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Radiographical and Implant-Related Complications in Adult Spinal Deformity Surgery

Incidence, Patient Risk Factors, and Impact on Health-Related Quality of Life

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Study Design. A multicenter, prospective review of surgical patients with adult spine deformity.

Objective. Assessment of the incidence, risk factor, and impact of radiographical and implant-related complications (RIC) on health-related quality of life measures.

Summary of Background Data. This study provides assessment of the incidence of RIC in adult spinal deformity surgery and impact of these complications on need for reoperation. Risk factors for development of RIC are also assessed, as well as the impact of these complications on health-related quality of life (HRQOL) outcomes measures.

Methods. A multicenter, prospective database of surgical patients with adult spinal deformity was reviewed. All patients with complete 2-year follow-up were included. HRQOL was measured using the Oswestry Disability Index, General Health Survey (36-Item Short Form Health Survey [SF-36]), and Scoliosis Research Society-22 (SRS-22r) at baseline, 6 weeks, 1 year, and 2 years postoperatively. Univariate testing was performed as appropriate. Multivariate logistic regression modeling was used to determine independent predictors of RIC. Multivariate repeated-measures mixed models were used to examine HRQOL, accounting for confounders.

Results. A total of 245 patients met inclusion criteria. The incidence of RIC was 31.7% and 52.6% of those patients required reoperation. Rod breakage accounted for 47% of the implant-related complications, and proximal junctional kyphosis accounted for 54.5% of radiographical complications. Univariate analysis identified the following potential risk factors for RIC: weight, American Society of Anesthesiologists score, revision, stopping the fusion in the lower thoracic spine, worse SRS-Schwab classification modifiers (pelvic tilt++, pelvic incidence minus lumbar lordosis++, sagittal vertical axis++), higher T1 spinopelvic inclination, and higher T1 slope. Independent predictors of RIC as identified on multivariate logistic regression included American Society of Anesthesiologists (odds ratio: 1.75, $P = 0.029$) and sagittal vertical axis modifier ++ (odds ratio 3.43, $P = 0.0001$). The RIC and no RIC groups each experienced significant improvement over time, as measured on the Oswestry Disability Index ($P = 0.0001$), SF-36 ($P = 0.0001$), and SRS-22r ($P = 0.0001$). However, the rate of improvement over time was less for patients with RIC (SRS-22r $P = 0.043$, SF-36 $P = 0.0001$).

Conclusion. This study identified that nearly one-third of patients undergoing adult spinal deformity surgery experienced a radiographical or implant-related complication, and that just more than one-half of these patients experiencing complication required a reoperation within 2 years of surgery. These complications significantly affected HRQOL measures. Baseline patient characteristics and parameters of the SRS-Schwab classification can be used to help identify those patients at greater risk.

Key words: adult spinal deformity, complications, radiographical, implant-related.

Level of Evidence: 3

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Spinal deformity is the oldest diseases known to humankind.[1] Adult spinal deformity (ASD) is common and its incidence increases with age. A recent study by Schwab *et al*[2] showed a prevalence of 68% in patients older than 60 years. Radiographical imaging originally developed by Roentgen[3] remains a fundamental tool for ASD diagnostic approaches. Frontal and sagittal full-length radiographs allowed physicians to better study spinal deformity. Based on the established correlations between radiographical parameters and health-related quality of life (HRQOL) scores,[4,5] Schwab *et al*[6] proposed a clinically relevant classification for ASD that has the advantages of highlighting the radiographical severity of disease and guiding treatment. This classification, known as the SRS-Schwab classification, is well established.[7,8]

The surgical treatment of spinal deformity has evolved with the revolution of spinal fusion by Hibbs,[9] Albee,[10] King,[11] and implants' applications to stabilize the spine by Lange,[12] Harrington,[13] and Cotrel and Dubousset.[14] Implants and surgical techniques have advanced over the past years, allowing surgeons to treat more complex deformities. Today, the utilization of deformity-specific implants and spinal osteotomies has further improved the surgical treatment of ASD.[15–18] Nevertheless, deformity surgery is challenging and complex procedure with high reported complication rates.[19–21] Complications related to spine surgery are typically classified as minor or major,[22] and some authors further divided between surgical and medical.[23]

Surgical complications encompass a variety of entities, which can be further differentiated into surgical complications that are mechanical in nature (*e.g.*, radiographical complications include proximal junctional kyphosis (PJK) and implant-related complications, such as pullout and implant fracture) and those that are not (*e.g.*, neurological deficits, incidental durotomy, and wound dehiscence). Few studies investigated the impact of implant-related complications on surgical outcomes in disease-specific cohorts[24] or investigated specific mechanical complications.[25–28] The present study investigated the incidence of both radiographical and implant-related complications (RICs) in ASD, identified risk factors, and examined the impact of these types of complications on patient-reported outcomes.

MATERIALS AND METHODS

Database

This study is a retrospective analysis of a multi-institutional prospective database of consecutively enrolled patients with ASD. This database comprised patients enrolled at 11 high-volume institutions. The study was approved by the institutional review board of all participating centers.

Inclusion Criteria

Inclusion criteria for the whole database were age more than 18 years and presence of spinal deformity, as defined by at least 1 of the following: scoliosis Cobb angle of 20° or greater, sagittal vertical axis (SVA) of 5 cm or greater, pelvic tilt (PT) of 25° or greater, and/or thoracic kyphosis of 60° or more. The present study included patients only with completed 2-year follow-up:

Exclusion criteria were spinal deformity of a neuromuscular etiology and presence of active infection or malignancy.

Data Collection

Demographic Data

The following demographic and clinical data were obtained for each patient: age, sex, body mass index (BMI), American Society of Anesthesiologists (ASA) grade, smoking status, comorbidities, and surgical history.

Surgical Data

Surgical approach, osteotomies performed, levels fused, operating room time, estimated blood loss, utilization of interbody fusion, whether decompression was performed, and length of hospital stay.

Radiographical Data

All patients had obtained standing 36-in. posteroanterior and lateral spine radiographs at baseline and at 6-week, 1-year, and 2-year follow-up. To ensure consistency, radiographical evaluations were performed at a central location using validated spine software (SpineView; Laboratory of Biomechanics ENSAM ParisTech, Paris, France).[29] Coronal plane measurements included upper thoracic, thoracic, thoracolumbar, and lumbar Cobb angles. Sagittal plane measurements included thoracic kyphosis (T4–T12), thoracolumbar kyphosis (T10–L2), lumbar lordosis (L1–S1), T1 slope (TS), T1 spinopelvic inclination (T1SPI), SVA. Pelvic parameters included sacral slope, PT, and pelvic incidence (PI). Preoperative radiographs were classified according to the SRS-Schwab adult spinal classification.[6]

Health-Related Quality of Life

Standardized HRQOL measures included the Oswestry Disability Index (ODI),[30] Refined Scoliosis Research Society-22 (SRS-22r),[31] and 36-Item Short Form Health Survey (SF-36)[32] questionnaires and were collected at baseline and at 6-week, 1-year, and 2-year follow-up.

Complications

Implant-related complications included rod breakage, dislodgement or prominence, screw malposition or fracture, interbody subsidence, migration or fracture, dislodgement, and painful or prominent implants. Radiographical complications included PJK, distal junctional kyphosis, pseudarthrosis, adjacent segment degeneration, Sagittal malalignment, curve decompensation, heterotopic ossification, fracture, and flatback (Table 1).

Statistical Analysis

Statistical analysis was performed using Stata v13 (StataCorp, College Station, TX). Potential predictors of RICs were identified among baseline patient demographic factors, baseline

TABLE 1. Radiographical and Implant-Related Complications

Complication	N	%
Implant-related		
Rod breakage	16	47
Prominence	5	14.70
Painful implant	4	11.70
Screw breakage	3	8.80
Screw loosening	2	5.90
Screw malposition	2	5.90
Implant dislodgement	2	5.90
Total	34	
Radiographical		
Proximal junctional kyphosis	24	54.50
Pseudarthrosis	5	11.40
Adjacent segment disease	5	11.40
Distal junctional kyphosis	5	11.40
Sagittal malalignment	3	6.80
Implant fracture	2	4.60
Flatback	1	2.30
Total	45	
Total (radiographical + Implant-related)	79	

TABLE 2. Univariate Analysis Comparing Between Patients' Demographics and Surgical Factors Between the No RIC and RIC Groups

Univariate Analysis: Baseline Patient Demographics			
	No RIC	+RIC	*P*
Weight (kg)	70.8	76.3	0.019
American Society of Anesthesiologists score	2.17	2.5	0.0029
Previous spine surgery	37.9%	53.33%	0.025
Diabetes	3%	7.6%	0.1
Smoking	11.8%	4.22%	0.07
Osteoporosis	8.5%	13%	0.457
Body mass index	26.7	27.9	0.92
Sex (female)	85.4%	85%	0.98
Univariate Analysis: Surgical Factors			
	No RIC	+RIC	*P*
Long TL fusion (UIV T1–T5)	52.4%	37.1%	0.026
Three-column osteotomy	16.6%	25.97%	0.09
Interbody	48.8%	61.53%	0.06
Bone morphogenetic protein (BMP2)	60.7%	62.8%	0.75
Rod material	Stainless: 41%	Stainless: 53.9%	0.16
	Titanium: 35.5%	Titanium: 23.7%	
	Other: 23.5%	Other: 22.4%	
Rod diameter	5.00	4.98	0.43

RIC indicates radiographical and implant-related complications; TL, thoracolumbar; UIV, upper instrumented vertebrae.

patient comorbidities, baseline radiographical features, and perioperative factors using univariate analysis (*t* tests, or χ^2 tests, as appropriate). Multivariate Poisson regression was used to determine independent predictors of medical complications. The model was built using an automated stepwise method (significance level for removal of 0.1). The effect of RICs on HRQOL outcome measures (SRS-22r, ODI, and SF-36) was determined using multivariate repeated-measured mixed models with accounting for confounders.

RESULTS

A total of 246 patients met inclusion criteria. A total of 78 RICs (incidence of 31.7%) were identified, including 34 implant-related complications and 44 radiographical complications. A descriptive summary of the RICs is presented in Table 1. Rod breakage accounted for 47% of the implant-related complications, and PJK accounted for 54.5% of radiographical complication. Patients (52.6%) who sustained a postoperative radiographical or implant-related complication required a reoperation.

Results of univariate analysis looking at the impact of patient demographics and baseline comorbidities on the incidence of RICs are shown in Table 2. Patients who experienced radiographical and implant-related comorbidities were on average heavier (76.3 kg *vs*. 70.8 kg, $P = 0.019$), had more comorbidities (ASA scale score of 2.50 *vs*. 2.17, $P = 0.0029$), and had a higher incidence of previous spine surgery (53.3% *vs*. 37.9%, $P = 0.025$) than patients who did not experience these complications. Patients who sustained RICs had a trend toward having a higher incidence of diabetes ($P = 0.07$) and fewer smokers ($P = 0.1$). There were no statistically significant differences between the 2 groups with regard to average BMI, history of osteoporosis, or sex distribution.

Results of univariate analysis looking at the impact of surgical factors on the incidence of RICs are presented in Table 2. Patients who experienced a postoperative radiographical or implant-related complication had a lower proportion of long thoracolumbar fusions with an upper instrumented vertebrae between T1 and T5 (37.1% *vs*. 52.4%, $P = 0.026$). They also had a trend toward having a higher incidence of 3-column osteotomies (0 = 0.09) and interbody fusions ($P = 0.06$)

TABLE 3. Univariate Analysis Comparing the Impact of SRS-Schwab Modifiers and Sagittal and Spinopelvic Parameters Between the No RIC and RIC Groups

Univariate Analysis: Schwab SRS Classification			
	No RIC	+RIC	*P*
Coronal curve N	21.5%	32.5%	0.067
PT modifier ++	22.15%	35%	0.033
PI-LL modifier ++	26.9%	48.05%	0.001
SVA modifier ++	19.8%	42.67%	0.0001
Univariate Analysis : Sagittal and Spinopelvic Parameters			
	No RIC	+RIC	*P*
PT	21.73	25.53	0.014
C7 SVA	41.1	86.2	0.0001
Sacral slope	33.09	29.27	0.02
LL	44.55	35.09	0.0013
PI	54.83	54.8	0.987
PI-LL mismatch	10.24	19.76	0.0009
Thoracic kyphosis (T4–T12)	31.19	31.69	0.83
Thoracolumbar kyphosis (T10–L2)	12.19	13.75	0.49
T1 slope	23.67	27.99	0.0175
T1 spinopelvic inclination	−2.87	0.51	0.0001

RIC indicates radiographical and implant-related complications; PT, pelvic tilt; PI, pelvic incidence; LL, lumbar lordosis; SVA, sagittal vertical axis.

performed. There were no statistically significant differences between the 2 groups in terms of bone morphogenetic protein utilization, average rod diameter, or rod material used.

Results of univariate analysis looking at the impact of the preoperative SRS-Schwab classification on the incidence of RICs are shown in Table 3. Patients who experienced RIC had a higher incidence of severe sagittal malalignment, as demonstrated by all 3 SRS-Schwab sagittal spinopelvic modifiers. The RIC group had a higher proportion of patients with ++ PT modifier (35% *vs*. 22.15%, $P = 0.033$), a higher proportion of patients with ++ pelvic incidence minus lumbar lordosis (PI-LL) modifier (48.05% *vs*. 26.9%, $P = 0.001$), and a higher proportion with ++ SVA modifier (42.67% *vs*.19.8% $P = 0.0001$). There was a trend toward more N-type coronal curves in the RIC group (32.5% *vs*. 21.5%, $P = 0.067$).

Results of univariate analysis looking at the impact of preoperative sagittal and spinopelvic parameters on the incidence of RICs are presented in Table 3. In keeping with the results of the SRS-Schwab sagittal modifier comparisons, the RIC group had a lower lumbar lordosis (35.09° *vs*. 44.55°, $P = 0.0013$) and similar PI (54.80° *vs*. 54.83°, $P = 0.987$), resulting in a larger baseline PI-LL mismatch (19.76° *vs*. 10.24°, $P = 0.0009$). When compared with the non-RIC group, patients who experienced RICs also had a higher preoperative PT (25.53° *vs*. 21.73°, $P = 0.014$), a higher C7 SVA (86.2 mm *vs*. 41.1 mm, $P = 0.0001$), a lower sacral slope (29.27° *vs*. 33.09°, $P = 0.02$). They also had a higher T1 slope (27.99° *vs*. 23.67°, $P = 0.0175$) and a higher T1 spinopelvic inclination (0.41° *vs*. −2.87°, $P = 0.0001$). The 2 groups were similar with regard to thoracic (T4–T12) and thoracolumbar (T10–L2) kyphosis.

The results of multivariate logistic regression analysis looking at independent predictors of RICs among baseline demographic parameters, preoperative radiographical parameters, and surgical factors are shown in Table 4. Positive predictors of RICs (factors associated with higher odds of experiencing a radiographical or implant-related complication within 2 years of the index procedure) included higher ASA grade and worse SRS-Schwab SVA sagittal modifier ++. Each increase of 1 point on the ASA scale corresponded to a 1.75-fold increased odds of developing a radiographical and/or implant-related complication ($P = 0.029$). Patients having an SVA sagittal modifier ++ had 3.43 times the odds of experiencing an RIC compared with those having an SVA sagittal modifier of 0 or +($P = 0.0001$). Having an interbody fusion performed was associated to a trend toward being a positive predictor of RICs, without reaching statistical significance (odds ratio = 1.77, $P = 0.082$).

The results of the magnitudes of correction in the coronal and sagittal plane between the 2 groups are presented in Table 5. On average, the RIC group had a correction of greater magnitude in the sagittal plane, as shown by the amount of PI-LL correction (16.02° *vs*. 8.50°, $P = 0.0046$) and the amount of SVA correction (51.42 mm *vs*. 25.36 mm, $P = 0.0059$). Of note, PI-LL is spinopelvic mismatch measure; a concept was proposed by Schwab *et al*[34] to quantify the regional lumbar deformity with respect to the pelvic morphology measured by PI; a threshold of 10° is accepted as ideal. In the coronal plane, patients who experienced radiographical and/or implant-related complications had less correction

TABLE 4. Multivariate Analysis Reporting the Independent Predictors of Radiographical and Implant-Related Complications

Predictors	OR	Standard Error	*P*	95% CI
American Society of Anesthesiologists Scale score	1.75	0.45	0.029	1.06–2.9
SRS-Schwab SVA	3.43	1.18	0.0001	1.75–6.73
Interbody fusion	1.77	0.58	0.082	0.93–3.39

OR indicates odds ratio; CI, confidence interval; SRS, Scoliosis Research Society; SVA, sagittal vertical axis.

TABLE 5. Univariate Analysis Comparing Coronal and Sagittal Plane Correction Between No RIC and RIC Groups

Coronal and Sagittal Correction (Preoperative to 6 wk)			
	No RIC	+RIC	*P*
Pelvic incidence minus lumber lordosis difference	8.58	16.02	0.0046
Sagittal Vertical Axis (C7 SVA) difference	25.36	51.42	0.0059
Pelvic tilt difference	8.58	16.02	0.0046
Upper thoracic Cobb difference	18.28	13.53	0.0335
Thoracic Cobb difference	25.65	18.24	0.067
Thoracolumbar Cobb difference	20.54	17.84	0.2497
Lumbar Cobb difference	8.15	6.56	0.26

RIC indicates radiographical and implant-related complications; SVA, sagittal vertical axis.

of their upper thoracic curve (13.53° *vs*. 18.28°, $P = 0.033$). The 2 groups had similar surgical corrections of their thoracic ($P = 0.067$), thoracolumbar ($P = 0.25$), and lumbar ($P = 0.26$) coronal curves.

With regard to HRQOL outcomes (Figures 1–3), both groups experienced significant improvement over time, as measured by the ODI ($P = 0.0001$), SF-36 ($P = 0.0001$), and SRS-22r ($P = 0.0001$). However, the rate of improvement over time was lower for patients who experienced radiographical and/or implant-related complications based on the SRS-22r ($P = 0.043$) and the SF-36 ($P = 0.0001$). Results were adjusted for major complications (other than radiographical and implant related), revision surgery, and comorbidities through multivariate analysis.

DISCUSSION

Patient Demographics

The present study combined radiographical and implant-related complications as 1 entity due to their overlapping biomechanical nature. Assessment of biomechanical complications as a separate entity has previously been described in the literature,[21,33–35] and examining these complications in the context of ASD surgery allows identification of specific risk factors for these types of complications. The present study demonstrated that patients who experienced these types of complications were different in terms of baseline demographics than those who did not; they had more comorbidities, a higher incidence of previous spine surgery, and heavier

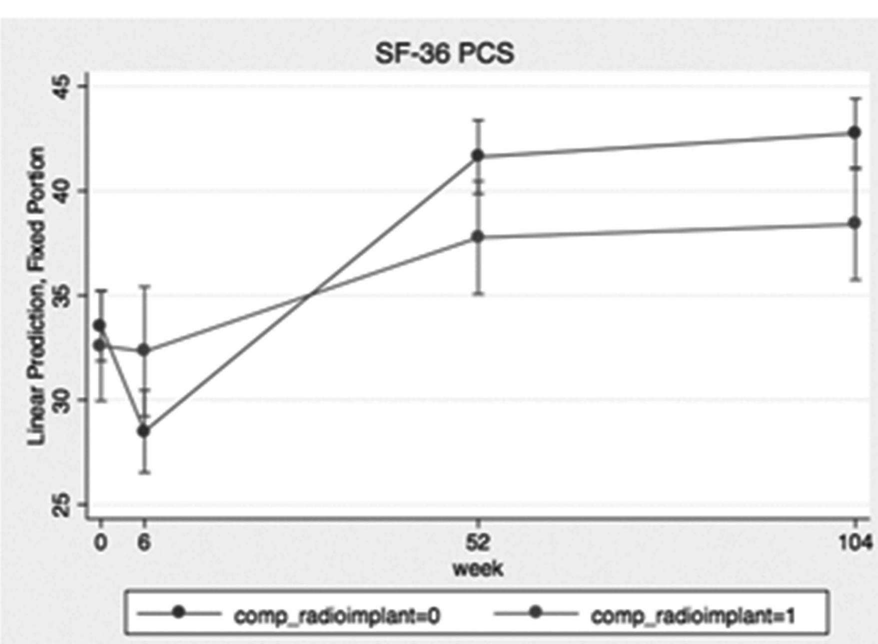

Figure 1. Multivariate repeated-measures mixed models results comparing the rate of SF-36 improvement between patients who sustained radiographical and implant-related complications and patients who did not. Results were adjusted for major complications (other than radiographical and implant-related), revision surgery, and comorbidities. SF-36 indicates 36-Item Short Form Health Survey; PCS, physical component score.

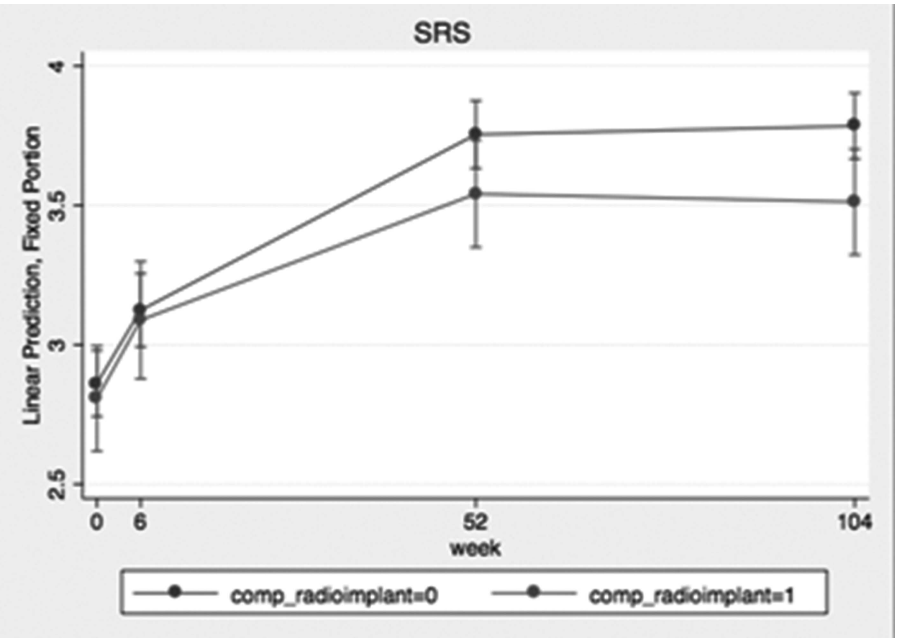

Figure 2. Multivariate repeated-measures mixed models results comparing the rate of SRS improvement between patients who sustained radiographical and implant-related complications and patients who did not. Results were adjusted for major complications (other than radiographical and implant-related), revision surgery, and comorbidities. SRS indicates Scoliosis Research Society.

weight. Interestingly, although the baseline weight between the 2 groups was significantly different, there were no differences in regard to BMI. This leads us to hypothesize that absolute weight, rather than BMI or obesity itself, may play a more important role in biomechanical complications, likely because BMI underestimates the absolute weight in subgroups of patients (extremes: tall or short). Among baseline demographics, patient comorbidities (measured by the ASA grade) were the only demographic variable identified to be an independent risk factor for RIC through multivariate modeling.

Surgical Factors

Univariate analysis revealed that patients who developed RIC had a lower proportion of fusion to the upper thoracic spine than those who did not develop these complications. There is some debate in the literature on the topic of long *versus* short thoracolumbar fusions for ASD.[36–38] A recent study by Kim *et al*,[39] concluded that patients who underwent surgery with long fusion and an upper instrumented vertebrae in the upper thoracic region had comparable outcomes and complication rates in comparison with patients who underwent fusion to the lower thoracic region. The current study investigated a

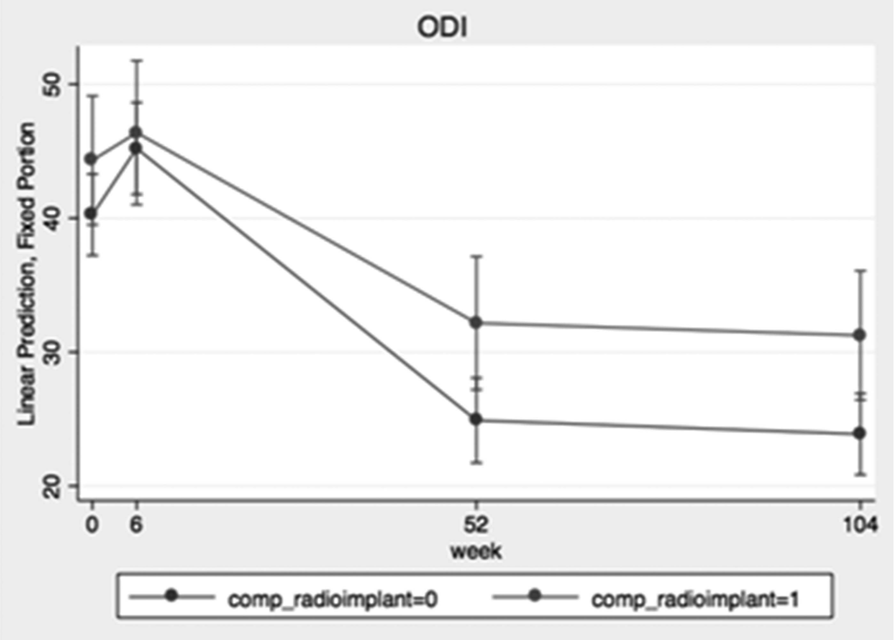

Figure 3. Multivariate repeated-measured mixed models results comparing the rate of ODI improvement between patients who sustained radiographical and implant-related complications and patients who did not. Results were adjusted for major complications (other than radiographical and implant-related), revision surgery, and comorbidities. ODI indicates Oswestry Disability Index.

specific group of complication, with a longer follow-up of the study population, and although we identified short fusions as a potential risk factor for RIC, it was not found to be an independent predictor in multivariate analysis.

Patient-Specific Deformity

On univariate analysis, patients who experienced RIC had greater baseline sagittal spinopelvic malalignment than those who did not experience these complications, as measured by the SRS-Schwab modifiers (PI-LL, SVA, and PT). Consequently, patients who experienced radiographical and/or implant-related complications were those who had a sagittal correction of a larger magnitude performed. Moreover, on multivariate analysis, having the worst preoperative SVA Schwab modifier ++ was an independent positive predictor of radiographical and implant-related complications. ASD is a heterogeneous pathology, with some patients having primarily a coronal deformity, some having primarily a sagittal malalignment, and others having both. Our findings suggest that patients whose pathology is primarily in the sagittal plane are more at risk of developing radiographical and implant-related complications, and that those who have less sagittal deformity and a main coronal malalignment are at less risk of developing these types of complications. We hypothesize that this might be related to the fact that sagittal malalignment requires more correction, which might necessitate the use of osteotomies, putting more stress on implants, thus leading to more RICs. These findings are consistent with previous studies and showed that more noticeable correction might provoke directly uppermost vertebral collapse and lead to PJK, and that the preoperative large SVA was a causative factor for radiographical complication.[40–43] By better defining which patients are at a higher risk, we have highlighted a patient population in which strategies to decrease these biomechanical complications should be studied.

RIC and Health-Related Quality of Life

In the present study, both patients who experienced RIC and those who did not had significant improvements in HRQOL outcomes scores over time. Although both groups had similar scores at the 2-year follow-up, the rate of improvement over time was slower for patients in the RIC group on the SRS-22r and SF-36. The impact of complications on patient-reported outcomes after ASD surgery is controversial in the literature. Some studies suggest that complications significantly affect HRQOL scores, with patients who experience late complications having a lesser improvement in ODI[44,45] and those sustaining a major complication having lower postoperative SF-12 general health scores.[22] Other studies showed no relationship between experiencing postoperative complications and achieving favorable outcomes after ASD surgery.[45,46] We hypothesize that the conflicting publications regarding the impact of complications on HRQL are in part due to the heterogeneity of the complications themselves, and that by looking at specific groups or types of complications, we will be better able to determine their impact on patient outcomes. This study shows that RICs do have an impact on postoperative HRQOL improvements. Collectively, these findings emphasize the importance of further studying ways to decrease these types of complications as means of improving patient outcomes.

CONCLUSION

In this study of surgical patients with ASD with 2-year follow-up, the RICs' rate was 31.7%, with half of those patients requiring revision surgery. These mechanical complications affected HRQL by decreasing the rate of improvement over time after ASD surgery. By quantifying the incidence of these types of complications, surgeons can be better equipped to counsel patients with ASD considering surgical intervention about the possible risk and clinical implications.

Baseline patient characteristics and parameters of the Schwab classification can be used to predict who is at higher risk of experiencing this type of complications. According to our study, patients who had more comorbidities (ASA scale) and more significant deformity in the sagittal plane (SVA) were at greater risk. Identifying risk factors is the first step in an effort to decrease these types of complications.

Patient-specific deformity is multifactorial. Future research endeavors should investigate the relationship between the ethnical characteristics of deformity and mechanical complications in order to define patients at higher risk and focus on trying to identify surgical strategies to decrease the incidence of RICs.

➢ Key Points

- ❑ Radiographical and implant-related complications had an incidence of 31.7%, and half of them required reoperation.
- ❑ Independent risk factors for radiographical and implant-related complications, identified through multivariate analysis included ASA and SRS Schwab SVA modifier ++.
- ❑ Radiographical and implant-related complications significantly affected health-related quality of life measures.

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