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ORIGINAL ARTICLE

Lack of improvement in health-related quality of life (HRQOL) scores 6 months after surgery for adult spinal deformity (ASD) predicts high revision rate in the second postoperative year

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Abstract

Purpose ASD is assessed radiologically with the spino-pelvic parameters and clinically with HRQOL scores. The revision rate after ASD surgery is high and usually occurs during the first or second postoperative year. The aim of this study is to find clinical or radiological factors that could predict revision surgery in the second postoperative year.

Materials and methods Inclusion criterion: ASD patients operated on by instrumented posterior fusion with more than 2 years follow-up were enrolled prospectively. Additional criterion was no revision surgery during the first postoperative year. From a multicenter database of 560 operated ASD patients, 164 patients met these criteria. The patients were divided into two groups depending on the need of revision surgery during the second postoperative year. Preoperative, 6-month, 1-year and 2-year data were collected and compared for both groups.

Results A total of 22 patients needed revision surgery and 142 did not. All revisions were for mechanical complications (non-fusion and implant related). Preoperatively, there was a significant difference between the groups (no revision vs. revision) for age (48 vs. 60 years), ODI (37 vs. 53), and SVA (29 vs. 76 mm), respectively. At 6 months, a significant difference in sagittal alignment was found, though HRQOL scores were similar. At 1 year, the no revision group scores improved, whereas the revision group scores remained stable or worsened. At 2 years, the no revision group scores remained stable. Comparing 6- and 12-month data, patients with improved, stable and worsened HRQOL scores had 8, 15 and 28% revision rates, respectively.

Conclusion The revision rate at the second-year post-surgery (13.4%) remains high and demonstrated that a 2-year follow-up is mandatory. In addition to usual risk factors for mechanical complications in ASD surgery, stabilization or worsening of the HRQOL scores between the 6th and 12th month postop was highly predictive of revision rate. This observation is beneficial for ASD patient follow-up as clinical symptoms clearly precede mechanical failure.

Keywords Adult spinal deformity · Complications · Health-related quality of life scores · Revision surgery · Predictive value

Introduction

Adult spinal deformity (ASD) has become a frequent condition with the aging population, leading to functional limitations and disability in the elderly group [1]. Its management poses great challenges to the spine deformity surgeon in relation to its assessment, surgical treatment and

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mostly to its follow-up, with a high revision rate, ranging between 10 and 25% [2]. Revision surgery most frequently occurs during either the first or the second postoperative year [3], which emphasizes the fact that a long follow-up of at least 2 years is mandatory in such spinal disease. The main reasons for late reoperation are pseudarthrosis, implant failure and proximal junctional kyphosis.

ASD, frequently associated with sagittal malalignment [4, 5], is classically assessed radiographically with the different spinal and pelvic parameters, and clinically with the health-related quality of life scores (HRQOL) [6, 7]; these scores have become of great importance not only in comparing the benefits from the different lines of management for ASD but also in the patient's evaluation preoperatively and postoperatively, and they also may help the surgeon in early detection of a complication that may lead to reoperation. The goals of the surgical treatment include correction of the deformity, with restoration of the spinal sagittal and coronal alignment, and depending on the deformity stiffness and severity, different kind of aggressive procedures such as vertebral column osteotomies may be used.

Studies have mainly focused on the first postoperative year after ASD surgery [8], to determine within that time frame the prevalence of reoperation, its relation to the spinopelvic parameters and its impact on the HRQOL scores. There is a lack of information concerning revisions after the first year. These late revisions are difficult for the patient to apprehend, as the perioperative period seemed passed. The purpose of this study is to find if some early clinical or radiological factors could predict late revision surgeries.

Materials and methods

This study is a retrospective review of a prospective, multicenter adult spinal deformity database. Data from consecutive cases involving patients treated between October 2009 and November 2013 were obtained, and all patients were enrolled into an institutional review board-approved protocol by the respective sites. Inclusion criteria are: age of at least 18 years, presence of a spinal deformity defined by at least one of the following parameters: Cobb angle $\geq$20°, pelvic tilt (PT) $\geq$25°, sagittal vertical axis (SVA) $\geq$5 cm, or thoracic kyphosis $\geq$60°, with minimum of 2 years of follow-up, and no revision surgery during the first postoperative year.

Data collected included age, sex, date of surgery, total operative time, number of levels included in the instrumentation, estimated blood loss, osteotomy type according to Schwab's classification [9], complications, reoperation dates.

Different radiological parameters were assessed preoperatively, at 6 months, 1 year, and 2 years after the index surgery and included [10]: sagittal vertical axis (SVA: distance between the C7-plumb line and posterior superior margin of S1), global tilt (GT: angle formed by the intersection of two lines, the first line is drawn from the center of C7 to the center of the sacral endplate and the second line is drawn from the center of the femoral heads to the center of the sacral endplate), pelvic incidence (PI), pelvic tilt (PT), lumbar lordosis (LL), thoracic kyphosis (TK), lumbar lordosis index (LLI: ratio between lumbar lordosis and pelvic incidence) [11], PI-LL mismatch [12], Cobb angle.

The HRQOL scores were collected preoperatively, at 6 months, 1 year, and 2 years after the index surgery and included Oswestry Disability Index (ODI), Short Form 36 (SF36) mental and physical component summary (MCS and PCS), Core Outcome Measure Index (COMI), and Scoliosis Research Society 22 questionnaire (SRS22).

Two groups were identified, one group with no revision surgery during the second postoperative year, and one group with revision surgery during the second postoperative year. All clinical (HRQOL) and radiological (spinopelvic parameters) data were compared for both groups at the different time intervals.

Statistical analysis was performed using the IBM SPSS Statistics V20.0.0 software. Non-matched *t* tests were used to assess the distributions of the "revision group" and "no revision group" patients, and matched *t* tests were used to assess, in the same cohort, the differences between the mean values of the different parameters at different follow-up periods (baseline, 6 months, 1 year, 2 years). Crossed tables and Pearson's Chi-square tests were done to compare the distributions of the demographic and clinical variables. The minimum clinically important difference (MCID) [13, 14] is a commonly used method to quantify a threshold of improvement that is clinically relevant to the individual patient for various outcome measures. Calculation of the MCID was done for the ODI score, which means that ODI scores above the MCID would state an important improvement of the patients' quality of life; therefore, we compared ODI scores between the 6-month and 1-year periods. Patients were classified into three sub-groups according to the differences found between the aforementioned periods with a threshold set at 12.8 points: the "best" group when the improvement difference is above 12.8, the "worst" group when the worsening difference was more than 12.8, and the "no change" group when the difference between the two values was between the previous limits. For each group, we assessed the revision frequency and did a *z* score transformation to determine if the difference in frequency between the groups was significant. p values <0.05 are considered statistically significant.

Results

From the multicenter database of 560 operated ASD patients, 164 patients met the inclusion criteria, of which 22 patients required reoperation during the second-year follow-up (13.4%), thus the "revision group" (RG) included 22 patients, and the "no revision group" (NRG) included 142 patients.

Preoperatively (Table 1), there was a significant difference between both groups for the age (48 ± 18 years for the NRG, 60 ± 15 years for the RG), the ODI score (37 ± 20 for the NRG, 53 ± 23 for the RG), the SF-36 PCS score (36 ± 9 for the NRG, 31 ± 7 for the RG), and the following radiological parameters: the SVA (29 ± 63 mm for the NRG, 76 ± 66 mm for the RG), the PI (53° ± 12° for the NRG, 62° ± 10° for the RG), the PT (19° ± 11° for the NRG, 32° ± 10° for the RG), the GT (22° ± 16° for the NRG, 41° ± 19° for the RG), the LLI (−0.88 ± 0.45 for the NRG, −0.61 ± 0.32 for the RG) and the PI-LL (16 ± 21 for the NRG, 28 ± 18 for the RG).

At 6 months (Table 2), significant difference was found between both groups for the SVA (8 ± 45 mm for the NRG, 42 ± 48 mm for the RG), the PI (53° ± 12° for the NRG, 62° ± 8° for the RG), the PT (18° ± 10° for the NRG, 30° ± 9° for the RG), the GT (18° ± 12° for the NRG, 34° ± 12° for the RG), the LLI (−1.02 ± 0.28 for the NRG, −0.78 ± 0.21 for the RG) and the PI-LL (9 ± 12 for the NRG, 18 ± 12 for the RG). There was no significant difference between both groups in the various HRQOL scores at 6 months.

At 1 year (Table 3), the significant difference between both groups regarding the aforementioned radiological parameters remained; in addition, the various HRQOL scores for the NRG continued to improve, whereas the RG scores remained the same or worsened with a significant difference between both groups (except for SF-36 PCS score): the SF-36 MCS (47 ± 11 for the NRG, 41 ± 13 for the RG), the SF-36 PCS (43 ± 10 for the NRG, 39 ± 8 for the RG), the ODI (26 ± 17 for the NRG, 39 ± 21 for the RG), the COMI (3 ± 2 for the NRG, 5 ± 2 for the RG), and the SRS-22 (3.5 ± 0.7 for the NRG, 3.2 ± 0.7 for the RG).

Table 1 Baseline parameters for NRG and RG

Baseline	NRG	RG	*p*
Age (years)	48 ± 18	60 ± 15	<0.01
ODI	37 ± 20	53 ± 23	<0.01
SF-36 PCS	36 ± 9	31 ± 7	<0.01
SVA (mm)	29 ± 63	76 ± 66	<0.01
PI (°)	53 ± 12	62 ± 10	<0.01
PT (°)	19 ± 11	32 ± 10	<0.01
GT (°)	22 ± 16	41 ± 19	<0.01
LLI	−0.88 ± 0.45	−0.61 ± 0.32	<0.01
PI-LL (°)	16 ± 21	28 ± 18	<0.01

Table 2 6-month postoperative parameters for NRG and RG

6 months	NRG	RG	*p*
ODI	29 ± 18	36 ± 23	0.11
SF-36 PCS	39 ± 9	40 ± 10	0.57
SF-36 MCS	46 ± 12	42 ± 11	0.15
COMI	4 ± 2	4 ± 3	0.79
SRS-22	3 ± 1	3 ± 1	0.64
SVA (mm)	8 ± 45	42 ± 48	<0.01
PI (°)	53 ± 12	62 ± 8	<0.01
PT (°)	18 ± 10	30 ± 9	<0.01
GT (°)	18 ± 12	34 ± 12	<0.01
LLI	−1.02 ± 0.28	−0.78 ± 0.21	<0.01
PI-LL (°)	9 ± 12	18 ± 12	<0.01

Table 3 1-year postoperative parameters for NRG and RG

1 year	NRG	RG	*p*
ODI	26 ± 17	39 ± 21	<0.01
SF-36 PCS	43 ± 10	39 ± 8	0.07
SF-36 MCS	47 ± 11	41 ± 13	<0.01
COMI	3 ± 2	5 ± 2	<0.01
SRS-22	3.5 ± 0.7	3.2 ± 0.7	<0.01
SVA (mm)	15 ± 47	61 ± 50	<0.01
PI (°)	53 ± 12	61 ± 10	<0.01
PT (°)	19 ± 10	29 ± 7	<0.01
GT (°)	19 ± 14	35 ± 12	<0.01
LLI	−0.97 ± 0.34	−0.78 ± 0.16	<0.01
PI-LL (°)	12 ± 17	18 ± 10	<0.01

At 2 years, the NRG scores remained stable; the RG patients underwent surgery during the second year (Figs. 1, 2, 3, 4, 5). The functional data for the RG group after revision surgery were not collected, as the effectiveness of revision surgery was not the point of the study. Moreover, the follow-up after revision surgery was too short to assess the revision outcome.

Comparing 6- and 12-month data, and calculating the MCID for the ODI, patients with improved, stable and worsened HRQOL scores had 8, 15 and 28% revision rates, respectively (Table 4).

All the complications that occurred after the first postoperative year were mechanical complications with 17 non-union (77%), 3 intolerable remaining malalignment

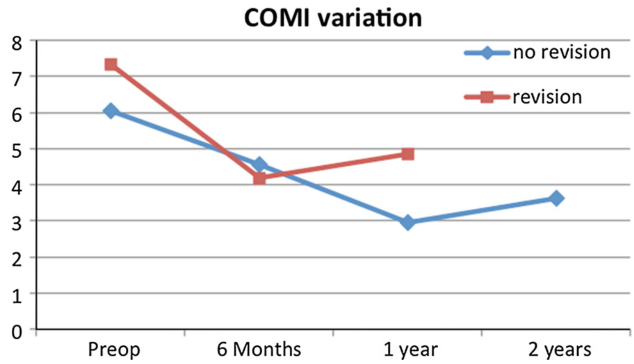

Fig. 1 HRQOL scores fluctuation over time. At 6-month follow-up no differences occur between RG and NRG groups. The NRG scores keep on improving after 6 months as the RG scores stabilize after 6 months

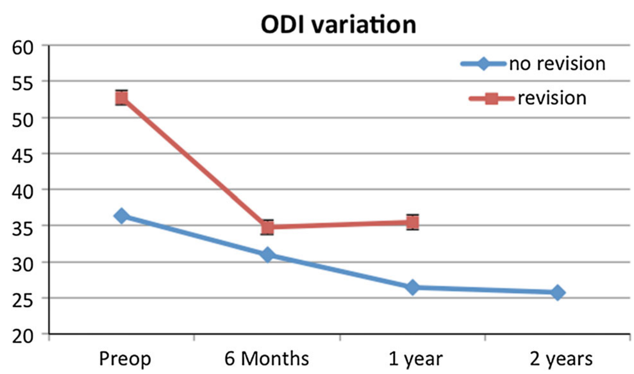

Fig. 2 HRQOL scores fluctuation over time. At 6-month follow-up no differences occur between RG and NRG groups. The NRG scores keep on improving after 6 months as the RG scores stabilize after 6 months

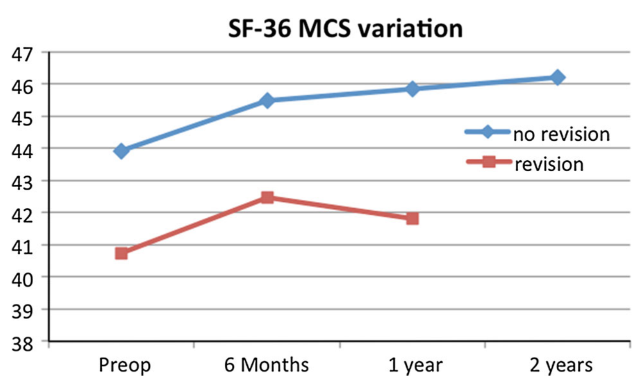

Fig. 3 HRQOL scores fluctuation over time. At 6-month follow-up no differences occur between RG and NRG groups. The NRG scores keep on improving after 6 months as the RG scores stabilize after 6 months

(13.6%, coronal or sagittal), 1 painful implant and 1 adjacent segment degeneration (Table 5). Patients with non-union presented a persistent low back pain that did not exist before, with progressive difficulty to walk in some

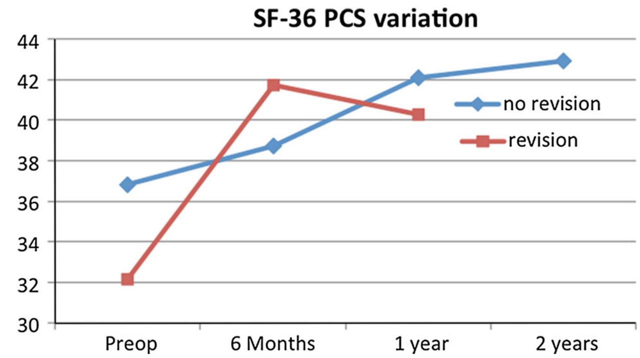

Fig. 4 HRQOL scores fluctuation over time. At 6-month follow-up no differences occur between RG and NRG groups. The NRG scores keep on improving after 6 months as the RG scores stabilize after 6 months

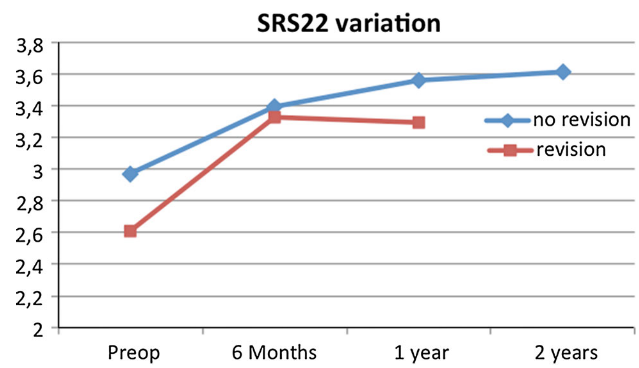

Fig. 5 HRQOL scores fluctuation over time. At 6-month follow-up no differences occur between RG and NRG groups. The NRG scores keep on improving after 6 months as the RG scores stabilize after 6 months

Table 4 Minimum clinically important difference (MCID) for the ODI when comparing the 6-month and 1-year scores for NRG and RG

ODI status 6 months–1 year	NRG	RG	Frequency (%)
Best	25	2	8.00
No change	99	15	15.15
Worse	18	5	27.78
Total	142	22	

cases, X-rays revealed in all cases a fracture of either one rod or the two rods at the concerned level.

No PJK, neurological complications or infections were reported. No patient died or was lost to follow-up.

Of the total of 164 patients, 29 patients had a three-column osteotomy (17.6%), and 8 of the 29 required reoperation. Indications for reoperation were pseudarthrosis in all cases. Therefore, patients that underwent a PSO revealed a revision rate of 27.6%, while a revision rate of 10.4% was seen when a PSO was not done ($p = 0.014$).

Table 5 Complications during the second year following ASD surgery

Complications	Number	Percentage
Non-union	17	77.3
Intolerable remaining malalignment	3	13.6
Painful implant	1	4.5
Adjacent segment degeneration	1	4.5
Proximal junctional kyphosis	0	0
Infection	0	0
Death	0	0

Discussion

To our knowledge, no previous study on ASD had specifically analyzed the reoperation rate during the second postoperative year and looked into its possible predictive factors, clinical or radiological.

The rate of mechanical complications after the first year (13.4%) remains high and definitely demonstrates that a 2-year minimum follow-up is mandatory after ASD surgery, and should even be extended further [15]. We should remember that this rate concerns the revision only during the second postoperative year, and that it should be added to the revision rate that occurs during the first year to have a global revision rate during the 2 years following the index surgery, which emphasize the fact that surgical management of ASD patients remains, nowadays, challenging despite the better knowledge of sagittal alignment with all its radiological spinal and pelvic parameters. This study showed that in addition to the radiological parameters, the HRQOL scores are equally important in the assessment of ASD patients and can also help significantly in the prediction of complications.

Predictive factors for complications are: elderly patient [16], preoperative greater sagittal malalignment, poorer baseline HRQOL scores [17], postoperative residual sagittal malalignment, and postoperative stabilization or worsening of the HRQOL scores between the 6-month and 1-year period. Calculation of the MCID for the ODI score showed that, comparing 6- and 12-month data, patients with improved, stable and worsened scores had 8, 15 and 28% revision rates, respectively.

The type of surgery (degree of osteotomy) seems to be a clear factor of complications as the difference between revision rates when comparing patients with or without a PSO was statistically significant ($p = 0.014$).

Despite a residual sagittal malalignment at 6 months compared to the NRG, the HRQOL scores of the RG do not seem to be affected, which would make the surgeon think, wrongly, that the outcome is globally satisfying; this is probably due to the fact that the patient had initially an important baseline disability with significant radiological malalignment, and that in spite of the residual postoperative malalignment, the daily life was relatively improved.

The most interesting follow-up period is the time interval between the 6th month and 1 year after the index surgery. This study showed that the NRG continued to improve the HRQOL scores, whereas the RG either stabilized or worsened their scores, despite the fact that no complication still occurred and that the radiological status remained globally stable. The clinical impact of an eventual future complication assessed by the HRQOL scores seems to precede the occurrence of that complication by several months; this observation should help the surgeon in identifying the patients at risk for a future complication and prepare them for an eventual reoperation.

In a study by Smith [18] comparing patients with ASD with best vs. worst clinical outcomes following surgical treatment, the following factors were found to predict a non-favorable clinical outcome: greater baseline ODI scores, greater baseline comorbidities, BMI and depression, greater baseline SVA, and greater baseline PI-LL mismatch. These results are very similar to our study preoperative predictive factors. They also noticed postoperatively that a residual positive SVA, a greater PI-LL mismatch, and the occurrence of complications might predict a bad outcome.

Ayhan et al. [8], in a study on ASD surgical management with the use of osteotomies, stipulated that improvement of HRQOL scores mostly take place in the first 6 months after the index surgery, and he mentioned that these improvements are not necessarily adversely affected by the presence of complications. Our study showed that in the NRG, the HRQOL scores continued to improve not only after the 6-month period but even after the 1-year period, and also that no improvement or worsening of the HRQOL scores after the 6-month period is highly correlated with the occurrence of a complication after the 1-year period, which means that the complication does not only affect the clinical status after it occurs but also earlier before its occurrence.

Scheer et al. [2] showed a reoperation rate of 17% at a mean follow-up of 1.6 years after the index procedure for ASD patients, age did not have in this study a significant effect on the revision rate, and instrumentation complications were the main indication for revision, which is similar to our results. Their patients worsened their HRQOL after the revision surgery (during the first year) but the scores improved progressively to reach a similar result of their no revision group at 2 years. In our study, the effectiveness of revision surgery has not been evaluated. A 2-year follow-up since the revision surgery would be an interesting point to study to evaluate the effectiveness of these revision surgeries.

In this same study by Scheer, 12% of the patients who underwent a three-column osteotomy had a revision surgery during the first year, and 7% had a revision surgery during the second year.

In our study, three-column osteotomy was predictive of reoperation during the second year ($p = 0.014$).

Relative shortcomings of the study include those inherent to the data registries in general, i.e., the potential bias in data entry especially in regard to the reporting of complications, and the retrospective nature of data analysis. Another limitation may be the significant age difference between both studied groups.

In addition to usual risk factors for mechanical complications in ASD surgery, we found interestingly that stabilization or worsening of the HRQOL scores between the 6th and 12th month postop is highly predictive of revision rate, as almost one third of the patients that worsened their ODI score was revised (28%). This observation adds a key value to the ASD patient follow-up as clinical symptoms clearly precede mechanical failure.

The need for reoperation may be minimized by the following different factors: thorough preoperative planning with special attention to the patients with high PI (60° and above), achieving the best sagittal alignment especially the lumbar lordosis, avoiding a more aggressive correction technique (three-column osteotomy) when possible may be advised, anterior column realignment may be a good alternative in that case [19], precautions to avoid rods failure by the use of multiple rods constructs [20], and the number of levels to be instrumented taking into account the coronal and sagittal planes especially to avoid stopping on a kyphotic area.

In conclusion, this study demonstrated a reoperation rate of 13.4% during the second postoperative year after ASD surgery. The early identification of HRQOL scores that stabilize or worsen between the 6-month and 1-year period may help the surgeon, not only in predicting an eventual future complication, but also to prepare the patient for the probability of a reoperation, therefore, avoiding sudden surprises. Patient would probably appreciate this scientific honesty and transparency from the surgeon, which would be beneficial for the surgeon–patient confidence and relationship, part of the success of ASD management.

Compliance with ethical standards

Conflict of interest There are no conflicts of interest for this article.

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