CLINICAL ARTICLE

Risk Factors for the Drift Phenomenon in O-arm Navigation-Assisted Pedicle Screw Placement during Spinal Deformity Surgery

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Objective: Intraoperative O-arm navigation systems improve the accuracy of spinal instrumentation placement. However, deviation of the pedicle screw from the guide line might occur. The aim of the present study was to explore the causes of and countermeasures for the drift phenomenon during pedicle screw implantation with the aid of an O-arm three-dimensional navigation system in spinal deformity surgery.

Methods: This was a retrospective analysis of 341 patients with spinal deformity who underwent O-arm navigation system-assisted pedicle screw placement from July 2015 to June 2019. The patient's general condition, Cobb angle, apical vertebra position, softness index, spinal release status, fixed reference frame position, and distance between the navigation vertebral body and the reference frame were collected and compared by independent-samples *t* test or Pearson's chi-square analysis. The potential risk factors for the drift phenomenon were identified using binary logistic regression analysis.

Results: The drift phenomenon occurred in 57 patients during the first navigation-assisted pedicle screw placement, for an incidence of 16.7% (57/341). There were significant differences in factors such as the apical vertebra position, softness index, spinal release status, and distance between the vertebral body and the reference frame when the drift phenomenon occurred ($P < 0.05$). Binary logistic regression analysis showed that the softness index, spinal release status, and distance between the vertebral body and the reference frame when drifting occurred were independent risk factors for the drift phenomenon during O-arm navigation-assisted pedicle screw placement.

Conclusion: During the use of an O-arm navigation system to assist with pedicle screw placement, pedicle screws should not be placed away from the reference frame, and spinal osteotomy and release should be performed after pedicle screw placement. In addition, the accuracy of O-arm navigation-assisted pedicle screw placement will be affected more in those with larger softness indices.

Key words: Deformity; Drift phenomenon; Navigation; O-arm; Pedicle screw

Introduction

Since 1969, posterior pedicle screws have been widely used in spinal surgery due to their strong fixation effect and excellent biomechanics.[1] However, due to the proximity to major blood vessels and nerve tissues, deviations in pedicle screw placement may cause catastrophic neurological and vascular complications.[2] In addition, improper screw placement may affect the biomechanical strength of the implant. Screw pull-out may occur during orthopedic manipulations or reduction, and correction may be lost during

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follow-up. Especially in adolescents with pedicle dysplasia and severe spinal deformity, the precise placement of pedicle screws presents great challenges.

Navigation technology that has emerged in recent years can significantly improve the accuracy of screw placement during spinal deformity surgery.[3] Based on the intraoperative use of an O-arm-based navigation system, the convenience and accuracy of pedicle screw placement under navigation is further improved, and many studies have reported that O-arm navigation has increased the accuracy of intraoperative pedicle screw placement compared with traditional C-arm fluoroscopy navigation.[4–7] However, we found that patients with spinal deformity showed abnormal vertebral body development, even when the pedicle screws were implanted with the aid of O-arm navigation, which is not satisfactory. After excluding systematic errors and misuse, we named the phenomenon where the pedicle screw deviates from the guide line during O-arm navigation-assisted pedicle screw placement the drift phenomenon. At present, there have been few studies exploring the related risk factors for deviation during O-arm navigation, and there have been no reports related to the drift phenomenon.[4]

Therefore, we retrospectively analyzed the process and results of pedicle screw placement under O-arm navigation during spinal deformity surgery at our hospital and explored the causes of the drift phenomenon and related risk factors during screw placement. We assumed that the characteristics of the spinal deformity (such as the Cobb angle, apical vertebra position, and softness index), operation protocol (spinal release status, i.e., whether the spine has been released before screw placement) and O-arm position (such as the fixed reference frame position and the distance between the navigation vertebral body and the reference frame) might affect the accuracy of instrumentation placement.

The objectives of this retrospective study were as follows: (i) elucidate the incidence of the drift phenomenon in O-arm navigation-assisted pedicle screw placement during spinal deformity surgery; (ii) identify the potential risk factors for the drift phenomenon; and (iii) make recommendations for avoiding this phenomenon.

Materials and Methods

Inclusion and Exclusion Criteria

Ethics approval (2019CZH078-5443) for the present study was obtained from the ethics committee. The following inclusion criteria were used: (i) scoliosis with a Cobb angle greater than 50° in the main curve; (ii) thoracic or lumbar pedicle screw implantation performed with intraoperative O-arm assistance; and (iii) complete preoperative and postoperative X-ray and CT scans of the total spine. Cases in which CT showed that the pedicle was too thin or hypoplastic to accommodate pedicle screws were excluded.

General Information

A retrospective analysis of patients with spinal deformity who underwent treatment with an intraoperative CT scanning system (O-arm; Medtronic) combined with an intraoperative navigation system (Stealth Station; Medtronic, Minneapolis, MN, USA) for assisted pedicle screw placement at Shanghai Changzheng Hospital from July 2015 to June 2019 was performed. This study finally included 341 patients, including 106 males and 235 females, with an average age of 21.2 ± 17.5 years (5–63 years). The preoperative Cobb angle of the main scoliosis curve was 76.5° ± 11.7° (50°–117°). All operations were performed by two senior spinal surgeons with at least 15 years of experience in spinal surgery who were also very familiar with performing O-arm-assisted pedicle screw placement.

Surgical Methods

During the operation, the patient was in the prone position on a Jackson table, and intraoperative neuromonitoring (Cadwell Laboratories, Kennewick, WA, USA) was used to monitor neural integrity. After routine sterilization and draping, the incision was created along the midline of the back. The navigation operation tool was registered, and the navigation reference frame was stably fixed on the caudal or rostral spinous process of the vertebral body to be navigated. After the target segment was determined by O-arm 2D fluoroscopy(Medtronic, Minneapolis, MN, USA), the scanning parameters were set to 200 mAs and 80 kV for the first intraoperative O-arm 3D scan. After scanning, the data were transmitted to the Stealth Station system. The navigation probe was used to select the screw entry point; then, the pedicle of the target vertebral body was opened and explored with a pedicle ball scout. The actual implant depth and width of the screw were determined based on real-time prompts from the navigation system to fit the screw into the pedicle. After all screws were placed, an intraoperative scan was performed with the O-arm to assess the position of the screws.

Drift Phenomenon and Corresponding Treatment

The pedicle screw track was prepared using a circuit opener with a positioning ball according to the pedicle guide line of the navigation system, followed by the insertion of a pedicle ball scout to confirm the integrity of the pedicle wall. The deviation of the pedicle screw guide line from the true pedicle was defined as "drift" after errors and inaccuracies in use were excluded. That is, the screen navigation guide line was in the pedicle, but the pedicle ball scout indicated damage to the pedicle wall (Fig. 1). If it was determined that the drift phenomenon occurred, we recorded the vertebral body, the distance of the segment from the reference frame, and the general condition of the patient. The occurrence of the drift phenomenon during navigation indicated that the intraoperative navigation data of the previous O-arm scan were inaccurate. Therefore, the O-arm scan was performed

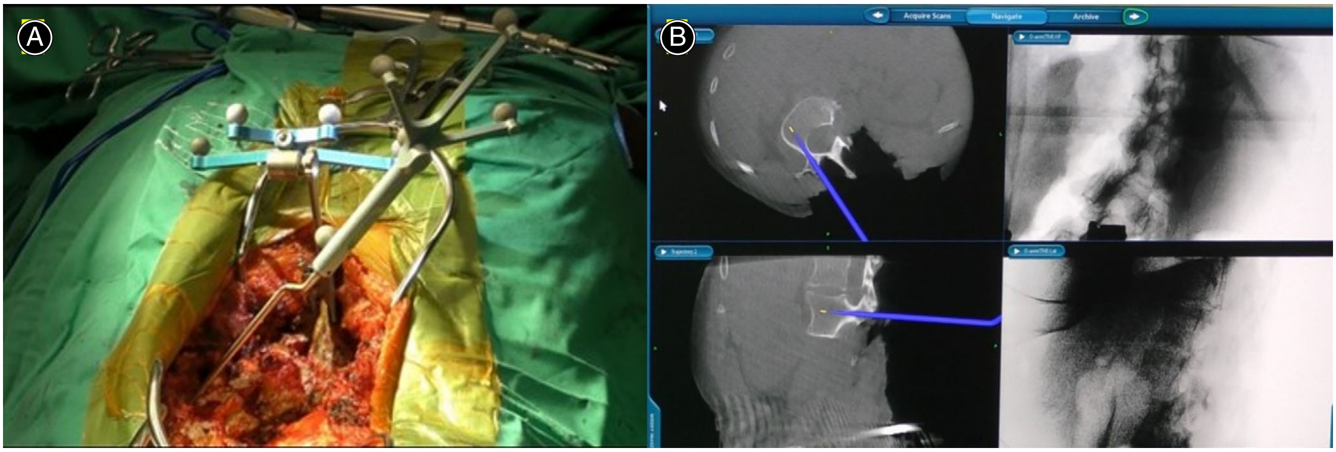

Fig. 1 The navigation probe on the left (A) is not within the pedicle; the navigation probe on the right (B) is within the pedicle

again to confirm that the drift phenomenon was eliminated before continuing to place the pedicle screw under navigation guidance.

Statistical Analysis

The mean and standard deviation were calculated for continuous variables, and frequencies and percentages were calculated for categorical variables. For comparisons between the two groups, an independent-samples *t* test was used for continuous variables, and Pearson's chi-square analysis was used for categorical variables; $P < 0.05$ was considered to indicate a statistically significant difference. Independent variables with statistical significance in the first univariate analysis were included in the binary logistic regression ($P < 0.05$). Processing of independent variables was performed as follows: The index was divided into two levels for assignment and quantification. If the apical vertebra was located in the thoracic spine, the softness index was less than 25%, the screw was installed and before spinal release, and the distance between the target vertebra and the reference frame was 1–2 segments, a value of 0 was assigned. A value of 1 was assigned when the softness index was ≥25%, the screw was placed after spinal release, the position of the apical vertebra was in the lumbar spine, or the distance between the target vertebra and the reference frame was ≥3 segments. Dependent variable processing was performed as follows: the drift phenomenon was divided into two levels for quantification. If there was no drift phenomenon, a value of 0 was assigned, and if the drift phenomenon was observed, a value of 1 was assigned. Binary logistic regression was then performed to identify risk factors associated with the occurrence of the drift phenomenon. Statistical analysis was performed with SPSS statistical software version 25.0, (SPSS, Inc., Chicago, IL, USA). The study was approved by the hospital ethics committee, and informed consent was obtained from the patients.

TABLE 1 Risk factors for the drift phenomenon when using O-arm navigation-assisted screw placement during spinal deformity surgery

	Drift phenomenon			
	Yes (n = 57)	No (n = 284)	X^2	*P*
Sex				
Male	19	87		
Female	38	197	0.161	0.754
Age				
<50	17	71		
≥50	40	213	0.577	0.507
Cobb angle				
<70	21	126		
≥70	36	168	0.710	0.464
Apical vertebra position				
Thoracic vertebrae	35	173		
Lumbar vertebrae	22	111	0.005	0.945
Softness index				
<25%	14	164		
≥25%	43	120	20.952	0.000
Loosening condition				
Screw first and then release	11	134		
Release first and then screw	46	150	15.103	0.000
Fixed position of the reference frame				
Rostral	42	198		
Caudal	15	86	0.358	0.635
Distance between the navigation vertebral body and the reference frame				
1–2	13	169		
≥3	44	114	25.984	0.000

Results

General Results

The drift phenomenon occurred in a total of 16.7% (57/341) of scoliosis patients during intraoperative navigation-assisted

TABLE 2 Binary logistic regression analysis of the drift phenomenon

	Comparison	Odds ratio	95% CI	P value
Softness index	≥25%	5.267	1.593–13.356	0.008
Loosening condition	Release first and then screw	3.036	1.012–7.060	0.004
Fixed position of the reference frame	≥3	1.400	1.063–1.845	0.017
Apical vertebra position	Lumbar vertebrae	3.178	0.889–11.361	0.075

pedicle screw placement, including 19 males and 38 females, aged 5–53 years (22.5 ± 15.2 years).

Univariate Logistic Regression Analysis

Univariate analysis showed no significant differences in sex, age, Cobb angle of scoliosis, or reference frame position between the two groups ($P \geq 0.05$), but there were significant differences in the apical vertebra position, softness index, spinal release status, and distance between the vertebral body and the reference frame when drift occurred ($X^2 = 25.984$, $P < 0.05$, Table 1).

Binary Logistic Regression Analysis

Binary logistic regression analysis was carried out on the position of the apical vertebra, softness index, spinal release status, and distance from the vertebral body to the reference frame when drift occurred. The results showed no significant difference according to the position of the apical vertebra (thoracic or lumbar spine) (OR = 3.178, [95% CI, 0.889–11.361], $P = 0.075$). However, significant differences were found for a softness index ≥25% (OR = 5.267, [95% CI, 1.593–13.356], $P = 0.008$), screw placement performed after spinal release (OR = 3.036, [95% CI, 1.012–7.060], $P = 0.004$), and a distance between the target vertebral body and reference frame ≥3 segments (OR = 1.400, [95% CI, 1.063–1.845], $P = 0.017$), indicating that these were risk factors for drift in O-arm navigation-assisted screw placement during spinal deformity surgery (Table 2).

Complications

Perioperative complications occurred in 17 patients; two patients experienced the transient disappearance of somatosensory evoked potentials (SEPs) and motor evoked potentials (MEPs) during surgery, and one patient experienced postoperative paresthesia and movement disorders in both lower extremities. This patient's muscle strength returned to grade 4 at the follow-up 3 months later. Additionally, minor trunk displacement occurred in six patients.

Discussion

In our study, the incidence of the drift phenomenon in O-arm navigation-assisted pedicle screw placement in scoliosis surgery was 16.7%. The softness index, spinal release status, and distance between the vertebral body and the reference frame when drift occurred were identified as independent risk factors for the drift phenomenon.

Challenge of Manual Pedicle Screw Placement

Techniques for spinal surgery have advanced tremendously during the past few decades. This technical progress has led to many changes in the understanding of the spinal anatomy, but the accurate placement of pedicle screws during orthopedic surgery remains challenging due to abnormal pedicle development in patients with scoliosis.[8,9] Previous studies have reported a pedicle screw misplacement rate of 31.5% in manual manipulation.[10] A good postoperative radiological view might not always show acceptable results.[11] Pedicle screw misplacement not only carries the risk of potential complications, such as nerve, blood vessel, and organ damage, but also results in reduced pull-out strength, increasing the chance of implant and surgical failure.[12]

Drift Phenomenon in O-Arm Navigation

Over the past 20 years, the development of intraoperative navigation devices and techniques has improved the safety of surgery for complex spinal deformities. A large number of studies have reported that in conventional thoracolumbar surgery, compared with traditional freehand screw placement, the accuracy of intraoperative pedicle screw placement has been improved with O-arm intraoperative navigation technology. However, studies have reported pedicle screw implantation failure rates of approximately 4–10%, even with the assistance of navigation.[13,14] In a meta-analysis of more than 8000 pedicle screws, the risk of perforation was 6% for pedicle screws placed with navigation and 15% for screws placed manually.[15] Jin *et al.* found that in neurofibromatosis scoliosis surgery in patients with poorly developed spinal pedicles, the accuracy of using O-arm navigation to place pedicle screws was significantly better than that of the freehand technique.[16] Rivkin *et al.* reported a 5.3% pedicle breach rate in patients who underwent thoracolumbar pedicle screw fixation with the O-arm imaging system in conjunction with Stealth Station navigation and a 13.21% rate in the 30 patients over the initial 6 months postoperatively.[17] Jin *et al.* found that the overall malpositioning rate of pedicle screws was 9.8% in scoliosis surgery assisted by O-arm navigation.[18] In our study, 16.7% (57/341) of patients experienced drift during pedicle screw implantation. After the intraoperative detection of drift, we immediately performed another O-arm scan and re-established the reference frame to prevent drift-induced pedicle screw misplacement. Therefore, the incidence of navigation-assisted pedicle breach in our study was 1.7% (43/2512), which is lower than that reported in other studies. The main reason for the occurrence of pedicle breach was considered to be a change of direction when screwing in the pedicle screw, which broke the originally prepared intact screw channel.

Risk Factors for the Drift Phenomenon

Thoracic movement caused by the patient's breathing, limitations of the accuracy of the navigation instrument itself, and deviation of the signal transmission between the O-arm and the navigator will cause errors in screw placement.[19] During the operation, we found that even if the standard operation was completely followed and the screwtrack was guided by the navigation system, there was still a phenomenon in which the guide line deviated from the real pedicle after exploration. A review of the literature revealed that such phenomena are rarely reported, and no one has conducted in-depth and systematic research on their causes.

This study showed that the distance between the target vertebral body plane and the reference frame was closely related to occurrence of the drift phenomenon during navigation. One reason may be that the vertebral bodies of the spine are connected by intervertebral discs, and the elasticity of the intervertebral discs gives the spine a certain flexibility. When the patient is anesthetized and treated with muscle relaxant drugs, the mobility of the spine will increase without the support of the muscles, and the spine will be more deformed away from the reference frame after force is applied during the operation. In addition, Rivkin *et al.* found that when the reference frame and the target vertebral body for navigation are in close proximity, the likelihood of accidental contact between the reference frame and the surgical instrument increases, and such contact may affect the surgical operation and the view of the image-guided instrument or reduce the accuracy of the navigation system.[17]

Any changes in the anatomy of the spine will cause an inconsistency between the navigational image and reality. In scoliosis surgery, release of the posterior column of the spine is required to obtain good deformity correction. According to the surgeon's operating habits, the sequence of pedicle screw placement and release may vary. This study showed that in the case of spinal release before screw placement, the relative range of motion of the vertebral body increases, as does the relative displacement between the vertebral body and the reference frame, which leads to inaccurate navigation. Therefore, we recommend that the pedicle screw track be prepared and the screw placed under O-arm guidance after the appropriate position to fix the reference frame is selected and the navigation device is registered, rather than performing decompression, reduction, and intervertebral disc placement, including operations such as resection and spinal release, before screw placement.

With the deepening of the theoretical understanding of scoliosis, preoperative standing and supine bending films can be used to evaluate the spinal flexibility of patients with scoliosis in terms of the softness index, which has become the "gold standard" for evaluating spinal flexibility in scoliosis.[20] The softness index is determined by subtracting the bending Cobb angle from the standing Cobb angle and then dividing by the standing Cobb angle. When the softness index is less than 25%, the spine is considered rigid. The larger the index is, the more flexible the spine, which is convenient for intraoperative correction and derotation operations. However, at the same time, the spine is easily deformed by external forces, resulting in the drift phenomenon during intraoperative navigation. Our study confirmed that the drift phenomenon occurred in a significantly higher proportion of patients with a softness index greater than 25% than patients with a softness index less than 25%, indicating that patients with good spinal flexibility have greater spinal mobility under the action of external forces and are more likely to develop relative displacement between the reference frame and the target vertebral body, affecting the accuracy of O-arm navigation-assisted screw placement.

Recommendations for Avoidance of Drift

In addition to the above possible independent risk factors, some operators' habits may affect the accuracy of O-arm navigation, resulting in the artificial drift phenomenon. First, due to the long incision in scoliosis surgery, the position of the spreader needs to be adjusted for O-arm scanning as the surgery proceeds. Respreading may cause relative displacement of the spine, and the edge of the incision may accidentally touch the reference frame and cause displacement, affecting the accuracy of navigation for pedicle screw placement. Therefore, we recommend not moving the spreader as much as possible after spreading to avoid inaccurate navigation caused by displacement of the reference frame. Second, when the pedicle is thin and the patient's bone is sclerotic, the operator must use a large force to insert the circuit opener or screw, thereby causing a large deviation in the position of the navigation instrument. In this case, we recommend the following steps after each pedicle screw is screwed in a certain distance: loosen the operating instrument to allow the spine to assume a natural state; observe whether the navigation position is good with the spine in the natural state; and try to avoid observing the navigation position with the spine in a state of stress to reduce the chance of error. In addition, due to respiration, the spine will move vertically somewhat, especially in the thoracic region. This movement will generate artifacts during scanning, which may cause navigation errors. Since the scan time is only 15–20 s, it is recommended to terminate breathing movement during the O-arm positioning scan to try and avoid the deviation caused by the patient's breathing movement. Because the O-arm cannot provide real-time navigation, O-arm scanning needs to be repeated in the above situations, which increases intraoperative radiation and prolongs the surgical process.

Limitations and Strengths

The clinical significance of this study is to emphasize the drift phenomenon in O-arm navigation during scoliosis surgery. This study found that during intraoperative navigation operations, the softness index, loosening condition, and distance between the vertebral body and the reference frame were found to be associated with screw misplacement due to drift during navigation. Therefore, it is important to clearly identify the anatomical structures intraoperatively and avoid the above-mentioned causes of drift. Repeated scan and re-establish of the reference frame after intraoperative detection of drift might be needed to reduce the misplacement of pedicle screws.

This was a retrospective single-center study with a limited sample size. All procedures were performed by two surgeons at different times; thus, the results may be affected by the preference and experience of the surgeons. In addition, our study only focused on the causes of the "drift phenomenon" as identified during screw implantation and on postoperative radiological examination. Clinical outcomes, such as chronic postoperative pain, disability, and the ability to return to work, are also important but were not evaluated in this research. To overcome these limitations, large-scale, prospective, multicenter controlled cohort studies should be carried out to fully investigate the intraoperative drift phenomenon and its correlations with postoperative quality of life.

Conclusion

For patients with complex and severe deformity, intraoperative O-arm navigation technology can be used to achieve faster and more accurate pedicle screw placement. However, the accuracy of navigation-assisted pedicle screw placement has not reached 100%, and various errors or deviations may occur during the operation. Therefore, in the process of screw implantation, it is necessary to identify anatomical landmarks, not rely solely on navigation, and not operate blindly when the navigation view does not match the anatomical landmarks. At the same time, during the operation, risk factors including the softness index, spinal release status, and distance between the vertebral body and the reference frame that may cause the drift phenomenon should be eliminated as much as possible to make better use of the advantages of O-arm navigation-assisted pedicle screw placement technology and improve the accuracy of the operation.

Author Contributions

All authors have contributed significantly to this study. Jianquan Zhao, Heng Jiang and Yingjie Zhuge had directly participated in the planning and execution of the study and were the major contributors in drafting the manuscript. Rui Gao and Ce Wang had reviewed the patients' medical record and collected the clinical data. Jun Ma and Xuhui Zhou had designed the study and revised the manuscript critically. All authors read and approved the final draft of the manuscript.

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