

DEFORMITY

Does Patient Frailty Status Influence Recovery Following Spinal Fusion for Adult Spinal Deformity?

An Analysis of Patients With 3-Year Follow-up

Katherine E. Pierce, BS,* Peter G. Passias, MD,[†] Haddy Alas, BS,* Avery E. Brown, BS,* Cole A. Bortz, BA,* Renaud Lafage, MS,[‡] Virginie Lafage, PhD,[‡] Christopher Ames, MD,[§] Douglas C Burton, MD,[¶] Robert Hart, MD,^{||} Kojo Hamilton, MD,** Michael Kelly, MD,^{††} Richard Hostin, MD,^{‡‡} Shay Bess, MD,^{§§} Eric Klineberg, MD,^{¶¶} Breton Line, BS,^{§§} Christopher Shaffrey, MD,^{***} Praveen Mummaneni, MD,[§] Justin S Smith, MD, PhD,^{||||} and Frank A. Schwab, MD,[‡], on behalf of the International Spine Study Group (ISSG)

Study Design. Retrospective review of a prospective database.
Objective. The aim of this study was to evaluate postop clinical recovery among adult spinal deformity (ASD) patients between frailty states undergoing primary procedures
Summary of Background Data. Frailty severity may be an important determinant for impaired recovery after corrective surgery.

From the *Department of Orthopaedics, NYU Langone Orthopedic Hospital, New York, NY; [†]Departments of Orthopaedic and Neurologic Surgery, NYU Langone Orthopedic Hospital; New York Spine Institute, New York, New York; [‡]Department of Orthopedics, Hospital for Special Surgery, New York, NY; [§]Department of Neurological Surgery, University of California, San Francisco, San Francisco, CA; [¶]Department of Orthopedic Surgery, University of Kansas Medical Center, Kansas City, KS; ^{||}Department of Orthopaedic Surgery, Swedish Neuroscience Institute, Seattle, WA; **Department of Neurological Surgery, University of Pittsburgh School of Medicine, Pittsburgh, PA; ^{††}Department of Orthopaedic Surgery, Washington University, St. Louis, MO; ^{‡‡}Department of Orthopaedic Surgery, Baylor Scoliosis Center, Dallas, TX; ^{§§}Rocky Mountain Scoliosis and Spine, Denver, CO; ^{¶¶}Department of Orthopaedic Surgery, University of California, Davis, Davis, CA; ^{||||}Department of Neurosurgery, University of Virginia, Charlottesville, VA; and ^{***}Departments of Neurosurgery and Orthopaedic Surgery, Duke University Medical Center, Durham, NC.

Acknowledgment date: May 20, 2019. First revision date: July 22, 2019. Acceptance date: September 4, 2019.

The manuscript submitted does not contain information about medical device(s)/drug(s).

The International Spine Study Group (ISSG) is funded through research grants from DePuy Synthes and individual donations.

Relevant financial activities outside the submitted work: board membership, consultancy, grants, payment for lecture, stocks, royalties.

Address correspondence and reprint requests to Peter G. Passias, MD, New York Spine Institute, Division of Spinal Surgery, Departments of Orthopaedic and Neurological Surgery, NYU Langone Medical Center, Orthopaedic Hospital—NYU School of Medicine, 301 East 17th St, New York, NY 10003; E-mail: Peter.Passias@nyumc.org

DOI: 10.1097/BRS.0000000000003288

Methods. It included ASD patients with health-related quality of life (HRQLs) at baseline (BL), 1 year (1Y), and 3 years (3Y). Patients stratified by frailty by ASD-frailty index scale 0-1 (no frailty: <0.3 [NF], mild: 0.3–0.5 [MF], severe: >0.5 [SF]). Demographics, alignment, and SRS-Schwab modifiers were assessed with χ^2 /paired *t* tests to compare HRQLs: Scoliosis Research Society 22-question Questionnaire (SRS-22), Numeric Rating Scale (NRS) Back/Leg Pain, Oswestry Disability Index (ODI). Area-under-the-curve (AUC) method generated normalized HRQL scores at baseline (BL) and f/u intervals (1Y, 3Y). AUC was calculated for each f/u, and total area was divided by cumulative f/u, generating one number describing recovery (Integrated Health State [IHS]).

Results. A total of 191 patients were included (59 years, 80% females). Breakdown of patients by frailty status: 43.6% NF, 40.8% MF, 15.6% SF. SF patients were older ($P = 0.003$), >body mass index ($P = 0.002$). MF and SF were significantly ($P < 0.001$) more malaligned at BL: pelvic tilt (NF: 21.6°; MF: 27.3°; SF: 22.1°), pelvic incidence and lumbar lordosis (7.4°, 21.2°, 19.7°), sagittal vertical axis (31 mm, 87 mm, 82 mm). By SRS-Schwab, NF were mostly minor (40%), and MF and SF markedly deformed (64%, 57%). Frailty groups exhibited BL to 3Y improvement in SRS-22, ODI, NRS Back/Leg ($P < 0.001$). After HRQL normalization, SF had improvement in SRS-22 at year 1 and year 3 ($P < 0.001$), and NRS Back at 1Y. 3Y IHS showed a significant difference in SRS-22 (NF: 1.2 vs. MF: 1.32 vs. SF: 1.69, $P < 0.001$) and NRS Back Pain (NF: 0.52, MF: 0.66, SF: 0.6, $P = 0.025$) between frailty groups. SF had more complications (79%). SF/marked deformity had larger invasiveness score (112) compared to MF/moderate deformity (86.2). Controlling for baseline deformity and invasiveness, SF showed more improvement in SRS-22 IHS (NF: 1.21, MF: 1.32, SF: 1.66, $P < 0.001$).

Conclusion. Although all frailty groups exhibited improved postop disability/pain scores, SF patients recovered better in SRS-22 and NRS Back. Despite SF patients having more

complications and larger invasiveness scores, they had overall better patient-reported outcomes, signifying that with frailty severity, patients have more room for improvement postop compared to BL quality of life.

Key words: adult spinal deformity, ASD, AUC, frailty, recovery kinetics, spine surgery.

Level of Evidence: 3

Spine 2020;45:E397-E405

As it is known that health and age deteriorate at different rates, there is a growing interest in quantifying and interpreting one's physiologic age. Frailty, a dynamic measure transcending age, encompasses a patient's sum deficits in health. Increase in the volume of such deficits (rise in frailty status) coincides with heightened vulnerability to adverse outcomes.¹ Frailty scores and indices have been well developed in many surgical fields, successfully corresponding with mortality, prediction of postoperative outcomes, and overall risk stratification.²⁻⁵

Given the number of adult patients categorized as "frail" or "severely frail" undergoing elective correction of adult spinal deformity (ASD), accurate assessment of baseline (BL) impact upon postoperative recovery is very important. Previous studies have assessed patient physical recovery, noting that with increase in frailty severity, perioperative outcomes deteriorate.^{6,7} Few studies exist to compare clinical patient-reported outcomes (PROs), rather than just physical recovery, among frailty statuses across follow-up time points.

Liu *et al* developed a novel area-under-the-curve (AUC) methodology, allowing for comparison across dissimilar patients. This proposed method normalizes follow-up health-related-quality-of-life (HRQL) follow-up scores relative to preoperative score. The scores are plotted against follow-up time points upon a graph, to compute an AUC, generating a single number, quantifying a patient's recovery trajectory across a given timespan.⁸ These AUC scores consider how a patient's BL frailty status can impact recovery from the patient's point-of-view.⁹ The goal of this study was to define recovery patterns of ASD patients in differing frailty groups for various patient-reported assessments.

METHODS

Data Source

This study is a retrospective review of a prospective, multi-center International Spine Study Group (ISSG) ASD database from 2008 to 2018. Patients were enrolled at 12 participating centers around the United States. All patients were enrolled into an institutional review board-approved protocol by each site, and consent was obtained by each of the sites. The database inclusion criteria were patients >18 years undergoing operative or non-operative treatment for ASD, defined as: coronal Cobb angle $\geq 20^\circ$, sagittal vertical axis (SVA) ≥ 5 cm, pelvic tilt (PT) $\geq 25^\circ$, and/or thoracic

kyphosis $>60^\circ$. Exclusion criteria from the database included patients with spinal deformity of neuromuscular etiology, presence of active infection, or malignancy. Included in the present study were surgical ASD patients with available HRQL data at BL, 1-year postoperative (1Y), and 3-year postoperative (3Y).

Data Collection and Radiographic Assessment

Frailty status was assessed by the ASD frailty index (ASD-FI)^{6,10} (Figure 1). Standardized HRQL assessments

Health deficits
Documented by physician
>3 medical problems
Body mass index <18.5 or >30 kg/m ²
Cancer
Cardiac disease
Currently on disability
Depression
Diabetes
Hypertension
Liver disease
Lung disease
Osteoporosis
Peripheral vascular disease
Previous blood clot (deep vein thrombosis/pulmonary embolism/stroke)
Smoking status
Patient-reported (questionnaire, question no.)
Bladder incontinence
Bowel incontinence
Deteriorating health this yr (SF-36v2, 2)
Difficulty climbing 1 flight of stairs (SF-36v2, 3e)
Difficulty driving a car (LSDI, 3)
Difficulty getting dressed (SF-36v2, 3j; LSDI, 1 & 2)
Difficulty getting in/out of bed (LSDI, 6)
Difficulty sleeping >6 hrs (ODI, 7)
Difficulty walking 100 yards (SF-36v2, 3i)
Difficulty w/ light activity (SF-36v2, 3b)
Feeling downhearted/depressed most of the time (SF-36v2, 9f; SRS-22r, 16)
Feeling tired most of the time (SF-36v2, 9i)
Feeling worn out most of the time (SF-36v2, 9g)
General health: fair/poor (SF-36v2, 1)
Inability to bathe w/o assistance (SF-36v2, 3j; LSDI, 8)
Inability to cheer up often (SF-36v2, 9c; SRS-22r, 7)
Inability to do normal work/schoolwork/housework (ODI, 10; SRS-22r, 9 & 12)
Inability to lift heavy objects (SF-36v2, 3c; ODI, 3)
Inability to travel >1 hr (ODI, 9)
Inability to walk w/o assistive device (ODI, 4)
Leg weakness
Loss of balance
Not in excellent health (SF-36v2, 11d)
Personal care dependency (ODI, 2)
Restricted activity level (SRS-22r, 5)
Restricted social life (ODI, 8; SRS-22r, 14 & 18)

Figure 1. Factors included in the ASD-FI by Miller *et al*.

were collected preoperatively and at 1Y and 3Y follow-up time points. HRQL assessments included the Oswestry Disability Index (ODI), numeric rating scale back (NRS-Back) and leg (NRS-Leg) pain scores, and the Scoliosis Research Society 22-question Questionnaire (SRS-22).

Full-length free-standing lateral spine radiographs were used to assess patients at BL and follow-up intervals. Radiographs were analyzed with SpineView (ENSAM, Laboratory of Biomechanics, Paris, France) software according to the literature.¹¹⁻¹³ Spinopelvic radiographic parameters assessed included 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 SVA (C7 plumb line relative to the posteriosuperior corner of S1).¹⁴

Statistical Analysis

Statistical analysis was performed using SPSS software (version 21.0 IBM, Armonk, NY). Patients were stratified into three frailty severity groups by BL frailty score by the Miller *et al*: ASD-FI scale from 0 to 1: <0.3 as no frailty (NF), 0.3 to 0.5 as mildly frail (MF), and >0.5 as severely frail (SF). Descriptive analyses assessed demographic, clinical, surgical, and complication-related data. Frequency analysis evaluated categorical variables with χ^2 analysis. Comparison of means from preoperative to 1- and 3-year postoperative follow-up visits utilized paired samples *t* tests or Wilcoxon rank-sum tests, as appropriate. In a sub-analysis, the SRS-Schwab ASD classification system, to account for BL deformity status, age, and ISSG-invasiveness scores was controlled for via propensity score matching to further assess frailty impact on recovery.¹⁵ Level of significance was set to $P < 0.05$.

Development of the Normalized Integrated Health State

Normalized HRQLs (ODI, SRS-22, NRS-Back, NRS-Leg) were developed and analyzed allowing for the calculation of an integrated health state (IHS) with validated AUC methodology.^{8,9,16,17}

All reported BL and postoperative (1Y and 3Y) values for each HRQL outcome measure were divided by the corresponding BL score for each patient in each frailty severity category. The resulting BL normalized HRQL score was 1 for all patients across the three frailty groups. Any follow-up normalized HRQL scores were >, =, or <1, depending on the improvement or deterioration of PROs relative to BL. The normalized HRQL scores were plotted on the *y* axis of an area graph, with the *x* axis representing the duration of follow-up (in months, beginning with BL). After connecting all plotted points, trapezoidal shapes (corresponding to the change in *x* and *y* from one follow-up interval to the next) were created. The area of each trapezoid was calculated and summed together to create a total follow-up length area. Total area was divided by the cumulative follow-up time (156 weeks for patients with complete 3Y data). A single

value (IHS) was obtained representing a patient's recovery timeline for each HRQL outcomes metric across frailty severity groups.

Regarding IHS values for the various HRQL outcome metrics assessed, lower ODI, NRS-Back and NRS-Leg IHS scores indicate a better outcome (superior recovery process), whereas a greater SRS-22 IHS score indicated better recovery course. IHS means were compared across categorical frailty severity (by way of the ASD-FI) utilizing parametric and nonparametric tests as appropriate.

Due to the inherent overlap of ASD-FI factors with the HRQL forms assessed for IHS recovery values, an additional analysis was performed with a "modified" frailty score removing the ASD-FI factors including SRS-22 and ODI components.

RESULTS

Cohort Characteristics Between NF, MF, and SF Patients

A total of 191 operative ASD patients met inclusion criteria, with complete BL, 1Y, and 3Y follow-up data of 322 eligible operative ASD patients. Mean patients' age was 59 ± 12.0 years, mean body mass index (BMI) was $27.4 \pm 68 \text{ kg/m}^2$, and 80% of patients were female. By categorical frailty severity, 43.6% of patients were classified as NF, 40.8% MF, and 15.6% SF. MF and SF patients were found to be significantly older (MF: 61.7, SF: 61.2 *vs.* NF: 55.0 years, $P = 0.003$) with greater BMI (29.5 *vs.* NF: 25.5 and MF: 28.4 kg/m^2 , $P = 0.002$). SF had a significantly greater Charlson Comorbidity Index score (2.79) when compared to NF (1.02) and MF (1.84) categorical groups ($P < 0.001$) (Table 1).

Surgical Details and Complications by BL Frailty Severity

Surgical approach (anterior, posterior, and combined) was similar between NF, MF, and SF patients ($P > 0.05$). NF, MF, and SF had similar average number of levels fused (NF: 10.3, MF: 11.6, SF: 10.6; $P = 0.330$) and total operative time (NF: 369.2, MF: 385.7, SF: 419.1 minutes; $P = 0.188$). MF/SF displayed significantly greater estimated blood loss (MF: 2166/SF: 1968 mL *vs.* NF: 1416; $P = 0.029$) and longer overall length of hospital stay (MF: 8.3/SF: 8.64 days *vs.* NF: 6.68; $P = 0.012$). Revision rates were similar across frailty (NF: 33.3%, MF: 26%, SF: 28.6%; $P = 0.616$).

Although overall rates of postoperative complication were similar across frailty severity groups (NF: 62.8%, MF: 71.2%, SF: 78.6%; $P = 0.286$), MF/SF patients demonstrated significantly higher rates of major postop complications (MF: 35.6%/SF: 42.9% *vs.* NF: 16.7%; $P = 0.006$) and intraoperative complications (MF: 30.1%/SF: 32.1% *vs.* NF: 14.1%; $P = 0.033$). Specifically, excessive bleeding complications (SF: 14.3%, MF: 12.3%, NF: 1.28%; $P = 0.015$) and visceral injury (SF: 7.14% *vs.* MF/SF: 0%, $P = 0.004$) were significant between the frailty groups (Table 2).

TABLE 1. Demographics and Comorbidities Between Frailty Severity Groups.

	Not Frail	Mildly Frail	Severely Frail	P
Age, y	55.02	61.71	61.17	0.003
Sex (female)	82.1%	76.7%	85.7%	0.535
BMI, kg/m ²	25.54	28.45	29.46	0.002
Race				0.400
White	83.3%	93.2%	96.4%	
Black	7.7%	4.1%	3.6%	
Hispanic	1.3%	1.4%	0%	
Asian	-	-	-	
CCI	1.02	1.84	2.79	<0.001
Arthritis	28.2%	49.3%	75%	<0.001
Depression	7.7%	24.7%	57.1%	<0.001
Diabetes	2.6%	9.6%	17.9%	<0.001
Hypertension	21.8%	43.8%	57.1%	0.001
Lung disease	1.3%	2.7%	14.3%	0.007
Smoker (yes)	9%	11%	0%	0.201
Osteoporosis (yes)	7.7%	12.3%	25.0%	0.057

CCI indicates charlson comorbidity index.

Sagittal Alignment Parameters by BL Frailty Severity
 MF/SF patients demonstrated significantly greater spinal malalignment at BL. BL PT by frailty severity, NF: 21.6°, MF: 27.3°, and SF: 22.1° demonstrated significant difference across frailty groups ($P=0.003$), as well as PI-LL (NF: 7.4°, MF: 21.2°, SF: 19.7°; $P<0.001$), and SVA (NF: 30.7 mm, MF: 87.1 mm, SF: 81.7 mm;

$P<0.001$). Stratification by the SRS-Schwab modifier severity across frailty displayed NF patients with greater incidence of BL “0” or minor deformity for SVA (NF: 64.1%, MF: 19.2%, SF: 35.7%; $P<0.001$), PI-LL (NF: 55.1%, MF: 26.0%, SF: 28.6%; $P=0.001$), and PT (NF: 43.6%, MF: 24.7%, SF: 32.1%; $P=0.048$). Meanwhile, MF patients demonstrated significantly greater

TABLE 2. Surgical Details and Complications Between Frailty Severity Groups.

	Not Frail	Mildly Frail	Severely Frail	P
Surgical details				
Anterior only approach	2.56%	1.37%	0%	0.644
Posterior only approach	64.1%	75.34%	60.7%	0.221
Combined approach	33.33%	23.29%	39.29%	0.213
Decompression	59%	65.8%	60.7%	0.688
Osteotomy	74.4%	61.6%	53.6%	0.084
Total levels fused	10.31	11.56	10.65	0.330
Operative time, min	369.2	385.7	419.1	0.188
EBL, cc	1415.8	2166.3	1967.9	0.029
LOS	6.68	8.3	8.64	0.012
Complications				
Any complication	62.8%	71.2%	78.6%	0.257
Major	16.7%	35.6%	42.9%	0.006
Minor	38.5%	48%	53.6%	0.300
Intraoperative	14.1%	30.1%	32.1%	0.033
Cardiopulmonary	14.1%	9.6%	17.9%	0.494
Gastrointestinal	10.3%	10.9%	0%	0.196
Infection	9%	15.1%	14.3%	0.496
Instrumentation	18%	21.9%	25%	0.694
Neurologic	16.7%	20.6%	14.3%	0.716
Radiographic	25.6%	27.4%	25%	0.958
Wound	0%	2.7%	7.1%	0.085
Dural Tear	9%	16.4%	14.3%	0.384
Pseudoarthrosis	3.9%	5.5%	3.6%	0.863

EBL indicates estimated blood loss.

TABLE 3. Pre- and Postoperative Sagittal Radiographic Parameters Between Frailty Severity Groups.

	Not Frail	Mildly Frail	Severely Frail	P
Sagittal radiographic parameters				
BL C7-S1 SVA	30.7mm	87.1mm	81.7mm	<0.001
SRS-Schwab 0 Modifier	64.1%	19.2%	35.7%	<0.001
SRS-Schwab + Modifier	15.4%	42.4%	21.4%	0.005
SRS-Schwab ++ Modifier	17.9%	38.4%	42.9%	0.007
BL PI-LL	7.4°	21.2°	19.7°	<0.001
SRS-Schwab 0 Modifier	55.1%	26.0%	28.6%	0.001
SRS-Schwab + Modifier	23.1%	24.7%	17.9%	0.766
SRS-Schwab ++ Modifier	21.8%	49.3%	53.6%	<0.001
BL PT	21.6°	27.3°	22.1°	0.003
SRS-Schwab 0 Modifier	43.6%	24.7%	32.1%	0.048
SRS-Schwab + Modifier	35.9%	37%	53.6%	0.230
SRS-Schwab ++ Modifier	20.5%	38.4%	14.3%	0.012
Y1 C7-S1 SVA	17mm	27.7mm	32.3mm	0.325
Y1 PI-LL	1.8°	2.5°	4°	0.785
Y1 PT	20.3°	22.2°	19.4°	0.327
Y3 C7-S1 SVA, mm	16.2mm	37.1mm	59mm	0.001
Y3 PI-LL°	1.2°	5.1°	7.9°	0.080
Y3 PT°	21.1°	24°	20.7°	0.120

BL indicates baseline; PI-LL, pelvic incidence and lumbar lordosis; PT, pelvic tilt; SVA, sagittal vertical axis.

“+” SRS-Schwab modifier or moderate deformity at BL for SVA (NF: 15.4%, MF: 42.4%, SF: 21.4%; $P = 0.005$). Lastly, SF had significantly greater BL marked “++” Schwab modifier for SVA (NF: 17.9%, MF: 38.4%, SF: 42.9%; $P = 0.007$) and PI-LL (NF: 21.8%, MF: 49.3%, SF: 53.6%, $P < 0.001$). Following corrective surgery, no significant differences were observed between frailty severity groups at 1Y follow-up for SVA, PI-LL, or PT ($P > 0.05$). Similar alignment was seen at 3Y follow-up for PI-LL and PT, whereas SVA at 3Y was significantly greater for SF patients (NF 16.2 mm, MF: 37.1 mm, SF: 59 mm; $P = 0.001$) (Table 3).

Standard and Normalized HRQL Analysis

When assessing standard HRQL scores at BL, 1Y, and 3Y, NRS-Leg, NRS-Back, ODI, and SRS-22 scores worsened with increasing severity of frailty, (all $P < 0.001$). HRQL scores were then normalized against the preoperative visit, and compared among frailty groups. Frailty categories exhibited significantly different normalized NRS Back scores at 1 year (NF: 0.39, MF: 0.56, SF: 0.50; $P = 0.030$). SF patients displayed significantly improved normalized SRS-22 scores at 1Y (SF: 1.85 vs. NF: 1.26/ MF: 1.40; $P < 0.001$) and at 3Y follow-up (SF: 1.79 vs. NF: 1.23/MF: 1.38; $P < 0.001$) (Table 4).

TABLE 4. Pre- and Postoperative HRQL Comparison Between Frailty Severity Groups.

	Not Frail	Mildly Frail	Severely Frail	P	Not Frail	Mildly Frail	Severely Frail	P
Standard HRQLs					Normalized HRQLs			
BL NRS Leg	3.83	5.49	7.07	<0.001	1	1	1	1
BL NRS Back	6.30	7.53	8.50	<0.001	1	1	1	1
BL ODI	30.58	50.36	67.71	<0.001	1	1	1	1
BL SRS-22	3.33	2.50	1.85	<0.001	1	1	1	1
Y1 NRS Leg	1.43	3.16	3.33	<0.001	0.35	0.53	0.56	0.172
Y1 NRS Back	2.31	4.07	4.25	<0.001	0.39	0.56	0.50	0.030
Y1 ODI	15.54	34.19	38.43	<0.001	0.58	0.69	0.57	0.344
Y1 SRS-22	4.14	3.43	3.31	<0.001	1.26	1.40	1.85	<0.001
Y3 NRS Leg	2.09	3.49	4.44	<0.001	0.51	0.64	0.89	0.088
Y3 NRS Back	2.76	4.7	4.82	<0.001	0.48	0.63	0.55	0.166
Y3 ODI	19.07	37.52	42.29	<0.001	0.67	0.78	0.65	0.425
Y3 SRS-22	4.05	3.34	3.17	<0.001	1.23	1.38	1.79	<0.001

BL indicates baseline; HRQL, health-related quality of life; NRS, Numeric Rating Scale; ODI, Oswestry Disability Index; SRS-22, Scoliosis Research Society 22-question Questionnaire.

TABLE 5. Postoperative Integrated Health State Between Frailty Severity Groups.

Integrated Health State	Not Frail	Mildly Frail	Severely Frail	P
NRS Leg	0.52	0.64	0.69	0.182
NRS Back	0.52	0.66	0.60	0.025
ODI	0.68	0.77	0.67	0.284
SRS-22	1.20	1.33	1.69	<0.001
After controlling for baseline deformity, age, BMI, CCI, invasiveness, and major postoperative complications				
NRS Leg	0.61	0.73	0.68	0.767
NRS Back	0.48	0.73	0.62	0.019
ODI	0.71	0.76	0.69	0.784
SRS-22	1.19	1.31	1.71	<0.001

NRS indicates Numeric Rating Scale; ODI, Oswestry Disability Index; SRS-22, Scoliosis Research Society 22-question Questionnaire.

Integrated Health State Comparison

Frailty groups exhibited similar IHS recovery patterns for NRS-Leg and ODI (both $P > 0.05$). IHS-adjusted HRQL outcomes from BL to 3Y showed a significant difference in SRS-22 scores (NF: 1.2 vs. MF: 1.32 vs. SF: 1.69, $P < 0.001$) and NRS-Back (NF: 0.52, MF: 0.66, SF: 0.60, $P = 0.025$) between frailty groups (Table 5) (Figure 2A-D).

Propensity Score Match for BL Deformity and Invasiveness

Analysis of ISSG invasiveness score found that SF patients with marked (“++” SRS-Schwab modifier) deformity

had a larger invasiveness score (112) compared to MF and moderate (“+” SRS-Schwab modifier) deformity patients (86.2) and NF with minor (“0” SRS-Schwab) deformity had an invasiveness score of 79.5 ($P = 0.003$). After controlling for BL deformity SRS-Schwab modifier, Charlson comorbidity index (CCI), BMI, age, invasiveness, and major postoperative complications by way of PSM, SF/MF patients continually showed significantly more improvement in SRS-22 IHS (NF: 1.19, MF: 1.31, SF: 1.71; $P < 0.001$), as well as in NRS-Back (0.019) and NRS-Leg (0.005) pain scores when compared to the NF group (Table 5).

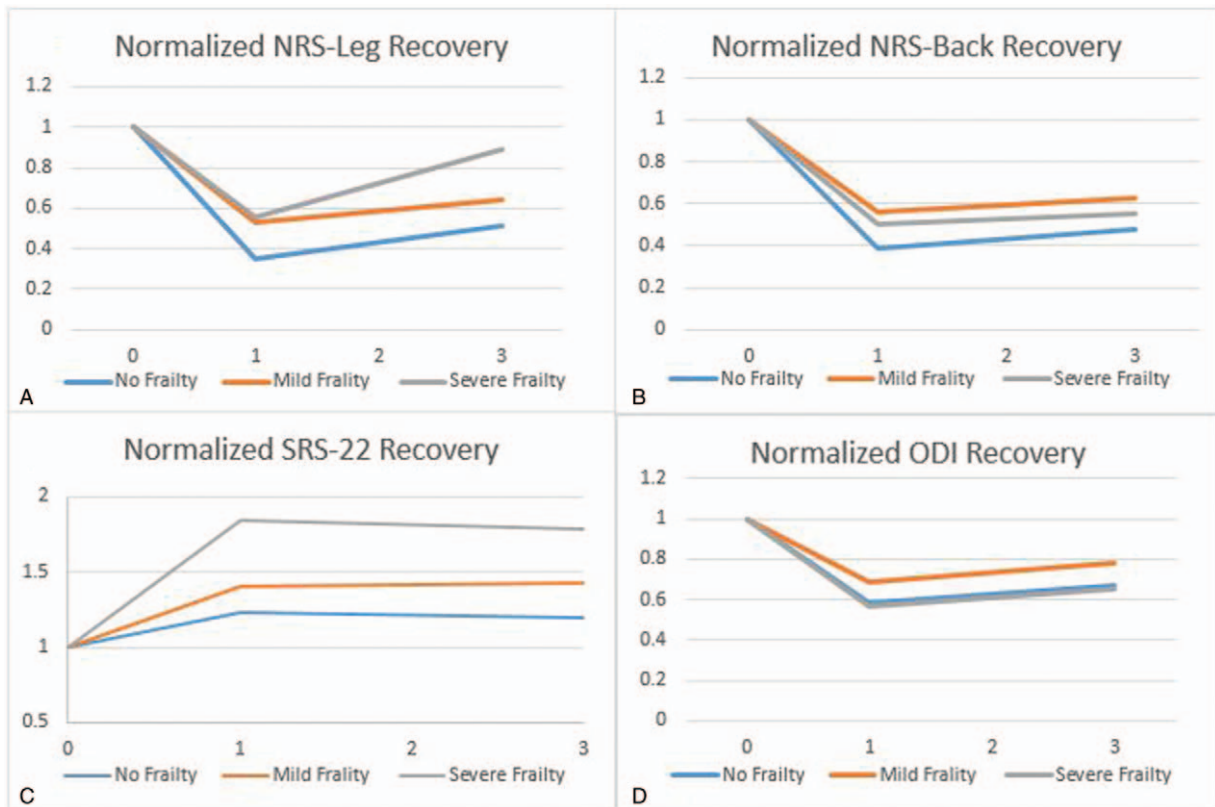


Figure 2. Area graph representation of normalized HRQL scores by frailty severity up to 3 years. (A) Normalized NRS-Leg recovery timeline area of no frailty (NF), mildly frail (MF), severely frail (SF) patients over 3 years. (B) Normalized NRS-Back recovery timeline area of NF, MF, SF patients over 3 years. (C) Normalized SRS-22 recovery timeline area of NF, MF, SF patients over 3 years. (D) Normalized ODI recovery timeline area of NF, MF, SF patients over 3 years. NRS indicates Numeric Rating Scale; ODI, Oswestry Disability Index; SRS-22, Scoliosis Research Society 22-question Questionnaire.

Removal of the HRQL Components of the ASD-FI

After modifying the frailty index to not include factors that incorporate HRQLs utilized in the ASD-FI, the following factors were excluded: frailty sleeping, frailty downhearted, frailty inability to cheer up, frailty normal work, frailty lifting, frailty travel, frailty walking, frailty personal care, frailty restricted activity, and frailty social life (10/40 factors). The average frailty score was found to be 0.27, with 60.5% categorized as NF, 33.7% as MF, and 5.8% as SF. IHS analysis with the modified frailty score demonstrated similar results as the validated ASD-FI by Miller *et al* as NRS Back Pain trended toward improved recovery for the SF patients (NF: 0.546, MF: 0.651, SF: 0.659, $P=0.096$) and IHS SRS-22 showed a significant difference (greater improvement) from BL to 3Y across frailty scores (NF: 1.224, MF: 1.432, SF: 1.687, $P<0.001$).

DISCUSSION

The interest surrounding the clinical recovery kinetics between different groups has been growing among the surgical literature, notably spine-related. Liu *et al*⁸ developed a novel AUC method for patients with cervical spondylotic myelopathy comparing anterior versus posterior surgical approaches. This study established a means to control for clinical heterogeneity. As the concept of frailty has become an increasingly important preoperative differentiating factor to consider, the recovery patterns of “not frail” *versus* “mildly frail” and “severely frail” patients had to be considered.^{18,19} With the utilization of the Liu *et al*'s method, we had the ability to adjust for BL severity score of various health-related-quality-of-life assessments. The Integrated Health State methodology of patient-reported score regulation provided a good estimate and platform for comparison of ASD corrective surgery recovery by follow-up time points across frailty severity groups.

Our study stratified 191 ASD patients by their BL frailty status to contrast their recovery trajectory over 3 years. Physical outcomes, such as postoperative complications, length of stay, and morbidity/mortality, have been shown to associate with frailty status in a positive correlation.^{20–22} Miller *et al*⁶ reported that an increase in frailty among ASD patients predicted major complications, proximal junctional kyphosis, pseudoarthrosis, deep wound infection, wound dehiscence, reoperation, and length of stay. Our present analysis exhibited this relationship, where patients classified with BL mild and severe frailty had increased length of stay, estimated blood loss, and occurrence of intraoperative and major complications. Total operative time trended toward an increase with greater frailty severity, which could be because of the increase in age, comorbidities or BMI (all $P<0.05$) that was seen in MF and SF patients. With greater preoperative risk factors, surgeons may have approached cases of MF and SF patients more cautiously, which could have added to the time spent in the operating room.

BL radiographic parameters stratified by frailty status showed that SF and MF patients presented as more malaligned. Interestingly, SVA was significant between all frailty

groups; however, MF and SF SVA's were relatively similar (SF: 81.7 mm *vs.* MF: 87.1 mm). Compared to the SVA at 3Y follow-up, all frailty groups were corrected in terms of SVA; however, we can see that the MF group was corrected to 37.1 mm and the SF to 59 mm, causing there to be a significant P value. This discrepancy in corrective SVA values for the SF groups could possibly be because of the increased caution taken on patients who fall into the high-risk group.

PROs portrayed a different story. As clinical decision-making has been transitioning from healthcare provider recommendation to understanding the patient perspective, HRQL assessments have become increasingly important in spine surgery. Elective spine surgery, especially the correction of ASD, is becoming more driven by clinical symptoms, rather than radiographic appearance.²³ Within this cohort, one can conclude that MF/SF ASD patients began in a comparably poor condition in part because of the basic definition of frailty status (a worse health state at BL), in addition to the detrimental BL radiographic alignment, and inferior standard HRQLs. Reid *et al* demonstrated this, that increasing frailty severity is associated with worse BL and postoperative PROs.²⁴ That study outlined that frail patients met SCB at 2 years for ODI, SF-36, and Leg pain scores in ASD patients, despite frailty's predictive ability for major complications and length of stay. Other studies note that patient satisfaction, by way of HRQL assessment, is unrepresented by complications and postoperative alignment.²⁵ We found that standard HRQL's at BL BL, 1Y, and 3Y follow-up demonstrated worse outcomes with frailty regardless of questionnaire type, yet following control by score normalization, the converse was observed. SF patients exhibited significantly improved patient-reported IHS recovery in the SRS-22 assessment, despite increase in deformity severity, surgical invasiveness, and postoperative complications.

We demonstrated that there are patient-specific expectations following ASD corrective surgery. NF, MF, and SF patients have different perceptions of their quality of life in relation to their scoliosis, and by way of the SRS-22 questionnaire, specifically their quality of physical function, pain, mental health, satisfaction/dissatisfaction. With worse BL frailty, in addition to increased malalignment, and lower HRQLs across all patient self-assessments, SF patients have room for greater recovery in relation to their low BL quality of life.

Preoperative risk assessment by surgeons consider the threat of detrimental postoperative complications, and although frailty status may be a good representation of risk stratification, HRQLs do not.^{23,26} This study revealed that despite a better recovery trajectory and PRO benefit, SF patients underwent more invasive surgeries with resulting increased risk for major complications. Frail patients carry a greater likelihood of adverse outcomes, and although not reflected in HRQL scores, should be considered in the physician decision-making process for patients undergoing corrective surgery for ASD.

Limitation

The required follow-up time points for our analyses caused the sample sizes to lessen, which may have impacted the reflection of postoperative recovery courses between NF, MF, and SF ASD patients. Another limitation lies in the Integrated Health State methodology, assuming that recovery between time points is linear, as well as may bias the data analysis by neglecting BL differences in HRQL scores. By normalizing the patient-reported scores at BL, the worse pain/state that many patients start at is not accounted for, which may misguide the observation of a patient's quality of recovery. Also, the normalization of HRQL scores at BL only controls for BL severity score, not other factors contributing to heterogeneity across frailty groups. Selection bias may also play a part in the study, as SF patients may tend to not revisit the hospital because of maloutcomes or various comorbidity involvement, skewing the results toward the patients who actually completed the patient-reported surveys, or the SF with marked improvement.

CONCLUSION

Despite SF patients having more complications and larger invasiveness scores, they had overall better recovery in SRS-22 scores and NRS Back Pain, signifying that with frailty severity, patients have more room for improvement postoperatively compared to BL quality of life. Surgeons should consider to perform major deformity correction on the SF ASD patients, since they have greater opportunity for positive improvement both clinically and radiographically, despite their expected negative association with postoperative complications because of their inherent BL frailty.

➤ Key Points

- ❑ Frailty status is an important factor to characterize one's preoperative health state, transcending the standard measurements of age and BMI.
- ❑ After stratifying by the ASD-FI, SF patients were found to be significantly older, with a greater BMI, CCI, as well as demonstrated increased operative invasiveness scores and postoperative complications.
- ❑ With the use of a novel AUC methodology, the impact of BL frailty severity on postoperative recovery kinetics demonstrated that SF patients recovered better in the HRQL of SRS-22 and NRS Back Pain.
- ❑ Controlling for BL deformity by SRS-Schwab ASD modifier and ISSG invasiveness scores confirmed similar improved recovery trajectory (as defined by Liu *et al*) for SF patients.
- ❑ With preoperative frailty severity, patients have more room for improvement postoperatively compared to BL quality of life.

References

1. Searle SD, Mitnitski A, Gahbauer EA, et al. A standard procedure for creating a frailty index. *BMC Geriatr* 2008;8:24.
2. Rockwood K, Blodgett JM, Theou O, et al. A frailty index based on deficit accumulation quantifies mortality risk in humans and in mice. *Sci Rep* 2017;7:1–10.
3. Stow D, Matthews FE, Barclay S, et al. Evaluating frailty scores to predict mortality in older adults using data from population based electronic health records: case control study. *Age Ageing* 2018;47:564–9.
4. Lin H-S, Watts JN, Peel NM, et al. Frailty and post-operative outcomes in older surgical patients: a systematic review. *BMC Geriatr* 2016;16:157.
5. Hall DE, Arya S, Schmid KK, et al. Association of a frailty screening initiative with postoperative survival at 30, 180, and 365 days. *JAMA Surg* 2017;152:233–40.
6. Miller EK, Neuman BJ, Jain A, et al. An assessment of frailty as a tool for risk stratification in adult spinal deformity surgery. *Neurosurg Focus* 2017;43:E3.
7. Rothrock RJ, Steinerger JM, Badgery H, et al. Frailty status as a predictor of three month cognitive and functional recovery following spinal surgery: a prospective pilot study. *Spine J* 2019;19:104–12.
8. Liu S, Tetreault L, Fehlings MG, et al. A novel method using baseline normalization and area under the curve to evaluate differences in outcome between treatment groups and application to patients with cervical spondylotic myelopathy undergoing anterior versus posterior surgery. *Spine (Phila Pa 1976)* 2015;40:E1299–304.
9. Segreto FA, Lafage V, Lafage R, et al. Recovery kinetics: comparison of patients undergoing primary or revision procedures for adult cervical deformity using a novel area under the curve methodology. *Neurosurgery* 2019;85:E40–51.
10. Charlson M, Szatrowski TP, Peterson J, et al. Validation of a combined comorbidity index. *J Clin Epidemiol* 1994;47:1245–51.
11. Champain S, Benchikh K, Nogier a, et al. Validation of new clinical quantitative analysis software applicable in spine orthopaedic studies. *Eur Spine J* 2006;15:982–91.
12. Rillardon L, Levassor N, Guigui P, et al. Validation of a tool to measure pelvic and spinal parameters of sagittal balance. *Rev Chir Orthop Reparatrice Appar Mot* 2003;89:218–27.
13. O'Brien MF, Kuklo TRTR, Blanke KM, et al. Spinal Deformity Study Group Radiographic Measurement Manual. Available at: <http://www.oref.org/docs/default-source/default-document-library/sdsg-radiographic-measurement-manual.pdf?sfvrsn=2>. 2005.
14. Terran J, Schwab FJ, Shaffrey CI, et al. The SRS-Schwab Adult Spinal Deformity Classification: assessment and clinical correlations based on a prospective operative and nonoperative cohort. *Neurosurgery* 2013;73:559–68.
15. Schwab F, Ungar B, Blondel B, et al. SRS-Schwab adult spinal deformity classification: a validation study. *Spine (Phila Pa 1976)* 2012;37:1077–82.
16. Passias PG, Jalai CM, Lafage V, et al. Kinetics of radiographic and implant-related revision patients following adult spinal deformity surgery. *Neurosurgery* 2018;83:700–8.
17. Ames CP, Scheer JK, Mundis GM, et al. The Effect of Patient Age on Recovery Kinetics in 149 Adult Spinal Deformity Patients with 2-year Follow-up: A Novel Area Under the Curve Analysis. In: Scoliosis Research Society (SRS); September 10-13. Anchorage, Alaska; 2014.
18. Leven D, Cho SK. Pseudarthrosis of the cervical spine: risk factors, diagnosis and management. *Asian Spine J* 2016;10:776–86.
19. Miller EK, Lenke LG, Neuman BJ, et al. External Validation of the Adult Spinal Deformity (ASD) Frailty Index (ASD-FI) in the Scoliosis RISK-1 Patient Database. *Spine (Phila Pa 1976)* 2018;875:61.
20. Yagi M, Fujita N, Okada E, et al. Impact of frailty and comorbidities on surgical outcomes and complications in adult spinal disorders. *Spine (Phila Pa 1976)* 2018;1.

21. Yagi M, Hosogane N, Fujita N, et al. Predictive model for major complications 2 years after corrective spine surgery for adult spinal deformity. *Eur spine J* 2019;28:180–7.
22. Leven DM, Lee NJ, Kothari P, et al. Frailty index is a significant predictor of complications and mortality after surgery for adult spinal deformity. *Spine (Phila Pa 1976)* 2016;41:E1394–401.
23. Glassman SD, Bridwell KH, Shaffrey CI, et al. Health-related quality of life scores underestimate the impact of major complications in lumbar degenerative scoliosis surgery. *Spine Deform* 2018;6:67–71.
24. Reid DBCC, Daniels AH, Ailon T, et al. Frailty and health-related quality of life improvement following adult spinal deformity surgery. *World Neurosurg* 2018;112:548–54.
25. Reid DBCC, Daniels AH, Ailon T, et al. Patient satisfaction after adult spinal deformity surgery does not strongly correlate with health-related quality of life scores, radiographic parameters, or occurrence of complications. *Spine (Phila Pa 1976)* 2017;42:764–9.
26. Cho SK, Bridwell KH, Lenke LG, et al. Major complications in revision adult deformity surgery: risk factors and clinical outcomes with 2- to 7-year follow-up. *Spine (Phila Pa 1976)* 2012;37:489–500.