Assessing the Accuracy and Safety Thresholds of Patient-Specific Screw Guide Template System in Cervical and Thoracic Spine Surgeries Using DAST Measurements

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Abstract:

Introduction: To analyze the reliability of the newly developed patient-specific Screw Guide Template (SGT) system as an intraoperative navigation device for spinal screw insertion.

Methods: We attempted to place 428 screws for 51 patients. The accuracy of the screw track was assessed by deviation of the screw axis from the preplanned trajectory on postoperative CT. The safety of the screw insertion was evaluated by the bone breach of the screw. The bone diameter available for screw trajectory (DAST) was measured, and the relations to the bone breach were analyzed.

Results: In the inserted screws, 98.4% were defined as accurate, and 94.6% were contained in the target bone. In the cervical spine, the screw deviation between breaching (0.57 mm) and contained screws (0.43 mm) did not significantly differ, whereas DAST for breaching screws (3.62 mm) was significantly smaller than contained screws (5.33 mm) ($p<0.001$). Cervical screws with ≥4.0 mm DAST showed a significantly lower incidence of bone breach (0.4%) than ≤3.9 mm DAST (28.3%) ($p<0.001$). In the thoracic spine, screw deviation and DAST had significant differences between breaching (1.54 mm, 4.41 mm) and contained (0.75 mm, 6.07 mm) ($p<0.001$). The incidence of the breach was significantly lower in thoracic screws with ≥5.0 mm (1.9%) than ≤4.9 (21.9%) DAST ($p<0.001$).

Conclusions: This study demonstrated that our SGT system could support precise screw insertion for 98.4% accuracy and 94.6% safety. DAST was recommended to be ≥4.0 and ≥5.0 mm in the cervical and thoracic spines for safe screw insertion.

Keywords:

patient-specific surgery, 3D printer, navigation template, Screw Guide Template system

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Introduction

The development of clinical tools for computer-aided design (CAD) and three-dimensional (3D) printing has led to many advances in orthopaedic surgeries. Recently, the technology is used for numerous purposes, such as pre-operative planning, the production of intraoperative navigation tools, and personalized implants[1-5]. This novel technique has been successfully applied in spinal surgery as a personalized intraoperative screw navigation template and contributed to safe and accurate spinal instrumentation surgeries.

Berry et al.[6] originally introduced the idea of personalized image-based 3D navigation templates. Further, several researchers conducted cadaveric studies or clinical trials[7-11] to explore this concept. As digital technology, 3D imaging, and 3D printing technique[12,13] advanced rapidly, the recognition and dissemination of 3D navigation templates also increased. Our previous studies demonstrated the high accuracy, reliability, and reproducibility of planned screw trajectory[14-19] achieved by our SGT system for screw insertion in cervical and thoracic spine. However, ensuring the safety of screw insertion procedures also depends on the size of the target bone structure. Hence, establishing an acceptable range of bone size for safe screw insertion is required. In

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Table 1. Results of Screw Insertion with the SGT (Screw Guide Template) System.

Screws	Number of screws	DAST	Deviation	Accurate	Inaccurate	Containing	Breach
C1LMS	8	6.39±2.43	0.83±0.60	8	0	8	0
C2LS	18	5.02±0.99	0.24±0.32	18	0	18	0
C2PS	71	6.32±1.43	0.55±0.53	71	0	71	0
C3PS	15	4.45±0.93	0.35±0.42	15	0	12	3
C4PS	51	4.46±0.88	0.39±0.38	51	0	45	6
C5PS	53	4.68±0.80	0.31±0.26	53	0	50	3
C6PS	42	4.93±0.86	0.48±0.46	41	1	40	2
C7PS	30	5.62±1.02	0.49±0.47	30	0	30	0
T1PS	72	6.42±1.29	0.84±0.69	67	5	70	2
T2PS	56	5.46±1.08	0.78±0.57	55	1	51	5
T3PS	4	4.25±0.19	0.55±0.39	4	0	2	2
TLS	5	6.20±1.27	0.62±0.49	5	0	5	0
Cervical overall	288	5.24±1.33	0.44±0.44	287	1	274	14
Thoracic overall	137	5.96±1.30	0.80±0.63	131	6	128	9
Overall	425	5.47±1.36	0.55±0.53	418	7	402	23

DAST: bone diameter available for screw trajectory, LMS: lateral mass screw, LS: laminar screw, PS: pedicle screw, TLS: thoracic laminar screw

this investigation, we assessed the applicability of 3D printing technology in spinal instrumentation surgery using the SGT system and analyzed the correlations between screw insertion deviation, bone structure size, and screw-induced bone breach to determine the acceptable ranges of bone structures.

Materials and Methods

We obtained approvals from the Ethics Committees of our institution for this investigation. Each patient provided a written informed consent following oral explanations regarding the present study.

Study population

This study enrolled 51 patients, who underwent posterior cervicothoracic reconstruction surgery for cranio-cervico-thoracic lesions. The study population comprised 22 males and 29 females of 11-86 years (average age, 64.6 years). The patient cohort included individuals with various conditions, including cervical kyphosis (11 patients), cervical myelopathy due to rheumatoid arthritis (nine patients), cervical myelopathy due to athetoid cerebral palsy (six patients), postoperative deformities (six patients), ossification of posterior longitudinal ligament (four patients), congenital deformities (three patients), idiopathic deformities (three patients), cervical fractures (three patients), spinal tumors (three patients), destructive spondyloarthropathy (one patient), pyogenic spondylitis (one patient), and metastatic cervical tumor (one patient).

We attempted to place 428 screws for the C1-T3 level, and the details of the total attempts were shown in the Table 1. For the C2 and C7-T3 level, screws with a diameter of 4.0 mm were used unless the diameter of the targeted bone was narrower than 4.0 mm. Along the C1 and C3-6 level, screws with a diameter of 3.5 mm were used, even if the bone diameter was wider than 4.0 mm.

Preparation of template

As previously described[14-19], the templates were customized to suit the laminar structures of each patient. Briefly, preoperative spinal computed tomography (CT) images were acquired using a high-precision 3D CT scanner with a slice thickness ranging from 0.5 mm to 0.75 mm. These images were exported in the DICOM format to 3D/multiplanar imaging software (such as Ziostation; Ziosoft, Redwood City, CA, USA, or similar software), allowing for the visualization of reconstructed bone images on various planes. After careful evaluation, the optimal trajectory and depth for screw placement were planned to accommodate the dimensions of the pedicle, pars, or lamina. Subsequently, the entry points and screw tips were determined for each trajectory (Fig. 1).

Bone data were transferred to a 3D modeling software (Freeform; Data Design, Nagoya, Japan) to design the templates and 3D models of the target vertebrae (Fig. 2).

To ensure precise multistep guidance for the screws, three types of templates were manufactured for each screw, all specifically designed to conform to and securely attach to the patient-specific 3D shape of the lamina. “Location templates” with 3-mm diameter holes were employed to indicate the screw entry points on the lamina. “Drill guide templates” with drill guide sleeves, 3-4-mm-diameter cylindrical structures (depending on the drilling tool diameter), were created to facilitate prescrew hole drilling. “Screw guide templates” with screw guide cylinders, 13-15-mm-diameter by 30-mm-length cylindrical structures (depending on the screwdriver diameter), were developed for screw insertion (Fig. 3).

The patient-specific templates and vertebra models were fabricated using a 3D printing system (Connex 500; Objet Ltd, Rehovot, Israel) with nonsoluble acrylate materials.

Surgery

Before surgery, the templates' interaction with the 3D laminae model and screwing simulation was verified. Subsequently, the templates underwent sterilization using a plasma sterilizer and were employed for intraoperative navigation. Thorough exposure was achieved for the spinous process and lateral margin of each lamina in the target vertebra. To engage the templates, soft tissues were meticulously removed, and the paraspinal muscles were appropriately retracted. The screw navigation process followed a three-step procedure: marking the entry points using the location templates, drilling the screw holes with a power drill utilizing the drill guide templates, and inserting the screws aided by the screw guide templates. Fluoroscopic assistance was generally deemed unnecessary or even obstructive, as it occupied significant space and interrupted the surgeon's workflow during screw insertion.

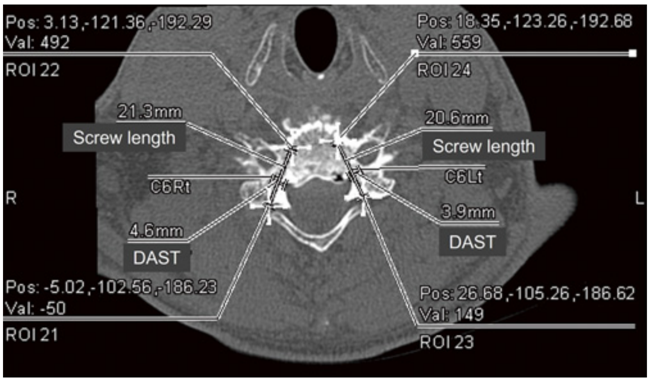

Figure 1. Screenshot of 3D/multiplanar imaging software for planning trajectories of screws; ideal trajectories and their coordinates of the bone entry points and the tips of the screws were determined in a three-dimensional manner. Screw lengths and bone diameters minimal available for screw trajectories (Diameter Available for Screw Trajectory: DAST) were also measured.

Follow-up evaluation

To evaluate the accuracy and safety of screw insertion using the SGT system, postoperative CT scans were conducted for all patients, and the screw positions were assessed based on two criteria[15].

The accuracy of screw insertion with the SGT system was determined by measuring the screw deviation, which refers to the distance between the planned trajectory and the axis of the inserted screw. The deviation was calculated as the difference between the distance from the edge of the target bone to the planned screw trajectory at the site with the smallest target bone width on the preoperative CT and the corresponding distance to the axis of the inserted screw on the postoperative CT (Fig. 4). The deviations were categorized into four classes: Class 1 (Accurate), Class 2 (Inaccurate), Class 3 (Deviated), and Class 4 (Failed), with specific threshold values defining each category. Measurements were performed in both the sagittal and axial planes for each screw, and the most significant deviation was recorded for analysis.

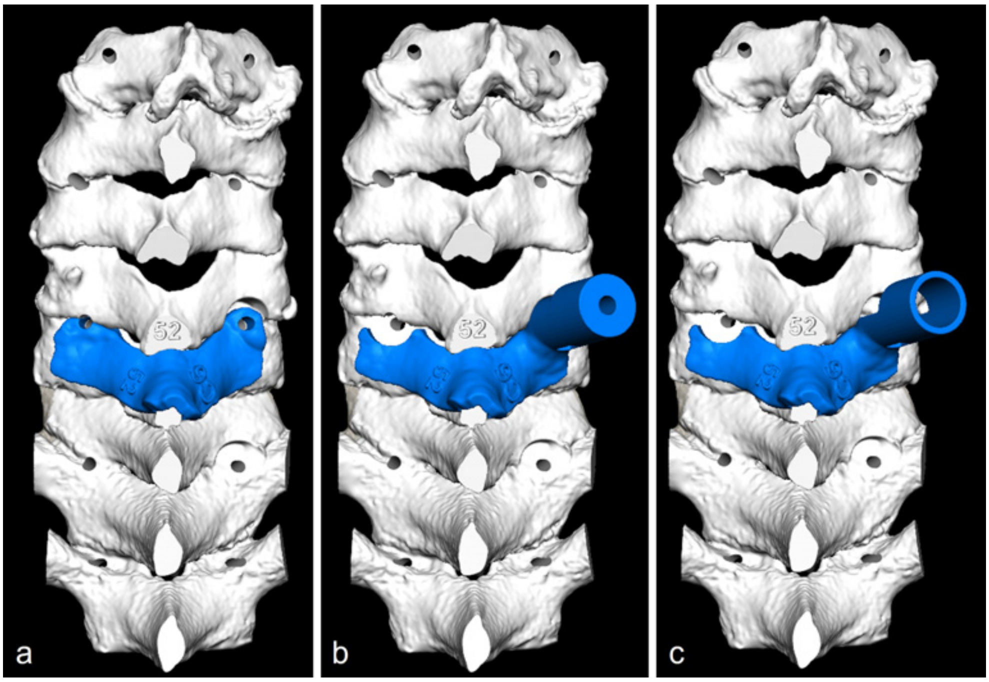

Figure 2. 3D computer model of the Screw Guide Template system: location template with marking hole for making screw entry point (a), drill guide template with drill guide cylinder for drilling and tapping the screw hole (b), and screw guide template with screw guiding cylinder for accurate screw insertion (c).

Figure 3. Three types of templates are created according to the 3D computer model by the 3D printing system. (a) location template, (b) drill guide template, (c) screw guide template.

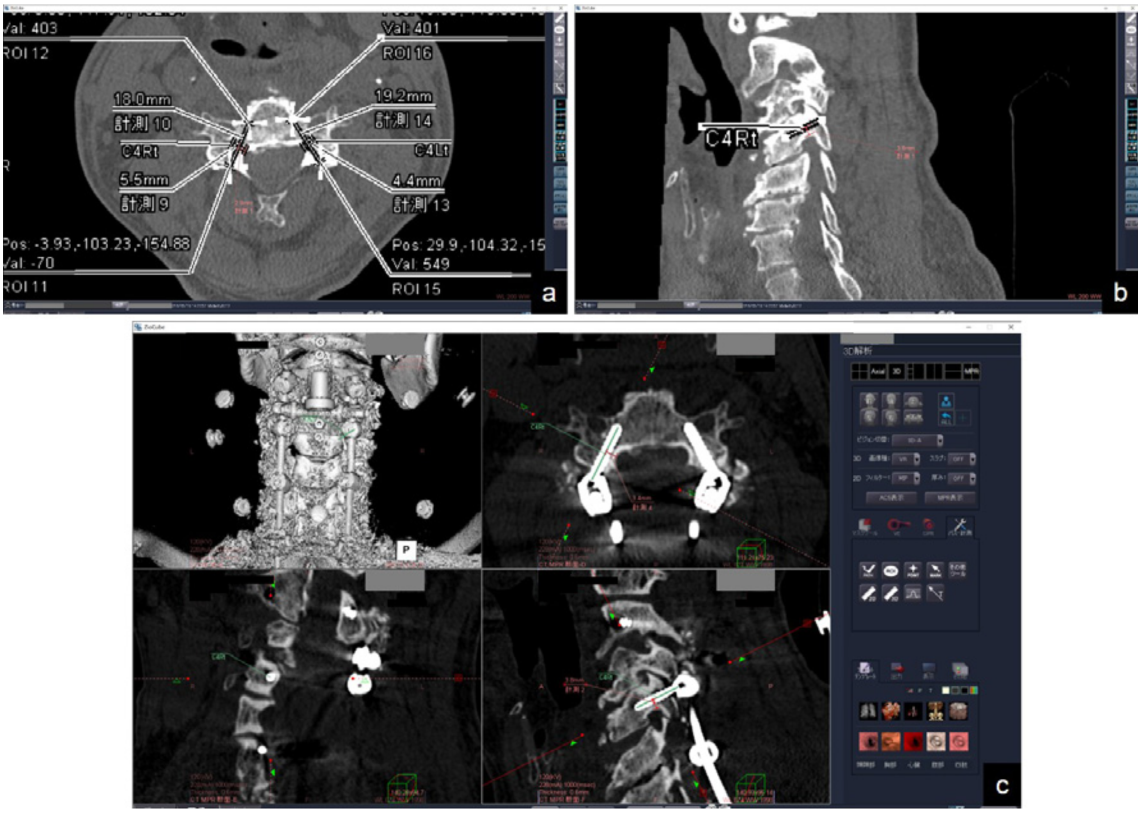

Figure 4. Measurement and calculation of deviation; deviation was calculated as the difference between the distance from the edge of the target bone to the planned screw trajectory at the site with the smallest target bone width on the preoperative CT (a, b) and the corresponding distance to the axis of the inserted screw on the postoperative CT (c). The deviation was calculated to be 0.5 mm in the case shown in this figure (Preoperative distances were 2.9 and 3.8 mm in the axial and sagittal sections, and postoperative distances were 3.4 and 3.8 mm, respectively).

To assess the safety of screw insertion using this device, the breaches of the pedicle wall caused by the inserted screws were evaluated in the sagittal and axial planes. The assessment criteria were as follows: Grade 0 (Containing), indicating the screw was entirely within the bone structure wall; Grade 1 (Exposure), the screw penetrated the bone structure wall, but >50% of the screw diameter remained within the bone; Grade 2 (Perforation), the screw penetrated the bone structure wall with >50% of the screw diameter outside the pedicle; Grade 3 (Penetration), the screw completely penetrated outside the bone structure. Screws falling into Grade 0 were classified as "completely containing," while the remaining grades were categorized as "bone breach." As pedicle breaches exceeding 2 mm or half the diameter of the inserted screw pose a potential risk of neurovascular injury[20-23], breaches falling into Grades 2 or 3 were considered critical. Furthermore, the minimal bone diameter available for the intended screw trajectory was measured on preoperative CT scans and referred to as Diameter Available for Screw Trajectory (DAST) (Fig. 5). Measurements were taken in both the sagittal and axial planes for each screw, and the smaller diameter was recorded.

Statistical analysis

The differences in screw deviation and DAST between screws with and without bone breach were evaluated using

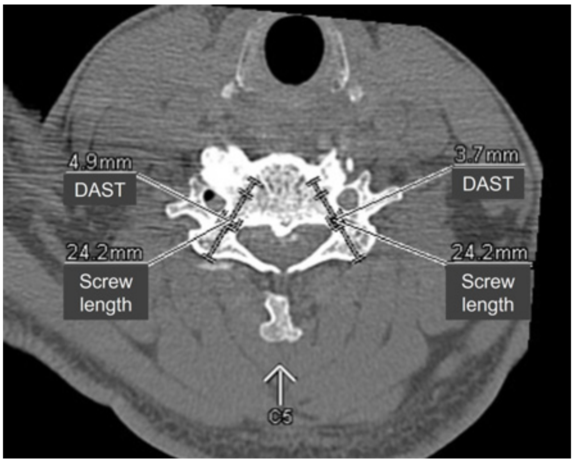

Figure 5. Definition of DAST (Diameter Available for Screw Trajectory). DAST was measured as a minimal available diameter of the bone structure for the intended screw trajectory.

the Student's t-test. To assess and compare the predictive reliability of these two parameters for bone breach occurrence, receiver operating characteristic (ROC) curves were constructed separately, and the corresponding area under the curve (AUC) was calculated. AUC exceeding 0.9 indicated high accuracy, while, 0.7-0.9 indicated moderate accuracy, 0.5-0.7 indicated low accuracy, and 0.5 indicated a chance result[24]. The optimal cut-off points for predicting bone breach were determined using the Youden index (J)[25,26]. Statistical analyses were performed using Microsoft Excel 2013 (Microsoft, USA) with the Ekuseru-Toukei 2012 add-in software (SSRI, Tokyo, Japan) or EZR (Jichi Medical University, Saitama, Japan)[27].

Results

In total, 425 screw insertion procedures were successful (288 cervical and 137 thoracic screws), while three attempts were unsuccessful. These three unsuccessful attempts were specifically for the C2 vertebra. One failure resulted from inadequate muscle retraction, leading to inadequate fitting of templates to the target laminae. The remaining two failures were attributed to flaws in the screw trajectory plans, involving a steep entry point and a trajectory tangential to the bony structure. Consequently, a diagonal slit formed at the entry point, causing the drills and screws to deviate from the intended trajectory.

Out of 425 inserted screws, 418 (98.4%) were classified as accurate insertions, and 402 (94.6%) remained completely contained within the target bone structure (Table 1). Among the 23 breaches observed, none were categorized as critical breaches. The average screw deviation and DAST were recorded as 0.55±0.53 mm (0.0-3.2 mm) and 5.47±1.36 mm (2.8-11.0 mm), respectively. For cervical screws, the respective values were 0.44±0.44 mm (0.0-2.1 mm) for screw deviation and 5.24±1.33 mm (2.8-11.0 mm) for DAST. Meanwhile, for thoracic screws, values were 0.80±0.63 mm (0.0-3.2 mm) for screw deviation and 5.96±1.30 mm (3.0-9.6 mm) for DAST. Both screw deviation and DAST were significantly greater in the thoracic spine than the cervical spine (p<0.001). In the cervical spine, there was no significant difference in screw deviation between screws that breached (0.57±0.34 mm) and screws that remained contained (0.43±0.45 mm) (p=0.247) However, the DAST for breaching screws (3.62±0.25 mm) was significantly smaller than contained screws (5.33±1.31 mm) (p<0.001). In the thoracic spine, screw deviation and DAST exhibited significant differences between breaching (1.54±1.18 mm, 4.41±0.85 mm) and contained screws (0.75±0.54 mm, 6.07±1.25 mm) (p<0.001) (Table 2). Analysis of the ROC curves using the Youden index revealed that the optimal cut-off values for DAST in cervical and thoracic spines were 3.9 mm (AUC: 0.94) and 4.9 mm (AUC: 0.86), respectively (Fig. 6). Notably, cervical screws with a DAST of 4.0 mm or more exhibited a significantly lower incidence of bone breach (0.4%) compared to cervical screws with a DAST of 3.9 mm or less (28.3%) (p<0.001, sensitivity: 0.93, specificity: 0.88) (Table 3a). Additionally, the incidence of bone breach was significantly lower in thoracic screws with a DAST of 5.0 mm or more (1.9%) compared to those with a DAST of 4.9 mm or less (21.9%) (p<0.001, sensitivity: 0.89, specificity: 0.71) (Table 3b). No neurovascular complication associated with the screws was experienced, and all patients showed improvement in symptoms and neurological recovery after surgery. Illustrative CT images demonstrating accurate/inaccurate and containing/breach screw position are shown in Fig. 7.

Table 2. Comparison of Screw Deviation and DAST between Containing Screw and Breaching Screw (Student's t-test).

		Containing	Breach	p-value
Cervical spine	Deviation	0.43±0.45	0.57±0.34	0.247
	DAST	5.33±1.31	3.62±0.25	<0.001
Thoracic spine	Deviation	0.75±0.54	1.54±1.18	<0.001
	DAST	6.07±1.25	4.41±0.85	<0.001

Discussion

Rigid fixation with spinal instrumentation is imperative for the excellent reconstruction of unstable or deformed cervical spine. Nevertheless, the process of spinal screw insertion remains technically challenging and poses potential risks of iatrogenic injury to the spinal cord, nerve root, or vertebral artery, which could result in fatal outcomes.

Despite numerous attempts to achieve precise screw insertion, unacceptable rate of screw malpositioning has been reported[28-31]. The lack of accuracy in screw insertion for the cervical and upper thoracic spine is primarily attributed to the anatomical characteristics of these regions and the technical challenges involved. The featureless surface of the

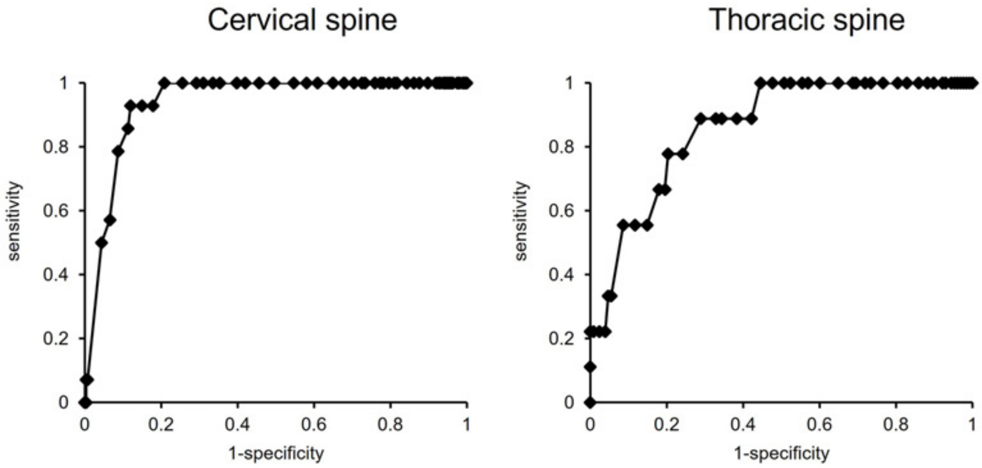

Figure 6. Receiver operating characteristic (ROC) curves to predict the bone breach. The optimal cut-off values of DAST to predict bone breach were 3.9 and 4.9 mm in the cervical and thoracic spine, respectively, with the Youden index. The area under the curve (AUC) for parameters: cervical spine; 0.94, thoracic spine; 0.86.

Table 3a. Chi-square Analysis for the Relation between the DAST and the Incidence of the Bone Breach in the Cervical Spine.

Cervical DAST	Containing	Breach	Breach (%)
≥4.0 mm	241	1	0.40
≤3.9 mm	33	13	28.30
Total	274	14	5.10

(p<0.001)

Table 3b. Chi-square Analysis for the Relation between the DAST and the Incidence of the Bone Breach in the Thoracic Spine.

Thoracic DAST	Containing	Breach	Breach (%)
≥5.0 mm	103	2	1.90
≤4.9 mm	25	7	21.90
Total	128	9	6.70

(p<0.001)

lamina, coupled with the small and varied size and shape of vertebral structures, makes it difficult to accurately identify the appropriate insertion point and angle[32-36]. Other factors contributing to the inaccuracy include discrepancies between preoperative supine position imaging and intraoperative prone position imaging, intraoperative changes in spinal alignment resulting from surgical procedures, which can lead to misdirection during probing or screw insertion[20,21], as well as the presence of bulky paraspinal muscles or a thick and solid cortex in the spinal canal, which can misguide the direction of the screws laterally[14,22,31].

The recent remarkable advancements in 3D rapid prototyping techniques and equipment have enabled the development of intricate templates that firmly engage with the surface of bone structures and accurately indicate the desired screw trajectory. This study highlights the efficacy of the SGT system in facilitating precise screw insertion, achieving an accuracy rate of 98.4% with a deviation of only 0.55 mm, and ensuring a high level of safety with a success rate of 94.6% in preventing critical bone breaches. The SGT system overcomes the challenges associated with screw placement and achieves exceptional precision through its advantageous features. Firstly, it provides surgeons with a comprehensive 3D visualization of the safe screw trajectory using multiplanar imaging, facilitating accurate planning. Moreover, the SGT system ensures accurate screw insertion even in cases where the laminae lack prominent features by directly fitting onto the target laminae. This eliminates alignment discrepancies caused by variations in patient positioning and ensures reliable screw navigation. Additionally, the system's accuracy and reliability allow surgeons to utilize power drills, enabling the drilling of dense and solid cortex in mid-cervical pedicles. This capability guarantees the precise reproduction of the intended screw trajectory, even in cases of sclerotic bone. Furthermore, the SGT system employs a multistep screwing technique that mitigates errors at each step of the screw placement process, including entry point marking, screw hole drilling, and screw insertion. In contrast, other navigation template systems rely on a single-step drilling guide for screw insertion, which may carry a higher risk of screw malpositioning[6-13].

However, it is important to note that the SGT system has certain limitations in terms of accuracy and safety, as indicated by the DAST criteria. In the cervical spine, for instance, a screw deviation of less than 0.5 mm has been observed, highlighting a current limitation of the system. To ensure safe screw insertion, a recommended DAST of 4 mm or larger is advised in the cervical spine. The SGT system has demonstrated high reliability with a bone breach incidence of 0.4% when the DAST is 4 mm or larger. Con-

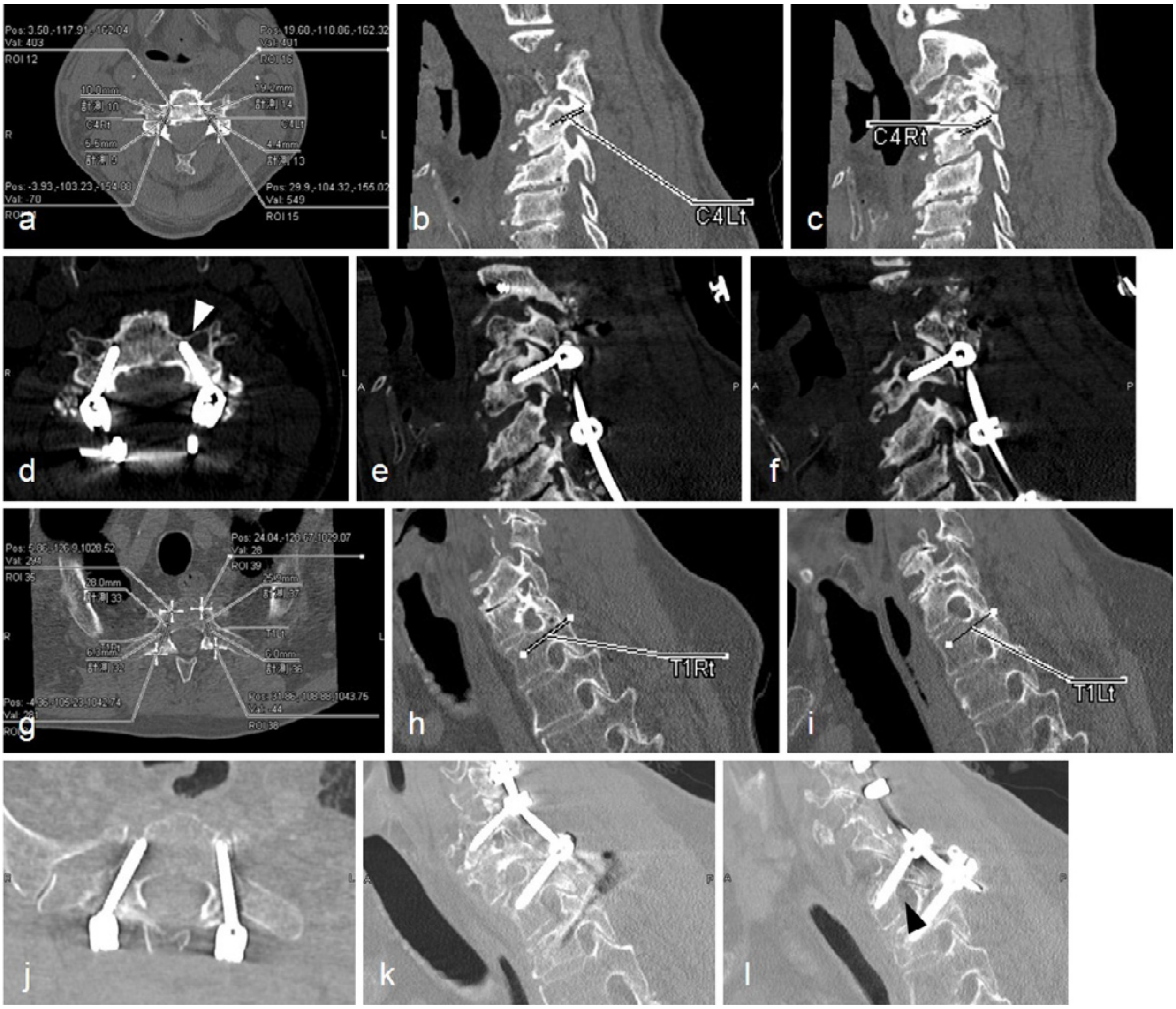

Figure 7. Illustrative CT images demonstrating accurate/inaccurate and containing/breach screw position. a-c) Plan of C4 pedicle screws in the axial section (a), the right sagittal section (b), and the left sagittal section (c). d-f) Postoperative CT images of the C4 pedicle screws. Both screws were inserted accurately with a deviation of 0.5 mm in the right screw (e) and 0.8 mm in the left screw (f), but a bone breach arose in the left screw (d: white triangle). g-i) Plan of T1 pedicle screws in the axial section (g), the right sagittal section (h), and the left sagittal section (i). j-l) postoperative CT images of the T1 pedicle screws; both screws were inserted inaccurately, with a deviation of 2.9 mm in the right screw (j) and 2.5 mm in the left screw (l), but the right screw was contained within bone cortex (k) while the left screw showed bone breach (l: black triangle).

versely, inserting a screw with a diameter of 3.5 mm into a bone structure less than 4 mm, with an error of 0.5 mm, may lead to an expected bone breach, although critical breaches are unlikely to occur. Furthermore, in light of the potential long-term risks associated with such practices, although clinical issues have not arisen in current investigations or in previous reports[12,14-19,21,22], it is important to recognize that the use of cervical screws in locations with a DAST less than 4.0 mm may carry inherent risks. While screw insertion in high-risk areas may be necessary to consider if it is essential for fixation and stability of the spine or as an anchor for correction, our general recommendation remains to avoid pedicle screw insertion in such locations as a precautionary measure.

In the thoracic spine, significant differences have been observed in both screw deviation and DAST between cases with and without bone breach. Moreover, the magnitude of screw deviation is notably larger compared to the cervical spine. This is primarily attributed to the challenges associated with proper retraction of the paraspinal muscle in the distal end of the surgical field. Therefore, it is crucial to make a longer incision, ensure adequate muscle retraction, and precisely fit the SGT system to enable accurate screw insertion.

While the SGT system facilitates precise screw insertion by simply fitting templates onto the target lamina, it is essential to be aware of certain pitfalls and technical considerations. Surgeons should avoid designing steep entry points when planning the screw trajectory. During surgical exposure, adequate muscle retraction and accurate fitting of the SGT system are essential. Additionally, during the screw insertion procedure, enlarging entry points and proceeding with slow drilling can help avoid complications such as a diagonal slit.

By emphasizing the limitations of the SGT system in terms of accuracy and safety through the DAST criteria, surgeons can make informed decisions and take necessary precautions to ensure successful screw insertion.

Limitations

While we believe our study provides valuable insights into the utility of patient-specific 3D navigation templates in spinal surgery, it is important to acknowledge the inherent limitations attributed to its retrospective design, potentially introducing biases. Moreover, the absence of a comparative study restricts our ability to draw direct comparisons and make robust causal inferences, underscoring the need for future comprehensive research in this domain. Additionally, it is essential to note the potential limitations associated with the categorization of screws as either cervical or thoracic, highlighting the need for more nuanced and comprehensive evaluation criteria for different screw types, such as pedicle, C1 lateral mass, and lamina screws. Future research endeavors will focus on establishing more comprehensive evaluation criteria or conducting detailed assessments tailored to each specific type of screw, thus providing a more nuanced and precise understanding of their individual characteristics and performance. Furthermore, the reliance on specialized imaging equipment led to the evaluation of DAST, screw deviation, and bleaching grade by a single analyst, raising potential concerns regarding the generalizability of our results. While measures were taken to ensure consistency, the absence of multiple examiners might have influenced the determination of outcomes, particularly in cases of discrepancies in breach grading.

Conclusion

In conclusion, this study highlights the utility of our SGT system for intraoperative screw navigation with high reliability in the cervical and upper-thoracic spine. To ensure safe screw insertion, a DAST of 4.0 mm or more is recommended for the cervical spine, and 5.0 mm or more for the thoracic spine. This straightforward method offers exceptional accuracy in spinal screw insertion; however, it's important to note that there are inherent limitations in precision, necessitating case selection based on DAST criteria for surgery. Further innovations and supportive devices could enhance the applicability of the SGT system.

Conflicts of Interest: The authors declare that there are no relevant conflicts of interest.

Sources of Funding: None

Author Contributions: Taku Sugawara designed and produced this device; Shuichi Kaneyama and Taku Sugawara performed the surgery; Shuichi Kaneyama designed the study and collected and analyzed the data.

Ethical Approval: The study protocol was reviewed and approved by the Clinical Research Ethics Committee of the Kobe Rosai Hospital (6th/March/2012).

Informed Consent: Written informed consent was obtained from each patient after the verbal explanations of the present study.

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