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Impact of New Motor Deficit on HRQOL After Adult Spinal Deformity Surgery

Subanalysis From Scolio Risk 1 Prospective Study

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Study Design. International, multicenter, prospective, longitudinal observational cohort.

Objective. To assess how new motor deficits affect patient reported quality of life scores after adult deformity surgery.

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Summary of Background Data. Adult spinal deformity surgery is associated with high morbidity, including risk of new postoperative motor deficit. It is unclear what effect new motor deficit has on Health-related Quality of Life scores (HRQOL) scores.

Methods. Adult spinal deformity patients were enrolled prospectively at 15 sites worldwide. Other inclusion criteria included major Cobb more than 80°, C7–L2 curve apex, and any patient undergoing three column osteotomy. American Spinal Injury Association (ASIA) scores and standard HRQOL scores were recorded pre-op, 6 weeks, 6 months, and 2 years.

Results. Two hundred seventy two complex adult spinal deformity (ASD) patients enrolled. HRQOL scores were worse for patients with lower extremity motor score (LEMS). Mean HRQOL changes at 6 weeks and 2 years compared with pre-op for patients with motor worsening were: ODI (+12.4 at 6 weeks and –4.7 at 2 years), SF-36v2 physical (–4.5 at 6 weeks and +2.3 at 2 years), SRS-22r (0.0 at 6 weeks and +0.4 at 2 years). Mean HRQOL changes for motor-neutral patients were: ODI (+0.6 at 6 weeks and –12.1 at 2 years), SF-36v2 physical (–1.6 at 6 weeks and +5.9 at 2 years), and SRS-22r (+0.4 at 6 weeks and +0.7 at 2 years). For patients with LEMS improvement, mean HRQOL changes were: ODI (–0.6 at 6 weeks and –16.3 at 2 years), SF-36v2 physical (+1.0 at 6 weeks and +7.0 at 2 years), and SRS-22r (+0.5 at 6 weeks and +0.9 at 2 years).

Conclusion. In the subgroup of deformity patients who developed a new motor deficit, total HRQOLs and HRQOL changes were negatively impacted. Patients with more than 2 points of LEMS worsening had the worst changes, but still showed overall HRQOL improvement at 6 months and 2 years compared with pre-op baseline.

Key words: adult spinal deformity, HRQOL, motor deficit.

Level of Evidence: 3

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With an aging population and increased awareness, adult spinal deformity (ASD) is a growing diagnosis.¹ ASD arises from multiple etiologies, but most commonly from arthritic spondylosis and iatrogenic causes leading to asymmetric degeneration of

discs, facet joints, and other spinal elements.² The sum of these abnormal changes may result in structural coronal and sagittal spinal deformities, and additionally, often results in nerve root and spinal cord compression. Patients may present with radiculopathy, myelopathy, inability to ambulate, and/or debilitating axial back pain.² It has been well-proven that global spinal misalignment is strongly correlated with disability and pain outcomes—greater imbalance is correlated with greater functional disability.^{3–6} Fortunately, the surgical correction and reestablishment of age-appropriate global spinal alignment and spinopelvic parameters can significantly improve patient function, pain, and appearance on multiple outcome scales.^{7–9}

Surgery is warranted for ASD when conservative management fails. Surgical correction of ASD can be technically challenging. Cases of fixed, non-mobile deformities require high grade osteotomies, such as Grade 3 to 5 (pedicle subtraction osteotomy [PSO] to vertebral body resection [VCR]).¹⁰ While osteotomies are powerful techniques for correction, mechanical realignment of the spine can be associated with significant complications, at a relatively high rate compared with degenerative cases. The reported complication rates range from 8% to 59% depending on various factors such as ASD severity and osteotomy grade.^{11–20} One of the most dreaded complication is neurological injury. The previously reported intraoperative complication rate is approximately 7%, and based on prior studies, new neurological deficits are observed immediately after surgery in 7% to 35% of cases.^{21–24} Fortunately, catastrophic permanent neurological injury occurs less than 3% of the time.²⁵

Nonetheless, based on the Scoli-RISK-1 trial, just over 20% of patients who underwent complex ASD surgery had a decline in lower extremity motor score (LEMS) at hospital discharge.^{24,26} More recently, follow-up results from the Scoli-RISK-1 trial showed that 10% of those patients continued to have lower extremity weakness at 2 years follow-up.^{27,28} However, the effect of lower extremity weakness and changes in LEMS on tasks of daily life and health related quality of life (HRQOL) outcomes remained to be studied and understood. This is a critical item in understanding the significance of neurological changes after ASD surgery and we hypothesized new motor deficits (defined by LEMS worsening) leads to worsened HRQOL scores. Therefore, in this study, an analysis of the Scoli-RISK-1 trial was performed to determine how worsening LEMS is associated with outcome measures at the 6-week, 6-month, and 2-year time points.

METHODS

Patients aged 18 to 80 above with a diagnosis of adult spinal deformity were eligible for enrollment at 15 sites worldwide (North America [nine], Europe [three], and Asia [three]). Other inclusionary criteria were: apex of major deformity between C7 and L2 inclusive, primary scoliosis, kyphosis or kyphoscoliosis with 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 due to 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. Patients with a recent history of substance dependency or psychosocial disturbance, spinal trauma or injury, malignancy, and those who are pregnant, institutionalized, or unlikely to comply with follow-up were excluded from the study. Patients were enrolled from 2011 to 2012.

LEMS was computed based on the American Spinal Injury Association (ASIA) scoring system.²⁹ Each of five muscles (iliopsoas, quadriceps, tibialis anterior, extensor hallucis longis, and gastrocnemius) was tested bilaterally for motor strength on a 0 (no movement) to 5 (full strength) scale, resulting in a LEMS range of 0 (paraplegia) to 50. HRQOL tests included the Oswestry Disability Index (ODI), Short Form 36 version 2 (SF-36v2, divided into mental and physical components), and SRS-22r (SRS). LEMS scores and HRQOL scores were recorded pre-op, 6 weeks and 6 months, and 2 years. Patients were divided into three groups comparing LEMS score to pre-op baseline: LEMS more than 2 points worse (defined as “motor-worse”), LEMS 0–2 points worse (“motor-neutral”), or improved LEMS score (“motor-improved”). HRQOL change from pre-op baseline was computed for each subgroup. Patients were re-classified into these three groups at each post-op time point, based on their LEMS score at that time point relative to pre-op baseline.

RESULTS

Two hundred ninety five patients were screened for the study, of which 280 enrolled from 2011 to 2012. After eight exclusions, 272 patients remained. There were 184 female (67%) and 89 male (33%) patients. Mean age was 56.9 years (SD 15.3, range 18–80). Two hundred forty six patients were non-smokers (90.4%), while 26 patients (9.6%) were smokers. 22% of patients undergoing complex adult spinal deformity surgery suffered a new motor deficit at hospital discharge and 29.2% showed a decrease in LEMS at any point in their postoperative follow-up. Table 1 shows complete HRQOL results at 6 weeks, 6 months, and 2 years post-op.

Table 2 shows HRQOL changes relative to LEMS changes. The number of patients can be lower than Table 1 in cases where a specific HRQOL baseline value was not available. At 6 weeks, there was an increase in ODI of 12.4 ± 17.5 (mean \pm standard deviation) in motor-worse patients ($n = 25$), while the motor-neutral patients showed a mean ODI change of 0.6 ± 20 at 6 weeks ($n = 175$) and the motor-improved patients was associated with ODI improvements of -0.6 ± 19.6 ($n = 39$). At 6 months, the patients with worsening in LEMS at that time point ($n = 11$) had an ODI decrease of -7.3 ± 14.3 , the patients with motor-neutral showed a mean ODI change of -9.5 ± 18.5 ($n = 177$) and the motor-improved patients was associated with highest ODI decrease of -13.7 ± 16.6 ($n = 49$) as well. At 2 years,

TABLE 1. Severity of Motor Deficit Versus HRQOL

	Change in LEM Score From Baseline		
	Decrease of >2 Points in LEMS	No Significant Change in LEMS (Decrease of 2-0)	Increase in LEMS
Oswestry disability index			
6 weeks			
n	26	177	41
Mean (sd)	58.1 (19.0)	44.1 (17.3)	53.9 (19.5)
6 months			
n	11	182	51
Mean (sd)	56.6 (15.3)	32.4 (18.9)	42.5 (17.1)
24 months			
n	9	159	34
Mean (sd)	49.3 (16.6)	29.1 (20.8)	35.8 (20.5)
SF-36v2 physical component summary score			
6 weeks			
n	23	171	40
Mean (sd)	27.0 (9.6)	31.6 (8.1)	27.8 (6.4)
6 months			
n	9	182	50
Mean (sd)	23.3 (9.3)	36.3 (8.8)	33.4 (6.8)
24 months			
n	9	154	34
Mean (sd)	27.4 (8.0)	39.2 (10.7)	34.9 (10.6)
SF-36v2 mental component summary score			
6 weeks			
n	23	171	40
Mean (sd)	42.2 (14.7)	45.4 (13.3)	42.0 (14.6)
6 months			
n	9	182	50
Mean (sd)	38.5 (16.0)	48.0 (13.7)	44.4 (13.9)
24 months			
n	9	154	34
Mean (sd)	39.0 (17.7)	48.5 (12.5)	48.2 (13.8)
SRS-22r			
6 weeks			
n	26	177	41
Mean (sd)	2.9 (0.7)	3.2 (0.6)	2.9 (0.5)
6 months			
n	10	183	50
Mean (sd)	2.6 (0.5)	3.5 (0.7)	3.2 (0.7)
24 months			
n	9	160	34
Mean (sd)	2.9 (0.7)	3.6 (0.8)	3.3 (0.8)

LEMS indicates lower extremity motor score; HRQOLs, Health-related Quality of Life scores; SF-36v2, Short Form 36 version 2.

the patients with motor worsening (n = 9) had a decrease of -4.7 ± 19.7 , the motor-neutral group showed a mean ODI change of -12.1 ± 16.5 (n = 157), and the motor-improved group was associated with highest ODI decrease of -16.3 ± 18.7 (n = 33). Figure 1 shows these data. Number of patients of LEMS change groups was different at each time point due to re-assessments of ASIA at corresponding visit.

Figure 2 shows changes in the physical component of SF-36v2 at each time point for each group. At 6 weeks, the motor-worse patients worsened by 4.5 ± 9.1 (n = 22), the

motor-neutral patients decreased by 1.6 ± 11 (n = 165), and the motor-improved patients were the only group to have SF-36v2 physical improvement apparent with a change of 1.0 ± 8.9 (n = 39). At 6 months, the motor-worse patients improved by 0.8 ± 7.4 (n = 8), the motor-neutral patients improved by 2.7 ± 9.6 (n = 174), and the motor-improved patients have SF-36v2 physical improvement by 6.1 ± 7.5 (n = 49). At 2 years, the motor-worse patients improved by 2.3 ± 8.9 (n = 8), the motor-neutral patients improved by 5.9 ± 10.4 (n = 148), and the motor-improved patients have SF-36v2 physical improvement by 7.0 ± 9.2 (n = 34).

TABLE 2. Severity of Motor Deficit Versus Change in HRQOL From Baseline

	Change in LEM Score From Baseline		
	Decrease of >2 Points in LEMS	No Significant Change in LEMS (Decrease of 2-0)	Increase in LEMS
Oswestry disability index change from baseline			
6 weeks			
n	25	175	39
Mean (sd)	12.4 (17.5)	0.6 (20.0)	-0.6 (19.6)
6 months			
n	11	177	49
Mean (sd)	-7.3 (14.3)	-9.5 (18.5)	-13.7 (16.6)
24 months			
n	9	157	33
Mean (sd)	-4.7 (19.7)	-12.1 (16.5)	-16.3 (18.7)
SF-36v2 physical component summary score change from baseline			
6 weeks			
n	22	165	39
Mean (sd)	-4.5 (9.1)	-1.6 (11.0)	1.0 (8.9)
6 months			
n	8	174	49
Mean (sd)	0.8 (7.4)	2.7 (9.6)	6.1 (7.5)
24 months			
n	8	148	34
Mean (sd)	2.3 (8.9)	5.9 (10.4)	7.0 (9.2)
SF-36v2 mental component summary score change from baseline			
6 weeks			
n	22	165	39
Mean (sd)	-1.7 (13.7)	1.7 (13.3)	0.6 (12.6)
6 months			
n	8	174	49
Mean (sd)	-1.9 (16.5)	3.9 (13.3)	5.7 (13.0)
24 months			
n	8	148	34
Mean (sd)	-1.5 (12.8)	3.1 (11.5)	7.6 (12.0)
SRS-22r change from baseline			
6 weeks			
n	19	154	35
Mean (sd)	-0.0 (0.5)	0.4 (0.6)	0.5 (0.6)
6 months			
n	7	157	43
Mean (sd)	0.3 (0.7)	0.7 (0.7)	0.8 (0.6)
24 months			
n	8	136	29
Mean (sd)	0.4 (0.6)	0.7 (0.6)	0.9 (0.6)

LEMS indicates lower extremity motor score; HRQOLs, Health-related Quality of Life scores; SF-36v2, Short Form 36 version 2.

Changes in SF-36v2 mental score similarly varied by LEMS group. Figure 3 shows these data. At 6 weeks, motor-worse patients, motor-neutral patients, and motor-improved patients showed changes of scores of -1.7 ± 13.7 (n = 22), 1.7 ± 13.3 (n = 165), and 0.6 ± 12.6 (n = 39) respectively. At 6 months, the changes were -1.9 ± 16.5 (n = 8), 3.9 ± 13.3 (n = 174), and 5.7 ± 13.0 (n = 49) respectively, while at 2 years, the changes were -1.5 ± 12.8 (n = 8), 3.1 ± 11.5 (n = 148), and 7.6 ± 12.0 (n = 34) respectively.

SRS-22r scores were also affected by LEMS changes. Figure 4 shows changes in SRS-22r score from pre-op baseline. At 6 weeks, motor-worse patients, motor-neutral patients, and motor-improved patients showed score changes of 0.0 ± 0.5 (n = 19), 0.4 ± 0.6 (n = 154), and 0.5 ± 0.6 (n = 35), respectively. At 6 months, the changes were 0.3 ± 0.7 (n = 7), 0.7 ± 0.7 (n = 157), and 0.8 ± 0.6 (n = 43) respectively, while at 2 years, the changes were 0.4 ± 0.6 (n = 8), 0.7 ± 0.6 (n = 136), and 0.9 ± 0.6 (n = 29)

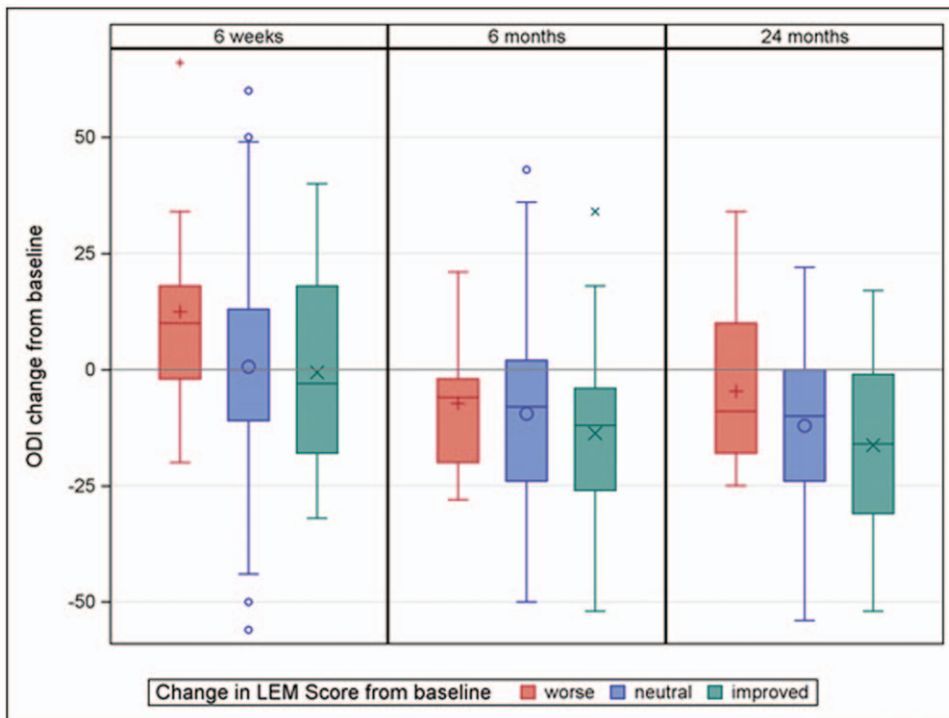


Figure 1. ODI change at 6 weeks, 6 months, and 2 years *versus* LEMS change. Data are plotted as box-plot. Motor-worse, neutral, and improved classification is as defined in the methods section. LEMS indicates lower extremity motor score; ODI, Oswestry Disability Index.

respectively. Specific patient composition in each group differs at each time point due to re-assessments of LEMS.

The largest group of patients were those who started motor intact (LEMS = 50), so we sub-analyzed this group. For the starting LEMS = 50 “motor-neutral” patients, ODI change was 1.0 ± 19.8 at 6 weeks, -9.5 ± 18.5 at 6 months, and -12.0 ± 16.4 at 2 years. In the same group,

change was -1.6 ± 11.1 at 6 weeks, 2.9 ± 9.6 at 6 months, and 6.0 ± 10.5 at 2 years. SRS-22r was 0.4 ± 0.6 at 6 weeks, 0.7 ± 0.7 at 6 months, and 0.8 ± 0.6 at 2 years.

In contrast, those who started intact (LEMS = 50) but were later “motor-worse,” ODI change was 14.7 ± 18.1 at 6 weeks, -7.6 ± 15.0 at 6 months, and -6.3 ± 21.1 at 2 years. In the same subgroup, SF-36 PCS change was -6.8 ± 10 at 6

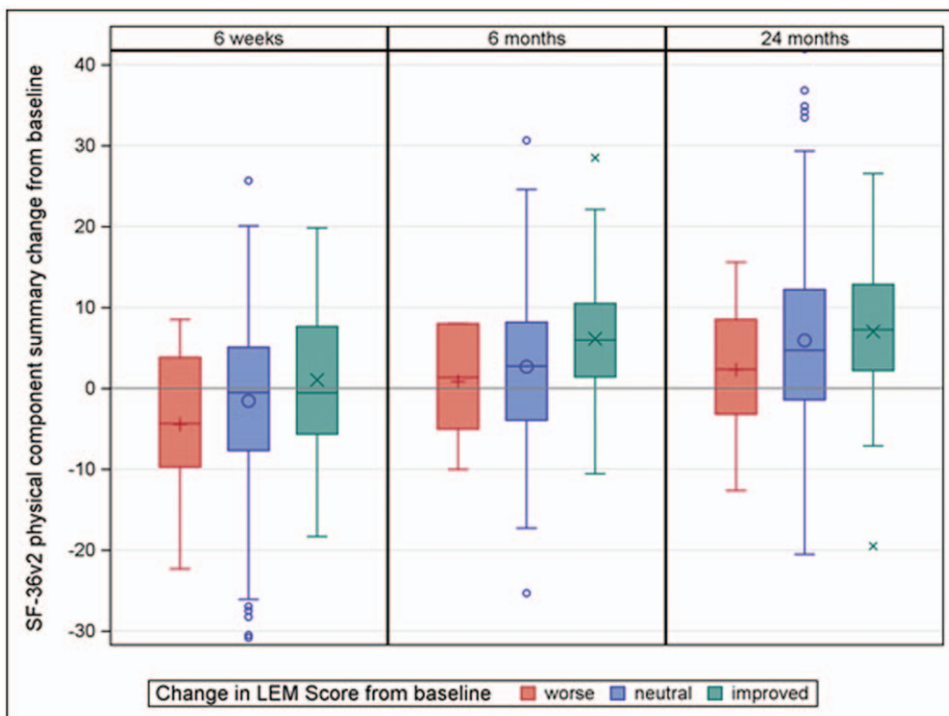


Figure 2. SF-36v2 physical score change at 6 weeks, 6 months, and 2 years *versus* LEMS change. Data are plotted as box-plot. LEMS indicates lower extremity motor score; SF-36v2, Short Form 36 version 2.

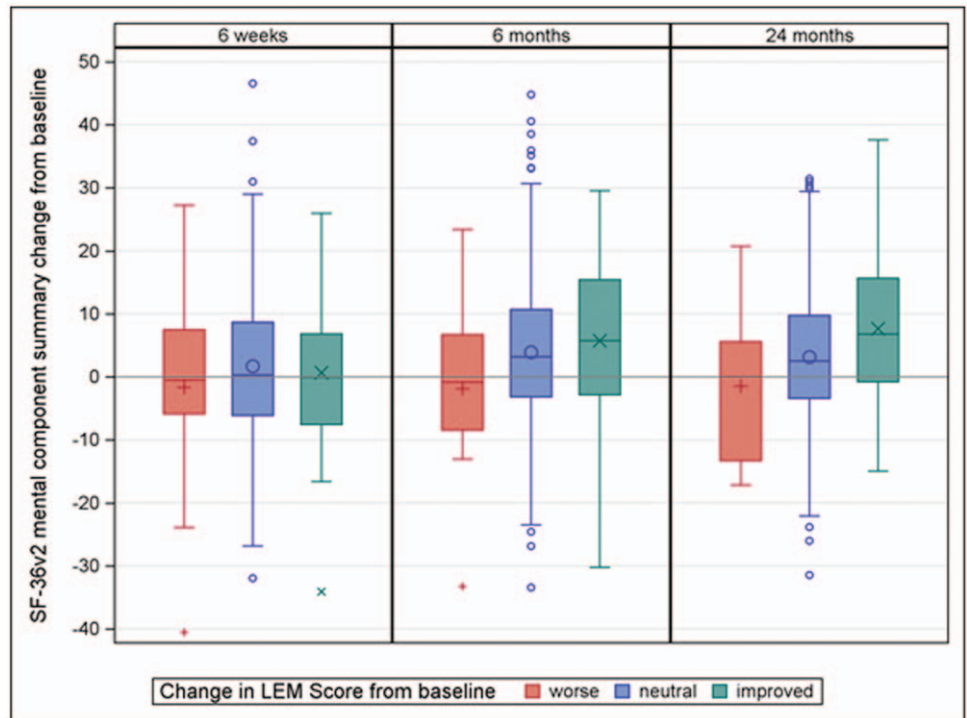


Figure 3. SF-36v2 mental score change at 6 weeks, 6 months, and 2 years *versus* LEMS change. Data are plotted as box-plot. LEMS indicates lower extremity motor score; SF-36v2, Short Form 36 version 2.

weeks, -0.2 ± 7.4 at 6 months, and 1.44 ± 5.3 at 2 years. SRS-22r change was 0 ± 0.6 at 6 weeks, 0.4 ± 0.8 at 6 months, and 0.4 ± 0.5 at 6 months. Complete results comparing starting sub-groups of LEMS = 50 to LEMS < 50 are shown in the supplementary tables, <http://links.lww.com/BRS/B684>.

DISCUSSION

The data herein showed that lower extremity motor function changes correlate with changes in patient-reported quality-of-life measures. As shown in the Figures 1–4, there was improved HRQOL outcome with improved LEMS

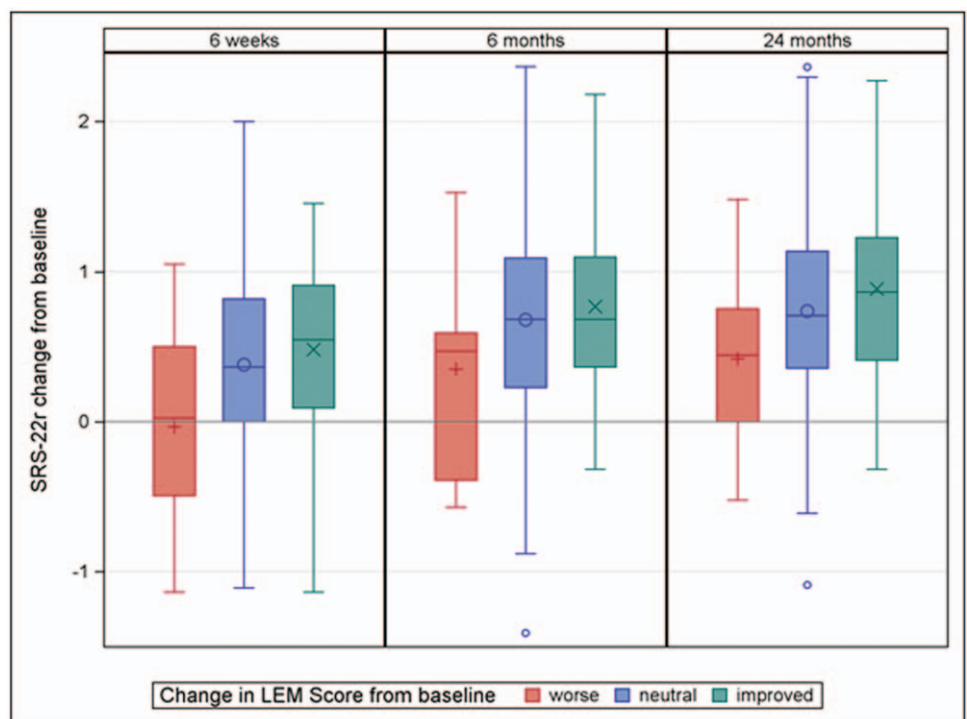


Figure 4. SRS score change at 6 weeks, 6 months, and 2 years *versus* LEMS change. Data are plotted as box-plot. LEMS indicates lower extremity motor score; SRS, SRS-22r.

outcome at almost all time points. The only exception was for SF-36v2 mental scores at 6 weeks, which were marginally better in motor-neutral patients (LEMS worsening by 0–2 points) than the motor-improved patients. Patients with more than 2 points decrease (“motor-worse”) on the 50 points LEMS scale saw the greatest decrease in early postoperative HRQOLs, as measured by ODI, SF-36 physical, SF-36 mental, and SRS scores. However, even these patients with the greatest motor deficit, showed improvement in three of the four HRQOL tests by 6 months. The only HRQOL test with a persistent negative change for motor-worse patients was SF-36v2 mental.

Analysis was completed at a descriptive level. Our statistician deemed it problematic to run tests for significance with such low sample size. For example, the group with LEMS decrease more than two contained only eight or nine patients. The great majority of patients were classified as motor-neutral. An additional statistical limitation was the ceiling effect of LEMS. For patients who are motor intact and start with a LEMS value of 50, further improvement is obviously not possible.

Within-group changes could not be compared to each other over time because the patient populations differed at timepoint. For example, patients with a decrease of more than 2 points in LEMS at 6 weeks were not identical to the patients with decrease of more than 2 points in LEMS at 6 months due to reassessment of ASIA at 6 months. Additionally, a few specific baseline HRQOL assessments were missing, leading to slight differences in patient number for the HRQOL change calculations between tests. For example, there were 30 motor-worse patients at 6 weeks, but only 25 patients had fully available scores for calculating ODI change. A total of 239 patients had sufficient data available for calculating ODI change at 6 weeks, which decreased to 199 total patients for ODI analysis at 2 years, a drop-off of 16.7%. Thus, there could have been some attrition bias, although the overall follow-up rate was high compared with similar studies.

Of note, we chose to consider LEMS 0–2 points worse as “motor-neutral.” This grouping was chosen in order to separate out patients with larger motor deficits of 3 points or more. The question we sought to answer was whether patients with large motor deficits still see any HRQOL improvement. We found that even this group has modest mean improvements in ODI, SF-36 PCS, and SRS scores.

In order to not discount those patients who started neuro intact and may notice an even a small worsening in LEMS, we analyzed those with starting LEMS = 50. Those patients who started neuro intact and were later “motor-worse” also still saw modest improvements in HRQOLs, such as mean ODI change of –6.3 at 2 years compared with mean ODI change of –12.0 at 2 years in pre-op LEMS = 50 patients who were “motor-neutral.” Thus, starting motor-intact and later encountering motor worsening did not prevent patients from achieving some HRQOL improvement, but the mean improvement did fall below MCID. The difference in mean ODI change between “neutral” and “worse” groups for pre-op LEMS = 50 patients was smaller than the those in the pre-op LEMS < 50 group, where motor-neutral patients had

ODI change of –13.4 compared with motor-worse patients who had ODI change of –1.3. However, the standard deviations were large in each group.

These data are presented in descriptive format (see Supplementary Tables, <http://links.lww.com/BRS/B684>) and statistical significance is not defined due to low sample size in many of the subgroups. The descriptive format still allows assessment of whether HRQOL changes exceeded minimum detectable measurement difference (MDMD). The MDMD for a HRQOL measurement is defined as the smallest change above measurement error and is preferred to minimal clinically important difference (MCID) when comparing differences between groups.³⁰ In ASD patients, MDMD for total SRS-22r score was calculated at 0.2; MDMD for ODI was 7.0, and MDMD for SF-36 PCS was 5.4.³⁰ Thus, all groups achieved SRS-22r improvements above MDMD by 2 years. However, only the motor-worse group did not achieve ODI improvement nor SF-36 PCS improvement above MDMD at 2 years.

In spite of these limitations, we were able to evaluate the between-group effect at each timepoint. In examining the entire cohort, the motor-neutral group showed a 6 week postoperative worsening of ODI and SF-36v2 physical scores, but improved for all other scores and timepoints. Patients with LEMS improvement showed ODI, SF-36v2 physical, SF-36v2 mental, and SRS score improvement at all time points compared with baseline. Taken together, these data emphasize the importance of neurological outcome on patient-reported quality of life outcomes after adult spinal deformity surgery.

CONCLUSION

An ambispective, multicenter observational study (Scoli-Risk-1) was completed to determine the impact of neural injury on HRQOLs. 31.9% of patients suffered any ASIA LEMS worsening during the first 2 years after surgery. Within three subcategories of LEMS change (>2 points worsening, 2 points worsening to no change, or LEMS improvement), ODI, SRS, SF-36v2 mental, and SF-36v2 physical scores worsened with LEMS worsening at 6 weeks, 6 months, and 2 years. LEMS worsening by more than 2 points led to diminished ODI, SF-36v2 mental, and SF-36v2 at 6 weeks. HRQOLs improved over time and were most improved in the group with improved LEMS. However, even patients whose LEMS worsened by more than 2 had improved ODI, SF-36v2 physical, and SRS at final follow-up.

➤ Key Points

- ❑ An ambispective, multicenter study (Scoli-Risk-1) was completed to determine the impact of motor deficits on HRQOLs after adult spinal deformity surgery.
- ❑ HRQOLs improved over time and were most improved in the group with improved LEMS.
- ❑ Even patients whose LEMS worsened by more than 2 points had improved ODI, SF-36v2 physical, and SRS at final follow-up.

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