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DEFORMITY

# Neurologic Outcomes of Complex Adult Spinal Deformity Surgery

*Results of the Prospective, Multicenter Scoli-RISK-1 Study*

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**Study Design.** Prospective, multicenter, international observational study.

**Objective.** To evaluate motor neurologic outcomes in patients undergoing surgery for complex adult spinal deformity (ASD).

**Summary of Background Data.** The neurologic outcomes after surgical correction for ASD have been reported with significant variability and have not been measured as a primary endpoint in any prospective, multicenter, observational study.

**Methods.** The primary outcome measure was the change in American Spinal Injury Association (ASIA) Lower Extremity Motor Scores (LEMS) obtained preoperatively, and at hospital discharge, 6 weeks and 6 months postoperatively.

**Results.** A total of 273 patients with complex ASD underwent surgery at 15 sites worldwide. One patient was excluded for lack of preoperative LEMS. The remaining 272 patients were divided into two groups: normal preoperative LEMS (=50) (Preop NML, N = 204, 75%) and abnormal preoperative LEMS (<50) (Preop ABNML, N = 68, 25%). At hospital discharge, 22.18% of patients showed a decline in LEMS compared with 12.78% who showed an improvement. At 6 weeks, there was a significant change compared with discharge: 17.91% patients showed a decline in LEMS and 16.42% showed an improvement. At 6 months, 10.82% patients showed a decline in preoperative LEMS, 20.52% improvement, and 68.66% maintenance. This was a significant change compared with 6 weeks and at discharge.

**Conclusion.** Although complex ASD surgery can restore neurologic function in patients with a preoperative neurologic deficit, a significant portion of patients with ASD experienced postoperative decline in LEMS. Measures that can anticipate and reduce the risk of postoperative neurologic complications are warranted.

**Key words:** acute neurologic complications, adult spinal deformity (ASD), ASIA neurologic exam, lower extremity motor score (LEMS), spinal deformity surgery, spinal osteotomy.

**Level of Evidence:** 3

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The surgical correction of adult spinal deformity (ASD) continues to evolve with the use of pedicle screw fixation and complex osteotomies. Goals of surgical correction, including restoration of spinopelvic alignment and sagittal balance, are now better defined. Surgical complications have been reported extensively; however, most studies were retrospective and lacked rigorous validated assessment.[1–32] The aim of this analysis was to report lower extremity motor function before and after surgical correction of complex ASD and evaluate the change in function over time.

## MATERIALS AND METHODS

This prospective, observational, international, multicenter cohort study evaluated the neurologic complications associated with surgical correction of complex ASD. For this study, complex ASD surgery was defined as: a major Cobb angle of $\geq 80^\circ$ in the coronal and/or sagittal plane; corrective osteotomies for congenital spinal deformity; corrective osteotomies for revision of spinal deformity (any type); 3-column spinal osteotomy (*i.e.*, pedicle subtraction osteotomy (PSO), vertebral column resection (VCR) between C7-L5 inclusive); reconstruction for myelopathy because of spinal deformity; or deformity reconstruction with concomitant spinal cord decompression with ossification of the ligamentum flavum (OLF) or ossification of the posterior longitudinal ligament (OPLL).

Of more than 100 spinal deformity centers that applied, 15 were selected to participate—nine in North America, three in Europe, and three in Asia. The respective ethical committees or Institutional Review Boards at all participating sites granted study approval. All patients signed informed consent prior to enrollment. The study is registered with clinicaltrials.gov under NCT01305343.

From September 2011 to October 2012, 43 surgeons enrolled 273 consecutive patients. One patient lacked a baseline neurologic lower extremity motor score, leaving 272 patients for analysis. The surgical approach, instrumentation, corrective maneuvers, and use of bone grafts and bone substitutes were at the discretion of the operating surgeon. Key inclusion criteria were patient age between 18 and 80 years and diagnosis of ASD with an apex of the major deformity in the cervicothoracic or thoracolumbar region between C7 and L2 inclusive (Table 1).

Preoperative upright coronal and sagittal X-rays were performed in all patients. The patient-reported outcomes collected before surgery and at 6 weeks and 6 months postoperative included the Oswestry Disability Index (ODI) v2.1a, Numeric Pain Rating score (NPR) at back, NPR at leg, SF-36v2, and Scoliosis Research Society (SRS-22R) questionnaire. An American Spinal Injury Association (ASIA, Figure 1) neurologic examination was performed by an ASIA-certified examiner within 6 weeks before surgery, at hospital discharge, and at 6 weeks and 6 months. Anticipated and unanticipated adverse events (AE) were collected at each visit.

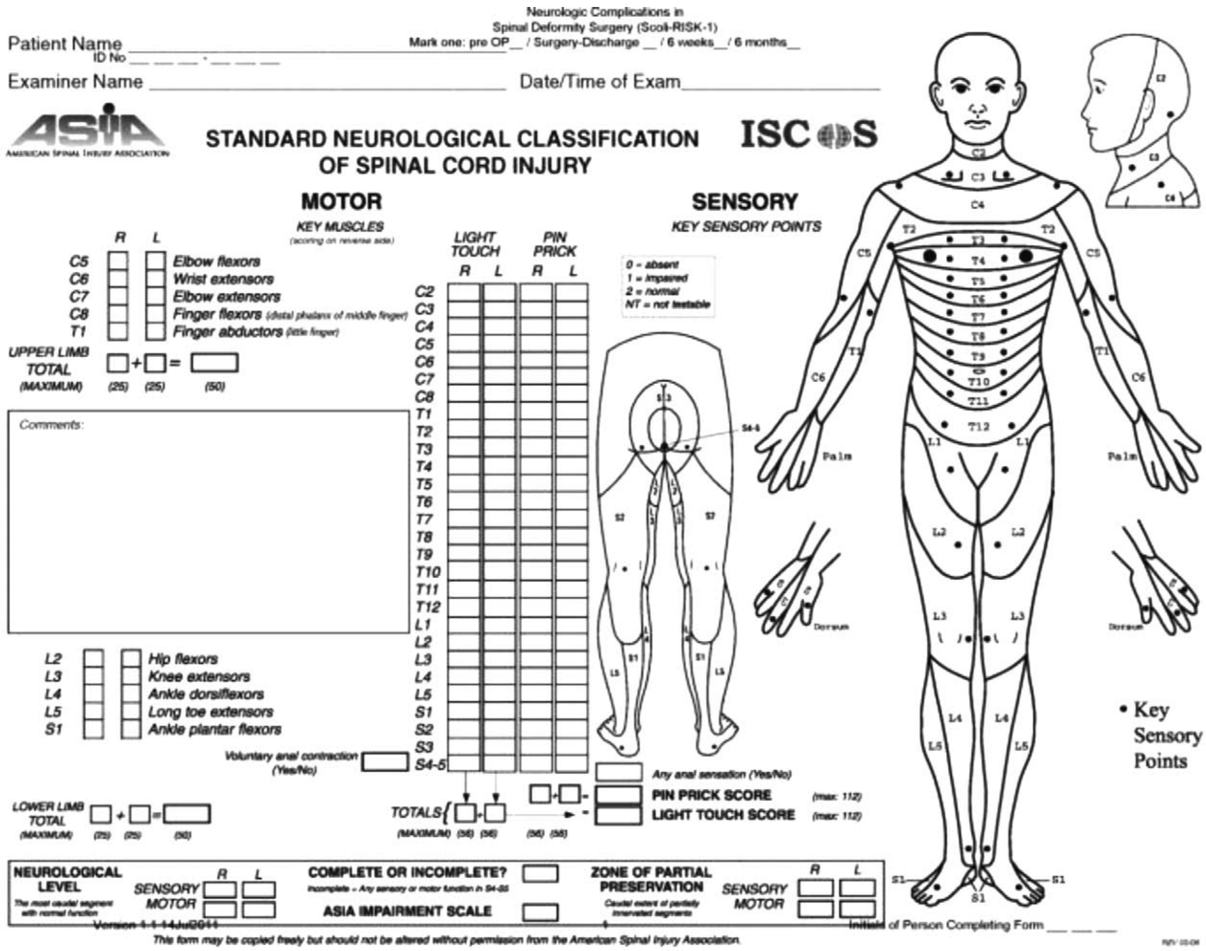
The primary outcome measure was the change in ASIA LEMS at each time-point. The LEMS evaluates motor function on a scale of 0 (no motor function) to 5 (full motor function) for five lower extremity muscle groups: hip flexors (psoas-L2), knee extension (quadriceps-L3), ankle and toe dorsiflexion (anterior tibialis-L4), great toe extension (extensor hallucis longus-L5), and plantar flexion (gastric soleus-S1). Each muscle group is rated on a scale of 0 (no motor function) to 5 (full motor function). The LEMS has a maximum of 50 points (25 points per side).

Differences in preoperative characteristics and surgical approach between Preop NML and Preop ABNML LEMS groups were analyzed using Fisher exact test for categorical variables and the *t* test for continuous variables. Changes in LEMS were analyzed using two-way Repeated Measurements Analysis of Variance (ANOVA) with one fixed factor ("GROUP" Preop NML, Preop ABNML), one repeated factor ("TIME") with three levels (preoperative, 6 weeks, 6 months), and the interaction effect between GROUP and TIME factors. Differences between follow-up and preoperative values within each LEMS group were analyzed using a paired *t* test. A *P* value was adjusted using the Hochberg approach for family-wise multiplicity in testing. LEMS changes were classified as "maintenance," "improvement," and "decline" compared with the preoperative score.

**TABLE 1. Study Inclusion and Exclusion Criteria**

| | |
|---|---|
| Inclusion Criteria | Signed informed consent |
| | Age 18 to 80 years old inclusive |
| | Diagnosis of ASD with an apex of the major deformity in the cervicothoracic or thoracolumbar region (apex between C7 and L2 inclusive) with any of the following deformity characteristics |
| | Primary scoliosis, kyphosis, or kyphoscoliosis with a major Cobb $\geq 80^\circ$ in the coronal or sagittal plane |
| | Congenital spinal deformity undergoing corrective spinal osteotomy |
| | Revision spinal deformity undergoing corrective spinal osteotomy |
| | Any patient undergoing a 3-column spinal osteotomy (*i.e.*, pedicle subtraction osteotomy, vertebral column resection) from C7 to L5 inclusive |
| | Any patient with preoperative myelopathy because of their spinal deformity |
| | Any patient with ossification of the ligamentum flavum or posterior longitudinal ligament and a deformity that needs concomitant reconstruction along with decompression of the spinal cord |
| Exclusion Criteria | Unlikely to comply with follow-up |
| | Recent history $\leq 3$ months of substance dependency or psychosocial disturbance |
| | Presence of active malignancy |
| | Has active, overt bacterial infection, systemic or local |
| | Recent ($\leq 3$ months) history of significant spinal trauma/injury/fracture/malignancy in the spinal region |
| | Patients with complete, long-term paraplegia |
| | Pregnant or nursing women, unable to agree not to become pregnant for a period of 6 months after surgery |
| | Prisoners |
| | Institutionalized individuals |

*ASD indicates adult spinal deformity.*


Neurologic Complications in
Spinal Deformity Surgery (Scoli-RISK-1)

Patient Name ______ Mark one: pre OP__ / Surgery-Discharge __ / 6 weeks__/ 6 months__
ID No __ __ __ - __ __ __

Examiner Name ______ Date/Time of Exam ______

ASIA AMERICAN SPINAL INJURY ASSOCIATION

STANDARD NEUROLOGICAL CLASSIFICATION
OF SPINAL CORD INJURY

ISCoS

MOTOR
KEY MUSCLES

| | R | L | |
|---|---|---|---|
| C5 | | | Elbow flexors |
| C6 | | | Wrist extensors |
| C7 | | | Elbow extensors |
| C8 | | | Finger flexors (distal phalanx of middle finger) |
| T1 | | | Finger abductors (little finger) |

UPPER LIMB TOTAL (MAXIMUM) (25) + (25) = (50)

Comments:

| | R | L | |
|---|---|---|---|
| L2 | | | Hip flexors |
| L3 | | | Knee extensors |
| L4 | | | Ankle dorsiflexors |
| L5 | | | Long toe extensors |
| S1 | | | Ankle plantar flexors |

Voluntary anal contraction (Yes/No)

LOWER LIMB TOTAL (MAXIMUM) (25) + (25) = (50)

SENSORY
KEY SENSORY POINTS

LIGHT TOUCH R L; PIN PRICK R L

C2, C3, C4, C5, C6, C7, C8, T1, T2, T3, T4, T5, T6, T7, T8, T9, T10, T11, T12, L1, L2, L3, L4, L5, S1, S2, S3, S4-5

0 = absent
1 = impaired
2 = normal
NT = not testable

TOTALS (MAXIMUM) (56) (56) (56) (56)

Any anal sensation (Yes/No)
PIN PRICK SCORE (max: 112)
LIGHT TOUCH SCORE (max: 112)

• Key Sensory Points

NEUROLOGICAL LEVEL — The most caudal segment with normal function — SENSORY R L; MOTOR R L

COMPLETE OR INCOMPLETE? Incomplete = Any sensory or motor function in S4-S5

ASIA IMPAIRMENT SCALE

ZONE OF PARTIAL PRESERVATION — Caudal extent of partially innervated segments — SENSORY R L; MOTOR R L

Version 1.1 14Jul2011

Initials of Person Completing Form __ __ __

This form may be copied freely but should not be altered without permission from the American Spinal Injury Association.

**Figure 1.** American Spinal Injury Association (ASIA) examination form.

Analysis was generated using SAS/STAT software v9.3 of the SAS System for Windows (SAS Institute Inc, Cary, NC). The study utilized the Web-based online data capture system (eCRF) OpenClinica.

## RESULTS

Between September 2011 and October 2012, 273 patients were enrolled. One patient lacked preoperative LEMS and was excluded. The remaining 272 patients were divided into the Preop NML group (N = 204, 75%), with preoperative LEMS of 50 (no abnormalities), and the Preop ABNML group (N = 68, 25%), with preoperative LEMS < 50.

Thirteen patients (4.78%) missed their 6-week assessment; eight of these 13 missing values were imputed with the available 6-month data for the same patients utilizing a last value carry backward (LVCB) approach. Twenty (7.35%) patients missed their 6-month assessment; 16 of these 20 missing values were imputed with the available 6-week values for the same patients utilizing a last value carry forward (LVCF) approach. Consequently, data were available for 266 of 272 patients (97.80%) for hospital discharge, and 268 (98.53%) for 6-week and 6-month assessments.

There were 183 (67.28%) women and 89 (32.72%) men. Mean age was 57.42 (SD = 15.31, range 18–80 yrs). Diagnoses included primary coronal/sagittal deformity > 80° (n = 87, 31.99%); congenital deformity requiring osteotomy (n = 13, 4.78%); revision deformity requiring osteotomy (n = 132, 48.53%); and/or patients undergoing a 3-column spinal osteotomy (3-CO) (n = 215, 79.04%). Curve magnitudes for the congenital deformity patients averaged: coronal 54° (range 36–94°) and sagittal 60° (range 35–99).

There were more women in the Preop NML group than in the Preop ABNML group (70.59% and 57.35%, respectively, $P = 0.0525$). There were more patients with previous spine surgery in the Preop ABNML group than in the Preop NML group (76.47% and 56.37%, respectively, $P = 0.0038$). There were no differences between the groups in age, race, smoking status, surgical approach, or use of staged surgery (Table 2). No patient experienced sustained postoperative lower extremity paraplegia after the initial surgical procedure.

Overall, the Preop NML group showed a decline in LEMS while the Preop ABNML group showed improvement (GROUP effect $P < 0.0001$). Furthermore, there was a significant TIME effect ($P < 0.001$); the pattern of changes

**TABLE 2. Demographics and Surgical Approach by Preoperative LEMS Status Group**

| | NML (LEMS = 50) (N = 204) | ABNML (LEMS < 50) (N = 68) | *P* |
|---|---|---|---|
| Female sex | 144 (70.59%) | 39 (57.35%) | 0.0525 |
| Age (yr) | 56.81 (15.92) | 59.25 (13.26) | 0.2557 |
| Race | | | 0.0723 |
| White or Caucasian | 164 (80.39%) | 51 (75.00%) | |
| Black or African-American | 2 (0.98%) | 0 (0.0%) | |
| Native American | 1 (0.49%) | 0 (0.0%) | |
| East Asian | 36 (17.65%) | 14 (20.59%) | |
| Other | 1 (0.49%) | 3 (4.41%) | |
| Tobacco Smoking | 18 (8.82%) | 8 (11.76%) | 0.4796 |
| Previous spine surgery(ies) | 115 (56.37%) | 52 (76.47%) | 0.0038 |
| Surgical approach | | | 0.8691 |
| Posterior only | 155 (75.98%) | 53 (77.94%) | |
| Posterior + Anterior | 49 (24.02%) | 15 (22.06%) | |
| Number of surgical stages | | | |
| Single-stage | 164 (80.39%) | 55 (80.88%) | |
| Multi-stage | 40 (19.61%) | 13 (19.12%) | 0.7613 |

*LEMS indicates lower extremity motor score.*

over time differed between the two groups (GROUP∗TIME effect $P < 0.001$). The Preop NML group showed a decline in LEMS at all three follow-up assessments, whereas the Preop ABNML group showed significant improvement in LEMS at 6 months (Table 3).

At hospital discharge in the Preop NML group, 21.00% of patients showed a decline in LEMS, which was transitory in about half of those affected. At 6 months, 12.38% patients showed a persistent decline in LEMS. At hospital discharge in the Preop ABNML group, 25.76% of patients showed a decline in LEMS, but only 6.06% showed a persistent decline at 6 months.

At 6 months, the majority (83.33%) of patients in the Preop ABNML group showed significant improvement in LEMS (Table 4).

Overall, at hospital discharge, 22.18% of patients showed a decline in LEMS and 12.78% showed improvement. At 6 weeks, there was a significant change in LEMS compared with hospital discharge ($P = 0.0042$): 17.91% patients showed a decline in LEMS and 16.42% showed improvement. At 6 months, 10.82% of patients showed a decline in LEMS, 20.52% showed improvement, and 68.66% showed maintenance; this was a significant change compared with LEMS at 6 weeks ($P = 0.0011$) and at hospital discharge ($P < 0.0001$). At 6 months, five patients showed a 6 to 10 point decline in LEMS, four showed >10 point decline, 13 showed a 6 to 10 point improvement, and four showed >10 point improvement (Table 5).

We evaluated the LEMS decline in patients who were treated by those surgeons who only contributed one patient each to the study ($n = 18$) *versus* those who contributed at least two or more cases. By $\chi^2$ analysis, we found no difference in the rate of LEMS decline in those two surgeon populations at hospital discharge ($P = 0.285$), at 6 weeks postoperative ($P = 0.495$), or at 6 months postoperative ($P = 0.897$).

One patient with congenital thoracic kyphoscoliosis underwent a 3-CO with spinal cord monitoring loss and immediate postoperative acute paraplegia. The patient showed slow but steady recovery in LEMS, improving to 30 by hospital discharge, 40 at 6 weeks, and 50 (normal) at 6 months. Another patient underwent a TL-sacrum PSF for adult lumbar idiopathic scoliosis and underwent a revision surgery 7 weeks postoperative for proximal junctional kyphosis with spinal cord monitoring loss and clinical paraplegia that had not improved at 6 months follow-up.

**TABLE 3. ASIA LEMS by Follow-Up and Preoperative LEMS Status Group**

| | ABNML (LEMS < 50) | NML (LEMS = 50) |
|---|---|---|
| Preoperative | $43.78 \pm 7.58$ | $50.00 \pm 0.00$ |
| Hospital discharge | $43.67 \pm 8.33$ | $48.99 \pm 3.04^*$ |
| Six weeks | $44.98 \pm 8.05$ | $49.02 \pm 3.30^*$ |
| Six months | $47.02 \pm 6.28^*$ | $49.35 \pm 2.86^*$ |

**Significant difference compared with preoperative ($P < 0.05$).*
*LEMS indicates lower extremity motor score.*

**TABLE 4. Changes in LEMS Compared With Baseline**

| | Preop NML (LEMS = 50) | Preop ABNML(LEMS < 50) | *P** |
|---|---|---|---|
| Discharge (N = 266) | | | <0.0001 |
| Maintenance | 158 (79.00%) | 15 (22.73%) | |
| Improvement | 0 (0.00%) | 34 (51.52%) | |
| Decline | 42 (**21.00%**) | 17 (**25.76%**) | |
| Six weeks (N = 268) | | | <0.0001 |
| Maintenance | 166 (82.18%) | 10 (15.15%) | |
| Improvement | 0 (0.00%) | 44 (66.67%) | |
| Decline | 36 (17.82%) | 12 (18.18%) | |
| Six months (N = 268) | | | <0.0001 |
| Maintenance | 177 (87.62%) | 7 (10.61%) | |
| Improvement | 0 (0.00%) | 55 (83.33%) | |
| Decline | 25 (**12.38%**) | 4 (**6.06%**) | |

**Fisher exact test for the difference between the "LEMS = 50" and "LEMS < 50."*
*LEMS indicates lower extremity motor score.*

## DISCUSSION

Loss of neurologic function is one of the most significant complications after complex ASD surgery. The reported incidence of neurologic deficits in adults ranges from 0% to over 10%.[1–32] This variability is because of incomplete follow-up, heterogeneous patient cohorts and surgical procedures, and nonstandardized outcome measures. Only five studies in the literature[33–37] were based on prospectively collected data specifically identifying postoperative neurologic complications, and three were from a single institution.[34,35,37] None of those five studies used a rigorous and validated scoring system to quantify neurologic function before and after surgery. All five studies could more accurately be described as retrospective reviews of prospectively collected data. A prospective study design is required to collect accurate information on the rate, type, and outcome of postoperative neurologic deficits, information that is fundamental for informed decision-making and for use as a baseline when evaluating continuously evolving techniques and technologies.

Our study found a decline in LEMS at hospital discharge in 22.18% of patients who underwent correction of adult ASD; as neurologic function recovered over time, this rate decreased to 17.91% at 6 weeks and 10.82% at 6 months. These rates of perioperative motor decline are by far the highest reported to date, and the reasons are multifactorial: a study population of "high-risk" ASD patients undergoing complex reconstructions; the sensitivity to change of the ASIA neurologic examination; the prospective study design; a comprehensive data collection system; and high rates of patient follow-up at all time-points.

The Scoliosis Research Society Morbidity and Mortality Committee (SRS M&M) reported the largest review of new neurologic deficits after 108,419 spinal procedures. A new postoperative neurologic deficit was documented for 1064 (1.0%) patients, including 662 nerve root, 74 cauda equina, and 283 cord-related. Deficits were unspecified in 35 patients. Revision cases had a 41% higher rate of neurologic deficits compared with primary cases. Surprisingly, pediatric cases had a 59% higher rate compared with adult cases. This study had significant limitations, including a diverse range of diagnoses and surgical procedures; nonvalidated outcome measures; no quality assurance for data integrity; and undocumented follow-up time-points. Most importantly, the data were derived from voluntary reporting of complications by SRS members in a nonconsecutive patient series.[38] Our study eliminated these potential limitations in study design and management while evaluating only the most complex ASD reconstructions. In another study, the same SRS M&M database was queried for 683 procedures for Scheuermann's kyphosis patients. The acute neurologic complication rate was 1.9%, including four spinal cord deficits (0.6%). Not surprisingly, complications were more common among adults (22%) compared with pediatric patients (12%).[39]

In a large single-center study, Qiu *et al* found a 1.89% overall rate of neurologic deficits after 1373 scoliosis correction procedures. Per group, the rate was 1.06% in adolescent idiopathic scoliosis patients, 2.89% in congenital scoliosis patients, 3.32% in scoliosis patients with hyperkyphosis (>440°), and 1.38% in scoliosis patients without hyperkyphosis.[40] In a retrospective study of 306 adult scoliosis patients who underwent primary surgery, Charosky *et al*[41] reported a 7% rate of new neurologic deficits, with two patients (0.6%) developing late cord-level deficits.

Patients undergoing complex spinal osteotomy surgery for correction of a large magnitude scoliosis or kyphosis (*i.e.*, >80°), or those undergoing a 3-CO (PSO and VCR), are at a relatively high risk for postoperative neurologic deficits[42] because of the direct manipulation of neurologic elements and the acute change in spinal canal alignment and shape. Several studies have addressed complex spinal osteotomies for deformity.[37,43–48] Suk *et al* reviewed 70 adults

**TABLE 5. Changes in LEMS Compared With Baseline by Ordinal Categories**

| | ALL | Preop ABNML LEMS < 50 | Preop NML LEMS = 50 |
|---|---|---|---|
| Change in LEMS at discharge | | | |
| Decline | 22.18% | | |
| Decline more than 10 | 5 (1.88%) | 2 (3.03%) | 3 (1.50%) |
| Decline 6 to 10 | 12 (4.51%) | 4 (6.06%) | 8 (4.00%) |
| Decline 1 to 5 | 42 (15.79%) | 11 (16.67%) | 31 (15.50%) |
| Maintenance | 173 (65.04%) | 15 (22.73%) | 158 (79.00%) |
| Improvement 1 to 5 | 31 (11.65%) | 31 (46.97%) | 0 (0.0%) |
| Improvement 6 to 10 | 2 (0.75%) | 2 (3.03%) | 0 (0.0%) |
| Improvement more than 10 | 1 (0.38%) | 1 (1.52%) | 0 (0.0%) |
| Change in LEMS at 6 weeks | | | |
| Decline | 17.91% | | |
| Decline more than 10 | 7 (2.61%) | 3 (4.55%) | 4 (1.98%) |
| Decline 6 to 10 | 12 (4.48%) | 3 (4.55%) | 9 (4.46%) |
| Decline 1 to 5 | 29 (10.82%) | 6 (9.09%) | 23 (11.38%) |
| Maintenance | 176 (65.67%) | 10 (15.15%) | 166 (82.18%) |
| Improvement 1 to 5 | 33 (12.31%) | 33 (50.00%) | 0 (0.0%) |
| Improvement 6 to 10 | 10 (3.73%) | 10 (15.15%) | 0 (0.0%) |
| Improvement more than 10 | 1 (0.37%) | 1 (1.52%) | 0 (0.0%) |
| Change in LEMS at 6 mo | | | |
| Decline | 10.82% | | |
| Decline more than 10 | 4 (1.49%) | 1 (1.52%) | 3 (1.49%) |
| Decline 6 to 10 | 5 (1.87%) | 0 (0.0%) | 5 (2.48%) |
| Decline 1 to 5 | 20 (7.46%) | 3 (4.55%) | 17 (8.42%) |
| Maintenance | 184 (68.66%) | 7 (10.61%) | 177 (87.62%) |
| Improvement 1 to 5 | 38 (14.18%) | 38 (57.58%) | 0 (0.0%) |
| Improvement 6 to 10 | 13 (4.85%) | 13 (19.70%) | 0 (0.0%) |
| Improvement more than 10 | 4 (1.49%) | 4 (6.06%) | 0 (0.0%) |

*LEMS indicates lower extremity motor score.*

with spinal deformity who underwent posterior VCR. The neurologic complication rate was 8.6%, including two complete spinal cord injuries (2.9%) and four incomplete nerve root injuries (5.7%). The two complete spinal cord deficits occurred in patients with severe scoliosis and thoracic kyphosis, both of whom had significant preoperative cord compromise.[43] Buchowski *et al* assessed early complications in 108 adults who underwent PSO for fixed sagittal imbalance. Twelve patients developed new neurologic deficits (11.1%), three of which were permanent (2.8%).[37] Lu *et al* reviewed 54 patients who underwent single-stage posterior VCR for severe, rigid spinal deformity. Five patients (9.3%) developed neurologic complications, including one case of delayed complete paraplegia.[44] Lenke *et al* reviewed 43 children and adults with severe spinal deformity who underwent posterior VCR. Although seven patients (18%) lost intraoperative monitoring data during surgery, data returned to baseline after prompt surgical intervention. Two patients (4.7%) with postoperative nerve root deficits recovered at 2 weeks and 6 months, respectively.[45] Xie *et al* reviewed 28 adults treated with posterior VCR for correction of severe, rigid spinal deformity curves >100°. The authors reported a neurologic complication rate of 17.9%, including one case of late-onset paralysis.[46] Ma *et al* reviewed 321 children and adults with scoliosis or kyphosis treated with a posterior osteotomy (226 PSO and 95 VCR). Eleven patients (3.4%) developed new neurologic deficits. At last follow-up, seven patients had completely recovered, two were partially recovered, and two failed to improve. Patients with a pre-existing neurologic deficit had a higher risk of postoperative neurologic deficit than patients with intact preoperative neurologic function.[47] Kim *et al* reviewed 233 adults with spinal deformity treated with posterior VCR, and found an overall complication rate of 40.3%. There were more complications in older patients (>35 yr) than younger, and most cases of postoperative paraplegia had preoperative neurologic deficit.[48] We also found a higher rate of postoperative neurologic deficit (25.76%) in patients with a preoperative deficit compared with patients with intact preoperative neurologic function (22.17%). Importantly, in our study, there were no permanent complete neurologic deficits after the index procedure. Although one patient awoke with complete paraplegia, neurologic function was improved at hospital discharge and was normal at 6 months. Another patient revised for proximal junctional kyphosis was rendered paraplegic during the revision surgery. Potential risk factors for neurological complications such as EBL, type of approach, problems occurring during osteotomy, or screw placement are all discussed in a separate manuscript that is currently in progress.

One weakness of our study was its heterogeneous diagnostic and treatment-related inclusion criteria. Second, some subjective bias may have been introduced because the ASIA examination was performed by different examiners at multiple sites. We attempted to mitigate this potential bias by having all examiners become ASIA-certified. Third, we only reported on the ASIA LEMS component, as the sensory component would have introduced additional subjective assessment bias. Fourth, because we only studied spinal deformity patients undergoing the most complex and neurologically risky correction procedures, our results should not be applied to all spinal deformity patients undergoing spinal correction. Finally, although enrollment represented 43 surgeons from 15 high-volume academic medical centers, 67.6% of the patients were enrolled by the eight highest-enrolling surgeons with 18 surgeons enrolling only one patient, thus challenging the applicability of these results to other spinal deformity surgeons worldwide.

The strengths of our study included its prospective, multicenter nature and our use of the ASIA examination before surgery and at three postoperative time-points. Because many subtle neurologic deficits may go undetected by retrospective studies of single or multicenter databases, our rigorous assessment of neurologic function using a validated measurement system provided sensitivity for even subtle changes in postoperative neurologic function. Third, our study ensured that any new postoperative lower extremity deficit was documented as a surgical complication, even if minor and transient. Fourth, our study was adequately powered with a prestudy power analysis of patient enrollment exceeded by the actual consecutive enrollment in the expected study time frame. Finally, our study was supported organizationally and financially by the Scoliosis Research Society (SRS), the oldest and most prestigious global spinal deformity society, and AOSpine International, the largest organization of spinal surgeons in the world.

## CONCLUSIONS

Decline in neurologic function after complex ASD surgery is common and more frequent than reported previously. The Scoli-RISK-1 Trial documented a lower extremity motor weakness rate of 22.18% at hospital discharge after complex ASD surgery. Neurologic function recovered over time to 17.91% at 6 weeks and 10.82% at 6 months. Most patients with a decline in LEMS after surgery showed significant improvement by 6 months follow-up. The neurologic complication rate seen in our prospective, multicenter, observational study, which utilized a strict protocol of neurologic evaluations, should be considered the accurate and expected neurologic outcome after complex ASD surgery at this time. Future prospective studies evaluating new technologies, techniques, and therapies for the treatment of ASD may significantly improve postoperative neurologic decline and long-term neurologic function.

## ➢ Key Points

- ❑ The SRS/AOSpine collaborative Scoli-RISK-1 trial was a prospective, multicenter, international, observational study ascertaining neurologic outcomes after complex ASD surgery.
- ❑ Over a 13-month period, 273 patients were enrolled at 15 sites worldwide.
- ❑ At hospital discharge, 22.18% of patients showed a decline in lower extremity motor scores (LEMS). Motor neurologic function recovered over time with a 17.91% rate of decline at 6 weeks and 10.82% at 6 months postoperative.
- ❑ This reported rate of motor neurologic deficits should be considered the expected outcome for these complex ASD procedures because of the prospective, multicenter design, and strict protocol-driven nature of this study.

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