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A Comparative Study Between the Functional and Radiological Outcomes of ACDF Using Locking Stand Alone Cage And Anterior Cervical Plate With Titanium Disc Cage in Degenerative Cervical Spine Disease

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Abstract

Cervical spondylotic radiculopathy and myelopathy are common problems for which anterior cervical discectomy and fusion is a gold standard procedure. There are various implant options available, two of which are commonly used in practice. Anterior cervical cage with plate and locking standalone cage. Our study aims to compare these two methods to know the functional and radiological outcomes after Anterior cervical discectomy and fusion procedure.

Materials and Methods: We performed a prospective comparative study of 60 patients with single or two level degenerative cervical spine disease with failed conservative management. They were divided randomly into 2 groups of 30 patients each one group treated using locking standalone cage and the other with anterior cervical plate with cage using Smith Robinson approach. The clinical outcome was measured using visual analogue scores, Robinson's criteria and Neck disability index and the radiological outcome was assessed using cobb's angle, segmental height and segment angle with a follow up period of 2 years.

Results: At 2 years follow up, good functional outcomes were obtained in both implant groups in terms of Robinson criteria, neck disability index and visual analogue scale. And good radiological outcomes were obtained in both implant groups with 93.3% fusion rates in both groups. Significant dysphagia was seen in the cage with plate group(26.6%) and significant cage subsidence was noted in the standalone cage group(20%).

Conclusion: The functional and radiological outcomes are superior at 2 years follow up in both implant groups. Hence standalone cage and cage with plate technique both are equally safe and effective treatment options in 1 or 2 level degenerative cervical spine disease.

Keywords: Anterior cervical discectomy and fusion, Neck Disability Index, Visual Analogue scale, Locking standalone cage, Anterior cervical plate, cage subsidence, Robinson criteria.

Introduction

Cervical spondylotic radiculopathy and myelopathy represent one of the most common causes of progressive spinal cord dysfunction in the adult population [1]. It is established that surgical decompression of cervical canal is an effective treatment option [1]. ACDF is established as a gold standard for degenerative cervical spine disease, both for radiculopathy and myelopathy [2]. Commonly used cages include titanium disc cages, titanium mesh cages, disc PEEK cages [2]. Whenever cages are used, for additional stability, anterior cervical plating is done [3].

Locking standalone cages(LSC) are implants that does not require anterior plating [4]. Anterior plating poses risk of hardware related complications like screw or plate dislodgement, soft tissue injury, trachea esophageal lesions, dysphagia. The reported rate of transient dysphagia ranges from 2-67% [5].

With LSC, there is less dysphagia, minimal tissue disruption, and decrease in other plate related complications. Also it's trapezoid shape helps to provide a better lordotic angle, helping maintain cervical lordosis post operatively [5]. However, cage subsidence is a frequent problem which may lead to loss of segmental lordosis, narrowing of the transforaminal space with

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nerve root compression and accelerated adjacent segment degeneration [6].

Hence, our study aims to compare locking standalone cage and anterior cervical plating with titanium disc cage to know the functional and radiological outcomes after anterior cervical discectomy and fusion.

Aims and Objectives

1. To compare the clinical and radiological outcomes of ACDF using anterior cervical plate with titanium disc cage and locking standalone cage (LSC).
2. To assess the complications of anterior cervical plating with titanium disc cage and locking standalone cage.

Materials and Methods

Sampling Area: Sanjay Gandhi Institute of Trauma and Orthopedics, Bangalore.

Study Duration: Between July 2019 and December 2021.

Study Design: Prospective study.

Sample Size: A total of sixty patients of cervical spondylosis satisfying the inclusion and exclusion criteria were chosen for the study. Thirty patients each were randomly allocated into the 2 groups (one undergoing ACDF anterior cervical plate with cage and the other undergoing ACDF with locking standalone cage).

Inclusion criteria

1. Age between 18 years and 70 years.
2. Patients having single or double level cervical disc disease with failed conservative management for a duration of 6 months.
3. Patients having cervical disc disease with severe radiculopathy with failed conservative management.
4. Patients have cervical disc disease with severe cervical myelopathy with failed conservative management (Nurick's grade 3 and above)
5. Patients willing to give informed consent.

Exclusion criteria

1. Age less than 18 years and more than 70 years.
2. Patients having 3 or more level cervical disc disease.
3. Patients having OPLL (ossification of posterior longitudinal ligament).
4. Patients having traumatic cervical injuries.
5. Patients with cervical myelopathy belonging to Nurick's grade 1 and 2.
6. Patients having pathological fractures with cervical radiculopathy or myelopathy.
7. Patients having osteoporosis.
8. Patients having neurological disorders.
9. Medically unfit patients.

Sampling method

The patients with clinical and radiological evidence of cervical spondylosis being managed on out patient basis for long term(6 months) with conservative treatment without significant benefit satisfying the inclusion and exclusion criteria were included in the study. Presenting symptoms included: (a) Axial pain with neck stiffness radiating upto sub occiput region above or shoulders below. (b) Radicular pain with numbness and tingling with or without associated weakness of the shoulder, chest, arms or hands. (c) Motor deficits with weakness in the upper limbs, lower limbs or both. (d) Sensory deficits (e) Cervical Myelopathy (Nurick's grade 3 and above).

Methodology and Procedure

After obtaining informed consent from patients and ethical committee approval, the patients were taken up for the study. Demographic data, history, clinical examination, and details of the investigations were recorded.

The patients were randomly divided into 2 groups. The first group includes 30 patients who were managed with locking standalone cage. The second group included 30 patients who were managed with anterior cervical plate with cage. The Smith-Robinson's approach was used. The side of approach was the right side. The cartilaginous end plates of the upper and lower vertebrae were removed after interbody distraction under microscopic view. After adequate decompression, cage was inserted in the distracted intervertebral spaces with or without plate, under fluoroscopic guidance. All patients were managed post operatively with cervical collar for 2 to 3 months. All the surgeries were performed by one surgeon.

Patients were followed up post operatively for functional and radiological assessment at 3 months, 6 months and 1 year and 2 years. Results were evaluated with:

Clinical outcome

(1) Robinson's criteria
(2) Neck Disability index.

Radiological outcome

(1) Cobb's angle
(2) Segmental height
(3) Segmental angle.

NOTE: Significance is assessed at 5% level of significance.

Significant figures

Suggestive significance (P value: $0.05<P<0.10$)
Moderately significant (P value: $0.01< P< 0.05$)
Strongly significant (P value< 0.01).

Table 1: Age distribution

Variable	Category	Number	Percentage
AGE	31-40 years	16	25%
AGE	41-50 years	36	56.25%
AGE	51-60 years	10	15.63%
AGE	>60 years	2	3.12%

TABLE 2: MEAN VAS SCORES IN BOTH IMPLANT GROUPS

	IMPLANT	N	Mean	Std. Deviation	Std. Error Mean	P VALUE
VAS PRE OP	LSC	30	8.12	0.993	0.241	0.142
	APC	30	7.53	0.743	0.192	
VAS POST OP	LSC	30	4.47	1.179	0.286	0.39
	APC	30	4.07	0.258	0.067	
VAS 3 MONTHS	LSC	30	3.47	1.187	0.307	0.019*
	APC	30	4	0.378	0.098	
VAS 6 MONTHS	LSC	30	3.2	1.207	0.312	0.116
	APC	30	3.47	0.516	0.133	
VAS 1 YEAR	LSC	30	2.87	1.06	0.274	0.567
	APC	30	2.87	0.516	0.133	
VAS 2 YEARS	LSC	30	2.85	1.024	0.744	0.578
	APC	30	2.86	0.524	0.168	

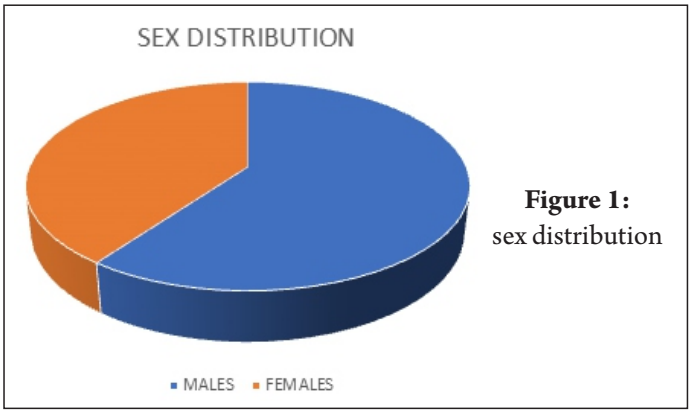

Figure 1: sex distribution

Results

Age distribution

Majority of the patients in our study, i.e. 36 patients (56.25 %) were in the age group of 41-50 years, the majority of people are over 40 years (75 %).

Sex

Of the 60 patients, 36 (60%) were males and 24 (40%) were females i.e. there was an overall male preponderance in this study.

Level of involvement

IVDP at C5-C6 level was the most common level of involvement and was seen in 32 of the 60 patients (53.3%). 8 patients (13.33%) had IVDP C6-C7, 4 patients (6.67%) had IVDP C4-C5 and 14 patients (23.33%) had a 2 level disc prolapse. There was no worsening of neurology in any of the patients following surgery.

TABLE 3: MEAN NDI SCORES IN BOTH THE IMPLANT GROUPS.

NDI	IMPLANT	N	Mean	Std. Deviation	Std. Error Mean	P VALUE
NDI PRE OP SCORE	LSC	15	29.88	4.152	1.007	0.024*
	APC	15	26	4.408	1.138	
NDI 3 MONTH SCORE	LSC	15	20.06	3.929	0.953	0.064
	APC	15	17.33	3.266	0.843	
NDI 6 MONTH SCORE	LSC	15	15.53	4.324	1.116	0.461
	APC	15	14.27	3.011	0.777	
NDI 1 YEAR SCORE	LSC	15	13.07	4.183	1.08	0.486
	APC	15	11.67	2.82	0.728	
NDI 2 YEAR SCORE	LSC	15	11.4	3.851	0.994	0.25
	APC	15	9.6	2.501	0.646	

TABLE 4: OVERALL NDI SCORES IN OUR STUDY.

	N	Mean	Std. Deviation	Std. Error Mean	P VALUE
NDI PRE OP SCORE	30	28.06	4.642	0.821	0.001*
NDI POST OP SCORE	30	18.78	3.833	0.678	0.0005*
NDI 6 MONTH SCORE	30	14.9	3.717	0.679	0.0008*
NDI 2 YEAR SCORE	30	10.5	3.319	0.606	0.0008*

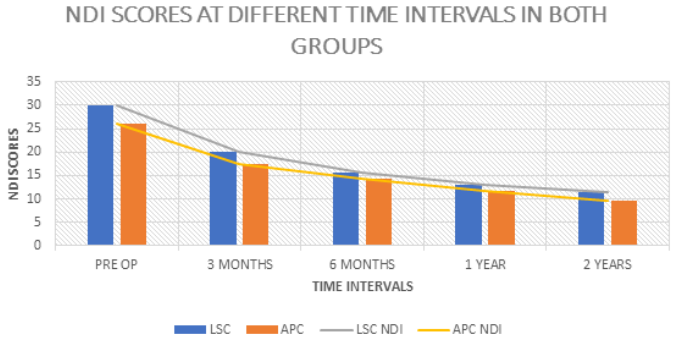

Figure 2: NDI Scores in Both Groups at Various Time Intervals

Functional outcome assessment

VAS SCORES: The mean VAS scores pre op was 8.12±0.99 for LSC group and 7.53±0.74 for APC group. At 3 months post op, the score was 3.47 ± 1.19 in LSC group and 4.0±0.38 in APC group, at 2 years post op was 2.85 ± 1.02 in LSC group and 2.86±0.52 in APC group.

This improvement was statistically significant (P< 0.001) in both groups. There was significant pain reduction post operatively in both groups and there was no significant difference in VAS scores between the two groups (Table 2).

Neck disability index

The mean NDI scores pre-op was 29.88 ± 4.15 for LSC group and 26.00±4.41 for APC group. At 2 years, was 11.40 ± 3.85 in LSC group and 9.60±2.50 in APC group. The improvement overall was statistically significant (P<0.001) using Friedman's test (Table 4).However, there was no significant difference in scores between the groups (Table 3).

Robinson's criteria

Based upon improvement in symptoms and abnormal physical

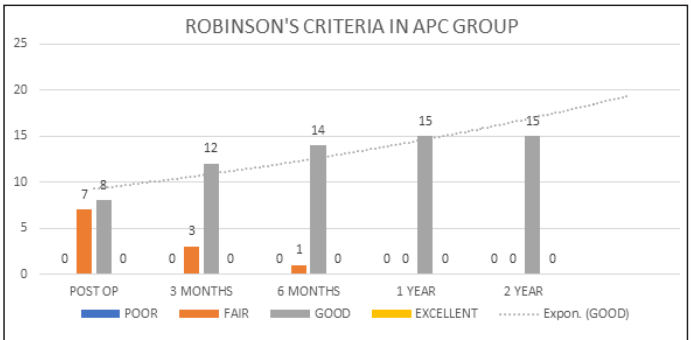

Figure 3: Robinson's criteria in the anterior cervical plate with cage group

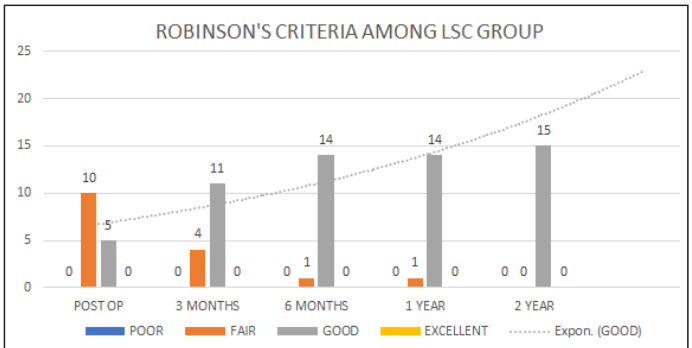

Figure 4: Robinson's criteria in the locking standalone cage group

TABLE 5: OVERALL COBB'S ANGLE IN OUR STUDY

	N	Mean	Std. Deviation	Std. Error Mean	P Value
COBB PRE OP	30	7.31	3.524	0.623	0.0004*
COBB POST OP	30	21.75	3.935	0.696	0.0006*
COBB 6 MONTHS	30	21.63	3.952	0.722	0.0007*
COBB 1 YEAR	30	20.83	3.94	0.719	0.0009*
COBB 2 YEAR	30	19.83	3.77	0.688	0.012*

TABLE 6: SEGMENTAL ANGLE IN BOTH IMPLANT GROUPS

	IMPLANT	N	Mean	Std. Deviation	Std. Error Mean	P VALUE
SEG.ANGLE PRE OP	LSC	15	3.88	1.536	0.373	0.132
	APC	15	3.07	0.884	0.228	
SEG.ANGLE POST OP	LSC	15	10	3.544	0.86	0.737
	APC	15	9.47	2.446	0.631	
SEG.ANGLE 3 MONTHS	LSC	15	9.94	3.78	0.976	0.806
	APC	15	9.47	2.446	0.631	
SEG.ANGLE 6 MONTHS	LSC	15	8.93	3.863	0.997	0.744
	APC	15	9.2	2.569	0.663	
SEG.ANGLE 2 YEARS	LSC	15	8.07	3.77	0.973	0.713
	APC	15	8.4	2.501	0.646	

TABLE 7: OVERALL SEGMENTAL ANGLE IN OUR STUDY

	N	Mean	Std. Deviation	Std. Error Mean	P Value
SEG.ANGLE PRE OP	30	3.5	1.32	0.233	0.0003*
SEG.ANGLE POST OP	30	9.72	3.04	0.537	0.0005*
SEG.ANGLE 3 MONTHS	30	9.73	3.14	0.573	0.0008*
SEG.ANGLE 6 MONTHS	30	9.07	3.226	0.589	0.001*
SEG.ANGLE 2 YEARS	30	8.23	3.148	0.575	0.040*

Figure 5: Mean segmental height in both implant groups

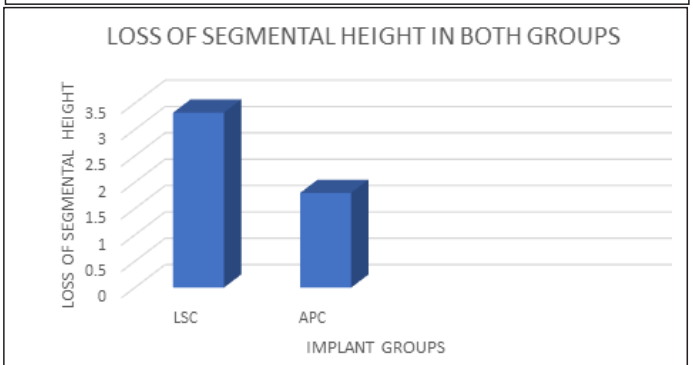

Figure 6: Loss of segmental height in both implant groups

findings, the patients would be categorized into 'excellent', 'good', 'fair' and 'poor' outcome categories using Robinson's criteria.

Cage group

Significant improvement in the outcome was seen in both groups. However, there was no statistically significant difference between the groups as shown by Pearson's Chi-square test in immediate post op period (p value-0.169), 3 months (p value-0.355), 6 months (p value-0.390) and at 2 years (p value-0.232) post operatively.

Radiological assessment

Cobb's angle

The mean cobb's angle pre op was 8.41 ± 4.00 for LSC group and 6.07±2.46 for APC group. This improved to 22.53 ± 4.73 in LSC group and 20.87±2.67 in APC group post- operatively. At 2 year post op, it was 20.20±4.71 in LSC and 19.47±2.64 in APC group (p value<0.05). However, there was no statistically significant difference of between the 2 groups.

Segmental height

Mean segmental height pre-op was 34.37±1.92 mm for LSC group and 34.31±1.94 mm for APC group. In the post-op period, it improved to 39.91±2.82 mm in LSC group and 39.21±2.36 mm in APC group. At 2 years post op, it was 36.48±2.82 mm in LSC and 37.47±2.12 mm in APC group.

Loss of segmental height

This is the difference between segmental height achieved in immediate post operative period and segmental height after 2 years follow up.

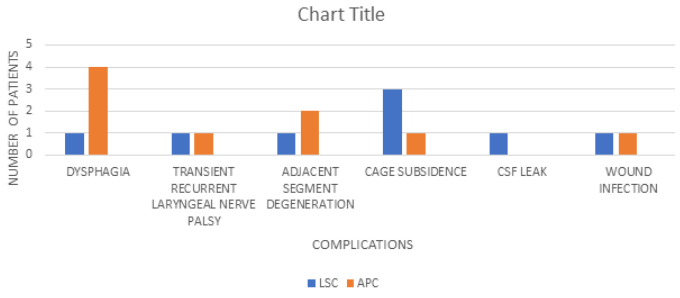

Figure 7: Complications in both implant groups

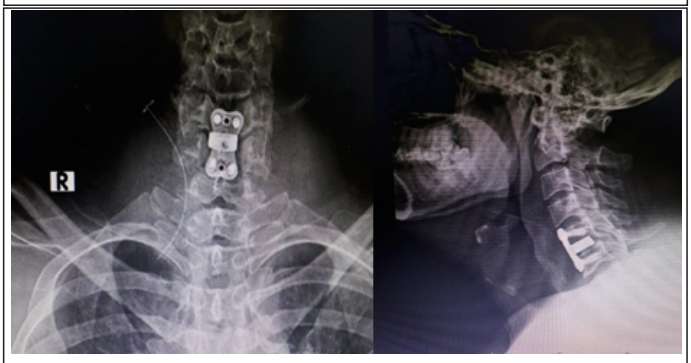

Figure 8: 2 year follow up- plate with cage

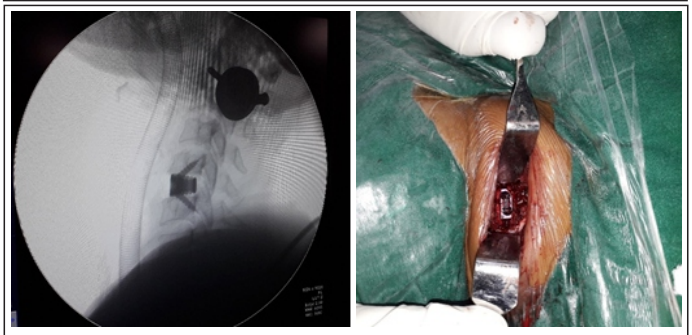

Figure 9: Intra op Pictures

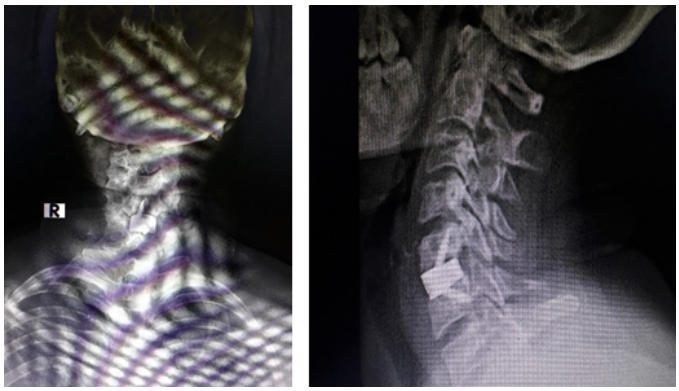

Figure 10: Post operative x ray at 1 year follow up

The mean loss of segmental height overall in our study was 2.56±1.15 mm [p value-0.099 (>0.05)]. Using the Mann-Whitney's U test, the loss of segmental height in LSC group was 3.32±0.88 mm, while in APC group was 1.80±0.86 mm (Figure 6) at 1 year follow up (p value- 0.0008).

Segmental angle

Mean segmental angle pre-op was 3.88±1.53 for LSC group and 3.07±0.88 for APC group. Post operatively, this improved to 10.00±3.54 in LSC and 9.47±2.45 in APC group. At 2 years, was 8.07±3.77 in LSC group and 8.40±2.50 in APC group (p value<0.05). However, there was no statistically significant difference between the groups (Table 6).

Complications:

One patient in LSC group showed mild dysphagia (6.67%) which persisted upto 6 weeks post op. Four patients of APC group showed dysphagia (26.6%), 3 of which subsided by 6 weeks and in 1 patient persisted upto 12 weeks. Two patients had transient recurrent laryngeal nerve palsy, one each in LSC and APC group (6.67% each) which persisted upto 6 weeks.

Adjacent disc degeneration developed in 2 patients of LSC group (6.67%) and 4 patients of APC group (13.33%). Adjacent segment degeneration was assessed using Goffin's criteria 20 (Based on 2 radiological parameters-disc height and appearance of anterior osteophytes over and under the segment of construct) as per which all 3 patients developed slight degeneration. Cage subsidence was noted in 3 patients of LSC group (20%) and 1 patient of APC group (6.67%).

Discussion

ACDF is established as gold standard procedure for cervical radiculopathy and myelopathy [2]. ACDF with anterior cervical plate is an effective method of fusion [6]. However, due to complications, there has been a rising interest in use of locking standalone cages. Our study was done to compare the functional and radiological outcomes of these 2 implant groups. Several studies have shown that anterior cervical plate is associated with dysphagia, adjacent segment degeneration and greater blood loss compared to stand alone cage, while standalone cage shows higher rates of cage subsidence, and decreased restoration of cervical lordosis [7].

Dysphagia is the most common complication of ACDF [8]. Exact mechanism is unknown. Fountas et al [8] suggested esophageal injury, soft tissue edema, hematoma and adhesion formation around the plate are potential contributors to development of dysphagia. Fogel and Mc Donnell in their metaanalysis, demonstrated that removal of plate and lysis of associated adhesions significantly reduced dysphagia rates in ACDF patients [9]. In our study, there is significantly higher rate of dysphagia (26.6%) in APC group compared to 6.7% in LSC group (p value<0.05).

Biomechanical studies reveal that ACDF with conventional cage plate technique increased stress and mobility in the adjacent segments, contributing to adjacent segment degeneration [10, 11]. This may necessitate additional

treatment years after index surgery [12, 13]. Theoretically, cage alone technique has decreased rates of adjacent segment degeneration [7]. In our study, ASD rate was higher (13.33%) in APC group compared to (6.67%) LSC group.

Standalone cage has higher rates of cage subsidence. This may cause local cervical kyphosis and hypermobility in posterior cervical region [10]. However, previous systematic reviews show that cage subsidence does not affect clinical outcomes or fusion rates [13]. We used the reference measurement total anterior vertebral body height(TAVBH). The anterior, middle and posterior disc heights were measured and the mean disc height(mDH) was measured. The ratio (mDH/TAVBH) was calculated in immediate post op and final follow up. A decrease in the ratio by 10% or more was considered cage subsidence [14, 15]. In our study, we found significantly higher rates of cage subsidence in patients of LSC group(20%) compared to (6.67%)APC group (p value<0.05). However, there was no significant difference in fusion rates at 1 year in both groups (93.33% in each).

Loss of cervical lordosis is a risk factor for ASD by increasing biomechanical stress in vertebral bodies of adjacent segments [16]. However, in our study there was no significant difference in the post op cervical lordosis in both groups.

In our study, good functional outcome was seen in both groups. Neurological symptoms improved. No significant difference was found in Robinson's criteria with all patients falling under "Good" outcome category in both groups at 2 years follow up. The NDI also showed significant improvement in both groups, with patients who had "severe" disability pre op, falling under "mild" category at 2 years, with no significant difference between the two groups. VAS scores also showed there was significant pain relief in both groups at each follow up (p value<0.05). Mean VAS score at 3 months follow up are transiently better in LSC group compared to APC group, but at 2 years follow up, this difference was negligible. This is probably due to lesser surgical site hematoma and soft tissue edema compared to APC group, which eventually subsided.

According to Lee et al, groups with higher cage subsidence have poorer outcomes [19]. However, a previous systematic review found that cage subsidence following ACDF does not affect clinical outcomes or fusion rates [13]. Therefore, clinical significance of higher cage subsidence in the LSC group in our study remains unclear, as there is no significant difference in outcomes in short and mid term follow up (i.e upto 2 years). Hence, longer term follow ups in future studies are warranted.

Conclusion

ACDF with stand alone cage is associated with reduced incidence of dysphagia and adjacent segment degeneration compared to anterior cervical cage with plate, with additional benefits of shorter operative time and lesser intra operative soft tissue damage. However, anterior cervical cage with plate shows lesser incidence of cage subsidence and loss of segmental height, with reduced loss of cervical lordosis. The functional outcomes of both these implant groups are superior and similar to each other in mid term follow up with excellent symptomatic relief, significant reduction in the neck disability and good functional outcomes.

Overall, in the mid term, ACDF using stand alone cage can be considered equally effective to anterior cervical cage with plate and both offer very good surgical options for the management of single or 2 level cervical disc disease.

However, long term follow up is warranted to understand long term clinical implications of cage subsidence, loss of cervical lordosis and adjacent segment degeneration.

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Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given his consent for his images and other clinical information to be reported in the Journal. The patient understands that his name and initials will not be published, and due efforts will be made to conceal his identity, but anonymity cannot be guaranteed.

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