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After 9 Years of 3-Column Osteotomies, Are We Doing Better? Performance Curve Analysis of 573 Surgeries With 2-Year Follow-up

BACKGROUND: In spinal deformity treatment, the increased utilization of 3-column (3CO) osteotomies reflects greater comfort and better training among surgeons. This study aims to evaluate the longitudinal performance and adverse events (complications or revisions) for a multicenter group following a decade of 3CO.

OBJECTIVE: To investigate if performance of 3CO surgeries improves with years of practice.

METHODS: Patients who underwent 3CO for spinal deformity with intra/postoperative and revision data collected up to 2 yr were included. Patients were chronologically divided into 4 even groups. Demographics, baseline deformity/correction, and surgical metrics were compared using Student *t*-test. Postoperative and revision rates were compared using Chi-square analysis.

RESULTS: Five hundred seventy-three patients were stratified into: G1 (n = 143, 2004-2008), G2 (n = 142, 2008-2009), G3 (n = 144, 2009-2010), G4 (n = 144 2010-2013). The most recent patients were more disabled by Oswestry disability index (G4 = 49.2 vs G1 = 38.3, *P* = .001), and received a larger osteotomy resection (G4 = 26° vs G1 = 20°, *P* = .011) than the earliest group. There was a decrease in revision rate (45%, 35%, 33%, 30%, *P* = .039), notably in revisions for pseudarthrosis (16.7% G1 vs 6.9% G4, *P* = .007). Major complication rates also decreased (57%, 50%, 46%, 39%, *P* = .023) as did excessive blood loss (> 4 L, 27.2 vs 16.7%, *P* = .023) and bladder/bowel deficit (4.2% vs 0.7% *P* = .002). Successful outcomes (no complications or revision) significantly increased (*P* = .001).

CONCLUSION: Over 9 yr, 3COs are being performed on an increasingly disabled population while gaining a greater correction at the osteotomy site. Revisions and complication rate decreased while success rate improved during the 2-yr follow-up period.

KEY WORDS: Spinal deformity, Spinal osteotomy, Complication rate, Revision rate

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Adult spinal deformity (ASD) results from the interplay of several factors, both biological and environmental. Age, gender, occupation, population dynamics, and comorbidities all play a significant role in the increasing incidence of ASD.¹⁻⁵ Dependent on

the patient's condition, treatment of ASD can either be conservative or surgical. For those that fail conservative treatment, surgical intervention is offered. Patients in this category tend to suffer from severe spinal malalignment and significantly diminished activities of daily living. One of the effective surgical options is the 3-column (3CO) osteotomy, which encompasses the pedicle subtraction osteotomy (PSO) and vertebral column resection (VCR).⁶

However, corrective spinal surgery is not risk-free. Three COs present intra- and postoperative complications. Intraoperative complications can include nerve root injury, cord deficit, pneumothorax, large vessel injury, and

ABBREVIATIONS: 3CO, 3-column; ASD, adult spinal deformity; BMI, body mass index; ODI, Oswestry disability index; OR, odds ratio; PI-LL, pelvic incidence minus lumbar lordosis; PJK, proximal junctional kyphosis; PSO, pedicle subtraction osteotomy; PT, pelvic tilt; SRS, Scoliosis Research Society; SVA, sagittal vertical axis; VCR, vertebral column resection

rarely cardiac arrest. Postoperative complications can also be significant, such as wound infection, deep venous thrombosis, rod breakage, proximal junctional kyphosis (PJK), and revision surgery.^{7,8} The occurrence of major complications in 3COs was reported to be 35% over a 13-yr retrospective review of 240 surgical cases at a single institution.⁹

While the literature offers ample evidence of the effectiveness and complication rate of adult deformity surgery,⁹⁻¹² there is little on the assessment of the change in performance for these often-challenging cases. This study focuses on the performance curve of a multicenter study group over 9 yr of utilizing 3COs for ASD. Authors aimed to investigate if surgical outcomes of spinal osteotomies improved over the last decade.

METHODS

Patient Sample

This study was a retrospective analysis of patients with ASD who underwent thoracic or lumbar 3CO for spinal deformity (mainly sagittal, or both sagittal and coronal). Patients were operated on between February 2004 and January 2013. After institutional review board approval, patients from 11 different sites were added into a retrospective 3CO database. Patient consent was not required because of the retrospective nature of the study. All patients were older than 18yr and had baseline 36-inch lateral and posteroanterior scoliosis radiographs. For this study, further inclusion criteria were patients with intra-, postoperative complications and revision data collected up to 2-yr follow-up only. Therefore, patients with loss to follow-up were excluded and 100% of patients analyzed had complications data collected. Patients were categorized into 4 groups with similar number of surgeries from older to more recent. Group 1 (n = 143, surgeries performed between February 2004 and April 2008 by 10 surgeons), group 2 (n = 142, April 2008-September 2009 by 10 surgeons), group 3 (n = 144, September 2009-November 2010 by 12 surgeons), group 4 (n = 144 November 2010-January 2013 by 12 surgeons). Ten of the same surgeons were represented in all 4 groups, while 2 additional surgeons were represented in groups 3 and 4.

Data Collection

Demographic data, including age, gender, body mass index (BMI), and history of prior spine surgery, were collected. Operative reports were reviewed to collect operating time, estimated blood loss, and procedure (3CO type and level). In addition, for this analysis, the occurrence of intra- and postoperative complications and revisions were assessed and limited to a 2-yr timeframe. The reasons for revision included instrumentation failure, pseudarthrosis, PJK, sagittal malalignment, neurological deficit, infection, and stenosis. Oswestry disability index scores (ODI) were also collected at baseline.

Radiographic Analysis

All radiographs were measured for sagittal parameters at baseline and 2-yr follow-up using a dedicated and validated software (Spineview, ENSAM ParisTech, Paris, France).¹³ Sagittal spinopelvic parameters of interest in this study were Scoliosis Research Society (SRS)-Schwab sagittal modifiers: pelvic tilt (PT), pelvic incidence minus lumbar lordosis (PI-LL mismatch), and sagittal vertical axis (SVA). The angle of osteotomy resection was also assessed.

Statistical Analysis

Comparisons of continuous variables between the groups were completed using ANOVA for normally distributed variables (SVA, PT, PI-LL, angle of osteotomy resection) and the Kruskal-Wallis test for nonparametric variables (ODI, operating time, blood loss). Categorical variables such as rates of revisions, intra- and postoperative complications and success rate (defined as surgeries with no major complications or revisions) were compared using Chi-square analyses. Binary logistic regression models controlling for age, gender, BMI, and preoperative sagittal deformity were utilized to investigate if the year of surgery is an independent predictor of complication, revision, and success rates. All statistical tests were performed using SPSS 20.0 (SPSS Inc, IBM, Armonk, New York). $P < .05$ was considered significant.

RESULTS

Patients Sample

Out of 725 patients, a total of 573 patients (18% VCR vs 82% PSO) were eligible for inclusion in the study. Patients in the most recent group were significantly older; the 4 groups had similar BMI and gender distribution. Recently operated patients in 2009 to 2010 and 2010 to 2013 had significantly worse ODI scores in comparison to patients operated between 2004 and 2008 in (49 and 50 vs 38, $P = .001$; Table 1).

The majority of cases were revisions in all groups (range 72%-84%, $P = .064$). Patients in all groups had similar sagittal deformities at baseline assessed by the SRS-Schwab modifiers: PT (29° - 32° , $P = .228$), PI-LL (27.6 , 29.9° , $P = .884$), SVA (112 - 133 mm, $P = .221$). Postoperatively, patients were corrected similarly in regard to PI-LL (22° - 29° of correction, $P = .123$), SVA (84 - 92 mm, $P = .900$) but significantly different in terms of PT (7.2° for group 1 vs 11° for group 4, $P = .041$). Mean postoperative SVA ranged between (39.9 - 47.7 mm, $P = .885$), PI-LL (5.5° - 8.1° , $P = .777$), and PT (23.5 - 24.0 , $P = .849$).

The groups had similar distributions of upper thoracic (6%-13%, $P = .268$), thoracic (6%-11%, $P = .159$), and lumbar osteotomies (76%-85%, $P = .292$). Recent surgeries had significantly higher utilization of PSO 93.6% vs VCR 6.4%. Recent surgeries had significantly larger angles of osteotomy resection and higher rates of iliac screws (Table 2). However, level of PSO and number of rods utilized were comparable over time (Table 3).

Revision and Complication Rates

Overall, 206 out of 573 patients were revised during the last 9 yr (35.9%). Revision rates significantly decreased among the groups at 2-yr follow-up: group 2004 to 2008: 45%; group 2008 to 2009: 35%; group 2009 to 2010: 33%; and group 2010 to 2013: 30%; $P = .039$. The number of revised and nonrevised cases and the revision rate in each group is illustrated in Figure 1.

Specifically, the revision rates for pseudarthrosis decreased from 16.8% in 2004 to 2008 to 6.9% in 2010 to 2013, $P = .007$. The revision rates for PJK were similar between the groups (2.8%-8.4%, $P = .126$). Revision rates following specific adverse events are reported in Table 4. Overall, the postoperative complication

TABLE 1. Demographic Comparisons Between Groups of Surgeries Performed Over 9 yr

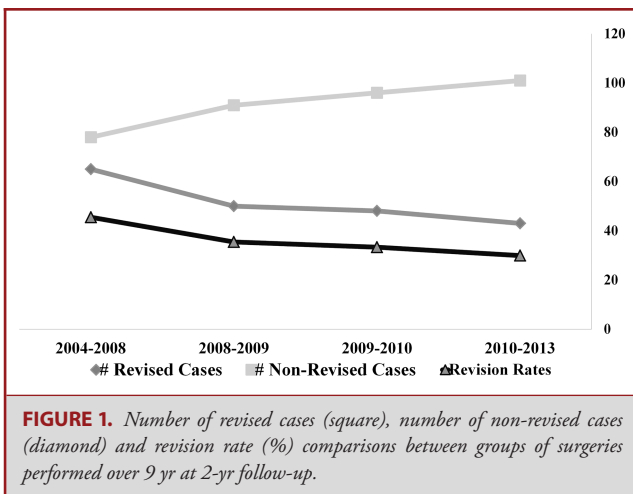
Group	2004-2008	2008-2009	2009-2010	2010-2013	P value
Age y/o	57.7	56.9	59.7	60.7	.001
Body mass index	25.8	27.3	26.5	28.1	.095
Gender (% Females)	70.6	71.1	67.4	69.6	.909
ODI scores	34	44	52	48	.001

TABLE 2. Surgical Techniques Comparisons Between Groups of Surgeries Performed Over 9 yr

Group	2004-2008	2008-2009	2009-2010	2010-2013	P value
% of PSO surgeries	79%	74.1%	81.2%	93.6%	.001
% of upper thoracic PSO vs total PSO	3.5%	5.8%	3.4%	3.8%	.791
% of lower thoracic PSO vs total PSO	1.8%	5.8%	6.0%	4.5%	.396
% of lumbar PSO vs total PSO	92.0%	88.3%	91.5%	90.9%	
Mean angle of osteotomy resection	20°	22°	24°	26°	.011
% of surgeries with iliac bolt screws as lower instrumented level	32%	44%	49%	58%	.001

TABLE 3. Comparisons between PSO Levels and Number of Rods Used Between Groups of Surgeries Performed Over 9 yr

	2004-2008	2008-2009	2009-2010	2010-2013	P value
PSO level					
T9 and above	3.5%	5.8%	3.4%	3.8%	.791
T10-T12	1.8%	5.8%	6.0%	4.5%	.396
L1	5.3%	5.8%	3.4%	6.1%	.117
L2	22.1%	11.7%	20.5%	12.1%	
L3	40.7%	36.9%	34.2%	47.7%	
L4	18.6%	27.2%	29.1%	22.7%	
L5	5.3%	4.9%	3.4%	2.3%	
S1	2.7%	1.9%	0.0%	0.8%	.198
Number of rods					
2	86%	86.2%	84.8%	84.1%	.893
3	8.1%	8.0%	7.6%	5.6%	
4 or more	5.8%	5.7%	7.6%	10.2%	



rate was 48% (274 out of 573 cases). The complication rate significantly improved from 57% in 2004 to 2008 to 39% in 2010 to 2013. The number of cases associated with major vs no complications in each group is illustrated in Figure 2.

Specifically, significant improvements were noted in the incidence of excessive blood loss (>4 L): group 2004 to 2008: 39/143 (27%) vs group 2010 to 2013: 24/144 (17%), $P = .023$. Of note, group 2008 to 2009 had the lowest incidence of excessive blood loss (14.1%). Bowel/bladder neurological deficit rates significantly decreased from 4.2% in 2004 to 2008 and 6.3% in 2009 to 2010 to 0.7% in 2010 to 2013 group, $P = .025$. However, the instrumentation failure rates including rod/screw breakage or loosening remained the same and ranged between 12% and 17%, $P = .469$. Rates of specific major complications are reported in Table 5. The success rate (defined as surgeries with no major complications or revisions) significantly improved from 25% in 2004 to 2008 to 48.6% in 2010 to 2013, $P = .001$.

TABLE 4. Comparisons of Revision Rates for Specific Pathologies Between Groups of Surgeries Performed Over 9 yr

% of cases revised for:	2004-2008	2008-2009	2009-2010	2010-2013	P value
Hardware failure	14%	14.9%	6.9%	9%	.095
Pseudoarthrosis	16.8%	12.1%	5.6%	6.9%	.007
Sagittal malalignment	7.7%	7.1%	2.8%	2.8%	.094
Neurological deficit	5.6%	2.1%	4.9%	5.6%	.452
Infection	7.7%	5.7%	4.2%	1.4%	.080
Painful Hardware	5.6%	3.5%	1.4%	1.4%	.108
Stenosis	3.5%	2.1%	4.2%	0.7%	.261
PJK	8.4%	5.7%	3.5%	2.8%	.126

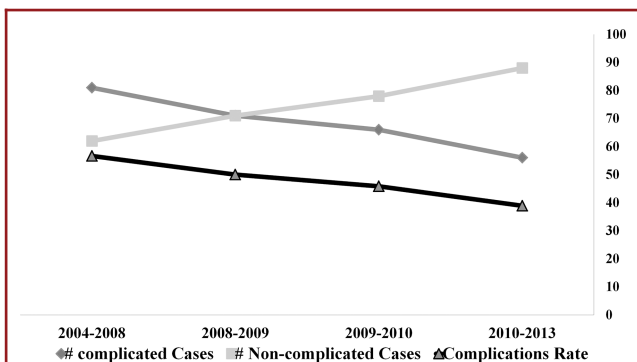


FIGURE 2. Number of surgeries with major complication (square), number of surgeries with no complications (diamond) and complications rate (%) comparisons between groups of surgeries performed over 9 yr at 2-yr follow up.

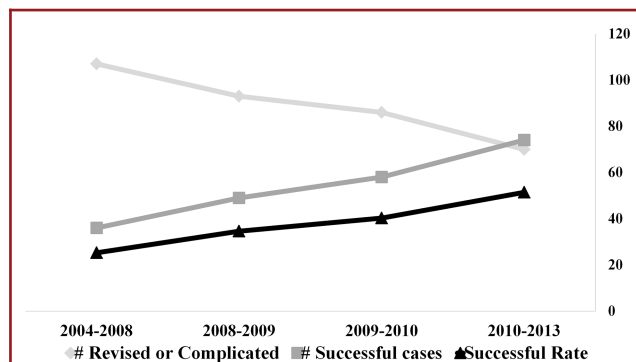


FIGURE 3. Number of successful cases (square), number of complicated or revised cases (diamond) and successful rate (%) comparisons between groups of surgeries performed over 9 yr at 2-yr follow-up.

The number of successful vs revised and/or complicated cases in each group is illustrated in Figure 3. Regression models revealed that increased surgery year was a significant predictor of decreased complication rate (odds ratio [OR]: 0.881 [0.806-0.963], $P = .005$, B Coefficient [-0.127]), decreased revision rate (OR: 0.872 [0.797-0.953], $P = .003$, B Coefficient [-0.137]) and increased

success rate (OR: 1.239 [1.125-1.364], $P < .001$, B Coefficient [0.214]). Younger age was also a significant predictor of increased success rate (OR: 0.984 [0.970-0.999], $P = .037$, B Coefficient [-0.016]).

TABLE 5. Comparisons of Complications Rates for Specific Pathologies Between Groups of Surgeries Performed Over 9 yr

% of complication of:	2004-2008	2008-2009	2009-2010	2010-2013	P value
Excessive blood loss >4 L	27.3%	14.1%	22.9%	16.7%	.023
Bowel/bladder neurological deficit	4.2%	1.4%	6.3%	0.7%	.025
Stroke	0.7%	0.7%	0%	0.7%	.798
Septic shock	0.7%	0%	0%	0.7%	.572
Pulmonary embolism	2.8%	2.8%	0.7%	0.7%	.292
Pneumonia	0.7%	1.4%	2.1%	0%	.339
Motor deficit or paralysis	11.2%	5.6%	11.1%	10.4%	.323
Deep infection	8.4%	7.7%	6.9%	4.2%	.503
Deep vein thrombosis	1.4%	2.8%	3.5%	0.7%	.333
Unplanned return to operating room	18.9%	15.5%	16%	14.6%	.779
Acute respiratory distress syndrome	4.9%	2.1%	1.4%	2.8%	.306

TABLE 6. Comparisons of Surgical Metrics Between Groups of Surgeries Performed Over 9 yr

Group	2004-2008	2008-2009	2009-2010	2010-2013	P value
OR time	438	437	444	428	.785
Blood loss	3037	2423	2857	2685	.077
Intraop complications rate	5.6%	7.7%	6.4%	7.4%	.638

Surgical Metrics

Recent surgeries showed similar operating times, blood losses, and intraoperative complications rates without excessive blood loss >4 L (Table 6).

DISCUSSION

This study shows that outcomes of 3CO surgeries improved over the last decade. Between January 2004 and January 2013, the complication and revision rates were reduced by 18% and 15%, respectively, even though the surgeries were performed on older and more disabled populations in the more recent groups. Intraoperative data analysis demonstrated a 38-min reduction of operating time with similar blood loss and intraoperative complication rates. Intraoperatively, the angle of osteotomy resection increased by 6°, and the data reported a significant shift toward more PSO surgeries in comparison to vertebral column osteotomy. In addition, the study demonstrates a significant increase in the utilization of iliac screws. However, the revision rates in conditions such as PJK and residual sagittal malalignment were comparable over the years. Medical complications, such as stroke, septic shock, pulmonary embolism, pneumonia, acute respiratory distress syndrome, and deep venous thrombosis, reported comparable complication rates over the 9 yr of the study. While the learning curve of 3CO osteotomy technique is expected to demonstrate improvement in the safety of the procedure, the low incidence of medical complications might have contributed to the difficulty with proving statistical significance.

Although numerous reports in the literature demonstrate the effectiveness of surgical treatment, there is an elevated rate of adverse events.^{6,14,15} Revision and complications rates are reported to be as high as 32% and 42%, respectively.^{7,16-21} Maier et al¹⁹ offered a potential system that examines practice variations between sites as a method in improving outcomes. Their study highlighted the potential of exchanging surgical techniques and medical knowledge between hospitals on improving outcomes. Bianco et al⁷ reported similar findings for complication rates. This current study, however, focuses on the importance of evaluating adverse events over time to more accurately assess performance.

There is a wide acceptance of the hypothesis that the quality of care improves with the experience of those providing it.²² Studies on other surgical procedures have shown that surgical volume has a significant impact on reducing adverse event rates.²³⁻²⁶ However, spinal deformity literature has yielded little evidence

that cumulative surgical performance has any benefit towards the reduction of adverse events. The increase in osteotomy resection angles over time reflects the associated rise in comfort and training in applying osteotomies by surgeons; this increase coincides with a decrease in undesirable complications in recent years. Another factor not specifically studied here is the effect of operations executed by 2-surgeon teams, which has been recently shown by Ames et al²⁷ as a factor that lowers complication rates and can potentially drive down operating time.

Possible explanations for this improvement are changes centers have made, such as increasing rod diameter and number, protecting the proximal junction, utilizing antibiotics powder, and preoperative planning for alignment targets. These advances were supported by the extensive research efforts by the group, regular annual internal meetings to exchange knowledge and expand understandings of such challenging procedures, as well as collaboration with other groups and exposure to other perspectives. Furthermore, with the support of the scientific and clinical communities, the recent years have witnessed a greater visibility into the performance and outcomes of deformity surgeries.^{20,28} This provides the opportunity for less experienced surgeons to improve their clinical practice earlier in their careers. Skovrlj et al²⁹ investigated the complication rates among candidates and members of the SRS, and demonstrated that the overall complication rates were similar.²⁹ However, SRS active members had significantly less spinal cord injuries. These results are in contrast with a study on the national level by Farjoodi et al³⁰ which demonstrated that, in lumbar spine surgery, lower complication rates were associated with high hospital and surgeon volume.

In the era of evidence-based medicine,³¹ it is of paramount importance to either raise awareness³² or to provide evidence on reducing adverse events following spinal reconstructive surgeries. The hypothesis of this study was that, for spinal osteotomies, increasing experience has the potential to improve quality of care. Nonetheless, risk should be further lessened and these procedures should prove their cost-effectiveness by maintaining acceptable outcomes over time.³³ In addition, ongoing studies strive to anticipate the risk of adverse events, leading to improvements in patient selection, operative preparation, and risk management.

Limitations

By design, this retrospective study is prone to methodological limitations. Presented in this paper is the aggregate data for 4 consecutive cohorts at multiple centers. There is no subanalysis of individual surgeons which might carry possible differences

in volume, skills and patients' selection. In addition, surgeries included both PSO and VCR cases with different distribution overtime. While this method increased the statistical power of the study, the authors acknowledge the potential variability in fusion rate, neurological risk, and amount of correction between these techniques. Patient-reported outcomes were not investigated over time and longer follow-up is important to examine the durability of surgical outcomes. Moreover, the data were unable to follow-up with patients who decided to move their health care to centers outside the group. Future studies should further analyze reasons behind advancement in surgical performance of 3CO column osteotomies.

CONCLUSION

Data collected over 9 yr of spinal osteotomy utilization revealed that recent surgeries are performed on a more disabled population with better technical ability reflected by increased bone resection angle. These surgeries are performed with similar operating times and with reductions in revisions and complications rates by 15% and 18%, respectively.

Disclosures

Dr Lafage holds a board membership with Nemaris Inc, grants from SRS, NIH, and Depuy, payment for lectures from Medicea, Nemaris Inc, MSD, and Depuy, and stock/stock options with Nemaris Inc. Dr Varghese has Grants from SRS. Dr Gupta is a consultant and has other financial relationships with DePuy Synthes, other financial support with Johnson & Johnson, Pfizer, Pioneer, and Proctor & Gamble, and is a consultant with Medicea. Dr Kim is a consultant for Biomet, K2M and Medtronic, and on the Speaker's Bureau of DePuy Synthes. Dr Ames is a consultant with Medtronic and Stryker Spine, receives other financial support from Biomet and Stryker Spine, has grants/research support from DePuy Synthes, and is on the Speaker's Bureau of Globus Medical. Dr Kebaish has grants/research support from DePuy Synthes, is a consultant with DePuy Synthes and K2M, and receives other financial support from DePuy Synthes, Orthofix, and SpineCraft. Dr Shaffrey is a consultant with Biomet, K2M, Medtronic, NuVasive, and Stryker, and receives other financial support from Biomet, Medtronic, and NnuVasive. Dr Hostin has grants/research support from DePuy Synthes and NuVasive and is a consultant with DePuy Synthes. Dr Obeid is a consultant with Alphatec Spine, DePuy Synthes, and Medtronic, has grants/research support from DePuy Synthes, and other financial support from Alphatec Spine. Dr Burton has grants/research support from, is a consultant for, and receives other financial support from DePuy Synthes. Dr Hart is a consultant for DePuy Synthes, Globus Medical, and Medtronic, is on the Speaker's Bureau of DePuy Synthes, receives grants/research support from Medtronic, and other financial support from DePuy Synthes and Seaspine. Dr Schwab has a board membership with Nemaris Inc, is a consultant for MSD, Medicea, and K2M, has grants from Depuy, MSD, and AO, has received payment for manuscript preparation from MSD, Nuvasive, Biomet, K2M, and Nemaris Inc, has patients with MSD, K2M, and Nemaris Inc, and receives royalties from MSD and K2M. The ISSG receives grants/research support from DePuy Synthes, Innovaxis, Medtronic, and Stryker Spine.

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