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DEFORMITY

Anterior Vertebral Body Tethering for Idiopathic Scoliosis

Two-Year Results

Amer F. Samdani, MD,* Robert J. Ames, BA,*† Jeff S. Kimball, BS,*† Joshua M. Pahys, MD,* Harsh Grewal, MD,*‡ Glenn J. Pelletier, MD,*§ and Randal R. Betz, MD¶

Study Design. Retrospective review.

Objective. To report the 2-year results of the initial cohort undergoing anterior vertebral body tethering (VBT).

Summary of Background Data. Anterior VBT is a promising new technique with abundant preclinical studies but very few clinical results. It is a growth modulation technique, which utilizes patients' growth to attain progressive correction of their scoliosis. We report 2-year results of the initial cohort undergoing this procedure.

Methods. After obtaining institutional review board approval, we retrospectively reviewed our first 11 consecutive patients who underwent anterior VBT with 2-year follow-up. We collected pertinent preoperative, intraoperative, and most recent clinical and radiographical data. Student *t* test and Fisher exact test were utilized to compare different time points.

Results. Eleven patients with thoracic idiopathic scoliosis (8 females) were identified, with a mean age of 12.3 ± 1.6 years. Preoperatively, all were skeletally immature (Sanders mean = 3.4 ± 1.1; Risser mean = 0.6 ± 1.1). All underwent tethering of an average of 7.8 ± 0.9 (range: 7–9) levels, with the most proximal being T5 and the most distal L2. Preoperative thoracic Cobb angle averaged 44.2 ± 9.0° and corrected to 20.3 ± 11.0° on first erect, with progressive improvement at 2 years (Cobb angle = 13.5 ± 11.6°, % correction = 70%; $P < 0.00002$). Similarly, the preoperative lumbar curve of 25.1 ± 8.7° demonstrated progressive correction (first erect = 14.9 ± 4.9°, 2 yr = 7.2 ± 5.1°, % correction = 71%; $P < 0.0002$). Thoracic axial rotation as measured by a scoliometer went from 12.4 ± 3.3° preoperatively to 6.9 ± 3.4° at the most recent measurement ($P < 0.01$). No major complications were observed. As anticipated, 2 patients returned to the operating room at 2 years postoperatively for loosening of the tether to prevent overcorrection.

Conclusion. Anterior VBT is a promising technique for skeletally immature patients with idiopathic scoliosis. This technique can be performed safely and can result in progressive correction.

Key words: adolescent idiopathic scoliosis, anterior vertebral body tethering, fusionless.

Level of Evidence: 4

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From the *Shriners Hospitals for Children, Philadelphia, PA; †Drexel University College of Medicine, Philadelphia, PA; ‡Cooper Medical School of Rowan University, Camden, NJ; §Nemours/Alfred I. duPont Hospital for Children, Wilmington, DE; and ¶ Institute for Spine & Scoliosis, Lawrenceville, NJ.

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Address correspondence and reprint requests to Amer F. Samdani, MD, Shriners Hospitals for Children, 3551 N Broad St, Philadelphia, PA 19140; E-mail: amersamdani@gmail.com

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The current standard of care for skeletally immature patients with idiopathic scoliosis and moderate curves (20°–40°) is thoracolumbosacral orthosis.[1] The recently completed BrAIST study reports on the efficacy of bracing in preventing curves from reaching 50° at skeletal maturity.[2] However, bracing is not always successful.[3] Psychosocial and practical issues may also add to problems with bracing.[4] In addition, when bracing is successful, it is most likely to work in curves measuring less than 40° and those with less growth potential.[2,5] Thus, there remains a practical need to develop growth- and motion-sparing technologies. Those patients who fail bracing and whose curves reach 50° are often offered a fusion. Fusion remains a viable option but limits spine mobility and may lead to adjacent segment disease.[6,7]

Growth- and motion-sparing strategies to treat idiopathic scoliosis seek curve stabilization to delay or avoid spinal fusion.[8–10] A variety of different strategies have been studied including growing rods,[10,11] growth guidance such as the Shilla procedure,[9] and vertebral body stapling.[8] However, each presents unique limitations such as multiple surgical procedures and unintended autofusion of the spine with growing rods.[12] The Shilla procedure requires an apical fusion, and the current limited literature suggests an appreciable reoperation rate.[9] Vertebral body stapling, a technique distinct from vertebral body tethering (VBT), is most effective for modest thoracic curves, that is, those measuring less than 35°.[8] The aforementioned limitations reinforce the need to develop effective growth modulation treatments. At our hospital, we pursued VBT because our data on vertebral body stapling revealed its lack of success in thoracic curves greater than 35°.[13]

Anterior VBT has been extensively studied in animal models. Newton *et al*[14,15] have demonstrated the ability of a unilateral tether to induce deformity in a bovine model with radiographical evidence of disc wedging and rotation, while retaining spine flexibility. Braun *et al*[16] have demonstrated similar results in a goat model. In contrast, clinical experience with the tether has been documented only with a single case report.[17] In this article, we present the 2-year results of our initial cohort of patients who have undergone anterior VBT.

Figure 1. Intraoperative photograph of patient in the lateral decubitus position, demonstrating the incisions utilized to perform thoracoscopic anterior vertebral body tethering (head is to the right, abdomen to the bottom). Three incisions approximately 3 cm long are placed in the posterior axillary line. Three 5-mm incisions are placed in the anterior axillary line and, as seen here, the chest tube is pulled out through the inferior most incision.

MATERIALS AND METHODS

After obtaining institutional review board approval, clinical and radiographical data for all patients who underwent anterior VBT with 2-year follow-up were identified. From a total of 65 patients who had undergone anterior VBT, 11 had reached their 2-year follow-up time point. Radiographical measurements analyzed included coronal Cobb angles (proximal thoracic, main thoracic curve, lumbar), T5–12 kyphosis, L1–S1 lumbar lordosis, coronal and sagittal balance, and shoulder heights. Shoulder heights were determined by measuring the difference between the coracoids. Rib prominence was determined with the scoliometer. Measurements were obtained and compared at the following time points: preoperatively, first erect, 1 year, and 2 years postoperatively. Radiographs were measured by 2 trained medical students after their intraobserver and interobserver variability was determined to be consistently less than 3°. Statistical analysis was performed with Student *t* test and Fisher exact test.

Surgical Technique

The patient is placed in the lateral decubitus position with the curve side up (in this cohort, 100% right side up). Patients underwent single lung ventilation with exclusion of the right lung. The first 5 patients underwent a mini thoracotomy at T9–10 to allow better 3-dimensional assessment of the anatomy and confirm safe bicortical screw placement. Subsequently, the procedure has been performed thoracoscopically. Three 5-mm working thoracoscopic ports are placed in a triangular configuration, with the apex at the fifth intercostal space in the anterior axillary line and the base formed from 2 ports in the midaxillary line, 1 in intercostal space 3 and the other in intercostal space 8 (Figure 1). A camera is inserted into 1 port, a harmonic scalpel in another, and an endoscopic "peanut" in the third port to begin the dissection. The parietal pleura is incised along the lateral aspect of the vertebral bodies anterior to the rib heads in sequential fashion along the length of the curve. Proper position and vertebral levels are checked and confirmed using C-arm fluoroscopy in anteroposterior and lateral positions.

Once the pleura has been incised for the length of spine to be tethered, it is carefully reflected off the anterolateral aspect of the vertebral bodies on the convex side of the curve. The segmental vessels are identified, coagulated, and divided. Care is taken to ensure that the disk spaces remain untouched. At this point, a 15-mm working port is placed in the posterior axillary line to allow for safe placement of vertebral body screws (usually 3 screws per incision). First, a 3-prong staple is placed on the anterior aspect of the vertebral body adjacent to the rib head. The proper position of the staple is confirmed using C-arm fluoroscopy in anteroposterior and lateral views. Care is taken to remain just anterior to the rib head to ensure that the staple is not in the foramen. Subsequently, the screw hole is tapped under fluoroscopic guidance aiming for the contralateral rib head. The optimal length is determined, and the screw is placed. Proper position is again checked and confirmed using C-arm fluoroscopy. The remaining screws are placed in a similar manner.

The tether is passed distal to proximal through the most caudal 15-mm port utilizing the working ports and placed into the screw heads. A tensioning device is placed on a caudal level screw and tensioned to remove any loose tether. Subsequently, utilizing a combination of apical translation, compression, and tensioning of the tether, the curvature of the spine is corrected and the set screws tightened to hold this correction. Fluoroscopy is utilized after each screw is engaged and tightened into the tether to confirm that there is continued correction of the curvature. At this point, the tether is trimmed, leaving approximately 2 cm of length on either side to accommodate potential future lengthening. A chest tube is placed through one of the 5-mm port sites, the hemithorax is irrigated, the lung reinflated under direct vision, and the incisions are closed in layers.

RESULTS

Patient Demographics

Of the 11 patients identified with 2-year follow-up, 8 were female (73%). The mean age was 12.3 ± 1.6 years. These patients all had Lenke 1 curve types with a major thoracic Cobb angle of 44°, which corrected to 19° on bending films (57% flexibility). These patients were skeletally immature, with a mean Risser score of 0.6 ± 1.1 and Sanders digital hand score[18] of 3.4 ± 1.1.

Intraoperative

Patients underwent tethering of an average of 7.8 ± 0.9 (range: 7–9) levels, with the most proximal being T5 and most distal L2. Mean blood loss was 281 mL, with 1 outlier of 950 mL who was a patient in which visualization was difficult secondary to the lung not remaining collapsed. This was a patient in whom a thoracic segmental vessel bled. Three patients underwent same day vertebral body stapling of their lumbar curves. Vertebral body stapling has previously been described.[8] These patients had larger lumbar curves than those patients not stapled (preoperative lumbar curve stapled = 35.3°, not stapled = 21.2°). The decision of whether or not to staple the lumbar curve was in part based on curve magnitude less than 30° and also individual surgeon preference. The mean surgical time for the thoracic tether was 348 minutes. Of note, increasing experience decreased the operative time from 362 minutes for the first 6 patients to 332 minutes for the last 5 patients (Table 1).

Spinal cord monitoring, including motor evoked potentials and somatosensory evoked potentials, was utilized on all patients. No intraoperative changes were seen, and no postoperative neurological deficits were noted.

Radiographical

Preoperative main thoracic Cobb angle averaged 44.2 ± 9.0°, with a compensatory lumbar curve of 25.1 ± 8.7° and a proximal thoracic curve of 21.2 ± 10.8°. The mean percent flexibility of the thoracic curve was 57%. On first erect, these corrected to main thoracic 20.3 ± 11.0°, lumbar 14.9 ± 4.9°, and proximal thoracic 13.4 ± 12.3°. By 1 year the values had improved to main thoracic 16.8 ± 10.6°, lumbar 9.8 ± 5.3°, and proximal thoracic 13.5 ± 15.7°, with continued improvement observed at the 2-year time point (main thoracic 13.5 ± 11.6°, lumbar 7.2 ± 5.1°, and proximal thoracic 15.4 ± 14.1°). Only 1 patient still has a thoracic curve measuring greater than 25°, and she is still skeletally immature (Table 2). Figure 2A-F demonstrates a typical result of the VBT procedure.

TABLE 1. Perioperative Data

Surgical procedure		
Vertebral body tethering	8 (73%)	
Tethering + lumbar stapling	3 (27%)	
	Mean	**Median**
Levels tethered	7.8 ± 0.9	8
Operative time (min) tethering only	348 ± 44	352
Operative time (min) tethering + VBS	512 ± 69	476
EBL (mL) tethering only	205 ± 161	113
EBL (mL) tethering + VBS	483 ± 404*	250

*One patient in the tether + VBS group had a segmental bleed with a total EBL of 950 mL.

EBL indicates estimated blood loss; VBS, vertebral body stapling.

Sagittal Measurements

The average preoperative thoracic kyphosis was 20.8 ± 13.3°. This decreased to 13.5 ± 8.7° on first erect and then gradually increased to 17.9 ± 7.0° at 1-year and 21.6 ± 12.7° at 2-year follow-up. The average preoperative lumbar lordosis was 47.5 ± 10.6° and remained stable (54.9 ± 13.1°) at 2 years. No statistically significant change occurred in the sagittal measurements (Table 3).

Rotation

Rotation was assessed by the attending spine surgeon during the clinic visit utilizing a scoliometer. Overall, the patients' thoracic scoliometer readings improved from a preoperative value of 12.4 ± 3.3° to most recent value of 6.9 ± 3.4°; $P < 0.01$. Whereas preoperatively all but 1 patient had a reading of greater than 10°, by 2-year follow-up, 9 of 11 measured less than 10° (Table 4). The tether likely improves the rotation through a coupling effect of the coronal and axial planes. As the coronal plane corrects, there is some coupled effect on the rotation. However, large rib prominences, particularly those with intrinsic rib deformity, will not correct with tethering.

Balance

Overall, coronal (preoperative = 1.6 ± 1.4 cm, 2 yr = 1.3 ± 6.5 cm; $P = 0.51$) and sagittal balance (preoperative = 3.1 ± 2.0 cm, 2 yr = 1.8 ± 0.9 cm; $P = 0.1$) remained stable. Similarly, shoulder balance did not significantly change (preoperative = 3.1 ± 1.8°, 2 yr = 2.2 ± 2.3°; $P = 0.16$) (Tables 2 and 3).

Complications

No neurological, infectious, or hardware-related complications occurred. One patient had persistent atelectasis, which required a bronchoscopy. Two patients returned to the operating room for loosening of the tether secondary to overcorrection. Both patients were 2 years post-tethering, and their curves had overcorrected by 10°. Clinically, the patients were not experiencing any symptoms. This required a thoracoscopic adjustment surgery where the distal 3 set screws were loosened, the tension removed from the tether, and the set screws retightened. After surgery, the curves in both patients were stabilized. We routinely counsel our patients and their families about the possibility of overcorrection.

DISCUSSION

In this report, we demonstrate the safety and proof of concept of anterior VBT for thoracic idiopathic scoliosis in patients who are skeletally immature. In this cohort, there was progressive improvement of their coronal Cobb angles

TABLE 2. Coronal Measurements

	Main Curve (°)	Lumbar Curve (°)	Proximal Curve (°)	Coronal Balance (cm)	Shoulder Angle (°)
Preoperation (range)	44.2 ± 9.0 (34.0–66.0)	25.1 ± 8.7 (7.8 ± 36.0)	21.2 ± 10.8 (5.7–39.0)	1.6 ± 1.4 (2.0–3.9)	3.1 ± 1.8 (1.0–7.5)
First erect (range)	20.3 ± 11.0 (8.3–42.0)	14.9 ± 4.9 (10.0 ± 26.0)	13.4 ± 12.3 (0.7–31.0)	1.6 ± 1.6 (5.0–5.9)	2.7 ± 2.4 (0.0–7.3)
24 mo (range)	13.5 ± 11.6 (−4.7 to 25.1)	7.2 ± 5.1 (0.0 ± 15.8)	15.4 ± 14.1 (0.0–32.6)	1.3 ± 6.5 (2.0–20.4)	2.2 ± 2.3 (0.0–5.8)
*P**	<0.00002	<0.0002	0.01178	0.51	0.16

*Preoperation versus 24 months.

and thoracic prominences; no patient demonstrated a worsening of their deformity, and no neurological, infectious, or instrumentation-related complications occurred.

Several preclinical studies document the promise of anterior VBT,[14–16,19] although the clinical reports remain sparse.[17,20] Our motivation for pursuing this promising technology stemmed from the publication of our recent results with anterior vertebral body stapling, a distinctly different procedure from tethering, for moderate thoracic scoliosis in the immature patient.[8] In summary, stapling effectively controls thoracic

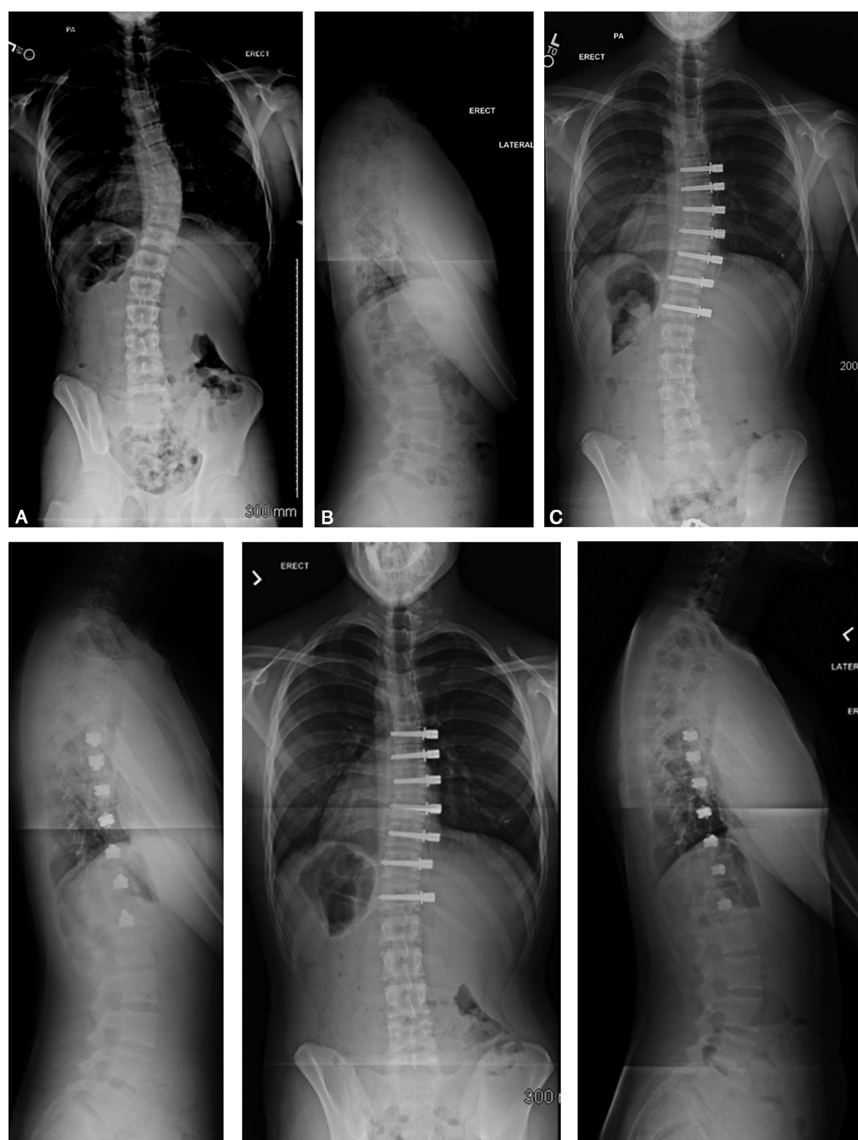

Figure 2. **A** and **B**, A 14-year-old boy (Risser 3, Sanders 4) presented to our institution with a 42° right thoracic curve that had failed bracing. He underwent a right T6-T12 anterior vertebral body tethering with correction to 25° on first erect films (**C** and **D**). At 2 years postoperation, he is now 16 years of age, Risser 5 with a 10° curve (**E** and **F**).

TABLE 3. Sagittal Measurements

	Thoracic Kyphosis (°)	Lumbar Lordosis (°)	Sagittal Balance (cm)
Preoperation (range)	20.8 ± 13.3° (1.7–46.0)	47.5 ± 10.6 (38.0–65.0)	3.1 ± 2.0 (0.3–7.9)
First erect (range)	13.5 ± 8.7 (0.2–30.0)	38.4 ± 9.2 (30.0–57.0)	5.9 ± 3.8 (0.1–11.9)
24 mo (range)	21.6 ± 12.7 (4.9–37.6)	54.9 ± 13.1 (45.2–69.8)	1.8 ± 0.9 (0.6–2.9)
*P**	0.13	0.66	0.10

**Preoperation versus 24 months.*

curves measuring less than 35°, with limited success in larger magnitude curves.[13] Currently, the options for patients with larger thoracic curves remain limited.

Bracing has efficacy for curves between 20° and 40°, although it is not successful for all patients.[21–23] Furthermore, the mean thoracic curve in our patients who had undergone VBT exceeded 40°, likely further diluting the potential benefits of bracing. The skeletal immaturity of our cohort puts them at risk for further progression.[3] Thus, anterior VBT offers a treatment alternative to patients with near surgical curves who are considered to be at very high risk for continued progression.

Many in our cohort were in the range for an eventual spinal fusion, which remains a satisfactory option.[24–26] However, the long-term implications of spinal fusion remain largely unknown. Some studies suggest an increased risk of disc degeneration and back pain,[6,7] although further study with modern instrumentation is needed. To date, the patients in our cohort have avoided spinal fusion and have subjectively retained spinal mobility. Further study incorporating mobility measures will objectively evaluate spine flexibility after tethering. The operative times for the tether likely are longer than those for a posterior spinal fusion being performed by an experienced surgeon, and blood loss is similar. With our most recent patients, we have found a marked decrease in operative time compared with our earlier patients.

Our current study invokes optimism for utilizing VBT in patients with thoracic scoliosis who are skeletally immature. Several issues mandate consideration. The procedure is performed through an anterior approach, which some literature suggests may impact pulmonary function.[27,28] However, several authors report minimal to no decline in pulmonary function after anterior spine surgery, with thoracoscopic approaches having the least effect.[29,30] Longer-term follow-up is required to prove the maintenance of correction observed to date. We remain hopeful, because the correction occurred progressively over time to imply growth sparing of the curve. The thoracic kyphosis increased over time in these patients. Although restoration of thoracic kyphosis is a goal for patients with adolescent idiopathic scoliosis,[31–33] excessive kyphosis is undesirable. To limit the potential hyperkyphosing effects of anterior surgery, a thoracic kyphosis of greater than 40° is considered a contraindication for tethering surgery.

TABLE 4. Rib Rotation

Preoperation (range)	12.4 ± 3.3° (6–17)
Most recent (range)	6.9 ± 3.4° (3–12)
P	<0.01*

**Statistically significant.*

In this cohort, 2 patients underwent repeat surgery for overcorrection. In our opinion, this is an anticipated outcome and part of our informed consent, because we currently lack the knowledge to know the goal for correction during the initial surgery. Typically, we aim to correct the curve to less than 20° intraoperatively, with the understanding that this increases by 5° to 10° on first erect. However, patients with more growth potential may warrant less correction. As our experience with anterior VBT increases, we hope to more accurately predict the gradual correction that occurs. In addition, the surgeon must be cognizant of the T9–L2 region which in a flexible curve can easily overcorrect. Our criteria for a second adjustment surgery include overcorrection of 10° or greater, and all patients and families are advised of this possibility.

Currently, we consider anterior VBT in skeletally immature patients with thoracic curves ranging from 35° to 60° and which demonstrate flexibility to less than 30°. Skeletal maturity is determined using a variety of factors including Risser sign (≤2), Sanders score (≤4), and menarche status. Although these are general guidelines, exceptions may occur on the basis of a multitude of factors including family history, parental height, secondary sex characteristics, and so forth. Generally, the upper limit of curve magnitude is 60°, but we may consider this procedure in larger curves as long as they demonstrate flexibility to less than 30°. Absolute contradictions include thoracic hyperkyphosis greater than 40° and a rotational prominence greater than 20°.

In this first report on 2-year follow-up of skeletally immature patients having undergone anterior VBT for thoracic scoliosis, the results suggest a gradual improvement of their spine deformity with a low-risk profile. Further study with longer-term follow-up will hopefully elucidate the potential risks and benefits of this innovative technology.

➢ Key Points

- ❑ Anterior VBT results in progressive improvement of thoracic scoliosis.
- ❑ The procedure can be performed safely with minimal occurrence of major complications.
- ❑ This powerful technique can result in overcorrection of the curve.

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