Eur Spine J (2011) 20:1039–1047
DOI 10.1007/s00586-011-1808-4

HEALTH TECHNOLOGY ASSESSMENT & TRANSFER

Right adolescent idiopathic thoracic curve (Lenke 1 A and B): does cost of instrumentation and implant density improve radiographic and cosmetic parameters?

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Received: 8 May 2010 / Revised: 28 January 2011 / Accepted: 12 April 2011 / Published online: 26 April 2011
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Abstract In adolescent idiopathic scoliosis (AIS) there has been a shift towards increasing the number of implants and pedicle screws, which has not been proven to improve cosmetic correction. To evaluate if increasing cost of instrumentation correlates with cosmetic correction using clinical photographs. 58 Lenke 1A and B cases from a multicenter AIS database with at least 3 months follow-up of clinical photographs were used for analysis. Cosmetic parameters on PA and forward bending photographs included angular measurements of trunk shift, shoulder balance, rib hump, and ratio measurements of waist line asymmetry. Pre-op and follow-up X-rays were measured for coronal and sagittal deformity parameters. Cost density was calculated by dividing the total cost of instrumentation by the number of vertebrae being fused. Linear regression and spearman's correlation were used to correlate cost density to X-ray and photo outcomes. Three independent observers verified radiographic and cosmetic parameters for inter/interobserver variability analysis. Average pre-op Cobb angle and instrumented correction were 54° (SD 12.5) and 59% (SD 25) respectively. The average number of vertebrae fused was 10 (SD 1.9). The total cost of spinal instrumentation ranged from \$6,769 to \$21,274 (Mean \$12,662, SD \$3,858). There was a weak positive and statistically significant correlation between Cobb angle correction and cost density ($r = 0.33$, $p = 0.01$), and no correlation between Cobb angle correction of the uninstrumented lumbar spine and cost density ($r = 0.15$, $p = 0.26$). There was no significant correlation between all sagittal X-ray measurements or any of the photo parameters and cost density. There was good to excellent inter/intraobserver variability of all photographic parameters based on the intraclass correlation coefficient (ICC 0.74–0.98). Our method used to measure cosmesis had good to excellent inter/intraobserver variability, and may be an effective tool to objectively assess cosmesis from photographs. Since increasing cost density only improves mildly the Cobb angle correction of the main thoracic curve and not the correction of the uninstrumented spine or any of the cosmetic parameters, one should consider the cost of increasing implant density in Lenke 1A and B curves. In the area of rationalization of health care expenses, this study demonstrates that increasing the number of implants does not improve any relevant cosmetic or radiographic outcomes.

Keywords Spine · Scoliosis · Cosmetics · Instrumentation

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Introduction

Preferred instrumentation for adolescent idiopathic scoliosis (AIS) remains controversial. Surgical correction is classically indicated for progressive curves more than 40° in the skeletally immature patient. Until recently, the use of hooks/hybrid instrumentation has been the most accepted method implemented to achieve correction of AIS [1].

Over the past decade, pedicle screw instrumentation has gained popularity. Studies have supported the clinical advantages of all pedicle screw constructs for Cobb angle correction versus conventional hook instrumentation [2]. However, pedicle screw instrumentation raises safety concerns including screw misplacement, neurologic, and vascular injuries [3, 4]. Additionally, cost is a concern. While Kim et al. aptly demonstrate increased cost associated with all pedicle screw instrumentation versus hooks and hybrids, they do mention that mixed constructs may lead to higher revision rate due to loss of fixation.

Cosmesis remains one of the most important outcomes for patients suffering from scoliosis [5–8]. While improved radiographic Cobb angle correction may be achieved with surgery, this does not necessarily transfer into improved cosmetic outcome. Evidence suggests that it is possible to reliably quantify cosmetic outcome in spite of its apparent subjective nature regardless of the curve type [7].

Several studies have attempted to evaluate postoperative cosmetic outcome with various assessment instruments [7, 9, 10]. While most surgeons agree on the importance of evaluating the postoperative decrease in cosmetic deformity, there continues to be little consensus on the most uniformly reliable way to do so [11]. Studies have demonstrated the utility of an automated stereophotogrammetric technique (ISIS) [12, 13] as well as Moire topography [9, 14] which perhaps due to time constraints in the routine clinic setting or high cost of equipment have not been widely adopted. There is a need for development of a simple, time and cost effective method to evaluate cosmetic outcome in AIS.

In the current health care environment focused on controlling cost, previous studies have not considered the relationship between cost density of instrumentation and cosmetic outcome. Recent surgical techniques have focused on improving angular correction and improving patient function. Increased implant density of pedicle screw instrumentation has been correlated with increased radiographic Cobb angle correction [15, 16]. However, it is unclear if increased implant density or cost results in the improvement of objective cosmetic results. The present study is designed to analyze the correlation between cost density and cosmetic outcomes in the surgical treatment of AIS through objective measurements of cosmetic variables on clinical photographs and radiographs obtained from an online scoliosis database.

Materials and methods

Patient selection

We performed a retrospective study of 58 cases of Lenke 1A and 1B thoracic AIS. Institutional review board of the primary author's institution approved the study protocol. The cases for the study were obtained from the online database Scolisoft, a multi-center database documenting radiographs, clinical outcomes, and photographs of surgical cases of AIS [17]. The database was queried for cases of Lenke 1A and 1B AIS cases, which returned 74 case results. Cases were included in the study if the data set included: complete preoperative and follow-up posteroanterior (PA) and lateral standing X-rays, posterior standing photographs, and posterior forward bending photographs. Complete radiographic or photographic data were not available for 16 cases and thus were excluded from the study. A total of 58 cases remained for analysis.

Radiographic measurements

Pre-operative and follow-up PA and lateral radiographs were evaluated for primary curve coronal Cobb angle, Cobb angle of the uninstrumented spine, and standard deformity measures for sagittal balance. Deformity measures of sagittal balance included sagittal Cobb angles for the levels T5–T12, T10–L2, and T12–S1 as described by Rhee et al. [18] and the C7 plumbline angle. The C7 plumbline angle was measured from the center of the C7 vertebral body to the center of the posterior superior border of the S1 vertebral body referenced from a vertical line. An angle from which the measurement on C7 was anterior to the measurement on S1 was noted to be a positive value, and vice versa. The C7 plumbline measurement was marked as an angle rather than a distance due to inter-case inconsistencies in magnification for uploaded radiographs in the database.

Photographic measurements

For each of the cases, preoperative and follow-up posterior and forward bending photographs were evaluated and measured for the following criteria: trunk shift, waist line asymmetry, shoulder balance at the level of the acromion and axillary fold, and rib hump. All measurements excluding waist line asymmetry were marked as angles in order to allow for comparison of photographs with differing magnification levels. Measurements were performed on using a photo analysis program Adobe Photoshop CS4 (San Jose, CA, USA).

Shoulder balance was defined as the angle measured from the left acromion and axillary fold to the right acromion and axillary fold, respectively on a posterior photograph, as referenced from horizontal (Fig. 1a, b). A distance measurement of shoulder balance was extrapolated as:

$$\text{Shoulder balance (cm)} = \text{Sine (shoulder balance angle)} \times \text{average biacromial distance (cm)}$$

The average biacromial distance for each age was obtained from anthropometric data of adolescents [19]. To perform a spearman's rank analysis for improvement or worsening between preoperative and follow-up photos, the shoulder balance was then graded as follows: Grade 0 (<1 cm), Grade 1 (1–2 cm), Grade 2 (2–3 cm), Grade 3 (>3 cm) as consistent with that in current literature [20].

Rib hump was defined as the angle measured from the apex of the hump of the left rib cage to the apex of the hump of the right rib cage on a posterior forward bending photograph, as referenced from horizontal (Fig. 1c, d). Rib Hump was graded as follows: Grade 0 (<5°), Grade 1 (5–10°), Grade 2 (10–15°), and Grade 3 (>15°). This grading system is clinically relevant in that 5–7° is the general screening cutoff for a scoliometer measurement as proposed by Bunnell et al. [20, 21] which falls within grade 1. For shoulder balance and rib hump, an angle in which the right side of the body was higher was defined as a positive value, and vice versa.

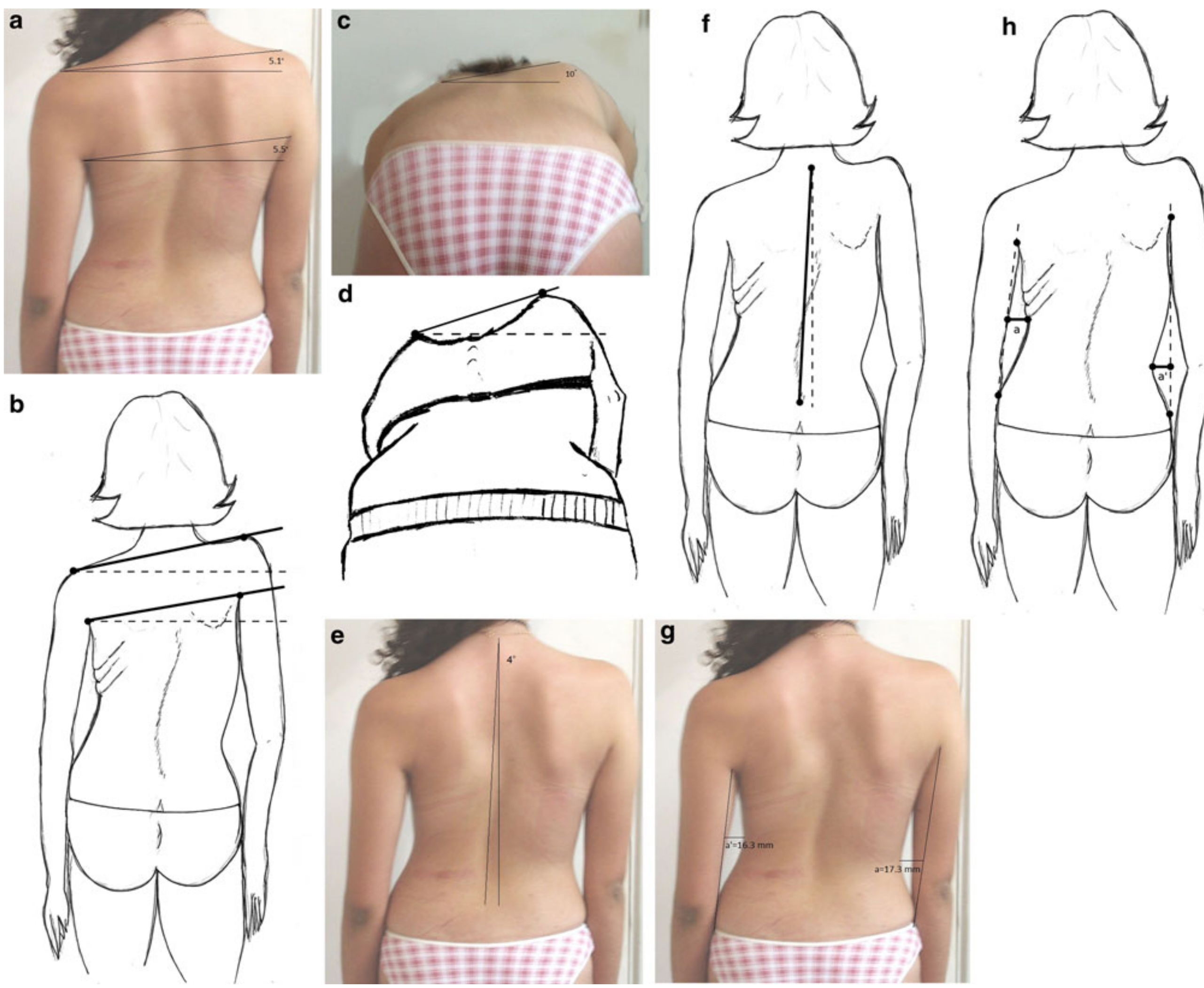

Fig. 1 Schematic and photographic measurements. **a**, **b** Shoulder balance: angle from the *left* acromion and axillary fold to the *right* acromion and axillary fold, respectively on a posterior photograph as referenced from *horizontal*. **c**, **d** Rib hump: angle from the apex of the *left* rib cage to the apex of *right* rib cage on a posterior forward bending photograph as referenced from *horizontal*. **e**, **f** Trunk shift: angle from the C7 spinous process to the midpoint of the two sacroiliac dimples on a posterior photograph as references from *vertical*. **g**, **h** Waist line asymmetry: a reference line is made on each side of a posterior photograph from the axillary fold to the iliac crest. A *horizontal* measurement is made on each side from the reference line to the apex of the concavity of the waist. Waist line asymmetry is the difference of the measurements from the two sides is divided by the larger of the two measurements (a−a′)/a

Trunk shift was defined as the angle measured from the C7 spinous process to the center of the sacrum (at the midpoint between two sacroiliac dimples) on a posterior photograph, as referenced from a vertical line (Fig. 1e, f). An angle in which the C7 spinous process is to the right of the center of the sacrum is noted to be a positive value, and vice versa. A distance measurement of trunk shift was extrapolated as:

$$\text{Trunk shift (cm)} = \text{Sine (trunk shift angle)} \times \text{average trunk height (cm)}$$

As with shoulder balance, the average trunk height for each age was obtained from anthropometric data of adolescents [19]. Trunk shift was then graded as follows: Grade 0 (<1 cm), Grade 1 (1–2 cm), Grade 2 (2–3 cm), and Grade 3 (>3 cm).

Waist line asymmetry was determined as follows: A reference line is made on each side of a posterior photograph from the axillary fold to the iliac crest. A horizontal measurement is made on each side from the reference line to the apex of the concavity of the waist. The difference of the measurements from the two sides is divided by the larger of the two measurements, which defines the waist line asymmetry (Fig. 1g, h).

Determination of cost

The type of instrumentation used for each case was obtained from the database and confirmed with radiographs. The total cost of instrumentation for each case was estimated from the 2009 list pricing of instrumentation from the manufacturers used in the study (Medtronic and Synthes), and included the sum of hooks and screws (including distinction between monoaxial and polyaxial). The cost was determined as follows: Hook $780, Monoaxial pedicle screw $967, and polyaxial pedicle screw $1,045. The cost of rods was not included, as all cases universally used two rods for which there would have been minimal cost differences. To allow for comparison of cases with variable number of fusion levels, the total cost of instrumentation was divided by the number of vertebrae being fused to determine a cost density value. The cost density was then used for correlation with radiographic and photographic measurements.

Statistical analysis

Distribution of variables is given as mean, standard deviation, and range. Interobserver variability of all photographic measurements were calculated using three independent observers including two orthopaedic surgery resident physicians and one spine surgery fellow. Intraobserver variability of all photographic measurements were calculated using two separate time points for one observer, spaced 6 weeks apart between measurements and blinded to previous measurements. Ten cases were randomly selected from the 58 cases for variability analysis of all photographic measurements. The analysis was performed using the interclass correlation coefficient on SPSS v17 (Chicago, IL, USA).

A linear regression model on SPSS v17 was used to correlate cost density with all radiographic outcomes and photographic waist line asymmetry. A spearman's rank order correlation was used to correlate cost density with photographic shoulder balance, trunk shift, and rib hump outcomes. One-way ANOVA was performed to determine statistical significance for linear regression correlations, and two-tailed t test was performed to determine statistical significance for spearman's rank order correlations. Significance was determined at a level of $p < 0.05$.

Results

The mean age of the population studied was 14.9 years (SD 3.1 years, range 10–29 years) with preoperative and postoperative Cobb mean angles 53.9° (SD 12.5°, range 30°–90°) and 16.8° (SD 8.9°, range 1°–42°) respectively. Lenke 1A curves represented 69% of the sample, while Lenke 1B curves represented 31%. The total cost of spinal instrumentation averaged $12,662 (SD $3,858, range $6,769–$21,274). The average number of instrumented levels was 10.0 (SD 1.9, range 7–14). The mean follow-up time period after surgery for radiographic and photographic analysis was 10.7 months (SD 7.7 months, range 3–36 months), and the median follow up period was 9 months.

The radiographic measurement results are summarized in Table 1. This study showed that there is a weak positive and statistically significant correlation between Cobb angle correction and cost density ($r = 0.33$, $p = 0.01$) of the instrumented spine (Fig. 2). There was however no statistically significant correlation between Cobb angle correction of the uninstrumented spine and cost density or all sagittal angles measured.

On all post-operative photographic variables measured there was no statistically significant correlation between increasing cost density and change in cosmetic variables from pre-op to follow-up (Table 2): trunk shift (rho = -0.16, $p = 0.23$), Waist line asymmetry ($r = -0.03$, $p = 0.80$), shoulder balance referenced from the acromion (rho = -0.05, $p = 0.74$), shoulder balance referenced from the axillary fold (rho = 0.11, $p = 0.41$), and rib hump ($r = 0.16$, $p = 0.23$).

There was good to excellent interobserver and intraobserver variability for all clinical photographic measurements based on the interclass correlation coefficient (ICC) as shown in Table 2.

Table 1 Summary of radiographic results

Variable	Preoperative mean	Preoperative standard deviation	Followup mean	Followup standard deviation	Correlation coefficient (of change of variable and cost density)	Statistical significance (of correlation between change of variable and cost density)
Cobb angle instrumented spine	53.9°	12.5°	16.8°	8.9°	$r = 0.33$	$p = 0.01$
Cobb angle uninstrumented spine	17.7°	8.0°	7.6°	6.7°	$r = 0.15$	$p = 0.26$
T12–S1 angle[a]	−50.4°	13.9°	−46.9°	13.9°	$r = 0.11$	$p = 0.43$
T5–T12 angle[a]	24.8°	12.0°	20.2°	8.4°	$r = 0.10$	$p = 0.48$
T10–L2 angle[a]	−8.2°	6.0°	−7.6°	5.6°	$r = 0.12$	$p = 0.38$
C7 plumbline[b]	−5.9°	10.4°	−6.7°	10.6°	$r = 0.11$	$p = 0.42$

[a] For T12–S1, T5–T12, T10–L2 angles, a positive value indicates kyphosis and a negative value indicates lordosis

[b] For C7 plumbline, an angle from which the measurement on C7 was anterior to the posterior superior body of S1 was noted to be a positive value, and vice versa

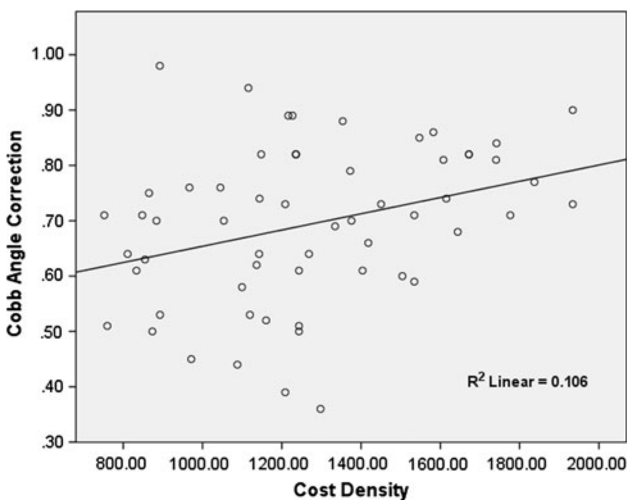

Fig. 2 Correlation between Cobb angle correction and cost density

Discussion

Study group

This study was limited to patients with purely right thoracic major curves to focus the radiographic and photographic outcomes in a group in which general principles of fusion and goals of treatment are similar. Many factors must be considered in surgical correction of AIS curves, including curve magnitude, curve flexibility, points of fixation, and the determination of the stable vertebra. Therefore, we restricted our patient population to study similar curves in order to compare “apples to apples.” Likewise we wanted to have a homogenous selection of the distal fusion, as most Lenke 1A and B curves are fused one or two levels proximal to the stable vertebra. This was reflected by our average number of vertebrae being fused as 10 levels and for most cases representing a fusion from T4 to L1. Current studies that have evaluated density of instrumentation included all types of scoliosis curves [15, 16] or correlate only radiographic parameters with density of instrumentation in Lenke 1 curves [16].

Radiographic findings

A mild positive correlation exists in this series between Cobb angle correction and cost density. Several studies confirm that increased density of instrumentation is correlated with increased coronal correction [15, 16]. D’andrea et al. [22] have shown that improvement in radiographic outcomes in AIS, however, does not translate into improved clinical outcomes as measured by Scoliosis

Table 2 Summary of photographic results

Variable	Correlation coefficient (of change variable and cost density)	Statistical significance (of correlation between change of variable and cost density)	Intraobserver ICC[a]	Interobserver ICC[a]
Trunk shift	Rho = −0.16	$p = 0.23$	0.92	0.92
Waist line asymmetry	$r = -0.03$	$p = 0.80$	0.87	0.74
Shoulder balance—from acromion	Rho = −0.05	$p = 0.74$	0.97	0.99
Shoulder balance—from axillary fold	Rho = 0.11	$p = 0.41$	0.97	0.97
Rib hump	Rho = 0.16	$p = 0.23$	0.98	0.98

[a] ICC value interpretation: ≥0.75 excellent agreement beyond chance, 0.40–0.74 fair to good agreement beyond chance, <0.40 poor agreement beyond chance

Research Society (SRS) questionnaire scores. The clinical relevance for example of correcting an initial 52° curve to 11° using high pedicle screw density when compared with 14° using lower density screw or hybrid instrumentation may be marginal. Kim et al., have reported no difference in SRS-24 follow-up scores between AIS cases instrumented with hook or hybrid instrumentation as compared to all pedicle screw instrumentation [2, 23]. Vora et al. [24] have also shown that when taking into account the preoperative flexibility of Lenke 1 curves, there was no 2-year follow-up difference between the adjusted Cobb angle correction when comparing hook and hybrid to pedicle screw instrumentation. Although there are clear benefits of pedicle screw implantation over other types of instrumentation including improved coronal cobb correction, decreased need for anterior release, as well as stable three column spinal fixation, [2] the use of high density of pedicle screw instrumentation at every level in treating Lenke 1 A and B AIS curves is not justified based on the weak positive correlation between cost density and Cobb angle alone.

The effect of the fusion on the non-instrumented portion of the lumbar spine may have greater clinical significance than that of evaluating Cobb angle correction of the instrumented spine as biomechanical factors may accelerate degeneration of the residual lumbar curve resulting in back pain and radiographic tilting of the last instrumented vertebra [25–28]. Increasing cost density in our study had no effect on the uninstrumented lumbar curve.

Cost density did not have an effect on the sagittal profile in this series. However, several studies have noted a thoracic hypokyphosis and flattening of the normal thoracic contour with pedicle screw instrumentation [24, 29–32]. Quan et al. [16] have shown that there was a statistically significant negative correlation between loss of thoracic kyphosis and the magnitude of coronal curve correction when all pedicle screw instrumentation is used suggesting that increasing coronal correction comes at a cost of flattening the thoracic contour. Although the achievement of overall sagittal balance is desirable, the clinical relevance of the loss of thoracic contour is not well understood in the treatment of AIS. If marked hypokyphosis or thoracic lordosis may have an impact on the respiratory function later in life, lack of normalization of thoracic kyphosis remains of unclear significance.

Cosmetic outcome

Trunk deformity in patients with scoliosis has been shown to significantly influence the patient's perception of function and self-image [33–36]. Especially in the adolescent population, cosmesis is an important outcome to measure in spinal deformities. Payne et al. [37] have demonstrated that the presence of scoliosis is significant risk factor for psychosocial disturbance in adolescence including increased suicidal ideation as well as alcohol consumption. A disturbance in body image in patients with scoliosis is very common, and adolescents with AIS are more likely to be dissatisfied with their appearance when compared with the general adolescent population [37, 38]. Hence, an assessment of cosmesis is critical in the overall outcome in the treatment of AIS.

In this study, we measured the cosmetic variables on clinical photographs of surgical patients of AIS (Fig. 1a–d) using an image analysis program. Earlier efforts at quantifying cosmesis have been done using ISIS and Moire topography [9, 12–14]. The advantage of these methods has been their non-invasive nature as opposed to routine X-ray use to evaluate deformity progression. However, the drawback of these methods is that they require additional equipment and may not suitable for a busy clinic setting. The multicenter scoliosis database accepts contributions from multiple practices in which the method of cosmetic analysis is not standardized. Although the utility of Moire topography has been validated in several studies, the universal availability of clinical photographs warrants the need for a method measurement and analysis based on photographs alone. Although a formal cost analysis has not been performed on various methods of cosmetic analysis, the method used in this study is inexpensive and a reliable measure of cosmesis with good to excellent interobserver and intraobserver reliability.

The rib hump deformity is a complex deformity that for which the convexity of the rib, the posterior concave chest depression, vertebral rotation, and sagittal profile of the thoracic spine all contribute. All pedicle screw instrumentation has shown to be associated with improved radiographic derotation of the spine on postoperative imaging studies than hook-rod instrumentation [39]. However, radiographic derotation of the apex vertebrae has not been demonstrated to be associated with a decrease in the amount of clinical rib hump deformity as in our study.

Raso et al. [40] showed that the shoulder balance plays an important role in the cosmesis of AIS patients. Shoulder imbalance is an obvious prominent deformity for typical Lenke 1 curves, in which it is typical to have a right shoulder elevation. Several studies have reported the phenomenon of a decompensated left shoulder elevation with instrumentation of the thoracic curve, though mostly in Lenke 2 curves with proximal fusions [41–43]. Recently Shufflebarger et al. [44] have shown even in Lenke 1 curves, more proximal instrumentation and increased fusion levels could lead to decompensated left shoulder elevation. Our study failed to demonstrate that increased implant density correlated with increased shoulder imbalance.

Trunk shift and waist line asymmetry are important cosmetic parameters reflective of the balance of the lumbar curve. Our study did not demonstrate any correlation between cost density and these cosmetic parameters. The waist line asymmetry can be attributed to a combination of the trunk shift and the residual lumbar curve. Therefore, the postoperative waist line asymmetry is dependent on the fusion selection level and the post instrumented correction of the lumbar curve. Our results support that increasing cost density has no significant effect on the cosmetic balance of the lumbar spine.

Arlet et al. [45] have shown no significant difference in cosmetic outcome score when medical judges or laypersons were blinded to the type of instrumentation in a group of AIS cases, suggesting that overall measurable differences in cosmetic parameters between different instrumentation groups may be indistinguishable from a viewer's assessment. In the present study, we found no significant correlation between the cost density and any of the different cosmetic variable measured objectively. Therefore, keeping in view that there is no significant correlation between cosmetic variable measurements and cost density of implants, one must consider the overall cost effectiveness of high density implants in treating AIS right thoracic curves.

Strengths

This paper is the first dealing with post-operative clinical photographs of patients and objective measurements on the photographs. The measurement methodology used is a cost efficient way to perform an analysis of cosmetic outcome, though is not clinically validated with actual patient or judge subjective assessment of cosmetic outcome. However, interobserver and intraobserver variability of the photographic measurements has been verified to be good to excellent in this study, suggesting that the photographic measurements are reproducible and consistent.

Weaknesses

Studies in scoliosis literature generally report at least 2 years of radiographic and clinical outcomes follow up as standard for surgical cases of AIS, though no common standard is reported for photographic outcomes. We chose a minimum of 3 months follow-up clinical photographs based on available complete data. Furthermore, changes in patients' body habitus over the course of 2 years may make photographic comparison difficult.

Surface topography analysis has been extensively explored, and found to be a useful adjunct in quantifying cosmetic defects in AIS. This study does not use surface topography methods including Moire or ISIS topography to analyze each patients' cosmetic outcome, and relies on two-dimensional measurements from photographic appearance due to lack of standardization of surface topography methods amongst multiple international contributors to the scoliosis database. Based on the availability of photographs, the authors created objective measures of cosmetic deformity. The measurements made on the photographs may be prone to minor variability that may not be clinically significant (i.e. 3.8° vs. 5.1° in shoulder balance), though have been shown to have excellent interobserver and intraobserver reliability.

This study is not a formal cost analysis, and does not include the costs of hospitalization, revision surgery, and other complications. Furthermore, the study does not adjust for differences in other variables of surgical techniques and curve characteristics such as preoperative curve flexibility, distal level of instrumentation, and anterior release. Nevertheless, Kamerlink et al. have performed an analysis of the cost of the initial surgery in AIS, and have demonstrated that implants representing the largest percentage of overall costs at 29%. The average cost of implants was $9,950 (SD $6,784), while the average costs of bone graft was $2,041 (SD $1,524). Other major costs included inpatient room costs (22%), operating room time (9.9%), and bone grafts (6%). The surgeon's role in cost remains in controlling implant density as well as the use of bone grafts. In our study, of 58 cases, 19 iliac crest autografts, 41 local autograft, 3 rib autografts, 18 bone allograft, and 2 demineralized bone matrix were used to assist fusion. Bone morphogenic protein and stem cells were not used on our study to achieve fusion. The use of adjunctive osteoinductive and osteoconductive materials to assist bony fusion does increase the cost of the procedure, though less significantly than implant density.

Conclusions

This study showed that for a similar group of patients with Lenke 1A and B curves increasing the cost density of instrumentation does not translate into improving the Cobb angle of the uninstrumented spine and does not change any of the cosmetic parameters measured on clinical patient photographs. In the era of health care rationalization increasing implant density does not translate into improved and measurable relevant outcome.

Acknowledgments This study was funded in part by Synthes through a research salary grant.

Conflict of interest None.

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