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CASE SERIES

Vertebral body tethering compared to posterior spinal fusion for skeletally immature adolescent idiopathic scoliosis patients: preliminary results from a matched case–control study

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Abstract

Purpose Direct comparisons between vertebral body tethering (VBT) and posterior spinal fusion (PSF) for adolescent idiopathic scoliosis (AIS) are limited. We aimed to evaluate 2-year results of VBT and PSF to report comparative outcomes.

Methods 26 prospectively enrolled VBT patients were matched 1:1 by age, gender, Risser sign and major curve magnitude with PSF patients. At a minimum 2-year follow-up, surgical results and radiographic outcomes were reviewed.

Results Operative time, anesthesia time, blood loss, and length of stay were significantly lower in the VBT group (< 0.001, $p = 0.003$, $p < 0.001$, $p < 0.001$, respectively). The major curve at 2 years was corrected by 46% in the VBT group vs. 66% in the PSF ($p = 0.0004$). Success following VBT, defined as no fusion surgery and Cobb angle < 35° at the 2-year follow-up, was seen in 20 VBT patients (77%) ($p = 0.0003$) and correlated with mean Cobb angle of < 35° on 3-month imaging. 12 VBT patients (46%) showed curve improvement over time, and those patients had significantly lower mean Cobb angle on the 3-month radiograph than non-modulators (23° vs 31°, $p = 0.014$). At 2 years, cord breakage occurred in five patients (19%). By 2 years, three VBT patients developed complications (2 pleural effusion and 1 overcorrection needing return to OR). In contrast to PSF, growth continued at T1–T12 (mean 13 mm) and over the instrumented levels (mean 10 mm) following VBT, compared to no growth over instrumented segments in the fusion cohort ($p = 0.011$, $p = 0.0001$).

Conclusion In Sanders stages 3 and 4 patients treated in the USA, Cobb angle < 35° on 3-month imaging was associated with success at the 2-year follow-up. Curve correction was superior in the PSF group with 96% achieving curve correction to < 35° vs. 77% of the VBT patients. Cord breakage was noted in 19% of VBT patients at the 2-year follow-up. Three patients developed complications in both the VBT and PSF cohorts.

Level of evidence Level II (prospective study with matched retrospective comparison group).

Keywords Growth · Modulation · Scoliosis · Spine deformity · Anterior spinal instrumentation · Outcomes · Adolescent · Idiopathic · Posterior fusion

Introduction

Adolescent idiopathic scoliosis (AIS) is the most common pediatric spinal deformity, and severe cases can result in curve progression in adulthood with possible pulmonary dysfunction for thoracic curve patterns [1, 2]. Posterior spinal fusion surgery is the primary surgical treatment option, although vertebral body tethering (VBT) is now being increasingly used to treat AIS [3]. VBT may leverage the Hueter–Volkmann principle, changing the load on the spine to alter vertebral growth patterns [4–6]. Proposed advantages of VBT are preserved spinal growth and spinal mobility, potentially decreasing the risk of adjacent segment

IRB approval was obtained for all aspects of this study, which was performed as part of a surgeon-sponsored investigation device exemption (IRB 17-007801, FDA IDE G18003, NCT03506334) and an institutional registry (IRB 14-004866).

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arthritis in the uninstrumented region of the spine [7–9]. However, early reports of VBT have found high rates of cord breakage, up to 50% by 2 years following surgery [6, 7, 10]. Also, there is little data to confirm that spinal growth and curve correction over time occur over the instrumented vertebrae. Although variable revision rates have been reported, only two studies to date have directly compared fusion to VBT at a minimum 2-year follow-up. Both studies were retrospective, with one lacking matched patients and the other focusing on patient-reported outcomes and tests of physical function [10, 11]. Thus, definitive comparative data is lacking on whether this novel procedure provides similar or superior results to the standard treatment of PSF for patients with adolescent idiopathic scoliosis and which patient and surgical factors are associated with a successful result following VBT.

We undertook a prospective matched case–control study to evaluate the results of VBT compared to PSF for the treatment of AIS including perioperative and radiographic outcomes, need for revision surgery, and evidence of spinal growth over the instrumented segments. We hypothesized that VBT results in shorter hospitalization, but decreased curve correction compared to traditional PSF. We further sought to determine the rate and effect of cord breakage on patient outcomes and need for revision surgery, and whether any perioperative factors were predictive of a successful result.

Materials and methods

AIS patients at a single tertiary referral center were prospectively enrolled in an Investigational Device Exemption study (IRB 17–007,801, FDA IDE G18003, NCT03506334). The aim of this study was to report the safety of VBT. Primary outcome measure was return to OR for cause related to index surgery prior to the 2-year follow-up, and also procedure- and device-related adverse events. Forty patients were enrolled in the IDE, of whom 26 had a minimum 2-year follow-up. Skeletally immature patients between the ages of 10–16 years with scoliosis curves and growth remaining as assessed by a Sanders skeletal maturity stage (SSMS) of 4 or less, or Risser 2 or less with a minimum 2-year follow-up were included. Exclusion criteria included congenital, neuromuscular, or syndromic scoliosis, nonflexible curves (bending films showing residual curves > 40°), thoracic kyphosis greater than 40°, and previous spinal surgery. All VBT surgeries were performed by the two experienced pediatric orthopedic surgeons in conjunction with one of two approach surgeons and a consistent surgical team. Spine fusion procedures were performed by one of five pediatric spine surgeons at the same tertiary referral center. Hospital record, complications, and preoperative, 3-months, 1-year and 2-year follow-up SRS scores and radiographs were reviewed.

The 26 VBT patients were prospectively enrolled and then matched 1:1 by age, gender, Risser sign and curve magnitude with a retrospective cohort of AIS fusion patients from an institutional registry. Hand bone age and SRS scores were not available for fusion patients. There were 23 females and 3 males in each cohort (Table 1). The majority of the patients in each cohort had a Lenke 1 curve (VBT 81% and PSF 73%). In the VBT group, 24 patients had instrumentation of a major thoracic curve, while 2 had both thoracic and lumbar instrumentation performed on the same day. Mean preoperative major Cobb angle was 50° (standard deviation, SD 8) in the VBT group and 52° (SD 5) in the fusion group. A mean of 8 (range, 6–12) levels were instrumented in the VBT patients and 11 (range, 7–15) levels in the PSF group.

In the 26 VBT patients, the angle between the screws was measured on radiographs from the 3-month, 1- and 2-year follow-up visits. A change in interscrew angle by 6° or more on subsequent radiographs was considered a suspected broken cord as previously defined [6–8]. T1–T12 height, T1–S1 height, and upper instrumented vertebra (UIV) to lower instrumented vertebra (LIV) heights were measured preoperatively and at 3-month, 1-year, and 2-year follow-up. Straight line measurements were used from the superior T1 endplate to the inferior aspect of T12 for T1–T12 or upper border of sacrum for T1–S1. Straight line measurements were made from the superior endplate of the UIV to the inferior endplate of LIV to assess if growth occurred following surgery over the instrumented vertebrae.

Matched pairs analysis was used to evaluate pre- and postoperative surgical outcomes. Chi-square analysis was used for discrete variables and Student's t test for continuous variables to compare parameters between VBT and PSF patients. Significance was defined as a p value less than 0.05. Growth modulation (progressive improvement in curve correction over time) was defined as 5 degree or more improvement in Cobb angle over maximally tilted vertebra at each time point at any two postoperative time points. Criteria for success for VBT was defined at the 2-year follow-up as major Cobb angle < 35° and no fusion surgery independent of suspected cord breakage. Success for the fusion cohort was defined as major Cobb angle < 35° and no reoperation.

Results

On comparison of the 26 VBT patients with the matched PSF group, we found that operative time and anesthesia time were significantly lower in the VBT group compared to the controls ($p < 0.001$, $p = 0.003$, respectively). Compared to the PSF cohort, VBT patients had decreased mean surgical

Table 1 Demographics

	VBT group	PSF group	*P* value
Age (years)	13.2 (12.8–13.7)	13.4 (13.0–13.8)	0.58
Gender	23 females 3 males	23 females 3 males	
Height (cm)	159 (SD 9)	161 (SD 6)	0.48
Weight (kg)	51 (SD 12)	52 (SD 10)	0.45
Risser			0.08
0	16	10	
1	4	6	
≥ 2	6	10	
Sanders			
2	0		
3	6		
4	20		
5	0		
Lenke			0.57
1	21	19	
2	2	4	
3	1	1	
4	0	0	
5	2	2	
6	0	0	
Preop mean major Cobb (°)	50 (SD 8)	52 (SD 5)	0.05
Preop mean T1–T12 (mm)	234 (SD 22)	253 (SD 26)	0.002
Preop mean T1–S1 (mm)	382 (SD 33)	416 (SD 39)	0.0001
Number of instrumented levels	8 (range, 6–12)	11 (range, 7–15)	< 0.0001
Mean follow-up time (years)	2.0 (range, 2.0–2.1)	2.4 (range, 2.1–2.6)	
Mean preop bending (major Cobb) (°)	23 (54%, SD 10.5)		

blood loss ($p < 0.0001$) and a significantly shorter hospital stay ($p < 0.0001$, Table 2).

At all time points, curve correction was superior in the fusion group compared to the VBT cohort (Table 2). At 2-year follow-up, percent curve correction was 46% in the VBT group compared to 66% in the fusion cohort ($p = 0.0004$). Of the 26 VBT patients, 8 (31%) had growth modulation or improvement in the major Cobb angle between 3-month and 1-year postoperative radiographs (Table 3). The remaining 18 patients (69%) maintained their Cobb angle. Between the 1- and 2-year follow-up, however, 4 of the 26 (15%) patients had improvement in their major Cobb angle, 14 maintained status quo (54%), and 8 (31%) worsened. Of the eight that worsened, two had broken tether cords at 2 years and the remainder had adding on. Overall, 12 of the 26 patients had improvement in the Cobb angle between any two time points. Those who had growth modulation or improvement, compared to those who did not, had a mean Cobb of 19° compared to 34° at the 2-year follow-up ($p = 0.0001$) (Table 3). There was no detected difference in SSMS, age, % correction at 3-month imaging, Cobb angle at 3-month imaging, or Risser score between those who had growth modulation and those who did not have curve improvement between any two time points.

Success in the VBT group was defined as no fusion surgery and Cobb angle < 35° at the 2-year follow-up [10]. Of the 26 patients, 19 (73%) met these criteria. Interestingly, of the seven patients with an unsuccessful outcome, six had a major Cobb angle greater than 35 degrees on 3-month X-ray. Correction on 3-month radiograph to < 35° was associated with success at 2 years ($p = 0.001$, Fig. 1). Success at 2-year follow-up was also associated with growth modulation or curve improvement over time ($p = 0.002$). Of the 11 patients who had growth modulation, 9 had a Cobb angle < 35° at 3-month imaging. The two who had growth modulation with Cobb angle more than 35° at 3 months were both SSMS 4, and the final major Cobb angles were 32° and 29°. At 2-year follow-up, 25 (96%) patients in the PSF cohort had a Cobb angle of < 35° (range 0–37).

Compared to the fusion group, VBT patients had similar preoperative standing heights, but shorter preoperative T1–12 and T1–S1 heights (Table 4). However, at the 2-year follow-up, change in T1–T12 from the 3-month follow-up was significantly greater in the VBT group as compared

Table 2 Surgical and radiographic results

	VBT (*N* = 26)	Fusion (*N* = 26)	*P*-values
Surgical results			
Blood loss (ml)	249 (SD 164)	998 (SD 768)	< 0.0001
Operative time (hrs)	4.9 (SD 1.7)	6.7 (SD 1.3)	< 0.0001
Anesthesia time (hrs)	7.4 (SD 1.8)	8.3 (SD 1.1)	0.003
Length of stay (days)	3.6 (SD 1)	5.0 (SD 1)	< 0.0001
Radiographic results			
Preop proximal thoracic curve (°)	23 (SD 9)	27 (SD 8)	0.08
Preop thoracic curve (°)	49 (SD 9)	51 (SD 7)	0.08
Preop lumbar curve (°)	31 (SD 11)	38 (SD 9)	0.008
3-Month proximal thoracic curve (°)	18 (SD 9)	13 (SD 5)	0.04
3-month thoracic curve (°)	27 (SD 8)	16 (SD 7)	< 0.001
3-month lumbar curve (°)	21 (SD 7)	17 (SD 11)	0.007
3-month major Cobb correction (°) (Preop – 3 mth)	22 (SD 8)	36 (SD 10)	< 0.0001
3-month % correction major Cobb	45 (SD 16)	68 (SD 17)	< 0.0001
1-year proximal thoracic curve (°)	18 (SD 9)	13 (SD 6)	0.04
1-year thoracic curve (°)	20 (SD 8)	16 (SD 10)	0.0004
1-year lumbar curve (°)	19 (SD 9)	16 (SD 10)	0.02
1-year major Cobb correction (°) (Preop – 1 year)	25 (SD 9)	36 (SD 9)	< 0.0001
1 year % correction major Cobb	50 (SD 18)	68 (SD 14)	0.0001
2-year proximal thoracic curve (°)	16 (SD 10)	14 (SD 6)	0.7
2-year thoracic curve (°)	27 (SD 12)	18 (SD 9)	0.002
2-year lumbar curve (°)	23 (SD 10)	15 (SD 11)	0.0025
2-year major Cobb correction (°) (Preop – 2 year)	23 (SD 12)	34 (SD 9)	0.0002
2-year % correction major Cobb	46 (SD 23)	66 (SD 15)	0.0004

Table 3 Change in major Cobb angle over time in VBT patients

	Modulation	No Modulation	*P* value
Change in major Cobb (°) (3 months – 1 year)	7 (*N* = 8)	0 (*N* = 18)	< 0.001
Change in major Cobb (°) (1 year – 2 years)	7 (*N* = 4)	−4 (*N* = 22)	0.002
Change in major Cobb (°) (3 months – 2 years)	9 (*N* = 10)	−5 (*N* = 16)	< 0.001

to the fusion cohort ($p = 0.011$). Also, mean change in the height of the instrumented levels was noted in the VBT group at the final follow-up ($p = 0.0001$), indicating that in contrast to PSF, growth continues over the instrumented levels following VBT with each instrumented level growing on average 1.3 mm over the study period (Fig. 2).

Segmental interscrew angle was measured in the 26 VBT patients to evaluate for cord breakage. Comparison of screw angle changes between 3 months and 2 years postop imaging revealed 5 of the 26 patients (19%) had > 5° change in the interscrew angle, suggesting cord breakage, with a total of six affected vertebral segments (Table 5). No cord breakage was noted between the 3-month and 1-year follow-up radiographs. Among the five patients with a suspected broken cord by the 2-year follow-up, mean major Cobb angle worsened from 25° to 30° between the 1- and 2-year follow-up. 11 of the 26 patients had 3-year follow-up radiographs and no additional suspected cord breakages were noted.

On analysis of the health-related quality-of-life (HRQOL) outcomes in children who underwent VBT, we found that the mean preoperative SRS-22R score was 4.1, while at 2-year follow-up it was 4.3 ($p = 0.16$). Compared to the preoperative values, SRS satisfaction scores improved for VBT patients at the 3-month, 1-year and 2-year satisfaction scores (< 0.0001, < 0.0001 and 0.001, respectively). There were no significant changes in the other SRS-22R domains between the preoperative and 2-year follow-up (Table 6).

By the 2-year follow-up, complications occurred in three VBT patients. These included two patients who developed pleural effusion within 30 days of surgery, one of which resolved with pigtail catheter placement and one with thoracentesis. One VBT patient underwent release of the cord due to overcorrection. Complications at 2 years in the PSF group included three patients who developed wound infection, one which resolved with antibiotics, one following irrigation and debridement and one with delayed deep infection which

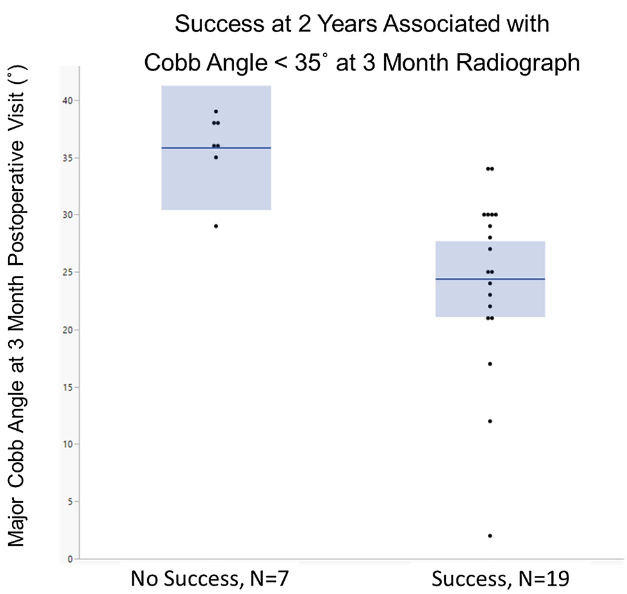

Fig. 1 Success as defined by no fusion and Cobb angle less than 35 degrees was associated with good correction on first standing postoperative radiograph

ultimately required implant removal and reimplantation after 2 years. One fusion patient had a residual curve greater than 35 degrees. Thus, there was a successful outcome in 23 of the 26 fusion patients (88%) compared to 73% in the VBT group.

There were 11 VBT patients with 3-year follow-up of whom an additional patient had lumbar curve progression and underwent lumbar tether, one patient with a Lenke 1AR curve pattern had coronal plane decompensation and curve progression and underwent fusion surgery at 4 years postoperatively. This patient had Cobb angle < 35 degrees at 3 months, then had a suspected broken cord, and went on to fusion 4 years later (Fig. 3). A final VBT patient underwent removal of symptomatic implants at 4 years postoperatively. Thus, at the time of the latest follow-up, 4 of the 26 underwent additional surgery including one fusion procedure (15%).

Discussion

In this study, we sought to report the comparative results of VBT and fusion surgery for a matched cohort of patients at the 2-year follow-up as approved by an IDE protocol. Reporting the results of a new surgical technique in conjunction with controls treated in the standard fashion is essential to expeditiously determine the best practices and appropriate inclusion criteria. This ultimately results in improved patient safety and lower revision rates, as more surgeons performing the new procedure can be informed regarding the new approach. Regarding vertebral body tethering, previous authors have described success as a major Cobb angle < 35° and no fusion surgery at the time of follow-up. We found that

Table 4 Spinal growth

	VBT	Fusion	*P* value
Mean preop standing height (cm)	159.4 (SD 9.1)	160.8 (SD 5.7)	0.48
T1–T12 height (mm)			
Mean preop	234 (SD 21.7)	253 (SD 26)	0.002
Mean 3-month	246 (SD 14.2)	265 (SD 21)	0.0012
Mean 2-year	264 (SD 31.8)	274 (SD 23)	0.03
Change from preop to 3 months	12 (SD 14.2)	16 (SD 25)	0.6
Change from preop to 2 years	23 (SD 12)	21 (SD 17)	0.73
Change from 3 months to 2 years	13 (SD 11)	4 (SD 19)	0.011
T1–S1 height (mm)			
Mean preop	382 (SD 33)	416 (SD 39)	0.0001
Mean 3-month	401 (SD 26)	425 (SD 31)	0.0083
Mean 2-year	423 (SD 31)	439 (SD 35)	0.12
Change from preop to 3 months	19 (SD 17)	19 (SD 28)	0.49
Change from preop to 2 years	42 (SD 20)	26 (SD 25)	0.028
Change from 3 months to 2 years	23 (SD 18)	10 (SD 32)	0.05
Height of instrumented levels (mm)			
Mean 3-month	171 (SD 42)	240 (SD 46)	< 0.0001
Mean 2-year (mm)	181 (SD 40)	240 (SD 45)	< 0.0001
Change from 3 months to 2 years	10 (SD 8)	0 (SD 11)	0.0001
Change from 3 months to 2 years per level instrumented	1 (SD 1)	0 (SD 1)	< 0.0001

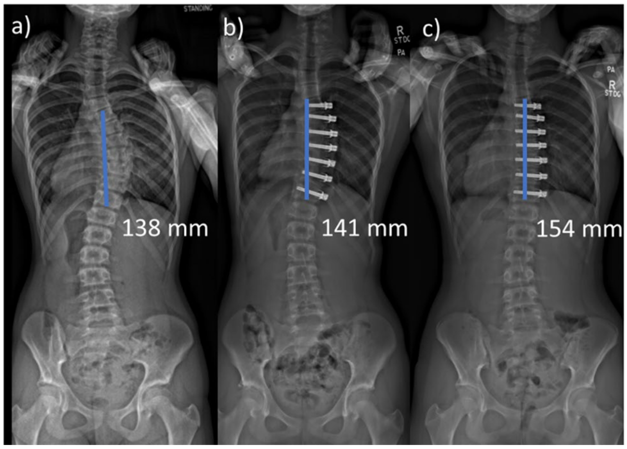

Fig. 2 PA radiographs of a 12-year-old female who presented with a 41° Lenke 1A curve at Sanders stage 3 (**a**). Between 3 months (**b**) and 2 years (**c**) following VBT, major Cobb angle improved from 30° to 19°, while the length over the instrumented levels increased from 141 to 156 mm and her standing height increased by 7.5 cm

77% of patients met this criterion at the 2-year follow-up. Previous studies report revision VBT rates of 15.8% to 30% at 2- to 5-year follow-up [9, 10, 12]. However, few comparative studies have been performed, especially those with matched patient cohorts [10, 11]. To our knowledge, this is among the first studies to compare prospective VBT patients to a 1:1 age-, gender-, Risser sign- and curve magnitude-matched fusion cohort from an institutional AIS registry.

Similar to previous reports, we found that the VBT patients had decreased blood loss, operative time, and length of stay compared to the fusion cohort, but reduced curve correction at all postoperative time points [10, 11]. We further evaluated spinal growth and found that on average 10 mm of growth occurred over the instrumented segments in VBT patients between the 3-month and 2-year follow-up, whereas no growth occurred over the instrumented segments in fusion patients. Flexibility over the instrumented levels has been demonstrated previously in VBT patients both on radiographs and clinical examination [11, 13]. Thus, in contrast to fusion, VBT provides shorter recovery, preservation of spinal growth and motion, but less curve correction. The impact of preserved growth and motion on patient function and health-related quality of life are unclear. In comparison to the VBT patients reported by Newton et al., the VBT patients in our series had similar 2-year SRS-22R scores of all domains and total SRS scores which were not significantly different from fusion patients in Newton et al.'s retrospective series [10].

VBT is thought to utilize the Hueter–Volkmann principle, resulting in improved curve correction over time [4–6]. In our series, 12 of the 26 VBT patients demonstrated evidence of improvement in major Cobb angle between any two time points (Fig. 4). Interestingly, ten additional patients had a

Table 5 Suspected tether cord breakage

	T4–T5	T5–T6	T6–T7	T7–T8	T8–T9	T9–T10	T10–T11	T11–	T12–L1	L–L2	L2–L3	L3–L4
Suspected breakage 1 year ($n=0$)	0	0	0	0	0	0	0	0	0	0	0	0
Suspected breakage 2 years ($n=6$, levels instrumented)	0	0	0	0	1 (T5–T12)	0	5 (T7–L1: 2, T5–T12: 2, T5–T11: 1)	0	0	0	0	0
Suspected breakage 3 years* ($n=0$)	0	0	0	0	0	0	0	0	0	0	0	0

*Only 11 of the 26 patients at the time of this study had a 3-year follow-up

Table 6 SRS-22R scores in VBT patients

SRS domain	Preop	3-Mon	1-Year	2-Year $N=22$	P value, Preop vs. 2-year
Pain	4.3	4.2	4.6	4.5	0.36
Mental health	4.3	4.3	4.5	4.4	0.91
Self-image	3.8	4.1	4.2	4.1	0.25
Satisfaction	3.4	4.4	4.6	4.4	0.001
Function	4.3	3.7	4.2	4.2	0.44
Total	4.1	4.1	4.3	4.3	0.16

successful result at 2 years, highlighting that what does not happen through modulation may be achieved through intraoperative correction, at least in the short term. The long-term durability of VBT requires further study. On average, our VBT patients achieved 46% correction from preop to 3-month imaging (range 24–95%). Newton et al. also showed no significant change in Cobb angle between the first postoperative visit and final follow-up, but only achieved 36% correction from the index surgery and also had a high rate of cord breakage (52%) without differentiating the effects of cord breakage vs. growth modulation [10]. Thus, intraoperative correction is a key step in this technique, as curve correction over time cannot be assured of in the US AIS population under current FDA indications.

In our series, patients most likely to meet 2-year success were those who had < 35° residual curve pattern at the 3-month visit. Interestingly, preoperative bending films closely reflect the degree of correction seen on postoperative imaging [13]. Thus, at our center, we only consider VBT for curves that are < 35° on a preoperative fulcrum bend radiograph and corrective maneuvers are routinely used intraoperatively [14].

Our study also sought to determine the timing and incidence of cord breakage and whether cord failure was associated with the need for revision surgery. Recent reports suggest that cord breakage may not correlate with an unsuccessful result [8, 9]. We found that 19% of cords broke at the 2-year follow-up, but in this study there was no association between cord breakage, Cobb angle at the 3-month follow-up, and need for revision surgery. This study is likely underpowered to evaluate these questions as well as reoperation rates, as this was a study of safety and reoperation rates at 2 years. The suspected breakage occurred at the apex in one case, and otherwise at the distal aspect of the construct.

Our study has several limitations. There were few patient numbers. Hand radiographs and patient-reported outcome scores were lacking in the retrospective fusion cohort. The retrospective cohort was somewhat historical, as we had to include fusion patients of the past two decades to achieve appropriate matching. Infection rates in this fusion cohort are surprisingly high, which is not representative of modern practice at our center and others. As this was an IDE with limited existing data regarding the procedure at the time of study initiation, no power analysis was performed. Since statistically significant differences were found between the VBT and fusion cohorts, we believe that our study was adequately powered.

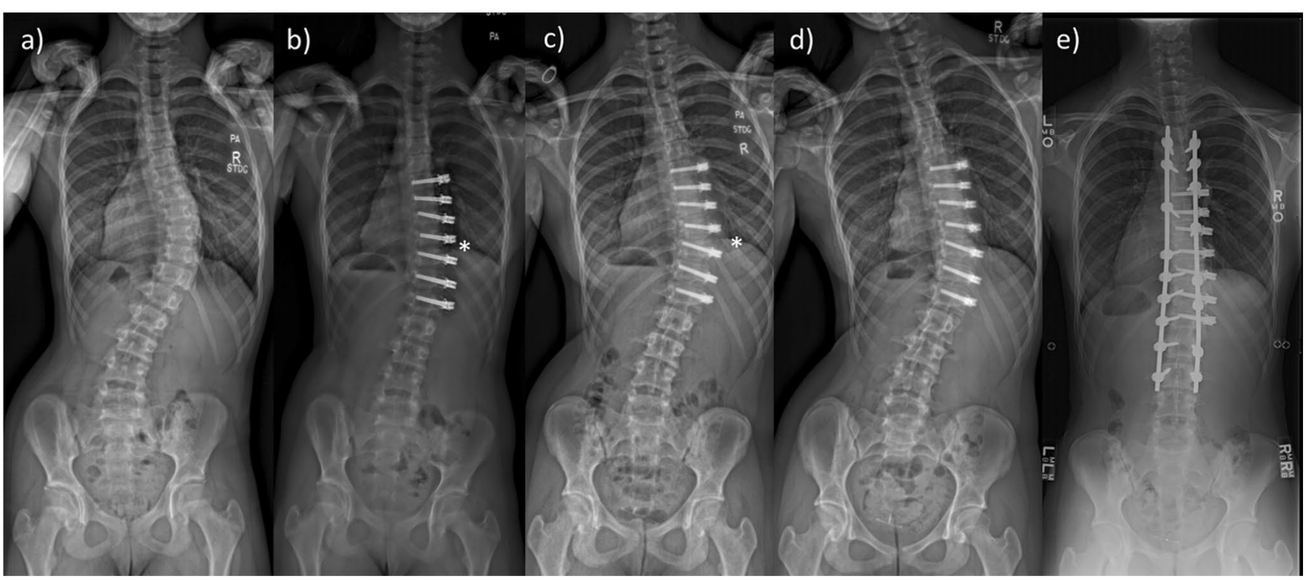

Fig. 3 PA radiographs of a 13-year-old female who presented with a 45° Lenke 1AR curve at Sanders stage 3 (**a**) which following VBT corrected to 23°(**b**). Between the 1- and 2-year radiographs, a suspected cord breakage was noted at T10–11 (*) resulting in loss of correction (**c**). Ongoing curve progression and trunk shift (**d**) prompted spinal fusion surgery at 4 years postoperatively (**e**)

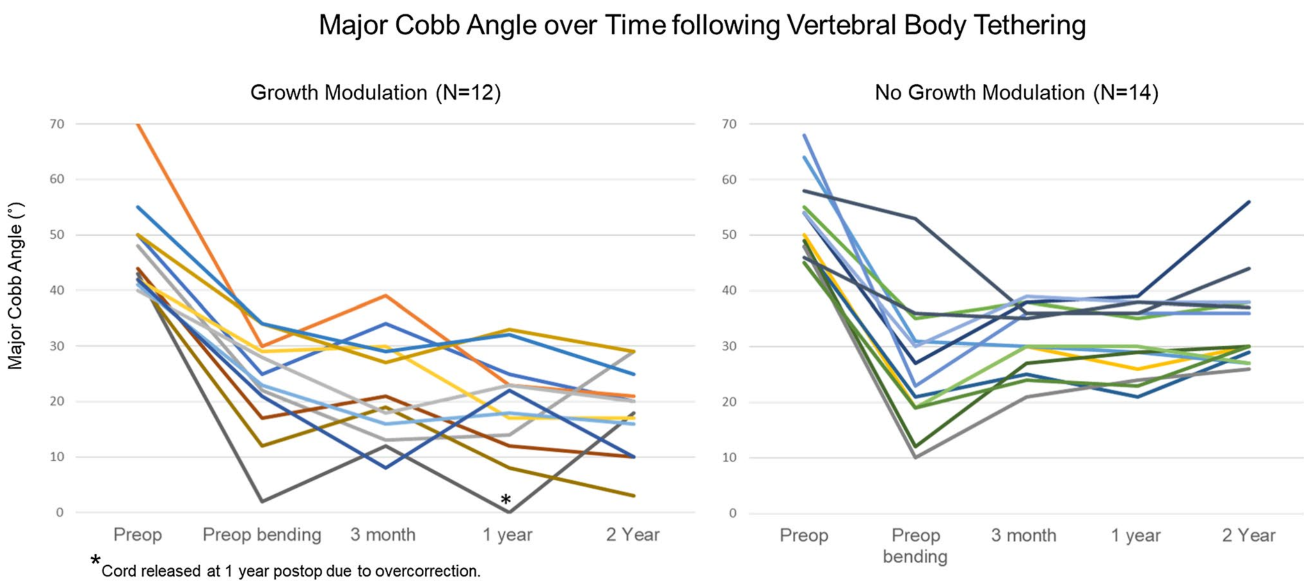

Fig. 4 Plot of major Cobb angle over time in patients who did and did not have growth modulation (improvement of the Cobb angle over time). Patients who had modulation of their curve over time were generally successful. Patients who had 3-month major Cobb angle < 35 degrees and who did not modulate also were successful at 2 years. Patients who had a 3-month major Cobb angle over 35 degrees and did not modulate were frequently unsuccessful at the 2-year follow-up

However, this is one of the few papers to present prospective 2-year US data on VBT patients. Patients in another large prospective series from Canada have a mean BMI of 18.3 and 43.7 kg compared to our population with a BMI of 20.5 and 51.3 kg, which is typical of the US population in general [12, 15]. Certainly, 5- or 10-year follow-up would be more helpful, as it is possible that the results of this procedure may degrade over time. We plan to continue to report on this cohort as additional follow-up becomes available. We did not complete a power analysis, as this study was primarily designed to report prospective data regarding reoperation rates and success following VBT. Patients over age 10 years undergoing VBT were considered to have AIS and our youngest VBT patients was 12.8 years; however, it is possible that some patients had juvenile-onset scoliosis. In the absence of symptoms or neurologic abnormalities on exam, we did not universally obtain an MRI on patients to rule out intrathecal abnormalities. Significant advancements have occurred in blood loss and operative time for AIS fusion surgery over the last several years. Intraoperative tensioning techniques were specific to our center and variabilities in the manipulation and tensioning of the cord may affect cord integrity. This cohort included thoracic, lumbar, and double curve patterns, which may have variable results following treatment.

Importantly, spinal growth was noted over the instrumented segments. Our radiographic measurement protocol was identical to that used in other publications, which has been shown to have reasonable inter-rater reliability [16]. Cord breakage occurred in 19% of our 26 patients by the 2-year follow-up and was not associated with the need for revision surgery, which occurred in 15% of our patients by the latest follow-up. In our cohort of Sanders stage 3 and 4 children, the best predictor of success was Cobb angle < 35° at the 3-month radiograph, highlighting the need for a flexible preoperative curve with a fulcrum bending radiograph of < 35° and aggressive intraoperative tensioning of the cord to achieve correction at the time of surgery. Fewer than half of the patients had growth modulation with improvement in the Cobb angle over time, although those who modulated in this series were more likely to have a successful result at 2 years. Based on these results of limited growth modulation, we have changed our selection criteria to include only patients who bend to < 35° on preoperative bending films, since we have shown previously that the amount of curve correction intraoperatively is similar to our bending films. Since the occurrence of curve correction over time is unpredictable, intraoperative correction of the curve is essential in our patient population.

In summary, for this matched cohort of VBT and fusion patients, curve correction was superior in the fusion group. Length of stay, operative time, and blood loss were lower in the VBT cohort, but additional data are needed regarding the long-term durability and functional outcomes of this procedure.

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Declarations

Conflicts of interest Outside of the study, Dr. Milbrandt reports consulting activities with Orthopediatrics, Medtronic, Zimmer and stock ownership in Viking Scientific. Dr. Larson reports consulting activities with Orthopediatrics, Medtronic, Zimmer, and Globus. Drs. Mathew, Stans, Shaughnessy, and J. Blade Hargiss have no conflicts to report.

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