

Distraction-to-stall Versus Targeted Distraction in Magnetically Controlled Growing Rods

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Background: Consensus is lacking regarding the lengthening procedures in magnetically controlled growing rods (MCGR), and no studies have compared the outcome between different distraction principles. The purpose of the present study was to compare distraction-to-stall with targeted distraction and identify variables associated with achieved distraction.

Methods: We performed a 2-center retrospective study of all children treated with MCGR from November 2013 to January 2019, having a minimum of 1-year follow-up and undergoing a minimum of 3 distractions. Exclusion criteria were single-rod constructs and conversion cases. In group 1 (21 patients), we used a distraction-to-stall (maximum force) principle where each rod was lengthened until the internal magnetic driver stopped (clunking). In group 2 (18 patients), we used a targeted distraction principle, where the desired distraction was entered the remote control before distraction. In both groups we aimed for maximal distraction and curve correction at index surgery. Achieved distraction was measured on calibrated radiographs and compared between the 2 groups using a linear mixed effects model. Univariate and multivariate analyses were performed to identify variables associated with achieved distraction within the first year.

Results: Mean age at surgery was 9.5 ± 2.0 years. Etiology of the deformity was congenital/structural ($n = 7$), neuromuscular ($n = 9$), syndromic ($n = 3$), or idiopathic ($n = 20$). Demographics and preoperative characteristics including spinal height (T1T12 and T1S1) did not differ significantly between the groups ($P \geq 0.13$). Time interval between distractions were mean 18 days (95% confidence interval: 10-25) shorter in group 1. Implant-related complications occurred in 10/39 patients, 5 in each group. We found no difference

in achieved distraction between the groups in the linear mixed effects model. In the multivariate analysis, preoperative major curve angle was the only independent variable associated with achieved distraction.

Conclusions: In 2 comparable and consecutive cohorts of patients treated with MCGR, we found no difference in achieved distraction between a distraction-to-stall and a targeted distraction principle. Preoperative major curve angle was the only independent predictor of achieved distraction.

Level of Evidence: Level III—retrospective comparative study.

Key Words: magnetically controlled growing rods, early-onset scoliosis, distraction, lengthening, growth, spinal height, thoracic height, spinal growth

(*J Pediatr Orthop* 2020;40:e811–e817)

Magnetically controlled growing rods (MCGR) has become one of the preferred surgical treatments of early-onset scoliosis (EOS).¹ The goal of the surgery is to halt progression of the deformity while allowing continuous growth of the spine. However, the technique is relatively new and despite showing advantages over traditional growing rods,^{2,3} the complication and revision rate remains high.⁴ Moreover, few studies have presented outcomes of patients undergoing final fusion after graduating from MCGR treatment.^{5,6} There is little consensus regarding indications and timing of surgery in EOS.⁷ For MCGR, there is no consensus regarding magnitude of distraction, ideal distraction length per distraction, technique and time interval between the lengthening procedures.^{1,8,9} Various distraction principles have been described. The “tail-gating” principle follows published growth charts¹⁰ with achieved distraction monitored after each distraction using ultrasound or fluoroscopy.^{5,11,12} In the maximum force distraction or distraction-to-stall principle the rods are lengthened until the internal magnetic driver stops (clunking) or the patient reports discomfort.¹³ Finally, a targeted distraction can be performed based on approximated growth without monitoring achieved distraction after each lengthening. Studies of MCGR so far show a discrepancy between the achieved distraction and the amount expected from the external remote controller (ERC).^{14–17} This is thought to be caused

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B.D. and M.G. received institutional grants from K2M and Medtronic. B.D. performed advisory board work for K2M. The remaining authors declare no conflicts of interest.

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DOI: 10.1097/BPO.0000000000001585

by increased tissue resistance against distraction due to stiffness and/or autofusion of the spine,^{16,17} and possibly also a lower force generated by the MCGR as the rods are lengthened.¹⁸ The different distraction principles and equipoise regarding indications and timing of surgery highlight the need for studies examining the outcome of different lengthening procedures. The purpose of this study was to compare achieved distraction between a targeted distraction and a distraction-to-stall principle. Second, we wanted to identify variables possibly affecting achieved lengthening.

METHODS

All patients regardless of etiology treated with MCGR at 2 tertiary referral centers from November 2013 through January 2019 were registered. Inclusion criteria were minimum 1-year follow-up and minimum 3 distractions. Exclusion criteria were single-rod constructs and conversion from other growth instrumentations. We identified 58 patients treated with MCGR in the study period; 11 patients did not fulfill the follow-up criteria, 3 had single-rod constructs and 5 were conversions, leaving 39 patients for analysis. From the first center we included 21 patients (group 1),¹³ and from the second center 18 patients (group 2). Patients were followed throughout the study period or until definitive fusion surgery.

Both centers used the same operative technique with dual rod constructs in accordance with international recommendations.^{1,9} Maximal curve correction and distraction were intended intraoperatively during insertion of the rods. The rods were contoured, and the actuator tested manually before insertion. Anchor point fixations were performed with pedicle screws, where applicable, and/or otherwise hooks. Additional hooks and cross-links were added at the discretion of the surgeon.

The lengthening procedures were generally performed in the outpatient clinic with the patient lying on the side or in a prone position according to the patient's preference. Position of the patient was not consistently reported in the patient files; however, the primary author and one of the coauthors participated in lengthening procedures at both centers. Distractions were performed on each rod separately. In group 1 we used a distraction-to-stall principle where distraction was stopped when clunking was felt or before if the patient reported discomfort; in group 2 we used a targeted distraction principle where the targeted amount was decided by the treating surgeon. For both groups, curve correction, implant failure and achieved distraction were monitored with radiographs every 6 months.

DATA

From a chart review we collected baseline characteristics including primary diagnosis, information about the surgery and lengthening procedures. Etiology was defined according to the Classification of Early-Onset Scoliosis (C-EOS).¹⁹ Complications were defined as infection- or implant-related.²⁰ Spinal height (T1S1), thoracic height (T1T12) and achieved distraction on both rods were measured at each

radiographic assessment by the primary author according to previously reported methods.²¹ Achieved distraction was reported as the mean of measurements between the 2 rods. Total achieved distraction within the first year was calculated for each patient. All images were calibrated with the diameter of the actuator to account for magnification error. Radiographs were uploaded to the validated online imaging software KEOPS (SMAIO, Lyon, France)²² where major curve angle and global kyphosis was measured. T1T12 and T1S1 were measured preoperatively and postoperatively, at 1- and 2-year follow-up.

The study was approved by the local institutional review board (BCM H-43238), local health authorities (j.nr: 3-3013-1911/1) and data protection agency (j.nr.: 2012-58-0004).

STATISTICS

Statistical analyses were performed using R, version 3.5.3. Data were assessed with histograms, scatter plots and quantile-quantile plots and presented as proportions (%), mean $\pm$ SD or medians with interquartile range. Repeated measures of spinal height and achieved distraction were visualized in linear plots. Categorical data were compared using Fisher exact test and continuous data with Student *t* test or Wilcoxon rank sum test. Achieved distraction over time was compared between the 2 groups with a fitted linear mixed effects model adjusting repeated measures for number of instrumented levels and differences in follow-up. Univariate analyses were performed to identify variables associated with achieved distraction within the first year. The variables included in the analyses were predetermined based on parameters previously reported in the literature.^{5,6,8,14-16,23-27} A multiple linear regression was performed to control for any potential confounding including variables significantly associated with achieved distraction in the univariate analysis ($P < 0.05$). The model was checked for interactions.

RESULTS

We included 39 patients treated with MCGR with a mean age at primary surgery of 9.5 ± 2.0 years. Mean follow-up to most recent distraction or definitive surgery was 28.1 ± 10.9 months with an average 11.2 months longer follow-up in group 1 ($P < 0.001$). All patients completed 1-year follow-up. One patient continued treatment at another hospital after 1 year and was lost to follow-up, and 2 patients underwent definitive surgery within 2 years from primary surgery. Furthermore, 9 patients did not reach 2-year follow-up within the study period resulting in 27 patients for radiographic assessment at 2-year follow-up. Etiology was congenital/structural in 7, neuromuscular in 9, syndromic in 3 and idiopathic in 20 patients, with no difference in distribution between the 2 groups (Table 1). There was no difference between the groups regarding preoperative major curve angle and kyphosis, curve correction, instrumentation length or preoperative T1T12 or T1S1 (Table 1). However, the mean time interval between lengthening was 18 days (95% confidence interval: 10-25) longer in group 2 compared with

TABLE 1. Demographic Data and Comparison of Baseline Variables Between the Groups

	Group 1 Distraction-to- Stall (n = 21)	Group 2 Targeted Distraction (n = 18)	P
Age at index surgery (y)	9.6 (1.8)	9.4 (2.3)	0.781
Sex (female) [n (%)]	10 (48)	11 (61)	0.523
Etiology [n (%)]			0.465
Congenital/structural	4 (19)	3 (17)	
Idiopathic	9 (43)	11 (61)	
Neuromuscular	5 (24)	4 (22)	
Syndrome	3 (14)	0	
Preoperative major curve angle (deg.)	73 (18.1)	82 (18.7)	0.138
Preoperative global kyphosis (deg.)	45.2 (21.7)	42.3 (20.9)	0.687
Curve correction [n (%)]	39.5 (15.5)	34.9 (11.5)	0.302
Mechanical complication [n (%)]	5 (24)	5 (28)	1
Medical complication [n (%)]	2 (10)	1 (6)	1
Unplanned reoperation [n (%)]	5 (24)	4 (22)	1
Time interval between lengthening (d)	78.5 (27.2)	96.2 (35.5)	< 0.001
Instrumentation length [median (range)]	12 (11-17)	12 (10-17)	0.293
Rod diameter [n (%)] (mm)			0.011
4.5	5 (24)	12 (67)	
5.5	16 (76)	6 (33)	
Preoperative T1T12 (mm)	182.6 (31.8)	175.4 (34.4)	0.509
Postoperative T1T12 (mm)	203.7 (29.9)	198.3 (26)	0.547
Preoperative T1S1 (mm)	296.1 (48.3)	294.1 (50)	0.899
Postoperative T1S1 (mm)	334.1 (42.9)	326.2 (41.1)	0.560

Bold indicates significance level $P < 0.05$.

Data are presented as means (SD) unless otherwise specified.

group 1. Complications were screw loosening (n=5), hook/rod dislodgement (n=2) and rod breakage (n=3). All rod breakages occurred with 4.5 mm rods. Medical complications

were aspiration pneumonia (n=1), superficial wound infection (n=1), and deep infection (n=1). We found no difference in complication or unplanned reoperation rates between the groups (Table 1).

The mean major curve angle between both groups was reduced from 77 ± 19 degrees preoperatively to 49 ± 18 degrees postoperatively, and correction was maintained at 1-year (51 ± 16 degrees) and 2-year (51 ± 14 degrees) follow-up ($P < 0.001$) (Fig. 1A). Similarly, mean global kyphosis was reduced from 44 ± 21 degrees preoperatively to 32 ± 15 degrees postoperatively; however, this reduction was not maintained at 1-year (42 ± 19 degrees) and 2-year (39 ± 14 degrees) follow-up ($P > 0.168$) (Fig. 1B). We found no difference between the groups at follow-up regarding major curve angle, global kyphosis, T1T12, and T1S1 (Table 2, Fig. 2).

In the linear mixed effects model, we found no difference in achieved distraction between the 2 groups ($P = 0.521$) (Fig. 3). Also, we found no difference in achieved distraction on the concave rod ($P = 0.202$) or the convex rod ($P = 0.916$). Mean achieved distraction within 1 year for both groups were 12.7 ± 6.2 mm (range: 2.6 to 25.6 mm), not adjusted for instrumentation length. Results from the univariate analysis are presented in Table 3. Preoperative major curve angle, instrumentation length and preoperative T1T12 and T1S1 were the only variables significantly associated with achieved distraction within 1 year. As T1T12 and T1S1 measures are strongly correlated, we chose to only include T1T12 in the multivariate model. Preoperative major curve angle was the only independent variable associated with achieved distraction (Table 4).

DISCUSSION

In this retrospective study of 2 consecutive and comparable cohorts of patients treated with MCGR, we found no significant difference in achieved distraction between a distraction-to-stall and a targeted distraction principle. In a multivariate analysis, the only independent variable associated with achieved distraction was preoperative major curve angle.

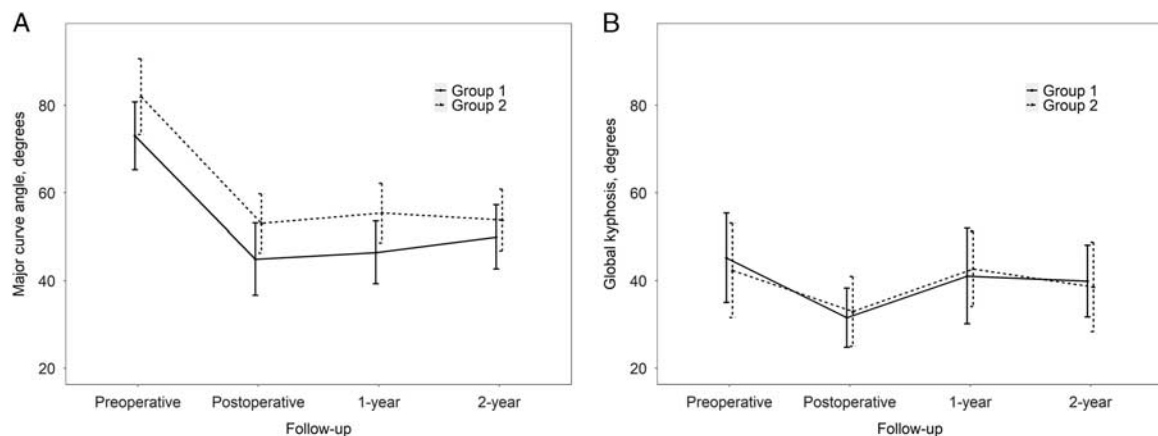


FIGURE 1. A and B, Follow-up of major curve angle and global kyphosis in the 2 groups. Reported as means with error bars representing 95% confidence intervals of the mean.

TABLE 2. Measures of Major Curve Angle, Global Kyphosis, T1T12, and T1S1 for Both Groups

	Group	Preoperative (n = 39)	Postoperative (n = 39)	1-Year Follow-up (n = 39)	2-Year Follow-up (n = 27)
Major curve angle (deg.)	1	73 (18)	45 (19)	46 (17)	50 (16)
	2	82 (19)	53 (15)	55 (15)	54 (11)
Global kyphosis (deg.)	1	45 (22)	32 (15)	41 (22)	40 (15)
	2	42 (21)	33 (16)	43 (17)	39 (13)
T1T12 (mm)	1	183 (32)	204 (30)	215 (29)	224 (29)
	2	175 (34)	198 (26)	209 (29)	229 (17)
T1S1 (mm)	1	296 (48)	334 (43)	344 (39)	359 (42)
	2	294 (50)	326 (41)	341 (47)	374 (30)

Data are presented as means (SD).

Increased focus has been raised towards lengthening procedures in MCGR.^{8,15,28} Corresponding to our findings, MCGR has been shown to correct the coronal deformity and maintain this correction throughout the treatment.^{3,5,6,14,16,23,24,26,29} Concurrently, the thoracic and spinal height (T1T12 and T1S1) in this study increased throughout treatment. However, changes in the sagittal profile such as proximal junctional kyphosis or adding on deformity can alter measurements of thoracic and spinal height, hence, they become unreliable as an outcome of successful distractions (Fig. 4). Achieved distraction was therefore chosen as the primary outcome, and the mean 12.7 mm/y reported in this study corresponds to the normal thoracic height gain during the growth spurt of 11 mm/y as reported by Dimeglio and Canavese.¹⁰

The primary purpose of this study was to compare 2 different distraction principles. We have previously described the distraction-to-stall principle used in group 1.¹³ The targeted distraction used in group 2 resembles the tail-gating principle by trying to predict spinal growth and follow this with distractions. We found no difference between these distraction principles in this study, despite a difference in time interval between lengthening procedures between the

groups. The question is whether the principles are equivalent. In maximum force distraction, the procedure is stopped when the resistance against further distraction exceeds the power transferred to the internal magnetic driver (clunking), and thus clunking should not be considered a failure of distraction. Achieved distraction still needs to be assessed with radiographs every 6 months along with monitoring for complications. Early clunking can together with no achieved distraction over several lengthening procedures indicate failure of the rod to distract. Clunking also occurred during the targeted distraction procedures, but the frequency of clunking was not consistently reported for patients in group 2 and any differences between the groups could therefore not be assessed. This information would have been valuable. With the targeted distraction technique, one must account for the discrepancy between expected distraction (the amount set on the ERC) and the achieved distraction.^{14-17,30} Factors such as body mass index, distance to and between the actuators has been suggested to be the cause,^{14,15,17} and over time the relationship between achieved and expected distraction might decrease to one third.¹⁷ Moreover, an in vitro study showed that the force generated by the implant itself decreased with the distracted length.¹⁸ These multiple factors illustrate the difficulties in predicting achieved distraction, and suggest that lengthening is closely monitored

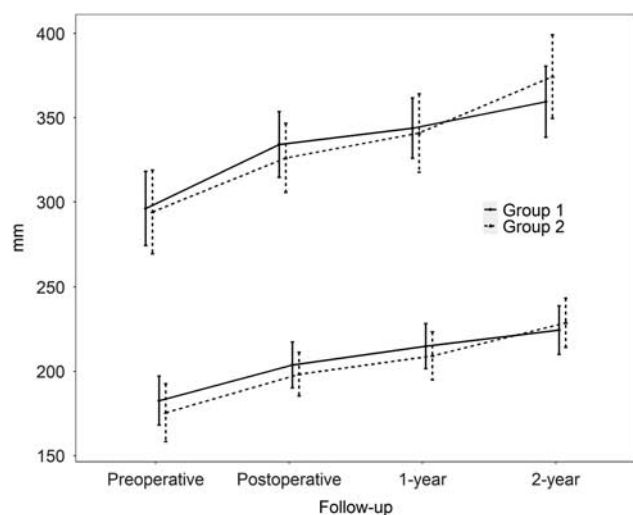


FIGURE 2. Follow-up of thoracic height T1T12 (bottom) and spinal height T1S1 (top) in the 2 groups. Reported as means with error bars representing 95% confidence intervals of the mean.

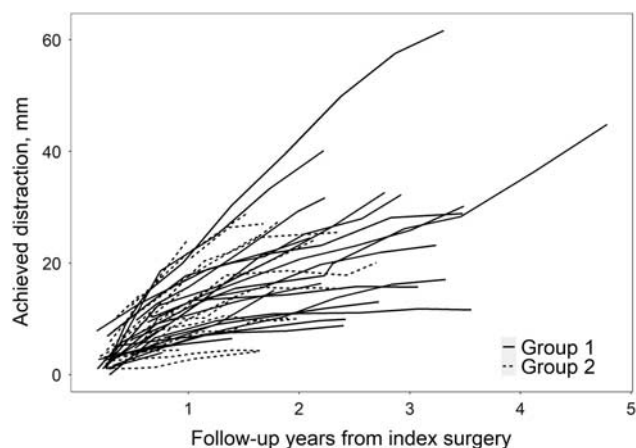


FIGURE 3. Linear plot of achieved distraction (mean of concave and convex rod) between the 2 centers. Each line represents the distraction in the individual patient.

TABLE 3. Univariate Analysis of Variables Associated With Achieved Distraction Within the First Year After Index Surgery

Variables	Estimate (95% Confidence Interval) (mm/y)	P
Age at index surgery (y)	-0.4 (-1.4 to 0.6)	0.421
Etiology*	—	0.066
Instrumentation length (n)	1.5 (0.5-2.4)	0.003**
Location of major curve, thoracic vs. lumbar*	—	0.289
Preoperative T1T12 (cm)	-0.7 (-1.3 to -0.2)	0.015**
Preoperative T1S1 (cm)	-0.5 (-0.9 to -0.1)	0.010**
Preoperative major curve (deg.)	0.17 (0.08 to 0.27)	<0.001**
Preoperative global kyphosis (deg.)	0.04 (-0.06 to 0.13)	0.462
Correction index (%)	-0.07 (-0.22 to 0.08)	0.341
Time interval between lengthening (wk)	0.31 (-0.42 to 1.04)	0.401

*Nonparametric test, estimates not applicable.

**Significance level <0.05.

fluoroscopically or with ultrasound.^{5,6} Nevertheless, we found no difference in achieved distraction over time between the distraction techniques in this study. It is likely that clunking will occur in targeted distraction when the amount set on the ERC is larger than the rod's capability to distract due to the abovementioned factors. In this case the 2 distraction techniques are equivalent. We encourage future studies to describe the lengthening procedure and the frequency of clunking in more detail.

Former studies of MCGR have shown a wide range in achieved distraction between individuals.^{5,6,26} The only independent predictor of achieved distraction was preoperative major curve. The 2 groups in the study were comparable apart from a longer time interval between lengthening in group 2. However, we found no association between the time interval and achieved distraction. Distraction interval is the focus of a planned randomized controlled trial⁸; however, other factors such as burden of care, travel distance to the hospital and an individualized approach to each patient might also influence on the decided lengthening interval. A 1-year achieved distraction outcome was chosen due to some patients in our cohort undergoing definitive fusion surgery within 2 years from index surgery. From the linear plots of achieved distraction over time (Fig. 3), distraction within the first year seemed to predict achieved distraction throughout follow-up with no sudden increase or decline in the slope for individual patients.

TABLE 4. Multivariate Analysis of Variables Significantly Associated With Achieved Distraction Within the First Year After Index Surgery

Variables	Estimate (95% Confidence Interval) (mm/y)	P
Preoperative major curve (deg.)	0.15 (0.03-0.26)	0.012
Instrumentation length (n)	1.04 (-0.03 to 2.10)	0.056
Preoperative T1T12 (cm)	0.11 (-0.61; 0.83)	0.753

Bold indicates significance level $P < 0.05$.
 R^2 for the model was 0.361.

The multivariate analysis showed an expected but not statistically significant tendency towards larger achieved distraction with the length of instrumentation. We suggest this variable should be included in the calculation of expected distraction and adjusted for in comparison between individuals.⁸ Preoperative T1T12 and T1S1 were inversely correlated with preoperative major curve which is probably why they had no effect in the multivariate analysis. The association between preoperative major curve and achieved distraction suggests that additional curve correction is achieved during the lengthening procedures. However, judged from the R^2 , there is still a large variation between individuals to be explained.

A high complication rate remains an unsolved problem in the MCGR treatment. Concerns has been raised that maximum correction during implantation of the rods might stress the implants and cause complications. However, a large proportion of spinal height increase is achieved at primary surgery and substantial curve correction beyond that achieved at implantation cannot be expected.⁵ The mechanical complication and unplanned reoperation rates in this study are lower than reported in a recently published review by Thakar et al⁴ (44.5% and 33%, respectively). All rod breakages in our cohort occurred in 4.5 mm rods outside the housing unit. However, absolute numbers of complications are still small, and the difference in follow-up time and number of patients with 4.5 mm rods between the 2 groups makes it difficult to draw any conclusions.

This is the first study to compare the outcome between distraction techniques in MCGR. Inherently, cohort studies of MCGR include relatively small number of patients with the risk of making false conclusions due to type 2 errors. However, this is one of the largest series of MCGR treated patients and we took caution not to include too many variables in the models. Nevertheless, the difference in follow-up between the groups limits the conclusions to the first 2 years of lengthening as we cannot assess what happens between the groups after 3 or 4 years of lengthening where stiffness or autofusion might affect the achieved distraction. The indications and timing of surgery is still debated.⁷⁻⁹ We only included age, thoracic and spinal height as variables representing growth stage. Risser grade could not be validly judged due to radiation sparring protection on radiographs (Fig. 4). To improve knowledge on patient selection, we encourage future studies to systematically include objective growth assessment other than age before surgery. A substantial remaining growth potential is imperative for justifying the MCGR procedure.

Both lengthening methods result in satisfactory distraction compared with expected normal spine growth¹⁰ and are equivalent as long as the targeted distraction amount is not underestimated. We do not consider it clinically important to monitor each distraction with ultrasound. Achieved distraction can be measured on the radiographs routinely performed every 6 months to monitor curve progression and complications.

In conclusion, we found no difference in achieved distraction between a distraction-to-stall and a targeted distraction principle. The groups were comparable apart

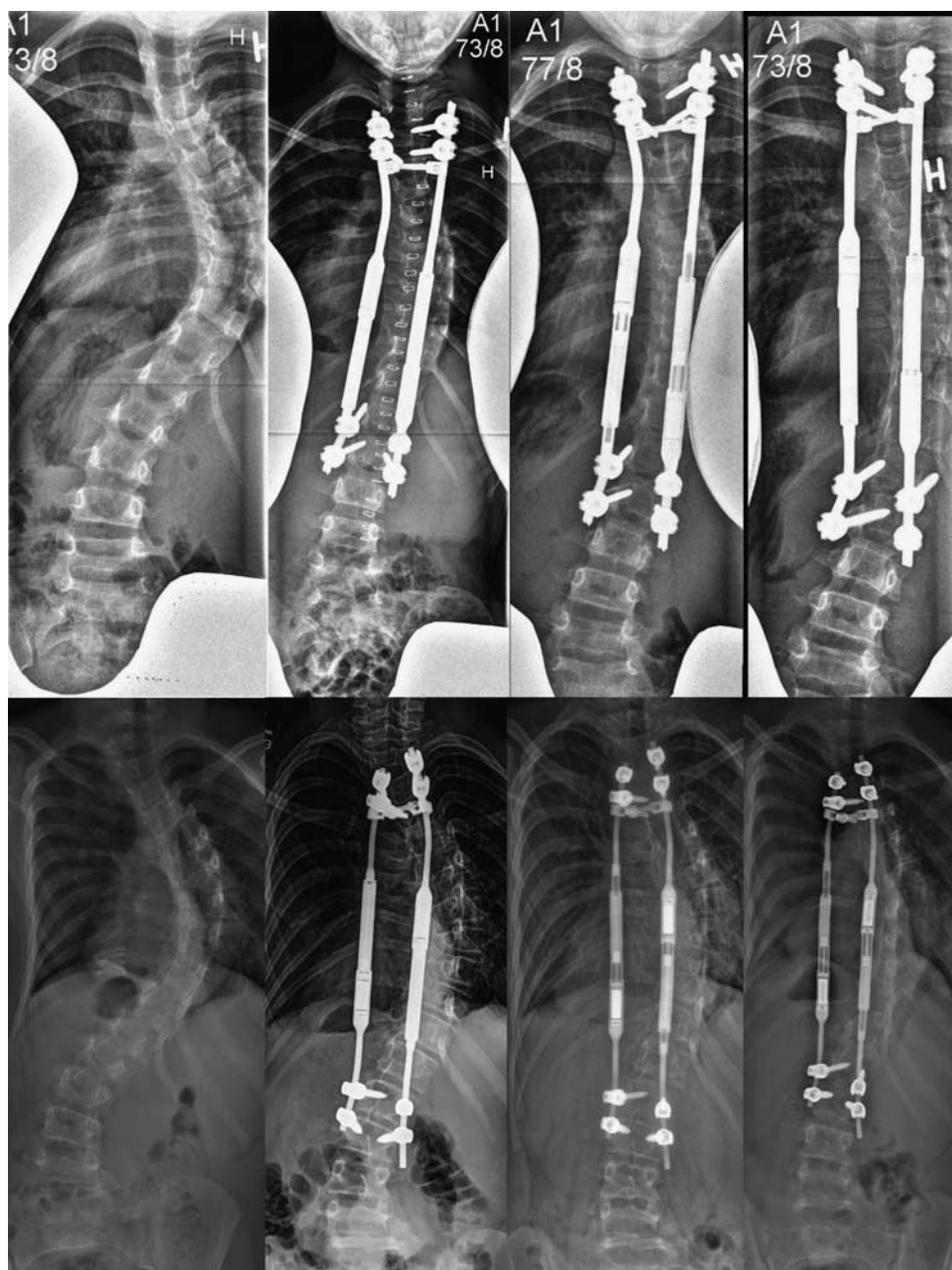


FIGURE 4. Radiographs of 2 girls with idiopathic early-onset scoliosis undergoing surgery almost 9 years old with similar curves. Radiographs shown are preoperative, postoperative, 1- and 2-year follow-up. The patient at the top underwent distraction-to-stall with a mean lengthening interval of 66 days. She underwent a revision after 1.5 years due to a distal screw loosening. The patient at the bottom underwent targeted distraction with a mean lengthening interval of 99 days and a targeted distraction amount of 6 to 8 mm at each lengthening. Mean achieved distraction for the 2 patients at 2-year follow-up were 18 and 19 mm, respectively. T1S1 for the top patient increased from 226 mm preoperatively to 343 mm at 2 years, and for the bottom patient from 333 to 390 mm. This difference occurred despite achieved distraction was similar and underlines how spinal height measures are influenced by progression of the deformity outside the instrumentation.

from a difference in time interval between the lengthening procedures, however, we found no association between the distraction interval and achieved distraction. The only independent variables associated with increased distraction was preoperative major curve angle.

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