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Impact of Cervical Disc Arthroplasty vs Anterior Cervical Discectomy and Fusion on Driving Disability: Post Hoc Analysis of a Randomized Controlled Trial With 10-Year Follow-Up

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ABSTRACT

Background: Driving an automobile requires the ability to turn the neck laterally. Anecdotally, patients with multilevel fusions often complain about restricted turning motion. The purpose of this study was to compare the effectiveness of cervical disc arthroplasty (CDA) with anterior cervical discectomy and fusion (ACDF) on driving disability improvement at 10-year follow-up after a 2-level procedure.

Methods: In the original randomized controlled trial, patients with cervical radiculopathy or myelopathy at 2 levels underwent CDA or ACDF. The driving disability question from the Neck Disability Index was rated from 0 to 5 years preoperatively and up to 10 years postoperatively. Severity of driving disability was categorized into “none” (score 0), “mild” (1 or 2), and “severe” (3, 4, or 5). Score and severity were compared between groups.

Results: Out of 397 patients, 148 CDA and 118 ACDF patients had 10-year follow-up. Driving disability scores were not different between the groups preoperatively (CDA: 2.65; ACDF: 2.71, $P = 0.699$). Postoperatively, the scores in the CDA group were significantly lower than those in the ACDF group at 5 (0.60 vs 1.08, $P \leq 0.001$) and 10 years (0.66 vs 1.07, $P = 0.001$). Mean score improvement in the CDA group was significantly greater than the ACDF group at 10-year follow-up (-1.94 vs -1.63 , $P = 0.003$). The majority of patients reported severe driving disability (CDA: 56.9%, ACDF: 58.0%, $P = 0.968$) before surgery. After surgery, a greater proportion of patients in the CDA group had neck pain-free driving compared with the ACDF group at 5 (63.3% vs 41.8%, $P < 0.001$) and 10 years (61.8% vs 41.2%, $P = 0.003$).

Conclusion: In patients with cervical radiculopathy/myelopathy and 2-level disease, CDA provided greater improvements in driving disability as compared with ACDF at 10-year follow-up. This is the first report of its kind. This finding may be attributable to preservation of motion associated with CDA.

Clinical Relevance: This study provides valuable information regarding the improvement of driving disability after both CDA and ACDF. It demonstrates that both procedures result in significant improvements, with CDA resulting in even better improvements than ACDF, up to 10 year follow-up.

Level of Evidence: 3.

Cervical Spine

Keywords: driving disability, cervical disc arthroplasty, anterior cervical discectomy, fusion

INTRODUCTION

Driving an automobile requires rotational cervical range of motion (ROM).¹ Not surprisingly, patients with cervical radiculopathy or myelopathy have increased driving disability, which is thought to be due to diminished cervical ROM and pain.² Despite the frequency of driving complaints in patients with cervical spine pathology, few studies have investigated it, and none have been published with long-term follow-up.²

Anterior cervical discectomy and fusion (ACDF) is the traditional surgical treatment strategy for patients with single-level or 2-level symptomatic cervical degenerative disc disease (DDD). Cervical disc arthroplasty (CDA) has emerged as an effective alternative for DDD with cervical myelopathy and/or radiculopathy.^{3–5} CDA is motion preserving, a characteristic that is potentially more important when considering 2-level disease. In patients with single-level disease, driving disability complaints

Table 1. Driving subsection of Neck Disability Index questionnaire.

Score	Driving
0	I can drive my car without any neck pain.
1	I can drive my car as long as I want with slight pain in my neck.
2	I can drive my car as long as I want with moderate pain in my neck.
3	I can't drive my car as long as I want because of moderate pain in my neck.
4	I can hardly drive at all because of severe pain in my neck.
5	I can't drive my car at all.

were not different between CDA and ACDF at 2-year follow-up.² However, the impact of CDA vs ACDF on driving disability in patients with 2-level disease at long-term follow-up remains unknown.

The purpose of this study was to determine the effect of CDA as compared to ACDF on driving disability in patients with 2-level cervical disease at up to 10-year follow-up. We hypothesized that ACDF patients would have more complaints than CDA patients.

METHODS

This is a post hoc analysis of prospective, multicenter, randomized, US Food and Drug Administration Investigational Device Exemption trial comparing CDA (Prestige LP, Medtronic, Memphis, TN) to ACDF in patients with 2-level disease.⁶ The randomized investigational device exemption study was extended with follow-up up to 10 years as a postapproval study.⁷ The study protocol and

informed consent form received Investigational Review Board approval (Western Investigational Review Board, protocol no. 20060636, study no. 1078218).

In summary, eligible subjects were older than 18 years with cervical DDD at 2 adjacent cervical levels (C3-C7) involving intractable radiculopathy and/or myelopathy. Additional inclusion criteria included: unresponsive to nonoperative treatment for at least 6 weeks or presence of progressive symptoms or signs of nerve root/spinal cord compression, no previous surgical intervention at the involved levels or any subsequent planned/staged surgical procedure at the involved or adjacent level(s), preoperative neck pain score ≥ 8 (out of a total of 20) and preoperative Neck Disability Index (NDI) score ≥ 30 . Patients were randomized in a 1:1 ratio to receive either CDA or ACDF. The surgical techniques have been previously published.⁶

The NDI questionnaire⁸ was completed preoperatively and postoperatively at 6 weeks, 3 months, 6 months, 1 year, 2 years, 3 years, 5 years, 7 years, and 10 years. Driving disability was assessed in question 8 of the NDI questionnaire and the driving disability score was rated on an ordinal scale of 0–5 (Table 1). The severity of driving disability was further categorized into the severity group as none (score of 0), mild (1 or 2), or severe (3, 4, or 5).

Statistical Methods

Differences in driving disability scores between the treatment groups were assessed using Wilcoxon

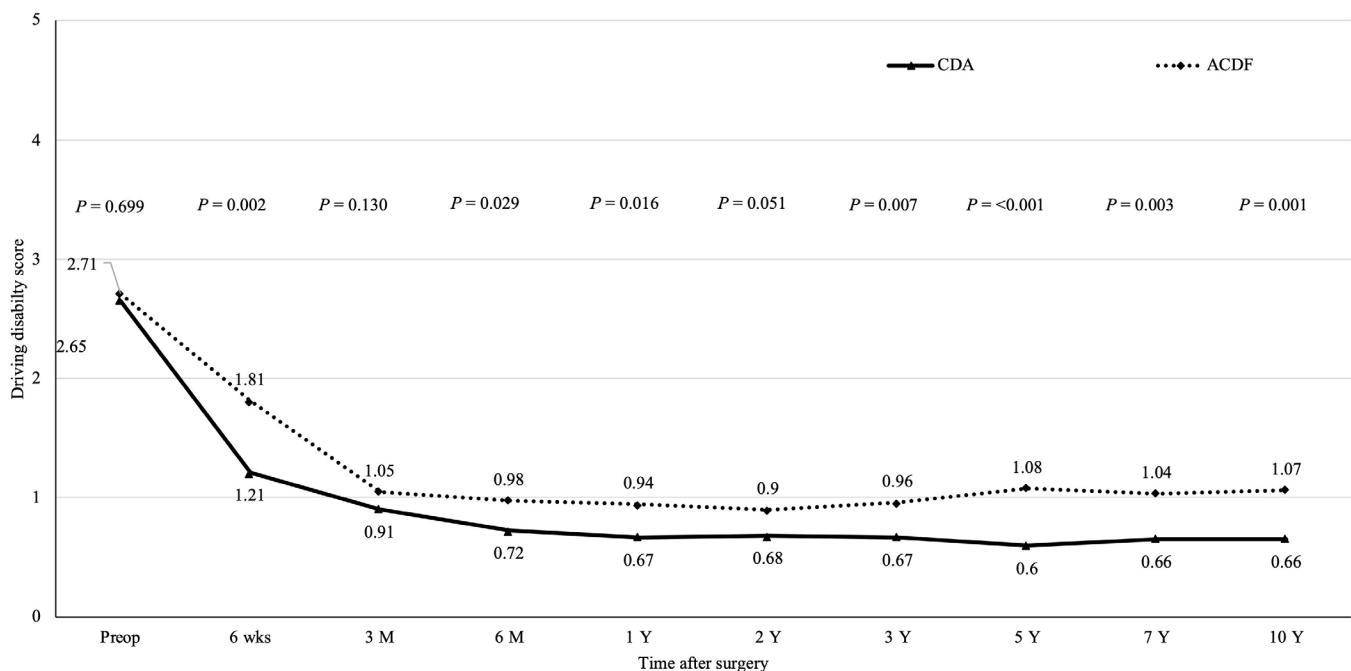


Figure 1. Mean driving disability scores in cervical disc arthroplasty (CDA) vs anterior cervical discectomy (ACDF) and fusion patients over time. *P* values represent the results of Wilcoxon rank-sum test comparing treatment groups.

rank-sum test at each timepoint. The overall difference in driving disability scores postoperatively between the treatment groups across different timepoints was assessed using a repeated measure analysis with a generalized linear model. The full model included time, treatment effect, and interaction between time and treatment effect, as well as the preoperative score as the covariate to adjust for the baseline differences. The driving disability score improvement at each timepoint from preoperative was compared with a generalized linear model, again controlling for preoperative scores. A similar repeated measure analysis for assessing the overall difference in the driving disability score improvements between the treatment groups across different timepoints was also performed with a generalized linear model.

The driving disability severity was compared between the treatment groups at each timepoint by using Fisher exact test. Level of significance was set to 0.05. All data analyses were performed with SAS version 9.4.

RESULTS

Demographics and Baseline Information

As previously reported, 397 patients were randomized to CDA or ACDF (209 CDA and 188 ACDF).⁷ Among them, 148 (70.8%) CDA and 118 (62.7%) ACDF patients completed 10-year follow-up. Of those who were not included, 28 CDA patients and 28 ACDF patients were from a study site that did not participate in postapproval study, 7 CDA and 18 ACDF patients withdrew, and 2 CDA and 3 ACDF patients had died. The remainder were lost to follow-up. The demographics between the CDA group (mean age: 47.1 years, 56.0% women, 93.3% white) and the ACDF group (mean age: 47.3 years, 52.1% women, 91.5% white) were not different ($P > 0.05$), except that more CDA patients than ACDF patients had worked preoperatively (69.9% vs 60.1%, $P =$

0.045) and have been previously reported.⁷ Preoperative medical conditions, medication usage, and baseline clinical measures, including neck pain, NDI, and Short Form-36 were also not different between groups. Overall demographics were not significantly different between those who were initially enrolled and those who completed 10-year follow-up.

Driving Disability Score

Driving scores were not different at enrollment (Figure 1) (CDA: 2.7; ACDF: 2.7, $P = 0.70$). The driving disability score improved postoperatively up to 10 years in both CDA and ACDF groups (Figure 1). Driving disability scores were significantly lower in the CDA group compared to the ACDF group at all postoperative timepoints except at 3 months and 2 years. Driving disability scores between the treatment groups across time were significantly different ($P = 0.003$).

Driving Disability Score Improvement

The preoperative to postoperative driving disability score improvement was significantly greater in the CDA group than the ACDF group at all timepoints except 3 months (Table 2). The overall driving disability score improvement between the treatment groups across different timepoints was significantly different ($P = 0.002$).

Driving Disability Severity

Preoperatively, the severity of driving disability was evenly distributed between groups ($P = 0.968$) with few subjects reporting neck pain-free in driving (CDA: 1.0%, ACDF: 0.5%) and the majority having severe driving disability (CDA: 56.9%, ACDF: 58.0%) (Table 3, Figure 2). Postoperatively, more subjects in the CDA group had neck pain-free driving as compared with the ACDF group at 6 weeks, 6 months, 3 years, 5 years, 7 years, and 10 years. Furthermore,

Table 2. Summary and comparison of driving disability score improvement from preoperative score over time.

Timepoint	Cervical Disc Arthroplasty (N = 209)	Anterior Cervical Discectomy and Fusion (N = 188)	P ^a
6 wk	-1.44 ± 1.44	-0.88 ± 1.68	<0.001
3 mo	-1.76 ± 1.25	-1.61 ± 1.18	0.103
6 mo	-1.94 ± 1.23	-1.68 ± 1.22	0.016
1 y	-1.98 ± 1.22	-1.68 ± 1.16	0.006
2 y	-1.96 ± 1.15	-1.75 ± 1.21	0.032
3 y	-1.94 ± 1.22	-1.68 ± 1.24	0.007
5 y	-2.01 ± 1.17	-1.57 ± 1.38	<0.001
7 y	-1.92 ± 1.26	-1.61 ± 1.31	0.004
10 y	-1.94 ± 1.22	-1.63 ± 1.39	0.003

^aP values were from a generalized linear model adjusted from preoperative score as the covariate.

Table 3. Summary and comparison of driving disability severity groups over time.

Timepoint	Severity Group	Cervical Disc Arthroplasty (N = 209)	Anterior Cervical Discectomy and Fusion (N = 188)	P ^a
Preoperative	None	2/209 (1.0%)	1/188 (0.5%)	0.968
	Mild	88/209 (42.1%)	78/188 (41.5%)	
	Severe	119/209 (56.9%)	109/188 (58.0%)	
6 wk	None	67/204 (32.8%)	42/179 (23.5%)	0.001
	Mild	106/204 (52.0%)	83/179 (46.4%)	
	Severe	31/204 (15.2%)	54/179 (30.2%)	
3 mo	None	94/202 (46.5%)	67/177 (37.9%)	0.217
	Mild	87/202 (43.1%)	91/177 (51.4%)	
	Severe	21/202 (10.4%)	19/177 (10.7%)	
6 mo	None	113/203 (55.7%)	79/171 (46.2%)	0.014
	Mild	77/203 (37.9%)	66/171 (38.6%)	
	Severe	13/203 (6.4%)	26/171 (15.2%)	
1 y	None	119/202 (58.9%)	78/164 (47.6%)	0.068
	Mild	66/202 (32.7%)	64/164 (39.0%)	
	Severe	17/202 (8.4%)	22/164 (13.4%)	
2 y	None	113/197 (57.4%)	78/157 (49.7%)	0.180
	Mild	69/197 (35.0%)	59/157 (37.6%)	
	Severe	15/197 (7.6%)	20/157 (12.7%)	
3 y	None	110/183 (60.1%)	68/146 (46.6%)	0.044
	Mild	59/183 (32.2%)	60/146 (41.1%)	
	Severe	14/183 (7.7%)	18/146 (12.3%)	
5 y	None	105/166 (63.3%)	56/134 (41.8%)	<0.001
	Mild	50/166 (30.1%)	59/134 (44.0%)	
	Severe	11/166 (6.6%)	19/134 (14.2%)	
7 y	None	94/153 (61.4%)	53/120 (44.2%)	0.014
	Mild	46/153 (30.1%)	49/120 (40.8%)	
	Severe	13/153 (8.5%)	18/120 (15.0%)	
10 y	None	89/144 (61.8%)	47/114 (41.2%)	0.003
	Mild	46/144 (31.9%)	51/114 (44.7%)	
	Severe	9/144 (6.3%)	16/114 (14.0%)	

^aP values were from Fisher exact test.

less subjects in the CDA group had severe driving disability as compared with the ACDF group at 6 weeks, 6 months, 3 years, 5 years, 7 years, and 10 years.

DISCUSSION

Driving disability is a common complaint among patients with neck disease, including those with cervical

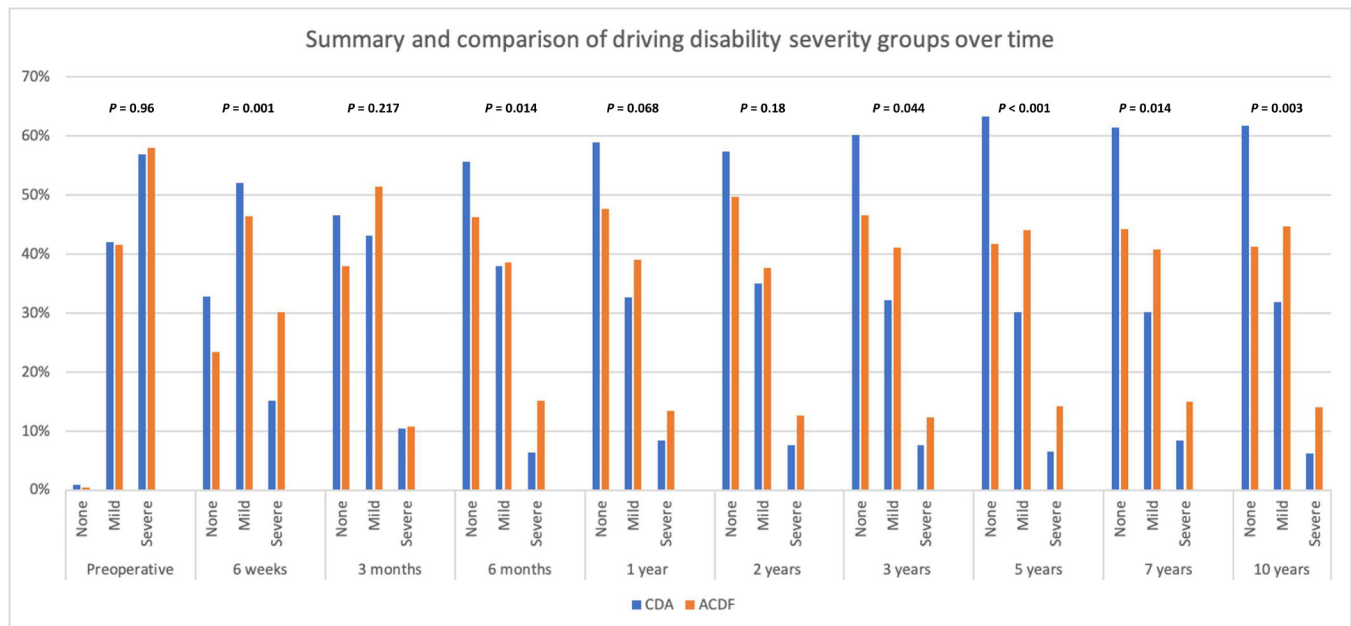


Figure 2. Summary and comparison of driving disability severity groups in cervical disc arthroplasty (CDA) vs anterior cervical discectomy and fusion (ACDF) patients over time. P values represent the results of the Fisher exact test.

DDD.^{2,9} Despite the frequency of this complaint in cervical patients, there is no consensus on return to driving.¹⁰ Cervical ROM is particularly important to driving, and the long-term differences between a motion-preserving CDA and motion-eliminating ACDF are unknown.^{1,11} This is particularly true for multilevel procedures, where more fusion may limit cervical ROM more than a single-level surgery. At 2-year follow-up, there was no difference between single-level CDA and ACDF with respect to driving disability.² The purpose of this study was to compare driving disability between CDA and ACDF in patients with 2-level disease at up to 10 years postoperatively.

In this post hoc analysis of a prospective randomized controlled trial, we found that in patients with 2-level cervical disc disease with radiculopathy and/or myelopathy, CDA provides greater improvements in driving disability as compared with ACDF up to 10 years postoperatively. Both groups had substantial improvements in driving disability rapidly by 6 weeks; however, CDA remained superior at multiple timepoints.

A study examining 2-year results from a randomized trial of CDA and ACDF found that both groups of patients had similar improvements in driving disability at 6-week and 2-year follow-up. The rapid improvement in pain complaints is not surprising and the return to normal driving is consistent with work showing that driving reaction times are almost normal at discharge.¹² Senior surgeons are more likely to allow for early return to driving, perhaps indicative of experience aligning with these research findings. In contrast, the present study demonstrated that CDA patients had greater improvements in driving disability than ACDF patients, and a greater proportion of CDA patients had pain-free driving than ACDF patients, benefits that were sustained to 10 years. This may be due to the difference of 1-level surgery in the previously cited study vs 2-level surgery in the present study, as well as the possible increasing importance of maintaining ROM as more levels are treated. Indeed, not surprisingly, patients who undergo CDA have been shown to have increased overall cervical ROM and segmental ROM as compared to patients who undergo ACDF in all planes of motion, including flexion-extension, rotation, and lateral bending.^{13,14} Driving in particular may be impacted by changes in ROM, because, as previously stated, it relies heavily on rotation.¹ It should be noted that the driving disability question of the NDI focuses on pain and does not specifically address ROM; restrictions regarding

ROM were not specifically addressed in the present study, nor were ROM parameters measured.

Furthermore, the present study demonstrated that this superiority of CDA over ACDF in driving disability is persistent over time up to 10 years postoperatively. It is also possible that the long-term superiority may be due to reduced rates of adjacent segment disease with CDA vs ACDF. Rates of adjacent segment disease are thought to be lower in CDA vs ACDF patients.¹⁵ Adjacent segment disease may impair ROM, which may interfere with driving ability. Importantly, ACDF patients still do well, with rapid improvements by 6 weeks postoperatively which continue to improve over 10 years.

Limitations

First, while the NDI is a validated patient-reported outcome tool for assessing clinical outcomes after CDA, its individual components are not.⁸ As such, it is difficult to evaluate the clinical relevance of the absolute improvements in the response to the driving question and in particular, that of a 0.3–0.4 difference when considering the superiority of CDA over ACDF. It was for this reason that the responses were categorized into pain-free driving, mild disability, and severe disability and further analyzed as such. The findings remained similar: overall, a higher proportion of patients in the CDA group had neck pain-free driving as compared with the ACDF group at multiple timepoints up to 10 years out.

Second, this study did not assess the timeline for return to driving. While the findings of this study may provide guidance, they only report on the subjective experiences of patients; this study does not measure reaction time or other factors necessary to operate a vehicle safely. Reaction times are known to be altered in patients undergoing spine surgery.¹⁶ Overall, there is no consensus on when patients can return to driving after anterior cervical surgery.¹⁰ Opioid use is an absolute contraindication to driving, and further recommendations must be made on an individual basis.

Third, the use of the c-collar and instructions on return to driving were left to the surgeon's discretion. This may impact the results of the driving disability question, especially in the short term. However, collar wear and postoperative instruction are unlikely to have persistent effects up to 10 years postoperatively.

Fourth, the patients were not blinded to their treatment in this study, which may introduce a source of bias if the patient did not receive their desired treatment.

Fifth, the lost to follow-up rate was substantial in this study—30% in the CDA group and 40% in the ACDF group. This may influence the findings.

Finally, this study is a post hoc analysis and the original study was not designed to specifically study driving disability, thereby limiting the conclusions.

CONCLUSION

We found that patients with 2-level cervical disc disease had, on average, improvements in driving disability after both CDA and ACDF. Mean improvements for CDA patients were greater, and this difference was maintained up to 10 years postoperatively. Surgeons may use this information when deciding between CDA and ACDF and to counsel patients on appropriate expectations regarding driving after surgery.

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