

# EFFICACY AND SAFETY OF GROWING RODS IN THE TREATMENT OF SCOLIOSIS IN CHILDREN UNDER 10

EFICÁCIA E SEGURANÇA DE HASTES DE CRESCIMENTO NO TRATAMENTO DA ESCOLIOSE EM CRIANÇAS MENORES DE 10

EFICACIA Y SEGURIDAD DE LAS BARRAS DE ALARGAMIENTO EN EL TRATAMIENTO DE ESCOLIOSIS EN NIÑOS MENORES DE 10 AÑOS

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## ABSTRACT

**Objective:** To determine the efficacy and safety of growing rods in the treatment of scoliosis in children aged under 10 years. **Methods:** A retrospective review of medical records of patients under 10 with scoliosis, treated with growing rods from the period between 1997 and 2012. **Results:** We identified 35 patients treated with growing rods who met the selection criteria. The average age at the start of treatment was  $5.9 \pm 2.3$  years. Most of the patients (51.4%) showed idiopathic etiology scoliosis. Pre-surgery and post-surgery radiographic change showed a 47.7% reduction in Cobb angle ( $p > 0.001$ ). We identified 8 patients with some complication, the most prevalent being instrumentation failure (22.9%). The only predicting factor for post-operative complications was the total number of lengthenings performed (OR=7.03; CI 95% [1.1-45.4];  $p=0.040$ ). **Conclusions:** Treatment of scoliosis with growing rods in patients aged under 10 achieved a significant reduction in the magnitude of the deformity before final bone fusion. However, the rate of complications is rather high, therefore we recommend reducing the frequency of lengthenings to the minimum needed to maintain correction and longitudinal growth of the spine. **Level of Evidence IV; Case series.**

**Keywords:** Scoliosis; Prostheses and implants; Child; Spinal curvature.

## RESUMO

**Objetivo:** Determinar a eficácia e segurança de hastes de crescimento no tratamento de escoliose em crianças menores de 10 anos. **Métodos:** Revisão retrospectiva de prontuários de pacientes menores de 10 anos com escoliose, tratados com hastes de crescimento entre 1997 e 2012. **Resultados:** Identificamos 35 pacientes, que foram tratados com hastes de crescimento, que satisfizeram os critérios de seleção. A idade média no início do tratamento foi de  $5,9 \pm 2,3$  anos. A maioria dos pacientes (51,4%) apresentou escoliose de etiologia idiopática. A alteração radiográfica pré e pós-operatória mostra uma redução de 47,7% do ângulo de Cobb ( $p > 0,001$ ). Foram identificados 8 pacientes com alguma complicação, sendo falha de instrumentação a mais prevalente (22,9%). O único fator preditivo para complicações pós-operatórias foi o número total de alongamentos realizados (OR = 7,03; IC95% [1,1-45,4];  $p = 0,040$ ). **Conclusão:** O tratamento para escoliose em pacientes com menos de 10 anos com hastes de crescimento alcançou uma redução significativa na magnitude da deformidade antes da fusão óssea final. No entanto, a frequência de complicações é bastante alta e, para isso, recomendamos reduzir ao mínimo a frequência de alongamentos, a fim de manter a correção e o crescimento longitudinal da coluna. **Nível de Evidência IV; Série de casos.**

**Descritores:** Escoliose; Próteses e implantes; criança; Curvaturas da coluna vertebral.

## RESUMEN

**Objetivo:** Determinar la eficacia y seguridad de las barras de alargamiento en el tratamiento de la escoliosis en niños menores de 10 años. **Métodos:** Revisión retrospectiva de registros médicos de pacientes menores de 10 años con escoliosis, tratados mediante barras de alargamiento entre 1997 y 2012. **Resultados:** Se identificaron 35 pacientes tratados con barras de alargamiento que satisfacían los criterios de selección. El promedio de edad al inicio del tratamiento fue de  $5,9 \pm 2,3$  años. La mayoría de los pacientes (51,4%) tenían escoliosis de etiología idiopática. El cambio radiográfico quirúrgico y postquirúrgico mostró reducción del 47,7% en el ángulo de Cobb ( $p > 0,001$ ). Se identificaron 8 pacientes con alguna complicación, siendo el fallo del instrumental más prevalente (22,9%). El único factor predictor de complicaciones postoperatorias fue el número total de alargamientos realizados (OR = 7,03; IC 95% [1,1-45,4];  $p = 0,040$ ). **Conclusiones:** El tratamiento de la escoliosis con barras de alargamiento en pacientes menores de 10 años logró una reducción significativa de la magnitud de la deformidad antes de la fusión ósea definitiva. Sin embargo, la tasa de complicaciones es bastante alta, por lo cual se recomienda disminuir la frecuencia de alargamientos al mínimo necesario para mantener la corrección y el crecimiento longitudinal de la columna vertebral. **Nivel de Evidencia IV; Serie de Casos.**

**Descriptores:** Escoliosis; prótesis e implantes; Niño; Curvaturas de la columna vertebral.

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## INTRODUCTION

The treatment of scoliosis in patients under 10 aims to reduce the magnitude and maintain the correction of the deformity while the longitudinal growth of the spine takes place, allowing expansion of the thorax and development of lung parenchyma.<sup>1</sup>

Four systems are currently used for surgical treatment of patients under 10 with scoliosis: single growing rods, dual growing rods, vertical expandable prosthetic titanium ribs (VEPTR), and magnet-controlled growing rods;<sup>1-5</sup> currently, growing rods are the standard treatment, and are therefore the most widely used therapy worldwide.<sup>1,6</sup>

Harrington rods are considered the precursors of the lengthening methods available nowadays.<sup>7</sup> In the late 70s and early 80s, these rods were used without vertebral fusion in patients with EPAT. They were inserted under the subcutaneous cellular tissue to produce stabilizing effects, rather like an "internal brace", which was complemented with an external postoperative brace.<sup>7</sup> The rods were periodically elongated upon finding an increase of 10 or more degrees in the deformity, which explains the unsatisfactory results of this treatment.<sup>7</sup> In addition, the instrumented segments only achieved 84% of the expected longitudinal growth, which contravened the purpose of the treatment.<sup>8</sup>

The lengthening systems available nowadays not only preserve the longitudinal growth of the spine;<sup>9</sup> Swine models and EPAT patient follow-ups have shown that the distraction forces they exert accelerate apophysis growth in the axial skeleton,<sup>9-11</sup> thereby achieving an increase in T1-S1 length that varies from 1 to 1.8 centimeters per year.<sup>12-14</sup>

Despite their efficacy in preserving the growth of the spine, one of the main disadvantages of growing rods are the complications related to instrumentation, or those associated with multiple extension procedures.<sup>14-18</sup>

The purpose of this study is to describe the efficacy and safety results of surgical treatment of scoliosis in children under 10 using growing rods, at a Colombian reference center.

## METHODS

Our ethics committee and the institutional review board approved the research protocol for this study. The authors declare no conflicts of interest in the performance of this work. We carried out a retrospective study of a series of cases in which we reviewed the clinical history records of patients under 10 diagnosed with scoliosis, treated in the Roosevelt Children Orthopedics Institute (IOIR, its acronym in Spanish) from the period between 1997 and 2012.

We carried out a convenience sampling, including all scoliosis patients who received surgical treatment with elongating rods in the period studied, and excluded all patients diagnosed with syndromic scoliosis, and with incomplete records in their clinical history.

Patients who, after surgical treatment, presented a Cobb angle of over 40 degrees, those with curves of between 20 and 40 degrees, and those who showed a progression in the deformity of more than 5 degrees despite the use of a brace, were also excluded. Treatment was only applied in patients with skeletal immaturity, under a clinical and radiological evaluation (Risser sign  $\leq 2$ ).

The following variables were recorded during the data collection: sex, age at the time of surgery, etiology of the scoliosis, number of rods inserted, preoperative and postoperative Cobb angle<sup>19</sup>, time between lengthenings, total number of lengthenings performed, surgery time, estimated bleeding, and rate of complications.

### Statistical Analysis

For quantitative variables, the central tendency and dispersion measures were calculated; for categorical variables, proportions were calculated. Statistical differences between preoperative and postoperative Cobb angle were obtained through t-student test for related samples. The relation between the presence of complications and the possible predictor variables was assessed in univariate analysis using the t-student test for independent samples

in continuous variables, and ji2 for dichotomous variables. The regression model<sup>20</sup> was built including those variables  $p < 0.250$  in the univariate analysis and in those significant variables within the model, the Odds Ratio (OR) is reported, with the corresponding 95% confidence interval (CI 95%).

All statistical analyses were performed with IBM SPSS (Statistical Package for the Social Sciences) statistical software, version 2.0 (SPSS, Inc., Chicago, IL, USA).

### Ethical Considerations

Given its observational design, this study has no ethical limitations regarding treatment indications; however, for the data gathering, we received the informed consent from patient's relatives. We also received approval from the Institutional ethics committee.

## RESULTS

A total 721 cases of scoliosis in patients under 10 were reviewed. Of these, 35 (5%) required surgical treatment with growing rods and met the selection criteria. Table 1 shows the characteristics of the sample. Table 2 summarizes the information on the surgical procedures performed.

The presurgical and postsurgical radiographic change showed a 47.7% reduction in the Cobb angle ( $31.8^\circ \pm 14.6^\circ$  difference), which was statistically significant ( $p < 0.001$ ; t-student).

During the study period, 8 patients (22.9%) showed some procedure-related complication; another 8 patients (22.9%) showed instrumentation failures, and 2 cases (5.7%) showed infection in the operated area which, it should be noted, was associated with instrumentation failure. Univariate analysis was performed to define which variables could be potential predictor factors of complications in our patient sample (Table 3).

Univariate analysis demonstrated that male gender, idiopathic and neuromuscular scoliosis diagnoses, preoperative Cobb angle and the number of lengthenings performed were potential predictor factors of postoperative complications ( $p < 0.05$ ), and were therefore included in a bivariate logistic regression model. This model showed that for every two lengthenings performed on patients in the sample, the risk of complications increased by a factor of 7 ( $\beta = 1.951$ ; OR=7.03; CI 95% [1.1-45.4];  $p = 0.040$ ). For the other preselected variables, no statistical significance was reached.

**Table 1.** Study sample characteristics.

Male gender	20 (57)
Age at time of surgery*	5.9 $\pm$ 2.3 years
Infantile idiopathic scoliosis	18 (51.4)
Congenital scoliosis	11 (31.4)
Neuromuscular scoliosis	6 (17.1)
Preoperative Cobb angle *	66.7 $\pm$ 14.4 degrees
Follow-up*	27.0 $\pm$ 15.7 months

Results are shown in frequencies, and proportions for each group appear in parenthesis; \* average  $\pm$  standard deviation.

**Table 2.** Surgical information.

Surgeries to place the system	35
System composition	
One rod	2 (6)
Two rods	33 (94)
Surgery time (min)*	233.4 $\pm$ 19.3
Intrasurgical bleeding (mL)	129.9 $\pm$ 13.4
Surgeries to elongate the system	106
Lengthenings per patient†	3 [2-4]
Months between lengthenings*	9.4 $\pm$ 6.1
Surgery time (min)*	118.2 $\pm$ 10.1
Intrasurgical bleeding (mL)	45.0 $\pm$ 42.4

Results are shown in frequencies and, proportions for each group appear in parenthesis; min: minutes; mL: milliliters; \* average  $\pm$  standard deviation † median [interquartile range]

**Table 3.** Univariate analysis of potential complication predictor factors.

Variable	Patients with complications (n = 8)		Patients without complications (n = 27)		p
	Frequency	Proportion (%)	Frequency	Proportion (%)	
Males	2	(25.0)	18	(66.7)	0.051
Two-rod fixation	7	(87.5)	26	(96.3)	NS
Idiopathic scoliosis	2	(25.0)	16	(59.3)	0.121
Neuropathic scoliosis	3	(37.5)	3	(11.1)	0.117
Congenital scoliosis	3	(37.5)	8	(29.6)	NS
Preoperative Cobb angle*	73.13	± 13.26	64.85	± 14.3	0.156
Number of lengthenings performed†	4	[3.25-5]	3	[2-4]	0.016

Results are shown in frequencies and, proportions are shown in parenthesis; \* average ± standard deviation † median [interquartile range].

## DISCUSSION

This study gathered, retrospectively, the results of the use of growing rods in the treatment of scoliosis patients aged under 10, including idiopathic, congenital, and neuromuscular scoliosis.

In this study, we found a statistically significant reduction in the preoperative Cobb angle of 47.7% vs. the postoperative angle. This degree of correction is slightly lower than that reported in literature,<sup>14,21-23</sup> which may be explained by the fact that the data was gathered from images prior to the final surgery, after which we would expect additional correction in most patients.<sup>24,26,27</sup>

In regards to the frequency of the lengthenings, our usual practice is to indicate them after six months; however, the median of the intervals between surgeries in this series was 8 months, which may possibly be due to logistic problems in the health system. Although the optimum interval between lengthenings is still unknown, and neither is it clear whether this interval should vary depending on the longitudinal growth peaks of the spine, preliminary studies indicate that patients who are subject to lengthenings at intervals of 6 months or less have a higher yearly growth rate (1.8 cm vs. 1.0 cm;  $P=0.018$ ), and a higher rate of definitive deformity correction (79% versus 48%;  $P = 0.007$ ) than patients in whom they were performed more frequently.<sup>12</sup>

The frequency of complications observed in the present study was within expectations, corroborating with literature (23.3% to

58%<sup>15</sup>).<sup>14-18</sup> The most frequent complications were related to instrumentation failure, particularly disconnections, loosening of the fixation points, and rod ruptures. These findings match the findings of a retrospective study carried out in 12 spine surgery units in Japan, which reported that implant failure accounted for 72% of the total complications recorded in patients with extension systems.<sup>28</sup> This is similar to the frequency described by other groups.<sup>14-18</sup>

In this study, the only factor related to postoperative complications was the number of lengthenings performed. Similarly, a multicenter study carried out by the Growing Spine Study Group also recently described this relation; estimating a 24% increase in the risk of complications for every additional procedure performed.<sup>15,28</sup> Based on these findings, it is advisable to delay the start of treatment, and minimize the frequency of the lengthenings as much as possible, in order to preserve the correction and the longitudinal growth of the spine.

Although the results of this study are quite similar to those reported in the literature, it is important to recognize several shortcomings of the study due to its retrospective design. For example, study sample does not strictly represent the total population attended during the described period, due to possible losses during some patient follow-ups (memory bias).

In addition, this study did not collect data on T1-S1 distances before and after each procedure, a difference that has been used in other studies as a secondary indicator of treatment effectiveness.<sup>22,25,29,30</sup> Neither did it record the behavior of sagittal curves, although prior studies have shown that growing rods maintain, and may even improve these parameters.<sup>25,28</sup>

## CONCLUSION

Treatment of scoliosis in patients under age 10 with growing rods has achieved a significant reduction in the magnitude of the deformity before final bone fusion. However, the rate of complications is rather high, and for this reason, we recommend reducing the frequency of lengthenings to a minimum, in order to maintain the correction and longitudinal growth of the spine.

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