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Evolution in Surgical Approach, Complications, and Outcomes in an Adult Spinal Deformity Surgery Multicenter Study Group Patient Population

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Abstract

Study Design: Retrospective review of a prospectively collected multicenter database.
Objectives: To evaluate the evolution of surgical treatment strategies, complications, and patient-reported outcomes for adult spinal deformity (ASD) patients.
Summary of Background Data: ASD surgery is associated with high complication rates. Evolving treatment strategies may reduce these risks.
Methods: Adult patients undergoing ASD surgery from 2009 to 2016 were analyzed (n = 905). Preoperative and surgical parameters were compared across years. Subgroup analysis of 436 patients with minimum two-year follow-up was also performed.
Results: From 2009 to 2016, there was a significant increase in the mean preoperative age (52 to 63.1, $p < .001$), body mass index (26.3 to 32.2, $p = .003$), Charlson Comorbidity index (1.4 to 2.2, $p < .001$), rate of previous spine surgery (39.8% to 53.1%, $p = .01$), and baseline disability (visual analog scale [VAS] back and leg pain) scores ($p < .01$), Oswestry Disability Index, and 22-item Scoliosis Research Society Questionnaire scores ($p < .001$). Preoperative Schwab sagittal alignment modifiers and overall surgical invasiveness index were similar across time. Three-column osteotomy utilization decreased from 36% in 2011 to 16.7% in 2016. Lateral lumbar interbody fusion increased from 6.4% to 24.1% ($p = .004$), anterior lumbar interbody fusion decreased from 22.9% to 16.7% ($p = .043$), and transforaminal lumbar interbody fusion/posterior lumbar interbody fusion utilization remained similar ($p = .448$). Use of recombinant human bone morphogenetic protein-2 (rhBMP-2) in 2012 was 84.6%, declined to 58% in 2013, and rebounded to 76.3% in 2016 ($p = .006$). Tranexamic acid use increased rapidly from 2009 to 2016 (13.3% to 48.6%, $p < .001$). Two-year follow-up sagittal vertical axis, pelvic tilt, pelvic incidence–lumbar lordosis, and maximum Cobb angles were similar across years. Intraoperative complications decreased from 33% in 2010 to 9.3% in 2016 ($p < .001$). Perioperative (<30 days, <90 days) complications peaked in 2010 (42.7%, 46%) and decreased by 2016 (24.1%, $p < .001$; 29.6%, $p = .007$). The overall complication rate decreased from 73.2% in 2008–2014 patients to 62.6% in 2015–2016 patients ($p = .03$). Two-year health-related quality of life outcomes did not significantly differ across the years ($p > .05$).

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Conclusions: From 2009 to 2016, despite an increasingly elderly, medically compromised, and obese patient population, complication rates decreased. Evolving strategies may result in improved treatment of ASD patients.
Level of Evidence: Level IV.

Keywords: Adult spinal deformity; ASD; Complications; Three-column osteotomy; Health-related quality of life

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Introduction

Operative treatment of adult spinal deformity has been shown to reduce disability and pain, and result in quality of life improvement in appropriately selected patients [1-3]. National retrospective database studies have found increasing rates of surgical treatment of adult spinal deformity (ASD), particularly in elderly patients [4-6], as well as increasing overall case cost and charges per inpatient [7,8]. Although both age and medical comorbidities have been associated with increased complications as well as cost of care [7], the association between national trends in demographic factors and overall complication rates are still unclear.

Multicenter study groups (MSGs) evaluating spinal deformity surgery patients have become increasingly prevalent over the last decade, and their contributions to clinical knowledge have been impactful [9-16]. Assessing MSG patient data over time provides high-quality patient follow-up data, which may assist in monitoring evolution in surgical techniques and outcomes. Though there have been few recent studies assessing surgical technique utilization trends over time for three-column osteotomies (3CO) and interbody (IB) techniques for correction of spinal deformity, MSG data can be used to assess these trends.

This study sought to evaluate surgical trends and practice patterns among spinal deformity surgeons participating in a MSGs. The goal was to examine trends in patient outcomes including complications, reoperation rates, and patient-reported outcome measures.

Materials and Methods

This study is a retrospective review of a multi-center, prospectively-collected database of ASD patients. Inclusion criteria were patients who underwent surgery from 2009 to 2016, were older than 18, and had one of the following parameters: Cobb angle >20°, spinopelvic alignment (pelvic incidence–lumbar lordosis [PI-LL]) >10°, or pelvic tilt >20°, sagittal vertical axis >5 cm. A total of 905 patients were included. Patients were stratified by time period of initial operation.

Age, Charlson Comorbidity Index (CCI), and body mass index (BMI) were recorded. Preoperative SF-36 Physical Component Summary and Mental Component Summary scores were additionally reported. Surgical strategy including performance of a 3CO and/or IB cage placement (anterior lumbar interbody fusion, lateral lumbar interbody fusion, transforaminal lumbar interbody fusion) was recorded. Intraoperative, <30-day postoperative, <90-day postoperative, and >90-day postoperative complication rates were recorded. Specifically, rod fracture, fusion, and reoperation rates were also assessed. Fusion was evaluated using a 4-point grading scale [17]: 1 = no arthrodesis (not fused); 2 = possible unilateral arthrodesis (not fused); 3 = unilateral bridging arthrodesis (fused); and 4 = bilateral bridging arthrodesis (fused).

All statistical analyses were performed using Statistical Package for Social Sciences v. 24 (IBM Corp., Armonk, NY). Chi-squared and nonparametric Kruskal-Wallis tests were used to compare categorical and continuous variables, respectively. Logistic regression was applied to determine an odds ratio (OR) between year with highest incidence of complication to most recent surgery year.

Subgroup analysis of 436/905 (48.2%) patients with at least 2 years of postoperative follow-up was also performed in order to evaluate complications and patient-related outcome measures. In addition, in order to evaluate the progress and trends throughout the course of the study group, 2 groups were created: Early (2009–2014) versus Late (2015–2016). The split between the groups after 2014 was chosen to assess whether accumulation of knowledge and studies from the first 6 years of the study group affected later surgeon behavior and patient outcomes. To evaluate overall complication rate as well as HRQoL measures, the groups were divided into 2009–2012 versus 2013–2014 to ensure full two-year follow-up.

Results

Patient demographics

Between 2009 and 2016, mean preoperative age increased from 52 versus 63.1 years ($p < .001$), BMI increased from 26.3 to 32.2 ($p = .003$), and CCI increased from 1.4 to 2.2 ($p < .001$). Patients also presented with more disability based on VAS back and leg scores ($p < .01$), Oswestry Disability Index and SRS-22 scores ($p < .001$) in 2016 compared to 2009 (Table 1). Preoperative patients in 2016 had lower SF-36 Physical Component Summary scores compared to those in 2009 (29.2 vs. 35.4; $p < .001$), and similar SF-36 Mental Component Summary scores (43.6 vs. 44.7; $p = .29$). The mean frailty index was 3 in 2009, peaked with 3.9 in 2011 and 2012 and declined slightly to 3.6 in 2016 ($p < .001$). The rate of previous spine surgery increased from 2009 to 2016 (39.8% vs. 53.1%; $p = .01$).

Baseline PI-LL peaked in 2012 (10.5° in 2009 vs. 22.8° in 2012 vs. 17.8° in 2016; $p < .001$) and trended downward after. Similarly, baseline sagittal vertical axis peaked in 2012 (44.6° in 2009 vs. 96.6° in 2012 vs. 76.8° in 2016; $p < .001$) and trended downward after.

There was also no statistically significant difference in Schwab sagittal alignment modifiers across years with a range of ++ modifier patients from 20.2% in 2009 to a high of 46% in 2012 ($p = .334$). The average coronal Cobb angle decreased from 48.0° in 2008 to 32.3° in 2016 ($p < .001$).

Variation in operative strategy and technique

When examining 3CO utilization, an early increase followed by gradual decline was observed; thus, there was not a significant linear trend across the entire study period regarding performance of 3COs ($p = .732$) (Table 2). However, 3CO utilization peaked in at 36% in 2011 and significantly dropped to 16.7% in 2016 ($p = .002$). Although the invasiveness of surgery index similarly peaked in 2012 (102.9) there were no statistically significant changes detected across year ($p = .696$). IB fusion overall was similar across years, however the specific approach favored changed over time. Specifically, lateral IB (lateral lumbar interbody fusion) increased from 6.4% in 2010 to 24.1% in 2016 ($p = .004$), anterior lumbar interbody fusion decreased from 22.9 in 2010 to 16.7% in 2016 ($p = .043$), and transforaminal lumbar interbody fusion use did not significantly change ($p = .448$).

The use of recombinant human bone morphogenetic protein-2 (rhBMP-2) surged in 2012 (84.6%), with a rapid decline in 2013 (58%), and rebound to 76.3% in 2016 ($p = .006$). Overall antifibrinolytic use increased from 49.2% in 2009 to 53.7% in 2017 ($p < .001$). Specifically, during this time period, however, there was a decline in aminocaproic acid (Amicar) use from 34.2% in 2009 to 4.7% in 2016 ($p < .001$), and a simultaneous increase in tranexamic acid (TXA) from 13.3% in 2009 to 48.6% in 2016 ($p < .001$). Supplemental rod use increased during the study period, with no patients receiving supplemental rods in 2010 and 19.6% of patients receiving them by 2016, although this trend was not statistically significant ($p = .657$). Across all years, there were no significant trends in terms of hospital length of stay ($p = .204$).

Table 1
Patient preoperative demographics.

Year	2009	2010	2011	2012	2013	2014	2015	2016	Overall	p
Age, years	52	56.6	60.9	60.3	57	59.7	62.3	63.1	58.8	<.001
Frailty index	3	3	3.9	3.9	3.4	3.5	3.4	3.6	3.4	<.001
BMI	26.3	27.1	28.2	27.4	28	27.5	30.8	32.2	28.5	.003
CCI	1.4	1.5	1.3	2.3	1.4	1.8	1.7	2.2	1.6	<.001
Prior spine surgery, %	39.8	43.1	53.4	60.0	52.8	47.7	58.6	53.1	50.0	.011
Preop max Cobb	48	45.3	37.2	37.6	35.2	38.7	33.4	32.3	38.8	<.001
Preop SS	32.8	32.7	30.5	30.5	30.3	30.8	31.2	31.9	31.3	.645
Preop PT	22.2	22.5	25.1	25.6	24.3	24.8	24.7	25.3	24.2	.192
Preop PI	55	55.2	55.6	56.1	54.5	55.6	56	57.3	55.5	.906
Preop PI-LL	10.5	14	20.8	22.8	16.5	17.8	19.4	17.8	17	.001
Preop LL	44.5	41.2	34.9	33.3	38.3	37.4	36.6	39.5	38.6	.007
Preop SVA	44.6	66	76.3	96.6	66.3	73.4	75.4	76.8	69.3	<.001
Preop SF-36 MCS	44.7	48.2	40	47.4	45.3	44.6	44.8	43.6	44.8	.29
Preop SF-36 PCS	35.4	33.4	29.9	27.9	30.1	29.8	31	29.2	31.1	<.001
Preop back pain	6.9	6.8	7.6	8	7	7.3	7.2	7.5	7.2	.011
Preop leg pain	3.6	4.5	4.3	5	5.3	5	4.7	5.2	4.7	.004
Preop ODI	39.1	40.6	50.1	48.4	45.9	46.4	46.1	46.5	44.9	<.001
Preop SRS-22 score	2.87	2.97	2.56	2.69	2.67	2.68	2.7	2.66	2.73	<.001
Schwab, %										.334
0	58.9	50.5	33.7	34.0	43.5	45.5	41.5	55.6	46.5	
+	21.0	22.0	34.8	20.0	27.4	26.9	28.9	17.6	25.1	
++	20.2	27.5	31.5	46.0	29.0	27.6	29.6	26.9	28.4	

BMI, body mass index; CCI, Charlson Comorbidity Index; LL, lumbar lordosis; max, maximum; MCS, Mental Component Summary; ODI, Oswestry Disability Index; PCS, Physical Component Summary; PI, pelvic incidence; Preop, preoperation; PT, pelvic tilt; SF-36, 36-Item Short Form Health Survey; SS, sacral slope; SSR-22, 22-item Scoliosis Research Society questionnaire; SVA, sagittal vertical axis.

Values are means unless otherwise noted.

Outcomes and complications

Two-year follow-up radiographic union was lowest at the beginning of the study in 2009 with a rate of 60.6%, and peaked with the most recent group in 2014 at 82.6% (OR 3.45, p = .007) (Table 3, Fig). Intraoperative complications decreased from 33% in 2010 to 9.3% in 2016 (OR 4.83 [2.25−10.37], p < .001) (Table 4). Perioperative (<30-day and <90-day) complications peaked in 2009 (42.7% and 46%) and significantly decreased by 2016 (24.1%, p < .001, and 29.6%, p = .007). Late (>90-day) complications also peaked in 2009 (63.7%) and decreased by 2016 (35.2%, p < .001). There was no significant difference in infection rates across years. Reoperation rates among those with two-year follow-up peaked in those who were operated on in 2011 (29.5%) and decreased to 8.9% in those operated on in 2014 (p = .036). The OR for a reoperation in 2011 versus 2014 was 3.9 (p = .005) and for rod breakage was 5.7 (20.6% vs. 4.3%, p = .026).

Table 2
Operative strategy.

Year	2009	2010	2011	2012	2013	2014	2015	2016	Overall	p
n	124	109	89	50	124	156	135	108	895	
Invasiveness index, mean	86.5	92.5	100.4	102.9	95.1	92.8	92	81.7	92.4	.696
LOS, days	8.3	8.8	9.2	9.8	9.2	9.5	9.5	8.1	9.1	.204
3CO	10.5	22.0	36.0	24.0	25.0	22.4	20.7	16.7	21.4	.732
Interbody fusion	66.1	58.7	52.8	66.0	59.7	62.8	55.6	58.3	59.9	.388
LLIF	11.3	6.4	6.7	18.0	7.3	6.4	14.8	24.1	11.2	.004
ALIF	33.1	22.9	14.6	22.0	15.3	19.9	25.2	16.7	21.7	.043
TLIF/PLIF	23.4	28.4	36.0	34.0	37.1	35.9	20.7	20.4	29.1	.448
Osteotomy	53.2	73.4	68.5	70.0	74.2	75.0	74.8	59.3	68.7	.079
rhBMP-2	71.3	41.2	65.6	84.6	58.0	63.4	81.0	76.3	67.6	.006
Supplemental rods		0.0	9.1	7.7	31.0	34.6	27.7	19.6	27.5	.657
Staged	35.3	66.7	72.2	66.7	75.0	47.2	76.1	36.6	55.9	.44
Antifibrinolytics	49.2	42.2	61.8	68.0	70.2	67.9	65.2	53.7	59.8	<.001
Amicar	34.2	27.5	46.1	40.0	32.2	24.5	9.2	4.7	25.6	<.001
TXA	13.3	14.7	15.7	28.0	37.2	43.2	55.0	48.6	33.6	<.001

3CO, three-column osteotomy; ALIF, anterior lumbar interbody fusion; LLIF, lateral lumbar interbody fusion; LOS, length of stay; PLIF, posterior lumbar interbody fusion; rhBMP-2, recombinant human bone morphogenetic protein-2; TLIF, transforaminal lumbar interbody fusion; TXA, tranexamic acid.

Values are percentages unless otherwise noted.

Table 3
Clinical outcomes in patients with minimum two-year follow-up (2009–2014).

Year	2009	2010	2011	2012	2013	2014	Overall	p
n	105	91	68	39	77	46	436	
2Y max Cobb	25.6	27	19.9	18.8	18	19.9	22.4	.001
2Y SS	34.4	34.7	33.8	34	32.4	32.3	33.6	.653
2Y PT	21.3	20.8	21.3	21.7	19.9	22.3	21.2	.827
2Y PI	55.7	55.5	55.1	55.7	52.3	54.5	54.8	.505
2Y PI-LL	4.4	2.3	4.2	4.1	1.1	2.3	3.3	.566
2Y LL	51.2	53.2	50.9	51.6	51.2	52.3	51.5	.914
2Y SVA	28.9	32.9	31.4	36.8	27.9	38.5	31.8	.82
2Y SF-36 MCS	48.1	52.8	47.4	50.8	48.3	51.1	49.6	.013
2Y SF-36 PCS	42.6	42	35.7	37.2	38.4	36.9	39.5	<.001
2Y back pain	3.3	3.2	4.4	4.1	4.3	3.2	3.7	.035
2Y leg pain	2.3	2.4	3.2	3.3	2.7	2.3	2.6	.181
2Y ODI	24.6	24.1	34.2	33.6	30	29.9	28.1	.004
2Y SRS-22 score	3.7	3.8	3.4	3.6	3.5	3.6	3.6	.008

2Y, two-year; LL, lumbar lordosis; max, maximum; MCS, Mental Component Summary; ODI, Oswestry Disability Index; PCS, Physical Component Summary; PI, pelvic incidence; PT, pelvic tilt; SF-36, 36-Item Short Form Health Survey; SRS-22, 22-item Scoliosis Research Society Questionnaire; SS, sacral slope; SVA, 2Y, two-year.

Early versus late patient-reported outcomes

Compared to the Early (2009–2014) group, the Late (2015–2016) group were older (57.4 vs. 62.7 years, $p < .001$), had a higher BMI (27.4 vs. 31.4, $p = .001$), and higher CCI (1.6 vs. 1.9, $p = .001$). There was no difference in frailty or invasiveness index, and baseline deformity and HRQoL measures were no different among groups ($p > .05$). Intraoperative (25.7% vs. 13.6%, $p < .001$), 30-day (32.5% vs. 25.1%, $p = .033$), and 90-day (38.8% vs. 31.7%, $p = .049$) complications were significantly lower in the Late patients, whereas the infection rates remained similar (8.6% vs. 7.4%, $p > .05$). When evaluating complications and HRQoL measures between groups with minimum two-year follow-up (2009–2012 vs. 2013–2014), the overall complication rate decreased from 73.2% to 62.6% ($p = .03$). Reoperations were significantly lower (30% vs. 14.6%, $p = .01$) and posterior fusion rates were higher (65% vs. 77.2%, $p = .045$). HRQoL (SRS-22, ODI, VAS back and leg) and deformity correction were similar between groups ($p > .05$ for all).

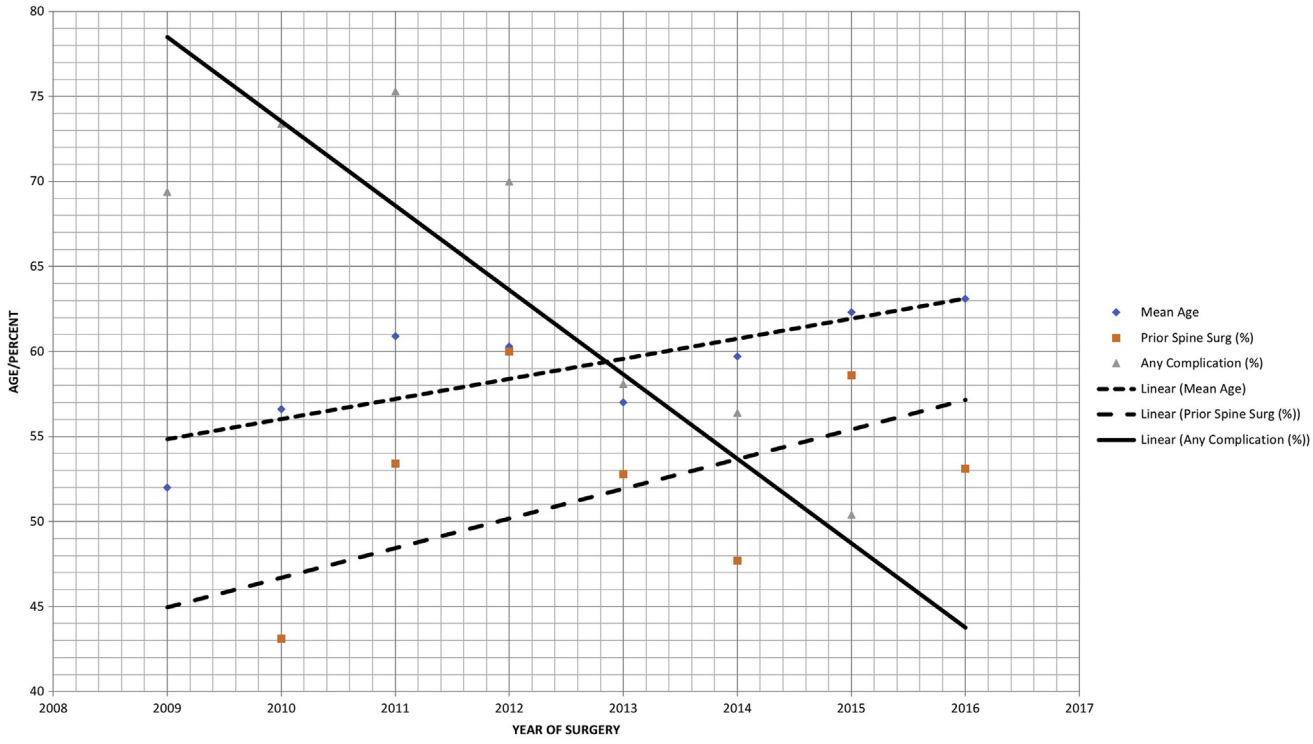

Fig. Trends in mean patient age, percent of patients with previous spine surgery, and overall complication rate (2009–2016).

Table 4
Complication rates, % (2009−2016).

Year	2009	2010	2011	2012	2013	2014	2015	2016	Overall	p
All Complications	69.4	73.4	75.3	70.0	58.1	56.4	50.4	36.1	60.1	<.001
Intraoperative	32.3	33.0	22.5	30.0	21.8	18.6	17.0	9.3	22.4	<.001
Before 30 days	42.7	39.4	28.1	22.0	29.0	27.6	25.9	24.1	30.5	<.001
Before 90 days	46.0	42.2	38.2	22.0	37.9	36.5	33.3	29.6	36.9	.007
After 90 days	63.7	58.7	50.6	46.0	43.5	46.2	43.7	35.2	48.5	<.001
Infection	8.1	7.3	6.7	10.0	9.7	9.6	6.7	8.3	8.3	.841
Rod breakage	3.2	14.7	21.3	10.0	9.7	4.5	3.7	0.0	7.5	<.001

Discussion

This study found that from 2009 to 2016, ASD patients were on average older, more obese, and had higher medical complexity in addition to having a higher incidence of prior spine surgery. Despite this trend toward treating more complex patients with a stable surgical invasiveness over time, the overall complication rate decreased significantly. One contributing factor that may have contributed to the decreasing complication rates is improvement in surgical technique. Techniques were shared in meetings between the group and may have influenced adoption at other centers over time. Specific techniques used changed substantially over the study period with an early peak in 3COs, followed by a later drop in their use whereas the use of lateral interbody fusion increased dramatically concurrent with increasing utilization of TXA. During the study period, 3CO osteotomies were found to be associated with increased rates of nonunion and early rod failure by the group, and lateral techniques were adopted as an alternative. The overall reduction in complications observed over the study period may in large part be related to the gradual reduction in the use of 3CO osteotomies in favor of lower-risk alternatives.

This study was able to carefully assess an evolution in treatment methods and patient-related outcomes after ASD surgery due to dedicated patient enrollment by the surgeons in an ASD MSG. MSGs have become increasingly popular over the last decade. Traditionally study groups were formed in order to study rare diseases or uncommon techniques in larger numbers and thus provide insight and clarity regarding the disease state or surgical procedure of interest. Some study groups are formed to evaluate one question and are dissolved once this question is answered or the study is concluded. Other groups use rolling enrollment to allow for continued database growth and analysis of trends in practice patterns. This is thought to provide room for evolutionary thought processes to be more clearly communicated with professional peers, and perhaps even third-party payers and policy makers. There are inherent drawbacks to study groups, however. There are significant administrative challenges to maintaining the study group data locally, including tracking follow-up and radiographic data. Study groups require surgeons to have dedicated research teams and coordinators who are able to collect and analyze patient data for quality assurance based on audits of the database. Finally, enrollment is surgeon-driven, and as such there is inherent risk of selection bias.

This investigation revealed several changes over time in surgical strategy. In recent years, there has been a substantial expansion in the techniques and in instrumentation available to spine surgeons for correction of adult spinal deformity. As the importance of sagittal parameters to patient outcomes has become more widely known [18-20], surgeons may be performing more aggressive measures to ensure optimal alignment [21]. Posterior column osteotomies such as Smith-Peterson osteotomies are commonly performed; however, they provide a limited capacity for sagittal correction. As such, 3COs such as pedicle subtraction osteotomies and vertebral column resections, which can provide significantly more correction, have been growing in popularity among spinal deformity surgeons for treatment of rigid and/or severe deformities. Gum et al. found increasing utilization of 3COs for correction of sagittal malalignment from 2008 to 2011 [21]. Both pedicle subtraction osteotomies and vertebral column resections are associated with high surgical and medical complication rates; however, it is unclear whether the presence of major complications affects long-term clinical outcome or patient satisfaction [22]. Surgeons in this MSG likely decreased their utilization of 3COs over time because of the high associated complication rates as well as the increasing availability and popularity of alternative techniques such as anterior column realignment via a lateral lumbar interbody fusion approach.

The full range of interbody fusion techniques can be used to correct deformity and improve fusion rates. Additionally, in patients with open disc spaces, these techniques may be able to avoid the need for 3CO as a more physiologic lordosis is achieved [23]. Similarly, some surgeons have combined posterior spinal fusion with multilevel lateral interbody fusions to achieve improved alignment parameters over posterior spinal fusion alone, although this was found to result in increased complications and no improvement in two-year outcomes [24].

Additional factors aside from surgical strategy alone may have contributed to the decreasing complication rate. Surgeon experience may contribute to the decreasing complication rate, as high-volume surgeons and those with

greater experience have been shown to have lower complication rates [25-29]. Furthermore, an increasing use of TXA was found in this population, which may be an additional contributing factor. Finally, preoperative optimization, not specifically examined in this study, such as the use of pre- and postoperative osteoporosis medication, frailty assessment, risk stratification, and nutritional therapy may have also contributed to the dropping complication rate.

This study has several potential limitations. Possible underreporting of complications may increase the risk of type II error. Additionally, it cannot be assumed that the decreasing complication rates over time are due to knowledge gained from the study group, as recent changes in practice such as widespread routine use of vancomycin powder [30,31] and TXA [32-34] have been adopted and this may additionally contribute to a decrease in complications. Furthermore, some complications such as rod fracture may still occur with longer follow-up, particularly in those patients with supplemental rods [35]; therefore, the apparent decrease in complication rate at two-year follow-up may be different at intermediate (3−5-year) or long-term (>5 year) follow-up.

This study found that from 2009 to 2016, despite operating on more complicated patients in terms of older age and higher BMI and CCI, this multicenter study group achieved a significant reduction in reoperation and complication rates at two-year follow-up. Further studies designed to evaluate intermediate and long-term outcomes are necessary and currently in process.

Key points

- From 2009 to 2016, this ASD patient population became more complex with increases in age, BMI, and CCI.
- Operative strategies evolved during the course of the study with an early spike in the use of 3COs, followed by a decrease in their use whereas LLIFs were increasingly used.
- Overall complication rates decreased over the study period despite an increasingly complex patient population.

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