RESEARCH ARTICLE

Treatment of Mature/Maturing Patients with Adolescent Idiopathic Scoliosis (Sanders ≥ 5) Using a Unique Anterior Scoliosis Correction Technique

Authors

Christopher L. Antonacci MD, MS, MPH (ORCID: 0000-0002-9793-0524) Institute for Spine & Scoliosis, PA, 3100 Princeton Pike, Lawrenceville, NJ 08648 Email: <u>clantonacci@gmail.com</u>

M. Darryl Antonacci MD Institute for Spine & Scoliosis, PA, 3100 Princeton Pike, Lawrenceville, NJ 08648 Email: <u>mdantonacci@spineandscoliosis.com</u>

William P. Bassett MD (ORCID: 0000-0003-3978-292X) Eastern Maine Medical Center at Northern Light Health 489 State Street, Webber West, Suite 340, Bangor, ME 04401 Email: <u>bassettmd86@gmail.com</u>

Laury A. Cuddihy MD (ORCID: 0000-0002-8042-2929) Institute for Spine & Scoliosis, PA, 3100 Princeton Pike, Lawrenceville, NJ 08648 Email: <u>lcuddihy@spineandscoliosis.com</u>

Allison R. Haas RNFA (ORCID: 0000-0002-5654-6243) Institute for Spine & Scoliosis, PA, 3100 Princeton Pike, Lawrenceville, NJ 08648 Email: <u>arhaas@spineandscoliosis.com</u>

Janet L. Cerrone PA-C Institute for Spine & Scoliosis, PA, 3100 Princeton Pike, Lawrenceville, NJ 08648 Email: jcerrone@spineandscoliosis.com

Dominique S. Haoson BS Institute for Spine & Scoliosis, PA, 3100 Princeton Pike, Lawrenceville, NJ 08648 Email: <u>DHaoson@gmail.com</u>

*Randal R. Betz MD (ORCID: 0000-0003-2368-9966) Institute for Spine & Scoliosis, PA, 3100 Princeton Pike, Lawrenceville, NJ 08648 Email: <u>randalrbetz@gmail.com</u>

Funding sources: None

Conflicts of interest: RRB has received royalties from DePuy Synthes Spine, Globus Medical, SpineGuard, Thieme Medical Publishers; Speakers Bureau payments from DePuy Synthes Spine and Globus Medical; Consulting fees from ApiFix, DePuy Synthes Spine, Globus Medical, and SpineGuard and Stock options from Abyrx, ApiFix, Electrocore, Medovex, Orthobond, SpineGuard, and Wishbone Medical. The other authors report no conflicts of interest.

IRB Approval: This retrospective study was approved by both the Mount Sinai and St. Peters University Hospital Human Subjects in Research Review Boards.

Abstract

Anterior vertebral body tethering (VBT) in growing children has been reported as an alternative to fusion for thoracic idiopathic scoliosis. Anterior scoliosis correction (ASC) is our multi-year, multi-generational advancement upon VBT and is a "de-tethering," not tethering, procedure. ASC incorporates cords/screws similarly to VBT but is a technique that allows for large derotation, curve correction, and restoration of kyphosis using anterior longitudinal ligament complex release (ligament, annular capsule, and disc). It has been used to treat adolescents with minimal or no growth remaining. In this retrospective IRB-approved analysis, we report outcomes of an early cohort of skeletally maturing/mature (Sanders \geq 5) patients undergoing ASC.

Methods: Inclusion criteria: patients with AIS, at least one operative curve $35-70^{\circ}$, Sanders ≥ 5 , age ≤ 21 years, minimum 2-year follow-up or failure before. Forty-nine patients with 82 treated curves with surgery from January 2015 to December 2017 met the criteria and were reviewed. Mean follow-up was 30.3 months range 24 to 50 months. Average age at surgery was 15.2 years. **Results:** The average coronal correction was 65.5% for thoracic curves and 66.7% for lumbar curves. 71.4% of patients with thoracic curves received at least 1 thoracic disc release. Kyphosis (T5-T12) calculated 3D corrected from average 2° pre to 34° post-op. Clinical success (final curve $\leq 30^{\circ}$) was achieved in 45/49 (92%) patients and in 78/82 curves (95%). One unanticipated revision was recommended but not performed.

Conclusion: The 2-4 year results of ASC in maturing and mature patients with AIS demonstrated average curve correction of 65.5% in thoracic and 66.7% in lumbar curves. Clinical success with residual curves $\leq 30^{\circ}$ was achieved in 47/49 (96%) of all thoracic curves and 31/33 (94%) of all lumbar curves. Average 3D thoracic kyphosis corrected from 2° pre to 34° post.

Keywords: Adolescent idiopathic scoliosis; anterior scoliosis correction; kyphosis; derotation; mature; maturing

Data Availability: Yes Level of Evidence: Level III (case-control) Consent to Participate: Retrospective IRB review Consent for Publication: Retrospective IRB review

1. Introduction

Treatment for adolescent idiopathic scoliosis (AIS) is dependent upon multiple factors, including curve type and magnitude, curve progression, skeletal maturity, cosmetic deformity. and limitations in cardiopulmonary function.¹ The most common indication for surgical intervention curve progression. Most surgeons is recommend surgery for skeletally mature adolescent or young adult patients with a curve > 50-60° due to the risk of significant progression into adulthood.^{1, 2} The current standard of care is to perform a posterior spinal fusion (PSF) of the involved vertebral body segments. While metal rod fusion is effective in achieving curve correction, it is associated with many problems, including development of adjacent level disc degeneration in the lumbar spine, decreased range of motion, and decreased functional spinal mobility.³⁻⁵ Additional concerns include the potential for longer term development of increased back pain and lower extremity joint problems.^{3, 5-8} Due to these issues with spinal fusion, surgeons have explored alternative surgical approaches to correct spinal deformity and halt curve progression using either growth modulation or remodeling of the spine while preserving motion.⁹⁻¹²

Modified surgical techniques for correction of scoliosis have been shown in animal models to modify spinal vertebral body growth with preservation of spinal motion.^{10,} ^{11,13} Anterior vertebral body tethering (VBT), also known as spinal growth tethering, which utilizes a single flexible cord and single row of vertebral body screws applied through an anterior approach, may have the potential to modify scoliosis through growth modulation with maintenance of spinal mobility.^{6, 12, 14} It employed is typically through thoracoscopic approach and has been shown to be safe in multiple studies of immature patients with AIS.^{6, 15, 16} Miyanji, et al.¹⁵ and Newton, et al.¹⁶ reported VBT to have 57% and 59% success rates (defined as having a radiographic major coronal curve angle < 30°), respectively, in studies treating AIS with minimum two-year follow-up. Hoernschemeyer, et al.¹⁷ demonstrated a success rate of 74% for VBT in mature patients.

Patients with thoracolumbar or lumbar curves, patients with large, stiff thoracic curves, or patients who are skeletally maturing or mature, are generally not considered candidates for VBT. We report the results of non-fusion anterior scoliosis correction (ASC), a procedure developed by authors MDA (primary surgeon), RRB, and LAC. This technique utilizes a musclesparing thoracotomy approach to thoracic, thoracolumbar, or lumbar curves and, in contrast to VBT, incorporates concepts of

spinal "de-tethering" using anterior releasing techniques of the anterior longitudinal ligament complex (ligament, annular capsule, and discs) as needed. In addition to allowing for significant curve correction through unrestricted derotation at surgery, ASC can restore normal kyphosis and spare segmental vessels.¹⁸ Unlike VBT, indications for ASC are broadened to include skeletally mature patients with moderate to large curves $(35 \text{ to} > 70^\circ)$ and without limitation of flexibility (VBT only accommodates curves that are $< 30^{\circ}$ on bending films).¹² The purpose of this study was to examine an early cohort of skeletally maturing (Sanders 5-7) and skeletally mature patients (Sanders 8) with the diagnosis of AIS treated with ASC. hypothesized that ASC would We demonstrate at least equivalent results in skeletally maturing and mature patients compared to immature patients and is applicable to both thoracic and lumbar scoliosis.

2. Methods

After obtaining Institutional Review Board approval from both of our operating facilities. we conducted a retrospective, consecutive review of all ASC procedures performed between January 2015 and December 2017. Inclusion criteria included patients ≤ 21 years of age with a diagnosis of AIS and at least one operative curve with minimum and maximum coronal curve angles of 35° and respectively. 70°, All instrumented secondary curves were included in our analysis. All patients had to be classified as skeletally maturing (Sander 5-7) or mature (Sanders 8) at the time of surgery and have minimum 2-year follow-up. Exclusion criteria included previous history of surgery for AIS or diagnosis other than AIS.

Radiographic variables analyzed included coronal curve angles of instrumented thoracic and lumbar curves, kyphosis, and Sanders stage. Measurements were made by one author for all patient imaging for consistency. Initial radiographic evaluation included preoperative posterior-anterior (PA) and lateral radiographs, preoperative bending radiographs, and left hand radiograph. Subsequent postoperative interval evaluations using PA and lateral radiographs occurred at first erect, 2 years, and the most recent clinic visit. Additionally, the number of levels instrumented, the performance of anterior releases, and intraoperative and postoperative complications including neuromonitoring changes were recorded.

T5-T12 two-dimensional (2D) thoracic kyphosis measurements were calculated using sagittal radiographs from preoperative imaging as well as most recent postoperative follow-up imaging. Estimated threedimensional (3D) kyphosis values were calculated utilizing the 2D measurements and a validated formula to predict 3D kyphosis as described by Parvaresh et al.¹⁹ The formula to estimate 3D kyphosis is the following: 3D T5-T12 kyphosis = 18.1 + (0.81*2D T5-T12)kyphosis) - (0.54*2D thoracic Cobb) degrees. Of note, this formula has an average model error between predicted and actual measurements of $\pm 7.0^{\circ}$.¹⁹

Implant failure was suspected to have occurred if there was $a > 5^{\circ}$ increase in angulation between any two adjacent screws (splaying) between comparative radiographs over time. This technique of accessing implant failure with VBT was first described by Newton et al.¹⁶.

ASC was considered successful if at the time of latest follow-up (> 2 years) the curve magnitude was $\leq 30^{\circ}$ and the patient did not undergo revision ASC or a subsequent PSF. The value of $\leq 30^{\circ}$ was chosen as a demarcation for success because the 50-year natural history studies conducted by Weinstein et al.²⁰ showed low risk of progression of curves at maturity if measured $\leq 30^{\circ}$. Additionally, this value falls below any indication for spinal fusion.^{21, 22} Furthermore, there is precedence for this in scoliosis correction procedures given a recent study by Miyanji, et al.¹⁵

2.1. Procedure

All surgeries were performed by surgeon MDA. Key differences between ASC and VBT are summarized in Table 1.

Table 1. Characteristics of Vertebral Body Tethering (VBT) versus Anterior Scoliosis Correction (ASC)

	Vertebral Body Tethering	Anterior Scoliosis Correction		
Curves 30-65°	Yes	Yes		
Curves $\geq 65^{\circ}$	No	Yes		
Flexible curves ($< 30^{\circ}$)	Yes	Yes		
Stiff curves (bend $> 30^{\circ}$)	No	Yes		
Growing spine (Sanders ≤ 4)	Yes	Yes		
Maturing spine (Sanders 5-7)	No	Yes		
Mature curves (Sanders 8)	No	Yes		
Correct thoracic hypokyphosis	No	Yes		
Derotation of the spine	Some	Yes		

ASC is performed through an anterior muscle-sparing thoracotomy to thoracic, thoracolumbar, and/or lumbar curves performed in the lateral decubitus position with the convexity of the curve oriented in the superior or "up" position. The average length of the single incision is 10-12 cm. There may need to be a port incision above for high access to T4 or T5. Additional port incisions are not typically needed for lumbar curves. Fluoroscopic views are taken prior to incision to determine the location of the vertebrae to be instrumented and mark the location for the incision. Patients undergo single lung ventilation of the ipsilateral lung to provide additional visualization into the chest cavity placement allow for of and to The parietal pleura is instrumentation. carefully dissected around the area of desired screw placement on the lateral aspect of the vertebral body anterior to the rib heads with sparing of many of the segmental vessels.

After the appropriate spinal levels requiring instrumentation are identified and exposed, and with the assistance of fluoroscopic imaging, 1- or 2 three-prong staples are inserted into each vertebra anterior to the rib head. A threaded tap is then utilized to create the screw trajectory through the vertebral body and to ascertain screw length. Use of the PediGuard (SpineGuard, Paris, France) reduces the need for fluoroscopy while identifying very accurate bicortical purchase with minimal excursion into the contralateral chest cavity to decrease the potential for vascular or lung injury. Screw length is confirmed via measurements on the PediGuard tap as well as with a ball tip probe. All screws come manufactured with a hydroxyapatite coating and are placed in this manner with their final positioning confirmed with AP and lateral views using fluoroscopic imaging.

Anterior longitudinal ligament (ALL) complex releases are considered for all

curves that are determined to be hypokyphotic, significantly rotated, and/or inflexible on coronal view to $< 20^{\circ}$ on intraoperative radiographs. These releasing procedures allow for additional segmental derotation to correct the scoliosis and/or recreate normal kyphosis.²³ Of note, these releasing procedures are performed in the thoracic and upper lumbar spine and the cartilaginous end plates are preserved. The disc release allows additional segmental derotation obtain correction to bv "detethering" the stiff and rotated scoliotic spine in the sagittal, axial, and coronal planes.²³ The released anterior longitudinal ligament, annular capsule, and disc complex then heal with the spine in its corrected position and help to hold the correction while remodeling occurs after detethering.

The cord, composed of polyethylene terephthalate (PET), is then introduced after screw placements from proximal to distal. segment is corrected vertebral Each segmentally. The correction is one of applying translation and derotation of the distal segment relative to the proximal segments. This is facilitated by having an open thoracotomy to allow for complete derotation of the vertebral segment by negating the countereffects of the ribs. Once translated and derotated, compression of the two vertebrae through the tensioner is applied. When the rod-cord is tensioned, the set screws are tightened to maintain the correction. This technique is repeated for each instrumented level. The current study is focused on and is a review of only single screw, single rod-cord constructs. In the majority of cases after 2018, we now use a 2-screw and 2-cord construct where the posterior cord is tensioned first and the anterior cord second. Preliminary unpublished biomechanical pilot work of the 2 screw/2 cord construct shows better stabilization of correction but no loss of

mobility compared to single screw/single cord constructs.

Maximum coronal, axial and sagittal correction is obtained in skeletally mature patients in the operating room as they have no significant growth modulation after Sanders 4. Whereas in skeletally immature patients (Sanders \leq 4), one leaves residual curves for growth modulation, in skeletally maturing and mature patients maximum correction at the time of surgery is the goal.

After final radiographs are taken, the parietal pleural is partially repaired, the hemithorax is irrigated, a chest tube is placed, the lung is reinflated, and the wound is closed in a multilayered fashion.

For patients with double curves (thoracic and lumbar), after completion of the thoracic curve, the patient is repositioned to the opposite lateral decubitus position and an identical procedure is performed with an additional fixation in transition vertebrae of the two curves (e.g., T11 or T12). Segmental vessels in the thoracic spine are preserved for as many vertebrae as possible.

3. Results

During the study period from January 2015 to December 2017, 208 patients underwent ASC surgery, of whom 74 met the criteria except for > 2-year follow-up at the time of

the study. Of these 74 patients, 49 (66.2%) had ≥ 2 year follow-up. Because of the large geographic (worldwide) origin of the patients, obtaining follow-up was difficult. The majority of the other 134 patients (208 minus 74) were either Sanders ≤ 4 with significant spine growth available, older than 21 years of age, or did not have AIS.

Of the 49 patients who met all the inclusion criteria, including \geq 2-year follow-up, 16 (32.7%) had a primary thoracic curve, none had a primary thoracolumbar/lumbar curve only, and 33 (67.3%) had both thoracic and lumbar curves instrumented for a total of 82 curves for analysis. Average age at the time of surgery was 15.2 ± 1.7 years and average Sanders score was 6.7 (range 5-8). At the time of surgery, 41 patients (83.7%) were considered skeletally maturing (Sanders 5-7) and 8 patients (16.3%) were considered skeletally mature (Sanders 8). Mean preoperative curves for the instrumented thoracic and lumbar curves were $55 \pm 11^{\circ}$ (range 30-84°) and $51 \pm 10^{\circ}$ (range 37-78°), respectively. Of note there was one thoracic curve instrumented at 30° as the patient had a Lenke 6 curve, but because of complete correction of the lumbar curve, the inflexible thoracic curve had to be instrumented in order to maintain shoulder balance. Mean follow-up was 30.3 ± 7.1 (range 22-48) Patient months. demographics are summarized in Table 2.

Patients, n (number of instrumented curves)	49 (82)
Thoracic only	16 (33%)
Thoracic and lumbar	33 (67%)
Sex, n (%)	
Female	41 (83.7%)
Male	8 (16.3%)
Age, mean \pm SD (range), years	$15.2 \pm 1.7 \ (11.4 - 21.5)$
Sanders Score, mean \pm SD, range	$6.7 \pm .9$ (5-8)
Follow-up duration, mean \pm SD (range), months	30.3 ± 7.1 (24-50)

The most superior thoracic level to be instrumented was T4 and the most inferior instrumented level was L4.

Data on anterior longitudinal ligament complex releases are shown in Table 3.

Table 3. Anterior	longitudinal	ligament com	plex releases	in instrumented	thoracic curves
	0	0			

Thoracic curves, n	49
Patients, n (%)	35 (71%)
Releases, n	92
Mean per case (range)	1.9 ± 1.4 (1-4)

Preoperative and postoperative coronal curve angles measurements for all instrumented curves are shown in Table 4. In patients with instrumented thoracic curves, the average preoperative curve of 55° (range 30-84°) was corrected to an average postoperative coronal curve angle of 19° (range 5° to 37°), for an average 66% correction (Figures 1-4).



Fig. 1. (A) Preoperative and (B) 50-month PA radiographs of 13-year-old girl (Lenke 6C, Risser 3, Sanders 5) with AIS who underwent ASC with no releases. Patient demonstrated preoperative curves of 40° (thoracic) and 51° (lumbar). Curves were 12° (thoracic) and 11° (lumbar) at 50-month follow-up. 3D kyphosis (C & D) improved from 4° preoperatively to 21° . There was suspected cord breakage at 3 levels (T9/10, T10/11, and L2/3) which occurred by 2-year follow-up with no further loss of correction.



Fig. 2 A-D



Fig. 2 E-J

Fig. 2 (A-D) PA and lateral radiograph of a 15-year-old girl, Risser 4, Sanders 6. She has a 59° right thoracic Lenke 1A curve. Fulcrum bends to 26°. Her 3-D kyphosis calculated was 13°. (E-F): First erect PA showing curve correction to 22° (63% correction) and lateral at 6 weeks following ASC from T7 to L1 with two thoracic disc releases. (G-H): PA and lateral at 1 year post-op with correction maintained at 23° (I-J): Most recent post-op: PA and lateral at 4 years follow-up. Correction was maintained at 24°. Her 3-D kyphosis calculated was 34° (a 21° correction).



Fig. 3A-D



Fig. 3E-J

Fig. 3 (A, B): Pre-op PA and lateral radiograph of a 17-year-old girl, Risser 4, Sanders 7+. Her thoracic curve is Lenke 1B and measures 68° . Her 3-D kyphosis calculated was -1° (C, D): Pre-op right thoracic fulcrum bends to 32° and left lumbar supine bends to 10° . (E, F): First erect PA showing thoracic correction to 22° and lateral at 4 months following ASC from T6 to L1 with 3 thoracic disc releases. (G, H): PA and lateral at 11 months post-op maintained correction at 21° . (I, J): Most recent post-op PA and lateral with 41 months follow-up maintained correction at 21° . Her 3-D kyphosis calculated was 33° (a 34° correction).



Fig. 4A-D



Fig. 4E-J

Fig. 4: (A, B): Pre-op PA and lateral radiographs of a 13-year-old girl, Risser 3, Sanders 6 with a Lenke 3C curve. Curves were 66° thoracic and 54° lumbar. Her 3-D kyphosis calculated was 8° (C, D): Right thoracic fulcrum bends to 44° and left lumbar supine bends to 32° . (E, F): Post-op PA and lateral 10 days after right ASC from T5 to T11 with 4 thoracic disc releases left ASC from T11 to L3. Thoracic curve is 19° (71 % correction) and lumbar curve is 16° (70 % correction). (G, H): Post-op PA and lateral 7 months following surgery. Balanced correction at 20° each. (I, J): Most recent PA and lateral radiographs with 4-year follow-up. Correction was maintained. Her 3-D kyphosis calculated was 37° (a 29° correction.)

Instrumented	Preoperative	Postoperative (> 2 years)	Percent	P-value
Curve Type	Measurements*	Measurements	correction	
Thoracic $(n = 49)$				
Coronal curve	$55^{\circ} \pm 11^{\circ}$	$19^{\circ} \pm 7^{\circ}$	65.5%	< 0.001
	(30° to 84°)	(5° to 37°)		
Lumbar $(n = 33)$				
Coronal curve	$51^{\circ} \pm 10^{\circ}$	$17^{\circ} \pm 10^{\circ}$	66.7%	< 0.001
	(37° to 78°)	(5° to 47°)		

Table 4. Pre- and postoperative coronal curve angles for instrumented curves.

*The values are given as the mean and standard deviation.

In patients with instrumented lumbar curves, the average preoperative curve of 51° (range 37° to 78°) was corrected to an average postoperative coronal curve angle of 17° (range 5° to 47°), for an average 66.7% correction. Of note, one patient had a Lenke

6 curve where the lumbar curve met the inclusion criteria, and the 30° thoracic curve was instrumented to balance the shoulders. Preoperative and postoperative kyphosis measurements for all instrumented curves are shown in Table 5.

Table 5. Kyphosis Measurements

3D kyphosis, mean ± SD (range), degrees	Preoperative	Postoperative	P-value
All patients (n=46) *	2.1° ± 16.1° (-22.4° to 35.6°)	33.6° ± 8.8° (13.8° to 53.2°)	<0.001

*n=46 because 1 lateral film was unavailable for review in 3 patients

On the basis of $a > 5^{\circ}$ increase in angulation between 2 adjacent screws, splaying was observed radiographically in 21 of the 49 patients (42.9%). Despite implant breaks in 42.9% of patients, curve correction was still largely maintained in the vast majority and often showed improvement in balance (Figure 5).



Fig. 5A-D





Fig. 5: (A, B): Pre-op PA and lateral radiographs of a 15-year-old girl, Risser 4, Sanders 6, Lenke 1B. Curves measured 77° thoracic and 46° lumbar. Her 3-D kyphosis calculated was minus 21° . (C, D): Right thoracic fulcrum bends to 50° and left lumbar supine bends to 12° . (E, F): PA and lateral first erect at 6 weeks following right ASC from T6-L1 with 3 thoracic disc releases at the apex. Thoracic curve is 23° (70% correction). (G, H): Most recent PA and lateral erect with 4-year follow-up. The thoracic curve measures 30° . Her 3-D kyphosis calculated was 11° (a 32° correction). Note the splaying of screws at T10-T11 and T11-T12. There is a 7° loss of original correction, but the patient is nicely balanced.

There were no revisions for implant breakage and only 1 recommended revision for a patient with both instrumented thoracic and lumbar curves. At 30-month follow-up, this patient demonstrated successful thoracic correction from 43 to 26° , but the lumbar correction was lost due to lumbar implant breakage (splaying at L1/2 and L2/3) and demonstrated lumbar curve loss of correction from 63° preoperatively to 10° immediately postoperatively to 47° at 30 months. Revision was recommended as the curve had progressed past 40° but the patient opted not to undergo revision since her thoracic curve was stable and she had no pain.

Clinical success (final curve $\leq 30^{\circ}$) at > 2year follow-up was achieved in 45/49 patients (92%), in 47/49 (96%) of all thoracic curves (range 5 to 37°), and in 31/33 (94%) of all lumbar curves (5 to 47°). The 2 thoracic curve progressions measured 31° and 37° at 2-year follow-up. The 2 lumbar curve progressions measured 32° and 47° at 2-year follow-up.

3.1. Adverse Events

In the 49 cases, there was 1 (2.0%) intraoperative neuromonitoring alert, without any sequelae. The patient was a 13-year-old girl, Lenke 3C, with a 63° thoracic curve and a 52° lumbar curve. She was undergoing a bilateral ASC and a loss of motor signal occurred during correction of the lumbar spine. Intraoperatively, loss of motor evoked potentials was noted, but the patient demonstrated normal movement with a wake-up test. Nonetheless, the lumbar surgery was stopped and screws removed. The procedure was subsequently completed 1 week later without any problem. She had normal motor signals during the completion surgery. This patient reported anterior thigh numbness and skin hypersensitivity for approximately 1 year postoperatively. Her thoracic and lumbar curve corrections were

considered successful at most recent followup (29 months).

There were 6 (12.2%) intraoperative and postoperative medical adverse events. There was 1 chylothorax and 1 intraoperative avulsion of a segmental branch off the inferior vena cava (IVC). The chylothorax was initially drained via a chest tube but was ultimately treated with embolization on postoperative day 12. The IVC leak was repaired intraoperatively, and the surgery was completed without transfusion, as estimated blood loss for the case remained low at 500ml. Four additional complications were considered minor: 3 cases of superior mesenteric artery (SMA) syndrome and 1 delayed minor hemothorax occurring on postoperative day 4 which resolved with observation as the chest tube was still in place.

4. Discussion

ASC for the treatment of skeletally maturing (Sanders 5-7) and mature (Sanders 8) patients with idiopathic scoliosis successfully corrected scoliotic curves to $\leq 30^{\circ}$ in 92% of our patients. The 2 patients with thoracic curve progression measured 31° and 37°, and the 2 patients with lumbar curve progression measured 32° and 47° at 2-year follow-up.

The majority of studies to date have utilized $\leq 30^{\circ}$ as a marker of clinical success at final follow-up in immature patients. Samdani, et al.²⁴ demonstrated an 80% success rate (< 30° at final follow-up in 45 of 56 patients treated). Miyanji, et al.¹⁵ demonstrated a 57% success rate for 28 treated patients. Newton, et al.¹⁶ used < 35° instead of < 30° and found that 59% of patients at 2-year follow-up had radiographic success. If we used success as < 35° as was done in the Newton et al. study,¹⁶ our clinical success would have been 47/49 (96%).

We suggest that our results with ASC in this series of maturing and mature patients may be equal to or better than those of VBT because of the additional techniques employed at the time of surgery to obtain an aggressive correction rather than dependence on growth modulation in this more mature group of patients.

The average preoperative thoracic curve in our cohort was 55° , while the average postoperative thoracic curve with a minimum of 2-year follow-up was 19° , indicating average curve correction of 65.5%. Newton et al.¹⁶ reported on a cohort of 17 patients whose average preoperative curve was 54° and final follow-up postoperative curve at 2year minimum was 27° (range -8° to 57°), with an overall correction of 51%. Samdani et al.²⁴ conducted the largest study, consisting of 56 patients, with average preoperative curve of $40^{\circ} \pm 7^{\circ}$ and final follow-up of $18.7^{\circ} \pm 13.4^{\circ}$, for an overall correction of 54%. The study by Miyanji et al.¹⁵ consisted of 28 patients with an average preoperative curve of 54° (range 35 to 81°) and final 2-year follow-up curve of 29° (range 4 to 46°), with an overall correction of 46%. Clinical success rates for these studies are summarized and shown in Table 6.

Table 6. Clinical success rates

	Antonacci	Newton et al.	Samdani	Miyanji	Hoernscheme
	et al. (mature)	(immature) ¹⁶	et al. ²⁴	et al. ¹⁵	yer et al. ¹⁷
		*	(immature)	(immature)	(immature)
Number of patients	49	17	56	28	27
Average	55°	52°	40° <u>+</u> 7°	54°	50°
preoperative thoracic	(30°-84°)	(40°-67°)		(35°-81°)	
curve					
Average	19°	27°	18.7° <u>+</u> 13.4°	29°	9°
Postoperative	(5°-37°)	(-8°-57°)		(4°-46°)	
thoracic curve					
2yr minimum					
Overall correction	92%	59%*	80%	46%	74%
major coronal curve					
$\leq 30^{\circ}$					

* Newton used $\leq 35^{\circ}$

It may be more prudent to compare our results to those of PSF due to the limited data available for VBT and other similar techniques in this maturing and mature group of patients. In a sample of 60 maturing and mature patients who underwent PSF, Newton, et al.²⁵ demonstrated 57% correction of primary thoracic curves at minimum 2-year follow-up. Comparatively, the ASC technique achieved 69.% of correction in this series at 2 years. ASC is shown to be an equally powerful technique of correcting thoracic scoliosis.

Important for future study is comparison of residual spinal motion and patient-reported outcomes between patients undergoing ASC or PSF to determine if the amount of maintained spinal motion correlates to patient ability in activities of daily living. Further longitudinal study of this group of patients is needed to examine maintenance of curve correction beyond 2-year follow-up.

The average preoperative instrumented lumbar curve was 51° corrected to an average of 17° at minimum 2-year follow-up, indicating average correction of 66.7%. To

date, there has been one paper published regarding results of patients who have undergone non-fusion instrumented lumbar or thoracolumbar scoliosis curvatures; Trobisch et al.²⁶ found a 49.7% correction in their VBTs of lumbar curves. Two studies have examined results for anterior single rod instrumentation and fusion. Kelly, et al.²⁷ examined anterior single rod instrumentation and fusion for thoracolumbar and lumbar scoliosis in AIS and found percent correction to be approximately 64%. A study by Sweet, et al.²⁸ utilizing an anterior approach found an average of 70% correction. Therefore, our ASC technique shows comparable overall correction to anterior spinal metal rod fusion at minimum 2-year follow-up.

Corrective force across the anterior column of the thoracic spine by utilizing compression forces can result in improved kyphosis.²⁷ Kyphosis analysis of both 2D and 3D approximation vielded a pattern of improvement of thoracic kyphosis between preoperative and postoperative time points after ASC (average 2D kyphosis changed from 20° to 31° and average 3D kyphosis changed from 2° to 34°). This improvement in thoracic hypokyphosis associated with AIS is likely due to the utilization of an anterior approach, as other studies have shown similar outcomes via improvement in kyphosis with anterior fusions.^{27, 28} Additionally, we suggest that the significant improvement in kyphosis is due to the effect of anterior longitudinal ligament complex (ligament, annular capsule, and disc) releases, which allow for effective correction of the lordotic thoracic spine and thus sagittal compensation. Previous work has shown correction of the thoracic spine kyphosis to > 30° may have a positive influence by initiating cervical lordosis.^{29, 30}

One patient in this study was recommended an unanticipated reoperation. Comparatively, Newton et al.¹⁶ in his series of VBT for immature patients demonstrated an 18% (3/17) unanticipated revision rate, with 1 patient requiring a contralateral lumbar cord, 1 requiring revision of a broken cord, and 1 conversion to PSF. The Newton et al. study reports that at latest follow-up, 3 additional patients were indicated for conversion to PSF and were considered both failures of treatment and unanticipated revisions, for a total percentage of 35% (6/17).¹⁶ This difference may be due to longer follow-up as well as larger residual postoperative curves at the time of surgery in Newton et al. We utilize ALL complex releases when needed to obtain the desired residual curve instead of allowing the stiffness of the curve to dictate the amount of correction on the table. Similarly, in a study by Miyanji et al.¹⁵, there were 2 patients (7%) reported to have failed treatment and were subsequently converted to fusion.

Of note, the 49 patients in our study included only cases of single vertebral screw and single cord constructs. Presently, however, the surgeons currently utilize multi-cord and multi-screw constructs to improve derotation and overall curve correction. Additionally, this helps to reduce loss of correction from intraoperative to first erect radiographs. The authors also postulate that increased number of ALL complex releases, meaning instead of an average of 1.7 per thoracic curve, we now perform an average of 3-5 per curve. This improves overall sagittal and coronal correction, stabilizes corrected curves longterm through tissue remodeling, and helps to prevent late curve decompensation.³¹ This technique modification requires future review of cases.

The rate and severity of adverse events reported in this study are comparable to those reported in VBT^{16, 25} and PSF³²⁻³⁶ studies. Our intraoperative and postoperative medical

complication rate of 12.2% is comparable to the VBT complication rate of 11.8% in Newton et al.¹⁶ The rate of complications associated with PSF in AIS ranges from 5 to 23%³²⁻³⁶; these complications include development of adjacent level disc degeneration in the lumbar spine, decreased range of motion, and decreased functional spinal mobility.³⁻⁵

The authors acknowledge that this study has significant limitations but felt it important to report these early results in maturing and mature patients as the literature is currently nonexistent. The relatively small sample size of each cohort and data from only one primary surgeon (MDA) may have decreased the margin of error and decreased generalizability of the results. However, this conversely enables consistency of surgical technique and postoperative care. As this is a retrospective study, there is an inferior level of evidence compared with prospective studies, and there exists the possibility of selection bias, recall bias, or misclassification bias. Other limitations include lack of patient-reported outcomes, lack of a concurrent comparison cohort with PSF, and a relatively short time frame (2-4 years) for a new technology.

5. Conclusion

The 2-4 year results of non-fusion ASC in maturing and mature patients with AIS showed average curve correction of 65.5% in thoracic and 66.7% in lumbar curves. Anterior longitudinal ligament complex (disc) releases were performed in 71% of patients having thoracic curves to help obtain adequate correction. Clinical success with residual curves $\leq 30^{\circ}$ was 94-96%. 3D thoracic kyphosis corrected an average of 32°. The rate of recommended reoperation was 1/49 patients (2%).

Randal R. Betz, et al. Medical Research Archives vol 9 issue 12. December 2021 Page 20 of 20

References

- Agabegi SS, Kazemi N, Sturm PF, Mehlman CT. Natural history of adolescent idiopathic scoliosis in skeletally mature patients: a critical review. J Am Acad Orthop Surg. 2015;23(12):714-23. http://dx.doi.org/10.5435/JAAOS-D-14-00037.
- Weinstein SL, Dolan LA, Wright JG, Dobbs MB. Effects of bracing in adolescents with idiopathic scoliosis. N Engl J Med. 2013;369(16):1512-21. http://dx.doi.org/10.1056/NEJM0a1307 337.
- Danielsson AJ, Romberg K, Nachemson AL. Spinal range of motion, muscle endurance, and back pain and function at least 20 years after fusion or brace treatment for adolescent idiopathic scoliosis: a case-control study. *Spine (Phila Pa 1976)*. 2006;31(3):275-83.
- Green DW, Lawhorne TW, Widmann 4. RF, Kepler CK, Ahern C, Mintz DN, et al. Long-term magnetic resonance follow-up imaging demonstrates minimal transitional level lumbar disc degeneration after posterior spine adolescent idiopathic fusion for scoliosis. Spine (Phila Pa 1976). 2011;36(23):1948-54. http://dx.doi.org/10.1097/BRS.0b013e3 181ff1ea9.
- 5. Kepler CK, Meredith DS, Green DW, Widmann RF. Long-term outcomes after posterior spine fusion for adolescent idiopathic scoliosis. *Curr Opin Pediatr*. 2012;24(1):68-75.
- 6. Samdani AF, Ames RJ, Kimball JS, Pahys JM, Grewal G, Pelletier GJ, et al. Anterior vertebral body tethering for idiopathic scoliosis: two-year results.

Spine (Phila Pa 1976).

2014;39(20):1688-93.

- 7. Samdani AF, Ames RJ, Kimball JS, Pahys JM, Grewal H, Pelletier GJ, et al. Anterior vertebral body tethering for immature adolescent idiopathic scoliosis: one-year results on the first 32 patients. *Eur Spine J*. 2015;24(7):1533-9.
- Kasliwal MK, Shaffrey CI, Lenke LG, Dettori JR, Ely CG, Smith JS. Frequency, risk factors, and treatment of distal adjacent segment pathology after long thoracolumbar fusion: a systematic review. *Spine (Phila Pa* 1976). 2012;37(22 Suppl):S165-79. http://dx.doi.org/10.1097/BRS.0b013e3 1826d62c9.
- 9. Betz RR, Ranade A, Samdani AF, Chafetz R, D'Andrea L, Gaughan JP, et al. Vertebral body stapling: a fusionless treatment option for a growing child with moderate idiopathic scoliosis. *Spine (Phila Pa 1976)*. 2010;35(2):169-76.
- 10. Newton PO, Farnsworth CL, Faro FD, Mahar AT, Odell TR, Mohamad F, et al. Spinal growth modulation with an anterolateral flexible tether in an immature bovine model: disc health and motion preservation. *Spine (Phila Pa 1976)*. 2008;33(7):724-33.
- 11. Newton PO, Fricka KB, Lee SS, Farnsworth CL, Cox TG, Mahar AT. Asymmetrical flexible tethering of spine growth in an immature bovine model. *Spine (Phila Pa 1976)*. 2002;27(7):689-93.
- 12. Crawford 3rd CH, Lenke LG. Growth modulation by means of anterior tethering resulting in progressive correction of juvenile idiopathic

scoliosis: a case report. J Bone Joint Surg Am. 2010;92(1):202-9.

- 13. Newton PO, Faro FD, Farnsworth CL, Shapiro GS, Mohamad F, Parent S, et al. Multilevel spinal growth modulation with an anterolateral flexible tether in an immature bovine model. *Spine (Phila Pa 1976)*. 2005;30(23):2608-13.
- 14. Lavelle WF, Moldavsky M, Cai Y, Ordway NR, Bucklen BS. An initial biomechanical investigation of fusionless anterior tether constructs for controlled scoliosis correction. *Spine J*. 2016;16(3):408-13. http://dx.doi.org/10.1016/j.spinee.2015. 11.004.
- 15. Miyanji F, Pawelek J, Nasto LA, Parent S. A prospective multicenter analysis of the efficacy of anterior vertebral body tethering (AVBT) in the treatment of idipathic scoliosis [abstract]. *Spine Deform.* 2018;6(6):820.
- 16. Newton PO, Kluck DG, Saito W, Yaszay B, Bartley CE, Bastrom TP. Anterior spinal growth tethering for skeletally immature patients with scoliosis. A retrospective look two to four years postoperatively. *J Bone Joint Surg Am.* 2018;100(19):1691-7.
- Hoernschemeyer DG, Boeyer ME, Robertson ME, Loftis CM, Worley JR, Tweedy NM, et al. Anterior vertebral body tethering for adolescent scoliosis with growth remaining: a retrospective review of 2 to 5-year postoperative results. J Bone Joint Surg Am. 2020;102(13):1169-76. http://dx.doi.org/10.2106/JBJS.19.0098 0.
- Betz RR, Antonacci MD, Cuddihy LA. Alternatives to spinal fusion surgery in pediatric deformity. *Curr Orthop Pract*. 2018;29(5):430-5.
- 19. Parvaresh KC, Osborn EJ, Reighard FG, Doan J, Bastrom TP, Newton PO.

Predicting 3D thoracic kyphosis using traditional 2D radiographic measurements in adolescent idiopathic scoliosis. *Spine Deform*. 2017;5(3):159-65.

- Weinstein SL, Dolan LA, Spratt KF, Peterson KK, Spoonamore MJ, Ponseti IV. Health and function of patients with untreated idiopathic scoliosis: a 50-year natural history study. *JAMA*. 2003;289(5):559-67.
- 21. Hasler CC, Wietlisbach S, Buchler P. Objective compliance of adolescent girls with idiopathic scoliosis in a dynamic SpineCor brace. J Child Orthop. 2010;4(3):211-8.
- 22. Nicholson GP, Ferguson-Pell MW, Smith K, Edgar M, Morley T. The objective measurement of spinal orthosis use for the treatment of adolescent idiopathic scoliosis. *Spine* (*Phila Pa 1976*). 2003;28(19):2243-50.
- 23. Antonacci CL, Antonacci MD, Bassett WP, Cerrone JL, Haas AR, Haoson DS, et al. Treatment of patients with scoliosis using a unique anterior scoliosis correction technique. *Med Res Arch* 2021;9(7).

http://dx.doi.org/https://doi.org/10.181 03/mra.v4i7.2463.

- 24. Samdani AF, Pahys JM, Ames RJ, Grewal H, Pelletier GJ, Hwang SW, et al. Prospective follow-up of anterior vertebral body tethering for idiopathic scoliosis: interim results from an FDA IDE study. *J Bone Joint Surg Am*. 2021;103(17):1611-9. http://dx.doi.org/10.2106/JBJS.20.0150 3.
- 25. Newton PO, Marks MC, Bastrom TP, Betz R, Clements D, Lonner B, et al. Surgical treatment of Lenke 1 main thoracic idiopathic scoliosis: results of a prospective, multicenter study. *Spine* (*Phila Pa 1976*). 2013;38(4):328-38.

http://dx.doi.org/10.1097/BRS.0b013e3 1826c6df4.

- 26. Trobisch PD, Baroncini A. Preliminary outcomes after vertebral body tethering (VBT) for lumbar curves and subanalysis of a 1- versus 2-tether construct. *Eur Spine J.* 2021. http://dx.doi.org/10.1007/s00586-021-07009-6.
- Kelly DM, McCarthy RE, McCullough FL, Kelly HR. Long-term outcomes of anterior spinal fusion with instrumentation for thoracolumbar and lumbar curves in adolescent idiopathic scoliosis. *Spine (Phila Pa 1976)*. 2010;35(2):194-8.
- 28. Sweet FA, Lenke LG, Bridwell KH, Blanke KM, Whorton J. Prospective radiographic and clinical outcomes and complications of single solid rod instrumented anterior spinal fusion in adolescent idiopathic scoliosis. *Spine* (*Phila Pa 1976*). 2001;26(18):1956-65.
- 29. Sitoula P, Verma K, Holmes L, Gabos PG, Sanders JO, Yorgova P, et al. Prediction of curve progression in idiopathic scoliosis: validation of the Sanders skeletal maturity staging system. *Spine (Phila Pa 1976)*. 2015;40(13):1006-13.
- Sucato DJ, Agrawal S, O'Brien MF, Lowe TG, Richards SB, Lenke L. Restoration of thoracic kyphosis after operative treatment of adolescent idiopathic scoliosis: a multicenter comparison of three surgical approaches. *Spine (Phila Pa 1976)*. 2008;33(24):2630-6.
- 31. Cuddihy LA, Swiercz M, Antonacci CL, Betz R, Antonacci MD. Predicting the major coronal curve angle on initial standing x-rays based on intraoperative correction during anterior scoliosis correction and vertebral body tethering: comparison of single vs. double

cord/screw constructs. 28th International Meeting on Advanced Spine Techniques; April 23-25, 2021 (Virtual).

- 32. Coe JD, Arlet V, Donaldson W, Berven S, Hanson DS, Mudiyam R, et al. Complications in spinal fusion for adolescent idiopathic scoliosis in the new millennium. A report of the Scoliosis Research Society Morbidity and Mortality Committee. *Spine (Phila Pa 1976)*. 2006;31(3):345-9.
- 33. Vigneswaran HT, Grabel ZJ, Eberson CP, Palumbo MA, Daniels AH. Surgical treatment of adolescent idiopathic scoliosis in the United States from 1997 to 2012: an analysis of 20,346 patients. *J Neurosurg Pediatr*. 2015;16(3):322-8. http://dx.doi.org/10.3171/2015.3.PEDS 14649.
- Reames DL, Smith JS, Fu KM, Polly DW Jr, Ames CP, Berven SH, et al. Complications in the surgical treatment of 19,360 cases of pediatric scoliosis: a review of the Scoliosis Research Society Morbidity and Mortality database. *Spine (Phila Pa 1976)*. 2011;36(18):1484-91. http://dx.doi.org/10.1097/BRS.0b013e3 181f3a326.
- 35. Carreon LY, Puno RM, Lenke LG, Richards BS, Sucato DJ, Emans JB, et al. Non-neurologic complications following surgery for adolescent idiopathic scoliosis. J Bone Joint Surg Am. 2007;89(11):2427-32. http://dx.doi.org/10.2106/JBJS.F.00995
- 36. Lykissas MG, Jain VV, Nathan ST, Pawar V, Eismann EA, Sturm PF, et al. Mid- to long-term outcomes in adolescent idiopathic scoliosis after instrumented posterior spinal fusion: a meta-analysis. *Spine (Phila Pa 1976)*.

Randal R. Betz, et al. Medical Research Archives vol 9 issue 12. December 2021 Page 20 of 20

2013;38(2):E113-9. http://dx.doi.org/10.1097/BRS.0b013e3 1827ae3d0.