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Effectiveness of 'O'-Arm Navigation-Assisted In-Out-In Pedicle Screw Technique for the Treatment of Congenital Scoliosis: A Study of 17 Cases

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Abstract

Objective: To investigate the efficacy and safety of internal fixation of narrow varicose vertebrae using the lateral in-out-in screw technique with the assistance of the "O" arm navigation system in 17 patients with congenital scoliosis.

Methods: A retrospective analysis was conducted on the clinical data of 17 patients with congenital scoliosis who underwent internal fixation surgery at Luohe Central Hospital from January 2019 to January 2021. During the procedure, the "O"-arm navigation system was utilized to assist in the placement of pedicle screws for narrow and variant vertebrae using the in-out-in technique. Pedicle screws were inserted into the normal pedicles with the assistance of the "O"-arm navigation system for internal fixation to correct lateral and posterior convex deformities. Post-screw placement, the accuracy of screw placement was evaluated using the "O"-arm machine scan. After satisfactory correction, residual gaps between vertebral bodies were filled with bone grafts and the surfaces of transverse processes and other posterior structures within the fusion range were decorticated before bone grafting. Preoperative Cobb angles of lateral and posterior convexities, as well as intraoperative details and the success of single-stage screw placement, were recorded. Follow-up was conducted until December 2023, documenting occurrences of postoperative complications such as spinal cord injury, cerebrospinal fluid leakage, wound infection, screw and rod loosening or displacement and fractures. Full-length anteroposterior and lateral X-rays of the spine were obtained at 1 week and 1 year postoperatively to record Cobb angles of lateral and posterior convexities and calculate the correction rate. Patient or caregiver satisfaction with surgical outcomes was assessed using the Scoliosis Research Society-22 (SRS-22) questionnaire. At the final follow-up, the bone fusion status was evaluated using the Eck fusion grading system

Results: (1) The mean operative time was (184.0±43.2) minutes, with an intraoperative blood loss of (632.0±192.7) ml. The highest instrumented vertebra was T5 and the lowest was S1. The mean number of fixed and fused segments was (9.0±2.7). A total of 216 pedicle screws were inserted, comprising 152 pedicle screws and 64 lateral pedicle screws, all successfully placed in a single attempt. Intraoperative "O"-arm scans revealed that all screws were positioned close to the inner wall of the pedicles and did not breach the vertebral canal. (2) Follow-up was conducted until December 2023, with a mean follow-up duration of (28.0±3.4) months. None of the 17 patients experienced complications such as spinal cord injury, cerebrospinal fluid leakage, wound infection, screw or rod loosening, displacement, or fracture. In 17 patients, the preoperative Cobb angle for lateral convexity was (57.8±6.6) ° and for posterior convexity was (44.0±9.6) °. At 1 week postoperatively, the Cobb angle for lateral convexity was (12.6±4.2) ° and for posterior convexity was (15.3±2.4) °. At 1 year postoperatively, the Cobb angle for lateral convexity was (15.3±2.4) ° and for posterior convexity was (15.4±2.3) °. The differences between preoperative and postoperative angles were statistically significant, while the differences between angles at 1 week and 1 year postoperatively were not statistically significant. At 1 week postoperatively, the correction rate for lateral convexity was (77.6±8.6) % and for posterior convexity was (63.9±8.4) %. At 1 year postoperatively, the correction rate for lateral convexity was (76.8±7.1) % and for posterior convexity was (63.6±8.6) %. There were no statistically significant differences in comparison between the two time points (t=0.272, P=0.789; t=0.123, P=0.904). The SRS scores of the 17 patients at baseline (71.8±4.2), 1 week postoperatively (83.1±4.4) and 1 year postoperatively (84.7±3.8) showed statistically significant differences (F=291.43, P<0.001). The baseline SRS score was lower than those at 1 week and 1 year postoperatively (P<0.05), but there was no significant difference between the scores at 1 week and 1 year postoperatively (P>0.05). At the final follow-up, all 17 patients achieved grade I fusion

Conclusion: The in-out-in screw technique for the treatment of congenital scoliosis using the "O"-arm navigation system for navigation-assisted internal fixation can safely insert the screws for the treatment of narrow variant lateral pedicles, which provides solid internal fixation, good orthopedic effect and fewer complications.

Keywords: Surgical navigation system; Spinal scoliosis; Pedicle screw; O-arm navigation; Internal fixation; Congenital scoliosis



Introduction

Congenital scoliosis (CS) is a condition where spinal curvature is caused by vertebral malformations. Posterior pedicle screw fixation surgery is a commonly used treatment for congenital scoliosis. Traditional surgery for congenital scoliosis relies on intraoperative C-arm fluoroscopy and the surgeon's subjective experience to determine screw placement. However, due to the variability of spinal anatomy and the limitations of two-dimensional imaging, repeated fluoroscopy is required during the procedure. Additionally, some patients with congenital scoliosis have vertebrae with narrow or rotated pedicles, which complicates the insertion of pedicle screws and increases the risk of screw injury to the spinal cord and loosening of the internal fixation [1-2]. The "O"-arm three-dimensional intraoperative imaging navigation system can quickly establish a three-dimensional image of the surgical site, enable precise screw placement while avoid surrounding critical blood vessels and nerves, thereby improving surgical safety. However, there are few reports on the use of the "O"-arm navigation system for congenital scoliosis patients with narrow and anomalous pedicles [1]. This study utilizes the "O"-arm navigation system to assist with the insertion of screws using the in-out-in technique for deformity correction in congenital scoliosis patients with narrow and anomalous pedicles, achieving good clinical results. The findings are presented below.

Materials and Methods

General information

Between January 2019 and January 2021, 17 patients with congenital scoliosis underwent spinal deformity correction surgery using the "O"-arm three-

dimensional intraoperative imaging navigation system at Luohe Central Hospital. Among the patients, 7 were male and 10 were female, with ages ranging from 4 to 16 years (mean (10.6 ± 4.5) years). The preoperative Cobb angle for scoliosis was $(57.8 \pm 6.6)^\circ$ and for kyphosis was $(44.0 \pm 9.6)^\circ$. Two patients had associated spinal cord longitudinal clefts (1 case from T10-L1, 1 case from T11-L2) and 1 patient had an associated tethered cord. The Scoliosis Research Society-22 (SRS-22) score was (71.8 ± 4.2) points.

Inclusion criteria: (1) Diagnosis of congenital scoliosis, (2) Underwent spinal osteotomy and deformity correction with internal fixation, (3) Complete clinical data. Exclusion criteria: (1) Patients with idiopathic scoliosis, (2) History of previous spinal surgery, (3) Presence of systemic or local infections or other factors affecting surgery, (4) Loss to follow-up. This study was approved by the Medical Ethics Committee of Luohe Central Hospital (Ethics Approval No.: LH-KY-2022-001-036) and patient informed consent was waived for this retrospective study.

Methods

Surgical method

General anesthesia was administered with endotracheal intubation and the patient was placed in the prone position on a radiolucent carbon fiber surgical table, allowing the abdomen to hang freely. Intraoperative spinal cord function was monitored using somatosensory evoked potentials (SSEP) to ensure surgical safety. The Medtronic "O"-arm Stealth Station S8 three-dimensional intraoperative imaging navigation system was used (**Figure 1**).



Figure 1: Photograph demonstrating intraoperative application of the Medtronic O-arm navigation system. (A) Intraoperative scan of the patient's spine obtained using the Medtronic O-arm system; (B) Implantation of spinal fixation screws performed under O-arm navigation.



A midline posterior incision was made and the required fixation segments were exposed by subperiosteal dissection, revealing the spinous processes, laminae and bilateral facet joints. A navigation tracker was fixed to one side of the spinous process and the "O"-arm system was used to scan and obtain three-dimensional spinal data, which was then input into the navigation system. A single scan could complete pedicle screw placement for 4 to 6 vertebrae; if the number of vertebrae exceeded 6, a second scan was performed. Navigation tools were registered and based on the real-time three-dimensional images provided by the system, the maximum inner diameter of the pedicle was measured on the thoracolumbar three-

dimensional image. Pedicles with a maximum inner diameter of less than 4 mm were classified as narrow anomalous pedicles [5]. A burr was used to create an opening on the lateral side of the narrow anomalous pedicle, ensuring that the medial cortical bone of the pedicle was preserved. The in-out-in technique was used to insert the screws at a 30° to 40° angle along the lateral side of the pedicle, ensuring the screw length was more than 2/3 of the vertebral body's anteroposterior diameter, but not exceeding the anterior cortical bone of the vertebral body (**Figure 2**). For normally developed pedicles, pedicle screws were inserted under the guidance of the "O"-arm navigation system.

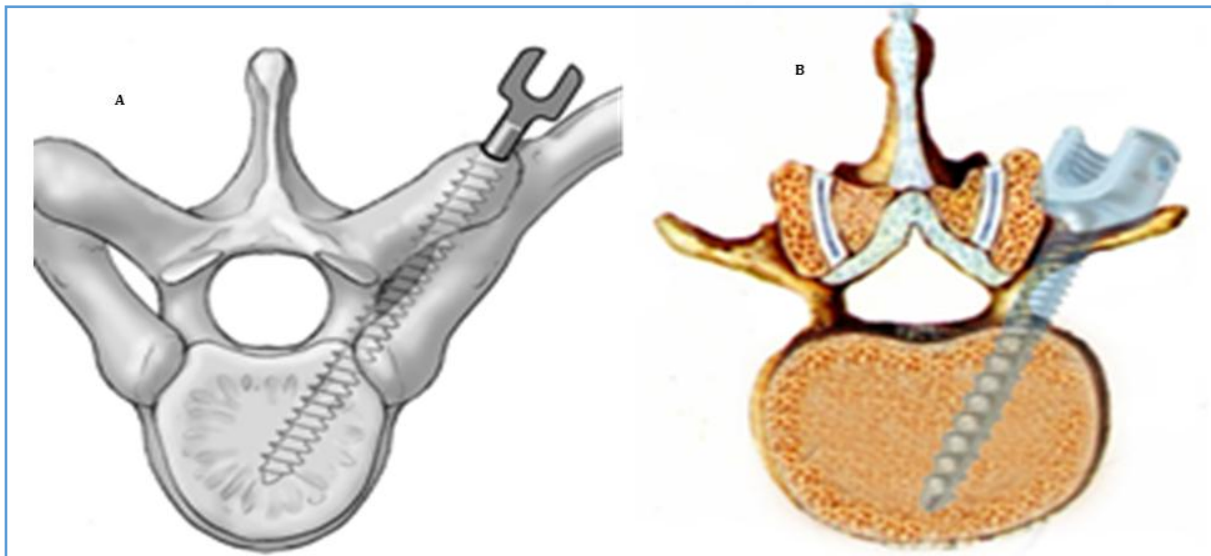


Figure 2: Schematic diagram of "in-out-in" technique; (A) In the case of a stenotic variant thoracic vertebra, the in-out-in technique was employed under navigation guidance. The entry point was created at the tip of the transverse process, ensuring preservation of the medial cortex of the pedicle. The screw was then placed lateral to the inner wall of the pedicle and advanced into the vertebral body; (B) In the case of a stenotic variant lumbar vertebra, the in-out-in technique was applied under navigation guidance. The entry point was established at the bony slope lateral to the superior articular process, with preservation of the medial cortex of the pedicle. The screw was subsequently positioned lateral to the inner wall of the pedicle and advanced into the vertebral body.

Then, depending on the type of spinal deformity, a partial vertebral body and attached ribs were resected. After installing a temporary convex-side short rod, the concave-side pedicle was exposed by approaching the vertebral body laterally. Scar tissue on the concave side was released and bone bridges were cut. A temporary short rod was installed on the concave side and the convex-side temporary rod was removed. A pre-bent short rod was shaped according to the normal physiological curvature in the sagittal plane for the fixed segment. Using the translation principle, the rod was inserted into the convex-side screws. After intervertebral compression, the rod was turned 90°, converting part of the coronal plane spinal deformity

into a physiological curve in the sagittal plane. Similarly, the rod on the concave side was pre-bent according to the normal physiological curvature in the sagittal plane for the fixed segment and using the translation principle, the rod was inserted into the screws to further correct the scoliosis and kyphosis. If dural folding occurred during the distraction and closure process, laminectomy was performed to increase the spinal canal's capacity and the neural foramina were checked for patency. If there was nerve root compression, the pressure gap was appropriately released. After satisfactory correction, the screw caps were locked and cross-connectors were installed. Residual intervertebral gaps were filled with bone grafts (excised



bone and allograft). The transverse processes and other posterior structures within the fusion area were decorticated before bone grafting. For the two patients with spinal cord longitudinal clefts, a spinal cord cleft resection was performed first, followed by deformity correction surgery. For one patient with tethered cord, tethered cord release surgery was performed first and spinal deformity correction surgery was performed 6 months later.

Intraoperative screw placement was recorded. Successful one-time screw placement was defined as completing the process of cortical bone opening, pedicle screw path dilation, tapping and screw insertion on the first attempt. If adjustments were needed for the cortical bone opening, screw path direction or if screws loosened after insertion, the screw placement was considered unsuccessful on the first attempt. After adjustment, the screw was successfully placed [3].

Follow-up

The follow-up continued until December 2023 and complications such as postoperative spinal cord injury, cerebrospinal fluid leakage, incision infection, screw and rod loosening or displacement and fracture were recorded. Postoperative X-ray examinations in standing full-length anteroposterior and lateral views were conducted at 1 week and 1 year after surgery. The scoliosis Cobb angle and kyphosis Cobb angle were recorded and the correction rate was calculated as follows:

Correction rate = (Preoperative Cobb angle - Postoperative Cobb angle) / Preoperative Cobb angle × 100% [4]. The Scoliosis Research Society-22 (SRS-22) scale was used to assess the patient's or family's satisfaction with the surgical outcome. The scale includes 5 dimensions (pain, activity/function, self-image/appearance, mental health, treatment satisfaction) and 22 questions, with scores ranging from 1 to 5 for each dimension. A higher score indicates greater satisfaction with the outcome. At the last follow-up, the fusion status of the bone graft was assessed using the Eck fusion grading system.

Grade I indicates definite fusion, where the bone graft space is completely bridged by trabecular bone and reshaped; Grade II indicates possible fusion, with trabecular bone appearing at the upper and lower edges of the graft, with no gaps and the graft edges are not fully reshaped; Grade III indicates possible non-fusion, where gaps appear at the upper or lower edge of the graft due to lack of trabecular bridging; Grade IV indicates definite non-fusion, with graft resorption or collapse; and Grade V indicates assessable fusion status [6].

Statistical analysis

Statistical analysis was performed using SPSS 26.0 software. Normally distributed continuous data were expressed as mean ± standard deviation ($x \pm s$). Paired t-tests were used to compare different time points before and after surgery. The significance level was set at $\alpha = 0.05$.

Results

Surgical outcomes

The average surgical time was (184.0 ± 43.2) minutes, with an average intraoperative blood loss of (632.0 ± 192.7) ml. The highest fixed segment was T5 and the lowest fixed segment was S1, with an average of (9 ± 2.7) fused segments. A total of 216 pedicle screws were placed, with 152 screws placed in the pedicle (70.4%) and 64 screws placed on the lateral side of the pedicle (29.6%). All screws were successfully placed on the first attempt. Intraoperative "O"-arm scanning showed that all screws were placed close to the inner wall of the pedicle and entered the vertebral body without penetrating the spinal canal.

Follow-up results

The follow-up lasted until December 2023, with an average follow-up period of (28.0 ± 3.4) months. None of the 17 patients experienced spinal cord injury, cerebrospinal fluid leakage, incision infection, screw or rod loosening, displacement or fracture complications. At the final follow-up, all 17 patients achieved Grade I fusion of the bone grafts.

Comparison of Cobb angles and correction rates before and after surgery

There were statistically significant differences in the scoliosis Cobb angle, kyphosis Cobb angle and correction rates between preoperative, 1-week postoperative and 1-year postoperative measurements in the 17 patients. The preoperative scoliosis Cobb angle was (57.8 ± 6.6)° and the kyphosis Cobb angle was (44.0 ± 9.6)°, both greater than the postoperative 1-week values [(12.6 ± 4.2)°, (15.3 ± 2.4)°] and the postoperative 1-year values [(15.3 ± 2.4)°, (15.4 ± 2.3)°] ($P < 0.05$). There was no statistically significant difference between the 1-week and 1-year postoperative measurements ($P > 0.05$) (**Table 1**). The correction rate for scoliosis Cobb angle at 1-week post-surgery was (77.6 ± 8.6)% and for kyphosis Cobb angle was (63.9 ± 8.4)%. At 1-year post-surgery, the correction rates were [(76.8 ± 7.1)%, (63.6 ± 8.6)%], with no statistically significant differences between the two time points ($t = 0.272$, $P = 0.789$; $t = 0.123$, $P = 0.904$).



Table 1: Comparisons the Cobb Angle of scoliosis and kyphosis, correction rate and SRS score before operation, 1 week after operation and 1 year after operation.

	Preoperative	Postoperative 1 week	Postoperative 1 year	F value	P value
Cobb angle of scoliosis	57.8 ± 6.6	12.6 ± 4.2a	15.3 ± 2.4a	291.43	<0.001
Cobb angle of kyphosis	44.0 ± 9.6	15.3 ± 2.4a	15.4 ± 2.3a	291.43	<0.001

Note: a vs. preoperative, P<0.05.

Comparison of SRS scores before and after surgery

The preoperative SRS score for the 17 patients was (71.8 ± 4.2), the postoperative 1-week score was (83.1 ± 4.4) and the postoperative 1-year score was (84.7 ± 3.8). The differences between these scores were

statistically significant (F = 291.43, P<0.001). The preoperative SRS score was lower than the postoperative 1-week and 1-year scores (P<0.05), while there was no statistically significant difference between the postoperative 1-week and 1-year scores (P>0.05). A typical case's preoperative and postoperative imaging can be seen in **Figure 3**.

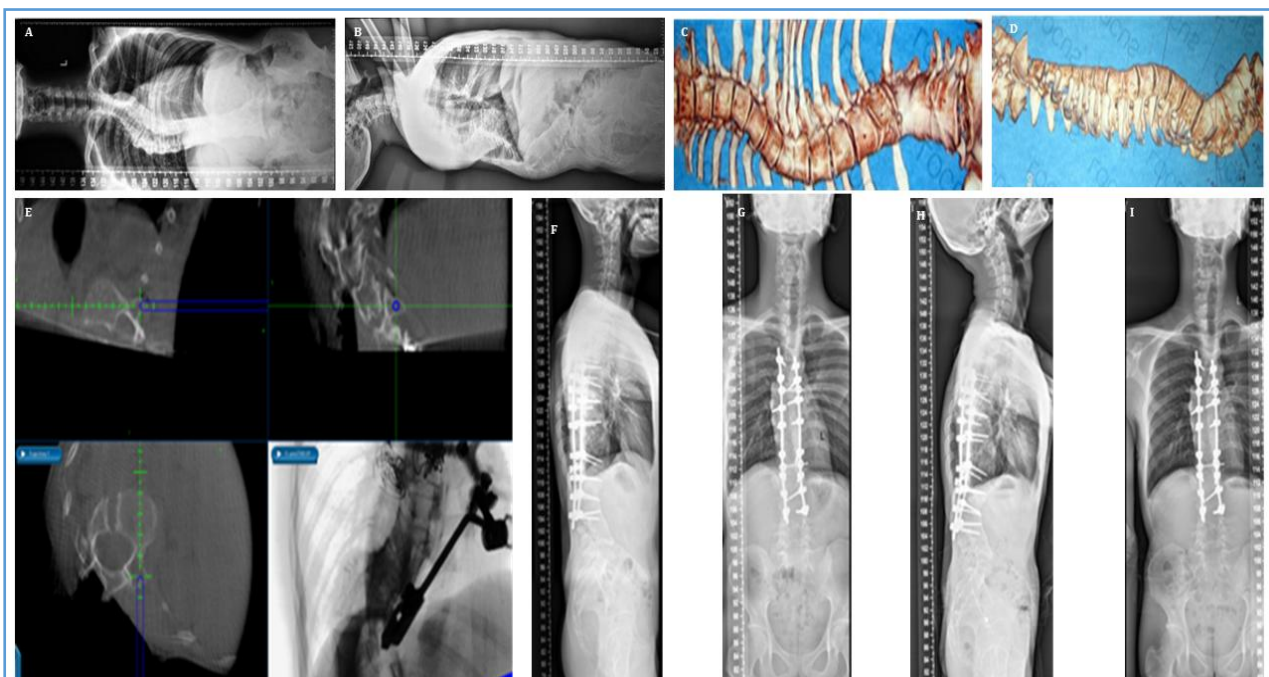


Figure 3: Pre and post operative images of a case of congenital scoliosis; Male, 16 years old. (A,B) Preoperative frontal and lateral spine radiographs, congenital scoliosis; (C,D) Preoperative three-dimensional reconstruction of the spine; (E) Intraoperative navigation-assisted screw placement using the In-Out-In technique; (F,G) Frontal and lateral spine radiographs taken at 1 week postoperatively; (H,I) Frontal and lateral spine radiographs taken at 1 year postoperatively.

Discussion

Congenital scoliosis is a three-dimensional deformity of the spine that primarily occurs in children and adolescents. Surgical treatment can effectively improve symptoms, reduce neural compression and result in a favorable prognosis. Internal fixation mainly involves the use of pedicle screws and screw-rod systems to secure the screws to the patient's spine, correct the spinal deformity and stabilize the spine, preventing further spinal deformity. The pedicle screw system is widely used in spinal surgery due to its strong fixation, reliable three-column stability and its powerful ability to correct spinal scoliosis through expansion,

compression and rotational correction [7-8]. However, clinical applications of thoracolumbar pedicle screws typically require a diameter greater than 4 mm. Many congenital scoliosis patients exhibit anomalous malformations of the vertebrae and pedicles, with some pedicles having an inner diameter of less than 4 mm. Narrow pedicle canals made of cancellous bone cannot accommodate the pedicle screws, increasing the risk of spinal deformity correction. Sarwahi et al., [5] reported that 31.9% of thoracolumbar pedicles in scoliosis patients had developmental abnormalities (pedicle width <4 mm). Sudarshan et al. [9] reported that 42% of concave-side thoracolumbar pedicles and 30% of



convex-side pedicles in scoliosis patients had developmental abnormalities. Brink reported that scoliosis patients exhibited asymmetry in the transverse sections of the vertebrae and pedicles [10]. In the apex of the curve, the pedicles became concave, narrower and longer, especially in severe scoliosis patients, where the concave-side pedicle was relatively thinner and hardened. The spinal cord directly contacts the medial wall of the pedicle. Due to the lack of compensatory space, pedicle screw penetration into the spinal canal can damage the spinal cord [11]. Therefore, accurately placing pedicle screws in scoliosis patients is crucial for reducing postoperative complications and improving patient outcomes.

The C-arm fluoroscopy system-assisted pedicle screw insertion is a commonly used surgical method; however, it cannot provide accurate positioning information for severely rotated vertebrae. During surgery, screws are placed in the pedicle by manual feel within the cancellous bone channel. Congenital scoliosis patients often have severely malformed spinal structures, such as asymmetric development of the spinal canal and pedicles, vertebral rotation, overly narrow pedicles and spinal cord displacement [12-14]. For abnormal pedicles (with pedicle width <4 mm and rotation), it is difficult to accurately place screws near the inner wall of the pedicle under C-arm fluoroscopy guidance. Additionally, narrow pedicles cannot accommodate screws with a diameter greater than 4 mm, leading to a high failure rate of screw placement in scoliosis patients [15-17]. Studies have reported that the misplacement rate of manually inserted pedicle screws in spinal deformity correction surgery ranges from 1.5% to 43% [18-19]. Screw penetration into the spinal canal can damage the spinal cord, while external screw misplacement can cause vertebral fractures and reduce fixation strength.

The O-arm navigation system, consisting of the O-arm intraoperative imaging and Stealth Station S8 surgical navigation system, provides three-dimensional images during surgery, offering a broader surgical view, more precise spinal assessments and accurate, stable screw placement paths. It helps avoid surrounding vital blood vessels and nerves, improving the precision and safety of pedicle screw insertion and reducing the risks of scoliosis surgery [15]. For vertebrae where pedicle screw placement is not possible, the lateral in-out-in pedicle screw technique can be used for deformity correction [7,9,16]. The in-out-in screw is inserted from the cortical bone projected by the pedicle, then the screw path is made close to the inner edge of the pedicle, exiting on the lateral side and entering the vertebral body. This technique ensures screw stability and avoids spinal canal penetration, preventing spinal cord nerve damage. In this study, a total of 216 pedicle screws were

placed, including 152 screws in the pedicle (70.4%) and 64 screws on the lateral side of the pedicle (29.6%). All screws were successfully placed on the first attempt. Intraoperative O-arm scanning showed that all screws entered the vertebral body close to the inner wall of the pedicle without penetrating the spinal canal, indicating that O-arm navigation-assisted surgery for congenital scoliosis helps improve screw placement accuracy, reduces spinal cord nerve damage and enhances safety.

Literature reported that the correction rate for kyphosis in congenital scoliosis was 48.1% to 57.5% and for scoliosis was 54.3% to 72% [5,14]. In this study, with a follow-up period of (28.0 ± 3.4) months, none of the 17 patients experienced spinal cord injury, cerebrospinal fluid leakage, incision infection, screw or rod loosening, displacement or fracture complications. At the final follow-up, all patients achieved Grade I fusion. The preoperative scoliosis Cobb angle and kyphosis Cobb angle were greater than those at 1 week and 1-year post-surgery. No significant differences were observed between the 1-week and 1-year postoperative measurements. The correction rates for scoliosis and kyphosis at 1-week post-surgery were comparable to those at 1-year post-surgery, with no significant differences. The preoperative SRS score was lower than the postoperative 1-week and 1-year scores and no significant differences were found between the 1-week and 1-year postoperative scores. These results suggest that the O-arm navigation system with lateral in-out-in pedicle screw insertion offers accurate fixation, strong stability, promotes patient recovery, reduces complications and provides good deformity correction outcomes. The reason for this is that the O-arm intraoperative imaging system can simulate three-dimensional and multi-planar images, plan the optimal surgical path and improve intraoperative efficiency. The Stealth Station S8 navigation system uses infrared optical principles to identify the instruments and reference markers in the surgical field, displaying their relative positions in the transverse, coronal and sagittal planes in real-time, guiding the surgical instruments to stay close to the inner wall of the pedicle for in-out-in screw placement.

Precautions for in-out-in pedicle screw insertion using the o-arm navigation system

- Carefully review CT and MRI images of the thoracolumbar pedicles before surgery, measuring the gap between the cortical bone of the pedicle, the inclination and inward angle of the pedicle and the relationship between the spinal cord and the inner wall of the pedicle.
- After the patient is under general anesthesia,



positioned appropriately and the spinous processes are exposed, install the reference frame. Then, use the O-arm to collect spinal skeletal data to avoid errors caused by position changes. Be cautious to ensure that the reference frame does not shift during the procedure, as this could cause discrepancies between the virtual anatomical structure and the actual anatomy.

- After collecting data with the O-arm, wait for 10 seconds before leaving the shielding panel to minimize X-ray exposure.
- The entry point for the In-Out-In screw is more lateral compared to traditional pedicle screws, located on the slope of the superior articular process edge. Increase the inward angle to increase the screw's insertion length, thus enhancing the screw's holding power.
- Under precise navigation, create the screw path close to the inner wall of the pedicle while ensuring the integrity of the inner pedicle wall. The screw length should be more than two-thirds of the vertebral body's length (but not exceeding the anterior cortical bone of the vertebral body).
- Use a burr to make an opening on the cortical bone, avoiding bone deformation that could cause image drift.
- After verifying the integrity of the pedicle's inner wall, to avoid difficulty in inserting the screw head into the vertebral body, the tapping should penetrate the distal vertebral body.
- Maintain the patient's tidal volume around 270 mL during surgery to reduce spinal movement.
- During the process of making the opening and placing the screw, place the probe at the tip of the spinous process to calibrate the accuracy of the screw placement tool, ensuring the precision of the navigation system.

Conclusion

The results of this study suggest that the O-arm navigation system-assisted internal fixation surgery for congenital scoliosis, using the In-Out-In screw technique on narrow anomalous pedicles, allows for safe screw placement with stable fixation, good deformity correction and few complications. However, the sample size of this study is small and no comparison was made with traditional C-arm fluoroscopy-assisted manual screw insertion. Further studies are needed to confirm these findings.

Acknowledgements

Not Applicable

Declarations

Consent to Publish Declaration: This manuscript includes details, images or videos relating to individual participants. Consent to publish has been obtained from all individuals involved in the study. All identifiable information has been removed or anonymized to protect participant privacy. All patients participating in this study, along with their guardians, have signed informed consent forms, granting permission for their participation in the study and the provision of relevant clinical data. The parents or legal guardians of all minor patients have signed written consent forms, granting permission for the publication of clinical details and/or clinical images.

Clinical trial number

Not applicable.

Ethical approval

The study was approved by the Luo Center Hospital of the Ethics Committee, under approval number (LH-KY-2022-001-036). All procedures followed were in accordance with ethical standards and the Declaration of Helsinki.

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Conflict of interest

The authors declare that there are no conflicts of interest regarding the publication of this paper.

Authors' contributions

Shifeng Gu, Wei Cui and Yan He analyzed data and prepared tables, Yuwei Li, Xiu-Zhi Li and Zimin Wang wrote the main manuscript text and prepared figures. Zimin Wang serves as the corresponding author of this manuscript. The corresponding author and the first authors contributed equally to this work. All authors read and approved the final manuscript.

Data availability

All data generated or analyzed in this study were included in this article. Due to patient privacy concerns, the patient identity data set for this study is not publicly available. For further information, researcher can contact the corresponding author at Email: orth301wzm@126.com



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