Original Article

Navigated versus conventional pediatric spinal deformity surgery: Navigation independently predicts reoperation and infectious complications

ABSTRACT

Context: Literature on treating pediatric spinal deformity with navigation is limited, particularly using large nationally represented cohorts. Further, the comparison of single-institution data to national-level database outcomes is also lacking.

Aim: (1) To compare navigated versus conventional posterior pediatric deformity surgery based on 30-day outcomes and perioperative factors using the National Surgical Quality Improvement Program (NSQIP) database and (2) to compare the outcomes of the NSQIP navigated group to those of fluoroscopy-only and navigated cases from a single-institution.

Settings and Design: Retrospective cohort study.

Subjects and Methods: Pediatric patients who underwent posterior deformity surgery with and without navigation were included. Primary outcomes were 30-day readmission, reoperation, morbidity, and complications. The second part of this study included AIS patients < 18 years old at a single institution between 2015 and 2019. Operative time, length of stay, transfusion rate, and complication rate were compared between single-institution and NSQIP groups.

Statistical Analysis Used: Univariate analyses with independent *t*-test and Chi-square or Fisher's exact test was used. Multivariate analyses through the application of binary logistic regression models.

Results: Part I of the study included 16,950 patients, with navigation utilized in 356 patients (2.1%). In multivariate analysis, navigation predicted reoperation, deep wound infection, and sepsis. After controlling for operative year, navigation no longer predicted reoperation. In Part II of the study, 288 single institution AIS patients were matched to 326 navigation patients from the NSQIP database. Operative time and transfusion rate were significantly higher for the NSQIP group.

Conclusions: On a national scale, navigation predicted increased odds of reoperation and infectious-related events and yielded greater median relative value units (RVUs) per case but had longer operating room (OR) time and fewer RVUs-per-minute. After controlling for operative year, RVUs-per-minute and reoperation rates were similar between groups. The NSQIP navigated surgery group was associated with significantly higher operative time and transfusion rates compared to the single-institution groups.

Keywords: Adolescent idiopathic scoliosis, complications, navigation, pediatric spinal deformity, reoperation

INTRODUCTION

The frequency of spinal deformity surgery has been increasing due to technological advancements.[1-5] The intricate complexities of spinal anatomy, particularly in deformity surgery, have led to the development of new techniques designed to minimize adverse events.[2,3,6-8] Navigation has been developed to maximize pedicle screw placement accuracy and has been of particular benefit in complex spinal

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deformity cases, with the goal of minimizing complications and hardware failure and reducing blood loss.[2,9-11]

While current research has demonstrated positive clinical satisfaction and radiographic accuracy with the use of navigation for treating degenerative disease, literature on treating pediatric deformity with navigation is limited, particularly using large nationally represented cohorts.[11,12] Further, comparison of single-institution data to national-level database outcomes is also limited. Such comparison could provide insight into learning curves and technique-related factors associated with better outcomes.

The purpose of this study was to compare navigated versus conventional posterior pediatric deformity surgery based on 30-day readmission, reoperation, and morbidity and perioperative factors using the NSQIP database and to compare the outcomes of the NSQIP navigated group to those of fluoroscopy-only and navigated cases from a single-institution.

SUBJECTS AND METHODS

Study design and population

This two-part study consists of a retrospective analysis of data from the Pediatric American College of Surgeons National Surgical Quality Improvement Program (NSQIP) database and a comparison to patients from a single institution who were operated on by the senior author. The first part of the project is exempt from Institutional Review Board (IRB) review and informed consent requirement as it utilized a de-identified, publicly available database, and no direct patient involvement occurred. For the second part of the study, IRB approval was obtained at the senior author's home institution (Feinstein Institute for Medical Research at Northwell Health, IRB #21-0165).

Part I

The NSQIP database began in 1994 as an initiative to improve the quality of surgical care in the Veterans Administration and later expanded to all participating hospitals in the United States. At present, there are over 680 participating hospitals with standardized clinical reviewers and routine site audits to ensure the reliable data. The database has frequently been used in the spine literature.[13,14]

Pediatric patients who underwent posterior deformity surgery were identified in the 2012–2018 NSQIP databases using Current Procedural Terminology (CPT) codes 22800-22804. Patients were stratified into groups with and without navigation using CPT code 61873. Patients were excluded if they had preoperative infection, open wound, cerebral hemorrhage, wound class >1, required Cardiopulmonary Resuscitation (CPR), transfusion, or inotropic support prior to surgery, or underwent surgery for revision, lesion, or nonelective or urgent purposes. Patients with missing 30-day outcomes were also excluded. Patients were also excluded if they had anterior fusion, nonelective, or lesion-related CPT codes.

Part II

The second part of this study consisted of an IRB-approved retrospective chart review of AIS patients, <18 years old, at a single institution between 2015 and 2019. Patients were excluded if they had <2 years of follow-up or had undergone previous spine surgery or surgery for a non-idiopathic etiology. The single-institution patients were divided into fluoroscopy (Fluoro) and "technique'n'technology" (TNT) groups and were compared to each other and to the navigated AIS patients from the NSQIP dataset (NAV). All pedicle screws were introduced by senior surgeons through freehand anatomic technique: Screws were placed based on anatomic landmarks, with ball-tipped probes used to palpate the screw tracts. In the Fluoro group, once placed, screw positioning was verified under fluoroscopy before rod placement. Patients operated on between 2015 and 2017 were placed in the Fluoro group. In the TNT group, once screws were placed using the freehand anatomic technique, Airo computed tomography (CT) scan navigation was utilized *in lieu* of fluoroscopy, whereby a reference clamp was attached to one of the spinous processes in the area of the arthrodesis based on surgeon preference. After clamp positioning, a radiology technician executed the CT scans with the mobile scanner and images were automatically transferred to the workstation. Screw positioning was once again verified before rod placement with no additional image guidance or navigation thereafter. Patients operated on between 2018 and 2019 were placed in the TNT group.

In 2018, the Airo CT scanner (Brainlab AG) was introduced at our institution for spine-related surgeries. The scanner consists of a CT table and image-guidance system that allows for real-time CT navigation. Surgeons conducted Airo procedures using the "TNT" approach.

Outcomes and statistical analyses

Part I

Primary outcomes were 30-day readmission, reoperation, overall morbidity, and specific complications. Readmission includes any inpatient stay to the same or another hospital related to the surgical procedure. Reoperation includes all major surgical procedures requiring return to the operating room for intervention of any kind. Morbidity includes infectious, pulmonary, cardiac, renal, neurological, hematologic, and thromboembolic complications reported in

the ACS-NSQIP dataset. In addition, reasons for reoperation were obtained from NSQIP-provided data and were compared between navigated and conventional groups.

Primary outcomes, as well as specific complications, were compared between navigated and conventional groups. Predictors of primary outcomes were analyzed for among the entire cohort. The variables evaluated as potential predictors included patient demographic, comorbidity, laboratory values, and procedural factors [Table 1]. Procedural factors specifically included operative time, length of hospital stay, and relative value units (RVUs) per case and per minute of operative time. The specific complications are provided in Table 2.

Demographic, comorbidity, laboratory, and procedural factors were individually analyzed for the baseline differences between navigated and conventional patients using Student's *t*-test for continuous and Chi-squared or Fisher's exact test for the categorical variables. The above factors were also individually analyzed for association with primary outcomes using univariate logistic regression. Variables significant in the univariate analyses ($P < 0.05$) were then evaluated for significance ($P < 0.05$) as independent predictors and

Table 1: Baseline differences in patient demographic, comorbidity, laboratory, and procedural factors, and primary outcomes by presence or absence of computer-assisted surgery

	With CAS (*n*=356)	Without CAS (*n*=16,594)	*P*	Cases available (*n*=16,950)
Demographics, *n* (%)				
Age (years), mean (SD)	13.8 (2.8)	13.8 (2.7)	0.866	16,950
African—American race	39 (11.8)	2696 (18.2)	**0.003**	15,120
Hispanic ethnicity	31 (8.8)	1625 (10.6)	0.292	15,712
Female gender	245 (68.8)	11,575 (69.8)	0.704	16,950
Comorbidities, *n* (%)				
Obese	56 (16.3)	2416 (15.3)	0.619	16,132
Pulmonary comorbidity	69 (19.4)	2795 (16.8)	0.206	16,950
Cardiac comorbidity	26 (7.3)	1453 (8.8)	0.337	16,950
Esophageal/GI disease	33 (9.3)	1692 (10.2)	0.567	16,950
Developmental delay	79 (22.2)	3505 (21.1)	0.625	16,950
Seizure disorder	31 (8.7)	1580 (9.5)	0.605	16,950
Cerebral palsy	30 (8.4)	1571 (9.5)	0.507	16,950
Structural CNS abnormality	49 (13.8)	2202 (13.3)	0.786	16,950
Neuromuscular disorder	72 (20.2)	3668 (22.1)	0.397	16,950
Preoperative steroid use	3 (0.8)	179 (1.1)	1.000[#]	16,950
Nutritional support	26 (7.3)	1274 (7.7)	0.793	16,950
Hematologic disorder	10 (2.8)	309 (1.9)	0.193	16,950
Congenital malformation	86 (24.2)	5077 (30.6)	**0.009**	16,950
Childhood malignancy	5 (1.4)	166 (1.0)	0.450	16,950
ASA-class ≥3	108 (30.4)	5055 (30.5)	0.977	16,932
Lab values, mean (SD)				
White cell count	7.0 (2.3)	6.9 (2.3)	0.758	14,089
Hematocrit	40.5 (3.6)	39.9 (3.4)	**0.005**	14,481
INR	1.1 (0.1)	1.1 (0.1)	0.672	9657
Procedural factors, median (IQR)				
Operative time (min)	331 (248–435)	269 (205–344)	**<0.001**	16,940
LOS (days)	4 (3–5)	4 (3–5)	0.304	16,909
Total RVUs	57.7 (49.3–77.4)	53.9 (45.6–74.4)	**<0.001**	16,950
RVUs per minute	0.18 (0.13–0.26)	0.21 (0.15–0.28)	**<0.001**	16,940
Total RVUs subtracting NAV	50.9 (42.5–70.6)	53.9 (45.6–74.4)	0.238	16,948
Unadjusted primary outcomes, *n* (%)				
Readmission	21 (5.9)	647 (3.9)	0.055	16,950
Reoperation	22 (6.2)	513 (3.1)	**0.001**	16,950
Mean days to reoperation	16.3 (7.4)	14.1 (8.4)	0.229	
Morbidity	269 (75.6)	11,199 (67.5)	**0.001**	16,950

[#]Fisher's exact test. Bold values indicate significance ($P<0.05$). Pulmonary comorbidities include ventilator dependence, asthma, chronic lung disease, chronic oxygen support, tracheostomy, or structural pulmonary or airway abnormalities. Cardiac comorbidities include previous cardiac surgery and cardiac risk factors. IQR - Interquartile ranges; ASA - American Society of Anesthesiologists; RVUs - Relative value units; CAS – Computer-assisted surgery; GI - Gastric/intestinal; CNS - Central nervous system; SD - Standard deviation; LOS - Length of stay; INR - International normalized ratio; NAV - Navigated patients from the NSQIP dataset

Table 2: Univariate and multivariate analysis of specific complication by presence or absence of computer assisted surgery

Specific complication	With CAS, *n* (%)	Without CAS, *n* (%)	Univariate *P*	OR (95% CI)	Multivariate *P*
Any wound complication	21 (5.9)	677 (4.1)	0.087		
Superficial site infection	4 (1.1)	124 (0.7)	0.417#		
Deep wound infection	9 (2.5)	134 (0.8)	**0.003#**	2.926 (1.305–6.563)	**0.009**
Organ space infection	1 (0.3)	39 (0.2)	0.573#		
Wound dehiscence	10 (2.8)	499 (3.0)	0.828		
Pulmonary complication	4 (1.1)	269 (1.6)	0.461		
Pneumonia	3 (0.8)	178 (1.1)	1.000#		
Unplanned intubation	1 (0.3)	134 (0.8)	0.536#		
Pulmonary embolism	0	4 (0.02)	1.000#		
Acute kidney injury	1 (0.3)	17 (0.1)	0.318#		
Urinary tract infection	3 (0.8)	122 (0.7)	0.748#		
Stroke/CVA	0	5 (0.03)	1.000#		
Seizure	0	10 (0.1)	1.000#		
Nerve injury	0	58 (0.3)	0.636#		
Cardiac arrest requiring CPR	1 (0.3)	23 (0.1)	0.399#		
Transfusion	262 (73.6)	10,938 (65.9)	**0.002**	0.977 (0.731–1.306)	0.874
Blood stream infection	0	5 (0.03)	1.000#		
Sepsis/septic shock	8 (2.2)	124 (0.7)	**0.007#**	3.192 (1.324–7.693)	**0.010**

#Fisher's exact test. Bold values indicate significance ($P<0.05$). CPR - Cardiopulmonary resuscitation; CVA - Cerebrovascular accident; CAS – Computer-assisted surgery; OR - Odds ratio; CI - Confidence interval

control variables in a series of multivariate logistic regression analyses of primary outcomes.

In addition, *post hoc* analyses controlling for operative year were performed for primary outcomes using multivariate logistic regression and for operative time, RVUs per case, and RVUs per minute, with multivariate analysis performed using quantile (median) regression.

Part II

The fluoro, TNT, and NAV were compared on the basis of operative time, length of stay, transfusion rate, and complication rate. In addition, the Fluoro and TNT groups were compared to each other on the basis of total radiation time and dose, preoperative and postoperative Cobb angle, correction of Cobb, preoperative and postoperative kyphosis, operative time, estimated blood loss, and length of stay.

Shapiro–Wilk test was used to confirm the distribution normality. Data were presented as medians and interquartile (25^{th}–75^{th} percentile) ranges in the continuous variables (Cobb, kyphosis, etc.) and frequency and percentages for the categorical variables (complication, transfusion, etc.). The continuous data were analyzed using Kruskal–Wallis or Wilcoxon rank-sum test and categorical data were analyzed using the Chi-square and Fisher's exact test. Statistical analyses were performed by an independent biostatistician with SAS version 9.3 (SAS Institute, Cary NC). All *P* values were two tailed, with $P < 0.05$ considered significant.

RESULTS

Part I

There were 16,950 patients included, with navigation utilized in 356 patients (2.1%). Significant baseline differences were only observed in only 3 of 22 demographic and comorbidity variables [Table 1]. Patients in the navigated group were significantly less likely to be African – American (11.8 vs. 18.2%, $P = 0.003$) or to have a congenital malformation (24.2 vs. 30.6%, $P = 0.009$), and had greater mean preoperative hematocrit (40.5 vs. 39.9, $P = 0.005$), compared to those in the conventional group, respectively.

Navigation was associated with longer median operative times (331 vs. 269 min) and total median RVUs per case (57.7 vs. 53.9), but fewer median RVUs per minute (0.18 vs. 0.21) compared to conventional surgery, respectively ($P < 0.001$). There was no difference in total median RVUs per case when subtracting the value of RVUs for navigation, 6.81, from the navigated cases (50.9 vs. 53.9, $P = 0.238$). The median length of stay was similar between groups (4 vs. 4 days, $P = 0.304$).

In univariate analysis [Tables 1 and 2], navigation was associated with greater rates of reoperation (6.2 vs. 3.1%, $P = 0.001$) and overall morbidity (75.6 vs. 67.5%, $P = 0.001$). Navigation was also associated with the greater rates of wound infection (2.5 vs. 0.8%, $P = 0.003$), transfusion (73.6 vs. 65.9%, $P = 0.002$), and sepsis/septic shock (2.2 vs. 0.7%, $P = 0.007$). Readmission rates (5.9 vs. 3.9%, $P = 0.055$) and mean duration from surgery to reoperation (16.3 vs. 14.1 days, $P = 0.229$) were similar between groups.

After adjusting for significant baseline differences and predictor variables in multivariate analysis [Tables 2-5], navigation predicted reoperation (odds ratio [OR] = 1.920, $P = 0.019$, 95% confidence interval [CI^{95}]: 1.115–3.306), deep wound infection (OR = 2.926, $P = 0.009$, CI^{95}: 1.305–6.563), and sepsis/septic shock (OR = 3.192, $P = 0.010$, CI^{95}: 1.324–7.693), but no longer predicted overall morbidity ($P = 0.955$) or transfusion ($P = 0.874$). Reoperation most commonly occurred due to site-related complications followed by hardware-related events [Figure 1].

Post hoc multivariate logistic regression analysis demonstrated that, after controlling for operative year, navigation no longer predicted reoperation (OR = 1.005, $P = 0.058$, CI^{95}: 1.068–1.230). Multivariate quantile regression revealed that, while navigation predicted a 44-min increase ($P < 0.001$, CI^{95}: 29–60 min) in median operative time, it also predicted an 8.2 unit increase in median RVUs per case ($P < 0.001$, CI^{95}: 5.7–10.7 RVUs), yielding a statistically insignificant 0.008 unit decrease in median RVUs per minute ($P = 0.293$, CI^{95}: −0.022–0.007) compared to conventional surgery.

Medical comorbidities predictive of poorer 30-day outcomes are provided in Tables 3-5. Of note, female gender was protective of readmission (OR = 0.787, $P = 0.021$), while obesity (OR = 2.010, $P < 0.001$), pulmonary comorbidity (OR = 1.463, $P = 0.001$), and developmental delay (OR = 1.637, $P < 0.001$) predicted readmission. Obesity (OR = 2.472, $P < 0.001$), developmental delay (OR = 1.926, $P < 0.001$), operative time (OR = 1.002, $P < 0.001$), length of stay (OR = 1.040, $P < 0.001$), and total RVUs (OR = 1.005, $P = 0.010$) predicted reoperation.

Table 3: Univariate and multivariate analysis of predictors of readmission

	Univariate			Multivariate	
	Readmitted (*n*=668), *n* (%)	**Not readmitted (*n*=16,282), *n* (%)**	***P***	**OR (95% CI)**	***P***
Demographics, *n* (%)					
Age (years), mean (SD)	13.4 (3.2)	13.8 (2.7)	**0.001**	0.998 (0.963–1.034)	0.902
African–American race	109 (18.0)	2626 (18.1)	0.947	1.144 (0.895–1.463)	0.281
Hispanic ethnicity	76 (12.0)	1580 (10.5)	0.209		
Female gender	377 (56.4)	11,443 (70.3)	**<0.001**	0.787 (0.642–0.964)	**0.021**
Comorbidities, *n* (%)					
Obese	139 (22.4)	2333 (15.0)	**<0.001**	2.010 (1.588–2.544)	**<0.001**
Pulmonary comorbidity	234 (35.0)	2630 (16.2)	**<0.001**	1.463 (1.157–1.850)	**0.001**
Cardiac comorbidity	91 (13.6)	1388 (8.5)	**<0.001**	1.006 (0.750–1.349)	0.970
Esophageal/GI disease	186 (27.8)	1539 (9.5)	**<0.001**	1.417 (1.083–1.854)	**0.011**
Developmental delay	329 (49.3)	3255 (20.0)	**<0.001**	1.637 (1.247–2.149)	**<0.001**
Seizure disorder	176 (26.3)	1435 (8.8)	**<0.001**	1.381 (1.011–1.888)	**0.043**
Cerebral palsy	170 (25.4)	1431 (8.8)	**<0.001**	0.949 (0.688–1.309)	0.749
Structural CNS abnormality	181 (27.1)	2070 (12.7)	**<0.001**	1.236 (0.969–1.576)	0.088
Neuromuscular disorder	307 (46.0)	3433 (21.1)	**<0.001**	1.391 (1.090–1.776)	**0.008**
Preoperative steroid use	16 (2.4)	166 (1.0)	**0.001**	1.166 (0.619–2.197)	0.635
Nutritional support	143 (21.4)	1157 (7.1)	**<0.001**	0.986 (0.711–1.367)	0.932
Hematologic disorder	23 (3.4)	296 (1.8)	**0.002**	0.713 (0.386–1.315)	0.278
Congenital malformation	330 (49.4)	4833 (29.7)	**<0.001**	1.083 (0.871–1.348)	0.474
Childhood malignancy	11 (1.6)	1.0)	0.092		
ASA-class ≥3	395 (59.1)	4768 (29.3)	**<0.001**	1.513 (1.161–1.970)	**0.002**
Lab values, mean (SD)					
White cell count	7.3 (2.5)	6.9 (2.3)	**<0.001**	1.043 (1.007–1.081)	**0.019**
Hematocrit	40.3 (4.2)	39.9 (3.8)	**0.009**	0.996 (0.971–1.021)	0.723
INR	1.1 (0.1)	1.1 (0.1)	0.433		
Procedural factors					
Computer assistance, *n* (%)					
With CAS	21 (5.9[a])	335	0.055	1.388 (0.807–2.388)	0.236
Without CAS	647 (3.9[b])	15,947			
Operative time	319 (112)	284 (109)	**<0.001**	1.001 (1.000–1.002)	**0.018**
LOS	6.4 (6.2)	5.3 (6.8)	**<0.001**	0.992 (0.977–1.007)	0.303
Total RVUs	66.1 (28.3)	60.1 (26.5)	**0.017**	1.004 (1.001–1.008)	**0.014**

[a]Percent of patients with CAS who were readmitted; [b]Percent of patients without CAS who were readmitted; Bold values indicate significance ($P<0.05$). Pulmonary comorbidities include ventilator dependence, asthma, chronic lung disease, chronic oxygen support, tracheostomy, or structural pulmonary or airway abnormalities. Cardiac comorbidities include previous cardiac surgery and cardiac risk factors. ASA - American Society of Anesthesiologists; RVUs - Relative value units; CAS – Computer-assisted surgery; GI - Gastric/intestinal; CNS - Central nervous system; SD - Standard deviation; OR - Odds ratio; CI - Confidence interval; LOS - Length of stay; INR - International normalized ratio

Finally, age (OR = 1.051, $P < 0.001$), African − American race (OR = 1.193, $P = 0.002$), Hispanic ethnicity (OR = 1.401, $P < 0.001$), developmental delay (OR = 1.291, $P < 0.001$), seizure disorder (OR = 1.384, $P = 0.004$), neuromuscular disorder (OR = 1.310, $P < 0.001$), operative time (OR = 1.005, $P < 0.001$), and total RVUs (OR = 1.009, $P < 0.001$) predicted morbidity.

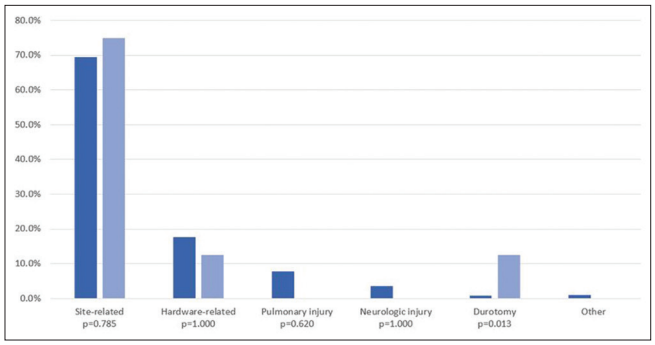

Figure 1: Reasons for reoperations among navigated and conventional pediatric spinal deformity fusion patients

Part II

There were 288 AIS patients who underwent posterior spinal fusion at our institution (136 Fluoro, 152 TNT), which were matched and compared to 326 NAV patients from the NSQIP dataset. NAV patients were significantly younger than both Fluoro and TNT patients [Table 6]. 30-day complication rates were similar between all three groups. In the Fluoro group, four patients returned to the OR for superficial site infections, which were all resolved with I&D; one patient required increased pain management; and one patient had desaturation events requiring

Table 4: Univariate and multivariate analysis of predictors of reoperation

	Univariate			Multivariate	
	Reoperation (n=535)	No reoperation (n=16,415)	P	OR (95% CI)	P
Demographics, *n* (%)					
Age (years), mean (SD)	13.4 (3.1)	13.8 (2.7)	**0.002**	1.012 (0.970–1.056)	0.586
African−American race	88 (18.3)	2647 (18.1)	0.922	1.083 (0.813–1.444)	0.585
Hispanic ethnicity	53 (10.6)	1603 (10.5)	0.989		
Female gender	325 (60.7)	11,495 (70.0)	**<0.001**	0.947 (0.745–1.203)	0.947
Comorbidities, *n* (%)					
Obese	131 (26.7)	2341 (15.0)	**<0.001**	2.472 (1.901–3.214)	**<0.001**
Pulmonary comorbidity	175 (32.7)	2689 (16.4)	**<0.001**	1.216 (0.922–1.604)	0.166
Cardiac comorbidity	77 (14.4)	1402 (8.5)	**<0.001**	1.067 (0.764–1.490)	0.704
Esophageal/GI disease	119 (22.2)	1606 (9.8)	**<0.001**	0.847 (0.608–1.179)	0.326
Developmental delay	260 (48.6)	3324 (20.2)	**<0.001**	1.926 (1.414–2.622)	**<0.001**
Seizure disorder	132 (24.7)	1479 (9.0)	**<0.001**	1.230 (0.861–1.758)	0.255
Cerebral palsy	125 (23.4)	1476 (9.0)	**<0.001**	1.064 (0.739–1.534)	0.738
Structural CNS abnormality	138 (25.8)	2180 (12.9)	**<0.001**	1.171 (0.883–1.554)	0.273
Neuromuscular disorder	244 (45.6)	3496 (21.3)	**<0.001**	1.533 (1.162–2.021)	**0.002**
Preoperative steroid use	13 (2.4)	169 (1.0)	**0.002**	1.056 (0.491–2.271)	0.889
Nutritional support	106 (19.8)	1194 (7.3)	**<0.001**	0.867 (0.588–1.277)	0.470
Hematologic disorder	23 (4.3)	296 (1.8)	**<0.001**	0.913 (0.487–1.711)	0.777
Congenital malformation	272 (50.8)	4,891 (29.8)	**<0.001**	1.091 (0.846–1.406)	0.502
Childhood malignancy	4 (0.7)	167 (1.0)	0.539		
ASA-class ≥3	321 (60.0)	4842 (29.5)	**<0.001**	1.519 (1.123–2.055)	**0.007**
Lab values, mean (SD)					
White cell count	7.4 (2.7)	6.9 (2.3)	**<0.001**	1.024 (0.981–1.069)	0.284
Hematocrit	39.8 (4.3)	39.9 (3.8)	0.551	0.982 (0.954–1.010)	0.195
INR	1.1 (0.1)	1.1 (0.1)	0.882		
Procedural factors					
Computer assistance, *n* (%)					
With CAS	22 (6.2[a])	334	**0.001**	1.920 (1.115–3.306)	**0.019**
Without CAS	513 (3.1[b])	16,081			
Operative time	333 (122)	284 (108)	**<0.001**	1.002 (1.001–1.003)	**<0.001**
LOS	10.7 (12.7)	5.2 (5.3)	**<0.001**	1.040 (1.031–1.050)	**<0.001**
Total RVUs	67.8 (29.4)	60.0 (26.5)	**<0.001**	1.005 (1.001–1.003)	**0.010**

[a]Percent of patients with CAS who returned to the operating room; [b]Percent of patients without CAS who returned to the operating room; #Fisher's exact test. Bold values indicate significance ($P<0.05$). Pulmonary comorbidities include ventilator dependence, asthma, chronic lung disease, chronic oxygen support, tracheostomy, or structural pulmonary or airway abnormalities. Cardiac comorbidities include previous cardiac surgery and cardiac risk factors. ASA - American Society of Anesthesiologists; RVUs - Relative value unit; CAS - Computer-assisted surgery; GI - Gastric/intestinal; CNS - Central nervous system; SD - Standard deviation; OR - Odds ratio; CI - Confidence interval; LOS - Length of stay; INR - International normalized ratio

Table 5: Univariate and multivariate analysis of predictors of morbidity

	Univariate			Multivariate	
	Morbidity (*n*=5482)	**No morbidity (*n*=16,282)**	***P***	**OR (95% CI)**	***P***
Demographics, *n* (%)					
Age (years), mean (SD)	13.9 (2.5)	13.5 (3.1)	**<0.001**	1.051 (1.034–1.069)	**<0.001**
African—American race	1966 (19.1)	769 (16.0)	**<0.001**	1.193 (1.068–1.333)	**0.002**
Hispanic ethnicity	1180 (11.0)	476 (9.6)	**0.008**	1.401 (1.206–1.628)	**<0.001**
Female gender	7826 (68.2)	3994 (72.9)	**<0.001**	0.959 (0.870–1.058)	0.403
Comorbidities, *n* (%)					
Obese	1638 (15.1)	834 (15.8)	0.264		
Pulmonary comorbidity	2132 (18.6)	732 (13.4)	**<0.001**	1.032 (0.906–1.177)	0.634
Cardiac comorbidity	1066 (9.3)	413 (7.5)	**<0.001**	1.113 (0.950–1.305)	0.184
Esophageal/GI disease	1366 (11.9)	359 (6.5)	**<0.001**	1.247 (1.045–1.487)	**0.014**
Developmental delay	2794 (24.4)	790 (14.4)	**<0.001**	1.291 (1.113–1.498)	**0.001**
Seizure disorder	1343 (11.7)	268 (4.9)	**<0.001**	1.384 (1.111–1.723)	**0.004**
Cerebral palsy	1338 (11.7)	263 (4.8)	**<0.001**	1.078 (0.859–1.353)	0.519
Structural CNS abnormality	1621 (14.1)	630 (11.5)	**<0.001**	0.798 (0.695–0.917)	**0.001**
Neuromuscular disorder	2894 (25.2)	846 (15.4)	**<0.001**	1.310 (1.150–1.492)	**<0.001**
Preoperative steroid use	141 (1.2)	41 (0.7)	**0.004**	1.294 (0.829–2.020)	0.256
Nutritional support	1088 (9.5)	212 (3.9)	**<0.001**	1.218 (0.958–1.548)	0.107
Hematologic disorder	249 (2.2)	70 (1.3)	**<0.001**	1.233 (0.885–1.718)	0.216
Congenital malformation	3610 (31.5)	1553 (28.3)	**<0.001**	0.863 (0.779–0.956)	**0.005**
Childhood malignancy	100 (0.9)	71 (1.3)	**0.010**	0.579 (0.392–0.855)	**0.006**
ASA-class ≥3	3847 (33.6)	1316 (24.0)	**<0.001**	0.904 (0.800–1.022)	0.106
Lab values, mean (SD)					
White cell count	6.9 (2.4)	6.9 (2.2)	0.423	0.993 (0.975–1.011)	0.442
Hematocrit	39.9 (4.4)	39.9 (4.4)	0.987	0.979 (0.968–0.991)	**0.001**
INR	1.1 (0.1)	1.1 (0.1)	0.228		
Procedural factors					
Computer assistance					
With CAS	269 (75.6[a])	87	**0.001**	0.992 (0.738–1.333)	0.955
Without CAS	11,199 (67.5[b])	15,947			
Operative time	304 (111)	247 (94)	**<0.001**	1.005 (1.005–1.006)	**<0.001**
LOS	5.6 (5.8)	4.9 (5.7)	**<0.001**	0.999 (0.991–1.007)	0.776
Total RVUs	62.9 (27.4)	54.7 (24.0)	**<0.001**	1.009 (1.007–1.011)	**<0.001**

[a]Percent of patients with CAS who experienced morbidity; [b]Percent of patients without CAS who experienced morbidity; [#]Fisher's exact test. Bold values indicate significance ($P<0.05$). Pulmonary comorbidities include ventilator dependence, asthma, chronic lung disease, chronic oxygen support, tracheostomy, or structural pulmonary or airway abnormalities. Cardiac comorbidities include previous cardiac surgery and cardiac risk factors. ASA - American Society of Anesthesiologists; RVUs - Relative value units; CAS - Computer assisted surgery; GI - Gastric/intestinal; CNS - Central nervous system; SD - Standard deviation; INR - International normalized ratio; OR - Odds ratio; CI - Confidence interval; LOS - Length of stay

Table 6: Comparison of clinical variables between navigated patients from the NSQIP dataset, fluoroscopy group, and "technique'n'technology" group utilizing the Airo CT navigation technology groups

	NAV (*n*=326)	**Fluoro (*n*=136)**	**TNT (*n*=152)**	***P*[a]**	***P*[b]**	***P*[3]**	***P*[d]**
Age (years)	13.8 (11.1–16.5)	14.7 (13.3–15.9)	14.8 (13.4–16.3)	**<0.001**	**0.010**	**<0.001**	0.450
Operative time (min)	323 (240–434)	304 (259–345)	247 (219–288)	**<0.001**	**0.050**	**<0.001**	**<0.001**
LOS (days)	4 (3–5)	4 (3–5)	3 (2–4)	**<0.001**	0.190	**<0.001**	**<0.001**
Transfusion, *n* (%)	236 (72.4)	30 (22.2)	41 (27.2)	**<0.001**	**<0.001**	**<0.001**	0.335
Complications, *n* (%)	22 (6.8)	7 (5.2)	4 (2.6)	0.180	0.67	0.070	0.558

[a]*P*-value for overall group difference; [b]*P*-value for Fluoro to NAV; [3]*P*-value for TNT to NAV; [d]*P*-value for Fluoro to TNT. Data are presented as median and IQRs or counts and percentages when applicable. Bold values indicate significance ($P<0.05$). Fluoro - Fluoroscopy group; TNT - "Technique'n'technology" group utilizing the Airo CT navigation technology; NAV - Navigated patients from the NSQIP dataset; LOS - Length of stay; IQRs: Interquartile ranges

BiPAP. One patient also developed a DVT, but this occurred after 30 days. In the TNT group, two patients developed superior mesenteric artery syndrome, which resolved through gastric decompression; one patient developed hypotensive shock; and one patient developed wound dehiscence.

Median operative time was 323 min for NAV, which was significantly higher than 304 min for Fluoro and 247 min for TNT. Transfusion rates were also significantly higher for the NSQIP NAV group (72.4%) than the Fluoro (22.2%) and TNT (27.2%) groups but were statistically equivalent between

Table 7: Comparison of radiographic and perioperative outcomes between fluoroscopy group and "technique'n' technology" group utilizing the Airo CT navigation technology patients

	Fluoro (*n*=136)	TNT (*n*=152)	*P*
Female, *n* (%)	105 (77.2)	109 (71.7)	0.290
Total radiation dose (mGy)	2.9 (1.9–4.3)	4.2 (1.6–12.9)	**0.040**
Total radiation time (s)	23.0 (15.4–33.0)	17.0 (9.4–22.6)	**0.001**
Preoperative major curve (°)	56.0 (50.0–63.5)	58.0 (54.3–63.9)	0.180
Postoperative major curve (°)	17.0 (12.2–22.9)	18.1 (12.7–24.8)	0.610
Cobb correction (%)	69.7 (59.9–78.7)	69.2 (59.4–80.1)	0.620
Preoperative kyphosis (°)	25.5 (17.0–36.2)	26.5 (15.6–37.5)	0.800
Postoperative kyphosis (°)	24.6 (18.0–31.0)	27.9 (18.1–37.6)	**0.001**
EBL (mL)	600 (400–700)	450 (300–700)	**<0.001**

Data are presented as median and IQRs or counts and percentages when applicable. Bold values indicate significance ($P<0.05$). Fluoro - Fluoroscopy group; TNT - "Technique'n' technology" group utilizing the Airo CT navigation technology; IQRs - Interquartile ranges; EBL - Estimate blood loss

the TNT and Fluoro groups. Median LOS for NAV was greater than that for TNT (4 vs. 3 days, $P < 0.001$).

Analysis of the fluoro versus TNT groups revealed similar pre- and post-operative Cobb angles with similar degrees of Cobb correction [Table 7]. The TNT group had greater postoperative kyphosis than the Fluoro group (27.9 vs. 24.6°, $P < 0.001$). The TNT group had less radiation time but had a greater radiation dose overall. Both groups had a median 13 levels fused ($P = 0.390$).

DISCUSSION

Improvements in imaging technology and computer-assisted surgery have allowed spine surgeons to operate on increasingly complex deformity cases with greater accuracy.[15-18] However, short-term outcomes evaluating navigated pediatric deformity surgery remain poorly studied. This is the first large-scale database study to evaluate navigation as a predictor of outcomes in posterior deformity surgery in pediatric patients and to compare the nationally represented navigated cohorts' outcomes to those of fluoroscopy-only and navigated cases performed at a single institution.

In the present study, after adjusting for patient-related and procedural factors, navigation in posterior fusion for pediatric spinal deformity predicted a 92% increase in odds of reoperation as well as a 2.9-times and 3.2-times increase in odds of deep wound infection and sepsis/septic shock, respectively. However, after controlling for operative year in a separate analysis, navigation no longer predicted reoperation, but remained associated with deep wound infection and sepsis-related events. Site-related events were the most common reason for reoperation. While navigation was associated with greater rates of morbidity and transfusion in univariate analysis, adjusted analysis demonstrated similar odds of morbidity and transfusion following navigation.

Compared to our single-institution data utilizing the TNT approach to navigated pedicle screw placement, whereby screws are initially placed under freehand anatomic technique followed by CT-based navigation, the NSQIP NAV group had statistically similar complication rates, but significantly greater operative times and transfusion rates. Notably, the Fluoro and TNT groups both had similar transfusion rates compared to each other, but significantly lower transfusion rates compared to the NAV group. Other studies have found similar levels of blood loss between navigated and nonnavigated surgery.[16] Our findings suggest that, while navigation may be associated with an increased risk of infectious-related events on a national scale, factors on an individual level, such as learning curve, sterile technique, minimized number of CT spins, and operative efficiency and reduced operative time, can have a profound impact on outcomes.[19,20] The factors such as increased operating room personnel, intraoperative O-arm spins and frequent relocations into sub-sterile rooms, and increased setup time may ultimately pose an increased risk of accidental contamination and associated infectious-related events.

Further, while learning curve cannot be evaluated directly in the present study, the finding that reoperation no longer statistically differed between navigated and conventional groups after controlling for operative year suggests that improvements in navigated technology during study period and increased surgeon experience can maximize the benefits of navigation. In a learning curve study of navigated vertebral body tethering, Mathew *et al*. demonstrated a steep learning curve over a 5-year period whereby operative time, hospital stay, and blood loss decreased and suggested that evolving technology may play a notable role.[19]

Prolonged operative time has been associated with navigation in prior deformity studies.[15,21] In addition, a large meta-analysis found that operative time was about 30-min longer on average in navigated versus nonnavigated surgery.[16] In the present study, multivariate quantile regression demonstrated that navigation independently predicted a 44-min increase in median operative time. Interestingly, in the treatment of single-level degenerative disease, navigation and nonnavigated cases have been found to have similar operative times, suggesting that case complexity likely plays an important role.[22] Compared to the single-surgeon Fluoro and TNT patients, NAV was associated with significantly higher OR time.

Moreover, we found that navigation predicted an 8.2-point increase in median RVUs per case. Unadjusted analysis demonstrated that navigation was associated with fewer RVUs per minute compared to conventional surgery, suggesting that there is a significant mismatch between efficiency and reimbursement. However, when taking into account operative year as well as significant patient-related variables, navigation was no longer associated with RVUs per minute in multivariate analysis. This is the first study to compare RVUs per case and per minute between navigated and nonnavigated surgery.

Comparison between the Fluoro to the TNT groups revealed that the TNT group still had a higher overall radiation dose despite having a lower radiation time. Radiation exposure is of particularly importance in children. Meta-analyses have demonstrated higher radiation dose in navigated surgery.[16] In the pediatric cervical spine literature, nonnavigated O-arm technique has been demonstrated to be effective in evaluating screw malposition without subjecting patients to radiation doses as high as those seen in navigation.[23] Interestingly, the Fluoro and TNT groups both had similar postoperative Cobb angles and degrees of Cobb correction, suggesting that both techniques allow for adequate coronal correction.

An important limitation of this study is the lack of granularity in data inherent to the utilization of a national surgical database, with an inability of the dataset to capture individual surgeon experience.[24-26] It is possible that newer, less experienced surgeons, are more frequently utilizing navigated technologies, which could skew outcomes more favorably toward conventional surgery. Other surgeon- and patient-related factors may influence operative time, blood loss, and infection with and without the use of navigation. Nevertheless, the current study provides interesting data regarding the use of navigation in pediatric deformity surgery on the national scale, which is currently lacking in the literature. The NSQIP dataset also does not provide details regarding the technique in which navigation is being utilized or the number of CT spins. In addition, the dataset does not provide specific information about pedicle screw placement (e.g., cortical vs. traditional screws). Although navigated versus conventional pedicle screw accuracy is a well-studied topic, our study did not evaluate for screw accuracy, which would have provided additional discussion points.

CONCLUSIONS

On a national scale, navigation predicted an increased odds of reoperation and infectious-related events and yielded greater median RVUs per case but had longer OR time and fewer RVUs-per-minute. However, after controlling for operative year, RVUs-per-minute and reoperation rates were similar between groups. The NSQIP navigated surgery group was associated with significantly higher median operative time and transfusion rates compared to the single-institution fluoroscopy-only and freehand followed by navigation, or "TNT," groups. Complication rates were similar between all three groups. These findings suggest that navigated technology could be utilized more efficiently on a national level and that learning curve, surgeon experience and technique, and improvements in technology can maximize the benefits of navigation. In addition, specific comorbidities and demographic factors, such as African – American race and Hispanic ethnicity, predicted poorer outcomes. The identification of such predictors can allow surgeons to identify and potentially target interventions for patients who are at risk.

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Conflicts of interest

There are no conflicts of interest.

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