Highest Achievable Outcomes for Adult Spinal Deformity Corrective Surgery

Does Frailty Severity Exert a Ceiling Effect?

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Study Design. Retrospective single-center study.

Objective. To assess the influence of frailty on optimal outcome following ASD corrective surgery.

Summary of Background Data. Frailty is a determining factor in outcomes after ASD surgery and may exert a ceiling effect on the best possible outcome.

Methods. ASD patients with frailty measures, baseline, and 2-year ODI included. Frailty was classified as Not Frail (NF), Frail (F) and Severely Frail (SF) based on the modified Frailty Index, then stratified into quartiles based on two-year ODI improvement (most improved designated "Highest"). Logistic regression analyzed relationships between frailty and ODI score and improvement, maintenance, or deterioration. A Kaplan-Meier survival curve was used to analyze differences in time to complication or reoperation.

Results. A total of 393 ASD patients were isolated (55.2% NF, 31.0% F, and 13.7% SF), then classified as 12.5% NF-Highest, 17.8% F-Highest, and 3.1% SF-Highest. The SF group had the highest rate of deterioration (16.7%, $P=0.025$) in the second postoperative year, but the groups were similar in improvement (NF: 10.1%, F: 11.5%, SF: 9.3%, $P=0.886$). Improvement of SF patients was greatest at six months (ΔODI of -22.6 ± 18.0, $P<0.001$), but NF and F patients reached maximal ODI at 2 years (ΔODI of -15.7 ± 17.9 and -20.5 ± 18.4, respectively). SF patients initially showed the greatest improvement in ODI (NF: -4.8 ± 19.0, F: -12.4 ± 19.3, SF: -22.6 ± 18.0 at six months, $P<0.001$). A Kaplan-Meier survival curve showed a trend of less time to major complication or reoperation by 2 years with increasing frailty (NF: 7.5 ± 0.381 yr, F: 6.7 ± 0.511 yr, SF: 5.8 ± 0.757 yr; $P=0.113$).

Conclusions. Increasing frailty had a negative effect on maximal improvement, where severely frail patients exhibited a parabolic effect with greater initial improvement due to higher baseline disability, but reached a ceiling effect with less overall maximal improvement. Severe frailty may exert a ceiling effect on improvement and impair maintenance of improvement following surgery.

Level of Evidence. Level III.

Key words: vertebral column, spine deformity, elective spine surgery, fraity

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Institutional Review Board approval was obtained before enrolling patients in the prospective database. Informed consent was obtained from each patient before enrollment.

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The prevalence of adult spinal deformity (ASD) has grown over the last three decades as the demographic ages, and the importance of spinal health is increasingly recognized. Patients with adult spinal deformities often have other medical comorbidities, including high levels of frailty. By accounting for physician-documented and patient-reported health deficits, frailty provides a more comprehensive assessment of a patient's well-being than age alone.[1–4] Frailty can moderate a patient's candidacy for adult spinal deformity surgery and also complicate postsurgical recovery. Previous studies have found that frailty can also stratify perioperative risks and inform certain surgical outcomes such as longer length of stay.[2] Retrospective studies have frequently shown that severely frail patients show the greatest improvement in HRQL following surgery because of high degrees of disability before the procedure.[1–4]

At the same time, it is unclear if severely frail patients can achieve the same levels of functional benefit as patients with lower levels of frailty at presentation. Furthermore, since the degree of frailty is associated with a higher risk of complications and failure, surgeons must balance the risks of these complex surgical procedures against anticipated benefits from the intervention.[3–5] At present, there is insufficient information in the literature regarding the influence of frailty severity on the long-term level of functional improvement that can be anticipated following corrective surgery. Specifically, the surgical community is left to wonder whether frailty exerts a ceiling effect on the best outcome that would otherwise be achievable in the absence of frailty.

In this context, we sought to use a large cohort of patients to evaluate the extent to which frailty severity at baseline may curtail the benefits of long-term surgical correction. We examined the time to the development of complications, reoperations, maximal improvement in Oswestry Disability Index (ODI), and maintenance of ODI as study outcomes. We hypothesized that severe frailty would be associated with shorter time to complications and readmissions, as well as lower levels of improvement in ODI and reduced ability to maintain postoperative improvements in ODI.

MATERIALS AND METHODS

Study Design and Inclusion Criteria

We used an adult spinal deformity (ASD) surgical registry for this investigation. Patients were included in this longitudinal, prospectively maintained data set if they underwent surgery and possessed at least one of the following radiographic parameters: Sagittal Vertical Axis (SVA) ≥ 5 cm, Cobb Angle $\geq 20°$, Pelvic Tilt (PT) $\geq 25°$, or Thoracic Kyphosis (TK) $\geq 60°$. Patients who were included in the present study also had available baseline (BL) and minimum two-year (2Y) Oswestry Disability Index (ODI) data.

Data Collection and Radiographic Parameters

Standardized collection forms and chart review were used to obtain demographic [age, body mass index (BMI), biological sex, Charlson Comorbidity Index (CCI)], surgical (levels fused, operative time, length of stay, surgical approach, performance of decompressions and osteotomies), and clinical (complications and reoperations) data. Complication and reoperation assessments were made based on a review of imaging, patient reports, and clinical follow-up. ODI scores were collected at baseline and regular follow-up intervals through two years following index surgery.

The Charlson comorbidity index is a method of evaluating medical comorbidities that has been widely applied in various surgical fields, including spine surgery.[6] Alignment proportionality (or “GAP proportionality”) was determined using the Global Alignment and Proportion (GAP) score, which uses pelvic incidence-based proportional metrics to determine ASD patients’ alignment proportions at any timepoint; with the reported added ability to predict mechanical complication risk.[7]

Full-length free-standing lateral spine radiographs (EOS or 36-inch cassette, if unavailable) were collected and assessed at baseline and follow-up time points. Radiographic images were analyzed using SpineView (ENSAM, Laboratory of Biomechanics, Paris, France) software. Spinopelvic radiographic parameters measured were sacral slope (SS), pelvic tilt (PT), pelvic incidence (PI), sagittal vertical axis (SVA), thoracic kyphosis (TK, T4-12), lumbar lordosis (LL, T12-S1), and mismatch between pelvic incidence and lumbar lordosis (PI-LL).

Frailty Categorization

Patients were stratified by their frailty score at presentation according to the modified frailty index (mFI) established in 2020.[2] The mFI is a frailty schema that has been validated in ASD patients and correlated with outcomes (Table 1). On the basis of their score, patients were categorized as either Not Frail (NF; score ≤ 7,) Frail (F; score ≥ 7 and ≤ 12), or Severely Frail (SF; score ≥ 12).

Highest Achievable Status

The difference between each patient’s two-year and baseline ODI score was calculated and divided into quartiles. The most improved quartile was classified “Highest.” These quartiles were calculated by frailty categorization, yielding “NF Highest,” “F Highest,” and “SF Highest” groups. These quartiles were considered to represent the highest achievable functional result for each of the three frailty categories.

Statistical Analysis

Frailty severity at presentation was considered the primary predictor, and our outcomes consisted of complications, reoperations, maximal improvement in ODI, and maintenance of ODI. A reduction in ODI between years 1 and 2 of ≥ 15 points was considered “improvement,” a change of ± 15 points denoted “maintenance,”

TABLE 1. Illustration of Components of the Modified Frailty Index

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

SF-36 indicates 36-Item Short Form Health Survey.

and an increase of ≥ 15 points denoted "deterioration." The 15-point minimal clinically important difference (MCID) threshold was based on previous studies by Smith *et al*.[8] Means comparisons tests assessed differences in baseline demographic and radiographic characteristics. χ^2 and linear regression were used to analyze correlations between baseline frailty category and baseline proportionality and two-year GAP proportionality.

Analysis of covariance (ANCOVA) was used to evaluate differences in outcome measures by frailty, adjusting for covariates including age, surgical invasiveness, and BL deformity (Sacral Slope, Pelvic Incidence, PI-LL, SVA). Kaplan-Meier curve estimated the time until either a major complication or reoperation, which was compared between frailty groupings. Linear regression analyzed ODI change between one-year and two-year follow-up. Statistical significance was established a priori for variables with regression coefficients and 95% CIs exclusive of 0.0 and $P<0.05$. All analyses were performed using SPSS software (IBM Corp. IBM SPSS Statistics for Windows, v28.0. Armonk, NY).

RESULTS

Patient Demographics

Overall, 393 patients were included in this analysis. The mean age of this cohort was 60.4 ± 13.9 years, with 80% of the cohort being female and a mean body mass index (BMI) of 27.0 ± 5.4 kg/m^2. The mean Charlson Comorbidity Index total score was 1.7 ± 1.7.

Surgical Characteristics

By surgical approach, 1% (4 patients) of the cohort had an anterior-only procedure, 61.8% (243 patients) had a posterior-only procedure, and 36.6% had a combined anteroposterior approach (APSF). The mean length of stay in the overall cohort was 7.5 ± 4.3 days, mean operative time of 358.6 ± 138.2 minutes, and mean estimated blood loss of 1400.7 ± 1315.6 mL. For the overall cohort, 56% received interbody fusion, 49% underwent a decompression, and 63% received an osteotomy.

Preoperative and Postoperative Radiographic Alignment

Baseline and 2-year follow-up radiographic measures can be seen in Table 2. At baseline, there was a statistically significant association between frailty and GAP classification, with F and SF patients being more likely to present as GAP-severely disproportioned (GAP-SD) than NF patients ($\chi^2(4)=17.334$, $P=0.002$). At two years, there was also a statistically significant association between frailty and GAP classification ($\chi^2(4)=9.697$, $P=0.046$). At baseline and 2 years, there were no significant associations between frailty and Roussouly classifications (all $P>0.05$). A binary logistic regression model was statistically significant in increasing frailty category predicting categorization of severe GAP disproportionality (OR: 1.477 [1.103-1.977], $P=0.009$).

TABLE 2. Baseline and Radiographic Measurements for the Overall Patient Cohort

	Baseline	2 yr	P
Sacral Slope	30.6 ± 11.8	33.8 ± 10.1	< 0.001
Pelvic Tilt	24.2 ± 11.3	21.1 ± 10.1	< 0001
Pelvic Incidence	54.7 ± 12.7	54.9 ± 12.7	0.236
PI-LL	16.1 ± 21.4	2.3 ± 14.3	< 0001
Lumbar Lordosis L1-S1	38.6 ± 21.9	52.5 ± 14.4	< 0001
SVA C2-S1	86.4 ± 72.5	48.3 ± 53.9	< 0.001

PI-LL indicates pelvic incidence minus lumbar lordosis; SVA, sagittal vertical axis.

Frailty Categorization

After categorizing patients by their baseline frailty score, 55.2% of the cohort was Not Frail (NF), 31.0% was Frail (F), and 13.7% was Severely Frail (SF). By frailty classification, there were significant differences in terms of age, BMI, and CCI at baseline, with F and SF patients being significantly older, having significantly higher BMI, and having higher CCI scores (all $P<0.001$). Gender was similar between groups ($P=0.406$). There were significant differences in baseline pelvic tilt ($P=0.004$), SVA ($P<0.001$), and lumbar lordosis ($P<0.001$) between NF and F patients, but F and SF patients had similar baseline radiographic measurements (all $P>0.05$). These findings are summarized in Table 3.

ODI Improvement Over Time

When comparing ODI change from baseline, SF patients showed the greatest improvement between groups at sex weeks ($P<0.001$) and at six months ($P= <0.001$). At one year and two years, F patients improved the most from baseline ($P=0.005$ and 0.067, respectively). Improvement of SF patients was greatest at six months (ΔODI of −22.5 ± 18.0), after which they experienced worsening ODI. NF and F patients reached maximal ODI at two years (ΔODI of −15.7 ± 17.9 and −20.5 ± 18.4, respectively). These results are shown in Figure 1. When adjusting for covariates of baseline deformity, age, and surgical invasiveness, F patients had the greatest two-year ODI improvement (20.2 ± 18.2) as compared with NF (15.7 ± 18.1) and SF (16.1 ± 20.7); however, this was not significant (all $P>0.05$).

Highest Achievable ODI Improvement

In the most improved quartile group (Highest), there were 49 NF (NF Highest), 70 Frail (F Highest), and 12 Severely Frail (SF Highest). There were significant differences in the highest-achieving quartiles among the frailty groups. The highest quartile of NF patients had an ODI improvement of 31.1 ± 14.8 between baseline and two years while this was 20.4 ± 23.0 for F Highest and 43.3 ± 9.2 for SF Highest ($P<0.001$), as shown in Table 4. The difference in ODI improvement was significant between NF Highest and F Highest ($P=0.010$) and SF Highest and F Highest ($P<0.001$), but not between SF Highest and NF Highest ($P=0.124$). SF Highest had the highest complication rate at 41.7% compared with 34.3%

TABLE 3. Baseline, Surgical, and Two-year Metrics by Frailty Status

	Not Frail (NF)	Frail (F)	Severely Frail (SF)	*P*
Age (yr)	58.2 ± 16.5	64.2 ± 11.0	63.7 ± 9.9	< 0.001
Sex (% female)	77	76	70	0.278
BMI (kg/m^2)	27.0 ± 5.9	29.4 ± 6.2	32.2 ± 6.0	< 0.001
CCI	1.2 ± 1.4	1.9 ± 1.6	3.1 ± 1.9	< 0.001
Levels fused (anteriorly)	2.4 ± 1.2	1.9 ± 1.2	1.9 ± 0.9	0.243
Levels fused (posteriorly)	10.7 ± 4.4	10.5 ± 4.7	11.3 ± 4.8	0.555
Interbody fusion levels	2.5 ± 1.6	2.3 ± 1.5	2.9 ± 1.9	0.194
Osteotomies (%)	70	74	66	0.115
EBL (mL)	1512.6 ± 1256.2	1690.2 ± 1326.3	1526.7 ± 1349.4	0.420
Pelvic tilt (°)	21.8 ± 11.1	26.9 ± 10.4	26.1 ± 11.2	0.001
Pelvic tilt 2Y (°)	19.5 ± 10.4	22.4 ± 9.0	22.7 ± 10.2	0.016
SVA (mm)	57.5 ± 61.2	105.7 ± 67.4	126.2 ± 76.1	0.001
SVA 2Y (mm)	33.2 ± 50.4	59.1 ± 53.7	74.5 ± 48.2	0.001
PI-LL (°)	9.4 ± 20.5	22.2 ± 18.7	22.3 ± 22.1	0.001
PI-LL 2Y (°)	0.3 ± 14.5	4.0 ± 13.5	4.3 ± 13.9	0.034

BMI indicates body mass index; CCI, Charlson Comorbidity Index; EBL, estimated blood loss; PI-LL, pelvic incidence-lumbar lordosis mismatch; SVA, sagittal vertical axis.

in F Highest and 28.6% in NF Highest. This difference was not significant when comparing SF Highest to F Highest ($P = 0.872$, 95% CI: −0.277 to 0.424) or NF Highest ($P = 0.667$, 95% CI: −0.231 to 0.493).

When assessing patients who did not experience any complications and had a two-year PI-LL < 10, corresponding to a "0" deformity based on SRS Schwab criteria, there were fewer SF patients who experienced this outcome (9.3%) compared with F (13.1%) and NF patients (17.1%) ($P = 0.291$). At one-year follow-up, the quartile of NF patients with the lowest ODI had a mean score of 2.3 ± 2.4, the quartile of F patients with the lowest ODI had a mean score of 5.6 ± 4.5, and the quartile of SF patients with the lowest ODI had a mean score of 13.8 ± 8.1 ($P < 0.001$).

Single-year ODI Improvement, Maintenance, and Deterioration

NF patients demonstrated the least deterioration (5.5%) between the first and second postoperative year, compared with F (9.0%) and SF (16.7%) patients, which was statistically significant ($P = 0.025$). Frailty groups were similar in the number that experienced improvement (NF: 10.1%, F: 11.5%, SF: 9.3%, $P = 0.886$).

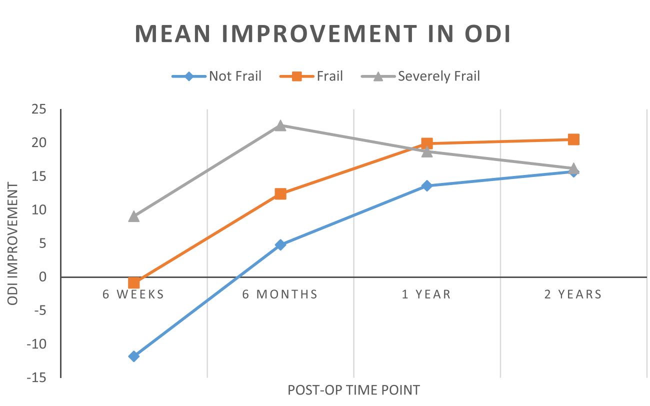

Figure 1. Mean improvement in ODI over time by frailty status.

Kaplan-Meier Curve Analysis

NF patients had the longest estimated time before experiencing either a major complication or readmission (7.5 ± 0.4 yr) when compared with F (6.7 ± 0.5 yr) and SF (5.8 ± 0.8 yr) patients; however, these findings were not significant ($P = 0.113$) (Figure 2).

DISCUSSION

Given a broader utilization of frailty as a risk assessment tool in the context of surgical intervention for adult spinal deformity, there is an increasing need to understand the dynamic role that frailty has in a patient's treatment plan, including prognosticating the anticipated benefits of surgery. Frailty can stratify patients by their lack of durability and susceptibility to potential operative and postoperative complications while also indicating potential gain from surgical correction of deformity.[1–5] Given the multifaceted nature of frailty within the spine deformity population, there is a need to examine the relationship between frailty and how it affects a patient's realistically attainable outcome, as this can inform surgical decision-making and perioperative management. In addition, given the modifiable nature of frailty, understanding the benefit of incremental changes that may result from preoperative physiologic optimization on long-term outcomes could also prove valuable.[9–11]

In the current study, we found that severely frail patients had the highest improvement in reported outcomes immediately following adult spinal deformity corrective surgery despite also having greater overall

TABLE 4. Oswestry Disability Index (ODI) Improvement by Frailty Grouping in Those that Achieved Highest Outcomes

	ODI improvement
Not Frail Highest	31.1 ± 14.8
Frail Highest	20.4 ± 23.0
Severely Frail Highest	43.3 ± 9.2
P	< 0.001

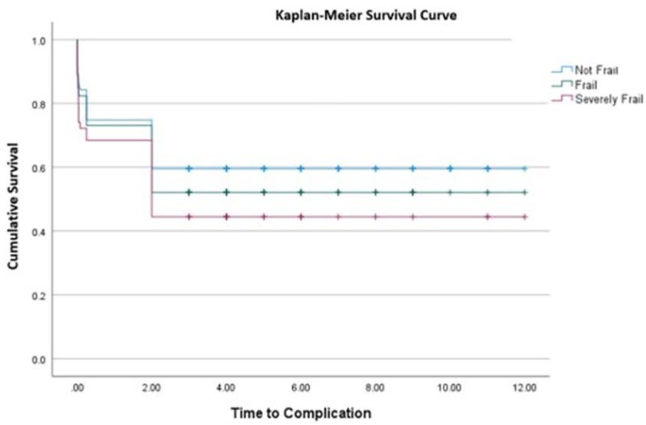

Figure 2. Kaplan-Meier curve showing time to complication by frailty status.

complication rates. They experienced a shorter time before experiencing a major complication, higher deterioration rates between 1 and 2 years follow-up, and a greater disability profile over the course of follow-up. Frailty, while able to stratify a patient's greater risk for complications and reoperations, is also a measure of medical deficit, which can be corrected to some degree before surgery as well as following surgical intervention. Thus, in the setting of adult spine deformity, severely frail patients have a greater capacity for improvement in reported outcomes based on the extent of their baseline disability, as well as concomitant improvement in frailty status as a result of the surgical intervention itself. We also found that severely frail patients experienced a ceiling of maximal potential improvement and also had difficulty maintaining the degree of initial postoperative improvement over the course of follow-up.

These findings are important for patients, surgeons, and third-party payers. Foremost, our results indicate that meaningful improvements can be achieved for patients irrespective of frailty status, although severe frailty could cap the extent of postoperative benefit. While maximal benefit in the severely frail was lower than that of frail or non-frail patients, it remained clinically meaningful and should not preclude consideration for these procedures in patients who are otherwise indicated for surgical correction of adult deformity. Our results also support consideration for preoperative medical optimization, including delaying surgery until meaningful frailty score improvement metrics are achieved. For example, severely frail patients with a borderline score would likely benefit substantially if preoperative optimization can lower their frailty category, reflected in a higher ceiling for improvement, as well as minimized risk for major complications or need for revision surgery. Beyond these anticipated benefits, the results presented here are useful in presurgical outcome prognostication, physician-patient discussions, and informed decision-making.

We recognize several limitations associated with this work. The design of this study raises the prospect for selection and indication bias, as well as expertise bias, and the results may not be generalizable to centers and clinical settings where the population of patients has substantially different clinical and surgical characteristics from those encountered here. We also recognize that, in light of the retrospective design, there may be restricted variation within the frailty cohorts, and the full breadth of this condition may not be present. This may be especially the case among the severely frail category, where there is the prospect for clinical truncation. We were also unable to determine the extent of preoperative optimization that may have occurred on the part of patients, indirectly or directly under the guidance of healthcare providers, before the surgical procedure. Therefore, determinations regarding anticipated impacts of medical optimization before surgical intervention must be considered theoretical at this time.

CONCLUSIONS

Severely frail patients had the lowest estimated time before a major complication or reoperation. Frail patients had the best maintenance of ODI scores between one and two years. Severe frailty may exert a ceiling effect on improvement and impair maintenance of any improvement gained following surgery. These findings support consideration for medical optimization of frailty before surgical intervention and can also be used to inform preoperative decision-making and prognosis, especially for those who present with severe frailty at baseline.

➢ Key Points

- ❑ Increasing frailty exhibited a negative effect on maximal improvement following ASD corrective surgery.
- ❑ Severely frail patients may have a ceiling effect on their potential maximal improvement.
- ❑ Severely frail patients may not maintain postoperative improvement, as well as less frail patients.

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