

Development of a Quantitative Method to Evaluate Pedicle Screw Loosening After Spinal Instrumentation Using Digital Tomosynthesis

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Abstract

Background

In general, the diagnosis of pedicle screw (PS) loosening is evaluated qualitatively based on the presence of a radiolucent area around the implant wider than 1 mm on plain radiographs and computed tomography (CT). Digital tomosynthesis is a novel imaging technology that can acquire reconstructed tomographic images of patients in different postures with relatively low radiation. In this study, PS loosening is evaluated quantitatively by measuring the PS displacement angle in the vertebrae using digital tomosynthesis.

Methods

We evaluated 41 patients who underwent posterior spinal fusion surgery using PS. The 72 pedicle screws at the cranial end of the fused segments were evaluated. The patients were divided in two groups, one with PS loosening (7 patients, 12 screws) and the other without PS loosening (34 patients, 60 screws), based on conventional CT findings. All patients underwent tomosynthesis in two different postures during a single CT session.

Results

The displacement angles of the PS in patients in a lying position and in a standing position were measured using selected slices of the same cross-sectional view from digital tomosynthesis. The displacement angle was significantly greater in the PS loosening group (5.7°) than in the group without PS loosening (0.6°) ($p < 0.01$). Based on the ROC analysis, the optimal cut-off value of the PS displacement angle for identification of loosened screws was 1.7° with a sensitivity of 100% and specificity of 93% (AUC=0.98).

Conclusions

This new method using digital tomosynthesis has the potential to aid diagnosis of PS loosening quantitatively and more accurately than conventional evaluations.

Background

As the number of elderly people grows, spinal fusion surgeries for vertebra fracture, degenerative lumbar spondylolisthesis, and adult spine deformities are becoming more common. The pedicle screw (PS) is used as a rigid fixator for spinal fusion.

Several reports have described PS loosening as a complication of spinal fusion surgery. PS loosening causes reduced fixation and significant clinical problems. The rate of PS loosening has been reported to range from 0.8–27% and may exceed 50% in patients with osteoporosis [1, 2, 3]. For these reasons,

fusion devices used for osteoporotic patients, which are of great interest to the research community [4, 5], require specific attention and design enhancement to improve the strength of the bone-screw interface.

For quality evaluation of a developed product, it is necessary to establish a quantitative method for evaluating PS loosening. Furthermore, early detection of PS loosening after surgery might save the patient not only painful spasms but also possible serious neural damage or screw breakage and revision surgery. A key problem for the investigation of screw loosening is the assessment of whether a screw is loosened or not, which is usually based on a radiological approach [6]. The diagnosis of PS loosening has been based on qualitative assessments from plain radiographs or computed tomography (CT) and is based on the presence of the halo sign, which is a radiolucent line around the implant wider than 1 mm². There are few quantitative methods to evaluate PS loosening [3, 5].

PS loosening is caused by displacement of the PS in the vertebra. Therefore, PS loosening can be quantitatively measured by measuring PS displacement. Emin et al. reported a quantitative method to diagnose PS loosening by measuring change in angle between the PS axis and the end plate of the vertebra on plain radiographs at different postoperative timepoints [3].

Digital tomosynthesis is a new radiographic technique that can produce an arbitrary number of section images of a patient from a single pass. Digital tomosynthesis is used to acquire tomographic images with lower radiation than CT and results in better visibility of structures such as the vertebral trabeculae. Furthermore, examinations by digital tomosynthesis with the patients lying and standing can be made easily, facilitating dynamic examination. One of the other major advantages of digital tomosynthesis is that it can provide the same slice images while the patient is lying and standing because of reconstruction within -20° to 20° against the operating table. This has been extremely difficult when using plain radiographs.

In this study, we devised a new quantitative method to diagnose PS loosening using digital tomosynthesis with the patient in different positions.

Materials And Methods

Verification of accuracy of angle measurement with digital tomosynthesis

Lumbar Sawbones (Model: Sawbones Co., product number SKU #1301-97, production: United States) that were specifically designed to be radio-opaque under fluoroscopy were prepared for screw insertion. The Sawbones have an inner cancellous core and an outer cortex layer that simulate human vertebrae with normal bone properties and morphometry. A single Sawbones lumbar vertebra was fixed laterally, and a hollow pedicle screw was inserted from the ventral side.

First, a guidewire was inserted and the hollow PS (Tanaka Medical Instrument Co., Ltd. RENG pedicle screw, size: $\Phi 5.5 \times 54$ mm, production: Japan) was inserted. Second, the guidewire was displaced within

the pedicle screw hole at several angles (4°, 6°, 8°, 10° and 12°) after drilling concentrically $\Phi 8.0$ mm diameter bone holes through the guidewire. The angle between the guidewire that was inserted first and the guidewire that was displaced was measured (Fig. 1a-c).

Each model was examined with digital tomosynthesis (SONIALVISION G4, Shimazu Co, Japan) and volume data were acquired. The protocol for the examination was TOMOS L-spine Metal for the thoracolumbar region (Fig. 1d, e). The SIDE STATION i3 at the image processing station installed in SONIALVISION G4 was used to reconstruct DICOM data. The angles between the PS axis and the cranial endplate (α), the caudal endplate (β), and the anterior wall (γ) of the vertebra were measured using digital tomosynthesis imaging (Fig. 1f).

The PS displacement angle was defined as the average of the three angles. The fixed point was determined by enlarging the image up to 3200 times using ImageJ (the U.S. National Institutes of Health, USA) and applying the pixel selection method [7].

The difference between the displacement angle measured by the guidewire and that measured on the image using digital tomosynthesis was calculated.

Clinical study design

This study was performed at the University of Tsukuba Hospital, and was approved by the responsible ethics committee at the University of Tsukuba Hospital.

The study design was retrospective with cross-sectional analysis of PS loosening on CT (Brilliance iCT Elite, Koninklijke Philips N.V.Co, Netherlands) and digital tomosynthesis. Before enrollment, written informed consent was obtained from all the patient participants.

Patients and the evaluated screws

The study included 41 consecutive patients (male 21, female 20, average age 67.5 years old) who underwent thoracolumbar spinal fusion surgery with PS in our institution between November 2017 and May 2020. All patients underwent CT and digital tomosynthesis within one month interval at the various time point after surgery (one week to 20 months after surgery).

The incidence of PS loosening has been reported to occur near the ends of the fusion levels [8]. Therefore, in this study, 72 pedicle screws at the cranial end of the fused segments were evaluated using CT and digital tomosynthesis. Screws that could not be visualized in the same slice as the screw axis in supine and upright positions in the digital tomosynthesis were excluded.

Evaluation of PS loosening by CT

All CT scans were performed at the University of Tsukuba Hospital. Screw loosening was determined on postoperative CT scans using conventional standard radiologic criteria, with or without a radiolucent area greater than 1 mm wide or the halo sign [2, 9, 10]. We divided the patients into two groups: one of seven patients (12 pedicle screws) who were diagnosed with pedicle screw loosening because of a radiolucent

area wider than 1 mm or the presence of the halo sign on CT (Fig. 2), and the other of 34 patients (60 pedicle screws) without PS loosening on CT.

Evaluation of PS displacement angle within the vertebrae by digital tomosynthesis in different postures

The examination of the digital tomosynthesis (SONIALVISION G4, Shimazu Co, Japan) image in different postures was performed at the University of Tsukuba Hospital. In the first step, patients were placed in a lateral lying position on the operating table and a lateral view of the thoracolumbar spine was obtained (Fig. 3a). Then, patients were placed in a standing position by tilting the operating table and a lateral view of the thoracolumbar spine was obtained in the standing position (Fig. 3b).

Those patients who were unable to maintain the standing position safely were placed in a sitting position.

After the examinations, the images were reconstructed at a workstation (SIDE STATION i3). The accuracy of coincidence of the same lateral plane between lying and standing positions was defined by the plane that depicted both the full length of the PS axes and the connecting rod. (Fig. 4).

Three different angle measurements (α , β , γ) were performed and compared for their capability to discriminate PS loosening between the lying position and the standing position: (1) the angle α between the PS axes and the cranial endplate of the same vertebra; (2) the angle β between the PS axes and the caudal endplate of the same vertebra; (3) the angle γ between the PS axes and the posterior wall of the same vertebra (Fig. 5).

The PS displacement angle was defined as the average of the change in the three angles between the lying and the standing positions.

In the second step, the PS displacement angles were compared between the groups with PS loosening and without PS loosening that were defined by CT diagnosis.

In the third step, a receiver operating characteristics (ROC) curve analysis was performed and the area under the curve (AUC) was assessed to identify optimal cut-off values for the displacement angle that discriminated between patients with and without screw loosening. The sensitivity and specificity of the optimal cut-off values were calculated.

Statistical analysis

Nominal patient characteristics between the groups were compared using the Chi-square test. The Mann–Whitney U test was used when studying the association of categorical and continuous variables. All statistical analyses were conducted using JMP software package, version 10.0.2 (SAS Institute, Inc., Cary, NC, USA). Significance was set at $p < 0.05$.

Results

The total mean difference of the radiographic displacement measurement using digital tomosynthesis and the actual measurement from the guidewires was accurate within 1° (Table 1).

Table 1
The total mean difference of the radiographic displacement measurement

		The actual displacement measurement from the guidewire									
		4.5°		6.0°		7.8°		10.5°		12.5°	
The displacement angle (degrees) using digital tomosynthesis and the difference (Δ)		Δ		Δ		Δ		Δ		Δ	
	α	4.4	0.1	6.6	0.6	7.1	0.7	9.6	0.9	12.7	0.2
	β	3.6	0.9	6.3	0.3	7.5	0.3	10.2	0.3	12.7	0.2
	γ	4.0	0.5	5.6	0.4	7.4	0.4	9.9	0.6	12.8	0.3
Average		0.50		0.43		0.47		0.60		0.23	

α : The angle between the PS axis and the cranial endplate of the vertebra

β : The angle between the PS axis and the caudal endplate of the vertebra

γ : The angle between the PS axis and the anterior wall of the vertebra

No significant differences in the average age or number of fused segments between patient groups were observed (Table 2). In the PS loosening group diagnosed by CT, the average PS displacement angle was $5.7^\circ \pm 5.1$. In the group without PS loosening, the average PS displacement angle was $0.6^\circ \pm 0.5$. The PS displacement angle was significantly different between the two groups ($p < 0.01$). There was no significant difference in the examination period between patient groups (Table 2).

Table 2
Demographic characteristics of the groups

	PS loosening (+)	PS loosening (-)	<i>P</i>
N	7	34	
age	69.8 ± 8.7	67.0 ± 10.9	0.23
Average N of fused segments of	5.5 ± 3.1	4.9 ± 4.1	0.51
Average of the examination period after surgery (weeks)	21.7	15.1	0.06
Displacement angle	5.7 ± 5.5	0.6 ± 0.5	< 0.00001
N of revision surgeries	2	0	

An ascending orders plot of the displacement angle of each screw was drawn as a continuous variable curve. Screw loosening was associated with large displacement angles (Fig. 6).

Based on the ROC analysis, the optimal cut-off value of the PS displacement angle for identification of loosened screws was 1.7° with a sensitivity of 100% and specificity of 93% (Fig. 7; AUC = 0.98).

Discussion

In general, the diagnosis of pedicle screw loosening after spine fusion surgery has been evaluated qualitatively by the presence of a radiolucent area and the halo sign surrounding the screw on plain X-rays and CT [9, 10]. In this study, we evaluated PS loosening quantitatively by measuring the displacement angle of the PS in the vertebrae while in a lying and a standing position using digital tomosynthesis. The results show that a displacement angle of at least 1.7° predicts screw loosening with a high sensitivity and specificity.

In a previous study, Emin et al. reported a quantitative method to diagnose PS loosening by measuring the change in angle between the PS axis and the end plate of the vertebra on plain radiographs at different postoperative timepoints. They suggested that a change of angle between the PS axis and the cranial endplate of at least 2° indicated PS loosening [3].

Digital tomosynthesis can provide the same slice images while the patient is in lying and standing positions because of reconstruction within -20° to 20° against the operating table. Previously we reported the usefulness of dynamic digital tomosynthesis radiculography to visualize the changes of nerve roots when the position of the patient is changed between prone and upright [11, 12, 13]. Because of its advantages, tomosynthesis can depict the unilateral PS on the same slice while the patient is in a lying and a standing position during the same period. Therefore, the new methods in this study are more accurate than those of previous reports. Furthermore, tomosynthesis can acquire images with a lower cost and lower radiation dose than CT.

The radiolucent zone and halo sign are thought to appear due to a decreased fit between the screw and bone. In a previous report, the presence of a radiolucent zone and halo sign surrounding the screw on plain X-ray and CT have been evaluated after at least 6 months postoperatively [10]. However, loosening of screws may occur during the early postoperative period (< 6 months) [14]. Mizuno et al reported that rotational micromovement occurs between the PS and the vertebral body, and repeated rotational micromovements might cause loosening of the screw [15]. We hypothesized that the displacement of the screw in the vertebra might occur first through screw loosening. PS loosening might be detected during the early postoperative period by evaluating the displacement of the screw.

Movement between screw threads and bone inhibits bone formation, revascularization and remodeling of dead bone. Movement causes the screw to become enveloped by fibrous tissue in response to necrosis and leads to resorption of adjacent dead cortical bone. This results in a radiologically discernible radiolucent "halo" about the screw, a certain sign of screw loosening [16]. Early diagnosis of screw

loosening can save the patient not only painful spasms but also possible serious neural damage or screw breakage [17].

There are several limitations to our study. First, the sample size is not big enough.

Second, this study is retrospective study not prospective study. Future studies should evaluate more patients in prospectively.

The new method of evaluating PS loosening quantitatively demonstrated by this study might be helpful to detect PS loosening during the early postoperative period and decrease the risk of serious neural damage or revision surgery. This study might be useful in the evaluation of new spinal fusion instrumentation and the new technique of pedicle screw trajectory, such as penetrating endplate screw (PES). Furthermore, this method might be an alternative of CT and could evaluating the PS loosening in less radiation exposure than CT.

Conclusion

The new quantitative method of diagnosing PS loosening using digital tomosynthesis in different postures is accurate. The optimal cut-off value of the PS displacement angle for identification of loosened screws is 1.7° .

Abbreviations

PS: pedicle screw

CT: computed tomography

ROC: Receiver Operating Characteristic

AUC: Area Under the Curve

PES: penetrating endplate screw

Declarations

Ethics approval and consent to participate

We obtained informed consent from all participants. This study was approved by the institutional Review Board of Tsukuba University (IRB approval No. H29–113) and was performed in accordance with the Declaration of Helsinki.

Consent for publication

Patients signed informed consent regarding publishing their data.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors have no possible conflict of interest related to the present manuscript to declare.

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Authors' contributions

Kentaro Mataki: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Validation, Writing - original draft, Writing - review & editing. **Yuki Hara:** Conceptualization, Funding acquisition, Investigation, Methodology, Project administration, Resources, Supervision, Writing - review & editing. **Eriko Okano:** Conceptualization, Methodology. **Katsuya Nagashima:** Recruited participants. **Hiroshi Noguchi:** Conceptualization, Methodology, Recruited participants. **Yosuke Shibao:** Recruited participants. **Kousei Miura:** Recruited participants. **Hiroshi Takahashi:** Recruited participants. **Toru Funayama:** Recruited participants. **Masao Koda:** Conceptualization, Recruited participants. **Masashi Yamazaki:** Conceptualization, Project administration, Resources, Supervision.

All authors read and approved the final manuscript.

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Conflicts of Interest/Disclosures

The authors have no possible conflict of interest related to the present manuscript to declare.

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Figures

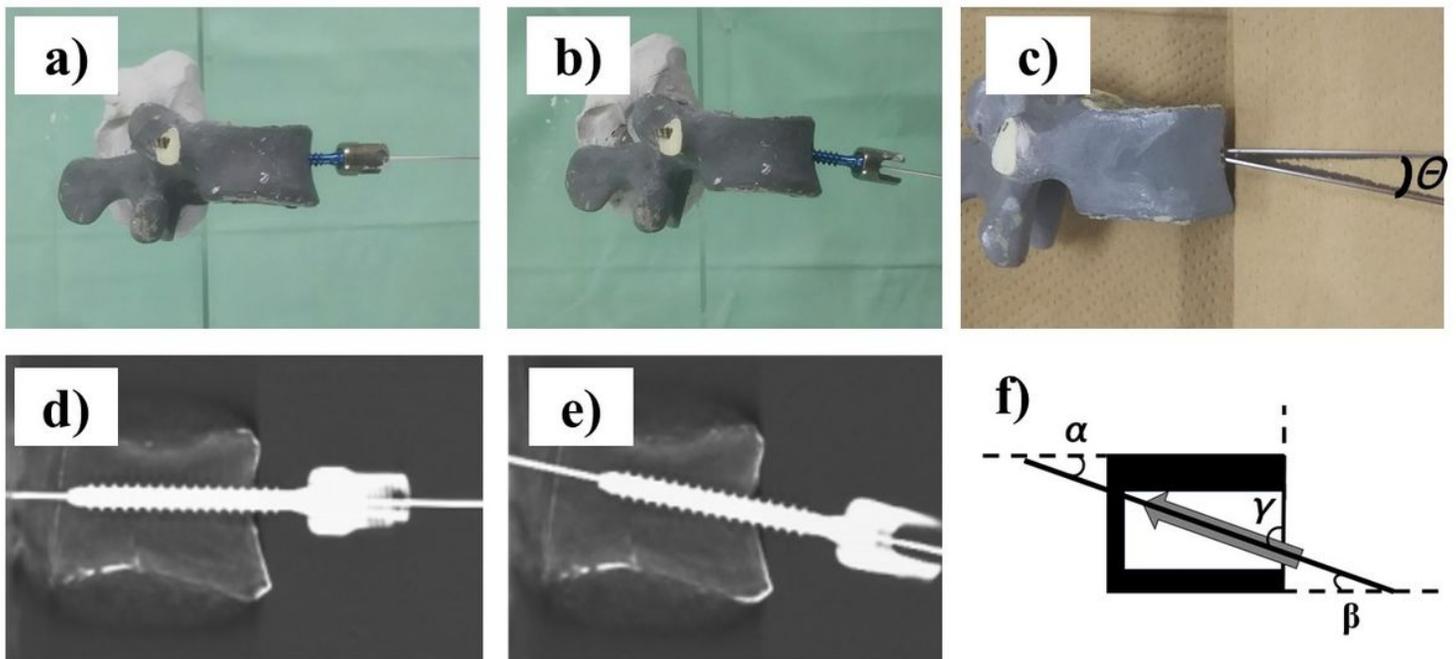


Figure 1

(a) The model without displacement. (b) The model with displacement. (c) The actual displacement angle (θ) between the guidewires. (d) The images using digital tomosynthesis of the model without displacement. (e) The model with displacement. (f) The schematic of the angles α , β , γ . The gray arrow represents the pedicle screw, and the black line means the guidewire.

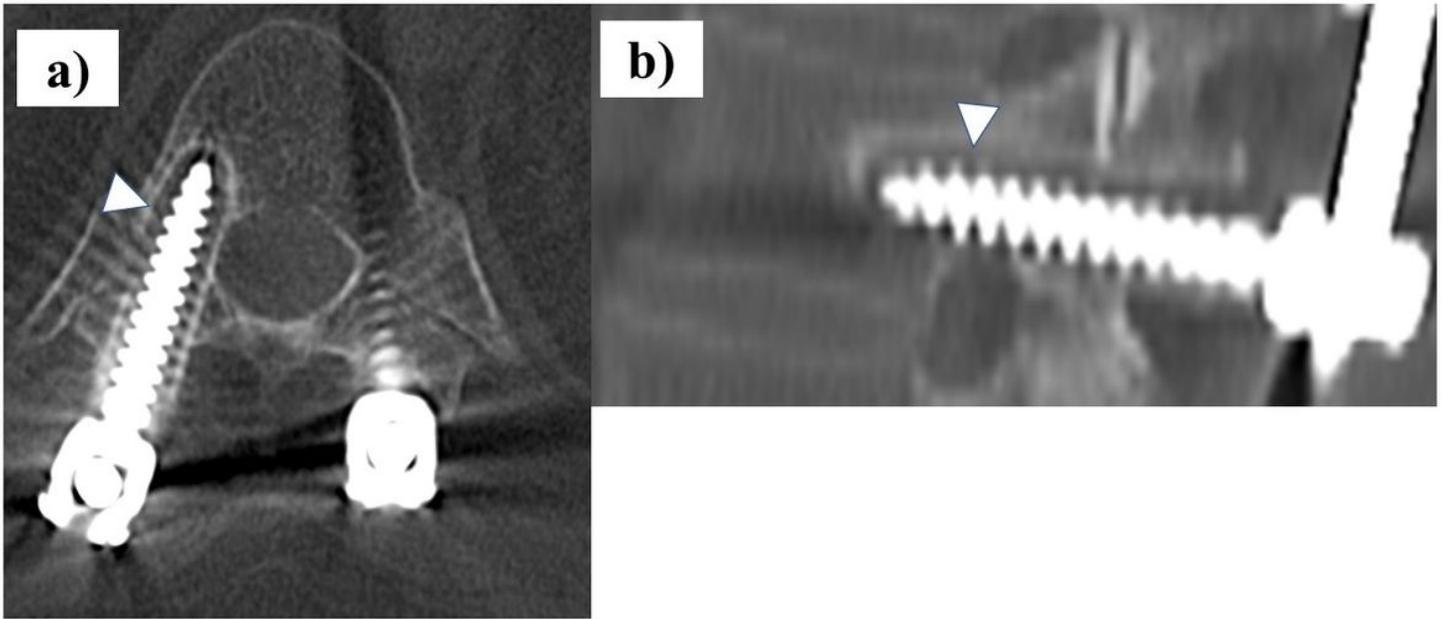


Figure 2

Axial (a) and sagittal (b) CT scan of a patient subjected to thoracolumbar posterior fixation showing a radiolucent area and the halo sign, indicative of screw loosening, indicated by the white arrowheads.

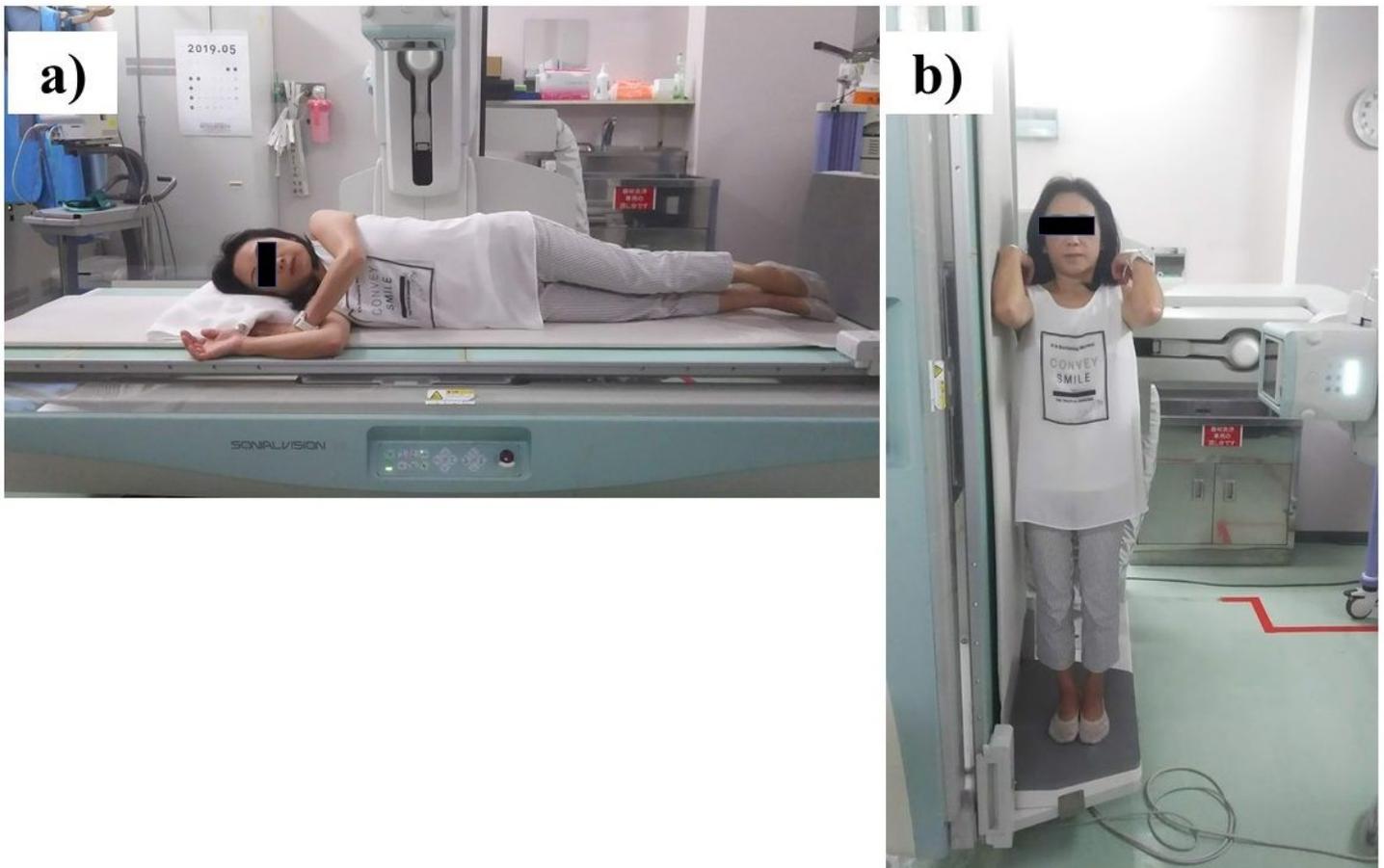


Figure 3

The examination using digital tomosynthesis (Shimazu SONIALVISION G4 Series) in different postures. (a) lateral lying position (b) standing position.

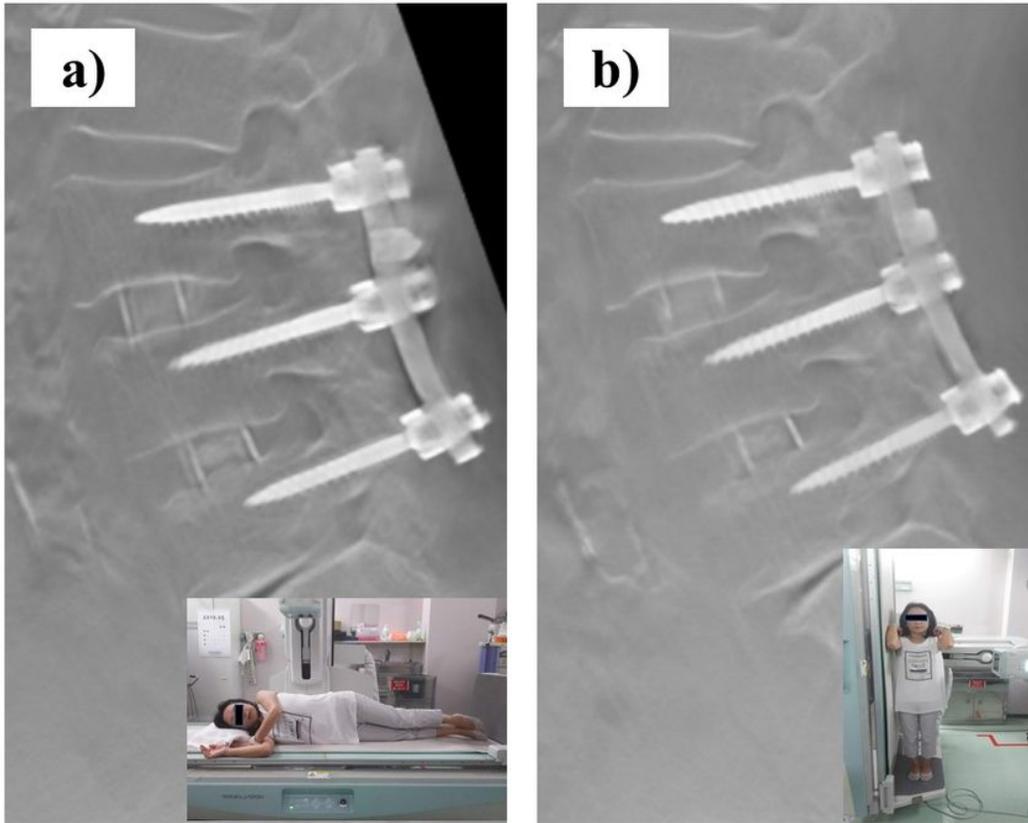


Figure 4

The same lateral plane between (a) lying (and (b) standing positions from digital tomosynthesis without PS loosening. The plane of evaluation depicted both the full length of the PS axes at the cranial end of the fused segments and the connecting rod.

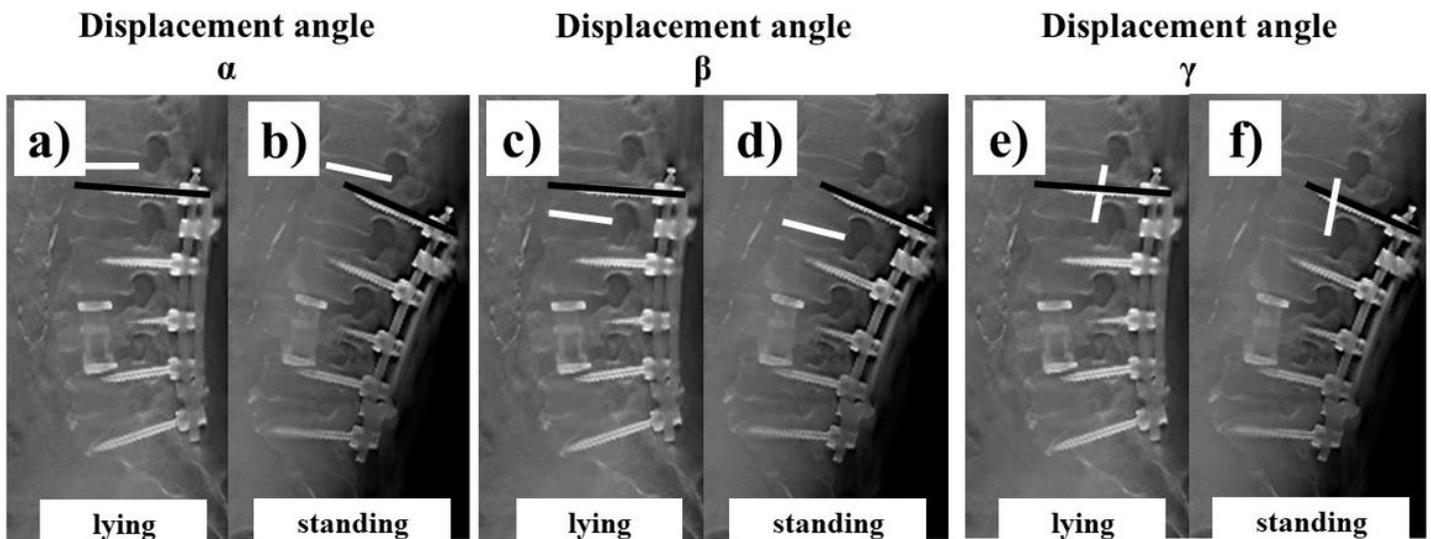


Figure 5

The same lateral plane between lying and standing positions from digital tomosynthesis in the PS loosening group. The displacement angle α between the PS axis (black line) and the cranial endplate (white line) of the same vertebra in the lying (a) and standing (b) position. The displacement angle β between the PS axis (black line) and the caudal endplate (white line) of the same vertebra in the lying (c) and standing (d) position. The displacement angle γ between the PS axis (black line) and the posterior wall (white line) of the same vertebra in the lying (e) and standing (f) position.

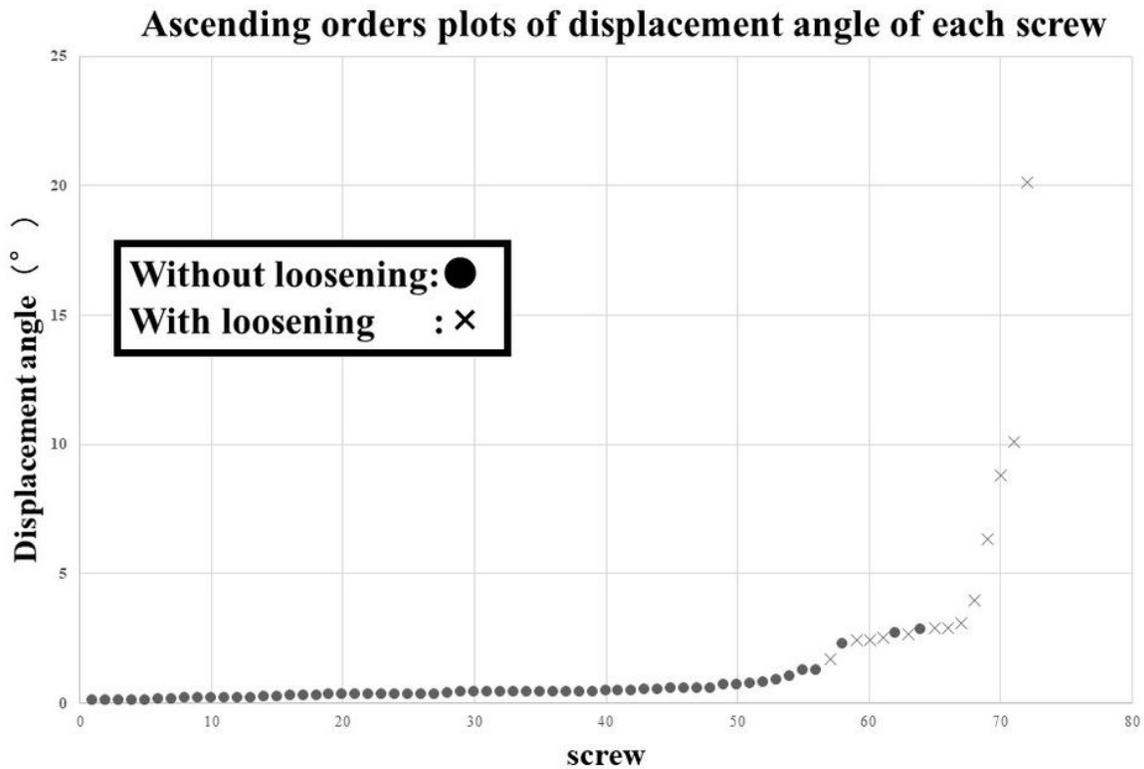


Figure 6

Ascending orders plot of displacement angle of each screw drawn as a continuous variable curve. The plots with screw loosening are indicated by a cross (×) and those without loosening are indicated by a circle (●). Screw loosening was associated with large displacement angles.

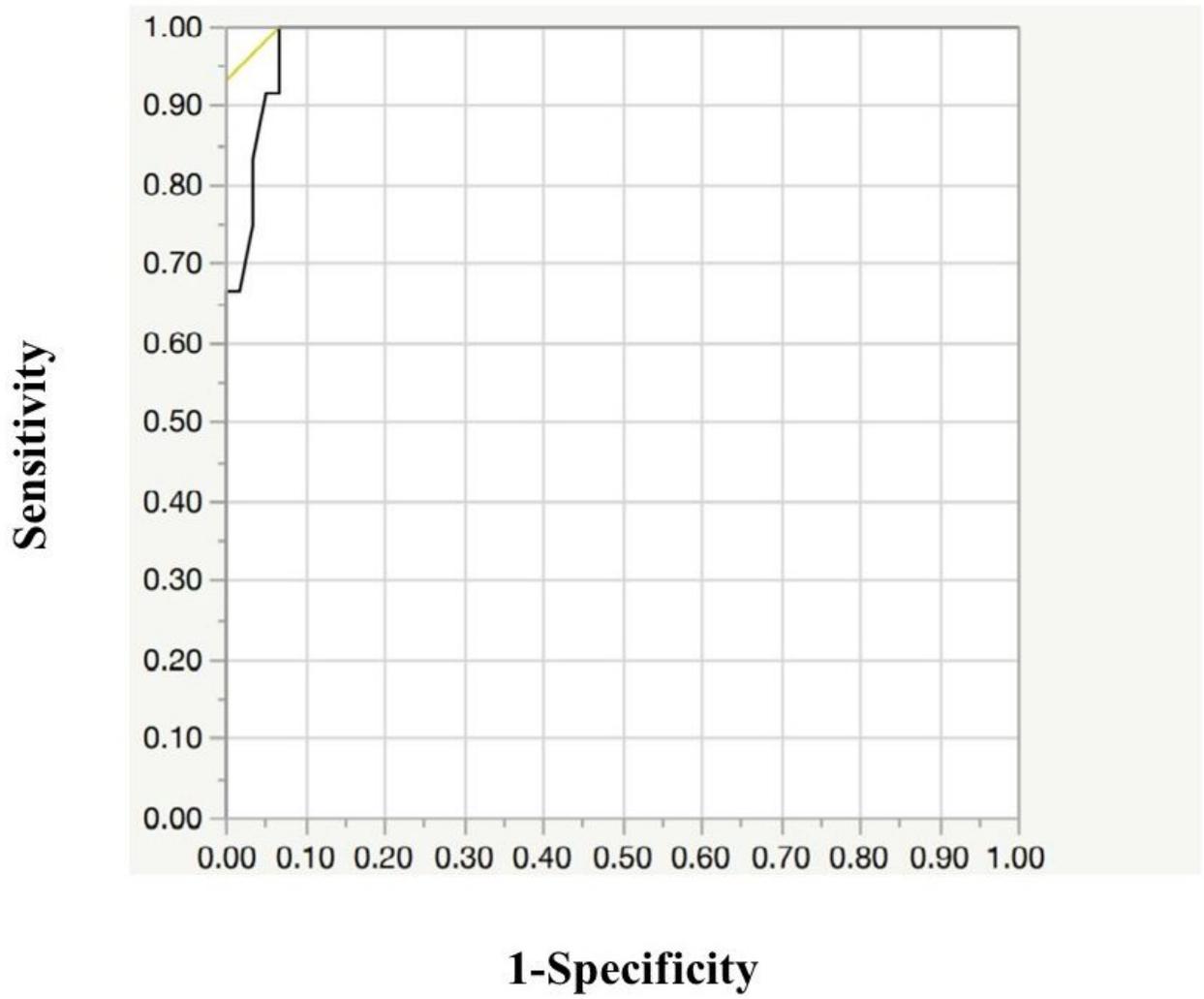


Figure 7

ROC curve analysis for the identification of an optimal cut-off value discriminating between those with and without PS loosening on CT images.