



The impact of lumbar alignment targets on mechanical complications after adult lumbar scoliosis surgery

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Abstract

Purpose The purpose of this study was to determine the discriminatory ability of age-adjusted alignment offset and the global alignment and proportion (GAP) score parameters to predict postoperative mechanical complications.

Methods Surgical patients from the Adult Symptomatic Lumbar Scoliosis cohort were reviewed at 2 year follow up. Age-adjusted alignment offsets and GAP parameters were calculated for each patient. A series of nonlinear logistic regression models were fit, and the odds of mechanical complications were calculated. The discriminatory ability of the GAP score, GAP score parameters, and age-adjusted alignment offsets were determined plotting receiver operative characteristic (ROC) with the C statistic (AUC).

Results A total of 165 patients were included. A total of 49 mechanical complications occurred in 41 patients (21 proximal junctional kyphosis and 28 pseudoarthrosis). The GAP score had no discriminatory ability in this cohort. Relative lumbar lordosis 15 degrees greater than ideal lumbar lordosis was associated with greater mechanical complications. A lumbar distribution index of 90% was associated with fewer mechanical complications compared to a lumbar distribution index of 65%. Age-adjusted offset alignment targets had no discriminatory ability to predict mechanical complications.

Conclusion Radiographic alignment targets using either age-adjusted alignment target offset or GAP score parameters had minimal ability to predict mechanical complications in isolation. Mechanical complications following adult spinal deformity surgery are complex, and patient factors play a critical role.

Clinical trial registration This study was registered at ClinicalTrials.gov (number NCT00854828) in March 2009.

Keywords Adult spinal deformity · Spinal alignment · Global alignment and proportion · Age-adjusted

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Introduction

Adult spinal deformity (ASD) is an abnormal curvature or alignment of the vertebral column with a predictable decline in health-related quality of life (HRQOL) [1–3]. In particular, sagittal plane malalignment correlates with declining HRQOL [4, 5]. Various classifications are used to guide sagittal plane correction [5–9]. Ideally, these sagittal plane alignment targets should optimize postoperative HRQOL while minimizing mechanical complication rates. Two diverging theories for ideal alignment target are the age-adjusted alignment targets and the Global Alignment and Proportion (GAP) score [6, 7]. Age-adjusted radiographic alignment targets were developed using HRQOL data from asymptomatic patients and ultimately allow for a greater deviation from “perfect” alignment with increasing age. Subsequent work suggests that age-adjusted alignment

targets may reduce the risk of proximal junctional kyphosis/failure (PJK) [10]. The GAP score was developed to predict mechanical complication rates. In the GAP score, the ideal alignment target is a function of patient-specific pelvic incidence (PI) and patient age, where older patients require alignments closer to “perfect” to minimize risk.

Ideal alignment targets remain a frequent topic of debate and discussion, due in part to the diverging theories presented above. External validation of both alignment schemes has proved difficult because many factors can attribute to PJK and pseudarthrosis beyond spinal alignment. The purpose of this study was to examine PJK and pseudarthrosis rates in a cohort of patients with adult symptomatic lumbar scoliosis and to compare rates of these failure mechanisms according to age-adjusted targets and GAP ideal measures.

Methods

This study is a post hoc analysis of patients enrolled in the multicenter Adult Symptomatic Lumbar Scoliosis (ASLS) trial (NIH R01 AR055176-01A2) [11]. Patients were eligible for enrollment if they were ages 40 to 80, with symptomatic lumbar scoliosis (defined as a lumbar curve with a coronal Cobb measurement $\geq 30^\circ$ and an Oswestry Disability Index (ODI) ≥ 20 or Scoliosis Research Society (SRS) 22 score ≤ 4.0 in the domains of pain, function, and/or self-image) and no history of prior spinal fusion. Enrolled patients were either randomized or chose operative versus non-operative treatment for their scoliosis. For the present study, all surgical patients with an upper instrumented vertebra (UIV) at or cephalad to L2 were included.

Data sources and radiographic alignment targets

Demographic data and procedure details were collected via case report forms. Full spine radiographs were evaluated preoperatively, at 3 months and at 2 years after surgery. Radiographic measurements were recorded and included pelvic incidence, L1–S1 lumbar lordosis (LL), L4–S1 lumbar lordosis, T1 pelvic angle, pelvic tilt, sacral slope, global tilt, and proximal junctional angle. The ‘age-adjusted offset’ for PI–LL mismatch, pelvic tilt, and T1 pelvic angle were computed by subtracting the age-adjusted ideal alignment value from initial postoperative value (i.e., measured value–age–adjusted ideal value = age–adjusted offset) [7]. The GAP score components were calculated: relative lumbar lordosis, relative pelvic version, lordosis distribution index, and the relative spinopelvic alignment. The GAP score was computed as previously described [6].

Study outcomes

The primary outcome was the development of a mechanical complication within the first 2 years following surgery. Mechanical complication was defined as symptomatic proximal junctional kyphosis and/or pseudarthrosis. Pseudarthrosis was defined as surgeon reported rod fracture or surgeon reported pseudarthrosis. Symptomatic proximal junctional kyphosis was defined as 1) surgeon reported proximal junctional breakdown or 2) a change in proximal junctional angle by > 10 degrees from 3-month to 2-year radiographs and a postoperative decline in numeric rating scale (NRS) back pain scores by 2 or more points. Pseudarthrosis and symptomatic proximal junctional kyphosis were considered individually and as a composite mechanical complication.

Statistical analysis

Baseline factors, surgical factors and alignment measures were compared between patients that did and did not develop a mechanical complication using the Fisher exact test for categorical variables and Wilcoxon test for continuous variables. A series of nonlinear univariate logistic regression models were fit to assess the predictive performance of the gap score, individual lumbar parameters of the gap score, and age-adjusted offsets, in predicting symptomatic proximal junctional kyphosis, pseudarthrosis, or any mechanical complications. The odds of a mechanical complication, pseudarthrosis or rod fracture, or symptomatic proximal junctional kyphosis, associated with deviations from the ideal targets for the lumbar gap score parameters (relative lumbar lordosis and lordosis distribution index), or age-adjusted lumbar targets (PI–LL mismatch and pelvic tilt), were computed. Discrimination, the ability to properly rank patients by risk of complication, was assessed for the GAP score, GAP score parameters, and age-adjusted offsets, by plotting the receiver operating characteristic (ROC) curve and computing the C statistic (AUC). All analyses were conducted using R 3.5.3, and the rms package [12, 13].

Results

Baseline characteristics, radiographic parameters and surgical data

Of the 180 patients included in the operative arm of the ASLS cohort, 15 were excluded (10 had follow up < 2 years, 4 had a UIV caudal to L2 and 1 had incomplete radiographic follow up). Of the 165 included in the final cohort, median

age was 60 (IQR, 54 to 66), 148 (89.7%) were female, and the median number of fusion levels was 12 (IQR, 8 to 14). The median body mass index (BMI) was 26.3 kg/m² (IQR, 23.5–29.9). The mean femoral neck T-score was -1.1 (Standard deviation 1.0). On preoperative radiographs, the median pelvic tilt was 24 (IQR, 19 to 30), median L1–S1 lordosis was 36.5 (IQR 25 to 47.8), and median PI-LL mismatch was 18 (IQR, 5.5 to 30) (Table 1).

Most patients were treated with some 360° fusion with 119 (72%) treated with 167 transforaminal lumbar interbody fusions. Sixteen (9.7%) patients underwent 25 anterior lumbar interbody fusion. The median anterior recombinant human bone morphogenetic protein-2 (rhBMP-2) dose was 10 mg (IQR 4,16). The median posterior rhBMP-2 dose was 48 mg (IQR 30, 104). Seven patients were treated with pedicle subtraction osteotomies (PSO); two sustained a mechanical complication ($p=0.7$). Three patients underwent

vertebral column resection (VCR); one sustained a mechanical complication ($p=1.0$). Ninety-nine (60%) were treated with posterior column osteotomies; 29 sustained a mechanical complication ($p=0.11$) (Table 2).

Twenty seven (16%) patients sustained rod fractures. The most common level was L4–L5 ($n=9$), followed by L5–S1 ($n=6$), and L3–L4 ($n=5$). Eight (5%) patients presented with unilateral rod fractures. Three progressed to bilateral rod fractures.

GAP score and mechanical complications

Of the 165 patients, 41 (25%) patients sustained 49 mechanical complications (21 had symptomatic proximal junctional kyphosis and 28 had pseudarthrosis or rod fracture). On 3-month postoperative radiographs, the median lordosis distribution index was significantly lower for

Table 1 Comparative table of postoperative alignment targets and radiographic parameters between patients with and without mechanical complications

	Overall	Mechanical complication		<i>p</i>
		No	Yes	
<i>n</i>	165	124 (75%)	41 (25%)	
Female, <i>n</i> (%)	148 (89.7)	114 (91.9)	24 (82.9)	0.18
Age, median (IQR)	60.1 (54.3, 65.9)	59.1 (53.5, 65.0)	62.4(56.5, 69.4)	0.06
Body mass index, median (IQR)	26.3 (23.5, 29.9)	25.9 (23.3, 29.4)	26.7 (24.3, 33.1)	0.06
Total fusion levels, median (IQR)	12 (8, 14)	13 (8, 14)	9 (8, 14)	0.75
Baseline radiographic measures, median (IQR)				
Pelvic incidence	54.0 (47.0, 61.0)	54.0 (46.4, 61.0)	64.0 (49.0, 62.0)	0.73
Pelvic tilt	24.0 (19.0, 33.0)	23.0 (19.0, 30.0)	24.0 (21.0, 31.0)	0.45
L1-S1 Lordosis	36.5 (25.0, 47.8)	37.0 (27.0, 47.0)	31.0 (21.0, 50.5)	0.42
PI – LL	18.0 (5.5, 30.0)	17.0 (6.0, 30.0)	22.0 (6.0, 34.5)	0.54
3 Month radiographic measurements, median (IQR)				
Pelvic tilt	22.0 (17.0, 28.0)	22.0 (17.0, 26.2)	23.0 (16.0, 32.0)	0.24
Sacral slope	32.0 (26.0, 38.0)	32.8 (26.5, 38.0)	29.0 (26.0, 36.2)	0.28
L1-S1 lordosis	50.9 (43.0, 58.6)	50.4 (43.0, 58.0)	50.9 (45.0, 62.0)	0.47
L4-S1 lordosis	33.0 (25.0, 39.0)	34.0 (25.8, 40.0)	27.0 (25.0, 38.0)	0.07
PI-LL	4.0 (– 4.0, 11.0)	3.6 (– 3.1, 10.6)	4.0 (– 6.0, 11.0)	0.90
T1 pelvic angle	16.0 (11.0, 23.0)	16.0 (11.0, 22.0)	18.9 (8.8, 26.0)	0.31
Postoperative GAP values, median (IQR)				
GAP relative pelvic version	– 9.5 (– 14.4, – 5.2)	– 9.2 (– 13.5, – 5.2)	– 10.5 (– 17.2, – 5.1)	0.27
GAP relative lumbar lordosis	– 11.9 (– 18.9, – 6.7)	– 11.6 (– 19.0, – 7.2)	– 13.0 (– 18.8, – 3.6)	0.78
GAP relative spinopelvic alignment	10.1 (4.1, 18.0)	9.6 (4.1, 16.0)	12.8 (4.3, 21.4)	0.17
GAP total score	4.0 (2.0, 7.0)	4.0 (2.0, 7.0)	6.0 (2.0, 9.0)	0.20
Postoperative age-adjusted offsets				
Pelvic tilt offset	0.1 (– 4.7, 5.8)	0.2 (– 4.6, 5.0)	0.1 (– 5.7, 8.8)	0.66
PI-LL offset	– 2.1 (– 9.7, 6.4)	– 2.0 (– 9.1, 6.6)	– 2.6 (– 11.1, 6.2)	0.45
TPA offset	– 2.0 (– 7.5, 3.8)	– 2.1 (– 6.5, 3.5)	– 0.6 (– 10.6, 6.9)	0.73
Complications, <i>n</i> (%)				
Symptomatic proximal Junctional kyphosis	21 (12.7)	–	21 (51.2)	
Pseudarthrosis or rod fracture	28 (17.0)	–	28 (68.3)	

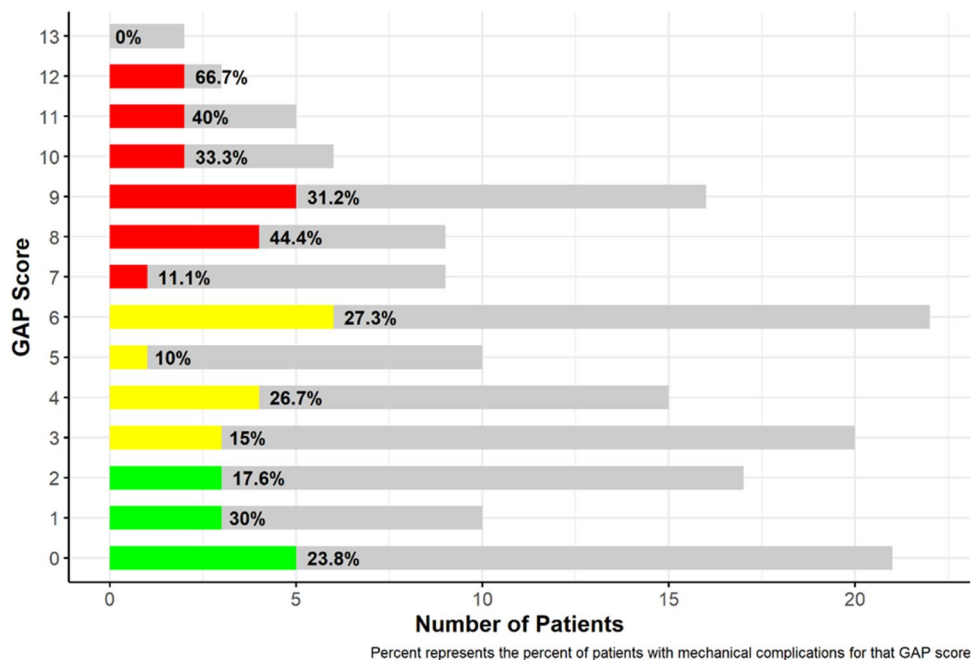
Table 2 Surgical Data including comparison of mechanical complication by osteotomy type and number, interbody type and number

	Entire Cohort (N= 165)	Mechanical Complication		
		No (N= 124)	Yes (N= 41)	p-value
Interbody fusion (#)				
P/TLIF				
0	66 (40%)	49 (74%)	17 (25%)	0.34
1	35 (21%)	24 (69%)	11 (31%)	
2	53 (32%)	44 (83%)	9 (17%)	
> 2	11 (7%)	7 (64%)	4 (36%)	
ALIF				
0	148 (89.5%)	111 (75%)	37 (25%)	*
1	5 (3%)	5 (100%)	0 (0%)	
2	9 (5.5%)	7 (78%)	2 (22%)	
> 2	3 (2%)	1 (33%)	2 (67%)	
Osteotomy				
posterior column	99 (60%)	70 (71%)	29 (29%)	0.11
Pedicle subtraction osteotomy	7 (4%)	6 (85%)	1 (15%)	0.7
Vertebral column Resection	3	2 (67%)	1 (33%)	1.0
Decompressions				
0	94 (57%)	74 (79%)	20 (21%)	0.13
1	21 (13%)	18 (86%)	3 (14%)	
2	24 (15%)	18 (75%)	6 (25%)	
3	16 (10%)	8 (50%)	8 (50%)	
> 3	10 (6%)	6 (60%)	4 (40%)	

those with a mechanical complication (57% [IQR, 46% to 63%] for those with a complication vs 65% [IQR, 54% to 78%] for those without a complication, $p = 0.002$). When comparing those with and without a mechanical

complication, no significant differences were observed in the other GAP parameters or total GAP score (Table 1). The proportion of patients with any mechanical complication was computed for each GAP score (Fig. 1). The total

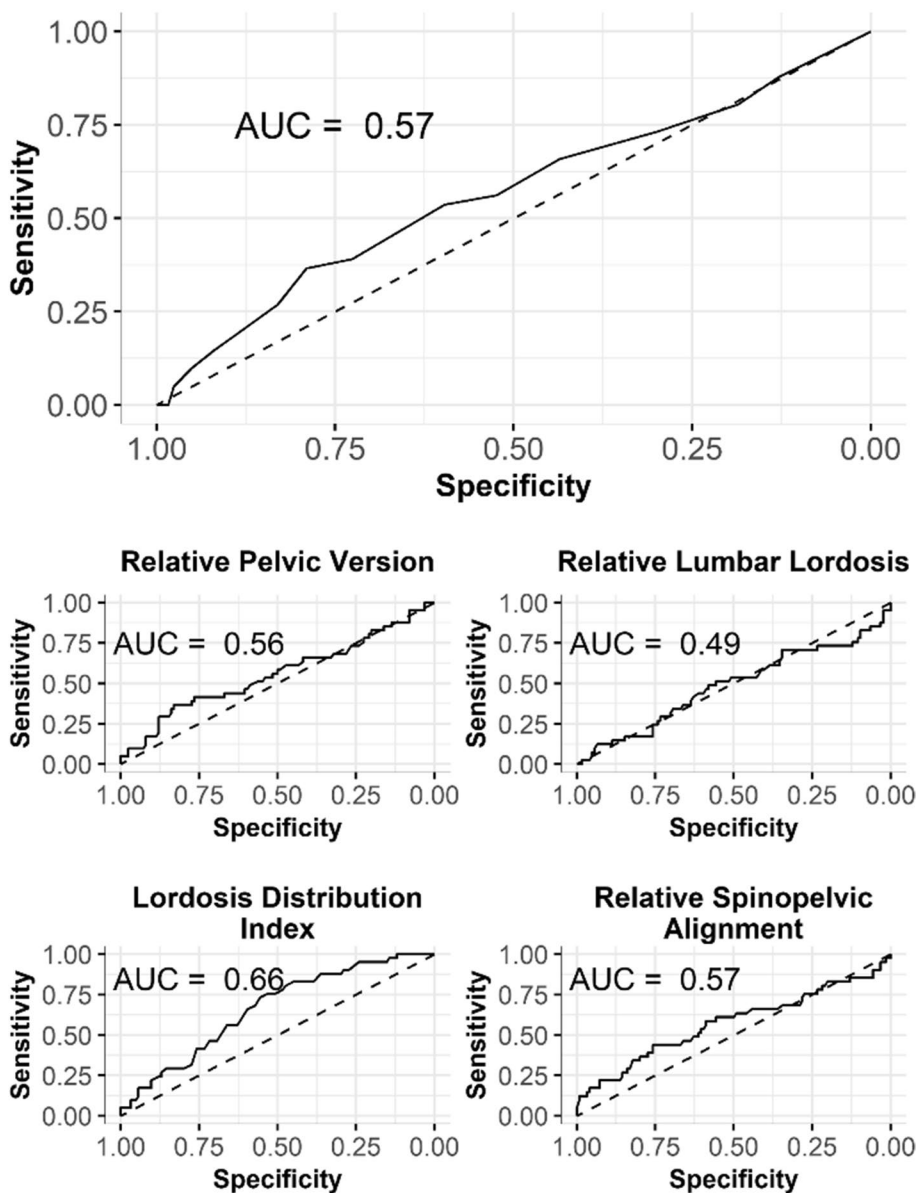
Fig. 1 GAP score and mechanical complications



GAP score had poor discrimination for risk of mechanical complications, with a C-statistic (AUC) of 0.57. None of the individual GAP parameters showed acceptable discrimination for risk of a mechanical complication (C-statistics, relative pelvic version = 0.56, relative lumbar lordosis = 0.59, lordosis distribution index = 0.66 and relative spinopelvic alignment = 0.57) (Fig. 2). The odds of a mechanical complication, pseudarthrosis or rod fracture, and symptomatic proximal junctional kyphosis were computed for deviations from ideal lumbar lordosis (-20° and 15° of relative lumbar lordosis compared to the

ideal) and deviations in lordosis distribution index (40% and 90% compared to 65%). Compared to 65%, a lordosis distribution index of 90% was associated with lower odds of a mechanical complication (OR 0.2; 95% CI, 0 to 0.9), and compared to achieving an ideal lumbar lordosis per the GAP score, 15° of relative lumbar lordosis (hyperlordosis) was associated with an increased odds of a mechanical complication (OR, 5.9; 95% CI, 1.1 to 32.3) and increased odds of pseudarthrosis or rod fracture (OR, 10.7; 95% CI 1.6 to 73). No other changes in GAP lumbar parameters were significantly associated with a mechanical complication (Fig. 3).

Fig. 2 GAP score and parameters predicting mechanical complications



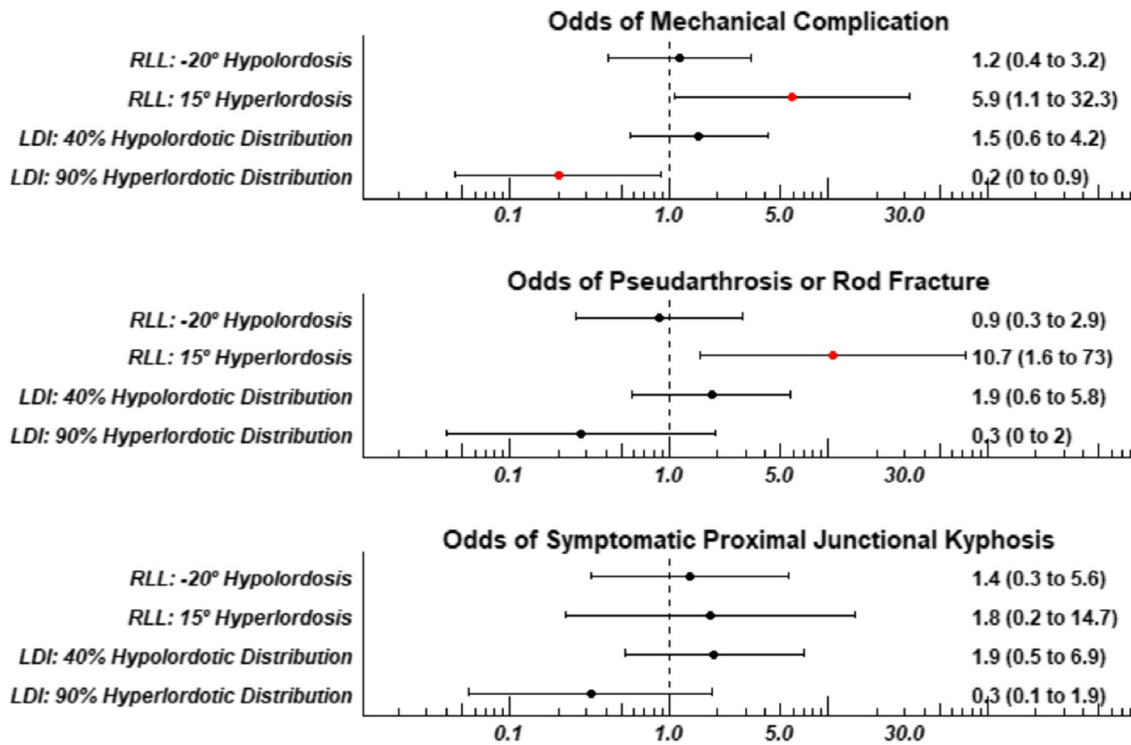


Fig. 3 GAP lumbar parameters: odds of complications associated with deviations from ideal

Age-adjusted goals and mechanical complications

At 3-month following surgery, the overall median pelvic tilt offset from the age-adjusted goal was 0.1 (IQR, - 4.7 to 5.8), the median PI-LL offset was - 2.1 (IQR, - 9.7 to 6.4), and the median TPA offset was -2 (IQR, - 7.5 to 3.7) (Fig. 4). No significant differences were noted between those with and without mechanical complications. The offset from

age-adjusted targets for pelvic tilt, PI-LL mismatch, and T1 pelvic angle had poor discrimination for predicting mechanical complications with C-statistics of 0.52, 0.54 and 0.48, respectively (Fig. 5). Compared to age-adjusted targets for PI-LL mismatch and pelvic tilt, neither overcorrection by 10° or 20° was associated with an increased odds of a mechanical complication, pseudoarthrosis or rod fracture, or symptomatic proximal junctional kyphosis (Fig. 6).

Fig. 4 Offset from age-adjusted targets and complications

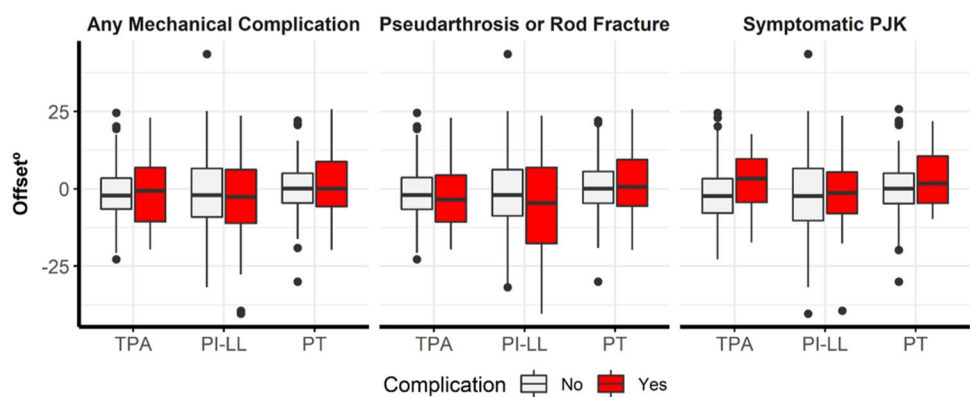


Fig. 5 Age-adjusted targets predicting mechanical complications

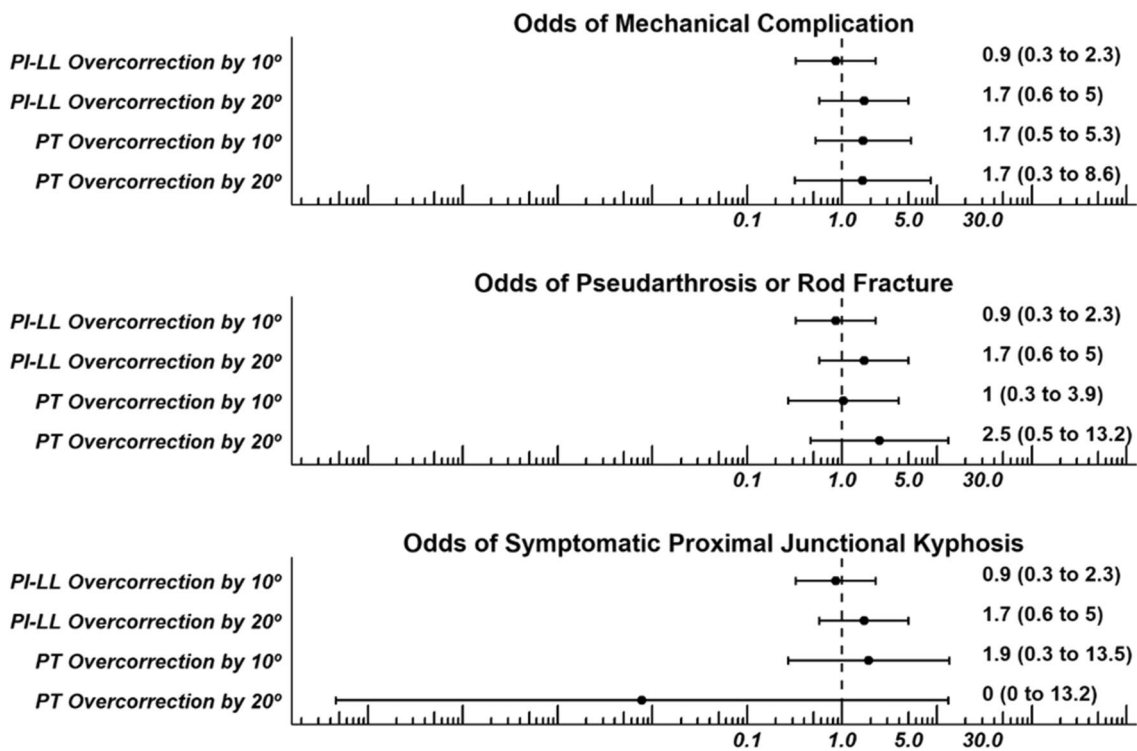
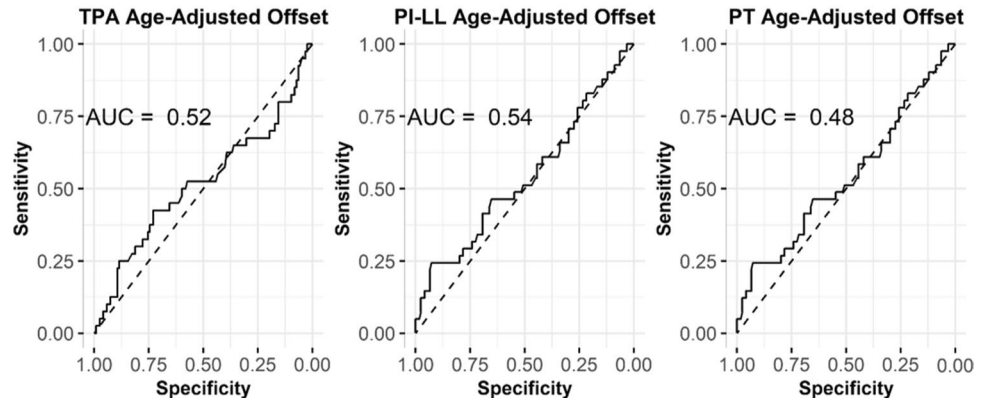


Fig. 6 Odds of complications associated with overcorrection from age-adjusted targets

Discussion

Ideal regional lumbar sagittal alignment remains debated in adult spinal deformity [5–9]. The purpose of this study was to investigate the mechanical complication risk as patients deviated from ideal regional lumbar age-adjusted targets and GAP score targets. Secondly, we investigated the capabilities of the GAP score, age-adjusted pelvic tilt offset, and T1 pelvic angle offset to predict

symptomatic proximal junctional kyphosis, pseudarthrosis, and the composite of the two.

A total of 41 (25%) patients had 49 mechanical complications within 2 years from surgery. Previously reported mechanical complication rates in adult spinal deformity range from 29.8 to 45% [6, 14–16]. The GAP score had poor ability to predict which patients would develop mechanical complications, with an ROC AUC approaching chance (AUC 0.57). Hyperlordosis, defined as greater than 15

degrees from the ideal relative lumbar lordosis, was associated with increased pseudarthrosis and overall mechanical complication risk. A hyperlordotic lumbar distribution index ($LDI > 90\%$) was associated with a reduced risk of mechanical complications. The age-adjusted PI-LL mismatch offset had no ability to predict mechanical complications, and overcorrection of the PI-LL mismatch was not associated with symptomatic proximal junctional kyphosis, pseudarthrosis, or composite mechanical complications.

The GAP score utilizes individual pelvic incidence to calculate ideal lumbar lordosis and categorizes patients by degree of malalignment from the ideal. In contrast with the age-adjusted alignment targets, the GAP score classification was designed to risk stratify patients for mechanical complications and HRQOL were not considered [6]. Two components of the GAP score describe ideal regional lumbar alignment, relative lumbar lordosis and the lumbar distribution index. To fall within the ideal range for relative lumbar lordosis, the difference between the measured and ideal lumbar lordosis needs to be between -14 and 11 degrees. In the GAP study, both under-correction and overcorrection of the lumbar lordosis increase the risk of mechanical complication. The lumbar distribution index represents the proportion of the lumbar lordosis that is between L4 and S1, with 50 – 80% considered “aligned” [8, 17]. The validation cohort from the GAP study demonstrated a high discriminatory ability of the GAP score to predict mechanical complications [6]. In a subsequent study of 282 patients when both the relative lumbar lordosis and the lumbar distribution index were aligned, the mechanical complication rate was 12.6% compared to 71% when both the relative lumbar lordosis and the lumbar distribution index were moderately malaligned [18]. Despite the encouraging initial work, subsequent external validations of the GAP score have been unable to confirm the high discriminative properties of the GAP classification [15, 19–21]. Our results are similar as we were unable to validate the ability of GAP scores to predict mechanical complications. Overcorrection with increased lumbar lordosis compared to the ideal lumbar lordosis was associated with pseudarthrosis and overall mechanical complication rates. Conversely, increased hyperlordotic lumbar distribution index was associated with fewer mechanical complications. Neither the relative lumbar lordosis nor the lumbar distribution index was associated with symptomatic proximal junctional kyphosis.

Age-adjusted alignment

Age-adjusted alignment targets were developed to match postoperative sagittal alignment to age-matched controls. These were not initially intended to predict mechanical complications. Age-adjusted alignment targets allow for greater PI-LL mismatch, pelvic tilt, sagittal vertical

alignment, and T1 pelvic tilt due to degenerative malalignment that frequently occurs with aging [7], since the initial publication of age-adjusted alignment subsequent studies suggests that undercorrection to age-adjusted targets may reduce proximal failures [10, 22, 23]. In one study, overcorrection of age-adjusted PI-LL mismatch offset was associated with radiographic proximal junctional kyphosis for patients greater than 40 years of age [10]. Subsequent studies have concluded that age-adjusted alignments reduce and increase proximal failure rates, emphasizing the complex and multifactorial nature of proximal failures [22–24]. Our results are consistent with other “negative” studies as we did not find age-adjusted alignments to be protective against proximal failure. We believe the forces that contribute to pseudarthroses and proximal failures are similar and that this is a subject worthy of investigation. As with proximal failure, we did not find a relationship between pseudarthrosis and an age-adjusted postoperative lumbar alignment.

Our rate of symptomatic proximal junctional kyphosis was 12.7% , slightly lower than frequently reported rates [25–27]. One reason for this is the heterogeneity in how proximal junctional kyphosis is defined. The most common definition for radiographic proximal junctional kyphosis is the Glattes criteria, postoperative proximal junctional angle $> 10^\circ$ and at least 10° greater than the preoperative proximal junctional angle [28]. Unfortunately, the Glattes criteria include many patients with subclinical proximal junctional kyphosis. Our definition for symptomatic proximal junctional kyphosis required a concomitant decline in NRS back pain score, as we consciously excluded cases of smaller, asymptomatic junctional kyphosis.

A significant limitation of this study is the presence of collider bias due to patient and treatment factors related to mechanical complication. Regional lumbar alignment is one treatment factor that impacts outcomes following adult spinal surgery, but without taking into consideration additional factors such as bone health, global alignment, proximal level selection, length of construct, transitional instrumentation at the upper instrumented level, surgical technique, graft and adjunct selection, and patient comorbidities it becomes difficult to accurately predict patients that will have a mechanical complication. A single-surgeon trial of random alignments can control for collider bias, though this is not a reasonable nor ethical expectation. Our sample size may be small, and if more patients were available to be analyzed, our confidence intervals would be more precise. Finally, there are emerging data regarding the relationship between hip and spine disease [29]. Hip contractures may affect pelvic version, which is directly related to standing alignment. While some propose normalization of pelvic version, this may not be possible in all situations and may be poorly advised with previously placed acetabular components.

Ideal lumbar alignment targets may minimize mechanical complication rates and optimize HRQOL. Age-adjusted alignment targets and the GAP score alignment targets are two of the commonly utilized philosophies to guide lumbar lordosis correction. Unfortunately, we found no clear relationship between the lumbar alignment targets and mechanical complication rates in a cohort of adult symptomatic lumbar scoliosis patients. This study provides further evidence that radiographic alignment targets in isolation do not accurately predict mechanical complication rates. Future work in the development of patient specific alignment targets likely requires consideration of surgical and patient factors to reduce mechanical complications.

Authors' contributions Drs. Dial, Hills, and Kelly involved in study conception and design, data analysis and interpretation, manuscript drafting. Drs. Shaffrey, Schwab, Smith, and Bridwell took part in data acquisition and interpretation of results. Drs. Bess, Lazaro, Bruni, Lafage, and Mr. Lafage involved in interpretation of results. All authors reviewed the results and approved the final version of the manuscript.

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Availability of data and material Data sharing request should be sent to KHB.

Code availability Not applicable.

Declarations

Conflict of interest Drs. Dial, Hills, Bridwell, Sardi, Lazaro, R Lafage, and Kelly report no conflicts of interest. Dr. Bess reports the following conflicts: royalties: Pioneer Spine; consulting: Allosource, DePuy, EOS, K2M, Medtronic, Misonix; scientific advisory board/other office: North American Spine Society, Scoliosis Research Society; research support (investigator salary, staff/materials): Allosource, Biomet Spine, DePuy, EOS, K2M, Medtronic, NuVasive, OrthoFix. Dr. V Lafage reports the following conflicts: stock ownership: Nemaris; consulting: Globus Medical; speaking and/or teaching arrangements: DePuy, K2M; scientific advisory board/other office: International Spine Study Group, Scoliosis Research Society; research support (investigator salary, staff/materials): Depuy, Medtronic, Nuvasive, Stryker. Dr. Shaffrey reports the following conflicts: royalties: Medtronic, Nuvasive, Zimmer Biomet; stock ownership: Nvasive; consulting: Biomet Spine, Medtronic, Nuvasive, Stryker; speaking and/or teaching arrangements: Medtronic, Nuvasive; board of directors: Spine Deformity; scientific advisory board/other office: AANS, Cervical Spine Research Society, Spine; research support (investigator salary, staff/materials): DePuy, Globus Medical, Medtronic, Neurosurgery RRC. Dr. Smith reports the following conflicts: royalties: Zimmer Biomet; consulting: Nuvasive, K2M, Allosource, Cerapedics; scientific advisory board/other office: Cervical Spine Research Society, Neurosurgery, Operative Neurosurgery. Dr. Schwab reports the following conflicts: grant: DePuy Synthes, SRS; royalties: K2M, MSD; stock ownership: Nemaris; speaking and/or teaching arrangements: Zimmer Biomet, NuVasive, K2M, MSD, Medica; board of directors: Nemaris.

Consent to participate All patients provided informed consent to participate.

Consent for publication Not applicable.

Ethics approval Washington University IRB approval 201102183.

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