CLINICAL ARTICLE

SAP Principle Guided Free Hand Technique: A Secret for T1 to S1 Pedicle Screw Placement

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Objective: Existing freehand techniques of screw placement mainly emphasized on various entry points and complex trajectory reference. The aim of this study is to illustrate a standardized and reliable freehand technique of pedicle screw insertion for open pedicle screw fixation with a universal entry point and a stereoscopic trajectory reference system and report the results from a single surgeon’s clinical experience with the technique.

Method: In this study, the author respectively reviewed a total of 200 consecutive patients who had undergone open freehand pedicle screw fixation with Superior Articular Process (SAP) technique from January 2019 to May 2020. For accuracy and safety, all 200 cases had undergone postoperative X-ray while 33 cases including spinal deformity, infection, and tumor had received additional CT-scan. Screw accuracy was analyzed via a CT-based classification system with Student’s t test.

Results: A total of 1126 screws had been placed from T1-S1 with SAP-guided freehand technique and the majority had been confirmed safe in X-ray without the need of CT scan. A total of 316 screws in deformity or infectious or tumor cases had undergone additional CT scan. Screw accuracy was analyzed via a CT-based classification system with Student’s t test.

Conclusion: SAP-guidance is a reliable freehand technique for thoracic and lumbar pedicle screw instrument. It allows accurate and safe screw insertion in both non-deformity and deformity cases with less radiation exposure.

Key words: freehand technique; pedicle screw; posterior fixation; radiation exposure; superior articular process

Introduction

Spinal fixation had undergone development of decades of years from the introduction of Harrington instrument in 1969. Pedicle screw fixation, since its advent by Roy-Camille and Judet in 1970s, have gradually become the routine for its effectiveness in producing ideal stability and deformity correction with maximum purchase in penetrating the whole three columns, which had been widely applied in spinal surgeries including tumor, trauma, and infection. However, despite of application for decades, pedicle screw fixation remains technically demanding for potential complications. Misplaced screw had been reportedly associated with pedicle fracture, instrument failure, dural tear, and neurological deficiencies. For safety concern, intraoperative fluoroscopy has been frequently used as assistance. Meanwhile, computerized tomography-based navigation has been developed to enrich the arsenal from which surgeons can choose depending on their experience, preference, and resource available. Nevertheless, technique advancement irrevocably results in unexpected challenges. More emphasis on

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Grant sources: The research has been funded by the Clinical Innovation Fund of Southwest Hospital (Grant No. SWH2017YBBXM-31) and the Joint Medical Research Project of Chongqing City (Grant No.2018ZDM002).

Disclosure: The corresponding author states that there is no conflict of interest.
Received 24 May 2022; accepted 23 August 2022

Orthopaedic Surgery 2022;14:2995-3002 • DOI: 10.1111/os.13513
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intraoperative radiography brings more radiation exposure, which has increasingly triggered health concerns considering the large number of operations performed every year.\textsuperscript{5,6} While navigation techniques deliberate surgeons from radiation exposure, it is the economic cost and equipment requirement that demands concerns especially in developing countries.\textsuperscript{7}

Therefore, despite of technique advancement these years, large numbers of surgeons still preferred freehand technique to X-ray or CT-based assistance for more streamlined procedure with less radiation exposure and less operation duration.\textsuperscript{8} We share the view that most of the routine operations could be well performed by reliable and reproducible freehand insertion without the assistance of fluoroscopy or navigation-based assistance. Lenke had developed SAP rule for entry point selection and two-step free hand technique for pedicle screw placement.\textsuperscript{9} Such freehand technique depends on “the visible” anatomical marks and “the invisible” tactile feedbacks to ensure screw’s safety and accuracy. Notably, “the invisible” relies extremely on surgeons’ experience, the attainment of which often requires a long learning curve. To simplify the difficulty of freehand insertion, many researchers have proposed various freehand techniques based on their experience and anatomical research focusing different entry point at different levels and complicated trajectory reference.\textsuperscript{10} Nevertheless, excessive complexity and inconsistence along the level had restrained their wide application especially among young surgeons. The purpose of the study was (i) to illustrate a standard and reproducible freehand screw fixation technique based on anatomic landmarks with advantages including a uniform entry location from T1-S1 regardless of levels and multiple references for trajectory; (ii) to assess the safety and accuracy of the technique at thoracic or lumbar level and in deformity or non-deformity cases; (iii) to provide surgeons with an alternative reliable approach for freehand screw placement free from radiation exposure.

\textbf{Materials and Methods}

\textbf{Patients’ Data}

Patients who met the following inclusion criteria were enrolled in the research: (i) spinal deformity cases treated with the present freehand technique; (ii) non-deformity cases including degeneration, infection, and tumor which were treated via open surgeries with the freehand technique. In contrast, patients who met the following criteria were excluded from the research: (i) severe anatomical deficiency with multi-revision history; (ii) obvious congenital anatomical disorder in which anatomical markers failed to act as references; (iii) cases treated with fluoroscopy or navigation assistance. Two hundred consecutive patients (120 male and 80 female) who had undergone open freehand pedicle screw fixation from T1-S1 between January 2019 to May 2020 were studied retrospectively. The research had been approved by the IRB of authors’ affiliated institution (No.(B)KY202271).

Indication for screw fixation included spinal deformity cases (12 cases) and non-deformity cases including spinal degenerative diseases (167 cases), spinal infection (17 cases), spinal tumor (4 cases), which could be further divided into non-deformity group and deformity group or thoracic group and lumbar group. The spine levels ranged from T1-S1, the age from 18 to 80 years old.

\textbf{Surgical Technique}

\textbf{Exposure:} The standard posterior mid-line approach was executed according to technique as described.\textsuperscript{11}

\textbf{Entry point:} From T1-T12, the entry point was located at the intersection of a horizontal tangent of the upper-middle third of transverse process and a vertical line along the exterior margin of superior articular access (Figure 1A). From L1-S1, the entry point was located at the junction point of lamina’s exterior margin and the accessory transverse process (Figure 1B,C).

\textbf{Cannulation:} The entry point confirmed, a 3.5-mm acorn-tipped burr was used to create a breach for subsequent cannulation. Contrary to classical Lenke’s gearshift featured by a slight curve, we perform the cannulation with a straight blunt-tipped gearshift. On inserting the gearshift, appropriate cranial-caudal angle and medial-lateral angle should be stuck with. A medial-lateral angle of 25° would be proper for T1, T2, L5; and 5° for T10-L2, and 20° for the rest (Figure 2).

With respecting to the cranial-caudal angle from T1-S1, it was agreed that an ideal orientation should be parallel to the upper endplate,\textsuperscript{12} which is hard to refer to without fluoroscopy. Instead, we have proposed an alternative reference system consisting of three parallel lines: (i) Line A along the external margin of SAP; (ii) Line B along the external margin of lamina; (iii) Line C along the upper margin of spinous processes (Figure 3). As all lines keep a vertical relationship with the upper endplate, orientation vertical to any of the lines would produce a similar parallel relationship to the upper endplate. Moreover, A three-dimensional structure facilitates a more direct and reliable vision reference in maintaining the trajectory.

In the process of cannulation, the gearshift should be executed with smooth feedback of constant resistance. Any abnormality of feedback might indicate unproper orientation. To avoid medial perforation, “a skillful force” should be executed without strong “pushing.” In detail, the tip of gearshift should progress forward in constant rotation, bearing a resemblance to technique used in “Tai Chi pedicle screw placement,” which adopted a low-speed drill for cannulation.\textsuperscript{13}

Screw insertion: Cannulation completed, a ball-ended feeler is used to confirm the intactness of the passage including five walls: superior, inferior, medial, lateral, and bottom. Consistent palpation indicates the intactness of passage while non-consistent palpation means risk of pedicle perforation.
requiring readjustment until safety was confirmed finally. Suitable screws should follow the same passage illustrated above. In screw insertion, constant feedback was a reliable indicator for safety and any sudden change in the feedback may suggest a breach in one of the pedicle walls and requires confirmation. Through the whole procedure, C-arm was only used for initial location and final confirmation after all screws had been placed including an anterior-posterior (AP) view and a lateral view.

Screw Evaluation
Standard AP view and lateral view were used to assess the accuracy and safety of pedicle screw. Considering radiation avoidance and economic factors, it wasn’t compulsory for all patients to receive a postoperative CT scan if good placement could be confirmed by X-ray. CT scans were only recommended in deformity cases for fusion evaluation and infectious or tumor cases for debridement assessment. Any patients with remaining neurological symptom were also suggested to receive a CT scan.

Screw classifications were made according to CT-based criteria from previous studies \(^{14,15}\): Grade A: screws were absolutely confined within pedicle without any perforation. Grade B: Screws with medial perforation <2 mm or lateral or superior perforation. Grade C: Screws with medial perforation within 2 mm–4 mm. Grade D: Screw with medial perforation >4 mm. Grade A was regarded as good placement and Grade B as acceptable while C and D as unacceptable for their risk of neurological injuries.

All surgeries were performed by one single senior surgeon (ZeHua Zhang, MD). The study was conducted in
accordance with the principles of the Declaration of Helsinki. The study protocol was approved by the ethics committee of Southwest Hospital, the Army medical University. Because of the retrospective nature of the study, patient consent for inclusion was waived.

**Statistical Analysis**

Statistical analysis was performed by using SPSS Software (Version 13.0; SPSS Inc, Chicago, Illinos, USA), the accuracy between the thoracic group and the lumbar group, the non-deformity group and the deformity group was compared via Student’s t test and \( p < 0.05 \) was statistically significant.

**Results**

**General Data**

The demographics of the patients enrolled had been summarized in Table 1. A total of 200 cases had been included in the series (120 for male and 80 for female). Indication for screw fixation including spinal deformity cases (12 cases) and non-deformity cases consisting of spinal degeneration (167 cases), infection (17 cases), and tumor (4 cases). A total of 1126 screws have been inserted from T1-S1, including 272 at thoracic levels and 854 at lumbar levels. Mean fluoroscopy was 0.73 shot per screw. Mean operation time was 165 minutes (range from 115 to 486).

**Screw Assessment**

As shown in Table 2, most cases had been confirmed safe in X-ray without need of CT scan. Thirty-three of 200 cases had been requested to receive a CT scan for evaluation of tumor incision or infection drainage or other purposes, including 12 deformity cases (Figure 4), 17 infectious cases, and four tumor cases. A total of 316 screws had received additional CT scan with 95.5% (189 of 198 screws) accuracy in thoracic group and 94.9% (112 of 118 screws) in lumbar group. In deformity group, the accuracy had been 90.5% (114 of 126 screws) and 95.8% (182 of 190 screws) in non-deformity group. All pedicle perforation had been rated Grade B (<2 mm) without significant difference between the medial and the lateral \( (p < 0.05) \). No cases had been detected with significant neurological deficiencies.

**Discussion**

In the present study, we have illustrated a feasible and producible freehand technique of screw placement with an universal entry point and a stereoscopic trajectory reference system, which had achieved satisfactory accuracy and safety in spinal deformity and non-deformity cases. Benefiting from

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**TABLE 1 Patients demographics**

| Parameter                        | Value                  |
|----------------------------------|------------------------|
| Number of patients               | 200 cases              |
| Mean Age                         | 46 (18–80) years       |
| Male                             | 120 cases              |
| Female                           | 80 cases               |
| Spinal degenerative diseases     | 167 cases              |
| Spinal deformity                 | 12 cases               |
| Spinal infection                 | 17 cases               |
| Spinal tumor                     | 4 cases                |
| X-ray shots in total             | 826 shots              |
| Screws in total                  | 1126 screws            |
| Mean fluoroscopy                 | 0.73 shot (826/1126)   |
a smooth learning curve, the present technique provided young spine surgeons a reliable method to achieve screw placement with safety free from radiation exposure.

**Disadvantages of Existing Freehand Techniques**

Pedicle screws have been widespread applied since its advent. Threading three columns produces satisfactory purchase against withdrawal and distortion, while also triggering irreversible risks of neural injuries if malposition occurs. Therefore, fluoroscopy assistance had been indispensable for young surgeons before their maturity into freehand insertion, which also caused increasingly health concerns for radiation exposure. Dewey et al. reported that consecutive radiation exposure per minute can be tantamount to at least 50 times of chest radiograph, and female orthopaedic surgeons suffered twice the expected rate of total cancer and 2.9 times of expected breast cancers than others.

Given the large quantity of operations orthopaedic surgeons performed each year, more attention should be paid to radiation avoidance and more measures be taken to decrease the dependency on fluoroscopy-assistance. The present progress for the purpose above could be classified into two strategies: (i) navigation techniques including CT and electromagnetic navigations; (ii) freehand techniques.

The former has greatly protected surgeons from radiation exposure with satisfactory safety and accuracy. However, navigation is not a flawless resolution due to its own risks including additional operative time, longer learning curve, and interruption to workflow. Therefore, a large percentage of surgeons were still preferring traditional freehand techniques in their routine practice due to more streamlined workflow. However, though various freehand techniques had been proposed to provide critical code for screw insertion with safety and accuracy, most of these techniques had been characterized with complex entry location and trajectory maintaining, rendering it difficult for young surgeons to master at their early stage.

**Advantages of SAP-Guided Freehand Technique**

Benefitting from a universal entry point regardless of levels involved and a multi-reference system for trajectory maintaining under direct vision, SAP technique manifested a significant advantage of convenience, which would smooth the whole procedure. Meanwhile, anatomy-based guidance obviously decreased intraoperative usage of fluoroscopy assistance with mere 0.73 fluoroscopic shot per screw in our practice, which would greatly protect surgeons and patients from radiation exposure. Moreover, the smoothed procedure and less radiation exposure wasn’t achieved at the cost of decreased accuracy and safety. Based on the criteria in which medial perforation <2mm was regarded safe while >4mm risk of neurological injury, the overall accuracy in this study had been above 90% at thoracic and lumbar level. In non-deformity group, the accuracy had been 95.8% (182 of 190 screws), which was comparable with other freehand techniques. In deformity group, 90.5% (114 of 126 screws)
FIGURE 4 Postoperative CT scan of pedicle position in a spinal deformity case. (A,B) Anterior–posterior view and lateral view of preoperative X-ray; (C,D) Anterior–posterior view and lateral view of postoperative X-ray; (E) T3, left defined as grade A, right as grade A; (F) T4, left defined as grade A, right as grade A; (G) T5, left defined as grade B for lateral, right as grade A; (H) T7, left defined as grade B for lateral, right as grade A for medial; (I) T8, left defined as grade B for lateral, right as grade B for medial; (J) T9, left defined as grade A, right as grade A; (K) T10, left defined as grade A, right as grade B for lateral; (L) T11, left defined as grade A, right as grade A; (M) L1, left defined as grade A, right as grade A; (N) L2, left defined as grade A, right as grade A; (O) L3, left defined as grade B for lateral, right as grade A.
had been rated as grade A. Though it was slightly inferior to the non-deformity group, as no screws had shown perforation >4mm, it still demonstrated reliable security without risk of neural injuries. In addition, we hadn’t found any obvious orientation preference among the perforations in deformity group as they were equally distributed in the medial and lateral. Analyzing the availability of SAP technique in deformity cases, it was focusing on local anatomy that achieves the availability because most spinal deformity was manifested in global alignment rather than local anatomical abnormality, which was still qualified as reference. Nevertheless, as for some severe congenital deficiency with local anatomy failing to act as reference, more precaution should be taken including pre-removal of bony structure such as articular process and partial lamina to expose pedicle position, which would effectively decrease the risk of screw malposition. In such cases, navigation was a feasible alternative option.

Tips of SAP-Guided Freehand Technique
The present technique has been used in cases requiring screw insertion including degeneration/tumor/infection/deformity. We will propose some suggestions regarding its application in future. Firstly, the present technique belongs to freehand techniques, dependent on anatomy landmarks while multiple-revision history may render it unpractical for anatomical disorder, whereas navigation may be a more suitable choice in such cases. Second, similar to other freehand techniques, the present technique relies on intraoperative palpation. Consistent and smooth feedback provides critical message for safety confirmation. Any abrupt loss of resistance may indicate breakage of pedicle and abrupt increase of resistance means collision with the cortical wall. In those conditions, screw should be withdrawn immediately, followed by re-probe and re-cannulation.

Strength and Limitations
Though this study had provided primary evidence of the present technique on safety and accuracy, several limitations should be considered as followings. Firstly, it was a retrospective study in one institution with data obtained from one senior surgeon. More perspective studies from multi-centers were required to provide a more convincing message. In addition, given the limited sample size in this study, a larger size was warranted to reinforce the credibility. Lastly, a randomized controlled trial comparing the present technique with fluoroscopy or navigation assistance was required to further assess its reliability and feasibility.

Conclusions
In summary, SAP-guided technique is a safe, reproducible, and reliable freehand method to perform pedicle screw instrument with from T1 to S1. With consistent entry point and stereoscopic trajectory reference system, the present technique provides surgeons with key codes for safe and efficient screw placement and assist young surgeons especially in achieving freehand screw insertion at their early stage.

Author Contributions
Jinyue He: Data curation; Writing-Original draft preparation; Writing-Review and Editing. Software. Luo Fei: Review; Methodology. Hao Wang: Investigation; Resources. Jianzhong Xu: Review; Editing. Zehua Zhang: Conceptualization; Supervision; Funding acquisition; Writing-Review and Editing.

Ethics Statement
The study was conducted in accordance with the principles of the Declaration of Helsinki and approved by the ethics committee of Southwest Hospital, the Army medical University.

Data Availability Statement
All the data and materials have been available and have not been under consideration prior to the submission.

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