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Multilevel Cervical Disc Arthroplasty: Long-Term Outcomes at 3 and 4 Levels

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ABSTRACT

Background: Multilevel cervical degenerative disc disease in 2 or more segments poses treatment challenges. Anterior cervical discectomy and fusion is a viable treatment option, but one with high rates of adjacent segment disease and pseudoarthrosis. Cervical disc arthroplasty (CDA) is approved by the US Food and Drug Administration for the treatment of 1- and 2-level cervical pathology, with established long-term safety and effectiveness. Limited evidence exists for CDA at more than 2 levels. This study investigates the long-term outcomes of 3- and 4-level CDA out to 7 years.

Methods: In a retrospective review of prospectively collected data, patient demographics and surgical characteristics were collected. Patient-reported outcomes (PROs) were collected preoperatively and at 6 weeks, 3 months, 6 months, and 12 months postoperatively, and annually thereafter, including: Neck Disability Index (NDI), numeric rating scales for neck pain and arm pain, the Veterans Rand 12-item Health Survey physical component summary (PCS) score and mental component summary (MCS) score, and patient satisfaction scores. Secondary surgery data were also collected. Predictive methods using mixed-effects regression models were used to analyze the data.

Results: Data for 139 CDAs were available for evaluation (n = 116 three-level and n = 23 four-level). Statistical improvement was shown for all PRO scores at all postoperative intervals ($P < .001$). From preoperatively to 7 years postoperatively, mean NDI decreased from 57.9 to 31.3 (45.9% improvement), mean neck pain decreased from 15.6 to 7.9 (49.4% improvement), mean arm pain decreased from 12.2 to 5.6 (54.1% improvement), mean PCS increased from 29.2 to 41.4 (41.8% improvement), and mean MCS increased from 37.1 to 44.5 (19.9% improvement). Five (3.6%) 3-level patients underwent secondary surgery. Patient satisfaction exceeded 88% 7 years after surgery.

Conclusion: Statistical improvement in PROs, with a low rate of secondary surgeries out to 7 years, demonstrates that 3- and 4-level CDA may be performed safely and effectively in appropriately selected patients.

Level of Evidence: 4.

Special Issue-Cervical Spine

Keywords: multilevel cervical disc replacement, cervical disc arthroplasty, 3- or 4-level CDA, ACDF, cervical fusion

INTRODUCTION

Cervical disc arthroplasty (CDA) has emerged as a proven alternative to anterior cervical discectomy and fusion (ACDF) to treat cervical degenerative disc disease (DDD) in appropriately selected patients.[1–4] By preserving segmental motion, CDA has the potential to reduce the incidence of adjacent segment disease while mitigating nerve root compression by restoring both intervertebral disc and foraminal heights.[5–9] Long-term clinical studies established the safety and effectiveness of single-level CDA, with superior clinical outcomes compared with ACDF.[10–15] The safety and effectiveness of CDA at 2 contiguous levels have also been evidenced with long-term clinical outcomes reported up to 84 months.[14–17] As a result of this large and growing body of evidence, more surgeons are choosing CDA for their patients.

ACDF has long been described as a gold standard treatment for cervical DDD.[18–20] Particularly for patients with pathology at 2 or more cervical levels, ACDF still poses many treatment challenges, including a high incidence of adjacent segment disease resulting from increased stresses. Hypermobility and other biomechanical alterations have been associated with multilevel ACDF.[21–23] In addition, high rates of pseudoarthrosis, associated with neck pain and other recurrent symptoms, have been reported for ACDF involving multiple levels.[24,25] Unsuccessful fusion in multilevel constructs has been attributed to, among other factors, the greater surface area required for fusion, multiple

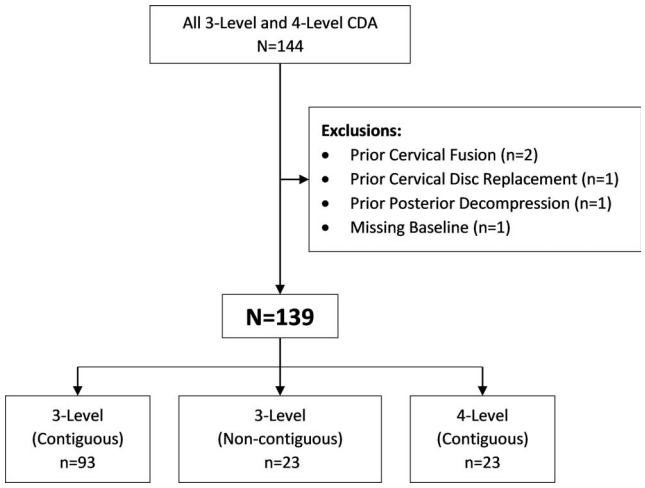

Figure 1. Patient flow chart.

hypermobile segments, and higher biomechanical loads across the fusion construct.[24]

In light of the extensive evidence now supporting the long-term safety of CDA at 1 or 2 levels, and the well-documented challenges after ACDF, surgeons are beginning to recognize that CDA has the potential to extend beyond 2 levels to treat multilevel cervical pathology. Some have reported positive CDA outcomes at 3 or 4 levels, but these studies have comprised very small cohorts and short follow-ups.[21,26–28] Hence, the objective of the present study was to evaluate the long-term safety and effectiveness of 3-level and 4-level CDA in patients treated for cervical disc disease at more than 2 levels.

PATIENTS AND METHODS

This study was designed to assess the patient-reported outcomes (PROs) of patients who underwent 3- or 4-level CDA. Data were collected prospectively following approval by an external Institutional Review Board. The study was conducted at 1 center by a single fellowship-trained surgeon. All patients were operated on at an ambulatory surgery center with 23-hour stay.

Patients

Of the total patients operated on between April 2008 and January 2018, 144 consecutive patients who underwent 3- or 4-level CDA were considered for this study (Figure 1). The artificial cervical disc designs used in this study included commercially available semiconstrained and unconstrained cervical discs based on patient suitability.

The inclusion criteria included a diagnosis of discogenic pain with or without radiculopathy and/or myelopathy in patients who had been unresponsive to at least 6 weeks of conservative nonsurgical care. Patients undergoing 3- or 4- level CDA at either contiguous or noncontiguous levels were included. Any patients with prior cervical spine surgery or missing baseline data were excluded. A total of 5 patients were therefore excluded from the analysis.

Materials

Patient demographic, diagnostic, and surgical characteristics were collected for all enrolled patients. The following patient-reported outcomes were collected preoperatively and postoperatively at 6 weeks, 3 months, 6 months, and 12 months, and annually thereafter: Neck Disability Index (NDI), numeric rating scales for neck and arm pain (pain intensity + frequency, 0–20 points), and the Veterans Rand 12-item health survey (VR-12). The VR-12 physical component summary (PCS) score and mental component summary (MCS) score were calculated. Patient satisfaction (5-point scale ranging from "definitely no" to "definitely yes") and patient global perceived effect (7-point scale from "vastly worsened" to "completely recovered") at each time point were also collected. All secondary surgeries were recorded for the safety assessment.

Statistical Methods

Mixed-effect regression models were used to assess the effect of time point on each PRO score after adjusting for age at surgery. These models effectively analyze the longitudinal data with repeated measures, allowing for irregularly timed intervals (eg, weekly, monthly, and yearly). The models yield a predicted PRO score for each patient at every time point, given there are no missing independent variables. Significance was set at $P = .05$. Proprietary SpineSys Web-based data collection and database software (SPIRITT Research, St Louis, MO) was used for this study; statistical analysis was performed using SAS 9.4 (SAS Institute Inc, Cary, NC).

RESULTS

In this study, 139 patients were included and had data available for the evaluations. Patient accountability is reported in Figure 1. Of the patients

Table 1. Operative levels description.

Levels	Patients, No. (%)
3-Level	116 (83.45)
Contiguous	93 (66.91)
C3–C6	25 (17.99)
C4–C7	67 (48.20)
C5–T1	1 (0.72)
Noncontiguous	23 (16.55)
C3–C4, C5–C7	19 (13.67)
C3–C5, C6–C7	4 (2.88)
4-Level	23 (16.55)
Contiguous C3–C7	23 (16.55)
Total	139 (100)

operated on at 3 levels, most surgeries were at contiguous levels from C4 to C7; the second most common was C3 to C6. A low number of 3-level surgeries were at noncontiguous segments C3 to C4 with C5 to C7, or C3 to C5 with C6 to C7 (Table 1).

This patient population was 56.8% male, with an average age of 48.84 ± 9.49 years and average body mass index of 29.55 ± 5.37 kg/m^2 (Table 2). The average operative time was 158.68 ± 41.96 minutes, and mean estimated blood loss was 48.92 ± 9.46 mL. Figures 2 and 3 display the preoperative and postoperative imaging studies of 2 illustrative 4-level patients.

Predictive methods using mixed-effects regression models demonstrated statistically significant improvement in all evaluated PRO scores from baseline to follow-up, at all postoperative intervals ($P < .001$ at all time points). The effect of age at surgery was statistically significant in the model for each outcome measure, except for neck pain ($P = .195$). From preoperatively to 7 years postoperatively, the output for each outcome measure analyzed was as follows: the mean NDI score decreased from 57.9 to 31.3 (45.9% improvement); the mean neck pain score decreased from 15.6 to 7.9 (49.4% improvement); the mean arm pain score decreased from 12.2 to 5.6 (54.1% improvement); mean PCS increased from 29.2 to 41.4 (41.8% improvement); and mean MCS increased from 37.1to 44.5 (19.9% improvement). Statistical improvement in PROs was observed at 6 weeks and was maintained through 7 years postoperatively. Figure 4 shows the mixed-effects regression model results at each individual time point. Patient satisfaction was also consistently strong at each postoperative time point; at 7 years, 88.2% of patients were definitely or mostly satisfied with their surgery; 82.4% of patients reported to be completely recovered or much improved.

Heterotopic ossification (HO) levels of grade 3 or grade 4 were observed in 21 of 122 patients (17.2%) for whom x-rays were available 1 or more years after surgery. Of the 387 total levels treated with CDA in those 122 patients, grade 3 or grade 4 HO was observed at 34, or 8.8%, of all treated levels.

Table 2. Demographic characteristics.

	3- and 4-Level (N = 139)	3-Level (n = 116)	4-Level (n = 23)
Age at surgery, y	48.84 ± 9.49	47.99 ± 9.57	53.13 ± 7.94
BMI, kg/m^2	29.55 ± 5.37	29.69 ± 5.54	28.82 ± 4.46
Male, No. (%)	79 (56.83)	62 (53.45)	17 (73.91)
Race, No. (%)			
White	113 (81.29)	93 (80.17)	20 (86.96)
Black or African American	19 (13.67)	16 (13.79)	3 (13.04)
Not specified	3 (2.16)	3 (2.59)	0 (0.00)
Asian	1 (0.72)	1 (0.86)	0 (0.00)
Asian and white	1 (0.72)	1 (0.86)	0 (0.00)
Hispanic or Latino/a	1 (0.72)	1 (0.86)	0 (0.00)
Other	1 (0.72)	1 (0.86)	0 (0.00)
Marital status, No. (%)			
Married/engaged	87 (62.59)	70 (60.34)	17 (73.91)
Divorced/separated	23 (16.55)	18 (15.52)	5 (21.74)
Single	23 (16.55)	22 (18.97)	1 (4.35)
Not specified	2 (1.44)	2 (1.72)	0 (0.00)
Living with partner	2 (1.44)	2 (1.72)	0 (0.00)
Widowed	1 (0.72)	1 (0.86)	0 (0.00)
Unknown	1 (0.72)	1 (0.86)	0 (0.00)
Education, No. (%)			
Less than high school diploma or GED	11 (7.91)	10 (8.62)	1 (4.35)
High school diploma or GED	74 (53.24)	64 (55.17)	10 (43.48)
Technical school or associate's degree	32 (23.02)	25 (21.55)	7 (30.43)
4-year college degree	16 (11.51)	14 (12.07)	2 (8.70)
Graduate or professional degree	6 (4.32)	3 (2.59)	3 (13.04)

Abbreviation: BMI, body mass index

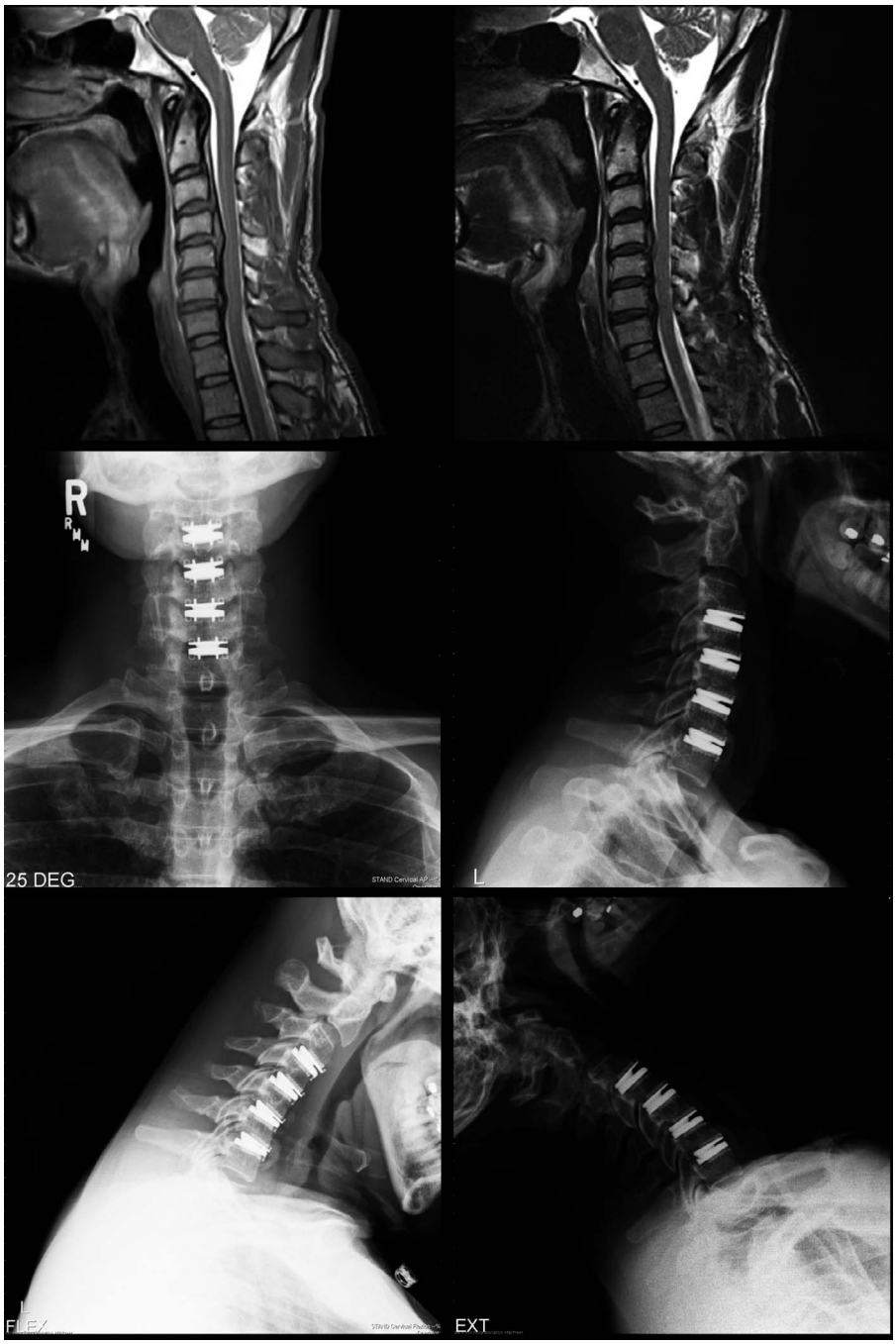

Figure 2. Illustrative patient: preoperative imaging studies reveal disease at 4 levels. No other treatment option available except decompression and fusion.

Five 3-level patients (3.60%) underwent a secondary surgery at an average of 13.80 ± 9.42 months after the index surgery (Table 3). Three of these patients had increased pain and underwent decompression surgery at 6, 14, and 25 months postoperatively. The 2 other patients experienced device subsidence. One patient (C4–C7) had subsidence at C5 to C6 and underwent implant removal, and subsequent anterior/posterior fusion, at C4 to C6, 21 months after the index surgery. The other patient (C3–C4, C5–C7) had subsidence at C4 to C5 and underwent an implant replacement after 3 months. No secondary surgeries were reported for 4-level patients.

DISCUSSION

ACDF has been the standard of care to treat cervical disc disease since the 1950s.[29–33] However, ACDF has been shown to alter natural spinal

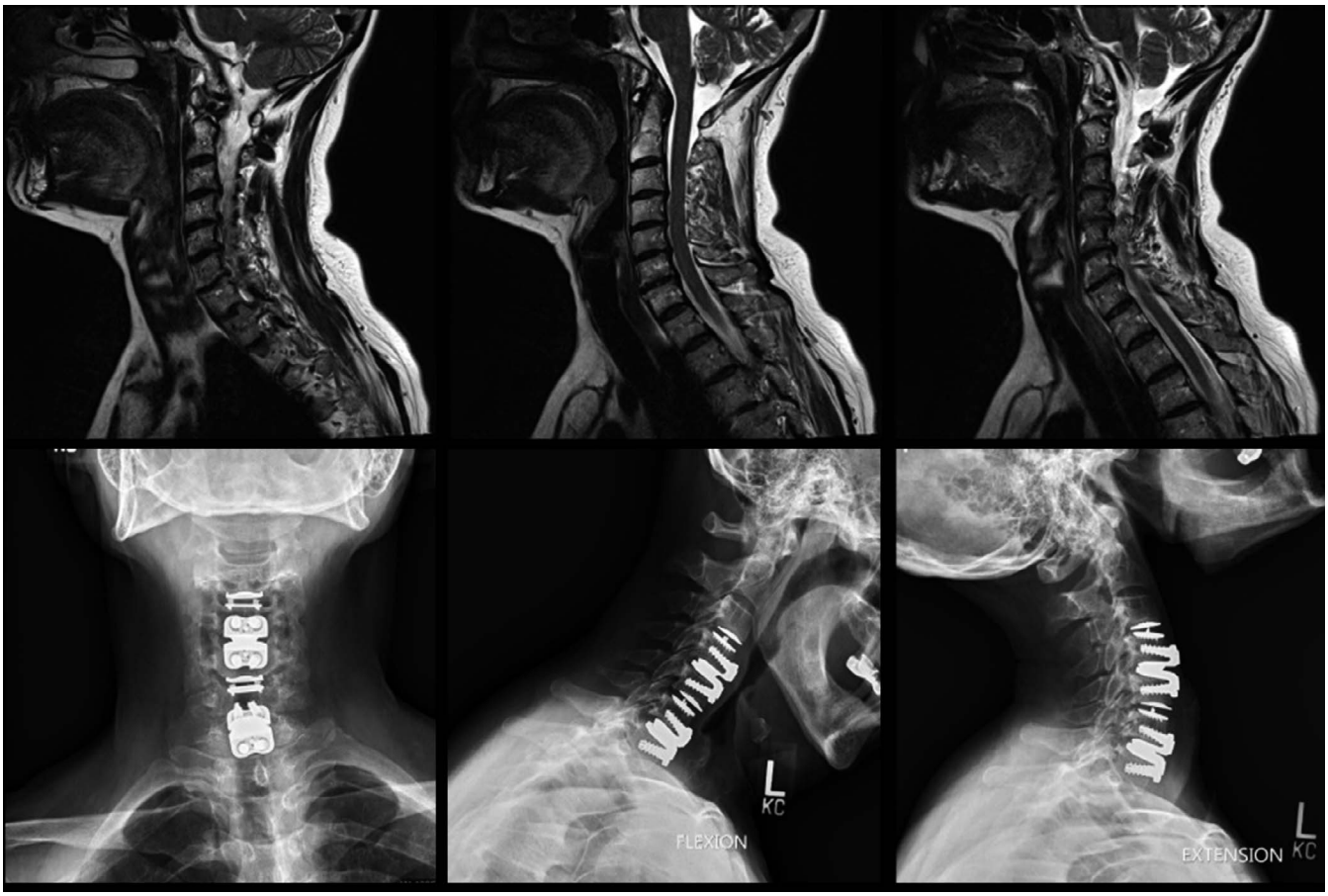

Figure 3. Illustrative patient: preoperative imaging studies reveal disease at 4 levels. No other treatment option available except decompression and fusion.

biomechanics, leading to adjacent segment degeneration and the recurrence of radiculopathy in up to 25% of patients.[34–37] The ACDF procedure intentionally restricts motion at the fused levels, thereby introducing abnormal loads, increased intradiscal pressure, stresses, and hypermotion at the levels adjacent to fusion.[22] For patients with multilevel disc degeneration, multilevel ACDF has been considered the most viable treatment modality, despite its limitations. In a recently published study, reductions of 26.1% in NDI, 33.4% in neck pain, and 50.4% in arm pain were reported for multilevel ACDF at 24 months.[38] However, multilevel ACDF may cause even greater stresses to adjacent discs, and, compared with single-level ACDF, multilevel ACDF yields higher rates of pseudarthrosis, complications, revisions, and reoperations. The 24-month reoperation rate has been reported elsewhere to be 35% for patients who underwent 3- and 4-level cervical fusion.[38] In an effort to preserve segmental motion, both multilevel CDA and a hybrid surgical treatment combining CDA and ACDF have been considered. However, the preference of either of these motion-sparing treatments is dependent on the severity of disc degeneration and optimized patient selection.

A hybrid surgical treatment has been shown in some reports to be a promising alternative to multilevel ACDF, with comparable PROs and the preservation of a normal range of motion at 24 months and beyond.[22,39] However, long-term outcomes have not been reported. For appropriately selected DDD patients, multilevel CDA could be a desirable alternative to multilevel ACDF that preserves segmental motion. The most favorable outcomes of CDA depend on optimized patient selection, which might include preoperative disc height of at least 3 mm, little or no facet joint degeneration or instability, and no confirmed osteoporosis (T-score greater than –1.5).[40]

The safety and efficacy of CDA as a treatment for both single- and 2-level cervical disc disease is now well established in the literature. There have been several clinical investigations comparing the safety and efficacy of single-level and multilevel CDA. With no statistical difference in the PROs, a

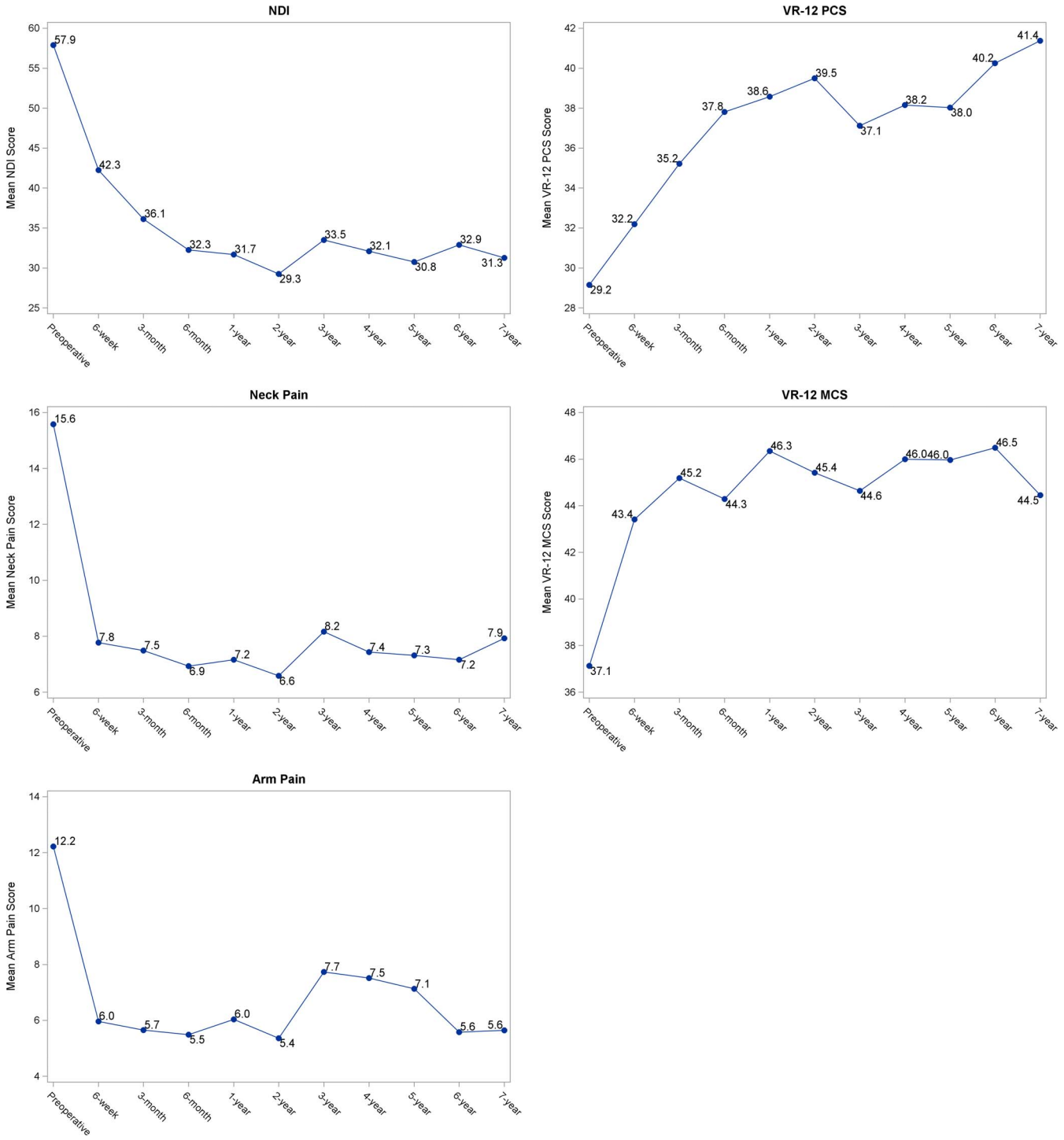

Figure 4. Predicted mean patient reported outcomes scores.

comparison of clinical outcomes at a single level and at multiple levels (2 levels or more) up to 48 months showed initial safety and effectiveness for the multilevel CDA.[21,41] In a retrospective review, Friesem et al[26] reported significant improvement in NDI, VAS neck and VAS arm scores for 3- and 4-level patients at 62 months. This study also compared outcomes for 3- and 4-level patients and 1- and 2-level patients and found similar -improvement in both groups. In contrast to the studies referenced above, Pimenta et al[27] found significantly improved clinical outcomes for multilevel CDA compared with single-level CDA. However, most of these reported outcomes have been limited by small

Table 3. Secondary surgeries.

Index Surgery Date	Index Operative Levels	Secondary Surgery Date	Secondary Surgery Operative Levels	Secondary Surgery Description
December 8, 2010	C4–C7	January 29, 2013	C6–7	Laminotomy and foraminotomy
October 10, 2012	C4–C7	April 30, 2013	C4–7	Laminotomy and foraminotomy
November 30, 2011	C4–C7	September 4, 2013	C4–C6	Disc replacement removal, anterior fusion, posterior fusion
January 15, 2014	C3–C4, C5–C7	May 13, 2014	C4–5	Hardware removal and disc replacement
February 10, 2015	C3–C6	May 3, 2016	C3–6	Keyhole foraminotomy, left

patient cohorts and short follow-ups. The results of the current study provide long-term clinical evidence that is consistent with previously reported, shorter duration improvement in clinical outcomes for CDA at more than 2 levels, confirming the long-term safety and effectiveness of CDA for these patients.

In the current study, grade 3 or grade 4 HO was reported in 17.2% of patients. A prior comparison of single-level CDA with 2-level CDA, with or without a fused level, concluded that HO occurrence increased with multilevel CDA but that HO did not affect the outcomes. In the current study, the statistical improvement in patient-reported outcomes and the rarity of secondary surgeries similarly indicate that HO, where present, remained mainly asymptomatic.

CDA, as a frontline surgical treatment for cervical disc degeneration, has gained credibility after taking into account the favorable outcomes consistent with long-term functional recovery, the rate of adverse events, the onset of adjacent segment disease, and the rate of subsequent surgeries.[42] In the United States, CDA has experienced a high rate of annual growth in its use both as a primary therapy (20.54%) and revision therapies (5.84%), attributed to better PROs compared with ACDF.[43] CDA as a good alternative to ACDF is further supported by the results of this current study. To our knowledge, this is the largest reported cohort to date of 3- and 4-level CDA patients reporting long-term clinical outcomes. In appropriately selected patients, the significant PRO improvement, high patient satisfaction, and low secondary surgeries, supplemented by the enhanced durability of CDA compared with ACDF,[44] support the viability of CDA at more than 2 levels.

The present study is not without limitations. First, this is a single-arm exploratory study with no opportunity for comparison to other treatment modalities. Second, this is a community-based, real conditions of use study at a single center. Although there is considerable value in the tracking of long-term outcomes in a non–US Food and Drug Administration cohort, patients at this center may not be generalizable to the population at large.

CONCLUSION

Only a few multilevel studies have reported on 3- and 4-level CDA, and long-term clinical data have not been reported in the literature. To our knowledge, this is the first study reporting on the long-term clinical outcomes of 3- and 4-level CDA, and the largest 3- and 4-level patient cohort to date. For appropriately selected patients with cervical DDD at more than 2 levels, CDA is safe and effective, and it may provide statistical improvement in patient-reported outcomes, high patient satisfaction, and low rates of secondary surgery.

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