



IMAGE ANALYSIS BETWEEN ZERO PROFILE CAGE AND TRADITIONAL PLATE AND CAGE IN ANTERIOR CERVICAL DISCECTOMY AND FUSION (ACDF)

Syed Saddam Hussain¹, Liu Yong Qiu^{1*}, Yin Jian¹, Asfandyar Khan² and Muhammad Mazhar³

¹Department of Spine Surgery, The First Affiliated Hospital of University of South China, Hengyang (421001), Hunan province, China.

²Department of Cardio-Thoracic Surgery, The First Affiliated Hospital of University of South China, Hengyang (421001), Hunan province, China.

³International College, University of South China, Hengyang (421001), Hunan province, China.

ABSTRACT

Cervical spine degenerative disorders have been successfully treated by anterior cervical discectomy and fusion (ACDF). ACDF is a most effective surgical option and a standard technique to treat cervical spondylosis. After ACDF many complications may develop; one notable is cage subsidence. The cage subsidence may be a contributing factor to develop kyphosis and restenosis. Despite all these facts, the detailed research comparing zero-profile cage (Zero-p) and traditional plate and cage (TPC) in terms was cage subsidence has been lacking. This study was a Control group study with six months follow-up time at the first affiliated Hospital of University of South China. The objective of the study was to compare image analysis between zero profile cage and traditional plate and cage in ACDF. Total of forty (40) patients were included and divided in two groups. The patients in group A (n=22) were treated with zero-p while the patients in group B (n=18) with TPC by the same level of competent surgeons. Patients with verified nerve root or spinal cord compression accompanied with classical signs or symptoms from C3-C7, conservative and formal treatment for above six months before the surgery were included in this study. This study was made by measuring and analyzing mean disc height (MDH), cage subsidence, Fused segment height (FSH), Cervical Cobb's angle (C2-C7), Fused segment Cobb's angle (FSC) and postoperative fusion. This study's findings point to zero-p and TPC having no statistically significant differences in image analysis but clinically meaningful patients outcomes and improvement after a six-months follow-up.

Keywords: cage subsidence, anterior cervical discectomy and fusion, over-distraction, multiple segments, zero-profile cages, traditional plate and cage.

INTRODUCTION

Cervical spondylosis is a frequently occurring and common disease characterized by cervical disc degeneration over the past decades [1]. It has been considered that ACDF was condition's golden standard treatment procedure [2]. This well-established surgery decompresses the nerve roots, and the spinal cord restores lordosis and enhances the spinal segment's stability by fusion[3]. While ACDF has profound applications, unfortunately, more problems are attributed to this surgery because of its follow-up time extension and constant acceleration in operation cases[4-5]. Several clinical research evidence indicates how ACDF potentially intensify adjacent segment degeneration (ASD) incidences, necessitating additional and long-term surgical interventions [6-9]. Moreover, additional postoperative issues, including pseudarthrosis at the operative level having persistent pain, should be considered [10-13]. Likewise, interbody fusion via unconnected cages lacking anterior cervical plating minimize complications and dysphagia with similar clinical and radiological outcomes in single-level fusions [14-17]. Nevertheless, no substantial evidence has established the efficacy and safety of zero profile cages used for ACDF procedures with radiculopathy and myelopathy symptoms [18-19]. Therefore, this study retrospectively explores the image analysis of zero-p and TPC in ACDF with symptoms of radiculopathy and myelopathy, with at least a follow-up period of six months. The findings will then analyze the risk factors and complications associated with the subsidence.

MATERIALS AND METHODS

Study design:

This study followed a retrospective single-centre study and analysis design, including forty patients who undertook single-level ACDF via the Zero-P and TPC with six months of follow-up performed between February 2017 and November 2021.

Exclusion and inclusion criteria:

The participants were included following criteria including (a) verified nerve root or spinal cord compression from image logical analysis, accompanied with classical signs or symptoms; (b) the intervertebral segment of the disc suffering from a C3-C7; (c) have undergone conservative and formal treatment for above six months before the surgery; (d) the patient had complete clinical data with ≥ 6 months post-operation follow-up period; (e) submitted informed consent as hospital's Ethics Board approved the testing and treatment program. And exclusion criteria were including (a)Surgery at the C2-3 disc levels; (b)Surgery at C7-T1 disc levels; (C)Severe cervical instability (d)Developmental stenosis; (e)The ossification of the posterior longitudinal ligament; (f)Previous medical records of cervical surgery, trauma, metabolic diseases, infection, or tumor; (g)Follow-up less than 12 months.

Statistical analysis:

All the statistical analysis were performed using the IBM SPSS for Windows version. 16.0. The basic information was presented using the mean, standard deviation (continuous variables including age, gender,

local segmental angles), and percentages (categorical variables including subsidence levels and fusion rates). Paired t-tests were conducted for comparing the continuous variables after and before the ACDF procedure. In contrast, the independent sample t-tests were performed for comparing continuous variables to determine those without or with subsidence as expected.

Measurement methods:

This study was made by measuring disc height(mDH) as mean of anterior disc height(ADH), middle disc height(MDH) and posterior disc height(PDH) from the CT-scan preoperative and postoperative(Fig.1) and the subsidence of the cage was measured from mean disc height reduction after three months and six months from post-operative one month postoperatively(Fig.1). Fused segment height (FSH)measured as mean of anterior segment height(ASH), middle segment height(MSH) and posterior segment height(PSH) from the CT-scan(Fig 2). Cervical Cobb’s angle (C2-C7) measured from the lower endplate of C2 vertebra to C7 lower endplate’s vertebra and fused segment Cobb’s angle (FSC) from the upper endplate of fused segment to the lower endplate of the segment as shown in the (x-ray Fig 3). The postoperative fusion was observed by intragraft bone bridging from the use of CT-scan(Fig 4).

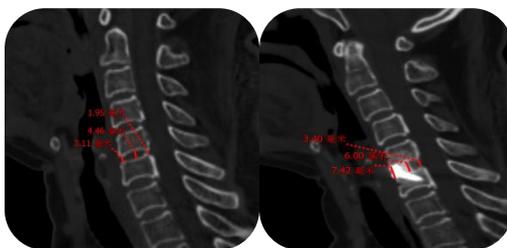


Figure 1: Demonstrated pre and postoperative (mDH)

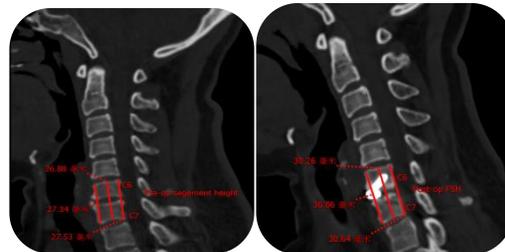


Figure 2: Demonstrate fused segment height measurement

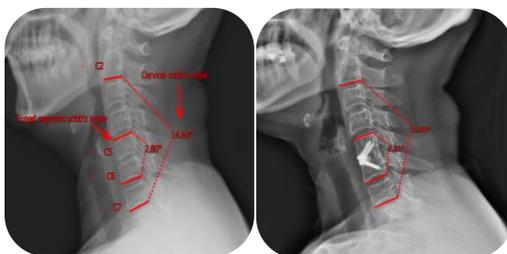


Figure 3: Demonstrated Cobb’s angle & fused segment angle

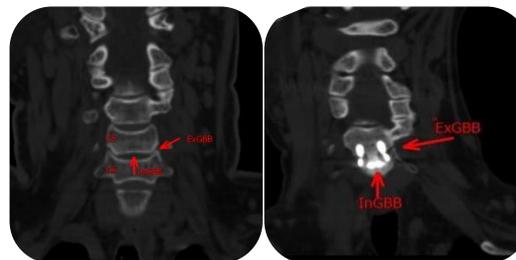


Figure 4: Demonstrated the fusion rates

Clinical outcomes:

The Japanese Orthopedic Association (JOA) and Neck Disability Index (NDI) scoring system were used to evaluate the functionality and neck disability preoperatively and postoperatively.

RESULTS AND DISCUSSION

Forty patients received zero-p and TPC in ACDF from February 2017 and November 2021, with follow-ups for all the patients going up to six months. Most of the patients were female (n=22) and rest were males (n=18). The mean age for the subjects included was 54.82 years (t= - 0.88 & p= 0.38). Out of forty patients, only four were active smokers postoperatively. 18 patients were treated with TPC and 22 patients were treated with Zero-p. Number of the segments in single level repeated in both groups C3-C4 (n= 8), C4-C5 (n=16), C5-C6 (n=25), C6-C7 (n=9), and number of segments in two levels were C3-C4, C4-C5 (n= 3), C4-C5, C5-C6 (n= 10), C5-C6, C6-C7 (n= 5), C3-C4, C6-C7 (n= 1) Segments were treated most commonly via this surgery were C5-C6 (n=25) in one level and C4-C5, C5-C6 in two levels.

Successful completion for operations was observed for all patients without any complications or incidences of cerebrospinal fluid leakage, hoarseness, or oesophageal fistulae in all representative cases for the zero-p and TPC. During the last follow-up, the cervical alignment, intervertebral height, and segmental angle of the two groups demonstrated improvements, unlike in the preoperative phase, as the pre-and postoperative findings were significant. Clinical symptoms and outcomes were improved significantly among all patients after the treatment and procedures, shown in table 1.

Variables	Zero-Profile Cage	Traditional Plate & Cage	p
JOA Scores			
Preop	10.5+_0.99	11.0+_0.91	0.440
Postop 1 M	15.22+_0.76	15.45+_0.81	0.551
Final FU	16.21+_0.54	16.41+_0.59	0.323
NDI scores			
Preop	39.13+_6.88	39.13+_7.21	0.080
Postop 1 M	18.13+_6.91	19.16+_6.18	0.301
Final FU	9.13+_5.46	9.01+_3.55	0.523

Table 1: Clinical outcomes pre-operative and postoperative in zero-p and TPC groups

Variables	Zero-Profile Cage	Traditional Cage	Plate & t	p
Patients (n)	22	18		
Gender (n)				
Male (n)	9	10		
Female (n)	13	8		0.36
Age (yr.)	54.82± 7.80	57.17± 8.95	-0.88	0.38
Diabetes Mellitus	3	2		
Smokers	2	2		
Diagnosis (n)				
Radiculopathy	7	5		
Myelopathy	6	7		
Combined Symptoms	9	6		
Number of Operated Levels	31	27		
One-level	13	9		0.57
Two-level	9	9		
Operation Time (mins)	140.64±41.10	123.89±25.81	1.5	0.14
Estimated Blood (mls)	91.36±53.30	92.78±80.86	-0.07	0.94
Hospital Stay (days)	11.63±2.75	11.27±3.53	0.36	0.72
Follow-up period (months)	6	6		

Table 2: Summary of preoperative and postoperatively.

*Statistically significant difference ($P < 0.05$).

Variable	Patients (n=22) Zero - P Cage (31)	Patients (n=18) TPC (27)	t	p
Cervical cobb's angle CA (C2-C7)				
PRE-OP	16.84±7.21	17.52±7.33	-0.29	0.77
POST OP (3 M)	14.47±7.72	16.63± 9.43	-0.79	0.43
FINAL FU (6 M)	14.42± 8.19	17.46± 9.06	-1.11	0.27
Fused segment cobb's angle (Cobb's - S)				
PRE-OP	4.45 ±2.79	4.02± 2.26	0.64	0.52
POST OP (1 M)	6.25± 3.26	4.41± 2.66	2.34	0.02
POST OP (3 M)	5.53 ±3.13	3.67 ±2.05	2.63	0.01
FINAL FU (6 M)	5.21 ±3.66	3.92± 1.56	1.69	0.1
ΔCOBB'S - S (3M)	0.72±3.71	0.73±3.58	-0.008	0.99
ΔCOBB'S - S (6M)	-1.045±4.71	-0.48±3.20	0.53	0.6
mDH (mm)				
PRE-OP	3.97±0.84	3.85 ±0.97	0.5	0.62
POST OP (1 M)	8.16 ±0.81	8.31 ±0.62	-0.75	0.46
POST OP (3 M)	6.45 ±0.80	6.54 ±0.83	-0.38	0.71
FINAL FU (6 M)	6.02±0 .61	6.30±0 .84	-1.48	0.14
FSH (mm)				
PRE-OP	28.38 ±2.65	28.75 ±2.42	-0.55	0.58
POST OP (3 M)	30.96± 2.66	29.99± 2.26	1.47	0.15
FINAL FU (6 M)	30.18 ±2.95	29.23± 2.47	1.31	0.2
Fusion Rate (%)				
POST OP (3 M)	80.65 (25/31)	81.48 (22/27)		0.94
FINAL FU (6 M)	96.77 (30/31)	92.59 (25/27)		0.59
Subsidence (%)				
> 2mm	POST OP (3 M)	29.03 (9/31)	25.92 (7/27)	0.41
	FINAL FU (6 M)	51.61 (16/31)	40.74 (11/27)	0.88

Table 3: Comparisons of Patient's image analysis in the zero-p and TPC.

*Statistically significant difference (P < 0.05).

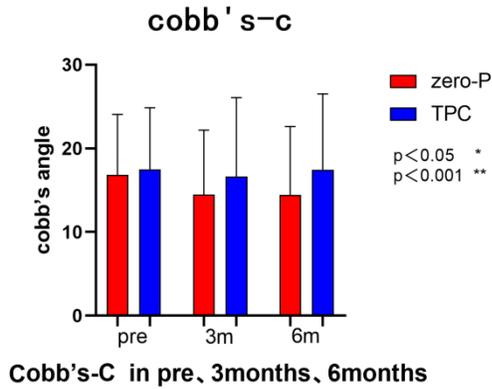


Figure 5

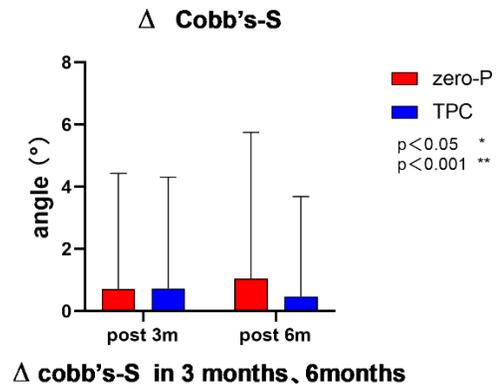


Figure 6

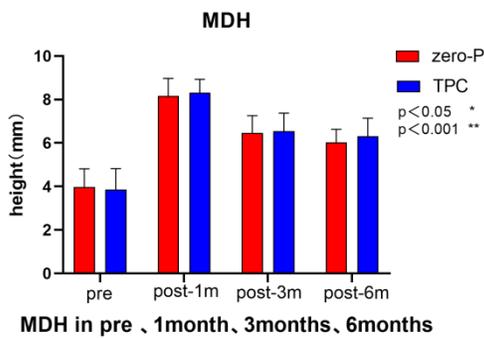


Figure 7

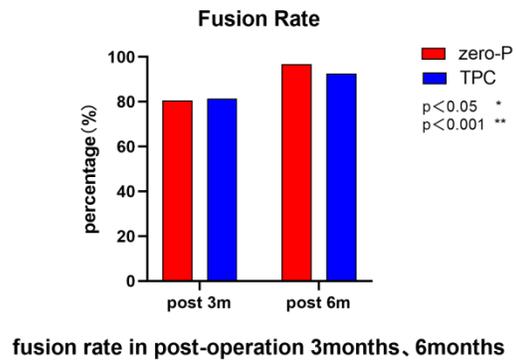
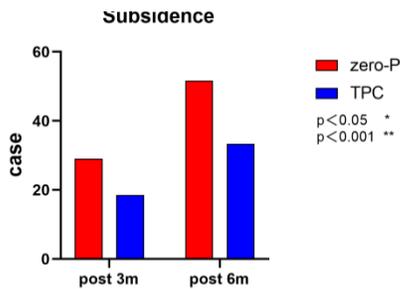


Figure 8



Subsidence rate in post-operation 3months, 6months

Figure 9

In Table. 3 we had the 22 patients of Zero-P with 31 segments and 18 patients of TPC with 27 segments. During the last follow-up, the cervical alignment, intervertebral height, and segmental angle of the two groups demonstrated improvements, unlike in the preoperative phase. The mDH and FSH values after surgery for both groups increased significantly ($P < 0.01$), with no significant differences between the two groups at each follow-up time point, indicating the restoration of disc height ($P > 0.05$). At the final follow-up, reductions in cervical Cobb angle, mDH, and FSH value were observed compared with the postoperative values for both groups.

Cervical Cobb's Angle:

Cervical Cobb's Angle (CA) pre-operation in Zero-P and TPC was 16.84 ± 7.21 and 17.52 ± 7.33 respectively. Cervical Cobb's Angle (CA) postoperative in Zero-P and TPC was 14.47 ± 7.72 and 16.63 ± 9.43 respectively and there is no significant difference between before and after the surgery ($p > 0.05$). Refer to fig.5.

Fused Segment Cobb's Angle:

Fused Segment Cobb's Angle (C-S) pre-operation in Zero-P and TPC was 4.45 ± 2.79 and 4.02 ± 2.26 respectively. Fused Segment Cobb's Angle (C-S) 1 month postoperative in Zero-P and TPC was 6.25 ± 3.26 and 4.41 ± 2.66 respectively. Fused Segment Cobb's Angle (C-S) 3 months postoperative in Zero-P and TPC was 5.53 ± 3.13 and 3.67 ± 2.05 respectively. Fused Segment Cobb's Angle (C-S) 6 months postoperative in Zero-P and TPC was 5.21 ± 3.66 and 3.92 ± 1.56 respectively and there is a significant difference between before and after the surgery ($p < 0.05$). Refer fig.6. Δ Cobb's means the changes in the Cobb's S angle after 1 month of surgery. Fused Segment Cobb's Angle (C-S) changed after 3 months is 0.72 ± 3.71 and 0.73 ± 3.58 and 6 months in both groups is -1.045 ± 4.71 and -0.48 ± 3.20 for Zero-P cage and TCP respectively. There is no significant difference between improvements after surgery ($p > 0.05$).

Mean disc height:

We observed while analyzing mean disc height (mDH) during the preoperative phases the Zero-P and TPC values were to be found 3.97 ± 0.84 and 3.85 ± 0.97 , after surgery of 1 month the values were 8.16 ± 0.81 and 8.31 ± 0.62 , after 3 months 6.45 ± 0.80 and 6.54 ± 0.83 and after 6 months were found to be 6.02 ± 0.61 and 6.30 ± 0.84 respectively. There is no significant difference between the two groups after the surgery ($p > 0.05$) Refer fig.7.

Fused segment height:

During our study Fused segment height (FSH) values found in both groups before the surgery were 28.38 ± 2.65 and 28.75 ± 2.42 , after 3 month of the surgery were 30.96 ± 2.66 and 29.99 ± 2.26 and finally were to be found 30.18 ± 2.95 and 29.23 ± 2.47 after 6 months of the surgery respectively. Hence, no significant difference was observed in both the groups ($p > 0.05$).

Fusion rate:

Fusion rate after 3 months of the operation time the rate recorded in Zero-P cage and TPC was 80.65% and 81.48% respectively in both the groups. However, it elevated to 96.77% and 92.59% respectively in both groups after 6 months of the surgery. There is no significance difference between the two groups ($p > 0.05$). Refer fig.8.

Subsidence rates:

Subsidence rates observed after 3 months of postoperative Zero-P cage and TCP were 29.03% and 25.92% respectively. Finally after 6 months of the surgery the rates recorded were 51.61% and 40.74% respectively. There is no significant difference in both the groups ($p > 0.05$). Refer to fig.9.

Arguments:

The Zero-P is the easiest method, with the mean operation time and blood loss being previously shown lowered in the TPC surgeries. In the previous studies it was reported to have a significant reduction in intraoperative blood loss[20]. Likewise, they showed a substantial decline in operating time for patients with the Zero-P device since a few steps were necessary for its insertion, placement, and fixation, as presented by [21]. During the research, the patients demonstrated the lowest operation time period and blood loss, resulting in no statistically significant differences. However, the Zero-P system insertion process makes it challenging to reach the optimal Cobb's angle in the C3/4 and C6/7, especially for patients having higher sternum and short necks. The decreasing operation period and intraoperative blood loss reduce the surgery-related complications and risk. Such factors contribute to post-operation patient recovery, allowing better outcomes and influencing hospitalization. Patients with cervical degenerative conditions most commonly undergo ACDF[22]. Initially, this operative procedure involved autologous iliac crest bone grafts usage but was later linked with substantial donor site morbidities [23-24]. Previous studies have established the safety and efficacy of single-level ACDF within locking stand-alone cages. The stand-alone cage construct usage reduces plate related complications, including screw loosening, dysphagia, foreign body sensation, or pull-out[25]. Cage-only constructs in a single-level ACDF attained the same radiological parameters and functional outcomes, including fusion rates, segmental Cobb's angle, and cervical lordosis, compared against plate constructs with cages[26]. The current study found that patients undergoing ACDF with zero-p and TPC significantly improved the InGBB scores. The average recovery period was six months, with the patients showing persisting improvements during the successive follow-ups since the first surgery. It was reported to have no significant differences in the radiological ASD rates on the stand-alone PEEK cage constructs for ACDF without a plate in their investigations[27-28], and no revision procedures were necessary for addressing any complications arising [29-30]. Further studies added that some of the reported ASD risk factors include ASD presence before the process, increased disc space distraction, and excess adjacent level motion, making the data suggestive of a clinically acceptable low postoperative dysphagia incidence[31]. Again, this study revealed no significant difference in the subsidence rate for the zero-p and TPC, occurring after follow-ups running for six months while remaining stable throughout the follow-ups. Previous literature has shown a substantial variation in the ACDF subsidence rate, where [32] and [33] performed different prospective studies and after the 24 months follow up found a 66.6% subsidence rate in where patients received single-level zero profile ACDF cage construct during the surgery. In retrospective studies using cage only constructs for 2-level ACDF, [34] reported a subsidence rate of 31.8%, and [35] found 36.8%. [36] in the single-level ACDF study, found a lower subsidence rate concerning the stand-alone PEEK cages use, which agrees to the considerable range in mean incidences reported [37]. The finding concurs with what [38] said earlier: intervertebral cage subsidence potentially induces various complications, such as loss of height of intervertebral disc height, segmental spinal instability, and intervertebral foramen loss. In their studies, reported that endplate preparation minimizes vertebral strength and stiffness, confirming the significance of preserving more cortical bone endplates for

reducing the intervertebral cage collapse risks[39-42]. Different procedural factors impact cage subsidence incidence during ACDF, as revealed higher cage subsidence in the C6–7 fusion level than the remaining fusion levels during the surgery[43]. Records show a correlation between subsidence and the greater distance between the cage and the upper vertebra's anterior and some smaller cage contact surface ratio[44]. Findings identified a correlation between more enormous intraoperative distractions and smaller anteroposterior diameter cages use with higher subsidence incidences [45]. This study did not reveal the potential impacts of age, fusion level, and gender with InGBB and ExGBB values. The patients exhibiting cage subsidence demonstrated identical scores compared to those without subsidence. The outcomes suggest that subsidence does not influence clinical outcomes; however, it may result in narrowing the intervertebral foramen and, ultimately, the exiting nerve roots compression [46-47]. The study produced a 100% fusion rate after follow up for 12 months, a finding that consents to the documented literature showing acceptable 2-level ACDF fusion rates [48-49]. A similar stance in the LSA lordotic change post-surgery was followed and recorded, resulting in kyphotic during the final follow-up period [50]. Some studies stated a 9.7° segmental lordosis loss from Cobb's angle within the six-month follow-up using standalone single-level cage surgery [51]. In contrast, reported for ACDF with 2-level cage-only a kyphotic LSA and C2–7 angle changes after 12- and 24-months follow-up respectively within the locally fused segments caused by cage subsidence, disc degeneration plus disc height loss, and adjacent segmental kyphosis [52-53]. The study found no cage-associated complications since using the zero-p maintains the sagittal spinal balance while preserving the cervical foramina height. Similarly, this study found a more pronounced fusion segment and cervical lordosis Cobb angle between the zero-p and TPC group. Δ Cobb's - S $> 0^\circ$ which means Cobb's - S has decreased after one month postoperative. We have found that Δ Cobb's - S has changed two times. It explains that this might be due to the subsidence of the operative segment between 3 and 6 months. But in 6 months we observed zero-p decrease is much more, though there is no significant difference. In addition, some patients also reported complications of subsidence, including neck and shoulder pain, numbness on the left and right limbs, and dizziness during the treatment. This effect suggests that an increased number of fused segments raises subsidence's impacts on general and local curvature on the overall clinical outcomes. The cervical cage insertion leads to increased foraminal size [54], thereby aiding the decompression of the nerve roots findings match the study's results revealing that PEEK cages only without the plate in three and four levels cause few postoperative morbidities[55-58]. Moreover, with its wedge-shaped cage construction, the lordosis becomes restored [59-61]. This study found that using a zero-p and TPC keeps and restores lordotic curvature. The fused segment height loss is mainly attributed to cage subsidence, further disrupting cervical stability. Similarly, the present study revealed that using a zero-p and TPC for ACDF had subsidence risks. The insertion of grafts leads to increased compressive forces and maximal distractive forces towards the endplate cage. Factors anticipate in cage subsidence are different surgeons ability and techniques, forceful endplate preparation, osteoporosis, differences in cervical segments, male sex, multiple-level, osteoporosis, over-distraction, cage size and cage materials. The limitations of this study includes short follow up time, small sample size and its retrospective nature.

CONCLUSION

This study's findings point to zero profile cage and traditional plate and cage having no statistically significant differences in image analysis but clinically meaningful patient outcomes and improvement after a six-months follow-up. Further studies can be done with large number of patients and longer follow up period to evaluate the changes in image analysis and clinical outcomes in ACDF.

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