



A comparative and prospective study of surgical outcomes of cervical artificial disc to anterior cervical discectomy and fusion in the treatment of symptomatic degenerative disc disease of cervical spine in a tertiary care center of Eastern India

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ABSTRACT

Background: Cervical disc degeneration is known to be a primary cause of neck pain and neurologic symptoms and can cause significant morbidity. Degeneration can be related to radiculopathy or myelopathy due to compression of spinal nerves and/or spinal cord. Disc pathology may manifest clinically as localized and radicular pain, myelopathy, and spinal joint instability. If severe, such as in degenerative disc disease, infections, and trauma, surgical methods are indicated. Some studies reported that compared to anterior cervical discectomy and fusion (ACDF), cervical artificial disc (CAD) could provide better neurological outcomes and reduce the rate of adjacent segment degeneration, whereas other studies reported no difference between the two procedures. **Aims and Objectives:** The aim of this study was to compare surgical outcomes of CAD to anterior cervical discectomy and fusion in the treatment of symptomatic degenerative disc disease in cervical spine. **Materials and Methods:** It was a comparative study with prospective design conducted among 40 symptomatic cervical disc degenerative disease patients (20 patients undergoing CAD and the remaining 20 anterior cervical discectomy and fusion) at the Department of Neurosurgery, Bangur Institute of Neurosciences, IPGMER and SSKM Hospital, Kolkata, from January 2021 to December 2022. Respective surgical procedures were done. All patients were required to return for follow-up. Clinical and radiological evaluations were performed at 1 month, 3 months, 1 year, postoperatively, and last follow-up (more than 18 months). Clinical effectiveness was evaluated by the visual analog scale (VAS) score, Japanese Orthopedic Association (JOA) score (17 points system, 1994 revised edition), and neck disability index (NDI) score. **Results:** Improvement in NDI, VAS, and JOA index was found to be more in CAD as compared to ACDF group with a statistically significant difference as $P < 0.05$. Subsequent surgical intervention was reported among four subjects, out of which one belonged to the CAD group while the rest three to ACDF. Overall success was found to be more in the CAD group (75%) as compared to the ACDF group (55%), though no significant difference was revealed as $P > 0.05$. **Conclusion:** The findings of the present study support the superior longevity and better outcome of CDA, as compared with ACDF, with regard to need for subsequent surgical intervention and also support better improvement in symptoms in subsequent follow-up in patients undergoing CDA as compared to ACDF despite having comparable mean operative time and blood loss.

Key words: Degenerative disc disease; Cervical spine; Anterior cervical discectomy; Cervical artificial disc

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INTRODUCTION

Cervical disc degeneration is known to be a primary cause of neck pain and neurologic symptoms and can cause significant morbidity. Degeneration can be related to radiculopathy or myelopathy due to compression of spinal nerves and/or spinal cord.^{1,2} Cervical disc disease affects up to 84 people/100,000 of the population, with the C7 segment being the most commonly affected. Disc pathology may manifest clinically as localized and radicular pain, myelopathy, and spinal joint instability. If severe, such as in degenerative disc disease, infections, and trauma, surgical methods are indicated.³

Anterior cervical discectomy and fusion (ACDF) which has been considered as the “gold standard” treatment of cervical degenerative diseases was founded by Smith-Robinson and Cloward in the 1950s.⁴ ACDF is a surgery to remove a herniated or degenerative disc in the neck. An incision is made in the neck anterior border of sternocleidomastoid and dissected along fascial plane retracting trachea and esophagus on one side and carotid sheath on the other side to reach anterior cervical disc space and to remove the disc. A graft is inserted to fuse together the bones above and below the disc. ACDF surgery may be an option if physical therapy or medications fails to relieve the radicular pain caused by compressed nerve roots.⁵

ACDF surgery has changed the original mechanical behavior of the spine at the expense of the activity of the fusion segment; and in theory, it may lead to the changes of adjacent vertebral stress distribution and the movement patterns, resulting in biomechanical changes including stress concentration of adjacent segments, compensatory increase in activity, and even instability.⁶⁻⁸ Although it generally provides good outcomes, potential risks include pseudoarthrosis and acceleration of adjacent segment degeneration (ASD).^{9,10}

Cervical artificial disc (CAD) as a motion-preserving alternative was introduced to address these adverse events. The biomechanical advantage of CAD has been demonstrated previously that it can maintain segmental range of motion (ROM) and cervical kinematics, theoretically reducing or avoiding ASD.^{11,12} However, CAD has its own potential disadvantages, such as a higher incidence of heterotopic ossification and implant migration or subsidence, apart from the cost factor. Many investigators have reported randomized control trials comparing CAD with ACDF for the treatment of symptomatic cervical disc disease. However, the findings of these studies are inconsistent.^{13,14} Some studies reported that compared to ACDF, CAD could provide better neurological outcomes and reduce the rate of ASD, whereas other studies reported no difference between the two procedures.¹⁵⁻¹⁷

To the best of our knowledge, few studies have examined the long-term efficacy between the two procedures. Hence, the present study was done to evaluate and compare the long-term safety and efficacy between CAD and ACDF in the treatment of symptomatic degenerative disc disease in cervical spine in a tertiary care center in Eastern India and to compare the post-operative complications and outcomes clinically and radiologically between CAD and ACDF in the treatment of symptomatic degenerative disc disease in cervical spine in a tertiary care center in Eastern India.

Aims and objectives

1. To evaluate and compare the long-term safety and efficacy between cervical artificial disc and Anterior cervical discectomy and fusion in treatment of symptomatic degenerative disc disease in cervical spine in a tertiary care centre in Eastern India.
2. To compare the post operative outcome clinically and radiologically between Cervical artificial disc and Anterior cervical discectomy and fusion in treatment of symptomatic degenerative disc disease in cervical spine in a tertiary care centre in Eastern India.

MATERIALS AND METHODS

It was a comparative study with prospective design conducted among 40 symptomatic cervical disc degenerative disease patients (20 patients undergoing CAD and the remaining 20 anterior cervical discectomy and fusion) in the Department of Neurosurgery, Bangur Institute of Neurosciences, IPGMER, and SSKM Hospital, Kolkata from January 2021 to December 2022. After confirmation of eligibility to enter the study by considering inclusion and exclusion criteria, patients of symptomatic cervical disc degenerative disease were included in our study. A pro forma was designed and findings recorded. There is a random selection of patients with respect to sex (male or female) for the procedure after they fulfill the inclusion and exclusion criteria. Patients were monitored regarding post-operative parameters including radiological and clinical findings.

Inclusion criteria

The following criteria were included in the study:

1. Single-level, radiculopathy;
2. Cervical disc herniation;
3. Degenerative cervical spinal canal stenosis;
4. Conservative treatment for at least 3 months;
5. Adult patients only;
6. No degeneration existing in the adjacent disc.

Exclusion criteria

The following criteria were excluded from the study:

1. Severe facet joint degeneration (bridging osteophytes, intervertebral disc height loss >50%, intervertebral activity <2);
2. Developmental cervical stenosis;
3. Ossification of the posterior longitudinal ligament (PLL);
4. Obviously unstable cervical spine with angular displacement >2° or vertical displacement >2 mm;
5. Osteoporosis, or with spinal compression fractures;
6. Cervical spine congenital anomalies;
7. Cervical spinal cord tumors;
8. Cervical spine infection;
9. Ankylosing spondylitis;
10. A history of cervical spine surgery.

Surgical procedures

Surgery was performed with conventional technique as follows. Briefly, a standard right-sided anterior approach was performed. The symptomatic disc was removed, and then the PLL was removed. For CAD, the cervical disc prosthesis as shown in figure 1 was implanted after accurate measurement and confirmed under c arm as shown in Figure 2 with proper intraoperative technique shown in Figure 3. The Syncage-C or PEEK-Cage with local bone or G bone was implanted into intervertebral space in the ACDF group with G bone implantation under c arm guidance shown in Figures 4 and 5.

Radiographic measurements

Radiographic parameters were collected by screening neutral and dynamic flexion-extension lateral radiographs, including cervical lordosis, operated segmental height, C2-7 ROM, operated segmental ROM, upper segmental ROM and lower segmental ROM, upper segmental height, and lower segmental height. Neutral-position and dynamic flexion-extension lateral radiographs during each follow-up examination were evaluated with the PACS software and a PACS workstation.

Adjacent segment disease (ASD) was assessed through lateral X-ray film and magnetic resonance imaging (MRI) T2-weighted images. The Kellgren X-ray cervical vertebra degeneration system was a method considering cervical degeneration just such as the anterior vertebral osteophyte, disc height collapse, endplate sclerosis, and anterior or posterior slip. The MRI manifestation of ASD was a new formation of intervertebral disc herniation and decreased signal intensity on MRI images using Miyazaki classification. All radiological outcomes were reviewed by an independent spine surgeon and a radiologist, who were unaware of the treatment details. At the last follow-up, the cases whose X-ray and (or) MRI appeared ASD performance were included in the ASD group, otherwise, included in the non-ASD group.

Outcome assessment

All patients were required to return for follow-up. Clinical and radiological evaluations were performed at 1 month, 3 months, 1 year, postoperatively, and last follow-up (more than 18 months). Clinical effectiveness was evaluated by visual analog scale (VAS) score, Japanese Orthopedic Association (JOA) score (17 points system, 1994 revised edition), and neck disability index (NDI) score. The recovery rate (RR) of the JOA score was calculated according to the following formula: $RR = \frac{\text{post-operative scores} - \text{pre-operative scores}}{(17 - \text{pre-operative scores})} * 100\%$.¹⁸

Data were collected and subjected to statistical analysis.

Statistical analysis

Data collected were tabulated in an Excel sheet, under the guidance of a statistician. The means and standard deviations of the measurements per group were used for statistical analysis (SPSS 22.00 for windows; SPSS inc., Chicago, USA). The difference between the two groups was determined using t-test as well as Chi-square test and the level of significance was set at $P < 0.05$.

RESULTS

The mean age in CAD and ACDF groups was 48.79 ± 7.64 and 47.23 ± 8.03 years, respectively. Hence, mean age was comparable among the study groups. In the CAD group, males were a little more while in the ACDF group; females were slightly more, though no significant difference was found. Mean body mass index was comparable among the study groups. About 70% and 65% of the patients in the CAD and ACDF group were able to work at the time of presentation in the hospital (Table 1).

Mean operative time (min) and blood loss (mL) were found to be comparable among the study groups. Mean operative time (min) and blood loss (mL) among the CAD and ACDF group were 77.19 ± 9.42 , 36.85 ± 7.20 , and 76.03 ± 8.37 , 36.06 ± 6.94 , respectively (Table 2).

The mean NDI score improved both in the CAD as well as ACDF groups. NDI score at baseline and 1 year was 54.12, 16.03, and 55.49, 25.61 in CAD and ACDF groups, respectively. Hence, there was more improvement in CAD as compared to the ACDF group with a statistically significant difference as $P < 0.05$ (Table 3).

The mean VAS score improved both in the CAD as well as ACDF groups. VAS score at baseline and 1 year was 78.11, 16.06, and 75.43, 23.61 in CAD and ACDF groups, respectively. Hence, there was more improvement in CAD as compared to the ACDF group with a statistically significant difference as $P < 0.05$ (Table 4).

Table 1: Gender distribution among the study groups

Gender	CAD		ACDF		Chi-square	P-value
	n=20	%	n=20	%		
Male	12	60	9	45	0.42	0.73
Female	8	40	11	55		
Work status (being able to work)	14	70	13	65	0.13	0.84
					t-test	P-value
Mean age (in years)	48.79±7.64		47.23±8.03		0.77	0.58
Mean BMI, kg/m ²	27.44±3.69		28.03±3.51		0.86	0.41

CAD: Cervical artificial disc, ACDF: Anterior cervical discectomy and fusion, BMI: body mass index

Table 2: Operative parameters among the study groups

Variables	CAD		ACDF		t-test	P-value
	Mean	SD	Mean	SD		
Operative time (min)	77.19	9.42	76.03	8.37	0.48	0.71
Blood loss (mL)	36.85	7.20	36.06	6.94	0.32	0.78

CAD: Cervical artificial disc, ACDF: Anterior cervical discectomy and fusion, SD: Standard deviation

Table 3: Comparison of NDI scores at different intervals among the study groups

Interval	CAD		ACDF		t-test	P-value
	Mean	SD	Mean	SD		
Baseline	54.12	14.83	55.49	13.30	0.19	0.81
1 month	49.26	13.05	51.37	11.58	0.85	0.48
3 month	21.64	9.81	29.74	10.44	3.71	0.022*
6 month	17.10	8.17	26.04	8.92	4.06	0.009*
1 year	16.03	7.60	25.61	7.55	4.23	0.007*

*Statistically significant, CAD: Cervical artificial disc, ACDF: Anterior cervical discectomy and fusion, NDI: Neck Disability Index, SD: Standard deviation

Table 4: Comparison of VAS score at different intervals among the study groups

Interval	CAD		ACDF		t-test	P-value
	Mean	SD	Mean	SD		
Baseline	78.11	12.09	75.43	13.46	0.47	0.74
1 month	62.22	11.5	63.45	10.32	0.43	0.77
3 month	20.07	8.98	28.70	9.24	3.91	0.013*
6 month	16.49	7.51	24.25	8.17	4.14	0.008*
1 year	16.06	7.72	23.61	7.14	4.19	0.005*

*Statistically significant, CAD: Cervical artificial disc, ACDF: Anterior cervical discectomy and fusion, VAS: Visual analog scale, SD: Standard deviation

Table 5: Comparison of JOA score at different intervals among the study groups

Interval	CAD		ACDF		t-test	P-value
	Mean	SD	Mean	SD		
Baseline	10.2	1.47	9.98	1.40	0.82	0.38
1 year	14.1	1.74	13.76	1.39	1.2	0.17

CAD: Cervical artificial disc, ACDF: Anterior cervical discectomy and fusion, JOA: Japanese Orthopaedic Association, SD: Standard deviation

The mean JOA score was comparable among the CAD (10.2) and ACDF (9.98) groups at baseline. The mean

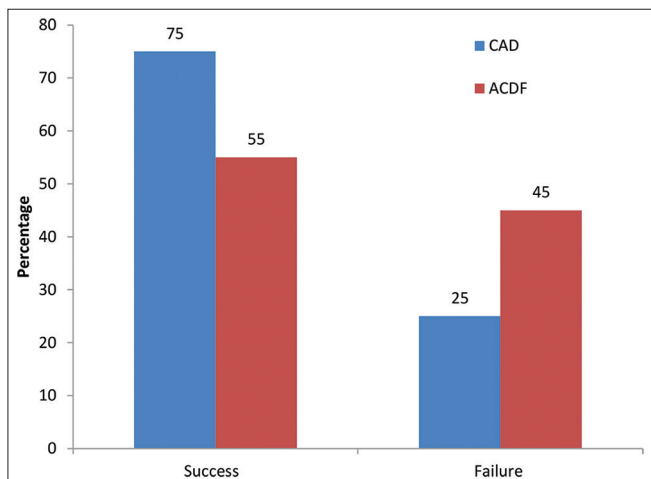
JOA score improved in both groups after 1 year, that is, 14.1 in the CAD group and 13.76 in the ACDF group. When the JOA score after 1 year was compared in CAD and ACDF groups, an insignificant difference was found as P>0.05 (Table 5).

Subsequent surgical intervention was reported among four subjects, out of which one belonged to the CAD group while the rest three to ACDF. The reason for subsequent surgical intervention in the CAD group was device removal while in the ACDF group; it was due to device removal and reoperations due to ASD. Overall success was found to be more in the CAD group (75%) as compared to the ACDF group (55%), though no significant difference was revealed as P>0.05 (Graph 1).

DISCUSSION

ACDF is a safe and effective treatment for cervical spondylosis causing radiculopathy or myelopathy. However, the elimination of segmental motion with arthrodesis may increase the risk of ASD. Cervical disc arthroplasty (CDA) has gained momentum over the last decade in an effort to overcome this critical limitation of ACDF. CDA achieves the goals of decompression of the neural elements and maintenance of disc height and segmental lordosis, while also preserving physiologic segmental motion. As a motion-sparing technology, CDA may mitigate the development of symptomatic ASD and need for subsequent reoperation. Nonetheless, clinical studies of CDA compared with ACDF have reported conflicting results.^{19,20}

In the CAD group, males were a little more while in the ACDF group; females were slightly more, though no



Graph 1: Overall comparison of success among the study groups



Figure 4: Post-operative radiograph image of anterior cervical discectomy and fusion with g bone and plating

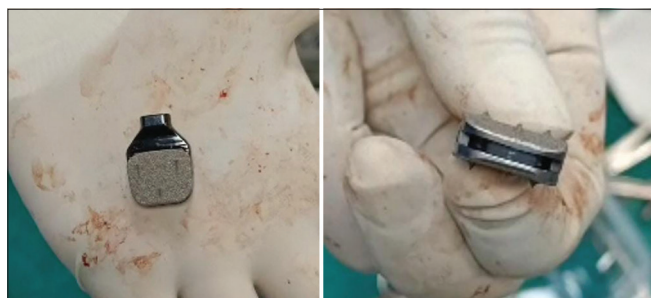


Figure 1: Implant used as an artificial disc in our study in our institute

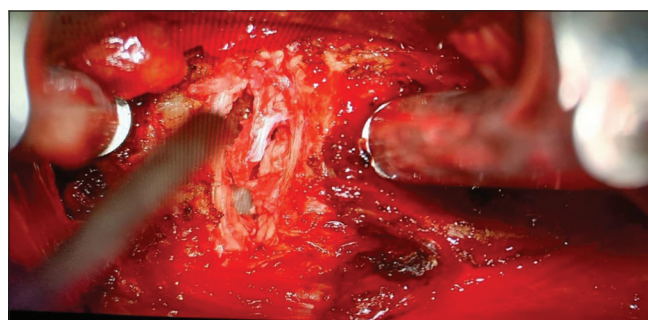


Figure 5: Intraoperative pictures during anterior cervical discectomy and fusion surgery

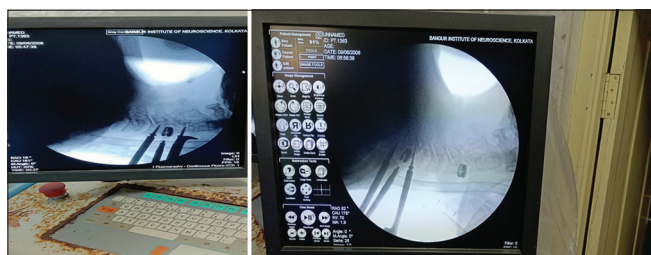


Figure 2: Intraoperative c-arm images of cervical artificial disc implant

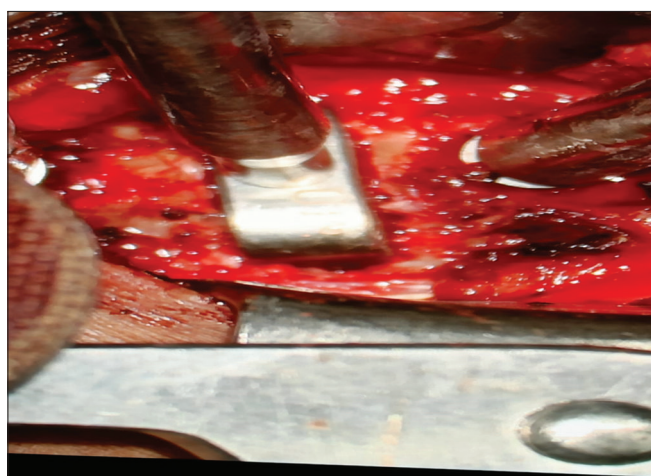


Figure 3: Intraoperative image showing insertion of artificial disc in disc space

significant difference was found. The mean age in the CAD and ACDF groups was 48.79 ± 7.64 and 47.23 ± 8.03 years, respectively. Hence, mean age was comparable among the study groups. Zigler et al.,²¹ in their study showed that similar age and gender distribution.

Mean operative time (min) and blood loss (mL) were found to be comparable among the study groups. Mean operative time (min) and blood loss (mL) among the CAD and ACDF group were 77.19 ± 9.42 , 36.85 ± 7.20 , and 76.03 ± 8.37 , 36.06 ± 6.94 , respectively in this study. Zigler et al.,²¹ in their study reported that ACDF group has statistically significantly lower operative time and estimated blood loss, although these differences are not thought by the authors to be clinically significant.

In the present study, the mean NDI score improved both in the CAD as well as ACDF group. NDI score at baseline and 1 year was 54.12, 16.03, and 55.49, 25.61 in CAD and ACDF group, respectively. Hence, there was more improvement in CAD as compared to the ACDF group with a statistically significant difference as $P < 0.05$. According to Davis et al.,²² patients in both groups showed significant improvements in NDI score from pre-operative

baseline to each time point. However, the TDR patients experienced significantly greater improvement than ACDF patients in NDI score at all-time points postoperatively. This is in accordance to the present study. Jackson²³ in their study similarly revealed that 2–10-year data indicate that both TDR and ACDF are effective treatments for symptomatic cervical degenerative disc disease with regard to neck and arm pain. There is a trend for better early and long-term results with regard to NDI scores in the TDR patients. Radcliff et al.,²⁴ in their study found that cervical total disc replacement (Mobi-C) patients had significantly more improvement than ACDF patients in terms of NDI score which is similar to the present study.

The mean VAS score improved both in the CAD as well as ACDF group. VAS score at baseline and 1 year was 78.11, 16.06, and 75.43, 23.61 in CAD and ACDF group, respectively. Hence, there was more improvement in CAD as compared to ACDF group with a statistically significant difference as $P < 0.05$ in this study. Radcliff et al.,²⁴ in their study revealed that cervical total disc replacement (Mobi-C) patients had significantly more improvement than ACDF patients in terms of VAS which is similar to the present study. Jackson²³ in their study similarly revealed that there is a trend for better early and long-term results with regard to VAS neck pain, arm pain, and NDI scores in the TDR patients. According to Davis et al.,²² patients in both groups showed significant improvements in visual analog scale (VAS) neck pain score, and VAS arm pain score from preoperative baseline to each time point. However, the TDR patients experienced significantly greater improvement than ACDF patients in VAS neck pain score at 6 weeks, and at 3, 6, and 12 months postoperatively. This is in accordance to the present study.

The mean JOA score was comparable among the CAD (10.2) and ACDF (9.98) groups at baseline. The mean JOA score improved in both groups after 1 year, that is, 14.1 in the CAD group and 13.76 in the ACDF group. When the JOA score after 1 year was compared in CAD and ACDF groups, an insignificant difference was found as $P > 0.05$ in this study. Similar results were revealed by Wang et al.,²⁵ Ding et al.,⁶ in their study.

In the present study, subsequent surgical intervention was reported among four subjects, out of which one belonged to the CAD group while the rest three to ACDF. Reason for subsequent surgical intervention in the CAD group was device removal while in the ACDF group; it was due to device removal and reoperations due to ASD. Overall success was found to be more in the CAD group (75%) as compared to the ACDF group (55%), though no significant difference was revealed as $P > 0.05$.

Other studies (using other implant systems) have also established more improvement in outcome and lower rates of reoperation with cTDR compared with ACDF for treatment of single-level pathology. Not unexpectedly, the rate of major neurological adverse events and gait dysfunction was low in both study populations, confirming the safety of both procedures. In contrast to previous studies, there was no significant increase in dysphagia associated with ACDF at any time point in this study using a validated dysphagia outcome measure.^{26–28} Radcliff et al.,²⁴ in their study showed that the Mobi-C patients had significantly more satisfaction with treatment at 60 months. The reoperation rate was significantly lower with Mobi-C (4%) versus ACDF (16%). There were no significant differences in the adverse event rate between groups. These findings are in accordance to the present study.

Jackson²³ in their study similarly revealed that 2–10-year data indicate that both TDR and ACDF are associated with low complication rates. In a meta-analysis by Badhiwala et al.,²⁹ the pooled treatment effect of CDA in reducing adjacent-level reoperations was statistically significant and the magnitude of the effect was quite large. According to Davis et al.,²² reoperation rate was significantly higher in the ACDF group at 11.4% compared with 3.1% for the TDR group. Furthermore, at 24 months, TDR demonstrated statistical superiority over ACDF based on overall study success rates. This is in accordance to the present study.

Strengths of the study include the rigorous methodology involving prospective randomization with adequate statistical power. As a result of randomization, at baseline, the demographics and outcome scores were balanced between groups.

Limitations of the study

The sample size of our study is small so it may affect the accuracy of results in the study.

CONCLUSION

It can be concluded from the results that CDA was associated with a statistically significant lower rate of index-level reoperation at all follow-up time points examined. The findings of the present study support the superior longevity and better outcome of CDA, as compared with ACDF, with regard to need for subsequent surgical intervention and also support better improvement in symptoms in subsequent follow-up in patients undergoing CDA, as compared to ACDF despite having comparable mean operative time and blood loss.

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