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Decision Making of Graduation in Patients With Early-Onset Scoliosis at the End of Distraction-Based Programs: Risks and Benefits of Definitive Fusion

Javier Pizones, MD, PhD*, Mar Pérez Martín-Buitrago, MSc, José Miguel Sánchez Márquez, MD, PhD, Nicomedes Fernández-Baíllo, MD, Montserrat Baldan-Martin, MSc, PhD, Francisco Javier Sánchez Pérez-Grueso, MD

Spine Unit, Department of Orthopaedic Surgery, Hospital Universitario La Paz, Madrid, Spain

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Abstract

Study Design: Retrospective comparative analysis.

Objective: Study early-onset scoliosis (EOS) graduated patients to establish founded criteria for graduation decision making and determine the risks and benefits of definitive fusion.

Summary of Background Data: EOS is treated by growth-friendly techniques until skeletal maturity. Afterwards, patients can be ''graduated,'' either by definitive fusion (posterior spinal fusion [PSF]) or by retaining the previous implants (Observation) with no additional surgery. Criteria for this decision making and the outcomes of definitive fusion are still underexplored.

Methods: We analyzed a consecutive cohort of ''graduated'' patients after a distraction-based lengthening program. We gathered demographic, radiographic, and surgical data. The results of the two final treatment options were compared after 2 years' follow-up.

Results: A total of 32 patients were included. Four patients had incomplete records. Thirteen underwent PSF, and 15 were observed. The mean age at initial treatment was 8 ± 3 years, with a mean follow-up of 8.3 ± 2.9 years. Both groups had similar preoperative and final radiographic parameters ($p > .05$). The criteria for undergoing PSF were as follows: implant-related complications, main curve magnitude (PSF = 63.2° ± 9° vs. OBS = 47.9° ± 15°; $p = .008$), curve progression >10°, and sagittal misalignment (SVA).

During PSF 12/13 patients underwent multiple osteotomies, one vertebrectomy, and 3 costoplasties. Surgical time was 291.5 ± 58 minutes; blood loss was 946 ± 375 mL; and the number of levels fused was 13.7. Coronal deformity was corrected 31%, T1–S1 length gained was 31 ± 19.6 mm and T1–T12 length gained was 9.3 ± 39 mm; kyphosis was reduced by 22%. However, coronal balance worsened by 2.3 ± 30.8 mm. No major complications were encountered in these patients.

Conclusions: Graduation by PSF depended on unacceptable or progressive major curve deformity, sagittal misalignment, or complications with previous implants. Observation depended on curve stabilization, Cobb <50°, and coronal misalignment <20 mm. Definitive fusion effectively corrected coronal and sagittal deformity and increased trunk height. However, it exposed patients to a very demanding surgery without improvement in coronal balance.

Level of Evidence: Level III, therapeutic.

Keywords: Early onset scoliosis; Traditional growing rods; VEPTR; Graduation; Thoracic lengthening; Scoliosis surgery; Scoliosis treatment; Observation

Introduction

For the management of immature patients with early-onset scoliosis (EOS), the aim is to delay final fusion as much as possible [1]. Distraction-based methods are one of the growth-friendly techniques that have been proposed to delay final fusion [2]. They allow deformity correction while preserving thoracic cage growth and pulmonary maturation, which occurs mainly during the first eight years of life [3,4].

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*Corresponding author. Department of Orthopaedic Surgery, Hospital Universitario La Paz, Paseo de la Castellana 261 28046, Madrid, Spain. Tel.: 0034616644876; fax: 0034913591351.

E-mail address: javierpizones@gmail.com (J. Pizones).

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When skeletal maturity is reached, these patients can be "graduated," either by definitive spinal fusion or by retaining the previous implants with no additional surgery. Flynn et al. tried to set the indications for final fusion in patients with limited remaining growth potential [5]. However, the authors were unable to identify the cause of final fusion in one third of their patients. Recently, Jain et al. [6] reported that in certain patients this final fusion can be avoided, especially in those patients with satisfactory alignment and trunk height, minimal gain in length at the last distraction, and no evidence of implant-related problems. However, these studies were both multicenter and limited by two facts. First, the decision-making process was impossible to accurately determine. Second, the criterion for considering a patient graduated was simply a lack of reported lengthenings after 2 years of follow-up.

The objective of this study was to evaluate the medical records from a cohort of consecutive EOS patients treated with distraction-based techniques until skeletal maturity to establish founded criteria for "graduation" decision making and determine the outcomes in terms of risks and benefits of definitive fusion.

Material and Methods

We retrospectively reviewed the records of a consecutive cohort of "graduated" EOS patients after a distraction-based lengthening program at a single institution. Patient's minimum follow-up after final decision (posterior spinal fusion or observation) was set at 2 years. We excluded patients who had not yet finished the lengthening program. All parents signed the informed consent documents and were aware of the clinical study, which followed the Declaration of Helsinki principles. The study had institutional review board approval.

Demographic data (gender, age, etiology, and type of scoliosis) were recorded. Surgical data of the distraction program were reviewed: type of instrumentation used, number of lengthenings, number of total surgeries, number of revisions, and levels fused. Patients were radiographically and clinically explored every six months, and lengthenings were performed once a year, except if unacceptable curve progression was discovered earlier.

Charts were reviewed to determine when decisions for final treatment were made and the reason for those decisions. Then, the cohort was divided into two subgroups: patients who underwent final posterior spinal fusion (PSF group) and patients retaining the previous implants with no additional surgery (observation group). For final PSF surgery, we gathered the number and types of osteotomy, surgical time, estimated blood loss, number of levels fused, and surgical complications.

Standing frontal and lateral radiographs were analyzed at different time points: before the initial surgery, after first device implantation, after the last lengthening, the date when final decisions were made, after posterior fusion surgery, and at final follow-up. In patients for whom observation was chosen, only the final follow-up was reviewed after the decision date. The following variables were measured: the coronal Cobb angle of the main curve and of the compensatory curves, the coronal balance, the thoracic T1–T12 height, the T1–S1 length, the thoracic T1–T12 kyphosis, the L1–S1 lumbar lordosis, and the sagittal vertical axis (SVA). Preoperative and final pulmonary function tests (PFTs) values were gathered. All complications were recorded.

Descriptive statistics were calculated using SPSS software (version 18, SAS Institute Inc., Cary, NC). The results of the two final treatment options were compared after 2 years' follow-up using nonparametric analysis (Mann-Whitney U) and chi-square. For PFT analysis, paired comparisons were performed with the Wilcoxon test.

Results

Thirty-two patients met the inclusion criteria. Four patients were excluded because of incomplete records. Scoliosis etiology was as follows: 28% neuromuscular, 25% syndromic, 18% congenital, 14% idiopathic, and 14% thoracogenic. A total of 23 patients were treated with traditional growing rods, and 5 were treated with vertical expandable prosthetic titanium rib (VEPTR).

From the whole cohort, the mean age at initial treatment was 8 ± 3 years, and the mean follow-up from the beginning of treatment was 8.3 ± 2.9 years. Thirteen patients underwent final PSF, and 15 patients were observed. Both groups had a similar number of lengthenings with a total mean of 5.1 ± 2.2, and a similar age at the different analyzed time points (Table 1). There was no significant difference between groups with regard to preoperative and final radiographic parameters ($p > .05$) (Tables 2 and 3).

Mean age when treatment decisions were made was 14.4 ± 2 years; no difference in age at decision making was found between groups. Decisions to undergo final PSF were associated with congenital scoliosis, while decisions for observation were associated with neuromuscular scoliosis. The comparison between the PSF group and the

Table 1
Comparison of demographic data between fused and observed graduated EOS patients.

Data	PSF	OBSV	p
Number of patients	13	15	
Initial age, years	8.2 (3.5); 7.8	7.9 (2.6); 8.8	.7
Age at last lengthenings, years	13.2 (1.9); 13	12.7 (1.7); 13.1	.6
Age at decision, years	15 (2.2); 15.4	13.8 (1.8); 14.1	.2
Final age, years	16.8 (1.9); 17	16 (1.6); 15.7	.1
Follow-up, years	8.7 (3.7); 9.2	8 (2.3); 8	.4
Number of lengthenings	5.5 (2.7); 7	4.7 (1.7); 5	.3
Gender	6 M/7 F	3 M/12 F	.1

EOS, early-onset scoliosis; F, female; M, male; OBSV, observation; PSF, posterior spinal fusion.

Data are expressed as mean (standard deviation); median.