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Complication rate evolution across a 10-year enrollment period of a prospective multicenter database

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OBJECTIVE Adult spinal deformity is a complex pathology that benefits greatly from surgical treatment. Despite continuous innovation, little is known regarding continuous changes in surgical techniques and the complications rate. The objective of the current study was to investigate the evolution of the patient profiles and surgical complications across a single prospective multicenter database.

METHODS This study is a retrospective review of a prospective, multicenter database of surgically treated patients with adult spinal deformity (thoracic kyphosis > 60°, sagittal vertical axis > 5 cm, pelvic tilt > 25°, or Cobb angle > 20°) with a minimum 2-year follow-up. Patients were stratified into 3 equal groups by date of surgery. The three groups' demographic data, preoperative data, surgical information, and complications were then compared. A moving average of 320 patients was used to visualize and investigate the evolution of the complication across the enrollment period.

RESULTS A total of 928/1260 (73.7%) patients completed their 2-year follow-up, with an enrollment rate of 7.7 ± 4.1 patients per month. Across the enrollment period (2008–2018) patients became older (mean age increased from 56.7 to 64.3 years) and sicker (median Charlson Comorbidity Index rose from 1.46 to 2.08), with more pure sagittal deformity (type N). Changes in surgical treatment included an increased use of interbody fusion, more anterior column release, and a decrease in the 3-column osteotomy rate, shorter fusion, and more supplemental rods and bone morphogenetic protein use. There was a significant decrease in major complications associated with a reoperation (from 27.4% to 17.1%) driven by a decrease in radiographic failures (from 12.3% to 5.2%), despite a small increase in neurological complications.

The overall complication rate has decreased over time, with the lowest rate of any complication (51.8%) during the period from August 2014 to March 2017. Major complications associated with reoperation decreased rapidly in the 2014–2015. Major complications not associated with reoperation had the lowest level (21.0%) between February 2014 and October 2016.

CONCLUSIONS Despite an increase in complexity of cases, complication rates did not increase and the rate of complications leading to reoperation decreased. These improvements reflect the changes in practice (supplemental rod, proximal junctional kyphosis prophylaxis, bone morphogenetic protein use, anterior correction) to ensure maintenance of status or improved outcomes.

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KEYWORDS adult spinal deformity; deformity surgery; thoracolumbar surgery; complications

ABBREVIATIONS ACR = anterior column release; AE = adverse event; ASA = American Society of Anesthesiologists; ASD = adult spinal deformity; BMI = body mass index; BMP = bone morphogenetic protein; CCI = Charlson Comorbidity Index; EBL = estimated blood loss; HRQOL = health-related quality of life; IBF = interbody fusion; ICU = intensive care unit; LOS = length of hospital stay; ODI = Oswestry Disability Index; PCS = physical component summary; PRO = patient-reported outcome; SF-36 = 36-Item Short Form Health Survey; SRS = Scoliosis Research Society; SVA = sagittal vertical axis; 3CO = 3-column osteotomy.

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ADULT spinal deformity (ASD) is a highly complex and at times debilitating condition.[1,2] ASD is also recognized as a heterogeneous disease with varying clinical and radiographic presentations. Some patients are completely debilitated, whereas others are mildly symptomatic.[3] With regard to radiographic presentation, patients can present with different degrees of coronal and/or sagittal deformity.[4,5] Patients with ASD have been shown to have significantly greater disability when compared with the general population.[6]

There is increasing concern about the prevalence of ASD in the elderly population, for which this condition affects a greater proportion. There have been reports that the prevalence in this population ranges from 32% to as high as 68%,[7] although the exact number is difficult to ascertain and is dependent on various criteria. Whereas many of these individuals have symptoms that may be addressed with nonoperative therapies, other patients may warrant surgical treatment to address more severe pain and disability. Studies have shown that patients with more severe ASD who undergo surgery may experience a greater benefit in relief of pain and disability compared to those who receive nonoperative treatment alone.[3]

Despite the benefits that patients with ASD may receive from undergoing surgery, these procedures are associated with relatively high rates of complications. It has been reported that the complication rate for those who undergo surgery for ASD may be as high as 70%.[3,8] Additionally, those who undergo surgery do not all benefit equally. As a result of complications following surgery, patient-reported outcomes (PROs) may also be negatively affected.[3,9]

In the last decade there have been numerous papers published on ASD. A PubMed search for "Adult Spinal Deformity" returned 1281 results. Of these, 94% were published in the last 10 years. This steep increase in publications is an indication of the growing importance of ASD and the desire to learn more about the topic. In particular, one of the main subjects of interest has been the significant changes made in practice over time as experience treating ASD has increased.

One of the factors contributing to the boom in recently published data was multicenter study groups. These groups are a collection of sites that compile and share their data, thereby increasing the participant pool and the information that can be studied. In addition to a more substantial amount of generated and published data, regular discussion among members of the group allows for thoughtful changes in practice that can benefit patient outcomes. For example, Diebo and colleagues reported on changes in outcomes of 3-column osteotomies (3COs) for ASD over a 9-year period.[10] Being able to examine a large group of patients over different periods of time is another benefit afforded by a study group. Taking advantage of the benefits of a multicenter study group, we sought to investigate the evolution of patient profile, surgical procedure, and complications over the last decade within a highly detailed and clinician-maintained database.

Methods

Patient Population

This study is a retrospective analysis of a prospective, multicenter database of patients with ASD. The database is a collection of information that included 21 sites across North America. Institutional review board approval was obtained for each site prior to data collection. Inclusion criteria for the database include the following: patient age > 18 years and presence of at least one of the following radiographic criteria for spinal deformity: coronal Cobb angle > 20°, sagittal vertical axis (SVA) > 5 cm, pelvic tilt > 25°, and thoracic kyphosis > 60°. Patients were prospectively enrolled at each site after being informed of the study details and signing a consent form. For the present study, only patients who were surgically treated were analyzed. In addition, patients must have a minimum 2-year follow-up. Patients were excluded if they had any trauma, active tumor, infection, or scoliosis other than degenerative or idiopathic types (e.g., paralytic/neuromuscular, congenital).

Data Collection

Data were collected from the preoperative baseline to at least the 2-year postoperative time point. However, the current analysis focused on the first 2 years immediately following surgical treatment and included basic demographic, clinical, surgical, and radiographic information, as well as standardized health-related quality of life (HRQOL) questionnaires. Demographic and clinical data consisted of age, sex, body mass index (BMI), and comorbidities, which were used to calculate a Charlson Comorbidity Index (CCI).[11] Surgical information included use of posterior instrumentation (uppermost instrumented vertebra, lowermost instrumented vertebra, number of levels, and supplemental rod use); interbody fusion (IBF); 3CO; anterior column release (ACR); and bone morphogenetic protein (BMP) use. Length of hospital stay (LOS), estimated blood loss (EBL), intensive care unit (ICU) stay and duration, and American Society of Anesthesiologists (ASA) score were also obtained. An invasiveness index score was also calculated for each patient.[12] Radiographic information consisted of Scoliosis Research Society (SRS)–Schwab classification for coronal and sagittal spine deformities.[3] These radiographic measurements were performed at a single center using validated and dedicated software (Spineview; ENSAM Laboratory of Biomechanics).[13] Standardized HRQOL questionnaires included the Oswestry Disability Index (ODI),[14,15] the 36-Item Short Form Health Survey (SF-36),[16] and the Scoliosis Research Society-22r patient questionnaire.[17,18]

Complications were only included in the present study if they occurred before the 2-year follow-up, in order not to penalize patients who were enrolled in the early phase of the study and therefore had a longer follow-up. Complications were then classified by category (e.g., medical or surgical) and subcategory, as well as by severity. The severity of the complication was classified based on perceived patient impact as an AE (adverse event, unrelated to surgery), minor (related to surgery but with minimal impact), major complication not leading to reoperation, or reoperation as a result of a major complication. To ensure consistency across sites and to avoid over- and underreporting due to local interpretation, each submitted complication was reviewed by a group of experienced spine surgeons and severity was adjusted based on real impact as reported by the site. This process was done systematically as part of the ongoing study to ensure quality of the data reported.

Moving Average

A moving average illustrates the trend of averages of a subset over a period of time. This allows us to represent and visualize the evolution of the complication rate of our patient population before the 2-year follow-up visit. A group of 320 patients was used to calculate the moving average. This number was identified as the minimum number of patients needed to determine a rate of 30% with a confidence interval of 95% and a margin of error of 5%. The moving average was calculated using consecutively enrolled patients. Expressed using a mathematical formula, the rate and average for group j was calculated for patient j to j + 320.

The moving averages were then graphically represented to visualize the evolution of the complication rate. The x-axis represented the time of enrollment from group 1 (composed of patients 1–321) to group 608 (composed of patients 608–928). The y-axis represented either the rate for logical and categorical variables, or it represented the mean for a given period for the continuous variables.

Statistical Analysis

Patients were separated into 3 different groups, each consisting of an equal number of individuals. Patients were stratified by enrollment position and organized by date of surgery, so the groups were titled "early," "middle," and "late." All groups were compared in terms of demographics, HRQOL questionnaires, radiographic variables, surgical data, and complication rates. Chi-square, ANOVA, or Kruskal-Wallis tests were used as appropriate for comparing categories and means. A paired t-test and McNemar test were also used to compare PROs and radiographic alignment, respectively. Moving average data were calculated and used to determine the maximum and minimum rate of complications for this cohort. Statistical analysis was performed using SPSS version 20.0 (IBM Corp.). A p value of 0.05 or less was considered statistically significant.

Results

Patient Population

Of the 1260 patients who met basic eligibility criteria for the study, 928 (73.7%) had completed their 2-year follow-up at the time of analysis and 332 (26.3%) were either lost to follow-up or still in the time windows for follow-up. Preoperatively, patients had a mean age of 60.4 years, a mean BMI of 27.8 kg/m^2, and a median [25th percentile; 75th percentile] CCI of 1 [0; 3]. A history of previous spine surgery was present in 49.9% of patients, and 76.6% were women. Preoperative radiographic data also demonstrated that patients had moderate to severe coronal and/or sagittal deformity (Table 1).

Surgical data showed that the median number of levels treated was 9 [8; 15], 70.2% of patients had an osteotomy, 26.6% of patients had 3COs or ACR, 62.7% underwent IBF, BMP was used in 74.7% of patients, and 17.8% of patients had supplemental rods placed. Using an invasiveness index, the median invasiveness score was 84.3 [62.6; 112.0]. Additionally, the median EBL was 1350 mL [700; 2238 mL], the median LOS was 7 days [5; 9 days], and 66.9% of patients were admitted to the ICU.

After 2 years postoperatively, significant improvement in PROs and radiographic measures were seen. ODI was significantly lower at the 2-year follow-up (44.3 ± 17.4 vs 23.3 ± 20.0, $p < 0.001$) and the SF-36 physical component summary (PCS) score was significantly higher (31.3 ± 9.7 vs 39.8 ± 11.5, $p < 0.001$). With regard to radiographic measures, there was a greater percentage of SRS type N (74.5% vs 39.2%, $p < 0.001$) and SRS-SVA 0 (57.7% vs 39.1%, $p < 0.001$) after 2 years.

The overall complication rate was 71.7%, with 68.3% of complications occurring before the 2-year follow-up. For the breakdown by severity of complications occurring before the 2-year follow-up, 34.7% were minor complications, 26.9% were major complications that did not lead to reoperation, 20.4% were major complications that led to reoperation, and 28.5% were AEs. The rate of complications outside of AEs was 59.9%. Of the complications observed in this study, 21.6% of patients experienced a medical complication and 51.1% of patients experienced a surgical complication (Table 2).

Stratification by Date of Surgery

Patients were separated into 3 groups stratified by their date of surgery. Groups consisted of "early," "middle," and "late" patients. The early and middle groups each consisted of 309 patients, whereas the late group consisted of 310 patients. The early group had surgeries performed between October 2008 and November 2012 with an average surgery date of July 15, 2010, ± 379 days. The middle group had surgeries performed between December 2012 and January 2016 with an average surgery date of July 8, 2014, ± 317 days. The late group had surgeries performed between February 2016 and May 2018 with an average surgery date of January 29, 2017, ± 211 days.

Table 3 provides details of comparisons across early, middle, and late groups of patients. Comparison of demographics shows a significant difference in age ($p < 0.0001$), BMI ($p = 0.0114$), CCI ($p < 0.0001$), and sex ($p = 0.0026$). With time, enrolled patients are older (56.7 ± 15 vs 64.3 ± 12.4 years), have higher BMI (27.1 ± 5.6 vs 28.4 ± 5.8), are sicker (CCI: 1.46 ± 1.6 vs 2.08 ± 1.78), and have a decreasing proportion of female patients (83.5% vs 72.3%). There is no significant difference between those undergoing primary spine surgery or surgery in the setting of a previous spine surgery.

A comparison of preoperative HRQOL questionnaires showed that there was only a significant difference in SF-36 PCS score across the 3 groups ($p = 0.0008$). Compared to the early group, the late group had a decrease in score (32.8 ± 10.3 vs 29.8 ± 8.6), suggesting that more recently treated patients are more physically disabled.

A comparison of preoperative radiographic data showed that there was a significant difference in sagittal deformity across the groups ($p < 0.0001$). Compared to the early and middle group, the late group had an increased

TABLE 1. Description of preoperative information and surgical data for the entire cohort of 928 patients with ASD

Characteristic	Value
Demographic data	
Age	60.4 ± 14.3
Sex	711 (76.6%)
BMI	27.8 ± 6.0
Prior spine op	463 (49.9%)
No. of comorbidities	2 [1; 3]
CCI	1 [0; 3]
PROs	
ODI	44.3 ± 17.4
SF-36 PCS	31.3 ± 9.7
SF-36 MCS	45.6 ± 13.6
SRS activity	2.87 ± 0.87
SRS pain	2.37 ± 0.83
SRS appearance	2.43 ± 0.73
SRS mental	3.43 ± 0.9
SRS total	2.77 ± 0.63
Radiographic data*	
SRS type	
N	364 (39.2%)
T	43 (4.6%)
L	299 (32.2%)
D	22 (23.9%)
SRS PT	
0	318 (34.3%)
+	342 (36.9%)
++	268 (28.9%)
SRS PI-LL	
0	333 (35.9%)
+	202 (21.8%)
++	268 (28.9%)
SRS SVA	
0	363 (39.1%)
+	268 (28.9%)
++	288 (31.0%)
Surgical data	
No. of levels treated	9 [8; 15]
No. of levels w/ pst fusion	9 [8; 15]
No. of levels IBF	2 [1; 3]
Osteotomy	648 (69.8%)
3CO/ACR	247 (26.6%)
IBF use	582 (62.7%)
Invasiveness	84.3 [62.6; 112.0]
Suppl rod	165 (17.8%)
BMP use	693 (74.7%)
ASA	2 [2; 3]
EBL	1350 [700; 2238]
LOS	7 [5; 9]
ICU	621 (66.9%)

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TABLE 1. Description of preoperative information and surgical data for the entire cohort of 928 patients with ASD

MCS = mental component summary; PI–LL = pelvic incidence–lumbar lordosis mismatch; pst = posterior; PT = pelvic tilt; Suppl = supplemental.
Variables are reported as the mean ± SD, the median [25th percentile; 75th percentile], or the number of patients (%).
* See Terran et al. for description of SRS categories.

proportion of pure sagittal deformity (SRS type N: 26.8% vs 40.3% vs 50.6%). There were, however, no significant differences in the sagittal modifiers across the 3 groups.

Comparisons of surgical parameters across the 3 groups were all significant except for the ASA score. The late group had the lowest number of levels treated (median 9 [7; 12], p < 0.0001). The late group also had the lowest rate of 3CO (33.8% vs 25.7% vs 18.1%, p = 0.0012); invasiveness scores (median 86 [63; 118] vs 89 [66; 109] vs 80 [59; 108], p = 0.0465); EBL (median 1500 mL [800; 2500 mL] vs 1500 mL [800; 2200 mL] vs 1000 mL [463; 1800 mL], p < 0.0001); and ICU admissions (71.9% vs 75.3% vs 53.5%, p < 0.0001). LOS also significantly decreased between the early group and the middle and late groups (median 7 [6; 10] vs 7 [5; 9] vs 7 [5; 9], p = 0.0029). The late group also had the highest rates of ACR (25.2%), IBF (69.4%), supplemental rod placement (27.1%), and BMP use (79.7%) (Table 3).

A comparison of complication rates across the 3 groups is provided in Table 4 and shows that there are significant differences. The rate of any complication is lower in the late group compared to the early group (66.5% vs 55.5% vs 57.7%, p = 0.0136). Further investigation shows that for complications of any severity, there is a significant decrease in the rates of pulmonary complications (8.1% vs 3.3% vs 6.5%, p = 0.0358) and implant malposition (5.5% vs 2.6% vs 1.9%, p = 0.0328) between the early and late groups. Between these groups, there is an increase in the rate of surgical wound issues (2.3% vs 1.3% vs 4.5%, p = 0.0400) (Supplemental Table 1).

When comparing differences in major surgical complications leading to reoperation, there was a significant decrease in complication rate (27.4% vs 16.6% vs 17.1% p = 0.0008), a decrease in radiographic imbalance (12.3% vs 8.1% vs 5.2%, p = 0.0064), and a significant increase in surgical neurological complications (4.8% vs 1.0% vs 6.1%, p = 0.0030) across the early, middle, and late groups (Supplemental Table 2). For major complications that did not lead to reoperation, there were significant increases in the rate of surgical wound complications (0.7% vs 0.0% vs 2.3%, p = 0.0128) and radiographic imbalance (0.7% vs 2.6% vs 5.5%, p = 0.0015) among the early, middle, and late groups (Supplemental Table 3). A comparison of minor complications shows significant decreases in the rates of pulmonary complications (7.1% v. 2.0% vs 3.9%, p = 0.0063) and implant malposition (3.2% vs 0.7% vs 0.3%, p = 0.0034) (Supplemental Table 4).

Evolution Across Enrollment

The moving average data were used to develop graphi-

TABLE 2. Rate of patients experiencing complications before their 2-year visit by type and severity (AEs excluded)

	Any Severity		Reop		Major		Minor	
	No.	%	No.	%	No.	%	No.	%
Complication	556	59.9%	189	20.4%	250	26.9%	322	34.7%
Medical	200	21.6%	5	0.5%	90	9.7%	140	15.1%
Cardiac	26	2.8%	1	0.1%	15	1.6%	11	1.2%
Coagulopathy	34	3.7%	0	0.0%	34	3.7%	0	0.0%
Gastrointestinal	64	6.9%	1	0.1%	8	0.9%	57	6.1%
Infection	43	4.6%	1	0.1%	17	1.8%	28	3.0%
Neurological	29	3.1%	0	0.0%	11	1.2%	18	1.9%
Pulmonary	55	5.9%	2	0.2%	14	1.5%	40	4.3%
Renal	7	0.8%	0	0.0%	5	0.5%	2	0.2%
Surgical	474	51.1%	186	20.0%	184	19.8%	228	24.6%
Implant failure	117	12.6%	54	5.8%	53	5.7%	15	1.6%
Implant malposition	31	3.3%	18	1.9%	1	0.1%	13	1.4%
Infection	36	3.9%	27	2.9%	6	0.7%	5	0.5%
Operative	158	17.0%	9	1.0%	77	8.3%	91	9.8%
Wound	25	2.7%	7	0.8%	9	1.0%	9	1.0%
Radiographic imbalance	178	19.2%	79	8.5%	27	2.9%	78	8.4%
Neurological	127	13.7%	37	4.0%	35	3.8%	59	6.4%

cal representation of the evolving trends of data over time. An increasing trend was seen for the evolution of mean age, BMI, and CCI from the first 320 patients to the last 320 patients (Fig. 1). This suggests that enrolled patients have become increasingly older, heavier, and less healthy. The graph also depicts a decreased proportion of women.

Graphical data showing the evolution of the radiographic classification show a continuous increase in the proportion of pure sagittal deformity (type N) (Fig. 2). Meanwhile, there are decreases in types T, L, and D, suggesting a decrease in coronal deformity (see Terran et al.[3] for description of SRS types). Graphs depicting evolution of PROs on HRQOL questionnaires indicate an overall increase in disability, as seen by an increase in ODI and decrease in SF-36 PCS score between the first 320 patients and the last 320 patients. Disability was highest for the group of patients who had an operation between August 2010 and September 2014 with an ODI score of 47.3 ± 16.9.

Evolution of surgical data was also graphically depicted using the moving average data (Fig. 3). Initially there was a higher rate of 3CO being performed, and that rate declined over time. There was a peak use of 3CO for surgeries between December 2009 and February 2014, after which there was a decrease from 26.4% to 12.7% between October 2015 and April 2018. During the period in which there was a declining use of 3CO, there was a rapid increase in the use of ACR in 2016. In addition to increasing use in ACR, there was also an upward trend in the use of supplemental rods and BMP until each reached a stable usage of 23% and 79%, respectively. The invasiveness index scores followed 3CO progression, reaching a maximum mean of 95.8 ± 37.5 in the same period and decreasing thereafter.

Moving average data were used to visualize the evolution of complications (Fig. 4). The overall complication rate has decreased, with the lowest rate of any complication of 51.8% occurring during the period from August 2014 to March 2017. When comparing complication rate by severity, major complications associated with reoperation decreased rapidly in the 2014–2015 period, declining from 25.7% to 17.1%. Major complications not associated with reoperation had the lowest level (21.0%) between February 2014 to October 2016. Breakdown by type of complications showed an increase in surgical neurological complications and a decrease in operative, implant failure, and implant malposition complications in the most recent patient group.

Discussion

This study shows the evolution of patient profile, surgical procedure, and complications for those who have been treated for ASD over a 10-year period. The overall rate of complications within the 2-year follow-up time frame was approximately 60%. Of the complications, 21.6% were medical and 51.1% were of a surgical nature. Between October 2008 and May 2018, significant changes were observed. With regard to the patient profile, patients were increasingly older and sicker over time. Surgical practices changed to include more correction through the disc spaces via ACR, and there was a decrease in more aggressive correction through the bone via 3CO. Additionally, the rate of complications decreased significantly (from 66.5% to 57.7%) despite operating on older and sicker patients. In particular, major complications leading to reoperation had the most notable decrease over time (from 27.4% to 17.1%). Although the complication rates decreased from

TABLE 3. Comparison of demographic, HRQOL, radiographic, and surgical data among early, middle, and late patient groups

	Early	Middle	Late	p Value
Demographic data				
Age	56.7 ± 15	60.1 ± 14.5	64.3 ± 12.4	<0.0001
BMI	27.1 ± 5.6	27.8 ± 6.4	28.4 ± 5.8	0.0114
No. of comorbidities	1 [0; 3]	2 [0; 3]	2 [1; 3]	0.0002
CCI	1 [0; 2]	1 [0; 3]	2 [1; 3]	<0.0001
Sex (F)	259 (83.5%)	228 (74.0%)	224 (72.3%)	0.0026
Prior spine op	146 (47.1%)	154 (50.0%)	163 (52.6%)	0.3317
PROs				
ODI	42.8 ± 19.4	44.9 ± 17.2	45.4 ± 15.2	0.1439
SF-36 PCS	32.8 ± 10.3	31.2 ± 9.9	29.8 ± 8.6	0.0008
SF-36 MCS	45.2 ± 13.7	45.7 ± 14.2	45.8 ± 12.8	0.8094
SRS activity	2.94 ± 0.92	2.87 ± 0.92	2.79 ± 0.78	0.1278
SRS pain	2.45 ± 0.86	2.33 ± 0.87	2.34 ± 0.75	0.1739
SRS appearance	2.43 ± 0.76	2.40 ± 0.76	2.45 ± 0.69	0.6893
SRS mental	3.41 ± 0.94	3.41 ± 0.93	3.48 ± 0.83	0.5635
SRS total	2.81 ± 0.69	2.75 ± 0.64	2.76 ± 0.55	0.4555
Radiographic data*				
SRS type (N/T/L/D)	26.8%/7.4%/34.8%/31%	40.3%/3.9%/32.8%/23.1%	50.6%/2.6%/29%/17.7%	<0.0001
SRS PT (0/+/++)	35.8%/38.4%/25.8%	34.4%/34.1%/31.5%	32.6%/38.1%/29.4%	0.5250
SRS PI-LL (0/+/++)	41.3%/21.3%/37.4%	34.7%/22.7%/42.5%	31.6%/21.3%/47.1%	0.0976
SRS SVA (0/+/++)	45.4%/24.2%/30.4%	37.8%/31.6%/30.6%	35.3%/31.7%/33%	0.0705
Surgical data				
No. of levels treated	9 [8; 15]	9 [9; 15]	9 [7; 12]	<0.0001
No. of levels w/ pst fusion	10 [8; 15]	10 [9; 15]	9 [7; 13]	<0.0001
No. of levels IBF	2 [1; 4]	2 [1; 3]	2 [1; 4]	0.0012
Osteotomy	201 (64.8%)	235 (76.8%)	212 (69.1%)	0.0045
3CO	68 (33.8%)	61 (25.7%)	39 (18.1%)	0.0012
ACR	0 (0%)	2 (0.6%)	78 (25.2%)	<0.0001
IBF	190 (61.3%)	177 (57.5%)	215 (69.4%)	0.0077
Suppl rod	1 (0.3%)	80 (26.0%)	84 (27.1%)	<0.0001
BMP use	200 (64.5%)	246 (79.9%)	247 (79.7%)	<0.0001
Invasiveness	86 [63; 118]	89 [66; 109]	80 [59; 108]	0.0465
ASA	2 [2; 3]	2 [2; 3]	2 [2; 3]	0.0851
EBL	1500 [800; 2500]	1500 [800; 2200]	1000 [463; 1800]	<0.0001
LOS	7 [6; 10]	7 [5; 9]	7 [5; 9]	0.0029
ICU	223 (71.9%)	232 (75.3%)	166 (53.5%)	<0.0001

Variables are reported as the mean ± SD, the median [25th percentile; 75th percentile], or the number of patients (%).
* See Terran et al. for description of SRS categories.

the beginning to the end of the analyzed time frame, the lowest point of complication rates was observed for the middle group.

Over the 10-year period of analysis, patients have become both older and sicker. With advancements in medical technology, people are living longer. During the time of analysis, the estimated life expectancy increased from 78.2 years to 78.7 years.[19] Given that ASD is of a degenerative nature, it would be expected that an increase in older patients would similarly increase the proportion of patients who have ASD. Therefore, a greater proportion of elderly patients would be seeking treatment for ASD to maintain a fair quality of life. In addition to patients getting older, they have more comorbidities as evidenced by increased CCI scores. Our study has shown that although patients are becoming older and sicker, they may experience a similar level of disability as noted by some HRQOL measures. Similarly, Nolte et al.[20] showed that there was no difference in PRO measures concerning pain and disability in patients with different CCI scores (0, 1–2, and > 3) who underwent lumbar surgery. Thus, regardless of patient differences there remains a similar potential for improvement. Moreover, Yang et al.[21] found that patients who were older or had a greater number of comorbidities were more

TABLE 4. Comparison of complication rates among early, middle, and late patient groups

	Early		Middle		Late		
Complication	No.	%	No.	%	No.	%	p Value
Any severity	206	66.5%	171	55.5%	179	57.7%	0.0136*
Medical	72	23.2%	64	20.8%	64	20.7%	0.6793
Surgical	173	55.8%	144	46.8%	157	50.7%	0.0780
Reop	85	27.4%	51	16.6%	53	17.1%	0.0008*
Medical	1	0.3%	1	0.3%	3	1.0%	0.4497
Surgical	84	27.1%	51	16.6%	51	16.5%	0.0007*
Major	85	27.4%	79	25.7%	86	27.7%	0.8195
Medical	25	8.1%	34	11.0%	31	10.0%	0.4473
Surgical	63	20.3%	53	17.2%	68	21.9%	0.3256
Minor	121	39.0%	95	30.8%	106	34.2%	0.0991
Medical	57	18.4%	38	12.3%	45	14.5%	0.1037
Surgical	78	25.2%	74	24.0%	76	24.5%	0.9474

* Statistically significant at p ≤ 0.05.

likely to represent the population that showed improvement after surgery. Therefore, despite increased risks of complications in older and sicker patients, the benefit of surgical treatment may still outweigh those risks.

In addition to these findings, there have been general improvements to healthcare that would also allow for older and sicker patients to undergo surgery for ASD. As spine surgery has become both more common and complex, implementation of effective interventions by anesthesia has improved patient outcomes after surgery.[22] In addition to improvements in anesthesia, there has also been the creation of enhanced recovery protocols designed to reduce morbidity and improve outcomes.[23] Last, there is now a greater general understanding of ASD as a disease.[24] As also evidenced by the spike in papers published in the last 10 years regarding ASD, greater knowledge of the topic will allow for better treatment of these patients. This increase in knowledge, combined with some change in surgical team structure (i.e., single surgeon vs dual-surgeon team) and the increased experience of the surgeons par-

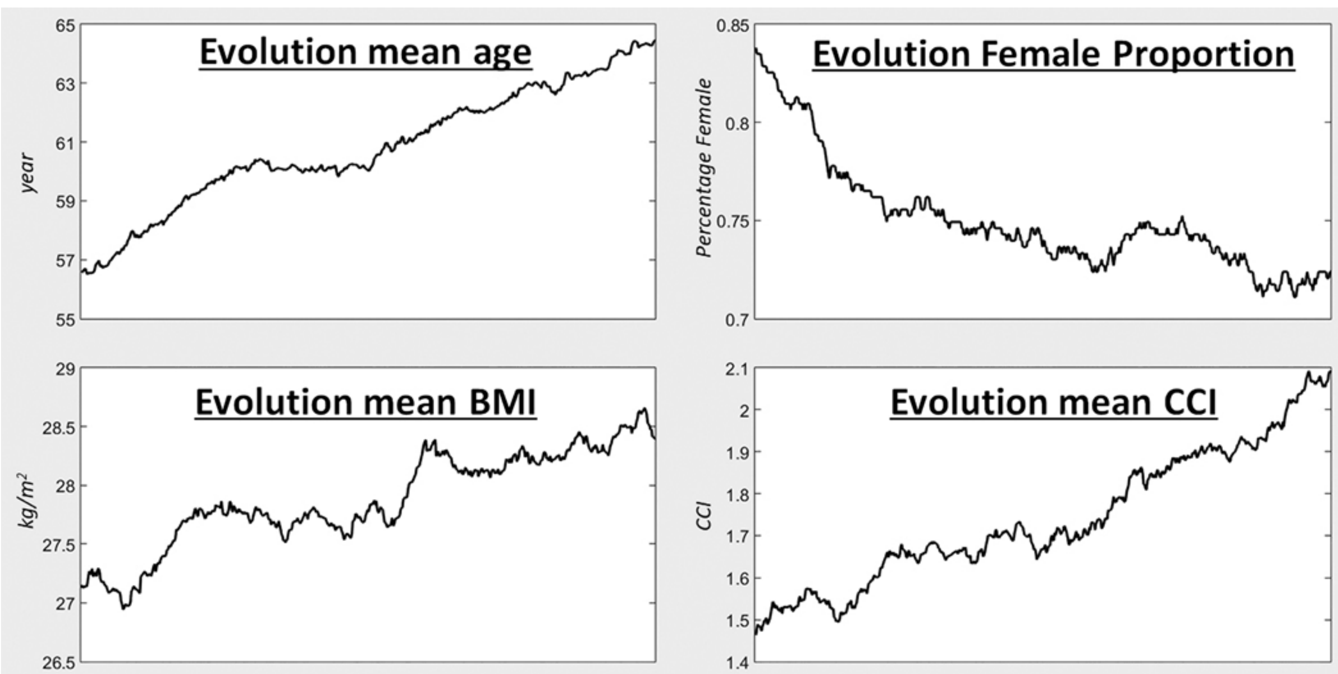

FIG. 1. Evolution of demographic data across the enrollment period demonstrated using a moving average of 320 patients. The x-axis represents the different groups of patients from group 1 (early—left side): patients 1–321 to group 608 (late—right side): patients 608–928.

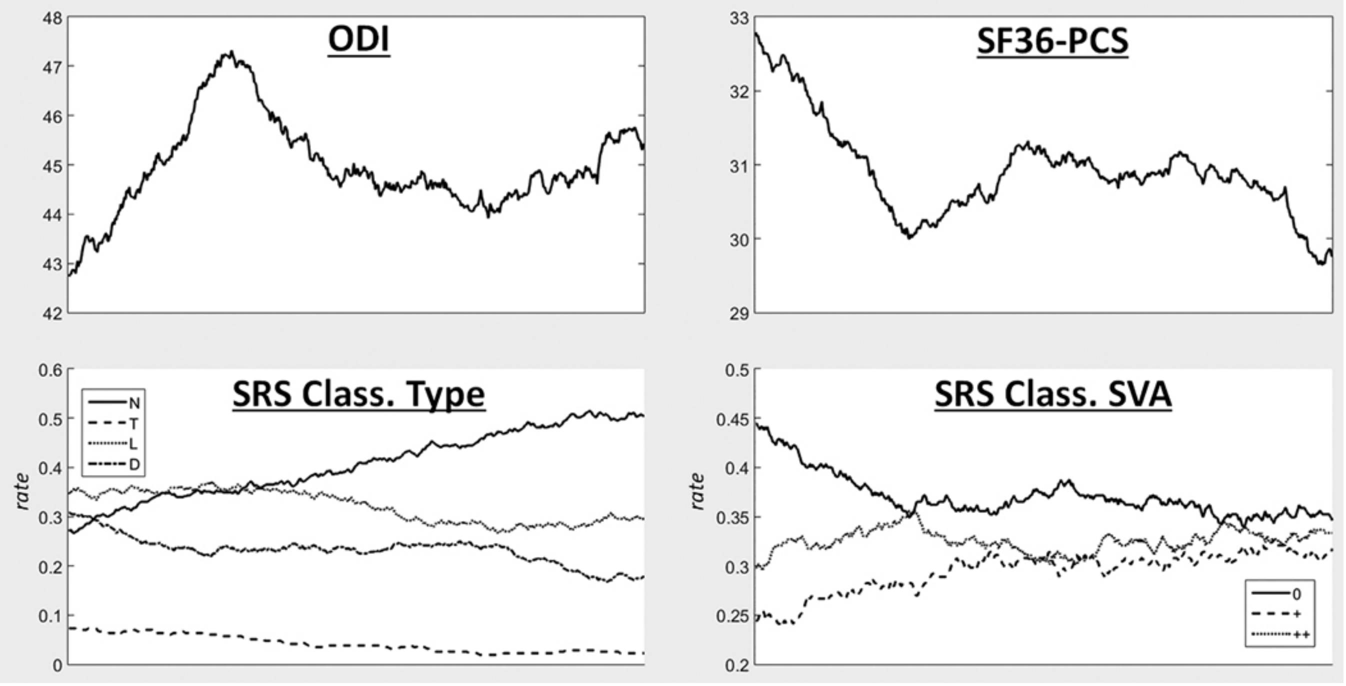

FIG. 2. Evolution of HRQOL (ODI and PCS score) and radiographic classification (SRS type and SRS SVA modifier) across the enrollment period demonstrated using a moving average of 320 patients. The x-axis represents the different groups of patients from group 1 (early—left side): patients 1–321 to group 608 (late—right side): patients 608–928. Class. = classification; D = double curve, with thoracic and thoracolumbar/lumbar curves > 30°; L = thoracolumbar/lumbar only, with thoracic curve < 30°; N = no major coronal deformity, all coronal curves < 30°; T = thoracic only, with lumbar curve < 30°; 0, +, ++ = sagittal modifier designating increases in deformity (see Terran et al.).

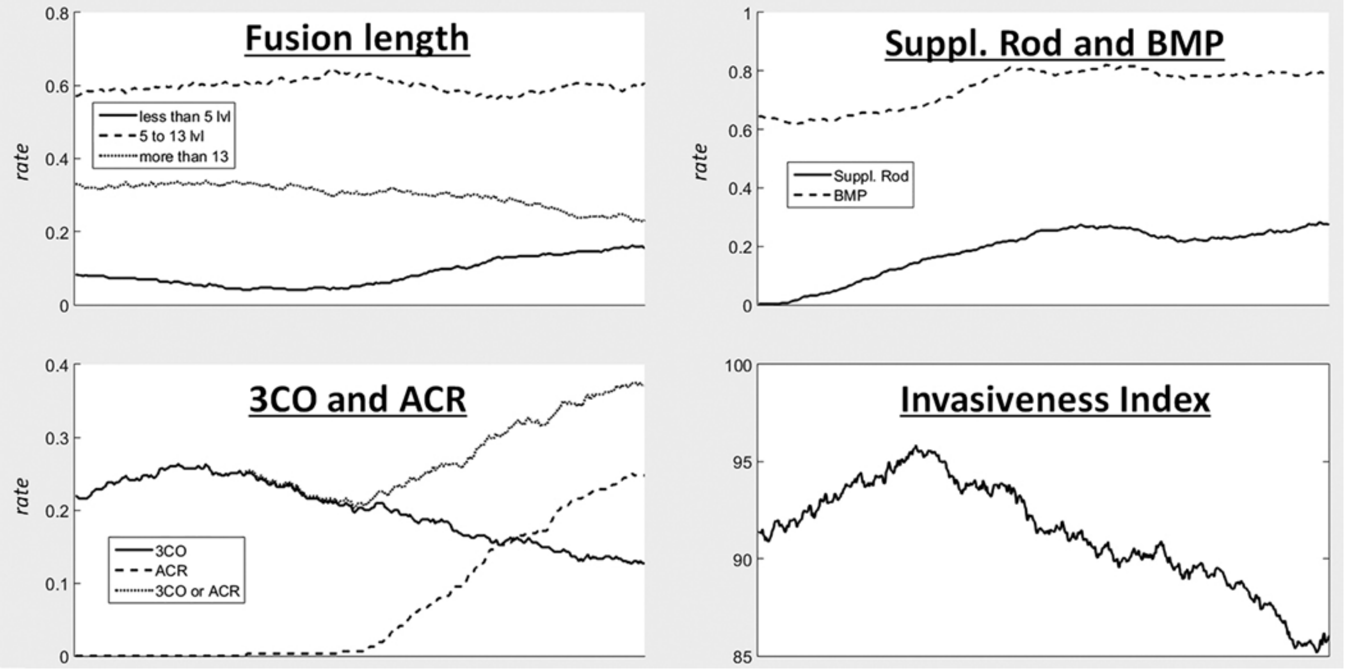

FIG. 3. Evolution of surgical data across the enrollment period demonstrated using a moving average of 320 patients. The x-axis represents the different groups of patients from group 1 (early—left side): patients 1–321 to group 608 (late—right side): patients 608–928. Lvl = levels; Suppl. = supplemental.

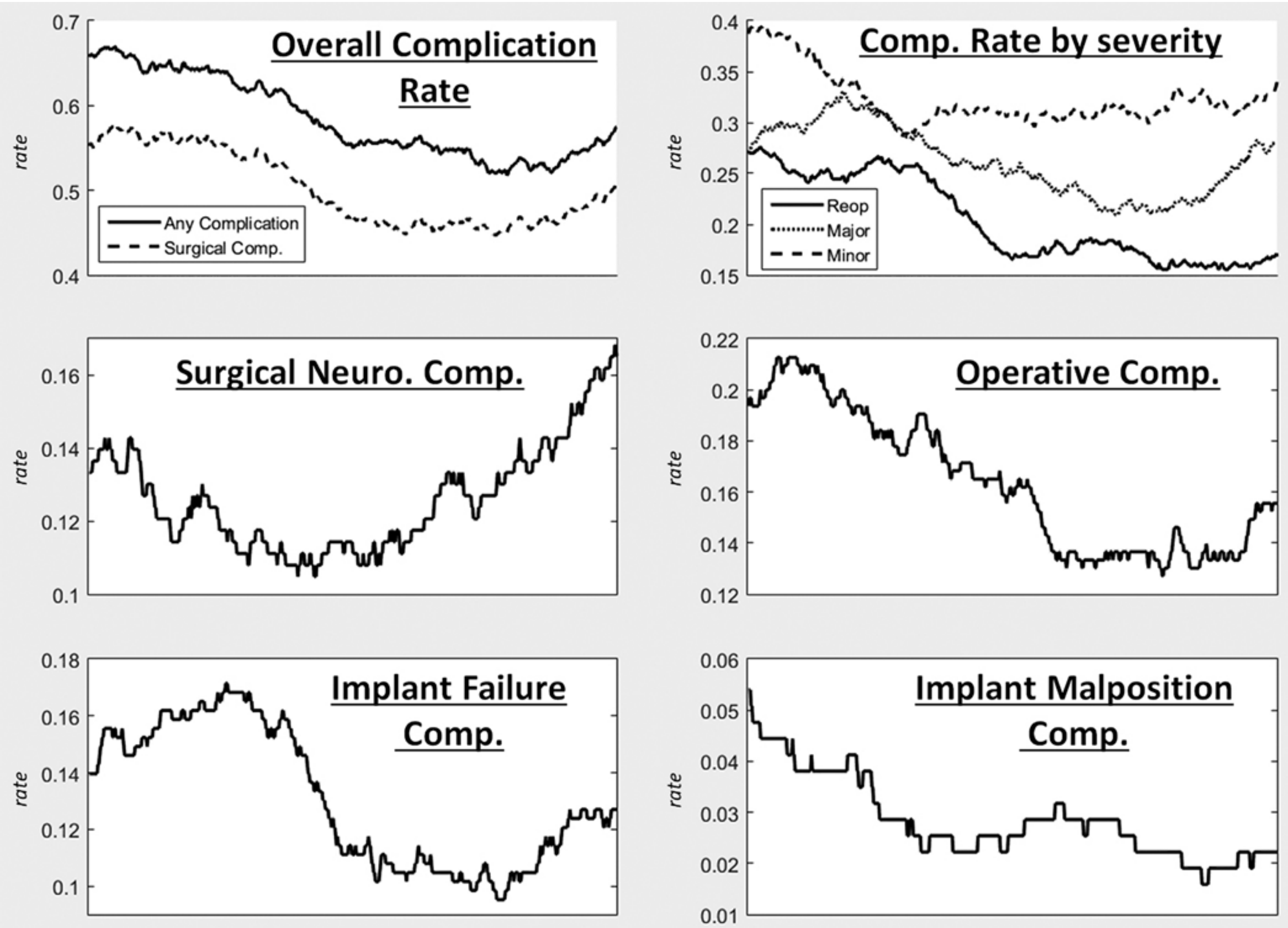

FIG. 4. Evolution of complications data across the enrollment period demonstrated using a moving average of 320 patients. The x-axis represents the different groups of patients from group 1 (early—left side): patients 1–321 to group 608 (late—right side): patients 608–928. Comp. = complication; Neuro. = neurological.

ticipating in this study may have some positive impact on outcomes.

Changes in surgical techniques were also noted during the study period. Some of the more noticeable trends that we identified were the evolution of 3CO and ACR rates. One such trend was the increasing number of ACR procedures in the last few years; as a result there was a decrease in the number of 3CO procedures performed. 3CO procedures started to increase in popularity starting around 2008,[25] and this was the main surgical correction technique for significant rigid sagittal plane deformities because it allowed for large degrees of correction.[26] However, there has since been increased awareness and reports of the high complication rate associated with 3COs.[27] Although 3CO has been shown to provide marked improvement in function despite complications, the desire to find an alternative solution with fewer complications drove the creation of the ACR procedure. We have since noticed an overall shift away from 3CO and toward ACR due to its minimally invasive approach, similar efficacy in the setting of unfused spine, and lower complication rates.[26–28] ACR has also been shown to be associated with a decrease in blood loss due to its less aggressive nature.[12,29] Whereas ACR has become more popular in recent years, both procedures are still used due to their good corrective ability when used on the appropriate patient.[26,28–30] It is interesting to note the simultaneous increased use of ACR and increased occurrence of neurological complications for the latest period. We can hypothesize that this slight increase in complications can be due to thigh pain and weakness associated with the lateral approach required.

Along with an increase in ACR procedures, there has also been an increased use of supplementary rods and BMP. The rate of implant failure appeared to be following the rate of 3CO use. Of note, an increased rate of implant failure was associated with an increased risk of pseudarthrosis, which could complicate 3CO procedures. It has been reported that the use of multirod constructs and BMP could decrease the risk of pseudarthrosis and reoperation by 7.5-fold.[31,32] The use of supplemental rods and BMP reached its peak during the middle of the study and has maintained a similar usage rate since then.

The use of a moving average allowed us to determine trends of averages across a period of time, including the evolution of those trends. Unlike a moving average analysis, a group comparison was the predominant method to provide simple and clear presentation of data. Group comparisons are very pragmatic. However, oftentimes cutoffs are arbitrary given that grouping may be done chronologically (e.g., year) or practically (e.g., first half and second half of the study). This type of grouping may mask larger trends and hinder the prediction of their evolution. Moving averages, on the other hand, are generally used in epidemiology to examine infection rates and in finance to examine stock prices. Using this analysis helps to visualize the data over time, which is helpful for observing trends and the evolution of those trends. In addition to aiding with visualization, it also provides data that are less sensitive to local events, such as clustering. It is possible to obtain the high and low data points regarding rate that could otherwise be inaccessible in a group comparison. Graphically, the data points can be superimposed to show evolution of several trends together. As such, one can see over time when trends change and how those trends may change in relation to each other.

Although this study provides a wealth of significant findings, it does have limitations. First, there was a large variability in our patient profiles. Patients with various types of ASD were included, and the data should be viewed as a general trend instead of being specific to any one type of deformity. Second, the examined data represent the change in multicenter data, not that of a single site. Not all sites enrolled patients across all time intervals, nor did they enroll comparable proportions of patients. Third, study enrollment was not strictly done on consecutive patients. This could create a bias of enrollment that could affect the evolution trends.

Conclusions

Despite the fact that operations were performed on older and sicker patients over time, changes in surgical procedures, among other practices, appeared to enable maintenance or improvement in complication rates following surgery for ASD. The lowest rate of complications before the 2-year follow-up time point was 50%. Monitoring these changes of practice and outcomes can provide an evidence-based estimation of the evolution of surgery for ASD.

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Supplemental Information

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