

Complication rates associated with 3-column osteotomy in 82 adult spinal deformity patients: retrospective review of a prospectively collected multicenter consecutive series with 2-year follow-up

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OBJECTIVE Although 3-column osteotomy (3CO) can provide powerful alignment correction in adult spinal deformity (ASD), these procedures are complex and associated with high complication rates. The authors' objective was to assess complications associated with ASD surgery that included 3CO based on a prospectively collected multicenter database.

METHODS This study is a retrospective review of a prospectively collected multicenter consecutive case registry. ASD patients treated with 3CO and eligible for 2-year follow-up were identified from a prospectively collected multicenter ASD database. Early (≤ 6 weeks after surgery) and delayed (> 6 weeks after surgery) complications were collected using standardized forms and on-site coordinators.

RESULTS Of 106 ASD patients treated with 3CO, 82 (77%; 68 treated with pedicle subtraction osteotomy [PSO] and 14 treated with vertebral column resection [VCR]) had 2-year follow-up (76% women, mean age 60.7 years, previous spine fusion in 80%). The mean number of posterior fusion levels was 12.9, and 17% also had an anterior fusion. A total of 76 early (44 minor, 32 major) and 66 delayed (13 minor, 53 major) complications were reported, with 41 patients (50.0%) and 45 patients (54.9%) affected, respectively. Overall, 64 patients (78.0%) had at least 1 complication, and 50 (61.0%) had at least 1 major complication. The most common complications were rod breakage (31.7%), dural tear (20.7%), radiculopathy (9.8%), motor deficit (9.8%), proximal junctional kyphosis (PJK, 9.8%), pleural effusion (8.5%), and deep wound infection (7.3%). Compared with patients who did not experience early or delayed complications, those who had these complications did not differ significantly with regard to age, sex, body mass index, Charlson Comorbidity Index, American Society of Anesthesiologists score, smoking status, history of previous spine surgery or spine fusion, or whether the 3CO performed was a PSO or VCR ($p \geq 0.06$). Twenty-seven (33%) patients had 1–11 reoperations (total

ABBREVIATIONS ASA = American Society of Anesthesiologists; ASD = adult spinal deformity; ASIA = American Spinal Injury Association; BMI = body mass index; CCI = Charlson Comorbidity Index; EBL = estimated blood loss; LEMS = Lower Extremity Motor Score; LL = lumbar lordosis; PI = pelvic incidence; PI-LL = mismatch between PI and LL; PJK = proximal junctional kyphosis; PSO = pedicle subtraction osteotomy; PT = pelvic tilt; SRS = Scoliosis Research Society; SVA = sagittal vertical axis; TK = thoracic kyphosis; VCR = vertebral column resection; 3CO = 3-column osteotomy.

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of 44 reoperations). The most common indications for reoperation were rod breakage ($n = 14$), deep wound infection ($n = 15$), and PJK ($n = 6$). The 24 patients who did not achieve 2-year follow-up had a mean of 0.85 years of follow-up, and the types of early and delayed complications encountered in these 24 patients were comparable to those encountered in the patients that achieved 2-year follow-up.

CONCLUSIONS Among 82 ASD patients treated with 3CO, 64 (78.0%) had at least 1 early or delayed complication (57 minor, 85 major). The most common complications were instrumentation failure, dural tear, new neurological deficit, PJK, pleural effusion, and deep wound infection. None of the assessed demographic or surgical parameters were significantly associated with the occurrence of complications. These data may prove useful for surgical planning, patient counseling, and efforts to improve the safety and cost-effectiveness of these procedures.

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KEY WORDS adult spinal deformity; complications; osteotomy; pedicle subtraction osteotomy; prospective; vertebral column resection

ALTHOUGH multiple studies have shown the potential for significant improvement in pain and disability with surgery for adult spinal deformity (ASD),^{11,12,53,56,59-61} these procedures are associated with high rates of complications.^{47,53,54,57,61,63} Correction of ASD often relies upon the use of osteotomies that range from simple facet releases to 3-column osteotomies (3COs), which include pedicle subtraction osteotomy (PSO) and vertebral column resection (VCR).^{13,14,49} Use of 3CO is typically reserved for the most severe and often rigid deformities that cannot be readily corrected with other techniques, since these osteotomies are the most aggressive and have been associated with the highest rates of complications.^{3,8,9,16,21,23,26,29,34,48,54,57,62}

Multiple previous reports have described 3CO techniques and have presented complications associated with these procedures.^{3,6,8,10,13-15,52} However, these studies have been limited by multiple factors, including retrospective collection of complications, relatively small numbers of patients, single-surgeon or single-center series, focus on only select types of complications, and lack of sufficient follow-up. An accurate and complete assessment of complications associated with 3CO procedures may prove useful for surgical planning, patient counseling, and efforts to improve the safety and cost-effectiveness of these procedures.

Our objective in the present study was to prospectively assess the rates of complications associated with ASD surgery that included 3CO with 2-year follow-up based on a multicenter study design that incorporated standardized data collection forms, on-site study coordinators, and regular auditing of data to help ensure complete and accurate reporting of complications. In addition, we provide assessment for associations between basic demographic and surgical parameters and the occurrence of complications.

Methods

Patient Population

This is a retrospective review of a prospectively collected multicenter registry of consecutive ASD patients. Patients were enrolled into an ongoing database through an IRB-approved protocol at 11 sites across the United States. At the time of enrollment, patients provided consent for participation. Database inclusion criteria are: age

> 18 years and at least one of the following radiographic measures: scoliosis $\geq 20^\circ$, sagittal vertical axis (SVA) ≥ 5 cm, pelvic tilt (PT) $\geq 25^\circ$, and thoracic kyphosis (TK) $\geq 60^\circ$. At the time of study enrollment, patients were classified into either operative or nonoperative treatment groups based on the initial management approach. For patients undergoing operative treatment, the procedural choice and instrumentation used, as well as the extent of surgery and operative objectives, were at the discretion of the operating surgeon. The present study focuses on patients who underwent operative treatment that included a 3CO (either PSO or VCR) and who had 2-year follow-up after surgical treatment at the time of data extraction. In addition, a summary of complications for patients who were treated with a 3CO but did not achieve 2-year follow-up is provided as a means of assessing for confounding effects on reported types and rates of complications that may be introduced by patients lost to follow-up.

Data Collection and Radiographic Assessment

As part of the standardized registry protocol, data collection forms were used to collect patient demographics, imaging studies, comorbidities, details of surgical procedures, and complications. During the perioperative period and at follow-up time intervals, patients were assessed for complications based on examination, imaging, and questioning. On-site study coordinators at each center assisted in collecting complications and, in combination with regular data auditing from the central core facility, helped to ensure accurate reporting and complete collection of complications. Coordinators assisted in collecting complications at each site through meeting with patients at clinic visits, communicating with the treating physicians, and reviewing imaging reports and clinic records. At each follow-up time point, the standardized complication data collection form was completed to indicate whether any of the listed complications had occurred. In addition, since no form can include every complication that can possibly occur, providers and coordinators were instructed to be vigilant of other less common complications not listed on the form and to report these as well. The deidentified data from each site were sent to a single center where the entire data sets were summarized and analyzed and the complications were reviewed.

Complications were classified as early or delayed and as minor or major. Early complications were those occurring within 6 weeks of surgery, and delayed complications were those occurring between 6 weeks after surgery and the time of last follow-up. A complication was classified as major if it substantially prolonged hospitalization, involved an invasive intervention, had prolonged or permanent morbidity, or resulted in death. For example, implant prominence or a painful implant that did not require revision was classified as minor, whereas if a revision procedure was required, it was classified as major. Any complication that resulted in the need for reoperation was considered major. In addition, complications that occurred in association with reoperations were also included in the present study. All complications were audited by a panel of surgeons and classified as minor versus major based on the above criteria. We do not currently employ strict criteria for factors such as the number of days that constitute a prolonged hospitalization, since this can vary substantially based on the specific complication, treatment required, and clinical situation. A complication that required multiple returns to the operating room was considered a single complication, and the number of reoperations was added to the total associated with the respective complication category. For example, a deep wound infection that was managed with 3 returns to the operating room for debridement was considered a single major complication, and these 3 reoperations were reported in association with the deep wound infection category.

All cases of rod fracture were classified as major complications, regardless of whether the patient had undergone a revision procedure to address this complication at the time of data extraction. Although a small subset of rod fractures may follow a relatively benign course, our experience has been that the distinct majority ultimately need a revision procedure. Although one could argue for attempting to split these into minor versus major, given that CT imaging was not available for all cases to more clearly assess fusion status, we decided to err on the side of upgrading these to the major category.

It remains controversial whether “excessive” blood loss without apparent sequelae should be considered a complication in spine surgery. Since blood loss was not clearly associated with the occurrence of any complications in the present series, we chose to present estimated blood loss (EBL) as a descriptive variable, rather than as a potential complication based on an arbitrary threshold.

Full-length free-standing posteroanterior and lateral spine radiographs were obtained at specified time intervals: preoperative, 6 weeks postoperative (window of 1–7 weeks), 1 year postoperative (window of 10–14 months), and 2-years postoperative (24–30 months). Radiographs were analyzed using validated software (Spineview, ENSAM Laboratory of Biomechanics).^{17,46} All radiographic measures were performed at a central location based on standard techniques^{2,43} including: scoliosis, lumbar lordosis (LL, Cobb angle between superior endplate of L-1 and superior endplate of S-1), sagittal vertical axis (SVA), pelvic tilt (PT), pelvic incidence (PI), and mismatch between PI and LL (PI-LL), as previously described.² Patients were classified based on the Scoliosis Research Society (SRS)-

Schwab adult thoracolumbar spinal deformity classification (Fig. 1).^{50,55,65}

Data and Statistical Analysis

Frequency distributions and summary statistics were calculated for all variables. The data were assessed using the Shapiro-Wilk test for normality. For categorical variables, cross-tabulations were generated and Fisher’s exact or Pearson chi-square tests were used to compare distributions. For continuous variables with normal distribution, statistical comparisons were performed using Student t-tests and ANOVA tests. For data that were not normally distributed, the Mann-Whitney U-test was used to determine statistical associations. Statistical analyses were 2-sided, and $p < 0.05$ was considered statistically significant.

Results

Patient Population

Following database enrollment, 174 patients were treated with a 3CO; 165 of these patients were treated with a 3CO at the time of initial enrollment, and 9 were treated with a 3CO as part of a revision procedure subsequent to the initial procedure at the time of database enrollment (Fig. 1). Excluding patients who were not yet eligible for 2-year follow-up ($n = 59$) and those with incomplete baseline data ($n = 9$), a total of 106 patients met the inclusion criteria. Note that since database enrollment is an ongoing process, the 59 patients not yet eligible for 2-year follow-up were those patients for whom a minimum of 2 years had not yet elapsed between the time of surgery and the point at which data were extracted for the present study. Of the patients meeting inclusion criteria, 82 (77%) achieved 2-year follow-up, and these patients are the primary focus of the present study. These 82 cases were contributed by 12 surgeons (contribution per surgeon ranged from 1 to 23 cases) and were from 10 centers. The patients who did ($n = 82$) and did not ($n = 24$) achieve 2-year follow-up did not significantly differ with regard to age ($p = 0.84$), sex ($p = 0.30$), body mass index (BMI) ($p = 0.96$), Charlson Comorbidity Index (CCI) ($p = 0.56$), American Society of Anesthesiology (ASA) score ($p = 0.79$), proportion with previous spine fusion ($p = 0.76$), and whether the 3CO was a PSO or a VCR ($p = 1.00$).

Demographic and operative parameters for the 82 study patients are summarized in Table 1. The mean age was 60.7 years, and the majority of patients (76%) were women. The mean BMI of 29.0 falls within the overweight category and borders on obesity. The mean CCI⁸ and ASA scores were 2.1 and 2.5, respectively. The majority of patients had a history of previous spine surgery (85.4%), and most (80.0%) had been previously treated with spine fusion. Of the 82 study patients, 68 were treated with PSO and 14 were treated with VCR. The most common PSO levels were L-3 ($n = 30$), L-4 ($n = 15$), and L-2 ($n = 9$). VCR levels ranged from T-6 through L-5, and the most common level was T-12 ($n = 3$). Two 3COs were performed in 5 patients (6.1%) (L-1 and L-2 VCRs, L-2 and L-3 PSOs, L-2 and L-5 VCRs, T-6 and T-7 VCRs, and T-8 and T-9 VCRs), and three 3COs were performed in 1 patient (1.2%) (T-9, L-3, and L-4 VCRs). Based on study inclusion criteria, all

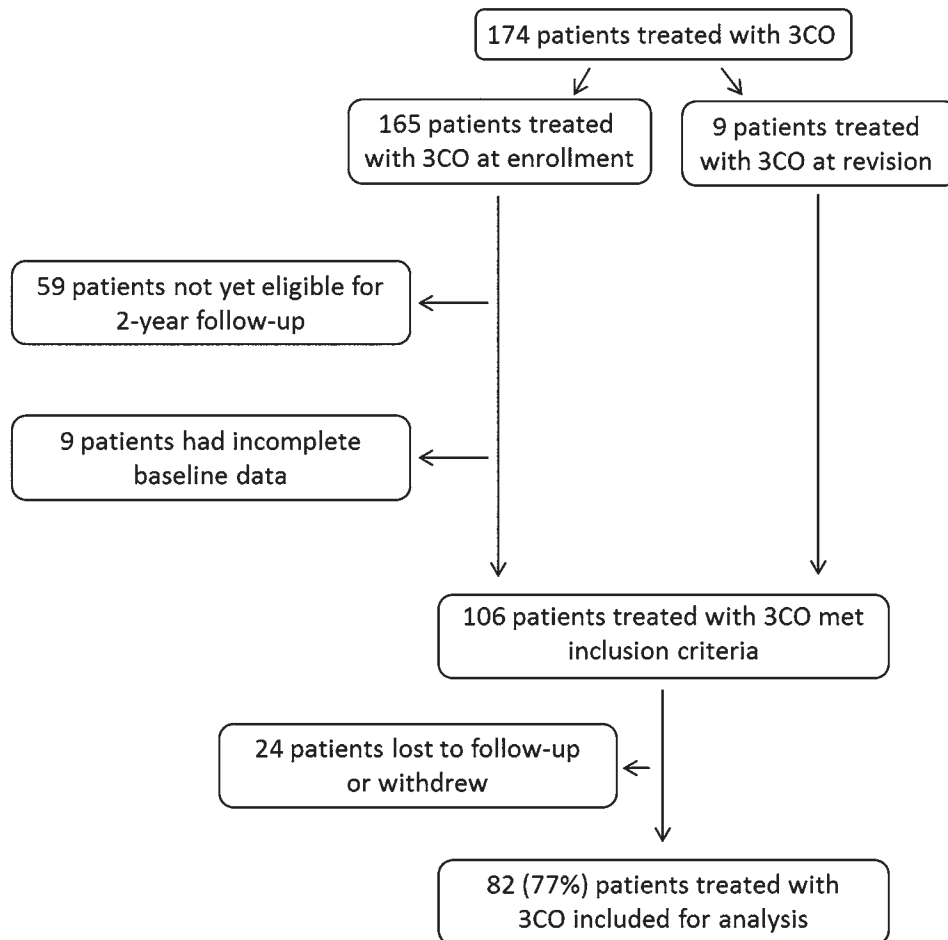


FIG. 1. Flow diagram for patient selection.

patients underwent a posterior surgical procedure, and the mean number of instrumented vertebral levels was 12.9. A subset of these patients (17.1%) also underwent an anterior procedure. The procedure included a decompression in the majority of patients (72.0%). Mean operating room time and estimated blood loss (EBL) were 8.0 hours and 3.3 L, respectively, and the mean length of hospital stay was 10.0 days. None of the assessed demographic or operative parameters differed significantly between the patients treated with PSO versus those treated with VCR, except for a modestly but significantly greater number of instrumented posterior vertebral levels in the VCR group (14.9 vs 12.5 levels, $p = 0.042$; Table 1).

Based on the SRS-Schwab ASD classification (Fig. 2 upper),^{51,55,65} almost one-half (47.6%) of patients had coronal curve type “N,” which reflects a spinal deformity that does not include any coronal curves greater than 30° (Fig. 2 lower). The remaining patients had coronal curves greater than 30° in the thoracic (1.2%), thoracolumbar/lumbar (31.7%), or both thoracic and thoracolumbar (19.5%) regions. The SRS-Schwab sagittal modifier grades (Fig. 2 upper) for the study population reflect substantial sagittal spinopelvic malalignment (Fig. 2 lower). For each modifier, more than 80% of patients demonstrated moderately (+) or severely (++) abnormal values (Fig. 2 lower).

Early and Delayed Complications by General Category

Rates of early and delayed complications are summarized based on general complication categories in Table 2. A total of 76 early (44 minor and 32 major) and 66 delayed (13 minor and 53 major) complications were identified. The mean numbers of early, delayed, and total complications per patient were 0.93, 0.80, and 1.73, respectively. Overall, 41 patients (50%) had at least 1 early complication, 45 (54.9%) had at least 1 delayed complication, and 64 patients (78.0%) were affected by at least 1 early or delayed complication (Table 2). At least 1 early or delayed minor complication occurred in 37 patients (45.1%), and at least 1 early or delayed major complication occurred in 50 patients (61.0%). Figure 3 summarizes the distribution of patients based on the numbers of minor and major complications that occurred. Although 22% of patients did not experience any early or delayed complications from surgery through 2-year follow-up, the remaining patients had from 1 to 9 complications (Fig. 3).

Based on general complication categories, the most common complications were implant related (2 minor and 31 major), neurological (8 minor and 16 major), operative (18 minor and 1 major), cardiopulmonary (10 minor and 9 major), radiographic (5 minor and 13 major), and infection (4 minor and 9 major) (Table 2).

TABLE 1. Demographic and operative parameters for 82 adults surgically treated for spinal deformity stratified and compared based on osteotomy type

Parameter	3-Column Osteotomy Type			All Patients
	PSO	VCR	p Value	
No. of patients (%)	68 (83)	14 (17)	—	82
Female/male	50:18	12:2	0.50	62:20
Mean age, yrs (SD)	61.1 (11.2)	58.6 (13.5)	0.46	60.7 (11.6)
Mean BMI (SD)	28.9 (5.9)	29.4 (6.5)	0.81	29.0 (6.0)
Mean CCI (SD)	2.0 (1.9)	2.5 (2.1)	0.41	2.1 (1.9)
Mean ASA (SD)	2.5 (0.6)	2.7 (0.6)	0.19	2.5 (0.6)
Current smoker (%)	3.2	0.0	1.00	2.6
Previous spine surgery (%)	88.2	71.4	0.21	85.4
Previous spine fusion (%)	82.1	69.2	0.28	80.0
Anterior procedure (%)	11 (16.2)	3 (21.4)	0.70	14 (17.1)
Mean levels (SD)	1.9 (0.8)	2.0 (1.0)	0.87	1.9 (0.8)
Posterior procedure (%)	82 (100)	82 (100)	—	82 (100)
Mean levels (SD)	12.5 (4.1)	14.9 (3.1)	0.042*	12.9 (4.0)
Decompression (%)	72.1	71.4	1.00	72.0
Mean OR time, hrs (SD)	7.9 (2.7)	8.3 (2.7)	0.581	8.0 (2.7)
Mean EBL, L (SD)	3.4 (2.5)	3.0 (1.7)	0.921	3.3 (2.3)
Mean LOS, days (SD)	9.8 (6.7)	11.1 (6.7)	0.471	10.0 (6.7)

EBL = estimated blood loss; LOS = length of stay (hospital); OR = operating room.

Boldface type indicates statistical significance.

* Mann-Whitney U-test.

Early and Delayed Complications by Subtype

Table 3 provides a summary of the subtypes of reported complications for each of the general complication categories from Table 2. The most common implant-related complication was rod breakage, which occurred in 26 patients and led to reoperation in 14 patients. The most common neurological complications were radiculopathy and motor deficit, which each occurred in 8 patients (9.8%) and led to 4 reoperations (radiculopathy, 3; motor deficit, 1). Dural tear occurred in 17 patients (20.7%) and accounted for the majority of operative complications but notably did not require any reoperations in this series. The most common cardiopulmonary complications were pleural effusion (8.5%), pulmonary embolism (3.7%), deep venous thrombosis (3.7%), arrhythmia (2.4%), and congestive heart failure (2.4%). Proximal junctional kyphosis (PJK) accounted for 44.4% of the radiographic complications and was associated with the need for reoperation in 6 patients. Deep wound infection was the most common type of infection reported and occurred in 6 patients (7.3%). A total of 15 reoperations were associated with the treatment of these deep wound infections. The most common wound complication (excluding infection) was dehiscence, which occurred in 6 patients (7.3%). Gastrointestinal and vascular complications were less common and included ileus and coagulopathy, respectively.

Assessment of Factors Associated With Complication Occurrence

Compared with patients who did not experience early or delayed complications, those who had these complications did not differ significantly with regard to age, sex, BMI, CCI, ASA, smoking status, history of previous spine surgery or spine fusion, or whether the 3CO performed was a PSO or VCR ($p \geq 0.06$; Table 4). The percentages of patients affected by complications (Fig. 4) and the mean numbers of complications per patient (Fig. 5) did not differ significantly based on patient age ($p \geq 0.61$). In addition, the overall complication rates did not differ significantly based on surgeon ($p = 0.65$) or contributing site ($p = 0.71$).

Complications in Patients Not Achieving 2-Year Follow-Up

Reported early and delayed complications for the 24 patients who did not achieve 2-year follow-up are summarized in Table 5. The mean duration of follow-up for these patients was 0.85 years (3 had no recorded follow-up beyond discharge; 7 had no follow-up beyond 6 weeks; 14 had no follow-up beyond 1 year). Among these patients, 10 (41.7%) had at least 1 early complication (8 minor and 2 major), which is comparable to the corresponding percentage for those who did achieve 2-year follow-up (50%; Table 2). Notably, the distribution and types of early and delayed complications encountered in those lost to follow-up were comparable to those who achieved 2-year follow-up (Tables 2 and 5).

Discussion

This study provides an assessment of complications associated with surgical treatment for ASD that included a 3CO based on a prospective, multicenter design with 2-year follow-up. To help ensure accurate and complete collection of complications, standardized data collection forms were used, each contributing center had at least 1 on-site study coordinator, and regular central auditing of the data was performed. Although several previous studies have reported on complications associated with 3CO for the treatment of ASD, these studies have been limited by multiple factors, including retrospective collection of complications, relatively small numbers of patients, single-surgeon or single-center series, focus on only selected types of complications, and lack of sufficient follow-up.^{3-5,8,9,13,16,19-21,23,29,33,34,57,58,62} The present study was designed in an attempt to overcome many of these limitations to provide a complete and detailed assessment of the types and incidences of complications encountered in the treatment of ASD with 3CO from the time of surgery through 2-year follow-up. These data may prove useful for surgical planning, patient counseling, and for efforts to improve the safety and cost-effectiveness of these procedures.

A total of 142 complications (57 minor and 85 major) were reported in this series, and 78% of patients experienced at least 1 complication from the time of surgery through 2-year follow-up. These complication rates are higher than those reported in many previous studies, which is likely reflective of the study design, focus on complication collection, and the length of follow-up. Importantly, the majority of reported complications likely

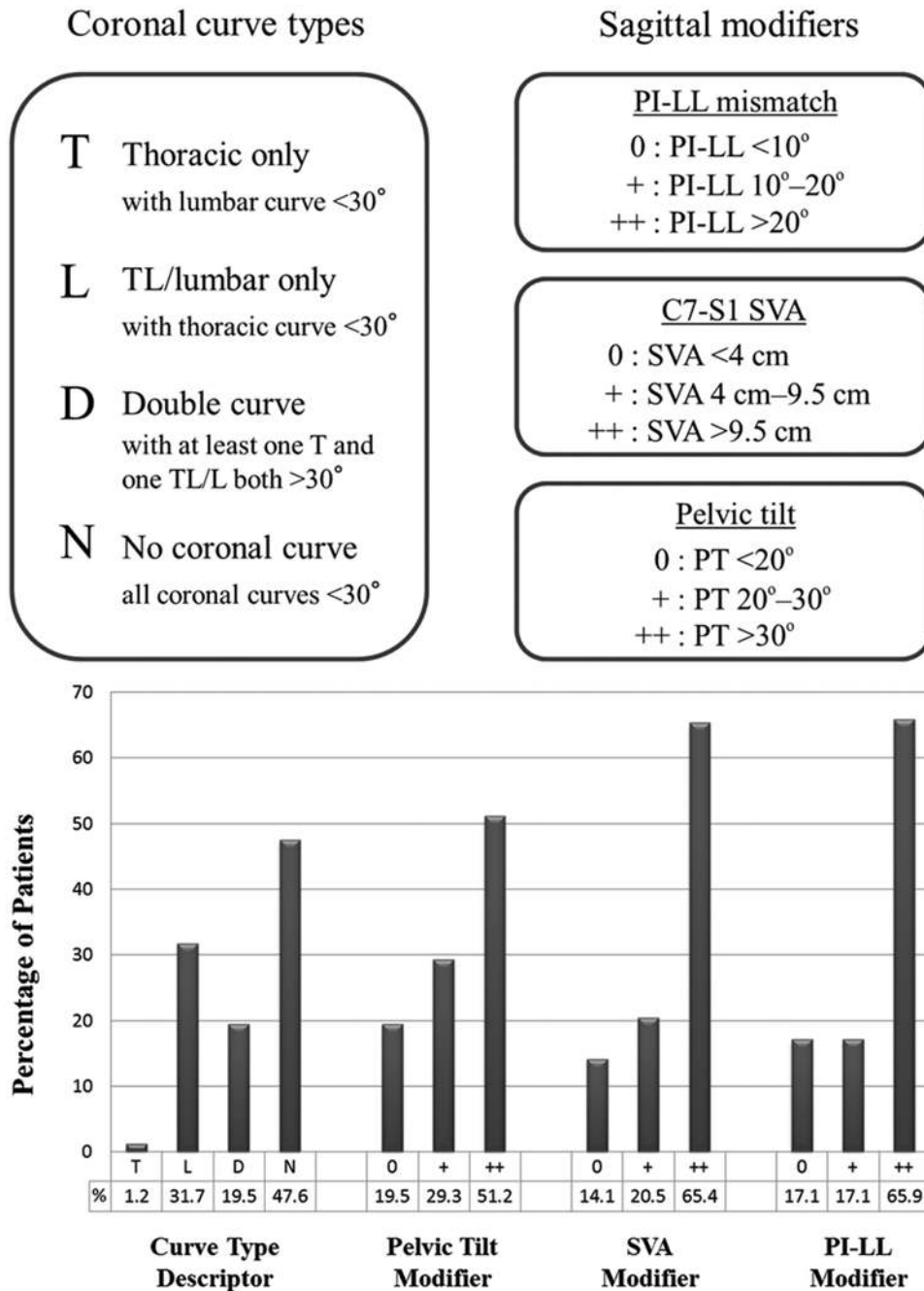


FIG. 2. Summary of the SRS-Schwab classification for adult thoracolumbar spinal deformity (**upper**)⁵⁰ and distribution of patients in the present study by SRS-Schwab curve type descriptor and sagittal spinopelvic modifier classification (**lower**). L = lumbar; PI-LL = pelvic incidence to lumbar lordosis mismatch; PT = pelvic tilt; SVA = sagittal vertical axis; TL = thoracolumbar; T = thoracic.

had limited to no impact on the ultimate outcomes of these patients. For example, a dural tear that is primarily repaired intraoperatively or a postoperative ileus that is treated medically would not typically be expected to result in long-term negative impact on clinical outcomes. Nevertheless, it is important to recognize that there are complications that can have a permanent impact and that even those without residual long-term effects can cause added patient pain and distress, increase the need for invasive interventions (including reoperation), prolong hos-

pital stays and recovery, and substantially increase the cost of these treatments.^{39–42,72} For example, although the occurrence of rod breakage, the most common complication observed in the present study, can typically be effectively treated with replacement of instrumentation and revision arthrodesis, such treatment requires the patient to undergo an additional surgical procedure with exposure to further risks of complications, necessitates additional recovery time, and diminishes the cost-effectiveness of treatment.⁷²

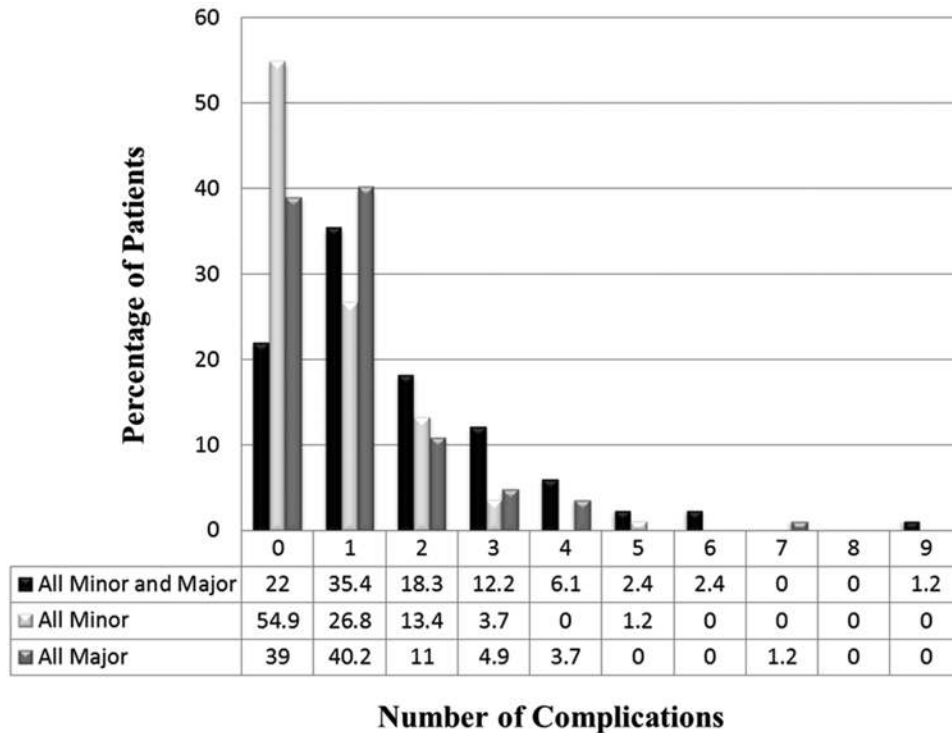


FIG. 3. Distribution of patients based on the numbers of minor and major complications that occurred (from 0 to 9). Complications include those occurring perioperatively through the 2-year follow-up time period.

A recent report by Lenke and colleagues³⁷ provided preoperative and serial postoperative neurological assessment of a series of 272 patients who were treated with surgery for complex ASD at 15 sites worldwide. At hospital

TABLE 2. Rates of complications in 82 adults with surgical treatment that included a 3-column osteotomy for spinal deformity with 2-year follow-up

Complication Category	No. of Complications, Major/Minor (%)		
	Early (≤6 wks)	Delayed (>6 wks)	Total
Implant	1/0 (1.2)	1/31 (39.0)	2/31 (40.2)
Neurologic	4/11 (18.3)	4/5 (11.0)	8/16 (29.3)
Operative	18/1 (23.2)	0/0 (0.0)	18/1 (23.2)
Cardiopulmonary	9/8 (20.7)	1/1 (2.4)	10/9 (23.2)
Radiographic	1/3 (4.9)	4/10 (17.1)	5/13 (22.0)
Infection	2/6 (9.8)	2/3 (6.1)	4/9 (15.9)
Wound (excluding infection)	4/3 (8.5)	0/3 (3.7)	4/6 (12.2)
Gastrointestinal	3/0 (3.7)	1/0 (1.2)	4/0 (4.9)
Vascular	2/0 (2.4)	0/0 (0.0)	2/0 (2.4)
Total (minor/major)	76 (44/32)	66 (13/53)	142 (57/85)
Mean no. of complications per patient (minor/major)	0.93 (0.54/0.39)	0.80 (0.16/0.65)	1.73 (0.70/1.04)
No. of patients affected (%)	41 (50.0%)	45 (54.9%)	64 (78.0%)

discharge, 22.2% of the patients in that series showed a decline in American Spinal Injury Association (ASIA) Lower Extremity Motor Score (LEMS) compared with preoperative assessment. This rate of motor decline is approximately double that observed in the present study. This difference may be partially accounted for by the focus on particularly complex deformities in the study by Lenke and colleagues, which may be expected to result in greater risk of neurological compromise compared with a study such as the present study, which included a greater range of deformity complexities. In addition, Lenke and colleagues included detailed assessment of the ASIA LEMS that likely detected many mild and more subtle changes in neurological function that could readily go undetected without such formal assessment.

The present study did not identify any factors that were significantly associated with the occurrence of early or delayed complications, including patient demographics and operative parameters. It is notable that neither patient age nor comorbidities were significantly associated with occurrence of complications. Several previous studies have reported significantly higher complication rates in older patients undergoing treatment for ASD compared with younger patients.^{3,54,61,62} In contrast, other studies have not found significantly higher complication rates in older patients.^{23,57} The reason for a lack of association between age and the incidence of complications in the present study may be due to the dominant types of complications encountered. For example, rod breakage was the most common complication, but the risk of this complication may derive more from the degree of biomechanical rod compromise across the 3CO level⁶⁴ than from patient age. Oth-

TABLE 3. Rates of complications in 82 adults with surgical treatment that included a 3-column osteotomy for spinal deformity with 2-year follow-up*

Complication Category	No. of Complications, Major/Minor (%)		
	Early (≤6 wks)	Delayed (>6 wks)	Total
Implant	1/0 (1.2)	1/31 (39.0)	2/31 (40.2)
Rod breakage	0/0	0/26 (14 reop)	0/26 (31.7)
Implant prominence	0/0	1/1 (1 reop)	1/1 (2.4)
Screw breakage	0/0	0/2	0/2 (2.4)
Implant loosening/dislodgement	1/0	0/0	1/0 (1.2)
Rod dislodgement	0/0	0/1 (1 reop)	0/1 (1.2)
Screw nerve impingement	0/0	0/1 (1 reop)	0/1 (1.2)
Neurological	4/11 (18.3)	4/5 (11.0)	8/16 (29.3)
Radiculopathy	2/4 (3 reop)	2/0	4/4 (9.8)
Motor deficit	0/5	0/3 (1 reop)	0/8 (9.8)
Nerve root injury	0/2 (2 reop)	0/1	0/3 (3.7)
Sensory deficit	0/0	2/0	2/0 (2.4)
Mental status change	2/0	0/0	2/0 (2.4)
Stroke	0/0	0/1	0/1 (1.2)
Operative	18/1 (23.2)	0/0 (0.0)	18/1 (23.2)
Dural tear	16/1	0/0	16/1 (20.7)
Pleural injury	2/0	0/0	2/0 (2.4)
Cardiopulmonary	9/8 (20.7)	1/1 (2.4)	10/9 (23.2)
Pleural effusion	6/0	1/0	7/0 (8.5)
Pulmonary embolism	0/3	0/0	0/3 (3.7)
Deep venous thrombosis	0/3	0/0	0/3 (3.7)
Arrhythmia	1/1	0/0	1/1 (2.4)
Congestive heart failure	0/1	0/1	0/2 (2.4)
Vascular edema	1/0	0/0	1/0 (1.2)
Other	1/0	0/0	1/0 (1.2)
Radiographic	1/3 (4.9)	4/10 (17.1)	5/13 (22.0)
PJK	0/3 (2 reop)	1/4 (4 reop)	1/7 (9.8)
Pseudarthrosis	0/0	0/4 (4 reop)	0/4 (4.9)
Global sagittal malalignment	1/0	2/1 (1 reop)	3/1 (4.9)
Global coronal malalignment	0/0	0/1 (1 reop)	0/1 (1.2)
Adjacent segment disease	0/0	1/0	1/0 (1.2)
Infection	2/6 (9.8)	2/3 (6.1)	4/9 (15.9)
Deep wound infection	0/4 (13 reop)	0/2 (2 reop)	0/6 (7.3)
Urinary tract infection	1/0	1/0	2/0 (2.4)
Pneumonia	0/1	0/0	0/1 (1.2)
Superficial wound infection	0/1 (1 reop)	0/0	0/1 (1.2)
Sepsis	0/0	0/1	0/1 (1.2)
<i>Clostridium difficile</i>	1/0	1/0	2/0 (2.4)

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TABLE 3. Rates of complications in 82 adults with surgical treatment that included a 3-column osteotomy for spinal deformity with 2-year follow-up*

Complication Category	No. of Complications, Major/Minor (%)		
	Early (≤6 wks)	Delayed (>6 wks)	Total
Wound (excluding infection)	4/3 (8.5)	0/3 (3.7)	4/6 (12.2)
Dehiscence	1/2 (2 reop)	0/3 (3 reop)	1/5 (7.3)
Erythema	1/0	0/0	1/0 (1.2)
Hematoma/seroma	2/1 (1 reop)	0/0	2/1 (3.7)
Gastrointestinal	3/0 (3.7)	1/0 (1.2)	4/0 (4.9)
Ileus	3/0	1/0	4/0 (4.9)
Vascular	2/0 (2.4)	0/0 (0.0)	2/0 (2.4)
Coagulopathy	2/0	0/0	2/0 (2.4)

* The number of reoperations indicates the subset of indicated major complications that were associated with the need for reoperation.

er complications, including implant prominence, screw nerve impingement, radiculopathy, motor deficit, nerve root injury, pleural injury, dural tear, and coronal imbalance, may be more influenced by operative technique rather than by patient age. In addition, the multirevision status of many patients who are ultimately treated with a 3CO may introduce a risk of deep wound infection that exceeds the added risk of this complication that may be expected with increased age. Thus, while older patients may be expected to face greater risks of medical complications, the dominant complications in the present series were operative, and the occurrence of these complications may not be primarily driven by patient age.

Documentation and assessment of complications provides a powerful means by which to develop techniques and approaches to reduce the occurrence of specific complications. In the present study, the most common complications included rod breakage, motor deficit, PJK, and deep wound infection. Even since the time of enrollment into the study database, our group and others have been actively developing and applying techniques to reduce many of these complications. There are several examples of these advancements. Among patients treated with 3CO, rod fracture has been reported to most commonly occur at or adjacent to the level of the 3CO,^{58,62,64} which has prompted application of supplemental shorter rods to span the osteotomy level.^{27,28} Gupta and colleagues recently reported a novel technique that utilizes 4 rods spanning the 3CO level and includes 2 independent rods that attach only to the vertebral levels immediately adjacent to the 3CO (unpublished data). This technique was reported to reduce the rod fracture rate from 25% to 0%. The most common radiographic complication and a common reason for reoperation in the present series was PJK. Advancements in our understanding of optimal radiographic alignment are promising in helping reduce this complication,^{2,25,35,38,51} and a classification has been developed to better appreciate factors associated with the need for revision surgery for PJK.³⁶ In addition, a recent report from Bess and colleagues

TABLE 4. Comparison between patients who did and did not sustain early or delayed complications based on demographic and surgical parameters

Parameter	Early Complication?			Delayed Complication?		
	No	Yes	p Value	No	Yes	p Value
Mean age (SD)	61.7 (12.0)	60.0 (11.4)	0.50	62.0 (12.2)	59.9 (11.3)	0.41
Female (%)	53.2	46.8	0.22	48.4	51.6	0.22
Mean BMI (SD)	29.2 (6.5)	28.9 (5.4)	0.83	27.7 (6.4)	30.1 (5.4)	0.06
Mean CCI (SD)	1.7 (1.4)	2.5 (2.2)	0.10	1.9 (1.8)	2.3 (2.0)	0.47
Mean ASA (SD)	2.6 (0.6)	2.6 (0.5)	0.93	2.5 (0.6)	2.6 (0.5)	0.69
Current smoker (%)	50.0	50.0	0.73	0.0	100.0	0.31
Previous spine surgery (%)	53.9	47.1	0.18	41.4	58.6	0.09
Previous spine fusion (%)	51.6	48.4	0.23	43.8	56.2	0.27
PSO (not VCR)	54.4	45.6	0.07	47.1	52.9	0.32

PSO = pedicle subtraction osteotomy; VCR = vertebral column resection. Early complications were defined as those that occurred within 6 weeks of surgery. Delayed complications were defined as those that occurred within the first 2 years of follow-up and more than 6 weeks after surgery.

suggests that posterior polyethylene tethers at the proximal junction may reduce the stress at the junctional level and in turn may reduce the risk of PJK.⁷ Infections accounted for 11% of all major complications, and deep wound infection was the most common infection. Multiple publications have suggested that the use of intrawound vancomycin powder may reduce the occurrence of deep wound infections.^{30,66} Major deformity surgeries have inherent risks of neurological deficits, and perioperative use of the drug riluzole, which modulates excitatory neurotransmission, is being explored as a protective measure for neurological complications.^{1,24,31,32,69} In addition, advances in less inva-

sive techniques, including the “mini-open PSO”⁷⁰ and the use of lateral approaches with anterior column release,⁶⁸ may help to reduce overall complication rates associated with the treatment of this patient population.

It remains controversial whether blood loss in spine surgery without apparent sequelae should be considered a direct complication and if so at what threshold it should be considered a complication. Nevertheless, it is important to recognize that substantial blood loss can be associated with complications such as hypotension, end organ damage, and coagulopathy. In addition, allogenic blood transfusions may introduce additional risks, including hemo-

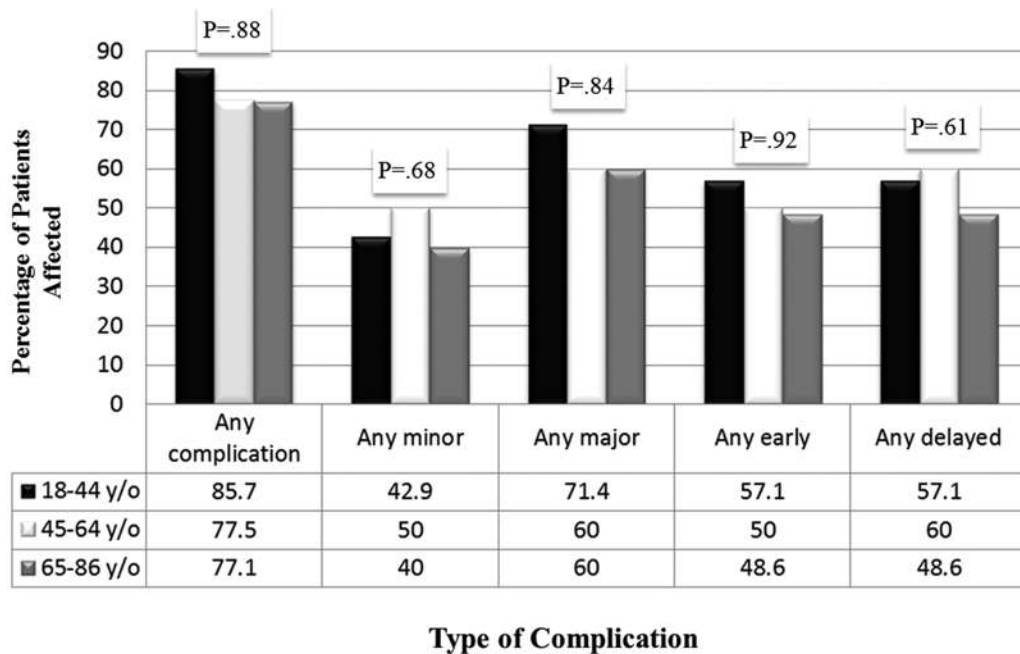


FIG. 4. Distribution of 82 adults surgically treated with a 3CO for spinal deformity with 2-year follow-up stratified based on age group and by percentages of patients affected by any complication and by any minor, major, early (within 6 weeks of surgery), or delayed (between 6 weeks after surgery and last follow-up) complications. The p values shown reflect comparisons of all 3 age groups.

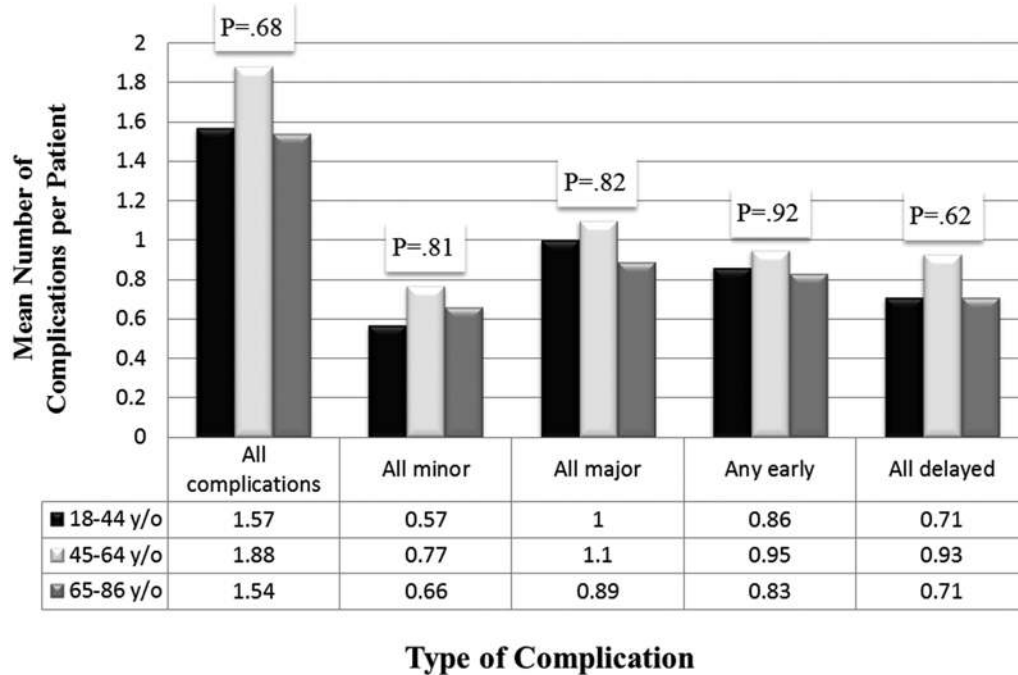


FIG. 5. Mean numbers of complications per patient (all, minor, major, early [within 6 weeks of surgery], and delayed [between 6 weeks after surgery and last follow-up]) for 82 adults surgically treated with a 3CO for spinal deformity with 2-year follow-up stratified based on age group. y/o = years old. The p values shown reflect comparisons of all 3 age groups.

lytic transfusion reactions, transfusion-related acute lung injuries, infection transmission, and immune modulation effects.¹⁹ Even though in the present study there were no reported complications that were attributed to blood loss, it remains important to minimize the amount of blood loss⁶⁷ and critically important to have an effective anesthesia team for resuscitation. The effectiveness of intraoperative antifibrinolytic therapy in significantly reducing blood loss has been suggested by several recent reports.^{19,22,44,45,71}

Two-year follow-up was achieved for 77% of patients in the present study, which is comparable to previous reports of outcomes for ASD surgery.^{12,59-61} Among the 24 patients who did not achieve 2-year follow-up, there were no known deaths. The reasons why these patients did not complete 2-year follow-up are unknown. To assess whether the lack of follow-up may relate to the occurrence of complications, we have provided a separate summary of the early and delayed complications for these patients. The types and overall rates of early complications were similar between those that did and did not achieve 2-year follow-up, and there did not appear to be an inordinate number or representation of particularly severe delayed complications in the patients lost to follow-up. Thus, it does not appear that that occurrence of complications is a primary factor for lack of patient follow-up.

Strengths of the present study include the prospective multicenter design for data collection, use of standardized data collection sheets, presence of on-site study coordinators, regular auditing of data, and the length of follow-up. Despite the prospective collection of data, the primary limitation of the present study is the retrospective design of the analysis, which could lead to underestimation of

complication rates and potentially impact the assessment of associations between complication rates and clinical parameters. In addition the study design had limited ability to detect some occult complications. For example, since many sites do not obtain routine CT imaging at follow-up, assessment of complications such as medial screw breaches and pseudarthrosis was limited to the clinically significant cases. The limited number of patients treated with more than one 3CO did not enable a meaningful sub-analysis of this patient group with regard to complication rates. Although we have endeavored to be as complete as possible with regard to the occurrence of complications in all patients in our data set, including those who did not achieve 2-year follow-up, it is possible that patients lost to follow-up may have experienced additional complications after their last study follow-up visit. This limitation should be considered when assessing the complications in those lost to follow-up and in comparing these complications and rates to those for patients with complete 2-year follow-up. In addition, in the present study we do not provide assessment of complication impact on patient outcomes, as this is beyond the scope of the present study and will be the subject of future efforts.

Conclusions

This study provides an assessment of the complications associated with surgery for ASD that included 3CO based on cases derived from a prospective, multicenter database with 2-year follow-up. Among 82 patients, a total of 76 early complications (44 minor and 32 major) were documented, and 50.0% of patients were affected by one or more of these complications. A total of 66 delayed compli-

TABLE 5. Rates of complications in 24 adults who underwent surgical treatment that included a 3-column osteotomy for spinal deformity and did not achieve 2-year follow-up*

Complication Category	No. of Complications, Major/Minor (%)		
	Early (≤6 wks)	Delayed (>6 wks)	Total
Operative	5/0 (20.8)	0/0 (0.0)	5/0 (20.8)
Implant	0/0 (0.0)	0/5 (20.8)	0/5 (20.8)
Radiographic	0/0 (0.0)	1/4 (20.8)	1/4 (20.8)
Neurologic	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)
Infection	1/1 (8.3)	1/2 (12.5)	2/3 (20.8)
Cardiopulmonary	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)
Wound (excluding infection)	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)
Gastrointestinal	2/1 (12.5)	0/0 (0.0)	2/1 (12.5)
Vascular	0/0 (0.0)	0/0 (0.0)	0/0 (0.0)
Total (minor/major)	10 (8/2)	13 (2/11)	23 (10/13)
Mean no. of complications/patient (minor/major)	0.42 (0.33/0.08)	0.54 (0.08/0.46)	0.96 (0.42/0.54)
No. of patients affected (%)	10 (41.7)	10 (41.7)	14 (58.3)

* The mean duration of follow-up for these 24 patients was 0.85 years. No follow-up beyond discharge was reported for 3 patients, 7 additional patients had no follow-up beyond 6 weeks, and 14 had no follow-up beyond 1 year.

cations were reported (13 minor, 53 major), and 54.9% of patients had one or more of these complications. The most common complications were rod breakage, motor deficit, PJK, and deep wound infection. This study represents one of the most complete and detailed reports to date of early and delayed complications associated with surgical treatment for ASD that includes 3CO. These findings may prove useful for treatment planning, patient counseling, benchmarking of complication rates, and ongoing efforts to improve the safety of patient care.

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