Lower Extremity Motor Function Following Complex Adult Spinal Deformity Surgery
AO Spine International and SRS Scoli-RISK-1 Study Group

Published in:
Journal of Bone and Joint Surgery: American Volume

DOI:
10.2106/JBJS.17.00575

Publication date:
2018

Document version
Publisher's PDF, also known as Version of record

Document license:
CC BY-NC-ND

Citation for published version (APA):
AO Spine International and SRS Scoli-RISK-1 Study Group (2018). Lower Extremity Motor Function Following Complex Adult Spinal Deformity Surgery: Two-Year Follow-up in the Scoli-RISK-1 Prospective, Multicenter, International Study. Journal of Bone and Joint Surgery: American Volume, 100(8), 656-665.
https://doi.org/10.2106/JBJS.17.00575
Lower Extremity Motor Function Following Complex Adult Spinal Deformity Surgery

Two-Year Follow-up in the Scoli-RISK-1 Prospective, Multicenter, International Study

Lawrence G. Lenke, MD, Christopher I. Shaffrey, MD, Leah Y. Carreon, MD, MSc,
Kenneth M.C. Cheung, MBBS, MD, FRCS, FHKCONS, FHKAM(Orth), Benny T. Dahl, MD, PhD, DMSci, and
Michael G. Fehlings, MD, PhD, FRCSC, on behalf of the AO Spine International and SRS Scoli-RISK-1 Study Group*

Background: The reported neurologic complication rate following surgery for complex adult spinal deformity (ASD) is variable due to several factors. Most series have been retrospective with heterogeneous patient populations and use of nonuniform neurologic assessments. The aim of this study was to prospectively document lower extremity motor function by means of the American Spinal Injury Association (ASIA) lower extremity motor score (LEMS) before and through 2 years after surgical correction of complex ASD.

Methods: The Scoli-RISK-1 study enrolled 272 patients with ASD, from 15 centers, who had undergone primary or revision surgery for a major Cobb angle of ≥80°, corrective osteotomy for congenital spinal deformity or as a revision procedure for any type of deformity, and/or a complex 3-column osteotomy.

Results: One of 272 patients lacked preoperative data and was excluded from the analysis, and 62 (22.9%) of the remaining 271 patients, who were included, lacked a 2-year postoperative assessment. Patients with no preoperative motor impairment (normal LEMS group; n = 203) had a small but significant decline from the mean preoperative LEMS value (50) to that at 2 years postoperatively (49.66 [95% confidence interval = 49.46 to 49.85]; p = 0.002). Patients who did have a motor deficit preoperatively (n = 68; mean LEMS, 43.79) had significant LEMS improvement at 6 months (47.21, p < 0.001) and 2 years (46.12, p = 0.003) postoperatively. The overall percentage of patients (in both groups combined) who had a postoperative LEMS decline, compared with the preoperative value, was 23.0% at discharge, 17.1% at 6 weeks, 9.9% at 6 months, and 10.0% at 2 years.

Conclusions: The percentage of patients who had a LEMS decline (compared with the preoperative score) after undergoing complex spinal reconstructive surgery for ASD was 23.0% at discharge, which improved to 10.0% at 2 years postoperatively. These rates are higher than previously reported, which we concluded was due to the prospective, strict nature of the LEMS testing of patients with these challenging deformities.

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

*AOSpine International and SRS Scoli-RISK-1 Study Group includes Christopher P. Ames, MD; Oheneba Boachie-Adjei, MD; Mark B. Dekutoski, MD; Khaled M. Kebaish, MD; Stephen J. Lewis, MD, MSc, FRCSC; Yukihiro Matsuyama, MD, PhD; Hossein Mehidian, MD; Ferran Pellisé, MD, PhD; Yong Qiu, MD; and Frank J. Schwab, MD.

Disclosure: This study was supported organizationally and financially by the Scoliosis Research Society (SRS), Norton Healthcare, and AOSpine International. AOSpine is a clinical division of the AO Foundation—an independent medically guided nonprofit organization. On the Disclosure of Potential Conflicts of Interest forms, which are provided with the online version of the article, one or more of the authors checked “yes” to indicate that the author had a relevant financial relationship in the biomedical arena outside the submitted work and “yes” to indicate that the author had a patent and/or copyright, planned, pending, or issued, broadly relevant to this work (http://links.lww.com/JBJS/E641).

Copyright © 2018 The Authors. Published by The Journal of Bone and Joint Surgery, Incorporated. All rights reserved. This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal.
Adult spinal deformity (ASD) is a condition often requiring complex surgical interventions to improve the patient’s quality of life. Procedures for surgical correction continue to evolve with pedicle screw fixation and complex osteotomies. Neurologic impairment of the lower extremities may be present before surgery or as a postoperative complication. Neurologic deficits after ASD surgery have been reported in numerous studies; however, the true prevalence is difficult to ascertain because of the extreme heterogeneity of the populations being evaluated and treatments rendered. The majority of these reports were on patients with mild or moderate deformities (<70°) or did not present information about curve severity. Very few studies have included results regarding neurologic deficits after spinal reconstruction in patients with more severe spinal deformity (curves of >70° or sagittal imbalance of >10 cm). Additionally, most of the reports were retrospective, and often the methods for determining neurologic deficits were not well described. The aim of the present analysis was to prospectively document lower extremity motor function using the American Spinal Injury Association (ASIA) lower extremity motor score (LEMS), a validated outcome instrument, before and after surgical correction of complex ASD and to report changes in motor function through 2 years postoperatively.

### Materials and Methods

This prospective, observational, international, multicenter study evaluated neurologic complications associated with surgical correction of complex ASD, defined as surgery for a major Cobb angle of ≥80° in the coronal and/or sagittal plane, corrective osteotomy for congenital spinal deformity or as a revision procedure for any type of deformity, 3-column osteotomy (i.e., pedicle subtraction osteotomy and vertebral column resection between and including C7 and L5), reconstruction for deformity-induced myelopathy, or deformity reconstruction with concomitant spinal cord decompression due to deformity and ossification of the ligamentum flavum or posterior longitudinal ligament.

The study was conducted in 15 spinal deformity centers in North America (9), Europe (3), and Asia (3). The ethics committees or institutional review boards granted approval at all sites, and patients signed informed consent forms prior to enrollment. The study is registered with ClinicalTrials.gov (NCT01305343).

The operating surgeon decided on the surgical approach, instrumentation, corrective maneuvers, and use of bone grafts or substitutes. Patients were between 18 and 80 years old and had ASD with the major deformity apex in the cervicothoracic or thoracolumbar region. Detailed inclusion and exclusion criteria are listed in Table I.

An ASIA neurologic examination was performed by an ASIA-certified examiner (each site had multiple certified examiners performing this function) within 6 weeks preoperatively; at hospital discharge; and at 6 weeks, 6 months, and 2 years postoperatively. Standing coronal and sagittal radiographs were made and patient-reported outcomes as well as adverse events were recorded at each visit.

The primary outcome measure was the change in the 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 5 lower extremity muscle groups with a 50-point maximum (25 per side).

For analysis, the patients were divided into 2 groups: those with a normal preoperative LEMS (50) and those with an abnormal preoperative LEMS (<50). Differences in demographic characteristics and surgical approach between the normal and abnormal groups were analyzed using the Fisher exact test for categorical variables and the t test for continuous variables. Changes in the LEMS were analyzed using a mixed

### TABLE I Study Inclusion and Exclusion Criteria

| Inclusion Criteria                                                                 | Exclusion Criteria                                      |
|-----------------------------------------------------------------------------------|--------------------------------------------------------|
| Signed informed consent                                                           | Unlikely to comply with follow-up                      |
| Age 18 to 80 yr, inclusive                                                        | Recent history (≤3 mo) of substance dependency or       |
| Diagnosis of ASD with apex of major deformity in cervicothoracic or               | psychosocial disturbance                                |
| thoracolumbar region (apex between C7 and L2, inclusive) with any of              | Active malignancy                                       |
| following deformity characteristics:                                              | Active, overt bacterial infection (systemic or local)  |
| ● Primary scoliosis, kyphosis, or kyphoscoliosis with major Cobb angle of ≥80°   | Recent history (≤3 mo) of substantial spinal trauma/   |
| in coronal or sagittal plane                                                      | injury/fracture/malignancy in spinal region            |
| ● Congenital spinal deformity treated with corrective spinal                      | Complete, long-term paraplegia                         |
| osteotomy                                                                         | Pregnant or nursing or unwilling to agree not to       |
| ● Spinal deformity treated with revision corrective spinal                        | become pregnant for 6 mo postop.                       |
| osteotomy                                                                         | Incarcerated                                           |
| 3-column spinal osteotomy (pedicle subtraction osteotomy and vertebral column    | Institutionalized                                       |
| resection from C7 to L5, inclusive                                                |                                                        |
| Preop. myelopathy due to spinal deformity                                         |                                                        |
| Ossification of ligamentum flavum or posterior longitudinal ligament and         |                                                        |
| deformity needing concomitant reconstruction along with                          |                                                        |
| decompression of spinal cord                                                      |                                                        |

**Materials and Methods**

This prospective, observational, international, multicenter study evaluated neurologic complications associated with surgical correction of complex ASD, defined as surgery for a major Cobb angle of ≥80° in the coronal and/or sagittal plane, corrective osteotomy for congenital spinal deformity or as a revision procedure for any type of deformity, 3-column osteotomy (i.e., pedicle subtraction osteotomy and vertebral column resection between and including C7 and L5), reconstruction for deformity-induced myelopathy, or deformity reconstruction with concomitant spinal cord decompression due to deformity and ossification of the ligamentum flavum or posterior longitudinal ligament.

The study was conducted in 15 spinal deformity centers in North America (9), Europe (3), and Asia (3). The ethics committees or institutional review boards granted approval at all sites, and patients signed informed consent forms prior to enrollment. The study is registered with ClinicalTrials.gov (NCT01305343).

The operating surgeon decided on the surgical approach, instrumentation, corrective maneuvers, and use of bone grafts or substitutes. Patients were between 18 and 80 years old and had ASD with the major deformity apex in the cervicothoracic or thoracolumbar region. Detailed inclusion and exclusion criteria are listed in Table I.

An ASIA neurologic examination was performed by an ASIA-certified examiner (each site had multiple certified examiners performing this function) within 6 weeks preoperatively; at hospital discharge; and at 6 weeks, 6 months, and 2 years postoperatively. Standing coronal and sagittal radiographs were made and patient-reported outcomes as well as adverse events were recorded at each visit.

The primary outcome measure was the change in the 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 5 lower extremity muscle groups with a 50-point maximum (25 per side).

For analysis, the patients were divided into 2 groups: those with a normal preoperative LEMS (50) and those with an abnormal preoperative LEMS (<50). Differences in demographic characteristics and surgical approach between the normal and abnormal groups were analyzed using the Fisher exact test for categorical variables and the t test for continuous variables. Changes in the LEMS were analyzed using a mixed
model for repeated measures with an unstructured covariance. This model has advantages over simple imputation using the last, or baseline, observation carried forward method and has been recommended for handling missing data in longitudinal clinical trials. Missing values are dealt with by taking into account data derived from the same patient at other time points to calculate estimates. P values and 95% confidence intervals (CIs) for changes from baseline within each group were derived from the mixed model and adjusted for multiple testing using the simulation-based adjustment. Changes in the LEMS from

### TABLE II Surgical Procedures

| Procedure (Combinations Possible)* | No. (%) (N = 272) |
|------------------------------------|-------------------|
| Primary or revision surgery for scoliosis, kyphosis, or kyphoscoliosis with major Cobb angle of ≥80° in coronal or sagittal plane | 79 (29.0) |
| Osteotomy (any PSO, VCR, and/or SPO) | 259 (95.2) |
| Revision surgery including osteotomy (any PSO, VCR, and/or SPO) | 165 (60.7) |
| 3-column osteotomy | 206 (75.7) |
| Spinal reconstruction due to deformity with preop. myelopathy | 12 (4.4) |
| Spinal reconstruction and decompression of spinal cord due to deformity and ossification of ligamentum flavum or posterior longitudinal ligament | 5 (1.8) |

*PSO = pedicle subtraction osteotomy, VCR = vertebral column resection, and SPO = Smith-Petersen osteotomy.

### TABLE III Demographics and Surgical Approach by Group

| Characteristic                      | Normal Group | Abnormal Group | P Value |
|-------------------------------------|--------------|----------------|---------|
| Sex                                 | N = 203      | N = 68         | 0.053   |
| Male                                | 60 (29.6)    | 29 (42.6)      |         |
| Female                              | 143 (70.4)   | 39 (57.4)      |         |
| Age (yr)                            | N = 203      | N = 68         | 0.236   |
| Mean ± standard deviation          | 56.3 ± 15.9  | 58.8 ± 13.2    |         |
| Median (Q1, Q3)                     | 60.0 (49, 68) | 60.5 (53, 69)  |         |
| Range                               | 18-80        | 19-81†         |         |
| Race                                | N = 202      | N = 68         | 0.051   |
| White                               | 163 (80.7)   | 51 (75.0)      |         |
| Black                               | 2 (1.0)      | 0 (0)          |         |
| Native American                     | 1 (0.5)      | 0 (0)          |         |
| East Asian                          | 36 (17.8)    | 14 (20.6)      |         |
| Other                               | 0 (0)        | 3 (4.4)        |         |
| Smoker                              | N = 202      | N = 67         | 0.478   |
| No                                  | 184 (91.1)   | 59 (88.1)      |         |
| Yes                                 | 18 (8.9)     | 8 (11.9)       |         |
| Previous spine surgery              | N = 203      | N = 68         | 0.006   |
| No                                  | 86 (42.4)    | 16 (23.5)      |         |
| Yes                                 | 117 (57.6)   | 52 (76.5)      |         |
| Surgical approach                   | N = 203      | N = 68         | 0.869   |
| Posterior only                      | 154 (75.9)   | 53 (77.9)      |         |
| Anterior + posterior                | 49 (24.1)    | 15 (22.1)      |         |
| No. of surgical stages              | N = 203      | N = 68         | 1.000   |
| 1                                   | 165 (81.3)   | 55 (80.9)      |         |
| ≥2                                  | 38 (18.7)    | 13 (19.1)      |         |

*Unless otherwise indicated. †One patient was enrolled at age 80 and turned 81 on the day of surgery.
baseline were classified as “maintenance,” “improvement,” or “decline” and compared between the 2 groups with the Fisher exact test or chi square test. The statistical analysis was performed using SAS software, version 9.2 (SAS Institute). The study utilized the web-based online data-capture system eCRF (OpenClinica). Additionally, a clinical end point committee evaluated all neurologic and non-neurologic complications, which were assessed and adjudicated to ensure their accuracy.

**Results**

From September 2011 to October 2012, 43 surgeons enrolled 272 consecutive patients. One patient lacked a preoperative LEMS; therefore, only 271 patients could be included in the group analyses. Preoperatively, 203 patients (74.9%) had no lower extremity motor impairment (LEMS of 50; normal group) and 68 (25.1%) had a LEMS of <50 (abnormal group). Thirteen patients (4.8%) had no or incomplete LEMS

---

**Fig. 1**

A line graph showing the mean LEMS and the mean change in LEMS from baseline over time in the normal (NML) and abnormal (ABNML) groups.

---

**TABLE IV Change in LEMS Compared with Preoperative Score by Group**

| Change in LEMS Compared with Baseline | Total     | Normal Group | Abnormal Group | P Value |
|--------------------------------------|-----------|--------------|----------------|---------|
| Discharge                            | N = 265   | N = 199      | N = 66         | 0.542*  |
| Maintenance/improvement              | 204 (77.0)| 155 (77.9)   | 49 (74.2)      |         |
| Decline                              | 61 (23.0) | 44 (22.1)    | 17 (25.8)      |         |
| 6 wk                                 | N = 258   | N = 194      | N = 64         | 0.677*  |
| Maintenance/improvement              | 214 (82.9)| 162 (83.5)   | 52 (81.3)      |         |
| Decline                              | 44 (17.1) | 32 (16.5)    | 12 (18.8)      |         |
| 6 mo                                 | N = 252   | N = 190      | N = 62         | 0.293*  |
| Maintenance/improvement              | 227 (90.1)| 169 (89.0)   | 58 (93.5)      |         |
| Decline                              | 25 (9.9)  | 21 (11.1)    | 4 (6.5)        |         |
| 2 yr                                 | N = 209   | N = 163      | N = 46         | 0.417†  |
| Maintenance/improvement              | 188 (90.0)| 148 (90.8)   | 40 (87.0)      |         |
| Decline                              | 21 (10.0) | 15 (9.2)     | 6 (13.0)       |         |

*Chi square test. †Fisher exact test.
The study population included 182 women and 89 men. The mean age (and standard deviation) was 56.9 ± 15.3 years. The procedures included primary or revision surgery for ASD with a major Cobb angle of ≥80° in the coronal or sagittal plane in 29.0% of the patients, revision surgery including osteotomy in 60.7%, and/or a 3-column osteotomy in 75.7%, emphasizing the complex nature of these patients’ conditions and their surgical treatments (Table II).

The normal group included a higher percentage of women than the abnormal group (70.4% and 57.4%, p = 0.053) and a lower percentage with previous spine surgery (57.6% and 76.5%, p = 0.006). No significant differences between groups were seen with respect to age, race, smoking status, surgical approach, or prevalence of multistage surgery (Table III).

The proportion of patients with a postoperative LEMS decline was similar in the 2 groups at all time points; this decline was most pronounced at discharge, with gradual improvement over time (Table IV). Compared with baseline, 23.0% of all patients experienced a LEMS decline at discharge, with this rate decreasing to 17.1% at 6 weeks and to 9.9% at 6 months and remaining stable at 10.0% at 2 years. Compared with baseline, the LEMS declined for 22.1% of the patients in the normal group and 25.8% in the abnormal group at discharge; 11.1% and 6.5%, respectively, at 6 months; and 9.2% and 13.0%, respectively, at 2 years. There was a small significant decline in the mean LEMS at all follow-up assessments as compared with baseline (p = 0.001 up to six months and p = 0.002 at 2 years) in the normal group, whereas the abnormal group had a significant improvement at 6 months (p < 0.001) and 2 years (p = 0.003) (Fig. 1 and Table V).

Analysis of the LEMS over time in both groups revealed a significant time effect (p < 0.001). The pattern of changes significantly differed between the 2 groups (group × time effect, p < 0.001). Most declines in the LEMS, compared with preoperatively, were ≤5 points, with 72.1%, 65.9%, 76.0%, and 76.2% of the declines being ≤5 points at discharge, 6 weeks, 6 months, and 2 years, respectively (Table VI).

One patient with congenital kyphoscoliosis who had a 3-column osteotomy demonstrated loss of signals on spinal cord monitoring and acute paraplegia immediate postoperatively. The patient showed slow but steady recovery of the LEMS, which improved to 30 by discharge, 40 at 6 weeks, and 50 (normal) at 6 months postoperatively. A 60-year-old patient who had a posterior spinal fusion for adult lumbar scoliosis required revision surgery at 7 weeks postoperatively due to a fall causing proximal junctional kyphosis and acute paraplegia. Following the revision surgery, the clinical paraplegia persisted and the patient died 23 months after the index surgery (Table VII). Importantly, no patient in this study experienced permanent postoperative paraplegia following their index surgical procedure.

**Discussion**

This prospective study analyzed lower extremity motor function after complex spinal reconstruction in patients with severe ASD. To our knowledge, this is the largest series of patients with such severe deformities whose neurologic function was documented prospectively with a validated outcome instrument.

Loss of neurologic function is one of the most important complications following complex ASD surgery. The decreased mobility directly impacts the patient’s quality of life and may lead to additional adverse events such as lower extremity deep vein thrombosis, pulmonary embolism, and pneumonia.

We found a decline in the LEMS at hospital discharge, compared with preoperatively, for 23.0% of the patients who underwent correction of ASD. As motor function recovered over time, this rate decreased to 17.1% at 6 weeks and then to 9.9% at 6 months, and then remained stable at 10.0% at 2 years. These rates of perioperative motor decline are by far the highest reported to date, for multiple reasons: our “high-risk” study
### TABLE VI Change in LEMS Compared with Preoperative Score in Ordinal Categories

| Change in LEMS Compared with Preop. | Total | Normal Group | Abnormal Group |
|-------------------------------------|-------|--------------|----------------|
| Discharge                           | N = 265 | N = 199      | N = 66         |
| Decline                             | 23.0%  |              |                |
| Decline >10                         | 4 (1.5) | 2 (1.0)      | 2 (3.0)        |
| Decline 6-10                        | 13 (4.9)| 9 (4.5)      | 4 (6.1)        |
| Decline 1-5                         | 44 (16.6)| 33 (16.6)  | 11 (16.7)      |
| Maintenance                         | 170 (64.2)| 155 (77.9) | 15 (22.7)      |
| Improvement 1-5                     | 31 (11.7)| 0 (0)       | 31 (47.0)      |
| Improvement 6-10                    | 2 (0.8)| 0 (0)        | 2 (3.0)        |
| Improvement >10                     | 1 (0.4)| 0 (0)        | 1 (1.5)        |
| **6 wk**                            | N = 258 | N = 194      | N = 64         |
| Decline                             | 17.1%  |              |                |
| Decline >10                         | 6 (2.3)| 3 (1.5)      | 3 (4.7)        |
| Decline 6-10                        | 9 (3.5)| 6 (3.1)      | 3 (4.7)        |
| Decline 1-5                         | 29 (11.2)| 23 (11.9)  | 6 (9.4)        |
| Maintenance                         | 172 (66.7)| 162 (83.5) | 10 (15.6)      |
| Improvement 1-5                     | 31 (12.0)| 0 (0)       | 31 (48.3)      |
| Improvement 6-10                    | 10 (3.9)| 0 (0)        | 10 (15.6)      |
| Improvement >10                     | 1 (0.4)| 0 (0)        | 1 (1.6)        |
| **6 mo**                            | N = 252 | N = 190      | N = 62         |
| Decline                             | 9.9%   |              |                |
| Decline >10                         | 2 (0.8)| 1 (0.5)      | 1 (1.6)        |
| Decline 6-10                        | 4 (1.6)| 4 (2.1)      | 0 (0)          |
| Decline 1-5                         | 19 (7.5)| 16 (8.4)    | 3 (4.8)        |
| Maintenance                         | 175 (69.4)| 169 (88.9) | 6 (9.7)        |
| Improvement 1-5                     | 37 (14.7)| 0 (0)       | 37 (59.7)      |
| Improvement 6-10                    | 12 (4.8)| 0 (0)        | 12 (19.4)      |
| Improvement >10                     | 3 (1.2)| 0 (0)        | 3 (4.8)        |
| **2 yr**                            | N = 209 | N = 163      | N = 46         |
| Decline                             | 10.0%  |              |                |
| Decline >10                         | 0 (0)  | 0 (0)        | 0 (0)          |
| Decline 6-10                        | 5 (2.4)| 3 (1.8)      | 2 (4.4)        |
| Decline 1-5                         | 16 (7.7)| 12 (7.4)    | 4 (8.7)        |
| Maintenance                         | 153 (73.2)| 148 (90.8) | 5 (10.9)       |
| Improvement 1-5                     | 26 (12.4)| 0 (0)       | 26 (56.5)      |
| Improvement 6-10                    | 9 (4.3)| 0 (0)        | 9 (19.6)       |
| Improvement >10                     | 0 (0)  | 0 (0)        | 0 (0)          |

### TABLE VII Data on Patients with >10-Point Decline in LEMS

| Case | Group | Preop. | Discharge | 6 Wk | 6 Mo | 2 Yr | Change in LEMS Compared with Preop. |
|------|-------|--------|-----------|------|------|------|-------------------------------------|
|      |       |        |           |      |      |      | Discharge 6 Wk 6 Mo 2 Yr            |
| 1    | Abnormal | 43     | 28        | 50   | 50   | 50  | −15  7  7  7                      |
| 2    | Normal  | 50     | 28        | Not avail. | 39  | Not avail. | −22  Not avail. −11  Not avail. |
| 3    | Normal  | 50     | 30        | 40   | 50   | 50  | −20  −10 0 0                   |
| 4    | Abnormal | 49     | 29        | 32   | 33   | 40  | −20  −17 −16 −9                 |
population of patients with ASD who underwent complex re-
constructions; the prospective study design with frequent and
structured data-collection time points; and the sensitivity to
change of the ASIA neurologic examination, in which a single
structured data-collection time points; and the sensitivity to
constructions; the prospective study design with frequent and
population of patients with ASD who underwent complex re-
constructions; the prospective study design with frequent and
structured data-collection time points; and the sensitivity to
change of the ASIA neurologic examination, in which a single
structured data-collection time points; and the sensitivity to
constructions; the prospective study design with frequent and

Several reports that specifically address complications subse-
to spinal deformity reconstruction in large series of
patients have been published, even though the severity of the
deformity in those publications may not be comparable with
that in our population (Table VIII). In what we believe is
the largest review of new neurologic deficits—after 108,419
spinal procedures—the Scoliosis Research Society (SRS) Mor-
bidity and Mortality Committee stratified their analyses by
primary diagnosis and reported a prevalence of neurologic
deficits of 1.8% after surgery for scoliosis and 3.4% after sur-
gery for kyphosis. The neurologic deficit rate was 41% higher
after revisions than after primary procedures. Of note, the
study depended on voluntary surgeon/center retrospective data
entry, without prospective performance of neurologic assess-
ment with a validated instrument. Therefore, selection and
detection bias are distinct possibilities.

In a retrospective study of 306 patients who underwent primary
surgery for adolescent idiopathic scoliosis with a mean
defor-me of 50°, Charosky et al. reported a 7% rate of new neurolog-
deficits, with 2 patients (0.6%) developing late cord-
level deficits. Buchowski et al. assessed early complications in 108
adults who underwent a pedicle subtraction osteotomy for
an average +13-cm fixed sagittal imbalance and a mean lor-
dosis of −17°. Twelve patients (11.1%) developed new
neurologic deficits, which were permanent in 3 (2.8%). Kim
et al. performed a retrospective study of 233 patients with a
mean local kyphosis of 51°, thoracic scoliosis of 64°, and
thoracolumbar or lumbar scoliosis of 50°. They found the
prevalence of transient neurologic deficits to be 31.8% in those
treated with a posterior vertebral column resection and 7.5%
in those treated with a decancellation osteotomy whereas the
prevalences of permanent neurologic deficits were 3.3% and 1.2%, respectively. Most patients who had postoperative

| Study                      | Year Published | No. of Patients | Study Type         | Single Vs. Multicenter | Type of Deformity                        | Surgical Procedures                                                                 | Neurologic Complication Rate |
|----------------------------|----------------|-----------------|--------------------|------------------------|------------------------------------------|----------------------------------------------------------------------------------|-----------------------------|
| Charosky et al.            | 2012           | 306             | Retrospective review of prospectively collected data | Multicenter            | Adult degenerative scoliosis             | Primary                                                                          | 7% with 2 cases (0.6%) of late cord-level deficits |
| Buchowski et al.           | 2007           | 108             | Retrospective radiographic review of prospectively collected clinical data | Single center         | Scoliosis and kyphosis                   | Pedicle subtraction osteotomy                                                    | 11.1% (12), 2.8% (3) with permanent neurologic deficits |
| Kim et al.                 | 2012           | 233             | Retrospective      | Single center          | Scoliosis and kyphosis                   | Posterior vertebral column resection vs. decancellation osteotomy                | Transient: 31.8% after posterior vertebral column resection vs. 7.5% after decancellation osteotomy; permanent: 3.3% vs. 1.2% |
| Bomback et al.             | 2007           | 34              | Retrospective case-control | Single center          | Thoracic curves >50°                     | Thoracoscopic surgery vs. thoracotomy                                             | No neurologic complications in either group |
| Shapiro et al.             | 2003           | 16              | Retrospective case series | Single center          | Adult idiopathic thoracolumbar and/or lumbar scoliosis | Anterior and posterior spinal reconstructive surgery | No neurologic complications |
| Suk et al.                 | 2005           | 16              | Retrospective      | Single center          | Severe rigid scoliosis                   | Posterior vertebral column resection                                             | 1 patient developed complete paralysis |
| Xie et al.                 | 2012           | 28              | Retrospective      | Single center          | Severe rigid scoliosis with curves >100° | Posterior vertebral column resection                                             | 17.9% |
| Lenke et al.               | 2010           | 43              | Retrospective      | Single center          | Severe scoliosis, global kyphosis, angular kyphosis, or kyphoscoliosis | Posterior vertebral column resection                                             | 4.7% (2) with postop. nerve root deficits |
| Swanek et al.              | 1981           | 222             | Retrospective      | Single center          | Idiopathic scoliosis, congenital scoliosis, and paralytic scoliosis | Primary                                                                          | 1 patient became paraparetic postop. |
| Qiu et al.                 | 2008           | 1,373           | Retrospective      | Single center          | Scoliosis                                | Anterior, posterior, and anteroposterior techniques                            | 3.7% |
paraplegia had had a preoperative neurologic deficit and >5 levels fused.

We do not know of any published prospective studies of a large patient population with deformities comparable with those in our series. A prospective study with predefined data-collection time points strongly increases data accuracy and result validity. This is particularly important for analyses of neurologic deficits, which may be subtle and/or transient and thus remain undetected in retrospective studies. Understanding the risk of such defects is fundamental to patients’ ability to provide informed consent and to clinical decision-making.

There have been only a few retrospective reports in the literature on populations with deformity severity and interventions comparable with ours, with only 2 comprising >100 patients and several others consisting of small series. Bomback et al. performed a case-control study, which included children and adults, comparing 17 patients treated with video-assisted thoracoscopic surgery with 17 treated with thoracotomy. The mean major coronal curves were 81° and 101° in the respective treatment groups. No neurologic complications occurred in either group. Shapiro et al. reviewed records of 16 children and adults with a mean major curve of 71° and reported that no major neurologic deficits occurred. Suk et al. studied 16 consecutive patients who underwent posterior vertebral column resection for severe rigid scoliosis with a mean major curve of 109°. One patient with Beals syndrome and a preoperative Frankel grade of C developed complete paralysis (Frankel grade A) postoperatively. The autopsy showed no definite pathological finding or abnormality accounting for the neurologic deterioration. Xie et al. reported a neurologic complication rate of 17.9% in 28 adults who had undergone posterior vertebral column resection for correction of severe, rigid spinal curves of >100°. These complications included 1 case of late-onset paraparesis in a patient without any preoperative or immediate postoperative neurologic deficit who developed complete spinal cord dysfunction 8 hours later. The patient received medical therapy with methylprednisolone, and the neurologic function gradually improved to normal after 2 weeks. Lenke et al. reviewed the cases of 43 children and adults with severe spinal deformities who underwent posterior vertebral column resection. Twelve patients had preoperative Cobb angles of >75°. Although 7 patients (18%) lost monitoring signals intraoperatively, the signals returned to baseline following surgical intervention. No patients developed any spinal cord-related neurologic dysfunction. Two patients (4.7%) had postoperative nerve root deficits, which resolved at 2 weeks and 6 months.

Two larger retrospective studies of populations comparable with ours have been published. Swank et al. reviewed the charts of 222 patients with an average initial curve of 80° who had undergone scoliosis correction. One patient in this series became paraparetic postoperatively. A myelogram detected a block at L1. The patient underwent decompres-sion/laminectomy and neurologic function improved, but urinary retention, anal pain, and loss of sensation over the penis and perineum remained. In a large single-center study, Qiu et al. reviewed data on 1,373 patients (the majority [1,074] of whom were <18 years old) and analyzed neurologic deficits stratified by curve severity and procedure type. The prevalence of neurologic deficits was 3.7% for major curves with a preoperative Cobb angle of ≥90° and only 1.5% for smaller curves (p = 0.015). The neurologic deficit prevalence was 0.9% after anterior procedures versus 1.2% after posterior procedures, and 3.4% after combined anterior and posterior procedures. The influence of procedure type was significant (p = 0.028), while the influence of age was insignificant (neurologic deficit rate of 1.9% in patients <18 years old versus 2% in those ≥18 years old; p = 0.87).

Two important aspects of all of these publications are the variability in the prevalences of the neurologic deficits and the fact that these prevalences always appeared lower than those in our study. We believe that the reasons for both are multifactorial. The high variability can be explained by the heterogeneity of individual study populations and the multitude of treatment modalities employed. Retrospective evaluations without preset data-collection time points or standardized/validated outcome instruments increased the variability. Additionally, selection and detection bias may have played larger roles in these cohort studies than in our multicenter cohort.

Several additional factors likely contributed to the lower prevalences of neurologic decline reported in other studies. First, rigorous data collection as well as the use of the ASIA LEMS instrument may have allowed us to detect more subtle changes than retrospective studies can. Second, our study population was more homogeneous, with all patients having severe deformity (a major curve of ≥80°) and/or being treated with a complex operation (e.g., 3-column osteotomy). Although different procedures were performed in our series, all were complex reconstructions in a population at a high risk for neurologic deterioration. The high risk involved in complex osteotomy surgery for correction of a large deformity or procedures such as 3-column osteotomy (pedicle subtraction osteotomy and vertebral column resection) with direct manipulation of neural elements and acute changes in spinal canal alignment and/or shape has been emphasized by other authors.

Some authors performed analyses stratified by deformity severity and procedure complexity and found that both factors increased the likelihood of a patient developing a neurologic deficit. Some authors reported cases of permanent paraplegia after the index procedure, but that was not seen in any of our patients. Although 1 patient awoke with complete paraplegia, neurologic function improved by hospital discharge and was normal at 6 months. Thus, considering that we evaluated only the most complex ASD reconstructions and used standardized/validated outcome instruments with predefined data-collection time points, we believe that our results present an accurate risk of neurologic complications.

Our study also has limitations. We used heterogeneous diagnostic and treatment-related inclusion criteria. Also, some subjective bias is possible since the ASIA examination was performed by different examiners at multiple sites. We attempted to minimize this potential bias by having all examiners become...
ASIA-certified. Additionally, the availability of 2-year data was lower than anticipated (some patients were seen at 2 years but a LEMS was not obtained). We tried to mitigate the effect of missing data by using a mixed-effects model for repeated measures for the statistical analysis. Finally, we only studied patients who had undergone the most complex and neurologically risky procedures for their deformity; therefore, our results are valid only for this specific population and are difficult to compare with other studies. The surgeons and centers selected saw and treated a high volume of patients with severe deformity, so the results of this study may not be typical of those at centers and surgeon practices that do not routinely include this patient population.

The strengths of our study include its prospective/multicenter nature and use of the ASIA LEMS instrument preoperatively and at 4 postoperative time points. This neurologic assessment using a validated measurement system provided sensitivity with regard to the ability to detect subtle changes postoperatively. Although several studies of smaller series of patients with a deformity severity similar to that in our population have been published, our large sample size allowed sufficient power to detect relatively rare events and our data-collection procedure ensured that any new postoperative lower extremity deficit was captured as a surgical complication, even if it was minor and transient.

In conclusion, this Scoli-RISK-1 study revealed that a decline in lower extremity motor function after complex ASD surgery is common and more frequent than previously reported. We identified such a decline in 23.0% of patients at discharge, with neurologic function recovering over time to a decline (compared with preoperatively) in 17.1% of the patients at 6 weeks, 9.9% at 6 months, and 10.0% at 2 years after the operation. Thus, many patients with a postoperative decline in LEMS showed motor function improvement (compared with the initial decline) by 6 months postoperatively. The neurologic complication rate in our study, determined with a strict protocol of neurologic evaluations, should be considered the accurate and expected neurologic outcome following complex ASD surgery at this time.

The Journal of Bone & Joint Surgery - jbjs.org
Volume 100-A - Number 8 - April 18, 2018

Lawrence G. Lenke, MD
Christopher I. Shaffrey, MD
Leah Y. Carreon, MD, MSc
Kenneth M.C. Cheung, MBBS, MD, FRCS, FHKCOS, FHKAM(Orth)
Benny T. Dahl, MD, PhD, DMSc
Michael G. Fehlings, MD, PhD, FRCSC
on behalf of the AO Spine International and SRS Scoli-RISK-1 Study Group

1Columbia University Medical Center, New York, NY
2University of Virginia Medical Center, Charlottesville, Virginia
3Norton Leatherman Spine Center, Louisville, Kentucky
4The University of Hong Kong, Hong Kong
5Rigshospitalet and University of Copenhagen, Copenhagen, Denmark
6Toronto Western Hospital, Toronto, Ontario, Canada

E-mail address for L.G. Lenke: ll2989@columbia.edu

ORCID iD for L.G. Lenke: 0000-0002-5595-4958

References

1. Ahn UM, Ahn NU, Buchowski JM, Keboah KM, Lee JH, Song ES, Lemma MA, Sieber AN, Kostuk JP. Functional outcome and radiographic correction after spinal osteotomy. Spine (Phila Pa 1976). 2002 Jun;27(12):1303-11.
2. Berven SH, Deviren V, Smith JA, Hu SH, Bradford DS. Management of fixed sagittal plane deformity: outcome of combined anterior and posterior surgery. Spine (Phila Pa 1976). 2003 Aug 1;28(15):1710-5; discussion 1716.
3. Boachie-Adjei O, Ferguson JA, Pigeon RG, Peskin MR. Transpedicular lumbar wedge resection osteotomy for fixed sagittal imbalance: surgical technique and early results. Spine (Phila Pa 1976). 2006 Feb 15;31(4):485-92.
4. Chang KW, Cheng CW, Chen HC, Chang KI, Chen TC. Closing-opening wedge osteotomy for the treatment of sagittal imbalance. Spine (Phila Pa 1976). 2008 Jun 1;33(13):1470-7.
5. Charrosky S, Guigui P, Blamoutier A, Roussouly P, Chopin D; Study Group on Scoliosis. Complications and risks of primary and revision adult scoliosis surgery: a multicenter study of 306 patients. Spine (Phila Pa 1976), 2012 Apr 15;37(8):693-700.
6. Khan SN, Hofer MA, Gupta MC. Lumbar degenerative scoliotic outcomes of combined anterior and posterior pelvis surgery with minimum 2-year follow-up. Orthopedics. 2009 Apr;32(4):pilo.orthospersite.com/view.aspx?lID=38060.
7. Pateler BS, Keboah KM, Cascio BM, Neubauer P, Matusz DM, Kostuk JP. Posterior only versus combined anterior and posterior approaches to lumbar scoliosis in adults: a radiographic analysis. Spine (Phila Pa 1976). 2007 Jun 15;32(14):1551-4.
8. Peele MW, Boachie-Adjei O, Charles G, Kanazawa Y, Mestfn A. Lumbar curve response to selective thoracic fusion in adult idiopathic scoliosis. Spine J. 2008 Nov-Dec;8(6):S97-903. Epub 2008 Feb 8.
9. Rhee JM, Bridwell KH, Lenke LG, Baldus C, Blanke K, Edwards C, Berra A. Staged posterior surgery for severe adult spinal deformity. Spine (Phila Pa 1976). 2003 Sep 15;28(18):2116-21.
10. Suk SI, Chung ER, Lee SM, Lee JH, Kim SS, Kim JH. Posterior vertebral column resection in fixed lumbosacral deformity. Spine (Phila Pa 1976). 2005 Dec 1;30(23):E703-10.
11. Wang ST, Ma HL, Lin CF, Liu CL, Yu WK, Lo WH. Surgical treatment of adult idiopathic scoliosis - comparison of two instrumentations. Int Orthop. 2002;26(4):207-10. Epub 2002 Apr 26.
12. Yang BP, Ondra SL, Chen LA, Jung HS, Koski TR, Salehi SA. Clinical and radiographic outcomes of thoracic and lumbar pedicle subtraction osteotomy for fixed sagittal imbalance. J Neurosurg Spine. 2006 Jul;5(1):9-17.
13. Ali RM, Boachie-Adjei O, Rawlins BA. Functional and radiographic outcomes after surgery for adult scoliosis using third-generation instrumentation techniques. Spine (Phila Pa 1976). 2003 Jun 1;28(11):11639; discussion 11697-10.
14. Bess RS, Lenke LG, Bridwell KH, Cheh G, Mandel S, Sides B. Comparison of thoracic pedicle screw to hook instrumentation for the treatment of adult spinal deformity. Spine (Phila Pa 1976). 2007 Mar 1;32(5):555-61.
15. Chang KW, Chen YY, Lin CC, Hsu HL, Pai KC. Closing wedge osteotomy versus opening wedge osteotomy in ankylosing spondylitis with thoracolumbar kyphotic deformity. Spine (Phila Pa 1976). 2005 Jul 15;30(14):1584-93.
16. Deviren V, Patel VV, Metz LN, Lenke LG, Hu SH, Bradford DS. Anterior arthrodesis with instrumentation for thoracolumbar scoliosis: comparison of efficacy in adults and adolescents. Spine (Phila Pa 1976). 2008 May 15;33(11):1219-23.
17. Eck KR, Bridwell KH, Ungacta FF, Riew KD, Lapp MA, Lenke LG, Baldus C, Blanke K. Complications and results of long adult deformity fusions down to L4, L5, and the sacrum. Spine (Phila Pa 1976). 2001 May 1;26(9):E182-92.
18. Emami A, Deviren V, Berven S, Smith JA, Hu SS, Bradford DS. Outcome and complications of long fusions to the sacrum in adult spine deformity:
