European Spine Journal
https://doi.org/10.1007/s00586-025-08683-6

ORIGINAL ARTICLE

Long-term follow-up of non-neurologic and neurologic complications after complex adult spinal deformity surgery: results from the Scoli-RISK-1 study

Meghan Cerpa[1] · Scott L. Zuckerman[2] · Lawrence G. Lenke[1] · Leah Y. Carreon[3] · Kenneth M. C. Cheung[4] · Michael P. Kelly[5] · Michael G. Fehlings[6] · Christopher P. Ames[7] · Oheneba Boachie-Adjei[8] · Mark B. Dekutoski[9] · Khaled M. Kebaish[10] · Stephen J. Lewis[6] · Yukihiro Matsuyama[11] · Ferran Pellisé[12] · Yong Qiu[13] · Frank J. Schwab[14] · Justin S. Smith[15] · Christopher I. Shaffrey[16]

Received: 20 August 2024 / Revised: 23 December 2024 / Accepted: 20 January 2025

Abstract

Purpose To report all complications that occurred during the 2 to 5-year postoperative period, describe reoperations during this time period, and compare patients who did and did not have major, surgery-related complications and/or reoperations during this time period.

Methods The Scoli-RISK-1 study enrolled 272 ASD patients undergoing surgery from 15 centers. Inclusion criteria were Cobb angle of > 80°, corrective osteotomy for congenital/revision deformity, and/or 3-column osteotomy. At each follow-up visit, any neurologic or non-neurologic adverse event(AE) was documented & categorized.

Results 77 patients had a minimum 5-year follow-up. 35 surgery-related AE's occurred during the 2 to 5-year period in 25(32.5%) patients. 23/35(65.7%) major, surgery-related complications occurred in 17 patients, 22/35(62.9%) requiring reoperations in 16 patients. Rod fracture and/or pseudarthrosis was the most common complication. The most common minor, surgery-related complication was asymptomatic rod fractures with no alignment changes. Four neurological complications were reported, one of which did not require reoperation. One death occurred at 6.1 years postoperative after multiple reoperations for mechanical complications. 14/17(82.4%) patients with major, surgery-related complication had a preceding AE during the initial 2-year postoperative period. 53 non-surgery-related AEs occurred in 21(27.3%) patients with musculoskeletal(37.7%) occurring most often. No differences were observed in ODI or SRS-22r in those with/without major surgery-related complications or those with/without reoperation.

Conclusion During the study period, 25(32.5%) patients experienced 35 surgery-related complications, of which 23(65.7%) were major. Rod fracture with pseudarthrosis was the most common major, surgery-related complication. Neurologic complications were not found to be major drivers of reoperation. Surprisingly, PROs were similar in those with/without a major, surgery-related complication during the study period.

Abstract presentation This work has been presented as a podium presentation at the 55th Scoliosis Research Society annual meeting, Sep 9–13, 2020.

Keywords Adult spinal deformity · Spinal deformity surgery · Postoperative complications · Mechanical complications · Non-neurologic complications · Scoli-RISK-1

Extended author information available on the last page of the article

Published online: 12 February 2025

Introduction

Adult spinal deformity (ASD) often causes pain, disability, and weakness, leading to a significantly decreased quality of life. While surgery has been shown to improve patient-reported outcomes (PROs) compared to non-operative medical treatment [1], operative intervention is not without risk. Complication rates have been reported to be as high as 70% [2, 3], with approximately 20% requiring reoperation [4]. ASD is often seen in older populations with many existing comorbidities, which further increases the risk of perioperative medical complications. Even after a successful perioperative recovery, the risk of longer-term complications such as proximal junctional kyphosis or failure (PJK/F), implant failure, or rod fracture lingers. Given the wide range of adverse events (AE) that can occur after ASD surgery, knowing long-term complications can be of benefit to both patients and surgeons.

The Scoli-Risk-1 study was a prospective, international, multicenter, observational study assessing the incidence of neurologic and non-neurologic complications in patients undergoing complex ASD surgery [5]. Postoperative neurologic deficits were noted in 10.0% of patients at 2-years, and non-neurologic adverse events occurred in 67.6% of patients [6, 7]. During the 2-year postoperative follow-up period, the most common surgery-related AE's were unintended durotomy (15.8%) and implant failure (14.7%), and the only independent predictor of non-neurologic complications was previous spine surgery [6]. Less is known about complications that occur in the 2 to 5-year follow-up period.

Thus, we sought to study the long-term, non-neurologic and neurologic complications in the prospective Scoli-RISK-1 study at a minimum 5-years postoperative. The current objectives were to: (1) report all complications that occurred during the 2 to 5-year postoperative period; (2) describe reoperations during this time period; and (3) compare patients who did and did not have major, surgery-related complications and/or reoperations during this time period.

Methods

Study Design and Patient Population

The Scoli-RISK-1 study was a prospective, observational, international study evaluating neurologic and non-neurologic complications after surgical correction of complex ASD. Inclusion criteria were: ages 18–80 years, deformity apex between C7-L2, major sagittal/coronal Cobb angle ≥ 80°, congenital or revision deformity undergoing corrective spinal osteotomy, patient undergoing three-column spinal osteotomy (3CO) (i.e. pedicle subtraction osteotomy or vertebral column resection) from C7 to L5, reconstruction or decompression for preoperative myelopathy secondary to their deformity, or reconstruction or decompression due to deformity and ossification of the ligamentum flavum or posterior longitudinal ligament. Exclusion criteria were: unlikely to comply with follow-up, substance dependency or psychiatric disturbance in ≤3 months from operation, active malignancy/infection, spinal trauma/injury/fracture/malignancy in ≤3 months from operation, long-term paraplegia, pregnancy, or incarcerated/instituitnalized.[7]

Fifteen international centers with the following breakdown– North America (9), Europe (3), and Asia (3)– enrolled patients from 43 surgeons, and all centers obtained local ethics committees and institutional review board approval (IRB-AAAR2375). Informed consent was obtained from all individual participants included in the study. Decisions about surgical approach, instrumentation, corrective maneuvers, and use of bone grafts or substitutes were at the discretion of the primary surgeon. The study was registered with ClinicalTrials.gov (NCT01305343). Though funding for the Scoli-Risk-1 study was obtained from AOSpine, the Scoliosis Research Society, and Norton Healthcare, no funding was obtained for this secondary analysis.

Data Collection

Basic demographic and surgical data were collected, including age, gender, race, American Society of Anesthesia (ASA) grade, body mass index (BMI), number of comorbidities, prior spine surgery, levels fused, operative time, estimated blood loss (EBL), 3CO performed, and surgical approach, among others. All patients had an American Spinal Injury Association (ASIA)-certified neurologic exam at each follow-up time points.

Though the study's primary outcome was the presence of any neurologic complications, the objective of the current analysis was to study both non-neurologic and neurologic complications. Given earlier publications summarizing perioperative complications up to 2-years [6], only longer-term complications that occurred in the 2 to minimum 5-year follow-up window were presented. A comprehensive list of long-term complications occurring in the 2 to minimum 5-year period, modified from previous reports [6, 8] to fit the long-term time period, is seen in Table 1. While previous reports listed each general system complication accordingly, we decided to group them according to previous reports, expert opinions based on what was most clinically useful, and the number of patients that experienced these complications In accordance with prior studies [6, 8, 9], complications were categorized as major vs. minor and surgery-related or not surgery-related [10]. We

Table 1 Categorization of non-neurologic adverse occurring in the 2 to 5-year time period

Surgery-related	
Major	**Minor**
Rod fracture and pseudarthrosis	Rod fracture (asymptomatic)
Pseudarthrosis without rod fracture	PJK (radiographic, asymptomatic)
Proximal junctional kyphosis/failure (PJK/PJF)	Residual imbalance (minor)
Screw fracture	Surgical site infection (superficial no surgery)
Residual imbalance requiring operation	Minor motor neurologic deficit
Prominent or painful implants	Minor sensory neurologic deficit
Surgical site infection requiring operation	
Major motor neurologic deficit	
Major sensory neurologic deficit	
Wound dehiscence	
Death	
NOT Surgery-Related	
Major	**Minor**
Cerebrovascular accident (stroke/TIA)	Trauma (no surgery)
Pulmonary	Musculoskeletal
Cardiac	Minor motor neurologic deficit
Trauma (requiring surgery)	Minor sensory neurologic deficit
	Genitourinary
	Ophthalmologic
	Gastrointestinal

included musculoskeletal complications as a minor non surgery-related complication in this study to capture any related patient complaints within the 2 to 5 year postoperative period. Any reoperation was considered major. A non-surgery-related AE that required an operation (i.e. traumatic injury) was also considered major, except for total joint replacements, which were categorized as minor. Neurological complications were listed in both surgery-related and non-surgery-related and their severity (major vs. minor) was determined on whether reoperation was required. Classifications were determined by a panel of experts involved in the study, and discrepancies were resolved by consensus review.

Neurologic function was measured with the ASIA lower extremity motor score (LEMS) by an ASIA-certified examiner [11, 12]. PROs were also collected at each time point and included Scoliosis Research Society (SRS-22R) Instrument [13] and Oswestry Disability Index (ODI) version 2.1a [14, 15].

Statistical analysis

Descriptive statistics were used to summarize demographic and surgical data (mean and standard deviation or median and range for continuous variables; absolute number and percentage for categorical variables). Complications were evaluated only in the 2 to 5-year period, and for complication rates, 95% confidence intervals (CIs) were calculated using the Clopper-Pearson method. Demographic variables and surgical details were compared between patients with and without a major, surgery-related complication in the 2 to 5-year period using t-tests, Mantel-Haenszel Chi-Square test, Chi-Square test and Fisher's exact test as appropriate. The same comparisons were done for patients with and without a reoperation in the 2 to 5-year period. ODI and SRS-22 total scores at 5-year follow-up were compared between the groups using t-tests. All statistical tests were performed at a significance level of 0.05. Due to the small sample size, it is important to note that only large effects could be detected. The statistical analysis was performed using SAS software, version 9.4 (SAS Institute).

Results

Demographic and operative variables

Seventy-seven (28.3%) patients from the original cohort had a minimum 5-year follow-up **(**Table 2**).** The mean age at surgery was 57.8 years and 80.5% were female. A total of 57 (74.0%) patients had a 3CO, and posterior-only was the most common approach (77.9%). The majority of patients had ASA class of II or III (97.4%). Median (range) number of levels operated on was 10 (4–19).

Complications between 2 and 5 years

A total of 37 (46.8%, 95% CI: 35.3–58.5%) patients experienced 88 total complications in the 2 to 5-year period **(**Table 3**)**. Thirty-five surgery-related complications occurred in 25 patients (32.5%, 95% CI: 22.2–44.1%) with four instances (11.4%) of neurological complications Of the 35 surgery-related complications that occurred in the 2 to 5-year window, 65.7% were major and 62.9% required reoperation. Rod fracture with pseudarthroses ($N=13$) was the most common major, surgery-related complication, followed by PJK/PJF ($N=3$) and residual imbalance ($N=2$). Several asymptomatic rod fractures ($N=9$) were seen causing no pain, disability, or malalignment, in addition to one case of radiographic PJK and one case of a reported sensory deficit. No intervention was required for these patients. The majority of the 53 non-surgery-related complications were

Table 2 Demographics of all patients with 5-year follow-up

	N=77
Age, mean (SD); range	57.8 (15.5); 19.0–80.0
Female, n (%)	62 (80.5)
Race, n (%)	
White	50 (64.9)
East Asian	26 (33.8)
Other	1 (1.3)
Smoker, n (%)	4 (5.2)
BMI, mean (SD); range	26.4 (5.7); 17.0–39.7
Previous spine surgery, n (%)	44 (57.1)
Preoperative neuro deficit, n (%)	20 (26.0)
Number of documented comorbidities, median; range	2; 0–12
Operative time in minutes*, mean (SD); range	426 (149); 159–1023
Total estimated blood loss in ml*, median; range	2026; 250–12,000
Three-column osteotomy, n (%)	57 (74.0)
Surgical approach, n (%)	
Posterior only	60 (77.9)
Anterior-posterior combined	17 (22.1)
Levels involved in surgery, median; range	10; 4–19
ASA Grade**, n (%)	
I	2 (2.6)
II	44 (57.1)
III	31 (40.3)

*for staged procedures the sum over the stages was calculated

**for staged procedures worst ASA grade

Table 3 All surgery-related and non-surgery-related complications occurring in the 2 to 5-years interval

Surgery-related	*N*	Not Surgery-related	*N*
Total adverse events, n	35	Total adverse events	53
Total patients, n (%)	25 (32.5%)	Total patients	21 (27.3%)
Neurologic, n	4	Neurologic, n	10
Reoperations, n	22 (16 pts)	Operations, n	14 (9 pts)
Major	**23 (17 pts)**	**Major**	**9 (4 pts)**
Rod fracture and/or pseudarthrosis	13	Trauma	3
PJK/PJF	3	Sensory	2
Residual imbalance	2	Cardiac	1
Surgical site infection (deep) requiring operation*	2	VTE	1
Painful/prominent implants	1	Pulmonary	1
Pseudarthrosis (no rod fracture)	1	Stroke/TIA	1
Screw fracture	1		
Minor	**12 (10 pts)**	**Minor**	**44 (20 pts)**
Rod fracture (asymptomatic)	9	Musculoskeletal	20
PJK (radiographic/asymptomatic)	1	Sensory	15
Infection minor	1	Genitourinary	4
Sensory	1	Trauma	3
		Ophthalmologic	2

*Of note, one deep surgical site infection resulted in sepsis and death

minor musculoskeletal complaints (37.7%), followed by sensory (32.1%) and trauma (11.3%) related events. Fourteen non-surgery-related operations occurred, most often from incidental trauma or elective joint replacement surgery.

Complications requiring revision spine surgery

Twenty-two reoperations occurred in 16 pts (20.8%, 95% CI: 12.4–31.5%). All complications requiring revision spine surgery are summarized in Table 4, with description of each patient's PROs in Table 5. The majority of reoperations were for rod fractures and pseudarthrosis, and PJK/PJF was the second most frequent reason for reoperation, often presenting with neurologic deficit. In most cases, revision surgery most commonly involved extending levels, adding additional rods, and upsizing screws, while addressing any evident pseudarthrosis with revision arthrodesis.

Risk factors for major surgery-related complications between 2 and 5 years

Several patient/surgical factors and PROs were compared between patients with major surgery-related complications and/or reoperation vs. those without **(**Table 6**)**. There was no difference between the two groups in age ($p=0.85$), gender ($p=0.30$), and 3COs ($p=0.36$). The 17 patients with major surgery-related complications had a higher frequency of ASA grade III (52.9% vs. 36.7%), preoperative motor deficit (35.3% vs. 23.3%), previous spine surgery (64.7% vs. 55.0%), adverse events in the first 2-years after surgery (major: 35.3% vs. 21.7%; all: 82.4% vs. 65.0%), and a greater ODI at the 5 year follow up (34.9 ± 21.8, 26.5 ± 21.8), but none of these reached statistical significance. Similar trends were seen in the 16 patients requiring reoperation.

Course of patients with major surgery-related complications in 2–5 years

Figure 1 shows the postoperative course of patients with major surgery-related complications in the 2 to 5-year period. With the exception of 3 patients (2, 6 and 9), 14 of 17 (82.4%) patients with major, surgery-related complications in the 2 to 5-year interval had some form of adverse event occur in the first 2 years after surgery.

Table 4 Major surgery-related complications requiring revision spine surgery in the 2 to 5-year period (22AE in 16 pts)

Age/Sex	Diagnosis & Original Surgery	3CO	Complication	Onset (Yrs)	Revision Surgery(ies)
66/F	T3-pelvis PSF, L1 VCR, T12/L1 interbody	Y	Rod fracture L4/5, pseudarthrosis	2.2	Revision posterior spinal instrumentation and fusion T10-sacrum, L5/S1 ALIF
71/F	L2-pelvis PSF, L5 PSO	Y	PJF with myelopathy	2.5	Extension of previous fusion T2 -pelvis, laminectomy T10/11, SPO at T9/10.
60/F	T8-pelvis PSF, T12 VCR,	Y	Rod fracture L5/S1, pseudarthrosis	3.0	Patient underwent re-instrumentation and fusion T3-pelvis, T7 PSO, interbody T6/7
52/M	T9-pelvis PSF, L3/4 VCR, L5/S1 TLIF	Y	Rod fractures T8/9, L3/4, L5/S1, Pseudarthrosis	3.0	Revision fusion and extension T4-pelvis; additional left satellite rod placed from T8/9 to L5/S1, BMP Revision T4-pelvis fusion and at pseudrthrosis site
70/F	T3-pelvis PSF, L5/S1 TLIF, L3 PSO	Y	Coronal malalignment Iliac screw fracture	3.1 4.1	Revision T3-pelvis fusion, revision asymmetric L3 PSO, L4/5 TLIF, third lumbar rod on left from L2/3 to S1/iliac, fourth rod on the right side from L3/4 to S1/iliac Revision surgery to remove/replace fractured right iliac screw.
60/F	T10-pelvis PSF, L4 PSO, L5/S1 interbody	Y	Rod fracture (level unknown) PJF with myelopathy	2.0 2.9	Removal and replacement of broken rod, BMP Extension of prior fusion (levels unknown)
44/M	T10-S1 PSF, L2 PSO	Y	Rod fracture L1/2, pseudarthrosis	2.0	Removal and replacement of broken rod, placement of 3rd rod spanning pseudarthrosis site, BMP
42/F	T7-S1 PSF, L2 PSO	Y	Rod fracture L3/4, pseudarthrosis	3.6	Removal and replacement of broken rod, revision fusion at L3/4, and an additional rod spanning pseudarthrosis site
62/M	T10-pelvis PSF, L1-3 PCOs	N	Rod fracture L3/4, pseudarthrosis x2	5.0	Removal and replacement of broken rod, revision fusion at L3/4, additional rod spanning pseudarthrosis site
51/F	T12-pelvis PSF, L2 PSO	Y	PJK	4.1	Revision fusion and extension T5-pelvis, replacement of previous implants
63/M	T10-pelvis PSF, L2 PSO	Y	Rod fracture L5/S1, pseudarthrosis	6.0	Revision fusion T10-pelvis, revision iliac fixation
72/F	T2-pelvis PSF, T11-L3, L5/S1 PCO, T11/12, L5/S1 interbody	N	Rod fracture L5/S1, pseudarthrosis Additional rod fracture	2.1 5.7	Revision T2-pelvis fusion, additional rods added crossing the L5/S1 junction Revision fusion T2-pelvis, removal and replacement of broken rod, revision fusion at L5/S1
63/F	T2-pelvis PSF, T9 VCR, L4/5, L5/S1 interbody	Y	Rod fracture L3/4, pseudarthrosis	4.4	Revision fusion of T10-pelvis, PCOs L3/4 and scar dissection at pseudarthrosis site, interbody at L3/4, BMP
61/F	T11-S1 PSF, L1/2 PCO	N	Rod fracture T9-11, pseudarthrosis	4.3	Revision fusion T3-pelvis and exploration of pseudarthrosis at T9-11, BMP
54/F	T2-pelvis PSF, T7-L3 PCO, L4/5 interbody	N	Rod fracture (level unknown), pseudarthrosis	2.0	Removal and replacement of broken rod, revision fusion spanning pseudarthrosis site (levels unknown)
61/F	T1-pelvis PSF, T7-11 PCO	N	Pseudarthrosis Prominent implant Infection and wound dehiscence Surgical site-infection (deep)	4.5 5.6 5.6 6.1	Revision spinal fusion, additional rod crossing pseudarthrosis site Removal left T1 screw and rod Irrigation and debridement of wound Deep surgical site infection leading to sepsis and death

Discussion

During the 2 to 5-year follow-up period of 77 patients enrolled in the Scoli-RISK-1 study, 25 patients (32.5%) experienced 35 surgery-related complications, 65.7% of which were major and 62.9% required reoperation. Four neurological complications were reported in this group, one of which was a sensory deficit that did not require reoperation. Rod fracture and/or pseudarthrosis was the most common major, surgery-related complication. When comparing patients with and without major, surgery-related complications, those with major, surgery-related complications were more medically complex (ASA grade III), more often had preoperative motor deficits and prior spine surgeries and sustained more complications in the preceding 2-years based, on simple comparison of relative frequencies, though these were non-significant trends. In comparing those with and without major, surgery-related complications and/or reoperation to those without, ODI and SRS-22r scores were not statistically different between both groups. These results emphasize the importance of long-term follow-up after complex ASD surgery, and that nearly 2 out of

Table 5 PROs of patients requiring revision spine surgery in the 2 to 5-year period (22AE in 16 pts)

Age/Sex	Diagnosis & Original Surgery	PROs Preop / 6 Wk / 6 Mo / 2 Yr / 5Yr
66/F	T3-pelvis PSF, L1 VCR, T12/L1 interbody	NRS-B/L: 4–4 / 0–0 / 3−0 / 0–0 / 3−0 ODI: 28 / 38 / -- / 6 / 2 SRS-22r: 3.52 / 3.77 / 4.18 / 4.64 / 4.55
71/F	L2-pelvis PSF, L5 PSO	NRS-B/L: 9−8 / 2−1 / 0–0 / 2−0 / 2−0 ODI: 72 / 40 / 40 / 44 / 11 SRS-22r: 2.68 / 3.68 / 4.24 / 2.91 / 4.50
60/F	T8-pelvis PSF, T12 VCR,	NRS-B/L: 7−5 / 4−2 / 4−0 / -- / 3–4 ODI: 76 / 52 / 46 / 54 / 56 SRS-22r: 1.82 / 2.36 / 2.86 / 3.00 / 2.62
52/M	T9-pelvis PSF, L3/4 VCR, L5/S1 TLIF	NRS-B/L: 6−2 / 2−1 / 6−3 / 4–7 / 3−1 ODI: 56 / 40 / 56 / 32 / 28 SRS-22r: 2.64 / 2.95 / 2.50 / 3.27 / 4.05
70/F	T3-pelvis PSF, L5/S1 TLIF, L3 PSO	NRS-B/L: 6−0 / 5−4 / 6–8 / 6–6 / 5−0 ODI: 76 / 68 / 60 / 62 / 50 SRS-22r: 1.67 / 2.32 / 2.91 / 2.68 / 2.68
60/F	T10-pelvis PSF, L4 PSO, L5/S1 interbody	NRS-B/L: 2–9 / 3–3 / 3–3 / 8–9 / 3–3 ODI: 58 / 44 / 31 / 62 / 42 SRS-22r: 2.60 / 3.57 / 3.57 / 3.10 / 3.15
44/M	T10-S1 PSF, L2 PSO	NRS-B/L: 4−0 / 4–5 / 1–4 / 1–1 / 0–0 ODI: 44 / 62 / 40 / 24 / 2 SRS-22r: 3.18 / 3.23 / 3.5 / 3.68 / 4.55
42/F	T7-S1 PSF, L2 PSO	NRS-B/L: 5−0 / 0–0 / 2−0 / 0–0 / 2–2 ODI: 42 / 14 / 24 / 0 / 2 SRS-22r: 3.48 / 3/86 / 4.14 / 4.14 / 4.05
62/M	T10-pelvis PSF, L1-3 PCOs	NRS-B/L: 2–3 / 1–1 / 2−0 / 7−0 / 2–2 ODI: 42 / 24 / 20 / 44 / 40 SRS-22r: 3.09 / -- / 4.27 / 3.18 / 3.32
51/F	T12-pelvis PSF, L2 PSO	NRS-B/L: 7−6 / 8−4 / 8−7 / 8−7 / 8−6 ODI: 60 / 64 / 62 / 67 / 60 SRS-22r: 3.00 / 2.95 / 3.32 / 3.23 / 3.41
63/M	T10-pelvis psf, L2 PSO	NRS-B/L: 7–7 / 2−1 / 2–4 / 2–2 / 2–2 ODI: 62 / 54 / 47 / 42 / 31 SRS-22r: 2.18 / 2.91 / 2.86 / 3.45 / 3.82
72/F	T2-pelvis PSF, T11-L3, L5/S1 PCO, T11/12, L5/S1 interbody	NRS-B/L: 7−5 / 4−0 / 0–0 / 0–0 / 3−0 ODI: 54 / 27 / 18 / 16 / 16 SRS-22r: 2.14 / 3.50 / 4.32 / 4.41 / 3.50
63/F	T2-pelvis PSF, T9 VCR, L4/5, L5/S1 interbody	NRS-B/L: 1−0 / 5−3 / 2–3 / 1–4 / 6–6 ODI: 6 / 72 / 40 / 40 / 58 SRS-22r: 2.77 / 2.82 / 3.24 / 3.18 / 2.32
61/F	T11-S1 PSF, L1/2 PCO	NRS-B/L: 9−7 / 0–0 / 1−0 / 10−2 / 2–5 ODI: 74 / 18 / 24 / 70 / 31 SRS-22r: -- / 3.59 / 4.32 / 2.23 / 3.81
54/F	T2-pelvis PSF, T7-L3 PCO, L4/5 interbody	NRS-B/L: 9–9 / 9–9 / 6–8 / 9−8 / 6–8 ODI: 78 / 70 / 56 / 70 / 60 SRS-22r: 1.95 / 2.67 / 3.05 / 3.09 / 2.95
61/F	T1-pelvis PSF, T7-11 PCO	NRS-B/L: 7−1 / -- / 0–0 / 0–0 / 0–4 ODI: 58 / -- / 38 / 33 / 62 SRS-22r: -- / -- / 3.27 / 3.45 / 2.45

3 complications that occur in the 2 to 5-year window were major and required reoperation.

Major, surgery-related complications

The majority of surgery-related complications that occurred in the 2 to 5-year window were major, surgery-related complications. It appears that if a complication occurs during the long-term follow-up period, the complication has potential to significantly impact the patient, as the treatment is likely to require a reoperation. Bridwell and colleagues [16] summarized complications in 113 patients with 3 to 5-year follow-up after ASD surgery and found that approximately 1 in10 patients experienced a new complication during this long-term follow-up window. The most common complications were implant failure, pseudarthrosis, or PJK, all of which negatively affected PROs.

Table 6 Comparison of those with major, surgery-related complications and those requiring revision spine surgery during the 2 to 5-year period

	Any major, surgery-related adverse event in the 2–5 year period			Revision spine surgery in the 2–5 year period		
Variable	No *N*=60	Yes *N*=17	*p*-value	No *N*=61	Yes *N*=16	*p*-value
Age, mean (SD)	57.9 (16.2)	57.1 (13.1)	0.849¶	57.3 (16.8)	59.5 (8.9)	0.479
Female, n (%)	50 (83.3)	12 (70.6)	0.300‡	50 (82.0)	12 (75.0)	0.500
BMI, mean (SD)	26.3 (5.8)	26.7 (5.7)	0.770¶	26.2 (5.8)	27.2 (5.6)	0.519
ASA grade*, n (%)			0.209**			0.190**
I	2 (3.3)	0 (0.0)		2 (3.3)	0 (0.0)	
II	36 (60.0)	8 (47.1)		37 (60.7)	7 (43.8)	
III	22 (36.7)	9 (52.9)		22 (36.1)	9 (56.3)	
Preop motor deficit, n (%)	14 (23.3)	6 (35.3)	0.356‡	15 (24.6)	5 (31.3)	0.749
Previous spine surgeries, n (%)	33 (55.0)	11 (64.7)	0.475†	33 (54.1)	11 (68.8)	0.292
Three-column osteotomy, n (%)	46 (76.7)	11 (64.7)	0.356‡	46 (75.4)	11 (68.8)	0.749
Prior major surgery-related adverse event in first 2-years, n (%)	13 (21.7)	6 (35.3)	0.339‡	14 (23.0)	5 (31.3)	0.523
Prior adverse event in first 2-years, n (%)	39 (65.0)	14 (82.4)	0.173†	40 (65.6)	13 (81.3)	0.364
ODI score at 5 years follow-up, mean (SD)	26.5 (21.8)	34.9 (21.8)	0.167¶	26.7 (21.7)	34.4 (22.4)	0.217¶
SRS-22r-total score at 5 years follow-up, mean (SD)	3.68 (0.69)	3.44 (0.74)	0.216¶	3.67 (0.69)	3.48 (0.75)	0.358¶

*for staged procedures worst ASA grade

¶t test

†Chi-Square test

‡Fisher's exact test

**Mantel-Haenszel Chi-Square test

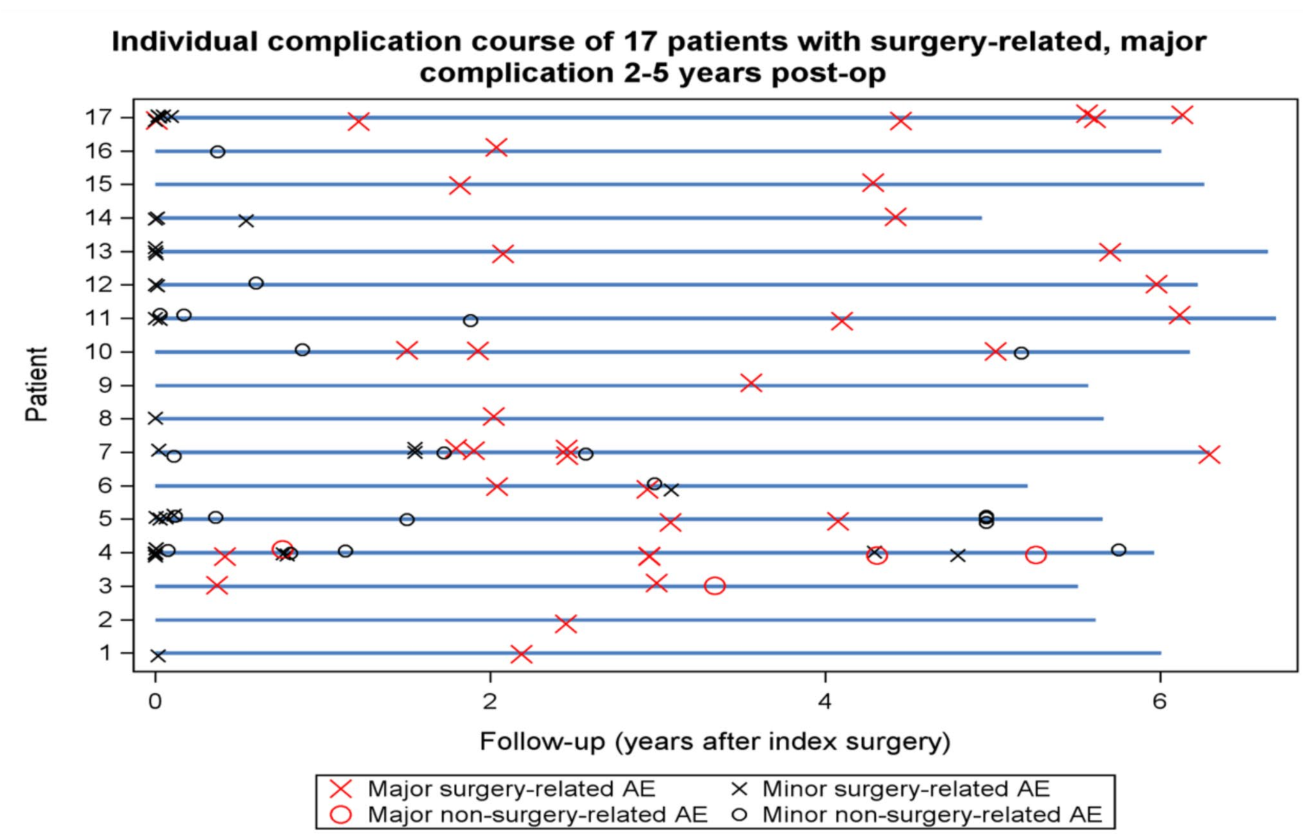

Fig. 1 Individual course of patients with major, surgery-related complications in the 2 to 5-year period

Rod fracture and/or pseudarthrosis comprised the majority of the major surgery-related complications in the 2 to 5-year follow-up period. In previous ASD series, up to 30–35% of rod fractures and/or pseudarthrosis occurred in patients undergoing a 3CO, and in the current study, almost 3 out of 4 patients underwent a 3CO [9, 17–19]. A prospective series of 287 ASD patients with 1-year follow-up reported a 22% rod fracture rate after PSO [20], and that rod breakage occurred at the PSO level in 61-72% of cases [21, 22]. In the current series, patients underwent a primary 3CO in 11/16 of the reoperations, four of which were a primary PSO, and only one of the rod fractures occurring at the PSO site. A likely explanation for these findings is that the fusion has not fully occurred, and it takes many years for the non-union to become symptomatic and place enough stress on the rod to fracture. Using satellite rods at the site of the PSO as well as utilization of multi-rod constructs may help reduce the risk of rod fractures and/or pseudarthrosis [23, 24].

PJK/F is a well-known, frustrating complication in ASD surgery, and occurred in 3 patients during the 2 to 5-year period. Once PJK has been adequately treated with a reoperation, studies have shown similar 5-year PROs between patients with and without PJK [25]. Similarly, other studies have reported that SRS scores did not differ in patients with PJK versus without, except for the self-image domain when PJK exceeded 20° [26]. In terms of risk factors, while some authors have shown that more PJK/F is seen in lower thoracic fusions [27], a systematic review found that an upper thoracic fusion to T1-3 was also risk factor for PJK [28]. Different mechanisms may underlie PJK that occurs in the lower versus upper thoracic region as well, such that lower thoracic failures are due to fractures from poor bone density, and upper failures are more soft-tissue-related [29]. In terms of alignment changes that occurred in 2 patient, Ploumis et al. [30] analyzed 54 ASD patients from a single-center and found that patients were more likely to develop coronal imbalance (defined as a coronal C7 plumb-line > 4 cm) in the 2 to 5-year follow-up window if the they had osteoporosis and/or previous same-site posterior spine surgery with a new anterior approach. Both PJK and residual malalignment remain concerns in the long-term follow-up window.

Regardless of the etiology, reoperation was required in 16 of 25 (64%) patients with surgery-related complications. The most common reason for reoperation was rod fracture with pseudarthrosis, which was revised with several strategies including interbody placement, additional rod placement, upsized implants, and bone morphogenic protein (BMP); all of which can also be utilized in an index procedure to potentially mitigate this complication from occurring [23]. PJK/PJF was also seen, commonly resulting in neurologic deficit. Kryola et al. [31] retrospectively evaluated 79 ASD patients from a single institution with 5-year follow-up and found that the risk for the first reoperation due to mechanical failure within the first year was 13.9%, and risk of reoperation increased to 29.8% during the 5-year follow-up. Among 134 patients undergoing long segment fusion with mean follow-up of 5.8 years, over 1 in 3 patients required reoperation, and 43.8% did so multiple times [32]. Overall, each of these commonly encountered complications confirms that predominantly mechanical complications occur in the 2 to 5-year window. That said, non-mechanical complications still occur, albeit at a lower rate, and include neurological/sensory deficits or deep wound infection.

Minor, surgery-related complications

The most common minor, surgery-related complication was asymptomatic rod fracture with no displacement and no alignment changes. In a large study of 526 patients undergoing long-construct posterior fusions with a median of 2.8 years follow-up, 96 (18.3%) patients developed rod fractures, of which 73% were unilateral and 27% were bilateral [33]. Patients with unilateral rod fracture not requiring revision surgery maintained sagittal alignment correction and had similar mean PROs at 1-year; however, bilateral rod fractures often required surgery with inferior PROs. A similarly large study of rod fractures in 304 ASD patients found that of 54 total rod fractures in 53 patients, 17 (32.1%) were asymptomatic and did not require an operation [34]. Our results confirm these findings that a substantial portion of rod fractures, especially if unilateral and asymptomatic, may not require reoperation, though close follow-up is required. Additional minor, surgery-related complications was radiographic PJK, which also does not always require a reoperation [35]. Surgery for PJK is considered if there is severe deformity, progressive deformity, worsening pain, or neurologic compromise [36]. However, both radiographic PJK and asymptomatic rod fractures require patient counseling and additional surveillance.

No complication vs. complication group comparisons

Although not reaching statistical significance, differences existed between patients who experienced complications between 2 and 5-year follow-up and those without. Patients with major surgery-related complications had a higher ASA grade, more preoperative neurologic deficits, and more previous spine surgery, based on raw comparison of frequencies. We strongly caution against interpretation of these results due to the small sample size; however, clinically meaningful inferences can still be drawn, especially in the follow-up period to 5 years. One important theme, emphasized graphically in Fig. 1, is that earlier complications seemed to be associated with later complications. Except for 3 patients, 14 of 17 patients with major, surgery-related complications in 2 to 5-years had some form of adverse event occur in the preceding 2 years after surgery. Thus, patients with major or minor adverse events in the perioperative to 2-year window after surgery should be closely watched for longer-term complications. In terms of PROs, although lacking statistical significance, patients who experienced complications between 2 and 5-year follow up presented with worse PROs at the 5 year follow up, particularly among the ODI and SRS-22r total scores. In a multicenter, prospective, longitudinal study, Pellise et al. found that the unplanned reoperation following the index surgery was associated with a diminished gain in health related quality of life (HRQOL) scores at 5 years of follow up [37]. The authors also found that although resolution of the denoted complication reduced the impact reoperations have on HRQOL gain, it did not entirely neutralize it and return it to the same levels as those who did not experience reoperations. This may explain the differences in PROs observed among our patient sample with the lack of statistical difference possibly being related to insufficient study power.

Limitations

Despite its prospective, multicenter design, many patients were unfortunately lost-to-follow-up in the 5-year window, which undermines the validity of these results. Only 28.3% of patients had data complete enough to perform the minimum 5-year analysis. The loss of patients speaks to the difficulty of long-term follow-up in a global surgical population and also questions the generalizability of our findings. It is unknown whether patients more or less satisfied with their surgical care returned to clinic, which makes the current data vulnerable to bias. However, it is fair to assume that patients who were also satisfied with their care may be more reluctant to return to clinic for follow up. Second, as with multicenter, international studies, significant heterogeneity existed in each patient, as surgical plans and decisions are variable among all of the surgeons participating in this study possibly affecting the patients' postoperative recovery. Third, due to small sample sizes, we could not conduct a predictive analysis of patient and surgical risk factors associated with complications. Fourth, because the original study was meant to close at 2-years, some operative details were missing from the revision surgeries performed in the 2- to 5-year range due to insufficient study documentation. Lastly, while mean values for each PRO at the different time point would have been helpful for Table 5, we decided to focus on a granular description of each patient and tell each patient's individual postoperative trajectory.

Conclusions

During the 2 to minimum 5-year follow-up period of the Scoli-RISK-1 study, 25 patients (32.5%) experienced surgery-related complications, 65.7% of which were major and 62.9% required reoperation Rod fracture and/or pseudarthrosis was the most common major, surgery-related complication. Neurologic complications were not found to be major drivers of reoperation within the aforementioned time period. Surprisingly, 5-year PROs were similar regardless of whether the patient had a major, surgery-related complication in the 2–5-year follow-up time period.

Acknowledgements This study was funded by AO Spine through the AO Spine Knowledge Forum Deformity, the Scoliosis Research Society (SRS), and Norton Healthcare. AO Spine Knowledge Forum Deformity is a focused group of international deformity experts. AO Spine is a clinical division of the AO Foundation, which is an independent medically-guided not-for-profit organization. Study support was provided directly through the AO Spine Research Department and the AO Innovation Translation Center, Clinical Evidence.

Declarations

Ethical approval Not applicable.

Financial disclosures None.

Conflicts of interest None.

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Authors and Affiliations

Meghan Cerpa[1] · Scott L. Zuckerman[2] · Lawrence G. Lenke[1] · Leah Y. Carreon[3] · Kenneth M. C. Cheung[4] · Michael P. Kelly[5] · Michael G. Fehlings[6] · Christopher P. Ames[7] · Oheneba Boachie-Adjei[8] · Mark B. Dekutoski[9] · Khaled M. Kebaish[10] · Stephen J. Lewis[6] · Yukihiro Matsuyama[11] · Ferran Pellisé[12] · Yong Qiu[13] · Frank J. Schwab[14] · Justin S. Smith[15] · Christopher I. Shaffrey[16]

✉ Lawrence G. Lenke
ll2989@cumc.columbia.edu

1 Department of Orthopaedic Surgery, New York Presbyterian, The Daniel and Jane Och Spine Hospital, Columbia University Medical Center, Broadway, New York, NY 5141, 10034, USA

2 Vanderbilt Univerity Medical Center, Nashville, TN, USA

3 Norton Leatherman Spine Center, Louisville, KY, USA

4 Li Ka Shing Faculty of Medicine, The University of Hong Kong, Pokfulam, Hong Kong

5 Rady's Children's Hospital, San Diego, CA, USA

6 University of Toronto and Toronto Western Hospital, Toronto, ON, Canada

7 University of California San Francisco, San Francisco, CA, USA

8 The FOCOS Hospital, PantangPantang West, Republic of Ghana

9 Marshfield Clinic Eau Claire Center, Eau Claire, WI, USA

10 Johns Hopkins University, Baltimore, MD, USA

11 Hamamatsu University School of Medicine, Hamamatsu, Shizuoka, Japan

12 Hospital Universitari Vall d'Hebron, Barcelona, Spain

13 Affiliated Drum Tower Hospital of Nanjing University Medical School, Nanjing, China

14 Hospital for Special Surgery, New York, NY, USA

15 University of Virginia, Charlottesville, VA, USA

16 Duke University Medical Center, Durham, NC, USA