

Placement of pedicle screws using three-dimensional fluoroscopy-based navigation in lumbar vertebrae with axial rotation

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Abstract Despite potential advantages of three-dimensional fluoroscopy-based navigation, there still remain a lot of controversies about the indications of this technology, especially whether it is worthy of being used in placement of pedicle screws in lumbar spine. However, according to the inconsistent conclusions reported in the literature and our experiences, the traditional method relying on anatomical landmarks and fluoroscopic views to guide lumbar pedicle screw insertion is unable to meet the requirement of precise screw placement. Based on our observation, screw malposition seems to occur concomitant with vertebral axial rotation which is a ubiquitous phenomenon. Three-dimensional fluoroscopy-based navigation can provide the most valuable axial images in real-time, so it may be useful for placement of pedicle screws in lumbar spine. This study was intended to evaluate the effect of axial rotation of lumbar vertebrae on the accuracy of pedicle screw placement using the traditional method, as well as assess the value of three-dimensional fluoroscopy-based navigation in improving the accuracy. Sixteen lumbar simulation models at different degrees of axial rotation (0° , 5° , 10° , and 20°), with every four assigned the same degree, were equally divided into two groups (traditional method group and three-dimensional fluoroscopy-based navigation group). Random placement of pedicle screws was carried out, followed by CT scan postoperatively. Then the outer pedicle cortex contours were depicted from reconstructed sectional pedicle images using Photoshop. The accuracy of pedicle screw placement was evaluated by determining the

interrelationship between screw trajectory and pedicle cortex (quality), and measuring the shortest distance from pedicle screw axis to outer cortex of the pedicle (quantity). Eighty pedicle screws were implanted, respectively, in each group. In traditional method group, statistical difference existed in the accuracy of pedicle screw placement at different axial rotational degrees ($P < 0.05$). With degrees increasing, the accuracy declined. The accuracy of three-dimensional fluoroscopy-based navigation group was higher than traditional method group in vertebrae with axial rotation ($P < 0.01$). In qualitative evaluation, the accuracy of the two methods had statistical difference when the degree was 20° , and in quantitative evaluation, statistical difference existed in 5° , 10° , and 20° of vertebral axial rotation.

Keywords Lumbar spine · Pedicle screw · Vertebral rotation · Three-dimensional fluoroscopy-based navigation · Accuracy

Introduction

Since Amiot [1] first described pedicle screw fixation using a computer navigation system in 1995 this technology has dramatically developed in the following years. After the era of CT-based navigation and two-dimensional fluoroscopy-based navigation, three-dimensional fluoroscopy-based navigation system was introduced to spine surgery in recent years. With the advantages of obtaining intraoperative real-time images, automatic registration and three-dimensional navigation, three-dimensional fluoroscopy-based navigation is thought to be a very promising technology to improve surgical accuracy and reduce the complications.

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Despite the potential advantages of three-dimensional fluoroscopy-based navigation, there still remain a lot of controversies about the indications of this technology. Most spinal surgeons tend to accept this system in cervical and thoracic spine owing to high risk in these regions, whereas its value in lumbar spine has been questioned. Some surgeons believe that there is no need to use navigation system for pedicle screw placement in lumbar spine because pedicles are large enough to guarantee accuracy and safety. But the fact is, in clinical practice, we still found that screw malposition occurred at times in lumbar spine using traditional method, which will reduce the biomechanical stability and increase the risk of neurovascular complications. Careful study of preoperative CT or MRI of these patients reveals that, in most cases, vertebral axial rotation exists. To our knowledge, vertebral axial rotation is a ubiquitous phenomenon [24], so three-dimensional fluoroscopy-based navigation which can provide the most valuable axial images in real-time may be very useful for accurate placement of pedicle screws in lumbar spine.

This study was conducted to evaluate whether vertebral axial rotation and its extent have any impact on the accuracy of pedicle screw placement in lumbar spine, as well as whether three-dimensional fluoroscopy-based navigation can improve the accuracy in this condition, so as to reveal its value in lumbar spine.

Materials and methods

16 whole simulation lumbar spine models (Sawbone[®], Pacific Research Laboratories, Inc.) made up of high-resolution foam cortical shell with cancellus were used for this study.

The equipment of three-dimensional fluoroscopy-based navigation consists of a modified C-arm CT system (Arcadis Orbic 3D; Siemens, Medical Solutions, Erlangen, Germany), a workstation with navigation software (The Stryker[®] Spine Navigation System, version 1.2) and specific instruments (patient tracker, pointer, pedicle awl, pedicle probe) equipped with light-emitting diodes and tracked by an optoelectronic three-dimensional motion measurement system (also known as the sensor array or the camera).

Model preparation

A modeling holder and three wedges with different degrees (5°, 10°, and 20°) were made to maintain simulation lumbar spine models at certain degrees of axial rotation (Fig. 1). They are all radiolucent to optimize image quality and minimize artifact.

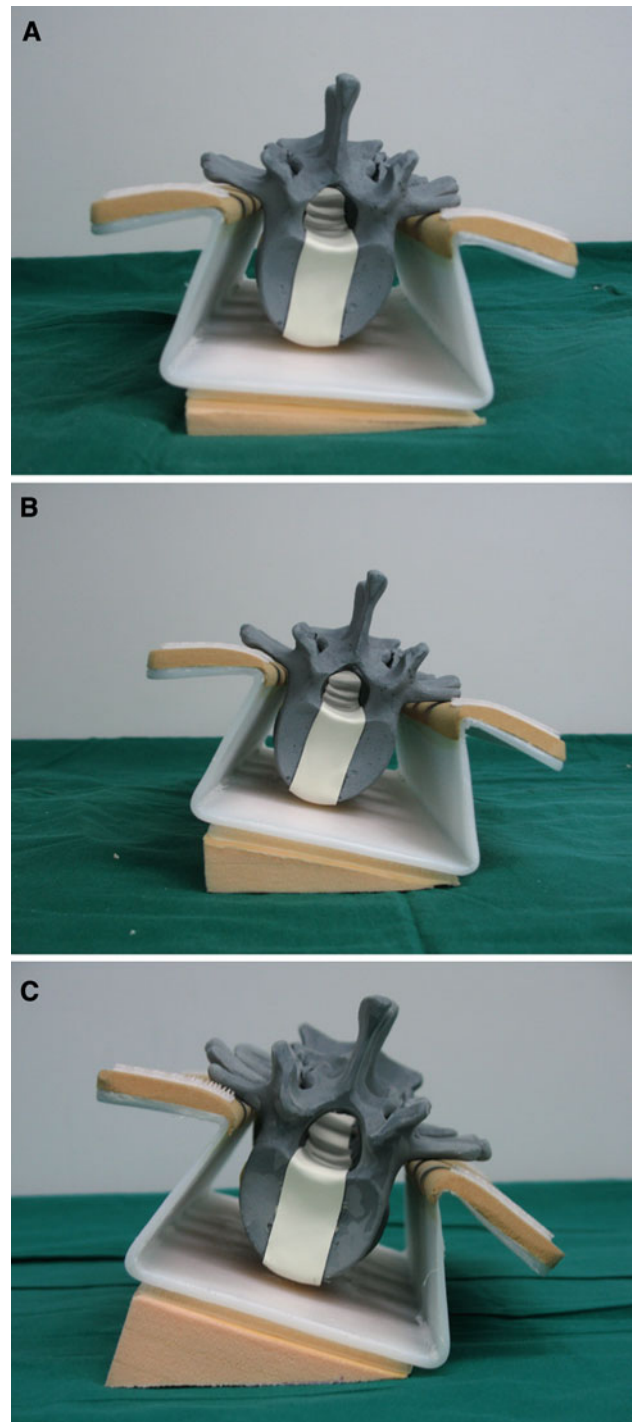


Fig. 1 Pictures showing the simulation lumbar spine models were maintained at certain degrees of axial rotation by a radiolucent holder and wedges with given grades (5°, 10° and 20°)

16 whole simulation lumbar spine models were assigned randomly into two groups: eight models to traditional method group and the others to three-dimensional fluoroscopy-based navigation group. And then eight models in each group were further assigned randomly into four sub-groups which correspond to different degrees of axial

rotation (0° , 5° , 10° , and 20°), ensuring each subgroup consists of two models with one rotating to the right and the other to the left. An electronic random number generator was used to create a random sequence of numbers from 1 to 160, which ensures that 160 pedicles in our study were given different values. This number sequence identified the order of screw placement.

Each simulation lumbar spine model was embedded with sponge by an assistant, with both transverse processes completely covered; only exposing the same operative field as in clinical practice. The model with its holder was firmly fixed on the radiolucent carbon operating table by adhesive tape and draped to ensure the rotational degree and direction unknown to the operator (Fig. 2).

Surgical technique

All lumbar pedicle screws (6-mm diameter, 45-cm length, USS, Synthes, Paoli, PA) were placed by an operator using either traditional method or three-dimensional fluoroscopy-based navigation according to the random sequence.

Traditional method

The operator predicted entry point and direction on the basis of preoperative anteroposterior and lateral fluoroscopic images, inserted a tag pin after successful drilling, and then placed the pedicle screw. Intraoperative fluoroscopy was allowed only once for each pedicle after inserting the tag pin, and the operator was permitted to adjust screws as he thought necessary according to the intraoperative judgment and fluoroscopic images.

Three-dimensional fluoroscopy-based navigation

The operator fixed patient tracker on the spinous process of assigned vertebra, and the assistant positioned the sensor array to make the instruments localize in the middle of the sensor array's working volume. During three-dimensional

image acquisition with the Orbic, the motorized C-arm moved continuously around 190° . During the rotation, 100 fluoroscopic projection images were acquired at equidistant angles. Subsequently, a high resolution three-dimensional image data set was reconstructed. The three-dimensional images obtained was then transferred to the navigation workstation and registered automatically. The operator placed pedicle screws under the guidance of three-dimensional fluoroscopy-based navigation (Fig. 3). In situations wherein the operator disagreed with the image guidance system on the position or trajectory of the screw, the operator was instructed to use the position indicated by the image system.

After each screw had been placed in the model, the assistant removed it and filled the screw trajectory with bone wax before the operator instrumented the same model. The operator was not allowed to observe the model preparation, examine the screw trajectories, and be involved in data collection or data analysis.

Image processing

After all screws had been placed and removed, CT scans (L1–L5) were obtained with slice thickness 5 mm. Then CT volume data was imported into navigation workstation and three-dimensional images of lumbar spine were reconstructed. In 'Screw Planning' program, the simulating screws were placed along with screw trajectories. After that, a series of parallel sections perpendicular to the axis of the screw were automatically acquired with slice thickness 1.5 mm. The pedicle images were picked out and imported into Photoshop CS 8.0 software in order to depict the contours of outer pedicle cortex in different sections. All the contour lines were then projected on the same plane and concentric circles were made with axis of the simulating screw being the center until a circle intersected with the innermost contour line (Fig. 4). The radius of this circle is the shortest distance from pedicle screw axis to the outer cortex of the pedicle.

Fig. 2 Picture showing a model was embedded in the sponge with both transverse processes completely covered, followed by fixation on an operating table and draping

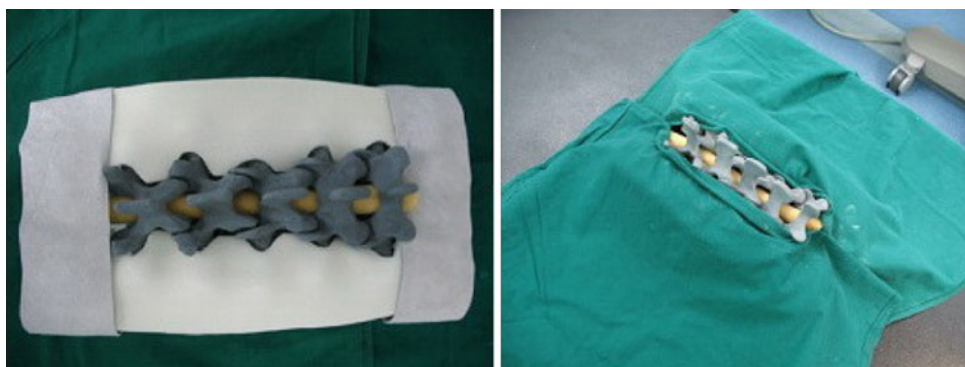


Fig. 3 Image from three-dimensional fluoroscopy-based navigation system showing pedicle screw placement in lumbar spine was guided by images of axial, sagittal, and coronal planes

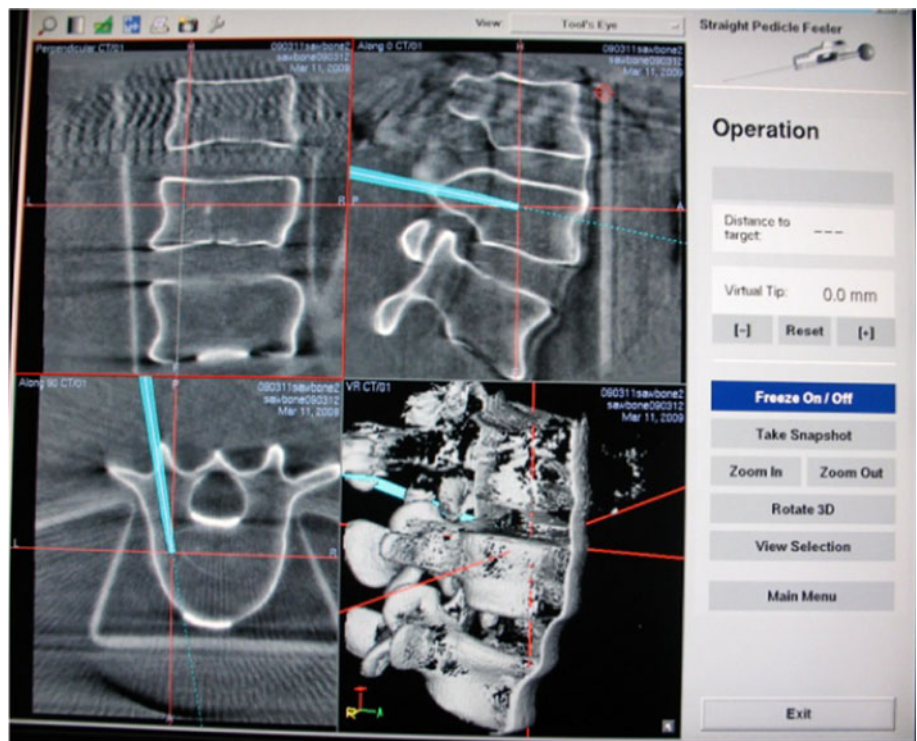
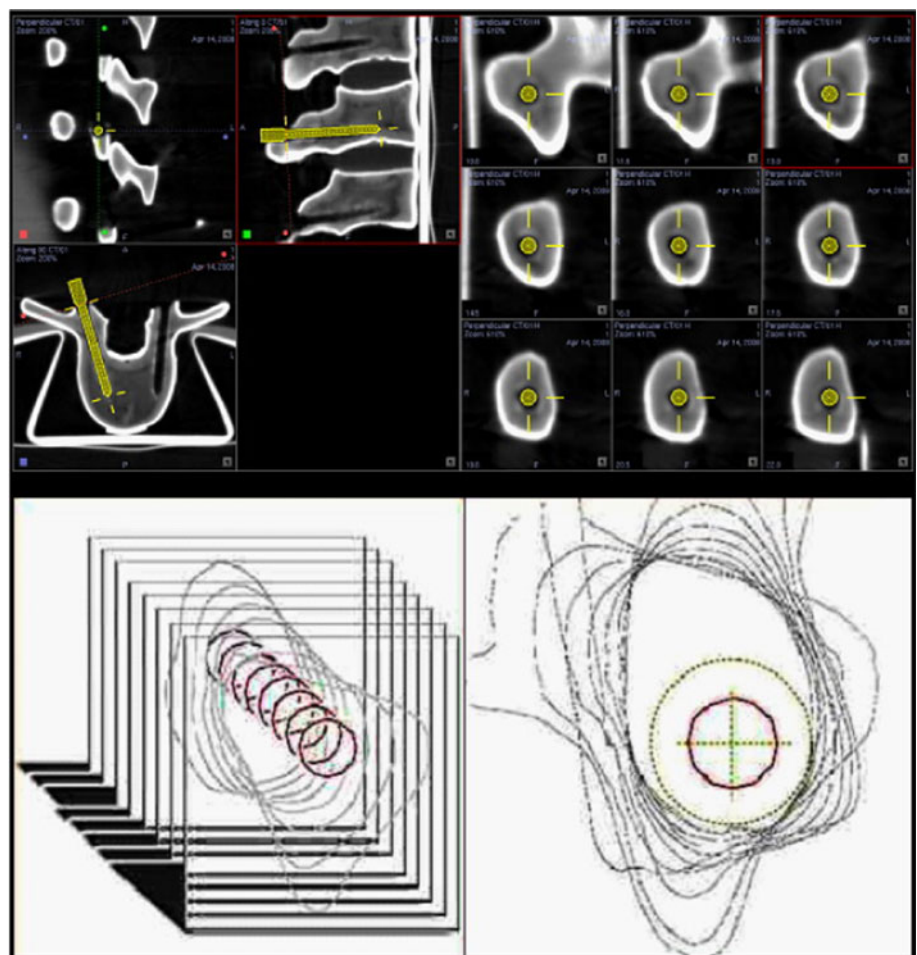


Fig. 4 Illustration showing the process of measuring the shortest distance from pedicle screw axis to the outer cortex of the pedicle. The radius of the circle intersected with the innermost contour line is the shortest distance



Accuracy of screw position judgment

Qualitative evaluation

CT images of all models were visually inspected by one independent observer. Screw position was classified into two categories on the basis of the following definitions.

Perfect Screw	The screw trajectory is completely contained within the cortical margins of the pedicle and vertebral body.
Perforating Screw	The screw trajectory partially or completely perforates the cortical margins of the pedicle or vertebral body.

Quantitative evaluation

One month later, the same independent observer was asked to measure the shortest distance from pedicle screw axis to the outer cortex of the pedicle.

Statistical analysis

Fisher's exact test in qualitative evaluation and one-way ANOVA in quantitative evaluation were used, respectively, to determine whether vertebral axial rotation has any effect on the accuracy of pedicle screw placement in lumbar spine using traditional method.

To investigate whether difference exists in qualitative and quantitative evaluation between traditional method and three-dimensional fluoroscopy-based navigation at different degrees of vertebral axial rotation, Fisher's exact test and independent-samples *t* test were used, respectively. Statistical significance was set at $P < 0.05$.

Results

A total of 160 pedicle screws were inserted in the 16 whole simulation lumbar spine models, with 80 screws assisted by three-dimensional fluoroscopy-based navigation and the others by traditional method. At each assigned degree of vertebral axial rotation (0°, 5°, 10°, and 20°), 20 screws were placed under the guidance of each method.

Qualitative evaluation

Perforations occurred in eight pedicles in traditional method group (10%), of which three occurred at 10° of vertebral axial rotation, while the other five occurred at 20°. Among the eight perforating pedicle screws, one screw penetrated the anterior cortex of the vertebral body

(occurred in L5 at 10° of vertebral axial rotation), while the rest of seven screws breached the medial pedicle cortex. In the three-dimensional fluoroscopy-based navigation group, there was no perforation (0%).

In traditional method group, we found that there was statistical difference in accuracy of pedicle screw placement at different degrees of vertebral axial rotation ($P = 0.017$). The accuracy showed negative linear correlation with the degrees of axial rotation ($r = -0.8$, $P = 0.002$).

Compared with traditional method group (90%), three-dimensional fluoroscopy-based navigation group (100%) demonstrated higher accuracy ($P = 0.007$). Regarding each assigned rotational degree, we found no difference between the two study groups except 20° of vertebral axial rotation ($P = 0.047$).

Quantitative evaluation

The shortest distance from pedicle screw axis to the outer cortex of the pedicle was used to evaluate the accuracy. In traditional method group, the values were, respectively (5.7 ± 0.9 mm, 5.5 ± 1.0 mm, 5.1 ± 1.6 mm, and 4.4 ± 2.2 mm) at 0°, 5°, 10°, and 20° of vertebral axial rotation. Statistical difference was revealed among them ($F = 2.761$, $P = 0.048$). Linear regression analysis showed that there was negative linear correlation between the degrees of axial rotation and the shortest distance ($r = -0.313$, $P = 0.002$). The regression equation was $y = -0.066x + 5.750$ ('*x*' stands for the degree of axial rotation, '*y*' stands for the shortest distance).

The shortest distance in traditional method group was (5.2 ± 1.6 mm) and the value was (6.0 ± 0.8 mm) in three-dimensional fluoroscopy-based navigation group. Again, the navigation group demonstrated higher accuracy than traditional method group ($t = -4.097$, $P = 0.000$). We used independent-samples *t* test to compare the shortest distance at different assigned rotational degrees in two study groups. The details are shown in Table 1. The results represented statistical difference when the degrees of vertebral axial rotation were 5°, 10°, and 20° ($P < 0.05$).

Table 1 Quantitative comparison of accuracy of pedicle screw placement at assigned degrees of axial rotation in two study groups (mm, $\bar{x} \pm s$)

Degree of axial rotation (°)	Traditional method group	Three-dimensional fluoroscopy-based navigation group	<i>P</i>
0	5.7 ± 0.9	6.2 ± 0.8	0.067
5	5.5 ± 1.0	6.0 ± 0.7	0.044*
10	5.1 ± 1.6	6.0 ± 0.9	0.033*
20	4.4 ± 2.2	5.7 ± 0.8	0.025*

Discussion

Since originally described in 1979 by Roy-Camille and Saillant [2], the pedicle screw has become widespread owing to its biomechanical superiority over other methods of spinal fixation [3–7]. However, relatively deep location, anatomic variations, and close relationship with neurovascular tissues make pedicle screw placement challenging [5, 8–10]. Screw malposition can result in biomechanical weakness [11], as well as make neurological deficits more likely, which increase the risk of patients' disability and socio-economic burden [12].

With three-dimensional fluoroscopy-based navigation introduced to spinal surgery in recent years, the promising technology gradually showed the advantage of precise positioning due to its characteristics of obtaining intraoperative real-time images, automatic registration, and three-dimensional navigation.

Although the literature has reported on three-dimensional fluoroscopy-based navigation can improve the accuracy of pedicle screw placement [13–16], its value in different segments of spine has been still controversial. Pedicle screw placement in cervical and thoracic spine is challenging due to specific anatomical structures and adjacent neurovascular tissues, and consequences caused by screw malposition will be disastrous; therefore, three-dimensional fluoroscopy-based navigation is relatively easier to be accepted in these regions. Whereas, some surgeons believe that there is no need to use navigation system for pedicle screw placement in lumbar spine as lumbar pedicles are large enough to guarantee accuracy and safety. In addition, conclusions reported in different literature are not consistent [17–19]. Inconsistent conclusions, as well as varying experiences in different research centers, result in application of three-dimensional fluoroscopy-based navigation in lumbar spine being questioned.

Actually there is an overall high rate of screw malposition in lumbar spine using traditional method. Schizas et al. [20] reported on 130 studies from the published literature in the past 40 years. In this meta-analysis, they found without using navigation only 86.5% pedicle screws were identified as accurately placed in lumbar spine of cadaveric populations, while the rate was only 87.3% in vivo. Soyuncu et al. [21] quantitatively analyzed the anatomic relations between the lumbar pedicle and the adjacent dural sac and nerve roots in 10 adult cadavers. On the basis of data acquired, they reported that improper placement of pedicle screws will carry a great risk of injury to the dural sac and nerve root. In our study, the accuracy of pedicle screw placement was only 90% in qualitative evaluation, much lower than the three-dimensional fluoroscopy-based navigation group (100%). There was statistically significant difference between the two groups

($P = 0.007$), and the quantitative results ($P = 0.000$) further confirmed the conclusion.

Accuracy of pedicle screw placement can be affected by surgeons' experience and proficiency, surgical techniques to guide screw placement, the way to evaluate the accuracy, as well as the anatomy of vertebrae. Regrettably, most reported literature does not include these information details. Thus, reasons for the difference in accuracy of pedicle screw placement are not entirely understood. In clinical practice, we found that lumbar pedicle screw malposition was often concomitant with vertebral axial rotation, which was more common than anatomical variations and less likely to arouse attention of surgeons before and during surgery. Approved in this study, vertebral axial rotation in lumbar spine is indeed a factor that affects the accuracy of pedicle screw placement using traditional method ($P = 0.017$ in qualitative evaluation, $P = 0.048$ in quantitative evaluation), and there exists negative linear correlation between them, that means accuracy declines with the increase of axially rotational degrees.

Vertebral rotation occurs in three-dimensional space, rather than one single plane. In order to simplify the influencing factors, in this study only vertebral axial rotation which is most likely to carry the risk of neurovascular deficits has been studied, without considering rotation in the sagittal and coronal planes. Because fluoroscopic images are demonstrated in one single plane, it may be displayed as normal even though vertebral rotation in three-dimensional space exists. This artefactual rotation is named 'introduced vertebral rotation' by Hecquet et al. [22]. The phenomenon will mislead surgeons, reducing the accuracy of pedicle screw placement.

In addition, vertebral rotation, especially in the axial plane, will have a significant impact on transverse angles of pedicle screw placement. The incidence of screw perforation will increase if the surgeon still inserts screws on the basis of conventional thinking; therefore, increasing the risk of neurovascular damage.

Moreover, vertebral rotation often appears with anatomical variations, such as pedicular asymmetry, absence of anatomical landmarks, etc. Weinstein et al. [23] reported that there were frequent false-positive and false-negative results when only plain radiography was used to assess the placement of the screws. Thus, even with the aid of fluoroscopy, accurate determination of entry point and direction of the pedicle screws are still difficult. This depends mostly on experiences of the surgeon; however, it is still a challenging task to accurately insert screws in rotational vertebrae with anatomical variations even for experienced surgeons.

Kouwenhoven et al. [24] investigated vertebral axial rotation in the normal nonscoliotic spine, and clarified vertebral rotation is a widespread physiological

phenomenon. In our study the accuracy of pedicle screw placement shows correlation with vertebral axial rotation, hence it is necessary to explore the value of three-dimensional fluoroscopy-based navigation in this condition. To our knowledge, three-dimensional fluoroscopy-based navigation system can provide the most valuable axial images; therefore, it is likely to improve the accuracy of pedicle screw placement in lumbar spine without regard to vertebral rotation, anatomical variations, and artifacts due to two-dimensional fluoroscopic images. In addition, three-dimensional fluoroscopy-based navigation is able to provide real-time images, giving surgeons the chance to dynamically adjust screw entry points and directions, thereby enhancing the accuracy of pedicle screw placement. Confirmed in our study, three-dimensional fluoroscopy-based navigation can significantly improve the accuracy of pedicle screw placement in lumbar spine in the case of vertebral axial rotation compared with the traditional method ($P = 0.007$ in qualitative evaluation, $P = 0.000$ in quantitative evaluation).

For each assigned degree of axial rotation, statistical difference occurs between the two groups when it is 20° in qualitative evaluation, while 5° , 10° , and 20° in quantitative evaluation. The reason for no statistical difference in qualitative evaluation may be attributed to insensitive qualitative indices. Although the accuracy is 100% in both groups in qualitative evaluation when they are 0° and 5° , quantitative data show there are differences between the two. Screw malposition can result in biomechanical weakness of internal fixation [11], so it is not precise enough to evaluate the accuracy of pedicle screw placement using qualitative methods which are commonly used in the past. Because there is no uniform standard currently to evaluate the accuracy of pedicle screw placement, we propose that more precise approaches should be considered in the development of standardized evaluation methods. The quantitative evaluation method used in our study may provide a new way to solve this problem.

Precise positioning, ensuring both safety of surgery and biomechanical stability of internal fixation, is the development trend of spine surgery. Regrettably, traditional methods cannot meet this requirement even in lumbar spine. Three-dimensional fluoroscopy-based navigation can offer high precision in pedicle screw placement; therefore, its application in lumbar spine should be highly valued.

Conclusion

Pedicle screw malposition can be caused by vertebral axial rotation in lumbar spine using traditional method. There is negative linear correlation between the accuracy and the

degrees of axial rotation. However, the accuracy can be improved by three-dimensional fluoroscopy-based navigation.

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