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DEFORMITY

A Risk-Benefit Analysis of Increasing Surgical Invasiveness Relative to Frailty Status in Adult Spinal Deformity Surgery

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Study Design. Retrospective review of a prospectively enrolled multicenter Adult Spinal Deformity (ASD) database.

Objective. Investigate invasiveness and outcomes of ASD surgery by frailty state.

Summary of Background Data. The ASD Invasiveness Index incorporates deformity-specific components to assess correction magnitude. Intersections of invasiveness, surgical outcomes, and frailty state are understudied.

Methods. ASD patients with baseline and 3-year (3Y) data were included. Logistic regression analyzed the relationship between increasing invasiveness and major complications or reoperations and meeting minimal clinically important differences (MCID) for health-related quality-of-life measures at 3Y. Decision tree analysis assessed invasiveness risk-benefit cutoff points, above which experiencing complications or reoperations and not reaching MCID were higher. Significance was set to $P<0.05$.

Results. Overall, 195 of 322 patients were included. Baseline demographics: age 59.9 ± 14.4, 75% female, BMI 27.8 ± 6.2, mean Charlson Comorbidity Index: 1.7 ± 1.7. Surgical information: 61% osteotomy, 52% decompression, 11.0 ± 4.1 levels fused. There were 98 not frail (NF), 65 frail (F), and 30 severely frail (SF) patients. Relationships were found between increasing invasiveness and experiencing a major complication or reoperation for the entire cohort and by frailty group (all $P<0.05$). Defining a favorable outcome as no major complications or reoperation and meeting MCID in any health-related quality of life at 3Y established an invasiveness cutoff of 63.9. Patients below this threshold were 1.8[1.38–2.35] ($P<0.001$) times more likely to achieve favorable outcome. For NF patients, the cutoff was 79.3 (2.11[1.39–3.20] ($P<0.001$), 111 for F (2.62 [1.70–4.06] ($P<0.001$), and 53.3 for SF (2.35[0.78–7.13] ($P=0.13$).

Conclusion. Increasing invasiveness is associated with increased odds of major complications and reoperations. Risk-benefit cutoffs for successful outcomes were 79.3 for NF, 111 for F, and 53.3 for SF patients. Above these, increasing invasiveness has increasing risk of major complications or reoperations and not meeting MCID at 3Y.

Key words: adult spinal deformity, complications, outcomes, revision, risk benefit.

Level of Evidence: 3

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Adult spinal deformity (ASD) is a complex disease state that pathologically alters standing upright posture and is associated with substantial pain and disability.[1] Spinal deformity is a prevalent disease with some studies suggesting approximately 32% of the adult population and more than 60% of the elderly US population suffer from scoliosis.[2] Over the last 30 years, there is evidence that the rates of spine surgery have increased significantly in the USA.[3] A variety of factors may have contributed to this phenomenon, including improved biomechanical understanding of the human spine, advances in diagnostic imaging and device technology, as well as the increased life expectancy of the population.[3]

However, ASD surgery continues to have significant risk of complications and morbidity (Predictive model for major complications 2 yrs after corrective spine surgery for adult spinal deformity, plus sources 6–12). The reported major complication rate for ASD surgery varies from 15% to 78% at 2 years postoperation (Predictive model for major complications 2 yrs after corrective spine surgery for adult spinal deformity, plus sources 6–12). Given this potential, better tools for preoperative risk stratification and planning have been developed to predict potential outcomes for ASD patients. The ASD-specific invasiveness index incorporates ASD-specific parameters, such as osteotomies, revision surgery, pelvic fixation, and correction of alignment, to more accurately gauge the magnitude of surgery a patient is undergoing.

Frailty, a dynamic measure of physiologic age taking into account sensory impairments, poor social conditions, chronic diseases, psychological disorders, and disability, has become an increasingly more relevant concept amongst a continually aging population.[4–6] The frailty index gives a more global description of a given patient's ability to tolerate physiological stressors than traditional descriptors such as age and comorbidity. The Adult Spinal Deformity Frailty Index (ASD-FI) was specifically designed to assess surgical risk following ASD surgery.[7] 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.[7]

As the discussion of value-based care continues to evolve, there needs to be a better understanding of ways to improve both patient and surgical outcomes. As such, this study assessed risk-benefit cutoff points for the ASD invasiveness index among frailty groups, below which patients had significantly higher odds of having both good clinical and surgical outcomes.

MATERIALS AND METHODS

Study Design and Data Source

This study was a retrospective review of a prospective, multicenter ASD database. Patients were consecutively enrolled from 13 participating centers across the United States from 2008 to 2017. Institutional Review Board Approval and informed patient consent was obtained at each site prior to enrollment. Database inclusion criteria were patients $\geq$18 years undergoing either operative or nonoperative treatment for ASD, defined as: coronal Cobb angle $\geq 20^\circ$, sagittal vertical axis (SVA, distance between C7 plumb line and sacral posterior superior margin) $\geq$5 cm, pelvic tilt $\geq 25^\circ$ and/or thoracic kyphosis $>60^\circ$. Database exclusion criteria were patients with spinal deformity of neuromuscular etiology, presence of active infection, or malignancy.

Data Collection

Patient demographic and clinical data collected for this study were age, sex, body mass index (BMI), comorbidity status, comorbidity severity (Charlson Comorbidity Index), and ASD-FI.[8,9] Surgical data included surgical approach, operative time, estimated blood loss, and length of stay, construct length (levels fused), and technique (*e.g.*, osteotomy, decompression). Health-related quality of life data was collected and assessed for reaching the minimal clinically important differences (MCID) for the Oswestry Disability Index, SF-36 Physical Component Scores, and Scoliosis Research Society Scores.

Full-length free-standing lateral spine radiographs (36'' cassette) were used to assess patients at baseline, 6-weeks, 1-year (1Y), 2Y, and 3Y follow-up intervals. Radiographs were analyzed using SpineView (ENSAM, Laboratory of Biomechanics, Paris, France) software according to validated and standardized techniques previously described in the literature.[10–12] Spinopelvic radiographic parameters assessed included pelvic tilt (PT), pelvic incidence minus lumbar lordosis, and T1 pelvic angle. Global sagittal alignment parameters assessed included the sagittal vertical axis (C7-S1 SVA). Cervical alignment was assessed using thoracic T1 slope, C2-C7 cervical lordosis (CL), T1 slope minus cervical lordosis, and C2-C7 SVA (cSVA).

Study Inclusion Criteria

Operative ASD patients with 3 year postoperative radiographic imaging and undergoing surgical treatment between the years of 2009 and 2017 were included for study. Patients undergoing operative correction during the year of 2008 were excluded from analysis on the basis of incomplete data and a small sample size. Included patients were then stratified according to their preoperative frailty scores into either not frail (NF), frail (F), or severely frail (SF) groups. Patients were also stratified and assessed based on their preoperative Schwab sagittal vertical angle modifiers grades.[13] Groups included: low SVA (LSVA) whose SVA < 4 cm, moderate SVA (MSVA) whose SVA was between 4 and 9.5 cm, and high SVA (HSVA), whose SVA were >9.5 cm.

Invasiveness Calculation

Invasiveness was calculated according to definitions established by Neuman *et al*.[14] The invasiveness index included; posterior decompression (1 point), posterior fusion (2 points), posterior instrumentation (1 point), 3-coloumn osteotomy (14 points), Ponte osteotomy (1 points), anterior lumbar interbody fusion (8 points), transforaminal/posterior lumbar interbody fusion (2 points), iliac fixation (2 points), revision surgery (3 points) (Table 1).

TABLE 1. Factors Included in Invasiveness Index

Surgical Component	Points
Posterior	
Decompression	1 per vertebra
Fusion	2 per vertebra
Instrumentation	1 per vertebra
Osteotomies	
Three-column	14 per osteotomy
Smith-Petersen	1 per osteotomy
Interbody fusion	
Anterior lumbar	8 per interbody fusion
Transforaminal/posterior lumbar	2 per interbody fusion
Iliac fixation	2
Revision surgery	3

Frailty Calculation

Frailty was calculated utilizing the ASD-FI, developed by Miller *et al* based on the standard procedure published by Searle *et al*.[5,4] Standard frailty indices sum the total health deficits a patient has, and assign each deficit an equal "weight," typically 0 or 1 indicating the absence or presence of the deficit. The ASD-FI includes 40 binary variables relating to both objective and subjectively reported mental, physical, and functional health values.[5] The mean score of all deficits is calculated, resulting in a frailty index ranging from 0 to 1. Patients with scores <0.3 are considered not frail, scores between 0.3 and 0.5 are considered frail, while scores ≥0.5 are deemed severely frail. These cutoffs were determined utilizing mortality risk curves. The ASD-FI has been validated using the International Spine Study Group ASD database, European Spine Study Group ASD database, and the Scoli-RISK-1 Patient Database.[5]

Statistical Analysis

All statistical tests were performed using SPSS software (v23.0, Armonk, NY). Descriptive analyses assessed means and frequencies of demographic variables, clinical characteristics, surgical variables, and radiographic alignment parameters. Paired samples *t* tests determined whether significant differences existed between preoperative and postoperative radiographic measures at 3Y follow-up. Logistic regression analysis assessed the relationship between increasing invasiveness and major complications or reoperations and meeting MCID for any of the measured HRQLs at 3Y. Decision tree analysis assessed thresholds for an invasiveness risk-benefit cutoff point, above which experiencing complications or reoperations and not reaching MCID were higher. Significance was set to $P < 0.05$.

RESULTS

Patient Demographics

One hundred ninety-five ASD patients met inclusion criteria. The mean age of the cohort was 59.9 ± 14.4 years old, 75% were women, and the average BMI was 27.8 ± 6.2. There were 98 NF, 65 F, and 30 SF patients. When grouped by preoperative Scoliosis Research Society (SRS) Schwab SVA modifier, there were 94 LSVA patients, 34 MSVA patients, and 67 HSVA patients.

Surgical Details

Of included patients, 82.0% had a posterior approach and 18% a combined approach. ASD correction for these patients involved a mean 11.0 ± 4.1 levels fused, with 61% undergoing an osteotomy, and 54% decompression. The average estimated blood loss was 1370.6 ± 1235, length of stay was 8.2 ± 6.0 days, and the mean operative time was 375.1 ± 142.5 minutes. Revision rates by 3 years were: 9% for NF patients, 15% for F patients, and 17% for SF patients. Reasons for revision included: postoperative proximal junctional kyphosis, rod fracture, neurologic complications, and infections.

Pre- and Postoperative Radiographic Alignment

Preoperatively, patients in the NF group had the least baseline disability, with the lowest average SVA, SS, PT, CL, and cSVA scores (Table 2). F and SF patients exhibited similar radiographic baseline disability, with comparable SVA, SS, PT, CL, and cSVA measurements. However, by 3 years postop, all groups exhibited improvements in their radiographic measurements. F and SF patients achieved significant deformity correction, with an average 3 year postop SVA in the moderate range for Schwab SRS-ASD classifications.

Frailty Invasiveness Index Cutoffs

When assessing the relationship between increasing invasiveness and the odds of experiencing a major complication or reoperations, there was a significantly positive relationship for all patients, as well as each frailty subgroup (Table 3). Invasiveness cutoffs were determined for each group, below which patients had increased odds of no major complications or reoperations and reaching MCID for any of the measured health-related quality of life data. For all patients, the invasiveness cutoff was found to be 63.9, above which the odds of having the defined favorable outcome were significantly lower ($P < 0.001$, Table 4). For each frailty group specifically, the cutoff was 79.3 for NF patients, 111 for F patients, and 53.3 for SF patients ($P < 0.001$, $P < 0.001$, and $P = 0.13$).

SVA Invasiveness Index Cutoffs

The relationship between increasing invasiveness and the odds of experiencing a major complication or reoperation was assessed according to SRS Schwab SVA modifier groups. For LSVA patients, the cutoff was found to be 76.4; however, there was no significant relationship ($P = 0.47$). HSVA patients, cutoff of 75.9, also did not have a significant relationship between invasiveness and the odds of experiencing a major complication or reoperation and reaching MCID at 3Y ($P = 0.49$). However, for MSVA

TABLE 2. Preoperative and 3Y Postoperative Radiographic Measurements

	Baseline	3 Years Postop	Significance (*P*)
Not frail			
SVA	25.7 ± 60.1	16.2 ± 49.4	0.114
SS	23.7 ± 12.6	30.4 ± 14.3	0.712
PT	19.6 ± 10.5	19.8 ± 9.9	0.394
PI	53.5 ± 11.7	53.8 ± 12	0.091
PI-LL	6.1 ± 19.6	2.4 ± 15	0.134
T4-T12 TK	−32.3 ± 19	−38 ± 15.7	<0.001
TS-CL	19 ± 10.3	21.4 ± 10	0.035
C2-C7 CL	3.8 ± 14.9	8.8 ± 17.7	0.009
cSVA	3.6 ± 16.9	28.2 ± 12.5	0.194
C2-T3	26.4 ± 13.9	3.2 ± 16.2	0.341
Frail			
SVA	87 ± 79.5	43.8 ± 61.6	<0.001
SS	28.8 ± 13.8	35.3 ± 12.1	0.002
PT	28.4 ± 11	25 ± 9.9	0.004
PI	56.4 ± 13.9	57.2 ± 14	0.349
PI-LL	23.6 ± 18.1	7.7 ± 15	<0.001
T4-T12 TK	−31 ± 16.1	−44.6 ± 14.5	<0.001
TS-CL	16.6 ± 12.6	24.3 ± 14.2	<0.001
C2-C7 CL	11.8 ± 16.8	10.8 ± 13.3	0.253
cSVA	12.1 ± 20	32 ± 16.4	0.004
C2-T3	27.4 ± 16.1	5.4 ± 17.6	0.006
Severely frail			
SVA	83.1 ± 77.1	69.3 ± 58.9	0.393
SS	28.8 ± 15.1	35.6 ± 12.8	0.624
PT	23.7 ± 9.9	23.6 ± 9	0.750
PI	52.9 ± 10.4	53.5 ± 11.2	0.556
PI-LL	19.9 ± 22.8	13.8 ± 16.9	0.105
T4-T12 TK	−30.8 ± 23.7	−39.8 ± 18.3	0.009
TS-CL	15.7 ± 10.2	23.9 ± 10.5	0.003
C2-C7 CL	13 ± 18.7	10.4 ± 16.5	0.651
cSVA	12.8 ± 18.1	32.7 ± 13.4	0.210
C2-T3	33.7 ± 14.8	7.8 ± 19.6	0.323

TABLE 3. The Linear Relationship Between Increasing Invasiveness and Experiencing a Major Complication or Revision

Increasing Invasiveness	OR	95% CI for EXP(B)		
		Lower	Upper	Significance
All patients	1.01	1	1.02	$P = 0.01$
Not frail patients	1.01	1	1.03	$P = 0.05$
Frail patients	1.01	1.01	1.02	$P < 0.001$
Severely frail patients	1.01	1	1.01	$P < 0.001$

TABLE 4. Invasiveness Cutoffs and the Odds of Reaching Minimal Clinically Important Differences and No Major Complications or Revision If Below the Cutoff

Group	Invasiveness Risk-benefit Cutoff Point	OR	95% CI for EXP(B)		
			Lower	Upper	Significance
All patients	63.9	1.8	1.38	2.35	$P < 0.001$
Not frail patients	79.3	2.11	1.39	3.2	$P < 0.001$
Frail patients	111	2.62	1.7	4.06	$P < 0.001$
Severely frail patients	53.3	2.35	0.78	7.13	$P = 0.13$

TABLE 5. Invasiveness Cutoffs and the Odds of Reaching Minimal Clinically Important Differences and No Major Complications or Revision If Below the Cutoff

Group	Invasiveness Risk-benefit Cutoff Point	OR	95% CI for EXP(B)		Significance
			Lower	Upper	
LSVA patients	76.4	0.43	0.43	4.3	$P=0.47$
MSVA patients	60.6	4.29	0.59	15.2	$P=0.15$
HSVA patients	75.9	1.88	0.32	11	$P=0.49$

HSVA indicates high-sagittal vertical axis; LSVA, low-sagittal vertical axis; MSVA, moderate-sagittal vertical axis.

patients, the cutoff was 60.6, and trended toward significance ($P=0.15$, Table 5).

Frailty Risk-Benefit Cutoffs Case Examples

Figure 1 presents the pre- and 3 year postoperative radiographs of a severely frail patient with a previous history of posterior spinal fusion with osteotomy from L4-S1 and lumbar fusion at L2–3 with instrumentation who underwent an uncomplicated posterior spinal fusion with pedicle subtraction osteotomy from T10 to the ilium. Their ASD invasiveness was 107.0, above the risk-benefit cutoff of 53.3 for severely frail patients. At 3Y postop, they experienced no major complication or revisions, but had failed to reach MCID for any measured HRQL.

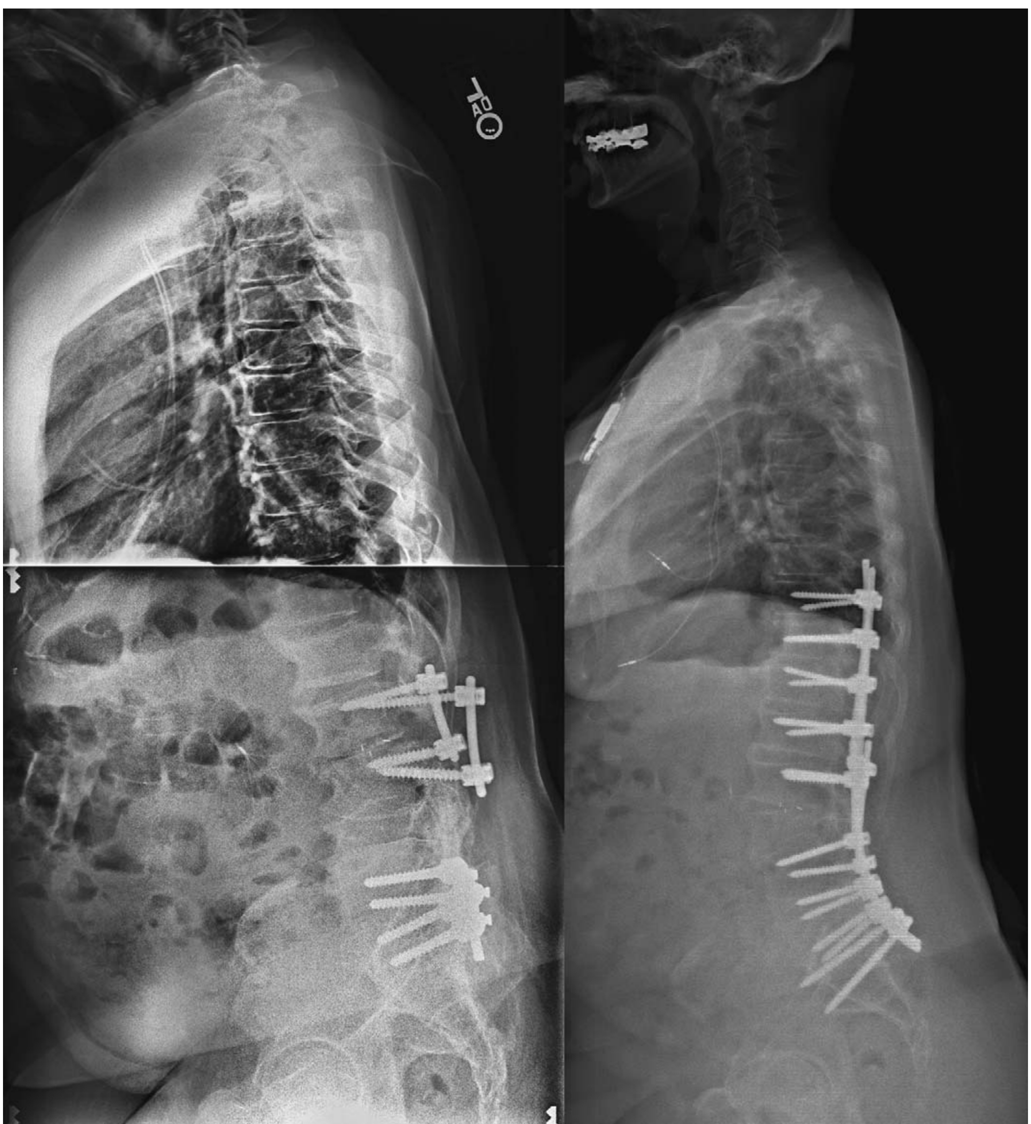

Figure 1. Pre- and 3Y postop radiographs of SF patient with history of spinal surgery who underwent uncomplicated posterior spinal fusion with PSO from T10 to ilium.

Figure 2. Pre- and 3Y postop radiographs of NF patient who underwent uncomplicated posterior spinal fusion from T2 to the ilium with Harrington rod removal. NF indicates not frail.

Figure 2 presents the pre- and 3 year postoperative radiographs of a not frail patient who underwent an uncomplicated posterior spinal fusion from T2 to the ilium with Harrington rod removal. Their invasiveness was 122.7, above the risk-benefit cutoff of 79.3 for not frail patients. By 3 years postoperation, the patient had undergone a revision surgery. However, they did reach MCID for the SRS Pain HRQL.

Figure 3 presents the pre- and 3 year postoperative radiographs of a not frail patient with a previous history of spinal surgery who underwent an uncomplicated posterior spinal fusion from T1 to S1. Their invasiveness was 50.2, below the risk-benefit cutoff of 79.3 for not frail patients. By 3 years postoperation, the patient had not experienced a major complication or revision. In addition, they had achieved MCID for the Oswestry Disability Index (ODI).

Figure 4 presents the pre- and 3 year postoperative radiographs of a not frail patient who underwent a posterior decompression and fusion of the spine from the level of T4 through the sacroiliac joints with bilateral rods and pedicle screws. Their invasiveness, 151.8, was above the risk-benefit cutoff of 79.3 for not frail patients. By 3 years postop, the patient had experienced a major complication, rod breakage, though they were not indicated for revision surgery. At 3 years, the patient had reached MCID for the ODI and SRS HRQLs.

DISCUSSION

In appropriately indicated patients, surgery for ASD can lead to improvements in pain, disability, and health-related quality of life.[15–19] Surgery often involves complex reconstruction with multiple soft-tissue releases, osteotomies,

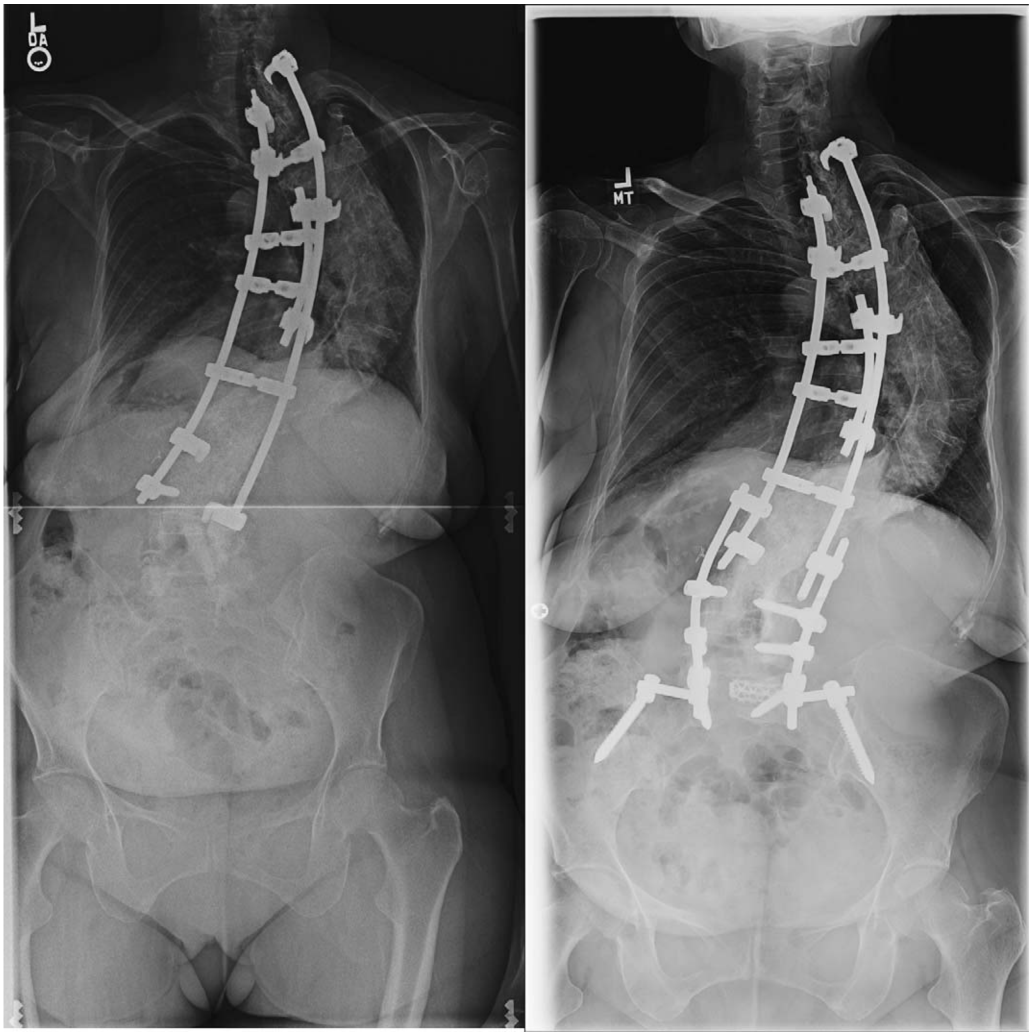

Figure 3. Pre- and 3Y postop radiographs of NF patient with history of spinal surgery who underwent uncomplicated posterior spinal fusion from T1 to S1. NF indicates not frail.

segmental instrumentation through multiple levels, placement of interbody grafts, and major procedures to restore spinal alignment.[15,20,21] With the magnitude of complexity involved in the surgeries, there is substantial risk to patients of serious complications and mortality.[15,19,22–26] As such, this study assessed risk-benefit cutoff points for ASD patients of differing frailty and deformity to determine optimal levels of invasiveness for achieving favorable outcomes.

When assessing risk-benefit cutoff points, this investigation found specific cutoffs for all patients, as well as for each frailty and SRS-Schwab SVA deformity group. Patients below the cutoffs had significantly higher odds of achieving favorable outcomes by 3 years postoperation, which included reaching MCID for any measured HRQL, and not experiencing a major complication or revision. While previous studies have assessed ASD outcomes, most incorporate a limited number of either surgical complications and revisions or clinical outcomes, in addition to shorter follow-up time. Yagi *et al*[27] created a predictive model for all major complications occurring within 2 years after surgery for middle-aged to elderly ASD patients. While their model, which included demographic and surgical factors, was 92% accurate with an area under the curve of 0.96, it was limited in that it did not include an assessment of HRQL outcomes of their patients. Pellisé *et al*[28] were similarly restricted, as their complexity index for ASD surgery assessed perioperative complications only and had no inclusion of clinical outcomes. As healthcare moves to a more value-driven model, Ames *et al*[29] recently developed models for predicting MCID at 2 years following ASD surgery, as patient HRQLs are the tools which value is measured. While successful in developing their models, as well as identifying the most influential variables predicting MCID, increasing value in healthcare is achieved by lowering total surgery costs, such as complication and revisions, in addition to improving patient-reported outcomes. An assessment of either component alone, surgical or clinical, is no longer sufficient given the evolving standards of value-based care.

This investigation assessed the invasiveness risk-benefit cutoff points for each frailty group. Frailty has been consistently shown to be a significant predictor of worse

Figure 4. Pre- and 3Y postop radiographs of NF patient who underwent posterior decompression and fusion from T4 through SI joints with bilateral rods and pedicle screws. NF indicates not frail.

postoperative outcomes in ASD patients.[30–32] In the initial assessment of the ASD specific frailty index, Miller *et al*[33] found that increasing frailty was associated with significantly higher odds of any complication, major complication, proximal junction kyphosis, pseudoarthrosis, and reoperation. As such, the invasiveness risk-benefit cutoff point for severely frail patients was substantially lower than it was for not frail and frail patients. Whether this is a reflection of these patients requiring too high a magnitude of correction or the inability to recovery from such an operation, requires further research. However, frail patients were found to have the highest risk benefit cutoff point. Similarly, this may be a reflection of frail patients requiring significant deformity correction but possessing a better physiologic reserve to improve following surgery, unlike older, more comorbid severely frail patients.

The SRS Schwab SVA invasiveness risk-benefit cutoff point was also assessed for each group. However, the cutoffs failed to reach significance for all deformity groups (LSVA, MSVA, and HSVA). The extent of correction needed was not able to predict the odds of having a favorable outcome, suggesting that a more dynamic measure like frailty is better at stratifying preoperative patients into the likelihood of having a successful outcome.

This study is not without limitations. The data was obtained through a retrospective review, which represents inherent limitations and the introduction of biases including the potential for provider selection to confound results. In addition, there was significant loss to follow-up at 3 years, which presents additional potential to confound results. There may be cases of deformity that require invasive surgical techniques without the option for decreased invasiveness, rendering these cutoffs inapplicable. However, despite these limitations, this study offers significant insight on ASD surgery outcomes and the potential to increase healthcare value.

CONCLUSION

This study assessed the relationship between increasing surgical invasiveness and outcomes in Adult Spinal Deformity Surgery. A risk-benefit cutoff for no major complications or reoperations and meeting the minimal clinically important difference for various health-related quality-of-life measures was assessed for each frailty group. By frailty, the cutoffs were found to be 79.3 for not frail patients, 111 for frail patients, and 53.3 for severely frail patients. Patients with invasiveness above these thresholds were less likely to achieve successful outcomes.

➢ Key Points

- ❑ The impact of increasing surgical invasiveness on the outcome of corrective adult spinal deformity surgery was analyzed.
- ❑ A risk-benefit cutoff threshold was determined for patients meeting MCID and having no major complications or reoperations according to each frailty state.
- ❑ Patients above the established thresholds were less likely to achieve optimal outcomes.

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