Original Article

Pedicle screw piercer with warning device - A technique to increase accuracy of pedicle screw placement
A cadaveric study

Lin Bin, He Yong, Xu Yang, Zhang Bi, Sha Mo, Guo Zhi-Min

Abstract

Background: Pedicle screw fixation has achieved significant popularity amongst spinal surgeons for both single and multilevel spinal fusion. Suboptimal placements of pedicle screws may lead to neurological and vascular complications. There have been many advances in techniques available for navigating through the pedicle; however, these techniques are not without drawbacks. The purpose of this study was to investigate the efficacy and feasibility of the pedicle piercer with warning device.

Materials and Methods: Eight normal adult thoracolumbar specimens from cadavers consisting of 80 vertebras (T_8–L_5) were selected and randomly allocated into four groups. Each group contained 20 vertebra. Group 1 was tested for maximum pressure of the piercer within the vertebrae (F_1). Group 2 was tested for maximum pressure of the warning piercer penetrating front cortex of the vertebral body (F_2). Group 3 was tested for the maximum pressure of piercer penetrating vertebral body endplate (F_3) and pedicle notch (F_{41}, F_{42}). Group 4 was tested for maximum pressure of the piercer penetrating the vertebral lateral cortex (F_6), the medial and lateral cortex of pedicle (F_{51}, F_{52}). In the second experiment of this study, 4 normal adult specimens consisting of 40 vertebra and 80 pedicles were used for testing the alarm effects of pedicle piercer. The following indicators were adopted for the tests including true positive/negative, false positive/negative, sensitivity, specificity, availability, Youden index, and diagnostic efficiency. SPSS 16.0 was used for statistical analysis.

Results: There were statistically significant differences between F_1, and F_2, F_3, F_{41}, F_{42}, F_{51}, F_{52} respectively ($P < 0.05$). $F_1 = 8.970 \pm 0.2698$, $F_3 = 13.055 \pm 0.6718$. We found that the threshold value of piercer warning was from 9.6 to 12.3 Kgf. Sensitivity was 92.31%, specificity was 95.12%, usability was 87.45%, Youden index was 87.43% and diagnostic efficiency was 92.5% respectively.

Conclusion: Warning piercer is a safe, simple, sensitive device for detecting pedicle breach during regular pedicle screw placement surgery.

Key words: Pedicle screw piercer, thoracolumbar specimens, warning device, cadaveric study
MeSH terms: Spine, thoracic injuries, lumbar region, bone screws, cadaver

Introduction

Pedicle screw system is a common fixation device in spinal surgery.[1-3] Accurate placement of pedicle screw is important for achieving a successful outcome. According to statistics, the incidence of pedicle screw piercing the pedicle wall is 20%.[4] The incidence of misplaced pedicle screws with conventional techniques is of the order of 10-42%,[5-8] resulting in a higher occurrence of a series of complications.[9-11] Several techniques have been used to increase the accuracy of screw placement and the navigation system has demonstrated the advantages in improvement of accurate pedicle screw positioning. However, Kosmopoulos and Schizas[12] pointed out that thoracic vertebral navigation system was unable to provide the sufficient benefits to meet the requirements of the operation. Here, We designed a handheld pedicle piercer with warning device specifically for preparing the channel of pedicle screws, so as to increase the accuracy of placement of pedicle screws during surgical procedure

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Access this article online	
Quick Response Code:	Website: www.ijoonline.com
	DOI: 10.4103/0019-5413.144205

Materials and Methods

Intact 8 normal adult thoracolumbar specimens (from Cadaver Organ Donation, sex ratio is 1:1) were selected from patients at the age of 20-45 years without deformities were selected to obtain the baseline of threshold values. 80 vertebrae (T_8-L_5) were equally allocated at random into four groups. Group 1 was used for testing the maximum pressure of warning piercer within the vertebrae (F_1), Group 2 was for testing maximum pressure of the warning piercer penetrating front cortex of the vertebral body (F_2), Group 3 was for testing maximum pressure of warning piercer penetrating the endplate up and down of vertebral body (F_3) and pedicle notch up and down of vertebral pedicle (F_{41}, F_{42}), and Group 4 was for testing maximum pressure of warning piercer penetrating lateral cortex of vertebral (F_6), and the medial and lateral cortices of vertebral pedicle (F_{51}, F_{52}). In the second protocol of this study, four normal thoracolumbar adult specimens consisting of 40 vertebra and 80 pedicles were selected to test the warning effect of the piercer. Experimental parameters include true positive/negative, false positive/negative, sensitivity, specificity, usability, Youden index, and diagnostic efficiency were collected. The SPSS 16.0 software (SPSS Inc. Chicago, IL, USA) was adopted for statistical analysis.

Design

During the time of pedicle screw tract preparation, the pressures of the screw piercer were different on cortical and cancellous bone. At the time of warning pedicle piercer, the pressure variation was converted to audiovisual signals to reflect the real-time changes. The piercer is composed of an awl instrument with a hollow handle that has a built in electronic printed circuit board [Figure 1a], a piercer installed pressure....sensor, a warning control devices and an alarm system [Figure 1b]. The output line of the piezoelectric device was connected with the alertor. Therefore, it could trigger the audiovisual signals and then alert the surgeon to adjust the drilling direction when pressure approaching to a critical level. The digital screen would display the pressure values [Figure 1c]. Compared with traditional pedicle screw piercer, it would decrease the incidence of pedicle and vertebral body wall perforation.

The specimens were randomly allocated into four groups with equal 20 vertebrae in each group. The bone mineral density was measured by dual photon absorptiometry (Mazess, America).[2] Group 1 was tested for the maximum pressure of warning screw piercer in vertebrae. Hence, two normal adult thoracolumbar specimens with clear exposure of local anatomical marks were selected. The anterior bone cortex was chiseled up to 3.5 mm and the needle point of thoracic vertebrae was determined using Ebraheim method[13] and the needle point of lumbar vertebrae was determined using Magerl method.[14] After opening, the warning device via pedicle and vertebral body was applied. The maximum pressure of this process was recorded and marked as F_1 (n = 40). Group 2 was tested for the maximum pressure of the warning piercer penetrating front cortex of vertebral body. The operation steps were similar to those in Group 1. The maximum pressure of this process was recorded, and marked as F_2 (n = 40). Group 3 was tested for the maximum warning pressure of the screw piercer throughout the endplate and notch of pedicle. Thus, two thoracolumbar specimens consisting of 20 vertebral bodies and 40 pedicles dividing along the midcourt line of pedicle [Figure 2a] were chosen and used with warning piercer throughout the endplate center, and was marked as F_3 (n = 40). The maximum pressures of notch penetration of pedicle was marked as F_{41}, F_{42} respectively (n = 40). Group 4 was tested for the maximum pressure of warning

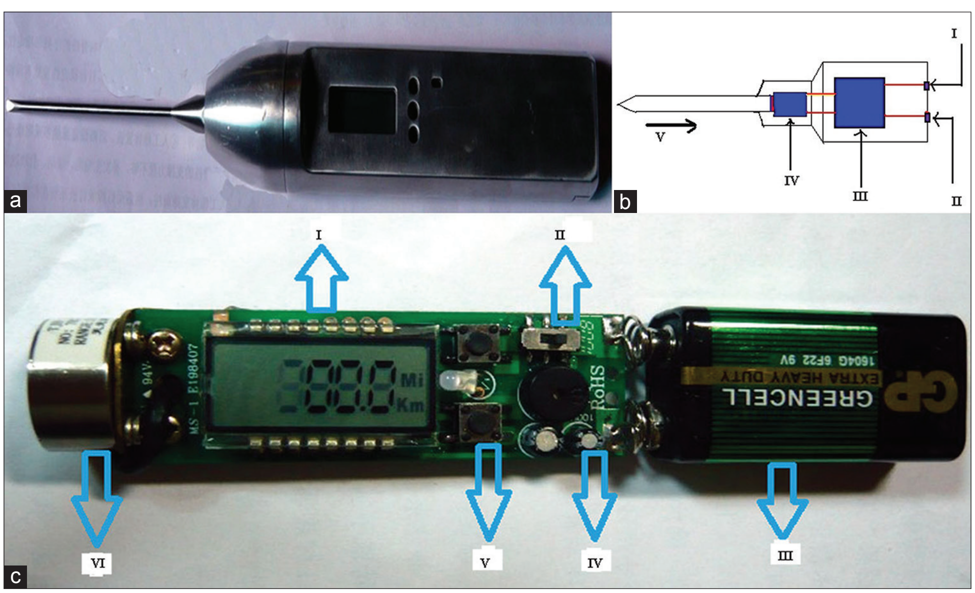

Figure 1: Clinical photograph showing (a) overview of warning piercer (b) schematic diagram of warning piercer (I) visual alarm (II) audible alarm (III) warning device (IV) pressure sensor (V) pressure generating direction (c) Built in structure of warning piercer (I) viewing screen (II) power switch (III) battery (IV) audible alarm (V) adjustment button (VI) pressure receptor

piercer throughout the lateral cortex of vertebral body and the medial and lateral cortices of pedicle. Therefore, two thoracolumbar specimens were chosen, which consisted of 20 vertebral bodies and 40 pedicles dividing along sagittal plane of each pedicle [Figure 2b] and longitudinally dividing pedicle as well as the vertebral body. Pedicle screw piercer was applied throughout the lateral cortex of vertebral body, medial and lateral cortex of pedicle, and were marked as F_{51}, F_{52}, F_6 respectively ($n = 40$).

Test of alarm effect

A total of 40 vertebrae and 80 pedicle specimens from four normal adult were selected. Alarm threshold of warning piercer was set up between 9.6 and 12.3 kgf. The gold standard of experiment was to observe the relationship between nail channel and cortex of vertebrae under direct vision. The vertical distance from the end of channel to the outer cortex <3.5 mm was considered to arrive the cortex. Absence of alarm in preparation of nail way was recorded as negative, and the converse was recorded as positive. If warning piercer passing every pedicle and vertebral body, the emergency alarm was recorded as positive. Otherwise, it was recorded as negative. The thoracic needle distance was 4.0 cm, while the lumbar needle distance was 4.5 cm. The thoracolumbar vertebrae were then removed out of specimens and soft tissues were discarded. Kirschner wire was inserted into the pin tract to explore warning piercer throughout the cortex, and the vertebrae was split using hacksaw along with the direction of Kirschner wire. The distance of nail way and vertebral cortex was measured with a Vernier caliper. All screws were evaluated by postoperative computer tomography with parameters similar to those in intraoperation scan.

True positive was indicated by warning piercer alarm reaching cortex through nail way. True negative was suggested by absence of alarm and failure of reaching cortex. False positive signal was characterized by alarm though piercer untouched with cortex. False negative alarm was signified when vertebral cortex was topped by piercer without any alert.

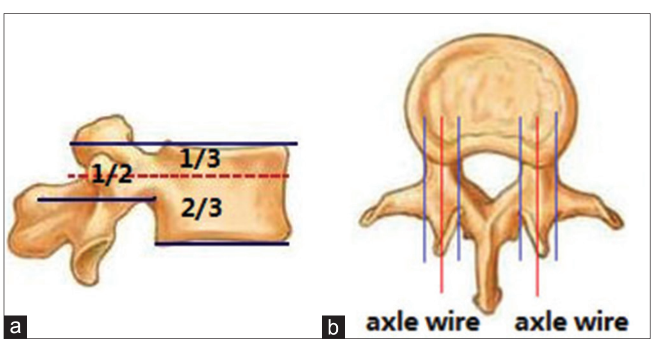

Figure 2: (a) Schematic diagram of Group 3 showing midcourt lines dividing pedicle (b) Schematic diagram of Group 4 showing longitudinal lines dividing pedicle

Degrees of sensitivity and specificity were determined. SPSS 16.0 was used for statistical analysis. One-way analysis of variance was accepted to analyze data pertaining to F_1, F_2, F_3, F_{41}, F_{42}, F_{51}, F_{52}, and F_6. $P < 0.05$ was considered as statistically significant differences. The alarm effect was determined by the levels of sensitivity, specificity, availability, Youden index and diagnostic efficiency.

Results

There were statistically significant differences between the threshold value of F_1 and F_2, F_3, F_{41}, F_{42}, F_{51}, F_{52} and F_6 respectively ($P < 0.05$). F_2 and F_6, F_{41} and F_{42} and F_{51} and F_{52} showed no significant difference ($P = 0.352$; $P = 0.690$; and $P = 0.626$) respectively. The value of the F_1 was significantly less than that of the maximum pressure of warning piercer penetrating vertebral cortex. The mean maximum pressure of warning piercer on the inside vertebrae was 8.970, $S_1 = 0.5698$, $F_1 = 8.970 \pm 0.5698$. The minimum pressure F_3 which stands for maximum pressure of warning piercer throughout the endplate was equal to 13.055 ± 0.6718 [Figure 3]. The pressure was between 12.38 and 13.73 kgf [Table 1]. Therefore, the alarm threshold value was calculated as 9.6-12.3 kgf. In total of 40 vertebrae and 80 pedicles, the frequency of applied piercer was 80, including 38 alarms and 42 no alarms. We found there were 80 nail ways during the operation. Of the 38 alarms, 36 vertebrae were not throughout cortex and 2 failed to reach cortex. Another 42 vertebrae without alarm were consisted of 39 vertebrae without touching the cortex, 1 throughout lateral cortex, and 2 throughout anterior cortex. The 80 pedicles included 38 positive (36 truly positive, 2 false positive) and 42 negative (39 true negative, 3 false-negative). The 36 truly positive nail ways included 18 lateral cortices of vertebrae, 6 reaching the medial cortex of pedicle, 9 reaching lateral cortex of pedicle

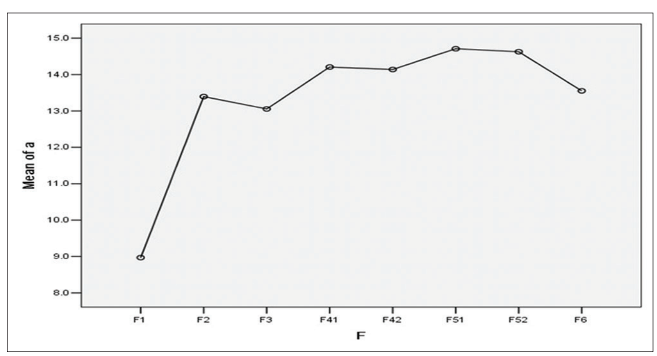

Figure 3: A graph showing the maximum pressure of pierce in various study groups F_1: The maximum pressure of piercer within the vertebrae F_2: The maximum pressure of piercer exceeded anterior cortex of vertebral body F_3: The maximum pressure of piercer penetrating vertebral body endplate F41, F_{42}: The maximum pressure of piercer penetrating pedicle notch F_{51}, F_{52}: The maximum pressure of piercer penetrating medial and lateral cortex of pedicle F_6: The maximum pressure of piercer penetrating vertebral lateral cortex

Table 1: Maximum pressure range of piercer in various study groups

Groups	Sample size	Mean	Standard deviation	Pressure range (kgf)
F_1	40	8.970	0.5698	8.40-9.54
F_2	40	13.395	0.8152	12.58-14.21
F_3	40	13.055	0.6718	12.58-13.73
F_{41}	40	14.208	0.8815	13.33-15.09
F_{42}	40	14.140	0.8521	13.29-14.99
F_{51}	40	14.710	0.6408	14.07-15.35
F_{52}	40	14.268	0.8115	13.82-15.44
F_6	40	13.553	0.7442	12.81-14.30

F_1=The maximum pressure of piercer within the vertebrae, F_2= The maximum pressure of piercer exceeded anterior cortex of the vertebral body, F_3= The maximum pressure of piercer breakthrough vertebral body endplate F_{41}, F_{42} = The maximum pressure of piercer breakthrough the pedicle notch F_{51}, F_{52}= the maximum pressure of piercer breakthrough the medial and lateral cortex of pedicle, F_6= The maximum pressure of piercer breakthrough the vertebral lateral cortex

and 4 reaching endplate. The degree of sensitivity was 92.31% (100% × [36/36 + 3]), degree of specificity was 5.12% (100% × [39/39 + 2]) and the degree of usability was 87.45%. The Youden index was 87.43% and the diagnostic efficiency was 92.5%.

Discussion

Pedicle screw fixation is quite popular amongst the spinal surgeons for both single and multilevel spinal fusion procedures. The accurate preparation of nail channel and the protection of vessels neighboring vertebrae has become a hot point in the field of neurosurgery. Because of the specific anatomic structure of pedicles, pedicle screw nail way must be implanted via the pedicle shaft axis to prevent the complications such as leakage of cerebrospinal fluid, injury of root and artery, and even paraplegia. The advent of minimally invasive procedures for spinal fixation has led to the advances of placing pedicle screw holes and implants percutaneously. However, this method increases the risk of misplacement implant and neural structure's injury as well. Schizas *et al.*[15] reported that 30% (18/60) of patients implanted with pedicle screws percutaneously manifested the perforation of pedicular wall, in which 2 of 60 (3.3%) cases required repeated surgery.

Multiple devices such as somatosensory evoked potentials, electromyographic recordings (EMG) and navigation system were tested by investigators to reduce the morbidity. Neurophysiological monitoring required the involvement of professional neurophysiologists during the process of screw placement. Recording of sensory or motor evoked potentials depended on the detection of impingement onto nervous tissue, which suggested a full cortical breach. Being a warning system, these methods were imperfect because it was too late to alert the surgeon after detecting impaired nerve function in the whole process. Some studies reported that the false negative result was as high as 23% determined by continuous EMG monitoring during the course of pedicle screw placement. Both compound muscle action potential and EMG recordings required subtotal neuromuscular blockade. With the rapid progress of computer technology, spinal navigation system became an interactive tool with a surgical pointer or tool used for reviewing images at computer workstation in the operating theatre. Computed tomography (CT) based image navigation systems were reported in conjunction with pedicles perforation up to 0-2.5%.[16,17] Clinical studies of computer assisted image guided implant placement revealed the deviation rates were between 1% and 9%.[8,18,19] However, some studies disclosed there were no significant differences of perforation rate between image guided and two dimensional fluoroscopy guided systems.[20]

Sasso and Carrido reported that intraoperative navigation system did not prolong the surgical time compared with serial two dimensional fluoroscopy.[13] Nevertheless, other studies showed there were significantly differences of surgical time between image guided screw placement and conventional surgical procedure.[14] Assistant devices for improving accuracy of screw placement were also developed. For example, Bolger *et al*. designed a piercer to avoid penetrating the vertebral wall by differential impedance between soft tissue and bone structure in preparative nail way. Its alarm rate was 98%, but risk of vertebral hemorrhage was accompanied.[21] Similarly, Kantelhardt *et al.*[22] used intraosseous ultrasound for nail way preparation. Its accurate rate reached 99%.

Traditional screw insertion technique was mainly depend on the hand felling of the surgeon to judge and adjust the direction through the alteration of resistance during drilling. However, the alarm piercer was able to convert the experienced hand felling into the objective indexes by gauging the difference of mechanical strength between changed bone density of vertebral cortex and cancellous bone. The changeable resistance can activate the alarm within first time to alert the surgeon adjusting the needle power and drilling direction before cortex was penetrated. The warning piercer was also occupied the exceptional advantages of shorter operation time, less radiation and reduced learning curve. This unique design of warning piercer took the piezoelectric converter as a main body to make an audiovisual signal system, which could provide early real time warning for surgeon to adjust the nail direction accordingly. Meantime, it ensured the pedicle screw was correctly placed in right position and hence reduced the injury to adjacent nerves and vessels.

Our study demonstrated that the transpedicular approach to the vertebral body exerted a pressure of 8.970 ± 0.5698 kgf and the pressure of piercer penetrating endplate was 13.055 ± 0.67188 kgf. There is no overlap between the minimum and maximum pressure values within the vertebrae and penetration through the cortical bone. The threshold guaranteed by the vertebrae within the cancellous bone, not penetrating the cortical bone was 9.6-12.3 kgf. Preoperative CT scanning or planning were not required. Since this tool does not require computer registration or vertebral tracking, it can be used in all aspects of spinal fixation including fractures and spondylolisthesis, regardless of the severity of fracture and dislocation. The warning piercer is an auxiliary device to improve the accurate rate of pedicle screw placement and reduce the dependence on fluoroscopy. This device can reduce radiation exposure to the surgeon while maintaining safe pedicle screw placement for the patient and does not require navigation or vertebral tracking. It can be widely used in all aspects of spinal fixation including fracture and degeneration, no matter what degree of pars fractured and dislocated. It provides a real time monitoring for operation with minimal impact on the standard surgical procedure.

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How to cite this article: Bin L, Yong H, Yang X, Bi Z, Mo S, Zhi-Min G. Pedicle screw piercer with warning device - A technique to increase accuracy of pedicle screw placement A cadaveric study. Indian J Orthop 2014;48:545-9.

Source of Support: Nil, **Conflict of Interest:** None.