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Are Higher Global Alignment and Proportion Scores Associated With Increased Risks of Mechanical Complications After Adult Spinal Deformity Surgery? An External Validation

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Abstract

Background The Global Alignment and Proportion (GAP) score, based on pelvic incidence-based proportional parameters, was recently developed to predict mechanical complications after surgery for spinal deformities in adults. However, this score has not been validated in an independent external dataset.

Questions/purposes After adult spinal deformity surgery, is a higher GAP score associated with (1) an increased risk of mechanical complications, defined as rod fractures, implant-related complications, proximal or distal junctional kyphosis or failure; (2) a higher likelihood of undergoing revision surgery to treat a mechanical complication; and (3) is a lower (more proportioned) GAP score category associated with better validated outcomes scores using the Oswestry Disability Index (ODI), Scoliosis Research Society-22 (SRS-22) and the Short Form-36 questionnaires?

Methods A total of 272 patients who had undergone corrective surgeries for complex spinal deformities were enrolled in the Scolio-RISK-1 prospective trial. Patients were included in this secondary analysis if they fulfilled the original inclusion criteria by Yilgor et al. From the original 272 patients, 14% (39) did not satisfy the radiographic inclusion criteria, the GAP score could not be calculated in 14% (37), and 24% (64) did not have radiographic assessment at postoperative 2 years, leaving 59% (159) for analysis in this review of data from the original trial. A total of 159 patients were included in this study, with a mean age of 58 ± 14 years at the time of surgery. Most patients were female (72%, 115 of 159), the mean number of levels involved in surgery was 12 ± 4 , and three-column osteotomy was performed in 76% (120 of 159) of patients. The GAP score was calculated using parameters from early postoperative

radiographs (between 3 and 12 weeks) including pelvic incidence, sacral slope, lumbar lordosis, lower arc lordosis and global tilt, which were independently obtained from a computer software based on centralized patient radiographs. The GAP score was categorized as proportional (scores of 0 to 2), moderately disproportional (scores of 3 to 6), or severely disproportional (scores higher than 7 to 13). Receiver operating characteristic area under curve (AUC) was used to assess associations between GAP score and risk of mechanical complications and risk of revision surgery. An AUC of 0.5 to 0.7 was classified as “no or low associative power”, 0.7 to 0.9 as “moderate” and greater than 0.9 as “high”. We analyzed differences in validated outcome scores between the GAP categories using Wilcoxon rank sum test.

Results At a minimum of 2 years’ follow-up, a higher GAP score was not associated with increased risks of mechanical complications (AUC = 0.60 [95% CI 0.50 to 0.70]). A higher GAP score was not associated with a higher likelihood of undergoing a revision surgery to treat a mechanical complication (AUC = 0.66 [95% 0.53 to 0.78]). However, a moderately disproportioned GAP score category was associated with better SF-36 physical component summary score (36 ± 10 versus 40 ± 11 ; $p = 0.047$), better SF-36 mental component summary score (46 ± 13 versus 51 ± 12 ; $p = 0.01$), better SRS-22 total score (3.4 ± 0.8 versus 3.7 ± 0.7 , $p = 0.02$) and better ODI score (35 ± 21 versus 25 ± 20 ; $p = 0.003$) than severely disproportioned GAP score category.

Conclusion Based on the findings of this external validation study, we found that alignment targets based on the GAP score alone were not associated with increased risks of mechanical

complications and mechanical revisions in patients with complex adult spinal disorders. Parameters not included in the original GAP score needed to be considered to reduce the likelihood of mechanical complications.

Level of Evidence Level III, diagnostic study.

Introduction

Adult spinal deformities can result in symptoms of back and leg pain, lower-limb neurologic deficits, and compensatory mechanisms that lead to inefficient energy expenditure [1, 4, 18, 23]. In patients who fail to respond adequately to

nonoperative treatment, surgical corrections have been shown to improve their health-related quality of life outcomes [26, 27, 34]. One of the main goals of surgery is restoration of sagittal alignment, which has a direct effect on postoperative pain and functional outcomes [12]. To achieve a balanced sagittal alignment of the postoperative spine, complex surgical techniques with increased magnitude and complexity are often used, and high complication rates have been reported in this patient population [2, 5, 7, 9, 11, 24, 25, 29-31]. Failure to restore an appropriate sagittal alignment (that is, over-correction or undercorrection) has been considered the main cause of mechanical complications and revision surgery

Funding received to conduct Scolio-RISK-1 was from the Scoliosis Research Society and AO Foundation, AO Spine. The study was managed by AO Foundation and AO Spine through the AO Spine Knowledge Forum Deformity. Study support was provided directly through AO Spine's Research department and AO's Clinical Investigation and Documentation unit.

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Each author certifies that his or her institution approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.

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[6, 10, 32]. Using a prospective, multicenter, international study (Scoli-RISK-1) database, we reported that implant failure was among the most frequently encountered non-neurologic adverse events (9.1% of all non-neurologic adverse events, occurring in 14.7% of patients) [8, 20]. The ability to anticipate mechanical complications accurately after surgery to treat adult spinal deformities is of great clinical importance.

Although restoring the sagittal plane's alignment is central in surgeries for adult spinal deformity, the cutoff points of postoperative parameters to avoid poor outcomes remain controversial. The most commonly used targets are based on the Scoliosis Research Society-Schwab classification, whose regional sagittal alignment modifier cutoffs were determined by health-related quality of life measures [28]. However, although postoperative radiographic alignments fall within these targets, 31.7% of patients had implant-related complications, 52.6% of whom subsequently underwent revision surgeries [30]. Yilgor et al. [33] first proposed the Global Alignment and Proportion (GAP) score that made use of pelvic incidence-based proportional parameters to predict mechanical complications in a cohort of adult spinal deformity patients after posterior fusion of four or more levels. Although the GAP score's ability to predict mechanical complications was high in the validation cohort in their original study, attempts to validate this score externally suffered from several methodological limitations: They did not follow the original methodology, they had a small sample size, they used patient cohorts that did not fulfil the original inclusion criteria, or they had unclear definitions of mechanical complications [3, 16]. Thus, it is not possible to draw definitive conclusions from the outcomes of these studies, and the association between the GAP score and mechanical complications in patients after surgical fusion for adult spinal deformity remains uncertain. Thus, a robust external validation study is required.

We therefore applied the strict methodology for the inclusion criteria and definitions of mechanical complications and revisions as described in the original study [33] for the GAP score and asked whether after adult spinal deformity surgery, is a higher GAP score associated with (1) an increased risk of mechanical complications, defined as rod fractures, implant-related complications, proximal or distal junctional kyphosis or failure; (2) a higher likelihood of undergoing revision surgery to treat a mechanical complication; and (3) is a higher GAP score category associated with worse validated outcomes scores using the Oswestry Disability Index (ODI), Scoliosis Research Society-22 (SRS-22) and the Short Form-36 questionnaires?

Patients and Methods

Overview

We performed a retrospective analysis of a previous prospective, multicenter study that recruited patients after fusion

for adult spinal deformity with minimum of 2 years follow-up as part of the Scoli-RISK-1 trial. From this cohort, the GAP score was applied to patients who fulfilled these inclusion criteria: (1) age ≥ 18 years; (2) at least one of the following radiological parameters preoperatively: scoliosis $\geq 20^\circ$, sagittal vertical axis (SVA) ≥ 5 cm, thoracic kyphosis $> 60^\circ$, pelvic tilt $> 25^\circ$; (3) undergone \geq four-vertebrae posterior instrumented fusion; and (4) minimum of 2 years follow-up. Patients were excluded from this secondary analysis if they had neuromuscular disease, active infections, trauma or tumors, if a full-length radiograph was not available at baseline, early postoperative period (between 3 and 12 weeks) or latest follow-up, or if the planned uppermost instrumented vertebra was within a previously fused segment.

There were 272 patients in the original Scoli-RISK-1 cohort. Patients with fewer than four levels of fusion (0.7%; 2 of 272), those who dropped out before the 2-year timepoint (20%; 55 of 272), those without postoperative whole-spine standing radiographs at 2 years (24%; 64 of 272), and those whose GAP score could not be calculated on 3- to 12-week radiographs because of missing data (14%; 37 of 272) were excluded, leaving 159 patients (58%) were included in the current analysis (Table 1). The baseline characteristics and radiographic parameters used to calculate the GAP score were similar between the patients who were included in this study and those who were excluded (Table 2).

The mean (range) age of the analyzed patients at the time of surgery was 58 ± 14 years (18 to 80), and the median number of levels involved in the surgery was 11 (4 to 23). Sixty-two percent (99 of 159) had previous spine surgery. The median total operative time was 405 minutes (interquartile range [IQR] 329 to 499 minutes), with a median estimated total blood loss of 2000 mL (IQR 1500 to 3000 mL). Seventy-five percent (120 of 159) of the patients underwent a three-column osteotomy.

Ethical approval was waived for the analysis and publication of a retrospective review of anonymized data obtained from an institutional review board-approved prospective clinical trial.

Participants in the Scoli-RISK-1 Study

Patients between 18 and 80 years of age were prospectively recruited into the Scoli-RISK-1 trial if they were undergoing surgery for adult spinal deformity and met any one of the following criteria: (1) a major Cobb angle of $\geq 80^\circ$ in the coronal and/or sagittal planes; (2) congenital or revision spinal deformity undergoing corrective osteotomy; (3) presence of preoperative myelopathy; (4) ossification of the ligamentum flavum, or ossification of the posterior longitudinal ligament with a deformity; or (5)

Table 1. Patient selection

Selection criteria	Number of patients (n = 272)
Patients aged \geq 18 years, % (n)	100 (272)
Patients who had at least one radiographic event at baseline, % (n)	86 (233)
Patients who underwent an operation of \geq four vertebrae posterior levels, % (n)	99 (270)
Patients with 2-year follow-up visit, % (n)	80 (217)
Radiographic assessments at 2-year visit available, % (n)	76 (208)
Patients whose GAP score could be calculated based on 6-week radiologic data, % (n)	86 (235)
Patients selected for analysis, that is, met all inclusion criteria, % (n)	58 (159)

patients who had undergone corrective osteotomy or three-column osteotomy. The Scolio-RISK-1 trial was registered with clinicaltrials.gov under NCT01305343, but registration is not required for this secondary data analysis of the primary clinical trial.

Validation of the GAP Score Using the Scolio-RISK-1 Cohort

The following radiographic parameters were obtained by using a computerized software-based service provided by

Nemaris Inc (New York, USA) using centralized patient radiographs taken between 3 and 12 weeks postoperatively: pelvic incidence, sacral slope, L1-S1 lordosis, L4-S1 lordosis, and global tilt. We calculated GAP parameters from the ideal sacral slope, lumbar lordosis, and global tilt, as described by Yilgor et al. [33]. The GAP score, which was calculated by adding the scores for relative pelvic version, relative lumbar lordosis, lordosis distribution index, relative spinopelvic alignment, and the age factor, can range from 0 to 13 points. A GAP score of 0 to 2 was considered to indicate a proportioned spinopelvic state, 3 to 6 as a moderately disproportioned state, and 7 or higher as a severely disproportioned state.

Distribution of GAP scores and Mechanical Complications

The mean (range) postoperative GAP score was 7 ± 3 (0 to 13). Five percent (8 of 159) of the patients had a proportional spinopelvic state according to the GAP score, whereas 35% (55 of 159) and 60% (96 of 159) had moderately and severely disproportioned states, respectively (Fig. 1).

Twenty-eight percent (44 of 159) of the patients had mechanical complications: 11% (17 of 159) had proximal junctional kyphosis, 19% (31 of 159) had other implant-related complications, and 2% (3 of 159) had distal junctional kyphosis or failure. Sixteen percent (25 of 159) of patients underwent revision surgery for mechanical complications.

Table 2. Comparison between patients included and excluded from the current analysis

Variable	Excluded n = 113	Included n = 159	Total n = 272	p value
Age, mean \pm SD	56 \pm 17	58 \pm 14	57 \pm 15	0.40 ^a
Sex, % (n)				0.04 ^b
Male	40 (45)	28 (44)	33 (89)	
Female	60 (68)	72 (115)	67 (183)	
Race, % (n)				0.15 ^c
White or Caucasian	84 (95)	75 (120)	79 (215)	
East Asian	15 (17)	21 (33)	18 (50)	
Other	1 (1)	4 (6)	3 (7)	
Patients with previous spine surgeries, % (n)	62 (70)	62 (99)	62 (169)	0.96 ^b
GAP category, % (n)				0.07 ^b
Proportioned	12 (9) ^d	5 (8)	7 (17) ^d	
Moderately disproportioned	41 (31) ^d	35 (55)	37 (86) ^d	
Severely disproportioned	47 (36) ^d	60 (96)	56 (132) ^d	

^at test.

^bChi-square test.

^cFisher's exact test.

^dFor patients excluded from the current analysis, information sufficient to calculate the GAP score was only available in 76 patients.

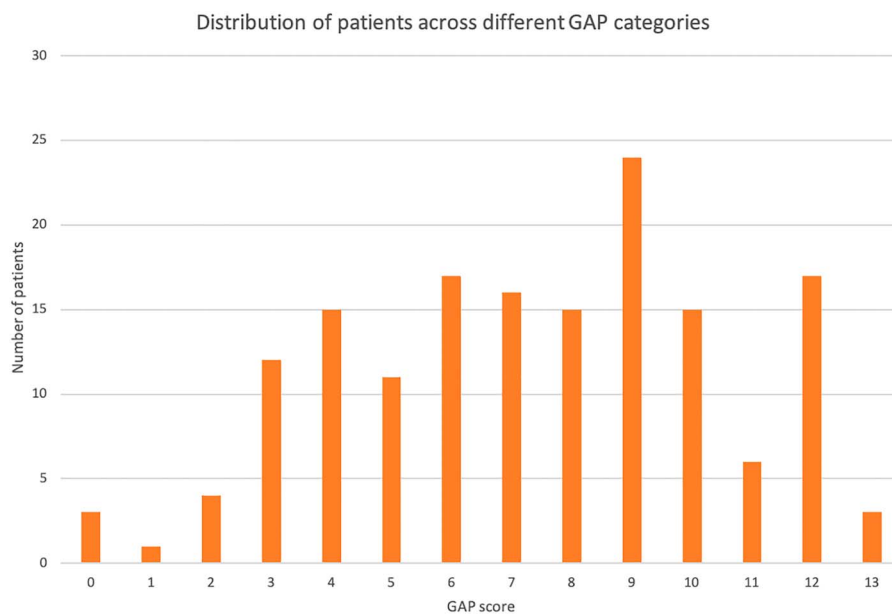


Fig. 1 This graph shows the distribution of patients across different GAP categories.

Primary and Secondary Study Outcomes

Our primary study outcome was to determine the association between the GAP score and the occurrence of any mechanical complications. Postoperative radiographs between 12 weeks and final follow-up were assessed for the following mechanical complications: (1) rod fractures (single or double rods, symptomatic or incidental findings); (2) proximal junctional kyphosis, defined as $\geq 10^\circ$ increase in kyphosis between the uppermost instrumented vertebra (UIV) and UIV+2 between early postoperative and follow-up radiographs; (3) proximal junctional failure, defined as fracture of UIV or UIV + 1, pullout of UIV instrumentation, or presence of sagittal subluxation; (4) distal junctional kyphosis or failure, defined as $\geq 10^\circ$ increase in kyphosis between the lowermost instrumented vertebra (LIV) and LIV-1 between early postoperative and follow-up radiographs, or pullout of LIV instrumentation; and (5) implant-related complications, such as screw loosening, pullout or fracture, interbody graft, hook or set screw dislodgement; or failure because of adverse events identified independently by two authors (KYHK, KMCC). Additionally, a clinical endpoint committee evaluated all reported complications for its accuracy and re-categorized as necessary.

Our secondary study outcomes were to determine the association between the GAP score and the occurrence of mechanical revisions, and between the GAP category and validated outcome scores. Mechanical revisions were defined as any additional surgery performed to treat a mechanical complication stated above. Validated outcome scores were collected as part of the original prospective

trial, which included ODI, SRS-22 and the Short Form-36 questionnaires.

Statistical Analysis

Descriptive statistics were used to present demographics and radiographic parameters. Categorical data are presented using absolute frequency and percentages; continuous data are presented as the mean with SDs for normally distributed data or median and interquartile ranges for non-normally distributed data. Using a receiver operator characteristic curve, we calculated the area under the curve (AUC) to assess the association between the GAP score and the likelihood of mechanical complications, and that of revision surgery to treat a mechanical complication. An AUC of 0.5 to 0.7 was classified as no or low associative power, 0.7 to 0.9 as moderate and > 0.9 as high. Additionally, we analyzed differences in validated outcome scores between the GAP categories using Wilcoxon rank sum test. Significance was defined as $p < 0.05$. All statistical analyses were performed using SAS (version 9.4, SAS Institute Inc, Cary, NC, USA).

Results

GAP Score and Risk of Mechanical Complications

Mechanical complications were found in 13% (1 of 8) patients with proportioned GAP scores, 24% (13 of 55)

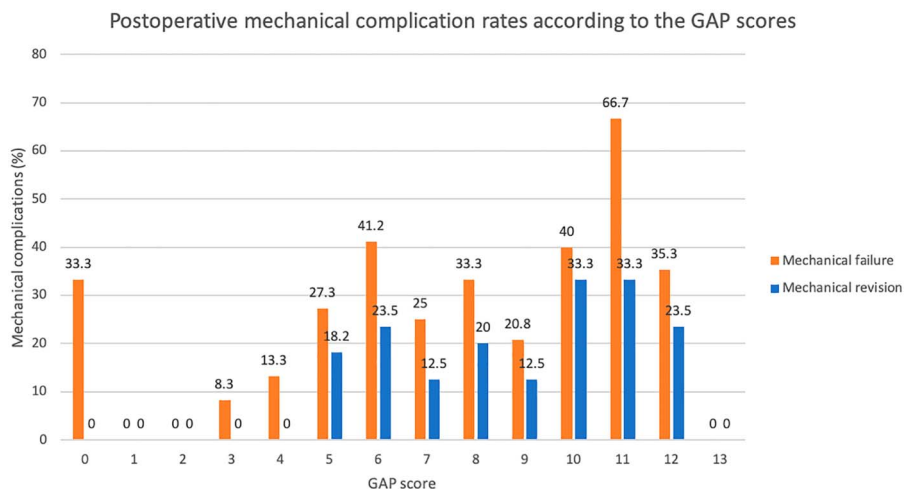


Fig. 2 This graph shows postoperative mechanical complication rates according to GAP scores.

patients with moderately disproportioned GAP scores, and 31% (30 of 96) patients with severely disproportioned GAP scores (Fig. 2). Using receiver operating characteristic curve, we found that higher postoperative GAP scores were not associated with increased risks of mechanical complications with minimum of 2 year follow-up (AUC = 0.60 [95% CI 0.50 to 0.70]).

GAP Score and Revision Surgery

Mechanical revision surgeries were performed in 0% (0 out of 8) patients with proportioned GAP scores, 11% (6 of 55) patients were moderately disproportioned GAP scores, and 20% (19 of 96) patients with severely disproportioned GAP scores. Using receiver operating characteristic curve, we found that higher postoperative GAP scores were not associated with increased risks of mechanical revision during a minimum of 2 years’ follow-up (AUC = 0.66 [95% CI 0.53 to 0.78]).

GAP Category and Validated Outcomes Scores

In all four validated outcome measures, we found lower (better) gap score category was associated with better quality-of-life status at minimum of 2 years’ follow-up. Moderately disproportioned GAP score category was associated with a better SF-36 physical component summary score (40 ± 11 versus 36 ± 10; p = 0.047), a better SF-36 mental component summary score (46 ± 13 versus 51 ± 12; p = 0.01), a better SRS-22 total score (3.4 ± 0.8 versus 3.7 ± 0.7; p = 0.02) and a better ODI score (35 ± 21 versus 25 ± 20; p < 0.001) than severely disproportioned GAP score category (Table 3).

Discussion

The prevalence of radiographic and clinically symptomatic mechanical complications after surgery for adult spinal deformity has been reported to be 30%, and more than 50% of these patients underwent a revision surgery to treat them. Yilgor et al. [33] proposed a new pelvic incidence-based proportional method of analyzing the sagittal alignment, known as the GAP score, to predict mechanical complications in patients undergoing surgery for adult spinal deformity. Although the GAP score performs accurately on internal validation, it has not been validated externally using the same inclusion criteria and strict definitions of mechanical complications as described in the original study. We therefore applied the GAP score as additional analysis on the Scolio-RISK-1 database. We found that higher GAP scores were not associated with increased risks of mechanical complications nor revision surgeries due to mechanical complications. However, we found that moderately proportioned GAP score category was associated with better validated outcome scores than severely proportional GAP score category.

Limitations

This study had several limitations. First only 159 of the 272 patients in the Scolio-RISK-1 database could be included in the study because of the strict inclusion criteria. The Scolio-RISK-1 study was initiated to provide a complete risk profile of neurologic and non-neurologic adverse events after surgeries to treat complex adult spinal deformities, and a 6-week postoperative radiograph was not mandatory. Although our analyses showed the baseline characteristics did not differ between patients who were included in this current study and those who were not, we cannot rule out the possibility of

Table 3. Comparison of postoperative health-related quality of life scores at 24 months by GAP categories

Health-related quality of life measure	GAP category			p value ^a
	Proportioned (n = 8)	Moderately disproportioned (n = 55)	Severely disproportioned (n = 96)	
SF-36 physical component summary	44 ± 8	40 ± 11	36 ± 10	0.047
SF-36 mental component summary	48 ± 7	51 ± 12	46 ± 13	0.01
SRS total score	3.5 ± 0.5	3.7 ± 0.7	3.4 ± 0.8	0.02
ODI	27 ± 18	25 ± 20	35 ± 21	0.001

^aComparison was made between moderately and severely disproportioned groups only; data are presented as the mean ± SD. SF-36 = Short Form-36; SRS = Scoliosis Research Society; Oswestry Disability Index = ODI.

selection bias. Second, patients included in the Scolio-RISK-1 database had more complex deformities than those described in the original GAP study [33], and the magnitude of correction was substantial. However, the GAP score should be able to predict the mechanical outcomes of patients who undergo more complex surgeries. Third, the patients were not equally distributed among each GAP score category since the original Scolio-RISK-1 study was powered to evaluate neurologic complications after surgery for complex spinal deformities only. We used as many patients as possible from the original cohort who matched the inclusion criteria to perform external validation, but there was a lower statistical power than might be expected in a planned validation study. The statistical analysis was based on only eight patients in the GAP proportioned group with a broad confidence interval of mechanical revision; it is possible that the statistical significance may have varied if more patients from the original cohort could have been included. In addition, the health-related quality of life scores could not be reliably compared for the GAP proportioned group. However, the GAP score was developed to evaluate mechanical complications only, and outcome scores only indirectly reflected the consequences of sagittally-malaligned spines.

GAP Score and Risk of Mechanical Complications

We found no association between the postoperative GAP score and mechanical failures two years after surgery. The original study that described the GAP score showed that it was highly predictive of mechanical complications in its validation cohort, with an AUC of 0.92 [33]. However, the external validity of the GAP score has not been established. Bari et al. [3] studied 149 patients and did not find any association between the GAP score and mechanical failure. However, the patient population in that study was not matched to the population originally described in terms of patient characteristics and the number of levels fused. Although Bari et al. [3] argued that the GAP score described a general spinopelvic state that should apply to all lumbosacral surgeries, their study methodology did not

follow the strict criteria of an external validation study, therefore rendering their interpretation based on these results is inconclusive. Jacobs et al. [16] studied 39 patients from two centers and compared the predictive value of the GAP score and that of Schwab sagittal modifiers for mechanical complications. Both classification systems could predict radiographic mechanical complications, but the GAP score was superior ($p = 0.03$). However, only a small number of patients were included, and one of the original Schwab classification parameters was not available for analysis.

Although our present study was not designed and powered to validate the GAP score, we included a large number of patients and followed the strict inclusion criteria and definitions of mechanical complications. The narrow focus on sagittal alignment does not consider other non-mechanical risk factors, including neurologic disorders [13], visual impairment, and vestibular dysfunction, which may impact balance. Moreover, a mathematical approach using formulae is not necessarily predictive in large cohorts because of heterogeneity in patient factors, surgical variations, and postoperative regimens. Inoue et al. [15] found that three or more medical comorbidities and smoking were major risk factors for mechanical failure. Recently, a study found that the multifidus and erector muscles play a role in the maintenance of spinopelvic alignment [17], and a lower thoracolumbar muscle volume was associated with the development of proximal junctional kyphosis in one series [19]. The lack of association between the postoperative GAP score and mechanical complications demonstrated by our study suggests factors other than radiologic parameters are important in the occurrence of mechanical complications after surgeries for adult spinal deformity.

GAP Score and Revision Surgery

Likewise, we found no association between the postoperative GAP score and mechanical revision. In the validation cohort of the original description of the GAP score, Yilgor et al. [33] found that the mechanical revision rates

were 3%, 21%, and 55% for the proportioned, moderately disproportioned, and severely disproportioned groups, respectively. The Cochran-Armitage test also showed a significant linear trend, with higher GAP scores being associated with higher rates of mechanical revisions (chi-square [1] = 19.4; $p < 0.001$). However, mechanical revisions may be due to a wide variety of reasons apart from alignment issues. Maier et al. [22] found that in 335 patients with adult spinal deformity, revision rates varied across eight different sites (range 6.3% to 31.9%; $p = 0.001$). They also reported that choosing a more caudal level of three-column osteotomy had a greater tendency to lead to revisions. Another study found higher revision rates were associated with the etiology of adult spinal deformity (degenerative and congenital) and the types of implant construct (hybrid constructs) [35]. A further possible factor that we were unable to differentiate from our current study is the contribution of previous spinal surgery. It is highly conceivable that violation of the posterior lumbar musculature and previous spinal reconstructions can contribute to higher revision rates. Hu and Lieberman [14] found that adult spinal deformity patients who had three or more previous operations had higher reoperation rates than those who only had one (22% versus 8%; $p = 0.07$). Mechanical revisions, therefore, may result from factors other than spinopelvic alignment alone.

GAP Score and Validated Outcome Scores

We found some associations between lower (better) GAP score category and better patient-reported outcomes scores; this is not surprising as the GAP score describes a spinopelvic state according to the sagittal physiological alignment of the normal spine that is most efficient for muscular forces to function [21]. Patients in the study described by Yilgor et al. [33] also found better health-related quality of life measures for patients with lower GAP score categories. However, the original purpose of the GAP score was to predict the occurrence of mechanical complications, and its association with outcome scores was not the primary intent. Nonetheless, this highlights the importance of sagittal balance in the treatment of adult spinal deformity [12].

Conclusions

Our external validation study using a prospective, multicenter database of patients with complex adult spinal deformities did not find any association between the GAP score and mechanical complications nor mechanical revisions. There is insufficient evidence to apply the GAP score in the surgical planning of adult spinal deformity in routine clinical practice currently. Future directions should include prospective trials powered specifically to study the predictive value of GAP

score, strict patient inclusion criteria, and prospective documentation of all symptomatic and asymptomatic radiographic mechanical complications. This will improve our understanding of the multiple factors, including the different components of the GAP score, that give rise to mechanical complications in adult spinal deformity surgeries.

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