

Design and application of subaxial cervical pedicle screw placement guide device

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Abstract. In the present study, a novel subaxial cervical pedicle screw placement guide device was designed and developed. In cervical specimens (C3-C7), a pedicle screw was inserted into the left pedicle using the guide device with a keyhole partial laminectomy and tapping technique, and the right pedicle by drilling using the Abumi technique. After removing the pedicle screws, the channel wall of each pedicle screw was probed with a pedicle probe. The vertebral body was then dissociated for direct observation of the screw channel. Among the 10 specimens, 2 of the 50 pedicles (4%) in the guide device group were perforated. Screw placement failed in 8 of 50 pedicles (16%) in the Abumi technique group. Significant differences were observed in the outcomes for the guide device and Abumi technique groups. The subaxial cervical pedicle screw placement guide device developed in the present study decreased the failure rate of pedicle screw placement.

Introduction

In cervical surgery, the pedicle screw technique has demonstrated reliable biomechanical compatibility and a high rate of bone fusion (1). However, accurate placement of the screw is difficult, as the outer diameter of the cervical pedicle is smaller than the thoracolumbar pedicle (2). Furthermore, the cervical pedicle has a large range of variation and adjoins the vertebral artery, nerve root and spinal cord (3) Pedicle perforation from any direction is associated with a considerable risk, intra-operative complications, including the rupture of the bone wall, may decrease the clamping force of the screw, and the rate of grade 2 and 3 screw perforation is ~20% (4). A previous study has demonstrated a low rate of intra-operative complications associated with cervical pedicle screw fixation,

but a high incidence of mild to moderate screw deviation, which may cause complications including the perforation of the pedicle wall, vertebral artery injury, nerve root injury and spinal cord injury (5).

Therefore, the present study performed a detailed applied anatomy investigation of the cervical pedicle and designed a novel subaxial cervical pedicle screw placement device to increase the accuracy of subaxial cervical pedicle screw placement and to reduce the occurrence of complications during screw placement.

Materials and methods

Structure of the guide device. The subaxial cervical pedicle screw placement guide device comprises two parts: The positioning and orientation. Its structural features are presented in Fig. 1. The upper part of a fixed positioning pin is connected to an arcuate sliding groove, the center of which is located 1.5 mm from the tip of the fixed positioning pin. The sliding groove is marked with a 0-45° graduation, and two tightening screws are present at 30 and 45°, respectively. These two tightening screws are used to tighten the sliding groove and fix the working sleeve. Inside the sliding groove, there are four working sleeve slots at 30, 35, 40 and 45°, in which to place the working sleeve. The guide device is made of surgical steel and produced by Suzhou Qingniu Medical Device Co., Ltd. (Suzhou, China) in strict accordance with the principles and structural features of invention patent no. ZL200810123915.6.

Preparation of specimens. Subaxial cervical specimens of 10 antiseptically treated adult male human cadavers were selected (aged 60-80 years). A longitudinal posteromedial incision was made to bilaterally expose the outer edge of the facet joints. In total, 100 cervical pedicles of 50 vertebral bodies (C3-C7) were measured. The inclination and sagittal angles of the pedicle were measured via the X-ray examination (Fig. 2). The 100 cervical pedicles were randomly divided into two groups according to the different screw-setting techniques; in the guide device group, the Subaxial Cervical Pedicle Screw Placement Guide Device was used, and in the control group, the Abumi technique was applied.

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Subaxial cervical pedicle screw placement guide device. The subaxial cervical pedicle screw placement guide device (Fig. 3)

was used in combination with a keyhole partial laminectomy and tapping technique (6). A keyhole fenestration of ~5 mm was created between the fixed vertebral body and adjacent vertebral plate for placement of the locator. After identification of the medial, superior and inferior borders of the pedicle, the positioning pin was fixed in the center of the medial border of the pedicle. The direction of the working sleeve was identified by regulating the direction of the fixed positioning pin and the angle of the sliding groove. The inclination angle of the working sleeve was 40-45° at C3-C6 and 30-40° at C7. The sagittal angle of the working sleeve was parallel to the vertebral upper endplate (caudally inclined to C3-C4 at an angle of ~10°, resembling a pointed cone; cephalically inclined to C6-C7 at an angle of ~10° and perpendicular to the posterolateral surface of the C5 vertebral body). After the working sleeve had been fixed with the tightening screw, the heading device of the pedicle was rotated in the pedicle. Finally, a pedicle screw of suitable diameter and length was implanted.

Abumi technique. After determining the position of the nail, high-speed grinding is used to drill the bone cortex of the nail point to create a suitable round hole. The diameter of the hole is approximately equal to the screw neck, so that the entrance of the pedicle canal may be seen directly. The small probe was moved into the vertebral body by the pedicle of the medullary cavity under X-ray C arm monitoring, after the pedicle screw entered slowly into the pedicle. An inward tilt angle should be applied combined with pre-operative computed tomography (CT) and intra-operative assessment. Intra-operative lateral X-ray monitoring was used to ensure that the probe is located in the pedicle and along the probe, and inserted into the location and direction of tapping. Combined with pre-operative CT, the distance of the pedicle to the vertebral anterior, the pedicle medullary cavity diameter and intraoperative examination were used select the appropriate pedicle screw.

Statistical analysis. The success rate of the screw placement and the incidence of bone wall, blood vessel, nerve root and spinal cord injury were determined. The results were compared between the two groups using the chi-square test. $P < 0.05$ was considered to indicate a statistically significant difference.

Results

Clinical outcomes. After the removal of the pedicle screws, the channel wall of each pedicle screw was probed with a pedicle probe to check the integrity of the screw channel wall. The vertebral body was dissociated. The screw channel was directly observed after creation of the incision (Fig. 4).

In the guide device group, 2 of the 50 pedicles (4%) were perforated (C3 vertebral artery injury and C5 nerve root injury, respectively). In the Abumi technique group, screw placement failed in 8 of the 50 pedicles (16%; C3 nerve root injury, C3 spinal cord injury, C4 nerve root injury, C4 vertebral artery injury, C5 nerve root injury, C5 vertebral artery injury, C5 spinal cord injury and C6 nerve root injury, respectively; Table I).

Statistical analysis. The chi-squared test revealed that the screws had been correctly implanted. However, the success

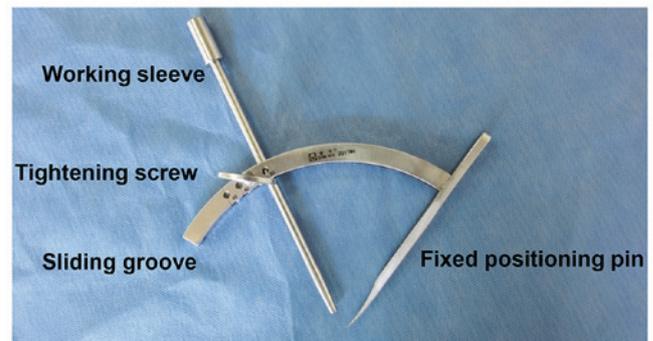


Figure 1. Subaxial cervical pedicle screw placement guide device. Fixed positioning pin, sliding groove, tightening screw and working sleeve are indicated.

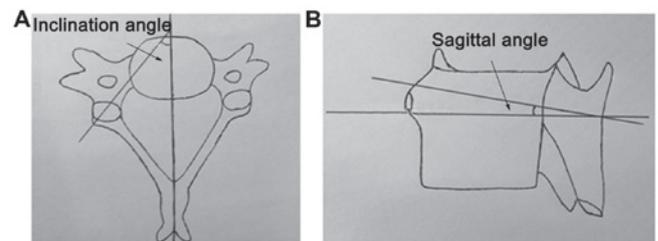


Figure 2. Inclinatio and sagittal angles of the pedicle detected by X-ray. (A) Inclinatio angle and (B) sagittal angle of the cervical pedicle.

rate of screw placement in the left pedicle (treated with the guide device) was significantly higher than that in the right pedicle (treated without the guide device; $\chi^2 = 4.00$, $P < 0.05$).

The incidence of perforation of the pedicle wall, as well as the vascular injury, nerve root injury and spinal cord injury resulting from it, was recorded in Table I.

Discussion

Prior to the development of subaxial cervical pedicle screw fixation, a large number of studies had assessed the three-dimensional morphology of the subaxial cervical pedicle. For instance, Reinhold *et al* (7) indicated that the coronal plane of the subaxial cervical pedicle is elliptical, and its inner width is shorter than its height. They also reported that the internal width of the pedicle gradually increased from C3 to C7. The width of C3, C4, C5 and C6 ranged from 4.2 to 5.6, 4.4 to 5.4, 4.7 to 5.6 and 4.7 to 6.5 mm, respectively. However, the height of C3, C4, C5, C6 and C7 did not exhibit any substantial variation. Karaikovic *et al* (8) identified that only a small proportion of the subaxial cervical pedicles had no medullary cavity.

The front part of the subaxial cervical pedicle connects to the upper posterolateral vertebral body, and the back connects to the upper lateral mass. The entry site of the pedicle screw is located at the intersection of the vertical center line and horizontal midline through the upper 1/4 of the lateral mass (9). The axis of the subaxial cervical pedicle at the C3-C4 level is relatively close to the upper endplate, but is slightly lower at C5-C7 (10). The anterior border of the upper endplate of the subaxial cervical pedicle is a slope. If the pedicle screw is

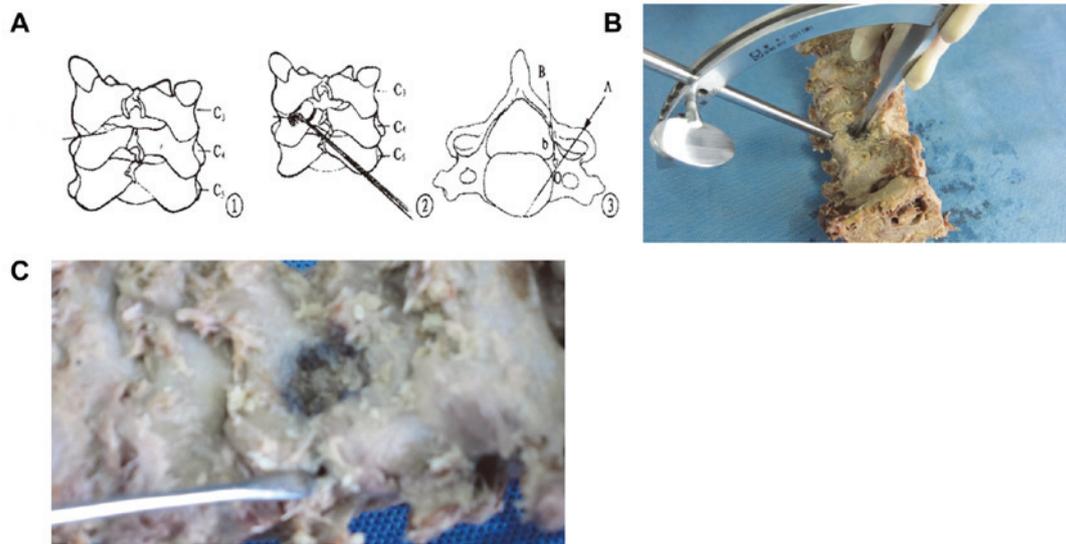


Figure 3. (A) Combined application of subaxial cervical pedicle screw placement guide device and 'keyhole' partial laminectomy and tapping technique. 1, Keyhole fenestration; 2, the nerve probe is used to probe the medial, superior and inferior borders of the pedicle; 3, the line A-O indicates the direction of the working sleeve, line B-O indicates the direction of the fixed positioning pin, and point O indicates the intersection of the extension lines of the directions of the abovementioned objects. Point b indicates the center of the medial wall of the pedicle and is used to fix the position of the end of the fixed positioning pin. The fixed positioning pin is utilized to probe the medial, superior and inferior borders of the pedicle and thus to identify the center of the pedicle. The direction of the pedicle is simultaneously probed and the direction of the working sleeve is adjusted accordingly. Finally, the pedicle screw is implanted. (B) 'Keyhole' fenestration is performed with the fixed positioning pin, which is used to probe the pedicle. (C) Keyhole fenestration and the mouth of the screw channel.

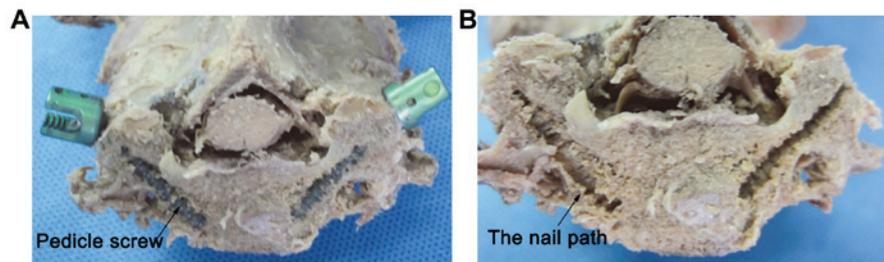


Figure 4. Screw channel following the creation of the incision. (A) Pedicle screw placement in cervical specimens. (B) The nail path after removing the screws.

too long, it may perforate the upper endplate when implanted along the axis of the pedicle.

In a study by Yukawa *et al* (11), the inclination angle of the subaxial cervical pedicle was 41.6-49.4°. The effective width of the screw channel is maximal when the inclination angle of the subaxial cervical pedicle screw channel is identical to the inclination angle of the pedicle itself (12).

The medial wall of the subaxial cervical pedicle is thin (13,14); thus, its resistance to external force is relatively low (15). Previous studies have suggested that the medial wall of certain subaxial cervical pedicles has a nourishing vessel entrance that results in congenital bone defects and reduced bone strength of the pedicle (16).

The height and width of the transverse foramen gradually increases from C3 to C6. The vertebral artery generally originates from the subclavian artery and enters the transverse foramen of C6, while some enter the transverse foramen at C3-C5 and C7 (17). The vertebral artery is surrounded by a venous sinus and distributes into the transverse foramen. The portion of the transverse foramen that is not traversed by the vertebral artery is relatively small (18).

The cervical nerve root tightly attaches to the inferior border of the intervertebral foramina and distributes forward and outward. The subaxial cervical pedicle, upper nerve root, and dural sac mostly attaches to one another at 1.0-2.5 mm from the lower nerve root. The cervical cord is packed within the dural sac and surrounded by cerebrospinal fluid, resulting in a great distance between the cervical cord and the pedicle (19). The anatomy of the subaxial cervical pedicle is controversial among researchers worldwide due to differences in ethnicity, sex and age, the dryness and storage period of the specimens and the methods of measurement (20,21).

In 1991, Panjabi *et al* (22) determined the three-dimensional anatomical morphology of the human cervical pedicle and reported that pedicle screw fixation was successfully performed. In 1998, Wang *et al* (13) provided the measurement results of cervical specimens of 54 adult Chinese patients. The inclination angle at C3, C4, C5, C6 and C7 was 42.97, 44.28, 44.80, 42.26 and 35.23°, respectively. The sagittal angle (positive above the horizontal line and negative below the horizontal line) at C3, C4, C5, C6 and C7 was -5.16, -0.32, 2.40, 5.00 and 5.47°, respectively. In 1994, Abumi (1) reported the application

Table I. Incidence of failure in the two groups (n=50).

Type	Control group	Guide device group	X ²	P-value
Perforation of pedicle wall	8 (16)	2 (4)	4.00	0.046
Vertebral artery injury ^a	2 (4)	1 (2)		
Nerve root injury ^a	4 (8)	1 (2)		
Spinal cord injury ^a	2 (4)	0 (0)		

^aConsequence of perforation of the pedicle wall (subgroups).

of pedicle screw fixation in the treatment of subaxial cervical spine injury and obtained satisfactory clinical outcomes. In 2000, Abumi (23) reported on various complications associated with cervical pedicle fixation.

Ludwig *et al* (24) studied 67 pedicles at C3-C7 from 7 patients using the Abumi technique and obtained an overall pedicle cortical penetration rate of 40.3% (mild, 28.4%; severe, 11.9%) and an overall success rate of 88.0% (placement within pedicle, 59.7%; slight penetration of cortex, 28.4%). Abumi *et al* (23) performed cervical pedicle screw placement in 180 patients using a total of 669 screws. Post-operative CT revealed that 45 screws (6.7%) penetrated the pedicle; 1 patient developed vertebral artery injury and 2 developed neurological symptoms.

The standards of subaxial cervical pedicle screw placement are not uniform. Five methods are currently utilized: The Abumi technique, the standard pedicle screw method, the partial laminectomy pedicle probe method, the dredging pipe method and three-dimensional computer navigation. As the classic Abumi technology has been used in our department for cervical screw placement, a group treated with the Abumi technique was used in the present study as a control. The Abumi technique involves partial removal of cortical and cancellous bone from the back of the lateral mass to expose the pedicle entrance, and the screw is then inserted either by direct visualization or under X-ray fluoroscopy.

The standard pedicle screw method involves identification of the pin entrance site and direction of entry according to anatomical landmarks. This technique may utilize a variety of positioning methods, all of which have common features. For instance, the pin entrance site is located within the outer quadrant superior to the cervical lateral mass. The inclination angle is 30-45°. The sagittal angle is negative at C3-C4, 0° at C5 and positive at C6-C7 (25).

The dredging pipe method was described in 2001 by Karaikovic *et al* (8). Specifically, the cortical bone of the lateral mass is removed at the site of pin entrance by a rongeur or bone drill. The cancellous bone is removed by a curette with a 2- to 3-mm diameter rotated along the axis of the pedicle, exposing the flared pedicle entrance. Cancellous bone in the pedicle tube is then scraped in a rotating manner with the curette. The depth of the pedicle tube is 3-5 mm under direct visualization. If any resistance is encountered, the direction may be slightly adjusted. If screwing is still not possible, a new pin entrance site should be selected. Upon penetration of the pedicle tube, the screw is inserted along the medullary cavity. Ebraheim *et al* (26) first reported fenestration and laminectomy in 1997. The vertebral plate was partially removed to

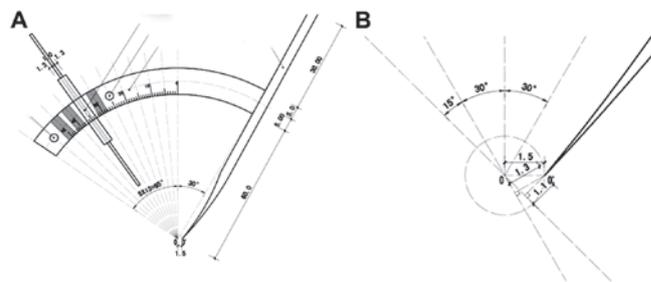


Figure 5. Distance (OO') between the center of the sliding groove and the tip of the fixed positioning pin. (A) Diagram of the cervical vertebra positioner. (B) Diagram of the angles guided by the cervical vertebra positioner (the coronal plane).

directly probe the position of or to expose the pedicle. Thus, the pedicle may be safely inserted under direct visualization. Fenestration and laminectomy increases the accuracy of pedicle screw placement, but exposes the cervical cord, which may then be inadvertently injured. Three-dimensional computer navigation includes computer processing of the results of three-dimensional C-arm X-ray fluoroscopy and establishment of three-dimensional dynamic images to navigate the pedicle screw placement during the operation, thus increasing the safety of pedicle screw placement.

The criteria to evaluate the screw position differ among previous studies. Neo *et al* (15) classified the screw position into four grades: Grade 0, correct entrance of the screw channel along the axis of the subaxial cervical pedicle; grade 1, screw channel displacement of <2 mm; grade 2, screw channel displacement of >2 and <4 mm; and grade 3, screw channel displacement of >4 mm. Yoshimoto *et al* (27) defined partial screw perforation as a displacement distance of <0.5 times the screw diameter and complete screw perforation as a displacement a distance of >0.5 times the screw diameter. Kast *et al* (28) defined correct screw placement as ≤1 mm penetration of the subaxial cervical pedicle into the cortex, mild screw perforation as perforation that occurred lateral or anterior to the vertebral body or occupied the spinal lateral recess, did not contact the dural sac or extended outward to induce vertebral artery stenosis, and was <1/4 the diameter, and severe perforation as >25% involvement of the vertebral artery or the occurrence of downward perforation-induced potential nerve compression or injury. Reinhold *et al* (7) classified screw placement results into four grades: Grade I, the subaxial cervical pedicle screw is located at the center of the pedicle; grade IIa, the subaxial cervical pedicle screw penetrates the

medial wall of the pedicle, but the displacement is $<1/4$ of the screw diameter; grade IIb, the displacement distance of the subaxial cervical pedicle screw is $>1/4$ of the screw diameter and the screw does not contact peripheral nerves or blood vessels; and grade III, the displacement distance is $>1/4$ of the screw diameter and the screw is attached to peripheral nerves and blood vessels.

The subaxial cervical pedicle screw placement guide device is able to probe the midpoint of the medial wall of the cervical pedicle using the fixed positioning pin. The guide sleeve was adjusted and fixed according to the angle measured by pre-operative X-ray fluoroscopy and multi-slice spiral CT. The working sleeve was connected to the sliding groove using the tightening screw. The ability to individually regulate the pin entrance angle for each vertebral body and guide the placement of the fixed positioning pin greatly assists clinicians in overcoming factors of uncertainty during screw placement. Thus, accurate and relatively safe screw placement may be achieved using the subaxial cervical pedicle screw placement guide device.

This guide device combined with the keyhole partial laminectomy and tapping technique allows the medial wall of the pedicle to be probed under direct visualization and facilitates assessment of the pin entrance site and direction. The design core concentrates on an arcuate sliding groove. The distance (OO') between the center of the sliding groove and the tip of the fixed positioning pin is 1.5 mm (Fig. 5). At various pin entrance angles, the vertical distance between the tip of the fixed positioning pin and the line of the pin entrance direction is ≥ 1.1 mm (it is precisely 1.1 mm when the pin entrance angle is 45°). After measuring the thickness of the cortical bone in the medial wall of the subaxial cervical pedicle, >1.1 mm was the safest measurement that ensured the screw did not penetrate the medial wall due to the junction of the different intensities of cortical and cancellous bones in the pedicle. Only 2 cases of screw perforation occurred in the guide device group of the present study.

However, the design of the subaxial cervical pedicle screw placement guide device has certain limitations. The direction of the guide sleeve should be adjusted according to the angle measured by pre-operative X-ray fluoroscopy and CT. The inclination angle may be fixed by adjusting the position of the guide sleeve on the sliding groove, but the sagittal angle must be artificially adjusted according to the pre-operative evaluation. The outcomes are associated with the experience of the surgeon and the accuracy of the pre-operative CT evaluation. In addition, the precision of the guide device affects the direction of the guide sleeve. The midpoint of the medial wall of the pedicle is more readily identified by surgeons with greater experience. Based on the current study's operational experience in surgery, displacement may interfere with the direction of the guide device.

In the present study, two pedicles (4%) in the guide device group were perforated, causing external injury in one case and inferior injury in the other. When the vertebral body was horizontally cut after completion of the procedure, it was revealed that the abovementioned injuries had been induced due to the direction from which the pin had been inserted, i.e., the pin entrance angle was too large. However, further in-depth studies are still required to address these issues.

In conclusion, application of the subaxial cervical pedicle screw placement guide device is more accurate and safer than

previous techniques. This guide device overcomes certain anthropic factors during screw placement and ensures for an individually optimal pin entrance. However, further in-depth studies are required to reduce screw placement errors.

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Availability of data and materials

The analyzed data sets generated during the study are available from the corresponding author on reasonable request.

Authors' contributions

The final version of the manuscript has been read and approved by all authors, and each author believes that the manuscript represents honest work.

Ethical approval and consent to participate

The current study was approved by the Medical Ethics Board of Nanjing Hospital Affiliated to Nanjing Medical University (Nanjing, China). Informed consent was obtained from the families of the patients.

Patient consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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