

Analysis of correlation between regional implant density and the correction rate in treatment of Lenke 1A and 1B adolescent idiopathic scoliosis with pedicle screws

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Abstract

A retrospective study.

The optimal implant density in patients with Lenke type 1 adolescent idiopathic scoliosis (AIS) is undefined, and there is no study reporting the correlation between the partitioned implant density and the correction outcome.

To determine whether the implant density in structural and nonstructural regions would affect the coronal correction outcome of Lenke 1A and 1B AIS.

Preoperative general data and postoperative follow-up data of Lenke 1A and 1B AIS patients who received posterior fusion with the pedicle screw system were analyzed. Correlations between the implant density in structural and nonstructural regions and the correction rate of coronal Cobb angle, as well as between the correction rate and loss of the coronal correction angle during a 2-year follow-up period were analyzed. According to the implant density, the patients were classified into 2 groups: structural region group (including A1 and A2), and nonstructural region group (including B1 and B2). Differences in related parameters between the 2 groups were compared statistically.

Except for the mean implant density, there was no statistical difference in the other parameters between group A1 and A2. In group B1 and B2, the correction rate of the main thoracic (MT) curve was 63.0% and 71.6% ($P = .022$), and the loss of the correction angle was 2.1° and 4.2°, respectively ($P < .01$), showing a statistical difference in the correction rate and postoperative angle loss of the MT curve between group B1 and B2.

The correction rate of the MT curve at the coronal plane and postoperative loss of the correction angle were not related to the implant density in structural regions but may be related to the implant density in nonstructural regions in the treatment of Lenke type 1A and 1B AIS with pedicle screw instrumentation.

Abbreviations: AIS = adolescent idiopathic scoliosis, LEV = lower end vertebra, LIV = lower instrumentation vertebra, MT = main thoracic, NV = neutral vertebra, RDT = rod derotation technique, SV = stable vertebra, UEV = upper end vertebra, UIV = upper instrumentation vertebra.

Keywords: adolescent idiopathic scoliosis, angle loss, Cobb angle, coronal plane, correction rate, implant density, instrumentation, non-structural region, pedicle screw, structural region, X-ray

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1. Introduction

All pedicle screw instrumentation via the posterior approach is a revolutionary progress in spinal deformity surgery. It is reported in the literature^[1–3] that compared with the use of hooks, wires, or hybrid systems, the pedicle screw system can obtain better correction outcomes within a shorter fusion segment in the treatment of adolescent idiopathic scoliosis (AIS). In patients with relatively rigid scoliosis, all pedicle screw instrumentation via the posterior approach can reduce the need for anterior release,^[4,5] and therefore has become the most common technique in spinal deformity correction.

Some studies^[6] have demonstrated that the more anchoring points there are, the higher the correction rate would be, regardless of the type of instruments used, which tempts more researchers to use more screws to improve the outcome of correction. Although the segmental pedicle screw technique can improve the correction rate of spinal deformity, relatively high costs and multiple anchoring points increase both the expenditure of the patient and the risk of injury to nerves and vessels. Some recent studies^[7–9] reported that decreasing the implant density within a certain range did not significantly affect the correction rate in patients with Lenke 1 type AIS.

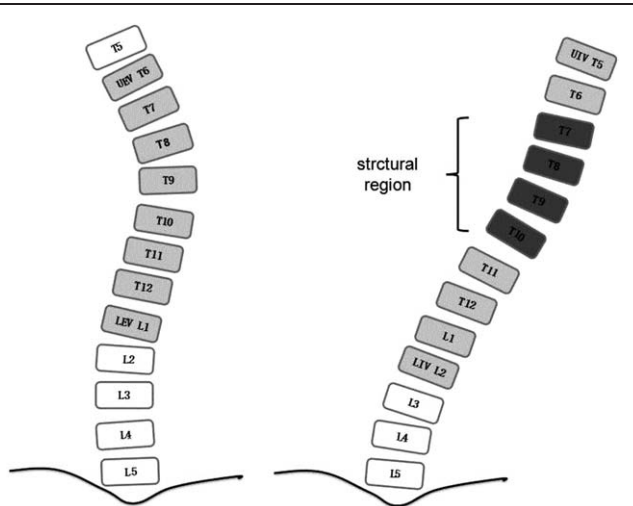


Figure 1. A sketch map of the structural and nonstructural regions. Left posteroanterior standing radiogram before operation, showing the main thoracic curve of the spine (T6–L1); Right bending radiogram before operation, showing the structural region (T7–T10) and nonstructural region (T5–T6, T11–L2). LEV=lower end vertebra, LIV=lower instrumentation vertebra, UEV=upper end vertebra, UIV=upper instrumentation vertebra.

However, they did not consider the impact of the pedicle screw location on the correction outcome. It is common knowledge that the apical region of idiopathic scoliosis is relatively rigid. To understand the impact of the implant density in the rigid apical region of idiopathic scoliosis and that in the less rigid nonapical region of idiopathic scoliosis on the correction outcome, we herein introduce 2 concepts: the structural region, the region between the upper and lower vertebrae with the maximum tilt angle on the preoperative bending imaging, and the nonstructural region, the region beyond the structural region within the fusion segment (Fig. 1). At the same time, we define the implant density in the structural region as the number of screws implanted/(the number of vertebrae in the structural region $\times 2$), and the implant density in the nonstructural region as the number of screws implanted/(the number of vertebrae in the nonstructural region $\times 2$). To the best of our knowledge, there is no study reporting the correlation between the implant density in the structural and nonstructural regions and the correction outcome. In the present study, we retrospectively analyzed the medical records and follow-up imaging data of 63 patients with Lenke type 1A and 1B AIS who received posterior pedicle screw instrumentation in our hospital between January 2010 and January 2012 to explore the correlation of the implant density in the structural and nonstructural regions with the coronal correction outcome and loss of curve correction.

2. Materials and methods

2.1. Inclusion and exclusion criteria

Inclusion criteria were patients with Lenke type 1A and 1B AIS without previous spine surgery histories, who underwent posterior pedicle screw fixation and fusion. Exclusion criteria were patients who received osteotomy technique or nonpedicle fixation for correction of scoliosis.

2.2. General data of the patients

Included in this study were 63 patients (11 men and 52 women) ranging in age from 10 to 18 years with a mean of 14.9 years. In

terms of the Lenke classification lumbar curve modifier, there were 50 cases of type A and 13 cases of type B, and in terms of the Lenke classification sagittal modifier, there were 16 cases of type (–), 45 case of type N, and 2 cases of type (+).

2.3. Surgical procedures

All surgical procedures were completed by the corresponding author of this study as the chief surgeon using the same technique (posterior pedicle screw fixation and fusion) under general anesthesia and the controlled hypotension condition. Pedicle screw placement was performed first on the concave side. The rod was prebended to a certain curve a bit larger than the scoliotic angle. The spinal deformity was corrected in a 3-dimensional manner by translation in combination with the rod derotation technique, followed by distraction on the concave side and compression on the convex side for further correction. In principle, the upper end vertebra or the neutral vertebra was selected as the fixation vertebra in the proximal end, and the stable vertebra –1 was selected as the fixation vertebra in the distal end. With respect to the selection of vertebrae for pedicle screw placement, at least 2 vertebrae were selected at both ends of the segment that needed fixation and fusion. Screw placement was also done in the vertebrae of the apical vertebral region on the concave side. Screw placement in other parts depended on the intraoperative situation and the economic condition of the patients. Autogenous bone and freeze-dried bone allografts were usually used as the fusion material. Screw placement was performed manually and confirmed by intraoperative fluoroscopy. The arterial blood pressure was maintained at 60 to 65 mm Hg on average during operation.

2.4. Parameters collection

Observation parameters were routine X-ray standing posteroanterior and lateral views, and bending left–right lateral view of the full spine before surgery, and X-ray standing posteroanterior and lateral views at 2 weeks and 2 years after surgery. Standing and bending Cobb angle and thoracic kyphotic angle were measured before surgery. The location of the structural and nonstructural regions and the implant density in these 2 regions were analyzed statistically. The curve flexibility ($[\text{main thoracic [MT] Cobb angle} - \text{bending Cobb angle on the convex side}] / \text{MT curve angle} \times 100\%$) was calculated. The correction rate ($[\text{MT curve Cobb angle} - \text{postoperative MT Cobb angle}] / \text{MT Cobb angle} \times 100\%$) was also calculated at 2 weeks after surgery. The correction ratio^[10] was used to eliminate the impact of flexibility on the correction rate. The calculation was performed as: $\text{correction ratio} = \text{MT curve correlation rate} / \text{MT curve flexibility}$. The implant density in the structural or nonstructural region was the number of screws in the related region/(the number of vertebrae in the same region $\times 2$). According to the implant density in the structural region, the patients were classified as 2 groups: high-density (>0.6) group (group A1) and low-density (≤ 0.6) group (group A2). Group A1 included 23 patients (5 men and 18 women) with a mean age of 15.2 years. Group A2 included 40 patients (6 men and 34 women) with a mean age of 14.8 years. According to the implant density in the nonstructural region, patients were also classified as 2 groups: the high-density (>0.8) group (group B1) and the low-density (≤ 0.8) group (group B2). Group B1 included 27 patients (6 men and 21 women) with a mean age of 15.8 years. Group B2 included 26 patients (5 men and 31 women) with a mean age of 14.3 years.

Table 1**Comparison of parameters between high-density group and low-density group in the structural region.**

Variables	High-density group	Low-density group	P
Number	23	40	
Age (y)	15.2±0.4	14.8±0.4	.524
Risser sign	4.0±0.2	3.6±0.2	.336
Screw density of structural region	0.7±0.0	0.5±0.0	<.001*
Cobb angle of MT			
Preop	45.8±2.4	49.1±2.0	.296
Bending	22.1±3.0	23.9±2.0	.614
Two-weeks postop	17.1±1.9	15.0±1.2	.370
Two-y postop	19.1±2.3	17.5±1.4	.482
Angle loss postop	3.2±0.6	3.3±0.5	.971
MT flexibility (%)	53.3±4.0	52.9±3.2	.940
MT correction rate (%)	63.7±3.2	70.3±2.0	.089
MT correction ratio	1.3±0.1	1.6±0.2	.313

MT indicates main thoracic curve.

*P<.05, statistical significance in difference in the comparison between 2 groups.

MT=main thoracic.

2.5. Statistical analysis

All statistical analyses were performed using SPSS16.0 statistics software. Correlations between the parameters were compared by Pearson correlation analysis. Differences between independent samples were analyzed by *t* test. Values of *P*<.05 were considered statistically significant.

3. Results

The mean age of the 63 patients was 14.9 years. The mean MT Cobb angle before surgery was 47.9°, and the flexibility of the angle was 53%. The mean MT Cobb angle was 15.8° and 18.1° at postoperative 2 weeks and 2 years, respectively. The mean correction rate at postoperative 2 weeks was 68%, and the mean loss of the MT curve correction was 3.2°.

In the structural region, the mean number of the vertebrae was 5.2, the mean number of the screws implanted was 6.2, and the mean implant density was 0.59. The correlation coefficient between the MT curve flexibility and the implant density in the structural region was 0.08 (*P*=.534). The correlation coefficient between the correction rate and the implant density in the structural region at postoperative 2 weeks was -0.19 (*P*=.151), and the correlation coefficient between the correction ratio and the implant density was -0.16 (*P*=.209). The correlation coefficient between the loss of MT curve Cobb angle and the implant density was -0.11 (*P*=.415). The mean implant density in group A1 and group A2 was 0.74 and 0.51 (*P*<.01), respectively. No significant difference in the other parameters was noticed between the 2 groups (Table 1).

In the nonstructural region, the mean number of the vertebrae was 5.8, the mean number of the screws implanted was 8.9, and the mean implant density was 0.79. The correlation coefficient between the MT curve flexibility and the implant density in the nonstructural region was -0.12 (*P*=.369). The correlation coefficient between the correction rate and the implant density in the nonstructural region at postoperative 2 weeks was -0.25 (*P*=.052), and the correlation coefficient between the correction ratio and the implant density was -0.09 (*P*=.492). The correlation coefficient between the loss of the MT curve Cobb angle and the implant density was -0.27 (*P*=.036), suggesting a low-grade negative correlation between them. The mean implant

Table 2**Comparison of parameters between high-density group and low-density group in the nonstructural region.**

Variables	High-density group	Low-density group	P
Number	27	36	
Age (y)	15.8±2.2	14.3±2.1	.008*
Risser sign	3.9±1.2	3.6±1.5	.342
Screw density of structural region	0.9±0.1	0.7±0.1	<.001*
Cobb angle of MT			
Preop	46.0±9.4	49.3±13.1	.284
Bending	23.1±13.2	23.4±12.6	.942
Two-weeks postop	17.6±9.1	14.4±8.9	.176
Two-y postop	18.2±8.9	18.0±8.4	.944
Angle loss postop	2.1±2.6	4.2±3.0	<.001*
MT flexibility (%)	51.9±19.4	53.9±18.2	.672
MT correction rate (%)	63.0±14.2	71.6±14.5	.022*
MT correction ratio	1.4±0.5	1.6±1.2	.378

MT indicates main thoracic curve.

*P<.05, statistical significance in difference in the comparison between 2 groups.

MT=main thoracic.

density in group B1 and group B2 was 0.91 and 0.70, respectively (*P*<.01). The mean age of the patients in the 2 groups was 15.8 and 14.3 years, respectively (*P*<.01). The correction rate of the MT curve was 63.0% and 71.6%, respectively (*P*=.022). The loss of the correction angle of the 2 groups was 2.1° and 4.2°, respectively (*P*<.01), suggesting that there was significant difference in the correction rate of the MT curve and the postoperative loss of the correction angle between the 2 groups. No significant difference in the other parameters was noticed between the 2 groups (Table 2).

No screw misplacement was observed on postoperative X-ray films. No implant-related complication was observed or reported during the follow-up period.

4. Discussion

The pedicle screw technique has been used for the treatment of scoliosis for more than 20 years. It is better than the hook technique for coronal deformity correction in that it increases the correction rate in the coronal plane.^[1] The reasons may be that pedicle screws can provide more secure and powerful fixation because the instrumentation reaches the vertebral body through the pedicle in the posterior aspect of the spine; and the instrumentation has more anchoring points so that the load disperses more uniformly, thus reducing the possibility of fracture. However, like other fixation techniques, the pedicle screw fixation system has its shortages. The all pedicle screw fixation system is relatively expensive. The large number of pedicle screws needed for the correction of scoliosis is a high economic demand on the patient. Whether it is possible to reduce the number of screws used without affecting the fixation outcome is a problem that spine surgeons have to consider. The all pedicle screw fixation system is confronted with a problem of safety because it runs a risk of injuring the spinal cord, nerve roots, and major vessels. Although the risk may be minimal in most cases, the consequence is extremely serious once it occurs.

The goal of surgical treatment of AIS is to correct coronal and sagittal deformities to the best under the premise of maintaining stability of the trunk and obtaining secure fusion. Factors that may affect the posterior surgical correction rate and outcome of scoliosis include the severity of the scoliosis, selection of the

fixation vertebrae, density of fixation, surgical skills, and selection of the instruments.

Clements et al^[6] and Karatoprak et al^[11] reported that the number of fixation points had an important impact on the correction outcome regardless of the instruments selected: the more fixation points the higher the correction rate. However, some other studies^[3,9,12,13] argued that decreasing the implant density in a certain range did not seem to affect the correction outcome of the scoliosis. Rushton et al^[8] found that the implant density affected the cost but not the coronal and sagittal correction of thoracic AIS. Neither larger nor stiffer curves necessitate high implant density. Yang et al^[13] pointed out that increasing the density of screw placement did not seem to improve the cosmetic and radiological outcomes in Lenke 1A and 1B type AIS patients. Min et al^[14] found that 50% density of screw placement was safe enough for posterior pedicle screw fixation of thoracic AIS, and could maintain the correction effect for a long time to the satisfaction of the patient. Wang et al^[15] also found that the same correction effect could be achieved by using a relatively low density of screw placement provided the fusion segment was the same.

In this study, we proposed the concept of the structural region and nonstructural region for the first time. The structural region is located in the segmental vertebrae adjacent to the apical vertebra. It is a relatively rigid region that has the greatest tilting on bending X-ray radiograms. The nonstructural region is the region beyond the structural region within the fusion segment. In this single-center study, we analyzed the correlation of the implant density in the structural and nonstructural regions with the correction outcome. All the surgical procedures were performed by a single surgeon, thus excluding the bias arising from different operation performers and making the results more reliable. It was found in our study that the mean flexibility of the MT curve was 53% (8–93%), showing a good representation because of the wide range of flexibility. There was no significant difference in flexibility between the high- and low-density groups of both structural and nonstructural regions. The mean implant density in the structural region was 59% (34–100%), which was significantly lower than 79% (56–100%) in the nonstructural region ($P < .01$). This is because the structural region is located in the apical region where vertebral rotation and tilting were the most severe, making screw placement relatively difficult.

The result of the present study showed no significant correlation between the implant density in the structural region and the coronal correction outcome and loss of the curve correction in patients with Lenke 1A and 1B AIS. Given the implant density in the structure region $>34\%$ in our series, whether further reduction of the implant density in the structural region would reduce the correction rate and loss of the correction angle needs to be verified in more clinical trials.

Additionally, we found that the correction rate of the MT curve of the high- and low-implant density in the nonstructural region was 63.0% and 71.6% ($P = .022$), and the correlation coefficient between the correction rate and the implant density at 2 weeks after surgery was -0.25 ($P = .052$), showing a difference in the correction rate between the 2 groups. In addition, there was a low-grade negative correlation between the correction rate and the implant density in the nonstructural region, interestingly suggesting that the lower the implant density the higher the correction rate. The reason may be that although our data showed that flexibility of the MT curve in the high-density group was 51.9% versus 53.9% in the low-density group (showing no significant difference between the 2 groups), the distribution of

flexibility was different between the 2 groups: there were more patients with good flexibility in the low-density group, and therefore the operation performer subjectively used fewer screws in these patients. Postoperative loss of the correction angle in these 2 groups was 2.1° and 4.2° , respectively ($P < .01$). The correlation coefficient between loss of the MT Cobb angle and the implant density in the nonstructural region was -0.27 ($P = .036$), suggesting that there was a low-grade negative correlation between postoperative loss of the correction angle and the implant density in the nonstructural region: the higher the implant density the less the postoperative loss of the correction angle, and vice versa.

The result of the present study suggests that there is no significant correlation between the implant density in the structural region and the correction rate and postoperative loss of the correction angle in Lenke type 1A and 1B AIS patients, and therefore appropriately reducing the implant density ($>34\%$) should not affect the correction outcome of scoliosis and correction maintenance after correction. As there was a low-grade negative correlation between postoperative loss of the correction angle and the implant density in the nonstructural region, increasing the implant density in the nonstructural region may be able to reduce postoperative loss of the correlation angle.

5. Conclusion

The correction rate of the MT curve at the coronal plane and postoperative loss of the correction angle are not related to the implant density in the structural region but may be related to the implant density in the nonstructural region in the treatment of Lenke type 1A and 1B AIS with pedicle screw instrumentation.

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