

A Nomogram for Predicting Screw Loosening after Single-Level Posterior Lumbar Interbody Fusion utilizing Cortical Bone Trajectory Screw: A Minimum 2-year Follow-up Study

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Research Article

Keywords: Cortical bone trajectory, Screw loosening, Lumbar spine, Nomogram

Posted Date: May 26th, 2022

DOI: <https://doi.org/10.21203/rs.3.rs-1672101/v1>

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Abstract

Purpose: To investigate the risk factors for screw loosening after single-level posterior lumbar interbody fusion (PLIF) utilizing cortical bone trajectory (CBT) screw and establish a nomogram for predicting screw loosening

Methods: A total of 79 patients (316 screws) underwent single-level PLIF with CBT screw were included in the study. Preoperative, postoperative and final follow-up demographic data, surgical data and radiographic parameters were documented and analyzed to identify risk factors and a predictive nomogram was established for screw loosening. The nomogram was assessed through concordance index (C-index), calibration plot, decision curve analysis (DCA) and internal validation.

Results: The incidence of screw loosening was 26.6% in 79 patients, and 11.4% in 316 screws. Multifactorial regression analysis confirmed that fixed to S1 (FS1, OR=3.82, 95%CI 1.12-12.71, P=0.029), coronal angle of the screw (CA, OR=1.07, 95%CI 1.01-1.14, P=0.039) and cortical bone contacted layers (CBCL, OR=0.17, 95%CI 0.10-0.29, P<0.001) were risk factors and incorporated in the nomogram for predicting screw loosening after single-level PLIF with CBT screw. The C-index of the nomogram was 0.877 (95%CI 0.818-0.936) which demonstrated good predictive accuracy. The Calibration plot indicated an acceptable calibration of the nomogram that also had a positive benefit guiding treatment decision.

Conclusion: FS1, CA and CBCL are identified to be significant risk factors for screw loosening after single-level PLIF with CBT technique. The nomogram we have established can be used to predict screw loosening and contribute to surgical decision.

Introduction

Cortical bone trajectory (CBT) was an alternative approach first proposed by Santoni et al as the treatment for lumbar degenerative disease¹. CBT screw was inserted via the trajectory that could engage the pars, medial and superior cortices of the pedicle isthmus for spinal fusion and theoretically, it provided comparable pullout resistance and stability as traditional pedicle screw (TPS)²⁻⁴. Likewise, good results were shown in literatures reporting the application of CBT screw in osteoporosis lumbar spine^{1 5 6}. The main role of screw in lumbar fusion is to reduce the motion of spine and to conduct the stabilization, whereas, screw loosening is observed in quite a few literatures⁷⁻⁹. As reported, the incidence of screw loosening in TPS was 1%-60%^{7 10 11}, and risk factors were related to osteoporosis, sacrum instrument, excessive load and local high strains, etc., however, it was not unified. CBT screw conducts a comparable fixation as TPS according to the characteristic, and it may reduce the risk of screw loosening due to the loading resistivity of cortical bone of the pedicles. Nevertheless, screw loosening rate was still observed up to be 62.5%^{9 12-14} and the risk factors were also uncertain. This leads to consideration about the differences of risk factors for screw loosening between CBT screw and TPS.

Screw loosening in both TPS and CBT screw may require a revision surgery due to symptomatic spinal instability and instrument failure^{9 11 15 16}, thus comprehension of screw loosening is essential. Previous studies were researched and we found few studies have concentrated on CBT screw loosening, or most of them lacked of long-term follow-up and sufficient evidence. Hence a clear exploration of screw loosening of CBT screw is demanded with an available analysis of the literature.

The aim of the present study was to detect the prevalence of screw loosening in single-level PLIF using CBT screw with a minimum 2 years follow-up, and to establish a nomogram for predicting screw loosening individually in each vertebra.

Methods

This was a retrospective study in the institution. A total of 88 consecutive patients were included in the study from November 2017 to January 2020, and 79 eligible patients were evaluated (**Fig.1**). Inclusion criteria were listed: (1) patients diagnosed as lumbar degenerative disease (lumbar disc herniation, lumbar spinal stenosis and lumbar spondylolisthesis) and underwent single-level PLIF with CBT screw; (2) minimum follow-up time over 2 years; Excluded criteria were: (1) incomplete radiological data; (2) patients underwent the surgery diagnosed as lumbar infection, lumbar vertebral tumor, history of lumbar surgery. The study was approved by the institutional review board of the hospital.

Surgical Technique

The patient was placed in a prone position. A 5 cm midline skin incision was performed at lumbar area. Muscular dissection was performed till the vertebral isthmus was exposed. The facet joints were exposed and adjacent facet joints of the fusion area were avoided. The entry point was selected as intersection of a vertical line through the center of inferior facet joint of the cephalic adjacent vertebra and horizontal line 3-4 mm below the inferior facet joint of cephalic vertebra (A notch might be identified on the isthmus). The track was drilled with a 2 mm burr into the cortical bone with an approximate 10° -15° angle from medial to lateral and 20° - 25° angle from caudal

to cranial. Locating pins were placed into the track and fluoroscopy was made to check the position. Then decompression was performed and cage (PEEK) filled with autogenous bone was implanted into intervertebral space after end plate preparation and autogenous bone insertion. After the decompression, pins were removed and CBT screws (For S1 vertebra, the screw was 45 mm for length and 6.0 mm for diameter, and for other vertebrae, the screw was 35 mm for length and 5.5 mm for diameter) were inserted through the tracks with spinous process preservation. Bended rods were then positioned and tightened bilaterally after compression performed. Finally, fluoroscopy was made to re-check the position of screws and cage before the skin was sutured layer by layer.

Clinical and Radiological Evaluations

Clinical demographic data and surgical data including age, gender, body mass index (BMI), operation time and estimate blood loss (EBL) were collected. Radiological parameters including coronal angle of the screw (CA), sagittal angle of the screw (SA), fixed to S1 (FS1), Hounsfield unit (HU) measurement of trabecular bone of screw location and cortical bone contacted layers (CBCL) were evaluated (**Fig.2, 3**). HU measurement was defined as the average of 3 points located in the screw track in preoperative CT scan. Screw loosening was defined as a continuous lucent zone with size more than 1 mm and surrounded by a thin sclerotic zone in CT scan^{7 17 18}. Bone fusion was graded according to Bridwell classification into three grades based on lumbar CT scan¹⁹ Grade I, complete fusion with bridging bone bonding with both adjacent vertebral bodies; Grade II, incomplete fusion with bridging bone bonding with either superior or inferior vertebral bodies; Grade III, failed fusion with incomplete bony bridging. Bone fusion was assessed by CT scan slices selected from the center of the cage or the largest bone grafting²⁰. Oswestry Disability Index (ODI) was used to evaluate back pain preoperatively and at postoperative time point of 6 month and final follow-up.

Statistics analysis

SPSS Statistics Version 23.0 (IBM, Armonk, New York) and R software (version 4.1.2) were used for data analysis. Univariate analysis was performed with independent t test and Mann-Whitney U test for continuous data and discontinuous data, respectively, and quantitative data are listed as means \pm SD with normal distribution, or as medians with interquartile range with non-normal distribution. Chi-squared test was used for categorical data analysis.

Multiple logistic regression model was applied to select significant variables with stepwise forward method and the odds ratio (OR) and 95% confidence interval (CI) of the variables were recorded. A nomogram was established with R software. Concordance index (C-index) of the nomogram was calculated to evaluate the predictive accuracy of the nomogram utilized "rms" package. Calibration plot was used to assess the calibration and bootstraps of 1000 resamples were validated internally for the model. Decision curve analysis (DCA) was calculated by "rmda" package to evaluate the clinical usefulness of the nomogram. Reliable outcome is considered as C-index > 0.75 and P value <0.05 was considered statistically significant for all data.

Results

A total of 88 consecutive patients were identified and 79 patients (316 screws) were included in the study. The cohort contained 35 (44.3%) male patients with an average age of 65.14 ± 9.74 years old, and the average of BMI was 26.83 ± 4.49 . The mean follow-up time were 25.38 ± 1.77 months (Table 1). The incidence of screw loosening was 26.6% (21) in the cohort, and 11.4% (36) in 316 screws, and a total of 5 patients presented back pain and received conservative treatment and other patients (16) were asymptomatic. The patients were divided into two groups according to the presence of screw loosening presence as screw loosening group (SL) and No screw loosening group (Non-SL). Statistically significant differences were shown in CA (P = 0.039), FS1 (P = 0.029) and CBCL (P < 0.001) between the two groups

(Table 2). These parameters were put into the multiple logistic regression and the results demonstrated that FS1 (OR = 3.82, 95%CI 1.12–12.71, P = 0.029), CA (OR = 1.07, 95%CI 1.01–1.14, P = 0.039) and CBCL (OR = 0.17, 95%CI 0.10–0.29, P < 0.001) were risk factors for screw loosening after single-level PLIF with CBT screw (Table 3).

Table 1
Baseline characteristics and surgical data of patients.

Factors	Total number (n = 79)	SL (n = 21)	Non-SL (n = 58)	P value
Demographics				
Age (y)	65.14 ± 9.74	64.62 ± 11.93	62.60 ± 8.87	0.420
Male, n (%)	35(44.3)	11(52.4)	24(41.4)	0.385
Height (m)	1.63 ± 0.78	1.66 ± 0.08	1.62 ± 0.07	0.053
Weight (kg)	71.13 ± 13.01	74.29 ± 15.50	69.98 ± 11.94	0.196
BMI	26.83 ± 4.49	26.93 ± 4.17	26.79 ± 4.64	0.905
Follow-up time (mon)	25.38 ± 1.77	25.43 ± 1.43	25.36 ± 1,89	0.884
Surgical data				
Operation time (min)	176.54 ± 41.46	172.62 ± 43.18	177.97 ± 41.12	0.616
EBL (ml)	213.54 ± 74.13	190.00 ± 63.64	222.07 ± 76.29	0.089
Fusion grade, n (%)	-	-	-	0.267
I	29 (36.7)	10 (47.6)	19 (32.8)	-
II	42 (53.2)	8 (38.1)	34 (58.6)	-
III	8 (10.1)	3 (14.3)	5 (8.6)	-
ODI (%)				
Preoperative	49.10 ± 6.50	49.52 ± 8.68	48.95 ± 5.60	0.731
6 months	22.52 ± 4.65	23.33 ± 4.53	22.22 ± 4.70	0.353
Final follow-up	21.03 ± 4.50	21.90 ± 4.58	20.71 ± 4.47	0.299
BMI: Body mass index				
EBL: Estimate blood loss				
ODI: Oswestry Disability Index				

Table 2
Characteristics of screw related parameters.

Factors	Total number (n = 316)	SL (n = 36)	Non-SL (n = 280)	P value
FS1, n (%)	22 (7.0)	9 (25.0)	13 (4.6)	< 0.001
Hu	165.18 ± 84.08	179.04 ± 83.63	163.40 ± 83.64	0.294
SA (°)	75.97 ± 7.10	75.72 ± 8.05	76.01 ± 6.99	0.822
CA (°)	10.77 ± 5.72	13.94 ± 6.53	10.36 ± 5.49	< 0.001
CBCL (n)	4 (3–4)	2 (2–3)	4 (3–4)	< 0.001
FS1: Fixed to S1				
SA: Sagittal angle of the screw				
CA: Coronal angle of the screw				
CBCL: Cortical bone contacted layers				

Table 3
Multivariable analysis of radiological parameters.

Variable	OR	95% CI	P value
FS1, n (%)	3.82	1.12–12.71	0.029
CA (°)	1.07	1.01–1.14	0.039
CBCL (n)	0.17	0.10–0.29	< 0.001
FS1: Fixed to S1			
CA: Coronal angle of the screw			
CBCL: Cortical bone contacted layers			

The nomogram was conducted by R software (version 4.1.2) with a 0.877 (95%CI 0.818–0.936) C-index, which demonstrated a good discrimination and predictive accuracy (Fig. 4). Calibration of the nomogram was evaluated by calibration plot (Fig. 5) and the internally validation by bootstraps of 1000 resamples was excellent with a 0.880 (95%CI 0.815–0.932) C-index. Decision curve analysis was performed as shown in Fig. 6, and when the threshold probabilities ranged from 0–60%, the nomogram showed a positive net benefit, which means clinical interventions implemented in those patients guided by the nomogram could obtain more benefit compared with treating all or treating none.

Application indication of the nomogram is explained (Fig. 7): A 62-year-old male patient underwent single-level PLIF with CBT screw at L4/5. Postoperative CT scan showed the CA of L4L was 5° and 15° at L4R. CA of L5L and L5R were 16° and 17°, and CBCL of each screw was 3, 3, 2 and 1. Thus, according to the prediction nomogram, the score of each screw was approximately 45, 59, 92 and 126, which indicated that the incidence of screw loosening was < 10%, 11%, 42% and > 80%. At the 1-year follow-up, we identified asymptomatic screw loosening at L4L, L5L and L5R, which verified the accuracy of the nomogram. And the patient maintained asymptomatic at final follow-up.

According to whether the screw's location was in S1, three-dimensional surface plots were shown in Fig. 8A and 8B to indicate the impact of CA and CBCL on probability for screw loosening.

Discussion

Screw loosening is common as reported in PLIF with an incidence of 1%-60%^{7 10 13}. Risk factors as explored are connected with osteoporosis, incorrect failing loading scenario, insufficient fusion or screw stress distribution⁷, however, most of researches have not reached consensus. CBT screw has comparable pullout resistance and stability as TPS since 2009 by Santoni et al¹. It can provide enhanced screw purchase and preferable interface strength attribute to characteristics of engaging higher density cortical bone even in osteoporosis patients²¹⁻²³. Perez-Orribo et al explored the biomechanics of TPS and CBT and concluded that equivalent stability was found between TPS and CBT fixation³. Matsukawa et al found the screw insertion torque of CBT was 1.71 times higher compared to TPS²⁴. Thus, theoretically, CBT screw has been proposed to promote pull-out strength and enhance the construct stability. In the present study, we found a 26.6% incidence of screw loosening in a total of 79 sample (11.4% in 316 screws). To investigate the risk factors of screw loosening, we documented and analyzed the mentioned parameters of each screw which would be more beneficial for surgery and the results of risk factor analysis showed three main factors (FS1, CA and CBCL) mainly constituted the predict scoring nomogram.

The odds ratio of FS1 was highest compared other parameters (OR = 3.82). In our study, there were 22 screws fixed in S1 vertebra, and 9 of them (40.9%) were found obvious lucent zone in CT scan. Grigoryan et al²⁵ conducted a cadaveric biomechanical study and considered lumbosacral fixation with CBT screw was stable against loosening, which is contrary compared the results of our study. The reasons of FS1 was concluded as a risk factor of screw loosening were assessed: First, lumbosacral fixation is inherently thought to have higher risk of screw loosening due to alignment restoration and holding strength²⁶⁻²⁸. Second, the learning curve of lumbosacral fixation with CBT is relative higher. Matsukawa et al²⁹ elucidated the penetrating S1 endplate CBT technique with a mean cephalad angle of 30.7° could provide favorable stability for lumbosacral fixation, while during our work, especially for early cases, it was hard to identify a content position for instrument in S1, and repeating screw track adjustment might result in instability, and this also occurred in other segment for early cases. Therefore we considered fixation to S1 need experienced surgeons to perform, and despite the result was not good for FS1, we

believe CBT screw for S1 is an alternative method for fixation due to the reduction for paraspinous dissection and facility for retraction in sacrum.

With regard to CA and CBCL. CBCL possessed an important role in screw loosening of CBT screw according to the nomogram. Typical trajectory of CBT contains four parts as the cortical bone to increase the stability of fixation, and among these, the lateral part as the start point is essential. The lateral part is an identifiable structure as entry point and is less influenced by degenerative change to provide good bony reference in the surgery^{30 31}. And the start point could also have influence on CA. Literatures recommended an approximate 10° -14° angle to medial^{32 33}, and in our study, the mean CA was 10.36° in Non-SL group and 13.94° in SL group, which concluded similar to the previous studies. Matsukawa⁴ stated that CA was more variable than SA, and CA might have been derived from differences in the location of the starting point. We believe biochemical studies would be performed to clarify the mechanism in the future.

In the present study, we have documented and provided a reference for the measurement of SA as angle between screw line and vertical line because we think this might reduce the error for measurement of wedge-shaped vertebra in some cases, while some authors recommended a measurement method of angle between screw and vertebral endplate^{33 34}. However, the results showed no statistically significant difference between the two groups but there was no denial that SA was an important parameter.

Lower BMD evaluated by dual x-ray absorptiometry (DXA) was significantly associated with screw loosening by influencing the pullout strength^{1 35 36}, nevertheless, it was an average value to assess BMD by DXA. In addition of DXA, the use of HU based on CT scan has been applied and clarified to be a reliable method for BMD evaluation³⁷⁻³⁹, which can be used to assess the region involved by each screw. However, literatures revealed that there was no consensus for a value of HU to evaluate a low BMD as a risk for osteoporosis. In the current study, BMD around the screw was assessed by HU value to explore if BMD would be a risk factor for screw loosening and the result was negative. This demonstrated that the BMD of the region where screw threaded could not make much difference. Lee et al³³ have reported a HU measurement of cortical bone, however, we have attempted to make the repetition, and the results showed a poor Inter-rater reproducibility due to the thin wall of cortical bone and we didn't adopt the method to replace CBCL.

The study had some limitations, mainly due to retrospective analysis with a small sample size. The surgery with CBT technique was performed during learning curve of the early period, and this might contribute to the loosening of S1 screw. Further studies with experienced surgical technique will be performed to validate the present study.

Conclusion

CBT technique offers an alternative method for lumbar surgery with TPS. Although CBT screw provides good stability for fixation, we have identified significant risk factors of screw loosening. A perioperative

evaluation with the nomogram can provide reliable prediction of screw loosening with CBT screw and contribute to surgical decision to avoid the complication.

Declarations

Conflict of interest

There is no financial or personal relationship with a third party. On behalf of all authors, the corresponding author states that there is no existed conflict of interest.

Ethical review statement

The study was approved by the institutional review board of our hospital, and informed consent was obtained from all patients.

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Figures

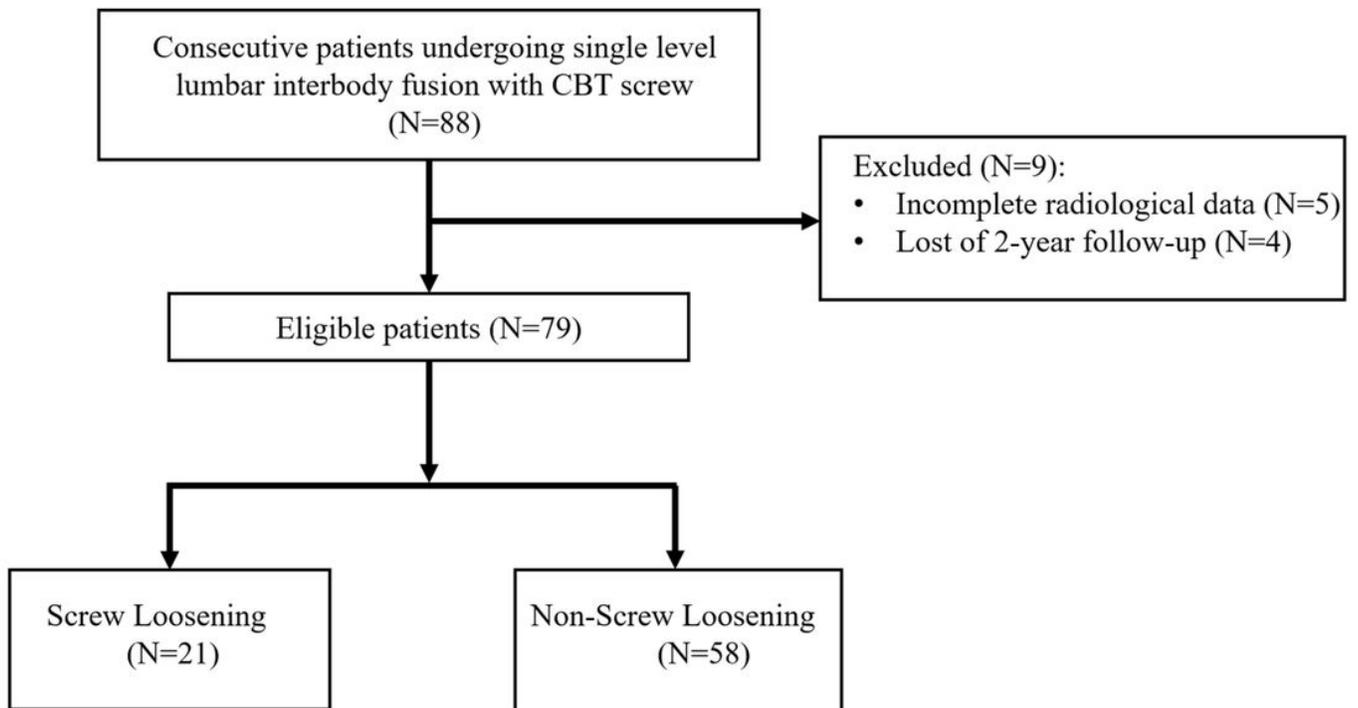


Figure 1

The flowchart of the study.

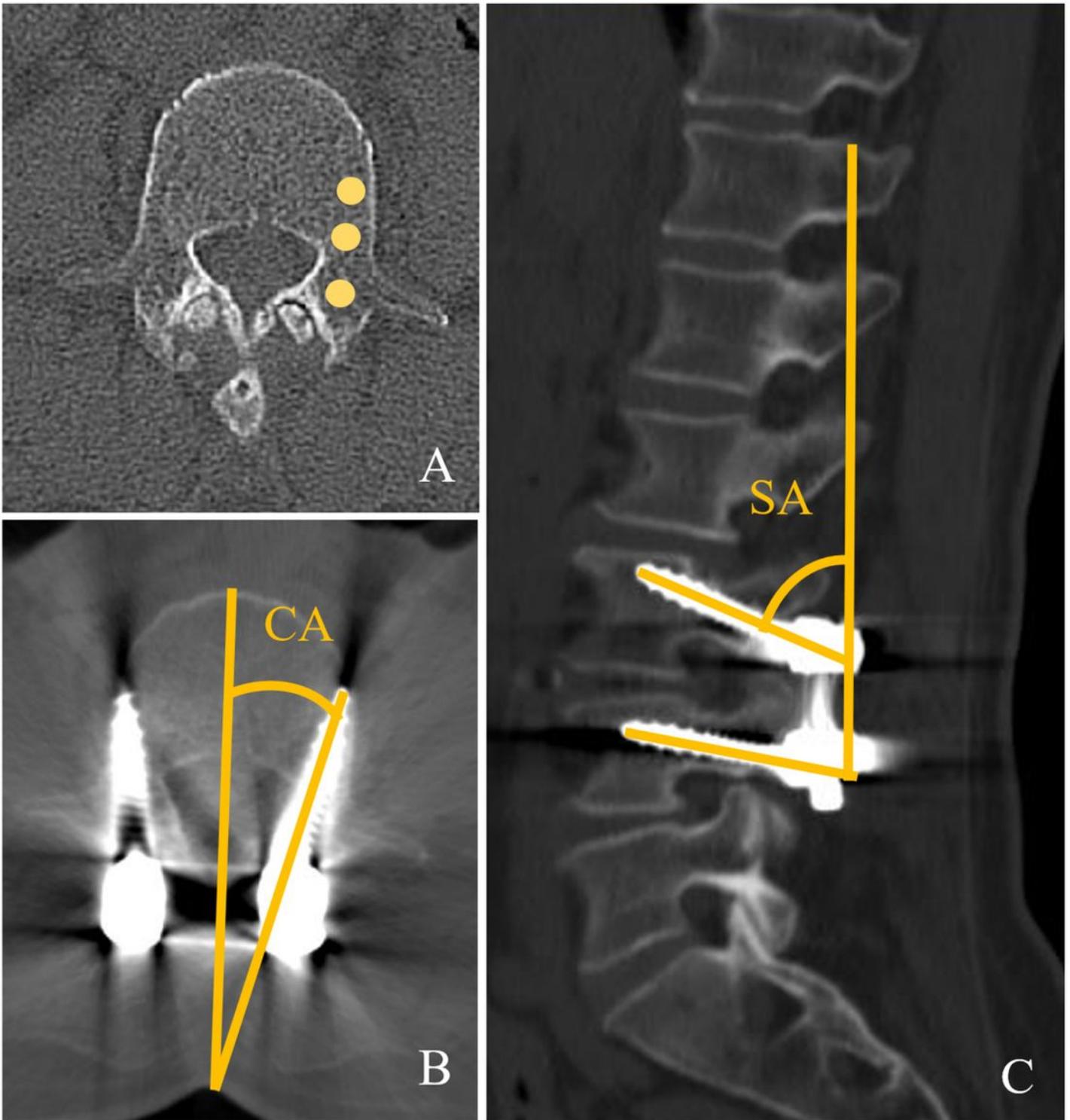


Figure 2

A. HU measurement was an average of 3 points identified according to screw track in preoperative lumbar CT scan. B. CA was defined as the angle between screw and spinous process in axial plane. C. SA was defined as the angle between screw line and vertical line in sagittal plane.

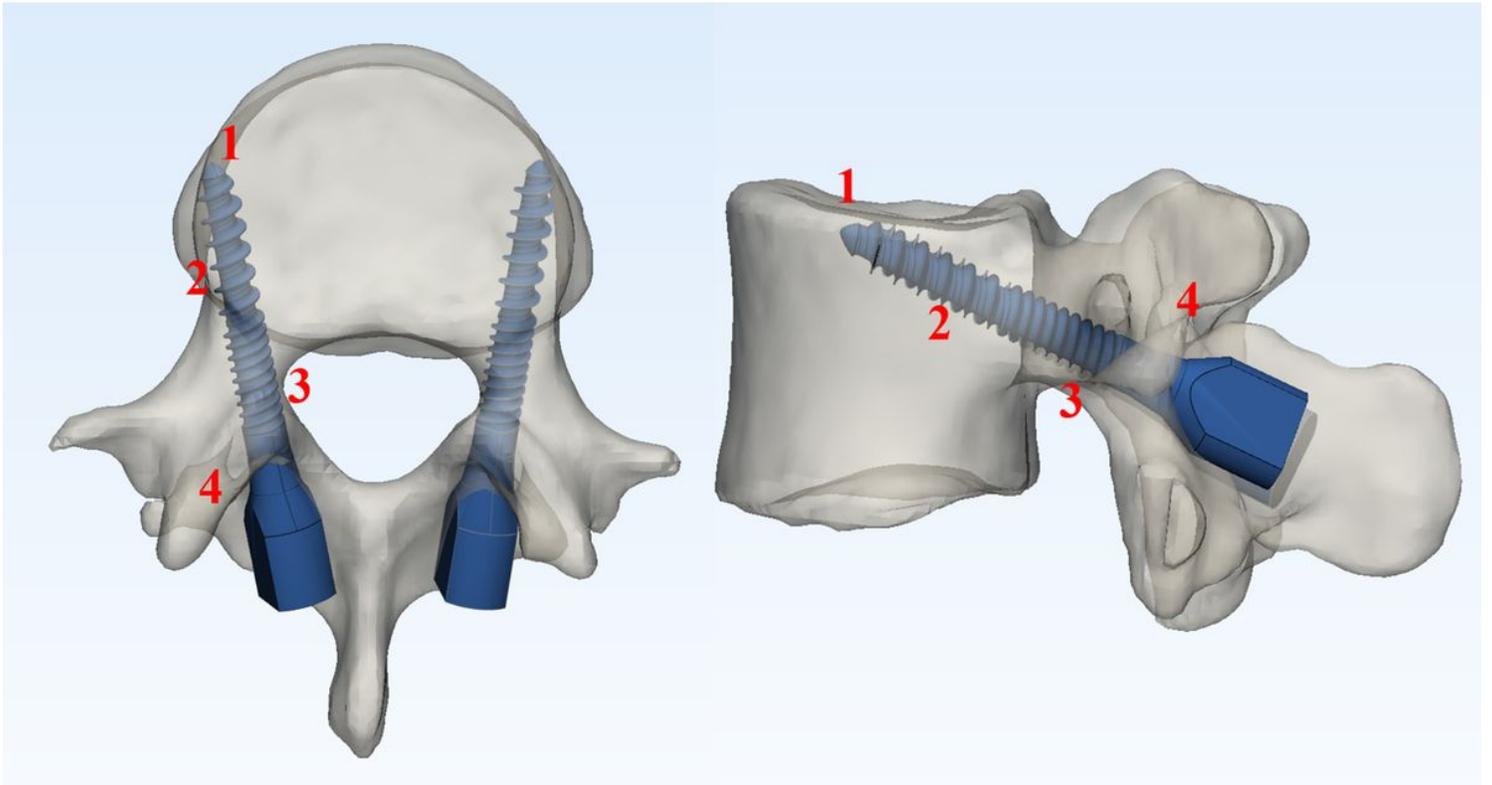


Figure 3

3D illustration of maximum contact of cortical bone.

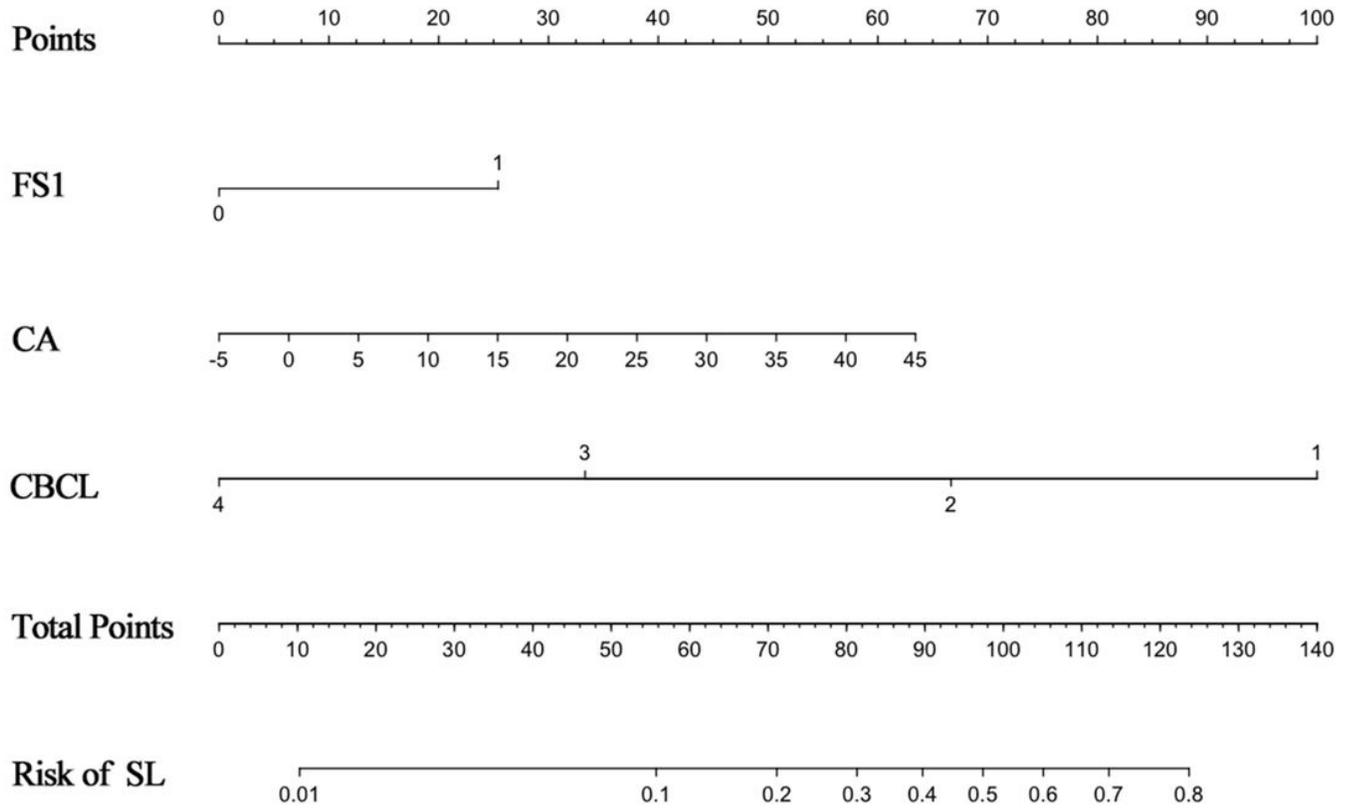


Figure 4

Detail of the nomogram.

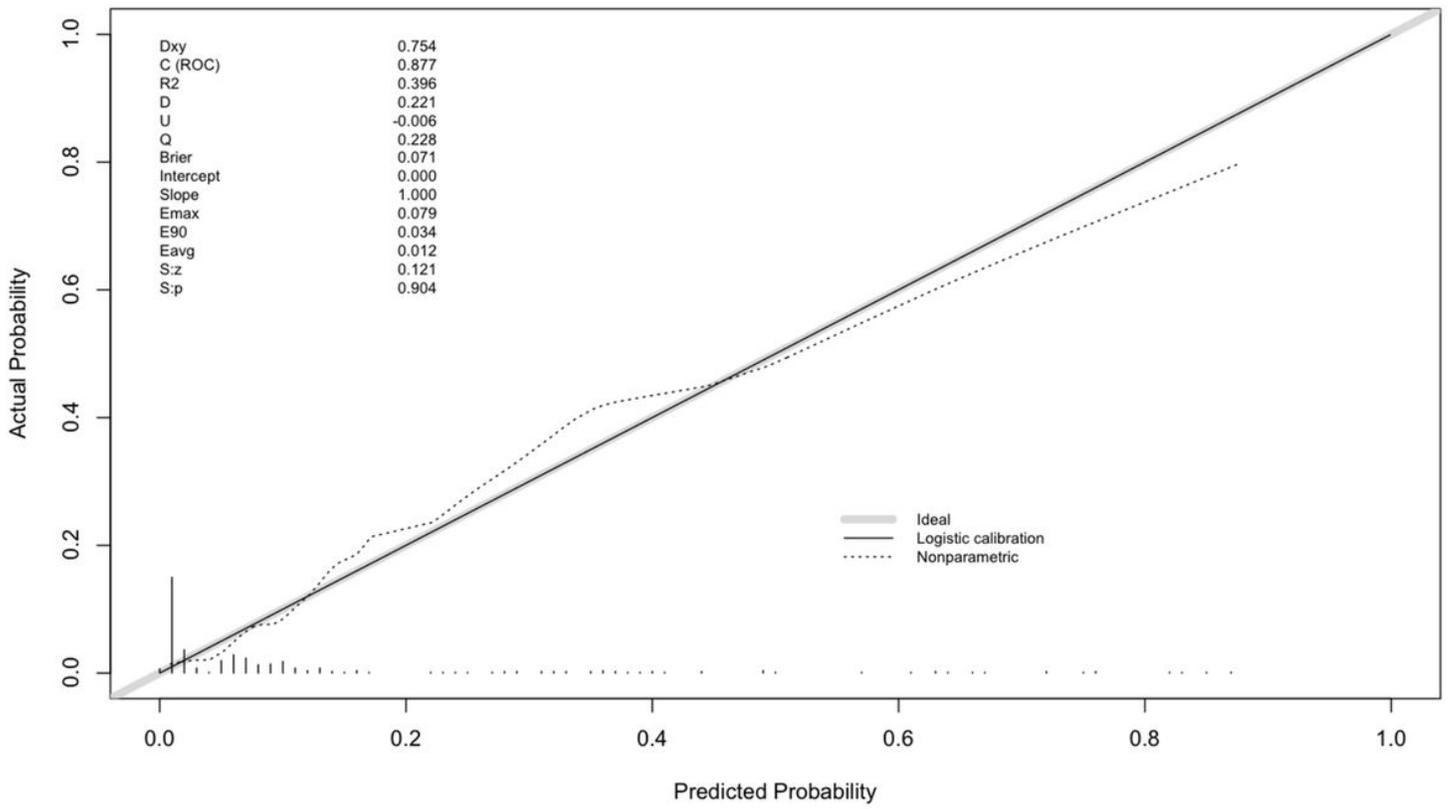


Figure 5

Calibration plot. The calibration of the nomogram was represented by the solid line, and any bias in the nomogram was corrected by the dashed line. The gray bold line indicated the reference line of an ideal nomogram.

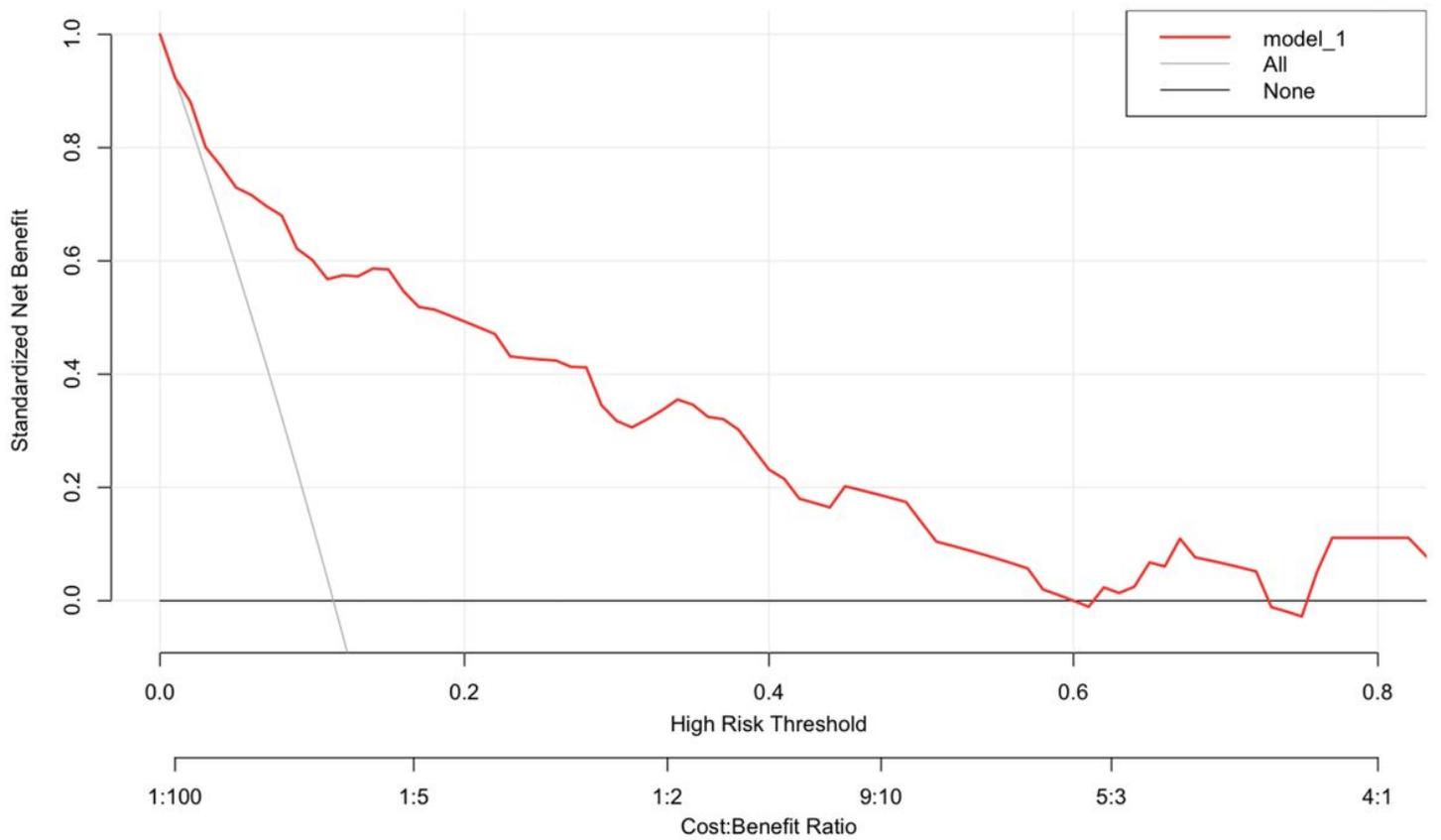


Figure 6

Decision curve analysis of the nomogram. The red line indicates the model. The x-axis and y-axis displayed the threshold probability and net benefit, respectively. The gray line represented the net benefit of treating all patients. The horizontal black line displayed the net benefit of treating no patients.

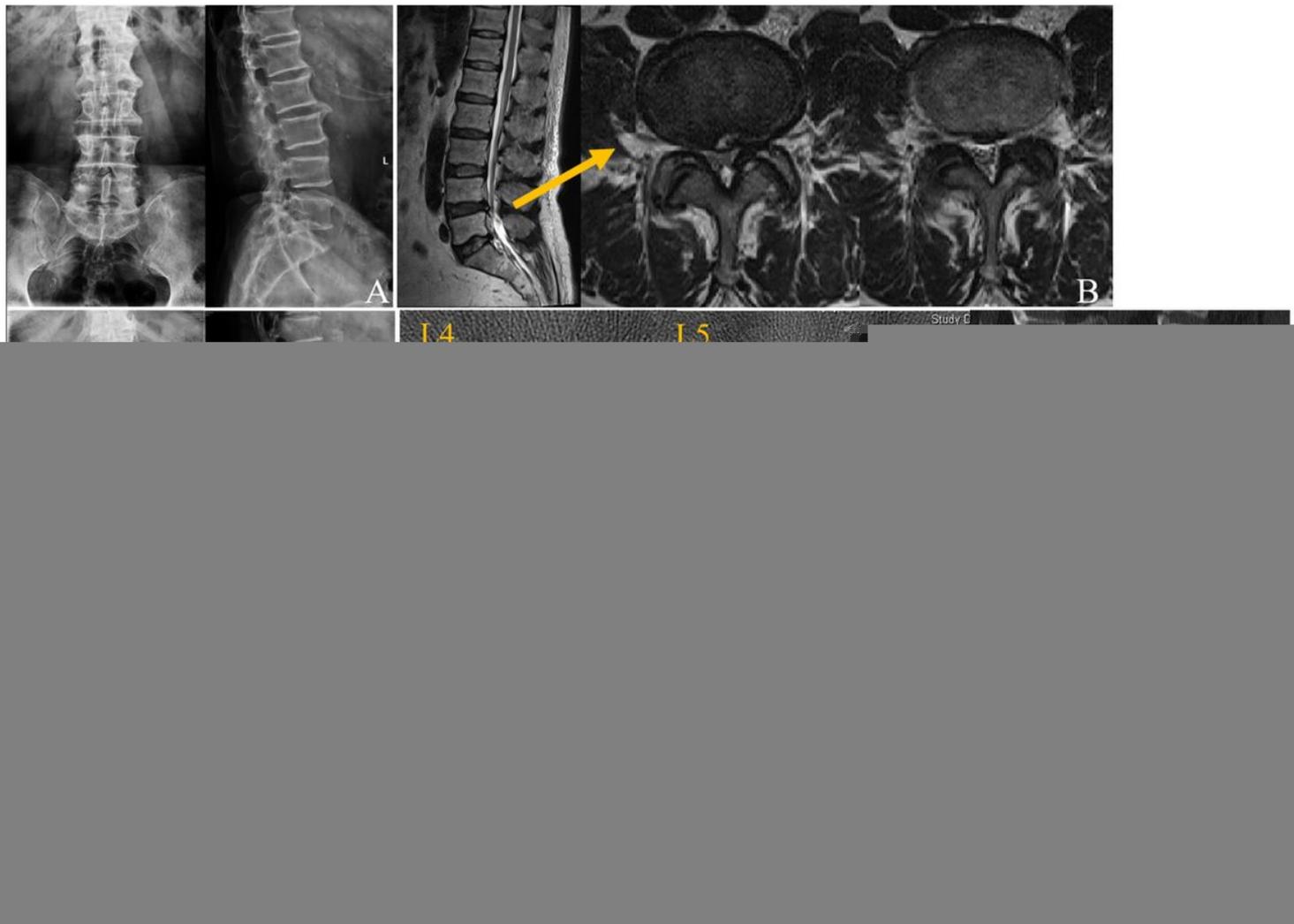


Figure 7

The case for application of the nomogram. A-B: preoperative radiological data. C-E: immediately postoperative radiological data. F-H: radiological data at one-year follow-up time. A: lumbar spine X-ray. B. Lumbar spine MRI demonstrated lumbar stenosis at L4/5. C. postoperative lumbar spine X-ray. D. postoperative lumbar spine CT scan indicated CBCL of L4L, L4R, L5L, L5R were 2, 3, 1, 2 respectively. E. sagittal view of lumbar spine CT scan. F. one-year follow-up lumbar X-ray demonstrated lucent zone at L4R and L5R. G. lumbar spine CT scan showed obvious screw loosening at L4L, L5L and L5R. H. sagittal view of lumbar spine CT scan.

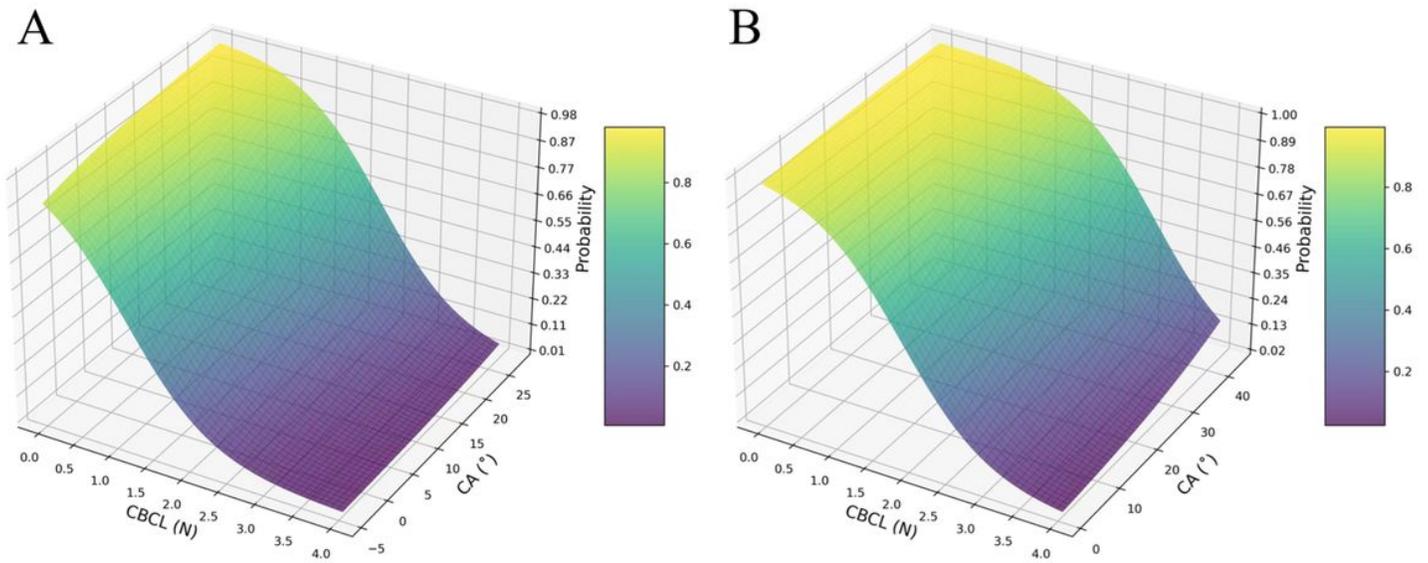


Figure 8

The three-dimensional surface plot demonstrated the impact of CBCL (x-axis) and CA (z-axis) on probability for screw loosening after lumbar surgery with CBT technique. (A) Probability for screw loosening when the screw was not instrumented in S1; (B) Probability for screw loosening when the screw was instrumented in S1.