Spine

SPINE Volume 48, Number 13, pp 930–936

DEFORMITY

Should Global Realignment Be Tailored to Frailty Status for Patients Undergoing Surgical Intervention for Adult Spinal Deformity?

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Study Design. Retrospective cohort study.

Objective. Assess whether modifying spinal alignment goals to accommodate frailty considerations will decrease mechanical complications and maximize clinical outcomes.

Summary of Background Data. The Global Alignment and Proportion (GAP) score was developed to assist in reducing mechanical complications, but has had less success predicting such events in external validation. Higher frailty and many of its components have been linked to the development of implant failure. Therefore, modifying the GAP score with frailty may strengthen its ability to predict mechanical complications.

Materials and Methods. We included 412 surgical ASD patients with two-year follow-up. Frailty was quantified using the modified Adult Spinal Deformity Frailty Index (mASD-FI). Outcomes: proximal junctional kyphosis and proximal junctional failure (PJF), major mechanical complications, and "Best Clinical Outcome" (BCO), defined as Oswestry Disability Index < 15 and Scoliosis Research Society 22-item Questionnaire Total > 4.5. Logistic regression analysis established a six-week score based on GAP score, frailty, and Oswestry Disability Index US Norms. Logistic regression followed by conditional inference tree analysis generated categorical thresholds. Multivariable logistic regression analysis controlling for confounders was used to assess the performance of the frailty-modified GAP score.

Results. Baseline frailty categories: 57% not frail, 30% frail, 14% severely frail. Overall, 39 of patients developed proximal junctional kyphosis, 8% PJF, 21% mechanical complications, 22% underwent reoperation, and 15% met BCO. The mASD-FI demonstrated a correlation with developing PJF, mechanical complications, undergoing reoperation, and meeting BCO at two years (all $P < 0.05$). Regression analysis generated the following equation: Frailty-Adjusted Realignment Score (FAR Score) = 0.49 × mASD-FI+0.38 × GAP Score. Thresholds for the FAR score (0–13): proportioned: <3.5, moderately disproportioned: 3.5–7.5, severely disproportioned: > 7.5. Multivariable logistic regression assessing FAR score demonstrated associations with mechanical complications, reoperation, and meeting BCO by two years (all $P < 0.05$), whereas the original GAP score was only significant for reoperation.

Conclusion. This study demonstrated adjusting alignment goals in adult spinal deformity surgery for a patient's baseline frailty status and disability may be useful in minimizing the risk of complications and adverse events, outperforming the original GAP score in terms of prognostic capacity.

Key Words: adult spinal deformity (ASD), clinical outcomes, realignment, mechanical complications, reoperations, junctional failure

Level of Evidence. 3.

Spine 2023;48:930–936

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Acknowledgment date: June 30, 2022. First revision date: July 20, 2022. Acceptance date: July 21, 2022.

The authors report no conflicts of interest.

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DOI: 10.1097/BRS.0000000000004501

Adult spinal deformity (ASD) is increasing in prevalence and enthusiasm for surgical correction of this conditions has expanded in recent decades.[1–4] Procedures for the correction of ASD are known to carry high

rates of complications and other adverse events, including longer term mechanical failure and need for revision surgery.[4] The risk of such adverse events are known to be greater in patients with multiple comorbidities and frailty, which reduces physiological reserve and simultaneously increases the potential for perioperative morbidity, wound complications, and construct failure.[3–7]

To assist surgeons in maximizing outcomes, while minimizing the prospect for complications, realignment schemes, such as the Global Alignment and Proportion (GAP) score, have been proposed as a means to individualize target goals for patients based on presenting deformity.[8,9]

However, the GAP score has not been found to perform to the degree anticipated in external validation studies.[10–13] These findings have prompted additional efforts that explore the effects of incorporating patient-specific factors into realignment strategies, including age, body mass index (BMI), and bone mineral density.[14–16] The inclusion of these nonradiographic parameters into realignment schemes has demonstrated substantial clinical benefit.[16,17] At the same time, as one of the main drivers of adverse events following ASD correction surgery, the omission of frailty from modified GAP scoring criteria would appear to be a critical oversight.[18,20]

In this context, we sought to evaluate the effects of incorporating frailty within the GAP score to better tailor realignment goals to patient-specific presentation. This study utilized a prospectively collected ASD registry, with broad clinical variation, that has been used in the past to study clinical interventions and outcomes in patients with spinal deformity.[18,19,21] We hypothesized global alignment goals accounting for frailty would perform better at potentiating clinical success and minimizing complications compared with radiographic criteria alone.

MATERIALS AND METHODS

Data Source and Study Design

This is a retrospective analysis of a prospectively collected, single-center database containing ASD patients. institutional review board (IRB) approval was obtained before enrollment and all patients provided informed consent. General inclusion criteria and the means through which data are collected and outcomes defined have been described extensively in prior publications. For inclusion in this specific study, we required operative ASD patients, treated from 2012 to 2020, to have complete demographic and surgical data, as well as radiographic, clinical, and complications data at two years following surgery.

Data Collection and Radiographic Assessment

Standardized data collection forms assessed patient demographics {including age, sex, race, BMI, frailty [as assessed by the Passias *et al*[5] modified Adult Spinal Deformity Frailty Index (mASD-FI); Table 1], and comorbidities [assessed by Charlson Comorbidity Index]} and surgical parameters at the initial presentation.[18] Functional outcome assessments consisted of the Oswestry Disability Index (ODI) and the Scoliosis Research Society 22-item Questionnaire (SRS-22). Lateral spine radiographs were used to assess radiographic parameters at baseline and follow-up intervals. All images were analyzed with SpineView® (ENSAM, Laboratory of Biomechanics, Paris, France).[22–24]

TABLE 1. Variables Comprising the Modified Adult Spinal Deformity Frailty Index

Variables
BMI <18.5 or >30 kg/m^2
Depression
Difficulty climbing 1 flight of stairs (SF-36v2, 3e)
More than 3 medical comorbidities
Leg weakness
Difficulty getting dressed (SF-36v2, 3j, or LSDI 1 and 2)
Bladder incontinence
Deterioration of health within the past year (SF-36v2, 2)

BMI indicates body mass index; SF-36, 36-Item Short Form Survey.

Spinopelvic radiographic parameters assessed included pelvic tilt (PT: the angle between the vertical and the line through the sacral midpoint to the center of the two femoral heads), the mismatch between pelvic incidence and lumbar lordosis (PI–LL), and the sagittal vertical axis (SVA: C7 plumb line relative to the posterosuperior corner of S1), T1 pelvic angle (T1PA), and each parameter of the GAP score [Lumbar Distribution Index: L4–S1 lordosis divided by L1–S1 lordosis; relative pelvic version: the measured sacral slope minus ideal (PI×0.59+9); relative lumbar lordosis: the measured lumbar lordosis minus the ideal (PI×0.62+29); relative spinopelvic alignment: the measure global tilt minus the ideal (PI×0.48–15)].[8,25]

Clinical Outcomes Assessment

As previously defined in a study by Smith *et al*,[7] the Best Clinical Outcome (BCO) criteria was defined as: a two-year ODI score <15 (out of a 100 scale) and an SRS-22 Total score >4.5.[26] Substantial Clinical Benefit for ODI was designated as an improvement >18.8 from baseline disability, as per published results. Good Outcome was defined as either meeting BCO or Substantial Clinical Benefit for ODI by two years.

Complication Assessment

Proximal junctional kyphosis (PJK) was defined by a PJK angle of <–10° and a PJK angle difference of <–10° from baseline at any time point up to two years. Proximal junctional failure (PJF) was defined using the criteria of Lafage *et al*[6]: a PJK angle of <–28° and a difference in PJK angle of <–22° from baseline at any follow-up time point up to two years.[14]

Mechanical complications were defined as any complication related to the implant, including implant prominence, implant malposition, painful implant, implant failure, interbody dislocation, screw nerve impingement, screw fracture, rod dislocation, and rod fracture. Mechanical complications were classified as major if involving invasive intervention or causing prolonged or permanent morbidity or mortality.

Development of Frailty-Adjusted Realignment (FAR) Score

Logistic regression analysis established a six-week score based on the GAP score, frailty, and US Norms for ODI based on published work from Lafage *et al*.[15] The score was based on the correlation of these factors with achieving BCO and the development of mechanical complications or PJF. Logistic regression followed by conditional inference tree (CIT) analysis generated categorical thresholds based on rates of mechanical complications.

Statistical Analysis

The primary predictor was the frailty-modified GAP score with cutoff thresholds derived from the CIT analysis. The primary outcome consisted of achieving BCO at two years. Secondary outcomes included: major mechanical complications, PJK, PJF, and reoperations. Multivariable logistic regression analysis controlling for age, revision status, number of levels fused, baseline ODI and GAP score was used to assess the performance of the frailty-modified GAP score within the various outcomes of interest. All P values <0.05 were considered significant. All statistical analyses were conducted using SPSS, version 25 (Armonk, NY).

RESULTS

Cohort Overview

A total of 412 operative patients with ASD met the inclusion criteria. The mean age in this cohort was 60.1 ± 14.2 years. In all, 80% were female, mean BMI was 26.9 ± 5.4 kg/m^2, mean Charlson Comorbidity Index was 1.7 ± 1.7, and mean frailty of 6.5 ± 4.8.

Baseline Radiographic Descriptors

Mean preoperative radiographic parameters were as follows: PT of 23.8 ± 11.2°, pelvic incidence of 54.4 ± 12.4°, PI–LL of 15.8 ± 21.3°, L4–S1 of 34.1 ± 14.4°, SVA of 65.2 ± 71.1 mm, T1PA of 22.7 ± 13.4°, T4–T12 thoracic kyphosis of –34.0 ± 19.4°, and GAP score of 7.7 ± 4.3.

Surgical Descriptors

In terms of surgical characteristics, mean levels fused was 11.2 ± 4.4, mean estimated blood loss was 1580 ± 1274 mL, and mean operative time was 416 ± 176 minutes. By surgical approach, 63.6% underwent posterior only and 35.0% underwent a combined approach, with incorporation of a decompression in % of procedures, an osteotomy performed in 72.8%, and a three-column osteotomy (pedicle subtraction osteotomy or vertebral column resection) in 19.9%. The mean hospital length of stay was 7.7 ± 4.2 days.

Complication and Clinical Outcomes

Overall by two years, 39.1% of patients developed PJK, 8.3% developed PJF, 21.1% developed mechanical complications (8.7% were considered major), and 91 patients (22.1%) underwent reoperation. Regarding clinical outcomes, 15.2% met BCO.

Radiographic Outcomes

Mean postoperative radiographic parameters were as follows: PT of 19.2 ± 10.2°, PI–LL of 1.3 ± 13.9°, L4–S1 of 33.9 ± 11.8°, SVA of 24.5 ± 44.2 mm, T1PA of 15.1 ± 9.6°, T4–T12 thoracic kyphosis of –42.4 ± 14.6°, and GAP score of 4.4 ± 3.6. This categorized 35.9% of patients as proportioned in GAP postoperatively.

Initial Regression Analysis

When assessing the cohort as a whole, increasing six-week GAP score had less odds of meeting BCO [odds ratio (OR): 0.9; 95% CI: 0.8–1.0; $P = 0.031$], but no association with greater odds of developing mechanical complications (OR: 1.0; 95% CI: 1.0–1.1; $P = 0.229$), undergoing reoperation (OR: 1.0; 95% CI: 1.0–1.1; $P = 0.196$), PJK (OR: 1.0; 95% CI: 1.0–1.1; $P = 0.534$), or PJF (OR: 1.0; 95% CI: 0.9–1.1; $P = 0.623$). The mASD-FI demonstrated a higher frailty score had higher odds with developing PJF (OR: 1.1; 95% CI: 1.0–1.2; $P = 0.049$), undergoing reoperation (OR: 1.1; 95% CI: 1.0–1.1; $P = 0.046$), and less odds of meeting BCO by two years (OR: 0.8; 95% CI: 0.8–0.9; $P < 0.001$), but not mechanical complications (OR: 1.0; 95% CI: 1.0–1.1; $P = 0.078$) or PJK (OR: 1.0; 95% CI: 1.0–1.1; $P = 0.104$).

Development of the FAR Score

Multiple logistic regression models were derived to develop an equation from a six-week GAP score and baseline frailty correlated to both BCO and development of mechanical complications by two years. The following equation for the FAR score was:

$$\text{Frailty–Adjusted Realignment Score} = 0.49 \times \text{mASD–FI} + 0.38 \times \text{GAP Score}.$$

Comparison of Outcomes Between GAP and FAR Scores

Adjusted analysis controlling for age, revision status, number of levels fused, baseline disability, and deformity, assessed for associations between the continuous six-week GAP and FAR scores and either development of complications or rates of meeting BCO. For the GAP score, there was no association seen with PJK (OR: 1.0; 95% CI: 0.9–1.1; $P = 0.630$), PJF (OR: 1.0; 95% CI: 0.9–1.1; $P = 0.732$),

mechanical complications (OR: 1.1; 95% CI: 1.0–1.1; $P = 0.212$), or reoperation by two years (OR: 1.1; 95% CI: 1.0–1.2; $P = 0.078$), as well as meeting BCO (OR: 0.9; 95% CI: 0.9–1.0; $P = 0.282$). However, for an increasing FAR score, there was increased likelihood of developing mechanical complications (OR: 1.1; 95% CI: 1.0–1.2; $P = 0.043$), undergoing reoperation (OR: 1.1; 95% CI: 1.0–1.2; $P = 0.019$) and less odds of meeting BCO (OR: 0.7; 95% CI: 0.6–0.9; $P < 0.001$), but not PJK (OR: 1.0; 95% CI: 0.9–1.1; $P = 0.543$) or PJF (OR: 1.1; 95% CI: 1.0–1.2; $P = 0.249$).

Derivation of Categorical Thresholds

Using CIT machine learning algorithm analysis, categorical thresholds were developed for the score corresponding to meeting BCO and not developing a mechanical complication. Upon threshold derivation, the categories were as follows: FAR score <3.5 was considered proportioned, 3.5–7.5 moderately disproportioned, and >7.5 was considered severely disproportioned.

Performance of the Categorical Thresholds

Tables 2 and 3 outline the results of an unadjusted analysis of variance on outcomes for categories of both the FAR and the GAP scores, while Table 4 shows the dispersion of original GAP scores within the FAR categories (*ie*, the differences in categorization between the GAP and the FAR scores). Adjusted analysis controlling for age, revision status, number of levels fused, baseline disability, and deformity, assessed for associations between the categories and either development of complications or rates of meeting BCO. For the GAP score, there was an association seen with undergoing reoperation by two years (OR: 1.7; 95% CI: 1.2–2.4; $P = 0.003$), but not development of PJK (OR: 0.9; 95% CI: 0.6–1.1; $P = 0.293$), PJF (OR: 1.0; 95% CI: 0.6–1.6; $P = 0.916$), mechanical complications (OR: 1.3; 95% CI: 0.9–1.9; $P = 0.120$), as well as meeting BCO (OR: 0.7; 95% CI: 0.5–1.1; $P = 0.145$). However, for an increasing FAR score, there was increased likelihood of developing mechanical complications (OR: 1.6; 95% CI: 1.1–2.2; $P = 0.018$), undergoing reoperation (OR: 1.6; 95% CI: 1.1–2.3; $P = 0.007$) and less odds of meeting BCO (OR: 0.3; 95% CI: 0.2–0.6; $P < 0.001$), but not for PJK (OR: 0.9; 95% CI: 0.6–1.2; $P = 0.326$) or PJF (OR: 1.3; 95% CI: 0.8–2.1; $P = 0.380$).

DISCUSSION

It is now generally accepted that surgical planning for ASD correction should use target goals that not only align with clinical success but also mitigate complications in this already "at-risk" population. Although the GAP score was developed with this express purpose in mind, previous assessments seeking to validate this utility have demonstrated inadequate performance.[10–13] We believe that some of these issues derive from the inability of the GAP score to account for patient frailty, a critically important driver of adverse events following ASD correction. In the current work, we modified GAP score realignment goals accounting for frailty to better tailor correction to the patient's baseline deformity as well as their physiological tolerance for surgical intensity. In doing so, a simplified FAR score was developed that balances achieving a good clinical outcome against the chances of developing mechanical or radiographic complications.

In our analysis, patients proportioned in the frailty-modified score sustained significantly less mechanical complications, even when accounting for baseline deformity and invasiveness during the procedure. Previous work has identified the importance of BMI and regional osteopenia in contributing to adverse events following ASD surgery.[20] We believe that the frailty-modified score is advantaged over these other more simplistic parameters as BMI and low bone mineral density are items recorded in the ASD-FI.[27] As a composite measure incorporating this triumvirate of negative risk factors, the FAR score presents a more holistic assessment of patient risk while minimizing data inputs and the cumbersome nature of having to deploy multiple scoring utilities. As seen in the distributions of the final table, over

TABLE 2. Comparison of Complication Rates by Original GAP and FAR Scores

Values	Patients	Range of Frailty	PJK (%)	*P*	PJF (%)	*P*	Mechanical Complications (%)	*P*	Any Reoperation (%)	*P*
FAR score										
P	146	2.2	37.7	0.907	6.2	0.153	15.8	0.025	15.8	0.027
MD	176	6.8	39.7		7.5		20.7		23.0	
SD	90	12.8	40.2		13.0		30.4		30.4	
Original GAP score										
P	148	5.6	37.8	0.698	7.4	0.871	17.7	0.345	13.5	0.006
MD	156	6.7	41.7		8.3		21.8		28.2	
SD	108	7.5	37.0		9.3		25.0		25.0	

FAR indicates Frailty-Adjusted Realignment; GAP, Global Alignment and Proportion; MD, moderately disproportioned; P, proportioned; PJF, proximal junctional failure; PJK, proximal junctional kyphosis; SD, severely disproportioned.

TABLE 3. Comparison of Meeting Smith and Collegaues' Best Clinical Outcome by Original GAP and FAR Scores

Values	Patients	Range of Frailty	Met Best Clinical Outcome (%)	*P*
FAR score				
P	146	2.2	27.6	<0.001
MD	176	6.8	10.7	
SD	90	12.8	3.4	
Original GAP score				
P	148	5.6	19.1	0.041
MD	156	6.7	16.3	
SD	108	7.5	7.8	

FAR indicates Frailty-Adjusted Realignment; GAP, Global Alignment and Proportion; MD, moderately disproportioned; P, proportioned; SD, severely disproportioned.

one third of the patients proportioned in the FAR score were disproportioned in the GAP score. This further highlights the differences in how patients are categorized between each score, possibly serving as the reasoning for the better correlation with outcomes for the FAR score.

While avoidance of complications and unplanned revisions should definitely be a focus during preoperative planning, the ultimate goal of surgical correction is to relieve the majority of disability and dysfunctionality that impacts the quality of life in patients with spinal deformity. Therefore, realignment goals targeting clinical success is paramount. The FAR score demonstrated superior clinical utility compared with the GAP score, regardless of a patient's baseline deformity. Our study indicates patients proportioned in the FAR score were more than three times as likely to achieve BCO compared with those moderately disproportioned. Similar sensitivities were not appreciated for the original GAP score in this work. Yet, notably, patients moderately disproportioned were also three times more likely to meet the outcome compared with patients severely disproportioned in the FAR score postoperatively. This finding is important, as patients with severe deformity at baseline may present with many comorbidities and a high degree of frailty, leaving them at risk of adverse events given the surgical invasiveness required to correct them to an idealized FAR score. However, our results indicate that even correcting these patients to a moderately disproportioned alignment can significantly decrease their chances of mechanical and radiographic complications resulting in reoperation, while placing them on a path of relative clinical success.

The modification of global realignment and its clinical utility has shown promise. However, this exploratory approach to examining the effects of patient-specific factors on complications and their incorporation into realignment targets is limited by the retrospective nature of the current study as well as the prospects for selection and expertise bias. Alongside our findings, we encourage surgeons to heed the use of our results before further prospective and more rigorous studies evaluate this score in separate contexts, to expand its generalizability within the field of ASD. Therefore, we do not recommend stratifying surgical candidacy based solely on our findings as the underlying diagnoses, surgical approaches taken, and single-center aspect of our work may represent important confounders. Additional limitations include the potential for restricted clinical variation, classification bias for some of the adverse events we considered, and multiple comparisons using an exploratory approach. As such, we encourage cautious interpretation for the secondary outcomes considered in this investigation.

CONCLUSIONS

This study demonstrated adjusting alignment goals in ASD surgery for a patient's baseline frailty status and disability may be useful in minimizing the risk of complications and adverse events. The FAR score presented here outperforms the original GAP score in terms of prognostic capacity for

TABLE 4. Prevalence Comparison of Original GAP and FAR Scores

FAR Proportionality	Patients	Original GAP Score [Mean (Range)]	GAP Proportionality (%)		
			P	MD	SD
FAR score					
P	146	2.1 (0–9)	63.0	35.6	1.4
MD	176	4.8 (0–13)	26.7	42.0	31.3
SD	90	7.4 (1–13)	10.0	33.3	56.7
Original GAP score					
P	148	0.9 (0–2)	100	—	—
MD	156	4.2 (3–6)	—	100	—
SD	108	9.6 (7–13)	—	—	100

FAR indicates Frailty-Adjusted Realignment; GAP, Global Alignment and Proportion; MD, moderately disproportioned; P, proportioned; SD, severely disproportioned.

all outcomes we considered, including achieving BCO at two years, major mechanical complications, PJK and PJF, as well as reoperations.

➢ Key Points:

- ❑ The GAP score was originally studied to decrease mechanical complications following ASD surgery, although the results of recent validation studies have been inconsistent.
- ❑ Given the correlation between frailty and the clinical outcomes and complications following ASD corrective surgery, we modified the GAP score to formulate an equation accounting for global alignment and frailty, as measured by the mASD-FI.
- ❑ Our study found the FAR score to be correlated to clinical outcomes, mechanical, and radiographic complications, as well as reoperation following surgical intervention for ASD.
- ❑ The findings of this study not only individualize alignment goals to a patient's baseline radiographic presentation but also incorporate the patient's medical and physical profile into surgical planning as well, possibly bridging the connection between optimal alignment and optimal outcomes.

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