the end of one year, which is comparable with the existing literatures on degenerative and traumatic C-spine [10, 11, 12, 24, 25, 26, 27]. Good fusion across the motion segment depends upon appropriate preparation of endplates and bone grafting around and inside the spacer [28]. Incidence of cage subsidence (15%) in our study was also comparable with the existing literature on Zero-P use in traumatic and degenerative C-spine. The possible explanations were as follows: elastic modulus of PEEK cage was equivalent to the normal human cortical bone, and superior and inferior sections of the self-locking anchoring screws contributed to the stability. Therefore, both the techniques could reduce the risks of displacement and subsidence and promote the bony fusion; the surgeons had excellent surgical techniques in preserving the bony endplate, selecting the appropriate size of cage, and avoiding overdistraction. In addition, sagittal alignment, including the Cobbangle and the segmental angle, werealso well maintained postoperatively. These observations were similar to the existing literature on stand-alone cages in treating traumatic C-spine [11, 12, 24].

Chronic dysphagia following ACDF will develop due to post-operative soft tissue swelling, hematoma at the operative site, esophageal injury, and adhesion formation around implanted cervical plates. It has a wide variability (3% - 21%) and is supposed to be related with the thickness of the implant at the fusion level [29, 30]. The Zero-P device with a smaller volume completely got contained inside the intervertebral disc space and exhibited its zero-profile property. It requires a smaller incision and less operating time than plating, thereby allowing more limited resection and avoiding mechanical stimulus to the surrounding structures which does not result in adhesion formation. The incidence of chronic dysphagia in this study was quite less than the existing literature [10, 11, 12, 24, 25, 26, 27, 29 30]. We applied aerosol inhalation (Dexamethasone 5mg + Chymotrypsin) and humidifier thrice daily to the five patients with mild to moderate dysphagia. At one month, three of them got completely cured. Less retraction of the prevertebral soft tissue also avoids stretching of recurrent laryngeal nerve, thereby causing less incidence of hoarseness with Zero-P [30]. This finding corroborates with the existing literature. No incidence of major CSF leak. Two cases with minor CSF leak stopped eventually with gel-foam and methylcellulose patty.

Though in this study, the incidence of adjacent segment degeneration (ASD) and ossification have not been considered, its incidence has been documented much less in using Zero-p. This Zero-P spacer has been proven to convey less stress to the adjacent levels and they remain contained far away from the adjacent disc space (>5 mm). Both of these factors contribute in avoiding ASD and ossification [8, 31].

Clinical outcomes such as neck and radicular pain, as well as other neurologic deficits, were alleviated 12 months postoperatively, when compared to the patients' preoperative symptoms. The increase in JOA scores and the proportion of grades combining "excellent" and "good" (65%) using Odom's criteria were comparable with the existing literatures [11, 12].

However, this study has few limitations, such as A) the number of patients with traumatic cervical injury were quite small (n=20), B) follow-up period was quite short, C) Biomechanical testing in the sitting of traumatic C-spine was lacking, D) the inclusion criteria was very subjectiveand finally E) control population in terms of conservative treatment or cervical plating has not been evaluated.

Conclusion

The overall results in performing ACDF with Zero-P implant has produced satisfactory clinical and radiological outcome in a short span of time. Though this study has certain limitations, but we believe that in the scenario of scanty scientific literature with this implant in trauma, multicentric trials with a larger patient population and with longer follow-ups can be started.

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Nil.

Conflicts of interest

No potential conflict of interest relevant to this article was reported.

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