

## DEFORMITY

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## Anterior Vertebral Body Tethering for Treatment of Idiopathic Scoliosis in the Skeletally Immature

Results of 112 Cases

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The device(s)/drug(s) that is/are the subject of this manuscript is/are not FDA approved for this indication and is/are not commercially available in the United States.

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Goals of treatment in idiopathic scoliosis include halting progression and reducing deformity while limiting complications. Though bracing of small to moderate size curves in the skeletally immature can be effective, it relies on compliance, may adversely affect patient quality of life and many still progress to surgery.<sup>1–3</sup> Spinal fusion for larger curves is well established with medium term results demonstrating significant deformity correction, high fusion rates, and improved patient quality of life.<sup>4–6</sup> Yet even with modern instrumentation the revision rate at 10 years is 7%.<sup>7</sup> Observed increased range of motion with accelerated disc degeneration caudal to fusions raise questions about long-term outcomes.<sup>8,9</sup> Thus fusionless treatments of progressive curves in the skeletally immature are appealing.

AVBT aims to correct the characteristic idiopathic lordoscoliosis exploiting the Hueter–Volkman principle. The tether compresses the convex vertebral growth plates inhibiting their growth, while allowing the concave growth plates to grow. In vitro models have demonstrated both the creation of spinal deformity as well as its correction by placement of a flexible cord along the anterior spinal column.<sup>10–13</sup>

Knowledge of the clinical value of AVBT remains poor given the paucity of available data.<sup>14–18</sup> The aim of our study

was therefore to evaluate the clinical, radiographic, and perioperative outcomes and complication rates to determine the efficacy of AVBT in a prospective multicenter cohort of skeletally immature patients with idiopathic scoliosis.

## MATERIALS AND METHODS

Consecutive patients with idiopathic scoliosis treated by one of two surgeons working at two independent centers were treated with AVBT between 2012 and 2018 and followed up for >2 years. Typical indications for AVBT were skeletally immature patients with progressive major main thoracic and/or lumbar curves  $\geq 40^\circ$ . Thoracic tethers were performed thoracoscopically as previously described.<sup>15</sup> Thoracolumbar/lumbar tethers required a miniopen approach. L1 and commonly L2 were accessed via a rib sparing thoracotomy with incision of the posterior aspect of the diaphragm and development of a plane anterior to psoas to allow instrumentation. Lower lumbar levels were accessed through a second incision via an anterolateral retroperitoneal approach. Single screws (Zimmer Dynesys, Winterthur, Switzerland) were placed in each vertebra aside from in double tethers when the inflection vertebra was typically instrumented from both sides. Levels were typically instrumented Cobb to Cobb and tether tensioned to bring the tilted discs into neutral alignment where possible.

Clinical and radiographic data were compiled prospectively on a multicenter database and supplemented retrospectively where necessary. Data were collected by independent researchers not involved in the patients' clinical care. In addition to conventional radiographic measures the angulation between upper and lower instrumented vertebra was measured in coronal and sagittal planes and termed "instrumented Cobb." Tether breakage was suspected radiographically if there was increased convergence of vertebral body screws between interval radiographs. Rib hump and lumbar prominence were measured with scoliometer. Outcomes were assessed preoperatively, at time of first erect (FE) radiograph (typically 6 weeks), at 1 year and at most recent follow up (FU). FU outcomes were collected after any non-fusion revisions. In cases converted to fusion the FU outcomes were included prior to fusion.

"Clinical success" was defined a priori based on previously described criteria.<sup>14,18</sup> Cases were considered a success if at FU they had not undergone (or awaiting) fusion and their tethered curve(s) was  $< 35^\circ$ .

Data distribution was largely non-parametric. Analyses included between group comparisons using Mann-Whitney *U* tests. Wilcoxon signed-rank test was used to assess interval changes. Categorical variables were compared with  $\chi^2$  test. All statistical analyses were performed with SPSS v22 (IBM-SPSS, Armonk, NY), with  $P < 0.05$  considered significant.

## RESULTS

### Patients

One hundred fourteen consecutive cases with idiopathic scoliosis underwent tethering procedures, two were lost to follow up and excluded from the study. The remaining

112 patients underwent 116 primary tethering procedures. Preoperative values are detailed in Table 1. Of the 104 females, 22 were recently post-menarchal. All cases were skeletally immature, Risser  $0.5 \pm 0.9$  (0–3). 51% had undergone previous bracing treatment. Mean follow up was  $37 \pm 9$  months (15–64). At which point 94 cases (84%) were Risser 4/5. Two patients underwent fusion procedures <2 years post AVBT (15 and 19 months) hence excluded from further follow up, the remaining cases had >2 years follow up.

### Operative Data

Of the 116 tethering procedures 108 were performed as a single stage, of which 104 were thoracic tethers and four were lumbar tethers. Eight tethers were performed on four patients via a planned staged approach undergoing a lumbar tether followed by a thoracic tether 1 to 2 days later. Overall 108 thoracic tethers were performed and eight lumbar tethers.

Operative data are summarized in Table 2. No patient received an allogeneic blood transfusion.

### Surface and Radiographic Measurements

Data are summarized in Table 3. Preoperative rib hump of  $14.1^\circ \pm 4.8$  (0–26) was corrected significantly at first post-operative visit, after which it was stable over follow up measuring  $8.8^\circ \pm 5.4$  (0–22) at FU ( $P < 0.001$ ). Lumbar prominence improved from  $3.6^\circ \pm 4.7$  (0–17) preoperatively to  $2.5^\circ \pm 4.4$  (0–18) at FU ( $P = 0.03$ ).

The preoperative mean coronal Cobb angle of the 116 tethered curves was  $50.8^\circ \pm 10.2$  (31–81) and were  $49\% \pm 19\%$  (0–94%) flexible on supine side bending radiographs. This was corrected significantly to  $26.6^\circ \pm 10.1$  (–3–61) at time of FE radiograph ( $P < 0.001$ ). Further significant improvement was seen between this point and 1-year, to mean Cobb angle  $23.1^\circ \pm 12.4$  (–37–57) ( $P < 0.001$ ). There was a small but significant increase in Cobb angle from 1-year to FU averaging  $25.7^\circ \pm 16.3$  (–32–58) ( $P < 0.001$ ). These changes were reflected in instrumented Cobb angle measurements.

Give the loss of correction seen between 1 year and FU cases were evaluated to identify any influence of tether breakage. Thirty six tethers were suspected/confirmed broken over follow up, with two replaced by FU. The 34 suspected/confirmed broken tethers at time of FU had a significant increase in Cobb angle from  $26.1^\circ \pm 11.6$  (3–57) at 1-year to  $35.1^\circ \pm 12.4$  (14–58) at FU ( $P < 0.001$ ). This reflected an increase in the instrumented Cobb angle from  $17.1^\circ \pm 13.3$  (–18–49) to  $28.3^\circ \pm 13.8$  (–1–57) over this time ( $P < 0.001$ ). Those with intact tethers maintained the mean Cobb angle at 1-year of  $21.7^\circ \pm 12.6$  (–37–55) to FU  $21.8^\circ \pm 16.1$  (–32 to 55) ( $P = 0.10$ ). The instrumented Cobb in these cases was maintained from at 1-year to FU measuring  $14.2^\circ \pm 12.3$  (–12–55) and  $15.2^\circ \pm 15.0$  (–29–51) respectively ( $P = 0.38$ ).

As 108 single tethers were composed of 104 thoracic tethers and four lumbar tethers the minor "untethered"

**TABLE 1. Included Cases**

Variable			Value
Age at surgery			12.7 ± 1.4 (8.2 to 16.7)
Sex Female: Male			104:8
Lenke curve type: 1:2:3:4:5:6			85:15:5:2:3:2
Preoperative	Risser	Mean	0.5 ± 0.9 (0 to 3)
		0:1:2:3:4:5	78:16:13:5:0:0
	Sanders (n = 33) <sup>19</sup>		3.4 ± 1.3 (2 to 6)
	Height, cm		153.8 ± 8.8 (135.0 to 179.1)
	Mass, kg		45.1 ± 11.2 (24.5 to 81.1)
	BMI, kg/m <sup>2</sup>		18.9 ± 3.6 (12.9 to 31.7)
Duration of follow up, mo			37 ± 9 (15 to 64) $\Psi$
Most recent follow up	Risser	Mean	4.0 ± 1.2 (0 to 5)
		0:1:2:3:4:5	5:2:4:7:52:42
	Height, cm		162.2 ± 7.3 (145.6 to 180.0)
	Mass, kg		55.7 ± 11.1 (33.0 to 103.5)
	BMI, kg/m <sup>2</sup>		21.2 ± 3.6 (13.4 to 36.2)
$\Psi$ 2 cases underwent fusion <2 years post AVBT, remaining cases have >24 months follow up.			

curve represented the lumbar curve in 104 and the main thoracic curve in four cases. Mean preoperative Cobb angle of 31.0° ± 9.5 (3–57) was significantly corrected to 20.3° ± 10.3 (0–52) at FE radiograph (*P* < 0.001). Further improvement to 18.1° ± 10.8 (–22–50) (*P* < 0.001) was seen over the first year, after which the correction stabilized.

Preoperative T5–T12 kyphosis of 18.6° ± 11.4 (–8–47) was stable to 1-year, after which there was a small but significant increase to FU to 21.4° ± 13.0 (–14–66) (*vs.* preop *p* = 0.004). Despite this kyphosis across the instrumented levels in thoracic tethers remained stable over follow up. No overall change was seen in lumbosacral lordosis (*P* = 0.86).

**Clinical Success**

Of the 112 cases seven had undergone or were awaiting a fusion. Of the remaining cases 80 (71%) had tethered curve(s) <35° at FU and were considered successful. The successful group had similar age, Risser grades and Sanders score to those unsuccessful (Table 4). Those considered

clinically successful had smaller preoperative major curves (48.3° *vs.* 56.5° *P* < 0.001) that were more flexible (43% *vs.* 35% *P* = 0.046) than those considered unsuccessful. There was a trend to incrementally lower success rates in groups of increasing major curve size (*P* = 0.03). Tether breakage was more common in those considered unsuccessful (53% *vs.* 24% *P* = 0.003). Duration of follow up was shorter in the group considered successful (36 *vs.* 42 months, 0.001).

**Complications and Revisions**

Twenty five patients (22%) had 28 complications (Table 5). Fifteen patients (13%) required 18 revision operations. One case also required tethering of a progressive lumbar curve after initial thoracic tethering. Given the natural history of idiopathic scoliosis and surgery was distant from the initial tether it was not considered a complication or revision operation.

Four cases had atelectasis requiring admission to intensive care for respiratory support. Two hemothoraces occurred. One required drainage with the other returning

**TABLE 2. Operative Data**

Variable		Value	<i>P</i>
Single <i>versus</i> two stage surgery	Single stage tethers	108 patients	
	Staged lumbar then thoracic tethers	4 patients	
Tether location	Thoracic	108	
	Lumbar/ thoracolumbar	8	
Vertebrae tethered	Thoracic tether	7.3 ± 0.7 (6 to 9)	<0.001
	Lumbar tether	5.3 ± 0.5 (5 to 6)	
Operating time, min	Thoracic tether	232 ± 102 (110 to 585)	0.03
	Lumbar tether	295 ± 65 (163 to 387)	
Blood loss, mL/kg	Thoracic tether	5.0 ± 3.3 (0.5 to 18.8)	0.61
	Lumbar tether	5.1 ± 2.5 (1.3 to 9.4)	
Length of stay, days	Single stage thoracic/lumbar	4.7 ± 1.4 (3 to 11)	0.001
	Planned 2 stage	10.5 ± 4.0 (7 to 16)	

**TABLE 3. Radiographic and Surface Measurements**

	Preop	FE	1 year	FU
<b>Coronal plane</b>				
Tethered curve Cobb	50.8° ± 10.2 (31 to 81)	26.6° ± 10.1 (−3 to 61) $\psi$	23.1° ± 12.4 (−37 to 57) $\Phi$	25.7° ± 16.3 (−32 to 58) $\lambda\Sigma$
Tethered curve correction (%)		47.7 ± 16.2 (7 to 107)	55.1 ± 22.7 (5 to 184) $\Phi$	49.6 ± 30.5 (−16 to 159) $\lambda$
Instrumented Cobb		22.7° ± 10.6 (−1 to 57)	15.1° ± 12.6 (−18 to 55) $\Phi$	19.0° ± 15.8 (−29 to 57) $\lambda$
Untethered minor curve Cobb	31.0° ± 9.5 (3 to 57)	20.3° ± 10.3 (0 to 52) $\psi$	18.1° ± 10.8 (−22 to 50) $\Phi$	18.4° ± 14.2* (−13 to 62) $\Sigma$
Untethered minor curve correction (%)		34.3 ± 33.8	43.5 ± 31.3 $\Phi$	41.6 ± 60.9
<b>Sagittal plane</b>				
Thoracic kyphosis T5–T12	18.6° ± 11.4 (−8 to 47)	18.8° ± 11.8 (−12 to 45)	18.6° ± 12.3 (−14 to 55)	21.4° ± 13.0 (−14 to 66) $\lambda\Sigma$
Lumbosacral lordosis L1–S1	−55.9° ± 10.5 (−99 to −28)	−54.0° ± 10.9 (−88 to −30) $\psi$	−55.7° ± 10.9 (−87 to −24) $\Phi$	−56.2° ± 11.4 (−83 to −24)
Thoracic tether instrumented sagittal Cobb		16.6° ± 12.2 (−12 to 50)	16.7° ± 13.0 (−13 to 54)	17.1° ± 13.1 (−12 to 51)
Lumbar tether instrumented sagittal Cobb		−10.5° ± 12.9 (−35 to 5)	−10.8° ± 11.5 (−24 to 6)	−8.8° ± 10.2 (−20 to 9)
<b>Surface measurements</b>				
Rib hump	14.1° ± 4.8 (0 to 26)	8.1° ± 4.3 (0 to 22) $\psi$	8.6° ± 4.7 (0 to 25)	8.8° ± 5.4 (0 to 22) $\Sigma$
Lumbar prominence	3.6° ± 4.7 (0 to 17)	2.2° ± 3.6 (0 to 16) $\psi$	2.4° ± 3.6 (0 to 15)	2.5° ± 4.4 (0 to 18) $\Sigma$
<p><i>Changes from preop to FE: <math>\psi</math> denotes significance; tethered curve Cobb/tethered curve correction/untethered minor curve Cobb/rib hump all <math>P &lt; 0.001</math>, lumbosacral lordosis <math>P = 0.03</math> (non-significant); thoracic kyphosis <math>P = 0.58</math>, lumbar prominence <math>P = 0.052</math>.</i></p> <p><i>Change from FE to 1 year: <math>\Phi</math> denotes significance; tethered curve Cobb/ tether curve correction/ instrumented Cobb/untethered minor curve Cobb/untethered minor curve correction all <math>P &lt; .001</math>, lumbosacral lordosis <math>P = 0.04</math> (non-significant); thoracic kyphosis <math>P = 0.50</math>, thoracic tether instrumented sagittal Cobb <math>P = 0.80</math>, lumbar tether instrumented sagittal Cobb <math>P = 0.67</math>, rib hump <math>P = 0.40</math>, lumbar prominence <math>P = 0.91</math>.</i></p> <p><i>Change 1 year to FU: <math>\lambda</math> denotes significance; tethered curve Cobb/tethered curve correction/instrumented Cobb all <math>&lt; 0.001</math>, thoracic kyphosis <math>P = 0.002</math> (non-significant); untethered minor curve Cobb <math>P = 0.37</math>, untethered minor curve correction <math>P = 0.60</math>, thoracic kyphosis <math>P = 0.26</math>, lumbosacral lordosis <math>P = 0.45</math>, thoracic tether instrumented sagittal Cobb <math>P = 0.80</math>, lumbar tether instrumented sagittal Cobb <math>P = 0.14</math>, rib hump <math>P = 0.55</math>, lumbar prominence <math>P = 0.52</math>.</i></p> <p><i>Change preop to FU: <math>\Sigma</math> denotes significance; tethered curve Cobb/untethered minor curve Cobb/ rib hump 0.000 all <math>P &lt; 0.001</math>, thoracic kyphosis <math>P = 0.004</math>, lumbar prominence <math>P = 0.03</math> (non-significant); lumbosacral lordosis <math>P = 0.86</math>.</i></p> <p><i>*One cases underwent delayed lumbar curve tethering between 1 year and MRF, thus excluded and <math>n = 107</math> for this time point.</i></p>				

to theater for bleeding control. Two patients developed pneumonia after discharge and were managed by family doctors. One case had a small pneumothorax after chest drain removal, which resolved spontaneously. Two patients had cerebrospinal fluid (CSF) leaks presenting with orthostatic headaches and vomiting 1 to 2 weeks postoperatively. One related to a T12 screw narrowly breaching the posterior wall requiring revision and the other without obvious cause was treated conservatively.

Eight patients required replacement/extension/loosing of tethers. At FU six cases had undergone fusion operations with one awaited (6%). One case subsequently required revision for distal junctional failure.

**Tether Breakage**

Three cases had confirmed tether breakage (two verified at tether replacement and one at fusion). In addition 33 cases had radiographs suggestive of tether breakage, two of these had two sites of suspected breakage. Thus 36/112 cases had a confirmed/suspected tether breakage (32%). The most common sites for breakage were T9/10, T10/11, and T11/12 occurring in 11, 13, and seven cases respectively. Tether breakage was noted on radiographs taken mean 31 months (12–43 months) postoperatively.

**DISCUSSION**

This study represents the largest series of patients treated with AVBT currently available. In showing progressive

deformity correction over the first year it suggests growth modulation, validating the premise of AVBT in skeletally immature cases. 71% of cases were considered successful with tethered curves  $< 35^\circ$  and without a fusion being undertaken or awaited. However variability is seen within the cohort with 22% of patients having a complication and 13% undergoing revision surgery over the follow up period.

Deformity correction resulting from growth modulation by AVBT is not uniform over reported series. Newton *et al*<sup>11</sup> reported mean 2.5 year follow up of 17 skeletally immature cases noting progressive correction over the first 2 years, from a mean  $52^\circ$  preoperatively to  $31^\circ$  immediately postop and  $24^\circ$  after 2 years. According with the current series a loss in correction was seen to mean  $27^\circ$  at FU. Hoernschemeyer *et al*<sup>19</sup> reported 2 to 5 years follow up for cohort of 29 cases with varied skeletal maturity at time of surgery noting progressive correction in thoracic tethers. Samdani *et al*<sup>16</sup> reported 2-year outcomes in 11 patients noting greater initial correction from  $44^\circ$  to  $20^\circ$  with progressive correction to  $14^\circ$  at 2 years and also reported 12 months follow up for a larger cohort of 32 cases, again noting progressive correction.<sup>17</sup> Corbetto *et al*<sup>22</sup> reported progressive correction in 20 cases from mean  $59^\circ$  preoperatively to  $37^\circ$  immediately postop and  $23^\circ$  at 2 years. Whereas Newton *et al*<sup>18</sup> in a further study noted no significant improvement in main thoracic Cobb angle after the FE radiograph in their skeletally immature group of 23 cases, variability in response between cases was noted. Wong *et al*<sup>20</sup> using a

**TABLE 4. Comparison of Those Considered Successful and Unsuccessful**

		Success (n = 80)	Failure (n = 32)	P
Preoperative				
Age at surgery		12.7 ± 1.5 (8.2 to 16.7)	12.5 ± 1.0 (10.2 to 14.7)	0.54
Sex (% Female)		94%	91%	0.56
Females premenachal (%)		77%	82%	0.52
Mass		45.2 ± 11.1 (24.5 to 81.1)	44.8 ± 11.6 (30.8 to 78.0)	0.32
BMI		18.9 ± 3.7 (12.9 to 31.7)	18.9 ± 3.5 (14.1 to 27.7)	0.92
Risser	Mean	0.6 ± 0.9 (0 to 3)	0.4 ± 0.8 (0 to 3)	0.29
Risser: number of cases	0	53	25	0.66
	1	13	3	
	2	10	3	
	3	4	1	
Sanders score (n = 33)		3.5 ± 1.3 (2 to 6)	2.8 ± 0.8 (2 to 4)	0.69
Major coronal Cobb		48.3° ± 8.9 (31 to 70)	56.5° ± 11.1 (35 to 81)	<0.001
Major Cobb group (% success for group)	30–39°	10 (83%)	2	0.03
	40–49°	36 (78%)	10	
	50–59°	25 (73%)	9	
	>60°	9 (45%)	11	
Flexibility		42.3% ± 19.2 (0 to 100)	34.6% ± 20.9 (2 to 91)	0.046
Intraoperative				
Tether location				
Thoracic		74	30	N/A ψ
Lumbar		3	1	
Dual		3	1	
Postoperative				
Tether breakage		19/80 (24%)	17/32 (53%)	0.003
Follow up, mo		35.6 ± 8.7 (24 to 61)	41.7 ± 10.9 (15 to 64)	0.001

ψ Small group numbers preclude meaningful statistical analysis.

technique avoiding intraoperative tether tensioning also saw a mixed response in their five cases. All cases were Risser 0 but progressive correction was seen only in two cases with open triradiate cartilages at time of surgery.

We noted a small but significant increase thoracic kyphosis from 1-year to FU yet this did not appear associated with

progressive kyphosis over the instrumented segment. In general it appears, despite anterior growth modulation, AVBT is not strongly kyphogenic.<sup>14–16,18,20,21</sup>

Rib hump improvement is a key expectation for parents and adolescents considering fusion surgery and hence likely important to AVBT patients too.<sup>5</sup> We observed a 38% rib

**TABLE 5. Complications and Revision Further Operations**

Nature of Complication/ Revision Operation			Number Cases	Number Revision Operations
Perioperative	Pulmonary	Atelectasis	4	
		Hemothorax	2	1
		Pneumonia	2	
		Pneumothorax	1	
	GI	<i>Clostridium difficile</i> infection	1	
	Infection	Superficial wound	1	
	CSF leak	2	1	
Prompting revision of tether	Overcorrection (loosening tether)		5	5
	Tether breakage (replaced)		2	2
	Adding on (extension of tether)		1	1
Prompting fusion	Inadequate curve correction with no apparent tether breakage		3	3
	Inadequate correction tethered curve with tether breakage ± fusion of progressive untethered lumbar curve		2	3*
	Adding on		2	2

\*One case required subsequent revision of fusion for distal junctional failure.

hump resolution at FU. This is similar to previous studies reporting 30% to 45% rib hump correction.<sup>14–16</sup> These corrections are in keeping with finite element analyses but less than available axial plane data following AVBT.<sup>20–22</sup> Comparative data does highlight rib hump resolution as a key difference in outcome with fusion surgery, where rib hump resolution is typically greater.<sup>18</sup> This should be discussed with patients and families considering treatment.

The observed 22% complication and 13% revision rates is in keeping with the available literature for this novel technique. In the 23 cases reported by Newton *et al*<sup>14</sup> seven (30%) underwent nine revision operations of which three were fusions. Three further fusions were indicated but not yet performed, thus potentially 26% of the cohort resulting in fusion. The completed revisions included similar indications to the current series including three tether loosening/removal for overcorrection, two replacement of broken tethers, and one delayed lumbar tether. Overall 12 (52%) cases had suspected/confirmed tether breakage. In their smaller series 7/17 (41%) cases required revision over follow up including four tether loosening/removal for overcorrection, one delayed lumbar tether, one replacement of broken tether, and one conversion to fusion. Two tethers were confirmed broken at reoperation with a further six suspected radiographically (47%).<sup>14</sup> Similarly, in their cohort of 29 cases Hoernschemeyer *et al*<sup>19</sup> noted 14 broken tethers (48%) with six revision operations (two fusions) undertaken. Unsurprisingly shorter term follow up studies such as Samdani *et al*<sup>16</sup> are more reassuring regarding tether breakage. Though revision surgery was necessary to loosen tethers in 2/11 cases by 2 years. Overall this series accords with the literature, suggesting that complication and revision rates for AVBT are not insignificant and in excess of that of spinal fusion for AIS.<sup>18,23</sup> Given the relative differences in clinical experience with these procedures this is perhaps to be expected. However, such differences should be highlighted to patients considering this procedure. There is limited data with which to compare the complications of AVBT with other growth modulation techniques for AIS. Floman *et al*<sup>24</sup> reported results of 45 patients following implantation of a posterior dynamic correction system noting a 9% revision rate at 2 years, all for implant issues, but no conversion to fusion. Betz *et al*<sup>25</sup> reported a 14% complication rate in 28 patients treated with vertebral body stapling at mean 3.2 years postoperatively.

A specific complication of AVBT is tether breakage which is common after 2 to 3 years and associated with loss of correction. Those with a tether breakage were less likely to be considered “successful” at FU. Logically all tethers will fatigue fail eventually, most likely after skeletal maturity. The ramifications of tether breakage in these cases will be determined by the degree of true growth modulation altering the vertebrae/disc morphology *versus* the “brace effect” evident immediately after surgery. It is concerning that some loss of correction was evident amongst those with

tether breakage indicating at least some remaining “brace effect.” Whether subsequent further loss of correction will be seen at failed levels as well as with eventual tether breakage at other levels remains to be seen. These observations suggest prolonged follow up is needed in AVBT cases. The observed tether breakage rates and associated loss of correction may also refute the concept of using anterior tethering devices in skeletally mature cases. It also suggests instrumentation could be improved upon to at least delay tether breakage until after skeletal maturity. Further work involving larger patient cohorts is needed to understand the factors influencing tether breakage including patient, surgical, and implant factors.<sup>20</sup>

The observed “clinical success” is favorable compared with the literature. In a study of 23 cases at mean 3.4 years follow up Newton *et al*<sup>18</sup> reported 52% were without fusions surgery with thoracic curves  $<35^\circ$  in comparison to 71% in the current series. In this group’s earlier series of 17 cases, 59% had tethered curves  $<35^\circ$  and no fusion.<sup>14</sup> 27/29 of the cohort reported by Hoernschemeyer *et al*<sup>19</sup> had reached skeletal maturity of which 20 (74%) were deemed clinically successful having curves  $\leq 30^\circ$  and no fusion surgery. Samdani *et al*<sup>16</sup> reported all 11 of their cases remained without fusion with residual curves  $<35^\circ$  at 2 years. Two of five cases reported by Wong *et al*<sup>20</sup> had been converted to fusion after  $>4$  years follow up with two of the remaining cases having residual curves  $>35^\circ$  but  $<50^\circ$ . The definition of success used in this study is debatable. We chose to mirror the work of Newton *et al*,<sup>14</sup> to allow easy comparison. But a cut off of for success of  $<35^\circ$ , well below traditional thresholds for fusion surgery could be considered a harsh benchmark. Variability in the response of patients to tethering is clear. We identified larger preoperative curve magnitude and stiffness as well as tether breakage were associated with “failure.” However it is clear that analysis of larger datasets is needed to understand the interplay between the many patient, implant, and surgical factors influencing outcomes.

This study has several limitations. Preoperative Sanders score was only available for 33 patients. We analyzed lumbar and thoracic tethers together. Further work is needed to determine if their responses to AVBT differ. No patient reported outcome measures (PROMS) are reported. Our concern for the latter was that many patients present with the desire to undergo AVBT hence cognitive dissonance may impede meaningful interpretations of PROMS. In addition duration of follow up is inadequate with longer term results needed to understand the true value of AVBT. This study, however, is strengthened by the sample size and the combined work of two independent centers and so the results may be more generalizable.

This study is the largest cohort of AVBT patients reported to date and shows that AVBT results in reliable deformity correction at minimum 2 years follow up. Further work is needed to examine the variability seen in patient responses

to tethering and impact of tether breakage. Prolonged follow up of AVBT patients will be needed until we can understand the true value of this technique.

## ➤ Key Points

- ❑ This study represents the largest series of patients treated with AVBT currently available.
- ❑ Progressive deformity correction was seen over the first year, suggesting growth modulation in the included skeletally immature cases.
- ❑ 71% of cases had curves  $<35^\circ$  and no completed/indicated fusion and were considered "successful" at last follow up.
- ❑ Tether breakage was common (32%) which is associated with loss of correction.

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