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ORIGINAL ARTICLE

Alignment of pedicle screws with pilot holes: can tapping improve screw trajectory in thoracic spines?

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Abstract Pedicle screws are placed using pilot holes. The trajectory of pilot holes can be verified by pedicle sounding or radiographs. However, a pilot hole alone does not insure that the screw will follow the pilot hole. No studies have characterized the risk of misalignment of a pedicle screw with respect to its pilot hole trajectory. The objective of this study was to measure the misalignment angles between pedicle screws and pilot holes with or without tapping. Six human cadaveric thoracic spines were used. One hundred and forty pilot holes were created with a straight probe. Steel wires were temporarily inserted and their positions were recorded with CT scans. The left pedicles were tapped with 4.5 mm fluted tap and the right pedicles remained untapped. Pedicle screws (5.5 mm) were inserted into the tapped and untapped pedicles followed by CT scans. The trajectories of pilot holes and screws were calculated using three-dimensional vector analysis. A total of 133 pilot holes (95%) were inside pedicles. For the untapped side, 14 out of 68 (20%) screws did not follow the pilot holes and were outside the pedicles. For the tapped side, 2 out of 65 (3%) did not follow and breached the pedicles. The average misalignment angles between the screw and pilot hole trajectory were $7.7° \pm 6.5°$ and $5.6° \pm 3.2°$ for the untapped side and tapped side, respectively ($P < 0.05$). Most pedicle screws had lateral screw breach (13 out of 16) whereas most pilot holes had medial pedicle breach (6 out of 7). Tapping of pilot holes (1 mm undertap) helps align pedicle screws and reduces the risk of screw malposition. Although most pedicle screws had lateral breach, the risk of medial pedicle breach of the pilot holes must be recognized.

Keywords Thoracic spine · Pedicle screw · Trajectory · Tapping

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Introduction

Transpedicular screw fixation of thoracic spines has been widely used for a variety of surgical indications, including adolescent idiopathic scoliosis [14, 26], kyphotic deformities [18, 32], fracture [22, 34], and tumor [8, 24]. The small diameter of thoracic pedicles and proximity of vital structures can lead to high risks of screw malposition and neurological complications [3, 11, 27, 28, 33]. Common surgical complications due to pedicle screw malposition include pedicle fracture, vascular injury, dural tear, and temporary or permanent neurologic injury [4, 6, 15, 30]. Despite these complications, many clinical studies have suggested that pedicle screws can be inserted with acceptable accuracy and safety in thoracic spines with careful surgical planning and techniques [1, 4, 9, 25].

Pedicle screws are placed with the guidance of pilot holes. The correct trajectory of pilot holes can be verified by meticulous attention to technical detail, tactile pedicle sounding, radiographic imaging, and intraoperative monitoring techniques [9, 10, 13, 16, 20, 21, 35]. However, the pilot hole alone does not insure that the screw will follow the pilot hole trajectory. To our knowledge, no studies have characterized the risk of misalignment of a pedicle screw with respect to its pilot hole trajectory. In this study, we developed a technique to qualitatively measure the misalignment of screws with computer tomography (CT).

Pedicle screws can be inserted into their pilot holes without tapping, with undertapping (0.5 or 1 mm), or with same size tapping. The effect of tapping on bone purchase has been investigated in a number of studies [2, 7, 12]. Same size tapping is found to significantly reduce screw purchase and is not recommended [7, 12]. One millimeter undertapping is very popular among spine surgeons and has comparable pullout strength to that of screws inserted without tapping [2, 7]. Tapping helps to redefine the pilot hole for easier screw insertion. However, the tapping procedure may require additional operating time and have potential trauma. Considering the pros and cons of tapping, the choice of tapping or no tapping has been primarily based on surgeon's preference. Excessive misalignment can cause severe damage to the surrounding neural and vascular elements. The objective of this study is to measure and compare screw and pilot hole trajectory misalignment with and without tapping. The hypothesis is that tapping improves screw alignment with respect to the pilot hole.

Fig. 1 Straight steel wires inserted into the pilot holes to measure the orientation angles

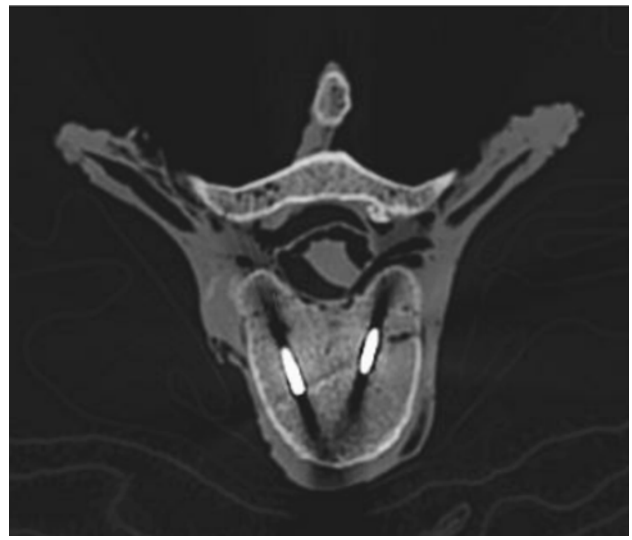

Fig. 2 An axial CT image of the pilot holes with the steel wires inserted

Materials and methods

Six human cadaveric thoracic spines of age ranging from 45 to 74 years (5 males, 1 female) were used in this study. Two vertebrae were excluded due to bony damage during dissection. None of the specimens had gross spinal deformity, previous surgery, or spinal tumors. Dual energy X-ray absorptiometry (Lunar Prodigy, GE, Louisville, KY) was performed in anterior–posterior position to determine the bone mineral density of all vertebrae. The mean T-score was -1.54 ± 1.18 with an average bone mineral density of 1.01 ± 0.14 g/cm^2. The specimens were stored in double plastic bags at −20°C. These were allowed to thaw slowly at room temperature (20°C) for 24 h. All soft tissue was cleaned in order to expose the posterior bony elements of the vertebrae.

The entry point of each pilot hole was created with a 4 mm burr under fluoroscopic guidance. Pilot holes (30 mm deep) were introduced with a 3 mm straight pedicle probe along the anatomic trajectory. The tip of the pedicle probe is 2.2 mm in diameter and 20 mm in length. Pilot holes were introduced on both sides of each vertebra. Straight steel wires (1.6 mm in diameter) were temporarily inserted into all pilot holes and CT scans (GE Lightspeed) were performed at 1.25 mm resolution to record the position of each pilot hole. Figure 1 shows the steel wires inserted into each pilot hole and Fig. 2 shows one axial cut of the CT scan images. The white ovals represent the sections of the wires.

In the second step of this study, all left pedicles were tapped using a 4.5 mm tap (1 mm undertap), whereas the right pedicles remained untapped. The steel wires were inserted again into the tapped pilot holes and CT scans were performed at the same resolution to evaluate its position and measure the orientation of each tapped hole with respect to its pilot hole.

The steel wires were removed after CT scans were completed. One hundred and forty polyaxial legacy titanium pedicle screws (Medtronic Sofamor-Danek, Memphis, TN) were inserted into the tapped and untapped pilot holes. The screws were 5.5 mm in diameter and 45 mm in length. CT scans were performed following pedicle screw placement. Although the screw size is often selected according to each pedicle's anatomy in clinical practice, the screw size in this study was held constant to avoid confounding factors. All screws were directed along the

Fig. 3 Pedicle screws inserted on tapped (left) and untapped (right) pilot holes

Fig. 4 An axial CT image of the pedicle screws. The screw in the right side pedicle did not follow the untapped pilot hole

pilot hole trajectory. All surgical procedures were performed by the same fellowship trained spine surgeon. Figures 3 and 4 show the pedicle screws and CT scan images, respectively.

Vitrea® Software (Vital, Minnetonka, MN) was used to reconstruct the axial images of CT scans. To measure the orientation of steel wires and screws, a vector is defined for each wire and screw with respect to the reference coordinate system. The reference coordinate system was constructed with two orthogonally oriented straight wires driven into the T12 vertebra. The embedded steel wires kept a constant spatial relation to the spine regardless of the position of the spine among different CT scans. The trajectories of pilot holes and screws are represented by these three-dimensional vectors. The misalignment angle is defined as the angle between the initial pilot hole trajectory and screw trajectory and was calculated based on vector analysis. A detailed description of this measurement is presented in Appendix. Repeated measurement of a single scan showed that this approach had a repeatability of 0.5°. Due to the micro deformation of the spine with slight change in prone position and manipulation of the spine during screw insertion and tapping, the repeatability of different scans was found to be approximately 1°. The positions of the pilot holes and pedicle screws were also qualitatively evaluated with CT scans by experienced spine surgeons to determine the number of pilot holes and screws that were in or outside the pedicles.

Statistical analysis

The misalignment angle between the screw and pilot hole trajectory for the untapped and tapped side were compared using *t* test. The number of screws that were outside the pedicles was compared for both the tapped and untapped sides using χ^2 test. Pilot holes that were outside pedicles were excluded. Significance was defined as $P < 0.05$. Statistical analyses were performed using SPSS version 11.0 (Chicago, IL).

Results

One hundred and thirty-three pilot holes (95% of 140 holes) were inside pedicles from CT scan evaluation. Five pilot holes were out on the tapped side (left) and two pilot holes were out on the untapped side (right). These perforated pilot holes were excluded. According to the reconstructed CT scan images, 2 out of 65 screws on the tapped side and 14 out of 68 screws on the untapped side were out of the confines of the pedicles. The χ^2 test suggested that these results were statistically significant between tapping or no tapping ($P < 0.05$).

The average misalignment angle between the screw and pilot hole trajectory was $7.7° \pm 6.5°$ (SD) and $5.6° \pm 3.2°$ (SD) for the untapped side and tapped side, respectively. *T* test results suggested that the misalignment angles on the untapped side were significantly greater ($P = 0.01$). The scattering (represented by standard deviation) of the alignment angle without tapping is twice as much as that with tapping. The average misalignment angle between the screw and tapped hole trajectory was measured as $4.0° \pm 2.0°$. The results are summarized in Table 1.

The average misalignment angle of the screws that perforated pedicles were $13.9° \pm 2.0°$ ($n = 14$) on the untapped side, whereas it was $3.5° \pm 2.1°$ ($n = 2$) on the tapped side. Detailed examination of the pedicle screws that perforated pedicles showed that 2 out of 14 screws without tapping had medial wall penetration. On the tapped side, one screw had medial breach and the other screw had lateral breach. There were no screws with superior, inferior, and anterior violation. For all seven excluded pilot holes, the number of holes with medial wall breach was six.

Table 1 Summary of pilot hole and screw accuracy

Pilot hole preparation methods	Tapped	Untapped
Total number of pedicles	70	70
Number of pilot holes inside pedicles	65	68
Number of screws out of pedicles	2	14
Number of screws with medial breach/lateral breach	1/1	2/12
Number of pilot holes with medial breach/lateral breach	6/1	

Discussion

This study presented a new measurement technique that quantitatively measures the misalignment of screws with respect to pilot holes using CT scans. The technique extracted the orientation of pilot holes or screws using vector representation of trajectory defined with respect to a reference coordinate system rigidly attached to the lower thoracic vertebrae. Deformation of the spine was minimal among different CT scans on the same specimen. The overall accuracy of this method is approximately 1°, primarily caused by the deformation of the spine after surgical manipulation and variation in positioning during CT scan. The results suggest that the pilot hole alone does not insure that the screw will follow the pilot hole.

An entry point located properly is crucial for correct screw positioning along the pedicle and vertebral body. The trajectory or angle of pilot holes has been shown to correlate with the levels. A number of anatomic studies have proposed guidelines regarding locating the entry point according to anatomic landmarks as well as the correct angle of the pilot holes [11, 17, 23, 27, 28, 30]. However, these general guidelines must be applied with caution because the dimension and orientation of thoracic vertebral pedicles have regional variations. In patients with deformity, the variation of pedicle trajectory becomes more dramatic and elusive. Intraoperative confirmation of the pilot holes should always be performed. The results of this study showed that a screw could significantly deviate from the pilot hole trajectory. The risk of misalignment is lower when the screw is inserted with 1 mm undertapping. Tapping appears to be a useful strategy to improve the accuracy of screw placement despite its additional surgical time and effort. This is consistent with the recommendation reported for free hand pedicle insertion [9].

One reason for the results in this study is that with 1 mm undertapping, the relative difference in size between the pilot hole and tap is smaller. In this case, it is easy to advance the tap without applying significant axial force. This is also true when the screw is driven into the tapped hole. Examination of the two screws that were considered outside pedicles on the tapping side suggests that the pedicle breach was not caused by misalignment but because of the small pedicle size and non-ideal pilot hole trajectory. In this case, the minor pedicle breach may not cause neurological deficit or injury [5, 27, 29]. The human bone is rather tolerant. The tolerance for misalignment measured in this study is much greater than the reported theoretical margin of error [19]. However, if the screw is forced into the hole as typically seen on the untapped side, it is more likely to deviate significantly because the surgeon cannot see the exact direction of the pilot hole during screw insertion. Although one may argue that the size of the pilot hole can be enlarged so that the pedicle screw can be inserted without tapping, it is generally not recommended due to the concern of reduced bone screw purchase.

One limitation of the study is that it does not include those pilot holes (7 out of 140 holes) that perforated pedicle walls. This is not uncommon in a clinical setting. In many cases, the surgeons are able to feel and redirect the screw [9]. However, extreme caution must be used. A second or even a third tract should always be avoided. Multiple tracts along the screw trajectory can reduce screw purchase significantly. It has been shown that thoracic pedicle screws can follow in–out–in with lateral breach of the pedicle [1]. It must be noted that even if the pilot hole is within the confinement of pedicle wall, lateral breach does not necessarily lead to in–out–in trajectory because the blunt tip of the screw typically slides along the lateral cortex of the vertebral body rather than penetrates through the cortical bone. This is confirmed on the screws that had lateral breach on the untapped side. Another limitation of this study is that the side chosen for tapping and no tapping was not randomized. The pilot holes were always created on the proximal side of the surgeon. The specimens were turned 180° to create pilot holes on the contralateral side. The same rule was applied to pedicle screw insertion. Hence, the effect of side choice is minimal. This can be confirmed on the accuracy of the pilot holes. The left and right side had no statistical difference (see Table 1). In fact, the pilot holes on non-tapped side had higher accuracy (68 out of 70). Thus, the side choice should not affect the conclusions in this study. Finally, the results in this study were obtained only on one fellowship trained spine surgeon. Further studies should include more surgeons.

The majority (6 out of 7) of the pedicle breach of the pilot holes was medial. This is contrary to the results of the screws with pedicle breach (12 out of 14 screws). Other clinical studies also suggest that screws are more likely to go out laterally [1, 9]. This was attributed to thicker cortical bone on the lateral side. The results of this study imply that this trend does not apply to the trajectory of pilot holes. The tip of a pedicle probe is usually sharper than the screw tip. Furthermore, the axial driving force on the probe is much greater than that applied to drive the screw. It is thus not surprising that pilot holes can breach on the medial side easily. Pilot holes going out of pedicles medially can cause injury to the spinal cord, but can be detected by feeling, pedicle sounding, radiographic verification, or electrical stimulation. A corrective trajectory may be created but its risk of injury to the spinal cord should be recognized.

The percentage of malpositioned screws in this study is comparable to those studies in the literature ranging from 3% to 41% [1, 3, 14, 26, 29, 31, 33]. Not all malpositioned pedicle screws cause neurological deficit. The rate of neurologic sequelae from screw and instrument misplacement has been reported <7% [4, 6, 15]. Nevertheless, the authors believe that screw malposition should always be avoided. A malpositioned pedicle screw not only poses risk to the neural and vascular elements, but also reduces the amount of bone surrounding the screw and thus reduces bone screw purchase. The results of this study suggest that tapping is one of the useful techniques to reduce that risk. However, it must also be recognized that tapping has its own risk and must be performed with caution because its sharp grooves can potentially trap neural tissues if the tap has severe medial breach.

In conclusion, this study developed a method using CT scans to measure the misalignment angle of a pedicle screw with respect to its pilot hole trajectory. The results of this study showed that the pedicle screw trajectory could be improved with 1 mm undertapping in thoracic spines. While most thoracic pedicle screws have lateral breach, the risk of medial breach of the pilot holes must be recognized.

Appendix

The raw images of the axial CT scans were acquired at 1.25 mm resolution. Each image was identified with its position along the z-axis. On the axial images, the position of a particular location expressed in x and y coordinates can be measured by moving the crosshair over it. In Fig. 5, the crosshair was positioned over the center of the section of the steel wire. The sections of the wire are typically elliptic on each image and appear in several consecutive images. The point defined by the displayed x, y, and z coordinates represents a point along the center of the steel wire in three-dimensional space. Another centered point on the wire can be measured to define the vector representing the trajectory of this wire. Two elliptic sections near both ends of the steel wire were used to define the vector. The measurement was verified using the reconstructed three-dimensional images as shown in Fig. 5. Similarly, the trajectory of the pedicle screw can also be defined by locating two points along the center of the screw axis. The second point along the screw axis was selected near the screw head.

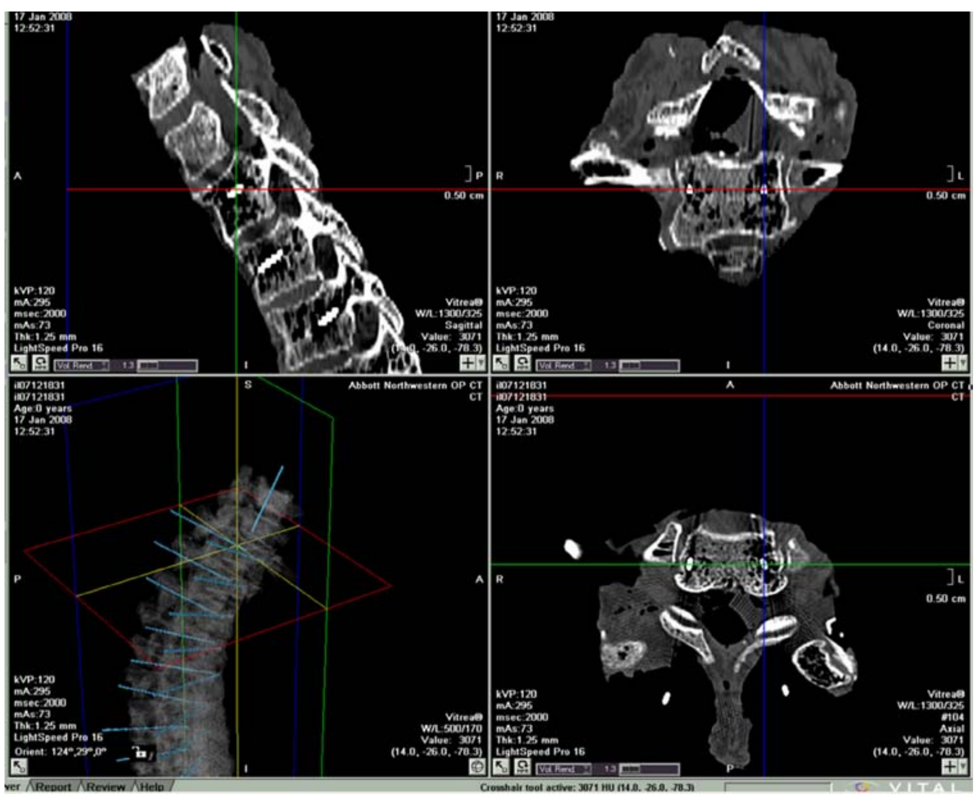

Fig. 5 The coordinates of a point along the axis of each steel wire measured by moving the crosshair over the white ellipse

The vectors calculated with the coordinate data of two points are defined with respect to the global coordinate system of the CT scan equipment and do not relate to the position of the spine. To compensate for the position difference among different scans, a reference coordinate system attached to the spine was established using two straight steel wires driven into the lower thoracic spine. These two wires were oriented perpendicularly (approximately) to each other such that an orthogonal coordinate system can be easily and reliably constructed. The vectors representing these two wires are designated as **A** and **B**. The xR axis was chosen to be aligned with A. The yR axis was defined as the cross product of **A** and **B**. The zR axis can be established using the right hand rule. The origin can be conveniently located on the start point of **A**. Assume that the rotation matrix that transforms the reference coordinate system (xRyRzR) to the global coordinate system is **R**. The vector defined in the global coordinate system is **v**. Thus, the vector calculated by $\mathbf{R}^{-1}\mathbf{v}$ represents the orientation of the steel wire or screw with respect to the reference coordinate system on the spine. The variation in the orientation of the spine during CT scans can thus be cancelled out. The dot product of the vector of the pilot hole and the vector of the screw gives the cosine of the misalignment angle of the screw with respect to the pilot hole trajectory.

The repeatability of the measured orientation of each steel wire or screw on the same CT scan was <0.5°. However, the small deformation of the spine because of the surgical manipulation of the spine during tapping and screw insertion can lead to greater measurement error. The dissected thoracic spine was laid prone on top of folded towels. Slight variation of the position may also lead to deformation of the spine due to gravity. To quantify and monitor this deformation, two additional straight wires were driven into the upper thoracic vertebrae to record the rotational deformation of the spine. The difference of the orientation change among the three scans of each thoracic spine of the two additional wires was of the order of 1°. Thus, the overall accuracy of this measurement technique was 1°. Comparison of the orientation of the untapped pilot holes between the first scan (after pilot hole creation) and second scan (after tapping on the left side) showed similar accuracy.

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