Frailty and Health-Related Quality of Life Improvement Following Adult Spinal Deformity Surgery

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BACKGROUND: **Although the Adult Spinal Deformity Frailty Index (ASD-FI) predicts major complications and prolonged hospital length of stay after adult spinal deformity surgery, the impact of frailty on postoperative changes in health-related quality of life (HRQoL) is unknown.**

METHODS: **Patients who underwent instrumented fusion of ≥4 levels for adult spinal deformity with minimum 2-year follow-up were stratified by Adult Spinal Deformity Frailty Index score into 3 groups: nonfrail, frail, and severely frail. Baseline and follow-up demographics, HRQoL measures, and radiographic parameters were analyzed. Primary outcome measures included proportion of patients who achieved substantial clinical benefit (SCB) in terms of Oswestry Disability Index, 36-Item Short Form Health Survey Physical Component Summary, and numeric back and leg pain scores.**

RESULTS: **Inclusion criteria were met by 332 patients (135 nonfrail, 175 frail, 22 severely frail). Frail and severely frail patients were older and had more comorbidities, worse baseline HRQoL and pain scores, and worse radiographic deformity than nonfrail patients ($P < 0.05$). At 2-year follow-up, all outcome scores were worse in frail and severely frail patients compared with nonfrail patients. Frail patients improved more than nonfrail patients and were more likely to reach SCB for Oswestry Disability Index (43.7% vs. 29.3%; $P = 0.025$), 36-Item Short Form Health Survey Physical Component Summary (56.9% vs. 51.2%; $P = 0.03$), and leg pain (45.8% vs. 23.0%; $P = 0.03$) scores, but not back pain (57.5% vs. 63.4%; $P = 0.045$) score.**

CONCLUSIONS: **Despite higher risk stratification and worse baseline HRQoL, frail patients were more likely to reach SCB for most HRQoL measures compared with nonfrail patients. Severely frail patients were the least likely to reach SCB for most HRQoL measures.**

INTRODUCTION

Surgery for adult spinal deformity (ASD) has been shown to provide substantial clinical benefit in elderly patients, but it is associated with a high complication rate.[1-6] Chronologic age is associated with a greater number of preoperative comorbidities, more perioperative complications, and increased risk of

Key words
- Adult spinal deformity
- Frailty
- Frailty index
- Fusion
- Health-related quality of life
- Patient-reported outcome measures
- Scoliosis

Abbreviations and Acronyms
ASD: Adult spinal deformity
ASD-FI: Adult Spinal Deformity Frailty Index
HRQoL: Health-related quality of life
ODI: Oswestry Disability Index
PCS: Physical Component Summary
SCB: Substantial clinical benefit
SF-36: 36-Item Short Form Health Survey

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mortality and has historically been used as a surrogate for surgical risk.[7-10] However, chronologic age is not equivalent to physiologic age; thus, frailty has been studied and has been found to be a stronger predictor of morbidity and mortality in hospitalized geriatric patients compared with age or American Society of Anesthesiologists score.[11-14]

The Adult Spinal Deformity Frailty Index (ASD-FI) was specifically designed to assess surgical risk following ASD surgery.[15] The ASD-FI has been shown to be a significant predictor of perioperative medical and surgical complications, prolonged hospital stay, proximal junctional kyphosis, and deep wound infection in patients undergoing surgery for ASD.[15] This index may be a useful preoperative risk stratification tool that may assist surgeons in patient selection and preoperative counseling. However, a potential concern is that such information could be used as justification for rationing care to only patients less likely to experience higher-cost and increased rates of complications. Thus, it is imperative to evaluate functional outcomes in high-risk groups to determine the potential benefits of surgical treatment. The relationship between the ASD-FI and postoperative changes in health-related quality of life (HRQoL) has not been previously reported. Our hypothesis was that frailty, as measured by the ASD-FI, would be associated with poorer HRQoL outcomes at 2 years postoperatively as measured by Oswestry Disability Index (ODI) scores, 36-Item Short Form Health Survey (SF-36) scores, and numeric back and leg pain scores.[16-19]

MATERIALS AND METHODS

Patient Population

This study is a retrospective review of a multicenter, prospectively collected database of patients with ASD. Inclusion criteria included patients who underwent instrumented fusion of ≥4 levels for ASD and who had a minimum of 2-year follow-up. Exclusion criteria included pediatric patients (<18 years old) and patients without 2-year postoperative HRQoL scores available in the database. Additionally, to avoid bias from more frail patients undergoing smaller operations on average, patients undergoing fusions of <4 levels were excluded. These criteria were met by 332 patients in the database (**Figure 1**).

Data Collection

Baseline demographics were collected for all patients, including age, sex, comorbidities (including Charlson Comorbidity Index), number of levels fused, and radiographic parameters (pelvic tilt, pelvic incidence, lumbar lordosis, spinopelvic mismatch, and sagittal vertical axis). Baseline and postoperative HRQoL scores, including ODI, SF-36 Physical Component Summary (PCS), numeric back pain, and numeric leg pain scores, were collected preoperatively and at 2 years postoperatively.[16-18]

A primary study outcome measure was whether or not patients reached substantial clinical benefit (SCB) for ODI, SF-36 PCS, back pain, and leg pain scores postoperatively. The SCB thresholds as published by Glassman et al.[20] for lumbar spine fusions were used. These include an 18.8-point change in ODI score, 6.2-point change in SF-36 PCS score, 2.5-point change in back pain score, and 2.5-point change in leg pain score. Secondary outcomes included the absolute values and change in values for ODI, SF-36 PCS, back pain, and leg pain scores.

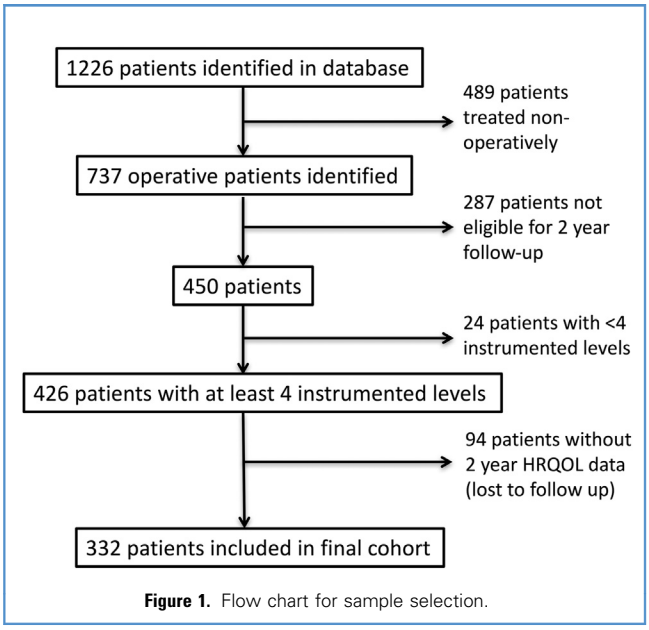

Figure 1. Flow chart for sample selection.

Adult Spinal Deformity Frailty Index

Variables for inclusion in the ASD-FI were chosen based on the standard procedure published by Searle et al.[21] This is a validated method for the development of individualized frailty indices designed for use in pre-existing databases. Greater than 40 variables were selected, each of which relates to mental, physical, or functional health and each of which increases in prevalence with age but does not become universal too early. All variables included

Objective:	Patient reported:
BMI	General health status (SF36 1)
Bowel incontinence	Less than excellent health (SF36 11d)
Bladder incontinence	Health deterioration (SF36 2)
Weakness	Necessity to modify activity (SF36 3b)
>3 comorbidities	Lifting (SF36 3c, ODI 3)
Disability status	Stairs (SF36 3e)
Diabetes	Walking (SF36 3i, ODI 4)
Cancer	Dressing (SF36 3j, LSDI 1,2)
Heart Disease	Bathing (LSDI 8)
Hypertension	Personal Care (ODI 2)
Kidney Disease	Inability to cheer up (SF36 9c, SRS 7)
Liver Disease	Downhearted/Depressed (SF36 9f, SRS 16)
Lung Disease	Worn out (SF36 9g)
Blood clot (includes DVT, PE, or patient-reported "blood clot")	Tired (SF36 9i)
	Social life (ODI 8, SRS 14, SRS 18)
Osteoporosis	Employment (SRS 5, ODI 10)
Peripheral vascular disease	Activity (SRS 5, ODI 10)
Depression	Travel (ODI 9)
Smoking	In/out of bed (LSDI 6)
	Sleep (ODI 7)
	Drive car (LSDI 3)
	Loss of balance

Figure 2. Variables included in Adult Spinal Deformity Frailty Index. All questions were recorded in a binary fashion, yes (1) or no (0). BMI, body mass index; SF-36, 36-Item Short Form Health Survey; ODI, Oswestry Disability Index; LSDI, Lumbar Stiffness Disability Index; SRS, Scoliosis Research Society; DVT, deep vein thrombosis; PE, pulmonary embolism.

Table 1. Baseline Characteristics According to Frailty Category

	Total	Nonfrail	Frail	Severely Frail	*P*
Number of Patients	332	135	175	22	
Age, years	56.7 (14.8)	48.9 (16.5)	62.1 (10.9)	61.3 (7.7)	<0.0001
Female sex	82.20%	88.10%	79.40%	68.20%	0.028
CCI	1.7 (1.7)	0.7 (1.1)	2.2 (1.7)	3.9 (1.8)	<0.0001
Baseline ODI	43.5 (18.9)	27.6 (13.3)	52.5 (12.4)	69.5 (13.8)	<0.0001
Baseline SF-36 PCS	32.2 (10.2)	40.1 (9.4)	27.0 (6.8)	24.9 (4.0)	<0.0001
Baseline SF-36 MCS	44.8 (13.9)	51.5 (11.2)	42.1 (13.1)	25.4 (8.7)	<0.0001
Baseline back pain	7.2 (2.3)	6.1 (2.3)	7.9 (1.9)	8.7 (1.4)	<0.0001
Baseline leg pain	4.4 (3.4)	3.2 (3.3)	5.3 (3.2)	5.7 (3.1)	<0.0001
Levels fused	11.9 (3.8)	11.4 (3.8)	12.1 (3.9)	12.8 (3.3)	0.17
PT, °	23.6 (11.1)	18.6 (10.3)	27.2 (9.9)	26.1 (12.8)	<0.0001
PI-LL, °	15.9 (22.0)	4.6 (19.6)	23.4 (19.6)	25.5 (24.5)	<0.0001
C7 SVA, mm	65.6 (78.3)	28.4 (61.8)	85.9 (76.1)	130.5 (86.3)	<0.0001
SRS-Schwab curve type					
N	98 (29.5%)	24 (17.8%)	62 (35.4%)	12 (54.5%)	<0.0001
T	17 (5.1%)	11 (8.1%)	5 (2.9%)	1 (4.5%)	
L	128 (38.6%)	42 (31.1%)	79 (45.1%)	7 (31.8%)	
D	89 (26.8%)	58 (43.0%)	29 (16.6%)	2 (9.1%)	

Mean (SD).
CCI, Charlson Comorbidity Index; ODI, Oswestry Disability Index; SF-36, 36-Item Short Form Health Survey; PCS, Physical Component Summary; MCS, Mental Component Summary; PT, pelvic tilt; PI-LL, spinopelvic mismatch (pelvic incidence—lumbar lordosis); C7 SVA, C7 sagittal vertical axis; SRS, Scoliosis Research Society; N, no major coronal deformity; T, thoracolumbar curve; L, lumbar curve; D, double curve.

in the index were measured preoperatively. Some individual questions were selected from SF-36 and ODI as variables for use in construction the ASD-FI; however, total SF-36 and ODI scores did not influence the index. These variables were identified, collected, and recorded as binary score of 0 (no) or 1 (yes) for each patient (Figure 2). The mean of all variables for each patient was calculated, giving a final ASD-FI for each patient from 0 to 1. The patients were then stratified into 3 groups: nonfrail (score

Table 2. 2-Year Outcome Measures

	Total	Nonfrail	Frail	Severely Frail	*P*
Number of Patients	332	135	175	22	
ODI	28.2 (20.5)	16.1 (15.2)	34.0 (18.2)	58.7 (13.2)	<0.0001
ODI change	−14.4 (17.3)	−10.3 (17.1)	−18.1 (16.7)	−9.1 (16.9)	<0.0001
SF-36 PCS	40.0 (11.5)	47.8 (9.9)	35.5 (9.6)	28.8 (5.0)	<0.0001
SF-36 PCS change	7.1 (9.9)	6.2 (10.9)	8.4 (9.3)	2.4 (4.8)	0.011
Back pain	3.6 (3.1)	2.6 (2.7)	4.2 (3.1)	6.6 (2.6)	<0.0001
Back pain change	−3.4 (3.2)	−3.6 (3.1)	−3.3 (3.4)	−2.5 (3.0)	0.44
Leg pain	2.7 (3.0)	1.7 (2.6)	3.4 (3.0)	4.6 (3.6)	<0.0001
Leg pain change	−1.6 (3.5)	−1.0 (3.1)	−2.0 (3.8)	−1.4 (3.1)	0.087

Mean (SD).
ODI, Oswestry Disability Index, SF-36, 36-Item Short Form Health Survey; PCS, Physical Component Summary.

Table 3. 2-Year Health-Related Quality of Life Outcomes and Likelihood of Reaching Substantial Clinical Benefit Thresholds Stratified by Frailty Category

	Nonfrail	Frail	Severely Frail	*P*
Number of Patients	135	175	22	
ODI				
2-year score	16.1 (15.2)	34.0 (18.2)	58.7 (13.2)	<0.0001
2-year change	−10.3 (17.1)	−18.1 (16.7)	−9.1 (16.9)	<0.0001
SCB	39 (29.3%)	76 (43.7%)	6 (28.6%)	0.025
SF-36 PCS				
2-year score	47.8 (9.9)	35.5 (9.6)	28.8 (5.0)	<0.0001
2-year change	6.2 (10.9)	28.8 (5.0)	2.4 (4.8)	0.011
SCB	66 (51.2%)	95 (56.9%)	4 (18.2%)	0.03
Back pain				
2-year score	2.6 (2.7)	4.2 (3.1)	6.6 (2.6)	<0.0001
2-year change	−3.6 (3.1)	−3.3 (3.4)	−2.5 (3.0)	0.44
SCB	64 (63.4%)	51 (57.5%)	4 (28.6%)	0.045
Leg pain				
2-year score	1.7 (2.6)	3.4 (3.0)	4.6 (3.6)	<0.0001
2-year change	−1.0 (3.1)	−2.0 (3.8)	−1.4 (3.1)	0.087
SCB	23 (23.0%)	49 (45.8%)	4 (30.8%)	0.003

Mean (SD). SCB values are number (%).
SCB, substantial clinical benefit; ODI, Oswestry Disability Index, SF-36, 36-Item Short Form Health Survey; PCS, Physical Component Summary.

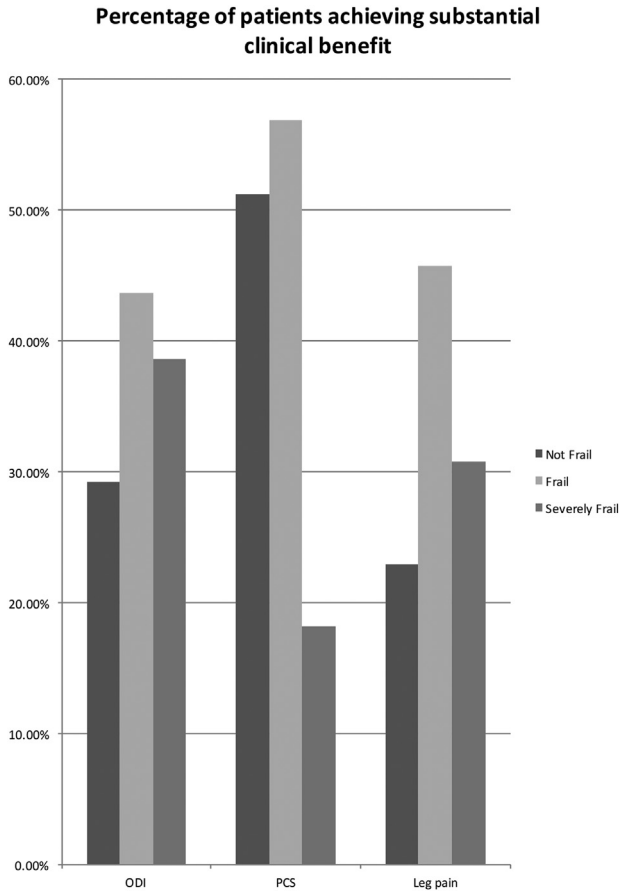

Figure 3. Proportion of each group achieving substantial clinical benefit at 2 years in terms of Oswestry Disability Index, 36-Item Short Form Health Survey Physical Component Summary, and leg pain.

<0.3), frail (score 0.3–0.5), and severely frail (score >0.5). These thresholds were based on values used previously by Searle et al.[21] and represent inflection points in their graph of the rate at which addition health deficits were accumulated.

Statistical Analysis

Nonfrail patients were compared with frail and severely frail patients to assess the proportion of patients who reached SCB in terms of ODI, SF-36 PCS, and numeric back and leg pain scores. Secondary outcomes included absolute values and 2-year postoperative changes in ODI, SF-36 PCS, and back and leg pain scores based on frailty category. Analysis of variance was used for significance testing when comparing means (e.g., 2-year absolute change in HRQoL measures in nonfrail vs. frail vs. severely frail groups). χ^2 test was used when comparing proportions (e.g., percentage of nonfrail vs. frail vs. severely frail groups reaching SCB for ODI, SF-36 PCS, and back and leg pain score). Statistical significance was set at $P < 0.05$ a priori. Additionally, a bivariate linear regression between the ASD-FI and preoperative ODI score was performed to examine the correlation between the measures. Pearson correlation coefficients (r^2) were defined as follows: weak, 0.0–0.2; mild, 0.2–0.4; moderate, 0.4–0.6; moderately strong, 0.6–0.8; and strong, 0.8–1.0.

RESULTS

Eligibility criteria were met by 426 patients, of whom 332 (78%) had complete 2-year follow-up data, including 135 nonfrail patients, 175 frail patients, and 22 severely frail patients (Table 1). Frail and severely frail patients were significantly older than nonfrail patients (mean age: nonfrail, 56.7 years; frail, 62.1 years; severely frail, 61.3 years; $P < 0.0001$). In each group, there were more women than men, with a higher proportion of women in the less frail groups (nonfrail, 88.1% women; frail, 79.4% women; severely frail, 68.2% women; $P = 0.028$). Frail and severely frail patients had a higher number of baseline comorbidities than nonfrail patients (Charlson Comorbidity Index: nonfrail, 0.7; frail, 2.2; severely frail, 3.9; $P < 0.0001$).

There was a significantly higher pelvic tilt in frail and severely frail patients compared with nonfrail patients (nonfrail, 18.6°; frail, 27.2°; severely frail, 26.1; $P < 0.0001$). There was also significantly worse spinopelvic mismatch (nonfrail, 4.6°; frail, 23.4°; severely frail, 25.5°; $P < 0.0001$) and C7 sagittal vertical axis (nonfrail, 28.4 mm; frail, 85.9 mm; severely frail, 130.5 mm;

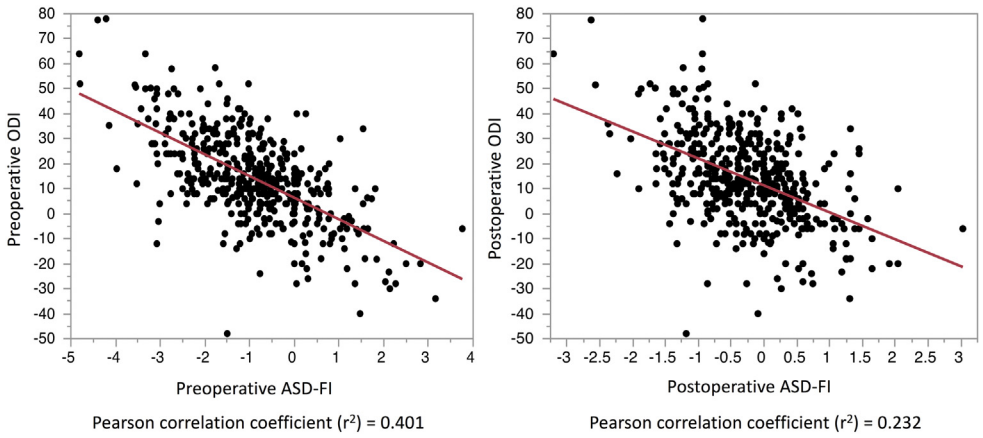

Figure 4. Bivariate linear regression between preoperative Adult Spinal Deformity Frailty Index and preoperative Oswestry Disability Index (left panel) and between 2-year postoperative Adult Spinal Deformity Frailty Index and 2-year postoperative Oswestry Disability Index (right panel). ASD-FI, Adult Spinal Deformity Frailty Index; ODI, Oswestry Disability Index.

$P < 0.0001$) in frail patients compared with nonfrail patients. There was no statistically significant difference between the 3 groups with regard to number of levels fused (nonfrail, 11.4 levels; frail, 12.1 levels; severely frail, 12.8 levels; $P = 0.12$).

All baseline HRQoL and pain scores were significantly worse in frail patients than in nonfrail patients ($P < 0.0001$) (Table 1). Additionally, all baseline HRQoL scores were worse in severely frail patients than in frail patients ($P < 0.0001$). At 2 years postoperatively, patients in all frailty categories experienced improvement in HRQoL measures (Table 2). Compared with baseline, the absolute change in postoperative ODI, SF-36 PCS, and leg pain scores was greatest in frail patients. Mean improvement in ODI score was −10.3 for nonfrail patients, −18.1 for frail patients, and −9.1 for severely frail patients ($P < 0.0001$). Mean improvement in SF-36 PCS score was 6.2 for nonfrail patients, 28.8 for frail patients, and 2.4 for severely frail patients ($P = 0.011$). The mean improvement for leg pain was −1.0 for nonfrail patients, −2.0 for frail patients, and −1.4 for severely frail patients ($P = 0.087$). There was no significant difference in back pain improvement between the groups with a mean improvement of −3.6 for frail patients, −3.3 for frail patients, and −2.5 for severely frail patients ($P = 0.44$).

The proportion of patients reaching SCB was greatest among frail patients compared with nonfrail and severely frail patients for ODI, SF-36 PCS, and leg pain scores (Table 3 and Figure 3). Specifically, for ODI score, 43.7% of frail patients reached SCB versus 29.3% of nonfrail patients and 28.6% of severely frail patients ($P = 0.025$). For SF-36 PCS score, 56.9% of frail patients reached SCB compared with 51.2% of nonfrail patients and 18.2% of severely frail patients ($P = 0.03$). For leg pain score, 45.8% of frail patients reached SCB compared with 23.0% of nonfrail patients and 30.8% of frail patients ($P = 0.003$). A significantly larger proportion of nonfrail patients reached SCB for back pain compared with frail and severely frail patients (nonfrail, 63.4%; frail, 57.5%; severely frail, 28.6%; $P = 0.045$).

Bivariate regression between preoperative ASD-FI and preoperative ODI score revealed an r^2 of 0.40, indicating a moderate correlation (Figure 4).

DISCUSSION

Despite higher preoperative risk stratification scores, increased complication rates, and worse baseline HRQoL scores, frail patients achieved greater improvements in most HRQoL measures following ASD surgery compared with nonfrail patients. In this cohort, frail patients had greater improvements in ODI, SF-36 PCS, and leg pain scores than nonfrail and severely frail patients. Although risk stratification is an essential component of preoperative evaluation of patients with ASD, this study highlights the need to examine clinical outcomes in addition to complication rates and cost. As further knowledge is gained regarding the impact of patient-specific factors on complications and cost, it must be balanced with these data showing that higher-risk patients may actually benefit equally or more from ASD surgery than lower-risk patients.

The greater improvement in HRQoL scores among frail patients was counter to our initial hypothesis, in which we suspected that patients with higher frailty index scores would be likely to have poorer outcomes given increased physiologic age, higher number of comorbidities, and known increased risk of medical and surgical complications. The only outcome score measured that confirmed our initial hypothesis was the numeric back pain score, in which frail and severely frail patients were less likely to reach SCB than nonfrail patients. In all other outcome measures, patients in the frail group were the most likely to reach SCB.

Although ASD surgery is associated with high complication rates,[1,22-24] several studies have reported substantial benefit in HRQoL measures.[1,24,25] A recent study by Riley et al.[26] examining HRQoL measures after complex ASD surgery found significant postoperative improvements in pain, self-image, function, satisfaction, and mental health. Even patients who do experience

complications have no significant difference in rate of improvement and overall improvement in HRQoL measures compared with patients without complications.[1,27] In an increasingly cost-conscious medical climate, it is important to evaluate the value of surgical interventions in terms of direct costs, risk of costly complications, and clinical and quality-of-life benefits. An important consideration in this study was that frail patients had worse preoperative sagittal imbalance compared with nonfrail patients. Global sagittal alignment is directly correlated with HRQoL scores[28-31]; thus, correcting their deformity may partially explain why frail patients improved to a greater magnitude than nonfrail patients.[32-34]

This study has several potentially important limitations. Several of the frailty index variables are derived from the HRQoL measures that were studied as primary outcome measures. Specifically, some individual questions from the ODI and SF-36 were used as binary variables to formulate the ASD-FI, whereas the overall ODI and SF-36 PCS scores were also used as outcome measures in this study. There may be some concern that a correlation between the ASD-FI and outcome variable such as ODI and SF-36 PCS may confound the results. However, the r^2 of preoperative ASD-FI to ODI was 0.40, indicating only a moderate correlation between the measures, leaning toward the independent value of the ASD-FI and suggesting that additional factors aside from those included in the patient-reported outcome measures used are important. Additionally, although there is some overlap in concepts characterizing activities and health status between the ASD-FI and our outcome measures of interest, there is no evidence that patients would be likely to answer the same binary output questions differently if asked outside of a commonly used HRQoL measure such as ODI or SF-36 versus within the measure. Furthermore, it is possible that some of the deformity-related functional limitations assessed in the ASD-FI may actually be making patients more frail, and thus by addressing these limitations surgically, one may be able to decrease the patient's degree of frailty and risk of accumulating further frailty-related deficits. Assessing frailty is an emerging science, without uniformly agreed upon methodology. This study and the ASD-FI represent an early attempt to create a disease-specific frailty index, and further refinement may be needed to create a frailty index that does not use HRQoL measures if that index is to be used to assess clinical outcomes.

CONCLUSIONS

The ASD-FI requires ongoing testing and refinement before widespread clinical utilization. Strengths of the present study include the use of a prospectively collected surgeon-maintained database, 2 years of complete follow-up, and the use of a comprehensive and validated frailty index. This study provides evidence that frail patients benefit from ASD surgery regardless of higher surgical risk.

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