Low Density Implants in Adolescent Idiopathic Scoliosis Correction

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Abstract

Background: Adolescent idiopathic scoliosis (AIS) is the most common type of spinal deformity, affecting the physical and mental health of adolescent. The low density (LD) screw constructs can provide significant radiographic and clinical outcomes. The use of fewer pedicle screws indicated a reduction of hospital expenses and risk of neurologic complications. We aim to evaluate perioperative functional and radiological outcomes of low density pedicle screw patterns by radiographic, perioperative outcomes in AIS patients.

Methods: This is a prospective case study of 30 patients with AIS. Functional evaluation was done by SRS 30 questionnaire pre operatively and at final follows up. Screw density was calculated by number of screws per level in post op. AP film. Radiological outcomes was evaluated by Measurement of Cobb s angles in AP standing film preoperatively, degree of correction post-operative at 1, 3, 6, 12 months, loss of correction and relation between screws density, degree of correction and loss of correction. Thirty AIS patients underwent primary posterior fusion with pedicle screw instrumentation were prospectively reviewed. Implant density was defined as the screws number per fused spinal segment. The correlations between three-dimensional curve correction, Functional and radiographic parameters and anchor density were analyzed, implant density in this study was below 1.6 screws / level.

Results: This study showed that the mean age of patients was 15.5 years, We achieved correction of mean preoperative curve 59.47° degree to 17.83° degree (69.33 %) by low density implants constructs (mean: 1.12). SRS 30 score improved from 75.63 ± 8.18 preoperative to 127.13 ± 3.39 postoperative p value < 0.001. Mean loss of correction 2.9° degree (6.9%) after 12 months follow up. There was positive but non-significant correlation between screws density and correction rate (P value = 0,089). Operative time and blood loss significantly increase with screws density (P value =0,001).

Conclusions: Low anchor density with longer fusion level achieves excellent curve correction and stability. Low density implants constructs decrease operative time, blood loss, cost and risk of complications.

Keywords: *Low density screws, angle correction, adolescent scoliosis.*

INTRODUCTION

Scoliosis comes from the Greek Word "skoliosis" meaning crooked. It is a complex three-dimensional deformity of the spine characterised by a lateral deviation of at least 10 degrees with a rotation of the vertebra and usually associated with reduction of normal kyphotic curvature of the spine (Hypokyphosis) (1).

The vast majority of patients initially present due to a deformity. This may be a perception of asymmetry about the shoulders, waist, or rib cage. Asymmetry of breasts might be the first thing noticed by female patients. The most typical presentation of AIS is a right-sided thoracic curve in a female patient, which is painless, without any abnormal neurological findings. Curves that are greater than 90 degrees are rare, but associated with pain and decreased self-image (2).

A new classification system which was presented by Lawrence Lenke in 2001. In order to define a curve type by the Lenke classification, one must identify the curve type, the lumbar modifier and, for the first time in any classification system for scoliosis, the sagittal profile was also included (3). Pedicle screw construct systems have been increasingly popular for treating patients with spinal deformities, and a significant correlation between the implant density and major curve correction has been reported .Previous studies have demonstrated that high density thoracic pedicle screw constructs could further improve the correction of spinal deformities (4-6). However, substantial research has shown that low density (LD) screw constructs can provide similar radiographic and clinical outcomes (7). The use of fewer pedicle screws indicated a reduction of hospital expenses and risk of neurologic complications. If neurological complications or spinal cord injuries occur, the consequences could be disastrous (7).

The aim of the present study is to notice the correction degree and functional outcomes of AIS by low density instrumentation by perioperative radiographic imaging. We hypothesize that there would be significant correction results by LD instrumentation. The treatment cost of LD could be reduced, and there would be decreased risk of complication by the LD instrumentation.

Patients and Methods:

A prospective study was carried out on 30 patients diagnosed as adolescent idiopathic scoliosis corrected by low density implant constructs with major curve not more than 85° and at least 1 year' follow-up in radiographic out comes and age ranged from 11 to 19 years in Agouza spine center in Cairo, Egypt starting from January 2018 till January 2019.

An informed consent was obtained from each participant and the study was approved by the Ethical Committee.

Exclusion criteria included non idiopathic scoliosis and previous spine surgery.

All the study participants underwent the following: patient counselling and patient evaluation by history taking, physical examination, laboratory and radiological investigations.

AIS patients underwent primary posterior fusion with pedicle screw instrumentation were prospectively reviewed. All cases were operated under hypotensive general anesthesia (Mean arterial pressure (MAP) of 60 – 70. The patients were positioned in prone position on a radiolucent table with blocks under the thorax and the iliac crests so as to prevent abdominal compression, hips in neutral position or in extension to put the lumbar spine in lordosis, knees in flexion to decrease sciatic nerve stretching. A midline skin incision & wide exposure from the midline out to the tips of the transverse processes was done with sub periosteal dissection of the paraspinal muscles. The diameters of the screws were selected by careful evaluation of the preoperative radiographs. We used the screws with the diameter 4.5 mm for the upper thoracic pedicles and between 5.5 and 6.5 mm for the lower thoracic and upper lumbar pedicles. Pedicle screws were placed using a freehand technique, based on recognition of anatomical landmarks. Entry point to the pedicle was at the junction of the bisected transverse process and the lateral margin of the facet joint from T1 to T5. The upper instrumented vertebra was T4 if the patient had high right shoulder, T3 if the patient had balanced shoulders and T2 if the left shoulder was high. Once all pedicle screws were placed, and before rod engagement, we used fluoroscopic imaging (AP and lateral views) to confirm adequate screw positioning. Minimize radiation exposure to 3 or 4 views in each plane.

Follow up postoperatively was done by functional evaluation was by SRS 30 questionnaire. SRS - 30 is comprised of 5 domains including function/activity (7-35 points), pain (6-30points), self-image/cosmesis (9-45 points), mental health (5-25 points), and satisfaction with management (3-15). Maximum total score of the questionnaire is 150 with higher scores indicating better outcomes. Screw density was calculated by number of screws per level in post opertation. AP film. Radiological outcomes was evaluated by Measurement of Cobb s angles in AP standing film preoperatively, degree of correction post-operative at 1, 3, 6, 12 months, loss of correction and relation between screws density, degree of correction and loss of correction. Implant density was defined as the screws number per fused spinal segment. After screws insertion the inferior facets at every level across the thoracic and lumbar spine were excised & costotransversectomy was done to increase spinal flexibility and facilitates correction technique, costoplasty was done for cases had huge rib hump. Intra-operative neuromonitoring was checked after inserting the second rod in every patient to ensure neural integrity, the Stagnara wake-up test was performed in four cases. Posterior fusion was then done using autologous local bone graft. In this series, no iliac bone graft was used, no local antibiotic was added to the bone graft. At the end of procedure, posterior fusion performed with facet joint destruction and autograft at the instrumented levels were used.

Statistical analysis

The collected data were coded, processed and analyzed using the SPSS version 22 for Windows® (IBM SPSS Inc, Chicago, IL, USA). Data were tested for normal distribution using the Shapiro Walk test. Qualitative data were represented as frequencies and relative percentages. Quantitative data were expressed as mean ± SD (Standard deviation) and range. Paired samples t-test was used to compare the relation between normally distributed data at two different time points. Repeated measures ANOVA was used to test the relation between normally distributed data at more than 2 time points. Spearman’s correlation was used to test the correlation between two variables with quantitative data. The level of significance was tested and the test was considered significant if the p value is $\leqslant 0.05$.

Results

Baseline characteristics (age, hospital stay, gender and lenke type) of the studied patients are shown in table.1

Table1: Baseline characteristics (age, hospital stay, gender and lenke type) of the studied patients

Mean		
Age	15.5 ± 2.0	
Hospital stay	3.37 ± 0.67	
	No.	%
Male	2	6.7
Female	28	93.3
Lenke type		
I	15	50
II	1	3.3
III	2	6.7
IV	1	3.3
V	9	30
VI	2	6.7

Intraoperative data (operation time, blood loss, blood transfusion and statistical analysis) is shown in table.2 which reports significant increased operation time (p value: 0.001*), blood loss (p value 0.001*) with increase of screws density. However, no significant differences were detected in the hospital stays (p = 0.136). The bivariate analysis showed positive correlation but not significant correlation between screw density, correction rate and loss of correction the major curves (p =0.089, p = 0.169). There was no statistically significant correlation between screw density and SRS score.

Table 2: Intraoperative data and correlation between screw density and different variables

Intra operative data		
	Mean ± SD	
Blood Loss	842.0 ± 345.55	
Operation time	258.4 ± 37.64	
	No.	%
Blood Transfusion	10	33.3
Screw density	**1.12 ± 0.15**	
With	**Screw density**	
	r	P
Op. time	0.659	0.001*
Blood loss	0.840	0.001*
Hospital stay	0.215	0.136
Correction rate	0.316	0.089
Loss of correction	0.258	0.169
SRS score		
Change of value	- 0.141	0.459
% change of value	- 0.140	0.460

SRS change and its correlation with correction degree are shown in table.4 There was a statistically significant strong correlation between SRS score and correction degree.

Table 4: SRS change and its correlation with screw density and correction degree

SRS	**Preoperative**	**Postoperative**
Mean ± SD	75.63 ± 8.18	127.13 ± 3.39
P value	< 0.001*	
SRS score	Correction degree	
Change of value	0.886	< 0.001*
% change of value	0.876	< 0.001*

Radiological outcomes are shown in table.5

Table 5: radiological outcomes of studied patients

Radiological outcome	**Mean ± SD**
Loss of correction	2.0 ± 0.91
Correction degree	41.63 ± 13.0
Correction rate (%)	69.33 ± 9.16

Radiographic results of the studied patients are shown in table.6

Table 6: Radiographic results of the studied patients

	Pre	1 m.	3 m.	6 m.	12 m.
COBB	59.47 ± 14.11	17.83 ± 5.69	18.0 ± 5.78	19.07 ± 5.97	19.83 ± 5.97
P value	0.001*				

Complications

We had 2 cases suffered from postoperative severe anemia (HB = 7 gm) we stop suction of drain & make it passive & patients received 4 units of packed RBCs .One case had loosening of right L4 nut at 6th month follow up. One case had numbness in her right lower limb with difficult walking in first month treated with neurotonics & medications. One case had wound discharge for 2 weeks and treated by daily dressing and local and systemic antibiotic. One case suffered from persistent vomiting 2 days post-operative resistant to anti emetics & she had hypokalemia and admitted to ICU.

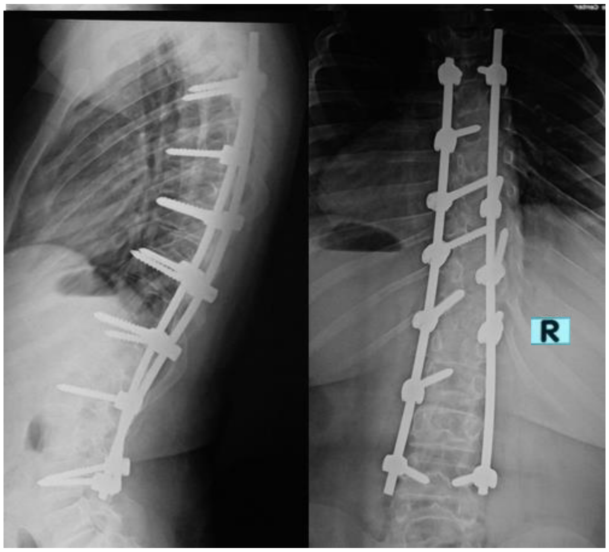
Case presentation

Case 1: Female patient 18 years old had Lenke 1BN pre cobbs angle of major curve was (85º) , pre-operative SRS score was 61 , she underwent posterior fixation , facetal release , and correction from T4 to L4 with low density implants (0.9 screw / level) , the results of correction was : Initial post: 20º. After 3 m: 22º. After 6 m: 22º. After 12 m: 22º (SRS 30 score = 133). Figures 1-3

Figure 1: Before and after surgery case 1

Figure 2: Preoperative images & immediate post-operative.

Figure 3: Final follow up of Case 1.



Case 2: Female patient 15 years old had Lenke 5 C N pre cobbs angle of major curve was (40º) , SRS 30 score was 85 , she underwent posterior fixation , facetal release , and correction from T9 to L4 with low density implants (1.25) , the results of correction was : Intial post: 10º. After 3 m: 10º. After 6 m: 11º. After 12m: 11º (SRS 30 score = 124). Figures 4-6

Figure 4: Before and after surgery case 2.

Figure 5: Preoperative images & immediate post op of case 2.

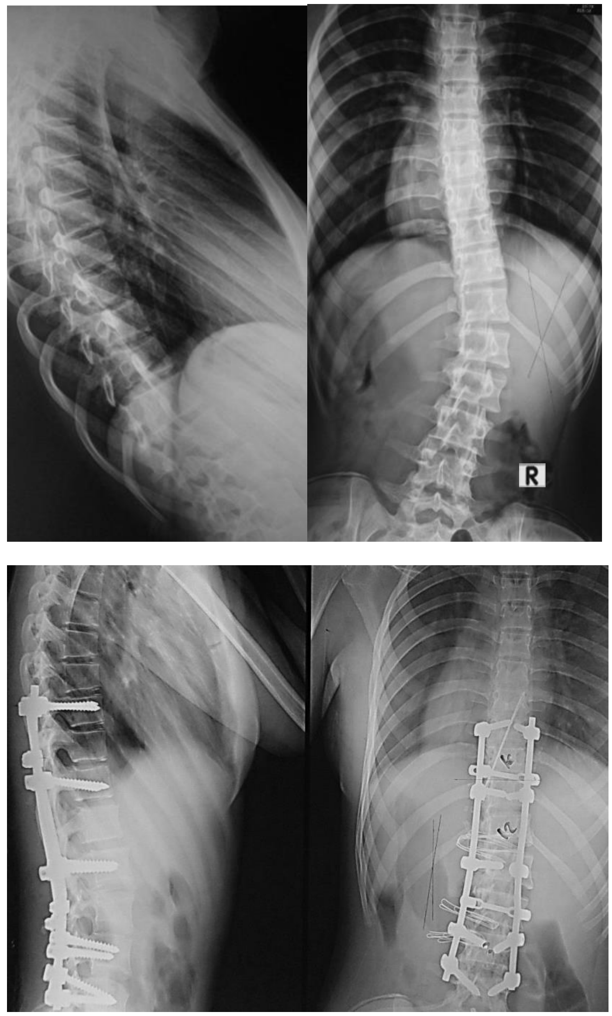
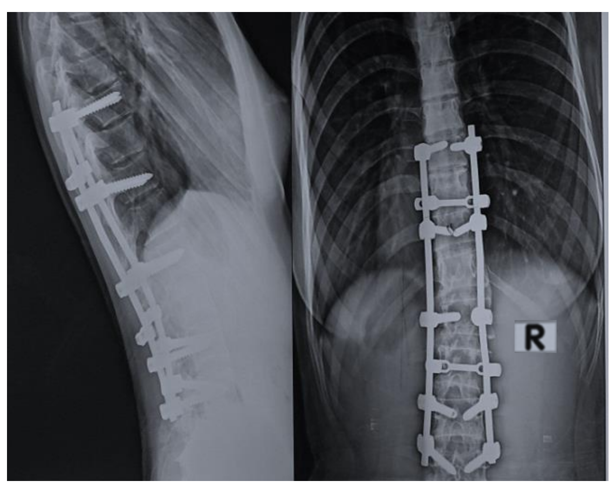


Figure 6: final follow up of case 2



Discussion

In this study, there was a statistically significant strong positive correlation between operation time and blood loss (p value 0.001*) with increase of screws density. However, no statistically significant correlation was detected in the hospital stays ($p = 0.136$). In the current study, we found significant correlation between SRS score and rate of correction (p value < 0.001), on the other hand there was non-significant correlation between screws density and SRS outcomes p value (p value = 0.459). Qadir I et al (8) reported that, health-related quality of life instruments such as the SRS 22, 24, or 30 seem to show little correlation with screws density. Ghandehari H et al (9) reported that the rates of curve correction and coronal balance correction can significantly affect the total SRS-30 score. Also, they found that the rate of correction was positively correlated with satisfaction.

In this study the mean screw density was 1.12 screws per fused levels. Yeh et al (10) reported that the mean anchor density of all patients was 1.60, Tannous et al (11) showed that the mean construct density was 1.2 screws per level fused, while Kilnic et al (12) reported that the overall mean implant density was 1.3. In this study, positive correlation but not significant between the implant density, correction rate and loss of correction the major curves at two days postoperatively ($p = 0.089$, $p = 0.169$).

Several studies reported no correlations between coronal curve correction and anchor density.

Similar results were shown by anchor density was not correlated with coronal curve correction or apical vertebral rotation (AVR) correction (correction rate: $r = -0.01$, $p = 0.88$; correction index: $r = -0.04$, $p = 0.63$; AVR correction: $r = 0.03$, $p = 0.75$) in all patients. Nevertheless, no correlations existed between anchor density and the two-plane corrections in all of the subgroup analyses (10). Li et al (13)reported that the correlation coefficient between the correction rate and the implant density in the non-structural 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. Quan et al (14)reviewed 49 Lenke1 patients and found no correlation between anchor density and coronal curve correction. Gebhard et al. (2014) also found no correlation between main thoracic curve correction and anchor density within 119 AIS patients (5). Also, Sariyilmaz et al (15) reported that high versus low-density comparison showed that there was no significant difference with regard to curve correction in early postoperative and last follow-up periods. Gotfryd et.al (16) studied and compared two groups of 23 patients with AIS who underwent surgeries with higher and lower implant density. No statistically significant difference was observed in the radiological results, but greater correction of the ribcage was shown.

In contrast to our results, several studies have shown positive correlations between AIS coronal curve correction and anchor density. Clements et al (4) observed weak but significant correlations with mixed types of implants. Yang et al (17) proposed a similar weak, but significant correlation within 58 Lenke 1A and 1B patients. Chen et al (18) further demonstrated a mild correlation ($r = 0.43$, $P < 0.05$) between thoracolumbar/lumbar curve correction and anchor density in 39 Lenke 5 AIS patients.

Ketenci et al (19) found a significantly better coronal and rotational correction of thoracic curve was observed in the consecutive pedicle screw group. Mac-Thiong et al (20) showed that the curve correction of anchor density < 1.4 was significantly inferior to the curve correction of anchor density ⩾ 1.8, whereas the curve correction of anchor density between 1.4 to 1.8 showed comparable results to an anchor density ⩾ 1.8.

In this study, the mean preoperative major Cobb angle measurement was 59.47º. There was a statistically significant decrease in the mean Cobb angle measurement at 1 month (17.83 ± 5.69), 3 months (18.0 ± 5.78), 6 months (19.07 ± 5.97) and 12 months (19.83 ± 5.97) respectively. Similar results were reported by who included 79 patients had a fixed pedicle screw density of 100%, while the other 33 patients had fixed pedicle screw density of less than 50%. There was a statistically significant difference in the postoperative Cobb angle as compared to the preoperative Cobb angle (in the two groups) (10° vs 56° respectively) in the group with 50% fixed pedicle screw density and (7° vs 53°) in the 100% fixed pedicle screw density group (21). The results of the current study also agreed with Kilinc et al (12) who showed that the preoperative mean main thoracic Cobb angle measured 61.2°, corrected to 25.3° postoperatively, and was 28.5° at 2-year follow-up.

In this study, the mean loss of correction was 2.0 ± 0.91, the mean correction degree was 41.63 ± 13 and the mean correction rate was 69.33 ± 9.16 with range between 54.84 and 87.34.

Tannous et. Al (11) reported the mean percent major curve correction was 71.2% at initial postoperative follow-up and 66.9% at latest follow-up. Lumbar fractional curves improved from a mean of 35.6° preoperatively to a mean of 10.6° (70% correction) at initial follow-up and 12.9° (63% correction) at final follow-up. Thoracic kyphosis decreased from a mean of 32.9° preoperatively to a mean of 29.5° postoperatively. The mean postoperative LIV angle measured 5.6° at latest follow-up

Regarding the complications occurred in this study, 2 cases suffered from postoperative severe anemia (HB = 7 gm), one case had numbness in her right lower limb, one case had wound discharge for 2 weeks, one case suffered from persistent vomiting 2 days post-operative resistant to anti emetics & she had hypokalemia and admitted to ICU. One case had loosening of right L4 nut at 6th month follow up. The operation was reported to be associated with lower incidence of complications. Al-Mohrejet. al (22) showed that for patients with AIS, spinal fusion surgery offers a means of deformity correction that is both effective and relatively safe. Surgeons report complications in between 5% and 25% of cases. It is important for surgeons, specialists, and residents who treat AIS patients to be fully conversant with the nature and management of potential complications. Furthermore, it is important to inform the patients of the potential complications before surgical intervention is commenced.

At the end of surgery we have to assess coronal and sagittal balance by continuous imaging of whole spine intra operative. The future studies should include larger number of cases & longer period of follow up to detect more accurate results.

Conclusion

The anchor density was not significantly related to coronal or axial curve corrections. Mild positive correlations with anchor density were found. Low anchor density with longer fusion level achieves excellent curve correction, stability. Therefore, spinal surgeons should consider the influences of anchor density on correcting deformities when planning the distributions of implants preoperatively. Operative time, blood loss, risk and cost are decreased with the use of low screw density constructs.

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