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RANDOMIZED TRIAL

Adjacent Segment Motion After Anterior Cervical Discectomy and Fusion *Versus* ProDisc-C Cervical Total Disk Arthroplasty

Analysis from a Randomized, Controlled Trial

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Study Design . *Post hoc* analysis of data acquired in a prospective, randomized, controlled trial.

Objective. To compare adjacent segment motion after anterior cervical discectomy and fusion (ACDF) *versus* cervical total disc arthroplasty (TDA).

Summary of Background Data. TDA has been designed to be a motion-preserving device, thus theoretically normalizing adjacent segment kinematics. Clinical studies with short-term follow-up have yet to demonstrate a consistent significant difference in the incidence of adjacent segment disease.

Methods. Two hundred nine patients at 13 sites were treated in a prospective, randomized, controlled trial of ACDF *versus* TDA for single-level symptomatic cervical degenerative disc disease (SCDD). Flexion and extension radiographs were obtained at all follow-up visits. Changes in ROM were compared using the Wilcoxon signed-rank test and the Mann-Whitney *U* test. Predictors of postoperative ROM were determined by multivariate analysis using mixed effects linear regression.

Results. Data for 199 patients were available with 24-month follow-up. The groups were similar with respect to baseline demographics. A significant increase in motion at the cranial and caudal adjacent segments after surgery was observed in the ACDF group only (cranial: ACDF: +1.4° (0.4, 2.4), $P = 0.01$; TDA: +0.8°, (−0.1, +1.7), $P = 0.166$; caudal: ACDF: +2.6° (1.3, 3.9), $P < 0.0001$; TDA: +1.3, (−0.2, +2.8), $P = 0.359$). No significant difference in adjacent segment ROM was observed between ACDF and TDA. Only time was a significant predictor of postoperative ROM at both the cranial and caudal adjacent segments.

Conclusion. Adjacent segment kinematics may be altered after ACDF and TDA. Multivariate analysis showed time to be a significant predictor of changes in adjacent segment ROM. No association between the treatment chosen (ACDF *vs.* TDA) and ROM was observed. Furthermore clinical follow-up is needed to determine whether possible differences in adjacent segment motion affect the prevalence of adjacent segment disease in the two groups.

Key words: adjacent segment ROM, adjacent segment motion, pseudoarthrosis, radiculopathy, radiographs, total disc arthroplasty.

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Anterior cervical discectomy and fusion (ACDF) is considered by many surgeons to represent standard of care for the surgical treatment of cervical myelopathy or radiculopathy with degenerative disc disease.[1] Among spinal procedures, ACDF has demonstrated high rates of clinical success in terms of relief of symptoms and favorable outcomes.[2,3] Limitations of ACDF, however, are well documented and include pseudarthrosis, graft donor site morbidity, and adjacent segment disease.[4–6] Long-term radiographic studies have reported variable rates of adjacent segment degeneration ranging as high as 92%, and the incidence of clinically significant adjacent segment disease (ASD) has been reported in up to 25% of patients at 10 years follow-up, with an annual incidence of 2.9%.[5,6]

The etiology of adjacent segment degeneration has been hypothesized to be increased tissue strain and/or increased intradiscal pressures at levels adjacent to the fusion.[7,8] Reoperation for ASD after ACDF has been reported to range from 6% to 16%.[5,9] This concern has led to the development of motion-preserving devices such as total disc arthroplasty (TDA). Preservation of motion at the treatment level may allow more normal kinematics at the adjacent segments, thus potentially

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delaying or preventing ASD.[10] The Food and Drug Administration (FDA) has recently approved several cervical disc arthroplasty designs after successful trials with 2-year follow-up.[11–13] Biomechanical studies have suggested that, compared to fusion, disc arthroplasty results in more physiologic motion at the treatment and adjacent levels.[10] Clinical studies to date have yet to demonstrate significant differences in either radiographic or clinical outcomes related to the adjacent segments after fusion or arthroplasty.

A multicenter, randomized, controlled investigational device exemption (IDE) trial for the ProDisc-C (Synthes USA Products, LLC, West Chester, PA) TDA has shown similar clinical outcome when compared to ACDF for symptomatic cervical disc degeneration.[13] At 2-year follow-up, this device has been shown to preserve motion at the index level when compared to ACDF. The purpose of this study is to determine the effect of ACDF *versus* TDA on postoperative adjacent level ROM over time by conducting a *post hoc* analysis of radiographic data collected during the IDE trial.

MATERIALS AND METHODS

Study Group

Two hundred nine patients were enrolled at one of 13 centers (IDE #G030059) and randomized in a 1:1 ratio to either control (ACDF) or investigational (TDA) groups between August 2003 and October 2004. Criteria for enrollment in the IDE trial consisted of: single-level symptomatic cervical disc disease (SCDD) with radiculopathy or myelopathy unresponsive to nonoperative management for a minimum of 6 weeks and a neck disability index (NDI) score of greater than 15/50 (30%).[13] Inclusion criterion for the current study was availability of preoperative radiographs and at least one set of postoperative radiographs. Exclusion criteria included segmental instability (defined as $\geq$ 3 mm of translation or at least 11° of flexion/extension relative to adjacent levels), evidence of facet arthrosis, no baseline measurement of cervical ROM, fusion adjacent to the level of intervention, any prior surgical interventions at the level of SCDD, as well as other medical comorbidities. These criteria have been previously presented.[13] Details of the treatment and postoperative protocols have been previously described.[13]

Data Collection

Radiographic evaluation was performed before surgery and after surgery at 6 weeks and 3, 6, 12, 18, and 24 months after operation. A series of three cervical spine plain radiograph lateral views in neutral, maximum active flexion, and maximum active extension was obtained at each time point. Radiographs were sent to an independent third party for radiographic measurement. Radiographic ROM from flexion through extension at levels cranial and caudal to the treatment level was calculated using pattern recognition software (Quantitative Motion Analysis, Medical Metrics, Houston, TX). This method has been used by other investigators to track vertebral motion with a high level of accuracy.[14] Mean error is reported as approximately 0.5° with excellent inter- and intraobserver reliability (Pearson A, Sengupta D, Wharton N, *et al,* unpublished data, ISSL 2007).

Statistical Analysis

Statistical comparisons of demographic variables between the treatment groups were performed using the Wilcoxon rank sum test for continuous and ordinal variables and Fisher exact test for categorical variables. Statistical significance was defined as $P < 0.05$. Ninety five percent confidence intervals are reported in lieu of *post hoc* power analyses.[15]

Postoperative ROM at the instrumented, cephalad, and caudal levels were analyzed using comparisons of means and regression analyses. First, comparisons of 24-month ROM and preoperative ROM by treatment specific to each level were made, for those patients with these data points available. The data were then aggregated and analyzed for all levels combined. The Wilcoxon signed-rank test for paired nonparametric data were used for within-group comparisons and the Mann-Whitney *U* test for unpaired nonparametric was used for between-group comparisons.

Next, linear mixed effects regression analyses were used to model postoperative ROM at the index, cranial adjacent, and caudal adjacent levels. Variables (main effects) included in the model were: treatment (ACDF or TDA), index level, and time. A two-way interaction between time and treatment was included as an additional variable (time-treatment). The time-treatment variable is used to investigate whether a significant interaction occurs between the treatment and time. The

TABLE 1. Patient Demographics

	TDA N = 100	ACDF N = 99	Two-sided *P*
Implant Level			0.80
C3–C4	2 (2%)	1 (1%)	
C4–C5	9 (9%)	6 (6.1%)	
C5–C6	57 (57%)	57 (57.6%)	
C6–C7	32 (32%)	35 (35.4%)	
Age	42.1 ± 8.4	43.5±7.1	0.17
Sex			0.78
Male	44 (44%)	46 (46.5%)	
Female	56 (56%)	53 (53.5%)	
Smoking Status			0.95
Never	50 (50%)	47 (47.5%)	
Former	17 (17%)	17 (17.2%)	
Current	33 (33%)	35 (35.4%)	
BMI (kg/m^2)	26.5 ± 5.4	27.3 ± 5.5	0.12
Prior surgical treatment			1.00
None	91	90	
Any prior surgery	9	9	

TABLE 2. Mean Segmental ROM (95% CI), Preoperative and 24-Month Values. Reported with P for Within Group Difference and Between Group Difference

Mean Range of Motion (95% Confidence Interval)						
Intervention Level	**Cranial Adjacent Segment**	**Within Group *P***	**Instrumented Motion Segment**	**Within Group *P***	**Caudal Motion Segment**	**Within Group *P***
C3–C4						
ACDF (N = 1)						
Preoperative	4.47	*	6.4	*	6.8	*
24 month	8.4		0.5		13.3	
TDR (N = 2)						
Preoperative	7.5 (2.5, 12.5)	0.90	5.8 (0.8, 10.8)	0.77	13.2(8.4, 18.1)	0.87
24 month	7.3 (4.5, 10.1)		4.7 (4.2, 5.3)		12.9 (11.4, 14.4)	
Between groups						
P	*		*		*	
C4–C5						
ACDF (N = 6)						
Preoperative	9.0 (7.4, 10.6)		12.2 (9.3, 15.1)		8.9 (5.8, 12.0)	
24 month	12.2 (9.6, 4.8)	0.046	0.6 (0.2, 1.0)	0.028	12.8 (7.9, 17.7)	0.046
TDR (N = 7)						
Preoperative	13.5 (11.1, 15.9)		14.4 (12.1, 16.7)		13.5 (9.3, 17.7)	
24 month	12.5 (9.6, 15.4)	0.31	11.0 (8.9, 13.1)	0.093	13.6 (9.6, 17.6)	0.401
Between Groups						
P	0.022		0.014		0.053	
C5–C6						
ACDF (N = 51)						
Preoperative	11.3 (10.0, 12.6)		7.9 (6.8, 9.0)		8.4 (6.7, 10.1)	
24 month	12.8 (11.2, 14.5)	0.058	0.8 (0.6, 1.0)	< 0.0001	10.8 (9.1, 12.5)	0.002
TDR (N = 53)						
Preoperative	11.8 (10.5, 13.2)		8.8 (7.4, 10.2)		7.5 (6.3, 8.7)	
24 month	12.7 (11.6, 13.8)	0.248	10.7 (9.0, 12.4)	0.133	9.1 (7.7, 10.5)	0.300
Between groups						
P	0.409		< 0.0001		0.291	
C6–C7						
ACDF (N = 34)						
Preoperative	9.4 (7.8, 11.1)		6.5 (5.2, 7.8)		NA	
24 month	10.4 (8.7, 12.1)	0.228	1.0(0.6, 1.4)	< 0.0001		
TDR (N = 31)						
Preoperative	10.0 (8.3, 11.7)		6.2 (5.1, 7.4)		NA	
24 month	11.0 (9.7, 12.3)	0.196	7.4 (5.5, 9.3)	0.504		
Between Groups						

TABLE 2. Continued

Mean Range of Motion (95% Confidence Interval)						
Intervention Level	**Cranial Adjacent Segment**	**Within Group *P***	**Instrumented Motion Segment**	**Within Group *P***	**Caudal Motion Segment**	**Within Group *P***
P	0.979		< 0.0001			
All levels combined						
ACDF	N = 91		N = 93		N = 51	
Preoperative	10.4 (9.4, 11.4)	0.01	7.7 (6.9, 8.6)	< 0.0001	8.4 (6.9, 9.9)	< 0.0001
24 month	11.8 (10.7, 13.0)		0.9 (0.7, 1.1)		11.1 (9.5, 12.7)	
TDR	N = 91		N = 94		N = 58	
Preoperative	11.3 (10.3, 12.9)	0.166	8.4 (7.4, 9.4)	0.275	8.6 (7.4, 9.8)	0.359
24 month	12.1 (11.3, 12.9)		9.5 (8.3, 10.7)		9.8 (8.5, 11.1)	
Between Groups						
P	0.27		< 0.0001		0.061	

**No comparison performed for N = 1.*

NA for levels without measurements.

difference in ROM between treatment groups were compared using estimates of least square means.

RESULTS

Demographic Data

Of 209 patients included in the IDE trial (ACDF, N = 106; TDA, N = 103), 199 had adequate baseline flexion and extension radiographs and therefore met inclusion criteria for this study (ACDF = 99, TDA = 100). The ACDF group consisted of 53 women and 46 men, and the TDA group consisted of 56 women and 44 men. Mean age was 43.5 years in the ACDF group and 42.1 year in the TDA group. No statistically significant differences in baseline data were detected between the two groups including level of treatment, history of surgery, smoking history, body mass index (BMI), and worker's

TABLE 3. Linear Mixed Effects Regression Analysis: Difference in Estimates of ROM at Operative Level for ACDF Versus TDA

Time Point	Difference in ROM*†	Standard Error	95% Confidence Interval	*P*
PreOp	−0.77	0.58	−1.92, 0.37	0.1831
3 month	−7.60	0.65	−8.87, −6.33	< 0.0001
6 month	−7.85	0.62	−9.06, −6.64	< 0.0001
12 month	−8.78	0.64	−10.04, −7.51	< 0.0001
18 month	−8.16	0.63	−9.39, −6.92	< 0.0001
24 month	−8.57	0.59	−9.73, −7.40	< 0.0001
Variable				Mixed effects *P*
Time				< 0.0001
Treatment				< 0.0001
Time*Treatment Interaction				< 0.0001

**Difference of Least Squares Means Estimates.*

†Negative value indicates greater ROM in TDA Group.

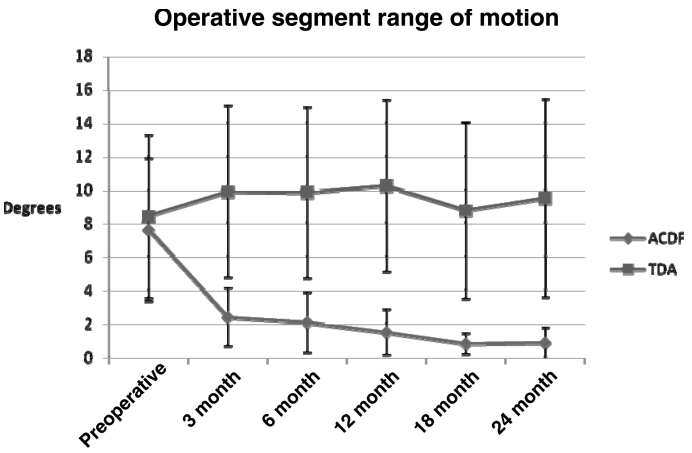

Figure 1. Segmental ROM at operative level (Mean ± SD), all levels.

compensation status (Table 1). The 10 patients excluded from the analysis were demographically similar to those included for all variables.

Index Level Range of Motion

The preoperative ROM at the index levels were 7.6° ± 4.3° (SD) for the ACDF group (N = 99) and 8.4° ± 4.9° for the TDA group (N = 100). This difference was not statistically significant ($P = 0.18$). The ROM for each specific level at baseline and at 24-month are found in Table 2, with between-group and within-group comparisons.

At 24-month follow-up, combining all index levels, the ACDF group was found to have a significant decrease in ROM (−6.8°, 95% CI: −6.0, −7.6, $P < 0.0001$), whereas the TDA group showed no significant change ($P = 0.275$). Between-group differences of least square means for the treatments are presented in Table 3. At every time point, the between-group differences in ROM are significant with substantial decreases in ROM observed in the ACDF group compared to the TDA group. A plot of segmental ROM is found in Figure 1. Linear regression analysis revealed treatment ($P < 0.0001$) and time ($P < 0.0001$) were significantly associated with changes in postoperative ROM. A significant interaction was observed between treatment and time ($P < 0.0001$), meaning that the effect of time differed between the ACDF and TDA groups.

Cranial Level Range of Motion

The preoperative ROM at the cranial levels were 10.3° ± 4.8° for the ACDF group (N = 99) and 11.1° ± 4.8° for the TDA group (N = 100). This difference was not statistically significant ($P = 0.22$). The ROM, at the preoperative visit and at 24-month follow-up, specific to each level for the two groups are found in Table 2, with within-group and between-group comparisons. An increase in ROM was observed in the ACDF group at the C4–C5 level (+3.2°, (0.3, 6.1), $P = 0.046$). The change in ROM observed at this level was significantly different ($P = 0.022$), with a greater change observed in the ACDF group, although this level included only 13 patients. No significant difference in ROM was observed between groups at the other levels. When all levels were combined, a significant increase in ROM was observed in the cranial segment in the ACDF group only (ACDF: +1.4° (0.4, 2.4), $P = 0.01$; TDA: +0.8°, (−0.1, +1.7), $P = 0.166$).

Combining all cranial levels for each group, regression analyses using least square means estimates of ROM indicated no significant differences in change of ROM between ACDF and TDA at any time point (Table 4, Figure 2).

Mixed effects regression analysis of 199 patients (801 follow-up measurements) found no association between level of intervention and postoperative ROM. For this reason, level

TABLE 4. Linear Mixed Effects Regression Analysis: Difference in Estimates of ROM at Cranial Level for ACDF Versus TDA

Time Point	Difference in ROM*†	Standard Error	95% Confidence Interval	*P*
PreOp	−0.82	0.68	−2.15, 0.50	0.2223
3 month	−1.37	0.71	−1.64, 1.15	0.7306
6 month	−.24	0.71	−1.64, 1.07	0.6198
12 month	−0.20	0.69	−1.55, 1.15	0.7667
18 month	−0.36	0.72	−1.78, 1.06	0.6196
24 month	−0.20	0.69	−1.55, 1.15	0.7667
Variable				Mixed Effects *P*-value
Time				< 0.0001
Treatment				0.3236
Time × treatment interaction				0.4894

**Difference of Least Squares Means Estimates.*

†Negative value indicates greater ROM in TDA Group.

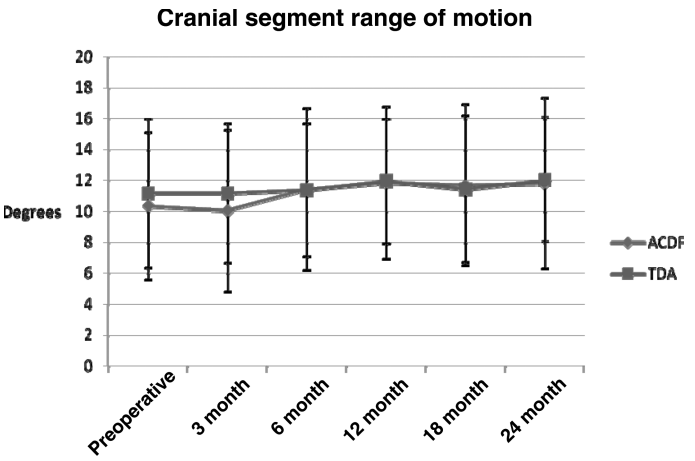

Figure 2. Segmental ROM at cranial segments (Mean ± SD), all levels.

of intervention was excluded from the final model, and all levels were combined. Time from surgery ($P < 0.0001$) was found to be significantly associated with postoperative ROM (Table 4). The treatment chosen was not significantly associated with a change in ROM, and no interaction between treatment and time was observed.

Caudal Level Range of Motion

The preoperative ROM at the caudal levels was 8.1° ± 5.3° for the ACDF group (N = 60) and 8.7° ± 4.9° for the TDA group (N = 63). This difference was not statistically significant ($P = 0.51$). Fewer caudal segments were measured in both groups, as C6–C7 was a treatment level and ROM at the C7–T1 segment could not be measured. As seen in Table 2, a significant change in ROM was observed at 24-month in the ACDF group at the C4–C5 level [+3.9°, (0.8, 7.0), $P = 0.046$] and C5–C6 level [+2.4° (1.0, 3.8), $P = 0.002$], although the ROM was not significantly different between groups. A significant increase in ROM was observed in the caudal segment, in the ACDF group only, when all levels were combined [ACDF: +2.6° (1.3, 3.9), $P < 0.0001$]; [TDA: +1.3, (−0.2, +2.8), $P = 0.359$].

Combining all caudal levels for each group regression analyses using least square means estimates of ROM indicated no significant differences in change of ROM between ACDF and TDA at any time point (Table 5, Figure 3).

Mixed effects regression analysis of 123 patients (483 follow-up measurements) found no association between level of intervention and postoperative ROM. For this reason, level of intervention was excluded from the final model, and all levels were combined. Time from surgery ($P < 0.0001$) was found to be significantly associated with postoperative ROM (Table 5). The treatment chosen was not significantly associated with a change in ROM, and no interaction between treatment and time was observed.

DISCUSSION

Our results confirm previous reports that have shown this TDA to be a motion-sparing device.[13] At the index level, nearly complete elimination of motion was observed after ACDF, whereas a small (1.01°) but statistically significant increase in ROM was observed at the TDA level. In addition, mixed effects analysis revealed time as a significant predictor of ROM as well as a significant interaction between time and treatment; this can be appreciated by the gradual decrease in ROM over time (Figure 1) as fusion occurs at the ACDF level, whereas TDA has immediate motion that is sustained throughout the follow-up period.

Conclusions regarding differences between treatments in adjacent segment motion are less clear. Our results suggest that adjacent segment kinematics may be altered after ACDF.

TABLE 5. Linear Mixed Effects Regression Analysis: Difference in Estimates of ROM at Caudal Level ACDF Versus TDA

Time Point	Difference in ROM*†	Standard Error	95% Confidence Interval	*P*
PreOp	−0.66	0.99	−2.61, 1.30	0.5089
3 month	−1.46	1.08	−3.57, 0.65	0.1755
6 month	−0.61	1.06	−2.68, 1.47	0.5674
12 month	−0.24	1.07	−2.35, 1.87	0.8221
18 month	1.12	1.07	−0.98, 3.22	0.2941
24 month	0.96	1.02	−1.05, 2.98	0.3473
Variable				Mixed effects *P*
Time				< 0.0001
Treatment				0.8631
Time × treatment interaction				0.0575

**Difference of Least Squares Means Estimates.*

†Negative value indicates greater ROM in TDA Group.

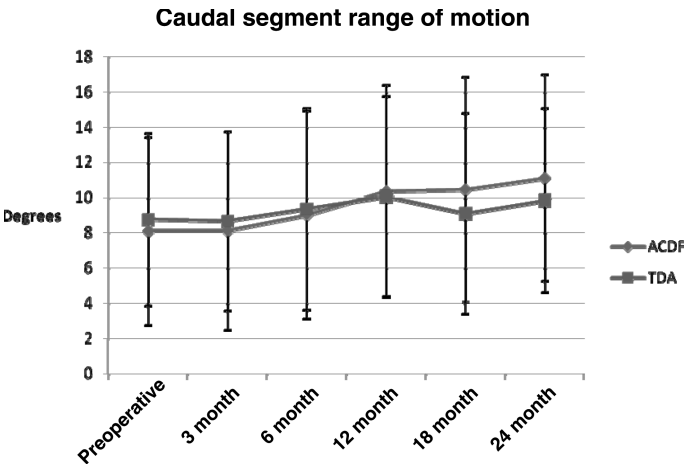

Figure 3. Segmental ROM at caudal segments (Mean ± SD), all levels.

After combining all levels, statistically significant increases from preoperative ROM were observed in the cranial (1.4°) and caudal (2.6°) segments in the ACDF group. However, increases in adjacent segment ROM were also observed after TDA in the cranial (0.8°) and caudal (1.3°) segments, though neither reached statistical significance. These increases in adjacent segment ROM observed after both ACDF and TDA led to no statistically significant differences between treatments in regards to postoperative ROM. The differences observed at C4–C5 are likely the result of the small number of patients and the relatively large difference in preoperative ROM (Cranial 4.5°, Caudal 4.6°) at this level. The results and conclusions are limited, however, by the wide confidence intervals observed.

A significant treatment effect resulting in differences in adjacent segment ROM was not supported by the multivariate analysis. Multivariate analysis revealed time from surgery to be a significant predictor of postoperative ROM, whereas treatment (ACDF *vs.* TDA) was not. No significant interaction was observed between time and the intervention at the cranial, nor at the caudal level.

Our findings of possibly increased adjacent motion after fusion are consistent with laboratory studies using cadaveric specimens.[16–18] Fuller *et al* and Schwab *et al* showed that, after single-level fusion, motion across all remaining open segments is increased in a compensatory manner, with greater compensatory motion observed at segments adjacent to fusions of the lower cervical spine.[17,18] As approximately 90% of the operated levels in our study were in the lower cervical spine, at C5–C6 or C6–C7, a significant relationship between specific level of treatment and ROM could not be determined.

The clinical significance of altered kinematics, at the intervention or adjacent segments, remains uncertain, as is the etiology of adjacent segment degeneration.[5,6] Prospective clinical studies of ACDF have not yet provided the unequivocal evidence linking adjacent segment ROM to ASD.[19,20] The pathophysiology of altered kinematics as an etiology of accelerated disc degeneration is the subject of investigation.[21] Eck *et al* found significantly increased adjacent segment intradiscal pressures in flexion after C5–C6 ACDF.[16] Increased intradiscal pressure is associated with disordered collagen, proteoglycan, and chondroitin sulfate expression. Proponents of TDA suggest that ROM closer to the physiologic range at the treatment level and adjacent segments, which has been shown in TDA implanted in cadavers, offers the possible advantage of preventing early disc degeneration and ASD.[10]

There have been numerous reports comparing adjacent segment motion after ACDF *versus* TDA, with conflicting results. Sasso and Best,[22] in a study of postoperative kinematics for the Bryan cervical disc replacement (Medtronic Sofamor Danek, Inc, Memphis, TN) reported increased ROM at adjacent segments in both the fusion and TDA groups and increased sagittal translation at the adjacent levels in the fusion group. In contrast, Kim *et al*[23] who performed a similar study using the same implant, reported near-equal increases in ROM at the cranial level, but found that the ACDF group became less mobile (−6%) and the TDA group more mobile (+5%) at the caudal level. The preoperative condition of the adjacent segments discs may be an important factor, as Wigfield *et al*[24] reported that patients who became hypermobile after TDA had normal adjacent discs before surgery, whereas those with degenerative discs at the adjacent level were unchanged. Robertson *et al*[25] reported an increased incidence of ASD after ACDF *versus* TDA, though it is important to note that this was not a randomized trial, but rather matched cohorts.

The possible roles of implant design and surgical technique remain unclear. The TDA device used in this study has a semiconstrained ball and socket design. A recent report on an unconstrained prosthesis has shown the loss of cervical sagittal alignment with longer follow-up.[26] It has been suggested that the loss of sagittal alignment may be due in part to implant design and surgical technique.[27] To date, reports on the TDA used in this study indicate cervical lordosis is maintained at 2 years' follow-up.[28] This may have particular implications for adjacent segment ROM, as cervical alignment has been shown to correlate with adjacent segment degeneration.[29] With further follow-up for both designs, the relative importance of implant design and TDA surgical technique might be elucidated.

The current study analyzes data obtained in a randomized, controlled trial, the highest level of clinical evidence. Additional strengths include the frequency of follow-up, the technique used for ROM measurement, and the statistical analysis. Mixed effects regression analysis permits analysis of the interactions between independent variables and how these interactions affect the dependent variable (postoperative ROM). This method was recently used in a similarly sized cohort,[23] although details of the model were not presented. In another, smaller, prospective, randomized study, no significant differences in adjacent segment ROM were detected between ACDF and TDA, though this may have been due to lack of power and statistical method.[22] Use of the Student *t* test, as performed in that study,[22] makes the assumption that the effects of time and treatment are similar across both groups. As the effect of time was found to be significant at all levels, we recommend the use of a mixed effects models in future studies comparing ACDF and TDA.

The major weakness of this study is the duration of follow-up, as 24-month may be inadequate to detect statistically or clinically significant differences in ROM. This is especially relevant as time was found to be a significant predictor of ROM for both cranial and caudal segments. With more follow-up, continued increases in adjacent segment ROM are expected. Another weakness of any study relying on radiographic outcomes is the lack of clinical correlation to the radiographic changes observed. Ultimately, outcome measures including change in quality of life, ASD, and reoperation for symptomatic ASD must be collected to validate theories that support the use of TDA. In this series, no patient in either group underwent reoperation for ASD within the 2-year follow-up period. Additional weaknesses are the lack of other radiographic measures of adjacent segment changes, such as translation of adjacent segments, adjacent disc heights, and total cervical (C2–C7) ROM. These measures may help more precisely define the nature of the altered cervical kinematics.[22] Also, the lack of caudal measurements at the C6–C7 level may emphasize the cranial level effects, and mask caudal level effects, when all levels are combined for analysis.

Consistent with previous reports, statistically significant increases in adjacent segment ROM were detected after ACDF, but they were small and no significant differences between ACDF and TDA adjacent ROM were observed. As indicated by the wide 95% confidence intervals in Tables 4 and 5, a very large sample size would be necessary to achieve enough statistical power to demonstrate a significant difference between treatments because the magnitudes of those differences are small. Alternatively, with a larger population, the confidence intervals may approach zero. The results suggest that time, rather than treatment, has a larger effect on adjacent ROM.

➢ Key Points

- ❑ Significant increases from baseline in adjacent segment ROM were observed in ACDF patients only, however, no significant differences in adjacent segment ROM were observed between ACDF and TDA.
- ❑ Time is a significant predictor of change in adjacent segment motion after ACDF and TDA.
- ❑ Furthermore follow-up, with clinical correlation, is needed to determine the effect of TDA on adjacent segment motion and disease.

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