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Original research article

Functional outcome of locking standalone cage and anterior cervical plating with titanium disc cage after anterior carpectomy discectomy and fusion in degenerative cervical disease

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Abstract

Recently, there has been a rise in the use of the locking stand-alone cages (LSC), which does not require an anterior plate.[4] It has found that disc titanium cages pose a substantial risk of hardware related complications such as screws or plate dislodgement, soft tissue injury, tracheoesophageal lesions, dysphagia. The reported rate of transient dysphagia ranges from 2% to 67%. After obtaining written informed consent, inpatient of Department of Orthopaedics fulfilling the inclusion and exclusion criteria. Demographic data, history, clinical examination and details of investigations and interventions will be recorded in the study proforma. In the post-operative period, the Robinson's criteria showed that among the 15 patients who underwent ACDF with LSC, 5 patients came under the "Good" category and 10 came under the "Fair" category. Among the 15 patients who underwent ACDF with APC, 8 patients came under the "Good" category and 7 patients came under the "Fair" category.

Keywords: Locking standalone cage, anterior cervical plating, titanium disc cage

Introduction

Cervical spondylotic radiculopathy and cervical spondylotic myelopathy represent one of the most common causes of progressive spinal cord dysfunction in the adult population [1]. It has been found that the surgical decompression of the cervical spinal is an effective treatment option, that halts the progression of symptoms and can also promote functional recovery [1]. The above conditions can be treated with anterior posterior and combined procedures, each with specific advantages and disadvantages [2]. Anterior cervical decompression and fusion is the established gold standard for degenerative cervical spine disease both for radiculopathy and for myelopathy. To prevent donor site morbidity, interbody fusion is preferred using various types of cages. Commonly used cages include Disc titanium cages, Disc PEEK cages, Titanium mesh cages [2]. Whenever these cages are used, for additional stability, anterior cervical plating is done [3].

Recently, there has been a rise in the use of the locking stand-alone cages (LSC), which does not require an anterior plate [4]. It has found that disc titanium cages pose a substantial risk of hardware related complications such as screws or plate dislodgement, soft tissue injury, tracheoesophageal lesions, dysphagia. The reported rate of transient dysphagia ranges from 2% to 67% [5]. It has also been found that cage subsidence is associated with loss of segmental lordosis, narrowing of the transforaminal space with subsequent nerve root compression, accelerated adjacent segment degeneration [6]. With the advent of LSC, there is less dysphagia, minimal tissue disruption, and decrease in other complications related to anterior cervical plates and titanium disc cages as it has got more anatomical shape which fits with the vertebral end plate. Also, the implant is trapezoid shaped which helps to provide a proper lordotic angle, there by helping to maintain cervical lordosis post operatively [5]. But it has been found in literature that with LCS, there is an increased risk of delayed or nonunion of interbody fusion, it is less stable and rigid when compared to anterior plating and disc cages [6].

Hence, the study is conducted to compare anterior cervical plating with titanium disc cage with LSC cages to know the functional and radiological outcomes after Anterior carpectomy, discectomy and fusion procedure.

Methodology

Study design: Prospective study.

Sample size: 30 cases (15+15).

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Inclusion criteria

1. Age between 30 years and 70 years.
2. Patients having single or double level extruded cervical disc disease with failed conservative management.
3. Patient having cervical disc disease with severe radiculopathy with failed conservative management.
4. Patient having cervical disc disease with severe cervical myelopathy with failed conservative management.
5. Patients willing to give Informed Consent.

Exclusion criteria

1. Age less than 30 years and more than 70 years.
2. Medically unfit patients.
3. Patients having more than 3 level cervical disc disease.
4. Patients having OPLL (Ossification of posterior longitudinal ligament.
5. Patients having traumatic cervical injuries.
6. Patients having pathological fractures with cervical radiculopathy or myelopathy.
7. Patients having neurological disorders.

After obtaining written informed consent, inpatient of Department of Orthopaedics fulfilling the inclusion and exclusion criteria. Demographic data, history, clinical examination and details of investigations and interventions will be recorded in the study proforma.

Patient were divided into two groups as surgeon choice, first group includes 15 patients who had been managed with anterior cervical plate with titanium cage. The second group included 15 patients who had been managed with locking standalone cage. The anterior cervical approach was used. The cartilaginous end plates of the upper and lower end plates were removed after inter body distraction under microscopic view the removal of the posterior osteophytes was associated with the incision of the posterior longitudinal ligament. After adequate decompression of two consecutive levels, cages were inserted in the distracted inter vertebral spaces with or without plate under fluoroscopic control. All patients were managed postoperatively with immobilization with cervical collar for 2-3 months.

Patient will be followed post operatively for functional and radiological assessment at 3months, 6months and 12 months.

Results

Robinson's criteria was used for assessment of the functional outcome of the patients following the ACDF procedure. The criteria is based upon the post-operative improvement in the symptoms of the patient and the abnormal physical findings. The criteria is as follows:

Table 1: Robinson's Criteria

Excellent	All pre-operative symptoms relieved; abnormal physical findings unchanged or improved.
Good	Minimal residual pre-operative symptoms; activities increased; abnormal physical findings unchanged or improved.
Fair	Definitive relief of some pre-operative symptoms, with others remaining unchanged or slightly improved.
Poor	Symptoms and signs unchanged from pre-operative period.

Table 2: Robinson's Criteria in the 2 Implant Groups

			Robinson Criteria				P Value
			Excellent	Good	Fair	Poor	
Robinson Post Op	Implant	APC	0	8	7	0	0.169
		LSC	0	5	10	0	
Robinson 3 Months		APC	0	12	3	0	0.355
		LSC	0	11	4	0	
Robinson 6 Months		APC	0	14	1	0	0.390
		LSC	0	14	1	0	
Robinson 1 Year		APC	0	15	0	0	0.232
		LSC	0	14	1	0	

Using this criteria, our patients were followed up at the immediate post-operative period, at 3 months, 6 months and 1 year post operatively.

In the post-operative period, the Robinson's criteria showed that among the 15 patients who underwent ACDF with LSC, 5 patients came under the "Good" category and 10 came under the "Fair" category. Among the 15 patients who underwent ACDF with APC, 8 patients came under the "Good" category and 7 patients came under the "Fair" category.

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At 3 months follow up, among the 15 patients who underwent ACDF with LSC, 11 patients came under the "Good" category and 4 came under the "Fair" category. Among the 15 patients who underwent ACDF with APC, 12 patients came under the "Good" category and 3 patients came under the "Fair" category.

At 6 months follow up, among the 15 patients who underwent ACDF with LSC, 14 patients came under the "Good" category and 1 came under the "Fair" category. Among the 15 patients who underwent ACDF with APC, 14 patients came under the "Good" category and 1 patients came under the "Fair" category.

At the end of 1 year post operatively, among the 15 patients who underwent ACDF with LSC, 14 patients came under the "Good" category and 1 patient came the "Fair" category. Among the 15 patients who underwent ACDF with APC, all 15 patients came under the "Good" category and there were no patients in the "Fair" category.

None of our study patients showed a "Poor" outcome as per Robinson's criteria and none of the patients showed "Excellent" outcome at any point of the 1 year follow up period.

There was significant improvement in the functional outcome as per Robinson's criteria in both the groups. However, there was no statistically significant difference in the functional outcome between the 2 groups as shown by the Pearson's Chi-square test in the immediate post-operative period (p value-0.169), 3 months post op (p value-0.355), 6 months post op (p value-0.390) and at 1 year (p value-0.232) post operatively.

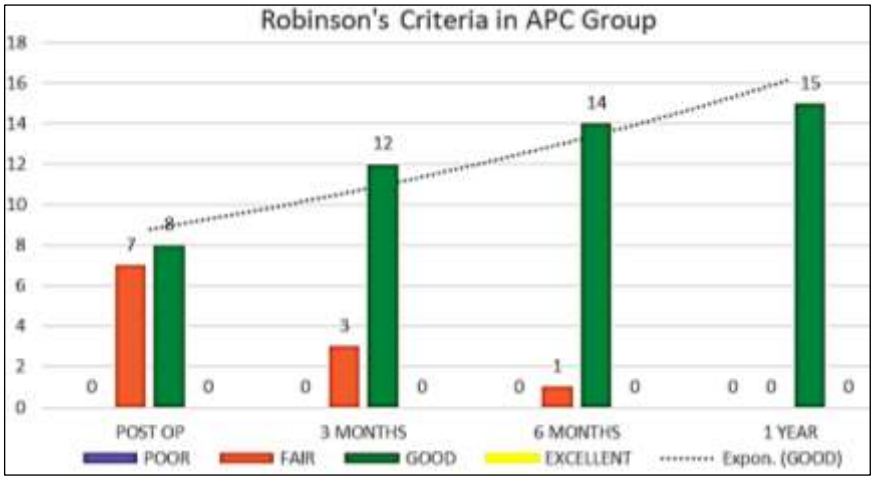

Fig 1: Robinson's Criteria in the Anterior Cervical Plate with Cage Group

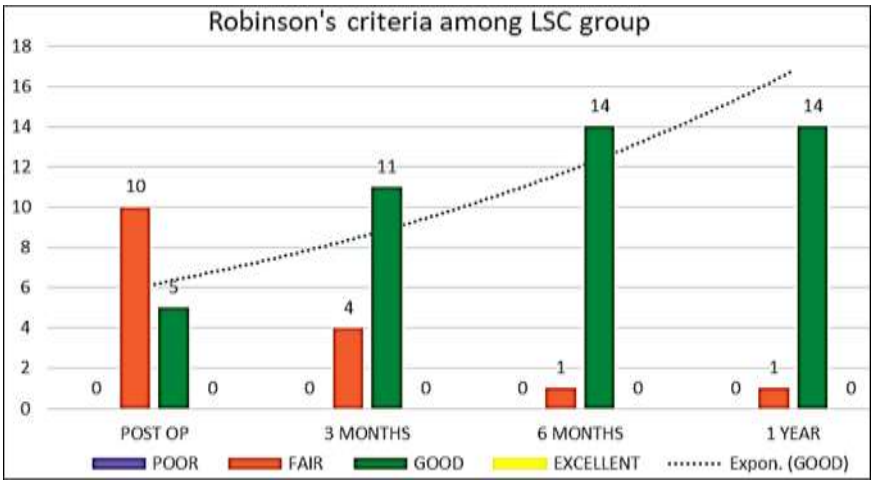

Fig 2: Robinson's Criteria in the Locking Standalone Cage Group

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Table 3: Cobb's Angle in Both Implant Groups

	Implant	N	Mean	Std. Deviation	Std. Error Mean	P Value
COBB Pre OP	LSC	17	8.41	4.001	.970	0.013
	APC	15	6.07	2.463	.636	
COBB Post OP	LSC	17	22.53	4.732	1.148	0.710
	APC	15	20.87	2.669	.689	
COBB 3 Months	LSC	15	22.53	4.912	1.268	0.806
	APC	15	20.73	2.549	.658	
COBB 6 Months	LSC	15	21.40	5.011	1.294	0.744
	APC	15	20.27	2.520	.651	
COBB 1 Year	LSC	15	20.20	4.709	1.216	0.775
	APC	15	19.47	2.642	.682	

The test results demonstrated the mean cobb's angle at different time intervals for both the implant groups i.e. locking standalone cage and anterior cervical plate with disc cage groups. The mean cobb's angle in the pre-op period was 8.41 ± 4.00 for LSC group and 6.07±2.46 for APC group. In the post-operative period the mean cobb's angle improved to 22.53 ± 4.73 in the LSC group and 20.87±2.67 in the APC group, at 3 months post op the angle was 22.53 ± 4.91 in the LSC group and 20.73±2.55 in the APC group, at 6 Months post op was 21.40 ± 5.01 in the LSC group and 20.27±2.52 in the APC group and at 1 year post op period, it was 20.20 ± 4.71 in the LSC group and 19.47±2.64 in the APC group.
There was a statistically significant improvement in the cobb's angle in both the implant groups. However, there was no statistically significant difference in the improvement of mean cobb's angle between the 2 implant groups.

Table 4: Overall Cobb's Angle in the Study

	N	Mean	Std. Deviation	Std. Error Mean
Cobb Pre OP	32	7.31	3.524	.623
Cobb Post OP	32	21.75	3.935	.696
Cobb 3 Months	30	21.63	3.952	.722
Cobb 6 Months	30	20.83	3.940	.719
Cobb 1 Year	30	19.83	3.770	.688

Table 5: One Sample Test

:	t	df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
Cobb Pre OP	-17.158	31	.000	-10.688	-11.96	-9.42
Cobb Post OP	5.391	31	.000	3.750	2.33	5.17
Cobb 3 Months	5.035	29	.000	3.633	2.16	5.11
Cobb 6 Months	3.939	29	.000	2.833	1.36	4.30
Cobb 1 Year	2.664	29	.012	1.833	.43	3.24

The one sample t test was carried out to assess the Cobb's angle in the study overall. The test shows a mean pre op Cobb's angle of 7.31±3.52 (reduced cervical lordosis), which improved to 21.75±3.94 in the post-operative period restoring near normal cervical lordotic curve. This Cobb's angle achieved post-surgery was significantly maintained with the mean values of 21.63±3.95 at 3 months post op and 20.83±3.94 at 6 months post op and 19.83±3.77 at the end of 1 year post operatively. The improvement achieved in the immediate post-operative period was statistically significant (p value- 0.0006) and this cobb's angle was maintained throughout the follow up period of 1 year. P value at the end of 1 year- 0.012 which was statistically significant.

Table 6: Segmental Height in Both Implant Groups

	Implant	N	Mean	Std. Deviation	Std. Error Mean	P Value
SEG. Height Pre OP	LSC	17	34.37	1.920	.466	0.710
	APC	15	34.31	1.935	.499	
SEG. Height Post OP	LSC	17	39.91	2.819	.684	0.064
	APC	15	39.21	2.358	.609	
SEG. Height 3 Months	LSC	15	38.84	2.827	.730	0.436
	APC	15	38.70	2.249	.581	
SEG. Height 6 Months	LSC	15	37.81	2.612	.674	0.806
	APC	15	38.18	2.146	.554	
SEG. Height 1 YEAR	LSC	12	36.48	2.824	.815	0.212
	APC	14	37.47	2.121	.567	

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The test results demonstrated the segmental height at different time intervals for both the implant groups i.e. locking standalone cage and anterior cervical plate with disc cage groups. The mean segmental height in the pre-op period was 34.37± 1.92 for LSC group and 34.31±1.94 for APC group. In the post-operative period the mean segmental height improved to 39.91±2.82 in the LSC group and 39.21±2.36 in the APC group, at 3 months post op, the height was 38.84±2.83 in the LSC group and 38.70±2.25 in the APC group, at 6 months post op was 37.81 ± 2.61 in the LSC group and 38.18±2.15 in the APC group and at 1 year post op period, it was 36.48±2.82 in the LSC group and 37.47±2.12 in the APC group.
There was a statistically significant improvement in the segmental height in both the implant groups in the post-operative period. However, at the end of 1 year follow up, the was a mean loss of segmental height in the LSC group was 3.32 ± 0.88mm and in the APC group was 1.80 ± 0.86mm. Hence, the LSC cage group showed a higher value of loss of segmental height compared to the APC group. However, at the end of 1 year follow up, the improvement in segmental height was significantly maintained in both implant groups and there was no statistically significant difference in the improvement of mean segmental height between the 2 implant groups. (p value- 0.212 i.e. >0.05).

Table 7: Segmental Height Overall in Our Study

	N	Mean	Std. Deviation	Std. Error Mean
SEG. Height Pre OP	32	34.34	1.896	.335
SEG. Height Post OP	32	39.59	2.596	.459
SEG. Height 3 Months	30	38.77	2.511	.458
SEG. Height 6 Months	30	37.99	2.356	.430
SEG. Height 1 Year	26	37.01	2.471	.485

Table 8: One Sample Test

	t	df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
SEG. Height Pre OP	-4.946	31	.000	-1.658	-2.341	-.974
SEG. Height Post OP	7.820	31	.000	3.589	2.652	4.524
SEG. Height 3 Months	6.048	29	.000	2.772	1.83	3.71
SEG. Height 6 Months	4.637	29	.000	1.995	1.11	2.87
SEG. Height 1 Year	2.092	25	.047	1.014	.02	2.01

The one sample test was used t carry out the assessment of the segmental height in our study overall. The test shows a mean pre op segmental height of 34.34±1.896 (reduced), which improved to 39.59±2.596 in the post-operative period. This segmental height achieved post-surgery was significantly maintained with the mean values of 38.77±2.51 at 3 months post op and 37.99±2.36 at 6 months post op and37.01±2.47 at the end of 1 year post operatively. The improvement achieved in the immediate post-operative period was statistically significant (p value- 0.0005) and there was a mean loss of segmental height of 2.58±5.11mm in the 1 year follow up. However, this loss of segmental height was negligible statistically and the height at the end of 1 year showed a p value of 0.047, which was still statistically significant.

Loss of segmental height

This is the difference between the segmental height achieved in the immediate post-operative period and the segmental height after 1 year follow up. There was loss of segmental height in both implant groups at the end of 1 year.
The mean loss of segmental height overall in our study was 2.56 ± 1.15mm with a p value of 0.099 (>0.05). Hence the overall loss of segmental height in our study was not statistically significant. However, using the Mann-Whitney's U test, the mean loss of segmental height in the LSC group was 3.32±0.88mm while that in the APC group was 1.80±0.86mm. There was a significantly greater loss of segmental height at the end of 1year follow up in the Standalone cage group as compared to the patients who underwent anterior cervical plate with cage. This difference was statistically significant (p value-0.0008).

Table 9: Segmental Angle

	Implant	N	Mean	Std. Deviation	Std. Error Mean	P Value
SEG. Angle Pre OP	LSC	17	3.88	1.536	.373	0.132
	APC	15	3.07	.884	.228	
SEG. Angle Post OP	LSC	17	10.00	3.544	.860	0.737
	APC	15	9.47	2.446	.631	
SEG. Angle 3 Months	LSC	15	9.94	3.780	.976	0.806
	APC	15	9.47	2.446	.631	
SEG. Angle 6 Months	LSC	15	8.93	3.863	.997	0.744
	APC	15	9.20	2.569	.663	

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SEG. Angle 1 Year	LSC	15	8.07	3.770	.973	0.713
	APC	15	8.40	2.501	.646	

The test results demonstrated the mean segmental angle at different time intervals for both the implant groups i.e. locking standalone cage and anterior cervical plate with disc cage groups. The mean segmental angle in the pre-op period was 3.88 ± 1.53 for LSC group and 3.07± 0.88 for APC group. In the post- operative period the mean cobb's angle improved to 10.00 ± 3.54 in the LSC group and 9.47±2.45 in the APC group, at 3 months post op the angle was 9.94 ± 3.78 in the LSC group and 9.47±2.45 in the APC group, at 6 Months post op was 8.93 ± 3.86 in the LSC group and 9.20±2.57 in the APC group and at 1 year post op period, it was 8.07 ± 3.77 in the LSC group and 8.40±2.50 in the APC group.

There was a statistically significant improvement in the segmental angle in both the implant groups. However, there was no statistically significant difference in the improvement of mean segmental angle between the 2 implant groups.

Table 10: Segmental Angle Overall in Our Study

	N	Mean	Std. Deviation	Std. Error Mean
SEG. Angle Pre OP	32	3.50	1.320	.233
SEG. Angle Post OP	32	9.72	3.040	.537
SEG. Angle 3 Months	30	9.73	3.140	.573
SEG. Angle 6 Months	30	9.07	3.226	.589
SEG. Angle 1 Year	30	8.23	3.148	.575

Table 11: One Sample Test

	t	df	Sig. (2-tailed)	Mean Difference	95% Confidence Interval of the Difference	
					Lower	Upper
SEG. Angle Pre OP	-15.001	31	.000	-3.500	-3.98	-3.02
SEG. Angle Post OP	5.059	31	.000	2.719	1.62	3.81
SEG. Angle 3 Months	4.768	29	.000	2.733	1.56	3.91
SEG. Angle 6 Months	3.509	29	.001	2.067	.86	3.27
SEG. Angle 1 Year	2.146	29	.040	1.233	.06	2.41

The one sample t test was carried out to assess the segmental angle in the study overall. The test shows a mean pre op segmental angle of 3.50±1.32, which improved to 9.72±3.04 in the post-operative period restoring near normal cervical lordotic curve. This segmental angle achieved post-surgery was significantly maintained with the mean values of 9.72±3.14 at 3 months post op and 9.07±3.23 at 6 months post op and 8.23±3.15 at the end of 1 year post operatively. The improvement achieved in the immediate post-operative period was statistically significant (p value- 0.0005) and this segmental angle was maintained throughout the follow up period of 1 year. P value at the end of 1 year-0.040 which was statistically significant.

Discussion

One of the major concerns of ACDF with stand-alone cage is the potential increase in the rates of cage subsidence. Studies have reported that cage subsidence may cause local cervical kyphosis and hypermobility in the posterior cervical region. However, it is also important to note that previous systematic reviews found that cage subsidence following ACDF does not affect the clinical outcomes or the fusion rates. To assess the occurrence of subsidence, we used the reference measurement total anterior vertebral body height (TAVBH). The anterior, middle and posterior dis heights were measured and the mean disc height (mDH) was measured. The ratio (mDH/TAVBH) was calculated in the immediate post op and final follow up. A decrease in the mDH leading to reduction in the ratio by 10% or more was considered cage subsidence. In our study, we found higher rates of cage subsidence in the patients who underwent ACDF with standalone cage (20%) as compared to the 6.67% in the cage with plate group. This difference was statistically significant (p value<0.05). However, there was no significant difference in the fusion rates achieved at the end of 1 year in both implant groups (fusion rate in each implant group was 93.33% at the end of 1 year follow up) [7].

Loss of cervical lordosis has been associated with post-operative pain and functional disability as per several studies. In addition, sagittal alignment also plays an important role in the in the distribution of stress across fixation devices. Loss of cervical lordosis is a theoretical risk factor for ASD, as cervical kyphosis accelerates degenerative changes of the cervical spine by increasing biomechanical stress on the anterior portion of the vertebral bodies of the adjacent segments. However, in our study there was no significant difference in the post-operative cervical lordosis achieved in both the implant groups. The mean loss of cervical lordosis was higher in the patients of the standalone cage groups (2.23 ± 0.23mm) as compared to the cage with plate group (1.40±0.27mm). However, this difference in the cobb's angle

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was not statistically significant (p value>0.05). While previous studies have shown that loss of cervical lordosis is associated with poorer clinical outcomes, we did not find worse clinical outcomes in the stand alone cage group. This may be due to the fact that the clinical sequalae resulting from the loss of cervical lordosis may take years to develop and thus were not captured in the relatively short follow up period of our study [8].

As far as the functional outcome are concerned, our study showed good results in both the implant groups. The neurological symptoms improved due to complete decompression. No significant difference was found between the 2 groups in terms of Robinson's criteria after surgery with almost all patients falling under the "Good" outcome category in both implant groups at the end of 1 year follow up. The neck disability index also showed significant improvement in both implant groups post-surgery, with patients who had "severe" disability pre operatively, fell under "mild" disability category at the end of 1 year follow up. There was no significant difference in the NDI scores of the 2 implant groups. The clinical outcomes in terms of VAS scores also showed that there was significant pain relief post-surgery in both the implant groups at each follow up (p value<0.05). Even though, the mean VAS scores at 3 months follow up are transiently better in the standalone cage group compared to the plate with cage group, at the end of 1 year follow up, there was no statistically significant difference in the mean VAS scores of the 2 implant groups. This could probably be due to the lesser surgical site hematoma and soft tissue edema in the patients who underwent ACDF with the stand alone cage compared with the cage with plate group, which eventually subsided in the further follow ups resulting in similar long term pain relief in both implant groups [9].

According to Lee *et al*., groups with higher cage subsidence rates have poorer clinical outcomes. This indicates that the potential long term drawbacks associated with subsidence need to be considered. However, it is also important to note that a previously published systematic review found that cage subsidence following ACDF does not affect clinical outcomes or fusion rates. Therefore the clinical significance of higher rate of cage subsidence in the stand alone cage group in our study remains unclear, as there is no significant difference in the clinical outcomes in the short and mid-term follow up (i.e. upto 1 year). Hence, longer term follow ups in future studies are warranted [10].

Conclusion

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

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