NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of vertebral body tethering for idiopathic scoliosis in children and young people

Scoliosis is the abnormal sideways curving of the spine, which in most cases has an unknown cause (idiopathic). It usually develops in childhood and early adolescence and can lead to deformity of the chest wall. In this procedure, under general anaesthesia, screws are put into the vertebral bodies (bone discs that make up the spine). A cord is fixed (tethered) to the screws and pulled taut restricting growth on the long side. This allows the spine to grow faster on the short side so that the curve is gradually corrected. The aim is to correct the scoliosis before the person reaches adulthood and their spine stops growing.

Contents

Abbreviations

Word or phrase	Abbreviation
Body mass index	BMI
Confidence interval	CI
Cerebrospinal fluid	CSF
Early-onset scoliosis 24-item questionnaire	EOSQ-24
Intensive care unit	ICU
Interquartile range	IQR
Investigational device exemption	IDE
Food and drug administration	FDA
Forced expiratory volume in 1 second	FEV1
Forced vital capacity	FVC
Lower instrumented vertebrae	LIV
Magnetically controlled growing rods	MCGR
Motor-evoked potentials	MEPs
Posterior spinal fusion	PSF
Standard deviation	SD
Short form 36 health survey questionnaire	SF-36
Scoliosis research society 22-item questionnaire	SRS-22
Somatosensory evoked potentials	SSEPs
Upper instrumented vertebrae	UIV
Unplanned return to the operating room	UPROR
Vertebral body tethering	VBT

Introduction

The National Institute for Health and Care Excellence (NICE) prepared this interventional procedure overview to help members of the interventional procedures advisory committee (IPAC) make recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and professional opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in July 2021.

Procedure name

- Vertebral body tethering for idiopathic scoliosis in children and young people

Professional societies

- British Association of Spine Surgeons
- British Scoliosis Society
- British Scoliosis Research Foundation
- United Kingdom Spinal Societies Board.

Description of the procedure

Indications and current treatment

Scoliosis causes the bones of the spine to twist or rotate so that the spine curves sideways. Scoliosis curves most commonly happen in the upper and middle back (thoracic spine). It can also develop in the lower back and, occasionally, happens in both the upper and lower parts of the spine.

Idiopathic scoliosis is the most common type of scoliosis. It is a progressive condition, and its exact cause is unknown. There are 3 types of idiopathic scoliosis: infantile idiopathic scoliosis, juvenile idiopathic scoliosis and adolescent idiopathic scoliosis.

Treatment of idiopathic scoliosis depends on a number of factors, including age, severity and location of the spinal curve, and the pattern and progression of the curve. In many cases, idiopathic scoliosis is mild (a curve of less than 25˚) and does not need treatment other than close monitoring and physical therapy. For moderate scoliosis (a curve between 25˚ and 45˚) and severe scoliosis (a curve greater than 45˚), treatment includes casting, bracing and surgery (such as spinal fusion and growing rods).

What the procedure involves

Vertebral body tethering is a nonfusion spinal treatment for idiopathic scoliosis. The aim is to preserve the flexibility of the spine and modulate its growth on the concave and convex sides, so slowly correcting the scoliosis.

In this procedure, under general anaesthesia, screws are placed into each vertebra at the convex side of the spine. The screws are connected by a flexible cord. Tension is then applied to the cord to partially correct and tether the convex side of the spine and so restrict its growth. Thoracic tethers are usually done through a thoracoscopic or open approach and lumbar tethers need a mini-open approach. After surgery, the cord continues to restrict growth on the convex side while allowing faster growth on the concave side, so potentially producing further correction of the scoliosis.

The technique exploits a known reaction of bone to being stretched or being compressed. This response is known as the Heuter–Volkmann law and notes that bone growth increases when stretched and decreases when compressed. In scoliosis this response can be used on a curved spine if the bones still have significant growth potential.

Outcome measures

The **Cobb angle** is used to quantify the magnitude of spinal deformities, especially in the case of scoliosis, on plain radiographs. Scoliosis is defined as a lateral spinal curvature with a Cobb angle of 10˚ or more. A Cobb angle can also aid kyphosis or lordosis assessment in the sagittal plane. Overall, if a greater than 10˚ change in Cobb angle is measured, it is 95% likely to represent a true difference.

The normal **ranges of motion** for the thoracic spine include 30˚ of rotation and 50˚ of kyphosis. The normal lumbar ranges of motion include 60˚ of flexion, 25˚ of extension, and 25˚ of lateral or side bending.

Pulmonary function tests measure how well the lungs work and include tests that measure lung volume, capacity and air flow, such as:

- FEV1 – the amount of air exhaled during the first second of the forced breath.
- FVC – the total amount of air that can be forcibly exhaled from the lungs after taking the deepest breath possible.

If the FVC and FEV1 are equal to or greater than 80% of the reference value, the results are considered normal. The normal value for the FEV1/FVC ratio is 70%

(and 65% in persons older than age 65). When comparing with the reference value, a lower measured value corresponds to a more severe lung abnormality.

The **Risser classification** is used to grade skeletal maturity based on the level of ossification and fusion of the iliac crest apophyses. It is primarily in planning corrective surgery for scoliosis, consisting of stage 0 to 5:

- stage 0: no ossification centre at the level of iliac crest apophysis
- stage 1: apophysis under 25% of the iliac crest
- stage 2: apophysis over 25% to 50% of the iliac crest
- stage 3: apophysis over 50% to 75% of the iliac crest
- stage 4: apophysis over >75% of the iliac crest
- stage 5: complete ossification and fusion of the iliac crest apophysis

The **Sanders maturity scale** gives a measure of progression of ossification and predicts the curve acceleration phase of growth.

- Sanders 1: epiphyses narrower than metaphyses, Tanner–Whitehouse stage-E or earlier.
- Sanders 2: epiphyses as wide as metaphyses, Tanner–Whitehouse stage-F.
- Sanders 3: digits are capping, Tanner–Whitehouse stage-G.
- Sanders 4 to 5: distal phalanges fusing/fused, Tanner–Whitehouse stage-H.
- Sanders 6 to 7: other phalanges fusing/fused, Tanner–Whitehouse stage-I.

The **EOSQ-24** is a validated questionnaire to measure the caregiver perspectives of health-related quality of life and burden of care of patients with early-onset scoliosis. It includes 24 items across 12 domains (general health, pain/discomfort, pulmonary function, transfer, physical function, daily living, fatigue/energy level, emotion, parental impact, financial impact, child satisfaction and parental satisfaction). Each domain is scored from 0 to 100, with lower scores indicating greater disability.

The **SRS-22** questionnaire is used to assess health-related quality of life in patients with scoliosis. It includes 22 items distributed among 5 domains (pain, self-image, function/activity, mental health, and satisfaction with management). Each item is scored from 1 (worst) to 5 (best).

The **SF-36** questionnaire is a measure of health status to determine the impact of interventions. It includes 36 items across 8 domains (physical functioning, physical role limitations, bodily pain, general health perceptions, energy/vitality, social functioning, emotional role limitations, and mental health). Each domain is scored from 1 to 100, with a higher score indicating a better health status.

Efficacy summary

Improvement in scoliotic curve

In a meta-analysis of 24 studies (n=1,280: 1,278 patients with idiopathic scoliosis and 2 patients with syndromic scoliosis), the pooled mean Cobb angle of the main thoracic curve was 46.0° (95% CI 42.3° to 50.0°; 10 studies) in patients who had anterior VBT and 53.3° (95% CI 52.8° to 53.9°; 14 studies) in patients who had PSF preoperatively (Shin 2021). Of the studies with a follow up of 36 months or more after operation (number of studies not reported), the mean main thoracic curve was corrected to 22.5° (95% CI 14.1° to 30.9°) for anterior VBT and 22.7° (95% CI 19.6° to 25.8°) for PSF. In the same meta-analysis, the pooled mean Cobb angle of the lumbar curve was 28.7° (95% CI 25.6° to 32.0°; 9 studies) for anterior VBT and 30.9° (95% CI 29.2° to 32.5°; 5 studies) for PSF preoperatively and corrected to 18.0° (95% 3.5° to 32.5°) and 15.2° (13.3° to 17.1°) at a follow up of 36 months or more (number of studies not reported).

In a non-randomised comparative study of 49 patients with thoracic idiopathic scoliosis, the anterior VBT and PSF groups were similar in upper (31°±9° compared with 30°±6°, p=0.633) and main thoracic curves (53°±8° compared with 54°±7°; p=0.444) preoperatively (Newton 2020). After operation, both groups obtained statistically significant corrections in upper and main thoracic curves at the final follow up (anterior VBT, 24°±8° before operation compared with 34±8° at a mean follow up of 3.4 years; PSF, 13°±5° before operation compared with 12±4° at a mean follow up of 3.6 years; all p<0.001). Comparative analysis between groups showed that the anterior VBT group had statistically significantly more spinal deformity than the PSF group at immediate postoperation and final follow up (immediate postoperation, 36% correction compared with 78% correction, p<0.001; final follow up, 43% correction compared with 69% correction, p=0.002).

In a non-randomised comparative study of 43 patients with adolescent idiopathic scoliosis, the mean magnitude of the main thoracic-thoracolumbar curve was statistically significantly corrected from 48.2° before operation to 9.1° at a mean follow up of 39.4 months in patients who had VBT (p<0.001; Pehlivanoglu 2021). In patients who had PSF, the main thoracic-thoracolumbar curve was also statistically significantly corrected from 48.8° to 9.7° during the same period (p<0.001).

In a non-randomised comparative study of 130 patients with idiopathic early onset scoliosis, the median major scoliosis curve was statistically significantly smaller in the VBT group (50°, range 43.5° to 58°) compared with the MCGR group (64.5°, range 55° to 75°) and the PSF group (63°, range 57° to 72°) preoperatively (p<0.0005; Mackey 2021). After operation, the median major scoliosis curve was statistically significantly corrected to 28° (range 21° to 35°) in patients who had VBT at a median follow up of 3 years, 42° (range 34.4° to 54.5°) in patients who had MCGR at a median follow up of 2.9 years and 29° (range 22° to 36°) in patients who had PSF at a median follow up of 3.6 years (all p<0.0005). Statistically significant difference was found in scoliosis curve correction between groups (VBT, 41% correction; MCGR, 27% correction; PSF, 52% correction; p<0.0005).

In a case series of 120 patients with idiopathic scoliosis who had anterior VBT, the mean thoracic scoliosis was 51.2° preoperatively and statistically significantly improved to 26.9° at immediate postoperation (p<0.05; Abdullah 2021). After 1 year, the curve was further corrected to 23.0°, which also statistically significantly improved compared with the immediately postoperative value (p<0.01). This statistically significant improvement did not happen at 2-year follow up (27.5°) compared with immediate postoperation (p=0.64).

In a case series of 112 patients with idiopathic scoliosis who had anterior VBT, the mean coronal Cobb angle was statistically significantly corrected from 50.8°±10.2° preoperatively to 26.6°±10.1° at time of first erect radiograph and 25.7°±16.3° at a mean follow up of 37 months (all p<0.001; Rushton 2021).

In a case series of 50 patients with idiopathic scoliosis who had anterior VBT, the mean Cobb angles of the proximal thoracic and main thoracic curves were 22.8°±8.8° and 49.4°±8.5° preoperatively (Miyanji 2021). After operation, the mean Cobb angles were corrected to 16.8°±8.8° and 27.1°±8.5° at immediate postoperation, 12.4°±8.1° and 22.1°±8.9° at 1-year follow up and 13.1°±7.5° and 24.9°±9.5° at a mean follow up of 2.1 years.

In a case series of 31 patients with adolescent idiopathic scoliosis who had VBT, the mean magnitude of the main thoracic curve improved from 47°±7.6° preoperatively to 21.8°±6.4° in first erect radiographs after operation (Alanay 2020).

In a case series of 57 patients with adolescent idiopathic scoliosis who had anterior VBT, the mean thoracic Cobb angle was 40.4°±6.8° before operation and was statistically significantly corrected to 19.3°±8.4° at first erect, 12.6°±7.2° at 1-year follow up, 13.8°±8.9° at 2-year follow up and 18.7°±13.4° at a mean follow up of 55.2 months (all p<0.0001; Samdani 2021). The mean proximal thoracic and lumbar curves were 25.0°±5.7° and 23.7°± 6.1°° before operation and were statistically significantly corrected to 17.9°±6.4° and 15.7°±8.4° (p<0.05) at a mean follow up of 55.2 months.

In a case report of 1 patient with adolescent idiopathic scoliosis, preoperative thoracic and lumbar curves were 25° and 22°, respectively (Rathbun 2019). After VBT, thoracic and lumbar curves improved to 22° and 3° at 2 weeks and then changed to 21° and 6° about 1 year.

Change in kyphotic or lordotic curves

In the meta-analysis of 24 studies (n=1,280), the pooled mean thoracic kyphosis was 24.3° (95% CI 17.8° to 30.8°; 8 studies) in patients who had anterior VBT and 23.0° (95% CI 20.7° to 25.2°; 8 studies) in patients who had PSF preoperatively. Of the studies with a follow up of 36 months or more after operation (number of studies not reported), the mean thoracic kyphosis changed to 22.5° (95% CI 12.0° to 33.0°) for anterior VBT and 24.5° (95% CI 21.9° to 27.1°) for PSF. In the same meta-analysis, the pooled mean lumbar lordosis was 52.0° (95% CI 46.2° to 57.9°; 5 studies) for anterior VBT and 47.2° (95% CI 28.1° to 66.3°; 5 studies) for PSF preoperatively and changed to 55.1° (95% CI 51.3° to 58.8°) and 46.1° (95% CI 25.0° to 67.1°) respectively at a follow up of 36 months or more (number of studies not reported).

In the non-randomised comparative study of 49 patients, the anterior VBT and PSF groups were similar in preoperative T2 to T12 kyphosis (anterior VBT, 24°±12°; PSF, 25°±12°; p=0.79; Newton 2020). After operation, there were statistically significant differences in T2 to T12 kyphosis between groups at the first postoperative and final follow up time points (immediate postoperation, 22°±12° in the anterior VBT group compared with 31°±8° in the PSF group, p=0.004; final follow up, 19°±13° in the anterior VBT group compared with 29°±8° in the PSF group, p=0.001).

In the case series of 120 patients, the mean global kyphosis was 28.5°±11.2° preoperatively and changed to 27.4°±11.4° at immediate postoperation and 29.2°±12.5° at 2 years (Abdullah 2021). During the same period, T5 to T12 kyphosis was 16.0°±11°, 16.9°±10.8° and 17.0°±11.8°, respectively. No statistically significantly differences were found between preoperation and 2-year follow up in global kyphosis and T5 to T12 kyphosis (all p>0.05).

In the non-randomised comparative study of 130 patients, the mean kyphosis T2 to T12 was statistically significantly lower in the VBT group (26.1°±12.3°) compared with the MCGR group (34.7°±16.3°) and the PSF group (35.9°±13.1°) preoperatively (p=0.010; Mackey 2021). After operation, the mean kyphosis T2 to T12 changed to 25.0°±13.0° in the VBT group (p=0.522) and 34.2º±12.0º in the MCGR group (p=0.887) and statistically significantly reduced to 25.8°±11.5° in the PSF group (p=0.022) at the most recent follow up. Statistically significant difference was found in the mean kyphosis T2 to T12 between groups at the most recent follow up (p=0.002).

In the case series of 112 patients, the mean thoracic kyphosis T5 to T12 statistically significantly increased from 18.6°±11.4° preoperatively to 21.4°±13.0° (p=0.004) at a mean follow up of 37 months (Rushton 2021). During the same period, the mean lumbosacral lordosis L1 to S1 changed from -55.9°±10.5° to -56.2°±11.4° (p=0.86).

In the case series of 31 patients, the median changes between preoperation and a mean follow up of 27 months for thoracic kyphosis were 4°, 3°, 0° and 0° in Sanders 2, 3, 4 to 5, and 6 to 7 groups, respectively, and for lumbar lordosis were 4°, 0°, -3° and -2° (Alanay 2020). There were no statistically significant differences in Sagittal Cobb angle changes between groups (all p>0.05).

In the case series of 57 patients, the mean thoracic kyphosis T5 to T12 changed from 15.5°±10.0° preoperatively to 17.0°±10.1° at the first erect measurement (p=0.40) and 19.6°±12.7° at a mean follow up of 55.2 months (p<0.05; Samdani 2021). No statistically significantly change was found in lumbar lordosis between the preoperative and 55.2-month measurements (51.9°±11.4° compared with 54.4°±11.8°, p=0.10).

Range of motion and muscle endurance

In the meta-analysis of 24 studies (n=1,280), the mean thoracic rotation was 13.7° (95% CI 12.1° to 15.2°; 6 studies) in patients who had anterior VBT and 15.4° (95% CI 12.4° to 18.4°; 3 studies) in patients who had PSF preoperatively (Shin 2021). After operation, thoracic rotation changed to 8.4° (95% CI 1.0° to 15.7°) and 13.0° (95% CI 3.3° to 22.6°) respectively at a follow up of 36 months or more (number of studies not reported).

In the non-randomised comparative study of 49 patients, the anterior VBT and PSF groups were similar in preoperative trunk rotation (thoracic angle of trunk rotation, 15°±4° compared with 17°±3°, p=0.109; lumbar angle of trunk rotation, 6°±5° compared with 8±5, p=0.213; Newton 2020). After operation, there were statistically significant differences in trunk rotation between groups at immediate postoperation and final follow up (thoracic angle of trunk rotation - immediate postoperation, 10°±3° in the anterior VBT group compared with 6°±4° in the PSF group, p=0.008; final follow up, 11°±5° in the anterior VBT group compared with 6°±3° in the PSF group, p<0.001; lumbar angle of trunk rotation - immediate postoperation, 6°±1° in the anterior VBT group compared with 1°±3° in the PSF group, p=0.016; final follow up, 6°±5° in the anterior VBT group compared with 3°±3° in the PSF group, p=0.021).

In the non-randomised comparative study of 43 patients, the mean lumbar ranges of motion in flexion, extension, lateral bending and rotation were statistically significantly superior in the VBT group compared with the PSF group at a mean follow up of 39.4 months (flexion, 78.2° compared with 58.1°, p<0.001; extension, 34.6° compared with 19.4°, p<0.001; lateral bending, 34.4° compared with 18.3°, p<0.001; rotation, 45.4° compared with 24.1°, p<0.001; Pehlivanoglu 2021). During the same period, the mean lumbar anterior and lateral bending flexibility were also statistically significantly superior in the VBT group compared with the PSF group (anterior, 3.7 cm compared with 23.4 cm, p<0.001; lateral, 22.4 cm compared with 11.3 cm, p=0.003). In the same study, the mean flexor and extensor trunk endurance were statistically significantly higher in the VBT group than the PSF group at a mean follow up of 39.4 months (flexor, 65.1 seconds compared with 19.2 seconds, p<0.001; extensor, 60.8 seconds compared with 28.7 seconds, p<0.001). The mean motor strength of the trunk extensor and anterior–lateral–oblique flexor muscles was statistically significantly superior in the VBT group than the PSF group (4.7 compared with 3.2, p=0.003).

In the case series of 57 patients, the mean trunk rotation based on thoracic sociometer reading was 13.6°±3.9° preoperatively and changed to 6.3°±3.0° at 2 years after operation and 8.6°±4.9° at a mean follow up of 55.2 months (Samdani 2021).

Improvement in thoracic and lumbar prominence

In the case series of 112 patients, the mean rib hump was statistically significantly corrected from 14.1°±4.8° preoperatively to 8.8°±5.4° at a mean follow up of 37 months (p<0.001; Rushton 2021). During the same period, the mean lumbar prominence statistically significantly improved from 3.6°±4.7° to 2.5°±4.4° (p=0.03).

In the case series of 31 patients, the median thoracic hump corrections between the preoperative and last follow up values were 67%, 50%, 36% and 58% in Sanders 2, 3, 4 to 5, and 6 to 7 groups, respectively (Alaney 2020). There was no statistically significant difference in hump angle between groups (p>0.05).

Shoulder height and balance

In the non-randomised comparative study of 49 patients, the mean shoulder height differences were 1±1 cm in the anterior group and 1.5±1 in the PSF group preoperatively and changed to 1± 1 cm and 1.3± 1 cm at the final follow up (Newton 2020). No statistically significant differences were found within and between groups (all p>0.05).

In the case series of 50 patients, the mean absolute shoulder height was 15.6±10.5 mm preoperatively and changed to 9.6±8.2 mm at immediate postoperation, 11.5±7.8 mm at 1 year and 11.3±8.3 mm at 2 years (Miyanji 2021). Preoperatively, there were 70% of patients (35/50) with acceptable shoulder balance, 28% (14/50) with moderate shoulder imbalance and 2% (n=1) with severe shoulder imbalance. At 2 years after operation, these proportions changed to 84% (42/50) of patients with acceptable shoulder balance and 16% (8/50) with moderate shoulder balance.

In the case series of 57 patients, clinically unlevel shoulders were reported in 54% of patients (28/52) preoperatively and reduced to 25% (14/55) at a mean follow up of 55.2 months (Samdani 2021).

Pulmonary function

In the case series of 57 patients, 42 patients had pulmonary function tests at both the preoperative evaluation and the 2-year follow-up evaluation or later (Samdani 2021). The mean FEV1 and FVC statistically significantly increased from 2.29 litres and 2.67 litres preoperatively to 2.77 litres and 3.17 litres at a mean follow up of 50.1 months (p<0.01). Based on normal subjects, the percentages of predicted FEV1 and FVC decreased from 83% and 83% to 75% and 74% respectively.

Improvement in quality of life

In the meta-analysis of 24 studies (n=1,280), there was no statistically significant difference found in the postoperative SRS-22 self-image or total scores between patients who had anterior VBT and patients who had PSF (self-image, 4.27 [95% CI 4.0 to 4.56; 2 studies] compared with 4.23 [95% CI 4.07 to 4.40; 7 studies]; total score, 4.36 [95% CI 4.06 to 4.65; 2 studies] compared with 4.30 [95% CI4.17 to 4.43; 7 studies]; Shin 2021).

In the non-randomised comparative study of 49 patients, there were no statistically significant differences in any SRS-22 domain or total score between the anterior VBT group and the PSF group (pain, 4.4±0.6 compared with 4.4±0.4, p=0.903; mental health, 4.3±0.6 compared with 4.0±0.7, p=0.279; self-image, 4.1±0.7 compared with 4.4±0.6, p=0.244; satisfaction, 4.3±0.7 compared with 4.7±0.5, p=0.053; general function, 4.3±0.4 compared with 4.3±0.4, p=0.748; total score, 4.2±0.4 compared with 4.4±0.4, p=0.29; Newton 2020).

In the non-randomised comparative study of 43 patients, the mean total SRS-22 and SF-36 MCS/PCS scores were comparable between the VBT and PSF groups before operation (SRS-22, 3.2 compared with 3.2; SF-36 MCS, 52.7 compared with 52.3; SF-36 PCS, 46.8 compared with 47.1; all p>0.05; Pehlivanoglu 2021). At a mean follow up of 39.4 months, the mean total SRS-22 and SF-36 MCS/PCS scores were statistically significantly higher in the VBT group than the PSF group (SRS-22, 4.9 compared with 3.8; SF-36 MCS, 56.9 compared with 52.3; SF-36 PCS, 57.2 compared with 53.1; all p<0.001).

In the non-randomised comparative study of 130 patients, the median EOSQ-24 scores statistically significantly improved in pain/discomfort (56.3 at baseline compared with 75 at 3-year follow up, p=0.023), emotion (75 compared with 93.8, p=0.020) and parental impact domains (70 compared with 87.5, p=0.020) in patients who had VBT at a mean follow up of 3 years (Mackey 2021). For patients who had PSF, the median EOSQ-24 score statistically significantly increased in parental impact domain (90 compared with 100, p=0.005). For patients who had MCGR, there was no statistically significant improvement in any domain (all p>0.05).

In the case series of 57 patients, the mean scores for SRS-22 and self-image were 4.5±0.4 and 4.4±0.7 respectively at a mean follow up of 55.2 months (Samdani 2021). The preoperative SRS-22 scores were not obtained.

Length of stay

In the non-randomised comparative study of 49 patients, the mean length of hospital stay was 5.0±1.3 days in the anterior VBT group and 4.9±1.2 days in the PSF group (p=0.7; Newton 2020).

In the case series of 120 patients, the mean length of ICU stay was 0.2±0.5 days and the mean length of postoperative hospital stay was 4.5±1.3 days (Abdullah 2021).

In a case series of 90 patients with adolescent idiopathic scoliosis who had single or bilateral VBT, the mean length of hospital stay was 8.3±3.1 days (Baroncini 2021). The first 20 patients who had VBT stayed at hospital statistically significantly longer than the last 20 patients who had VBT (9.3±2.1 days compared with 7.8±1.6 days, p=0.01).

In the case series of 112 patients, the mean length of hospital stay was 4.7±1.4 days for patients who had single stage thoracic/lumbar tethering procedures and 10.5±4.0 days for patients who had planned 2 stage procedures (p=0.001; Rushton 2021).

In the case series of 57 patients, the mean length of ICU stay after operation was 1.5±0.7 days and the mean length of stay at hospital was 4.8±1.4 days (Samdani 2021). The length of stay might be confounded by the long distance travelled by families, with most families flying.

In the single case report, the patient stayed at hospital for 15 days after operation while recovering with resolving pneumothorax and awaiting safe chest tube removal.

Safety summary

Overall complications

Overall complications were reported in 27% (10/37) of patients in the VBT group, 61% (31/51) in the MCGR group and 14% (6/42) in the PSF group in the non-randomised comparative study of 130 patients ($p<0.0005$; Mackey 2021).

The pooled complication rate was 26% (95% CI 12% to 40%, I^2=86.14%; 10 studies) in patients who had anterior VBT and 2% (95% CI 0% to 4%, I^2=19.21%; 9 studies) in patients who had PSF in the meta-analysis of 24 studies (n=1,280; Shin 2021). Of the studies with a follow up of less than 36 months (number of studies not reported), the pooled complication rate was 12% (95% CI 4.4% to 18.6%) for anterior VBT and 1% (95% CI 0.0% to 2.4%) for PSF. Of the studies with a follow up of 36 months or more (number of studies not reported), the pooled complication rate was 25% (95% CI 19.1% to 31.7%) and 3% (0.5% to 5.3%) respectively.

Pulmonary complications

Pneumothorax was reported in 1 patient at postoperative day 3 in the case series of 120 patients and this event resolved with reinsertion of chest tube (Abdullah 2021). Small pneumothorax was reported in 1 patient after chest drain removed in the case series of 112 patients and this event resolved spontaneously (Rushton 2021).

Pleural effusion was reported in 2 patients by 90 days postoperation in the case series of 120 patients (Abdullah 2021). Both patients needed chest tubes and antibiotics. Recurrent, right-side pleural effusion was reported in 3 patients at 2 to 6 weeks after surgery in the case series of 90 patients (Baroncini 2021). Of the 3 patients, 2 patients had chest-tube reinsertion and 1 had exploratory thoracotomy because of bleeding from the right pulmonary ligament, but this lesion could not be repaired, and a chest-tube was reinserted. All these 3 patients recovered well and without sequelae. Pleural effusion was reported in 1 patient in the case series of 31 patients and the patient needed readmission within 3 days, but a chest tube was not reinserted (Alanay 2020).

Pneumonia was described in 1 patient at 2 weeks after surgery in the case series of 120 patients (Abdullah 2021). The patient had oral antibiotics, and this even resolved by 6 weeks postoperation. Pneumonia was reported in 2 patients after discharge in the case series of 112 patients and they were managed by family doctors (Rushton 2021).

Minor pulmonary embolism was reported in 1 patient in the case series of 90 patients (Baroncini 2021). This event happened after a 24-hour flight. The patient had intramuscular low-molecular-weight heparin therapy for 1 month and then recovered well.

Persistent **atelectasis** of the lower left lobe was reported in 1 patient on the second postoperative day after thoracic VBT from the right side in the case series of 90 patients (Baroncini 2021). Since the patient did not tolerate non-invasive ventilation, intubation was needed for 3 days. The symptoms resolved after bronchoscopic removal of a large mucus accumulation. The patient recovered well and without sequelae. Atelectasis needed admission to intensive care for respiratory support was reported in 4 patients in the case series of 112 patients (Rushton 2021). Atelectasis was reported in 2 patients in the case series of 31 patients and these events resolved with intensive physical therapy (Alanay 2020). Atelectasis with pulmonary oedema was reported in the anterior VBT group (exact number of patients with this complication was not reported) but not in the PSF group in the non-randomised comparative study of 49 patients (Newton 2020). This event was treated with positive airway pressure and resolved by postoperative day 6.

Haemothoraces was described in 2 patients in the case series of 112 patients (Rushton 2021). One patient needed drainage and the other returned to theatre for bleeding control.

Chylothorax was reported in 1 patient in the case series of 31 patients and this event resolved with dietary precautions (Alanay 2020).

Pulmonary complications were reported in 11 patients who had anterior VBT and 1 patient who had PSF in the meta-analysis of 24 studies (n=1,280; Shin 2021).

CSF leak

CSF leak was reported in 2 patients who also presented with headaches (1 patient at 3 weeks postoperation and 1 patient at 4 months after surgery) in the case series of 120 patients (Abdullah 2021).

CSF leak was described in 2 patients who also presented with orthostatic headaches and vomiting at 1 or 2 weeks after operation in the case series of 112 patients (Rushton 2021). One related to a T12 screw narrowly breaching the posterior wall needing revision and the other without obvious cause was treated conservatively.

Mechanical complications

Cable failure was described in 4 patients by 2 years after surgery in the case series of 120 patients (Abdullah 2021). Of the 4 patients, 2 patients had surgery management (UPROR: 1 patient for tether replacement and 1 patient for PSF).

Tether rupture was reported in 28 patients in the case series of 90 patients with adolescent idiopathic scoliosis (Baroncini 2021). Tether breakage was reported in 12 patients who had anterior VBT and 2 of the 12 patients had revision because of progression associated with cord failure in the non-randomised comparative study of 49 patients (Newton 2020). Of the identified broken tethers, most broke at 1 level, but ranged from 1 to 3 levels. Tether breakage was reported in 36 patients (3 patients had confirmed tether breakage and 33 had radiographs suggestive of tether breakage) at a mean follow up of 31 months in the case series of 112 patients (Rushton 2021). The most common sites for breakage were T9/10, T10/11 and T11/12 happening in 11, 13 and 7 patients, respectively. Tether breakage was reported in 17 patients who had anterior VBT and no patients who had PSF in the meta-analysis of 24 studies (n=1,280; Shin 2021).

Adding-on was described in 7 patients who had anterior VBT and 2 patients who had PSF in the meta-analysis of 24 studies (n=1,280; Shin 2021). In the same meta-analysis, **screw pull-out/loosening** was reported in 1 patient who had anterior VBT and 6 patients who had PSF.

Mechanical complications were reported in 6 patients (1 UIV loosening, 1 pull-out, 1 migration, 1 LIV pull-out, loss of previously achieved correction, and 1 tether breakage) in the case series of 31 patients (Alanay 2020).

Curve progression or overcorrection

Compensatory curve progression was reported in 1 patient between 3 months and 1 year after surgery in the case series of 120 patients (Abdullah 2021). The patient had surgery (UPROR) for extension of the tether to the lumbar region. In the same study, curve progression was reported in 1 patient around 1 year after the initial surgery and the patient had UPROR for PSF.

Curve overcorrection was observed in 2 patients at 2-year follow up in the case series of 120 patients (Abdullah 2021). Both patients had surgical management (UPROR) for removal of the tether. Overcorrection was reported in 6 patients in the case series of 31 patients (Alanay 2020). Two overcorrections were greater than or equal to -10°, 1 was -3°, and 3 were less than -10°. Overcorrection was reported in 17 patients who had anterior VBT and 2 patients who had PSF in the meta-analysis of 24 studies (n=1,280; Shin 2021).

Revisions or reoperations

Revision was reported in 7 patients (9 revision procedures: 7 first revision and 2 second revision) in the anterior VBT group and no patients in the PSF group in the non-randomised comparative study of 49 patients (Newton 2020). The reasons for first revision which happened at a mean follow up of 2.3 years included overcorrection (n=3), broken tether with progression (n=2) and progression of lumbar curve (n=2). The reasons for second revision were broken tether with progression (n=1, at 2.8 years after the initial operation) and progression (n=1, at 3.1 years after the initial operation).

Planned revision was described in 3 patients who had VBT, 16 patients who had MCGR and no patients who had PSF (p<0.0005) in the non-randomised comparative study of 130 patients (Mackey 2021). Unplanned revision was reported in 6, 11 and 3 patients respectively (p=0.154). At the final follow up, 2 patients in the VBT group and 17 patients in the MCGR group had definitive fusions.

Revision surgery was needed in 3 patients in the case series of 90 patients (Baroncini 2021). Revision was for loss of correction caused by tether rupture.

Revision was reported in 15 patients who needed 18 revision procedures in the case series of 112 patients (Rushton 2021). Of these 15 patients, 8 needed tether revisions for replacement, extension or loosing of tethers and 7 needed fusion operations.

Revision surgery was needed in 7 patients in the case series of 57 patients (Samdani 2021). Of these 7 patients, 5 had a tether release for overcorrection and 2 had the tether extended for adding-on. In 1 patient whose curve had overcorrected, the tether release did not stop the curve overcorrection. Subsequently, this patient had PSF approximately 4.6 years after the original tether surgery.

The pooled reoperation rate was 14% (95% CI 5.6% to 22.6%) in patients who had anterior VBT (10 studies) and less than 1% (95% CI 0.0% to 2.3%) in patients who had PSF (4 studies) in the meta-analysis of 24 studies (n=1,280; Shin 2021). Of the studies with a follow up of less than 36 months (number of studies not reported), the pooled reoperation rate was 3% (95% CI 0.0% to 8.4%) for anterior VBT and 1% (95% CI 0.0% to 1.7%) for PSF. Of the studies with a follow up of 36 months or more (number of studies not reported), the pooled reoperation rate was 25% (95% CI 10.7% to 38.7%) and 2% (0.0% to 5.4%) respectively. In the same meta-analysis, the pooled conversion rate of anterior VBT-to-PSF was 1.4% (CI: 0% to 4.5%) in patients who had anterior VBT. All conversions were because of deformity progression despite tethering.

Infection

Chest infection was reported in 1 patient in the case series of 90 patients (Baroncini 2021). This patient was admitted to the local hospital 2 weeks after surgery because of fever and dyspnoea and had antibiotics for 2 weeks to treat chest infection. This patient recovered well and without sequelae.

Clostridium difficile infection was described in 1 patient in the case series of 112 patients (Rushton 2021).

Superficial wound infection was found in 1 patient after 1-week postoperation in the case series of 120 patients (Abdullah 2021). The patient had local wound care and oral antibiotics, and the event resolved by 2 weeks postoperation. Superficial wound infection was reported in 1 patient in the case series of 112 patients (Rushton 2021).

Infection (grouped category) was reported in 1 patient who had anterior VBT and 4 patients who had PSF in the meta-analysis of 24 studies (n=1,280; Shin 2021).

Others

Ureteral injury following VBT with subsequent erosion and stricture formation was reported in the single case report and the patient had definitive ureteral reconstruction (Rathbun 2019).

Neurological complications were reported in 2 patients who had anterior VBT and 6 patients who had PSF in the meta-analysis of 24 studies (n=1,280; Shin 2021).

Right arm and shoulder paraesthesia was reported in 2 patients after 3 months postoperation in the case series of 120 patients (Abdullah 2021). Both patients had outpatient medical management and the events did not resolve by 1-year follow up.

Right leg weakness was reported in 1 patient at 2-year follow up in the case series of 120 patients and the event was being observed (Abdullah 2021).

Pain radiating down the leg was reported in the anterior VBT group (exact number of patients with this complication was not reported) at 3 years postoperation but not in the PSF group in the non-randomised comparative study of 49 patients (Newton 2020). This event resolved with physical therapy and its relationship to procedure was unclear.

Horner syndrome with asymmetric pupils was reported in the anterior VBT group (exact number of patients with this complication was not reported) but not in the PSF group in the non-randomised comparative study of 49 patients (Newton 2020).

Anecdotal and theoretical adverse events

In addition to safety outcomes reported in the literature, professional experts are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never happened).

For this procedure, professional experts listed the following anecdotal and theoretical adverse events: aorta, lung and nerve injuries.

The evidence assessed

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to vertebral body tethering for idiopathic scoliosis in children and young people. The following databases were searched, covering the period from their start to 26 July 2021: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches (see the literature search strategy). Relevant published studies identified during consultation or resolution that are published after this date may also be considered for inclusion.

The inclusion criteria were applied to the abstracts identified by the literature search. Where selection criteria could not be determined from the abstracts the full paper was retrieved.

Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, or a laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising study methodology, unless they reported specific adverse events that were not available in the published literature.
Patient	Patients with idiopathic scoliosis in young people (Cobb angle of over 40˚).
Intervention/test	Vertebral body tethering.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the IP overview

This IP overview is based on 1,875 patients from 1 meta-analysis (Shin 2021), 3 non-randomised comparative studies (MacKey 2021; Newton 2020; Pehlivanoglu 2021), 6 case series (Abdullah 2021; Alanay 2020; Baroncini 2021; Rushton 2021; Samdani 2021) and 1 case report (Rathbun 2019).

Other studies that were considered to be relevant to the procedure but were not included in the main summary of the key evidence are listed in the appendix.

Summary of key evidence on vertebral body tethering for idiopathic scoliosis in children and young people

Study 1 Newton PO (2020)

Study details

Study type	**Non-randomised comparative study (retrospective)**
Country	US (single centre)
Recruitment period	2011 to 2016
Study population and number	n=49 (anterior VBT, n=23; PSF, n=26) Patients with thoracic idiopathic scoliosis
Age and sex	Anterior VBT: mean 12 years; 70% (16/23) female PSF: mean 13 years; 88% (23/26) female
Patient selection criteria	Inclusion criteria for anterior VBT: patients with idiopathic scoliosis who had anterior VBT with a minimum follow up of 2 years (82% of available cases). Inclusion criteria for PSF: patients identified by matching the demographic characteristics of the anterior VBT group and included patients with primary thoracic idiopathic scoliosis, curve magnitude of 40˚ to 67˚, Risser stage of ≤1, age of 9 to 15 years at the time of the surgical procedure, no prior spine surgery, surgery between 2011 and 2016, and minimum follow up of 2 years.
Technique	Anterior VBT: a right-side thoracoscopic approach with single-lung ventilation was used. The pleura overlying the convex lateral aspect of the thoracic vertebrae were divided, and the segmental vessels were ligated prior to the placement of pronged washers and bicortical vertebral body screws. Tensioning of the cord was done sequentially from proximal to distal, with the greatest tension placed at the apical segments. PSF: segmental pedicle screws were used.
Follow up	Anterior VBT: mean 3.4 years (range 2 to 5 years) PSF: mean 3.6 years (range 2 to 7 years)
Conflict of interest/source of funding	Conflict of interest: one or more of the authors indicated that the author had a relevant financial relationship in the biomedical arena outside the submitted work and indicated that the author had a patent and/or copyright, planned, pending, or issued, broadly relevant to this work. Funding: none

Analysis

Study design issues: This retrospective study compared outcomes for patients with thoracic idiopathic scoliosis between a group of patients who had anterior VBT and a matched cohort of patients who had PSF and instrumentation.

Outcome data included radiographic, and perioperative outcomes, complications, tether breakages (indicated by ≥6° increase of angulation between adjacent screws on any 2 postoperative radiographs), revision procedures, clinical deformity measurements, and SRS-22 outcomes. All radiographs were measured by trained research staff, who were not involved with the surgical or clinical care of the patients and were not blinded to non-radiographic clinical data. The number of patients having anterior VBT with an outcome that was considered a clinical success (defined as having a curve of <35° and no PSF done or indicated at the final follow up) and the number of patients with curves of <50° (≥50° is considered classically within the surgical range because of the risk of progression) at the time of the final follow up were recorded.

Study population issues: Preoperatively, the 2 groups were similar in age, Risser stage and height but the anterior VBT group was statistically significantly less skeletally mature in terms of triradiate cartilage and Sanders stage.

Other issues: There was a potential for selection bias for patients in the anterior VBT group because the data for this group were collected retrospectively, and, despite the best attempts at matching the PSF group, there were minor differences, particularly in skeletal maturity. Patients were also skeletally mature at the time of the final follow up. In addition, there was no available data on the amount of tension applied to the tethers at each level, which might play a role in the amount of correction achieved.

Key efficacy findings

Number of patients analysed: 49

Clinical success:

- Anterior VBT group: n=12
- PSF group: n=17

Length of hospital stay: 5.0±1.3 days in the anterior VBT group and 4.9±1.2 days in the PSF group (p=0.7).

Radiographic and clinical deformity measurements for the anterior VBT group

	Visit type				**P value**					
Variable	Preoperative	First postoperative	FU before any revision	Final FU or before PSF	Preoperative vs. first postoperative	Preoperative vs. pre-revision	Preoperative vs. final	First postoperative vs. pre-revision	First postoperative vs. final	Pre-revision vs. final
Upper thoracic curve (°) (n=22)	31±9 (16 to 52)	24±9 (10 to 42)	23±13 (1 to 59)	24±13 (1 to 59)	<0.001	0.001	0.012	0.99	0.99	0.99

Main thoracic curve (˚) (n=23)	53±8 (41 to 67)	34±8 (16 to 50)	30±21 (-12 to 62)	33±18 (-5 to 62)	<0.001	<0.001	<0.001	0.99	0.99	0.99
Lumbar curve (˚) (n=22)	34±8 (20 to 57)	26±7 (7 to 48)	26±11 (7 to 48)	29±11 (12 to 58)	<0.001	0.027	0.084	0.99	0.99	0.99
T2 to T12 kyphosis (˚) (n=22)	25±12 (6 to 54)	23±12 (8 to 62)	20±12 (-2 to 52)	19±13 (-2 to 52)	0.098					
Thoracic angle of trunk rotation (˚) (n=5)	7±3 (5 to 9)	7±1 (6 to 7)	8±4 (5 to 10)	8±4 (5 to 10)	NA					
Coronal imbalance (C7-central sacral vertical line) (cm)	1.1±1 (0.1 to 3.5)	1.2±1 (0.3 to 5)	1.3±1 (0 to 3.7)	1.4±1 (0 to 3.7)	0.91					
Shoulder height difference (cm)	0.7±0.8 (0 to 2)	0.9±0.4 (0.5 to 1.5)	0.7±0.7 (0 to 2)	0.8±0.7 (0 to 2)	0.55					

FU, follow up

Radiographic and clinical deformity measurements in the PSF group

	Visit type			P value		
Variable	Preoperative	First postoperative	Final follow up	Preoperative vs. first postoperative	Preoperative vs. final follow up	First postoperative vs. final follow up
Radiographic measurements (n=26)						

Upper thoracic curve (˚)	30±6 (17 to 42)	13±5 (2 to 23)	14±6 (2 to 24)	<0.001	<0.001	0.99
Main thoracic curve (˚)	54±7 (40 to 66)	12±4 (5 to 21)	16±6 (6 to 31)	<0.001	<0.001	<0.001
Lumber curve (˚)	34±9 (19 to 62)	13±8 (3 to 34)	12±6 (3 to 26)	<0.001	<0.001	0.99
T2 to T12 kyphosis (˚)	25±12 (3 to 51)	31±8 (18 to 44)	29±8 (16 to 50)	0.01	0.12	0.64
Thoracic angle of trunk rotation (˚) (n=15)	17±4 (10 to 22)	6±4 (0 to 14)	6±3 (0 to 10)	<0.001	<0.001	0.99
Lumbar angle of trunk rotation (˚) (n=7)	11±7 (0 to 21)	1±3 (0 to 7)	2±3 (0 to 7)	0.03	0.05	0.03
Coronal imbalance (C7-central sacral vertical line) (cm)	1.1±1 (0 to 3)	1.4±1 (0 to 3.8)	0.7±0.5 (0 to 1.8)	0.99	0.1	0.026
Shoulder height difference (cm)	1.4±1 (0 to 4)	1.2±1 (0 to 3)	1.2±1 (0 to 3)	0.99	0.99	0.99

Between-group comparisons of the radiographic and clinical measures of deformity

	Anterior VBT group	**PSF group**	**P value**
Preoperative			
Upper thoracic curve (˚)	31±9 (16 to 52)	30±6 (17 to 42)	0.633
Main thoracic curve (˚)	53±8 (41 to 67)	54±7 (40 to 66)	0.444
Lumbar curve (˚)	34±8 (20 to 57)	34±9 (19 to 62)	0.791
T2 to T12 kyphosis (˚)	24±12 (6 to 54)	25±12 (3 to 51)	0.79
Thoracic angle of trunk rotation (˚)	1±4 (5 to 24)	17±3 (10 to 22)	0.109
Lumbar angle of trunk rotation (˚)	6±5 (0 to 20)	8±5 (0 to 21)	0.213
Coronal imbalance (C7-central sacral vertical line) (cm)	1±1 (0.1 to 3.5)	1±1 (0 to 3)	0.81
Shoulder height difference (cm)	1±1 (0 to 3.5)	1.5±1 (0 to 4)	0.26
First postoperative			

Upper thoracic curve (˚)	24±8 (10 to 42)	13±5 (2 to 23)	<0.001
Correction of thoracic curve (%)	34±8 (15 to 50)	12±4 (5 to 21)	<0.001
Main thoracic curve (˚)	36±11 (18 to 65)	78±8 (57 to 90)	<0.001
Lumbar curve (˚)	26±7 (14 to 41)	13±8 (3 to 34)	<0.001
T2 to T12 kyphosis (˚)	22±12 (6 to 54)	31±8 (18 to 44)	0.004
Thoracic angle of trunk rotation (˚)	10±3 (5 to 24)	6±4 (0 to 14)	0.008
Lumbar angle of trunk rotation (˚)	6±1 (0 to 20)	1±3 (0 to 7)	0.016
Coronal imbalance (C7-central sacral vertical line) (cm)	1.2±1 (0.2 to 5)	1.4±1 (0 to 3.8)	0.47
Shoulder height difference (cm)	1±1 (0 to 2.7)	1.2±1 (0 to 3.1)	0.19
Final follow up			
Upper thoracic curve (˚)	24±13 (1 to 59)	14±6 (2 to 24)	0.001
Main thoracic curve (˚)	33±18 (-5 to 62)	16±6 (6 to31)	<0.001
Correction of thoracic curve (%)	43±38 (-3 to 154)	69±13 (34 to 89)	0.002
Lumbar curve (˚)	30±12 (12 to 58)	12±6 (3 to 26)	<0.001
T2 to T12 kyphosis (˚)	19±13 (-2 to 52)	29±8 (16 to 50)	0.001
Thoracic angle of trunk rotation (˚)	11±5 (2 to 22)	6±3 (0 to 10)	<0.001
Lumbar angle of trunk rotation (˚)	6±5 (0 to 20)	3±3 (0 to 11)	0.021
Coronal imbalance (C7-central sacral vertical line) (cm)	1.3±1 (0 to 3.7)	0.7±0.5 (0 to 1.8)	0.012
Shoulder height difference (cm)	1±1 (0 to 3)	1.3±1 (0 to 3)	0.39

Between-group comparisons of SRS-22 scores at the time of the final follow up

SRS-22 domain	Anterior VBT group (n=12)	PSF group (n=22)	P value
Pain	4.4±0.6 (3.6 to 5.0)	4.4±0.4 (3.2 to 5.0)	0.903
Mental health	4.3±0.6 (3.0 to 5.0)	4.0±0.7 (3.2 to 5.0)	0.279
Self-image	4.1±0.7 (2.8 to 5.0)	4.4±0.6 (2.8 to 5.0)	0.244
Satisfaction	4.3±0.7 (3.0 to 5.0)	4.7±0.5 (3.0 to 5.0)	0.053
General function	4.3±0.4 (3.4 to 4.8)	4.3±0.4 (3.4 to 4.6)	0.748
Total	4.2±0.4 (3.4 to 4.9)	4.4±0.4 (3.6 to 4.9)	0.29

Key safety findings

Revision procedures in the anterior VBT group

ID	Time to first revision (year)	Reason for first revision	First revision procedure	Time to second revision (year)	Reason for second revision	Second revision procedure
A3	2.7	Overcorrection	Tether removal		NA	NA
A6	3.7	Broken tether with progression	PSF T3 to L3		NA	NA
A10	1.7	Progression of lumbar curve	Removal of tether at distal 2 levels	2.8	Broken tether with progression	PSF T3 to L3
A11	2.5*	Broken tether with progression	Retethered		NA	NA
A12	1.2	Overcorrection	Tether removal	3.1	Progression	PSF T9 to L3
A13	2.1	Progression of lumbar curve	Lumbar curve tethered		NA	NA
A22	2.1	Overcorrection	Tether replaced with less tension		NA	NA

*Tether revised at outside institution.

Broken tether: n=12 (52%) in the anterior VBT group.

3 of these patients had revision linked to progression of the curve because of tether breakage. Of the identified broken tethers, the majority broke at 1 level, but ranged from 1 to 3 levels. The breakages happened at T8/T9 (6), T9/T10 (2), T10/T11 (4), T11/T12 (2), T12/L1 (2), and L1/L2 (1). Among the 12 patients with broken tethers, 3 had breakages at the apex only, 1 had breakage above the apex, 6 had breakages below the apex, and 2 had breakages both at and below the apex.

Medical complications:

- Anterior VBT group: atelectasis with pulmonary oedema treated with positive airway pressure that resolved by postoperative day 6, pain radiating down the leg 3 years postoperatively that resolved with physical therapy (relationship to procedure unclear), and Horner syndrome with asymmetric pupils remaining at the time of this retrospective review (exact data were not reported).

- PSF group: no postoperative complications.

Study 2 Pehlivanoglu T (2020)

Study details

Study type	Non-randomised comparative study (retrospective)
Country	Turkey (single centre)
Recruitment period	2016 to 2019
Study population and number	n=43 (VBT, n=21; PSF, n=22) Patients with adolescent idiopathic scoliosis
Age and sex	VBT: mean 11.1 years, 71% (15/21) female PSF: mean 10.9 years, 73% (16/22) female
Patient selection criteria	VBT: patients with Risser ≤2 - Sanders ≤4, Age: 9 to 14, thoracic-thoracolumbar curves (40° to 60°), and a minimum of 3-year follow up. PSF: To compare the functional outcomes of the VBT group, an age-gender-instrumented level and minimum follow-up duration matched PSF group was selected from the patients operated by the same surgical team.
Technique	VBT: VBT was applied to thoracolumbar levels (T5 to L3) using thoracoscopic approach and to lumbar levels using mini-retroperitoneal approach. The most proximal and most distal instrumented levels of VBT group were T5 and L3. PSF: Posterior segmental spinal fusion was applied to thoracolumbar levels. The most proximal and most distal instrumented levels of PSF group were T3 and L3.
Follow up	Mean 39.4 months (range 36 to 48 months)
Conflict of interest/source of funding	None

Analysis

Study design issues: This retrospective, comparative study compared clinical and functional outcomes of VBT and PSF in age-gender-instrumented level and minimum follow-up duration matched patients to assess if VBT was superior compared to PSF in terms of functional outcomes and health-related quality of life.

The functional evaluation, which was done in the last follow up, included lumbar range of motion, anterior (hand to feet distance)-lateral (pre–post-bending distance) lumbar bending flexibility (cm); flexor (evaluated with modified Kraus-Weber test) and extensor (evaluated with modified Biering-Sörensen test) endurances (sec) of trunk, and average motor strength of trunk muscles. Patient reported outcomes included SRS-22 and SF-36 MCS/PCS scores.

Study population issues: Patients in the VBT group had an average of 9.3 levels (range 6 to 11) of tethering. They had main thoracic-thoracolumbar curves with an average preoperative major curve magnitude of 48.2°. Patients in the PSF group had an average of 10.1 levels (range 8 to 12) of fusion. They had main thoracic-thoracolumbar curves with an average preoperative major curve magnitude of 48.8°. The curve flexibility was higher in the VBT group and curve magnitudes were higher in the PSF group at baseline, even if the patients were selected age-gender-follow-up duration and instrumented level matched.

Key efficacy findings

Number of patients analysed: 43

Radiographic data

	VBT group (n=21)	PSF group (n=22)
Average preoperative major curve magnitude (˚)	48.2	48.8
Average major curve magnitude at the last follow up (˚)	9.1 (p<0.001)	9.7(p<0.001)
Average preoperative coronal balance (cm)	1.9 (-0.6 to 2.4)	1.8 (-0.4 to 2.2)
Average coronal balance (cm) at the last follow up	0.8 (-0.6 to 1.2)	0.3 (-0.1 to 0.7)
Average preoperative sagittal balance (cm)	1.2 (-0.4 to 1.7)	1.0 (-0.6 to 1.4)
Average sagittal balance (cm) at the last follow up	0.4 (-0.3 to 1.1)	0.3 (-0.2 to 0.8)

Lumbar range of motion and lumbar bending flexibility at the last follow up

	Average lumbar ROM (º)				Average lumbar bending flexibility (cm)	
	Flexion	Extension	Lateral bending	Rotation	Anterior	Lateral
VBT group	78.2	34.6	34.4	45.4	3.7	22.4
PSF group	58.1	19.4	18.3	24.1	23.4	11.3
P value	<0.001	<0.001	<0.001	<0.001	<0.001	0.003

Trunk endurances and motor strength of trunk at the last follow up

	Average trunk endurance(s)		Average motor strength of trunk muscles
	Flexion	Extension	Extensor-Ant/Lat/Obl flexor
VBT group	65.1	60.8	4.7
PSF group	19.2	28.7	3.2
P value	<0.001	<0.001	0.003

SRS-22 scores

		Average preoperative SRS-22 scores	Average SRS-22 scores at the last follow up
VBT group	Function	3.4	4.8
	Pain	3.6	4.9
	Self-image	2.8	4.8
	Mental health	3.7	4.9
	Satisfaction	2.5	4.9
	Total	3.2	4.9
PSF group	Function	3.2	4.1
	Pain	3.5	4.1
	Self-image	2.9	3.3
	Mental health	3.6	3.9
	Satisfaction	2.6	3.6
	Total	3.2	3.8
P value		>0.05	<0.001

SF-36 scores

	Average preoperative SF-36 scores		Average SF-36 scores at the last follow up	
	MCS	PCS	MCS	PCS
VBT group	52.7	46.8	56.9	57.2
Fusion group	52.3	47.1	52.3	53.1
P value	>0.05	>0.05	<0.001	<0.001

Key safety findings

Safety data were not reported.

Study 3 Mackey C (2021)

Study details

Study type	**Non-randomised comparative study (registry)**
Country	International (multiple centres)
Recruitment period	VBT: 2013 to 2017 MCGR: 2013 to 2018 PSF: 2007 to 2017
Study population and number	n=130 (VBT, n=37; MCGR, n=51; PSF, n=42) Patients with idiopathic early onset scoliosis
Age and sex	VBT: median 11.3 years; 97.3% (36/37) female MCGR: median 9.6 years; 68.6% (35/57) female PSF: median 10.9 years; 80.9% (34/42) female
Patient selection criteria	Inclusion criteria: ambulatory children with idiopathic early onset scoliosis, ages 8 to 11 years at index surgery, index surgery of single PSF, MCGR or VBT and minimum follow up of 2 years.
Technique	VBT, MCGR or PSF was done. The most proximal UIV and most distal LIV were T5 and L3 for VBT, C7 and L4 for MCGRs and C5 and L5 for PSF.
Follow up	All groups: Mean 3.4±1.5 years VBT: median 3.0 years (range 2.1 to 3.6 years) MCGR: median 2.9 years (range 2.4 to 3.9 years) PSF: median 3.6 years (range 2.2 to 5.1 years)
Conflict of interest/source of funding	None

Analysis

Study design issues: This retrospective review of prospective data from an international multicentre spine registry compared outcomes of VBT versus MCGR versus single PSF in 8- to 11-year-old patients with idiopathic early onset scoliosis.

Major curve size was measured using the Cobb method. T2 to T12 Kyphosis and Proximal Junctional Angle (PJA) was measured. Spinal growth was assessed using thoracic height (T1 to T12) and spinal height (T1 to S1). Complications, additional surgeries and unplanned surgeries were recorded. Repeat surgical events were classified as either planned or unplanned returns to the operating room. Patient's health-related quality of life was assessed using the validated EOSQ-24, which was administered to families before their index surgery and during follow up.

Radiographic parameters were recorded pre-operatively and at most recent follow up. For VBT and MCGR patients undergoing final fusion, radiographic parameters at time of final fusion were included as most recent follow up. Unplanned returns were because of curve progression, hardware failure, pulmonary complications, pain, infection, or pseudoarthrosis. Planned returns included definitive spinal fusion events (in patients who previously had VBT /MCGR) and elective wound modifications (scar revisions).

Study population issues: VBT patients had higher median age at index surgery compared to MCGR and PSF patients (p<0.0005). Fewer patients in the VBT group had open triradiate cartilage (41% VBT compared with 96% MCGR compared with 65% PSF; p<0.0005) and when evaluating Risser stage 96% of MCGR patients fell into Risser Stage 0, compared with 82% of VBT and 82% of PSF patients (p=0.025). The VBT group included more females (97%) compared to the MCGR (69%) and PSF groups (81%) (p<0.0005).

Other issues: There were differences between centres including number of patients treated, surgeon experience and decision-making.

Key efficacy findings

Number of patients analysed: 130

Radiographic data

	VBT	**MCGR**	**PSF**	**P value**
Scoliosis curve				
Major scoliosis angle, preoperative (˚), median (IQR)	50 (43.5 to 58)	64.5 (55 to 75)	63 (57 to 72)	<0.0005
Major scoliosis angle, recent follow up (˚), median (IQR)	28 (21 to 35)	42 (34.4 to 54.5)	29 (22 to 36)	<0.0005
p-value pre-operative to recent follow up within surgical group	<0.0005	<0.0005	<0.0005	
Major scoliosis angle pre-operative to recent follow up (%), mean±SD	41.1±22.4	27.4±23.9	52.2±19.9	<0.0005
Kyphosis and proximal junctional angle				
Kyphosis T2 to T12, preoperative (˚), mean±SD	26.1±12.3	34.7±16.3	35.9±13.1	0.010
Kyphosis T2 to T12, recent follow up (˚), mean±SD	25.0±13.0	34.2±12.0	25.8±11.5	0.002
p-value pre-operative to recent follow up within surgical group	0.522	0.887	0.022	
Proximal junctional angle recent follow up (˚), median (IQR)	8 (5 to 12)	5.6 (3 to 12.2)	7.5 (4.7 to 12.8)	0.436
Thoracic height (T1 to T12)				
T1 to T12 pre-operative (cm), median (IQR)	21 (19.8 to 22.4)	19 (17.9 to 21)	21.5 (19.1 to 22.6)	0.004
T1 to T12 recent follow up (cm), median (IQR)	24.4 (22.9 to 25.6)	22.3 (21 to 23.5)	24.7 (23.4 to 23.6)	<0.0005

T1 to T12 pre to recent follow up (cm), median (IQR)	2.8 (1.9 to 4.4)	3.3 (1.5 to 6.2)	3.6 (2.9 to 5.3)	0.182
T1 to T12 pre to recent follow up (%), median (IQR)	13.7 (8.4 to 19.6)	16.8 (7.5 to 36)	16.6 (12.4 to 29.1)	0.346
Spinal height (T1 to S1)				
T1 to S1 preoperative (cm), median (IQR)	34.2 (31.9 to 35.6)	31.2 (29 to 35.1)	35.6 (32.9 to 36.9)	0.008
T1 to S1 recent follow up (cm), median (IQR)	39.3 (37.1 to 40.1)	36.1 (33.9 to 38.7)	39.6 (37.1 to 43.9)	<0.0005
T1 to S1 pre-operative to recent follow up (cm), median (IQR)	4.3 (3.7 to 6.4)	5.0 (2.7 to 8.7)	5.0 (3.2 to 8.2)	0.736
T1 to S1 pre-operative to recent follow up (%), median (IQR)	12.8 (10.1 to 19.7)	16.3 (7.8 to 29.7)	14.1 (9.3 to 22.9)	0.620

Health-related quality of life

EOSQ-24 domains, median (IQR)	VBT (n=10)	MCGR (n=30)	PSF (n=16)	P value
General health pre-operation	75 (75 to 87.5)	75 (75 to 87.5)	81.3 (65.6 to 87.5)	0.995
General health postoperation	62.5 (62.5 to 87.5)	75 (62.5 to 100)	93.8 (65.6 to 100)	0.103
Pre- to post-operative within surgical group	0.211	0.460	0.241	
Pain/discomfort pre-operation	56.3 (37.5 to 62.5)	75 (50 to 100)	75 (62.5 to 100)	0.041
Pain/discomfort post-operation	75 (50 to 100)	75 (50 to 100)	75 (50 to 96.9)	0.963
Pre- to post-operation within surgical group	0.023	0.381	0.306	
Pulmonary function pre-operation	93.8 (87.5 to 100)	100 (75 to 100)	100 (87.5 to 100)	0.734
Pulmonary function post-operation	100 (75 to 100)	100 (87.5 to 100)	100 (87.5 to 100)	0.889
Pre- to post-operation within surgical group	1.000	0.624	0.828	
Transfer pre-operation	100 (50 to 100)	100 (100 to 100)	100 (100 to 100)	0.108
Transfer post-operation	100 (100 to 100)	100 (72 to 100)	100 (100 to 100)	0.155
Pre- to post-operation within surgical group	0.313	0.065	1.000	
Physical function pre-operation	95.8 (83.3 to 100)	100 (83.3 to 100)	100 (93.8 to 100)	0.315
Physical function post-operation	100 (91.7 to 100)	95.8 (75 to 100)	100 (93.8 to 100)	0.178
Pre- to post-operation within surgical group	0.500	0.661	1.000	
Daily living pre-operation	100 (100 to 100)	100 (68.8 to 100)	100 (100 to 100)	0.013

Daily living post-operation	100 (87.5 to 100)	100 (75 to 100)	100 (100 to 100)	0.028
Pre- to post-operation within surgical group	0.250	0.555	1.000	
Fatigue/energy pre-operation	87.5 (62.5 to 87.5)	100 (75 to 100)	100 (75 to 100)	0.184
Fatigue/energy post-operation	75 (62.5 to 100)	71.9 (75 to 100)	93.8 (87.5 to 100)	0.241
Pre- to post-operation within surgical group	0.816	0.140	0.725	
Emotion pre-operation	75 (50 to 75)	62.5 (62.5 to 87.1)	81.3 (65.6 to 87.5)	0.102
Emotion post-operation	93.8 (75 to 100)	81.3 (50 to 100)	87.5 (75 to 100)	0.280
Pre- to post-operation within surgical group	0.020	0.062	0.090	
Parental impact pre-operation	70 (55 to 80)	75 (65 to 95)	90 (80 to 95)	0.017
Parental impact post-operation	87.5 (75 to 95)	90 (75 to 96.3)	100 (85 to 100)	0.094
Pre- to post-operation within surgical group	0.020	0.206	0.005	
Child satisfaction pre-operation	75 (50 to 75)	75 (50 to 100)	100 (75 to 100)	0.037
Child satisfaction post-operation	75 (75 to 100)	75 (50 to 100)	100 (75 to 100)	0.203
Pre- to post-operation within surgical group	0.219	0.873	1.000	
Parent satisfaction pre-operation	62.5 (50 to 75)	75 (50 to 100)	100 (75 to 100)	0.107
Parent satisfaction post-operation	75 (75 to 100)	75 (50 to 100)	100 (75 to 100)	0.067
Pre- to post-operation within surgical group	0.063	0.563	0.781	

Post-operative assessment was on average 3.0±1.3 years after index surgery.

Key safety findings

Complications

	VBT (n=37)	**MCGR (n=51)**	**PSF (n=42)**	**P value**
Complications	27.0% (n=10)	60.8% (n=31)	14.3% (n=6)	<0.0005
# complications	15	45	9	
Minor complications	10.8% (n=4)	17.6% (n=9)	4.8% (n=2)	0.151
# minor complications	5	11	3	
Intra-operative complication	0	5.9% (n=3)	4.8% (n=2)	0.443
# intra-operative complication	0	3	2	
Planned surgeries	8.1% (n=3)	31.4% (n=16)	0	<0.0005
# planned surgeries	3	16	0	

Unplanned surgeries	16.2% (n=6)	21.6% (n=11)	7.1% (n=3)	0.154
# unplanned surgeries	7	17	4	
Hardware issue	13.5% (n=5)	19.6% (n=10)	2.4% (n=1)	0.023

Time to planned or unplanned surgery

	Time to unplanned surgery (n=126 with 20 events)		**Time to planned or unplanned surgery (n=126 with 36 events)**	
	HR* (95% CI)	P value	HR *(95% CI)	P value
VBT	4.5 (0.8 to 24.5)	0.084	7.1 (1.4 to 36.4)	0.019
MCGR	5.6 (1.1 to 28.4)	0.038	21.0 (4.8 to 92.5)	<0.001
PSF (reference)	1.00		1.00	

* HR adjusted for age, gender and pre-operative major cobb

Reasons for unplanned revisions:

- VBT: curve progression (n=3), hardware failure (n=3) and pulmonary complication (n=1)
- MCGR: hardware migration (n=9), hardware failure (n=5), removal of hardware because of pain (n=2) and infection (n=1)
- PSF: hardware failure (n=1), infection (n=3), removal of hardware because of pain (n=1) and re-instrumentation after pseudarthrosis (n=1)

Study 4 Abdullah A (2021)

Study details

Study type	Case series (Paediatric spine study group registry)
Country	Canada (3 centres)
Recruitment period	2015 to 2018
Study population and number	n=120 Patients with idiopathic scoliosis
Age and sex	Mean 12.6 years; 89% female; median Risser 1
Patient selection criteria	Inclusion criteria: idiopathic scoliosis, immature skeleton with Risser score 0 to 3, Cobb angle 40˚ to 70˚, and main thoracic curve.
Technique	All patients had a thoracoscopic approach using 4 (64.1%) or 5 (35.9%) portals. Dynesys instrumentation (Zimmer Biomet Company, Warsaw, Indiana) was used for all surgeries. The most frequent upper instrumented vertebra was T5 (55.8%), T6 (35.8%), T7 (6.7%), and T4 (1.7%). The most frequent lowest instrumented vertebra was T12 (59.2%), T11 (23.3%), L1 (14.2%), L2 (2.5%), and T10 (0.8%).
Follow up	2 years
Conflict of interest/source of funding	Conflict of interest: 2 authors had nothing to disclose and other declared conflicts of interest. Funding: none.

Analysis

Follow-up issues: A total of 175 patients were treated with anterior VBT and 166 of these had the potential for 2-year follow up. Complete data was available for 120 patients who had main thoracic curve and only thoracic tether were included in this study.

Study design issues: This study determined perioperative morbidity associated with anterior VBT for idiopathic scoliosis. This study reported intraoperative and postoperative efficacy outcomes and follow-up data included complications, scoliosis curves and kyphosis measurements at 1 and 2 years. Unplanned return to the operating room was defined as a postoperative complication that could not be treated without an additional anaesthesia.

Study population issues: At baseline, the median Risser stage was 1 (Risser 0: 47.5%, Risser 1: 25.0%, Risser 2: 16.7% and Risser 3: 10.8%). The mean arm span was 162.0 cm (95% CI 159.2 to 164.8 cm). 99.2% of patients had a right thoracic curve and 0.8% of patients had a left thoracic curve.

Key efficacy findings

Number of patients analysed: 120

Perioperative data

Anterior VBT	Number of patients	Mean±SD	Range	95% CI
Surgical time (minutes)	99	215.3±78.9	111 to 472	199.6 to 231.0
Anaesthesia time (minutes)	86	303.5±76	207 to 480	287.2 to 319.8
Estimated blood loss (ml)	101	200±135.3	20 to 700	173.2 to 226.7
Estimated blood loss %	100	6.4±4	0.6 to 20	5.6 to 7.2
Postoperative hospital stay (days)	103	4.5±1.3	2 to 9	4.3 to 4.8
ICU stay (days)	73	0.2±0.5	0 to 2	0.1 to 0.3
Upper instrumented vertebra (UIV)	T5: 55.8%	T7: 6.7%	T6: 35.8% (minimum)	T4: 1.7%
Lower instrumented vertebra (LIV)	T12: 59.2%	L2: 2.5%	T11: 23.3% to L1: 14.2%	T10: 0.8%

Radiographic data

	Number of patients	Mean±SD	Range	95% CI
Pre-op scoliosis (°)	112	51.2±7.8	40 to 70	49.7 to 52.7
Pre-op bending (°)	104	32±11.5	9 to 63	29.8 to 34.2
Curve flexibility (%)	96	38.2±17.8	6.1 to 77.5	34.6 to 41.8
Post-op scoliosis (°)	120	26.9±8.9	6 to 53	25.3 to 28.5
1-year post-op scoliosis (°)	118	23.0±10.4	-11 to 50	21.1 to 24.8
2-year post-op scoliosis (°)	104	27.5±11.6	-5 to 52	25.2 to 29.7
Pre-op global kyphosis (°)	113	28.5±11.2	2 to 64	26.4 to 30.6
Post-op global kyphosis (°)	120	27.4±11.4	2 to 56	25.4 to 29.5
1-year post-op global kyphosis (°)	118	28.7±12.2	6 to 65	26.5 to 31.0
2-year post-op global kyphosis (°)	94	29.2±12.5	6 to 67	26.6 to 31.8
Pre-op T5 to T12 kyphosis (°)	113	16.0±11	-23 to 52	13.9 to 18
Post-op T5 to T12 kyphosis (°)	120	16.9±10.8	-7 to 44	14.9 to 18.8
1-year post-op T5 to T12 kyphosis (°)	117	17.5±11.8	-14 to 61	15.3 to 19.6.0
2-year post-op T5 to T12 kyphosis (°)	79	17.0±11.8	-10 to 50	14.4 to 19.7
Pre-operative standing height (cm)	118	154.4±8.3	137 to 179	152.9 to 155.9
Post-operative standing height (cm)	112	156.1±8.5	137.7 to 180.9	154.5 to 157.7

Preoperative mean main thoracic scoliosis was 51.2° (95% CI 49.7° to 52.7°) with correction to 32.0° (95% CI 29.8° to 34.2°) on bending radiographs and mean curve flexibility of 38.2% (95% CI 34.6% to 41.8%). The mean global kyphosis was 28.5° (95% CI 26.4° to 30.6°) and the mean T5 to T12 kyphosis was 16.0° (95% CI 13.9° to 18.0°).

Postoperative compared with preoperative standing height: t=14.4, df=110, $p<0.01$

Scoliosis:

- Immediate postoperative compared with preoperative standing radiographs: t=30, df=111, p<0.01
- Immediate postoperative compared with preoperative bending radiographs: t=5.1, df=103, p<0.01
- 1-year compared with immediate postoperation: t=6.6, df=117, p<0.01
- 2-year compared with immediate postoperation: t=-0.47, df=103, p=0.64

Global kyphosis: 2 years after surgery compared with preoperation: t=0.35, df=110, p=0.73

T5 to T12 kyphosis: 2 years after surgery compared with preoperation: t= -0.36, df=78, p=0.72

Key safety findings

Complication data

Complication	**Description**	**Classification according to**		**Unplanned return to operative room**
		Smith	Modified Clavien-Dindo-Sink system	
Early complications that developed during hospitalisation				
Pneumothorax	Developed on POD 3 and patient was transferred back to the ICU for 1 day, treated with BiPAP and Chest tube. The complication almost completely resolved after 3 days, and the chest tube was removed (POD 6) and patient discharged the day after (POD 7).	1	4a	No
Complications that developed after discharge and within 90 days from surgery				
Superficial wound infection	Developed after 1 week. Treated as outpatient with local wound care and oral antibiotics. Resolved by 2 weeks post-operative.	1	2	No
Pneumonia	Developed 2 weeks after surgery. The patient visited the ER with shoulder pain. CXR showed small right sided atelectasis with small effusion, treated as outpatient with oral antibiotics. Resolved by 6 weeks postoperation.	1	2	No
CSF leak	It was discovered when the patient presented with acute headaches at 3 weeks postoperation. The patient was managed with blood patch injection treatment as an inpatient. Resolved.	1	3	No
Pleural effusion	Discovered 3 weeks postoperatively. Patient was admitted and managed with chest tube for 4 days during and oral antibiotics. Resolved.	1	3	No

Pleural effusion	Discovered 2 months postoperatively. Patient was admitted for 1 week and managed with chest tube and antibiotics. Resolved.	1	3	No
Late complications that developed between 3 months and 1 year				
CSF leak	Discovered 4 months after surgery when the patient presented with headaches. Treated with blood patch injection in the clinic. The condition did not resolve. It was discovered to have screw threads in the spinal canal. The patient underwent planned surgical revision the screw and a lumbar drain installed for the CSF leak. Resolved.	2a	3	Yes
Right arm and shoulder paraesthesia	Developed 6 months after surgery with paraesthesia and neuropathic pain in the right arm and breast area. Symptoms progressed to sharp pain along her arm. Not resolved by 1-year follow up.	1	2	No
Right arm and shoulder paraesthesia	Right shoulder and posterior arm paraesthesia with pain inferior to right clavicle developed 1 year after surgery. Treated as an outpatient and not yet resolved by 1 year postoperative.	1	2	No
Compensatory curve add on	Lumbar curve add on, initially observed, then surgical management was chosen in the form of tethering the lumbar curve.	2a	3	Yes
Late complications 1 to 2 years postoperation				
Curve progression	Moderate pain in the lumbar spine and left hip developed around 1 year after the initial surgery which was thought to be a result of lumbar curve progression. The patient underwent PSFI.	3	3	Yes
Keloid	Developed keloid and underwent scar revision and steroid injection.	2a	3	Yes
Right leg weakness	Experienced weakness in the right leg, with right knee give away, experienced pain in the medial aspect of her right thigh and was unable to move her right leg at certain times and has been to the ER as a result of these complications, scheduled for MRI.	1	2	No
Cable failure	Discovered broken tether at 2-year follow-up (2 years and 3 months) from surgery, the tether was broken at three different places and the patient underwent tether replacement.	2a	3	Yes
Cable failure	The tether cable failed at T8 to T9, however the patient was treated conservatively as the curve did not progress.	1	2	No

Cable failure	The tether cable failed at T10 to T11 at 2 years follow up (2 year and 2 months from surgery), leading to curve progression, patient treated with PSF.	3	3	Yes
Cable failure	The tether cable broken between T10 and T11 discovered during 2-year follow up (2 years and 4 months from surgery) and was treated with observation.	1	2	No
Overcorrection	Overcorrection and progression discovered at 2-year follow up (2 years and 4 months from surgery), requiring cable removal. The patient underwent cable removal which was complicated by haemothorax of 1,700 ml as a result of bleeding from T4 segmental artery which required return to the OR to control the bleeding.	3	3	Yes
Overcorrection	Overcorrection discovered during follow up (1 year and 6 months), treated with removal of the cable.	3	3	Yes

Study 5 Baroncini A (2021)

Study details

Study type	Case series
Country	US (single centre)
Recruitment period	2017 to 2019
Study population and number	n=90 Patients with adolescent idiopathic scoliosis having single or bilateral VBT
Age and sex	Mean 14.6 years; 89% (80/90) female; mean Risser 2.3
Patient selection criteria	Inclusion criteria: patients diagnosed with adolescent idiopathic scoliosis and showing flexible curves (<30° on bending or traction X-rays). Exclusion criteria: patients with radiculopathy or other neurological symptoms deriving from spine pathology and/or previous spine surgery uncontrolled chronic disease; infections; malignancy; pregnancy; any blood anomalies; immunodeficiency; and other omitted criteria that could influence the results of this study.
Technique	Under general anaesthesia, patients were positioned on the side with the convex side of the curve facing up. Thoracic curves down to L1 were approached with video-assisted thoracic surgery, with 1 or 2 intercostal incisions, and 1 or 2 thoracoscopic portals. Lumbar curves were instrumented through a mini-retroperitoneal approach. For patients needing a bilateral correction, this was conducted in 1 stage with lumbar instrumentation performed first. After suturing and dressing the wounds, patients were repositioned for thoracic instrumentation. The screws were placed bicortically following anatomic landmarks and under antero-posterior fluoroscopic control. The screws were connected with a polyethylene tether and curve correction was performed. Lastly, a chest drainage was placed and removed when the output was less than 200 ml over 24 hours. For some patients, a double tether was added in lumbar curves to prevent tether ruptures or disc releases were done at the apex of thoracic curve to increase flexibility
Follow up	Range 6 to 24 months
Conflict of interest/source of funding	Conflict of interest: 2 authors, none; one author, consultant, paid lectures – globus medical. Funding: none

Analysis

Follow-up issues: VBT was done in 91 patients and 1 patient was excluded from the study: for 1 girl with bilateral scoliosis, after successful instrumentation of the lumbar curve, anterior, dynamic correction of the thoracic curve had to be abandoned because of diffuse pleural scarring and a second-time thoracic spondylodesis was done instead. Thus, 90 patients were included in the analysis.

Study design issues: This study investigated the intraoperative data and complications of the first 90 patients who had VBT, with the aim of defining the learning curve. This study was conducted according to the strengthening the reporting of observational studies in epidemiology: the STROBE statement.

All surgeries were done by 1 spinal deformity, (US) fellowship trained senior surgeon who had limited previous experience with anterior approaches to the thoracic and lumbar spine.

Study population issues: Of the 90 patients, most were skeletally immature (Risser ≤4 and/or Sanders ≤7) - Risser 2.3±1.7, Sanders 5.1±2. The mean height was 161±10 cm, the mean weight was 52.7±9.8 kg and mean BMI 20.3±3.11 kg/m^2. Before surgery, the mean Cobb angle of the instrumented curves was 55.7°±13.5°.

Other issues: The main limitation was the bias created by performing disc releases in selected patients. This study has not yet reached a plateau in intubation time, surgical duration and hospitalisation length so a longer observation period would be useful to measure the plateau values for these parameters. Radiologic data was not analysed, as no influence of the learning curve on scoliosis correction was observed. This was probably because of the heterogeneity of the treated curves. Further radiologic studies with a longer follow up are needed to analyse the results of VBT.

Key efficacy findings

Number of patients analysed: 90

First 20 patients (8 thoracic, 4 lumbar and 8 double instrumentations):

- The mean Cobb angle of the instrumented curves was 58°±11° before surgery and 24°±13° at the first standing X-ray.

Last 20 patients (5 thoracic, 4 lumbar and 11 double instrumentations):

- The mean Cobb angle was 58°±11° before surgery and 24°±12° at the first standing X-ray.

Within 6 months from surgery, none of the patients needed pain medication and all had returned to the daily activities and sports they were participating to before VBT.

Mean intubation time per screw: 33.1±7.6 minutes (range 15.4 to 61.6 minutes)

- First 20 patients: 439.2±52.8 minutes
- Last 20 patients: 358.4±83.4 minutes
- p=0.0007

Mean surgical duration per screw: 21.3±5.7 minutes (9.4 to 44.8 minutes)

- First 20 patients: 390±267.3 minutes
- Last 20 patients: 163±57.7 minutes
- p=0.0006

Mean estimated blood loss per screw: 21.3±18.2 ml (range 100 to 6.6 ml)

- First 20 patients: 286.5±86 ml
- Last 20 patients: 188.8±54.3 ml
- p=0.0001

Four patients had a transfusion from cell-salvage and 3 blood transfusions were done: all these patients were among the first 10 patients.

Mean hospitalisation length: 8.3±3.1 days (range 4 to 14 days)

- First 20 patients: 9.3±2.1 days
- Last 20 patients: 7.8±1.6 days
- p=0.01

There was evidence of a negative correlation between growing number of patients and the intubation time (ρ= -0.57; p<0.0001), surgical duration (ρ= -0.55; p<0.0001), total estimated blood loss (ρ= -0.66; p<0.0001), hospitalisation length (ρ= -0.32; p=0.002).

Key safety findings

No intraoperative complications, neuromonitoring anomalies or screw misplacements were reported.

Pulmonary complications within 6 weeks after surgery: n=6 (5 complications happened after double VBT and 1 after thoracic VBT)

- Recurrent, right-side pleural effusion at 2 to 6 weeks after surgery: n=3

  Two patients had chest-tube reinsertion and 1 had exploratory thoracotomy because of a bleeding from the right pulmonary ligament, but this lesion could not be repaired, and a chest-tube was reinserted.

- Chest infection: n=1

  This patient was admitted to the local hospital 2 weeks after surgery because of fever and dyspnoea and had antibiotics for 2 weeks.

- Minor pulmonary embolism after a 24-hour flight: n=1

  This patient had intramuscular low-molecular-weight heparin therapy for 1 month.

- Persistent atelectasis of the lower left lobe: n=1

  This happened on the second postoperative day after thoracic VBT from the right side. Since she did not tolerate non-invasive ventilation, intubation was needed for 3 days. The symptoms resolved after bronchoscopic removal of a large mucus accumulation.

All patients recovered well and without sequelae. Four of the reported complications were observed within the first 25 operated patients. No further complications were observed beyond 6 weeks after surgery.

Tether rupture: n=28

Because of a high rate of tether rupture, double tether was adopted and most in lumbar curves. Of the 28 patients, 3 patients needed revision surgery for loss of correction, the second tether might provide more stability to the construct. Data regarding the rupture rate with double tether was not available.

Study 6 Rushton PRP (2021)

Study details

Study type	Case series
Country	Canada (2 centres)
Recruitment period	2012 to 2018
Study population and number	n=112 (116 primary tethering procedures) Patients with idiopathic scoliosis
Age and sex	Mean 12.7 years; 93% (104/112) female; mean Risser 0.5
Patient selection criteria	Inclusion criteria: skeletally immature patients with progressive major main thoracic and/or lumbar curves ≥40°
Technique	Thoracic tethers were done thoracoscopically and thoracolumbar/lumbar tethers needed a mini-open 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.
Follow up	Mean 37 months (range 15 to 64 months)
Conflict of interest/source of funding	Funding: none Relevant financial activities outside the submitted work: consultancy, grants, royalties.

Analysis

Follow-up issues: A total of 114 patients with idiopathic scoliosis had tethering procedures, 2 were lost to follow up and excluded from the study. Two patients had fusion procedures within 2 years post anterior VBT (15 and 19 months) hence excluded from further follow up, the remaining patients had a follow up of more than 2 years.

Study design issues: This study evaluate the clinical, radiographic, and perioperative outcomes and complication rates to determine the efficacy of anterior VBT in a prospective multicentre cohort of skeletally immature patients with idiopathic scoliosis. Cases were considered a success if at follow up they had not undergone (or awaiting) fusion and their tethered curve(s) was <35°. 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’.

Study population issues: Of the 104 females, 22 were recently postmenarchal. All patients were skeletally immature, Risser 0.5±0.9 (range 0 to 3). 51% of patients had previous bracing treatment.

Of the 116 tethering procedures 108 were done as a single stage, of which 104 were thoracic tethers and 4 were lumbar tethers. Eight tethers were done on 4 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 done and 8 lumbar tethers.

Other issues: This study had several limitations: 1) preoperative Sanders score was only available for 33 patients; 2) lumbar and thoracic tethers were analysed together, so further work is needed to determine if their responses to anterior VBT differ; and 3) there were no patient reported outcome measures.

Key efficacy findings

Number of patients analysed: 112 (116 procedures)

Operative data

Variable		Value	P
Vertebrae tethered	Thoracic tether	7.3±0.7 (6 to 9)	<0.001
	Lumbar tether	5.3±0.5 (5 to 6)	
Operating time (minutes)	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)	

Radiographic and surface measurements

	Preoperation	First erect	1 year	Most recent follow up
Coronal plane				
Tethered curve Cobb (°)	50.8±10.2 (31 to 81)	26.6±10.1 (-3 to 61)[a]	23.1±12.4 (-37 to 57)[b]	25.7±16.3 (-32 to 58)[cd]
Tethered curve correction (%)		47.7±16.2 (7 to 107)	55.1±22.7 (5 to 184)[b]	49.6±30.5 (-16 to 159)[c]
Instrumented Cobb (°)		22.7±10.6 (-1 to 57)	15.1±12.6 (-18 to 55)[b]	19.0±15.8 (-29 to 57)[c]
Untethered minor curve Cobb (°)	31.0±9.5 (3 to 57)	20.3±10.3 (0 to 52)[a]	18.1±10.8 (-22 to 50)[b]	18.4±14.2[e] (-13 to 62)[d]
Untethered minor curve correction (%)		34.3±33.8	43.5±31.3[b]	41.6±60.9
Sagittal plane				
Thoracic kyphosis T5 to 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)[cd]
Lumbosacral lordosis L1 to S1 (°)	-55.9±10.5 (-99 to -28)	-54.0±10.9 (-88 to -30)[a]	-55.7±10.9 (-87 to -24)[b]	-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)
Surface measurements				
Rib hump (°)	14.1±4.8 (0 to 26)	8.1±4.3 (0 to 22)[a]	8.6±4.7 (0 to 25)	8.8±5.4 (0 to 22)[d]
Lumbar prominence (°)	3.6±4.7 (0 to 17)	2.2±3.6 (0 to 16)[a]	2.4±3.6 (0 to 15)	2.5±4.4 (0 to 18)[d]

- Changes from preoperation to first erect: [a]denotes significance; tethered curve Cobb / tethered curve correction/ untethered minor curve Cobb/ rib hump all p<0.001, lumbosacral lordosis p=0.03 (non-significant: thoracic kyphosis p=0.58, lumbar prominence p=0.052).

- Change from first erect to 1 year: [b]denotes significance; tethered curve Cobb/ tether curve correction/ instrumented Cobb/untethered minor curve Cobb/ untethered minor curve correction all p<0.001, lumbosacral lordosis p=0.04 (non-significant: thoracic kyphosis p=0.50, thoracic tether instrumented sagittal Cobb p=0.80, lumbar tether instrumented sagittal Cobb p=0.67, rib hump p=0.40, lumbar prominence p=0.91).

- Change 1 year to most recent follow up: [c]denotes significance; tethered curve Cobb/ tethered curve correction / instrumented Cobb all <0.001, thoracic kyphosis p=0.002 (non-significant; untethered minor curve Cobb p=0.37, untethered minor curve correction p=0.60, thoracic kyphosis p=0.26, lumbosacral lordosis p=0.45, thoracic tether instrumented sagittal Cobb p=0.80, lumbar tether instrumented sagittal Cobb p=0.14, rib hump p=0.55, lumbar prominence p=0.52).

- Change preoperation to most recent follow up: [d]denotes significance; tethered curve Cobb/ untethered minor curve Cobb/ rib hump all p<0.001, thoracic kyphosis p=0.004, lumbar prominence p=0.03 (non-significant; lumbosacral lordosis p=0.86).

- [e] 1 case had delayed lumbar curve tethering between 1 year and MRF, thus excluded and n=107 for this time point.

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	2	
	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 to 39°	10 (83%)	2	0.03
	40 to 49°	36 (78%)	10	
	50 to 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
Lumber		3	1	
Dual		3	1	
Postoperative				
Tether breakage[e]		19/80 (24%)	17/32 (53%)	0.003
Follow up (months)		35.6±8.7 (24 to 61)	41.7±10.9 (15 to 64)	0.001

[e]Three patients had confirmed tether breakage (2 verified at tether replacement and 1 at fusion) and 33 patients had radiographs suggestive of tether breakage (2 of these had 2 sites of suspected breakage). Thus 32% of patients (36/112) had a confirmed/suspected tether breakage. The most common sites for breakage were T9/10, T10/11 and T11/12 occurring in 11,13 and 7 cases respectively. Tether breakage was noted on radiographs taken mean 31 months (12 to 43 months) postoperatively.

Key safety findings

Overall complications: 22% (n=25) of patients who had 28 complications.

Revision: 13% (n=15) of patients who needed 18 revision operations.

Complications and revision further operations

Nature of complication/revision operation			**Number cases**	**Number revision operations**
Perioperative	Pulmonary	Atelectasis (needing admission to intensive care for respiratory support)	4	
		Haemothorax	2	1
		Pneumonia	2	
		Pneumothorax	1	
	GI	Clostridium difficile infection	1	
	Infection	Superficial wound	1	
	CSF leak (presenting with orthostatic headaches and vomiting)		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 related to a T12 screw narrowly breaching the posterior wall needing revision and the other without obvious cause was treated conservatively.

** At follow up, 6 patients had fusion operations with 1 awaited (6%). One patient subsequently needed revision for distal junctional failure.

***One patient needed subsequent revision of fusion for distal junctional failure.

Study 7 Miyanji F (2021)

Study details

Study type	Case series (retrospective; multicentre scoliosis registry)
Country	Canada (2 centres)
Recruitment period	2013 to 2017
Study population and number	n=50 Patients with idiopathic scoliosis
Age and sex	Mean 11.9 years; 92% (46/50) female
Patient selection criteria	Inclusion criteria: Patients with Lenke type 1 and Lenke type 2 juvenile idiopathic scoliosis/adolescent idiopathic scoliosis who had anterior VBT; a minimum of 2-year follow up. Exclusion criteria: patients who transitioned to primary fusion before 2 years postoperatively.
Technique	Anterior VBT was done.
Follow up	Mean 2.1 years
Conflict of interest/source of funding	None

Analysis

Follow-up issues: A total of 50 patients were included in the final case series. Although 55 patients with Lenke type 1 or 2 idiopathic scoliosis who had anterior VBT with 2-year follow up were identified, 5 patients were not included in the analysis. The reasons for exclusion were because of inadequate view of the shoulders on radiographs taken at 2-year follow up (n=4) and conversion to PSF before the 2-year time point (n=1) to address the remaining deformity.

Study design issues: This retrospective case series evaluated shoulder balance following anterior VBT of the spine for Lenke type 1 and 2 idiopathic scoliosis and reported the prevalence of postoperative shoulder imbalance in patients having anterior VBT for idiopathic scoliosis.

The primary outcome measure was shoulder balance assessed at the immediate, 1-year (10 to 18 months), and 2-year (22 to 30 months) postoperative follow-up visits. Radiographic shoulder height was used as the primary radiographic parameter to assess shoulder balance. Radiographic shoulder height was defined as the linear distance between the superior horizontal reference line, which passes through the intersection of the soft-tissue shadow of the shoulder and a line drawn vertically up from the acromial clavicular joint of the cephalad shoulder, and the inferior horizontal reference line, constructed in a similar fashion over the caudal acromioclavicular joint.

Secondary outcome measures included other surrogate radiographic markers of shoulder balance, such as clavicular angle and T1 tilt angle assessed at the preoperative, immediate postoperative, 1-year, and 2-year postoperative follow-up visits. Clavicular angle was defined as the angle between a horizontal line and a tangential line connecting the most cephalad points of each clavicle. T1 tilt angle was defined as the angle between a horizontal line and a line along the upper endplate of T1. Coronal balance was determined and defined as the horizontal distance between the central sacral vertical line and the C7 plumb line (C7CSVL) in the standing posteroanterior radiograph.

Study population issues: Of the 50 patients, 43 (86%) patients had Lenke type 1 and 7 (14%) patients had Lenke type 2 curves. Preoperatively, absolute radiographic shoulder height averaged 15.6±10.5 mm. 35 (70%) had acceptable shoulder balance, 14 (28%) had moderate shoulder imbalance, and 1 (2%) had severe shoulder imbalance. All patients with shoulder imbalance preoperatively had right-sided elevation (i.e., radiographic shoulder height ≤ -2 cm). 4 patients with acceptable shoulder balance preoperatively had slight left-sided elevation (i.e., 1 cm ≤ radiographic shoulder height <2 cm). Risser 0 was in 66% (33/50) of patients, Risser 1 in 20% (10/50), Risser 2 in 12% (6/50) and Risser 3 in 2% (1/50).

Other issues: This study had several limitations. Although a patient may have balanced shoulders radiographically, an imbalance may exist clinically and vice versa. Unfortunately, clinical photos were not available to verify shoulder imbalance in this study and the results should be considered preliminary. It was also important to note that most patients (66%) were Risser 0 and 30% of these patients had open triradiate cartilages. It was difficult to predict curve behaviour in these particularly skeletally immature patients. Furthermore, when stratifying by Lenke type, the Lenke 2 group suffered from small sample size. Finally, all patients with preoperative shoulder imbalance included in this study suffered from a right-sided imbalance, so, the effect of anterior VBT on left-sided shoulder imbalance cannot be concluded from this study.

Key efficacy findings

Number of patients analysed: 50

Radiographic results

	Preoperative	**Immediate postoperation**	**1-year postoperation**	**2-year postoperation**
Radiographic parameter (mean±SD [min to max])				
Proximal thoracic curve (°)	22.8±8.8 (7.7 to 43.4)	16.8±8.8 (3 to 36)	12.4±8.1 (0.2 to 33.4)	13.1±7.5 (1.2 to 30)
Main thoracic curve (°)	49.4±8.5 (32 to 75)	27.1±8.5 (14 to 52)	22.1±8.9 (4 to 41)	24.9±9.5 (6 to 46)
TL curve (°)	32.7±6.9 (18 to 46)	25±7 (11 to 42)	21.4±7.6 (10 to 40)	21.3±7.9 (10 to 39)
*Clavicular angle (°)	-1.9±3 (-7.8 to 3.6)	1±2.3 (-6.3 to 6.4)	1.5±2.4 (-4.1 to 6.5)	0.9±2.6 (-5 to 7.4)
IClavicular angle1 (°)	2.8±2.2 (0 to 7.8)	1.9±1.6 (0 to 6.4)	2.3±1.7 (0 to 6.5)	2.2±1.7 (0 to 7.4)
*T1 angle (°)	-1.1±5.9 (-12.4 to 10.7)	3.1±5.2 (-7.8 to 14.2)	2.4±4.8 (-8.9 to 12.1)	2.8±5.6 (-9.2 to 18.2)
IT1 angle1 (°)	4.8±3.5 (0 to 12.4)	4.9±3.6 (0 to 14.2)	4.2±3.3 (0 to 12.1)	4.7±4.2 (0 to 18.2)
*Shoulder height (mm)	-12.3±14.2 (-41.1 to 13.4)	3.4±12.3 (-24.3 to 28.4)	6.9±12.2 (-24 to 29.6)	2.6±13.8 (-21.4 to 32.4)

IShoulder height1 (mm)	15.6±10.5 (0 to 41.1)	9.6±8.2 (0 to 28.4)	11.5±7.8 (0 to 29.6)	11.3±8.3 (0 to 32.4)
C7CSVL (mm)	6±17.2 (-33.6 to 45)	0.6±13.5 (-24.3 to 30.3)	1±12.9 (-23 to 27.5)	-0.9±14.4 (-37 to 35)
IC7CSVL1 (mm)	13.7±11.9 (0 to 45)	10.6±8.3 (0 to 30.3)	10±8 (0 to 27.5)	11.4±8.7 (0 to 37)
Shoulder balance				
Acceptable balance ≤2 cm	70.0% (n=35)	82.0% (n=41)	70.0% (n=35)	84.0% (n=42)
2 cm ≤ moderate imbalance <4 cm	28.0% (n=14)	10.0% (n=5)	12.0% (n=6)	16.0% (n=8)
Severe imbalance ≥4 cm	2.0% (n=1)	0% (n=0)	0% (n=0)	0% (n=0)
Missing radiograph	0% (n=0)	8.0% (n=4)	18.0% (n=9)	0% (n=0)

*Measurement where negative value indicates right side up/left side down.

Radiographic results for Lenke type 1 compared with Lenke type 2 curves

	Lenke 1 (n=43), 86.0%)	Lenke 2 (n=7, 14.0%)	P value
Radiographic parameter (mean±SD)			
Preoperative proximal thoracic curve (°)	21.1±7.8	34.2±6.5	<0.001
2-year postoperative proximal thoracic curve	11.9±7.1	19.6±7	0.012
Preoperative main thoracic curve (°)	49±9	54±8	0.171
2-year postoperative main thoracic curve	24.5±10	27.7±5.5	0.419
Preoperative TL curve (°)	33±7	33±5	0.792
2-year postoperative TL curve	21±7.8	23.1±9.4	0.536
Preoperative Ishoulder height1 (mm)	3±2.3	2.4±1.8	0.571
2-year postoperative Ishoulder height1	2.2±1.6	2.6±2.5	0.514
Preoperative IClavicular angle1 (°)	5±3.7	3.7±2.5	0.372
2-year postoperative IClavicular angle1	4.2±4	7.4±5	0.066
Preoperative IT1 tilt angle1 (°)	15.7±11	14.8±7	0.829
2-year postoperative IT1 tilt angle1	10.9±7.9	13.7±10.8	0.419
Preoperative shoulder balance			
Acceptable balance ≤2 cm	67.4% (n=29)	85.7% (n=6)	0.328
2 cm ≤ moderate imbalance <4 cm	30.2% (n=13)	14.3% (n=1)	0.657
Severe imbalance ≥4 cm	2.3% (n=1)	0% (n=0)	1.000
2-year postoperative shoulder balance			
Acceptable balance ≤2 cm	86.0% (n=37)	71.4% (n=5)	0.310
2 cm ≤ moderate imbalance <4 cm	14.4% (n=6)	28.6% (n=2)	0.310
Severe imbalance ≥4 cm	0% (n=0)	0% (n=0)	-

In particularly skeletally immature patients (i.e., Risser 0 with open triradiate cartilage), mean |radiographic shoulder height| was 15.6±12.9 mm preoperatively and 12.0±10.1 mm at 2 years postoperatively (p=0.500). In more mature patients (i.e., Risser 0 with closed triradiate cartilage or > Risser 0), mean |radiographic shoulder height| was 15.6±10.0 mm preoperatively and 11.1±7.9 mm at 2 years postoperatively (p=0.028).

Key safety findings

Safety data were not reported.

Study 8 Alanay A (2020)

Study details

Study type	Case series (retrospective)
Country	Turkey
Recruitment period	2014 to 2018
Study population and number	n=31 Patients with adolescent idiopathic scoliosis
Age and sex	Mean 12.1 years; 94% (29/31) female; median Risser 0
Patient selection criteria	Inclusion criteria: patients having a Lenke 1 or 2 pattern, and more than or equal to a follow up of 12 months.
Technique	In lateral decubitus position, video-assisted thoracoscopy was done. Three visualisation and 3-to-4 working ports were used for T5 to L1. For Lenke 1Ar curves, L2 and L3 screws were inserted through a mini-open retroperitoneal approach. Hydroxyapatite-coated mono-axial screws were placed with a bicortical purchase. Staples were not used in first several patients as the necessary transportal insertion instruments were not available. While applying translation and derotation, the tether was tensioned. Slighter tension was applied at the UIV and UIV-1 disc and greater tension was applied at the apex. The movement of the screws during tensioning and the change in disc wedging guided the tensioning. Tension applied at the LIVþ1 and LIV disc was judged by the curve pattern under fluoroscopy and was mostly slight, sometimes even left slack. A chest tube was placed before closure.
Follow up	Mean 27.1 months (range 12 to 62 months)
Conflict of interest/source of funding	None

Analysis

Follow-up issues: Twenty-one patients (67.7%) had more than or equal to 2-year follow up. Four patients (12.9%) had a follow up of 18 months. Remaining 6 patients (19.4%) had a follow up of 12 months. Patients were followed up at the day before discharge (namely first erect), postoperatively at 6 weeks, at 3, 6, 12, 18 and 24 months, and each year thereafter.

Study design issues: This retrospective study reported the follow-up curve behaviours for patients in different Sanders groups who had similar curves preoperatively that were intraoperatively corrected with a similar strategy, to form a basis for clinical decision-making and surgical planning. Outcomes included perioperative data, radiographic and clinical measurements, overcorrection, pulmonary and mechanical complications, readmission, and reoperations.

To evaluate the height gained within the instrumented segment, UIV-LIV vertical height was measured. For both body height and UIV-LIV height, the difference from preoperative to 6 weeks was considered operative gain. The increase from 6 weeks onwards was considered follow-up gain. UIV-LIV follow-up height gain was divided by the number of instrumented levels to calculate gain-per-level.

Study population issues: Preoperatively, 14 patients were Lenke 1A, while 10 were 1B, 6 were 1Ar, and 1 was 2C. The median Sanders stage was 3 (1 to 7). The median Risser score was 0 (0 to 4). Of the female patients, 19 (66%) were premenarchal while the rest were on average 11.9±7.3 (1 to 24) months postmenarchal. All demographic and perioperative variables were similar between Sanders groups except age, Risser sign and postmenarchal status.

Key efficacy findings

Number of patients analysed: 31

A mean of 7.5±0.8 levels was tethered. UIV was T5 in 17 (54.8%) patients, while it was T6 in 11 (35.5%), T7 in 2 (6.5%) patients, and T8 in 1 (3.2%) patient. LIV was T11 in 13 (41.9%) patients, while it was T12, L1, L2, and L3 in 8 (25.8%), 6 (19.4%), 1 (3.2%), and 3 (9.7%) patients, respectively.

Sanders stage at the final follow up:

- Sanders 7 or 8: 74.2% (n=23)
- Sanders 6: 19.4% (n=6)
- Sanders 4 and 3B: 6.1% (n=2, both had a revision surgery)

The median Risser score was 5 (2 to 5). Of the female patients, all but 2 (93%) were postmenarchal. Of the 10 patients that had less than 2-years follow up, 7 (70%) were Sanders 7, and the remaining 3 (30%) were Sanders 6, at their final follow up.

Preoperative and follow-up total body height and UIV-LIV vertical height measurements, and amounts of operative and follow-up gain in Sanders groups

	Sanders 2	**Sanders 3**	**Sanders 4 to 5**	**Sanders 6 to 7**
Height, cm, median (range)				
Preoperative	145 (130 to 168)	157 (145 to 178)	160 (153 to 163)	157 (152 to 166)
6 weeks	148 (133 to 170)	158 (147 to 181)	161 (153 to 164)	158 (153 to 167)
Last follow up	162 (149 to 181)	164 (153 to 186)	164 (156 to 166)	159 (153 to 168)
Operative gain[a]	2 (1 to 3)	2 (0 to 3)	1 (0 to 2)	1 (0 to 2)
Growth gain[b]	13 (9 to 16)	5 (3 to 8)	3 (2 to 4)	1 (0 to 2)
UIV-LIV vertical height, mm, median (range)				
Preoperative	153.8 (119 to 181)	152.0 (129 to 201)	142.4 (135 to 162)	151.6 (127 to 191)
6 weeks	157.9 (127 to 187)	159.1 (134 to 209)	145.4 (139 to 165)	157.3 (132 to 198)
Last follow up	177.5 (136 to 204)	169.1 (140 to 223)	150.7 (143 to 169)	159.0 (133 to 197)
Operative gain[c]	4.0 (0.3 to 8)	7.2 (1.5 to 18)	3.1 (2 to 4.3)	5.7 (1.2 to 10)
Growth gain	19.7 (9.3 to 25.9)	10 (2.4 to 14.8)	5.3 (4.3 to 6.9)	1.7 (-1.3 to 4)

Growth gain per level[d]	2.4 (1.3 to 3.7)	1.3 (0.3 to 2.1)	0.7 (0.5 to 1)	0.2 (-0.1 to 0.6)

[a]X^2 (3) =5.355, p=0.148
[b]X^2 (3) =25.231, p<0.001; Sanders 2 to 4/5, p=0.010; Sanders 2 to 6/7, p<0.001; Sanders 3 to 6/7, p=0.002
[c]X^2 (3) =3.995, p=0.075
[d]X^2 (3) =21.4, p<0.001; Sanders 2 to 4/5, p=0.038; Sanders 2 to 6/7, p<0.001; Sanders 3 to 6/7, p=0.00

Mean operative height gain: 1.5±0.9 cm for all patients

Mean UIV-LIV follow-up height gain: 9.2±7.1 mm for all patients

Preoperative and follow-up Cobb angle measurements for upper thoracic, main thoracic and thoracolumbar/lumbar curves, and bending flexibility, and operative, follow up and total correction percentages in Sanders groups

	Sanders 2	**Sanders 3**	**Sanders 4 to 5**	**Sanders 6 to 7**
Upper thoracic curve degree, median (range)				
Preoperative	30 (14 to 37)	24 (14 to 55)	23 (17 to 44)	27 (20 to 31)
First erect	17 (6 to 28)	17 (8 to 37)	17 (15 to 36)	15 (6 to 27)
6 months	15 (5 to 27)	16 (3 to 40)	19 (12 to 32)	18 (15 to 29)
12 months	14 (4 to 18)	14 (3 to 31)	18 (13 to 33)	16 (5 to 27)
Last follow up	11 (1 to 19)	13 (2 to 31)	17 (12 to 36)	15 (5 to 24)
Follow-up correction	9 (4 to 17)	1 (-4 to 9)	5 (0 to 6)	1 (-3 to 5)
Percentage, median (range)				
Bending flexibility %	77 (60 to 90)	78 (35 to 96)	59 (41 to 84)	70.5 (37 to 80)
Operative correction %[e]	24 (20 to 71)	33 (19 to 73)	18 (10 to 55)	30 (0 to 70)
Follow-up correction %[f]	26 (19 to 71)	3 (-13 to 50)	0 (0 to 29)	5 (-10 to 23)
Total correction %	70 (46 to 93)	44 (17 to 86)	29 (18 to 55)	44 (201 to 75)
Main thoracic curve degree, median (range)				
Preoperative	46 (35 to 51)	50 (36 to 68)	43 (38 to 51)	47 (39 to 51)
First erect	24 (16 to 33)	24 (10 to 34)	21 (12 to 26)	20 (8 to 29)
6 weeks	17 (13 to 32)	27 (15 to 33)	20 (17 to 26)	24 (14 to 26)
6 months	15 (10 to 24)	22 (5 to 31)	19 (16 to 21)	22.5 (10 to 30)
12 months	10 (2 to 14)	16.5 (0 to 25)	17 (8 to 20)	19 (9 to 28)
Last follow up	-3 (-5 to 3)	17 (-6 to 280)	15 (6 to 20)	19 (9 to 27)
Follow-up correction	29 (18 to 30)	9 (-4 to 23)	6 (3 to 7)	0 (-2 to 6)
Percentage, median (range)				
Bending flexibility %	80 (30 to 100)	71 (52 to 94)	82 (70 to 88)	70 (63 to 94)
Operative correction %[g]	51 (13 to 63)	52 (27 to 80)	47 (40 to 72)	55 (40 to 83)
Follow-up correction %[h]	59 (37 to 79)	17 (-0.8 to 48)	14 (6 to 18)	0 (-4 to 12)

Total correction %	109 (92 to 111)	71 (41 to 112)	63 (53 to 86)	55 (44 to 81)
Toracolumbar/lumbar curve degree, median (range)				
Preoperative	26 (12 to 35)	32 (22 to 42)	28 (22 to 37)	32 (19 to 37)
First erect	13 (2 to 23)	16 (1 to 36)	15 (2 to 28)	17 (12 to 30)
6 months	8 (-5 to 6)	16 (0 to 29)	15 (1 to 29)	15 (9 to 24)
12 months	5 (-12 to 18)	11.5 (0 to 34)	15 (0 to 20)	14 (2 to 23)
Last follow up	-8 (-18 to 20)	4 (-5 to 31)	12 (-6 to 16)	14 (5 to 23)
Follow-up correction	13 (3 to 31)	11 (-5 to 23)	8 (-4 to 18)	6 (-1 to 12)
Percentage, median (range)				
Bending flexibility %	150 (65 to 242)	100 (57 to 178)	89 (61 to 191)	105 (75 to 258)
Operative correction %[i]	63 (0 to 83)	50 (14 to 96)	32 (18 to 93)	37 (13 to 62)
Follow-up correction %[j]	89 (9 to 142)	33 (-15 to 66)	27 (-14 to 53)	24 (-3 to 33)
Total correction %	131 (41 to 225)	85 (26 to 121)	57 (27 to 122)	50 (28 to 86)

[e]X^2 (3) =2.357, p=0.502
[f]X^2 (3) =6.103, p=0.107
[g]X^2 (3) =0.357, p=0.949
[h]X^2 (3) = 16.502, p<0.001; Sanders 2 to 6/7, p<0.001
[i]X^2 (3) =1.952, p=0.582
[j]X^2 (3) =6.295, p=0.098

Mean MT curve magnitude for all patients: preoperative, 47°±7.6°; first erect, 21.8°±6.4°

Preoperative and follow-up Cobb angle measurement for thoracic kyphosis, and lumbar lordosis, and amount of operative and follow-up change, and preoperative and last follow-up hump measurements and correction percentages in Sanders groups

	Sanders 2	Sanders 3	Sanders 4 to 5	Sanders 6 to 7
Thoracic kyphosis degree, median (range)				
Preoperative	34 (17 to 59)	25 (15 to 41)	31 (28 to 34)	22 (15 to 48)
First erect	28 (5 to 57)	30 (12 to 44)	29 (18 to 32)	28 (14 to 43)
6 months	31 (10 to 37)	30 (15 to 44)	28 (19 to 32)	32 (21 to 44)
12 months	32 (15 to 35)	30.5 (21 to 39)	24 (20 to 37)	25 (14 to 41)
Last follow up	30 (6 to 40)	30 (21 to 46)	28 (18 to 33)	29 (14 to 38)
Operative change[k]	-7 (-12 to -2)	0 (-15 to 11)	-3 (-10 to -2)	0 (-6 to 17)
Follow-up change[l]	4 (-17 to 11)	3 (-15 to 12)	0 (-11 to 10)	0 (-6 to 6)
Lumbar lordosis degree, median (range)				
Preoperative	55 (52 to 70)	61 (38 to 91)	61 (37 to 72)	65 (56 to 66)
First erect	52 (36 to 60)	48 (27 to 78)	51 (41 to 69)	53 (44 to 67)
6 months	56 (50 to 68)	55 (41 to 68)	61 (45 to 65)	55.5 (48 to 68)

12 months	53 (45 to 75)	56.5 (34 to 88)	52 (44 to 63)	60 (48 to 67)
Last follow up	53 (40 to 75)	55 (34 to 88)	52 (44 to 63)	60 (47 to 70)
Operative change[m]	-10 (-18 to 4)	-9 (-21 to -2)	-4 (-19 to 4)	-8 (-18 to 1)
Follow-up change[n]	4 (-4 to 18)	0 (-9 to 11)	-3 (-10 to 17)	-2 (-3 to 15)
Hump degree, median (range)				
Preoperative[o]	13 (12 to 16)	12 (8 to 21)	13 (6 to 17)	12 (11 to 16)
Last follow up	5 (3 to 8)	7 (1 to 10)	9 (2 to 10)	5 (3 to 10)
Correction %[p]	67 (38 to 80)	50 (27 to 93)	36 (30 to 67)	58 (25 to 73)

[k]X^2 (3) =6.255, p=0.100
[l]X^2 (3) =3.997, p=0.262
[m]X^2 (3) =0.817, p=0.845
[n]X^2 (3) =1.955, p=0.582
[o]X^2 (3) =0.975, p=0.807
[p]X^2 (3) =3.999, p=0.262

Key safety findings

Overcorrection: 19.4% (n=6)

- Overcorrections were greater than or equal to –10°: n=2 (both patients needed a tether release. Bottom 3 levels were released in 1 and completely removed for the other.)
- Overcorrection was -3° at 2 years: n=1 (a tether breakage and curve increase to 20° was noted on the 3rd year.)
- Overcorrections were less than -10°: n=3 (no intervention was considered necessary.)

Pulmonary complications: 12.9% (n=4)

- Atelectasis: n=2 (these events resolved with intensive physical therapy.)
- Chylothorax: n=1 (this event resolved with dietary precautions.)
- Pleural effusion: n=1 (the patient needed readmission within 3 days but a chest tube was not reinserted.)

Mechanical complications: 19.4% (n=6)

Overcorrection and mechanical complications overlapped in 3 patients, adding up to 9 patients (29%) where there was an adverse event related to either implantation or correction. Overcorrection was accompanied by UIV loosening and LIV pull-out in 2 separate cases. There were 1 UIV pull-out, and 1 UIV migration, both of which were stable during follow up and did not need a reintervention. A 51° main thoracic curve that was corrected to 16° at first year and had a gradual increase to 25° from 18 to 24 to 36 months, which was considered as loss of a previously achieved correction.

Overall, 1 patient (3.2%) had a readmission and 2 (6.5%) needed reoperation. Occurrence of pulmonary complications was similar in Sanders groups (p=0.804), while mechanical complications and overcorrection was higher in Sanders 2 (p=0.002 and p=0.018).

Study 9 Samdani AF (2021)

Study details

Study type	**Case series (FDA-IDE study)**
Country	US (single centre)
Recruitment period	2011 to 2015
Study population and number	n=57 Patients with adolescent idiopathic scoliosis
Age and sex	Mean 12.4 years; 86% (49/57) female; median Risser grade 0
Patient selection criteria	All skeletally immature patients (a Risser grade of 0 through 4 and a Sanders stage of <5) with Lenke type-1A or 1B curves between 30° and 65° who had anterior VBT, with a clinical visit at a minimum follow up of 2 years.
Technique	Anterior VBT was done.
Follow up	Mean 55.2 months (range 30.4 to 77.6 months)
Conflict of interest/source of funding	This study was funded by Zimmer Biomet.

Analysis

Follow-up issues: Of the 57 patients, 56 (98.2%) patients were available for analysis of the primary end point of the thoracic Cobb angle at the most recent visit.

Study design issues: This prospective review of a retrospective dataset presented the results from the first U.S. FDA-IDE study on anterior VBT. An outside independent radiologist carried out a comprehensive radiographic analysis to include major and minor Cobb angels, shoulder balance, coronal and sagittal balance, kyphosis, and lumbar lordosis.

Study population issues: With respect to preoperative skeletal maturity, the median Risser grade was 0 (range 0 to 4) and 96% (55/57) of patients had a Risser grade of ≤2. The median Sanders stage was 3 (range 2 to 5).

Key efficacy findings

Number of patients analysed: 57

Operative characteristics

Variable	**Findings**
Surgical approach	
Thoracoscopic access	56.1% (n=32)
Mini-thoracotomy	0

Thoracoscopic and mini-thoracotomy	43.9% (n=25)
Changes in MEPs and SSEPs from baseline	
Yes	0
No	100% (n=57)
Duration of surgery (minute)	223.2±79.4 (range 80 to 412)
Blood loss (mL)	105.7±85.9 (range 10 to 440)
Duration of chest tube (day)	2.3±1.1 (range 1 to 5)
Days in ICU	1.5±0.7 (range 1 to 5)
Length of stay (day)	4.8±1.4 (range 3 to 9)
Levels tethered	7.5±0.6 (range 6 to 9)

One patient needed a blood transfusion.

Coronal radiographic outcomes

Visit	Main thoracic curve (º)	Proximal thoracic curve (º)	Lumbar curve (º)
Preoperative	40.4±6.8 (n=56)	25.0±5.7 (n=14)	23.7±6.1 (n=45)
First erect	19.3±8.4 (n=42)	20.1±5.5 (n=16)	15.2±6.1 (n=35)
12 months	12.6±7.2 (n=48)	16.1±6.4 (n=19)	8.8±6.7 (n=42)
24 months	13.8±8.9 (n=46)	15.3±6.9 (n=22)	11.4±7.7 (n=42)
Most recent (a mean follow up of 55.2 months)	18.7±13.4 (n=56)	17.9±6.4 (n=27)	15.7±8.4 (n=49)
Comparison of outcomes	P value		
Preoperative compared with first erect	<0.0001		
Preoperative compared with most recent	<0.0001		
First erect compared with most recent	0.90		

Radiographic outcomes

Visit	T5 to T12 Kyphosis (º)	Lumbar lordosis (º)	Sagittal balance (mm)	Coronal balance (mm)	Total vertebral thoracic spine length (mm)
Preoperative	15.5±10.0 (n=55)	51.9±11.4 (n=55)	2.6±26.7 (n=55)	2.4±14.8 (n=56)	245.3±19.8 (n=56)
First erect	17.0±10.1 (n=39)	50.9±10.6 (n=38)	3.8±29.1 (n=38)	-2.5±15.6 (n=41)	250.7±16.4 (n=42)
12 months	17.9±11.1 (n=42)	52.4±11.6 (n=40)	-3.7±28.2 (n=39)	-8.4±13.0 (n=46)	258.5±19.1 (n=47)

24 months	17.8±11.9 (n=39)	53.0±10.3 (n=39)	-3.4±26.5 (n=39)	-7.5±11.7 (n=45)	263.0±17.9 (n=46)
Most recent (a mean follow-up of 55.2 months)	19.6±12.7 (n=56)	54.4±11.8 (n=55)	-8.8±30.1 (n=55)	-0.7±15.8 (n=55)	271.5±19.4 (n=56)
Comparison of outcomes	P value	P value	P value	P value	P value
Preoperative compared with first erect	0.40	0.46	0.99	0.07	0.11
Preoperative compared with most recent	0.0023	0.10	0.08	0.31	<0.0001
First erect compared with most recent	0.05	0.0126	0.08	0.59	<0.0001

Clinical trunk rotation based on thoracic sociometer readings: 13.6°±3.9° preoperatively; 6.3°±3.0° at 2-year follow up; 8.6°±4.9° at the most recent follow up.

Should balance: Clinically unlevel shoulders were reported in 54% (28/52) of patients preoperatively and in 25% (14/55) at the latest follow up.

SRS-22 scores: 4.5±0.4 at the most recent follow up (the preoperative SRS-22 scores were not obtained).

Self-image scores: 4.4±0.7 at the most recent follow up.

Measured and predicted lung function at the time of follow up

Follow-up period	No. of patients evaluated	FEV1	Percent of predicted FEV1	FVC	Percent of predicted FVC	FEV1/FVC	Percent of predicted FEV1/FVC
Preoperative	42	2.29	83.0	2.67	83.1	0.86	99.6
1 year	1	3.56	78.2	4.85	92.5	0.73	83.6
2 years	3	2.17	70.5	2.66	74.7	0.81	94.4
3 years	30	2.77	77.7	3.19	77.7	0.88	100.4
4 years	26	2.82	75.4	3.24	75.6	0.88	100.0
5 years	17	2.76	71.8	3.22	74.3	0.86	96.5
6 years	10	2.66	69.0	3.24	74.6	0.82	91.0
Last visit at ≥2 years for patients with preoperative lung function data*	42	2.77	74.9	3.17	74.1	0.88	100.9

*The mean follow up at the last visit was 50.1 months (range 30 to 76.6 months).

At the last follow-up evaluation, the average Risser grade was 4.2±0.9, with 93% of patients having a Risser grade of 4 or 5. The Sanders stage averaged 7.5±0.9, confirming that most patients had attained skeletal maturity.

Key safety findings

Revision: n=7 (12.3%). Of these 7 patients, 5 patients had a tether release for overcorrection and 2 had the tether extended for adding-on. In 1 patient whose curve had overcorrected, the tether release did not stop the curve overcorrection. Subsequently, this patient had PSF approximately 4.6 years after the original tether surgery.

No patients experienced a postoperative neurologic deficit.

Study 10 Rathbun JR (2019)

Study details

Study type	**Case report**
Country	US
Recruitment period	Not reported
Study population and number	n=1 Patient with adolescent idiopathic scoliosis
Age and sex	13 years; female
Patient selection criteria	Not reported
Technique	VBT with video-assisted thoracoscopic surgery was done – bilateral VBT with PET cored placement on the right T6 to T11.
Follow up	1 year
Conflict of interest/source of funding	None

Analysis

Study design issues: This case report presented a case of primary ureteral injury following VBT with subsequent ureteral erosion and stricture formation requiring definitive ureteral reconstruction.

Study population issues: The patient had VBT for growth correction after a trial of bracing for Cobb angles of 42° in the thoracic and lumbar spine each. Before operation, the patient was classified as Sanders score 6 with Lenke 2C modifier, and the traction films showed reduction of curves to 25° and 22°, respectively.

Key efficacy findings

Number of patients analysed: 1

The patient had successful placement of the device and desired curve reduction:

- Preoperation: thoracic and lumbar curves which were 25° and 22°, respectively.
- 2 weeks after operation: thoracic and lumbar curves which were 22.1° and 3.07°, respectively.
- About 1 year after operation: thoracic and lumbar curves which were 21° and 6°, respectively.

The patient progressed to Sanders stage 7 at 1 year after operation.

Length of hospital stay: 15 days after the procedure

The patient was in the hospital for 15 days after the procedure while recovering with resolving pneumothorax and awaiting safe chest tube removal.

Key safety findings

Mid-ureteral injury following VBT with subsequent erosion and stricture formation needing definitive ureteral reconstruction:

Approximately a month after discharge, the patient returned with complaints of left flank and abdominal pain and had CT scan revealing large fluid collection in the left retroperitoneal space and left hydroureteronephrosis. A drain was placed, and fluid was confirmed to be urine. Urology attempted endoscopic retrograde ureteral stent placement, but was unable to pass beyond the L2 screw, revealing a mid-ureteral injury. A couple days later, she had exploratory laparotomy with left ureterolysis, ureteroureterostomy, renal mobilisation with interposition of Gerota's fascia for tissue coverage, and stent placement. She was discharged home on the 4th postoperative day.

Endoscopic evaluation 6 weeks after primary repair showed ureteral narrowing with calcification on the polyethylene terephthalate cord in the ureteral lumen distal to the original repair. Prior to stent replacement, holmium laser lithotripsy was performed to remove encrustation of this cord. High-grade obstruction of the left kidney was confirmed on functional renal imaging.

Despite successful proximal primary repair, a ureteral stricture was the result of this erosion of the polyethylene terephthalate cord into the ureter. With stricture recurrence and high-grade obstruction, decision for second attempt definitive repair involved ureteral replacement with buccal mucosal graft with omental wrapping approximately 7 months after VBT. Her postoperative course was uncomplicated, and she was discharged on post-operative day 5 with stent removal 3 months later.

At most recent follow up (approximately 1 year after initial surgery), CT urogram showed 2 small ureteral diverticula with no hydronephrosis and appropriate left ureteral drainage. She is asymptomatic, and kidney function remains normal.

Study 11 Shin M (2021)

Study details

Study type	Meta-analysis
Country	Not reported for individual studies
Recruitment period	Publication year: anterior VBT, 2017 to 2019; PSF, 2013 to 2017
Study population and number	n=1,280 (24 studies; anterior VBT in 10 studies [n=211], PSF in 14 studies [n=1,069]) Patients with scoliosis
Age and sex	Anterior VBT: mean 12.4 years; 66.4% (140/211) female; mean Risser score 0.4 PSF: mean 14.2 years; 41.6% (445/1,069) female; mean Risser score 1.4
Patient selection criteria	Inclusion criteria: anterior VBT and/or PSF procedures; Lenke 1 or 2 curves; an age of 10 to 18 years for >90% of the patient population; <10% non-AIS scoliosis aetiology; and follow up of 1 year or more. Exclusion criteria: case reports; studies investigating anterior vertebral body stapling, Harrington rods, and anterior fusion.
Technique	Anterior VBT or PSF
Follow up	Anterior VBT: mean 33.7 months (range 14.4 to 49.5 months) PSF: mean 46.9 months (range 21.2 to 86.4 months)
Conflict of interest/source of funding	None

Analysis

Study design issues: This meta-analysis compared postoperative outcomes between patients with adolescent idiopathic scoliosis having anterior VBT and PSF. The primary objective was to compare complication and reoperation rates at available follow-up times. Secondary objectives included comparing mid-term SRS-22 scores, and coronal and sagittal-plane Cobb angle corrections.

This review followed the preferred reporting items for systematic reviews and meta-analyses guidelines. A systematic review of the literature was conducted for outcome studies following anterior VBT and/or PSF procedures. Reports from annual meetings of the SRS and in PubMed MEDLINE, Scopus, and Embase were included in the search. All studies underwent review by 2 independent reviewers. A single-arm, random-effects meta-analysis was carried out. To provide the most conservative estimates for curve measurements, worst-case imputation was used when averages for curve measurements were provided but SDs were not.

Study population issues: There were 10 case series, 12 retrospective cohort studies, 1 prospective cohort study, and 1 randomised controlled trial. Most anterior VBT studies were case series. Mean preoperative Sanders scores were 3.1 and 3.7 for anterior VBT and PSF patients, respectively. Of the 24 studies, 1 study included 2 patients with syndromic scoliosis who had anterior VBT, and 23 studies selected patients with idiopathic scoliosis. Mean preoperative flexibility was 44.6° for anterior VBT and 39.2° for PSF. The average number of vertebrae fused or tethered was 7.3 for patients who had anterior VBT and 10.2 for patients who had PSF.

Other issues: This meta-analysis had limitations. First, nearly all of the AVBT articles were case series, limiting the study design to a single-arm meta-analysis. Thus, the data in this study stem from heterogenous patient populations, and the potential for confounding abounds. Second, the lack of Cobb-angle-correction SDs precluded accurate estimations of the variability of correction rates. Third, SDs for curve measurements were frequently unreported in the PSF group, which necessitated imputation. Fourth, authors only assumed 0 complications and reoperations for studies that explicitly reported so. Therefore, it is possible that some patients who had PSF had unreported complications.

Key efficacy findings

Number of patients analysed: 1,280

Aggregate postoperative outcomes in anterior VBT and PSD studies

Outcomes	**Pooled mean (95% CI)**	
	Anterior VBT	**PSF**
Main thoracic curve (°)		
Preoperative	46.0 (42.3 to 50.0)	53.3 (52.8 to 53.9)
First erect	24.9 (20.1 to 29.8)	16.6 (12.8 to 20.3)
12 to <24 months	24.6 (17.8 to 31.4)	13.3 (8.7 to 17.8)
≥24 to <36 months	21.5 (8.3 to 34.7)	21.9 (17.4 to 26.4)
≥36 months	22.5 (14.1 to 30.9)	22.7 (19.6 to 25.8)
Compensatory lumbar curve (°)		
Preoperative	28.7 (25.6 to 32.0)	30.9 (29.2 to 32.5)
First erect	19.3 (16.6 to 22.4)	9.9 (8.1 to 11.7)
12 to <24 months	16.5 (11.2 to 21.7)	Insufficient data
≥24 to <36 months	13.2 (8.4 to 18.0)	10.7 (8.0 to 13.5)
≥36 months	18.0 (3.5 to 32.5)	15.2 (13.3 to 17.1)
Thoracic kyphosis (°)		
Preoperative	24.3 (17.8 to 30.8)	23.0 (20.7 to 25.2)
First erect	22.1 (16.5 to 27.7)	31.0 (27.9 to 33.3)
12 to <24 months	25.0 (13.4 to 36.6)	Insufficient data
≥24 to <36 months	23.0 (19.6 to 26.4)	17.9 (15.1 to 20.7)
≥36 months	22.5 (12.0 to 33.0)	24.5 (21.9 to 27.1)
Lumbar lordosis (°)		
Preoperative	52.0 (46.2 to 57.9)	47.2 (28.1 to 66.3)
First erect	46.5 (40.1 to 52.8)	Insufficient data
12 to <24 months	56.0 (47.2 to 64.9)	Insufficient data

≥24 to <36 months	52.7 (48.6 to 56.8)	46.3 (42.3 to 50.3)
≥36 months	55.1 (51.3 to 58.8)	46.1 (25.0 to 67.1)
Thoracic rotation (°)		
Preoperative	13.7 (12.1 to 15.2)	15.4 (12.4 to 18.4)
First erect	10.0 (8.7 to 11.2)	6.0 (4.5 to 7.5)
12 to <24 months	8.1 (5.9 to 10.3)	Insufficient data
≥24 to <36 months	6.9 (4.8 to 8.9)	8.07 (5.0 to 11.1)
≥36 months	8.4 (1.0 to 15.7)	13.0 (3.3 to 22.6)
Postoperative SRS-22 self-image	4.27 (4.0 to 4.56)	4.23 (4.07 to 4.40)
Postoperative SRS-22 total	4.36 (4.06 to 4.65)	4.30 (4.17 to 4.43)

No significant publication bias was detected.

Reporting of pre- and post-operative results

Characteristic	**Anterior VBT, studies (patients)**	**PSF, studies (patients)**
Pre-operative Risser score	8 (139)	5 (342)
Pre-operative Sanders score	7 (134)	1 (26)
Pre-operative flexibility	4 (34.6)	4 (265)
Complications	10 (211)	9 (610)
Reoperations	10 (211)	4 (312)
Main thoracic Cobb angle	10 (211)	14 (1,069)
Compensatory lumbar curve angle	9 (158)	5 (515)
Thoracic kyphosis angle	8 (187)	8 (662)
Lumbar lordosis angle	5 (94)	5 (421)
Thoracic rotation	6 (109)	3 (127)
SRS self-imaging	2 (76)	7 (616)
SRS total	2 (76)	7 (616)

Key safety findings

Aggregate postoperative outcomes in anterior VBT and PSD studies

Outcomes	**Pooled mean (95% CI)**	
	Anterior VBT	**PSF**
Complication rate (%)	26.0 (12.0 to 40.0)[a]	2.0 (0.0 to 4.0)[b]
<36 months	11.8 (4.4 to 18.6)	1.0 (0.0 to 2.4)

≥36 months	25.2 (19.1 to 31.7)	2.9 (0.5 to 5.3)
Reoperation rate (%)	14.1 (5.6 to 22.6)	0.6 (0.0 to 2.3)
<36 months	2.9 (0.0 to 8.4)	1.3 (0.0 to 1.7)
≥36 months	24.7 (10.7 to 38.7)	1.8 (0 to 5.4)
Conversion to PSF (%)	1.4 (0 to 4.5)	Not applicable

[a] I^2=86.14%; 10 studies with 211 patients
[b] I^2=19.21%; 9 studies with 610 patients

Characteristics of complications

Complication	Anterior VBT	PSF
Tether breakage	7.5% (n=17)	-
Overcorrection	7.5% (n=17)	0.15% (n=2)
Pulmonary	4.8% (n=11)	0.08% (n=1)
Neurological	0.88% (n=2)	0.46% (n=6)
Infection	0.44% (n=1)	0.31% (n=4)
Adding-on	3.2% (n=7)	0.30% (n=2)
Screw pullout/loosening	0.44% (n=1)	0.46% (n=6)
Other[c]	4.8% (n=11)	0.46% (n=6)
Overall	26.0% (n=67)	2.0% (n=27)

[c] Indicates complications mild in nature, reported as ‘other’ or with a frequency of 1 across all studies.

Reasons for reoperation

Reason	Anterior VBT	PSF
Tether breakage/pedicle screw loosening	3.2% (n=7)	0.15% (n=1)
Overcorrection	7.7% (n=17)	0 (0)
Adding-on	3.2% (n=7)	0.30% (n=2)
Other (rib hump deformity)	0 (0)	0.15% (n=1)
Overall	14.1% (n=31)	0.6% (n=4)

Validity and generalisability of the studies

- Where reported, studies were conducted in Canada (n=3), Turkey (n=2) and US (n=4); no data related to the UK context.
- All studies were analytical or descriptive studies.
- Shin (2021) included patients in Pehlivanoglu (2020) and Samdani (2021), but the total sample of 1,875 patients was derived from removing duplications.
- Most studies had a mean follow up of 2 to 3 years, so there is a need for long-term outcomes.
- There was variation in patient inclusion criteria and procedure technique.
- Most studies did not identify the specific devices used.
- Length of hospital stay varied across the studies and might be affected by procedure techniques, learning curve and social issues (such as long distance travelled by families). Other outcomes might also be affected by learning curve.
- Evidence on the efficacy of the procedure focused primarily on improving scoliotic curve. No evidence was found for gait analysis and there was limited evidence on other key outcomes, such as range of motion, pulmonary function and quality of life.

Existing assessments of this procedure

NHS England reviewed the evidence of treating idiopathic scoliosis in growing children with vertebral body tethering (NHS England, 2018). The evidence review included 10 papers. The review found that the biomechanical principle utilised by this technique was established in digital and animal models. There were case reports and case series, showing this technique could be effective in reducing scoliotic curves, with potential surgical complication and need for further surgery. This review, however, did not find evidence for other important outcomes, such as quality of life, range of motion (thoracic and lumbar). Therefore, NHS England's clinical commissioning policy (2019) concluded that there was not enough evidence to support the routine commissioning of this treatment for the indication.

Related NICE guidance

There is currently no NICE guidance related to this procedure.

Additional information considered by IPAC

Professional experts' opinions

Expert advice was sought from consultants who have been nominated or ratified by their professional Society or Royal College. The advice received is their individual opinion and is not intended to represent the view of the society. The advice provided by professional experts, in the form of the completed questionnaires, is normally published in full on the NICE website during public consultation, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

Two professional expert questionnaires for vertebral body tethering for idiopathic scoliosis in children and young people were submitted and can be found on the NICE website.

Patient commentators' opinions

NICE's Public Involvement Programme was unable to gather patient commentary for this procedure.

Company engagement

A structured information request was sent to 2 companies who manufacture a potentially relevant device for use in this procedure. NICE received 1 completed submission. This was considered by the IP team and any relevant points have been taken into consideration when preparing this overview.

Issues for consideration by IPAC

Ongoing trials:

- Anterior Vertebral Body Tethering (AVBT) Using Zimmer Biomet Tether System or Dynesys System Components to Treat Pediatric Scoliosis (NCT03506334); clinical trial; US; estimated enrolment, n=80; estimated study completion date, July 2027.

- Vertebral Body Tethering Treatment for Idiopathic Scoliosis (NCT03802656); clinical trial (single group assignment); US; estimated enrolment, n=40; estimated study completion date, February 2025.

- Safety Outcomes of Vertebral Body Tethering Technique (NCT04119284); clinical trial (single group assessment); US; estimated enrolment, n=30; estimated study completion date, September 2025.

- Safety and Efficacy Study of Spinal Tethering (NCT02897453); observational study (cohort); US; estimated enrolment, n=56; estimated study completion date, October 2020.

References

1. Newton PO, Bartley CE, Bastrom TP et al. (2020) Anterior spinal growth modulation in skeletally immature patients with idiopathic scoliosis: a comparison with posterior spinal fusion at 2 to 5 years postoperatively. The Journal of bone and joint surgery. American volume 102(9): 769-77
2. Pehlivanoglu T, Oltulu I, Ofluoglu E et al. (2020) Thoracoscopic vertebral body tethering for adolescent idiopathic scoliosis: a minimum of 2 years' results of 21 patients. Journal of pediatric orthopedics 40(10): 575-80
3. Mackey C, Hanstein R, Lo Y et al. (2021) Magnetically controlled growing rods (MCGR) versus single posterior spinal fusion (PSF) versus vertebral body tether (VBT) in older early onset scoliosis (EOS) patients: how do early outcomes compare? Spine.
4. Abdullah A, El-Hawary R, Parent S et al. (2021) Risk of early complication following anterior vertebral body tethering for idiopathic scoliosis. Spine Deformity
5. Baroncini A, Trobisch PD and Migliorini F (2021) Learning curve for vertebral body tethering: analysis on 90 consecutive patients. Spine Deformity 9(1): 141-7
6. Rushton PRP, Nasto L, Parent S et al. (2021) Anterior vertebral body tethering (AVBT) for treatment of idiopathic scoliosis in the skeletally immature: results of 112 cases. Spine
7. Miyanji F, Fields MW, Fano AN et al. (2021) Shoulder balance in patients with Lenke type 1 and 2 idiopathic scoliosis appears satisfactory at 2 years following anterior vertebral body tethering of the spine. Spine Deformity
8. Alanay A, Yucekul A, Abul K et al. (2020) Thoracoscopic vertebral body tethering for adolescent idiopathic scoliosis: follow-up curve behavior according to sanders skeletal maturity staging. Spine 45(22): e1483-92
9. Samdani AF, Pahys JM, Hwang SW et al. (2021) Prospective follow-up report on anterior vertebral body tethering for idiopathic scoliosis: interim results from an FDA IDE study. The Journal of bone and joint surgery. American volume
10. Rathbun JR, Wakefield MR, Malm-Buatsi EA et al. (2019) Ureteral injury following vertebral body tethering for adolescent idiopathic scoliosis. Journal of Pediatric Surgery Case Reports 46: 101219
11. Shin M, Arguelles GR, Cahill PJ et al. (2021) Complications, reoperations, and mid-term outcomes following anterior vertebral body tethering versus posterior spinal fusion. JBJS open access http://dx.doi.org/10.2106/JBJS.OA.21.00002

12. NHS England (2019) Clinical commissioning policy: vertebral body tethering for scoliosis (age 8-18 years). Available from https://www.england.nhs.uk/commissioning/publication/vertebral-body-tethering-for-scoliosis-age-8-18-years/
13. NHS England (2018) Evidence review: vertebral body tethering for treatment of idiopathic scoliosis. Available from https://www.england.nhs.uk/commissioning/publication/vertebral-body-tethering-for-scoliosis-age-8-18-years/

Literature search strategy

Databases	Date searched	Version/files
Cochrane Database of Systematic Reviews – CDSR (Cochrane Library)	26/07/2021	Issue 7 of 12, July 2021
Cochrane Central Database of Controlled Trials – CENTRAL (Cochrane Library)	26/07/2021	Issue 7 of 12, July 2021
International HTA database	26/07/2021	-
MEDLINE (Ovid)	26/07/2021	1946 To Aug 06, 2021
MEDLINE In-Process (Ovid) & MEDLINE ePubs ahead of print (Ovid)	26/07/2021	1946 to July 23, 2021
EMBASE (Ovid)	26/07/2021	1974 to 2021 July 23

Trial sources searched

- Clinicaltrials.gov
- ISRCTN
- WHO International Clinical Trials Registry

Websites searched

- National Institute for Health and Care Excellence (NICE)
- NHS England
- Food and Drug Administration (FDA) - MAUDE database
- Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP – S)
- Australia and New Zealand Horizon Scanning Network (ANZHSN)
- General internet search

The following search strategy was used to identify papers in MEDLINE. A similar strategy was used to identify papers in other databases.

Literature search strategy

Number	Search term
1	Scoliosis/
2	scolios*.tw.
3	(skelet* adj4 immatur*).tw.
4	or/1-3
5	(VBT or AVBT).tw.
6	Vertebral Body/
7	tether*.tw.

8	(verte* adj4 grow* adj4 modulat*).tw.
9	((non-fusion or non fusion or nonfusion or fusionless*) adj4 spin*).tw.
10	dynesys*.tw.
11	globus*.tw.
12	zimmer biomet.tw.
13	APIFIX.tw.
14	or/5-13
15	4 and 14
16	Animals/ not Humans/
17	15 not 16
18	limit 17 to english language

Appendix

The following table outlines the studies that are considered potentially relevant to the IP overview but were not included in the summary of the key evidence. It is by no means an exhaustive list of potentially relevant studies.

Additional papers identified

Article	Number of patients/ follow up	Direction of conclusions	Reasons for non-inclusion in summary of key evidence section
Ames RJ, Samdani A and Betz RR (2016) Anterior scoliosis correction in immature patients with idiopathic scoliosis. Operative Techniques in Orthopaedics 26(4): 247-57	Review	Anterior VBS and VBT have been shown to be useful in treating skeletally immature patients with idiopathic scoliosis. However, long-term follow up is lacking.	Review article
Aronsson DD and Stokes IAF (2011) Nonfusion treatment of adolescent idiopathic scoliosis by growth modulation and remodeling. Journal of pediatric orthopedics 31(1suppl): 99-106	Review	A brace that applies the appropriate loading and is worn as prescribed may dramatically improve the results of brace treatment. A procedure using external fixation or adjustable anterolateral tethering may achieve a nonfusion correction of AIS.	Review article
Baker CE, Kiebzak GM and Neal KM (2021) Anterior vertebral body tethering shows mixed results at 2-year follow-up. Spine Deformity 9(2): 481-9	Case series n=17	Despite several final curves >35°, 4 revisions, and 9 broken tethers, most patients (53%) were considered successful. Lumbar ABVTs correct more intraoperatively and faster postoperatively. Patients who are tethered during or slightly after the curve acceleration phase	Small sample

		of growth may have more successful outcomes than patients tethered prior to the curve acceleration phase. AVBT requires further study with longer outcomes to define best practices for indications, level selections, and surgical techniques	
Baker CE, Milbrandt TA and Larson AN (2021) Anterior vertebral body tethering for adolescent idiopathic scoliosis: early results and future directions. The Orthopedic clinics of North America 52(2): 137-47	Review	AVBT is a growing technique targeted for patients who are skeletally immature and desire to maintain spinal motion. It has shown early success to correct scoliosis and avoid fusion surgery, which is a major advancement in the care of AIS; however, it has shown a higher reoperation rate than PSF and long-term outcomes are yet to be defined, making appropriate patient counselling of utmost importance. The ideal surgical candidate and timing of intervention are still being determined. Patients who are motivated to maintain spinal motion can benefit from this technique.	Review article
Baroncini A, Kobbe P, Tingart M et al. (2021) Return to sport and daily life activities after vertebral body tethering for AIS: analysis of the sport activity questionnaire. European Spine	Case series n=31	VBT allows patients to quickly return to their preoperative activity level, irrespectively of the postoperative Cobb angle or type of instrumentation.	Small sample, analysis of the sport activity questionnaire

Journal 30(7): 1998-2006			
Baroncini A, Trobisch PD, Rodriguez L et al. (2021) Feasibility of single-staged bilateral anterior scoliosis correction in growing patients. Global Spine Journal 11(1): 76-80	Case series n=25	Data suggests that bilateral, single-stage surgery for dynamic scoliosis correction (VBT) is feasible albeit with an elevated complication rate that may partially attributable to the learning curve. Future research should focus on the cause of pulmonary complications and include a matched comparative analysis with traditional posterior fusion.	It was unclear how many patients had idiopathic scoliosis.
Baroncini A, Trobisch PD, Birkenmaier C et al. (2021) Radiographic results after vertebral body tethering. Zeitschrift fur Orthopadie und Unfallchirurgie	Systematic review n=175 (9 studies)	The mean correction on the coronal plane was 52%, and there was no significant change in sagittal parameters. The revision rate was 18.9%. The methodological quality assessment with the Coleman score gave unsatisfactory results, so that available data are not sufficient to propose general indications or guidelines to perform VBT.	Outcomes for idiopathic scoliosis were not reported separately.
Betz RR, Antonacci MD and Cuddihy LA (2018) Alternatives to spinal fusion surgery in pediatric deformity. Current Orthopaedic Practice 29(5): 430-5	Review	Fusionless surgery procedures may not have long-term data available today, but they may currently be acceptable for patients/parents who place a premium on motion and understand that long-term data are not available. Importantly, unlike fusion, these fusionless procedures do not burn any bridges and allow for any	Review article

		improvements in technology in the future.	
Boudissa M, Eid A, Bourgeois E et al. (2017) Early outcomes of spinal growth tethering for idiopathic scoliosis with a novel device: a prospective study with 2 years of follow up. Child's nervous system: ChNS: official journal of the International Society for Pediatric Neurosurgery 33(5): 813-8	Case series n=6	The procedure allowed a stabilisation of the deformity during growth spurt. Validated devices and further studies with longer term follow up are needed to confirm the efficiency of this technique. This small cohort of patients is a source of reflection for further medical devices developments.	Small sample
Braun JT (2014) Comparison of two fusionless scoliosis surgery methods in the treatment of progressive adolescent idiopathic scoliosis: a preliminary study. Darthmouth Orthop J	Non-randomised comparative study n=9 (VBT, n=5; vertebral body stapling, n=4)	Both initial correction and subsequent control of curve progression are important in the fusionless treatment of AIS. In this preliminary study, it appears that ligament tethering provides greater initial correction and subsequent control of AIS curve progression than vertebral stapling	Small sample
Buyuk AF, Milbrandt TA, Mathew SE et al. (2021) Measurable thoracic motion remains at 1 year following anterior vertebral body tethering, with sagittal motion greater than Coronal Motion. The Journal of bone and joint	Case series n=32	At 1 year following thoracic anterior VBT for the treatment of AIS, the thoracic spine showed a measurable range of coronal and sagittal plane motion over the instrumented levels without evidence of complete autofusion. Motion in the coronal plane decreased by 77% following anterior vertebral body tethering. These findings provide proof of	Small sample

surgery. American volume		concept that sagittal spinal motion is preserved after thoracic anterior VBT, although the functional importance remains to be determined.	
Buyuk AF, Milbrandt TA, Mathew SE et al. (2021) Does preoperative and intraoperative imaging for anterior vertebral body tethering predict postoperative correction? Spine Deformity 9:743-50	Case series n=51	Preoperative bending radiographs provide a reasonable estimate of postoperative correction for patients undergoing anterior VBT with tensioning of the cord. Surgeons should expect the major Cobb angle to increase on first erect radiographs compared to intraoperative radiographs. These findings may guide patient selection and assist surgeons in achieving appropriate correction intraoperatively.	Shot-term follow up (only postoperative data reported)
Chen E, Sites Brian DR, Lisa A et al. (2019) Characterizing anesthetic management and perioperative outcomes associated with a novel, fusionless scoliosis surgery in adolescents. AANA journal 87(5): 404-10	Non-randomised comparative study n=75 (anterior VBT, n=35; PSF, n=40)	This study suggested that patients having anterior VBT with neuraxial analgesia need less opioid administration than patients having PSF and may be discharged sooner. Although limited by several differences between the cohorts, the findings can inform both spine surgeons and their patients about the expected recovery profile and the likely decreased postoperative opioid requirement associated with anterior VBT and serve as a baseline for future adjustments to perioperative care.	Limited, short-term efficacy data were reported.
Cheung ZB, Selverian S, Cho B	Review	Recent developments in fusionless and growth	Review article

H et al. (2019) Idiopathic scoliosis in children and adolescents: emerging techniques in surgical treatment. World neurosurgery 130: e737-42		modulating techniques, including VBS, VBT, magnetically controlled growing rods, ApiFix, and sublaminar polyester bands, have attempted to address concerns about the performance of early fusion in young patients with AIS. Although these new emerging techniques have demonstrated promising results, larger prospective studies are still needed to better evaluate their safety and long-term efficacy in the treatment of AIS.	
Cobetto N, Aubin CE and Parent S (2020) Anterior vertebral body growth modulation: assessment of the 2-year predictive capability of a patient-specific finite-element planning tool and of the growth modulation biomechanics. Spine 45(18): e1203-e1209	Case series n=45	This study demonstrates the finite element model clinical usefulness to rationalise surgical planning by providing clinically relevant correction predictions. The AVBGM biomechanical effect on growth modulation over time seemed to be maximised during the first year following the installation.	Numerical planning and simulation
Cobetto N, Aubin CE and Parent S (2018) Contribution of lateral decubitus positioning and cable tensioning on immediate correction in anterior vertebral body growth modulation. Spine deformity 6(5): 507-13	Case series n=20	The majority of curve correction was achieved by lateral decubitus positioning. The main role of the cable was to apply supplemental periapical correction and secure the intraoperative positioning correction. Increases in cable tensioning furthermore rebalanced initially asymmetric compressive stresses.	Computational simulation

		This study could help improve the design of AVBGM by understanding the contributions of the surgical procedure components to the overall correction achieved.	
Cobetto N, Aubin CE and Parent S (2018) Surgical planning and follow up of anterior vertebral body growth modulation in pediatric idiopathic scoliosis using a patient-specific finite element model integrating growth modulation. Spine deformity 6(4): 344-50	Case series n=20	A numeric model simulating immediate and post-two-year effects of anterior vertebral body growth modulation enabled to assess different implant configurations to support surgical planning.	Numerical planning and simulation, with small sample
Cobetto N, Aubin CE and Parent S (2020) Anterior vertebral body growth modulation: assessment of the 2-year predictive capability of a patient-specific finite-element planning tool and of the growth modulation biomechanics. Spine 45(18): e1203-e1209	Case series n=45	This study demonstrates the FEM clinical usefulness to rationalize surgical planning by providing clinically relevant correction predictions. The AVBGM biomechanical effect on growth modulation over time seemed to be maximised during the first year following the installation.	Numerical planning and simulation
Cobetto N, Parent S and Aubin CE (2018) 3D correction over 2years with anterior vertebral body growth modulation: A finite element	Case series n=10	This study showed the biomechanical possibility to adjust the fusionless instrumentation parameters to improve correction in frontal and sagittal planes, but not in the transverse plane. The	Small sample, biomechanical study with limited efficacy outcomes.

analysis of screw positioning, cable tensioning and postoperative functional activities. Clinical biomechanics (Bristol, Avon) 51: 26-33		convex side stresses increase in the supine position may suggest that growth modulation could be accentuated during night-time.	
Courvoisier A, Eid A, Bourgeois E et al. (2015) Growth tethering devices for idiopathic scoliosis. Expert review of medical devices 12(4): 449-56	Review	Flexible tethers are promising new tools for patients with severe curves and significant remaining growth. The prerequisite for progressive correction is the flexibility of the curve (and consequently a significant correction of the curve) and ideally an open triradiate cartilage. A big issue is the amount of tension required in the tether to reach the desired correction.	Review article
Crawford CH and Lenke LG (2010) Growth modulation by means of anterior tethering resulting in progressive correction of juvenile idiopathic scoliosis: a case report. The Journal of bone and joint surgery. American volume 92(1): 202-9	Case report n=1	The present report demonstrates the intermediate term safety and efficacy of a novel procedure in a single patient. Careful ongoing assessment of the patient and others is needed to determine if this procedure will become accepted for the treatment of spinal deformities in the growing child.	Single case report
Hoernschemeyer DG, Boeyer ME, Robertson ME et al. (2020) Anterior vertebral body tethering for adolescent	Case series n=27	This study shows the success and revision rates as well as the impact of a suspected broken tether on the procedural success of VBT. Despite the patient population being	Small sample

scoliosis with growth remaining: a retrospective review of 2 to 5-year postoperative results. The Journal of bone and joint surgery. American volume 102(13): 1169-1176		slightly more mature at the time of the surgical procedure compared with previous studies, there was a higher success rate and a lower revision rate. A PSF was avoided in 93% of patients, indicating that VBT may be a reliable treatment option for adolescent scoliosis in skeletally immature individuals.	
Jain V, Lykissas M, Trobisch P et al. (2014) Surgical aspects of spinal growth modulation in scoliosis correction. Instructional course lectures 63: 335-44	Review	The early results for spinal growth modulation are promising and continued clinical studies are needed.	Review article
Mathew S, Larson AN, Milbrandt TA et al. (2021) Defining the learning curve in CT-guided navigated thoracoscopic vertebral body tethering. Spine Deformity	Case series n=67	This series has demonstrated improvements in surgical efficiency for VBT including reduced EBL, operative time, anaesthesia time and hospital stay over a 5-year period. This indicates improved surgical technique and outlines the significant learning curve for surgeons who wish to perform this procedure. Improved surgeon training programs and newer instrumentation may reduce this learning curve.	This study reviewed the learning curve of the navigated VBT technique, with 3-month follow-up outcomes.
Milbrandt TA, Mathew SE, Larson AN et al. (2021) Does preoperative and intraoperative imaging for anterior vertebral body	Case series n=51	Preoperative bending radiographs provide a reasonable estimate of postoperative correction for patients undergoing AVBT with tensioning of the cord. Surgeons should	Outcomes were measured at first erect imaging.

tethering predict postoperative correction? Spine Deformity 9(3): 743-50		expect the major Cobb angle to increase on first erect radiographs compared to intraoperative radiographs. These findings may guide patient selection and assist surgeons in achieving appropriate correction intraoperatively.	
Miyanji F, Pawelek J, Nasto L A et al. (2020) Safety and efficacy of anterior vertebral body tethering in the treatment of idiopathic scoliosis. The bone & joint journal 102b (12): 1703-8	Case series n=57	Anterior VBT is associated with satisfactory correction of deformity and an acceptable complication rate when used in skeletally immature patients with idiopathic scoliosis. Improved patient selection and better implant technology may improve the 15.8% rate of revision surgery in these patients. Further scrutiny of the true effectiveness and long-term risks of this technique remains critical.	Small sample
Newton PO (2020) Spinal growth tethering: Indications and limits. Annals of Translational Medicine 8(2): 159	Review	Initial results of anterolateral tethering in growing patients with spinal deformities are encouraging, however the results 3 to 4 years after the procedure are somewhat mixed. Further research is ongoing and many remain optimistic that improvements in technology and understanding will continue to lead to better patient outcomes.	review article
Newton PO, Kluck DG, Saito W et al. (2018) Anterior spinal growth	Case series	The results demonstrated that at mid-term follow-up, ASGT showed a powerful, but variable, ability to	Small sample and outcomes for idiopathic scoliosis

tethering for skeletally immature patients with scoliosis: a retrospective look two to four years postoperatively. The Journal of bone and joint surgery. American volume 100(19): 1691-7	n=17 (idiopathic scoliosis, n=14; syndromic scoliosis, n=3)	modulate spinal growth and did so with little perioperative and early postoperative risk. Fusion was avoided for 13 of the 17 patients. The overall success rate was 59%, with a 41% revision rate. Understanding the parameters leading to success or failure will be critical in advancing a reliable definitive nonfusion treatment for progressive scoliosis in the future.	not reported separately
Parent S and Shen J (2020) Anterior vertebral body growth-modulation tethering in idiopathic scoliosis: surgical technique. The Journal of the American Academy of Orthopaedic Surgeons 28(17): 693-699	Review	Fusionless treatment options, such as anterior vertebral body growth modulation, have been developed to treat these patients while avoiding the complications of posterior rigid fusion. Good results have been shown in recent literature with proper indications and planning in the skeletally immature patient.	Review article
Pehlivanoglu T, Oltulu I, Erdag Y et al. (2021) Double-sided vertebral body tethering of double adolescent idiopathic scoliosis curves: radiographic outcomes of the first 13 patients with 2 years of follow-up. European Spine Journal 30: 1896-904	Case series n=13	Double-sided VBT was detected to provide 80% of thoracic (48.2° to 9.7°) and 82% of thoracolumbar-lumbar curve correction (45.3° to 8.2°) as a result of average 2 years. As being a growth modulating treatment option, double-sided VBT as applied under strict inclusion criteria was shown to be safe and effective for the correction of double curves in skeletally immature patients with AIS, by yielding a gradual,	Small sample

		growth-assisted correction of both curves together with the preservation of coronal-sagittal balance without any major complications.	
Pehlivanoglu T, Oltulu I, Ofluoglu E et al. (2020) Thoracoscopic vertebral body tethering for adolescent idiopathic scoliosis: a minimum of 2 years' results of 21 patients. Journal of pediatric orthopedics 40(10): 575-80	Case series n=21	Anterior VBT as a growth modulating treatment option by allowing the correction of the scoliotic deformity and preserving coronal balance was detected to be a safe and effective option for the surgical treatment of AIS in skeletally immature patients, if applied under strict inclusion criteria. VBT by allowing preservation of spinal segmental motion is yielding promising radiographic results without causing any major complications.	Small sample
Oltulu I, Erdag Y, Korkmaz E et al. (2021) Double-sided vertebral body tethering of double adolescent idiopathic scoliosis curves: radiographic outcomes of the first 13 patients with 2 years of follow-up. European Spine Journal 30(7): 1896-904	Case series n=13	Double-sided VBT was detected to provide 80% of thoracic (48.2° to 9.7°) and 82% of thoracolumbar-lumbar curve correction (45.3° to 8.2°) as a result of average 2 years. As being a growth modulating treatment option, double-sided VBT as applied under strict inclusion criteria was shown to be safe and effective for the correction of double curves in skeletally immature patients with AIS, by yielding a gradual, growth-assisted correction of both curves together with the preservation of coronal-sagittal balance	Small sample

		without any major complications.	
Samdani AF, Ames RJ, Kimball JS et al. (2015) Anterior vertebral body tethering for immature adolescent idiopathic scoliosis: one-year results on the first 32 patients. European spine journal: official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society 24(7): 1533-9	Case series n=32	The results indicate that anterior VBT is a safe and potentially effective treatment option for skeletally immature patients with idiopathic scoliosis. These patients experienced an improvement of their scoliosis with minimal major complications. However, longer-term follow up of this cohort will reveal the true benefits of this promising technique.	Small sample with 1-year follow-up outcomes
Samdani AF and Betz RR. (2015) Growth modulation techniques for adolescent idiopathic scoliosis. Seminars in Spine Surgery 27(1): 52-7	Review	Growth modulation techniques, such as vertebral body stapling and vertebral body tethering, offer a fusionless option, which harnesses a patient's remaining growth to progressively correct the curve. These techniques offer a promising alternative to appropriately selected skeletally immature patients with idiopathic scoliosis.	Review article
Samdani AF, Ames RJ, Kimball JS et al. (2014) Anterior vertebral body tethering for idiopathic scoliosis: two-year results.	Case series n=11	Anterior VBT is a promising technique for skeletally immature patients with idiopathic scoliosis. This technique can be performed safely and can result in progressive correction.	Small sample

Spine 39(20): 1688-93			
Senkoylu A, Riise RB, Acaroglu E et al. (2020) Diverse approaches to scoliosis in young children. EFORT Open Reviews 5(10): 553-62	Review	Anterior VBT seems to be a promising novel technique for the treatment of idiopathic scoliosis in immature cases. It provides substantial correction and continuous curve control while maintaining mobility between spinal segments. However, long-term results, adverse effects and their prevention should be clarified by future studies.	Review article
Shen J and Parent S (2021) Iatrogenic dural tear after growth modulation in AIS: an unusual complication and its management. Spine deformity	Case report n=1	Iatrogenic CSF leak in AVBGM remains a rare complication. This is the first report of such a case that involves a Chiari-like deformity on initial MRI investigation. We suggest that an MRI is performed for all patients presenting with symptoms of CSF leak after AVBGM.	Single case report
Skaggs DL, Akbarnia BA, Flynn JM et al. (2014) A classification of growth friendly spine implants. Journal of pediatric orthopedics 34(3): 260-74	Review	Growth friendly spinal implant systems fall into 3 categories based on the forces of correction the implants exert on the spine: distraction based, compression based and guided growth. Each type of system has potential benefits and shortcomings.	Review article
Szapary, Hannah J., Greene, Nattaly, Paschos, Nikolaos K. et al. (2021) A Thoracoscopic Technique Used in Anterior Vertebral	Review	Although more studies will be needed to further characterise the outcomes and complications of anterior VBT, this thoracoscopic approach is a reproducible and	Review article

Tethering for Adolescent Idiopathic Scoliosis. Arthroscopy Techniques 10(3): e887-e895		effective treatment that takes advantage of continued spinal growth in paediatric patients with adolescent idiopathic scoliosis, who would otherwise require spinal arthrodesis.	
Takahashi Y, Saito W, Yaszay B et al. (2021) Rate of scoliosis correction after anterior spinal growth tethering for idiopathic scoliosis. The Journal of bone and joint surgery. American volume	Case series n=23	Scoliosis correction was associated with overall height changes and occurred primarily within 2 to 3 years after surgery in this cohort of largely Risser stage 0 patients. The correction rate was 2.8° per segment per year for the first 2 years in the Sanders stage 2 group, compared with 1.2° per segment per year for the Sanders stage 3 group. Surgical timing that considers the patient's skeletal maturity is an important factor in generating proper postoperative correction after anterior spinal growth tethering.	Small sample
Yucekul A, Yilgor C, Alanay A et al. (2021) Does vertebral body tethering cause disc and facet joint degeneration? A preliminary MRI study with minimum 2-years follow-up. Spine Journal	Case series n=35	Intermediate discs and facet joints were preserved after growth modulation with VBT surgery at a mean follow-up of 29 months. Studies in larger cohorts with longer follow-up are warranted to have more in-depth analyses of the effects of relative stabilisation and altered biomechanical loads.	Small sample with 2-year follow-up data