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Original Article

Comparison of surgical efficacy between O-arm combined with CT 3D real-time navigation system and Tinavi robot-assisted treatment of adolescent congenital scoliosis

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Abstract: Objective: To compare the orthopedic function and clinical efficacy between the orthopedic surgery guided by the Stealth Station 8 Navigation System and the Tinavi robot-assisted orthopedic surgery for the treatment of congenital scoliosis. Methods: A retrospective analysis was performed on the patients who underwent surgical treatment for congenital scoliosis between May 2021 and October 2021. Patients were divided into the navigation group or the robotic group according to the adjunct system used. Postoperative computed tomography (CT) and digital radiography (DR) scans were conducted to assess the orthopedic outcomes. Specifically, the pedicle screw placement accuracy was measured, and the accuracy rate was calculated based on the parameters of the Scoliosis Research Society (SRS), sagittal vertical axis (SVA), distance between the C7 plumb line and the central sacral vertical line (C7PL-CSVL), lumbar lordosis (LL), and spine correction rate. Clinical data of both groups were recorded. Results: A total of 60 patients, including 20 cases in the navigation group and 40 cases in the Tinavi group, were selected for this study. All patients were followed up for a mean of 12.1 months. We found that the spine correction rate, C7PL-CSVL, and SVA were better in the navigation group than in the robot group, while there was no significant difference in the pedicle screw placement accuracy between these two groups (P=0.806). However, the rate of small joint protrusion was significantly higher in the navigation group (P=0.000), and the screws were also closer to the anterior cortex in the navigation group (P=0.020). In contrast, the number of scans and intraoperative fluoroscopic dose were higher in the robot group than in the navigation group. The rest of the data were not significantly different between these two groups. Conclusion: O-arm combined with CT 3D real-time navigation system not only has a better orthopedic effect than Tinavi orthopedic robot which also uses optical tracking system in the treatment of adolescent congenital scoliosis, but also exhibits a satisfactory clinical effect. Therefore, although it has several drawbacks, the navigation system is still a good clinical treatment option for scoliosis.

Keywords: O-arm, 3D navigation system, Tinavi robot, adolescent congenital scoliosis

Introduction

Scoliosis is a complex three-dimensional deformity presenting with asymmetric changes in the spine as well as trunk and is usually accompanied by structural and biomechanical alterations around the vertebrae. The presence of hemivertebrae, with defects in vertebral body formation or segmentation, is one of the most common factors attributing to congenital scoliosis in adolescents [1]. Furthermore, the severity of scoliosis depends primarily on the type, location, and number of hemivertebrae [2].

Congenital scoliosis is mainly treated by posterior resection of the hemivertebrae combined with pedicle screw fixation to re-establish the coronal and sagittal balance of the spine [3]. Since the morphology of the pedicle is different among patients with scoliosis, the distribution

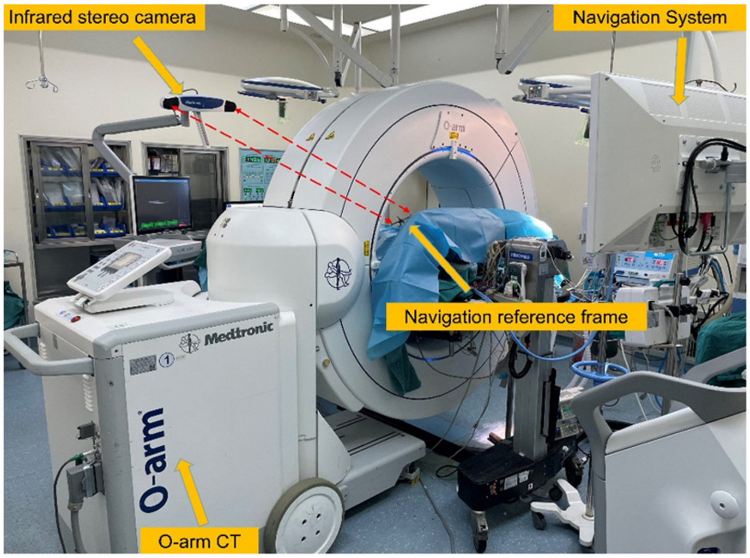

Figure 1. The three-dimensional view of the bavigation system.

of blood vessels varies greatly, and vertebral rotation is common. As a result, there is a high risk of pedicle screw misplacement, which can cause neurological and vascular injury [4]. In addition, the hemivertebral body is usually not well defined from the adjacent segment, and the extent of osteotomy relies on the surgeon's experience, which can affect the orthopedic results. Thus, new technologies, such as navigation systems and robotic systems, have been developed to improve the accuracy of pedicle screw placement and the precision of osteotomy.

The Tinavi orthopedic surgical robot system (codesigned by Beijing Jishuitan Hospital and Tinavi Medical Technologies Co., Ltd.) consists of a robotic arm, an optical tracking system, and a surgical navigation system. It provides an image-guided robotic positioning platform which is directly involved in the specific step of surgical screw placement. While the robotic arm in this system is highly flexible and stable, which is responsible for surgical planning and path positioning, the optical tracking system (consisting of an infrared stereo camera and a reference frame) is responsible for monitoring the patient reference frame and the robotic arm position, tracking data in real time. On the other hand, the surgical planning and navigation system collects 3D images reconstructed by intraoperative O-arm scanning. The integration of the robotic arm and the navigation system allows for information exchange between surgical planning and execution. Notably, the optical tracking system detects the patient's actual position as well as the subtle position changes in real time and works with the robotic arm for real-time motion compensation such that the arm is always accurately positioned on the preplanned screw placement trajectory [5].

Different from the Tinavi orthopedic surgical robot system, the O-arm combined with a CT 3D real-time navigation system (Stealth Station 8, Medtronic, Inc., USA), which consists of an infrared stereo camera, a navigation reference frame, and a navigation workstation, is a computerized image processing visualization system that provides the surgeon with the necessary information during the screw placement. It does not participate in the execution of the specific steps of the surgery, but instead uses the 3D image reconstructed from the intraoperative O-arm scan as a carrier to track the patient's anatomical position and the position of the surgical instruments in combination with the infrared stereoscopic positioning technology. Hence, it is highly precise for an immediate intraoperative navigation [6].

Although these new techniques have been reported to improve the accuracy of pedicle screw placement [7, 8], it is still not clear if a surgical robot or a navigation system is the best orthopedic aid for congenital scoliosis. In addition, no studies have compared the orthopedic efficacy of these two approaches. Therefore, the purpose of this study was to compare the imaging and clinical outcomes between these two systems for the orthopedic robot-assisted treatment of congenital scoliosis in adolescents (**Figures 1**, **2**).

Clinical data and methods

Patient enrollment

This retrospective study was approved by the Ethics Committee of Honghui Hospital, Xi'an Jiaotong University (approval number: 2021-0029) and was conducted in accordance with

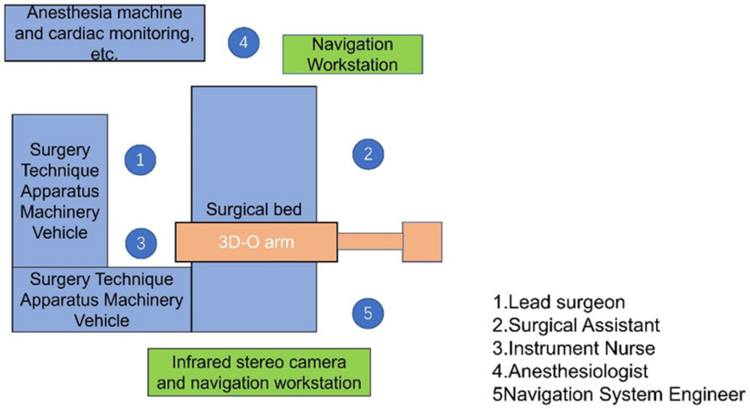

Figure 2. Aerial view of the navigation system.

the Declaration of Helsinki. Sixty patients with congenital scoliosis who underwent surgical treatment at our hospital from May 2021 to October 2021 were selected through the electronic medical record system.

The inclusion criteria were as follows: (1) adolescents with congenital scoliosis; (2) full-length frontal and lateral radiographs of the spine showing a coronal Cobb angle >40°, combined with thoracic hemivertebral deformity; and (3) a complete medical record was available, including current and past medical history, preoperative laboratory and imaging findings, and intraoperative information. It should be noted that the diagnosis of congenital scoliosis was made by clinicians with extensive experience in the diagnosis and treatment of scoliosis.

We excluded patients with: (1) magnetic resonance imaging (MRI) showing abnormal signal changes in the spinal cord; (2) ankylosing spondylitis with severe osteoporosis; (3) combined neurofibromas; and (4) other serious conditions that prevented the patient from surgery.

Data acquisition

Preoperative information was collected from the eligible patients, including sex, age, Cobb angle, vertebral rotation angle, body mass index (BMI), main bend direction, duration of disease, height, Risser's disease, pathological typing, follow-up time, and other comorbid vertebral skeletal deformities.

Intraoperative data were obtained from anesthesia and operative records, including surgical time, reference rack placement time, single screw placement time, total screw placement time, intraoperative bleeding, fusion extent, number of scans, intraoperative fluoroscopic dose, incision length, and small joint invasion. We manually reviewed the records of these 60 procedures and compared the results with those of the electronic data collection algorithm for these cases as well as confirmed that the data were correct.

Postoperative data, including the visual analog scale (VAS), neck disability index (NDI), Japanese Orthopedic Association (JOA) score, screw grading, screw distance from the cortex, screw density, mean spine correction rate, C7PL-CSVL, SRS, SVA, LL, PI, PT, and SRS-22, were also calculated. The indices were measured and graded by two spine surgeons who were not involved in the surgery. They used the Picture Archiving and Communication System (PACS) to review the medical records. Disputes were resolved by discussion to ensure data accuracy.

Surgery method

The whole process was monitored by motor evoked and somatosensory evoked potentials.

Treatment procedures in the navigation group

After general anesthesia, routine disinfection and towel laying were performed. The S8 navigation system was installed while revealing the surgical segment as well as completing and verifying the customized instrument match. The O-ARM acquired and transmitted the data to the S8 navigation system. The surgeon used the navigation probe to plan the screw placement scheme. A matched grinding drill was used to complete the opening, tapping, and implanting the screw. The screws were placed one by one, and imaging was used to confirm the correct placement of screws.

Next, the posterior structures of the hemivertebrae were excised, and the rib heads as well as

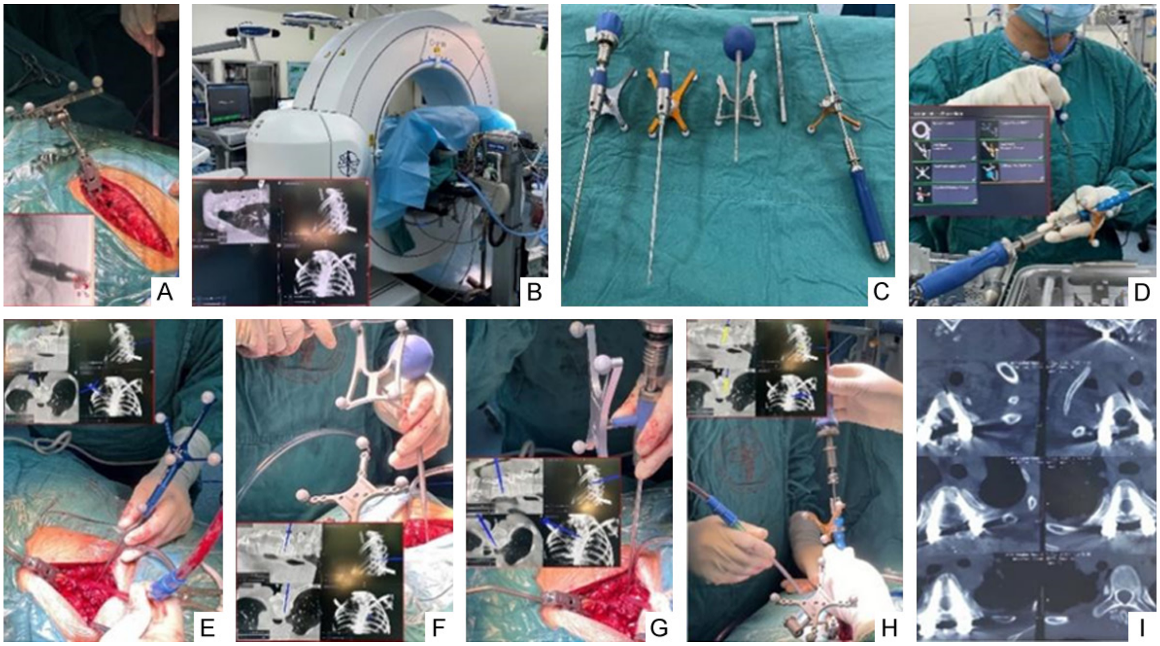

Figure 3. Flow Chart of the procedure. A: Reference rack placement. B: Data Acquisition. C: Instrument installation. D: Equipment configuration. E-G: Nail path preparation. H: Screw implantation. I: Verification.

the proximal ribs were severed. The spinal cord and nerve roots were separated, and the hemivertebral body was resected from the outside along the upper and lower edges of the pedicle with a matched ultrasonic bone knife, continuing with the resection of the adjacent intervertebral disc. Titanium rods were then installed, while alternating screws were used for compression and support.

If the hemivertebral body is large, anterior column reconstruction could be performed using a titanium cage; however, if the hemivertebral body was small without significant retroversion, an osteotomy gap graft could be performed. Specifically, the posterior vertebral plate and small joint of the fused segment were debrided, and autogenous bone was applied and mixed with allogeneic bone, if necessary, for Moe's bone grafting.

If the wound was irrigated and showed active bleeding, the wound was sutured and covered with a sterile dressing to complete the surgery (**Figure 3**).

Treatment procedures in the Tinavi group

After general anesthesia, routine sterilization was performed as usual. Then, the robotic system was installed, and the tracker was mounted on the bedside table. Vertebral data were obtained using an O-arm CT and transmitted to the operating table to plan the trajectories of the pedicle screws. After the robotic arm was run to the planned position, the guidewire was placed with the help of a high-speed electric drill, which was further confirmed by fluoroscopy and CT scans. The same procedure was applied to the rest of the vertebral implant. Based on the surgeon's experience, a hemivertebral osteotomy was then performed using an ultrasonic bone knife. The rest of the steps were the same as those described in the navigation group.

Postoperative treatment

Infection prevention, multimodal analgesia, swelling reduction, blood volume, electrolytes and nutritional support were routinely provided. The drainage tube was removed when the flow was approximately 50 mL/d, and the patient was instructed to start wearing a brace when moving around.

Evaluation indicators

Main indicators

Coronal balance: The Scoliosis Research Society (SRS) defines coronal balance (CB) as the distance from the C7PL-CSVL on a whole spine orthopantomography less than 3 cm and coronal imbalance (CIB) if the distance was >3 cm.

Sagittal balance: Sagittal vertical axis (SVA): sagittal balance refers to the spine that is within ± 2.5 cm of the C7 plumb line in the sagittal plane of the spine from the posterosuperior angle of S1 on the lateral image; otherwise, the spine is out of sagittal balance [9].

Lumbar lordosis (LL): the angle between the superior endplate of the vertebral body and the inferior endplate of the S1 vertebral body.

Spine correction rate: The spine correction rate was calculated using the formula: preoperative principal curvature Cobb angle - postoperative principal curvature Cobb angle/preoperative principal curvature Cobb angle × 100%.

Screw placement accuracy: All patients completed a postoperative CT examination, and the postoperative CT image data were measured using the Picture Archiving and Communication System (PACS). The pedicle screw positions were independently assessed by two spine surgeons who were not involved in the procedure. Disputes were resolved by deliberation. The accuracy of screw placement was assessed according to the Rampersaud scale [10] and was categorized into 4 grades. Grade 0: screws were completely within the pedicle; grade 1: screws penetrated <2 mm into the pedicle cortex; grade 2: screws penetrated <4 mm into the pedicle cortex; grade 3: screws penetrated ≥4 mm into the pedicle cortex. Grade 0 was considered "ideal" screw placement, while grades 1 and 2 were considered "clinically acceptable" screw placement. Grades 3 and 4 were "unacceptable" screw placement positions.

Secondary indicators

Pelvis-related parameters: Pelvic incidence angle (PI): the angle between the line from the midpoint of the S1 superior endplate to the center of the femoral head and the midplumb line of the S1 superior edge.

Pelvic tilt angle (PT): the angle between the upper edge of S1 and the horizontal line. The pelvic incidence angle matches the anterior lumbar lordosis angle (PI-LL).

Proximal synovial joint invasion: Proximal synovial joint invasion was evaluated according to the classification described by Kim et al.: Grade A = no contact, grade B = screw head contact or suspected contact with the small joint, and grade C = screw clearly invades the small joint [11].

Clinical outcomes

The following clinical outcomes were collected and compared: basic characteristics, surgical time, reference rack placement time, single screw placement time, total screw implantation time, intraoperative bleeding, fusion extent, screw density, mean curve correction rate, number of scans, intraoperative fluoroscopic dose, incision length, length of hospital stay, pre- and postoperative VAS score, NDI score, JOA score, and postoperative complications.

Multivariate analysis

Based on previously published studies, we included the data of confounding factors that might affect the results of our study, including BMI and the rotation of vertebrae. We conducted multivariate analysis to determine the influence of these confounding factors on our results and the credibility of our conclusions.

Statistical analysis

SPSS 25.0 statistical software was utilized to analyze the data. Measurement data were expressed as the mean ± standard deviation ($\overline{x}\pm s$). For intragroup comparisons before and intervention, paired sample t test was used, while for between-group comparisons, the independent sample t test was used. The significance level was set at α=0.05.

Results

As shown in **Table 1**, 60 patients met the inclusion criteria with 20 in the navigation group while 40 were in the Tinavi group. The male to female ratio of the patients was 33/27, and the age of patients ranged 9.3-17.6 years old, with the mean age of 13.6 years and a mean BMI of 22.82. A total of 484 screws were implanted in the navigation group, whereas 784 screws were implanted in the Tinavi group. The main diagnosis of the patients was adolescent congenital scoliosis. There was no statistically significant difference in any baseline data between the two groups.

Table 1. Baseline information of patients

Indicators	Navigation group	Tinavi group	t/Z/$\overline{x}$	P
	N=20	N=40		
Gender (female/male)	12.00/8.00	15.00/25.00	2.73	0.099
Age (years)	14.60±2.97	13.20±3.92	1.54	0.128
Main curve Cobb (°)	65.20±8.60	70.50±12.89	1.66	0.107
Vertebral body rotation (°)	20.10±2.60	19.60±2.1	0.75	0.459
Body mass index (BMI)	23.21±1. 62	22.43±1.89	1.58	0.120
Combination of other skeletal deformities	12.00	25.00	0.04	0.851
Main bend direction			0.00	1.000
Left	11	22		
Right	9	18		
Duration of disease (months)	9.43±2.79	9.88±2.91	0.46	0.648
Height	148.98±12.64	149.98±9.88	0.336	0.738
Risser's disease (0/I/II/III)	0/9/3/8	0/15/11/14	1.17	0.557
Pathological typing			0.05	0.976
Fully segmented type	8	15		
Nonsegmented closed type	6	13		
Partially segmented semiclosed type	6	12		
Follow-up time (months)	13.60±1.20	14.80±2.90	1.78	0.090

Table 2. Comparison of clinical parameters related to spinal orthopedics

Indicators	Navigation group		Tinavi group		t/Z/$\overline{x}$	P
	Preoperative	Postoperative	Preoperative	Postoperative		
C7PL-CSVL	30.67±12.92^{a}	13.6±10.6	30.11±11.86^{a}	18.75±2.43	0.044	0.022
SVA	45.80±7.62^{a}	17.6±8.8	46.20±6.99^{a}	26.31±2.43	0.000	0.000
LL	44.65±10.98^{a}	43.72±5.6	44.80±10.67^{a}	43.62±6.33	0.050	0.960
PI	42.86±7.90^{a}	47.6±6.2	41.15±6.17^{a}	45.32±5.80	0.166	0.083
PT	10.26±5.60^{a}	9.5±5.2	12.80±7.20^{a}	11.21±5.39	0.246	0.123
PI-LL	2.61±3.4^{a}	2.06±4.3	2.70±3.88^{a}	2.33±3.26	0.270	0.787
SRS-22	18.11±2.36^{a}	26.81±2.25	18.36±1.99^{a}	23.46±2.63	4.870	0.000

^{a}represents no statistically significant difference between the two groups compared in the same period.

Coronal balance

As shown in **Table 2**, C7PL-CSVL in the navigation group (13.6±10.6) was superior to that in the Tinavi group (18.75±2.43) (P=0.022). In addition, the SRS-22 was also better in the navigation group (26.81±2.25) than in the Tinavi group (23.46±2.63) (P=0.000). The remaining indicators were not significantly different between these two groups.

Sagittal balance

As shown in **Table 2**, the SVA in the navigation group (17.6±8.8) was better than that in the Tinavi group (26.31±2.43) (P=0.000). Similarly, LL in the navigation group (43.72±5.6) was also better than that in the Tinavi group (43.62±6.33) (P=0.960).

The mean spine correction rate

As shown in **Table 3**, the mean spine correction rate in the navigation group (72.80±10.70%) was better than that in the Tinavi group (60.60±8.90%) (P=0.000).

Accuracy of pedicle screw placement and small synovial invasion

The accuracy rates of "perfect" and "clinically acceptable" pedicle screws were 86.78% and 98.76%, respectively, in the navigation group, and were 87.63% and 98.60%, respectively, in

Table 3. Comparison of screw implantation ratings and small joint synapse invasion

Indicators	Navigation group	Tinavi group	t/Z/$\overline{x}$	P
Screw rating				
Level 0	420	687		
Level 1	58	86		
Level 0 + 1	478	773	0.060	0.806
Level 2	4	7		
Level 3	2	4		
Small joint invasion				
A	435	752	17.360	0.000
B	41	29		
C	8	3		

the Tinavi group, showing no statistically significant differences between the two groups (P=0.806). However, only 2 screws in the navigation group experienced pedicle encroachment with the most common direction was lateral (100%), whereas 4 screws in the Tinavi group exhibited pedicle encroachment. In terms of facet joint invasion, there were significant differences between the navigation group (grade A-C: 89.88%, 8.47%, 1.65%, respectively) and the Tinavi group (grade A-C: 95.91%, 3.69%, 0.38%, respectively) (P=0.000) (**Table 3**).

Clinical results

All patients were followed up with a mean follow-up time of 12.1 months. We found that the rate of small joint invasion was higher in the navigation group than in the Tinavi group (P=0.000). In addition, both the single screw implant time (P=0.000) and total screw implant time were higher in the navigation group than in the Tinavi group (P=0.02). However, the number of intraoperative scans (P=0.002) and fluoroscopic dose were significantly higher in the Tinavi group than in the navigation group (P=0.508). There were no significant differences between the two groups in other clinical parameters, such as surgical time, tracker placement time, intraoperative bleeding, degree of fusion, screw density, incision length, or hospital days. Furthermore, in the navigation group, screw correction was performed in 2 cases (0.41%) because the screws penetrated the pedicle cortex and irritated the nerve roots. Generally, the distances between the screw and the cortex were closer in the navigation group than in the Tinavi group (P=0.020). Importantly, the cost of using the Tinavi robot was approximately $428 per case, which was significantly less than that in the navigation group ($1,000). No serious complications, such as screw loosening or infection, occurred in either group, and nor a significant difference in the complication frequency between these two groups was observed (**Tables 4**, **5**; **Figures 4**, **5**).

Multivariate analysis

As shown in **Table 6**, the correction rate was a potential confounding factor affecting the results of coronal balance [P=0.012; Odds Ratio (OR): 2.631; 95% Confidence Interval (CI): 1.632-4.757], while BMI was a potential confounding factor affecting the results of sagittal balance (P=0.023; OR: 2.301; 95% CI: 1.087-4.964) (**Table 7**).

Discussion

Although utilizing pedicle screw systems for deformity correction and spinal stabilization has been widely accepted in spine surgery [12], the accuracy of screw placement is often influenced by the anatomical difference and surgical experience, which is evidenced by a report that the failure rate of pedicle screw placement is as high as 29.9% [13]. In addition, the clinical outcome of idiopathic scoliosis is also influenced by the outcome of hemivertebral resection. To overcome these clinical challenges, a variety of intelligent assistive systems have been developed and used in clinical practice.

In this study, we compared the performance between the S8 Navigation and Tinavi orthopedic robot systems and found that both systems had the ability to monitor the spatial position of the patient, which is closely related to their common structure, an infrared optical tracking system. This also explains why both systems are more accurate than unaided implantation, suggesting that the inclusion of an optical tracking system in any adjunct system could improve the accuracy of screw implantation.

Table 4. Comparison of perioperative-related indicators

Indicators	Navigation group	Tinavi group	t/Z/$\overline{x}$	P
Surgery time (min)	215.73±15.62	223.87±19.82	0.115	0.057
Reference rack placement time (min)	55.06±12.50	49.62±8.60	1.73	0.094
Single nail implantation time (min)	4.51±1.26	3.26±0.43	4.31	0.000
Total nailing time (min)	55.19±14.28	43.26±8.63	3.44	0.002
Screw distance from the cortex (mm)	6.88±3.72	8.96±2.18	2.48	0.020
Intraoperative bleeding (ml)	984.10±176.90	953.40±120.40	0.70	0.490
Fusion range	11.00±1.90	12.00±3.00	1.57	0.061
Screw density (%)	58.10±9.20	56.30±8.46	0.75	0.454
Average curve correction rate (%)	72.80±10.70	60.60±8.90	0.00	0.000
Number of scans (times)	2.20±1.50	3.40±1.20	3.28	0.002
Intraoperative fluoroscopic dose (mGy)	385.00±150.00	412.00±147.00	0.67	0.508
Incision length (cm)	26.36±8.45	25.12±7.52	0.58	0.566
Length of hospitalization (days)	9.86±2.67	10.12±2.43	0.70	0.353

Definition of single nail placement time: after adequate exposure, from the beginning of the selection of the needle entry point to the end of nail placement.

Table 5. Comparison of VAS, NDI, and JOA scores between patients in the two groups

	Navigation group			Tinavi group		
	VAS	NDI	JOA	VAS	NDI	JOA
Preoperative	1.76±0.30[a]	21.35±3.10[a]	19.90±1.45[a]	1.63±0.31[a]	22.01±2.60[a]	20.35±2.11[a]
Last follow-up visit	1.2±0.46[a]	19.26±2.98[a]	21.50±1.21[a]	1.26±0.38[a]	19.11±2.33[a]	21.44±1.35[a]
t/Z/$\overline{x}$	0.000	2.170	0.001	4.770	5.250	0.008
P	0.000	0.036	0.000	0.000	0.000	0.004

[a] represents no statistically significant difference between the two groups compared in the same period.

In osteotomy orthopedics, the surgeon can accurately plan the extent of hemivertebral resection with the S8 navigation real-time detection capability in conjunction with monitor-based guidance. In our study, the navigation system was superior to the Tinavi group in terms of mean spine correction rate, C7PL-CSVL, and SVA. In addition, due to the intraoperative multistep adjustment protocol, screws in the navigation group could be placed closer to the anterior cortex of the vertebral body, and even some double-cortical screw placements could be accomplished. This resulted in greater screw retention and allowed the surgeon to make more aggressive adjustments to the screws during subsequent compression bracing surgeries, which were more effective for spinal spine correction.

In this study, both the Tinavi and S8 navigation groups showed increased implantation density, which was consistent with the results from Liu Zhen et al. [14], as well as reduced the rate of postoperative correction loss. However, the reconstructed images were not effective in patients with severe deformities as there were overlapping multiple bony structures; therefore, the procedure would rely more on the surgeon's judgment and previous experience with screw placement. It is conceivable that combining neurophysiological monitoring and 3D printing for preoperative planning can make the procedure safer.

Although the principle of these two systems is the same, the implementation of the two systems is quite different. The O-arm combined with the CT 3D navigation system requires repeated adjustments at each step, similar to the multistep screw placement in conventional surgery, resulting in a significantly longer single and full screw placement time than using Tinavi robot. In addition, the repeated adjustments caused a significantly higher synaptic invasion of the small joints in the navigation group than in the Tinavi group. However, there were no sig-

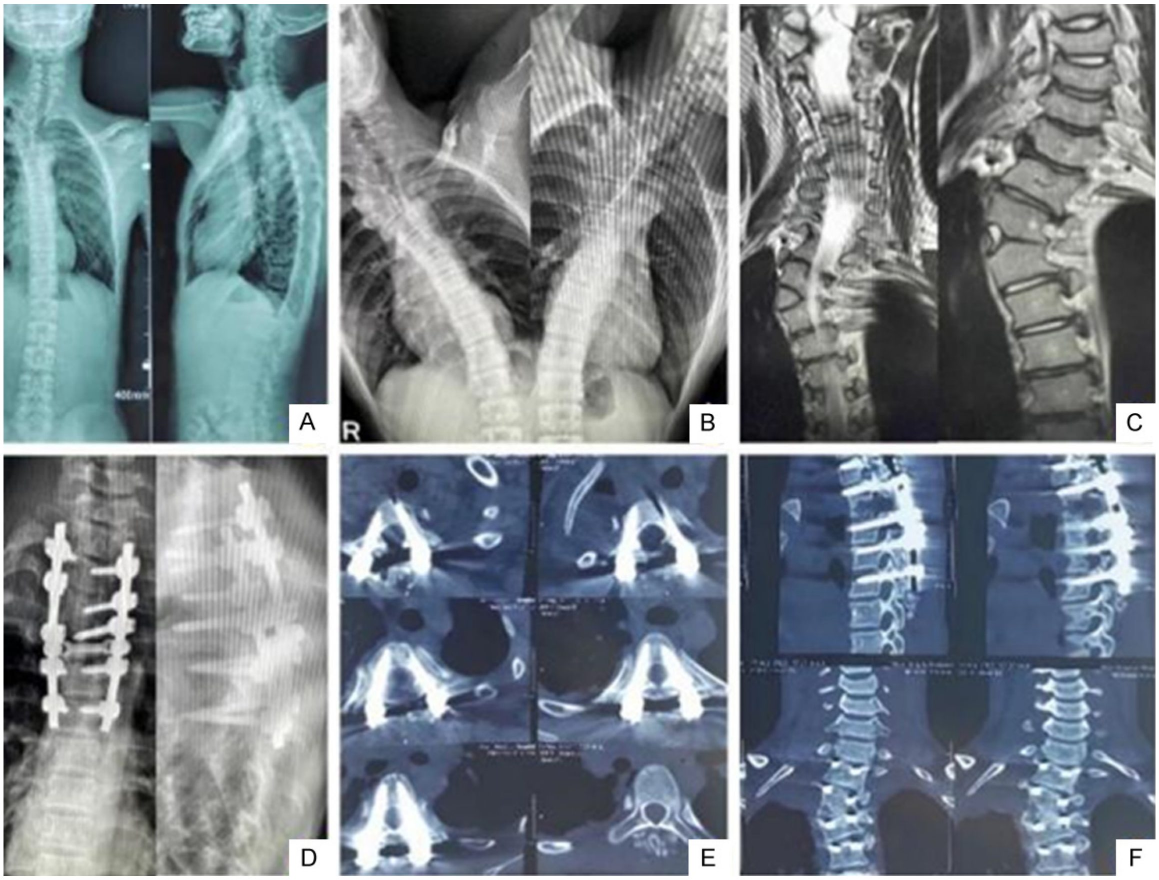

Figure 4. Typical case. Male, 11 years old, with congenital scoliosis. A. The patient presented with a thoracic hemivertebral spinal deformity. B. Preoperative full spinal hyperextension and hyperflexion position. C. Preoperative MRI suggests hemivertebral deformity. D. Postoperative frontal and lateral DR. E, F. Postoperative CT. The patient recovered well with no significant complications.

nificant differences in reference frame placement time, accuracy, wound length, bleeding, screw density, or hospital days between these two systems. Importantly, the accuracy of the S8 navigation group was high and was similar to the 99.3% screw accuracy reported by Larson et al. [15].

Furthermore, we found that both groups required a longer surgical time than conventional surgery due to the intraoperative information acquisition and screw path planning. While the navigation group implanted the screw more slowly than the Tinavi group, the osteotomy session was faster in the navigation group than in the Tinavi group; hence, when these two phases were balanced, there was no significant difference in surgical time between these two groups. Nevertheless, the Tinavi group usually required multiple scans for registration and thus experienced significantly higher radiation exposure than the navigation group, in which shorter scan time and less multiple scans were needed, though the radiation exposure in both groups was significantly higher than that in conventional free screw implantation, consistent with the study by Urbanski et al. [16], which was one of the drawbacks of all currently available orthopedic assist systems.

For congenital spinal deformities, we usually perform preoperative CT scans with 3D reconstruction, which also increases the cumulative radiation dose to the patient. However, compared to fluoroscopic techniques, intraoperative CT and navigation techniques reduce radiation exposure to the surgical team due to early planning.

As for the safety of these two systems, no significant postoperative vascular- or neurological-related complications were observed in either

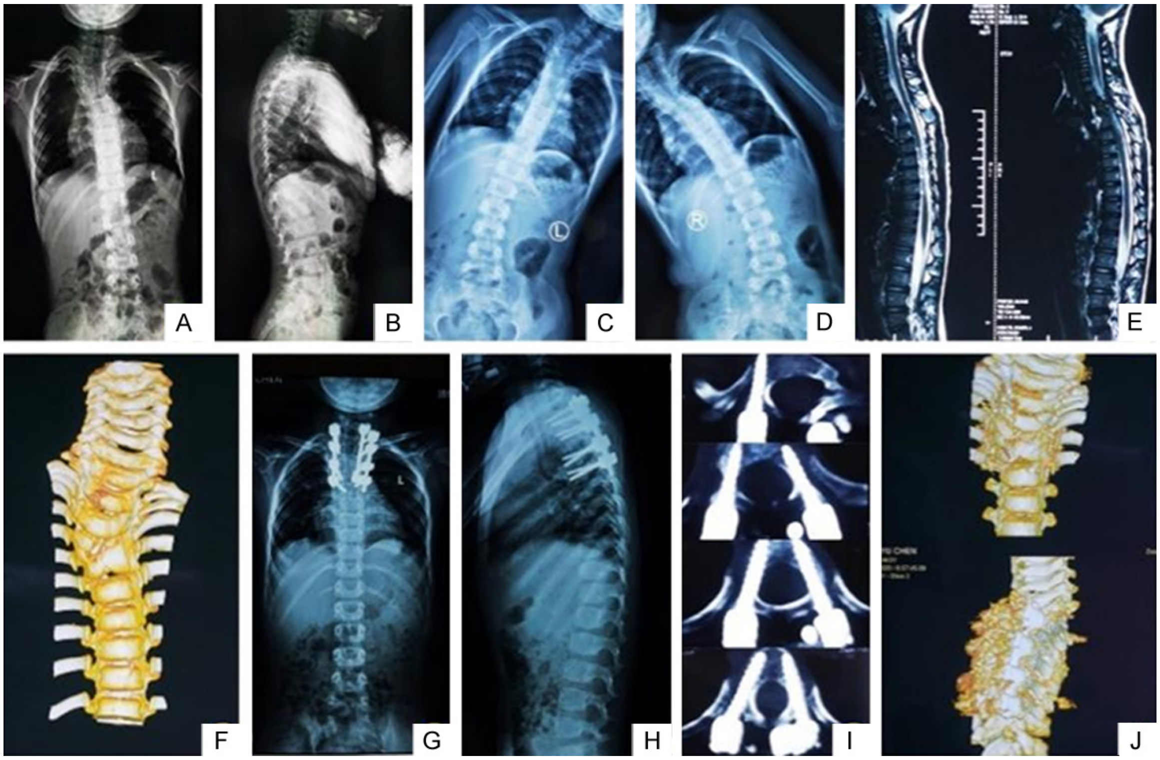

Figure 5. Typical case. Male, 10 years old, with congenital scoliosis. A-D. The patient presented with a thoracic hemivertebral spinal deformity. E. Preoperative MRI suggests hemivertebral deformity. F. CT suggests thoracic hemivertebral deformity. G, H. Postoperative frontal and lateral DR. I, J. Postoperative CT. The patient recovered well with no significant complications.

Table 6. Multifactorial analysis of coronal imbalance

Variable	Regression coefficient	Standard error	Wald value	P	OR	95% CI
Gender	0.884	0.327	4.221	0.071	1.121	0.972-1.521
Age	1.211	0.011	3.281	0.121	2.110	0.681-2.419
BMI	0.521	0.108	3.851	0.507	1.215	0.692-1.461
Main bend Cobb angle	3.211	1.101	8.412	0.634	4.393	0.524-9.520
Rotation of vertebrae	2.394	0.961	6.663	0.742	4.292	0.589-9.635
Screw density	2.371	1.021	4.381	0.689	1.221	0.851-7.846
Correction rate	3.211	0.681	3.271	0.012	2.631	1.632-4.757
Postoperative shoulder joint balance	2.316	1.108	4.317	0.711	1.417	0.881-4.421

OR: odds ratio. CI: Confidence Interval.

group, similar to the study by Verma et al. [17], indicating that S8 navigation did not increase the probability of complications. In addition, there were no significant differences in VAS, NDI or JOA scores between the two groups at the postoperative follow-up.

Bone tumor biopsies and other puncture biopsies are usually performed under a C-arm, where the physician constantly corrects the patient's position by trial positioning the sampling needle and observing the display on the X-ray image before extracting bone tissue from the lesion for tumor biopsy. As a result, both the surgeon and the patient are exposed to a large amount of X-ray radiation, and sometimes open surgery is required to extract the tissue sample from the lesion. In contrast, the O-arm combined with a CT 3D navigation system can effectively guide a precise puncture and allow the surgeon to adjust the sampling site at any time during the surgery. In patients who have

Table 7. Multifactorial analysis of sagittal imbalance

Variable	Regression coefficient	Standard error	Wald value	P	OR	95% CI
Gender	2.119	0.751	4.214	0.818	3.601	0.859-4.085
Age	3.861	1.218	5.381	0.119	4.311	0.619-6.721
BMI	3.271	1.101	3.061	0.023	2.301	1.087-4.964
Main bend Cobb angle	3.278	1.358	7.261	0.531	4.257	0.738-9.639
Rotation of vertebrae	3.976	1.694	5.762	0.782	3.211	0.862-5.311
Screw density	2.361	0.975	4.418	0.085	2.314	0.902-4.534
Correction rate	2.229	0.745	5.218	0.109	3.489	0.784-7.454

OR: odds ratio. CI: Confidence Interval.

undergone multiple surgeries resulting in unclear anatomic positions, 3D reconstruction images can be used to determine the position of the pedicle screw preoperatively and guide the revision surgery. However, artifacts from previous surgical screws may impact the accuracy of screw placement during revision surgery.

In traditional spine surgery, the surgeon relies heavily on his or her medical knowledge, clinical experience, and imagination of combining the 2D images such as X-rays, CTs, and MRIs to construct a 3D spine structure to plan the surgery, perform intraoperative positioning, and decompress the screw implant, which is a difficult task for beginners in spine surgery and requires clinical practice. In contrast, the combined O-arm navigation system is more three-dimensional and easier to control, and the navigation system can reconstruct the immediate intraoperative screw placement effectively from multiple angles with three-dimensional visual images, thereby alleviating the fatigue of the surgeon when the screw is difficult to place due to rotation or abnormal development.

Although it has great clinical potential, the navigation system still has several drawbacks: (1) Mastering the system is challenging due to the cumbersome registration and the extensive clinical experience, which leads to an increased surgical time and more patient trauma. Suspension of the patient's breathing to reduce the error and the temporary pause of the surgical team from the operating room during image acquisition increase the risk of surgery; (2) Various factors can interfere with the accurate assessment of the surgical instrument position in a timely manner, such as an unscientific placement of the reference frame, an accidental moving of the reference frame, relevant personnel obscuring the space between the optical components and the reference frame, a contamination of the navigation markers, and difficulty in aligning the markers with the infrared camera, which can increase the adjustment time as well as the risk of incorrect screw implantation and improper incisions; (3) Some vertebral bodies may move after the relax of paravertebral muscles in scoliosis patients, or the relative positions of vertebral bodies may move slightly during the screw implant process if the force applied is not appropriate, resulting in a decreased accuracy of screw implantation; (4) Navigation systems are developed for certain ethnic groups and adapted to specific brands of orthopedic instruments, which are less versatile and too expensive [18]; (5) The navigational screw placement requires repeated adjustment of the screw path. Hence, due to the different experiences of surgeons with screw placement, there is a nonnegligible error in the accuracy of the screw implantation during the adjustments to determine the screw path; (6) Current operating rooms are generally small, while the S8 navigation device has many components. The part in close contact with the patient needs to be highly aseptic, and the chance of contamination may be high during an actual operation.

To address the above obstacles, we propose the following suggestions. First, for experienced spinal deformity nailing surgeons, "simple spine" freehand nailing combined with "difficult spine" navigation system-assisted nailing can greatly reduce the operative time. Second, the placement of the navigational reference frame needs to be scientific to avoid difficult registration. The intraoperative images provided by the system are highly accurate. After registration, the navigational drill is applied to the obvious bony landmarks in the operative area to verify the accuracy of the navigational pins and, if necessary, to check the pedicle screws with fluoroscopy. The infrared stereo camera needs to be placed on the top of the surgical bed, directly connected to the robotic arm and the operative area. The surgical team must be familiar with the robotic overlay, and all assistants must be vigilant in maintaining a sterile area. The monitor should be placed in a position visible to the surgeon and assistants. Lastly, to navigate the system and reduce the screw implant error rate, no more than three segments of CT vertebral data should be acquired at a time [19]. During screw implantation, every effort should be made to avoid errors caused by the micromovements of the vertebral body due to improper force application.

In our multivariate analysis, only correction rate and BMI were identified as the potential confounding factors. Regarding coronal balance, the higher the correction rate, the more compensatory bending is required to provide more compensatory volume. The right and left lateral flexion films of all patients included in this study suggested that patients with compensatory bends were nonstructural bends (compensatory bends with Cobb angles less than 25° and bending Cobb angles less than 25°). Our study found that BMI was associated with sagittal balance, and a greater BMI might affect sagittal balance by compensating for some of the load bearing. However, the mean BMI of the patients in this study was low; thus, this confounding factor had a limited effect on the findings of this study. Overall, the confounding factors did not significantly affect the conclusion of this study.

This study also had some limitations. As we are still in the early phase of using these systems, the sample size in this study might be insufficient. Further study with increased number of cases will enhance the credibility of our conclusions. In addition, this retrospective study would inevitably lose some clinical data, and other clinical features need to be analyzed in future prospective studies which will be designed to combine with more comprehensive evaluation indicators.

Conclusion

O-arm combined with CT 3D real-time navigation system not only has a better orthopedic effect than Tinavi orthopedic robot which also uses optical tracking system in the treatment of adolescent congenital scoliosis, but also exhibit a satisfactory clinical effect. Therefore, even with several drawbacks, the navigation system presents as an excellent clinical treatment option for scoliosis.

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Written informed consent was obtained from all subjects involved in the study.

Disclosure of conflict of interest

The authors declare that this research was conducted without any commercial or financial relationships that could be construed as a potential conflict of interest.

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