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An investigation of the efficiency of pedicle screw simulator software in thoracic

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ABSTRACT

Aim: Fennell et al. describe a simple, effective freehand technique for thoracic pedicle screw insertion. In this study, we aimed to compare the patients undergoing upper thoracic pedicle screw insertion with the Fennell technique simulated on Pedicle Screw Simulator (PSS) and those recruited to the same procedure utilizing C-arm fluoroscopy.

Material and Method: First, we uploaded pre-operative CT images of 12 patients to the PSS module, which was used in our study to calculate the screw angle and visualize the pedicle screw entry point and trajectories. Then, we created three-dimensional vertebral models of the patients to simulate screw placement using visualization tool kit (VTK), open-source software for 3D computer graphics and visualization, available free of charge as part of 3D Slicer. Next, we placed pedicle screws through pre-determined anatomic regions. C-arm fluoroscopy-guided pedicle screws were placed in the patients in the control group. The amount of bleeding, operation times and correct screw placement data were recorded in both groups.

Results: 24 patients were included in the study. The mean age of the patients was 32.3±4.1 years. We applied 80 pedicle screws to Group 1 and 72 to Group 2. According to the malposition classification by Rao et al. on postoperative CTs, 68 patients in Group 1 were classified as Grade 0, 8 as Grade 1, 4 as Grade 2. Yet, there were no statistical differences between the groups by Rao et al.'s classification ($p>0.05$). While the mean operation time of Group 1 was 138±34 minutes, it was 162±44 minutes in Group 2. The groups significantly differed by operation time ($p<0.05$).

Conclusion: Overall, pre-operative simulation on PSS may allow more efficient and easier thoracic pedicle screw application. In addition, the simulator may contribute to the training of surgeons on upper thoracic pedicle screw application and increase the accuracy of pedicular screw placement.

Keywords: Freehand technique, pedicle screw simulator, upper thoracic pedicle screws

INTRODUCTION

Incorrect placement of pedicle screws can lead to serious complications (1-5). Pedicle screws can safely be inserted using intraoperative tools such as fluoroscopy and computed tomography-guided (CT) navigation (6). Yet, variations in vertebrae particularly make pedicle screw insertion difficult. Moreover, the use of navigation is not common in our country due to its high cost. In addition, surgeons have serious concerns about radiation exposure when using fluoroscopy.

Today, pre-operative simulation software serves to verify the reliability of various techniques in screw placement and is used in the training of spine surgeons (7-9). Accordingly, Pedicle Screw Simulator (PSS) is a versatile module that can be used for pre-surgical planning in 3D Slicer, an open-source platform developed for this purpose (10,11).

Placement of an upper thoracic pedicle screw with fluoroscopy, but without a pre-operative navigation system, is also challenging for surgeons. It also requires a large number of fluoroscopy shots. To overcome this situation, Fennell et al. describe a simple, effective freehand technique of thoracic pedicle screw insertion using a uniform entry point for all levels (12).

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Ultimately, this study aimed to compare the patients undergoing upper thoracic pedicle screw insertion with the Fennell technique simulated on pedicle screw simulator (PSS) and those recruited to the same procedure utilizing C-arm fluoroscopy.

MATERIAL AND METHOD

The study was carried out with the permission of Uşak University Non-Interventional Clinical Research Ethics Committee (Date: 23.09.2021, Decision No: 175-175-09). All procedures were carried out in accordance with the ethical rules and the principles of the Declaration of Helsinki.

We recruited 24 patients for whom a surgical treatment (pedicle screw) was planned for a pathological fracture (non-traumatic) in the upper thoracic region (T1-T6 vertebrae). We applied pedicle screwing on 12 patients (Group 1) with the Fennell technique simulated on PSS, while the procedure was performed on 12 patients in the control group (Group 2) with the help of C-arm fluoroscopy.

Patients who underwent posterior transpedicular screw for upper thorax pathological fracture and gave informed consent were included in the study. Patients with a history of trauma and thoracic spine surgery were excluded from the study.

Pre-operative Planning

In our study, we utilized PSS (http://www.slicer.org, Surgical Planning Lab (SPL), Boston, USA) module on the 3D Slicer environment coded in Python language. We reconstructed CT data with a slice thickness of 1 mm, a spacing of 1 mm between axial slices, and a matrix size of 512 × 512 for each slice.

We uploaded pre-operative CT images of Group 1 to the PSS module, which was used in our study to calculate the screw angle and visualize the pedicle screw entry point and trajectories. This method allowed the surgeon to finalize pre-operative planning in a short time. Then, we created three-dimensional vertebral models for the patients to simulate screw placement using VTK (Visualization Tool Kit), open-source software for 3D computer graphics and visualization, available free of charge as part of 3D Slicer (**Figure 1**).

Next, we set two trajectory planning modes using the respective vertebrae, with ET (Entry-Target mode) and EA (Entry-Angle mode) on the control panel. We then selected the desired vertebral level using the plus sign on the 3D Slicer toolbar (**Figure 2**).

In ET mode, we selected the entry and target reference points for the pedicle screw through axial, sagittal, and coronal CT series and the 3D vertebra model. Then, we calculated the pitch and deviation angles for the desired pedicle screw using the software and selected desired diameter of the pedicle screw on the PSS control panel. Afterward, we visualized the trajectory of the pedicle screw using the "place screw for given entry and target" button. The length of the screw was calculated on the program based on the Euclidean distance between the desired entry and target reference points (**Figure 3**).

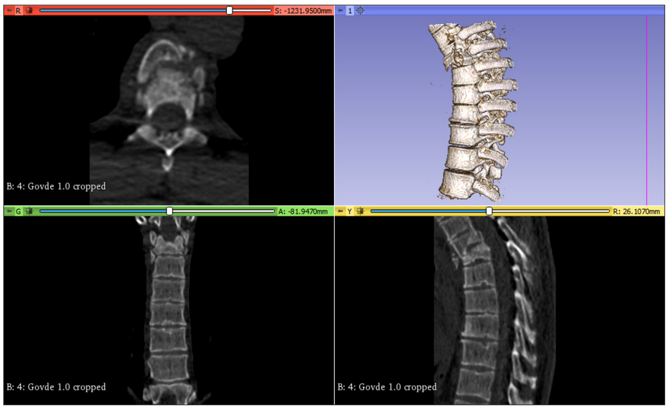

Figure 1. 3D vertebra model on preoperative CT images extracted using Visualization Tool Kit

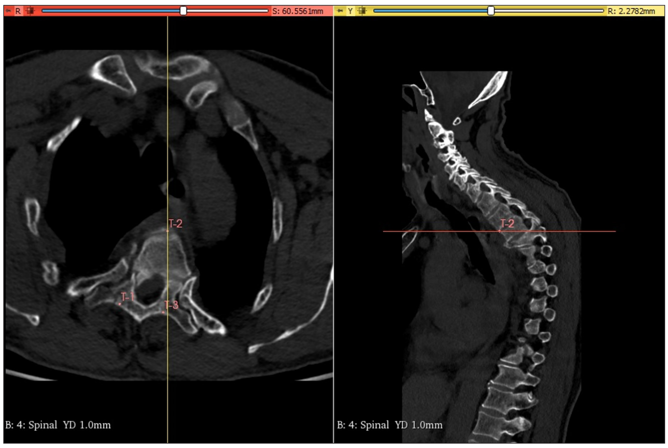

Figure 2. Selecting the desired vertebral level in 3D Slicer

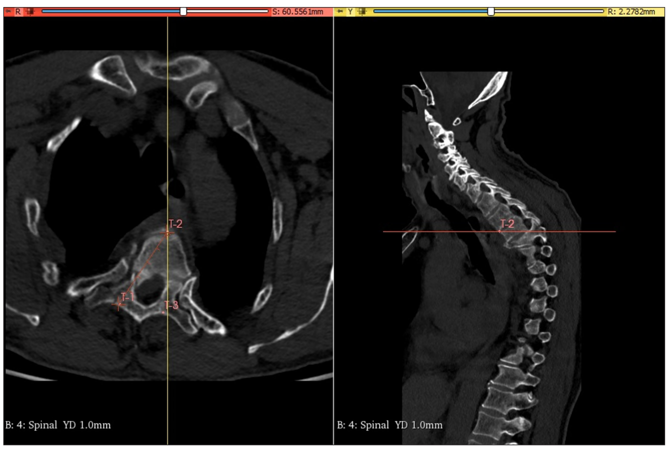

Figure 2. Calculation of Euclidean distance between reference points

On the other hand, in EA mode, the appropriate entry and reference points were selected on the panels through axial, sagittal, and coronal series and 3D vertebra models. Then, we entered the desired slope, deviation angle, length, and diameter values of the pedicle screw into the PSS control panel. The "insert the screw for given angle" tab button was activated to visualize the desired pedicle screw (**Figure 4**).

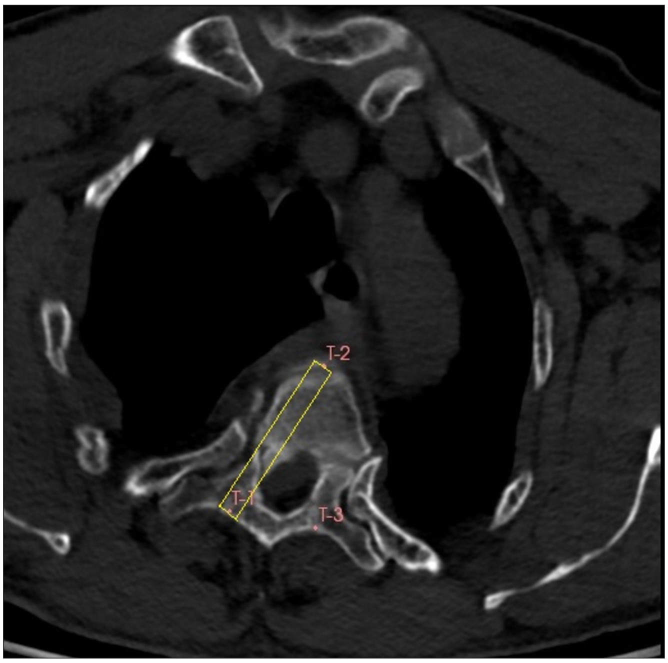

Figure 4. Visualization of the desired pedicle screw

Operational Methods

We placed pedicle screws through pre-determined anatomic regions. In the other group, pedicle screws were placed under fluoroscopic control.

Evaluation

The amount of intraoperative bleeding, operation times and screw placement success of the patients were recorded. We then performed control CT scans after the operations (**Figure 5**, **6**). We recorded screw malpositions evaluated them using Rao et al.'s classification (13). The grading scale is evaluated as follows: 0=no perforation of the pedicle; 1=< 2 mm pedicle perforation with one screw thread out of the pedicle; 2=2-4 mm pedicle perforation; 3=> 4 mm pedicle perforation.

Statistical Analysis

We analyzed the data using the SPSS (version 20, IBM Inc., Armonk, USA) program. Quantitative data were presented as means and standard deviations, while qualitative data were given as percentages. We performed Chi-square to compare the categorical variables. we considered a p-value of < 0.05 statistically significant.

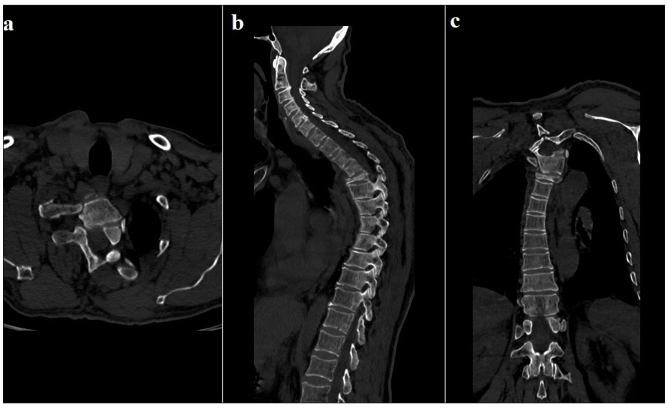

Figure 5. Preoperative CT images

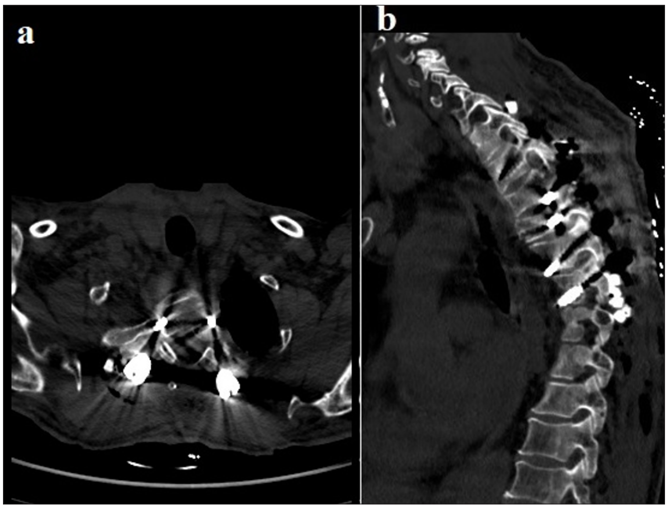

Figure 6. Postoperative CT images

RESULTS

We studied 24 patients (mean age=32.3±4.1 years, 14 (58.3%) were male, preoperative PSS was performed in 12 (50%) patients. There were no statistically significant differences between the groups by age and gender (p>0.05) (**Table 1**). We applied 80 pedicle screws to Group 1 and 72 to Group 2. According to the malposition classification by Rao et al. on postoperative CTs, 68 patients in Group 1 were classified as Grade 0, 8 as Grade 1, 4 as Grade 2. When it comes to the control group (Group 2), 61 patients were classified as Grade 0, 6 as Grade 1, 4 as Grade 2, and 1 as Grade 3. Yet, there were no statistical differences between the groups by Rao classification (p>0.05) (**Table 2**).

Table 1. Demographic information of the groups

	Group 1	Group 2	p-value †
Number of patients	12	12	-
Sex	8 males/4 females	6 males/6 females	0.234
Age	35.3±4.3	29.3±3.9	0.196

Table 2. Rao et al.'s malposition classification on postoperative CTs		
	Group 1 (n=80 screws)	**Group 2 (n=72 screws)**
Grade 0 (completely within the pedicle)	68	61
Grade 1 (perforation <2 mm)	8	6
Grade 2 (perforation between 2–4 mm)	4	4
Grade 3 (perforation >4 mm)	-	1
Accuracy †	95%	93.1%
† Accuracy = (Grade 0 + Grade 1)/n * %100		

While the mean operation time of Group 1 was 138±34 minutes, it was 162±44 minutes in Group 2. The groups significantly differed by operation time ($p<0.05$) (**Table 3**). Mean blood loss amounts were 662±92 mL in Group 1 and 732±88 mL in Group 2 ($p>0.05$) (**Table 3**).

Table 3. Surgical data			
	Group 1 (n=12)	**Group 2 (n=12)**	**p value †**
Operation time (min)	138±34	162±44	p<0.05
Blood loss (mL)	662±92	732±88	p>0.05

DISCUSSION

The developments in spine surgery have contributed to the common use of the posterior thoracic interpedicular screwing method today. Due to the complexity of the anatomy of the thoracic pedicles, screw placement is difficult, especially in thoracic fractures. Thoracic pedicles are thin, short, narrow and fragile, causing easy fracture of thoracic pedicles during screwing (14).

Malposition rates can reach 30-40% in thoracic pedicle screw placement (15). In general, pedicle screw placement is assisted with intraoperative aids such as C-arm fluoroscopy and computed tomography-guided (CT) navigation (6). Besides, CT-guided navigation is costly, so not widely adopted in our country (16). Instead, pedicle screws are commonly placed with the help of C-arm fluoroscopy. However, intraoperative fluoroscopy in long-level fusion surgeries leads surgeons and patients to be exposed to radiation for a longer time (17), which creates a significant problem.

3D Slicer is free and visualization software. This program has an extension called pedicle screw simulator (PSS), which is used in spinal surgery planning. The software allowed us to determine the entry point, direction, diameter, and length of pedicle screws under the guidance of the Fennell technique before spinal surgery; we effectively simulated the Fennell technique on PSS.

In their study, Swaminathan et al. (18) simulated the placement of 120 thoracic pedicle screws on the pre-operative PSS. They reported that the simulation allowed successful screw placement both in the craniocaudal and medial-lateral directions. In our study, we concluded that PSS was useful for surgeons, especially for understanding the craniocaudal angle when placing pedicle screws.

In the literature, there were high malposition rates in upper thoracic interpedicular screwing applied through C-arm fluoroscopy (19,20). Karagöz et al. (19) a study of 24 patients retrospectively analyzed 113 thoracic pedicle screws. As a result, they found the rate of incorrect pedicle screw placement to be 20.3%. Also, Vaccaro et al. found the rate of incorrect screw placement to be 41% on postoperative CT scans (20). In our study, the malposition rates in both the patient group (15%) and the control group (15.3%) were lower than those in the literature. In our study, there was no significant difference between the groups in terms of malposition rate ($p>0.05$).

The relevant literature proposes that the use of pre-operative simulation reduces the surgeon's margin of error and operation time (16). In our study, we found that operation time was significantly shorter in the patient group ($p<0.05$). Although the amount of bleeding was less in the patient group, the difference was not statistically significant ($p>0.05$). Further large-scale research may obtain significant results on bleeding amount and surgery duration.

It is known that complications occur in inserting pedicle screws, especially in the early learning period (21). In this context, the greatest advantage of such simulators may be that they allow novice surgeons and medical students to make effective pre-operative plans.

This study inevitably bears limitation. The sample size remained relatively small in this study. Hence, large-scale studies may be needed to conclude more robust results.

CONCLUSION

Overall, we concluded that pre-operative simulation on PSS may allow more efficient and easier thoracic pedicle screw application. In addition, the simulator may contribute to the training of surgeons on upper thoracic pedicle screw application and increase the accuracy of pedicular screw placement. The present study may guide further studies with diverse samples and simulators with more advanced technology.

ETHICAL DECLARATIONS

Ethics Committee Approval: The study was carried out with the permission of Usak University Non-Interventional Clinical Researchs Ethics Committee (Date: 23.09.2021, Decision No: 175-175-09).

Informed Consent: All patients signed the free and informed consent form.

Referee Evaluation Process: Externally peer-reviewed.

Conflict of Interest Statement: The authors have no conflicts of interest to declare.

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Author Contributions: All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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