

Surgical Management of Early Onset Scoliosis Cases

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Abstract

Background: Early-onset scoliosis (EOS) is defined as a scoliotic deformity (coronal imbalance $>10^\circ$) present between the ages of 4 and 10 due to heterogeneous etiologies. Traditional dual-growing rods (TDGR) are effective distraction-based methods used to correct and control the progressive. Nevertheless, these children may have complications with the initial surgery and following lengthening procedures. **Objective:** This study aims to evaluate the safety, efficacy, and complications of the TDGR technique in patients with EOS. **Methods:** This prospective clinical case series study was conducted on 18 patients with EOS more than 60° . All patients underwent an initial fusionless surgery using TDGR for correction of scoliosis followed by two serial distraction procedures for lengthening the growing rod at 6-month intervals. The Cobb's angle of the major curve, thoracic kyphosis angle, T1- S1 length, and coronal and sagittal balance were measured preoperatively, immediately postoperatively, and before and after every lengthening procedure. Due to anesthesia requirements, respiratory function tests were done preoperatively for 12 patients and performed postoperatively only for 12 patients. **Results:** The mean preoperative Cobb's angle decreased from 79.22° to 43.66° postoperatively (P-value= 0.005). The mean T1-S1 length increased from 24.13 cm pre-operatively to 27.38 cm after initial surgery and 28.2 cm after the 2nd lengthening procedure (P-value <0.05). The mean pre-operative thoracic kyphosis angle decreased significantly in comparison to immediate post-operative measurements and after the 2nd lengthening procedure (P-value <0.05). Pulmonary functions improved in 12 patients with an increase in FEV1 by a mean of 13%. The complication rate was 22.22 %. The specific complications reported were wound infection, rod malplacement, rod migration, and rod breakage, each occurring in a single case (5.55% each). **Conclusion:** The TDGR technique is a safe and effective treatment for deformity control and continuous spinal growth in selected patients with EOS.

Keywords: Early-onset scoliosis, Juvenile scoliosis, Traditional dual growing rods, Cobb's angle, Kyphosis.

Introduction

Early-onset scoliosis (EOS) is a term experts have adopted to refer to pathologies of the growing spine that manifest and progress in different forms [1-2]. Historically, its challenging nature has made it difficult to introduce a comprehensive definition that brings consensus in diagnosis and management. Initially, the term EOS was used by Ponseti and Friedman in 1950 to describe idiopathic scoliosis in patients less than 10 years old [2]. Years later, the Growing Spine Study Group (GSSG) and the Children Spine Study Group (CSSG) defined EOS as any spinal deformity that is present before the age of 10, regardless of the etiology. Traditional Growing Rods (TGR) constitute the most commonly applied technique and are considered the gold standard for EOS with long curves [3]. TGRs were first introduced by Harrington in 1962 [4]. After various modifications were made, the widely applied dual-rod growing rod technique was reported by Akbarnia et al. [5]. Correction is achieved by distraction and maintained by proximal and distal instrumentation and fusion. Growth potential, especially lung growth, is preserved by unfused spine segments and lengthening procedures [6]. The most widely agreed upon indication for growing-rod surgery is the failure of treatment with the bracing or casting, a degree of curvature of more than 60° , and ages younger than 10 years old. However, theoretically, TGRs can be indicated for any patient with skeletal immaturity. For the initial surgery, the correction rate has been reported to vary from 30% to 60%, and the lengthening interval has been shown to differ for different surgeons, mostly ranging from 6 to 12 months. [7]. The Shilla Growth Guidance System (SGGS) was first reported in 2014. SGGS guides spinal growth toward a normal alignment. The Shilla technique first corrects the apical deformity toward a neutral alignment. Then, the upper and lower growth guidance portions extend into the distal and proximal areas of the curve using polyaxially screws. These special screws have locking caps that fix to the top of the screws (not the rod) and capture the rod, allowing it to slide with growth in a longitudinal direction. Multiple open lengthening surgeries are avoided, as in genetically Controlled Growing Rod (MCGR). The indications for the SGGS include early-onset spinal deformity and coronal curves $>50^\circ$ [8]. This study aims to evaluate the safety, efficacy, and complications of the Traditional Dual Growing Rod (TDGR) technique in patients with EOS.

Methods

This is a single-arm clinical trial of a series of 18 patients designed to estimate the outcome of surgical intervention in correcting cases of early scoliosis. The study was conducted in the Neurosurgery Department of a tertiary university-

based hospital from January 2023 to April 2024. It included cases between 4 and 10 years old with EOS with progressive structural curves $\geq 60^\circ$. We excluded patients with diffuse complex congenital anomalies in the spine. The patients underwent a fusionless technique using TGR that included double-growing rods (EGY FIX SYSTEM®). They had three operations: an initial surgery and two serial distraction lengthening of the growing rods procedures at 6-month intervals, with intraoperative neurophysiology monitoring.

Sample Size

Using clinical sample size calculator for an intervention study, with 0.05 alpha error and power of the study 0.80, CI of 95%. According to the literature, the early surgical intervention correction rate has been reported to vary from 30% to 60%; the mean degree of curvature correction was 75° at the time of insertion and 47° at the last follow-up. Compared to 25.7% correction, 42.9% stabilization, and Cobb angle reduction of 15° in conventional non-operative treatment, the sample size calculated to detect surgical management of early onset scoliosis cases is 18 patients [REF].

Sampling Technique

A convenient sample of patients with the inclusion and exclusion criteria will be selected and assigned to the study until the total sample size is calculated.

Ethical Consideration

The detailed study protocol was discussed and agreed on by the institutional Ethical Research Committee (Code MD-40-2022). After participants' legal guardians were adequately briefed on the study's goals, their written informed consent was obtained. The subject was free to withdraw from the study at any moment; participation was entirely voluntary. In accordance with the Declaration of Helsinki, all steps of data collecting, entry, and analysis were conducted in a highly confidential and private manner.

Pre-Operative Assessment

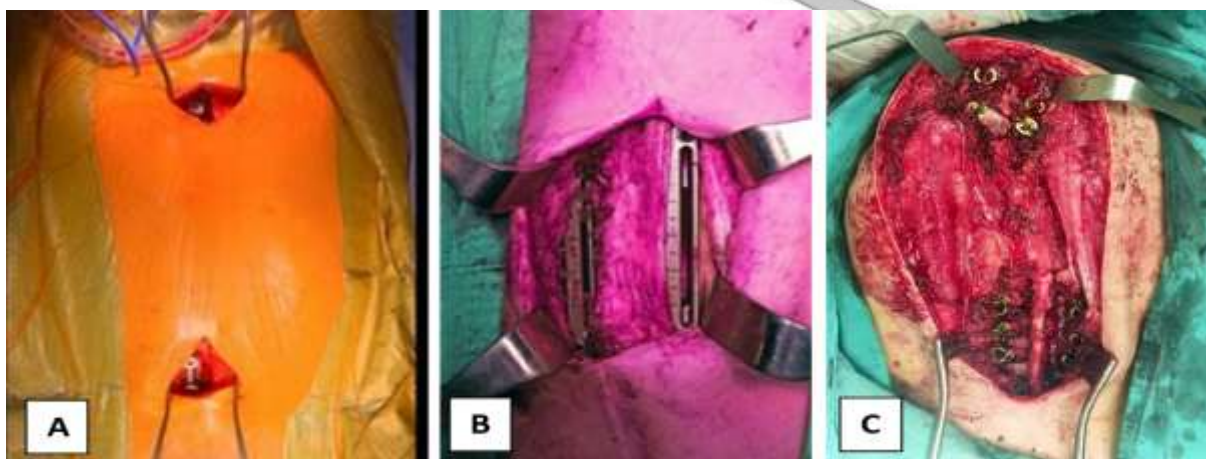
In the review of the case history, we gathered information on the diagnosis, sex, age at the commencement of treatment with expansible systems, the total number of lengthening procedures, and the interval between them. Analysis of the patients' X-rays (anterior-posterior and lateral planes) was done in the preoperative and immediate postoperative periods, along with before and after each lengthening procedure. In each X-ray, we registered the T1-S1 distance to evaluate the growth of the spinal column, and to analyze the correction of the deformity, we recorded the angle of the main curve using the Cobb technique in the coronal plane and the overall T2-T12 kyphosis in the sagittal plane. All the X-rays were calibrated. In addition, we performed a comparative analysis of longitudinal chest growth in the patients. Due to anesthesia requirements, respiratory function tests were performed in all patients preoperatively, but they were performed postoperatively only in 12 patients.

The operative technique

The Index Procedure

All patients were operated upon in a prone position with intravenous anesthesia without muscle relaxant, which was used only at induction of anesthesia. Cervical traction was done using Gardner Wells Tong, and lumbar traction was done using k-wire on both femurs. Intra-operative neurophysiological monitoring was used to assess motor evoked potential to reduce the risk of neurological deficit. Marking the two skin incisions at levels selected for upper and lower pedicle screws (or hooks anchoring on the transverse process, which was occasionally used as a salvage procedure if screw insertion was not possible) using fluoroscopy for proper level assessment. The skin incision was done, entry points for upper and lower selected pedicle screws were exposed to place them, then sub fascial rods placement bilaterally after connecting every two rods with tandem or domino connector on each side with minimal subperiosteal muscle separation to reduce fusion rate. It is worth mentioning that the mean arterial blood pressure was elevated at the time of correction to reduce the incidence of neurological deficit. Wound closure in layers [9], figure (1-A)

Lengthening Surgeries



In lengthening surgeries, a single midline skin incision was performed at the site of the connector of rods only to distract the rods bilaterally, figure (1-B)

Figure 1: A: Intra-operative image during index surgery showing two wounds for selected pedicle screw. B: Intra-operative image during lengthening procedure. C: Intra-operative image showing upper and lower pedicle screws in revision surgery

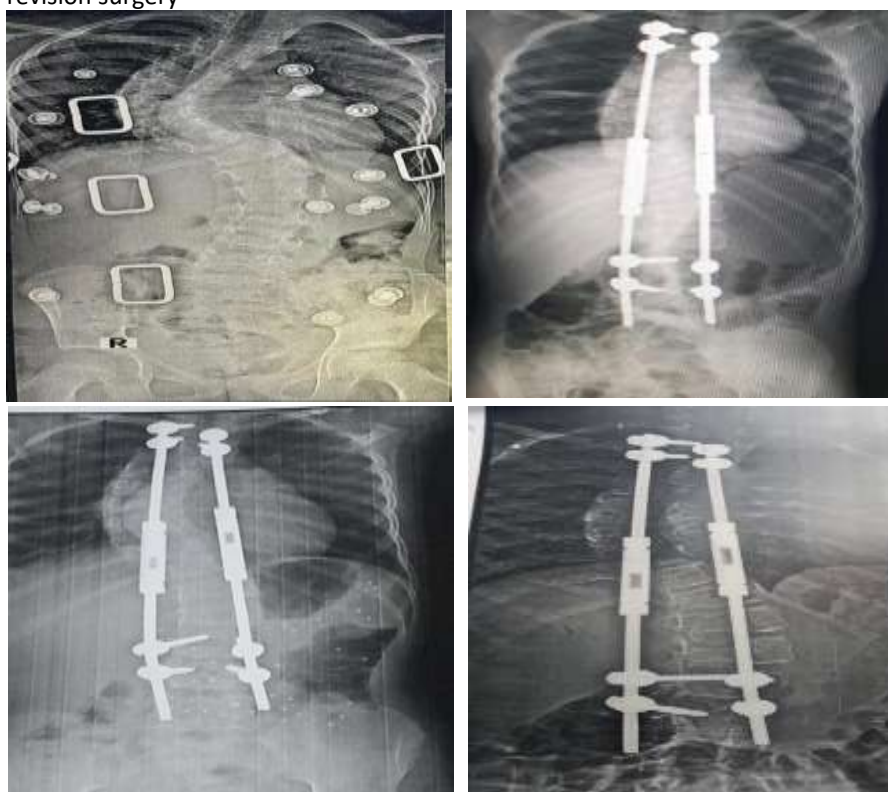


Figure 2: Serial X-ray Ap (A) preoperative (B) post-operative (C) after 1st tighten, (D) after 2nd tighten

Statistics data analysis

Data analysis was done using SPSS version 21, Qualitative data were presented by number and percentage; quantitative data were presented by mean, standard deviation (SD), median, and interquartile range (IQR). Parametric and non-parametric tests of significance were performed (chi-square, student t-test, and McNemar test), the level of significance was set at P equal to or below 0.05.

Results

This study included a series of 18 patients with EOS who underwent fusionless techniques for correction of the scoliosis. The studied patients had female predominance 55.6%. The mean age at the time of the index surgery was 6.8 ± 0.78 years, ranging from 5.5 to 8 years. The study cohort included 12 cases of idiopathic scoliosis, 5 of neuromuscular scoliosis, and 1 of congenital scoliosis. The mean follow-up time was 13 months (ranging from 11 to 15 months), with an average of 2 lengthening procedures per patient. The mean time interval between lengthening procedures was 6

months. The interval between tightening periods was not standardized and varied depending on the progression of the deformity during follow-up. The deformity was analyzed before and after the index surgery and in successive lengthening procedures after 6 and 12 months using the X-rays of the coronal and sagittal planes, the Cobb angle, T1-S1 length, and thoracic kyphosis angle. Cobb's angle decreased significantly from 79.22° pre-operatively to 43.66° immediately post-operatively, with a correction rate of 44.9% after the index surgery (P-value= 0.005). Also, a significant decrease was found when comparing pre-operative to 1st lengthening procedure (P-value= 0.007) and 2nd lengthening (P-value= 0.009). However, there was no statistically significant difference between 1st and 2nd tightening results (P-value= 0.720), table (1). There is a statistically significant decrease in the mean T1-S1 immediately post-operatively compared to pre-operative values (P-value= 0.007), where the length increased from 241.3 mm to 273.8 immediately post-operatively. Similarly, there is a statistically significant difference in the mean T1-S1 between the pre-operative and the 2nd tightening procedure results (P-value= 0.007) and a significant difference between the immediate postoperative values and the values after the 2nd tightening procedure (P-value= 0.007), table (1). A statistically significant decrease in the mean kyphosis angle from pre-operative values (a mean of 36.72°) to immediate post-operative values (a mean of 29.44°) (P-value =0.002). Furthermore, as a growth-friendly technique, after the 2nd lengthening procedure, the mean thoracic kyphosis angle was corrected to 39.44° with a statistically significant difference between the mean kyphosis pre-operatively and after the 2nd lengthening procedure was found (P-value =0.008) as well as between the mean kyphosis immediately post-operative and after the 2nd lengthening procedure (P-value =0.008), table (1).

Table 1: Cobb Angle, T1-S1, and Kyphosis changes following surgical intervention among the study participants

	Pre-operative	Immediately post-operative	Post-operative after 1 st lengthening	Post-operative after 2 nd lengthening
Cobb angle, mean ±SD	79.222° ±6.2077°	43.667°± 5.5307	41.611°± 5.1921	41.333°±5.6880
T1-S1 in mm, mean ±SD	241.333±5.3358	273.778±8.3705	--	282.111±8.3705
Kyphosis angle mean ±SD	36.722±5.2671	29.444±1.7226	--	39.444±4.0905

SD: Standard deviation.

The post-operative pulmonary function (FEV1) outcomes for all patients showed improvement in pulmonary function, with 100% of cases demonstrating an increase in FEV1. The individual percent improvement ranged from 10% to 20%, with a mean of 13% and the majority of patients falling within the 10-15% range. Additionally, 44.4% of patients experienced clinical improvement, table (2).

Table 2: Pulmonary function test (FEV1) outcomes after surgery among study participants

Variable	N (18)
Improved pulmonary function	18 (100%)
Percent of improvement:	
10.00%	2 (11.1%)
12.00%	2 (11.1%)
13.00%	1 (5.6%)
15.00%	1 (5.6%)
16.00%	1 (5.6%)
17.00%	1 (5.6%)
18.00%	1 (5.6%)
20.00%	1 (5.6%)
Clinical improvement	8 (44.4%)

The data indicates that 4 cases (22.22%) experienced a complication (5.5% each). Three patients suffered from hardware problems, two patients had misplaced rods and rod migration after the 1st lengthening procedure, and one patient had a superficial wound infection resolved after antibiotic treatment, table (3).

Table 3: Postoperative complications among study participants

Variable	N (18)	%
Wound infection	1	5.55
Rod malplacement	1	5.55
Rod migration	1	5.55
Rod breakage	1	5.55

Discussion

Long spinal fusion in patients with EOS may endanger thoracic growth and pulmonary function and is associated with an increased risk of the crankshaft phenomenon or decompensation [10]. Growth-friendly techniques for addressing EOS include distraction-based, compression-based, and growth-guided approaches, with Traditional Growing Rods (TGRs) recognized as the gold standard for long curves [11]. In our series of 18 EOS patients with structural curves (Cobb's angle $>60^\circ$), the initial surgery used TGR for scoliosis correction, followed by two distraction procedures at six-month intervals. The mean age at surgery was 6.5 years, with an average follow-up of one year. Initial curvature averaged 79.2° , improving to 41.3° at the last follow-up. Patients underwent a mean of three surgical procedures, including two lengthenings. Most of the reported studies included a somewhat similar population to the current one. McCarthy et al. [11] performed SGGs on 40 patients with EOS. The average age at the index surgery was 6 years and 11 months, and the average follow-up duration was 7 years. The average degree of curvature was 69° pre-operatively, 30° post-operatively, and 38.4° at the final follow-up [12]. Bess et al. tracked 140 patients (average age 6, follow-up 5 years) who underwent a total of 897 growing-rod procedures, achieving a mean curvature reduction from 75° to 47° over a higher number of surgeries than ours (average 6.4) and lengthenings (average 4.5) with longer intervals averaging 10.4 months [5]. For the initial surgery, the correction rate has been reported to vary from 30% to 60%, and the lengthening interval has been shown to differ for different surgeons, mostly ranging from 6 to 12 months [12]. Interestingly, the current study showed improvements in sagittal balance, with the kyphotic angle initially reducing from 36.2° to 29.4° but later worsening to 39.4° at the final follow-up. Comparative studies, such as those by Thompson et al., [13] and Hosseini et al. [14], highlighted similar outcomes using MAGEC and SGGs techniques, noting initial improvements but also risks like proximal junctional kyphosis (PJK) and varying rates of complications [15-16]. This kyphosis might be associated with complications, such as the implants in the cephalic area pulling out and the supra instrumentation kyphosis that often makes unplanned operations necessary. Research by Wilkinso et al. indicated that the apex of the fused primary curve shifted in approximately 62% of patients, often accompanied by distal migration (92%) [17]. Luhmann et al. also found the Shilla growth guidance system comparable to TGRs in terms of the degree of correction of the major curve, spinal length and growth, and maintenance of sagittal alignment, and offering an attractive alternative by significantly reducing additional surgery requirements [18]. In the present study, the preoperative height of the T1-T12 segment was recorded at 148.5 mm, which increased to 174.4 mm at the final follow-up. Similarly, the analysis indicated that the spinal column length, measured through the T1-S1 distance in the coronal plane, had an average increase of 37.2 mm after the initial surgery, rising from 241.3 mm to 273.8 mm following the placement of growing rods $P<.001$. This increase was directly associated with the correction of the spinal deformity. However, during the follow-up, there was only a slight additional increase of 9.8 mm, bringing the average to 282.2 mm after the second lengthening over one year. This limited growth may be attributed to a corresponding increase in overall kyphosis during the follow-up period, which could result in a reduced measurement of the T1-S1 distance in anterior-posterior X-rays after repeated lengthening procedures [3]. For EOS patients with good flexibility (without segmentation failure or multiple hemivertebrae at the apex), the TDGR technique combined with APSs can improve primary curve correction, maintain good correction results, and allow continuous spine growth, which may reduce the risks of complications during lengthening treatment. More multicenter prospective studies with larger samples are needed to validate the findings of this study further [19]. In a previous study, 20 patients under the age of 8 with a Risser score of 2 or less and a Cobb angle greater than 40° were evaluated [20]. The surgical approach involved a modified Shilla technique, where screws were placed on the convex side only, and no postoperative braces or casts were used. Preoperative and postoperative assessments showed significant curve correction, with the Cobb angle decreasing from 85.2° to 37.3° and improvements in thoracic kyphosis and spinal heights where T1-T12 was 146.5 mm versus 175.5 mm and T1-S1 height was 238.3 mm versus 281.1mm pre-operatively and at follow-up, respectively [21]. The results of such studies suggest that the TDGR technique with APC may enhance primary curve correction and allow for continuous spine growth, potentially reducing complications associated with lengthening treatments. However, further multicenter prospective studies with larger sample sizes are needed to validate these findings [22]. In the current study, all patients underwent three surgeries, unlike patients who operated with APC, only one operation except for complicated cases needed revision surgery. Great correction of the deformity is not expected after successive lengthening procedures, as applying excessive force during the distraction procedure could lead to implant breakage or dislodgement [23]. Furthermore, multiple lengthening procedures gradually lose their effectiveness over time due to spinal fusion. Consequently, it is advisable to consider delaying the commencement of instrumentation as long as possible. As in previous studies, in our series, we have found that the improvement in the deformity is produced fundamentally with the initial surgery. After the growing rods are implanted, no significant change in the Cobb angle is seen. In addition, if we analyze the sagittal plane, we see that an important reduction in kyphosis is achieved with the primary surgery but that the spinal kyphosis gradually increases throughout follow-up [24]. In the current study, the overall complication rate was 22.22%, which included incidents of superficial wound infections, rod malplacement, breakage, and distal rod migration; however, this was noted during a one-year follow-up period. A comprehensive analysis of complications associated with growing rods and MAGEC devices reveals significant concerns regarding patient outcomes. Bess et al. identified a complication rate

of 57.9% among 81 patients, highlighting that the risks of complications decrease by 13% for each additional year of patient age at the start of treatment while increasing by 24% with each additional surgical procedure. This suggests that deferring treatment until the patient is older might be beneficial, provided the spinal deformity remains manageable [25]. Common complications from growing rod techniques include implant failures, infections, and wound healing issues, often exacerbated by repeated lengthening procedures and unfused spines. The overall complication rate for the growing rod technique can reach as high as 40%, with risks linked to factors such as younger age at initial surgery, single-rod constructs, longer lengthening intervals, and specific spinal alignments. In a systematic review of MAGEC, complications were reported in 44.5% of patients, with high rates of unplanned revision surgeries (33%) and notable issues like implant failure 11.7% and rod breakage 10.6% [26]. A separate study indicated an alarming overall complication rate of 73% at medium-term follow-up for MAGEC, particularly due to instrumentation issues and necessary unplanned revisions [27-28]. Overall, the data underscores the importance of careful patient selection, informed consent, and diligent follow-up to minimize complications in both growing rod and MAGEC treatments.

Limitations

The heterogeneity of the study population, 12 cases of idiopathic scoliosis, 5 of neuromuscular scoliosis, and 1 of congenital scoliosis, resemble a limitation of our results. Also, the follow-up period lasted only one year, which could have given a clearer image of the long-term results. Adding to that, the noncompliance of some patients to the treatment protocol.

Conclusion

Overall, while TGRs and other growth-guided systems show promise in managing EOS, they come with significant rates of implant-related complications and surgical revisions. Our findings contribute to the ongoing evaluation of these techniques in relation to spinal growth dynamics and surgical efficacy with lower prices.

Conflict of interest

Authors declare no conflict of interest is present.

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