Int J Clin Exp Med 2015;8(6):8634-8640
www.ijcem.com /ISSN:1940-5901/IJCEM0008451

Original Article

A novel guide device improves the accuracy of pedicle screw placement

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Received March 26, 2015; Accepted June 4, 2015; Epub June 15, 2015; Published June 30, 2015

Abstract: Pedicle screw placement in thoracic and lumbar spine is technically demanding and involves radiation exposure. Commercially available systems for pedicle screw insertion are expensive and cannot be widely used for those less-developed areas. The purpose of our study was to develop a simple guide device assisting pedicle screw placement and improving the accuracy in the operation. A simple guide device was developed with the aim of improving accuracy of pedicle screw technique based on anatomical structures of the spine. We retrospectively collected clinical data of 111 consecutive patients who received treatment of pedicle screw internal fixation between January 2013 and September 2014. In total, 518 screws were inserted by the same surgeon, among which 280 screws were implanted in 60 patients (33 males and 27 females) with conventional freehand technique and 238 screws were implanted in 51 patients (27 males and 24 females) using the guide device. According to postoperative CT evaluation, screws were classified into different grades and accuracy rates were compared between the two groups. A total of 518 screws were placed (238 in the guide group, 280 in the conventional group). No intraoperative or postoperative complications such as infection, vessel and nerve injuries occurred. After postoperative CT evaluation, 215 from guide group and 236 from the conventional group were classified in Grade 1. Only screws in Grade 1 were considered as accurate insertion. Thus, the accuracy rates were 84.3% for the conventional group and 90.3% for the guide group respectively. Through statistical test, there was significant difference in the accuracy rate between two groups. The simple guide device significantly improves the accuracy of pedicle screw placement. Combined with the advantage of cheapness, it can be widely used in spinal internal fixations, especially suitable for those inexperienced spine surgeons in less-developed areas.

Keywords: Pedicle screw, guide device, radiation exposure, thoracolumbar spine, accuracy rate

Introduction

Use of pedicle screws for deformity correction and spinal stabilization has been widely accepted in spine surgeries [1-3]. In pedicle screw fixation, accurate insertion is essential to avoid neurological injury and weak stability. However, malposition is not a rare occurrence [4, 5]. Given this, various computed tomography (CT) and fluoroscopy-based navigation systems have been applied with the purpose of improving the accuracy in the process of pedicle screw placement. A number of robotic systems have been developed with demonstrated ability to increase screw accuracy [6, 7]. However, commercially available systems for pedicle screw placement are so expensive for those less-developed areas that they have not been adopted widely.

In the present study, we developed a simple guide device with the purpose of improving the screw insertion accuracy, and compared it with the conventional freehand technique.

Materials and methods

Design of the guide device

Based on anatomical structures of the spine, the guide device was designed and manufactured which was composed of three main parts (**Figure 1** in detail). Part 1 (Interspinous positioning frame) covers pedestal, C Handle, upper and lower sliding channel. The pedestal is equipped with several spicules that enables it to be firmly fixed on the supraspinous ligaments. Part 2 is mainly composed of sliding SSA (Sagittal Screw Angle) dial which can slide

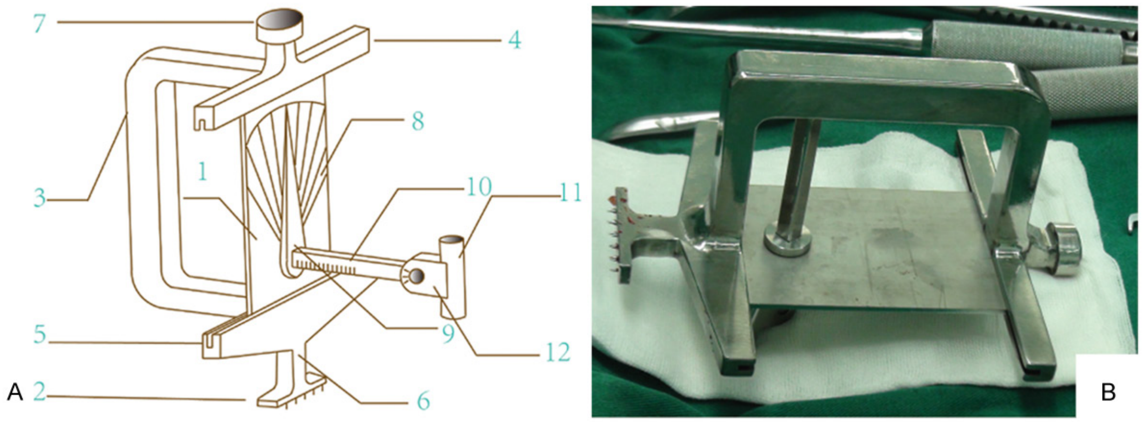

Figure 1. The schematic map (A) and physical map (B) of the new guide device. (A) shows the constructions of the invention: (1): sliding SSA (Sagittal Screw Angle) dial, (2): spicules, (3) C Handle, (4): upper sliding channel, (5): lower sliding channel, (6) pedestal, (7): the columnar bump, (8): scale of Section 1, (9): pointer, (10): scale rod, (11): pipe-like passage, (12): TSA (Transverse Screw Angle) dial.

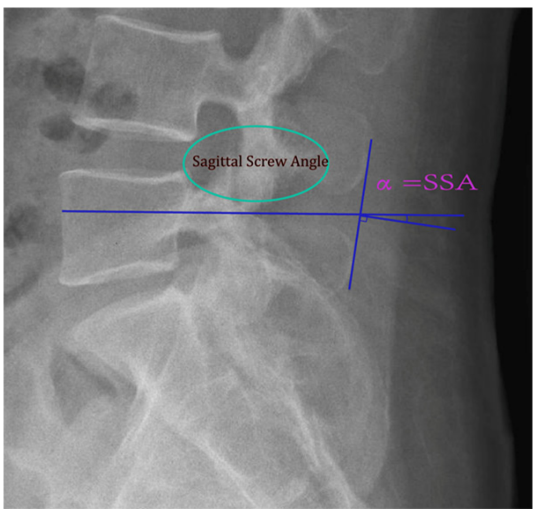

Figure 2. Measurement of SSA according to the X-ray.

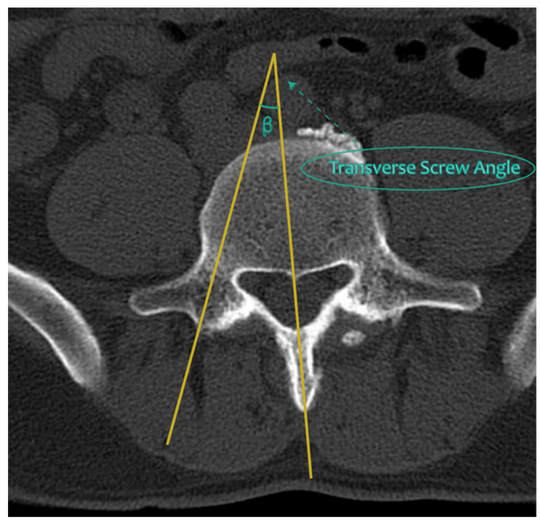

Figure 3. Measurement of TSA based on the CT image.

freely between the upper and lower sliding channels. Part 3 which contains pointer, scale rod, TSA (Transverse Screw Angle) dial and pipelike passage is mainly used to adjust the angle and distance. The above sections of Part 3 are linked, that is, the direction of the pointer changes with the rotation of pipelike passage in the sagittal plane. In addition, the pipelike passage can also be rotated in the horizontal plane. Obviously, the value of sliding dial and TSA dial refers to SSA (SSA in **Figure 2**) and TSA (TSA in **Figure 3**). Similarly, the reading of the scale rod represents the distance between the center of pedicle projection and connection of neighboring spinous processes (D in **Figure 4**).

Clinical application

A total of 111 consecutive patients who underwent posterior spinal fixation surgery in the period January 2013-September 2014 are included. Among them, 51 individuals received treatment using the novel guide technique, and the left 60 were treated in the conventional freehand manner. Totally, 238 pedicle screws were implanted in the guide group, 280 in the conventional group. Participants in both groups were operated by the same surgeon, the inventor of the guide device. Operations of internal fixation were carried out for thoracolumbar

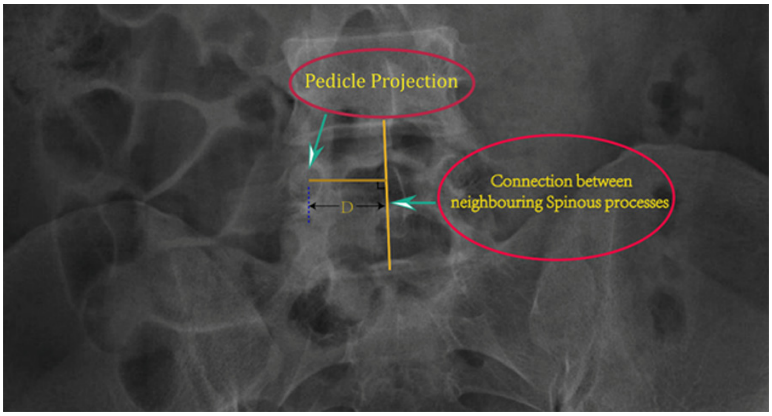

Figure 4. Measurement of D. D means distance between the center of pedicle projection and connection of neighboring spinous processes according to the radiograph.

fractures, lumbar spondylolisthesis, spinal stenosis etc. Data of patients and levels of inserted screws are shown in **Table 1** in detail (**Table 1**). The screw positions were evaluated by postoperative CT scan to check for malposition.

Preoperative planning

Determination of TSA: Before the operation, we need to select a representative computed tomographic (CT) image based on the level of PSP (pedicle screw placement), from this image, TSA (Transverse Screw Angle) can be measured which is shown in **Figure 3**.

Measurement of D (Distance between the center of pedicle projection and connection of neighboring spinous processes)

According to preoperative anteroposterior (AP) X-ray, distance between the center of pedicle projection and connection of neighboring spinous processes can be easily measured which may be used as a reference in the operation (**Figure 4**).

Determination of SSA: Considering the impact of patient positioning on SSA (**Figure 2**), we select a lateral X-ray obtained by C-arm after positioning and anesthesia. Based on this image, the value of SSA can also be easily measured.

Surgical procedures

In the guide group, the best entry point was preliminary determined based on anatomical landmarks after routine surgical exposure, the assistant was required to hold the C handle, and then the pedestal of the guide device was fixed on the supraspinal ligaments attached to the spinous processes of the target section and the upper one (**Figure 5**). Next, the columnar bump (Section 7 in **Figure 1**) was tapped by the surgeon in order to make sure that the device had been firmly positioned. Then the surgeon placed the open cone through the pipelike passage and positioned the tip of the open cone on the entry point. The next step was to rotate the pipelike passage in the sagittal plane to ensure that the value of the sliding dial was consistent with SSA which was determined by lateral X-ray preoperatively. Similarly, rotate the pipelike passage in the transverse plane to ensure that the value of the TSA dial was consistent with measured TSA according to the CT image. Finally, check the reading of the scale rod and compare it with D (the distance between the center of pedicle projection and connection of neighboring spinous processes). If the reading deviated largely from D, the surgeon could make proper adjustment in the selection of the entry point. Next, the guide wire was placed through the pipelike passage. After all guide wires were inserted, an X-ray examination by C-arm fluoroscopy was needed to assess the guide-wire position. There was no distinction between guide group and conventional group in the following steps. The detailed procedures for the guide group was shown in **Figure 6**.

In the conventional freehand group, all screws were implanted by freehand. C-arm was just intermittently used to check and adjust positions of the guide wires and screws. After all screws were inserted, the positions of screws were assessed by C-arm (AP and lateral).

Evaluation of pedicle screw position

CT images were obtained to evaluate the positions of the screws postoperatively. Position of each screw was graded according to the classification by Louis Philippe Amiot (**Table 2**) [8]. All screws were evaluated by two different

Table 1. Patient characteristics

		Guide group	Conventional group
Age	Mean	55.20	56.86
	Range	38-71	39-73
Gender	Male	27	33
	Female	24	27
Etiology	Thoracolumbar fracture	19	22
	Lumbar Spondylolisthesis	18	22
	Spinal stenosis	14	16
Number of screws in different vertebral level	T10	18	22
	T11	20	22
	T12	28	34
	L1	16	18
	L2	8	8
	L3	22	22
	L4	44	48
	L5	52	64
	S1	30	42
	Total	238	280

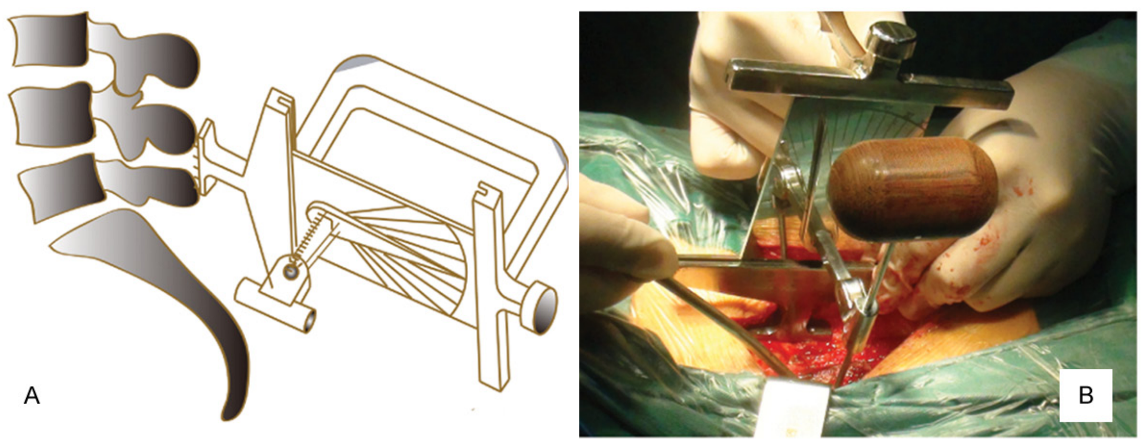

Figure 5. Use of the guide device assisting pedicle screw insertion. The device was fixed on the supraspinal ligaments between the target levels. The C handle was hold by the assistant; Direction of the passage was determined through adjustment of TSA and SSA dials.

investigators who were blinded to the study group assignment. If the two investigators' assessments were not consistent, then a discussion ensued the result of grading.

Statistics

Mean values and Standard deviations for all variable parameters were calculated for two groups. To test for the significance of the findings, statistical probability (*P* value) for comparison between the groups was calculated using SPSS 19.0. The significance level was set at *P* value less than 0.05. χ^2 test was used to compare the accuracy rates of pedicle screws between the two groups.

Results

Data of 111 patients were collected for analysis, 51 were assigned to the guide group, and the rest were in control group. A total of 518 screws were placed (238 guide group, 280 conventional group). No intra-operative or postop-

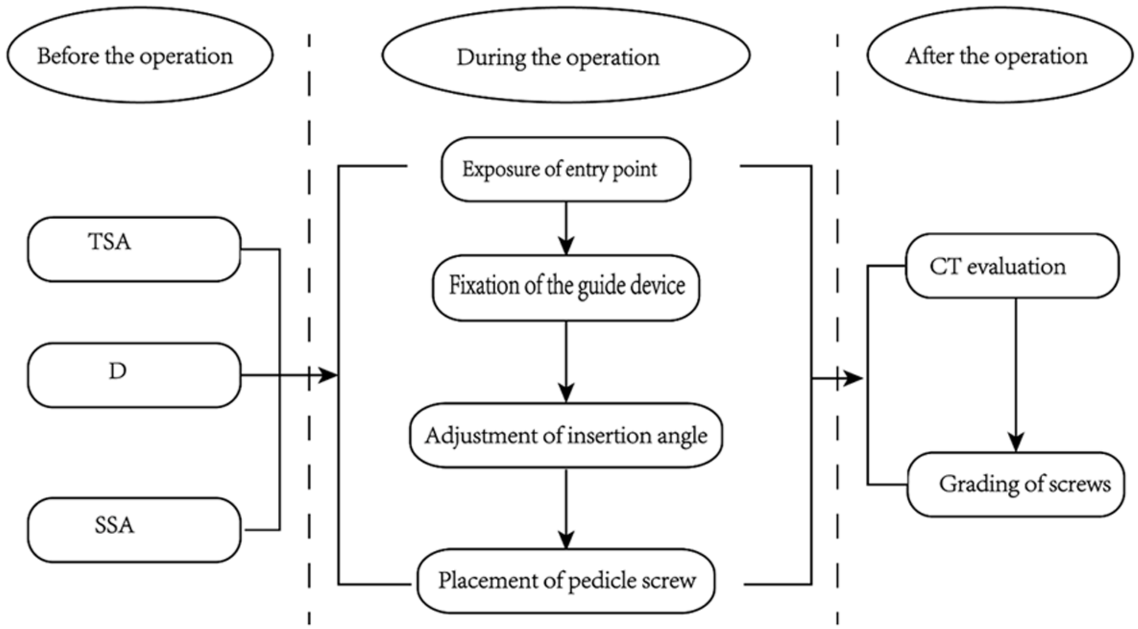

Figure 6. Flow diagram of operation using the guide device. TSA: Transverse Screw Angle; D: Distance between the center of pedicle projection and connection of neighboring spinous processes; SSA: Sagittal Screw Angle; Grading of screws was done according to the classification by Louis Philippe Amiot.

Table 2. Grading of screws

Classification (Louis Philippe Amiot)	Number of screws	
	Guide group (N=238)	Conventional group (N=280)
GRADE1 (fully contained)	215	242
GRADE2 (breach<2 mm)	21	27
GRADE3 (breach<4 mm)	2	9
GRADE4 (breach<6 mm)	0	2
GRADE5 (breach>6 mm)	0	0

Screws in GRADE1 were fully contained in the pedicle. In order, cortical breach of screws in GRADE2-5 was within 2 mm, 2-4 mm, 4-6 mm, and over 6 mm. A=Surgeon A, B=Surgeon B, C=Surgeon C, D=Surgeon D.

erative complications occurred, such as infection, vessel and nerve injuries.

In the present study, a total of 238 and 280 pedicle screws were placed in guide group and conventional group. According to the classification by Louis Philippe Amiot (**Table 2**). Only screws in Grade 1 were considered as accurate insertion.

In the Guide Group, 238 pedicle screws were inserted using the novel guide technique. Among these 238 screws, 215 were classified in Grade 1, 21 in Grade 2, 2 in Grade 3, none in Grade 4 or 5. The percentage of Grade 1 was calculated to be 90.3%, representing the accuracy rate.

In the Conventional Group, 280 pedicle screws were implanted by the same surgeon. After CT evaluation, 236 were classified in Grade 1, 31 in Grade 2, 11 in Grade 3, 2 in Grade 4, none in Grade 5. Accuracy Rate of PSP was calculated to be 84.3%.

Accuracy Rates were compared between the two groups using χ^2 test. Analysis of data was conducted using SPSS 19.0. The results showed that there was significant difference between the two groups in the accuracy rate (χ^2=4.182, P=0.041).

Discussion

Pedicle screw technique has been widely used in vertebral fractures and dislocations, spinal deformities, lumbar spondylolisthesis, spinal instability, etc. since it was proposed to treat in unstable thoracolumbar vertebral fractures by Roy-Camille in 1963 [1, 2]. Although the technology of PSP is becoming more and more mature, screw malposition still occurs occasionally which may lead to many complications, such as decrement of fixation strength, damage to vessels and nerves, etc. Naturally, much attention has been paid to the study of improving PSP accuracy [6, 7].

In order to ensure precise insertion, a series of complicated 3D image-guided navigation systems have been introduced [9-12]. However, the registration step in these image-guided navigation systems makes the surgery time-consuming [13]. Furthermore, repeated fluoroscopy is often required for some of these devices. Disadvantages such as complicated operations, high prices and long learning curves make most of these systems unable to be widely adopted [14]. At present, C-arm has widely been used in spinal surgeries and brought great conveniences. However, the radiation exposure also needs to be seriously taken into consideration [15-17]. Although many experienced surgeons can insert pedicle screws adequately just based on the anatomical landmarks without fluoroscopy [18], for those inexperienced operators, the accuracy of screw placement may not be guaranteed without imaging. In order to maintain the safety of surgery, they have to make compromises to use fluoroscopy.

In our study, we developed a simple guide device with the aim of improving the accuracy of pedicle screw technique. The results demonstrated that pedicle screws can be accurately and safely inserted with the assistance of the device. According to the statistical data, we can conclude that the device significantly improved the accuracy rate of pedicle screw placement. We retrospectively collected data of patients who underwent treatment of pedicle screw fixation using the conventional freehand method or the novel guide technique. All the operations were mainly done by the same surgeon, the inventor of the device with over 15 years of experience in placing pedicle screws. It is very easy for all the spinal surgeons to handle this device in the operation. According to our findings, accuracy rate of pedicle screw technique using the guide device varies little among surgeons with different experiences. For those surgeons with limited experience, it can significantly improve the accuracy in the operation. Even for these experienced surgeons like the inventor, this guide device can still improve the accuracy of pedicle screw insertion. Another advantage of this guide device is to be affordable. For many hospitals in a medically underserved areas, C-arm imaging was unavailable and surgeons were not experienced in pedicle screw technique. In this situation, this guide device can play an important role in the operations.

The biggest potential weakness of this study is that the guide device has not been applied to the internal fixations of upper thoracic and cervical vertebrae. In the future, we plan to carry out some cadaveric studies in levels of upper thoracic and cervical vertebrae and make some improvements in the device. It is important to note that it is not suitable for those cases with serious rotatory deformities. In these cases, the anatomical relationship between the supraspinal ligament and the entry point changed, thus may lead to errors for TSA and SSA determination. To emphasize an important point, the guide device only aids in determination of screw direction (TSA and SSA). The entry point still need to be determined based on the anatomical landmarks. Value of D is just validation for the entry point. Another point is that even though we've considered the effect of patient position of Sagittal Screw Angle (SSA), we cannot ensure that the patient position keeps unchanged in the entire operation process.

Conclusions

In conclusion, our study confirmed that use of the guide device can significantly improve the accuracy rate in the process of pedicle screw placement. With the aid of this device, operation can be done with little fluoroscopy. In addition, this device is very simple and cheap that those less-developed hospitals can afford it. Taken together, using this device produces four key benefits: accurate, safe, cheap, and easy-to-use.

Acknowledgements

This work was supported by the National Natural Science Foundation of China (Grant #30973058, #81171694), Jiangsu Province Nature Science Foundation (BE2010743), theProgram for Development of Innovative Research Team in The First Affiliated Hospital of NJMU (No. IRT-015), and A Project Funded by the Priority Academic Program Development of Jiangsu Higher Education Institutions.

Disclosure of conflict of interest

None.

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