Rib-based Distraction Surgery Maintains Total Spine Growth

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Background: For children undergoing treatment of early onset scoliosis (EOS) using spine-based distraction, recently published research would suggest that total spine length (T1-S1) achieved after the initial lengthening procedure decreases with each subsequent lengthening. Our purpose was to evaluate the effect of rib-based distraction on spine growth in children with EOS.

Methods: This was a retrospective multi-center review of 35 patients treated with rib-based distraction (minimum 5 y follow-up). Radiographs were analyzed at initial implantation and just before each subsequent lengthening. The primary outcome was T1-S1 height, which was also analyzed as: Change in T1-S1 height per lengthening procedure, percent of expected age-based T1-S1 growth per lengthening time interval, percent increase in T1-S1 height as compared with postimplantation total spine height, and percent of expected T1-S1 growth based upon patient age at time of lengthening procedure.

Results: Thirty-five patients with a mean age of 2.6 years at initial surgery were studied. Diagnoses included congenital (n = 18), syndromic (n = 7), idiopathic (n = 5), and neuromuscular (n = 5). Major Cobb angle was 63.5 degrees and kyphosis was 40.5 degree. Four postoperative time periods were compared: L1 (preoperative first lengthening surgery), L2-L5 (preoperative second lengthening to preoperative fifth lengthening), L6-L10 (preoperative sixth lengthening to preoperative 10th lengthening), L11-L15 (preoperative 11th lengthening to preoperative 15th lengthening). Cobb angle stayed relatively constant for each lengthening period while maximum kyphosis increased. Total spine height was 19.9 cm pre-implantation, 22.1 cm postimplantation, and 28.0 cm by the 15th lengthening ($P < 0.05$). Percent expected T1-S1 growth per lengthening was 62% for L2-L5, 95% for L6-L10, and 52% for L11-L15. As compared with postimplantation spine height, over the course of 15 lengthening procedures, a further 27% increase in spine height was observed. When lengthening procedures were performed when children were under age 5 years, 82% of expected growth was observed; between ages 6 and 10 years, 76% of expected growth was observed; and beyond age 10 years, 14% of expected growth was observed.

Conclusions: Patients treated with rib-based distraction surgery had an increase in total spine height from 20 cm preimplantation to 28 cm by the 15th lengthening. They maintained greater than 75% of expected age-matched spine growth until age 10 years and lengthening procedures did not appear to follow a law of diminishing returns. Rib-based distraction is an effective means of maintaining spine growth which is likely beneficial for pulmonary development as compared with the natural history of EOS.

Level of Evidence: Level IV—Therapeutic study, case series.

Key Words: spine growth, VEPTR, diminishing returns, spine height

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Early onset scoliosis (EOS) is a challenging condition to treat due to the dynamic and unpredictable nature of the growing spine. Goals of treatment are fairly straight forward: To prevent progression of spinal deformity while maintaining spine, chest wall, and lung development. However, achieving these goals often requires use of surgical intervention with dynamic stabilizing constructs. At present, posterior distraction-based implants, such as spinal growing rods and rib-based devices [ie, vertical expandable prosthetic titanium rib (VEPTR), Depuy-Synthes Spine, Raynham, Ma), are 2 of the most commonly used surgical treatments for EOS.[1]

Total spine height associated with growth can be defined radiographically as the growth per year from the first (most proximal) thoracic vertebrae to the first sacral vertebrae (T1-S1 height). Spinal growth is related to the age of the patient with T1-S1 growth of approximately 2 cm per year for children less than 5 years of age, 0.9 cm per year for children between 5 and 10 years of age, and 1.8 cm per year for children greater than 10 years of age.[2]

For children treated with spinal growing rods, recently published data confirms that T1-S1 length based on growth during treatment approaches normal values (3), but the authors express concern that the mechanical distraction of the rods during lengthening procedures deteriorated from 10 mm at first lengthening to 7 mm after

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the 5th lengthening. They coined the phrase "Law of Diminishing Returns" (LODR) to describe this small loss in mechanical expandability during lengthening procedures. They suggest that the LODR limits the effectiveness of surgical treatment over time and advocate delaying the onset of surgical treatment. It is difficult to understand what "returns" were diminished in this report since the clinically relevant T1-S1 growth in length was reported by the authors as normal and the Cobb angle remained stable.[3] Although the validity of the LODR is clinically questionable, many surgeons and parents have come to believe that the initial surgery should be delayed in an effort to avoid both this "law of diminishing returns" and the complications associated with repeated lengthening surgeries. For now, LODR has contributed to an evolving trend towards the use of serial casting as a "delay tactic" for the treatment of EOS.[4] Classically, the goals of maximizing surgical outcome while minimizing complications by delaying the onset of spinal growing rod surgery would seem logical if a long, straight spine is the primary outcome measure. However, there is also a school of thought that also emphasizes the importance of lung growth early in life to avoid severe restrictive lung disease in adulthood,[5,6] and it follows that early surgical intervention, as young as age 6 months with VEPTR expansion thoracoplasty[5] is needed to promote chest wall, spine, and lung development.

It is unclear whether rib-based surgery (VEPTR) has the same issue of mild decrease in mechanical lengthening over time, the so-called "law of diminishing returns," as spine-based distraction surgery (growing rods). Our purpose was to evaluate the effect of rib-based distraction surgeries on total spine growth in children with early onset scoliosis. The hypothesis was that rib-based distraction surgeries will increase the height of the spine; however, these gains may decrease over time and may be related to the normal slowing of T1-S1 growth between the ages of 5 and 10 years.

METHODS

This was a retrospective multi-center review of 35 patients from the Children's Spine Study Group Registry who were treated with the VEPTR rib-based distraction device. All patients had a minimum of 5 lengthening surgeries and at least 5 year follow-up from their initial implantation surgery. Radiographs were analyzed at initial implantation and before each subsequent lengthening procedure. Despite this being a multicenter study, the measurements were all performed by a single, unbiased observer at a central location. This was in an effort to decrease inter-observer variability of the measurements. Primary outcome was total spine height (T1-S1 height), which was also analyzed as: Change in T1-S1 height per lengthening procedure, percent of expected age-based T1-S1 growth per lengthening time interval, percent increase in T1-S1 height as compared with postimplantation total spine height, and percent of expected T1-S1 growth based upon patient age at time of lengthening procedure. Other variables measured or included in the analysis: Sex, diagnosis, age at each surgical intervention, coronal Cobb angle, maximum kyphosis, number of lengthening surgeries, thoracic spine height (T1-T12), and lumbar spine height (L1-S1).

Analysis of variance testing (IBM SPSS Statistics 20, Armonk, New York) was used to examine the raw data for T1-T12 height and for T1-S1 height. Only subjects with at least 3 data points were used for this analysis. Radiographs were obtained and analyzed at the following time points based on our inclusion criteria of a minimum of 5 lengthening surgeries. By using this value as our first increment to study, it is logical to continue to study spine growth in increments of 5 lengthening surgeries:

- Preimplantation surgery.
- L1, obtained pre-operative first lengthening surgery.
- L2-L5, preoperative second lengthening surgery to preoperative 5th lengthening surgery.
- L6-L10, preoperative 6th lengthening surgery to preoperative 10th lengthening surgery.
- L11-L15, preoperative 11th lengthening surgery to preoperative 15th lengthening surgery.

The measurement at time point L1 reflects both the height gained from the implantation surgery (biomechanical distraction) plus any growth from the time of implantation to just before the first lengthening surgery. The measurements at lengthening intervals L2-L5, L6-L10, and L11-L15 represent both the height gained from each lengthening surgery (biomechanical distraction) plus any growth from the time of each lengthening surgery to just before the subsequent lengthening surgery. These measurements may also include the potential growth stimulation from the effects of mechanical distraction.

Percentage of expected age-based T1-S1 growth was calculated before each lengthening procedure by using published values for expected spine growth.[2] As the initial T1-S1 height was variable between subjects, an analysis of the change in growth was performed by normalizing T1-S1 height gains to post-implantation T1-S1 height.

RESULTS

Thirty-five patients (17 females and 18 males) with a mean age of 2.7 years (6 mo to 7 y) at initial surgery were included in the study (Table 1). Using the Classification for Early Onset Scoliosis (C-EOS) system, diagnoses included congenital (n = 18), neuromuscular (n = 5), syndromic (n = 7), and idiopathic (n = 5). At implantation, the average major (Cobb angle was 63.5 degrees (18 to 102 degrees) and average maximum kyphosis was 40.5 degrees (3 to 77 degrees). Preoperatively, 15% of subjects were hypokyphotic (< 21 degrees), 55% had normal kyphosis (21 to 50 degrees), and 30% had hyperkyphosis (> 50 degrees). Mean thoracic height was 12.4 cm (8.4 to 17.6 cm), mean lumbar height was 8.1 cm (3.8 to 10.3 cm), and mean T1-S1 height was 19.9 cm (9.4 to 27.6 cm).

Patients underwent a mean of 9 lengthening procedures (5 to 15 lengthenings) and 15 patients had device migration during their treatment period (Table 1). Major

TABLE 1. Patient Preoperative and Surgical Characteristics

Patient	Sex	Diagnosis	Age (y)	Cobb (deg.)	Kyphosis (deg.)	T1-T12 (mm)	T1-S1 (mm)	Levels
1	Female	Beals syndrome	1	98	29	126.2	214.5	T2-Pelvis
2	Male	Central core myopathy	2	61	77	97.0	182.2	T4-Pelvis
3	Male	Congenital without fused ribs	0	56	59	88.5	145.9	T1-L4
4	Female	Congenital without fused ribs	3	57	26	111.1	189.6	T3-L3
5	Female	Congenital without fused ribs	7	47	58	180.5	281.1	T4-L1
6	Female	Congenital without fused ribs	4	61	29	154.0	244.0	T7-L2
7	Female	Congenital with fused ribs	1	57	61	124.6	209.5	T2-L2
8	Male	Congenital with fused ribs	4	73	53	131.9	234.0	T2-L4
9	Male	Congenital with fused ribs	2	89	3	102.7	152.7	T2-Pelvis
10	Male	Congenital with fused ribs	4	35	36	138.6	222.0	T4-L3
11	Female	Congenital with fused ribs	1	69	20	92.7	165.1	T3-T10
12	Female	Congenital with fused ribs	1	54	23	109.7	200.9	T3-L2
13	Female	Congenital with fused ribs	1	64	19	125.1	207.8	T2-L1
14	Male	Congenital with fused ribs	0	52	59	112.4	190.8	T4-T10
15	Male	Congenital with fused ribs	3	63	49	77.2	162.4	T2-L2
16	Female	Congenital with fused ribs	4	56	37	128.6	208.8	T4-Pelvis
17	Male	Congenital with fused ribs	1	68	39	110.0	190.2	T1-T10
18	Male	Congenital with fused ribs	3	47	15	130.0	214.0	T3-L3
19	Female	Congenital with fused ribs	1	73	39	121.3	202.9	T2-T11
20	Female	Congenital with fused ribs	5	66	62	137.1	237.0	T2-L2
21	Male	Goldenhar syndrome	0	81	38	84.0	151.4	T3-T13
22	Female	Infantile idiopathic	1	102	55	134.0	219.1	T5-L2
23	Female	Infantile idiopathic	5	64	35	151.7	246.3	T6-L3
24	Male	Infantile idiopathic	4	76	49	N/A	N/A	T5-L3
25	Female	Infantile idiopathic	4	66	N/A	N/A	N/A	T7-L5
26	Male	Infantile idiopathic	2	62	N/A	156.9	246.9	T6-L3
27	Male	Jarcho-Levin syndrome	2	44	28	79.8	N/A	T1-T10
28	Female	Jarcho-Levin syndrome	2	74	14	77.3	142.9	T2-T10
29	Male	Marfan syndrome	2	85	55	140.0	230.0	T8-L2
30	Female	Muscular dystrophy	2	38	47	139.0	225.0	T2-Pelvis
31	Male	Muscular dystrophy	7	18	44	173.0	276.0	T1-Pelvis
32	Male	Neurofibromatosis	4	61	43	194.5	299.7	T4-Pelvis
33	Male	Neurofibromatosis	1	88	64	108.2	184.1	T8-L3
34	Female	Spinal cord tumor	4	60	28	147.0	235.2	T9-L3
35	Male	Spinal muscular atrophy	6	56	43	176.0	266.0	T3-Pelvis

Cobb angle initially improved at implantation (L1 = 57.1 degrees) and then remained relatively constant over the subsequent lengthening periods: L2-L5 = 50.2 degrees, L6-10 = 48.5 degrees, and L11-L15 = 53.4 degrees (Fig. 1). However, maximum kyphosis was noted to increase for each period: L1 = 44.5 degrees, L2-L5 = 49.6 degrees, L6-L10 = 56.4 degrees, and L11-L15 = 64.8 degrees ($P < 0.05$) (Fig. 2). At each subject's final follow-up, kyphosis ranged from 22 to 122 degrees, with 27% of subjects having normal kyphosis and 73% of subjects having hyperkyphosis.

Average T1-T12 height was shown to increase over each lengthening period: L1 = 13.3 cm, L2-L5 = 14.0 cm, L6-L10 = 15.5 cm ($P < 0.05$), and L11-L15 = 16.4 cm. Likewise, lumbar spine height showed a progressive increase from each lengthening period to the next: L1 = 8.8 cm, L2-L5 = 9.5 cm, L6-L10 = 11.0 cm ($P < 0.05$), and L11-L15 = 11.6 cm. Mean T1-S1 height also increased: L1 = 22.1 cm, L2-L5 = 23.6 cm, L6-L10 = 26.4 cm ($P < 0.05$), and L11-L15 = 28.0 cm (Fig. 3).

The mean change in T1-S1 height secondary to the mechanical distraction from the implant procedure was L1 = 1.41 cm, and the mean change in T1-S1 height per lengthening interval was L2-L5 = 0.57 cm per lengthening ($P < 0.05$), L6-L10 = 0.63 cm per lengthening ($P < 0.05$), and L11-L15 = 0.36 cm ($P < 0.05$).

When expressed as a percentage of age-specific expected T1-S1 growth, the implant surgery realized 123% of expected growth as compared with preimplantation, L2-L5 achieved 62% of expected growth, L6-L10 achieved 95% of expected growth, and L11-15 achieved 52% of expected growth.

The implant surgery itself increased the T1-S1 height by 11% of the pre-implantation T1-S1 Height. Evaluating further changes in height using post-implantation T1-S1 height as the baseline, an increase was observed with lengthening surgeries: L2-L5 = 7% increase in T1-S1 height ($P < 0.05$), L6-L10 = 20% increase in T1-S1 height ($P < 0.05$), and L11-L15 = 27% increase in T1-S1 height ($P < 0.06$).

Expressing percentage of T1-S1 growth as a function of patient age at the time of lengthening: Subjects 0 to 5 years demonstrated 82% of expected growth, subjects 6 to 10 years = 76% of expected growth ($P < 0.05$), and subjects greater than 10 years = 14% of expected growth ($P < 0.05$).

DISCUSSION

In designing this study, our purpose was to evaluate the effect of rib-based distraction surgeries on spine

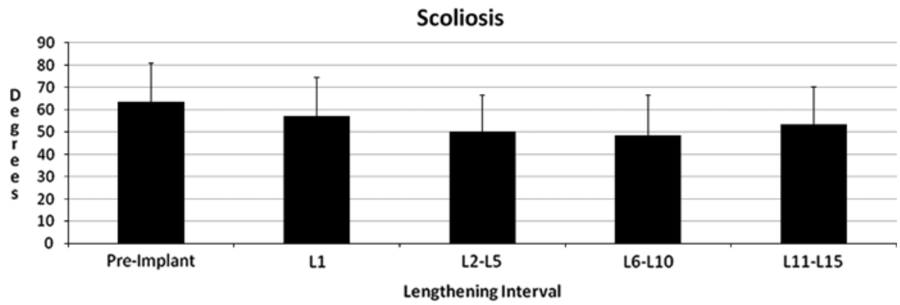

FIGURE 1. Major curve scoliosis pre-implantation, post-implantation (L1), and over the 3 lengthening periods.

growth in children with early onset scoliosis. The hypothesis was that rib-based distraction surgeries would enable close to normal spine growth; however, these gains would likely decrease over time and may be the result of the normal slowing of T1-S1 growth between the ages of 5 and 10 years. Our hypothesis was correct in that thoracic spine height, lumbar spine height, and total spine height all increased over the lengthening periods. Subjects maintained >75% of expected total spine growth until the age of 10 years and, by the 15th lengthening surgery, increased total spine height by a mean of 27% as compared with postimplantation.

One limitation of our study is the inherent heterogeneity and medical complexity of children with early onset scoliosis. As the reference data for spine growth is based on healthy children, it may be the case that patients with nonidiopathic scoliosis may not inherently grow at the same rate as patients with idiopathic scoliosis. As a result, our findings may under represent the growth expected for a child with a congenital, neuromuscular, or syndromic disorder. Unfortunately, there is no data that currently predicts expected growth in this complex group of patients. Because EOS is so uncommon, it is difficult to study large numbers of patients without examining a multi-center database. A second weakness of the study was the small number of patients included. Although our sample size of 35 subjects may seem low, it is similar to the sample size of 38 patients with spine-based distraction studied by Sankar et al in 2011.[3] Their widely quoted paper described a law of diminishing returns for spinal growing rods in a similarly heterogeneous patient population, and serves to support the fact that these patients are uncommon and difficult to study, but also demonstrates that important information can still be realized from these smaller patient cohorts. Strengths of our study include a minimum follow-up period of 5 years and a mean of 9 lengthening procedures per patient, which is a longer follow-up period and more total lengthenings than previously reported for spinal growing rods.

In our analysis, major Cobb angle initially improved from 63.5 degrees preoperatively and then stayed relatively constant over the 4 lengthening periods (57.1, 50.2, 48.5, and 53.4 degrees). This Cobb correction of approximately 20% is similar to the correction obtained for rib-based distraction from other studies.[5,7,8] This correction of scoliosis is less than that generally measured for the treatment of scoliosis with spine-based distraction implants.[9,10] During the course of lengthening, maximum kyphosis increased from 40.5 to 64.8 degrees. This initial mean kyphosis was in the normal range of kyphosis for children with early onset scoliosis.[11] Preoperatively 50% of subjects had normal kyphosis: 6 patients with congenital scoliosis and 1 patient each with central core myopathy, neurofibromatosis, Marfan syndrome, and

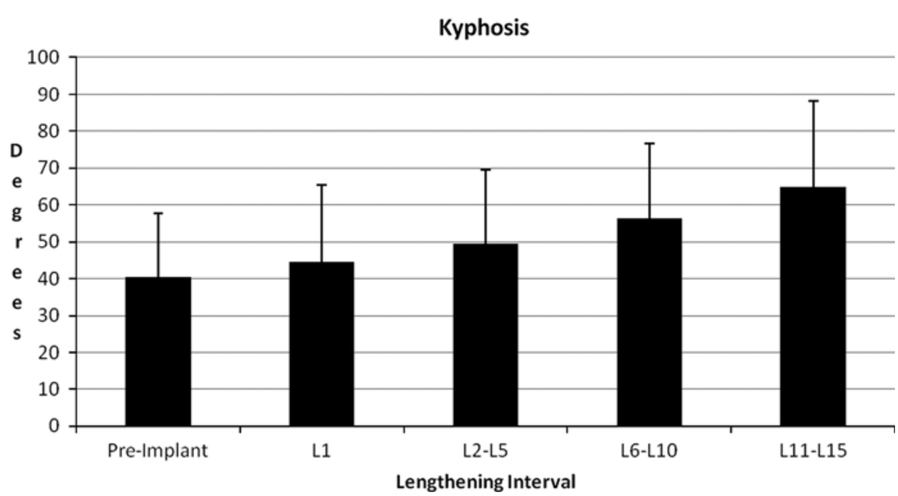

FIGURE 2. Maximal thoracic kyphosis preimplantation, postimplantation (L1), and over the 3 lengthening periods.

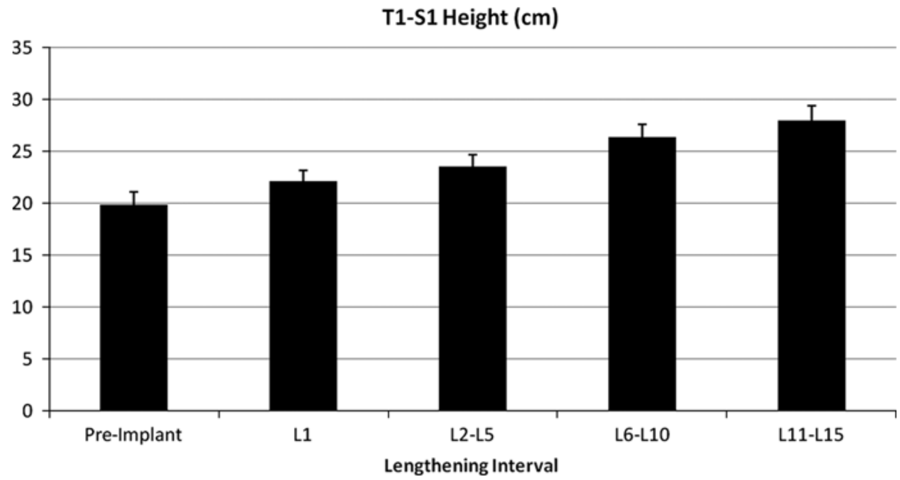

FIGURE 3. Total spine height preimplantation, postimplantation (L1), and over the 3 lengthening periods.

infantile scoliosis. At final post-operative follow up, only 27% had normal kyphosis and 73% were hyperkyphotic. Five of those patients had final postoperative kyphosis >70 degrees: 3 patients with congenital scoliosis/fused ribs (71,79,87 degrees, respectively), 1 patient with infantile idiopathic (89 degrees) and 1 patient with central core myopathy (122 degrees). As it is believed that posterior distraction surgery is kyphogenic by nature,[12] it is not surprising that after a mean of 9 lengthening procedures, this group of patients would become more kyphotic.

At initiation of rib-based distraction surgery, the mean age of the patients was 2.6 years with a mean preoperative thoracic height of 12.4 cm, mean preoperative lumbar height of 8.1 cm, and mean preoperative T1-S1 height of 19.9 cm. The mean thoracic height and mean T1-S1 height of 12.4 cm and 19.9 cm corresponded very closely to the mean thoracic height of 12 cm and mean T1-S1 height of 19.5 cm previously published for newborns without spinal deformity.[2] We suspect the effect of thoracic spinal deformity likely accounts for the thoracic and total spine heights to be within the newborn range (ie, less than would be expected for group of patients with a mean age of 2.6 y). Our initial spine height was less than the preoperative height of 24.9 cm found in Sankar's group of spinal growing rods patients, which is likely a reflection of the younger age of the patients in our study.[3]

With greater than 5 year follow-up and mean age greater than 7 years, average thoracic length increased from 12.4 cm at implantation to 16.4 cm, which only approached published values for 5 year old children without scoliosis.[2] As there is a positive correlation between thoracic height and percent predicted forced vital capacity, this improvement in thoracic height should improve the pulmonary function in these children.[6] Lumbar spine height also increased to 11.6 cm which surpassed the 10.5 cm average lumbar height published for 5-year-old children without scoliosis.

Total spine height improved from 19.8 cm to 28.0 cm, which is just under the 29 cm mark for 5-year-old children without scoliosis.[2] In our study, total spine length gained from the implantation surgery was 1.41 cm, which was less than the 3.2 cm of spine growth gained from the implantation surgery for the spinal growing rods group as observed by Sankar et al.[3] Because of the effect of mechanical distraction on the length gained during implantation surgery, we analyzed it separately from the actual lengthening surgeries (mean increase of 0.57 cm per lengthening for L2-L5). This amount of length gained was maintained for the sixth through tenth lengthening surgeries (0.63 cm per lengthening) and do not appear to follow a law of diminishing returns; however, mechanical distraction diminished for the eleventh through 15th lengthening period (0.36 cm per lengthening). This was statistically significant, but of no clinical significance, as growth in length of the spine continued. Although this amount of height gained may appear to be a very small gain, it equates to between 0.72 cm to 1.25 cm of height gained per year (ie, with an average of 2 lengthening surgeries per year). Remembering that normal total spine growth has been defined as 2 cm per year for children less than 5 years of age, 0.9 cm per year for children between 5 and 10 years of age, and 1.8 cm per year for children greater than 10 years of age, the growth gained by lengthening procedures should not be considered to be insignificant.[2] Expressing our results as a percentage of age-specific expected T1-S1 growth, the implantation surgery realized 123% of expected growth. As the index surgery achieved greater than expected age-related spine growth, the early implantation of these devices may maximize the early growth and development of the spine, chest wall, and pulmonary system during the key years in the growth of the respiratory system. Early implantation should be balanced with the potential for surgical complications from repeated lengthening operations.[9,10,13] The increase in T1-S1 height, expressed as a percentage of expected T1-S1 growth, for the second lengthening period (L2-L5) was 62% of expected normal growth, the third lengthening period (L6-L10) was 95% of expected normal growth, and the fourth lengthening period (L11-L15) was

52% of expected growth. These continued increases in spine height should be viewed as a success when compared with the natural history of early onset scoliosis and when compared with early spinal fusion. It was found that patients who had lengthenings under the age of 10 years consistently experienced greater than 75% expected spine growth as opposed to children who had lengthenings beyond the age of 10 years who only achieved 14% of expected growth with these procedures.

Because the majority of these patients had non-idiopathic scoliosis, it is reasonable to believe that their expected rate of spine growth may be less than that expected for children without scoliosis. To account for this potential, the results were also analyzed to evaluate the change in spine height as compared with post-implantation spine height. On average, the time frame for growth from 2nd through 5th lengthenings represented a 7% increase, the time frame for growth from 6th through 10th lengthenings represented a 20% increase, and the time frame for growth from 11th through 15th lengthenings represented a 27% increase as compared with post-implantation spine height.

There is inherent variability in radiographic measures. In a separate study, we performed a reliability analysis of coronal plane spine height measures in a group of children with early onset scoliosis. We examined 23 subjects with 4 reviewers assessing the images at two points in time, at least two weeks apart. Intra-class Correlation Coefficients for the vertical height measures were inter-observer 0.957 (95% CI: 0.918 to 0.980; $P < 0.05$) and intra-observer 0.911 (95% CI: 0.789 to 0.962; $P < 0.05$).

Other factors may influence the measurement of spine growth, which traditionally has been measured on coronal plane radiographs. True spine length may best be measured on a sagittal plane radiograph, which takes into account the patient's sagittal spine profile. This is analogous to measuring leg length discrepancy in patients with joint contractures. The thoracic kyphosis for this group increased on average from 40 degrees preoperatively to 65 degrees after 15 lengthenings. Kyphosis likely developed secondary to the posterior distraction forces inherent in rib-based distraction.[9] The first generation rib-based distraction system that we studied had a fixed radius of curvature that was designed to maintain thoracic kyphosis; however, over time, the sagittal plane may change as the spine follows the implant's fixed arc of curvature.[9] We have noted that as kyphosis increases, the anterior translation of T1 also increases and as a consequence, the superior translation of T1 tends to diminish. This geometric relationship results in a coronal plane measurement of T1-S1 height that may be less than the true spine length. Further study of the sagittal plane spine growth is required to further examine this potential relationship.

In conclusion, patients treated with rib-based distraction surgery had an increase in total spine height from 20 cm preimplantation to 28 cm by the 15th lengthening procedure. They maintained greater than 75% of expected age-matched total spine growth until 10 years of age and lengthening procedures did not appear to follow a law of diminishing returns. Rib-based distraction surgeries are an effective means of maintaining total spine growth which is likely beneficial for pulmonary development as compared with the natural history of early onset scoliosis.

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