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The Relationship Between Ideal Lumbar Pedicle Screw Position and Superior Facet in Adolescent Idiopathic Scoliosis

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ABSTRACT

Objective: The purpose of this study was to investigate the angular relationship between the anatomic inclination of the superior facet and the desired safe straight-forward (SF) transpedicular screw trajectory in the surgical treatment of patients with adolescent idiopathic scoliosis (AIS).

Methods: The study was conducted as a retrospective evaluation. One hundred and ten lumbar vertebrae were analyzed from the preoperative computed tomography scans of 22 patients with AIS scheduled for surgery. Each lumbar vertebral segment was prepared using reformat images obtained with three-dimensional (3D) volume-rendered images. The axial angles between the relative trajectory of the implant, which was planned to be placed according to the ideal SF transpedicular pedicle screw technique, and the inclination of the superior facet joint were measured.

Results: Two hundred and twenty pedicle-facet angles of 110 vertebrae were measured on image slices showing 3D volume rendering of pedicle and facet joint together. The ideal SF orientation angle at each vertebral level was more laterally oriented than the facet tilt. Fifteen (68%) of the patients had Lenke type 1 and 7 (32%) had Lenke type 5. When the patients were divided into two groups according to Lenke type (type 1 and 5), there was no statistically significant difference in terms of the angular values of the lumbar spine (p>0.05).

Conclusion: When implanting a transpedicular screw to correct a scoliotic deformity, a trajectory that is no more medially inclined than the inclination of the facet joint will reduce adverse events such as medial breeching. This information can be used as supporting information when placing pedicle screws in addition to other anatomical landmarks.

Keywords: Pedicle screw, facet joint, medial breeching

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INTRODUCTION

Adolescent idiopathic scoliosis (AIS) is a three-dimensional (3D) deformity with coronal, sagittal, and axial components (1). The current gold standard treatment method in the surgical treatment of AIS is instrumented fusion of the posterior segments with transpedicular screws (2). The incidence of misplacement of pedicle screws in the lumbar spine is reported to be 5% to 41% (3). To avoid complications in scoliosis surgery, it is crucial to avoid misplacement of transpedicular screws (4). The screws should be firmly seated in the medullary canal of the bony pedicle to also provide adequate correction of the rotational deformity (5).

Multiplanar images can be thickened into slabs according to the anatomical area of interest using projection techniques such as volume rendering. Volume rendering is a technique that combines 3D perspective with versatile and interactive rendering of the entire volume of reconstructed data (6). Radiological images obtained by volume rendering are closest to the image that the surgeon sees with the naked eye in the surgical field (7).

The purpose of the present study was to investigate the relationship between the anatomic inclination of the superior facet and the desired safe transpedicular screw trajectory in the surgical treatment of AIS. To this end, the angular relationship between the superior facet joint and the pedicle screw trajectory was evaluated using postoperative computed tomography scans and volume rendering projection techniques to obtain a reliable orientation angle in the axial plane.

METHODS

Two hundred and twenty pedicle facet regions of lumbar vertebral segments from 22 patients with AIS surgically treated in our department of orthopedics and traumatology between July 2020 and March 2022 were included in the evaluation based on preoperative tomography images. Demographic data (age, sex, Lenke subtypes) were recorded. Surgical treatment of AIS was accepted as an inclusion criterion, and patients with a diagnosis of known etiology or those with inadequate or poor imaging for measurements were excluded from the study. It was confirmed that no intracanal pathology was present on magnetic imaging studies. The study protocol was approved by the Ethics Committee of Başakşehir Çam and Sakura City Hospital (decision no: 2022.04.102). Informed consent was not needed given the nature of the study.

Radiological Evaluation

Each of the 3D lumbar vertebral images created using the volume rendering technique was sliced using the scalpel function of the program [RadiAnt DICOM Viewer (Software). Version 2021.1. Jun 27, 2021]. In this way, a bird's-eye view of the tip of the superior facet joint and the pedicle of each vertebra was obtained on the same screenshot. The screenshot was then opened in the Surgimap[®] measurement system (Nemaris Inc. USA) (https://www.surgimap. com/). For the lumbar vertebrae from L1 to L5, it was marked on the tomography that the junction of the middle and lateral thirds of the intersection of the midline of the transverse process and the corresponding superior articular process was the entry point of the pedicle screw. The trajectory of the pedicle screw was determined by combining this point with the most central point of the pedicle. The angle between the superior articular facet and the trajectory of the ideal screw passing through the pedicle was determined using the straight-forward (SF) technique (Figure 1, 2) (8). This measurement was performed for both the right and left sides. Radiographic measurements (measurements in the Surgimap app) were measured again 3 weeks later by the same observer.

Statistical Analysis

Data analysis was performed using the SPSS 24.0 program. For the descriptive characteristics, analyzes of number, percentage, mean, and standard deviation were performed. While the Mann-Whitney U test was used for paired groups, Kruskal-Wallis analyzes were performed for more than two groups. Spearman correlation test was performed for relational analysis. P<0.05 was considered significant.



Figure 1. Cutting a three-dimensional volume-rendering image with the scalpel feature at the L5 vertebral level (A). Identification of the planned ideal transpedicular pedicle trajectory and the superior facet inclination with the top view of the obtained single vertebral level (B)

RESULTS

80

The mean age of the 22 patients included in the study was 14.5±1.33 and two of them were male. In 3 of the patients, L5-S1 transitional vertebrae were observed as an additional anatomical variation. The angles between the axial superior facet inclination and the targeted SF pedicle trajectory of the measured vertebrae are shown in Table 1.

According to the values for skewness and kurtosis, except for the left L5 lumbar vertebra, a normal distribution was found for the angular measurements of all segments, as indicated in the

methodology, since they were all in the nominal range (-1.5)-(+1.5), parametric tests were used for the statistical analyzes. The consistency of the correlation coefficient between two separate calculation time intervals was above 0.8, indicating good agreement. According to Lenke classification, 68% of patients belonged to type 1 and 32% to type 5, and 32% had the level of lumbar apex at L2 (Table 2).

Considering the distributions of mean and standard deviation of angle measurements, the highest angles were observed at the L5 Right (18.47±8.62) and L5 Left (18.4±10.34) spine levels (Table 3).



Figure 2. In one of the patients included in the study, the angle between the pedicle and the inclination of the superior facet joint is observed during surgery. Angle between two pedicle guides in A. In B, the relationship to the facet joint during pedicle screw application is seen. Note how the imaginary lines drawn in yellow cross each other. The axis of the ideal pedicle screw is more laterally directed to the inclination of the facet joint and does not go further medially than the inclination of the facet joint

Table 1. Bilateral facet-SF pedicle trajectory angular measurements for each lumbar vertebral level								
Level	Mean	Minimum	Maximum	SD	Skewness	Kurtosis		
L5 right	16.5	10	45.7	10.3	0.92	1.86		
L5 left	15.9	12	42.6	8.9	1.2	2.92		
L4 right	11.4	2.3	21.1	5.4	0.19	-0.64		
L4 left	11.4	10	25.3	6.6	0.43	-0.18		
L3 right	8.5	0.3	19.9	5.6	0.28	-1.03		
L3 left	8.1	0.2	19.5	5.3	0.28	-0.86		
L2 right	9.1	0.4	18.5	4.8	0.13	-0.34		
L2 left	7.7	0.5	15.5	5.0	0.08	-1.2		
L1 right	10.8	0.6	23.7	5.0	0.17	1.4		
L1 left	10.4	0.5	24.8	5.4	0.45	1.3		
SD: standard deviation SE: straight-f	orward L · lumbar v	retebra						

No statistically significant difference was found between the age groups of the patients and the mean value of the angle measurement (p>0.05) (Table 4).

No statistically significant difference was found between the sex and mean angular measurements of the patients (p>0.05) (Table 5).

Of the patients, 15 (68%) had Lenke type 1 and seven (32%) had Lenke type 5. No statistically significant difference was found when patients' Lenke types were compared with the mean of the angle measurement (p>0.05) (Table 6).

The lumbar modifier type was type A in 4 of the patients and type C in the remaining 18 patients. The lumbar apex was at the L1 level in 5 (23%) of 22 patients, at the L2 level in 7 (32%), at the L3 level in 6 (27%), and at the L4 level in 4 (18%) patients. No statistically significant difference was found when comparing the Lenke Lumbar Modifiers and the patients' mean angle measurements (p>0.05) (Table 7).

No statistically significant difference was found when comparing measurements of Lumbar Apex and mean angle (p>0.05) (Table 8).

According to the Spearman correlation test, a positive and statistically significant relationship was found in the relational analyzes of the following angle measurements: Between L1 L and L1 R (strong relationship), L2 L (moderate), L2 R (moderate), and L3 R (moderate); between L1 R and L2 L (moderate), L2 R (moderate), and L3 R (moderate); between L1 R and L2 L and L2 R (strong), L5 L (moderate), L5 R (moderate), between L2 R and L5 R

Table 2. Lenke type and lumbar apex distributions								
	n (22)	%						
Lenke type								
1	15	68.2						
5	7	31.8						
Lumbar apex	Lumbar apex							
L1	5	22.7						
L2	7	31.8						
L3	6	27.3						
L4	4	18.2						
L: lumbar vertebra								

 Table 3. Distribution of mean and standard deviation values of angle measurements

Facet-screw angle	Mean + SD		Mean ± SD
L1 R	11.1±4.61	L1 L	10.78±5.05
L2 R	9.62±4.46	L2 L	8.82±3.95
L3 R	9.75±5.15	L3 L	9.41±5.07
L4 R	12.43±5.6	L4 L	12.46±5.84
L5 R	18.47±8.62	L5 L	18.4±10.34

R: the angle between the superior articular facet and the trajectory line of the ideal screw at the right side, L: same angle measurement fort he left side, SD: standard deviation

(moderate); between L3 L and L3 R (strong), L4 L (moderate), L4 R (moderate), L5 L (moderate), and L5 R (moderate); between L3 R and L4 L (moderate), L4 R (moderate), L5 L (moderate), and L5 R (moderate); between L4 L and L4 R (strong), L5 L (strong), and L5 R (strong); between L4 R and L5 L (moderate), L5 R; and finally between L5 L and L5 R (strong) (p<0.05) (Table 9).

It was found that the angles measured at each lumbar vertebral level varied within a wide scale, regardless of the patients' demographic characteristics and Lenke type classification (p<0.05), even at the same vertebral level in different patients. In all patients, the right and left angle measurements for each vertebra were found to be similar and did not show statistical significance (p>0.05). Statistically significant differences were observed in the angle measurements between the same vertebral levels in different patients (p<0.05).

In all patients, the calculated angle between the facet inclination and the imaginary trajectory of the pedicle screw had a positive numerical value, meaning that the trajectory of the pedicle was more laterally directed than the inclination of the facet cartilage (100%).

DISCUSSION

The current study reports that osteotomy of the inferior facet before pedicle screw placement helps surgeons avoid injury to nerve tissue in the canal and prevent possible medial breaching by guiding the pedicle screw at a lower inclination (more lateral) than the axial inclination of the exposed superior facet cartilage.

The open surgical technique for AIS uses a midline skin incision and subperiosteal dissection to expose the spinous processes, laminas, facet joints, and transverse processes. Inferior facet osteotomies are performed before or after screw placement in the fusion area to help identify pedicle screw entry points, promote arthrodesis, and allow easier correction of the deformity except at the superior and inferior levels (1,9). Mattei et al. (9) recommended partial facetectomy of the inferolateral third of the inferior articular process of the upper spine. With this osteotomy, the boundaries of the facet joints can be clearly determined, and the entry point for the pedicle screw can be properly designed by removing the hypertrophic and misleading tissue; it can be ensured that the screw head can sit on a smooth surface. The current study shows that it is probably a dangerous idea to guide a transpedicular screw trajectory more medially than the inclination of the superior facet joint in the axial plane. This information may be a valuable contribution to the literature.

Amaral et al. (10) studied the safe angle with the facets that could prevent facet joint violation during screw insertion regardless of the screw insertion technique in degenerative spines. The authors analyzed imaging of patients operated for degenerative lumbar spine pathologies and defined the angle between pedicle screw and facet joint inclination as Δ -angle. Accordingly, the rate of facet injury in patients with a Δ -angle of

Table 4. Comparisons of age groups and mean angle measurements							
	Age group	n (22)	Mean ± SD	U	р		
L5 R	<15	10	15.93±6.97	40	0.005		
	≥15	12	20.6±9.56	42	0.235		
151	<15	10	18.35±12.72	40 F	0.440		
LƏL	≥15	12	18.43±8.46	48.0	0.448		
	<15	10	11.02±6.15	44 E	0.373		
L4 K	≥15	12	13.61±5.07	40.0			
141	<15	10	11.7±6.65	52	0 508		
L4 L	≥15	12	13.1±5.27	JZ	0.370		
120	<15	10	9.19±4.9	52 5	0.668		
LJK	≥15	12	10.21±5.51	55.5			
131	<15	10	9.17±5.72	54 5	0.817		
	≥15	12	9.6±4.72	50.5			
120	<15	10	8.64±2.95	49	0.420		
	≥15	12	10.44±5.41	40	0.427		
121	<15	10	8.1±3.08	50 5	0 521		
	≥15	12	9.42±4.6	50.5	0.531		
11 D	<15	10	10.9±4.42	50	0.047		
	≥15	12	11.25±4.96	57	0.747		
111	<15	10	11.56±4.03	45	0 333		
	≥15	12	10.13±5.86	40	0.525		

SD: standard deviation, U: The Mann-Whitney U value, L: lumbar vertebra, R: right

Table 5. Comparisons of	of gender and mean an	gle measurements				
	Gender	n	Mean ± SD	U	р	
	Female	18	19.1±9.37	20	0.554	
L5 K	Male	4	15.65±3.2	29	0.551	
	Female	18	19.33±11.2	24	0.004	
LO L	Male	4	14.15±2.85	20	0.394	
14 D	Female	18	11.97±5.58	24	0.204	
L4 K	Male	4	14.52±6.04	20	0.374	
141	Female	18	12.13±5.53	24 E	0.898	
L4 L	Male	4	13.92±7.83	54.5		
120	Female	18	10.7±5.12	1 / E	0.047	
LJK	Male	4	5.5±2.74	14.5	0.007	
121	Female	18	10.21±5.04	14	0.089	
L3 L	Male	4	5.8±3.87	10		
100	Female	18	9.91±4.17	21	0.77	
LZ R	Male	4	8.32±6.2	51	0.67	
101	Female	18	8.92±3.7	20	0 722	
LZ L	Male	4	8.35±5.63	32	0.735	
11 D	Female	18	11.57±4.55	27	0.442	
LIK	Male	4	8.9±4.9	27	0.443	
111	Female	18	11.47±4.93	22	0.000	
	Male	4	7.67±5.04	ZZ	0.233	
SD: standard deviation U: Th	e Mann-Whitney U value 1.1	umbar vertebra R [.] right				

Table 6. Comparisons of lenke types and mean angle measurements							
	Lenke type	n (22)	Mean ± SD	U	р		
LED	1	15	16.94±5.97	4E	0.507		
LJ K	5	7	21.77±12.6	45	0.377		
151	1	15	18.08±10.28	50	0.072		
LJL	5	7	19.07±11.25	JZ	0.772		
1 / D	1	15	12.3±6.07	51 5	0.044		
L4 K	5	7	12.74±4.87	51.5			
141	1	15	12.1±6.06	17 5	0 724		
L4 L	5	7	13.25±5.7	47.5	0.724		
120	1	15	9.78±5.6	51 5	0.944		
LJK	5	7	9.67±4.42	51.5			
121	1	15	9.13±5.63	15 5	0.622		
LJL	5	7	10±3.93	45.5			
120	1	15	9.24±4.76	4.4	0.549		
LZ N	5	7	10.42±3.97	44			
121	1	15	8.68±4.13	40	0.905		
LZ L	5	7	9.11±3.84	47	0.005		
11 D	1	15	11.11±5.54	51 5	0.044		
LIK	5	7	11.04±1.73	51.5	0.944		
1.1.1	1	15	10.92±5.74	F1	0.01/		
L1 L	5	7	10.48±3.5	10	0.910		

SD: standard deviation, U: The Mann-Whitney U value, L: lumbar vertebra, R: right

Table 7. Comparison of lenke lumbar modifier and mean angle measurements							
	Lenke lumbar modifier	n (22)	Mean ± SD	U	р		
	А	4	15.07±5.5	24	0.205		
LOK	С	18	19.23±9.12	26	0.395		
	А	4	19.7±19.07	27	0.204		
LJL	С	18	18.1±8.21	20	0.394		
	А	4	10.725	2/ 5	0.410		
L4 K	С	18	12.81±5.42	20.0	0.418		
	А	4	9.55±6.64	22	0.249		
L4 L	С	18	13.11±5.64	23	0.200		
	А	4	6.46.46	17	0.090		
LJK	С	18	10.5±4.7	10	0.007		
	А	4	6.77±8.53	20	0 172		
LJL	С	18	10±4.11	20	0.175		
120	А	4	7.97±5.5	21	0.77		
LZ K	С	18	9.98±4.3	51	0.67		
121	А	4	8.42±5.51	20	0.400		
LZL	С	18	8.91±3.73	50	0.009		
11 D	А	4	8.75±5.76	27 E	0.440		
LIK	С	18	11.61±4.34	27.5	0.409		
111	А	4	9.35±6.46	24	0.945		
	С	18	11.1±4.85	34	0.003		
SD: standard deviation	, U: The Mann-Whitney U value	, L: lumbar vertebra, R: righ	t				

less than 5 degrees was found to be 65%. They found that it was 11% in patients with a Δ -angle between 5-15 degrees and 3% in patients with a Δ -angle higher than 15 degrees. Because an open surgical approach was used in our study and we assumed that there would be no force against the superior facet joint,

scenarios that could lead to screw misplacement in the canal were investigated. As the relative angular value decreased, the extent of facet injury in our study appeared to be correlated with the risk of medial breaching.

Table 8. Comparison	ns of lumbar apex an	d mean angle meas	surements		
	Lomber apex	n (22)	Mean ± SD	X ²	р
	L1	5	26.02±12.54		
15 R	L2	7	16.91±5.03	3 789	0.285
Lon	L3	6	16.28±7.92	5.767	0.200
	L4	4	15.07±5.5		
	L1	5	22.86±11.21		
L5 L	L2	7	16.28±5.19	2 /03	0.477
	L3	6	16.26±8.06	2.475	0.477
	L4	4	19.7±19.07		
	L1	5	14.34±4.95		
LAR	L2	7	11.97±4.72	0.925	0.819
	L3	6	12.53±7.09	0.725	0.017
	L4	4	10.72±6.97		
	L1	5	14.78±6.04		
	L2	7	12.21±3.68	1 083	0.576
L4 L	L3	6	12.76±7.67	1.705	0.570
	L4	4	9.55±6.64		
L3 R	L1	5	10.94±4.72		
	L2	7	8.21±3.95	E 004	0.170
	L3	6	12.78±4.98	5.004	0.172
	L4	4	6.4±6.46		
	L1	5	10.92±4.35		
121	L2	7	8.28±3.86	2 /1	0 222
LJL	L3	6	11.21±4.21	5.41	0.555
	L4	4	6.77±8.54		
	L1	5	10.54±4.85		
120	L2	7	10.27±5.08	0.201	0.044
	L3	6	9.2±3.44	0.201	0.704
	L4	4	7.97±5.5		
	L1	5	9.26±4.64		
121	L2	7	9.74±4.06	1 732	0.43
	L3	6	7.65±2.7	1.7 52	0.03
	L4	4	8.42±5.51		
	L1	5	10.54±1.75		
I 1 P	L2	7	12.17±5.45	1 276	0.711
LIK	L3	6	11.85±4.94	1.370	0.711
	L4	4	8.75±5.76		
	L1	5	9.4±3.47		
111	L2	7	12.31±6.1	0.704	0.872
	L3	6	11.1±4.6	0.700	0.072
	L4	4	9.35±6.46		
X ² : chi-square, , SD: stand	dard deviation, L: lumbar v	ertebra, R: right			

Table 9. Relational analysis of angle measurements											
		L1 L	L1 R	L2 L	L2 R	L3 L	L3 R	L4 L	L4 R	L5 L	L5 R
111	r	1.000	-	-	-	-	-	-	-	-	-
LIL	р	-	-	-	-	-	-	-	-	-	-
11 P	r	0.878**	1.000	-	-	-	-	-	-	-	-
LIK	р	0.000	-	-	-	-	-	-	-	-	-
121	r	0.511*	0.499*	1.000	-	-	-	-	-	-	-
LZL	р	0.015	0.018		-	-	-	-	-	-	-
L2 R	r	0.609**	0.625**	0.909**	1.000	-	-	-	-	-	-
	р	0.003	0.002	0.000	-	-	-	-	-	-	-
1.2.1	r	0.394	0.380	0.398	0.379	1.000	-	-	-	-	-
LJL	р	0.069	0.081	0.066	0.082	-	-	-	-	-	-
13 D	r	0.448*	0.494*	0.367	0.411	0.946**	1.000	-	-	-	-
LJIN	р	0.037	0.019	0.093	0.058	0.000	-	-	-	-	-
141	r	0.185	0.227	0.333	0.343	0.565**	0.553**	1.000	-	-	-
L4 L	р	0.409	0.310	0.130	0.118	0.006	0.008	-	-	-	-
IAD	r	0.169	0.230	0.189	0.224	0.500*	0.524*	0.897**	1.000	-	-
L4 K	р	0.451	0.304	0.399	0.317	0.018	0.012	0.000	-	-	-
151	r	0.265	0.361	0.459*	0.373	0.525*	0.567**	0.728**	0.592**	1.000	-
LJL	р	0.232	0.099	0.031	0.087	0.012	0.006	0.000	0.004	-	-
IED	r	0.325	0.419	0.518*	0.487*	0.517*	0.565**	0.711**	0.646**	0.931**	1.000
LJ K	р	0.140	0.052	0.014	0.021	0.014	0.006	0.000	0.001	0.000	-

*Significant at the p<0.05 level, **Significant at the p<0.001 level. L: lumbar vertebra, R: right

There are numerous studies in the literature on superior facet injury after pedicle screw placement (11-13). The aim of these studies was to increase surgical safety by revealing the risk factors influencing screw placement in the correct position. In this regard, Cong et al. (12) found that the use of an intraoperative navigation system was an important factor in preventing pedicle malposition. Because of the high cost of navigation systems and the fact that they cannot be used in every spine surgery clinic, special attention should be paid to the factors such as the use of fluoroscopy, printing of 3D spine models, neuromonitoring to increase reliability, and sensitive attention to anatomic markers during freehand techniques (14-16).

Facet tropism describes the presence of asymmetric angles on both sides of the facet joints and is common in various pathologies of the lumbar spine (17). In our study, we found that there was no statistical difference in the angle between the facet and pedicle trajectories on the right and left sides at each spinal level, except for the L5 vertebra in the 3 patients with sacralization. This finding suggests that there is no facet tropism in the scoliotic spine, unless there is some other anatomic variation. Can et al. (18) also found a possible link between facet tropism and sacralization, as observed in our study.

Study Limitations

One of the strengths of the study was the 3D evaluation of tomographic sections via reformat studies, so that the study came

closest to real anatomy (6). Because most studies in the literature use tomographic images without reformatting them to a focused true plane, it is possible that the anatomy will be evaluated in an incomplete plane due to the natural lordosis of the lumbar spine. The weakness of our study was that the patients were not evaluated for postoperative pedicle screw applications. We have two explanations for this. First, screw implantation was not performed at all levels of the lumbar spine (especially at L4 and L5) in patients with AIS, and second, we did not yet implement this method, which we examined in our study, sufficiently in our routine practice to test its effectiveness.

According to our results, the conclusion that "screw insertion with more lateral alignment than facet joint inclination is reliable" applies only to the transpedicular SF screw technique method. In this technique, the midpoint of the anterior cortex of the vertebral body of the screw tip is targeted through the junction of the entry point and the midpoint of the pedicle. In cases where the anatomical methodology is different, such as the cortical bone trajectory technique, this conclusion will not be valid (19).

In the statistical analysis, we could not find a practical margin of safety for any level as a general rule for the placement of pedicle screws. Each patient should be evaluated on his/her own merits in this regard. However, a screw inserted at an angle no more medial than the facet joint, has a higher probability of being in the correct trajectory. Careful review of radiographic images should be performed in each individual patient prior to surgical intervention when considering the angular inclination of the facet.

CONCLUSION

When implanting a transpedicular screw to correct a scoliotic deformity, a trajectory that is no more medially inclined than the inclination of the facet joint in the axial plane will reduce undesirable events such as medial breaching. This information can be used as supporting information in addition to other anatomical landmarks in pedicle screw applications.

Ethics Committee Approval: The study protocol was approved by the Ethics Committee of Başakşehir Çam and Sakura City Hospital (decision no: 2022.04.102).

Informed Consent: Informed consent was not needed given the nature of the study.

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