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DEFORMITY

Long-term Morbidity in Patients After Surgical Correction of Adult Spinal Deformity

Results From a Cohort With Minimum 5-year Follow-up

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Study Design. Retrospective.

Objective. The objective of this study is to describe the rate of postoperative morbidity before and after two-year (2Y) follow-up for patients undergoing surgical correction of adult spinal deformity (ASD).

Summary of Background Data. Advances in modern surgical techniques for deformity surgery have shown promising short-term clinical results. However, the permanence of radiographic correction, mechanical complications, and revision surgery in ASD surgery remains a clinical challenge. Little information exists on the incidence of long-term morbidity beyond the acute postoperative window.

Methods. ASD patients with complete baseline and five-year (5Y) health-related quality of life and radiographic data were included. The rates of adverse events, including proximal junctional kyphosis (PJK), proximal junctional failure (PJF), and reoperations up to 5Y were documented. Primary and revision surgeries were compared. We used logistic regression analysis to adjust for demographic and surgical confounders.

Results. Of 118 patients eligible for 5Y follow-up, 99(83.9%) had complete follow-up data. The majority were female (83%), mean age 54.1 years and 10.4 levels fused and 14 undergoing three-column osteotomy. Thirty-three patients had a prior fusion and 66 were primary cases. By 5Y postop, the cohort had an adverse event rate of 70.7% with 25 (25.3%) sustaining a major complication and 26 (26.3%) receiving reoperation. Thirty-eight (38.4%) developed PJK by 5Y and 3 (4.0%) developed PJF. The cohort had a significantly higher rate of complications (63.6% *vs.* 19.2%), PJK (34.3% *vs.* 4.0%), and reoperations (21.2% *vs.* 5.1%) before 2Y, all $P < 0.01$. The most common complications beyond 2Y were mechanical complications.

Conclusions. Although the incidence of adverse events was high before 2Y, there was a substantial reduction in longer follow-up indicating complications after 2Y are less common. Complications beyond 2Y consisted mostly of mechanical issues.

Key words: 5-year morbidity, adult spinal deformity, complications, reoperations

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With advances in modern surgical techniques,[1,2] adult spinal deformity (ASD) correction has been shown to lead to significant improvement in patient functionality and quality of life.[3,4] However, the durability of ASD surgery remains a clinical challenge,[5,6] and has been associated with high rates of intraoperative and postoperative complications.[7–9]

As complications related to ASD surgery are correlated with worse patient outcomes and satisfaction,[10,11] understanding them can lead to improvement in care. Prior studies have largely focused on adverse events and postoperative morbidity within the first two years (2Y) after ASD surgery.[12–14] However, there is concern that patients undergoing ASD surgery may have a longer event horizon for postoperative morbidity, with the risk of adverse events and mechanical failure extending well beyond the first few years after surgery. The current literature is very limited

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with respect to surveillance of postsurgical adverse events beyond the first 2Yof ASD corrective surgery.

In this context, we used prospectively collected data from a single center to evaluate longer term postoperative morbidity following ASD correction, up to five-years (5Y) after the procedure. At the time of this writing, this database represents one of the largest and most comprehensive spinal deformity data sets available. The means of patient enrollment and data collection have been described in previous work[15,16] and its data have been used to study both clinical and health policy aspects of adult deformity surgery in prior studies. We evaluated the natural history of postoperative adverse events in this cohort, stratifying patients based on whether the index procedure at our institution a primary surgery was or a revision of prior fusion.

METHODS

Data Source and Study Design

This is a retrospective analysis of a prospectively collected, single-center database containing ASD patients enrolled from 2012 to 2017. Institutional Review Board approval was obtained before enrollment and all patients provided informed consent. The means of patient enrollment and data collection have been described in previous published work. The inclusion criteria of the present study required operative ASD patients with complete radiographic data preoperatively and postoperatively, as well as complete surveillance for adverse events up to 5Y after surgery.

Data Collection and Radiographic Assessment

Standardized data collection forms assessed patient demographics, surgical parameters, and comorbidities at the initial presentation. Complications data were recorded during the procedure and at multiple follow-up time points, including medical, surgical, mechanical, and radiographic complications. Data for patients who underwent a reoperation were also collected.

Lateral spine radiographs were used to assess radiographic parameters at baseline and follow-up intervals. All images were analyzed with SpineView (ENSAM, Laboratory of Biomechanics, Paris, France).[17–19] Spinopelvic radiographic parameters assessed included the proximal junctional kyphosis (PJK) angle [measured between upper instrumented vertebrae (UIV) and UIV+2] and the difference in the PJK angle postoperatively.

Classifying Postoperative Adverse Events

Seven complication groups were defined in our cohort in Table 1, which included any, major, medical, surgical, mechanical, radiographic, and reoperation.

Classifying PJK/Failure

PJK was defined based on previously published values of a PJK angle of <–10° and a difference in PJK angle of <–10°.[20] Proximal junctional failure (PJF) was defined using the criteria of a PJK angle of <–28° and a difference in PJK angle of <–22°.[20]

Statistical Analysis

Frequency distributions and summary statistics were calculated for all demographic, clinical, surgical, and radiographic variables. Bivariate analysis was performed using Pearson chi-square tests to assess categorical variables. Independent sample *t* tests were used to assess differences in continuous variables. Paired-sampled means tests analyzed differences in complications, PJK, and PJF before and after 2Y follow-up. Multivariable logistic regression analysis was used to adjust for demographic and surgical confounders. In multivariable regression tests, primary fusion as compared with revision procedures were used as the primary predictor of postoperative adverse events. All analyses were performed using SPSS software (IBM Corp. IBM SPSS Statistics for Windows, v25.0. Armonk, NY). Statistical tests were two-tailed with significance set to $P < 0.05$.

RESULTS

Cohort Overview

Of 118 operative ASD patients eligible for 5Y follow-up, 99 (83.9%) had complete follow-up data and met inclusion criteria. The mean age in this cohort was 54.1 years, 83% were female, mean body mass index was 26.3 ± 5.7 kg/m^2, mean Charlson Comorbidity Index was 1.1 ± 1.5, and mean ASD-modified frailty index[15] was 5.1 ± 4.4.

Surgical Descriptors

In terms of surgical characteristics, mean levels fused was 10.4 ± 4.5, mean estimated blood loss was 1864 ± 1384 mL, and mean operative time was 405.0 ± 185.1 minutes. By surgical approach, 2.0% of patients (n = 2) underwent anterior-only approach, 66.7% (n = 66) posterior-only, 31.3% and (n = 31) combined. The most common UIV was T10, and most common lower instrumented vertebra was S2. 47.1% of the cohort had an upper thoracic UIV, while 52.9% had lower thoracic. Overall, 57.6% underwent osteotomy as part of their procedure. Of the cohort, 14.1% underwent three-column osteotomies.

Postoperative Adverse Events

Overall, 70.7% (n = 70) of the cohort were reported to have experienced a complication and 25.3% (n = 25) had a major complication. By 5Y postop, 26 patients (26.3%) required a reoperation. The cohort had a significantly higher rate of complications (63.6% *vs.* 19.2%), major complications (24.2% *vs.* 4.0%), and reoperations (21.2% *vs.* 5.1%) before 2Y, all $P < 0.01$. The most common occurring complications before 2Y were surgically related for this cohort of ASD patients. The most common occurring complications beyond 2Y were mechanical (Table 2).

PJK/Failure

By 5 years postoperatively, 38 (38.4%) patients developed PJK and 4 (3.0%) patients developed PJF (Table 3). Fifty percent of the cases that developed PJK had UIV in the upper thoracic, whereas the rest had it in the lower thoracic region.

TABLE 1. Complication Groups

	Complication groups	Description
1	Any	Any complication occurring before the five-yr follow-up time point.
2	Major	Any complication resulting in prolonged hospitalization, readmission, or reoperation.
3	Medical	Complications of cardiac, pulmonary, gastrointestinal, infectious, neurological, or renal etiology, which were not deemed to be a direct result of the index procedure.
4	Surgical	Complications directly related to surgery, including surgical site infection, wound dehiscence, or neurological deficits.
5	Mechanical	Complications related to implant prominence, implant malposition, painful implant, implant failure, interbody dislocation, nerve impingement, screw fracture, rod dislocation, and rod fracture.
6	Radiographic	Junctional kyphosis or pseudoarthrosis.
7	Reoperation	Any reoperation occurring before the five-yr follow-up time point.

Primary versus prior fusion

Thirty-three patients had a prior fusion and 66 were primary cases. Differences in demographic and surgical details are found in Table 4. Patients with a prior fusion were more likely to experience a surgical complication than primary ASD patients (48.5% *vs.* 24.2%, $P = 0.015$). Patients with a prior fusion were also more likely to undergo a reoperation within 2Y postoperatively (33.3% *vs.* 15.2, $P = 0.037$) and experience a major complication before 2Y follow-up (36.4% *vs.* 18.2%, $P = 0.047$). In a multivariable analysis controlling for age, invasiveness, and frailty, patients with a prior fusion were not more likely to experience a surgical complication [odds ratio (OR): 2.0 (CI, 0.7–5.8), $P = 0.197$], undergo a reoperation within 2-years [OR: 2.5 (CI, 0.8–7.9), $P = 0.111$], or experience a major complication within 2-years [OR: 1.8 (CI, 0.6–5.9), $P = 0.304$].

Approach

Thirty-three patients had anterior or combined surgical approach and 66 had posterior-only approach. Approach by prior fusion status are found in Table 5. Differences in demographic and surgical details are found in Table 6. Patients with anterior/combined approach were more likely to experience a surgical complication than primary ASD patients (45.4% *vs.* 25.89%, $P = 0.049$). Although not statistically significant, patients with anterior/combined approach had higher rates of reoperation within 2Y postoperatively (27.3% *vs.* 18.2%, $P = 0.302$) and experience a major complication before 2Y follow-up (33.3% *vs.* 18.2%, $P = 0.194$). In a multivariable analysis controlling for age, body mass index, invasiveness, and frailty, patients with posterior-only approach were not less likely to experience a surgical complication [OR: 0.35 (CI, 0.12–1.01), $P = 0.052$], undergo a reoperation within 2Y [OR: 0.82 (CI, 0.27–2.5), $P = 0.719$], or experience a major complication within 2Y [OR, 0.96 (CI, 0.31–2.9), $P = 0.940$].

Patient Reported Outcomes

Baseline ODI for cohort was 37.9 with improvement to 25.9 at one year, with no significant difference till last follow-up. MCID rates increased from 33% at one year to 47% at last follow-up for the cohort.

DISCUSSION

Corrective surgery is a promising option for patients suffering from ASD to achieve a higher quality of life. Outcomes after ASD corrective surgery is variable, with complications occurring commonly in complex deformity correction cases.[21–23] Encouraging results have previously been published in the literature on outcomes of ASD corrective surgery, but these have generally been relegated to the short term.[24–26] Here, we present the clinical experience with ASD surgery among contributors to a single-center database, with surveillance of complications and need for reoperation maintained to 5Y after the index procedure.

TABLE 2. Complications; Total, Before and After Two-year Follow-up for a Cohort of 99 ASD Patients

	Total, n (%)	≤2 yr, n (%)	> 2 yr, n (%)	*P*
Any	70 (70.7)	63 (63.6)	19 (19.2)	**< 0.001**
Major	25 (25.3)	24 (24.2)	4 (4.0)	**< 0.001**
Medical	30 (30.3)	28 (28.3)	2 (2.0)	**< 0.001**
Surgical	32 (32.3)	32 (32.3)	0 (0.0)	**< 0.001**
Mechanical	19 (19.2)	15 (15.2)	5 (5.1)	**0.018**
Radiographic	38 (38.4)	37 (37.4)	4 (4.0)	**< 0.001**
Reoperation	26 (26.3)	21 (21.2)	5 (5.1)	**0.001**

Significant values in bold.

TABLE 3. Proximal Junctional Kyphosis and Failure Before and After Two-year Follow-up for a Cohort of 99 ASD Patients

	Total	≤2 yr	>2 yr	*P*
PJK	38 (38.4)	34 (34.3)	4 (4.0)	**<0.001**
PJF	3 (3.0)	2 (2.0)	1 (1.0)	0.566

Significant value in bold.

PJF indicates proximal junctional failure; PJK, proximal junctional kyphosis.

This work is advantaged over previous contributions by the sample size and standardized prospective surveillance for all outcomes of interest up to 5Y after surgery.

Our results indicate that, at the 5Y follow-up, a substantial number of patients experienced at least one complication, with most complications occurring within 2Y postoperatively. Medical, surgical, and mechanical complications were all significantly more likely to occur before the 2Y follow-up than after (all $P < 0.05$). In terms of reoperations, roughly one in five required a revision surgery by 5Y with significantly more occurring by 2Y follow-up ($P < 0.05$). In addition, more than a third of the cohort developed PJK with only three patients developing PJF. Like the incidence of complications, PJK was significantly more likely to occur before 2Y follow-up ($P < 0.05$).

In this cohort of 99 ASD patients with 5Y follow-up, two thirds were primary cases. In a comparison between the groups, prior fusion cases were more likely to have surgical complications. However, when adjusted, prior fusion cases were not at increased odds of experiencing a surgical complication. Notably, prior fusion cases underwent significantly more three-column osteotomies, which have been associated with increased complication risk.[27–29] Prior fusion patients also had significantly more major complications and reoperations before 2Y follow-up.

TABLE 4. Mean Demographic and Surgical Parameters Between Primary and Prior Fusion ASD Patients

	Primary (n = 66)	Prior fusion (n = 33)	*P*
Age (yr)	53.1	56.1	0.427
Sex (% female)	79	91	0.095
BMI (kg/m^2)	26.2	26.5	0.828
CCI	0.97	1.42	0.169
ASD-mFI	4.7	5.8	0.287
Levels fused	10.9	9.4	0.142
3CO	5	33	**0.002**

Significant values in bold.

3CO indicates Three-column osteotomy; ASD-mFI, adult spinal deformity modified frailty index; BMI, body mass index; CCI, Charlson comorbidity index.

TABLE 5. Approach by Primary or Prior Fusion

	Anterior/combined approach (n = 33)	Posterior approach (n = 66)
Primary (n = 66)	24	42
Prior fusion (n = 33)	9	24

These significant findings were also lost in a multivariable analysis.

Complications in deformity surgery are not uncommon. Although patients are prone to experiencing minor or major adverse events, the fact remains that most patients achieve significant improvements in quality of life. Recent advancements in surgical techniques and increased surgeon experience allow for safer surgery to be performed,[30] and continued efforts at increasing surgical safety are underway.[31] The present study highlights the importance of long-term follow-up in clinical studies examining adult deformity patients. Continued efforts in minimally invasive approaches, multidisciplinary collaborations, reduction of blood loss, neuromonitoring, adverse event prediction, and biomechanics are needed.

This study has several notable limitations. The retrospective nature of this study could limit the findings and predispose to bias, including confounding by indication. The relatively small sample might also create potential for restricted clinical variation and truncation in certain areas. Further, as ASD is a heterogeneous condition, the radiographic parameters used to analyze ASD may lack precision. The statistical approach should also be viewed as exploratory, rather than definitive, given the nature of the sample and study design. Considering these issues, the

TABLE 6. Mean Demographic and Surgical Parameters Between Anterior/Combined Compared With Posterior Approach ASD Patients

	Anterior/combined approach (n = 33)	Posterior approach (n = 66)	*P*
Age (years)	59.5	51.4	**0.030**
Gender (% female)	85	82	0.710
BMI (kg/m^2)	28.8	25.1	**0.002**
CCI	1.76	0.80	**0.003**
ASD-mFI	5.8	4.7	0.246
Levels fused	9.5	10.8	0.189
3CO	9	17	0.313

Significant values in bold.

3CO indicates three-column osteotomy; ASD-mFI, adult spinal deformity modified frailty index; BMI, body mass index; CCI, Charlson comorbidity index.

findings presented here should be seen as hypothesis generating as opposed to prescriptive. Further external validation in additional large-scale studies remains to be done before the results presented here can be considered truly clinically actionable.

CONCLUSIONS

Although the incidence of complications was high before 2Y, there was a substantial reduction in complications following the 2Y time point, indicating complications after 2Y are less common. Complications beyond 2Y were mostly medically related issues or due to implant failure. Patients undergoing revision seem to have increase odds of undergoing a reoperation within 2Y of surgery compared with primary cases, but this risk did not persist after the 2Y follow-up period.

➢ Key Points

- ❑ Although the incidence of complications was high before two years, there was a substantial reduction in complications after the two-year time point.
- ❑ Complications beyond 2Y were mostly medically related issues or due to implant failure.
- ❑ Patients undergoing revision may have increased odds of undergoing a reoperation within 2Y of surgery compared with primary cases, but this risk did not persist after the 2Y time-point.

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