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Received, June 9, 2017.

Accepted, October 31, 2017.

Published Online, December 21, 2017.

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 Congress of Neurological Surgeons

Outcomes of Operative Treatment for Adult Cervical Deformity: A Prospective Multicenter Assessment With 1-Year Follow-up

BACKGROUND: Despite the potential for profound impact of adult cervical deformity (ACD) on function and health-related quality of life (HRQOL), there are few high-quality studies that assess outcomes of surgical treatment for these patients.

OBJECTIVE: To determine the impact of surgical treatment for ACD on HRQOL.

METHODS: We conducted a prospective cohort study of surgically treated ACD patients eligible for 1-yr follow-up. Baseline deformity characteristics, surgical parameters, and 1-yr HRQOL outcomes were assessed.

RESULTS: Of 77 ACD patients, 55 (71%) had 1-yr follow-up (64% women, mean age of 62 yr, mean Charlson Comorbidity Index of 0.6, previous cervical surgery in 47%). Diagnoses included cervical sagittal imbalance (56%), cervical kyphosis (55%), proximal junctional kyphosis (7%) and coronal deformity (9%). Posterior fusion was performed in 85% (mean levels = 10), and anterior fusion was performed in 53% (mean levels = 5). Three-column osteotomy was performed in 24% of patients. One year following surgery, ACD patients had significant improvement in Neck Disability Index (50.5 to 38.0, $P < .001$), neck pain numeric rating scale score (6.9 to 4.3, $P < .001$), EuroQol 5 dimension (EQ-5D) index (0.51 to 0.66, $P < .001$), and EQ-5D subscores: mobility (1.9 to 1.7, $P = .019$), usual activities (2.2 to 1.9, $P = .007$), pain/discomfort (2.4 to 2.1, $P < .001$), anxiety/depression (1.8 to 1.5, $P = .014$).

CONCLUSION: Based on a prospective multicenter series of ACD patients, surgical treatment provided significant improvement in multiple measures of pain and function, including Neck Disability Index, neck pain numeric rating scale score, and EQ-5D. Further follow-up will be necessary to assess the long-term durability of these improved outcomes.

KEY WORDS: Cervical deformity, Surgery, Outcomes, Spinal deformity, Quality of life

Neurosurgery 83:1031–1039, 2018

DOI:10.1093/neuros/nyx574

www.neurosurgery-online.com

Adult cervical deformity (ACD) may develop from degenerative, inflammatory, traumatic, infectious, iatrogenic, neoplastic, congenital, and neuromuscular pathologies. The clinical presentation is variable and may include neck pain, radiculopathy, and/or myelopathy.¹ More severe deformities such as “chin-on-chest” may compromise essential functions including swallowing,

breathing, and maintenance of horizontal gaze.^{2–4} Kyphosis is the most common deformity seen in the cervical spine and may be associated with myelopathy,^{2,5,6} and its occurrence as a delayed complication of cervical laminectomy has been well documented.^{7–10}

ACD may have a profound, negative impact on health-related quality of life (HRQOL).^{11–14} Smith et al¹⁵ found a mean EuroQol 5 dimension (EQ-5D) index of 0.51 in a population of 121 ACD patients which represented a score that is 34% below the bottom 25th percentile for age- and gender-matched US normative populations. However, there is a paucity of high-quality data on the management or outcome of this condition. Surgical treatment is often complex and may require multiple approaches

ABBREVIATIONS: ACD, adult cervical deformity; EQ-5D, EuroQol 5 dimension; HRQOL, health-related quality of life; MCID, minimal clinically important difference; mJOA, modified Japanese Orthopedic Association; NDI, Neck Disability Index; NRS, numeric rating scale; TCO, 3-column osteotomy; SVA, sagittal vertical axis

and an extended operative time with a potentially high rate of complications.¹ However, improvements in surgical technique, instrumentation, and perioperative care have facilitated a renewed interest of surgeons to study and surgically treat these higher risk deformities.^{5,6,16-21}

In recent years, our understanding of the classification, impact, radiographic features, and operative management of adult thoracolumbar deformity has grown considerably. In contrast, cervical deformity is much less well studied and understood. Indeed, a recent study highlighted significant variability in the surgical strategies employed by experienced surgeons in the management of ACD.²² The outcome of surgery for ACD represents an important knowledge gap in the current literature and an important milestone in improving the treatment of this condition.

Our objective was to determine the 1-yr HRQOL, pain, and disability outcomes after surgical management of ACD. We hypothesized that surgical treatment of the deformity would result in a reduction in pain and disability and a concomitant improvement in HRQOL. We report on a group of consecutively enrolled patients from an ongoing prospective, multicenter study.

METHODS

Study Population

Consecutive patients with ACD were prospectively enrolled in an ongoing multicenter study across 13 participating centers. Each institution obtained approval from their local Institutional Review Board to enroll patients in the prospective database. Patients provided consent for their involvement to study coordinators at their site of enrollment.

Patients were included in the present study if they were 18 yr of age or older, had cervical deformity, and underwent surgical treatment of their deformity. Cervical deformity was operationally defined as the presence of one or more of the following radiographic criteria: cervical kyphosis (C2-7 sagittal Cobb angle $\geq 10^\circ$), cervical scoliosis (C2-7 coronal Cobb angle $\geq 10^\circ$), C2-7 sagittal vertical axis (C2-7 SVA) ≥ 4 cm, or chin-brow vertical angle $\geq 25^\circ$ (Figure 1). The primary driver of deformity could be located in the cervical spine (cervical kyphosis) or in the thoracic spine (eg, causing elevated C2-7 SVA). Exclusion criteria were active neoplasm in the spine, spinal infection, acute cervical spine trauma, or pregnancy. The surgical approach, techniques, and instrumentation were conducted as prescribed by the treating surgeon.

Data Collection

Standardized data collection forms were used to collect baseline patient demographics, medical comorbidities, surgical details, baseline and follow-up patient-reported outcome measures. Clinical data collection adhered to the clinical practice pattern of participating surgeons including 6 wk, 3 mo (window of 8-16 wk), and 1 yr (window of 9-23 mo) follow-up. Deidentified data from each site was sent to a single center where the entire sets of data were summarized and analyzed.

Outcome Measures

The primary outcome measures included the change from baseline to 1-yr follow-up in the EQ-5D, Neck Disability Index (NDI), and neck pain numeric rating scale (NRS) score. Secondary outcomes included

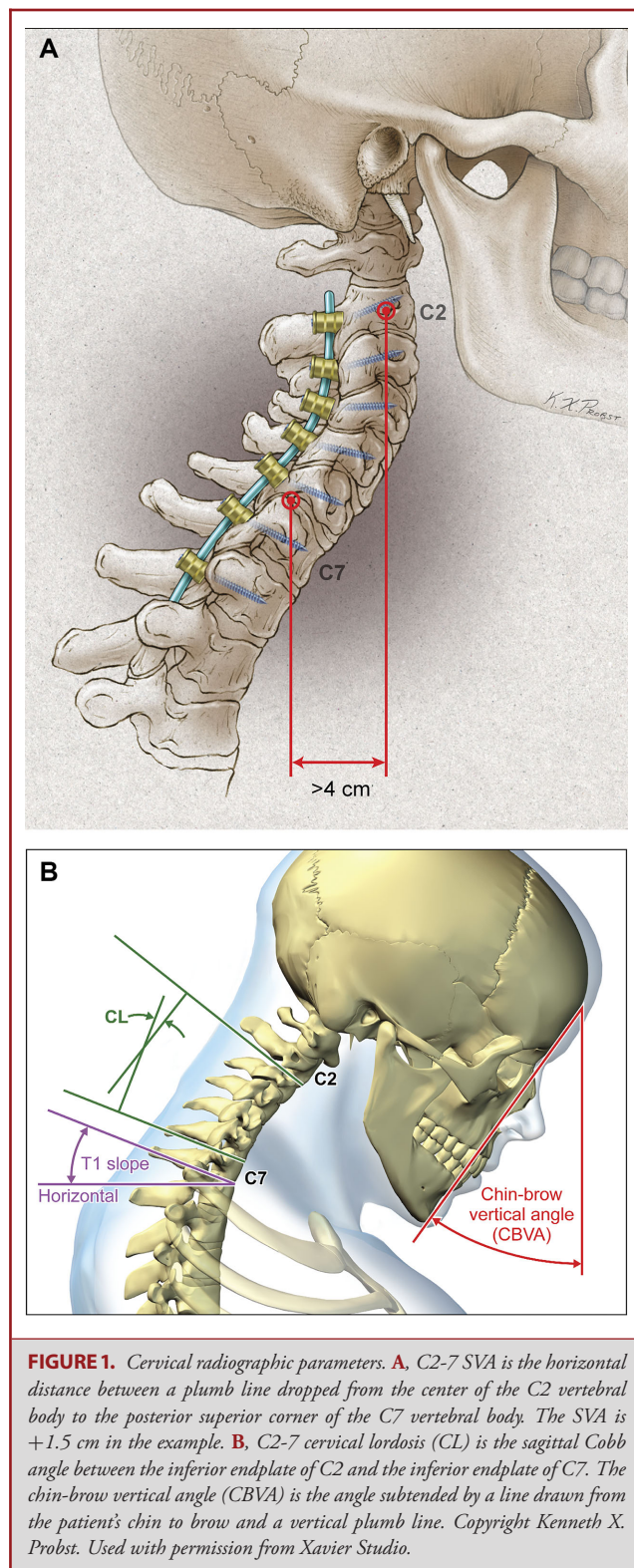
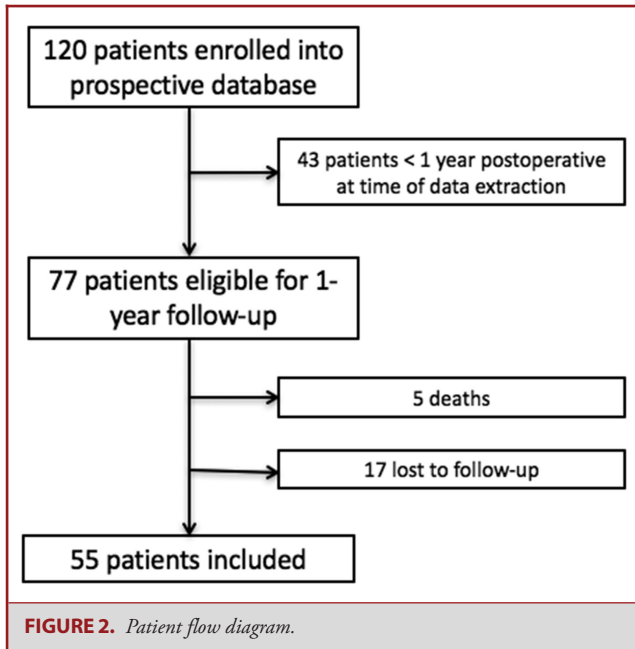


FIGURE 1. Cervical radiographic parameters. **A**, C2-7 SVA is the horizontal distance between a plumb line dropped from the center of the C2 vertebral body to the posterior superior corner of the C7 vertebral body. The SVA is +1.5 cm in the example. **B**, C2-7 cervical lordosis (CL) is the sagittal Cobb angle between the inferior endplate of C2 and the inferior endplate of C7. The chin-brow vertical angle (CBVA) is the angle subtended by a line drawn from the patient's chin to brow and a vertical plumb line. Copyright Kenneth X. Probst. Used with permission from Xavier Studio.



the EQ-5D subscores: mobility, usual activities, pain/discomfort, anxiety/depression, and self-care.

Data Analysis

Demographic, surgical, and radiographic data were tabulated and frequency distributions determined. For continuous data, the Kolmogorov-Smirnov test was used to test for normality. Normally distributed variables were compared using Student's paired *t*-test and analysis of variance (ANOVA), whereas the Wilcoxon test was employed for data that were not normally distributed. For categorical variables, the chi-squared or Fisher's exact test was used, depending on cell numbers. All statistical tests were 2-tailed and a *P* value < .05 was considered statistically significant. All statistical analyses were performed using IBM SPSS Statistics for Macintosh, Version 23.0 (IBM Corp, Armonk, New York).

RESULTS

Baseline Characteristics

Of 77 consecutively enrolled, eligible patients, 55 (71.4%) had 1-yr follow-up at the conclusion of the study period and were included in the present analysis (Figure 2). Table 1 includes baseline characteristics of the study population. The mean age was 61.6 yr, and 63.6% of the patients were women. Mean follow-up time was 28.5 mo. The most common deformity subtypes were cervical sagittal imbalance and cervical kyphosis, which were present in 56.4% and 54.5% of patients, respectively. The average modified Japanese Orthopedic Association (mJOA) was 13.3, reflecting moderately severe myelopathy.²³

Compared with patients who achieved 1-yr follow-up, those lost to follow-up did not differ significantly with regard to age (61.6 vs 62.0 yr; *P* = .74), gender (63.6% vs 52.4% women; *P* = .44), Charlson Comorbidity Index (0.6 vs 0.8; *P* =

TABLE 1. Demographic and Baseline Characteristics of Study Population (n = 55)

Age at initial surgery, mean (SD)	61.6 (10.2)
Female, n (%)	35 (63.6%)
Body mass index, mean (SD)	29.1 (8.4)
Charlson Comorbidity Index, mean (SD)	0.6 (1.1)
Smoker	3 (5.5%)
Diagnosis	
Cervical sagittal imbalance	56.4%
Cervical kyphosis	54.5%
Proximal junctional kyphosis	7.3%
Coronal deformity	9.1%
Previous cervical surgery, n(%)	
Anterior fusion	26 (47.3%)
Posterior fusion	5 (9.1%)
Modified Japanese Orthopedic Association score, mean (SD)	13.3 (2.6)

SD, standard deviation.

TABLE 2. Surgical Characteristics of Study Population (n = 55)

Approach, n (%)	
Anterior-only	8 (14.5)
Posterior-only	26 (47.3)
Combined anterior and posterior	21 (38.2)
Anterior then posterior	18 (32.7)
Posterior then anterior then posterior	3 (5.5)
Number of instrumented levels per patient, mean (SD)	
Anterior	4.9 (1.1)
Posterior	9.7 (3.7)
TCO, n (%)	
Pedicle subtraction osteotomy	10 (18.2)
Vertebral column resection	3 (5.5)
Operative time, mean (SD)	6.5 (3.9) h
Estimated blood loss, mean (SD)	894.0 (889.3) mL

SD, standard deviation; TCO, three-column osteotomy.

.46), number of fused anterior (4.9 vs 5.1; *P* = .77) or posterior (9.7 vs 8.9; *P* = .40) vertebral levels, baseline NDI (50.5 vs 46.1; *P* = .38), neck pain NRS (6.9 vs 6.4; *P* = .44), or EQ-5D scores.

Five deaths occurred (mortality 6.5%) among patients who were eligible for 1-yr follow-up. Causes included cardiac arrest (7 mo postop, 70 yr old), unrelated traumatic injury (2 yr postop, 49 yr old), anoxic brain injury secondary to sleep apnea and medications (1 wk postop, 53 yr old), cardiopulmonary failure (6 mo postop, 70 yr old), and unknown (unrelated to surgery according to the patient's family; 3 mo postop, 52 yr old).

Surgical characteristics are shown in Table 2. The most common surgical approach was posterior-only (47.3%) followed by combined approaches (38.2%), which were predominantly anterior followed by posterior. The mean number of anterior and posterior levels instrumented was 4.9 (range 2-10) and 9.7 (range 3-20), respectively. Three-column osteotomies were

performed in 23.7% of patients, of which the majority were pedicle subtraction osteotomies. Mean operative time was 6.5 h (range 1.4-19.7 h) and mean estimated blood loss was 894.0 mL (range 150-4500 mL).

One year following surgery, ACD patients experienced significant improvement in global health status as measured by mean EQ-5D (0.51 ± 0.2 to 0.66 ± 0.2 , $P < .001$; Figure 3A). Based on the previously reported minimal clinically important difference (MCID) for the EQ index of 0.074,²⁴ 56.6% of patients improved by at least 1 MCID. Similarly, all EQ-5D subscores improved significantly with the exception of self-care (Figure 3B). There was a reduction in neck pain and neck-related disability from baseline to 1-yr postoperative follow-up (Figure 4A and B). The average neck pain NRS decreased from 6.9 ± 2.3 to 4.3 ± 3.0 ($P < .001$) and mean NDI decreased from 50.5 ± 18.0 to 38.0 ± 19.9 ($P < .001$). This corresponded to an increase greater than or equal to the MCID for neck pain NRS (1.3)²⁵ in 61.8% of patients. A reduction of NDI by at least 1 MCID (19%)²⁵ was achieved in 55.6% of patients.

For the overall study population there was minimal change in myelopathy from a mean baseline mJOA of 13.3 ± 2.6 to 13.5 ± 3.0 ($P = .675$). Subgroup analysis of patients with moderate or severe myelopathy (mJOA < 15 ; $n = 30$) revealed a change from 11.8 ± 1.9 to 12.2 ± 2.6 ($P = .43$). Patients with severe myelopathy (mJOA < 12 ; $n = 10$) experienced a slightly greater improvement in mJOA from 9.7 ± 1.6 to 10.8 ± 3.3 , which did not reach statistical significance ($P = .30$).

DISCUSSION

The present study demonstrates that surgical management of ACD patients can lead to improvement in health status, neck pain, and neck-related disability. The EQ-5D is a standardized patient-reported HRQOL measure used for clinical and economic assessment.²⁶ The MCID for the EQ-5D index has been reported as 0.074;²⁴ however, the value differs by study in accordance with their method of derivation.²⁶ Based on this value, the increase in the mean EQ-5D index from preoperative to 1-yr follow-up of 0.15 (0.51-0.66) represents a clinically meaningful improvement. Similarly, the 2.6-point reduction in mean neck pain NRS is greater in magnitude than the suggested MCID (1.3).²⁵ Cleland et al²⁵ demonstrated that the MCID threshold for improvement in NDI was a 19% decrease. This was exceeded in the present study wherein we observed a 24.8% mean decrease in NDI from baseline to 1-yr follow-up. Taken together, these findings suggest that operative treatment of ACD patients produces clinically meaningful improvement in both generic and disease-specific HRQOL measures.

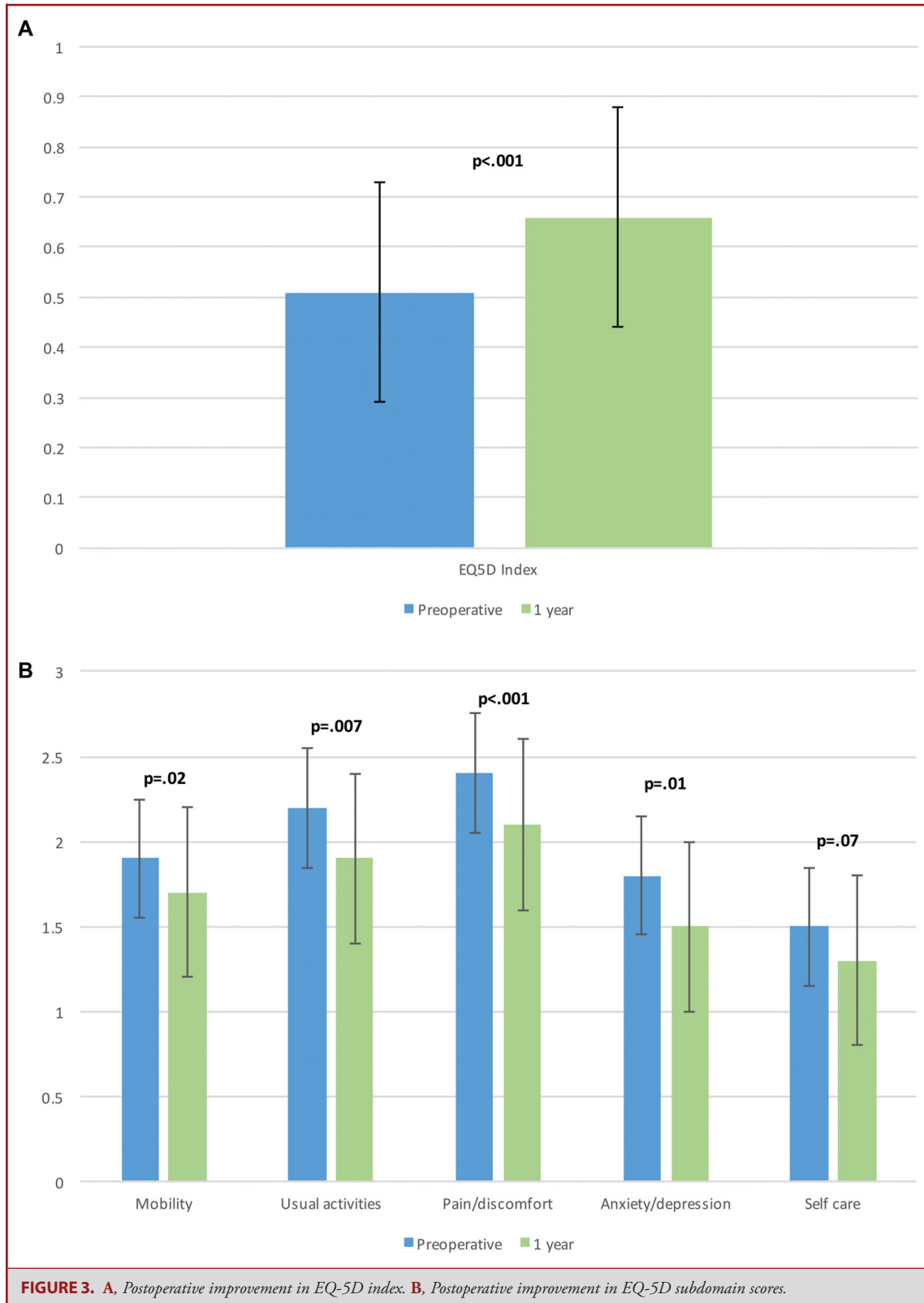
Although the majority of patients achieved at least 1 MCID improvement in EQ-5D index (56.6%), neck pain NRS (61.8%) and NDI (55.6%), a significant portion of patients did not. Many

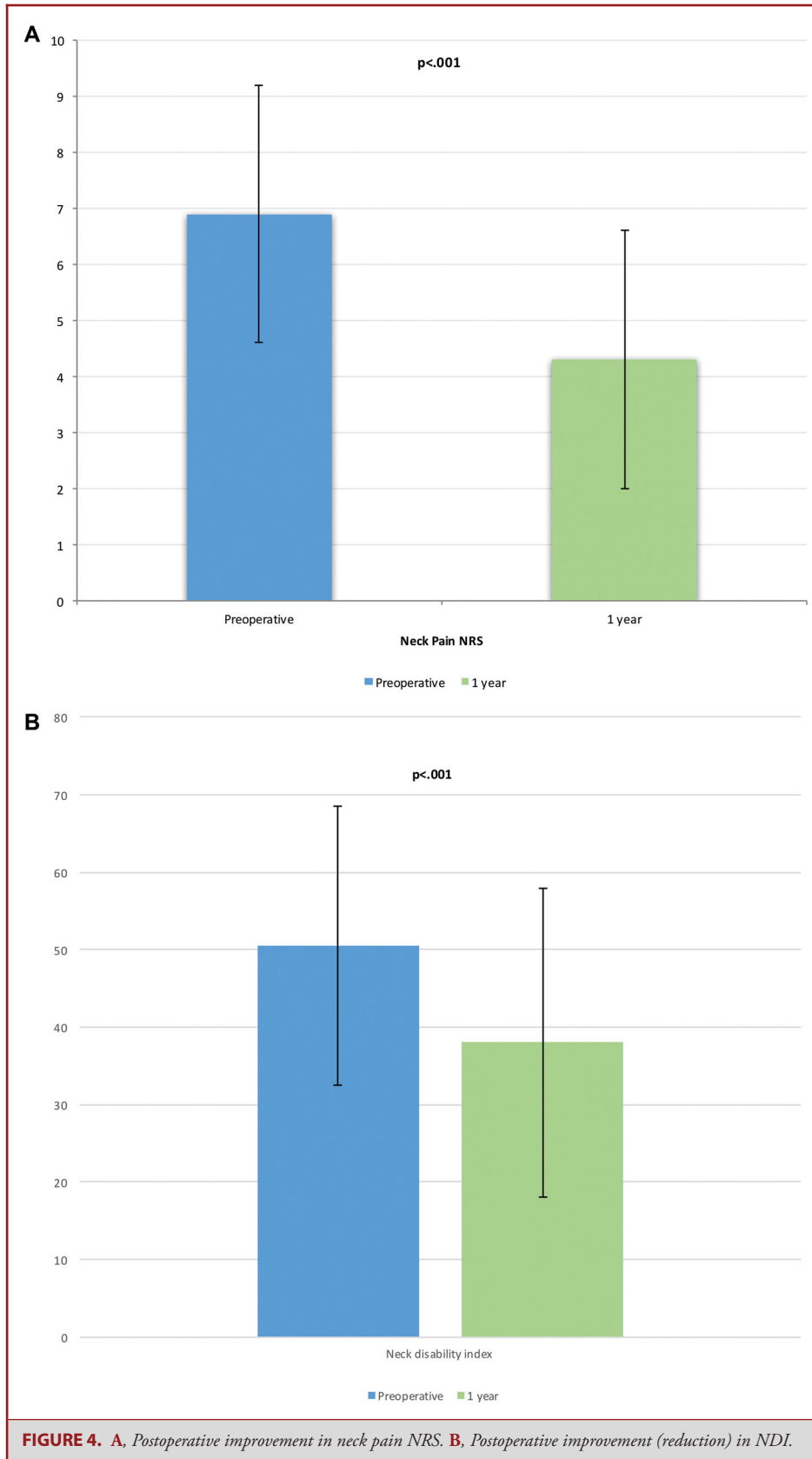
of these procedures are complex, with multiple approaches and potentially high-risk osteotomies. The definite possibility that patients can go through such operations and fail to improve by a clinically meaningful amount is sobering and may highlight the need for further improvements in patient selection and surgical outcomes.

The lack of significant improvement in mJOA is a striking finding in contrast to the majority of cervical spondylotic myelopathy studies that demonstrate significant postoperative improvements in this outcome measure. In a large, prospective study, Fehlings et al²³ reported an average improvement in mJOA of 2.88 1 yr after surgical decompression. As with our study, more severely affected patients experienced even greater improvements at 1 yr. Shamji et al²⁷ later identified a significantly attenuated postoperative improvement in patients with preoperative kyphosis (change in mJOA 1.4) than in those who were lordotic (change in mJOA 3.1; $P = .02$). Thus, it would seem that cervical deformity diminishes the improvement in myelopathy achieved through operative intervention. It is unclear what mechanism drives this finding and further biomechanical, imaging, and clinical studies will be required to elucidate this. One wonders whether dynamic compression of a spinal cord that is draped across a region of segmental kyphosis may be associated with chronic injury to the spinal cord that is less reversible than that caused by compression within a stenotic, but normally aligned spinal canal. It is an important finding to inform surgeons and prospective patients of the potential limitations in addressing myelopathy in the setting of significant deformity.

This study extends the work of Smith et al,¹⁵ which demonstrated the negative impact of ACD on HRQOL as measured by the EQ index. At baseline in our study, the mean EQ-5D of 0.51 corresponds to a value 34% below the 25th percentile for matched US normative population. At 1-yr follow-up, the mean EQ-5D increased to 0.66, which remains 15% below the 25th percentile. This suggests that although surgical treatment of ACD can yield clinically meaningful improvement in health status, on average, patients remain in a relatively poor state compared to the average population. Therefore, there is considerable room for improvement in the treatment of this challenging condition. It is also possible that the standardized measures of HRQOL employed in the present study are not sufficiently sensitive to the functional and health changes that occur in this population following surgical treatment.

It has been well established that appropriately selected patients with thoracolumbar deformity can obtain substantial improvement in HRQOL after surgery.²⁸⁻³⁰ To date, there have been no prospective studies that evaluate these outcomes specifically in the setting of cervical deformity. Theologis et al³¹ evaluated the outcome after three-column osteotomy (TCO) of the lower cervical and upper thoracic spine for cervicothoracic deformity. As in the present study, their retrospective review demonstrated improvement in NDI and a reduction in pain.³¹ The presence of concomitant cervical and thoracolumbar deformity in patients undergoing surgical correction of the





latter compromises the derived HRQOL benefit.¹³ Protosaltis et al¹² demonstrated poorer HRQOL in adult spinal deformity patients with elevated C2-7 SVA. They have also shown that improvements in regional cervical alignment following thoracolumbar deformity correction are correlated with improvement in HRQOL postoperatively.¹² Taken together, these data suggest that ACD negatively impacts HRQOL and improvement can be achieved through operative intervention.

Although the present study and previous reports suggest a beneficial effect of surgical treatment of ACD, this must be weighed against the operative risk. Smith et al¹ reported on early (<30 d) complications in 78 patients drawn from the same database employed in the present study that underwent surgical treatment of ACD and identified a complication rate of 43.6%. This included 24.4% of patients that experienced at least 1 major complication. The rates were significantly higher in patients who underwent combined anterior and posterior approaches (68.4%-79.3%). Theologis et al³¹ reported a similar complication rate of 37.5% in patients undergoing TCO of the cervicothoracic junction. In this study, the complication rate was more than double in lower cervical as compared with upper thoracic TCO (60% vs 27%).

The present study represents the first prospective, multicenter assessment of the impact of ACD surgery on postoperative HRQOL. However, our findings must be interpreted within the context of the study design. The participating centers were all high-volume institutions with experienced spinal deformity surgeons, which may compromise the generalizability of the results. The decision to operate was made by the treating surgeons without a standardized algorithm; therefore, the present study does not inform the selection process for determining operative candidates. The results should be considered preliminary given the relatively short follow-up and further longitudinal study is required to confirm the durability of these outcomes.

Limitations

The relatively high loss to follow-up of 29% represents a limitation of the study due to its potential to introduce selection bias. Encouragingly, a sensitivity analysis comparing baseline demographic, surgical, and HRQOL measures identified no significant differences between the study cohort analyzed and those lost to follow-up. Nevertheless, nondifferential loss to follow-up could have resulted in bias in outcome measures. It should be recognized that this study was conducted prospectively and involved centers with established research support to ensure maximum accuracy and thoroughness of data collection. In this context, the 29% loss to follow-up illustrates the challenges of ensuring full participation in postoperative assessments among this population.

The mortality rate of 6.5% is high for spinal surgery, including thoracolumbar deformity. Although several of the deaths occurred well outside the perioperative period and for seemingly unrelated reasons, it should serve as a warning of the potential for serious

adverse events in this highly vulnerable population. Ongoing studies to elucidate predictive factors for surgical complications will hopefully aid in selecting patients with acceptable risk profiles.

Many questions remain regarding the management of ACD. Optimizing patient selection will require a better understanding of prognostic factors, including baseline demographic, clinical, and radiographic factors. In particular, correlations between sagittal radiographic parameters and HRQOL are not as clear as with their thoracolumbar counterparts. Further research is required to delineate clinically relevant cervical radiographic parameters and postoperative alignment targets based on these. Surgical management can be enhanced by assessing the comparative effectiveness and risk profiles of the various approaches and techniques available. Future studies should comprise a multifaceted approach targeted at these questions.

CONCLUSION

Based on a prospective multicenter series of adults with cervical deformity, surgical treatment provided significant improvement in multiple measures of pain and function, including the NDI, neck pain NRS score, and EQ-5D. Further follow-up will be necessary to assess the durability of these surgical procedures and the resulting improved outcomes.

Disclosures

The International Spine Study Group (ISSG) is funded through research grants from DePuy Spine and individual donations. Disclosures for Dr Smith: Zimmer Biomet—consultant, honorarium for teaching, royalties; Nuvasive—consultant, honorarium for teaching; Cerapedics—consultant; K2M—honorarium for teaching; AOSpine—fellowship funding; NREF—fellowship funding. Disclosures for Dr Shaffrey: Medtronic—royalties, patents, consultant; Nuvasive—royalties, patents, consultant, stock holder; Zimmer Biomet—royalties, patents, consultant; K2M—consultant; Stryker—consultant; In Vivo—consultant; NIH—grants; Department of Defense—grants; ISSG—grants; DePuy Synthes—grants; AO—grants. Disclosures for Dr Kim: K2M—consultant; Zimmer Biomet—consultant; ISSGF—research funding; CSRS—research funding; HSS Journal—board membership; ASJ—board membership; GSJ—board membership. Disclosures for Dr Mundis: Nuvasive—consulting, royalties, research funding (not paid to Dr Mundis); K2M—consulting, royalties; DePuy Synthes—honorarium; DePuy Synthes/ISSG—research funding (not paid to Dr Mundis). Disclosures for Dr Gupta: DePuy Synthes—royalties, consultant, honorarium for lectures; Orthofix—consultant, honorarium for lectures. Disclosures for Dr Klineberg: DePuy—consulting; Stryker—consulting; AOSpine—paid speaker, fellowship support; K2M—paid speaker. Disclosures for Dr Schwab: Grants: SRS, DePuy Spine (through ISSGF); Speaking/teaching arrangements, consulting: Zimmer-Biomet, NuVasive, K2M, MSD, Medtronic; Board of Directors, Share holder: Nemaris INC; Royalties: K2M, MSD. Disclosures for Dr V Lafage: Depuy Synthes—paid lectures; Nuvasive—paid lectures; K2M—paid lectures; Medtronic—paid lectures; Nemaris—Board member and shareholder. Disclosures for Dr Passias: Medtronic—consultant. Disclosures for Dr Protosaltis: Consulting: Medtronic, Globus, Innovaxis, Nuvasive; Research support to my institution: Zimmer Spine, Cervical Spine Research Society. Disclosures for Dr Neuman: Depuy Synthes—research grant. Disclosures for Dr Daniels: Orthofix—consultant, research support,

fellowship support; DePuy Synthes—consultant; Stryker—consultant; Globus—consultant. Disclosures for Dr Hart: Globus—personal fees; Medtronic—grants; Seaspine—personal fees; DePuy Synthes—personal fees; CSRS—board member; ISSG—Executive Committee; ISSLS—board member; OHSU—patent. Disclosures for Dr Hostin: DePuy Synthes—consultant; Nuvasive—research support; Seeger—research support; DJO—research support. Disclosures for Dr Burton: DePuy Synthes—consultant, royalties, research support. Disclosures for Dr Deviren: Nuvasive—consultant, grants; Guidepoint—consultant; OREF—grants; AOSpine—grants; Globus—grants. Disclosures for Dr Albert: DePuy Synthes—royalties, consultant; Zimmer Biomet—royalties; Paradigm—stock; In Vivo—stock; Biometrix—stock; Invuity—stock; Spincity—stock; Gentis—stock. Disclosures for Dr Riew: Amedica—other financial or material support (royalties, patents, etc.); AOSpine—research support, advisory board or panel, other financial or material support (royalties, patents, etc.); Benevue—other financial or material support (royalties, patents, etc.); Biomet—other financial or material support (royalties, patents, etc.); Broadwater—other financial or material support (royalties, patents, etc.); Cerapedics—research support; Expanding Orthopedics—other financial or material support (royalties, patents, etc.); Expert Testimony—consultant; Medtronic—research support, other financial or material support (royalties, patents, etc.); Medyssey—other financial or material support (royalties, patents, etc.); Nexgen Spine—other financial or material support (royalties, patents, etc.); Osprey—other financial or material support (royalties, patents, etc.); Paradigm Spine—other financial or material support (royalties, patents, etc.); PSD—other financial or material support (royalties, patents, etc.); Selby Spine—other financial or material support (royalties, patents, etc.); Spinal Kinetics—other financial or material support (royalties, patents, etc.); Spineology—other financial or material support (royalties, patents, etc.); Vertiflex—other financial or material support (royalties, patents, etc.). Disclosures for Dr Bess: K2 Medical—consultant, royalties, research support; Allosource—consultant; Pioneer—royalties; Innovasis—royalties, research support; Nuvasive—royalties, research support; DePuy Synthes Spine—research support; Stryker—research support. Disclosures for Dr Ames: DePuy Synthes—consultant; Medtronic—consultant; Stryker—consultant, royalties; Zimmer Biomet—royalties; Fish & Richardson, PC—patents.

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COMMENT

In this manuscript, the authors present a prospective case series of patients with cervical deformity who underwent operative correction. The primary objective of the study was to determine changes in HRQOL after surgical treatment.

Overall, 77 patients were enrolled in this multicenter study. All types of cervical deformities were included in the study, with reasonable exclusion criteria. Procedures were performed at the discretion of the treating surgeon. The follow-up rate was 71.4% at 1 year.

The results showed a mortality rate of 6.5%, with statistically significant improvements in EQ-5D, NRS, and NDI. However, clinically significant improvements in EQ-5D, NRS, and NDI were only seen in 55.6%, 61.8%, and 55.6% of patients respectively. Statistically significant improvements in myelopathy were not seen.

As stated by the authors, this manuscript is best seen as preliminary. As such, it constitutes a starting point for future studies. There is no doubt that adult cervical deformity is a debilitating condition. Nevertheless, with a clinical success rate between 50%-60%, it is not clear from these data that the current state of the art is up to the task. Undoubtedly this situation will improve, and studies such as the present study establish the benchmark.

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