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Non-Fusion Surgical Correction of Thoracic Idiopathic Scoliosis Using a Novel, Braided Vertebral Body Tethering Device

Minimum Follow-up of 4 Years

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Investigation performed at National University Hospital, Singapore

Background: Anterior vertebral body tethering to effect scoliosis correction in a growing spine has been shown to work with varying degrees of success. This report describes the mid-term results of this technique using a new device composed of a braided ultra-high molecular weight polyethylene (UHMWPE) cord anchored to bone screws applied without segmental compression.

Methods: This was a single-center prospective observational study of an investigational device. Five female patients aged 9 to 12 years with thoracic scoliosis underwent thoracoscopic insertion of the UHMWPE tether. Radiographs and magnetic resonance imaging (MRI) were performed, and the Scoliosis Research Society (SRS)-22 was administered, preoperatively and at regular intervals after surgery, with a minimum of 4 years of follow-up.

Results: All tethering devices spanning the end vertebrae (range, 7 to 8 vertebrae) were implanted successfully. Mean blood loss was 136 mL, and the mean operative time was 205 minutes. The mean preoperative main thoracic Cobb angle was 40.1°. Curve correction of the tethered segment ranged from 0% to 133.3% at 4 years. We observed greater correction in 2 patients with open triradiate cartilage (TRC), achieving full scoliosis correction at 2 years and 121.5% at 4 years. MRI showed improvement in periapical disc wedging morphology and 55% improvement of rotation at 3 years. There were 20 adverse events, of which 16 were mild and 4 were moderate in severity. The 4 moderate events of pneumonia, distal decompensation, curve progression, and overcorrection occurred in 3 patients, 2 of whom required fusion.

Conclusions: Anterior vertebral body tethering resulted in scoliosis deformity correction in the coronal and axial planes, with preservation of curve flexibility. Actual correction by growth modulation was noted only in patients with open TRC, whereas curve stabilization was noted in patients with closed TRC. Overcorrection, curve progression, and distal decompensation are problems with this technique.

Level of Evidence: Therapeutic Level IV. See Instructions for Authors for a complete description of levels of evidence.

Curve progression in idiopathic scoliosis has been attributed to differential compressive loads in the concavity of the deformity causing diminished concave growth and accelerated convex growth. This leads to a vicious cycle of increased loading of the concave side and scoliosis progression[1-4].

Treatment recommendations for progressive scoliosis include bracing and fusion surgery. Bracing prevents curve progression in some patients, but residual curve size is a predictor for pain and the perception of inferior health status[5-8]. Spinal fusion has been shown to correct the deformity

Disclosure: The study sponsor, DePuy Spine, paid for the surgical, hospitalization, and outpatient attendance costs of all five patients. The surgeons and the institution involved in the study did not receive fees for performing the study. On the **Disclosure of Potential Conflicts of Interest** forms, *which are provided with the online version of the article*, one of the authors (P.O.N.) checked "yes" to indicate that the author had a relevant financial relationship in the biomedical arena outside the submitted work, including with DePuy Spine, and "yes" to indicate that the author had a patent and/or copyright, planned, pending, or issued, broadly relevant to this work and including DePuy Spine as the licensee (http://links.lww.com/JBJSOA/A132).

and improve quality of life, but it involves major surgery, substantial financial cost, and loss of spinal motion. An ideal solution for treating early progressive curves involves non-fusion deformity correction while allowing spinal growth and motion. Some of these methods, which use growing-rod systems[9-13] and expandable prosthetic ribs[14,15], are primarily recommended for early-onset and non-idiopathic scoliosis.

Growth modulation by means of anterior vertebral body stapling to reverse the compression-force gradient across the apex of the deformity has been described[1,16-18]. Asymmetric inhibition of vertebral growth using posterior tethers[19,20], and wedge-rod systems[21] have also been used.

Animal models have shown the feasibility of using an anterolateral tether that is made of ultra-high molecular weight polyethylene (UHMWPE) and anchored to bone screws to modulate spine growth[22-25]. Clinical application of this method using off-label implants has shown promising but unpredictable early results[26-29].

In the current report, we describe our initial experience using a novel anterolateral tethering device in patients with idiopathic scoliosis at risk of progression, with a minimum of 4 years of follow-up.

Materials and Methods

This was a single-center, Phase-2A pilot study involving 5 patients in whom a braided UHMWPE tether (MIScoli; DePuy Spine) was used in the surgical treatment of idiopathic scoliosis in the immature spine. This study received institutional review board approval.

Patient Assessment and Recruitment

From October 2010 to June 2016, 9 female patients with Lenke Type-1 scoliosis were consecutively recruited according to the inclusion and exclusion criteria (Table I). Candidates were given the option for brace treatment. Preoperative assessments included physical examination and standard full-length spine radiographs, radiographs of the left wrist/hand, and magnetic resonance imaging (MRI) of the entire spine.

Device Description

The MIScoli device is made up of 2 components (Fig. 1). The tether component is a flat braided construct with a uniform width and is manufactured from UHMWPE. It is anchored to a vertebral-body component made of titanium alloy (Ti 61A-4V) and consisting of 3 parts: a staple, a bone screw, and a set screw. The 4-pronged staple has a diameter of 11 mm, and the length of the bone screw ranges from 22 to 44 mm, in 2-mm increments.

Operative Technique

Instrumentation levels followed the standard recommendation for anterior fusion, i.e., from superior to inferior end vertebrae. The surgical technique for thoracoscopic access to the thoracic spine for scoliosis surgery has been previously

TABLE I Inclusion and Exclusion Criteria for Scoliosis Tether Pilot Study

Inclusion Criteria	Exclusion Criteria
1. Diagnosis of juvenile or adolescent idiopathic scoliosis	1. Age at enrollment of <8 or ≥15 yr
2. Age at enrollment of ≥8 and <15 yr	2. Bone age of >13 yr for females and males, as measured by hand/wrist radiograph assessment
3. Risser stage 0	3. Scoliosis curve of <35° or >55°
4. Bone age of ≤13 yr for females and males, as measured by hand/wrist radiograph assessment	4. Thoracic kyphosis (T5-T12) ≥40°
5. Major right thoracic scoliosis with a Cobb angle of 35°-55° and Lenke-1 curve pattern	5. Vertebrae <13 mm in height (cutoff based on the staple size)
6. Thoracic kyphosis (T5-T12) <40°	6. Congenital scoliosis
7. Instrumentation to be applied no more cephalad than T4 and no more caudal than L2 (inclusive)	7. Nonambulatory
8. Menses <4 months	8. Osteoporosis by clinical diagnosis
9. Physically and mentally willing and able to comply with postoperative and routinely scheduled clinical and radiographic evaluations	9. Prior ipsilateral thoracic surgery
10. Subject assent and parent/guardian consent obtained and documented	10. Left thoracic scoliosis
	11. Associated syndromes of intraspinal pathology that require neurosurgical intervention
	12. Prior surgical spinal treatment in the region of planned instrumentation
	13. Prior surgical procedure in the chest cavity on the side of scoliosis
	14. No tolerance to 1-lung anesthesia
	15. Infection in the disc or spine, past or present
	16. Evidence of active infection at the time of surgery
	17. Known allergy to polyethylene or titanium alloy (including the component elements of the alloy), the materials used in the device

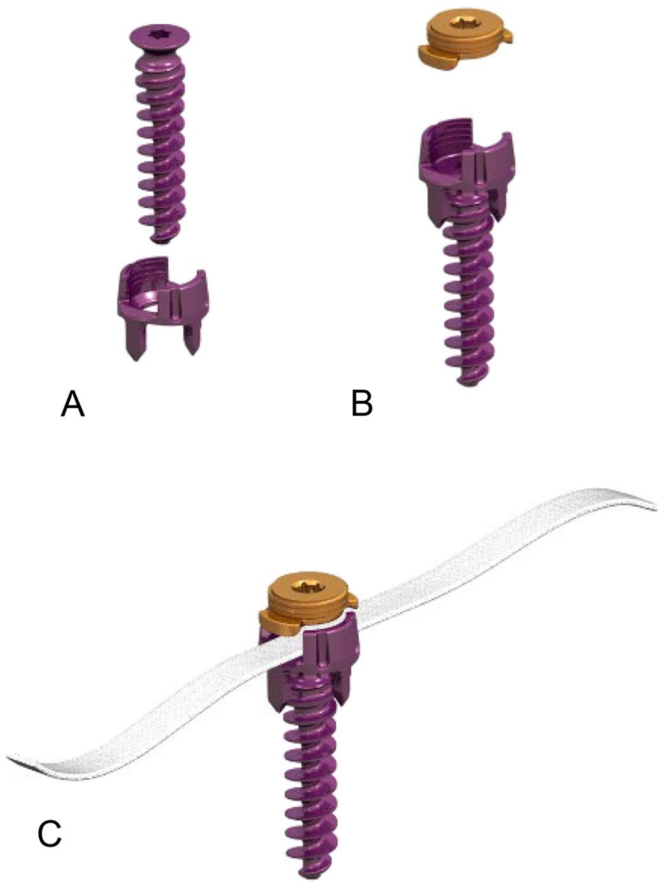

Fig. 1

Figs. 1-A, 1-B, and 1-C The MIScoli tethering device, including the staple and bone screw (**Fig. 1-A**), set screw (**Fig 1-B**), and polyethylene tether (**Fig. 1-C**) (Reproduced with permission of DePuy Spine).

described[30,31] and involves the use of 4 portals to access the thoracic cavity. One staple and 1 bone screw were placed at each level under image control. The UHMWPE tether was positioned onto the center of the staple yoke of the most cephalad tethered vertebra and secured with a set screw. The tether was then sequentially positioned onto the remaining segments, while slack in the tether was taken out by pulling on the tether by hand before the set screws were tightened. No segmental compression maneuvers between the vertebral bone screws to gain immediate curve correction were performed.

All patients followed our protocol for thoracoscopic-assisted scoliosis surgery. Follow-up visits were at 5 weeks and at 3, 6, 12, 18, 24, 30, 36, 42, and 48 months postoperatively or until skeletal maturity.

Outcome Parameters

Maturity was assessed on the basis of age, Risser stage triradiate cartilage (TRC) assessment, bone age by the Greulich and Pyle atlas[32], and Sanders stage[33]. Patient outcome parameters included the Scoliosis Research Society (SRS)-22 questionnaire. Radiographic measures included Cobb angles of the main thoracic, proximal thoracic, and lumbar curves as well as Cobb angles of the tethered segments. Intervertebral disc wedging at the tethered levels was assessed on the posteroanterior radiographs. Magnetic resonance imaging (MRI) preoperatively and at 12, 24, and 36 months postoperatively was performed to assess implant position/placement, intervertebral disc morphology, and axial rotation of the apical vertebrae. All radiographs were assessed by an independent radiographic laboratory (Medical Metrics). Descriptive statistical analysis and subgroup analysis comparing patients with closed or open TRC were performed using SPSS (version 23; IBM). All adverse events were recorded.

Results

Five female patients (age range of 9 to 12 years) were recruited after screening 9 candidates; 4 of the 9 initially screened did not opt for tether placement and were excluded from the study. The TRC was open in 2 of the 5 patients (Patients 3 and 5) and closed in the other 3 patients. In 1 patient, menarche occurred 5 days prior to surgery (Sanders stage 5). The other 4 were premenarchal (Sanders

TABLE II Patient Characteristics at the Time of Surgery

Patient No.	Chronologic Age *(yr + mo)*	Skeletal Age *(yr)*	Sanders Stage	Menarche	Triradiate Cartilage	Curve Type	Tethered Segments
1	12 + 2	13	5	Yes*	Closed	Lenke 1AN	T5 to T12
2	11 + 11	13	2	No	Closed	Lenke 1B-	T5 to T11
3	9 + 4	10	2	No	Open	Lenke 1AN	T5 to T12
4	12 + 11	13	2	No	Closed	Lenke 1AN	T6 to T12
5	12 + 4	12	2	No	Open	Lenke 1A-	T6 to T12

*Premenarchal at the time of surgical planning. Menarche for this patient occurred 5 days prior to the surgical date.

TABLE III Pre- and Postoperative Radiographic Measurements of the 5 Patients Who Underwent Application of the Tethering Device*

Patient and Observation Period	MT Cobb Angle *(deg)* (% Change from Preop.)	Cobb Angle of Instrumented/Tethered Segments *(deg)* (% Change from Preop.)	Right Bending Cobb Angle *(deg)*	PT Cobb Angle *(deg)* (% Change from Preop.)	Lumbar Cobb Angle *(deg)* (% Change from Preop.)	Axial Rotation† *(deg)*
Patient 1 (closed TRC)						
Preop.	44.0	39.6	28.9	24.6	22.7	13.3
5 wk	35.2	30.5		18.5	17.6	
3 mo	38.7	32.1		19.5	20.1	
6 mo	34.3	28.0		19.5	18.7	
12 mo	35.3 (19.8%)	26.5 (33.1%)	18.2	19.3 (21.5%)	16.9 (25.6%)	12.4
18 mo	35.2	27.9		19.2	18.4	
24 mo	36.4 (17.3%)	28.3 (28.5%)	13.9	19.4 (21.1%)	20.9 (7.9%)	6.6
30 mo	32.3	24.4		20.2	15.0	
36 mo	35.1 (20.2%)	26.1 (34.1%)	9.3	19.7 (19.9%)	18.5 (18.5%)	9.6
42 mo	35.6	26.3		21.5	17.3	
48 mo	36.0 (18.2%)	26.4 (33.3%)		23.5 (4.5%)	16.1 (29.1%)	
Patient 2 (closed TRC)						
Preop.	43.2	43.5	30.0	19.1	31.8	10.8
5 wk	42.1	41.9		14.2	35.0	
3 mo	40.5	39.8		11.0	33.1	
6 mo	42.9	36.7		9.9	28.6	
12 mo	35.4 (18.1%)	31.2 (28.3%)	25.7	7.1 (62.8%)	29.5 (7.2%)	6.5
18 mo	37.6	30.9		3.2	30.4	
24 mo	28.9 (33.1%)	26.3 (39.5%)	23.9	9.4 (50.8%)	21.7 (31.8%)	3.8
30 mo	38.9	30.5		3.2	32.3	
36 mo	42.9 (0.7%)	33.5 (23.0%)	22.3	0.0 (100%)	32.1 (−0.9%)	7.2
42 mo	47.6	37.5		1.4	36.3	
48 mo	50.6 (−17.1%)	39.1 (10.1%)		6.1 (68.1%)	32.3 (−1.6%)	
54 mo‡	58.0 (−34.3%)	48.0 (−10.3%)		5.4 (71.1%)	43.9 (−38.1%)	
Patient 3 (open TRC)						
Preop.	37.2	36.2	14.7	23.7	5.0	10.4
5 wk	30.7	28.8		12.4	15.4	
3 mo	31.8	28.3		10.3	8.8	
6 mo	27.8	24.7		17.7	14.9	
12 mo	18.7 (49.7%)	14.3 (60.5%)	19.8	17.3 (27.0%)	5.4 (−8.0%)	2.1
18 mo	22.0	8.5		6.5	−8.7	
24 mo	14.9 (59.9%)	−0.7 (101.9%)	4.2	7.4 (68.8%)	−11.8 (336%)	6.4
30 mo	31.7	−4.5		−0.8	−29.1	
36 mo§	21.0 (43.5%)	−7.9 (121.8%)	5.7	−4.9 (120.7%)	−49 (1,080%)	5.2
42 mo	43.5	−10.0		0.1	−31.7	
48 mo§	41.1 (−10.5%)	−3.3 (109.1%)		−2.8 (111.8%)	−31.5 (730%)	
Patient 4 (closed TRC)						
Preop.	37.9	36.0	25.2	15.3	24.8	10.0
5 wk	29.0	26.1		23.0	21.5	
3 mo	31.9	28.8		15.9	22.3	

continued

TABLE III (*continued*)

Patient and Observation Period	MT Cobb Angle *(deg)* (% Change from Preop.)	Cobb Angle of Instrumented/Tethered Segments *(deg)* (% Change from Preop.)	Right Bending Cobb Angle *(deg)*	PT Cobb Angle *(deg)* (% Change from Preop.)	Lumbar Cobb Angle *(deg)* (% Change from Preop.)	Axial Rotation† *(deg)*
6 mo	33.1	29.9		13.2	20.0	
12 mo	28.2 (25.6%)	28.0 (22.2%)	13.0	15.1 (1.3%)	10.6 (57.2%)	4.5
18 mo	34.1	31.0		15.1	2.5	
24 mo	34.8 (8.2%)	31.4 (12.8%)	8.2	12.9 (15.7%)	7.9 (68.1%)	5.4
30 mo	36.2	33.9		17.9	8.5	
36 mo	39.1 (−3.2%)	35.3 (1.9%)	11.9	17.3 (−13.1%)	4.1 (83.5%)	0.5
42 mo	38.6	35.7		22.4	11.4	
48 mo	38.1 (−0.5%)	36.0 (0%)		27.5 (−79.7%)	18.7 (24.6%)	
Patient 5 (open TRC)						
Preop.	38.0	37.2	29.4	19.4	19.1	5.4
5 wk	18.2	16.5		9.2	15.5	
3 mo	19.5	19.5		10.5	10.0	
6 mo	16.8	16.0		8.7	11.0	
12 mo	14.2 (62.6%)	8.3 (77.7%)	23.7	7.1 (63.4%)	4.9 (74.3%)	4.3
18 mo	10.8	4.8		5.6	−2.1	
24 mo	12.0 (68.4%)	−1.7 (104.6%)	28.0	1.0 (94.8%)	−3.4 (117.8%)	3.2
30 mo	0.0	−1.6		−5.9	−8.6	
36 mo	−2.8 (107.4%)	−10.0 (126.9%)	29.3	−4.3 (122.2%)	−15.2 (179.6%)	0.0
42 mo	−15.2	−15.2		−4.7	−20.8	
48 mo	−12.4 (132.6%)	−12.4 (133.3%)		−4.6 (123.7%)	−21.9 (214.7%)	

*Negative Cobb angles indicate reversal of curve, i.e., from right-sided to left-sided curve. MT = main thoracic, PT = proximal thoracic, and TRC = triradiate cartilage. †Measured from axial MRI scans of the apical vertebra with reference to the horizon. ‡Underwent posterior spinal fusion at 55 months for curve progression and distal decompensation. §Underwent tether removal at 38 months, for overcorrection and distal decompensation, and posterior spinal fusion at 52 months.

stage 2). All patients were seen until skeletal maturity. Patient demographics and pre- and postoperative radiographic parameters are shown in Tables II and III and Figures 2 and 3.

A mean of 7.4 spinal levels (range, 7 to 8 levels) received instrumentation. T5 and T12 were the most common cephalad and caudal instrumented segments, respectively. The mean operative time was 205 minutes (range, 189 to 243 minutes), with a mean blood loss of 136 mL (range, 80 to 200 mL). Hospital stay ranged from 4 to 5 days.

Thirty-seven staple-bone screw components were successfully implanted. Three screws in 3 patients were difficult to insert because of the small size of the most cephalad tethered vertebra. MRI assessment revealed good placement of all 37 staple-bone screw components, with no vertebral margin violations, disassembly, fracture, or pull-out at all time periods.

Coronal-Plane Assessment

The main thoracic (MT), proximal thoracic (PT), and lumbar curves before and after surgery for all 5 patients are presented in Table III and Figures 2 and 3. The MT curve improved from a preoperative mean of 40.1° (range, 37.2° to 44.0°) to 26.5° (range, 12.2° to 33.3°) in the immediate postoperative period. Subsequent postoperative corrections for each patient are shown in Table III and Figure 2.

The Cobb angles of the tethered segments were analyzed separately to assess the growth-modulation effect on these segments (red lines in Figure 2). We observed 2 correction patterns based on TRC characteristics (Table IV). The tethered segments in the 3 patients with closed TRC demonstrated a curve correction of 28.0% at 1 year, and a final correction of 14.9% at 4 years. Correction of the tethered segments was greater in the 2 patients with open TRC, with a 69.2% correction at 1 year, full scoliosis correction at 2 years, and overcorrection (121.5%) at 4 years. The magnitude of curve correction in these 2 patients was greatest at the time of TRC closure, coinciding with their growth spurt (Fig. 2-B). In those with closed TRC at the time of surgery, the curve returned to close to the immediate postoperative Cobb angle (Figs. 4 and 5), while those with open TRC continued to demonstrate correction (Fig. 6).

Two patients required additional surgical procedures. Patient 3 experienced overcorrection to −7.9° at 36 months.

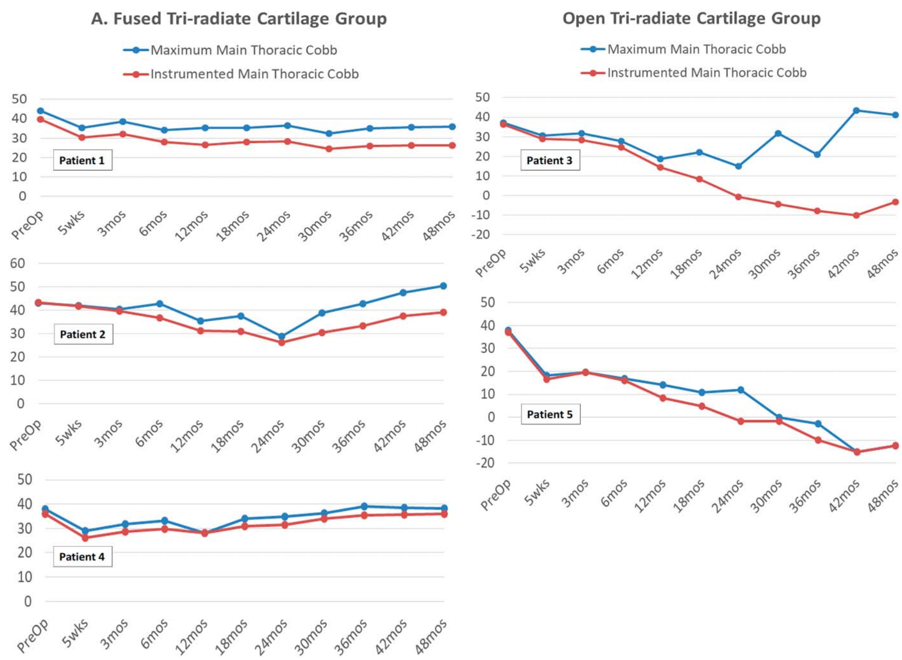

Fig. 2

Pre- and postoperative Cobb angles (in degrees) of the main thoracic curve and the tethered segments of the 5 patients who underwent application of the tethering device.

There was distal adding-on causing spinal imbalance, with the MT curve progressing to 21° (Fig. 7-A). She was the youngest patient and had open TRC at the time of surgery. Thoracoscopic removal of the tether was done at 38 months, followed by posterior fusion of the thoracolumbar curve 52 months after the index surgery (Fig. 7-B).

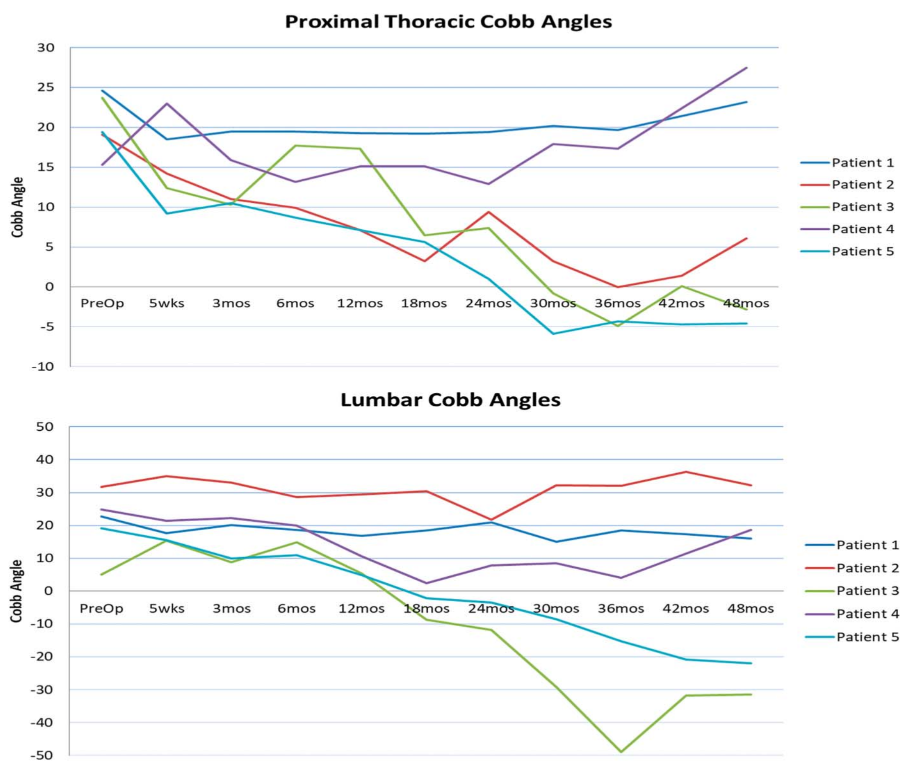

Fig. 3

Pre- and postoperative Cobb angles (in degrees) of the proximal thoracic and lumbar curves.

TABLE IV Cobb-Angle Improvement of the Tethered Segments After Surgery

	1 Yr Postop.	2 Yr Postop.	3 Yr Postop.	4 Yr Postop.
Overall	43.6%	56.6%	60.0%	55.3%
Closed TRC* group	28.0%	28.0%	20.4%	14.9%
Open TRC* group	69.2%	103.3%	124.5%	121.5%

*TRC = triradiate cartilage.

The other patient who required additional surgery (Patient 2) achieved modest correction until 24 months. The MT curve progressed thereafter, reaching 58° at 54 months, accompanied by distal decompensation of the lumbar curve to 44°. She underwent posterior thoracic fusion at 55 months without tether removal. Hers was the only case in this

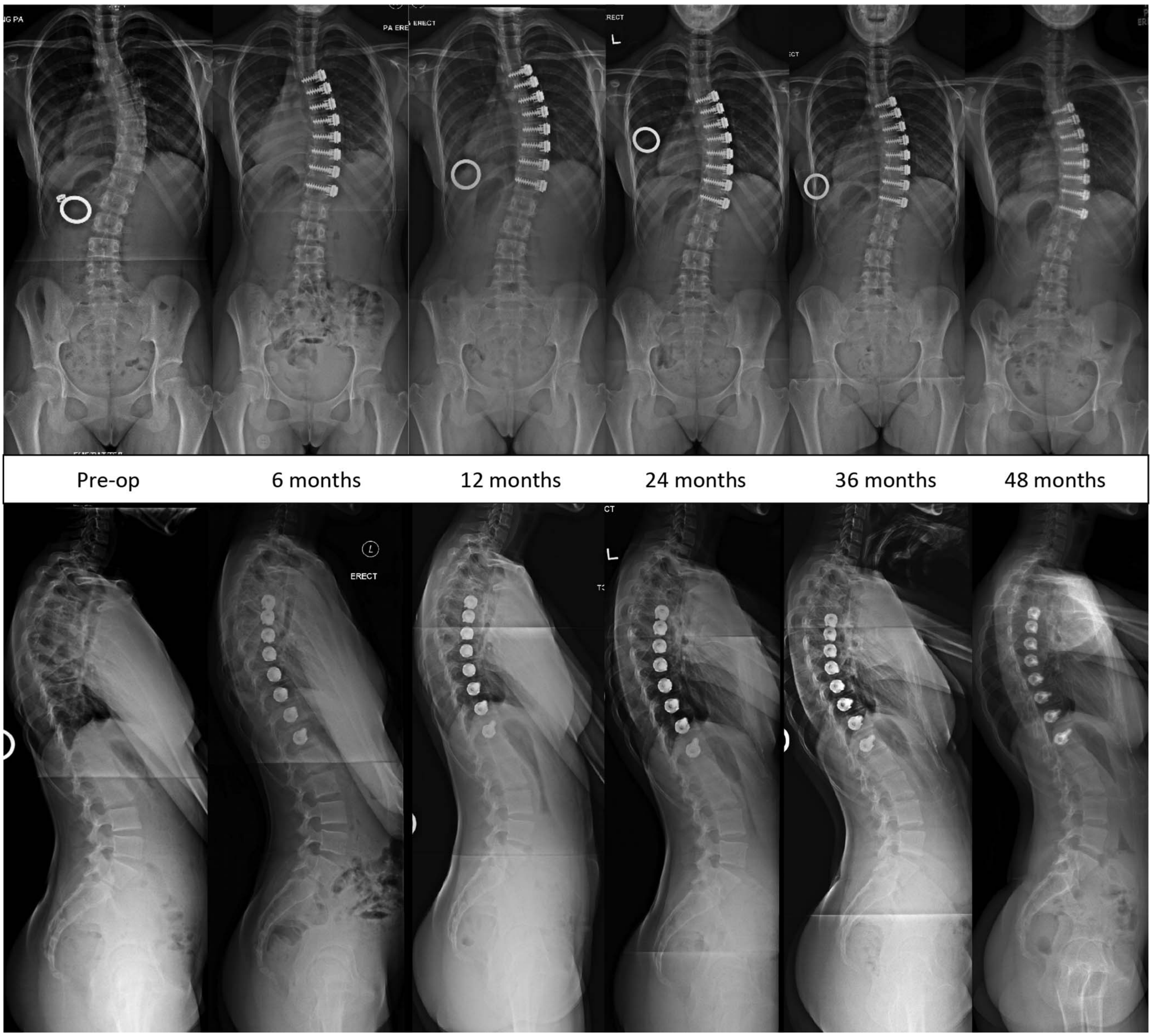

Fig. 4
Images of Patient 1 (closed triradiate cartilage), who demonstrated stability of the coronal and sagittal correction of the tethered segments until 4 years.

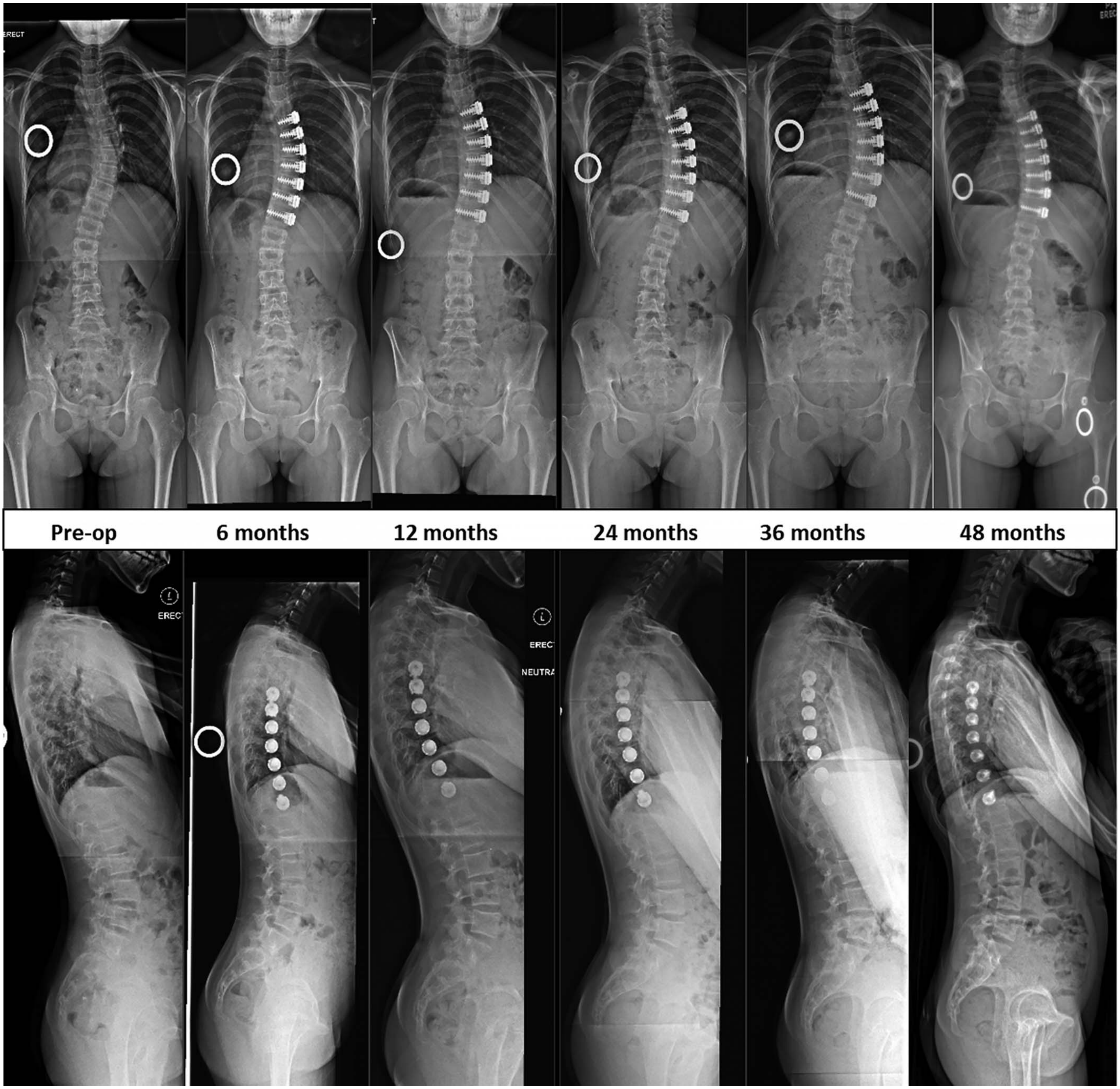

Fig. 5

Images of Patient 4 (closed triradiate cartilage), who demonstrated stability of the coronal and sagittal correction of the tethered segments until 4 years.

series with a Lenke “B” lumbar curve modifier preoperatively (Fig. 8).

The PT curve improved from a preoperative mean of 20.4° (range, 15.3° to 24.6°) to 15.5° (range, 9.2° to 23.0°) in the immediate postoperative period. Subsequent postoperative PT curve corrections for each patient are shown in Table III and Figure 3. However, the trend toward spontaneous PT curve correction was noted in the patients with open TRC (mean of −3.7°).

The lumbar curve was unchanged from a preoperative mean of 20.7° (range, 5° to 31.8°) to 21.0° (range, 15.4° to 35.0°) in the immediate postoperative period. Individual curve corrections at subsequent time points are shown in Table III and Figure 3. At 4 years, the patients with open TRC at the time of surgery showed lumbar-curve reversal (mean of −26.7°), which reciprocated the MT curve overcorrection in this group. At 4 years, the lumbar curve correction for the patients with closed TRC was sustained, with the exception of that for

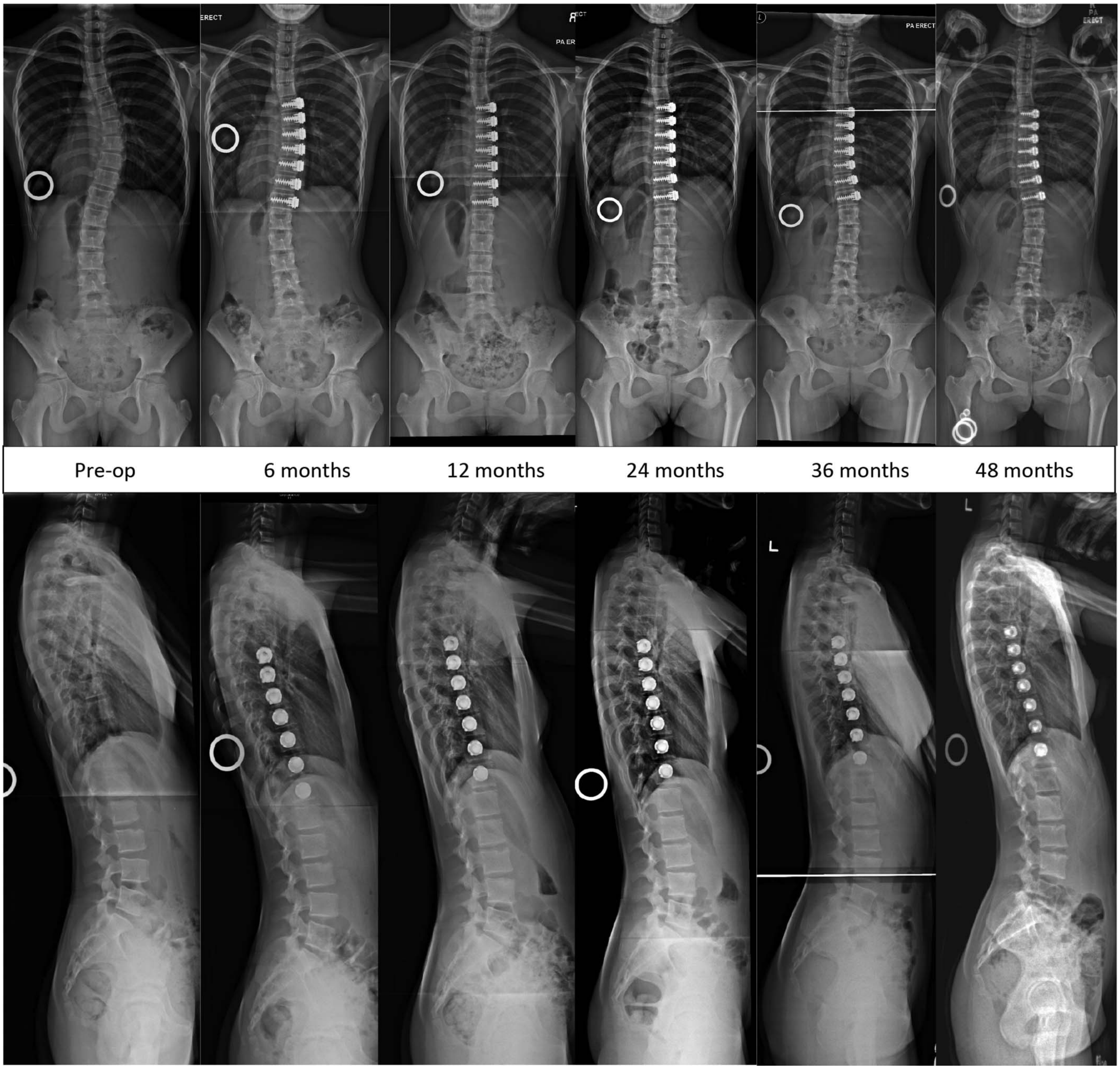

Fig. 6

Images of Patient 5 (open triradiate cartilage). A tethering effect with progressive coronal correction was achieved at 2 years after tether application, with reversal of disc wedging in the tethered segments, followed by slight overcorrection until 4 years, without decompensation.

Patient 2, in whom the lumbar curve increased, reciprocating the increase in the MT curve.

Sagittal-Plane Assessment and Curve Flexibility

There was no significant difference between the mean preoperative and 4-year postoperative thoracic kyphosis (16.0° compared with 17.8°) and lumbar lordosis (46.8° compared with 52.2°). Right side-bending analysis showed preservation of curve flexibility (preoperative range, 14.7° to 30.0°; latest postoperative range, 5.7° to 29.3°) (Table III).

Disc Height and Axial Rotation

Preoperative measurements of the left and right disc heights showed wedge-shaped discs in the periapical segments, with smaller disc heights in the curve concavity. Postoperative improvement in periapical disc wedging morphology was noted particularly for the discs caudal to the apex (Fig. 9).

Axial rotation of the apical segments of the scoliosis was assessed on the axial MRI images. The mean axial rotation decreased from 10° (range, 5.4° to 13.3°) preoperatively to 4.5° (range, 0° to 9.6°) at 36 months (Table III).

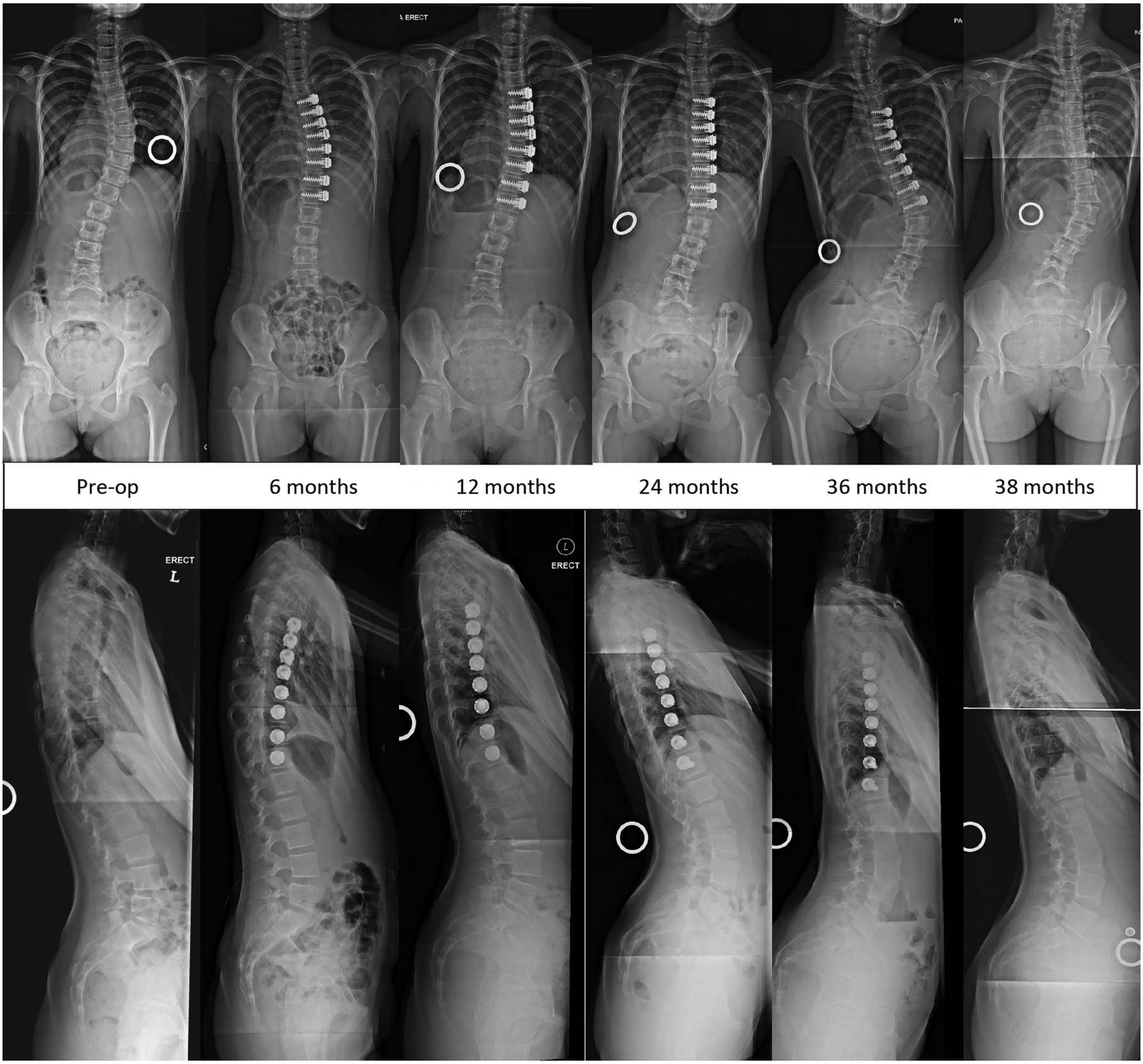

Fig. 7-A

Images of Patient 3 (open triradiate cartilage). **Fig. 7-A** A tethering effect with progressive coronal correction was achieved at 2 years after tether application, with reversal of disc wedging in the tethered segments, followed by overcorrection and distal decompensation requiring thoracoscopic removal of the tethering device at 38 months.

Adverse Events

There were 20 adverse events, of which 16 were mild and 4 were moderate in severity (Table V). The 4 moderate adverse events were observed in 3 patients. Patient 2 had curve progression and distal decompensation, whereas Patients 3 and 5 developed overcorrection and distal decompensation. Patient 3 also had difficult intubation due to small bronchial size and reactive airways. She developed community-acquired pneumonia during the second postoperative month, which was treated by intravenous antibiotics.

SRS-22 Questionnaire

The mean SRS-22 total score was 93.6, 89.4, 92.6, and 90.8 at the preoperative and 12, 24, and 36-month postoperative periods, respectively (p = 0.033 preoperative versus 36 months; higher score = better quality of life). An SRS-22 domain subanalysis showed improvement in self-image scores but did not reach significance (p = 0.301 preoperative versus 36 months). The mean satisfaction domain score decreased from 8.2 preoperatively to 7.0 at 12 months,

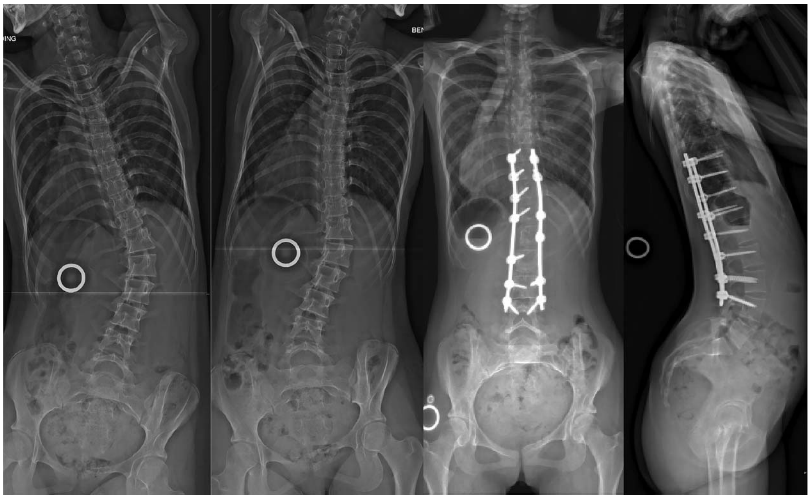

Fig. 7-B

Fig. 7-B Side-bending images showing rigidity of the previously tethered segments and images following definitive posterior fusion performed at 52 months after the index surgery.

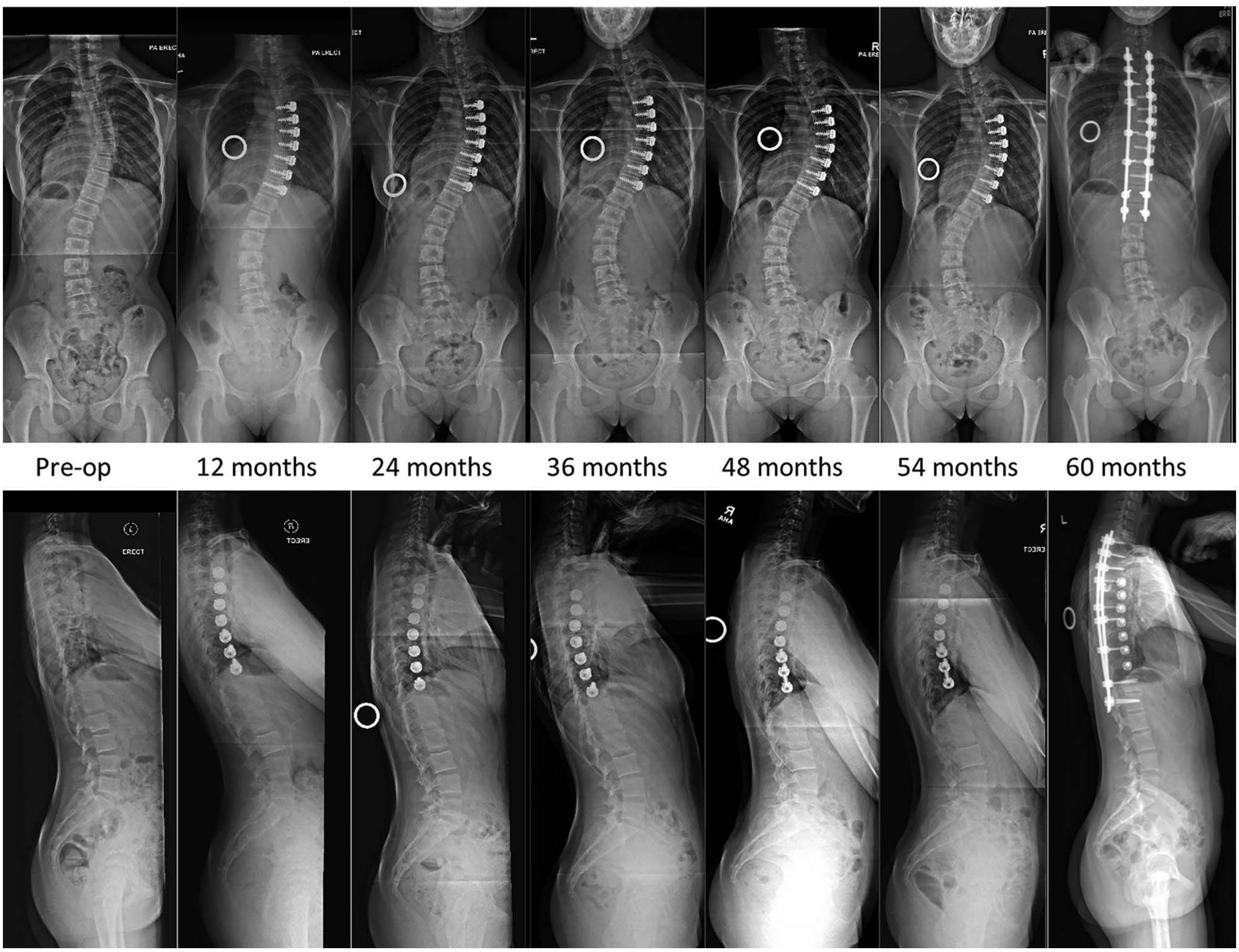

Fig. 8

Images of Patient 2 (closed triradiate cartilage), who experienced late curve progression and distal decompensation requiring posterior spinal instrumentation and fusion 5 years after tether application. The tether was not removed in this patient.

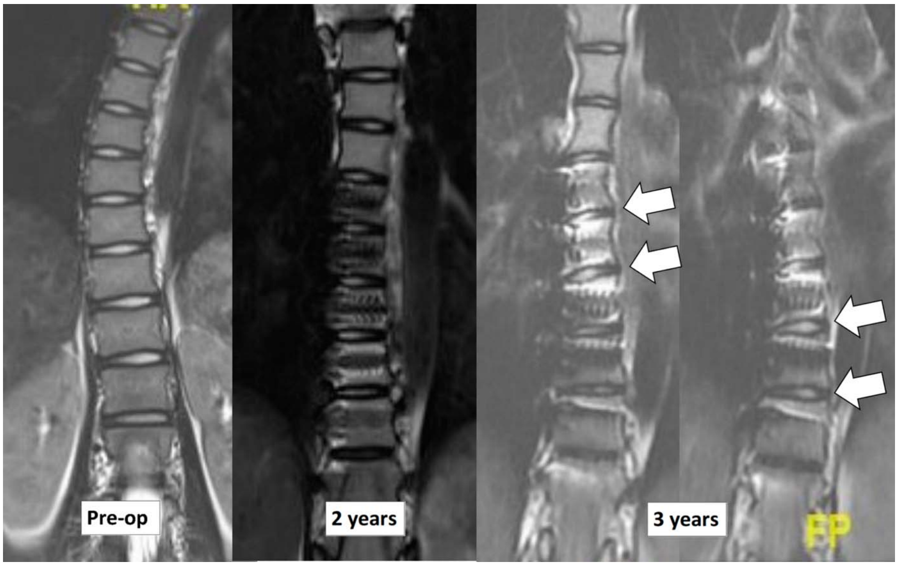

Fig. 9

MRI of the thoracic spine (T2-weighted sequence) of Patient 5 before tether application and at 2 and 3 years postoperatively, showing preservation of intervertebral disc signals and a disc-wedging effect (arrows) after tether application.

but improved between 12 months and 36 months to 7.6 (p = 0.047).

Discussion

Spinal growth modulation with an anterolateral tether in immature patients with thoracic scoliosis resulted in mixed outcomes in this small series of patients followed for at least 4 years. While in some patients, the desired progressive improvement of the scoliosis occurred with growth, in other cases, curve progression occurred or the growth-modulating effect was so powerful that overcorrection resulted. Understanding the ideal patient characteristics and surgical methods will be critical for this technique to provide a reliable means of treating immature patients with scoliosis.

The search for a corrective non-fusion option in scoliosis led to the development of surgical spinal growth-modulation techniques that address the shortcomings of external bracing, such as noncompliance, and allow the application of corrective forces directly on the spine as opposed to indirectly through the chest wall. These techniques exploit the patients' spinal growth and redirect it toward curve correction using the Hueter-Volkmann principle[4]. The desire (both of patients and surgeons) for such a non-fusion method must be tempered by the fact that much about this tethering approach remains to be understood.

TABLE V Adverse Events

Adverse Event	No.	Severity	Intervention
Fever (all subjects)	7	Mild	Medication
Postop. nausea (Patient 2)	1	Mild	Medication
Postop. vomiting (Patient 2)	1	Mild	Medication
Postop. hematuria (Patient 1)	1	Mild	Hydration
Reactive airways (Patient 3)	1	Mild	Pulmonary hygiene
Right pneumothorax (Patients 2 and 3)	2	Mild	Chest physiotherapy
Left/dependent lung pleural effusion (Patient 5)	1	Mild	Chest physiotherapy
Pneumonia (Patient 3)	1	Moderate	Antibiotics
Conjunctivitis (Patient 1)	1	Mild	None
Trunk listing (Patient 3)	1	Mild	Bracing
Overcorrection (Patients 3 and 5)	2	Moderate	Spinal fusion (Patient 3)
Curve progression/distal decompensation (Patient 2)	1	Moderate	Spinal fusion

Animal studies have shown that anterolateral UHMWPE tethers anchored to bone screws modulate spine growth[22-25,34] and are thought to act as a passive anterior convex restraint to growth without the need to resort to epiphysiodesis, allowing correction by continued concave vertebral growth.

We performed a tethering procedure using a novel device in 5 immature girls by applying a UHMWPE tether on the curve convexity. To our knowledge, only 2 reports on tethering have described the results in a similar series of patients. Samdani et al. reported 70% correction from a mean preoperative angle of 44.2° and 44% improvement in axial rotation in 11 patients after 2 years[28]. Newton et al. reported 51% correction from a mean preoperative angle of 52°, with no significant change in thoracic kyphosis, in 17 patients at 2.5 years[29]. Our results are comparable with the findings of these reports using anterior tethering techniques: a mean 55.3% coronal correction at 4 years and 55% axial correction at 3 years. The surgical technique in the above 2 reports differed from ours in that those authors utilized segmental compression of the device to achieve initial curve correction, while in our study, the tension in the device was allowed to build as growth occurred to the point that the force would limit further convex growth.

Overcorrection is an undesirable outcome following anterior tethering that may result if "too small" a deformity is treated in a patient with "too much" growth remaining. While 1 patient in our series with open TRC was able to maintain coronal balance at 4 years despite overcorrection, the other patient developed overcorrection accompanied by distal decompensation that manifested as deterioration of the overall Cobb angle. This patient was the youngest (age 9 at the time of surgery) and the only patient with thoracolumbar kyphosis. The combination of large growth potential, main curve overcorrection, and the presence of distal junctional kyphosis could be important factors in the development of distal adding-on and decompensation in this patient. These issues were alluded to in a recent report on the use of growth modulation in patients <10 years of age[35]. In the study by Samdani et al., there were 2 cases of overcorrection requiring another operation, wherein the distal tension from the tether was released by unlocking the caudal 3 set screws[28]. In their series, Newton et al. observed 4 cases of complete or overcorrection requiring tether removal, and 4 cases of curve progression and/or adding-on requiring posterior fusion[29].

The reason for late worsening and distal decompensation in Patient 2 is unclear. There was no acute angulation between screws to suggest tether breakage. Curve worsening could have been due to lumbar curve progression. Hers was the only case in this series with a Lenke "B" lumbar curve modifier preoperatively.

Our patient population was small owing to the investigative nature of the device. Nevertheless, this series of patients with a minimum of 4 years of follow-up demonstrates the potential for both successes and failures of this evolving technique.

The effect of the tether, used without segmental compression in our patients, can be summarized as follows: (1) Patients who had less growth remaining (closed TRC) had curve reduction that was mainly achieved from device implantation on a spine that had a smaller Cobb angle due to intraoperative patient position. In this group, the device prevented further progression, resulting in curve stability but with little overall additional growth modulation. These curves were at risk of progression given the curve size and remaining growth[36-39]. (2) Patients who were more immature (open TRC) had curve reduction that went on to complete correction/overcorrection. Progressive curve diminution was observed on reaching menarche and persisted until patients reached Risser stage 4. In this group, the device effected spinal growth modulation resulting in curve correction.

Attention to the optimal timing of tether application (based on skeletal maturity and estimates of growth remaining in combination with the size of the deformity), the magnitude of initial intraoperative active curve correction, and curve-pattern identification is likely necessary for consistent outcomes.

Our results suggest that if the tether is used in patients with less remaining growth, additional segmental compression during tether placement may be beneficial to achieve better correction. In very young and immature patients, additional segmental compression could be detrimental and may need to be avoided, as overcorrection may occur. The amount of tether tension (initial correction) is likely impacted by the curve size in addition to the remaining growth. The mild overcorrection in Patient 5 stabilized when she reached skeletal maturity 3 years following tether application, whereas leaving more slack between the tethered spinal segments in Patient 3 might have mitigated the strong overcorrection and subsequent decompensation. Developing algorithms to make predictions of the final outcome will require a much larger series of patients, to ultimately prevent the problems of overcorrection, curve progression, and distal decompensation associated with this technique, all of which may require additional surgical intervention.

Vertebral body tethering is a new growth-modulation procedure for the treatment of progressive thoracic scoliosis in the immature patient. Although 2 of the 5 patients experienced failure of treatment and required posterior fusion, 3 patients avoided fusion that was highly likely had they not been treated. Additional studies with more patients and longer follow-up will allow better evaluation of the indications and outcomes for this surgical procedure. ■

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