Original Study

Evaluating cervical deformity corrective surgery outcomes at 1-year using current patient-derived and functional measures: are they adequate?

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Background: Current health-related quality of life (HRQL) metrics used to assess patient outcomes following surgical correction of cervical deformity (CD) are not deformity-specific and thus cannot capture all aspects of a patient's deformity and outcomes. The purpose of this study is to evaluate the sensitivity of different HRQL outcome measures in assessing CD patients' outcomes 1-year post-operatively.

Methods: Retrospective review of prospective multi-center database. Inclusion criteria: CD patients ≥18 yrs with pre- and 1-year post-operative radiographs and HRQLs [modified Japanese Orthopaedic Association (mJOA), EuroQol five-dimensions (EQ-5D), neck disability index (NDI)]. Associations between changes in EQ5D and NDI with improvement at 1-year in mJOA scores were assessed by whether or not the patient met the minimum clinically important difference (MCID) as well as whether or not they improved by one or more categories (i.e., change from moderate to mild). Odds ratios reported with 95% confidence intervals.

Results: Sixty-three CD patients were included (mean 62 y, 55.6% F). Average baseline NDI scores were 46.75, mJOA was 13.68, and EQ-5D 0.74. Overall baseline myelopathy breakdown: none—9.5%, mild—30.2%, moderate—42.9%, high—17.5%. At 1-year, 46% of patients improved in mJOA, 71.4% NDI, and 65.1% EQ-5D. 19% of patients met mJOA MCID, 44.4% NDI MCID, 19% EQ-5D MCID. One-point improvement in NDI increased the odds of mJOA improvement and reaching mJOA MCID (improvement: OR, 1.06, CI: 1.01–1.10, P=0.01; MCID: OR, 1.06, CI: 1.02–1.11, P=0.006). Improvement in EQ-5D by 0.1 increased the odds of improving in mJOA and reaching mJOA MCID at 1-year (improvement: OR, 3.85, CI: 1.51–9.76, P=0.005; MCID: OR, 3.88, CI: 1.52–9.88, P=0.005). While correlations exist between outcome measures, when modeling these outcomes while controlling for confounders including cSVA change, surgical invasiveness, age and CCI, these HRQLs were not strongly correlated.

Conclusions: Improvements in functional outcomes, as defined by mJOA score, were correlated with changes in neck based disability and general health state, defined by NDI and EQ-5D respectively. In an adjusted model, however, these direct relationships were not maintained. A CD-specific HRQL might be more useful for surgeons in assessing patient outcomes using a single metric.

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Keywords: Cervical deformity (CD); health-related quality of life metrics (HRQL metrics); myelopathy; surgical correction; outcomes; sagittal malalignment; cervical spine; spinal deformity; spino-pelvic alignment; alignment

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Introduction

Cervical deformity (CD) is becoming increasingly recognized and effective surgical correction has received much attention recently (1-5). Classifications of CD are not yet fully established and treatment options and surgical correction are dependent on the specific nature of the condition. Assessment of cervical deformities is challenging, given the heterogenic nature of the condition and varying surgical strategies. The primary goals of CD treatment are to restore cervical sagittal alignment and improve horizontal gaze, decompress the neural elements, improve neck pain and overall functional outcomes.

The effects of surgical correction of CD on patient outcomes are not well-defined. Some studies have shown that the concomitant presence CD results in worse clinical outcomes for patients undergoing surgical correction of adult thoraco-lumbar deformity, though further work is warranted to assess extended follow-up for these patients (6,7). It has also been shown that a greater degree of deformity correction correlates with improvements in HRQLs and increased patient satisfaction following CD surgical correction (4,8-10). Tang *et al.* (10) found that positive sagittal malalignment in the cervical spine, using C2–C7 SVA, negatively impacts SF-36 physical component scores and positively correlates with NDI at early follow-up for multilevel posterior cervical fusions for stenosis, myelopathy, and kyphosis patients.

The current HRQL metrics used to assess patient outcomes following surgical correction of CD are not specific to a CD population. The modified Japanese Orthopaedic Association (mJOA) questionnaire has been validated for cervical myelopathy patients. The neck disability index (NDI) has been validated for cervical radiculopathy, unspecified neck pain, and mechanical neck disorders (11-14). Most recently, Carreon *et al.* used the NDI to assess cervical degenerative patients' outcomes following cervical fusions (15). EuroQol five-dimensions (EQ-5D) questionnaire has been used to assess overall health state of patients, but is not specific to CD patients (16).

The present study aims to evaluate the sensitivity of various health-related quality of life (HRQL) outcome measures in assessing CD patients' outcomes at 1-year post-operatively, in light of the fact that no current HRQL measure is CD specific.

Methods

Data source

This study is a retrospective review of a prospectively-collected database of adult CD patients enrolled from 13 sites around the U.S. Internal Review Board approval was obtained at each participating site prior to study initiation. Inclusion criteria for the database were patients ages ≥18 years, and radiographic evidence of CD at baseline assessment, defined as the presence of at least 1 of the following: cervical kyphosis (C2–7 Cobb angle >10°), cervical scoliosis (C2–7 coronal Cobb angle >10°), C2–7 sagittal vertical axis (cSVA) >4 cm, or chin-brow vertical angle (CBVA) >25°. Patients with active tumors or infections were excluded from the study.

Data collection

Demographic and clinical data collected included patient age, sex, body mass index (BMI), history of prior cervical surgery, baseline mJOA score and baseline T4–T12 thoracic kyphosis. Surgical data collected included operative time, estimated blood loss, surgical approach, bone morphogenetic protein 2 (BMP-2) use, osteotomy use and number of osteotomies, levels fused, and instrumentation used.

Patients were evaluated using full-length free-standing lateral spine radiographs (36' cassette) at baseline and 1-year post-operative follow-up visit. Radiographs were analyzed using dedicated and validated software (SpineView®; ENSAM, Laboratory of Biomechanics, Paris, France) at a single center with standard techniques (17-19). Measured cervical spine parameters (*Figure 1*) included cervical SVA (cSVA: offset from the C2 plumbline and the postero-superior corner of C7), C2–C7 lordosis (CL: Cobb angle between C2 inferior endplate and C7 inferior endplate),

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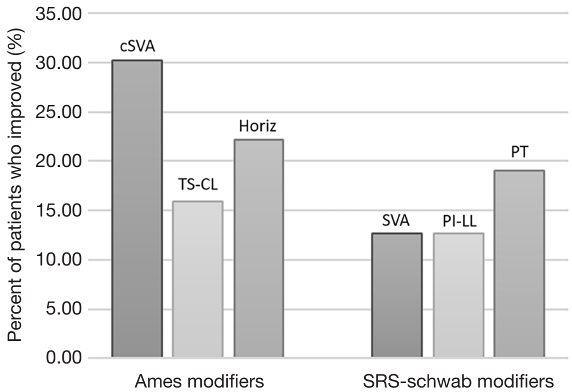

Figure 1 The breakdown of patients who improved in each radiographic modifier for both the Ames and SRS-Schwab classifications at 1-year follow-up. Improvement in modifier grade was assessed using baseline to 1-year changes in each modifier. cSVA, cervical sagittal vertical axis; TS-CL, T1 slope minus cervical lordosis; Horiz, horizontal gaze; SVA, sagittal vertical axis; PT, pelvic tilt; PI-LL, pelvic incidence minus lumbar lordosis.

T1 slope minus CL (TS-CL: mismatch between T1 slope and cervical lordosis), and CBVA (angle subtended between the vertical line and the line from the brow to the chin). Spinopelvic parameters (*Figure 1*) included: SVA (C7 plumb line relative to the posterosuperior corner of S1), pelvic incidence minus lumbar lordosis (PI-LL: mismatch between pelvic incidence and lumbar lordosis), and pelvic tilt (PT: angle between the vertical and the line through the sacral midpoint to the center of the two femoral heads).

Clinical outcomes assessment

Clinical outcomes were assessed using mJOA, NDI and EQ-5D scores at baseline and 1-year following surgery. The minimum clinically important difference (MCID) for the mJOA was set at 2 based on published values (20). The MCID for NDI was set as 15 (we doubled the published MCID value because our NDI is on a 0–100 scale) and the EQ5D MCID was recently set as 0.1 based on previously published values (15,21,22).

Statistical analysis

Descriptive statistics were first used to summarize the characteristics of the population. Proportions were used to summarize categorical variables and mean ± standard deviation for continuous variables.

To assess the sensitivity of mJOA and NDI in capturing outcomes for a CD population, five anchoring groups were created based on self-reported EQ5D scores: ‘much better’ was assigned to patients to reached the 1-year MCID in EQ5D, ‘better’ for patients who improved in EQ5D though did not reach MCID, ‘neither’ was assigned to patients whose EQ5D scores were the same at baseline and 1-year, ‘worse’ for patients who worsened in EQ5D from baseline to 1-year by 0.5 or less, and ‘much worse’ for patients who worsened in EQ5D by greater than 0.5. mJOA and NDI scores at baseline, 1-year post-operatively, and the change from baseline to 1-year in each metric were assessed among anchor groups. ANOVA with Bonferroni post-hoc analysis was used to assess outcomes based on mJOA and NDI scores among the anchoring groups.

Results are reported as coefficient with SD or odds ratios with 95% confidence intervals with P value. Two-sided P values <0.05 were considered to be statistically significant. All statistical analysis was conducted in SPSS version 23.

Results

Patient population

Sixty-three adult CD patients were included in the analysis. The mean age was 62.52±10.66 years old, mean BMI was 28.58±8.07 kg/m^2, average CCI was 0.54±0.89, and 55.6% were female. Twenty-three (37.7%) patients had a history of prior cervical spine surgery; 18 (30.5%) have a history of smoking, 7 (11.1%) have diabetes, 9 (14.3%) have osteoporosis, and 16 (25.4%) have depression. The average baseline NDI score was 46.75, mJOA score was 13.68, and EQ-5D was 0.74. The overall myelopathy score category breakdown at baseline: 9.5% none, 30.2% mild, 42.9% moderate, 17.5% high.

The average levels fused was 7.52±3.56 levels. The average estimated blood loos was 771.60±882.70 mL and the average operative time was 279.28±159.17 minutes. By surgical approach, 31 (49.2%) of surgeries were posterior-only, 11 (17.5%) were anterior-only, and 21 (33.3%) were combined approach. 41.3% of surgeries used BMP-2. Fifteen (23.8%) of patients had a Smith-Peterson osteotomy and 14 (22.2%) had a three-column osteotomy.

Radiographic improvement

The average baseline cSVA was 47.25±24.66 mm, TS-CL was 37.85°±19.99°, and global SVA was 4.81±70.88 mm

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Table 1 Pre-operative and 1-year post-operative sagittal plane deformity radiographic parameters

Radiographic parameter	Baseline	1 year	Difference	P value
PT (°)	18.93±10.34	17.74±10.51	−1.19±6	0.143
PI-LL (°)	0.89±14.37	0.95±14.74	0.05±11.06	0.971
SVA (mm)	4.81±70.88	26.37±60.85	21.56±60.11	0.010*
T4–T12 TK (°)	41.37±16.53	44.9±16.25	3.53±9.95	0.010*
T1 slope (°)	30.56±18.05	35.67±15.56	5.11±9.19	<0.001*
TS-CL (°)	37.85±19.99	26.17±12.86	−11.67±18.77	<0.001*
C2–C7 CL (°)	−7.00±22.55	9.29±17.64	16.29±20.03	<0.001*
C2–C7 SVA (mm)	47.25±24.66	41.18±17.24	−6.06±18.91	0.026*
C2–T3 (°)	−16.23±22	1.52±17.42	17.75±23.28	<0.001*
C2–T3 SVA (mm)	80.02±40.45	77.77±28.21	−2.25±27.52	0.562
C2 slope (°)	38.67±20.94	25.22±14.11	−13.44±19.42	<0.001*
C1 slope (°)	3.15±18.49	−7.98±13.74	−11.13±18.17	<0.001*
C0 slope (°)	0.18±14.77	−7.89±10.20	−8.06±15.22	<0.001*
C0–C2 angle (°)	32.99±12.07	27.78±10.84	−5.21±11.11	0.002*

*, represent a significance of P<0.05. PT, pelvic tilt; PI, pelvic incidence; LL, lumbar lordosis; TK, thoracic kyphosis; CL, cervical lordosis; SVA, sagittal vertical axis.

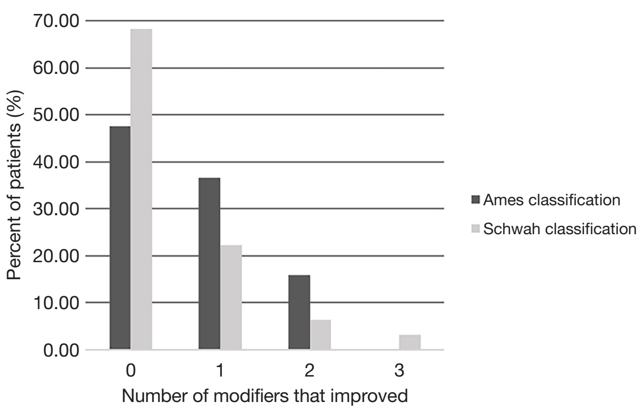

Figure 2 The distribution of the number of radiographic modifiers all patients improved in for both the Ames and SRS-Schwab classifications from baseline to 1-year follow-up. Improvement in modifier grade was assessed using baseline to 1-year changes in each modifier and the sum of the number of improved modifiers is reported. cSVA, cervical sagittal vertical axis; TS-CL, T1 slope minus cervical lordosis; Horiz, horizontal gaze; SVA, sagittal vertical axis; PT, pelvic tilt; PI-LL, pelvic incidence minus lumbar lordosis.

(*Table 1*). Patients significantly improved in SVA, TK, T1 slope, CL, cSVA, C2–T3, C2 slope, C1 slope, C0 slope, and C0–C2 angle from baseline to 1-year post-operatively (all P<0.05). Using the Ames classification for CD, 30.2% of patients improved in cSVA modifier grade from baseline to 1-year post-operative, 15.9% improved in TS-CL modifier grade, and 22.2% in the horizontal gaze modifier grade (*Figure 1*). Using the SRS-Schwab classification, 12.7% improved in SVA modifier grade, 12.7% in PI-LL grade, and 19.0% in PT grade. Overall, 52.3% of patients improved in at least one Ames modifier and 31.7% of patients improved in at least one SRS-Schwab modifier at 1-year (*Figure 2*).

Clinical improvement

At 1 y, 46.0% of patients improved in mJOA, 71.4% in NDI scores, and 65.1% improved in EQ5D (*Table 2*); 19.0% of patients met mJOA MCID, 44.4% met NDI MCID, and 19.0% met EQ5D MCID at 1 y. For patients who improved in mJOA at 1 y, baseline mJOA scores were 30.2% mild,

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Table 2 Pre-operative and 1-year post-operative outcome measures for NDI, EQ-5D, and mJOA as well as 1-year improvement and achievement of MCID

Outcome measure	Baseline	1 year	Difference	% improved	% MCID
NDI	46.75±17.49	34.42±19.60	12.3±15.7	45 (71.4%)	28 (44.4%)
EQ-5D	0.74±0.06	0.79±0.08	0.05±0.08	41 (65.1%)	12 (19.0%)
mJOA	13.68±2.53	14.23±2.87	0.53±2.60	29 (46.0%)	12 (19.0%)
None	6 (9.5%)	12 (19.0%)	–	–	–
Mild	19 (30.2%)	18 (28.6%)	–	–	–
Moderate	27 (42.9%)	22 (34.9%)	–	–	–
Severe	11 (17.5%)	11 (17.5%)	–	–	–

NDI, neck disability index; EQ-5D, EuroQol five dimensions; mJOA, modified Japanese Orthopaedic Association; MCID, minimum clinically important difference.

Table 3 Correlations between health-related quality of life metrics and radiographic improvement

HRQL improvement	Ames modifier improvements						SRS-Schwab modifier improvements					
	cSVA		TS-CL		Horizontal gaze		SVA		PT		PI-LL	
	r	P	r	P	r	P	r	P	r	P	r	P
mJOA improve	0.02	0.89	–0.14	0.27	0.12	0.35	0.13	0.32	–0.12	0.33	0.13	0.32
EQ5D improve	–0.03	0.84	0.14	0.29	0.07	0.58	0.08	0.54	0.02	0.90	0.08	0.54
NDI improve	0.03	0.80	–0.01	0.92	0.00	1.00	0.03	0.82	–0.05	0.69	0.03	0.82
mJOA MCID	0.12	0.34	–0.10	0.44	0.13	0.31	0.30	0.017*	–0.03	0.82	0.06	0.65
EQ5D MCID	–0.14	0.26	0.01	0.93	0.03	0.80	0.18	0.16	0.28*	0.027*	0.30	0.017*
NDI MCID	–0.03	0.81	0.14	0.29	0.06	0.64	0.23	0.06*	–0.05	0.69	0.03	0.81

*, represent a significance of P<0.05. NDI, neck disability index; EQ-5D, EuroQol five dimensions; mJOA, modified Japanese Orthopaedic Association; MCID, minimum clinically important difference; cSVA, cervical sagittal vertical axis; TS-CL, T1 slope minus cervical lordosis; SVA, sagittal vertical axis; PT, pelvic tilt; PI-LL, pelvic incidence minus lumbar lordosis.

42.9% moderate, and 17.5% severe myelopathy.

Correlations between HRQL and radiographic improvement

When looking at the correlations between radiographic and HRQL improvement, there was no correlation between improvement in Ames radiographic modifier grades and HRQL improvement in the overall cohort (*Table 3*). Improvement in Schwab SVA modifier grade correlated with reaching 1-year mJOA MCID (r=0.30, P=0.017). Both Schwab PT and PI-LL modifier grade improvements were correlated with reaching 1-year EQ-5D MCID (r=0.28, P=0.027; r=0.30, P=0.017). In looking only at patients without severe concomitant thoracolumbar malalignment, improvement in the Ames horizontal gaze modifier grade approached significant correlation with reaching 1-year mJOA MCID (r=0.27, P=0.051).

Multivariate analysis

A one-point improvement in NDI score increased the odds of improving in mJOA and reaching 1 y mJOA MCID (mJOA improvement: OR, 1.06, CI: 1.01–1.10, P=0.01; mJOA MCID: OR, 1.06, CI: 1.02–1.11, P=0.006). Improvement in EQ-5D by 0.1 increased the odds of improving in mJOA and of reaching mJOA MCID at 1 y (improvement: OR, 3.85, CI: 1.51–9.76, P=0.005; MCID:

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Table 4 Each outcome of the NDI and mJOA questionnaires for all five anchoring groups

HRQL	Time point	Total (N=63)	Much better (N=12)	Better (N=30)	Neither (N=5)	Worse (N=10)	Much worse (N=6)	P value
NDI	Pre-operative score	46.75±17.49	43.81±14.12	47.8±17.04	46.27±30.59	50.2±18.44	42±15.18	0.873
	Post-operative score	34.42±19.6	21.3±14.77	32.87±20.34	45.2±21.1	47.8±11.09	36.89±20.09	0.014*
	Change in score	−12.29±15.74	−22.51±13.64	−14.89±13.1	−1.07±13.2	−2.4±19.13	−5.11±13.4	0.006*
mJOA	Pre-operative score	13.68±2.53	14.17±2.55	13.6±2.69	13.4±1.14	13.5±3.03	13.67±2.25	0.968
	Post-operative score	14.23±2.87	16.08±2.84	14.28±3.02	13.8±1.1	12.6±2.22	13.33±2.66	0.057
	Change in score	0.53±2.61	1.92±3.09	0.66±2.76	0.4±0.55	−0.9±2.23	−0.33±0.82	0.126

*, represent a significance of P<0.05. NDI, neck disability index; EQ-5D, EuroQol five dimensions; mJOA, modified Japanese Orthopaedic Association; HRQL, health-related quality of life.

Table 5 Assessment of significant differences among the anchoring groups in both the NDI and mJOA scoring systems at baseline, 1-year follow-up, and baseline to 1-year change in scores across all anchoring groups. Bonferroni post-hoc test was used to assess these differences between anchoring groups

Anchoring group	NDI			mJOA		
	Pre-operative score	Change in score	Post-operative score	Pre-operative score	Change in score	Post-operative score
Much better versus better	1.0	1.0	0.691	1.0	1.0	0.6
Much better versus neither	1.0	0.068	0.167	1.0	1.0	1.0
Much better versus worse	1.0	0.018*	0.012*	1.0	0.121	0.044*
Much better versus much worse	1.0	0.185	0.921	1.0	0.815	0.489
Better versus neither	1.0	0.515	1.0	1.0	1.0	1.0
Better versus worse	1.0	0.21	0.293	1.0	1.0	1.0
Better versus much worse	1.0	1.0	1.0	1.0	1.0	1.0
Neither versus worse	1.0	1.0	1.0	1.0	1.0	1.0
Neither versus much worse	1.0	1.0	1.0	1.0	1.0	1.0
Worse versus much worse	1.0	1.0	1.0	1.0	1.0	1.0

*, represent a significance of P<0.05. NDI, neck disability index; mJOA, modified Japanese Orthopaedic Association.

OR, 3.88, CI: 1.52–9.88, P=0.005). Reaching 1 y mJOA MCID was correlated with EQ-5D score improvement (EQ-5D: r=0.355, P=0.004). While correlations were seen between outcome measures, when modeling these outcomes while controlling for confounders including cSVA change, surgical invasiveness, age and CCI, these HRQLs were not strongly correlated.

Anchoring groups and comparison of outcomes for mJOA and NDI

The breakdown of the anchoring groups was as follows: 12 patients (19%) were in the 'much better' group, 30 patients (47.6%) in the 'better' group, 5 patients (7.9%) in the 'neither' group, 10 patients (15.9%) in the 'worse' group, and 6 patients (9.5%) in the 'much worse' group (*Table 4*). One-year NDI score (P=0.014) and baseline to 1-year change in NDI score (P=0.006) were different across anchoring groups (*Table 5*). Baseline to 1-year change in NDI scores were significantly different between the 'much better' and 'worse' groups ('much better' Δ=−22.0 points, 'worse' Δ=−2.4 points, P=0.018). One-year NDI scores ('much better' =21.0, 'worse' =47.0, P=0.012) and 1-year mJOA scores ('much better' =16.08, 'worse' =12.60, P=0.044) were also different between those same two groups All other anchoring groups did not display significant differences in mJOA or NDI scores (all P>0.1).

Discussion

With the lack of a CD-specific patient outcomes measurement, the need arises to assess the current outcome metrics in the context of CD to evaluate their effectiveness. Improvements in NDI and EQ-5D increased the likelihood of improving or reaching MCID for mJOA. However, these direct relationships between mJOA, NDI, and EQ-5D were not maintained in an adjusted model controlling for confounding factors, possibly because these outcome measures assess different aspects of a patient's disability, and they are also not specific to a CD population. Outcomes following corrective surgery for CD are not as profound or clear as compared to adult spinal deformity results. There has been little work done to evaluate outcomes following surgical correction specifically for a CD population. Theologis *et al.* found that patients with cervicothoracic junction deformities had improved quality of life after three column posterior osteotomies (23). Another group reported NDI improvements following pedicle subtraction osteotomy at the cervicothoracic junction for cervical sagittal imbalance (3). In addition, studies have shown that patients with CD and concomitant thoracolumbar deformity have improved outcomes following corrective surgery (6,7,24). We found that at 1-year post-operatively, 46% of patients improved in mJOA, 71.4% in NDI, and 65.1% in EQ-5D, with a subset of patients reaching MCID improvements in each outcome measure.

When looking at the correlations between improvements in radiographic measures and HRQL measures, we found no significant relationships between improvements in Ames radiographic modifiers and improvements in mJOA, NDI, or EQ-5D. However, some improvements in SRS-Schwab modifiers (PT and PI-LL) were correlated with reaching the MCID for EQ-5D and SVA improvements were correlated with MCID for mJOA and NDI. There have been few studies to report the relationships between radiographic parameters in the cervical spine, specific to a deformity population, and HRQL measures (10,25). These relationships are not as well-established as the global and pelvic parameters' relationships with outcomes for thoracolumbar deformity (26-28). Of the few studies looking into these relationships for cervical patients, one found no significant relationships between segmental kyphosis and post-operative outcomes and another concluded that only segmental sagittal alignment correlated with clinical outcomes after cervical disc arthroplasty but overall cervical alignment did not correlate with outcomes (25,29,30). In addition, we found, using EQ-5D as an anchor, that patients who were 'much better' had significantly lower NDI scores and higher mJOA scores at 1-year follow-up than patients who were 'worse'.

This study is one of the first to investigate clinical outcomes following CD corrective surgery. We found that improving by one-point on the NDI or EQ-5D questionnaires increased the odds of improving in mJOA score and reaching the MCID for mJOA. However, no significant correlations were seen between radiographic parameters and improvements and HRQLs. This might be attributable to the use of current metrics that are not specific enough for CD or because we are weighting radiographic parameters too heavily, or possibly a combination of these two. Similarly, a recent study found that when looking at lumbar lordosis index and global tilt, only 2% of the variance in ODI was attributable to radiographic parameters (31). When modeling these outcomes, controlling for many confounding factors, we found that these HRQLs were not strongly correlated. Given that none of these outcome measures are specific for assessing CD, a strong correlation between outcome measures that assess various aspects of a patient's disability and health state might not be achievable.

Limitations

We appreciate several limitations. Firstly, the retrospective, multicenter nature of this study creates the possibility for surgeon and site variation, though the benefits of a multicenter study are that it allows for more generalizability to the findings. With relatively short follow-up, this study should be re-evaluated using longer follow-up to fully assess the relationship between these metrics in a CD population.

Conclusions

This study found that improvements in mJOA score were correlated with changes in NDI and EQ-5D. Using an adjusted model that took into account many factors including change in cSVA, invasiveness, CCI, and age, the direct relationships between these patient outcome measures were not maintained. Since these patient-reported outcomes do not strongly correlate with each other or

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with radiographic parameters, perhaps a metric that more strongly correlates with relevant radiographic and clinical outcome metrics specific to a CD population is necessary. Further studies with an increased number of patients and longer follow-up are required to fully assess these relationships between outcome measures and radiographic parameters as well as to work towards the development of a cervical-deformity specific outcome metric.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: The study was approved by their local Institutional Review Board (No. 12-02939) and written informed consent was obtained from all patients.

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