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Prioritization of realignment associated with superior clinical outcomes for surgical cervical deformity patients

ABSTRACT

Background: To optimize quality of life in patients with cervical deformity (CD), there may be alignment targets to be prioritized.

Objective: To prioritize the cervical parameter targets for alignment.

Methods: Included: CD patients (C2–C7 Cobb $>10^\circ$, C2–C7 lordosis [CL] $>10^\circ$, cSVA >4 cm, or chin-brow vertical angle $>25^\circ$) with full baseline (BL) and 1-year (1Y) radiographic parameters and Neck Disability Index (NDI) scores; patients with cervical (C) or cervicothoracic (CT) Primary Driver Ames type. Patients with BL Ames classified as low CD for both parameters of cSVA (<4 cm) and T1 slope minus CL (TS-CL) ($<15^\circ$) were excluded. Patients assessed: Meeting Minimal Clinically Important Difference (MCID) for NDI ($<-15 \Delta$ NDI). Ratios of correction were found for regional parameters categorized by Primary Ames Driver (C or CT). Decision tree analysis assessed cut-offs for differences associated with meeting NDI MCID at 1Y.

Results: Seventy-seven CD patients (62.1 years, 64%F, 28.8 kg/m²). 41.6% met MCID for NDI. A backward linear regression model including radiographic differences as predictors from BL to 1Y for meeting MCID for NDI demonstrated an $R^2 = 0.820$ ($P = 0.032$) included TS-CL, cSVA, MGS, C2SS, C2-T3 angle, C2-T3 sagittal vertical axis (SVA), CL. By primary Ames driver, 67.5% of patients were C, and 32.5% CT. Ratios of change in predictors for MCID NDI patients for C and CT were not significant between the two groups ($P > 0.050$). Decision tree analysis determined cut-offs for radiographic change, prioritizing in the following order: $\geq 42.5^\circ$ C2-T3 angle, $>35.4^\circ$ CL, $<-31.76^\circ$ C2 slope, <-11.57 mm cSVA, $<-2.16^\circ$ MGS, >-30.8 mm C2-T3 SVA, and $\leq -33.6^\circ$ TS-CL.

Conclusions: Certain ratios of correction of cervical parameters contribute to improving neck disability. Prioritizing these radiographic alignment parameters may help optimize patient-reported outcomes for patients undergoing CD surgery.

Keywords: Cervical deformity, prioritization, realignment

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INTRODUCTION

Incidence of adult cervical deformity (CD) as a distinct clinical diagnosis is rising, along with the literature concentrating on methodology for appropriately assessing the disease.^[1] As the condition is often associated with major disability and neurologic compromise, surgical correction of malalignment and addressment of symptoms are often warranted.^[2,3] Numerous studies have demonstrated radiographic alignment and achievement of sagittal balance as significant drivers of health-related-quality-of-life (HRQL) improvement in deformity patients, not specific to the cervical spine.^[4-6] Moreover, studies investigating the connection between cervical alignment parameters and HRQL outcomes is limited.

Restoration of cervical sagittal alignment involves neural element decompression and/or fusion of the cervical and caudal spinal regions, often invasive in nature and poses risks for major complications and poor patient-reported outcomes.^[7] Many patients are unable to undergo these major, invasive CD corrective procedures due to deformity severity, old age, comorbidities, and severe frailty status. Moreover, often baseline (BL) characteristics (body mass index [BMI], age, Charlson Comorbidity Index [CCI] score, frailty score) imply increased risk for certain postoperative complications and decline in HRQL outcomes.^[8,9] Alignment adjustments have been explored in the adult spinal deformity (ASD) population. Lafage *et al.* proposed a modified version of the validated SRS-Schwab ASD classification accounting for varying age ranges.^[10] More rigorous alignment objectives were determined to be warranted for younger patients, while less rigorous alignment objectives for elderly patients, to achieve normative HRQL scores for each age population.^[11] This alignment specificity for the individual patient needs to be considered to optimize patient-reported outcomes.

Explicitly, when assessing deformity specific to the cervical spine, a standardized classification system of deformity severity is in its preliminary stages. The most well-known classification was created by Ames and the International Spine Study Group (ISSG), but it has yet to be formally validated with connection to HRQL outcomes.^[12-14] Little is known regarding the order of addressing correction of certain cervical alignment parameters for peak improvement in postoperative patient-reported outcomes.^[15,16] Using a prospective multicenter collection of CD surgical patients, this study investigated the prioritization of cervical alignment parameters and their minimal degree of correction that contributes to optimal quality of life.

METHODS

Data source and inclusion criteria

This was a retrospective cohort study of a prospective, multicenter ISSG database of CD patients enrolled from 2013 to 2018 at 13 participating centers around the United States. Institutional Review Board approval was required protocol by each site and informed patient consent was obtained. Patients enrolled in the database were greater than 18 years with evidence of one of the following CD BL radiographic parameters: cervical kyphosis (C2–C7 Cobb angle $>10^\circ$), cervical scoliosis (C2–C7 coronal Cobb angle $<10^\circ$), C2–C7 sagittal vertical axis (cSVA) >40 mm or chin-brow vertical angle (CBVA) $>25^\circ$. Database exclusion criteria comprised of patients with spinal deformity of neuromuscular etiology, presence of active infection, or malignancy. The study inclusion criteria required complete BL and 1-year (1Y) radiographic measurements and the health-related quality of life (HRQL) measure, Neck Disability Index (NDI), as well as demonstrated Cervical or Cervicothoracic Ames sagittal deformity driver descriptor. To analyze a more homogenous CD population, patients were excluded if they were categorized with another Ames driver (Thoracic [T], Coronal [S]) or were classified as a low Ames CD modifier for both the parameters of cSVA (<4 cm) and T1 slope minus C2–C7 lordosis (TS–CL) ($<15^\circ$).

Data collection, radiographic, and health-related-quality-of-life assessment

Patient demographic and clinical data assessed patient age, gender, body mass index (BMI), and CCI. Operative factors assessed: surgical approach, levels fused, operative time, and estimated blood loss (EBL). Full-length free-standing lateral spine radiographs were used to assess the patient population at BL and 1Y. Radiographs were analyzed with SpineView® (ENSAM, Laboratory of Biomechanics, Paris, France) software according to the literature.^[17-19] Radiographic parameters assessed included cervical sagittal vertical axis (cSVA), C2–C7 lordosis (CL), TS–CL, CBVA, McGregor's slope (MGS), C2–T3 sagittal vertical axis (SVA), C2–T3 angle, C2 slope. The health-related quality of life questionnaire utilized in this study was the NDI administered by each of the participating centers.

Statistical analysis

Descriptive analyses determined demographic, clinical, and surgical data. Frequency analysis evaluated categorical variables with Chi-square analysis determining the significant variance of expected versus observed values. Patients were assessed based on meeting the Minimal Clinically Important Difference (MCID) for NDI scores at 1Y (<-15 Δ NDI). Proportion (%) and difference of correction from preoperative

measurement to 1Y were calculated for the following regional parameters: cSVA, CL, T1 Slope, TS-CL, CBVA, MGS, C2-T3 SVA, C2-T3 Angle, and C2 Slope. Backward linear regression model including the radiographic differences (1Y – BL) as predictors for meeting MCID for NDI found the parameters that contributed the greatest variation (with a significantly large R^2 value). The radiographic measures included in the model were then assessed for the proportion of correction stratified by C or CT Ames primary driver type. Analysis of variance compared the C and T ratios for any significant differences. Random forest analysis generated 20,000 Conditional Inference Trees to determine cut-off values of the radiographic difference variables included in the backward regression model, accomplished through iteration of multivariate regression equations. Radiographic change cut-offs were prioritized based upon their ordinal regression values when entered as sole predictors for meeting MCID for NDI through binary logistic regressions. All statistical analyses were performed using SPSS software (version 21.0 IBM, Armonk, NY, USA) and R-statistical package (www.r-project.org). All analyses were two-sided and the level of significance was set to <0.05 .

RESULTS

Overall cohort patient characteristics

Seventy-seven CD patients with complete radiographic and HRQL data met inclusion criteria for Ames driver descriptors of C or CT. 12 patients with S or T Ames driver descriptors were excluded. Mean patient age was 62.1 years, mean BMI of 28.8 kg/m², with 64% of the cohort as female. The average CCI score was 0.94. By approach, these CD patients underwent majorly posterior surgeries (41.6%), while 39% had combined approaches and 19.4% anterior. About 44.2% of patients underwent osteotomies and 53.2% decompression. The average levels fused was 7.5 (posterior: 8.3, anterior: 3.5). The mean total operative time was 553.1 min, with an EBL of 1128.1 ccs. 32 patients (41.6%) met MCID for NDI. 13% (10 patients) had a revision procedure. Table 1 summarizes the demographic and basic surgical factors for the cohort.

Baseline and 1-year radiographic parameters between C and CT ames drivers

Between C and CT groups, there were significant differences for both BL and 1Y cohort means of cSVA, T1 Slope, C2-T3 SVA, and C2 Slope. CT patients exhibited significantly greater malalignment at BL for cSVA (66.6 mm vs. 35.7 mm, $P < 0.001$), T1 slope (41.4° vs. 20.6°, $P < 0.001$), C2-T3 SVA (110.2 mm vs. 57.2 mm, $P < 0.001$), as well as MGS ($P = 0.042$) and C2 slope ($P = 0.008$). C driver patients had greater CL malalignment preoperatively (-17.5° vs. -4.5°). At 1Y CT

Table 1: Demographic and surgical characteristics of the cohort

Demographics	Mean
Age (years)	62.1
Gender (female) (%)	64
BMI (kg/m ²)	28.8
Race (%)	
White	91.6
Black	5.6
Other	2.8
CCI	0.94
Smoker (yes) (%)	6.5
Surgical details (%)	
Anterior only approach	19.4
Posterior only approach	41.6
Combined approach	39
Total levels fused	7.5
Osteotomy	44.2
Decompression	53.
Operative time (min)	553.1
EBL (ccs)	1128.1
Revision	13

BMI - Body mass index, EBL - Estimated blood loss, CCI - Charlson comorbidity index

patients remained significantly more malaligned in cSVA, T1 slope, C2–T3 SVA, and C2 Slope (all $P < 0.001$) [Table 2].

Radiographic corrective measures predictive of meeting minimal clinically important difference for Neck Disability Index

A backward linear regression model found the following radiographic differences as predictors of meeting MCID for NDI from BL to 1Y: TS-CL, cSVA, MGS, C2 Slope, C2–T3 angle, C2–T3 SVA and CL demonstrated the greatest variation contributing to MCID for NDI with an $R^2 = 0.820$ ($P = 0.032$). When assessing individual Ames driver type cohorts, C driver patients demonstrated an $R^2 = 0.844$ ($P = 0.029$) without the inclusion of the TS-CL or C2-T3 SVA parameter. CT patients had an $R^2 = 0.778$ ($P = 0.025$), without the TS-CL angle.

Ratios (%) of correction in predictors by Ames driver

Ratios of change in predictors for MCID NDI patients (BL-1Y) for C driver patients: 260.8% MGS, 140.3% CL, 121.2% C2-T3 angle, 49.6% C2 slope, 41.1% cSVA, 20.5% TS-CL, 3.1% C2-T3 SVA. Correction in CT driver patients included: 168.7% CL, 93% MGS, 70.8% C2-T3 angle, 31.1% cSVA, 27.5% C2 slope, 24.9% TS-CL, 13.7% C2-T3 SVA. The ratios of radiographic differences were not significant between the C and CT driver groups ($P > 0.050$) [Table 2].

Prioritization of realignment parameters and their corrective cut-off values

Decision tree analysis determined cut-offs for radiographic change, prioritizing in the following order (based upon ordinal regression values): a correction $\geq 42.5^\circ$ C2–T3

Table 2: Radiographic parameters at baseline and 1-year, as well as the difference between baseline and 1-year for cervical and cervicothoracic ames driver types

	C	CT	P
Baseline radiographic parameters			
cSVA (mm)	35.7	66.6	<0.001
CL	-17.5°	-4.5°	0.009
T1 slope	20.6°	41.4°	<0.001
TS-CL	37.7°	45.5°	0.086
CBVA	0.41°	0.48°	0.893
MGS	2.9°	8.6°	0.042
C2-T3 angle	-18.6°	-27.0°	0.113
C2-T3 SVA (mm)	57.2	110.2	<0.001
C2 slope	35.9°	49.2°	0.008
At 1-year			
cSVA (mm)	33.4	49.3	<0.001
CL	4.4°	10.9°	0.064
T1 slope	28.3°	44.7°	<0.001
TS-CL	23.9°	33.8°	0.001
CBVA	0.81°	3.3°	0.558
MGS	-2.2°	1.2°	0.150
C2-T3 angle	-0.29°	-2.3°	0.580
C2-T3 SVA (mm)	63.2	92.7	<0.001
C2 slope	21.9°	33.3°	<0.001
Percentage of correction BL to 1 year (%)			
cSVA	41.1	31.1	0.904
CL	140.3	168.7	0.753
TS-CL	20.5	24.9	0.775
MGS	260.8	93	0.209
C2-T3 angle	121.2	70.8	0.193
C2-T3 SVA	3.1	13.7	0.052
C2 slope	49.6	27.5	0.830

C - Cervical, CT - Cervicothoracic, SVA - Sagittal vertical axis, cSVA - Cervical SVA, CL - C2-C7 lordosis, TS-CL - T1 slope minus CL, CBVA - Chin-to-brow-vertical angle, MGS - McGregor's slope

angle (odds ratio [OR]: 5.667 [1.074–29.891], $P = 0.041$), $>35.4^\circ$ CL (OR: 4.636 [0.857–25.071], $P = 0.075$), $<-31.76^\circ$ C2 slope (OR: 3.2 [0.852–12.026], $P = 0.085$), <-11.57 mm cSVA (OR: 3.185 [1.137–8.917], $P = 0.027$), $<-2.16^\circ$ MGS (OR: 2.724 [0.971–7.636], $P = 0.057$), >-30.8 mm C2-T3 SVA (OR: 0.462), and $\leq-33.6^\circ$ TS-CL (OR: 0.271) [Table 3].

Health-related-quality-of-lives for patients with ideal prioritization

Patients who met thresholds for recommended cervical parameter prioritization trended toward improvement in both NDI and modified Japanese Orthopedic Association (mJOA) scale for all measurements at 1Y [Table 4].

Case examples

Figure 1 shows the BL and 1Y lateral cervical and whole spine radiographs of a 72 year-old female (33.3 kg/m²) and a history of diabetes mellitus and osteopenia who underwent CD corrective surgery. She presented with cervical

type Ames driver. According to proposed CD prioritization guidelines, this patient did not meet proposed prioritization correction thresholds for C2–T3 angle (-1.60°), CL ($+11.9^\circ$), C2 slope (-0.54°), cSVA (-2.03 mm), MGS ($+4.11^\circ$), and TS-CL (-0.69°). She did meet the threshold for C2-T3 SVA ($+16.8^\circ$). The patient had a 1Y NDI score of 46, did not meet MCID for NDI, and patient-reported mJOA score of 15.

Figure 2 shows the BL and 1Y lateral cervical and whole spine radiographs of a 61-year-old male (28.97 kg/m²) who underwent CD corrective surgery. He presented with cervical type Ames driver. According to proposed CD prioritization guidelines, this patient did meet all proposed prioritization correction thresholds for C2–T3 angle ($+76.1^\circ$), CL ($+67.9^\circ$), C2 slope (-44.9°), cSVA (-11.9 mm), MGS (-10.8°), C2-T3 SVA ($+11.7^\circ$) and TS-CL (-45.8°). The patient had a 1Y NDI score of 11.1, met MCID for NDI, and patient-reported mJOA score of 18.

DISCUSSION

High-risk cohorts undergoing treatment of adult CD include patients with advanced age, obesity, greater comorbidity burden, and severe frailty status. While classification systems, such as the one created by Ames and the ISSG, provide correction guidelines for the representative majority of CD patients, operating on patients with the preoperative presentation of increased risk for poor outcomes has facilitated the need for prioritization of alignment scheme for CD surgery.^[13] Therefore, the goal for this analysis was to establish an order of targeting alignment parameters and their projected minimal corrective degree to benefit operative decision-making and inherently improve HRQL outcome management.

Utilizing a CD prospective multicenter database and bi-planar stereoradiography, allowing for the acquisition of full-body imaging in the weight-bearing position, our analysis determined that prioritizing regional cervical radiographic alignment parameters in a certain order to a specific degree optimized reaching the MCID in a patient's self-reported neck disability. Despite the regional driver of CD (cervical or cervicothoracic), radiographic correction for patients who reached MCID for NDI was similar. The prioritization of parameters is as follows: C2–T3 angle, CL, C2 slope, cSVA, MGS, C2–T3 SVA, and finally, TS-CL.

First, we found that the C2-T3 angle should be corrected. This angle connects each of the regions of the spine, by incorporating the unequivocal relationship between the cervical and thoracolumbar spine morphology.^[20-22] By prioritizing next the CL correction, the natural cervical curvature is addressed secondarily. Cervical kyphosis is

Table 3: Order of prioritization based on binary logistic ordinal regression values of radiographic parameters and cut-off values for correction

Radiographic parameters	OR	Lower CI	Upper CI	P	Cut-offs of correction prioritized in order
C2-T3 angle	5.667	1.074	29.871	0.041	C2-T3 angle $\Delta \geq 42.5^\circ$
CL	4.636	0.857	25.071	0.075	CL $\Delta > 35.4^\circ$
C2 slope	3.200	0.852	12.026	0.085	C2 slope $\Delta < -31.76^\circ$
cSVA	3.185	1.137	8.917	0.027	cSVA $\Delta < -11.57$ mm
MGS	2.724	0.971	7.636	0.057	MGS $\Delta < -2.16^\circ$
C2-T3 SVA	0.462	0.116	1.849	0.275	C2-T3 SVA $\Delta > -30.8$ mm
TS-CL	0.271	0.048	1.1516	0.137	TS-CL $\Delta \leq -33.6^\circ$

SVA - sagittal vertical axis, cSVA - Cervical SVA, CL - C2-C7 lordosis, TS-CL - T1 slope minus CL, MGS - McGregor's slope, OR - Odds ratio, CI - Confidence interval

Table 4: Neck disability index and modified Japanese Orthopedic Association scale scores at 1-year between patients who met proposed prioritization cut-off values and those who did not

	Met improvement threshold	Did not meet improvement threshold	P
NDI scores at 1-year			
C2-T3 angle	23.8	38	0.035*
CL	24.7	37.6	0.071
C2 slope	31.8	37	0.398
cSVA	32.6	39.3	0.158
MGS	32.9	42.4	0.055
C2-T3 SVA	34.7	45.5	0.130
TS-CL	28.2	37	0.253
mJOA scores at 1-year			
C2-T3 angle	15.78	14	0.087
CL	15	14.15	0.442
C2 slope	14.58	14.19	0.673
cSVA	14.8	13.73	0.152
MGS	14.58	13.61	0.197
C2-T3 SVA	14.38	13.5	0.422
TS-CL	15	14.17	0.477

NDI - Neck disability index, SVA - Sagittal vertical axis, cSVA - Cervical SVA, CL - C2-C7 lordosis, TS-CL - T1 slope minus CL, MGS - McGregor's slope, mJOA - Modified Japanese Orthopedic Association scale

a major radiographic presentation of CD, with a strong connection to clinical impact, so direct correction to parameters encompassing the curve is imperative for improved patient-reported outcomes.^[20] In a previous study by Passias *et al.*, the preoperative cervical degree of lordotic compensation and higher C2-T3 angle were identified as risk factors for sagittal malalignment and decline in HRQL outcomes after thoracolumbar surgery.^[23] With prioritization of the lordosis of the spine, combined with the cervicothoracic junction as a site of transition between the highly mobile cervical and rigid thoracic systems, we can address the inherent relationship between cervical sagittal malalignment and clinical measures of disability.^[24]

The third parameter to prioritize in the correction of CD is the C2 slope. We found that correction of this radiographic measurement led to increased neck disability improvement.^[25] This parameter is a singular CD factor, a mathematical approximation of the mismatch between T1 slope and cervical lordosis.^[26] By factoring in the occipitocervical spine, the C2 slope accounts for an additional

aspect of radiographic alignment improvement and should be prioritized accordingly.

Then, the cSVA was found to be prioritized. The restoration of this parameter has been correlated with improved postoperative outcomes and the prevention of disability.^[27] It incorporates a global assessment of CD by measuring the distance between the C2 and C7 plumbines.^[28] Tang *et al.* suggested that an increasing cervical SVA is a cause for clinical concern of cervical malalignment, as >40 mm was correlated with worse NDI outcomes.^[29] As one of the main objectives of CD surgery is the maintenance or restoration of horizontal gaze, the next parameter to prioritize was found to be MGS.^[30] By correcting this angle, the symptoms of inability to look straight ahead or lie down flat that contribute to overall disability can be addressed. Another parameter appreciating cervical sagittal alignment is the C2-T3 SVA, which was found to be the 6th measure of prioritization. Prioritizing the two large measures of cervical sagittal alignment (C2-C7 SVA and C2-T3 SVA), accounting for the alignment of subjacent segments, including the thoracolumbar spine and pelvis,

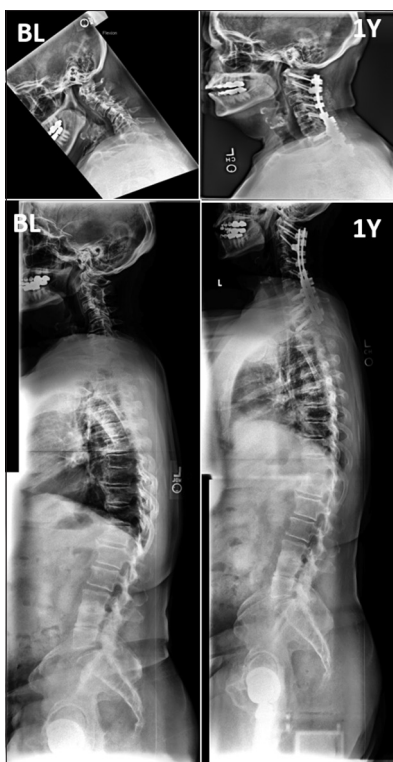


Figure 1: Baseline and 1-year cervical and whole spine radiographs of a 72-year-old female who did not meet proposed radiographic prioritization of alignment

along with horizontal gaze measurement, the global outlook of the spine is assessed.

Finally, the mismatch between T1 slope and CL parameter was prioritized. This relationship accounts for the intrinsic compensation of T1 slope on the CL to balance the head over the thoracic inlet and maintain the physiological neck tilting.^[31,32] The measure accounts for the patient's center of gravity and contributes to overall cervical integration into global alignment.

Through the combination of regional cervical radiographic factors, we found that prioritizing the lordosis of the cervical spine (through C2–C7 and C2–T2), followed by occipitocervical incorporation (C2 slope) global assessment (cSVA, C2–T3 SVA, TS–CL), and horizontal improvement (MGS). This proposed prioritization involves the innate interdependence of the spine: cervical lordosis depends on both thoracic kyphosis and lumbar lordosis. With the distinct diagnosis of CD, cervical lordosis adaptation is due to the cervical spinal segment changes relative to the global spine to attempt to maintain the head over the pelvis and horizontal gaze.^[28] Addressing the intertwined cervical parameters in a specific order to a certain degree of correction can contribute to improved patient-reported neck disability.

Our study is not without limitations, including the retrospective nature of this study and the small number

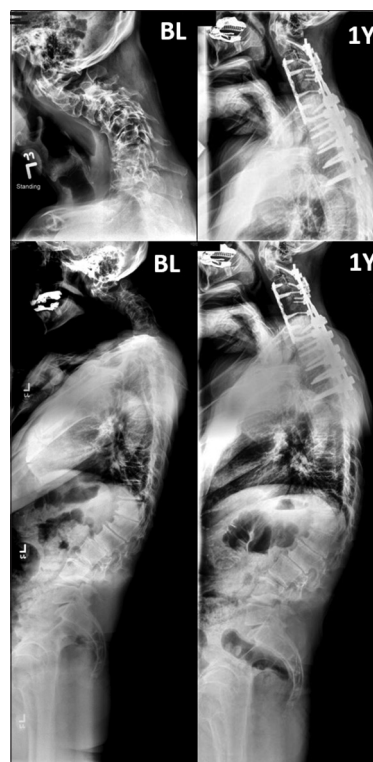


Figure 2: Baseline and 1-year cervical and whole spine radiographs for a 61-year-old male who met proposed radiographic prioritization of alignment

of patients. While the multicenter methodology used for database construction increases the generalizability of our findings, the data analyzed for the purposes of this study may be skewed toward more complex cases. Another limitation lies in the heterogeneous nature of the patient population in regards to cervical procedure and complexity, which may have been accounted for by removing thoracic and coronal Ames type CD drivers. Future studies should investigate the proposed prioritization and thresholds on a prospective trial with a larger, homogenous population of patients undergoing CD corrective surgery.

CONCLUSIONS

Certain ratios of correction of cervical parameters contribute to improving neck disability. Specific cut-offs of radiographic differences from BL to 1Y were found prioritizing C2–T3 angle, followed by cervical lordosis, C2 slope, C2–C7 plumb line, MGS, C2–T3 SVA, and TS–CL all strongly associated with meeting the MCID for the NDI score. Prioritizing these radiographic alignment parameters may help optimize patient-reported outcomes for patients undergoing CD surgery.

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Conflicts of interest

There are no conflicts of interest.

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