Comparative Analysis of Low Versus High Implant Density in Decreasing Cobb Angle in Lenke Type 1 Adolescents Idiopathic Scoliosis

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ABSTRACT

Objective: To compare low versus high implant density in decreasing Cobb angle in Lenke Type 1 Adolescent Idiopathic Scoliosis(AIS) treated with segmental spinal instrumentation and pedicle screws.

Methods: This retrospective Cohort study was conducted at Department of Orthopedic and Spine Surgery, Ghurki Trust Teaching Hospital/ Lahore Medical and Dental College, Lahore. The medical records of patients between 15th June 2015 to 15th June 2019 who underwent segmental spinal instrumentation for Lenke type 1 adolescent idiopathic scoliosis were reviewed. Low implant density was defined as patients with pedicle screw density per fused segment of 60 %(≤1.2) or less while high density patients had more than 60 % (> 1.2) screw density. Radiographs were evaluated preoperatively for Cobb angle of main thoracic curve, sagittal and lumbar modifier. Postoperative evaluation included postoperative Cobb angle, percent Cobb angle decease, implant density and implant cost. Independent sample t-test, paired Sample t-test and Chi-square test of association were applied to compare preoperative and postoperative variables between two groups. $P<0.05$ was set as significant.

Results: The total number of patients in our study was 66. Female patients were 47(71.2%) and male 19(28.7%). In low implant density group there were 25 patients including 17(68%) female and 8(32%) male. Mean pre-operative and post-operative Cobb angle was $62.6^0 \pm 13^0$ (45^0-90^0) and $13.8^0 \pm 8.07^0$ (0-25^0) respectively. Mean percent Cobb angle decrease, implant density and implant cost was 78.56±12.07% (50-100%), 1.11±0.083 (0.9-1.20) per fused segment and rupees 85248±13414.57 respectively. High implant density group included total 41 patients with 30(73.2%) females and 11(26.8%) males. Mean preoperative and postoperative Cobb angle was $65.24^0 \pm 16.16^0$ (45^0-100^0) and $13.29^0 \pm 8.18^0$ (0-25^0) respectively. Mean percent Cobb angle decrease, implant density and implant cost was 79.85±12.85%(44-100%), 1.499±0.09 (1.29-1.65) per fused segment and rupees 93658.53±10589.64 respectively. Comparison between the two groups showed no significant difference in percent Cobb angle decrease (*P=0.868).* However implant cost was significantly reduced in low implant density group (*p=0.000*)

Conclusion: Correction of Cobb angle was not significantly influenced by metal density and henceforth low implant density can be used to obtain excellent correction in Lenke type 1 idiopathic Scoliosis(AIS) treated with segmental spinal instrumentation and pedicle screws.

Keywords: Adolescent Idiopathic Scoliosis, Cobb angle, Lenke type 1, Pedicle screw, Segmental spinal instrumentation.

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INTRODUCTION

Scoliosis is lateral curvature of the spine of 10^0 or more with vertebral rotation. It is classified as congenital, neuromuscular and idiopathic scoliosis. Approximately 85% of cases of scoliosis are idiopathic. It affects 2-4% of adolescents between 10 to 16 years. Idiopathic scoliosis is further classified as infantile (0-3 years), juvenile (4-9 years) and adolescent (10-till maturity) idiopathic scoliosis (AIS).[1-3] Male and female are equally affected but female have 5 to 10 times more tendency towards progression. AIS is usually asymptomatic but with progression it leads to back pain, respiratory problems and changes in appearances and decrease quality of life.[4] Due to tendency of curve progression in skeletally immature children deformity of more than 50^0 need surgical treatment. Lenke type I AIS is characterized by structural main thoracic curve along with compensatory proximal thoracic and thoracolumbar or lumbar curve. Pedicle screw fixation is preferred method of treatment for spinal deformity correction due to superior coronal and sagittal curve correction and decreased fusion levels as compared to hook or hybrid instrumentation.[5-6]

Implant density is defined as the number of pedicle screw per fused segment. Different implant density is being reported in literature which range from 1.04 to 2.0 per segment. Optimum implant density and configuration is controversial. High implant density has been reported to result in better correction of coronal and sagittal deformity, but are associated with loss of thoracic kyphosis, increased blood loss and higher cost. However, there are reports in the literature which showed that similar correction can be achieved with limited implant density with benefit in terms of decreased blood loss, implant cost and duration of surgery.[7-9]

Scoliosis surgery is costly, technically difficult and time consuming surgery. It is associated with increased blood loss. The primary aim of surgery is to correct the deformity upto the maximum safe level. We hypothesized that low implant density can achieve same degree of correction as high implant density. If true, all the pitfalls associated with high implant density could be avoided and standard guidelines could be formulated for AIS surgery in our institution. The objective of our study was to compare low versus high implant density in decreasing Cobb angle in Lenke Type 1 Adolescent Idiopathic Scoliosis(AIS) treated with segmental spinal instrumentation and pedicle screws.

METHODS

This was a retrospective Cohort analysis of percent Cobb correction in patients with Lenke-type 1 adolescents idiopathic scoliosis between low and high implant density. The medical records of patients between 15th June 2015 to 15th June 2019 who underwent segmental spinal instrumentation for Lenke type 1 adolescent idiopathic scoliosis were reviewed. The Inclusion criteria were: (1) age between 9 to 19 years (2) Lenke type 1 adolescent idiopathic scoliosis with curve of $\geq 45^0$ (3) intact neurology (4) pre and post-operative radiographs available for evaluation. The exclusion criteria were: (1) Patients with congenital, neuromuscular and post traumatic scoliosis (2) patients with pre or post-operative record not available (3) previous spine surgery. The study was approved by the Ethical Committee of our hospital.

Pre-operative detailed history, physical and radiological evaluation was noted for each patient. Radiological evaluation included poster anterior and lateral x-rays of whole spine taken in standing position. Cobb angle of proximal thoracic (PT), main thoracic (MT) and thoracolumbar(T/L) or lumbar curve was measured from intersection of two lines drawn parallel to upper and lower end vertebrae. Thoracic modifier was measured by intersection of two lines drawn parallel between upper end plate of D5 and low end plated of D12 and was classified as normal hypokyposis (-), normal(N)and hypokyposis (+). Lumbar modifier was also measure and labeled as A, B, C depending on intersection of apical vertebrae of lumbar spine by central sacral vertical axis line (CSVL).[5]

Post-operative evaluation included posteroanterior (PA) x-rays of whole spine in standing position. Post-operative radiographs were evaluated for implant density and post-operative Cobb angle. Implant density was defined as numbers of screw per fused segment. Patients having implant density more than 1.2(60%) were classified as high density group (HD) and those having ≤1.2 (≤60%) implant density as low density group (LD).

Post-operative Cobb angle correction and implant density were calculated as follows:

1) % Cobb angle decrease= (preoperative Cobb's angle-postoperative Cobb angle) ×100/pre-operative Cobb angle.
2) Implant density was calculated as : (Number of pedicle screw/Number of fused segment)

OPERATIVE PROCEDURE

The medical record revealed that all surgical procedures were performed by single surgeon having more than 10 years of experience in scoliosis surgery. A standard uniform operative procedure was followed for each and every patient. All procedures were performed in prone position under controlled hypotensive anesthesia. Somatosensory evoked potential and motor evoked potential intra operative neuromonitoring (IONM) was done throughout of surgical procedure. Poly Nices Spine System (Kanghui Medical Innovation, Medtronics subsidiary, China) was use for instrumentation. Midline incision was given and sub periosteal dissection was done to expose the posterior elements. Pedicle screws were passed by free hand technique and confirmed by intraoperative fluoroscopy. In general, upper end vertebra or neutral vertebra was selected in proximal end of curve and stable -1 was selected in lower end of curve. In most patients screw were placed at alternate level. At least two vertebrae were selected at each end of curve. Rod was pre contoured to a certain angle to correct the coronal and sagittal deformity. Remaining deformity of spine was corrected by distraction of concave side of curve first then compression of convex side after placing the second rod. To correct rotational deformity rod de-rotation was done. Local autogenous bone graft and

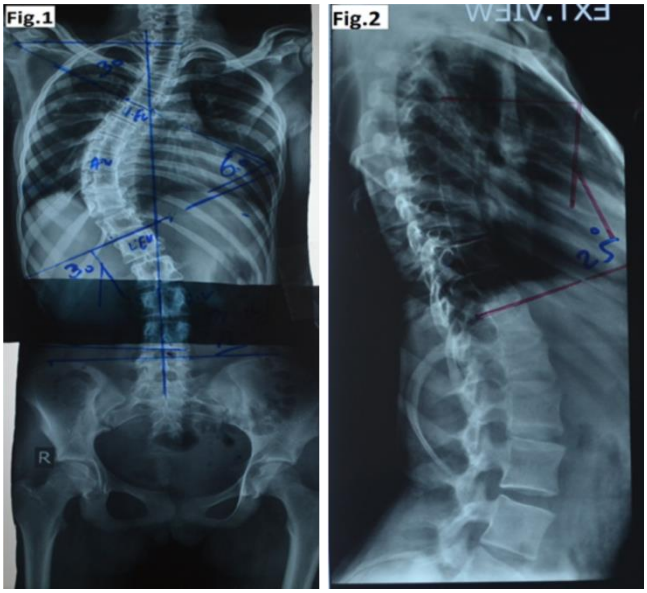

Fig.1 PA view of a 16 years old girl with Lenke type 1 AIS. Main thoracic curve of 60^0 between lower endplate of T5 and upper endplate of L1 with Lumbar modified.

Fig. II Lateral view of whole spine shows thoracic kyphosis of 25^0 between T5 and T12.

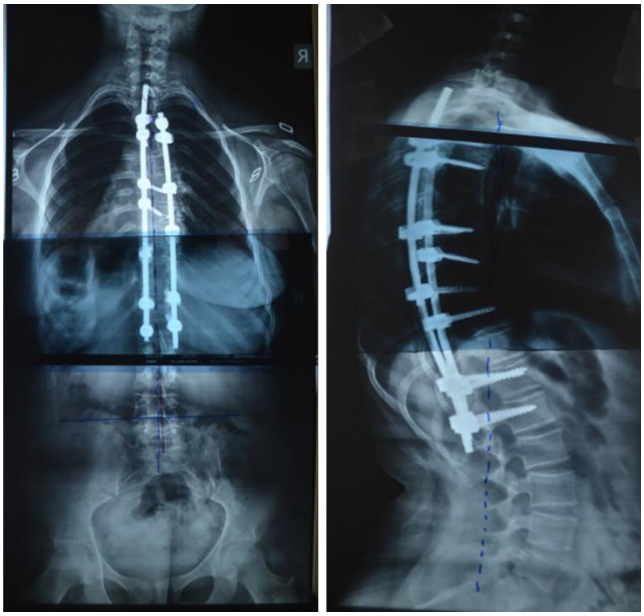

Fig. III Postoperative PA view of Lenke type 1 AIS patient treated with low implant density from T3 to L1.

Fig. IV Lateral view of whole spine of the same patient.

Bone substitute was used to achieve final spinal fusion (fig. I –IV).Wound was close over suction drain. Patient was mobilized next day and drain was removed.

The data was analyzed with IBM SPSS Statistics version 21.0(IBM Corp., Armnok, NY USA). Frequency, mean with standard deviation was calculated for age, gender, pre-operative and post-operative Cobb angle, implant density, percentage of Cobb angle decrease and implant cost . Independent Sample t-test, paired Sample t-test and Chi-square test were used to compare preoperative and postoperative parameters between two groups and $P< 0.05$ was considered significant. The data was presented in table where necessary. We reported our study in accordance with strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[10]

RESULTS

The total number of patients in our study were 66. Female patients were 47(71.2%) and male 19(28.7%). In low implant density group there were 25 patients. Majority (68%, n=17) of patients in this group were female while only 8(32%) patients were male. Mean age at time of operation was 14.32±2.13 years (range 12-18 years). There were 14(56%), 9(36%) and 2(8%) patient with Lumbar modifier A, B

and C respectively. Similarly according to sagittal modifier there were 6(24%), 14(56%) and 5(20%) in hypokyphotic (-), normokyphotic (N) and hyperkyphotic (+) group. Mean pre-operative and post-operative Cobb angle was 62.6^0±13^0 (45-90), 13.8^0±8.07^0 (0-25^0) respectively. Mean percent of Cobb angle decrease, implant density and implant cost was78.56±12.07% (50-100%), 1.11±0.083 (0.9-1.20) per fused segment and rupees 85248±13414.57 respectively.

High implant density group included total 41 patients with 30(73.2%) females and 11(26.8%) males. Mean age at time of operation was 14.46±2.1 (range 11 to 18 years). There were 29(70.7%), 11(26.8%) and 1(2.4%) patient with Lumbar modifier A, B and C respectively. Similarly according to sagittal modifier there were 10(24.4%), 21(51.2%) and 10(24.4%) in hypokyphotic (-), normokyphotic (N) and hyperkyphotic (+) group. Mean preoperative and postoperative Cobb angle was 65.24^0±16.16^0 (45-100) and 13.29^0±8.18^0 (0-25^0) respectively. Mean percent of Cobb angle decrease, implant density and implant cost was 79.85±12.85% (44-100%), 1.499±0.09 (1.29-1.65) per fused segment and rupees 93658.53±10589.64 respectively.

Based on comparison between two groups there was no significant difference between two groups in terms of age, gender, follow up, preoperative Cobb angle, post-operative cobb angle and percent Cobb angle decrease as *p>0.05.* However implant cost is significantly reduced in low implant density group (*P=0.000*) as shown in table I.

There was no case of neurological loss post operatively. On post-operative radiographs no screw misplacement was noted.

Table 1: Comparison of preoperative and postoperative variables of low density and high density group.

Variables	Low density	High density	*P* Value
Number	25	41	
Gender			
Female	17(68%)	30(73.2%)	
Male	8(32%)	11(26.8%)	0.653
Age(years)	14.32±2.13(12-18)	14.46±2.1(11-18)	0.791
Lumbar Modifier (number, %)			
A	14(56%)	29(70.7%)	
B	9(36%)	11(26.8%)	0.367
C	2(8%)	1(2.4%)	
Thoracic Modifier (number, %)			
- (<10^0)	6(24%)	10(24.4%)	
N (10-40^0)	14(56%)	21(51.2%)	0.905
+ (>40^0)	5(20%)	10(24.4%)	
Pre-op Cobb angle(degrees)	62.6±13(45-90)	65.24±16.16(45-100)	0.491
Post op Cobb angle(degrees)	13.8±8.07(0-25)	13.29±8.18(0-25)	0.807
%Cobb Angle Decrease	78.56±12.07(50-100)	79.85±12.85(44-100)	0.686
Implant density (%)	1.11±0.083(0.91-1.20)	1.499±0.09(1.29-1.65)	0.000
Implant cost(Rupees)	85248±13414.57	93658.53±10589.64	0.000

DISCUSSION

The main goal of scoliosis surgery is to correct coronal and sagittal plane deformity and achieve stable fusion. Posterior segmental spinal instrumentation for idiopathic scoliosis is an effective treatment with excellent correction of coronal and

sagittal deformity as compared to hooks. The reason being pedicle screw provide more secure fixation as compared to other devices. But pedicle screw has its own limitation such as cost, prolonged operation time and more blood loss. Spinal cord and nerve root damage associated with pedicle screw placement is although minimal but serious complication.[11]

Distribution of Cobb angle of the main thoracic curve in this series was $65.24^0 \pm 16.16^0$ (45^0-100^0) and $62.6^0 \pm 13^0$ (45^0-90^0) in high and low implant density group respectively. Jian[12] in his series of 40 patients had Cobb angle of main thoracic curve of about $51.17^0 \pm 10.72^0$. Luciano[13] in his series of 63 patient from Brazilian population had main thoracic curve of $58.5^0 \pm 11.8^0$ (20^0-91^0). Shunan[14] had 40 patients with Lenke type I scoliosis with mean preoperative Cobb angle of $49.40^0 \pm 9.8^0$. The Cobb angle of main thoracic curve in our patients was high as compared to other series. Most probable reason for this was lack of awareness, no screening facility at school level and low socioeconomic status of the patients which leads to late presentation of these patients to specialized spine centers.

There is no critical threshold for division into high and low implant density group in the literature. Instead there is relative screw density as number of screw per fused level. Similarly some reports categorized patients according to consecutive versus skipped versus interval screws. There are reports that a pedicle screw density up to 50% was sufficient to achieve long term stable curve. Biomechanical comparison of alternative screws technique also showed that high screw density failed to provide significantly high degree of correction. Similarly for a moderate curve angle between 40^0-70^0, pedicle screw density of less than 80% was adequate.[15,16] In our study the mean implant density in low implant density (LD) group was 1.11±0.083 (0.91-1.20) per fused segment and curve correction was comparable to high implant density (HD) group.

In our series the mean implant density in low and high implant density groups were 1.11±0.083 (0.91-1.20) and 1.499±0.09 (1.29-1.65) per fused segment respectively. In patients with low implant density construct mean preoperative, post-operative Cobb angle and percent cobb angle decrease (% CAD) was 62.6±13 (45-90) degrees, 13.8±8.07 (0-25) degrees and 78.56±12.07 (50-100) % respectively. While in patients with high density implant construct mean pre-operative, post-operative Cobb angle and % Cobb angle decrease was 65.24 ± 16.16^0 (45-100), 13.29 ± 8.18^0 (0-25) and 79.85±12.85% (44-100) respectively. Mean implant cost in low and high implant density patients were rupees 85248±13414.57 and 93658.53±10589.64 respectively. Both groups were comparable and there was no significant difference in terms of age, gender, preoperative Cobb angle, postoperative Cobb angle and % CAD except for implant cost (*P=0.000*). Hence implant density has no effect on postoperative Cobb angle correction. Contrary to our results Kilnic[17] in his comparative study of implant density of 120 patients in the management of 1B and 1C at two years follow up noted that high implant density group had better correction than lower implant density group (*P=0.0001*). But in patient with low pedicle screw density blood loss, operating time and screws related potential complications were reduced. Shen [18] and colleagues in their comparative study of low density and high density pedicle screw in Lenke type 1 AIS reported that there was no significant difference in postoperative Cobb angle correction in high and low implant density constructs (*P=0.275)*.However operating time, blood loss and implant cost was reduced in low pedicle screw construct. Li[19] in his comparative study of implant density in structural and nonstructural region of the curve noted that there was no difference in curve correction in structural region between low and high pedicle screw density constructs (*P=0*.089). However in the nonstructural region low implant density group had better correction than high density(*P=0.022*).Moreover the percentage of Cobb angle decrease in Li series was comparatively better than previous reports which was most probably due to multilevel Ponte's osteotomies and posterior release.

Limitations of our study were retrospective series, lack of randomization and small number of patients. Moreover we did not evaluate patient reported outcome, blood loss and operation time. We therefore suggest further studies to address all such limitations.

CONCLUSION

Correction of Cobb angle was not significantly influenced by metal density and henceforth low implant density can be used to obtain excellent correction in Lenke type 1 idiopathic Scoliosis(AIS) treated with segmental spinal instrumentation and pedicle screws.

Conflict of Interest: None
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