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Original Article

A digital simulation study of pedicle safe range and perforation risk with screw insertion: a retrospective case series

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Abstract: Objectives: This study focused on L2 pedicle safe range in the axial view. Perforation risk of the L2 pedicle with screw insertion was assessed through digital simulation, generating gradient diagrams for risk zone (RZ), safe zone (SZ), edge key points, and safe range of entry point to help achieve safer screw-setting positions. Methods: 28 healthy L2 vertebral pedicle models were constructed by computed tomography data and Mimics 17.0. After pedicle axis establishment and setting of auxiliary lines, the vertebra were rotated to correct the sagittal and transverse pedicle angle to obtain the axial direction. The gradient diagram for RZ, SZ, edge key points and a safe range of entry point were obtained after compiling all the original axial projections of vertebral pedicle into one image adjusted to match a normalized rectangle. Results: All 28 vertebral pedicles had RZs consisting of 4 parts, with perforation risk of 22.58±2.84%. Individual risks were 3.06±0.46%, 6.17±0.71%, 5.58±0.58%, and 8.23±0.95%, respectively, for parts I, II, III, and IV. Average width and height of the pedicle projection were 7.57 mm and 17.65 mm, respectively. Four edge key points, perforation risk, and safe range were analyzed on L2 for a 6.0 mm pedicle screw. Conclusions: The safe range of screw insertion was recommended by a digital simulation. In addition, a screw could generate an optical illusion of precise position on both axial and lateral radiographs with the perforation risk of vertebral pedicle, especially in the part IV.

Keywords: Digital simulation, pedicle safe range, pedicle screw insertion, case series

Introduction

After Roy-Camille et al. (1979) [1] proposed the posterior cervical stabilization technique, Roy-Camille, Saillant, & Mazel first applied the pedicle screw plating system for the lumbar spine in 1985 [2]. Meanwhile, pedicle screw fixation has been widely applied for surgical treatment of spinal fractures, deformities, and degenerative changes [3-5] by providing stable fixation and redressing spinal deformities. With widespread use of this fixation technique, however, many complications have been observed, e.g. screw perforation of vertebral pedicle, which results in neurovascular and serious spinal cord injury [6]. Indeed, the estimated screw misplacement rate widely ranges from 0.35% to 23% [7-14].

To improve the accuracy of screw placement and reduce the incidence of perforation related complications, studies have used different experimental techniques, including plain film, computed tomography (CT) scan, and direct cadaveric dissection, to assess vertebral morphometry [7, 15-19]. Previous literature has evaluated vertebral pedicle morphology, demonstrating the complexity of the pedicle. Kretzer RM noted that axial CT scanning is insufficient for pedicle assessment, because it just provides a 2D view of the pedicle while its actual shape is a complex 3D rather than a single regular cylinder [20]. Venita Simpson argued that minimum pedicle diameter, which is acquired in transverse CT reconstruction of a given pedicle versus coronal CT reconstruction, is different. Moreover, these authors found that such disparity is significantly related to the pedicular angulation in the coronal and transverse planes [21].

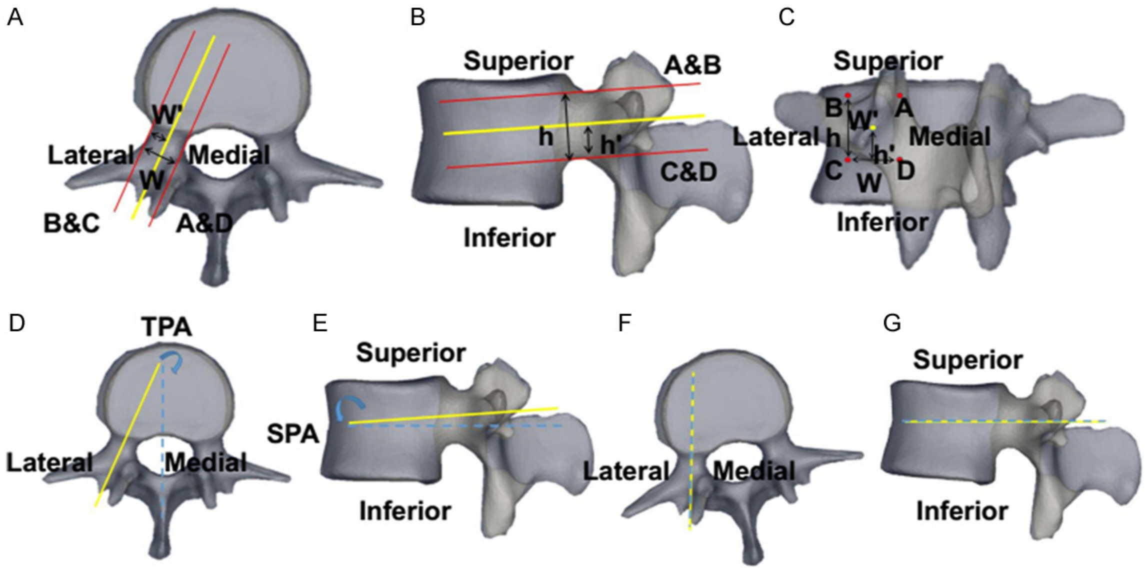

Figure 1. Model construction and simulated radiographs. Transverse view (A) The borderline A and D were tangential to the medial curve of the pedicle; the border B and C were tangential to the lateral curve. Lateral view (B) The borderline A and B were tangential to the superior curve of the pedicle; the borderline C and D were tangential to the inferior curve. Axial view (C) axial view was obtained after rotating vertebra (F, G) to correct for transverse (D) and sagittal pedicle angle (E), which showed the correlation of the pedicle axis (the yellow one) and border lines. h' is the distance from the pedicle axis to the inferior curve; h is the distance from the superior curve to the inferior curve; w' is the distance from the pedicle axis to the lateral curve; w was the distance from the lateral curve to the medial curve.

In addition, entry point selection of the posterior pedicle screw into the pedicle is crucial. Scholars have developed several techniques for selecting the entry location to the posterior zone of the pedicle. The pars interarticularis converges at the accessory process as an entry point described as an "^"-shaped crest [22]. Roy-Camille selected a starting point 1 mm below the inferior edge of the facet joint in the same line with the lateral margin of the facet joint [2]. Magerl opted for an entry point at the mid-portion of the transverse process, where it intersects the lateral edge of the superior facet [23].

As for the path of a pedicle-traverse screw, both the narrowest and all other sections traversed by the screw are of great importance. Anatomic distances between the pedicles and adjacent neural structures in the thoracolumbar spine provide actual safe distances between the pedicles and neural structures [24, 25]. Therefore, the in-out-in technique, which includes extra-pedicular penetration and entry into the vertebral body during the surgical process, was developed [26]. This screw insertion technique, however, has a high risk of injury to surrounding tissues. Therefore, a new concept of "all-through-pedicle" was proposed. With this approach, pedicle screws do not perforate the bone cortex of the pedicle while entering the vertebral body [16, 24, 26].

Typically, intraoperative fluoroscopy is used to assess screw insertion, but most C-arm machines only provide 2-dimensional images. A screw very close to the surface of vertebral pedicle on lateral and axial radiographs may have actually perforate the bone cortex of the pedicle while still be visualized in the pedicle. In particular, the bulky and thick configuration of obese patients may produce a fuzzy fluoroscopic view to increase the misplacement rate [7].

So far, few studies have assessed the morphological and anatomical structures of cortical perforation as well as its risk after screw insertion in spinal disorders. In this work, we aimed to assess the perforation risk of L2 pedicle with pedicle screw in the axial direction through digital simulation, drawing a gradient diagram of the risk zone (RZ), safe zone (SZ), and edge key points. This could help clinicians better understand the risk of cortical perforation, and provide a safe range of entry points in the axial direction, since a safe entry point achieves safer screw-setting positioning and reduces the perforation risk of the pedicle cortex.

Material and methods

This study was a retrospective analysis of a case series. It was conducted with consent of volunteers and approved by the Shanghai East Hospital Ethics Committee (Document number: 2017-020). The research was performed in accordance with the Declaration of Helsinki. For radiographic examination, patients with congenital bone disease and a history of trauma or fractures were excluded. Finally, computed tomography data of 28 L2 pedicles in 14 adults (7 women and 7 men; mean age of 40.5 years, ranging from 24 to 53 years) were obtained between January and March 2017 from the Shanghai East Hospital, a non-profit hospital affiliated to Tongji University School of Medicine. DICOM image data were acquired by scanning the L2 pedicle on a 64 channel CT scanning equipment (Siemens Somatom Sensation, Siemens, Erlangen, Germany) with the following parameters: tube voltage, 120 kV; tube current, 200 mA; slice thickness, 1 mm; interlayer spacing, 0.5 mm. Integrity assessment and quality control of CT data were routinely implemented before data processing. Considering the data consistency, the same investigator familiar with spinal anatomy measured all parameters. The following process was used for data analysis from each case.

Model construction

CT image data (DICOM format) were transformed into a three-dimensional reconstruction vertebral model of L2 with the interactive medical imaging control system Mimics 17.0 (Materialise, Leuven, Belgium). After setting image opacity to 50%, the superior view was observed as a transverse radiograph (**Figure 1A**), whereas the lateral direction was adjusted to simulate a lateral radiograph of the L2 pedicle (**Figure 1B**).

Vertebral pedicle axis generation

The direction of the pedicle axis could be described by two angles: sagittal pedicle angle (SPA, **Figure 1E**) and transverse pedicle angle (TPA, **Figure 1D**). After axis establishment, the vertebra were rotated to correct for SPA and TPA (**Figure 1F**, **1G**) Finally, an axial view was obtained (**Figure 1C**).

Marking the smallest cross-section of vertebral pedicle by setting auxiliary lines. First, four red lines were constructed. The borderline (A) was parallel to vertebral pedicle axis in transverse and lateral radiographs, tangential to the superior curve of vertebral pedicle in the lateral radiograph (**Figure 1B**) and to the medial curve of vertebral pedicle in the transverse view (**Figure 1A**). Using the same method, three other borderlines to the vertebral pedicle axis were identified (**Figure 1C**).

Creating a projective graph along the vertebral pedicle axis. The simulated view was rotated until the borderlines appeared as four dots (**Figure 1C**). With this simulated axial radiograph, a projection of the smallest cross-section of vertebral pedicle was observed and clearly depicted.

Analysis of the pedicle axial diagram

Within the projection image, we considered the position in which the screw both appeared to be and was actually inside the vertebral pedicle a safe zone (SZ) on all radiographs. A risk zone (RZ) was defined as the position in which the screw appeared to be within the vertebral pedicle on radiographs, but actually perforated the cortex. Perforation risk was calculated by the RZ area ratio.

The axis projective graph was analyzed by the image processing software Adobe Photoshop CS6 (USA). In the axial diagram (**Figure 2**), a rectangle depicted by four border lines (superior, inferior, medial, and lateral margins), was considered ALL. The vertebral pedicle projective area was considered a SZ. The remaining areas of the rectangle composed the risk zone (RZ), which consisted of 4 parts: I, II, III, and IV (**Figure 2**). Specifically, parts I and II represented the regions in which the screw may be pierced on the upper side of the medial and lateral pedicle, respectively. III and IV represented the regions in which the screw may be pierced on the lower side of the lateral and medial pedicle, respectively. The following data were assessed: ALL width and height, I/ALL×100%, II/ALL×100%, III/ALL×100%, and IV/ALL×100%.

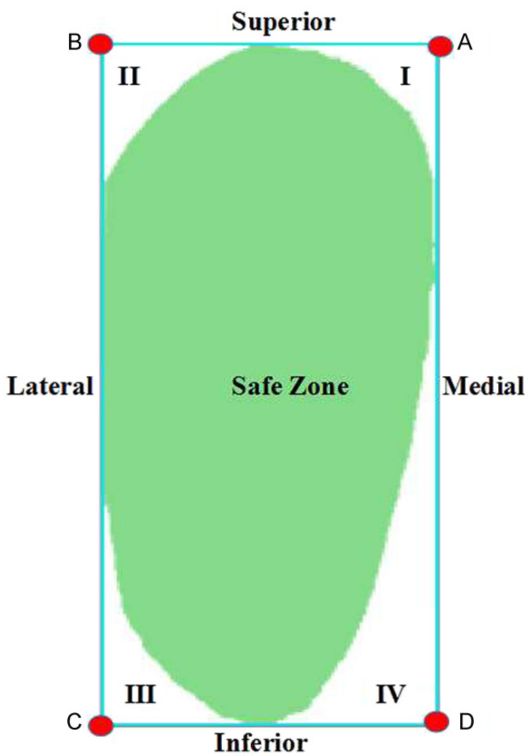

Figure 2. A projective graph along the vertebral pedicle axis. The rectangle was regarded as ALL; The vertebral pedicle projective area was considered a safe zone (SZ, green area); The remaining areas of the rectangle composed the risk zone (RZ), which consisted of 4 parts: I, II, III, and IV.

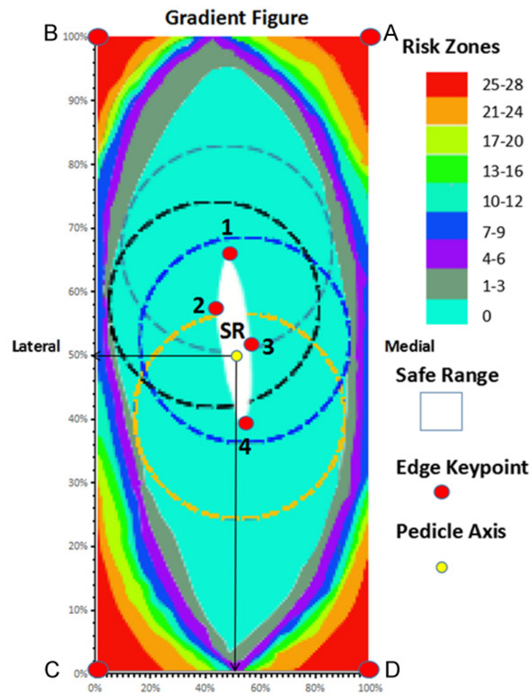

Figure 3. Gradient of risk zones. This picture reflects the correlation between screw position and the vertebral pedicle perforation risk; The coordinates (X = w'/w, Y = h'/h) indicate the positon of screw in axial direction. The irregular white center was SR for the guide wire (pedicel axis). The four edge key points of SR, namely the center of dashed circles show that 6.0-mm-diameter screws are safe and cortex touching in the entire pedicle. Key point 1, X = 48%, Y = 66%; key point 2, X = 44%, Y = 58%; key point 3, X = 56%, Y = 52%; key point 4, X = 54%, Y = 40%.

Gradient of risk zones and key edge points

After analyzing the projection on each axis, a gradient diagram for RZs was depicted, with 4 points (A, B, C, and D) as vertices. By adjusting and processing each original projection image to match the mean length and width values of ALL, we finally obtained the rectangle shown in **Figure 3**. Because the reshaped axis projections had the same calculated average rectangle, the RZs of the entire vertebral pedicle could be depicted and visualized in a single average axial shape. Compiling of all axial projections into one image yielded, a visualized gradient of RZs and a coordinate system was built (**Figure 3**). The coordinates (X = w'/w, Y = h'/h) indicated the screw position in the axial direction. In these zones, safe and cortex-touching zones (SCTZs) were identified in the entire vertebral pedicle when using 6.0-mm screws. The largest safe trajectory (SR) of the center of pedicle screw was built under the circumstances that the pedicle screw cannot perforate the bone cortex of vertebral pedicle. The four edge key points of SR (the centers of dashed circles) showed that 6.0-mm-diameter screws are safe and cortex-touching within the whole pedicle. Then, taking the pedicle axis as a reference point, the four key edge points were marked (**Figure 4**).

Statistical analysis

Statistical analysis was performed by the SPSS statistical software 22.0. T-test was used to assess data sets. Independent sample t-test was employed to detect differences in sexuality and limb side of the pedicle. **Table 1** presents descriptive statistics and t-test results. $P<0.05$ was considered statistically significant.

Results

All 28 vertebral pedicles had Risk Zones. RZ/ALL×100% was 22.58% (±2.84%). I/ALL×100%, II/ALL×100%, III/ALL×100%, and IV/ALL×100%

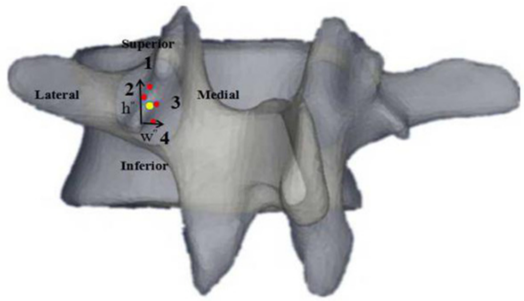

Figure 4. Safe range of entry point. In axial view, the distance between point 1 and point 4 in vertical direction is regarded as h". The distance between point 2 and point 3 in horizontal direction is regarded as w" (h" = 4.59 mm, w" = 0.90 mm). We found that the guide wire had a larger safe range (about 4.59 mm) in the vertical direction and the safe range of pedicle screws is less than 1 mm in the horizontal direction. The yellow point represents the projection of pedicle axis in axial view.

were 3.06±0.46%, 6.17±0.71%, 5.58±0.58%, and 8.23±0.95%, respectively. The vertebral SPA was 5.5±1.2° and the TPA was 12.4±2.8°. Moreover, average width and height of the pedicle projection were 7.57 mm and 17.65 mm, respectively. As shown in **Table 1**, gender and limb side of the pedicle were not significantly different (P>0.05).

Discussion

Pedicle violation by screw insertion can cause injury to adjacent neurovascular structures [27, 28] along any of the four pedicular quadrants. In this case, the negative consequences of screw placement may outweigh the advantages offered by various systems [29]. Previous studies have illustrated the complex morphology of vertebral pedicle. In addition, selection of an entry point for inserting the posterior pedicle screw into the pedicle is one of the key factors, along with the screw direction (TPA&SPA) and vertebral body. As mentioned above, three techniques are most commonly used in clinical application [2, 21, 22]. In addition, both the narrowest and all other sections traversed by the screw dictate the path of a pedicle-traverse screw. Despite new technologies for entry point selection, there is still no unified standard for internal fixation point due to the complex and variable morphology of the pedicle. Therefore, the complexity of pedicle contracture and the undefined standard for internal fixation point increase the risk of complications.

The current exploratory study aimed to assess the risk of vertebral pedicle projection by digital simulation and generating a gradient diagram for the risk zone (RZ) and the safe zone (SZ) in the axial view to obtain the safe range of the entry point. This was not described previously in term of the spine, and different from the entry points recommended by previous studies [2, 22, 23]. Meanwhile, the safe range could amplify the alternative area of the entry point for the insertion of screw which could not be restricted to some recommended points. Furthermore, four edge key points were recommended to help clinicians approach screw-setting positions in a safer way.

A drawback of iatrogenic perforation of the pedicle caused by screw misplacement is potential spinal cord injury, which may result in multiple negative effects. The screw misplacement rate is widely estimated at 0.35-23% [6]. To achieve accurate placement, not only superb surgical skills are necessary, but anatomical factors (e.g. pedicle height, pedicle width, pedicle level and et al.) also play a critical role [7]. Generally, for greater strength and fewer complications, clinicians seek the path of the pedicle screw, which is as close as possible to the pedicular axis. In this study, average width of the pedicle projection was 7.57 mm, with an average height of 17.65 mm (**Figure 2**).

In this work, a digital method was used to simulate intraoperative radiographs, including a transverse view that cannot be achieved by C-arm machines during the surgical operation. According to the axial projective images obtained, we conclude that the average perforation risk is nearly 22.58%. There were 4 RZs in which a screw could generate an optical illusion of precise position in radiographs, which actually may have perforated the bone cortex of the pedicle. The highest and lowest average perforation risks were found in parts IV (8.23%) and I (3.06%), respectively. These findings indicate that part IV may have the highest perforation risk in clinical practice. The accurate realization of RZs in the vertebral pedicle would help clinicians avoid complications such as iatrogenic cortical perforation, cortex breakage, vascular damage, and spinal cord injury.

According to the risk gradient diagram, the safe range (SR) could be constituted by the screw center, which does not perforate the bone cortex. We found 4 SCTZs in all 28 vertebral pedi-

Table 1. Perforation risk of four parts calculated by the risk zone area ratio (%)

	Mean	SD	Sexuality		Limb Side	
			T value	*P* value	T value	*P* value
I/ALL	3.059	0.455	1.051	0.303	-1.145	0.263
II/ALL	6.174	0.712	1.946	0.063	0.376	0.710
III/ALL	5.575	0.578	-0.436	0.667	-1.088	0.287
IV/ALL	8.233	0.948	-0.332	0.742	1.862	0.074

For all statistical tests, the *P* value of less than 0.05 was considered statistically significant. ALL: A rectangle depicted by four border lines of the pedicle projection image. I and II: The regions in which the screw may be pierced on the upper side of the medial and lateral pedicle, respectively. III and IV: The regions in which the screw may be pierced on the lower side of the lateral and medial pedicle, respectively.

cles, namely the 4 edge key points of SR (**Figure 3**) (key point 1, X = 48% and Y = 66%; key point 2, X = 44% and Y = 58%; key point 3, X = 56% and Y = 52%; key point 4, X = 54% and Y = 40%). Axial radiographs could observe these SCTZs. It is clear that pedicle screws should be placed to the vertebral pedicle axis as closely as possible. We therefore used the vertebral pedicle axis as a reference point. We also propose a new safe zone and configuration as follows (**Figure 3**): (1) The first guide wire (key point 1, X = 48% and Y = 66%) could be placed slightly superior (2.82 mm above and 0.15 mm lateral to the pedicle axis). (2) The second guide wire (key point 2, X = 44% and Y = 58%) could be placed slightly higher (1.41 mm above and 0.45 mm lateral to the pedicle axis). (3) The third guide wire (key point 3, X = 56% and Y = 52%) could be placed slightly higher (0.35 mm above and 0.45 mm medial to the pedicle axis). (4) The last guide wire (key point 4, X = 54% and Y = 40%) could be placed slightly lower (1.77 mm below and 0.30 mm medial to the pedicle axis). Eventually, we found that the guide wire had a larger safe range (about 4.59 mm) in the vertical direction. The above findings clearly suggest that the safe range of pedicle screws is less than 1 mm in the horizontal direction. Compared with superior and inferior walls, medial and lateral walls more easily developed iatrogenic perforation of the pedicle, corroborating Castro et al. [30]. At the L2 level, in order to avoid perforating the bone cortex of the pedicle, insertion should be performed between the two intersections located on the extending line of the lateral border of the superior facet, which intersect one-and two-thirds of the transverse process, respectively (**Figure 4**). Meanwhile, TPA (12.4°) and SPA (5.5°) should be taken into account.

The limitations of this study should be mentioned. First, different pedicle levels may lead to distinct results, and our findings may not apply to all spinal segments since we only assessed a single healthy vertebral level (L2). The study process and conclusion may also be limited due to the anatomical variations of vertebral pedicles. Second, it is obvious that the bigger the screw diameter, the smaller the SR both for the guide wire and the screw. In practice, screw diameters vary widely, and we only selected 6.0 mm in this study. Third, the sample size was relatively small. Other segments could be analyzed in larger sample trials to reduce potential sampling errors. Finally, this was a retrospective study, with inherent methodological difficulties. Double blind randomized clinical studies are warranted to assess safe zone usefulness.

Conclusion

Overall, a screw could generate an optical illusion of precise position on both axial and lateral radiographs, which actually may have perforated the bone cortex of the pedicle. Moreover, perforation risk was nearly 22.58%. Due to such high perforation risk, clinicians should pay more attention to screws when they appear close to the margin of vertebral pedicle on radiographs, especially in part IV. Based on L2 data, four key points are recommended, with a larger safe range (about 4.59 mm) in the vertical direction. Due to decreased perforation risk and reduced iatrogenic damage, we suggest generating a three dimensional spinal model for every patient to ensure the best pedicle screw selection before surgery, therefore eliminating the possibility of further complications caused by improper pedicle screw insertion [18].

Disclosure of conflict of interest

None.

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